The Relative Importance of Traditional Chinese Medicine Diagnosis & Treatment Individualisation as Seen Through a Study on Irritable Bowel Syndrome

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Abstract

Background: The past forty years have seen an increase in the number of people with chronic illness and a struggle for biomedicine to provide effective treatments. The lack of effective biomedical treatments for conditions such as IBS creates opportunities for Chinese medicine; however, in its growing popularity, Chinese medicine has had to adapt to biomedicine's dominant influence on research and practice. Purpose: The purpose of this thesis is to explore Chinese medicine's adaptations to biomedicine regarding diagnosis differentiation and treatment individualisation through a study that places Chinese medicine in the context of IBS. Methods: Methods were selected based on a pragmatic mixed methodological underpinning that allowed for the research questions to dictate appropriateness. As such, a mixture of qualitative and quantitative methods were used to assess acupuncturists' contextualisation and treatment of IBS; patient' experiences with acupuncture and perceptions of outcome; and patients', GPs', and acupuncturists' understanding of how acupuncture works and the impact of that understanding on outcome and acceptance of acupuncture. Findings: Acupuncturists contextualise IBS according to symptoms they perceive to be relevant, and do not perceive IBS to be a useful diagnosis. Acupuncture treatment of IBS incorporated three over-lapping approaches including: disease-specific, pragmatic, and individualised. The proportional influences of the approaches were different for different treatment aspects. Regarding how acupuncture works, patients, acupuncturists, and GPs used a variety of traditional, scientific, and physical explanations. Patients and acupuncturists perceived that the explanation may affect treatment outcome. Conclusions: Collective interpretation of the findings suggest that TCM diagnosis differentiation is fundamental to TCM treatment and plays a role similar to biomedical diagnoses in that it may validate patients' symptoms and identify conditions that are treated effectively. Additionally, the use of combined treatment approaches notes an over-emphasis on individualisation that may be a by-product of TCM's adaptation to biomedicine.

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Abbreviations

ACIBS – Acupuncture for IBS (name of trial)
BAcC – British Acupuncture Council
BC – Baltica Cabieses
CAM – Complementary & Alternative Medicine
CG – Core Group
CRH – Corticotrophin Releasing Hormone
CV – Conception Vessel (aka ren)
EBM – Evidence based medicine
EMF – Electromagnetic Field
EMS – Emotional Motor System
FBDSI – Functional Bowel Disorder Severity Index
FGID – Functional Gastrointestinal Disorder
GB – Gall Bladder
GI – Gastrointestinal
HC – Helen Cox
HM – Hugh MacPherson
HPA – Hypothalamus-pituitary-adrenal axis
HRQoL – Health related quality of life
Ht – Heart
HT – Helen Tilbrook
IBS – Irritable Bowel Syndrome
IBS-SSS – IBS Symptom Severity Scale
KA – Karl Atkin
KD – Kidney
KMO – Kaiser-Meyer-Olkin measure
LI – Large intestine
LR – Liver
LU - Lung
MCS – Mental health Composite Score
NICE – National Institute for Clinical Excellence
OC – Organising Centre
PC – Pericardium
PCS – Physical health Composite Score
RCT – Randomised controlled trial
SB – Sally Brabyn
SG – Support Group
SI – Small Intestine
SJ – San Jiao (aka triple energizer)
SI – Small Intestine
SJ – San Jiao (aka triple energizer)
SP – Spleen
ST – Stomach
STRICTA – standards for reporting interventions in clinical trials of acupuncture
TCM – Traditional Chinese Medicine
TENS – Transcutaneous nerve stimulation
UB – Urinary Bladder
VAS – Visual Analogue Scale
VG – Variable Group
VIF – Variance Inflation Factor
WHO – World Health Organisation

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Author's Declaration

I declare that this thesis is the product of my own work, other than that duly acknowledged to others below, and that the material contained within this thesis has not been previously submitted for a degree in this, or any other awarding institution.

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Chapter One

The relationship between Chinese medicine & biomedicine

Chapter highlights

- Chinese medicine and biomedicine co-exist in a dynamically evolving symbiotic relationship that influences clinical practice and research
- The symbiotic influence on research necessitates two research assumptions regarding the relative importance of Chinese medicine diagnosis and treatment individualisation
- To address the lack of information about the relative importance of Chinese medicine diagnosis and treatment individualisation this thesis answers three questions that when collectively analysed begin to address this knowledge gap

1.1 Introduction

Medicine has been evolving around the world for thousands of years being influenced by culture, environment, politics as well as geography. Currently, the scientifically based practice, biomedicine, holds a dominant position in many developed countries. On the other hand, Chinese medicine and more specifically traditional Chinese medicine (TCM), a systematized version of Chinese medicine that gained support from the Chinese government in the 1950s and has been exported to the West [2], often serves a complementary or alternative role. The co-existence of these two practices highlights the idea that neither biomedicine nor Chinese medicine is practiced in isolation; therefore, they may influence and/or adapt to each other. Chinese medicine practitioners receive training in basic biomedicine and may selectively incorporate that knowledge in practice. For example, a patient being treated for knee pain who also has hypertension may be closely monitored to ensure treatment does not induce a dramatic change in his/her blood pressure. Similarly, biomedical education at many (not all) schools now includes introductory courses on complementary and alternative medicine (CAM). Beyond impacts on training/education, the interaction between the practices raises a question about the relative importance of TCM diagnoses and treatment individualisation. In particular, within the context of the biomedically dominant health care arena do TCM diagnoses and treatments retain and/or alter their identities during the research process and is that important. To begin to answer this question, this thesis situates itself in the biomedical context of Irritable Bowel Syndrome (IBS) and explores how acupuncturists contextualise and treat IBS in routine practice compared to a pragmatic trial setting; examines how patients, GPs, and acupuncturists understand acupuncture to work and the impact of those understandings; and assesses the relative importance of TCM diagnosis differentiation and treatment individualisation. Before elaborating on different chapters (Section 1.4), the following sections provide more detail on the co-existence of biomedicine and Chinese medicine and how their relationship influences practice and research.

1.2 Symbiosis

Considering that biomedicine and Chinese medicine co-exist, along with a variety of other practices such as chiropractic and homeopathy, in the health care arena,

symbiosis provides an apt description of their relationship. Typically symbiosis refers to the co-existence of different organisms. For example, bacteria that coat our skin, nasal passages, and alimentary tracts demonstrate mutually beneficial symbiosis by generating vitamin K from our food as well as parasitic symbiosis by opportunistically infecting damaged tissue (e.g. cellulitis). The dynamic fluctuation from beneficial to parasitic symbiosis demonstrated by bacteria and our bodies exemplifies the relationship between biomedicine and Chinese medicine. Just as bacteria and humans share a survival instinct and use different approaches to achieve survival, so too do biomedicine and Chinese medicine share the goal of providing effective patient care via unique approaches. Laying bare the analogy, Chinese medicine identifies with the pre-historic, highly adapted yet simple organism that engages with nature at its most basic level such as yin-yang and the five elements (e.g. fire). Biomedicine, on the other hand, identifies with the more modern, cognitively adapted and complex organism that seeks to govern nature as in genetic engineering. At times their symbiosis appears mutually beneficial as both practices accentuate their strengths through interactions with each other as seen in treatments of cancer patients using chemotherapy to eradicate affected cells and acupuncture to suppress nausea and vomiting. Other times their symbiosis appears parasitic, wherein conditions that are ineffectively treated by one practice may be interpreted as a weakness by the other. For example, chronic conditions such as IBS that lack an effective biomedical treatment provide an opportunity for Chinese medicine to capitalise on this vulnerability by offering alternative treatments. In addition to treatment delivery and effectiveness, a variety of other factors induce fluctuations in the symbiotic dynamic; two noteworthy factors are legislation and patients.

Legislation and regulatory bodies that govern health care suppliers influence symbiotic expression via distinctions among practices and their implications. Prior to the Medical Act of 1858, health care in the UK was a pluralistic array of practices including: hydrotherapists, herbalists, apothecaries, physicians, surgeons, osteopaths, homeopaths, and mesmerists [3, 4]. Although health care in the UK may still be described as pluralistic, comprised of a variety of practices, the Medical Act formally established a state-endorsed register that allowed citizens to distinguish between qualified and unqualified practitioners [5]. Additionally, the Medical Act established

the General Medical Council (GMC) to monitor and accredit health care providers and institutions. Effectively, the Medical Act and subsequent GMC regulations truncated pluralistic care by relegating what are currently known as alternative or complementary providers [3] and laid groundwork for the dominant-ancillary positioning of biomedicine and Chinese medicine as health care suppliers. The broader movement driving the legislation and associated counterparts (e.g. licensing) through which biomedicine gained authority is known as professionalization [6, 7]. Professional status and a regulatory agency afford biomedicine the ability to selectively judge and potentially co-opt pluralistic therapies (e.g. physiotherapy) and/or modalities (e.g. acupuncture).

While professionalization allowed biomedicine to assume specialist status, the ensuing golden era of biomedicine produced advances in antibiotics and surgery. Despite the advances and accomplishments, biomedicine began to succumb to a variety of shifts that challenged its dominance around the mid 20th century [8]. For example, biomedical applications of diagnosing and treating patients' needs were particularly successful while infectious diseases dominated the medical landscape, possibly because infections such as diphtheria and whooping cough and their treatments are relatively uncomplicated. As infectious diseases became better managed and life expectancy increased the medical landscape was repopulated by complex, chronic diseases, which may be difficult to diagnose and treat from both a consumer and biomedical perspective [9]. IBS is a prime example of a complex chronic disease whose diagnostic understanding has fluctuated since identification and a disease which currently lacks an effective biomedical treatment. Furthermore, ineffective treatment delivery creates vulnerability in authority and/or gaps in the market [6] favouring revitalization of pluralistic interventions and altering the symbiotic dynamic. In addition to the increasing impact of chronic diseases, patients also began to apply pressure to biomedicine through increased knowledge and concerns.

In addition to the increase in complex chronic diseases, a variety of factors gained momentum in the 1960s ultimately coalescing in increased popularity of pluralistic interventions (Figure 1.1). Figure 1.1 illustrates how some people were drawn to

pluralistic interventions through the search for healthier lifestyles, an alternative to biomedicine, an unmet need, increased awareness of options, and more self-control and responsibility [10, 11]. With regard to increased awareness, patients obtained information from an increasing array of resources, specifically about symptoms and treatment options. The increase in available information diluted the 'asymmetry of expertise' wherein professionals' knowledge management creates a power dynamic captured by the motto 'doctor knows best' [6]. Patients' access to increased information redistributed power between doctors and patients, and allowed knowledgeable patients to question their doctors. According to Giarelli, the redistribution not only allowed patients to question their doctors but altered patients expectations and contributed to patients' desires to actively participate in their health care [9]. Patients' desires to actively participate in their health care were also influenced by the increased awareness of iatrogenic illnesses and depersonalization of the doctor-patient encounter [12]. Thus, patients more readily investigated and experimented with a range of treatment options regardless of their doctors' recommendations. Such experimentation may be particularly attractive to those patients diagnosed with conditions that lack effective biomedical treatments.

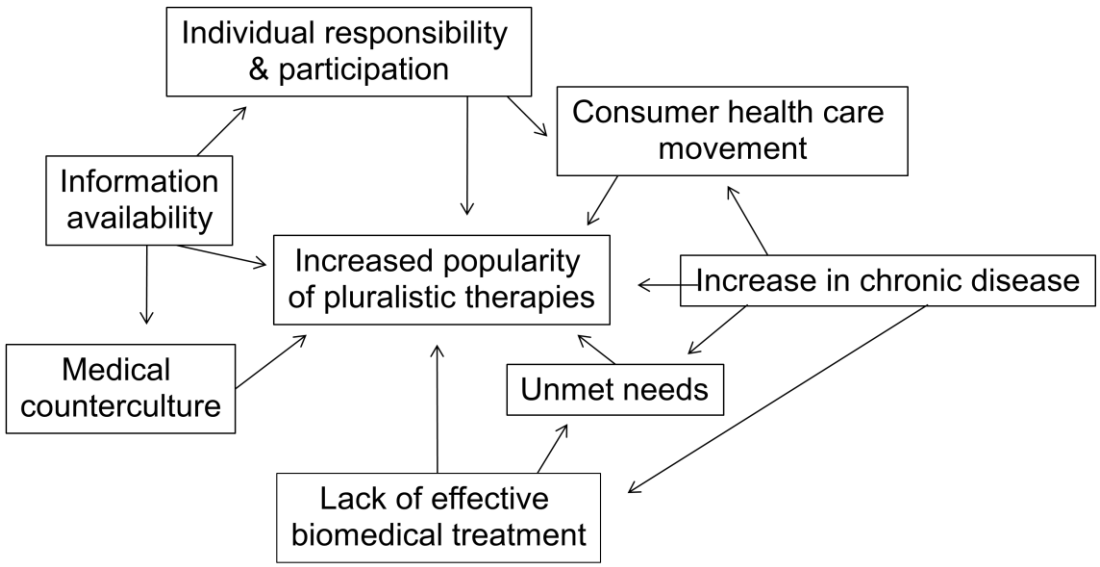


Figure 1.1 Factors influencing the popularity of pluralistic therapies

With regard to acupuncture, a predominant Chinese medicine modality, the increased availability of information, disenchantment with biomedicine, and renewed interest in pluralistic therapies made fertile ground for James Reston's article on acupuncture

in 1971 [13]. Mr Reston reported that he received acupuncture anaesthesia during an appendectomy in China, which catapulted acupuncture into the media spotlight. As the dominant science based medical system, biomedicine was proffered questions about the mechanism through which acupuncture may deliver anaesthetic effects. In order to allow biomedical practitioners to research such effects and experiment with acupuncture, the GMC was obliged to amend its fraternization policy that would otherwise penalise doctors for such work [14]. The articles and regulatory changes manifest a fluctuation in symbiosis as biomedicine became cognizant of acupuncture. Heightened awareness, whether toward the presence of bacteria or the usage of acupuncture, modifies the behaviour of the symbiotic counterpart that may manifest as adaptations and/or compromises. According to Wolpe, biomedicine employed two strategies to address heightened acupuncture awareness 1) implement a research agenda that aligned acupuncture with the biomedical model and 2) incorporate acupuncture into practice [7]. With regard to the symbiotic dynamic, both of these strategies highlight biomedicine's dominant position. To align with the biomedical model, Chinese medicine would need to shed its traditional language and adopt a systematic approach (condition → needles → outcome) to research. The shift may be identified in the literature as studies assessing acupuncture for specific and often chronic biomedical conditions. For example, the papers 'Preliminary clinical study on acupuncture in rheumatoid arthritis' (1974) [15], 'Efficacy of acupuncture on osteoarthritic pain – a controlled, double-blind study' (1975) [16], and 'Acupuncture for chronic shoulder pain – an experimental study with attention to the role of placebo and hypnotic susceptibility' (1976) [17], to name a few, illustrate this trend. The emphasis on chronic conditions outlines the gap that Chinese medicine could fill and reminds us that without a gap in treatment effectiveness the increased popularity of pluralistic therapies may have been short-lived.

To incorporate acupuncture into practice, biomedical research in the 1970s emphasised the physiological existence and function of acupuncture points further described in Chapter 3 [18-20]. Conducting clinical acupuncture trials and associating acupuncture points with physiological perturbations, such as stimulate endorphin production, implemented the first strategy. Subsequently, acupuncture points deemed capable of stimulating the nervous system were categorised as

"medical acupuncture points" [21]. Medical acupuncture points were effectively repackaged into a new style of acupuncture called 'medical acupuncture'. By establishing its own style of acupuncture, biomedicine implemented the second strategy, which was enacted by the British Medical Acupuncture Society (BMAS founded 1981) who instructed doctors in medical acupuncture. Currently, there are approximately 2,700 physicians and allied health care professionals who have received BMAS training [22].

Biomedicine's response to the growing popularity of Chinese medicine may be considered parasitic in that the co-optation of acupuncture was detrimental to traditional practitioners. However, fluctuation in the symbiotic dynamic may have provided Chinese medicine an opportunity to potentially alter its ancillary position in a favourable way. Prior to the 1970s people who wanted to practice acupuncture typically trained as an apprentice with one of the few acupuncturists in practice [23]. Heightened interest in acupuncture provided the impetus for practitioners to organise and expand their practices. Acupuncturists responded to the growing interest in acupuncture by opening schools, investing in holistic health centres, and increasing the publication of acupuncture books [23, 24]. As mentioned previously, information availability played a key role in the increased popularity of pluralistic therapies (Figure 1.1). Furthermore, the increased popularity of acupuncture and broader holistic health movement facilitated the collaboration of different professionals to establish polyclinics. Both acupuncture schools and visible professional clinics allowed acupuncturists to transition from a hidden collective to a more socially active and recognisable group. These common threads provided some of the unifying features necessary to build professional organisations that in turn could drive acupuncture's own professionalization process.

Although the increase in acupuncture's popularity and the pressure applied by biomedicine encouraged professionalization, acupuncture by non-medical practitioners remains unregulated in the UK. The consolidation of several self-regulated acupuncture organisations, into the British Acupuncture Council (BAcC), in 1995 marked an important development of a national register for acupuncture practitioners who met specific training, safety, and ethics requirements [25]. Self-

regulation provided by the BAcC indicated to the House of Lords (2000) that acupuncture was an 'appropriate' discipline for statutory regulation [26]. In 2008, the Department of Health issued a similar report with details outlining scope of practice, educational standards, and titles to be incorporated into the regulations [27]. Paragraphs regarding the use of titles portray the most conspicuous possibility as to why after forty years of increased interest, successful self-regulation, and two emphatic governmental calls for statutory regulation, acupuncture remains unregulated. Statutory regulation would effectively protect the title 'acupuncturist' insomuch as it could only be used by those practitioners on the professional register. Currently, anyone may use the title including doctors with BMAS training and BAcC members with TCM training. Although training requirement contrasts may fuel debates over title usage, beneath those debates lies an implementation argument. According to Bakx, the implementation of acupuncture, as to who will deliver it and for what conditions, was the principal barrier delaying regulation twenty years ago [28], and as discussed in subsequent chapters it still appears to be a principal barrier. The extent to which contentions around usage of the title 'acupuncturist', differences in training, or debates over implementation have delayed statutory regulation is unknown; however, professionalization and regulatory decisions will continue to influence symbiotic fluctuations and possibly redistribute the dominant-ancillary proportions.

To summarise, patients and their health needs lie at the heart of providing effective care and in doing so may influence fluctuations in the symbiotic relationship between Chinese medicine and biomedicine. Biomedicine dominates the health care scene, which it assumed by situating itself as the official state-supported system and by effectively treating infectious diseases and marginalizing pluralistic therapies. However, biomedicine has come under increasing scrutiny for a variety of reasons including an inability to meet patients' broad-ranging needs and effectively treat complex chronic conditions. The scrutiny has contributed to the porosity of biomedicine's dominance and allowed pluralistic forms of health care (e.g. Chinese medicine) to reassert themselves. Whether or not Chinese medicine may provide an effective treatment for IBS is unknown [29]; however, by continually redefining patients' needs and the abilities of both biomedicine and Chinese medicine to meet

those needs, patients may be better served. Continually redefining needs and abilities would also allow the practices to maximise their mutual benefits. Drawing on this brief summary, the reader should be able to identify some of the influences affecting the relationship between biomedicine and Chinese medicine; to perceive how the symbiotic relationship fluctuates over time; and to understand the reference to dominant-ancillary positioning. The following section elaborates on how the symbiotic dynamic has influenced an increase in acupuncture research as well as the assumptions employed to conduct acupuncture research and the impact those assumptions have on this thesis.

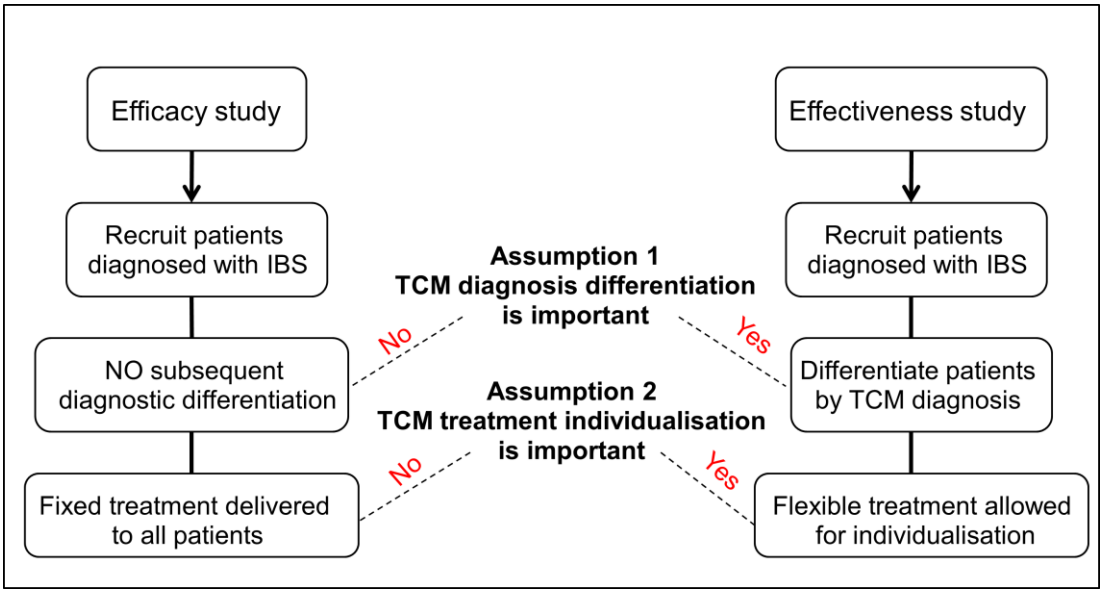
1.3 Research & symbiosis

The previous section explores how biomedicine and Chinese medicine engage in a dynamically fluctuating symbiosis, and introduces IBS as a complex, chronic condition in need of further research. With regard to research, the influence of the symbiotic dynamic manifests in biomedicine's increasing emphasis on evidence based medicine (EBM), wherein empirical evidence informs clinical practice. Although the concept of EBM can be traced to the mid 19th century, it was not until the mid to late 20th century that EBM as a movement gained momentum [30]. Recall around this same time acupuncture was gaining popularity and as Wolpe describes was being pressured to adopt a systematic research strategy [7]. A ten year literature survey (1993-2003) reports that the number of CAM articles including Chinese medicine on MEDLINE increased by 340% during the study period [31], which suggests that the emphasis on EBM and pressure to engage in research influenced the CAM community. The increase in research and the inclusion of biomedical courses in TCM curricula (mentioned previously) demonstrate TCM's compromise and adaptation to biomedicine. As such, a question arises about the effect the compromises and/or adaptations have had on clinical practice and research. Specifically, has TCM retained or altered its identity regarding diagnosis differentiation and treatment individualisation through its adaptations to biomedicine. By situating TCM within the biomedical context of IBS, this thesis intends to amplify the potential effects and evaluate the relative importance of TCM diagnosis differentiation and treatment individualisation. The following subsections introduce

research assumptions related to the fluctuating dynamic between TCM and biomedicine, and key themes in the literature.

Section 1.3.1 Research assumptions

To begin the amplification, we should familiarise ourselves with two implicit assumptions researchers make in efficacy and effectiveness studies of Chinese medicine interventions and specifically TCM based acupuncture. Box 1.1 illustrates a brief summary of how two different study designs operationalize assumptions about the importance of TCM diagnosis differentiation and treatment individualisation. Efficacy studies, typically employ a strict treatment protocol, recruit a homogeneous patient sample, and deliver care in controlled settings [32]. In comparison, effectiveness studies typically employ a flexible treatment protocol, recruit a heterogeneous patient sample, and deliver care in routine settings. In the example, both studies recruit patients diagnosed with IBS. Patients in the effectiveness study are subsequently differentiated by their TCM diagnoses, while patients in the efficacy study are not. As depicted in Box 1.1, the corresponding implicit assumptions are that TCM specific diagnoses are not important in efficacy studies and are important in effectiveness studies. To understand this more fully, it may be helpful to know that a single biomedical diagnosis corresponds with multiple TCM diagnoses and a single TCM diagnosis corresponds with multiple biomedical diagnoses [33]. Figure 1.2 illustrates how IBS may be associated with a variety of TCM diagnoses and that each TCM diagnosis is not only associated with IBS, but also a variety of other biomedical diagnoses. Therefore, all patients with IBS do not necessarily have spleen qi deficiency, nor do all spleen qi deficient patients have IBS. Although illustrative, Figure 1.2 does not represent an exhaustive diagram of associated diagnoses.



Box 1.1 Research assumptions. Compares the difference in assumptions between efficacy and effectiveness studies regarding the importance of TCM diagnosis differentiation and individualised treatment.

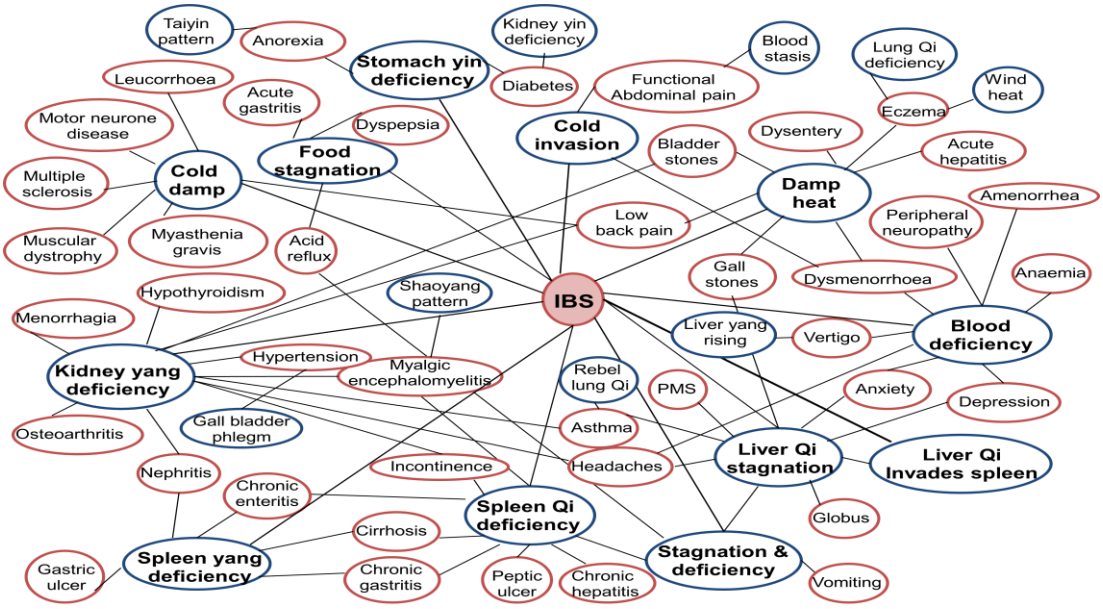


Figure 1.2 Complexity of Biomedical and Chinese medicine diagnoses. Blue circles with bold fonts indicate Chinese medical diagnoses related to IBS. Blue circles non-bold fonts illustrate some layering of associated diagnoses. Red circles indicate biomedical diagnoses associated with various Chinese medical diagnoses.

The entwined nature of diagnoses and treatments leads into the second assumption regarding the relative importance of treatment individualisation. Since efficacy studies evaluate the effectiveness of a very specific intervention, in this example a fixed set of acupuncture points, they assume that treatment individualisation is not important. One problem with the second assumption is that it discounts the fluid

delivery of TCM, wherein each treatment may combine various modalities (e.g. acupuncture, moxa, herbs) that in themselves also vary such as the selection of different acupuncture points. Furthermore, the assumption implies that the fixed point's prescription would be an appropriate treatment for all of the TCM diagnoses associated with a particular biomedical diagnosis. In other words, all IBS patients would receive the same treatment regardless of differences in their TCM diagnoses such as cold damp, damp heat, and kidney yang deficiency. From another perspective, we can invert the assumptions and ask whether it would be appropriate to recruit patients with kidney yang deficiency and apply the same treatment regardless of differences in their biomedical diagnoses such as asthma, headaches, menorrhagia, hypothyroidism, nephritis, and osteoarthritis. Simply put, the question reflects on a paradox in our approach to research. Given the research emphasis on biomedical conditions, the paradox may manifest biomedicine's growing ability to overcome the implementation barrier in favour of biomedical conditions.

In terms of application, Table 1.1 reveals how a variety of acupuncture for IBS studies employed the assumptions. Only two studies allowed for differential TCM or five elements diagnosis suggesting that they employed the assumption that diagnosis is important. Additionally, these two studies allowed for pragmatic selection of acupuncture points. In contrast, the majority of studies utilised an efficacy approach to research that did not allow for TCM diagnosis differentiation or treatment individualisation. Within the efficacy group, three studies described the TCM diagnoses they considered relevant, yet Schneider *et al* note that "the rules of TCM would have been best met if individual therapeutic schemes had been used" [34]. The comment highlights the perceived core of TCM treatment; however, literature discussed in the next section suggest that individualisation is only one aspect of treatment. To account for the potential importance of diagnosis, some efficacy studies employed a quasi-fixed approach to treatment that allowed practitioners to use a combination of fixed points and pre-selected additional points as they deemed appropriate. Overall, Table 1.1 illustrates that variations on the assumptions exist in practice, and that the assumptions to date favour the unimportance of diagnostic differentiation and treatment individualisation.

Study	Assumption 1 Diagnosis differentiation	Assumption 2 Treatment individualisation
Anastasi [35]	No†	No*
Chan [36]	No	No
Chu [37]	No	No
Fireman [38]	No	No
Forbes [39]	**Yes**	**Yes**
Huang [40]	No	No
Lembo [41]	No†	No*
Liao [42]	No	No
Liu [43]	No	No*
Liu [44]	No	No
Liu [45]	No	No*
Long [46]	No	unknown
Reynolds [47]	**Yes**	**Yes**
Rohrböck [48]	No	No
Schneider [34]	No†	No
Xiao [49]	No	No
Xing [50]	No	No

Table 1.1 Trial assumptions of acupuncture for IBS studies. † denotes studies that identified TCM diagnoses that may be important to treatment but did not allow for diagnosis differentiation. *denotes treatments that allowed practitioners to select individual points in addition to fixed points.

To summarise, efficacy and effectiveness models employ different assumptions about the relative importance of TCM diagnosis differentiation and treatment individualisation. Depending on the research question, one set of assumptions may be more applicable than the other. Due to emphases on routine settings, flexible protocols, and few restrictions on the delivery of TCM, the effectiveness approach has the potential to generate data that may be used to develop a hypothesis about the relative importance of TCM diagnosis differentiation and treatment individualisation. Therefore, subsequent chapters present data from an effectiveness study to accomplish this thesis' objectives (Section 1.4). While the general lack of information on the relative importance of TCM diagnosis differentiation and treatment individualisation necessitates this research, the following section introduces several papers that provide background on the topic and are related to the research assumptions.

Section 1.3.2Key themes in the literature

As mentioned in Section 1.1, TCM arose from an amalgamation of ideas from various schools of Chinese medicine in the 1950s [2]. Since different factors influencing an increase in pluralistic therapies were gaining momentum around the same time, it was potentially advantageous for TCM to highlight characteristics that aligned it with popular movements. Namely patient-centeredness and treatment individualisation were (are) emphasised as central to the practice of TCM as seen in the comment by Schneider *et al* [34] about the "rules" of TCM in the previous section. Additionally, Verhoef *et al* suggest that the effectiveness approach is a more valid means of evaluating the whole system[1] of TCM as an intervention because it allows for subsequent diagnosis differentiation [51]. The authors imply that the subsequent diagnostic differentiation informs an individualised approach that is central to treatment. Both of these papers provide illustrative examples of common teachings/opinions that diagnosis differentiation informs individualised treatment and that treatments are individualised.

In comparison, Unschuld provides a historical account of the different branches/schools of Chinese medicine and suggests that treatment individualisation is only one of three common approaches to treatment [52]. In addition to an individualised or patient-centred approach to treatment, Unschuld suggests that Chinese medicine practitioners employ disease specific and/or pragmatic (i.e. utilisation of useful remedy) treatments. Moreover, the three approaches may be used in combination, and are also employed by practitioners in other medical practices including biomedicine. As such, Unschuld suggests that the emphasis on individualised treatments may be promoting a stereotype that is not necessarily representative of routine practice or exclusive to TCM. Reflection on these papers raises a call for research on the role of treatment individualisation and/or other treatment approaches in routine practice. It also highlights the potential oversimplification that effectiveness studies provide more valid research.

[1] Whole systems refer to the practices such as TCM that deliver treatments that incorporate a combination of modalities such as acupuncture, lifestyle advice, herbs, and/or other additional therapies in an individualised approach.

Although primary research on TCM treatment approaches is sparse, acupuncture studies by Sherman *et al* [53] and Napadow *et al* [54] and a Chinese herbal medicine study by Bensoussan *et* al [55] provide some information about the utilisation and importance of various treatment approaches. The acupuncture studies list core points that were used across a variety of conditions illustrating the pragmatic approach, and infrequent points such as the scalp-speech point used for aphasia illustrating the disease specific approach. Treatment individualisation was described in two ways 1) regarding the patient such as the use of ashi (i.e. sensitive) points and 2) regarding the practitioner such as the use of his/her favourite points. These findings are important because they highlight the combined use of different treatment approaches in routine settings and the dual meaning of individualisation (i.e. patient and practitioner). As such, the findings support Unschuld's comment about individualisation being one of several approaches used in treatment. In comparison, the study by Bensoussan *et al* compared a pragmatic herbal formula to individualised formulas for IBS and found that both sets of treatments were significantly better than no treatment and that patients who received the individualised formulas maintained benefits longer than the pragmatic formula. While the acupuncture studies suggest that practitioners employ multiple treatment approaches, the study by Bensoussan *et al* suggests that the individualised approach may favourably impact outcome.

Similar to the information on treatment individualisation, the information on diagnosis differentiation is also sparse. The Huang di Nei Jing (classic Chinese medicine text) mentions inaccurate diagnosis as one of the five failings of a doctor in addition to ineptitude and incorrect treatment [56], while recent pragmatic studies by Sherman *et al* [53] and Forbes *et al* [39] report conflicting findings about the relative importance of TCM diagnosis to treatment. Specifically, Sherman *et al* suggest that the lack of consistency among diagnoses and treatments indicates that a patient's TCM diagnosis is not important to treatment, while Forbes *et al* suggest that it is important to treatment. Possible reasons for the contradictory findings are explored in Chapter 6 (Section 6.6). In contrast, there is an abundance of literature about the fundamental importance of biomedical diagnoses both in treatment and validation of symptoms. For example, diagnosis has been described as the cornerstone one of medical practice without which a patient may not progress through the health

services network [57, 58]; a treatment due to its potential impact on a patient's outcome regardless of prescribed treatment [59]; and a patient's biomedical diagnosis provides validation both in the form of a legitimate excuse to miss school/work and to receive sympathy from friends and family [57]. The lack of information on the importance and role of TCM diagnoses as well as the inconsistencies in findings necessitate further research on this topic. Additionally, the lack of information on the importance and role of TCM diagnosis in comparison to the abundance of information on biomedical diagnoses may favour the recruitment of patients to TCM studies by biomedical diagnosis, which is currently the typical recruitment strategy [60].

The previous section explores the symbiotic relationship between biomedicine and Chinese medicine, while this section describes how their dominant-ancillary positioning influences the research process. The discussion about the research assumptions raises a question about the relative importance of TCM diagnosis and treatment individualisation as well as the need to address this question. Given the lack of and contradictory information, a better understanding of the relative importance may enable researchers to determine the applicability of the assumptions and determine the applicability of the different models to their research questions. The following section outlines the specific questions explored in this thesis that undertake to address this issue.

1.4 Aims of thesis

Having established that a flexible approach to diagnosis and treatment may being to provide data to develop a hypothesis on the relative importance of TCM diagnosis and treatment individualisation, this section provides an overview of the aims and objectives of this thesis. As influenced by the symbiotic dynamic, TCM is explored in terms of IBS through IBS patients' treatments in routine practice compared with an effectiveness trial that allowed for diagnostic flexibility and treatment individualisation. Additionally, the emphasis on incorporating qualitative work in CAM studies (Chapter 3) prompted the exploration of patients, acupuncturists, and GPs understanding of how acupuncture works and the potential impact of that understanding. Research objectives include:

- Determine how acupuncturists contextualise and treat IBS in routine practice
- Evaluate how acupuncturists treat IBS in a pragmatic trial
- Explore the correlation between the routine and pragmatic trial treatments
- Investigate how trial participants understand acupuncture to work and assess whether that understanding affects the perceived treatment outcome
- Explore how acupuncturists understand acupuncture to work, how they explain it to patients, and whether they perceive the explanation to impact outcome
- Explore how GPs understand acupuncture to work and whether they perceive it to be a valid treatment
- Determine whether patients with particular TCM diagnoses experience a difference in outcome regarding their IBS symptoms
- Assess the relative importance of TCM diagnosis differentiation and treatment individualisation

To accomplish these objectives and formulate a hypothesis about the relative importance of TCM diagnosis and treatment individualisation, I undertook to answer two primary research questions (Box 1.2). The two primary research questions generate data from both the acupuncturists' and patients' perspectives regarding treatment delivery and outcomes respectively. As introduced in Chapters 2 and 3, controversy exists around how to best capture IBS and acupuncture outcomes, which necessitates the inclusion of several subsidiary questions. In particular, the subsidiary questions related to question two address the validity and reliability of the IBS severity measure, and the potential usefulness of practitioners' prognoses as predictors of outcome. Question three and its subquestions were included to address the necessity of incorporating qualitative work to reflect the range of patients' acupuncture outcomes as well as to better understand the dynamic between acupuncturists and GPs. If acupuncture is proven effective and is to become more widely available, data generated by question three may provide particularly useful information for future patients and policy makers. While the primary questions provide more direct evidence about the importance of TCM diagnosis and treatment individualisation, the subsidiary questions provide useful contextual data that contributes to the interpretation of the primary findings. As indicated by the complex

objectives, it was necessary to adopt a fluid mixture of methodologies and methods as deemed appropriate by the questions.

Overarching aim – formulate a hypothesis about the relative importance of TCM diagnosis and treatment individualisation from the data collected to address the following questions.

1. How do TCM acupuncturists treat IBS in routine practice and how do the treatments compare with treatments in a pragmatic study?
    a. What (if any) are the distinguishing features of treatment?
    b. How is IBS contextualised?
        i. Are treatments individualised?
2. Is there a difference in outcome for particular TCM diagnoses?
    a. Is the IBS Symptom Severity Scale (IBS-SSS) a valid and reliable measure of severity?*
    b. Can the acupuncturists' prognoses predict patient outcome?*
3. How do patients, acupuncturists, and GPs understand acupuncture to work?*
    a. Does the patient's understanding affect his/her perceived treatment outcome?*
    b. Do acupuncturists perceive their explanations to affect patients' outcomes?*
    c. Do GPs consider acupuncture a valid treatment modality?**

Box 1.2 Research questions. *Subsidiary questions asked to address the controversy around IBS and acupuncture outcomes. ** Subsidiary question asked to address potential integration and referral barriers that may affect clinical practice.

With regard to the subsequent chapters, Chapters 2 – 4 provide the background information used to develop the research questions and to select the research methods. Specifically, Chapter 2 summarises the biomedical interpretation of IBS through patients' and GPs' perspectives. As mentioned previously, the diagnostic understanding of IBS has fluctuated over time, and IBS currently lacks an effective biomedical treatment. Next, Chapter 3 explores the TCM understanding of IBS as well as patients' experiences with acupuncture. Chapter 3 also introduces the fundamental concepts of Chinese medicine necessary to navigate the chapters regarding outcomes. Having assembled the background information on the relationship between biomedicine and Chinese medicine as well as their perspectives on IBS, Chapter 4 describes the methodological approach and methods used to address the research questions.

Transitioning from the background, Chapters 5 – 9 present analyses and findings related to each of the research questions. Specifically, Chapter 5 presents the acupuncturists' contextualisation and treatments of IBS in routine practice, while Chapter 6 provides a detailed summary of the treatments delivered during the trial. Data from Chapter 5 informed the design of data collection tools for the trial as well as served as a basis for comparison to treatments thereby addressing question one. Turning to question two, Chapter 7 quantitatively evaluates the patients' outcomes to assess the change in IBS symptoms according to TCM diagnosis. Analyses in this chapter also investigate the controversy surrounding the validity and reliability of the IBS symptom severity scale (IBS-SSS), and relevance of the acupuncturists' prognoses. Chapters 8 and 9 address the third question by describing how patients, acupuncturists, and GPs understand acupuncture to work and the relative impact of that understanding. In addition to their interpretation of how acupuncture works, the patients also discuss their treatment experiences, attitudes, and relationships with the acupuncturists. The acupuncturists and GPs transcend their explanations of how acupuncture works via discussions on integration, regulation, and practice. Finally, Chapter 10 collectively interprets data from Chapter 5 – 9 to develop a hypothesis on the relative importance of TCM diagnosis differentiation and treatment individualisation. Chapter 10 also includes a discussion on contributions to the field and suggests future research.

Chapter Two

IBS Background: Biomedical Perspective

Chapter highlights

- IBS is a functional gastrointestinal disorder that may arise from a combination of aetiological factors including dysregulated communication between the brain and gut, dysmotility, and/or altered gut bacteria
- The various aetiological factors and combinations of factors give rise to a heterogeneous collection of signs and symptoms, and contribute to the difficulty in determining IBS severity
- The variety of symptoms also potentially contributes to the lack of a globally effective treatment for IBS; therefore treatments typically target particular symptoms and encourage patients to self-manage their conditions

2.1 Introduction

Since this thesis explores the treatment of patients with IBS and the relative importance of traditional Chinese medicine (TCM) diagnoses related to IBS, it is appropriate to begin the series of background chapters with a review of the biomedical perspective. As introduced in Chapter 1, there are three prominent themes associated with biomedical diagnoses including: the cornerstone of practice [57, 58], a treatment [59], and a means of validating a set of symptoms [57]. The importance each of these themes contributes to biomedical diagnoses and biomedicine's dominant position in its symbiotic relationship with TCM and encourages the recruitment of patients to research studies by particular biomedical diagnoses. Nevertheless, conditions such as IBS expose biomedicine's difficulty in defining and treating complex chronic conditions thereby favouring an increased popularity in pluralistic therapies and influencing a symbiotic fluctuation. Subsequent sections present the biomedical perspective on IBS in terms of its definition, prevalence, aetiology, signs and symptoms, treatments, and patients' perspectives. The sections highlight the heterogeneous nature of IBS and provide insight into the patient population. Additionally, this chapter provides the basis of comparison for the TCM understanding of IBS discussed in Chapter 3.

2.2 Definition & diagnosis

IBS appears in medical literature for the first time in 1950 and is associated with concomitant abdominal pain and constipation and/or diarrhoea with no known organic cause of disease [61], while in the 1970s IBS symptoms are defined as a "psychophysiological concomitant of an affective disorder" [62]. Currently, IBS falls into the category of functional gastrointestinal disorders (FGIDs) (Box 2.1), which are a collection of disorders arising from dysregulation of the brain-gut axis, altered gut physiology, and the interaction of those with psychosocial factors [63]. As indicated by Box 2.1, multiple gastrointestinal (GI) disorders lack an organic cause and share symptoms, such as abdominal pain, diarrhoea, and constipation, with IBS.

Functional Gastrointestinal Disorders

A. Functional Oesophageal Disorders

Functional heartburn
Functional chest pain of presumed oesophageal origin
Functional dysphagia
Globus

B. Functional gastroduodenal disorders

Functional dyspepsia
Postprandial distress syndrome
Epigastric pain syndrome
Belching disorders
Aerophagia
Unspecified excessive belching
Nausea and vomiting disorders
Chronic idiopathic nausea
Functional vomiting
Cyclic vomiting syndrome
Rumination syndrome

C. Functional bowel disorders

Irritable bowel syndrome
Functional bloating
Functional constipation
Functional diarrhoea
Unspecified functional bowel disorder

D. Functional abdominal pain syndrome

Box 2.1 FGIDs defined by the Rome III criteria [63]. Abbreviated list.

Within the FGID category, IBS is defined 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" [64]. Although the current definition of IBS has a less antagonistic tone than its association with an affective disorder, interview data indicate that GPs employ a textbook definition of symptoms and an experiential definition of characteristics such as frequently consulting, worried women [65, 66], which indicates that the general perception may favour the older definition. Additionally, the fluctuation in diagnoses over time illustrate biomedicine's struggle to make sense of IBS. Combined with the ambiguity of overlapping symptoms for multiple conditions (Box 2.1), the struggle to define IBS may be perceived as a weakness of biomedicine, which, as introduced in Chapter 1, may encourage patients to seek pluralistic therapies. Alternatively, it may be argued that diagnostic understandings routinely fluctuate as research and technological

advances refine the aetiology and pathology of a condition. For example, literature from the early 1980s describes HIV as an unexplained immune deficiency in previously healthy homosexual men [67]. Research has redefined HIV as a lentivirus that attacks immune cells (i.e. T cells) and is transmitted through body fluids. From this perspective, the criticism surrounding IBS may be related to the negative connotation of associated phrases such as 'worried women' or 'catch-all diagnosis' instead of the fluctuation in definition.

With regard to diagnosis, the lack of a definitive biomarker [68] allows individuals to subjectively interpret the definition. Manning *et al* developed the first diagnostic criteria (1978) intended to improve the consistency of IBS diagnoses, and described the diagnosis as 'one of exclusion' [69]. Of note, bloating, pain relief on defecation, and onset of pain with more frequent or loose stool were the predominant characteristics attributed to IBS. The presence and quantity of the aforementioned characteristics determined the likelihood of an IBS diagnosis. In the early 1990s, an international collaboration revised and renamed the criteria 'the Rome criteria' [70]. The Rome criteria provide standards for classifying and diagnosing FGIDs and associate IBS with recurrent abdominal pain and altered bowel habits (Box 2.2) [64]. Although the Rome criteria have undergone three revisions to date, controversy surrounds the categorisation of IBS as a FGID in lieu of post-infectious and tissue biopsy research further discussed in Sections 2.3 and 2.4.1 [71]. Additionally, a study by Mikocka-Walus *et al* questions the validity of the criteria based on their ability to detect approximately 50% of clinical cases diagnosed by gastroenterologists [72]. The disparity between the number of patients diagnosed by Rome III and by gastroenterologists may be attributed to the fact that the signs and symptoms are not specific to IBS [73] nor are they consistent across all patients as discussed in Section 2.4. Alternatively, the discrepancy may be an indication that gastroenterologists are over-diagnosing the condition thereby inflating the perceived prevalence of IBS as discussed in Section 2.3. Each of these arguments intensifies the ambiguity surrounding the foundation of IBS invariably obscuring information related to treatment and effectiveness.

Rome III diagnostic criteria for IBS*

-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. Symptoms improve with defecation
2. Onset associated with a change in stool frequency
3. Onset associated with a change in form (appearance) of stool

* 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.

Box 2.2 The Rome III criteria as written by Longstreth *et al* 2006 [64]

The current UK standards for diagnosing IBS were revised by the British Society of Gastroenterology in 2007, and emphasise eliminating the perception that IBS is a diagnosis of exclusion [74]. To disassociate IBS from the 'diagnosis of exclusion' stigma, the guidelines recommend GPs to tell patients that investigations are likely to be normal. Although investigations, including colonoscopy and abdominal ultrasound, routinely yield normal findings, they exclude organic causes of disease that may present similarly to IBS [75]. Additionally, the diagnostic process includes: a thorough medical history, which covers pain, bowel habit, psychological factors, family history, diet, and exacerbating factors. Alarm features such as rectal bleeding, anaemia, weight loss, nocturnal symptoms, male gender, recent antibiotic use, age over fifty, and family history of colon cancer may indicate a more serious condition. When symptoms correlate with the Rome III criteria (Box 2.2), alarm signs are absent, and investigations reveal a normal pathology, a diagnosis of IBS is recommended. Although GPs are aware that recommendations and diagnostic criteria exist, a study by Casiday *et al* reveals that GPs typically do not employ them to make an IBS diagnosis [66]. Instead, GPs base their conclusions on symptoms (e.g. alternating bowel movements) and/or triggers (e.g. frequent consultations) they consider diagnostic. Findings from the Casiday study imply that IBS diagnoses vary from GP to GP, while the disparity between guidelines and practice indicates that patients diagnosed with IBS may differ from the defined criteria. The implication of these differences is that they create a heterogeneous IBS population.

The word heterogeneous reflects the ambiguity around the composition of the IBS population that manifests in differences in GPs' diagnostic processes. Since GPs

diagnose IBS differently, their own IBS patients may have similar characteristics that are dissimilar from the characteristics of other GPs' IBS patients. Figure 2.1 illustrates this concept, which may also be applied to the different diagnostic criteria. Note that the figure conveys the idea that different GPs and diagnostic criteria identify different IBS populations, but does not accurately illustrate proportional agreement among practitioners or criteria. For example, a study by Mearin *et al* identified 211 IBS patients according to Rome I of whom only 31% also met Rome II [76]. As a whole, the IBS population includes patients diagnosed by GPs as well as those undiagnosed but who fit the defined criteria.

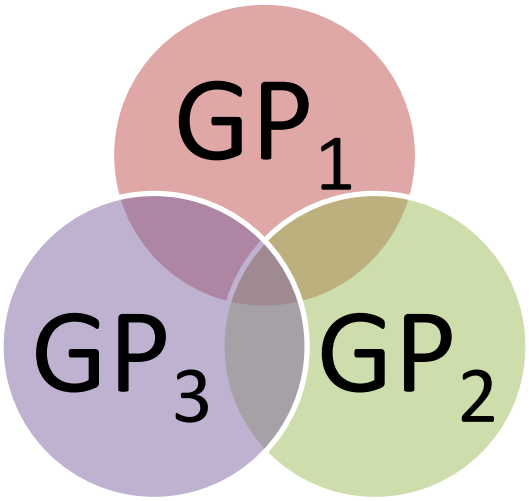


Figure 2.1 Heterogeneity in the IBS population. Each circle represents the IBS patients diagnosed by a particular GP and illustrate that the same patients may or may not be diagnosed with IBS by a different GP. Alternatively the GP labels may be substituted by criteria such as Manning, Rome I, Rome II, or Rome III.

Variations in the signs and symptoms manifested by IBS patients (Section 2.4) introduce a second layer of heterogeneity by identifying symptoms that are not consistent across the population such as rectal hypersensitivity. The Rome criteria take a simplified approach to disentangling this problem by categorising patients according to their predominant bowel pattern (Figure 2.2). Unfortunately, the simplified approach is complicated by patients' perpetual oscillation between subtypes and the inclusion of an 'un-subtype' category, which defeats the purpose of categorisation. Alternatively, Whitehead *et al* propose categorising IBS patients according to the precipitating factor of their illness such as biological or psychological factors [77]. Straightforward as this categorisation may seem, the cause for most patients' IBS symptoms is unknown as discussed in Section 2.3.

Although the categorisation schemes attempt to simplify the heterogeneous nature of IBS, the uncertainty around the cause and oscillation among subgroups undermines their usefulness. From a research perspective, heterogeneity carries a negative connotation; however, the heterogeneous context of IBS favours the use of an effectiveness approach, which also allows for the flexibility necessary to address the objectives of this thesis.

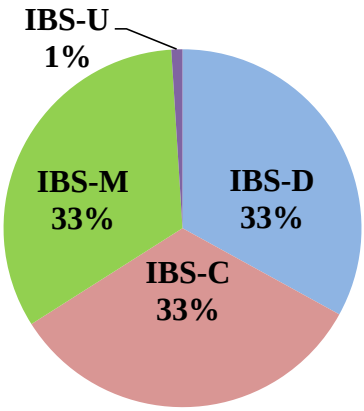


Figure 2.2 IBS subtypes (D-diarrhoea, M-mixed, C-constipation, and U-un-subtype) Percentages based on review by Longstreth *et al* [64].

While the definition and diagnosis constitute the foundation of IBS, the uncertainty cast by changing definitions as well as diagnostic inconsistency ensures that the foundation is unstable. Patients may perceive the changes and inconsistencies among doctors as a lack of information about IBS and support their perceived stigma of 'catch-all diagnosis' [65, 78]. The lack of information may also contribute to patients' misconceptions that IBS may develop into cancer or cause a decreased life expectancy, which contributes to patients' anxieties about IBS. In addition to creating a heterogeneous population and potentially contributing to patients' anxieties, the differences in definitions and diagnoses of IBS affect the prevalence, perceived severity, and treatment methods further complicating the understanding of a complex condition. As described in subsequent sections, the literature acknowledges the uncertainty around the prevalence, aetiology, and severity of IBS, which may contribute to the lack of an effective treatment introduced in Chapter 1.

2.3 Prevalence & aetiology

While the word 'heterogeneous' summarily describes the IBS population, it has also been used to describe the aetiology [79]. Consequently, the prevalence of IBS may be difficult to determine. Estimates of IBS prevalence vary between 2.5% and 37% of the population based on the criteria, such as Rome, used to make the diagnosis [74]. For example, a study by Hungin *et al* identified 3,880 people (11.5% prevalence) with IBS of whom 69% met the Manning criteria, 28% met the Rome I criteria, and 31% met the Rome II criteria [80]. Moreover, 51% of the 3,880 people had a formal IBS diagnosis, reiterating the difficulty in accurately establishing prevalence. As discussed in the previous section, GPs employ a mixture of defined and experiential criteria to diagnose IBS [65, 66], which may create differences in diagnosis rates and influence the prevalence of diagnosed cases. With regard to the question about over-diagnosis, inconsistencies across the defined criteria and GPs' diagnoses suggest that it is more important to define how the prevalence was estimated (thereby defining the population) rather than emphasising the differences in the number identified. In the UK, the point prevalence of IBS in the general population is estimated to be 10.5% as assessed by the Rome II criteria [81]. Based on the UK's current population (50 million), approximately 5.25 million people may have IBS. Differences in prevalence estimates are not unique to the UK; a European survey reports a similar finding across multiple countries [80]. To further complicate the issue, IBS sex reports are inconsistent. Specifically, women are two to three times more likely to be diagnosed with IBS than men; however, community estimates (capturing diagnosed and undiagnosed) indicated that the ratio is closer to 1:1 [82]. The female predominance among diagnosed cases may be related to health care seeking behaviour, the influence of menstruation, and/or GPs' willingness to diagnose men with IBS. According to a study by Williams *et al*, GPs were less likely to diagnose a man with IBS than a woman with the same symptoms [83]. Although the prevalence and sex of IBS patients varies according to the method of estimation, the consultation rate of two million visits for functional abdominal symptoms annually, in the UK, suggests that reducing the burden of this problem is important [84]. The indeterminant nature of IBS prevalence augments the ambiguity around the definition and diagnosis, and reveals the importance of defining the IBS study population.

In addition to a prevalence estimate, IBS has an aetiological estimate. Interactions among pathological factors including: intestinal dysmotility, visceral hypersensitivity, mucosal immune dysregulation, alterations in bacterial flora, and central nervous system (CNS) – enteric nervous system (ENS) dysregulation contribute to the development of IBS [85]. Although the combination of pathological factors necessary to trigger IBS is unknown, patients suffering from gastroenteritis are ten times more likely to develop IBS than the general population [86]. Because gastroenteritis induced by shigella, salmonella, and/or campylobacter has been associated with IBS, researchers conclude that IBS development is dependent on patients' characteristics instead of the pathogen [87]. Characteristically, the duration of gastroenteritis is the strongest predictor of IBS development [88], which together with the previous finding reinforce the importance of interactions among altered bacterial flora and some other factor(s) such as increased intestinal permeability [89] to trigger IBS. According to Kennedy *et al*, patients have a vague understanding of their IBS onset associating it with surgery, food poisoning, the environment and/or genetics [90]. On the other hand, patients consider symptom flare-ups to be specifically related to food or stress [78, 90-92]. Some patients express resentment towards the emphasis on stress because it is often regarded as a reason why doctors do not consider IBS a legitimate condition [90]. Although patients use generic terms to describe the onset and triggers of IBS, they reflect similar ideas to the biomedical factors, which are more clearly illustrated by the IBS disease models.

Several disease models attempt to explain how the interactions of multiple aetiological factors produce IBS. First, the three domain model suggests that the precipitating factor may arise from the CNS, viscera, or cognitive-behavioural domain, and contribute to the development of IBS (Figure 2.3) [93]. In addition to the suggestion that the cause of IBS could be anything acting on at least one of three complex areas of the body, the three domain model is interesting because of its year of publication (1998) roughly fifty years after IBS first appeared in the literature. Although not a new idea, causal models gained popularity in the 1990s [94] and provided biomedicine a concise method for illustrating complex disorders. In contrast to the three domain model, the linear model [95] provides a degree of specificity as illustrated by the association of early life events, psychosocial factors,

and physiology with disease development. Although the linear model depicts a more specific aetiology than the three domain model, both depict causation as a complex series of events. With regard to the patients, Figure 2.4 illustrates the clearest parallels (e.g. genetics) to their aetiological descriptions. The similarity suggests that patients recognise that IBS may be caused by a variety of different factors.

The third model incorporates specificity from the linear model and inter-relatedness from the three domain model to produce a biopsychosoical model (Figure 2.5). At the centre of the biopsychosocial model lies the emotional motor system (EMS), which embodies the collective functioning of the pain modulatory system, endocrine glands, and behaviour in response to stress [96]. The role of the EMS is further discussed in Section 2.4.3. Each of the models depicts the importance of both biological and psychological factors in IBS development. The significance of dual emphasis is that it pushes the biomedical boundary, necessitates the creation of new terms such as biopsychosocial, and links the biomedical understanding of IBS with Chinese medicine, which is rooted in dual emphasis as described in Chapter 3. Furthermore, dual emphasis may be a reflection of how biomedicine adapted to the increased popularity of pluralistic therapies.

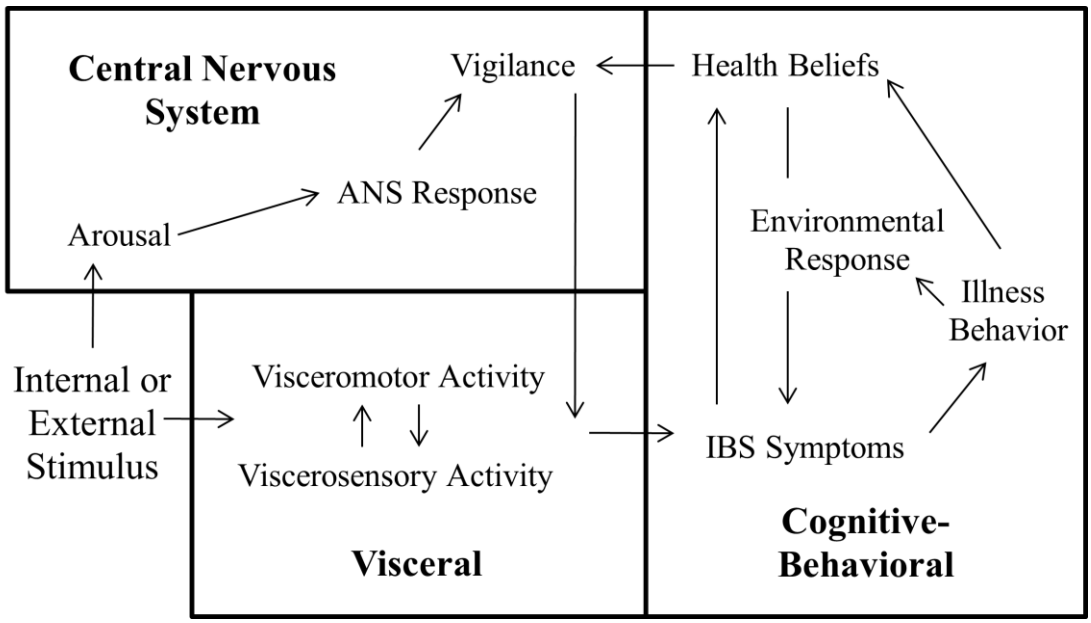


Figure 2.3 Three domain model of IBS development from Nailboff *et al* [93]. The three domains from which IBS could develop are the central nervous system, cognitive-behavioural, and visceral (organ).

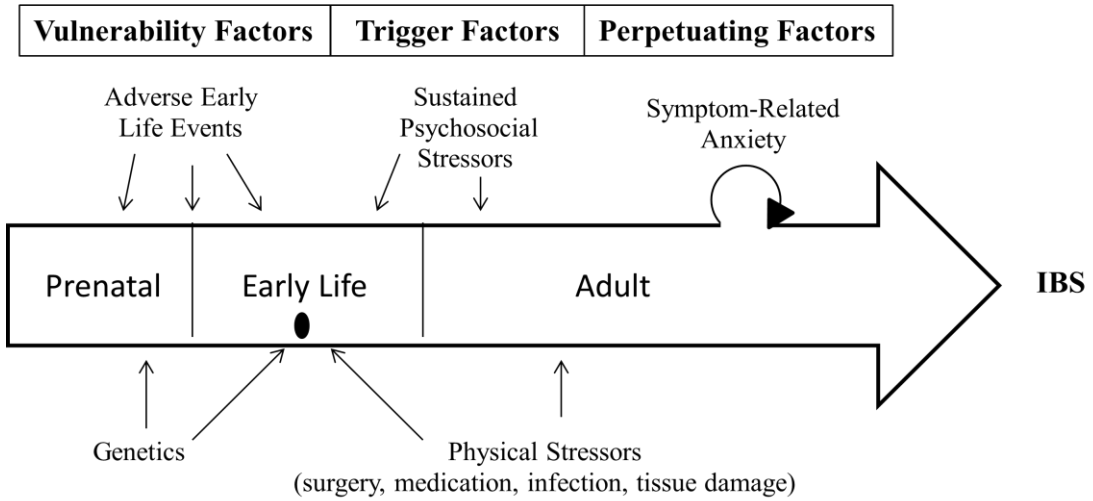


Figure 2.4 Linear model of IBS development from Mayer *et al* [95]. Depicts that early life events, psychosocial factors and physiology all influence the development of IBS.

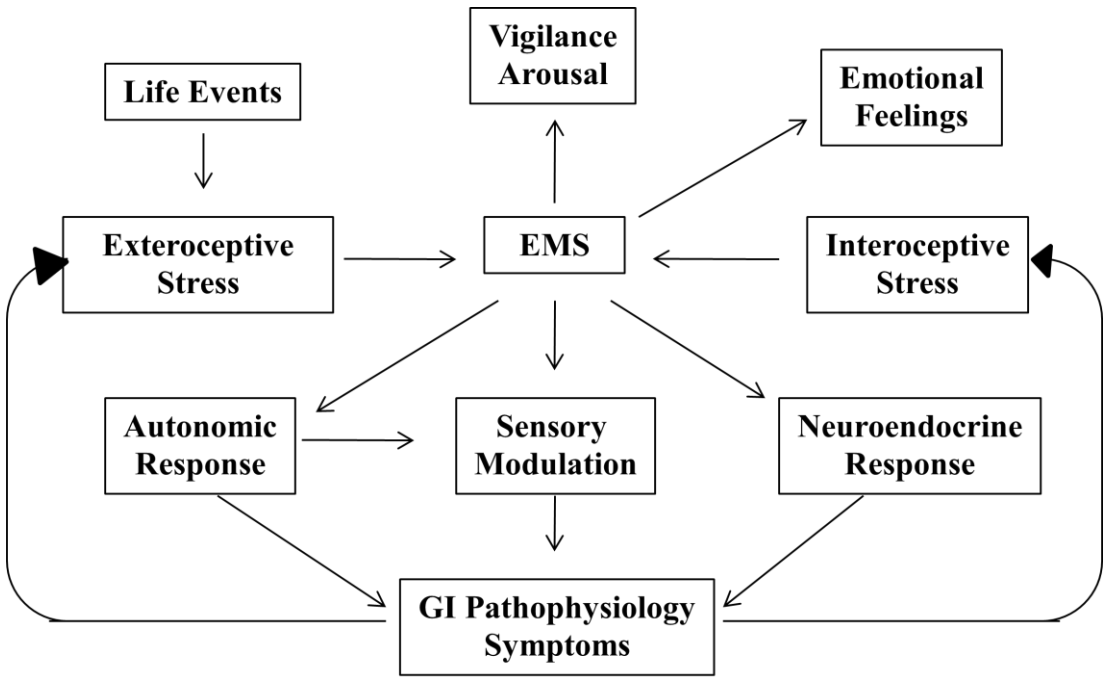


Figure 2.5 Biopsychosocial model of IBS from Mayer *et al* [95]. Depicts the cyclical influences of physiological, psychological, and social factors on the development of IBS.

Similar to the definition and diagnosis, the prevalence and aetiology of IBS lack clarity. Prevalence estimates vary depending on the criteria used to make the diagnosis as well as whether the estimate is based on known cases. With regard to aetiology, IBS may be caused by a variety of biological and/or psychological factors

as illustrated by the disease models. As mentioned in Section 2.2, Whitehead *et al* suggest categorising IBS patients by biological and psychological causes [77]. However, the various combinations of biological and psychological factors make this type of categorisation impractical. Variations in causative factors may also contribute to the diversity of signs and symptoms associated with IBS as discussed in the next section.

2.4 Signs & Symptoms

While the previous section describes the aetiology of IBS as a complex interaction among various biological and psychological factors, this section explores how those factors contribute to symptom manifestations. As alluded to in Section 2.2, 'heterogeneous' is an appropriate description of IBS signs and symptoms as evidenced by the findings, which refer to subsets of patients and are not consistent across the IBS population. Although each subsection emphasises a different aspect of the disease process (nervous, pain, immune, stress), manifestations arise from their inter-related functions. The language of the subsections is consistent with typical biomedical descriptions and provides explanations of normal physiology to contrast IBS abnormalities.

2.4.1 Pain & the Nervous System

According to the Rome III definition [64], abdominal pain is the principal symptom of IBS. Visceral (organ) pain tends to be classified as slow pain because of its burning, aching, and chronic nature, and is usually due to tissue damage [97]. Visceral pain may be triggered by excess distension or inflammation during non-pathologic or pathologic states [98]. Pain evoked in the absence of a pathologic condition or noxious stimuli is known as hyperalgesia or hypersensitivity, and may also be induced by repeated stimulation of the pain pathway. Spinal neurons provide the conduit for conveying visceral pain perceptions to the brain and inducing a stress response [99]. After accumulating in the spinal neurons, pain signals ascend to the thalamic region of the brain [100]. From the thalamus, pain signals contact a variety of other brain regions, which collectively integrate autonomic stimuli, emotional experience, pain representation, and endocrine information. The integration of this information contributes to the conscious perception of pain, difficulty in localizing

pain, amount of sensory information reaching the CNS and elicitation of general somatic and autonomic responses including: abdominal contraction, hunching, increased heart rate and increased blood pressure. Although all IBS patients may experience pain, the associated signs such as decreased brain activity in the pain processing area [101] and hypersensitivity to distension and contractile force are only present in a subset of patients [102]. The inconsistency across patients reaffirms the appropriateness of describing IBS signs and symptoms as heterogeneous.

In addition to abdominal pain, IBS patients suffer from diarrhoea, constipation, and/or a mixture of abnormal bowel habits. Motor and sensory functions, in the GI tract, responsible for propagating bowel movements are orchestrated by the ENS, which is composed of approximately one billion neurons interconnected by two plexuses 1) myenteric (outer), which controls GI movement and 2) submucosal (inner), which controls submucosal secretion and local blood flow (Figure 2.6) [97]. Myenteric stimulation generates increased contraction of the intestinal wall, increased intensity of contraction, increased rate of contraction, increased velocity of contraction, or inhibition of food movement. The signal to contract travels from the circular to longitudinal muscles at a rate of 3 – 12 contractions per minute, in an ever slower fashion from the stomach to colon [97]. Slow waves are continuous rhythmic contractions occurring in the absence of neuronal or hormonal stimulation that can be modulated by superimposed neuronal control [100, 103]. Even though slow wave initiation is continuous, contractions only occur when and where inhibitory motor neurons are inactivated [102]. Thus, for a wave to travel from point A to point B, inhibitory motor neurons must be inactivated along the entire route, or propagation fails. Damage to inhibitory motor neurons causes spastic intestinal contractions and propagates signals in either direction leading to enteric neuropathy. Enteric neuropathy identified by neuronal degeneration in the myenteric plexus has been identified in a subset of tissue biopsies from IBS patients and may give rise to their abdominal pain, diarrhoea, and/or constipation [104]. Additionally, the altered motor function allows for enteric bacteria proliferation and/or prolonged enteric infections [105], which may be influential in post-infectious IBS development.

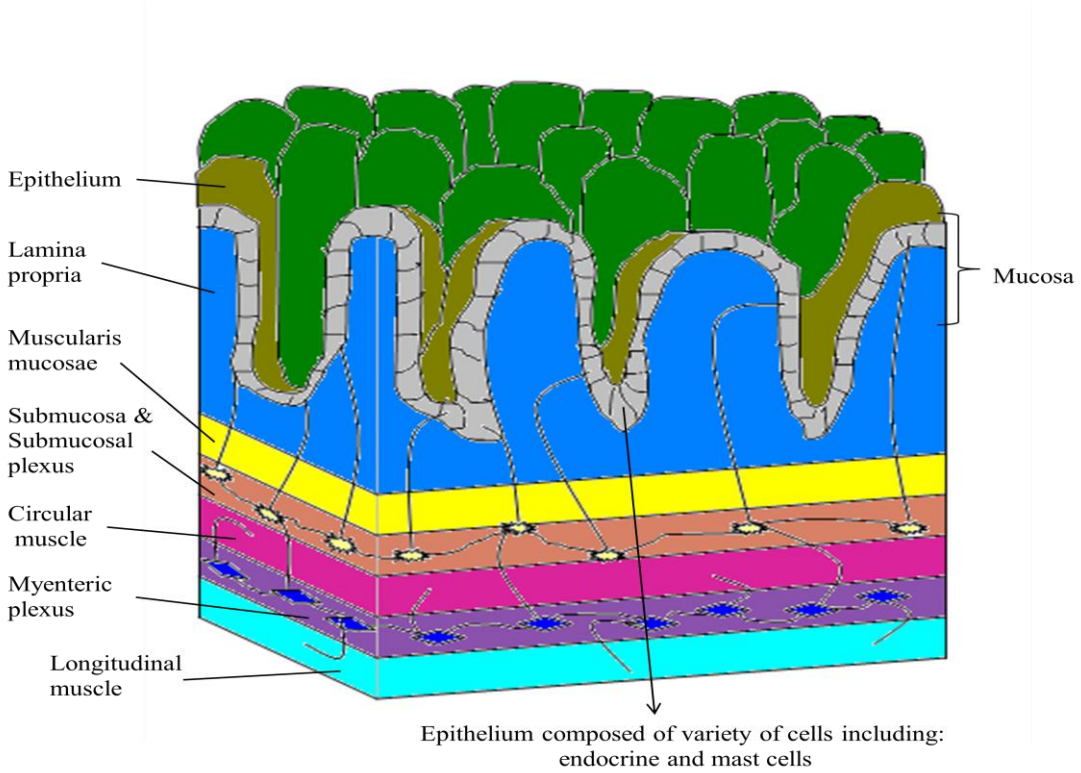


Figure 2.6 Tissue layers of the gastrointestinal tract from Guyton and Hall [97].

While myenteric stimulation influences intestinal contractions, mucosal stimulation generates secretomotory and vasodilatory responses in the submucosal plexus (Figure 2.6). Secretomotor activation results in secretion of water, sodium chloride, bicarbonate, and mucus [102]. Hyperactivity of secretomotor neurons is associated with neurogenic diarrhoea, while hypoactivity is associated with constipation and decreased mucus secretion. Hyperactivity of secretomotor neurons due to excessive serotonin release is another possible mechanism of diarrhoea in IBS patients. Before transitioning to the next subsection, it is necessary to establish the link between CNS-ENS communication and the immune system. With regard to homeostasis, the GI tract communicates through the brain-gut axis, which combines the motor and sensory functions of the GI tract as well as CNS functions [106]. Vagal neurons form a conduit of the brain-gut axis by transmitting signals directly from the GI tract to the brain stem regarding the nature of the lumenal contents and motility [100]. Information interpreted by the brain modulates digestive function through an inhibitory or faciliatory signal that is sent back to the GI tract; this information does not usually reach consciousness. Vagal neurons also relay information about inflammation and immune functioning in the GI tract [107].

Inflammation triggers a vagal response to limit tissue damage in the GI tract. Vagal stimulation by immune complexes elicits the activation of secondary support mechanisms for immune system functioning including: metabolic regulation, endocrine response, and behavioural modification [108]. Spazani *et al* found an abnormal autonomic nervous system response in IBS patients, indicating that vagal nerve function may be impaired [109]. Vagal nerve impairment could disrupt the communication along the brain-gut axis, which would subsequently affect digestion and immune functioning.

Although pain and abnormal bowel habits are primary symptoms of IBS the signs of altered brain activity, enteric neuronal degeneration, vagal nerve impairment, and altered secretomotor functions only provide explanations for subsets of patients. The differences among subsets may also contribute to the lack of an effective treatment and support a targeted approach. In addition to irregularities in the nervous system, IBS symptoms may be manifestations of irregularities in the immune and stress responses.

2.4.2 Immune Response

The description of vagal stimulation in the previous section introduces how interactions between the nervous and immune systems produce IBS symptoms. The purpose of this section is to explain the specific role of the immune system with regard to IBS symptoms. Due to the responsibilities of digesting both nutritional and potentially noxious/infectious materials, and securing the barrier between the environment and the interior of the body, the GI tract normally maintains a state of controlled inflammation [110] and a plethora of immune and endocrine cells. The endocrine and immune components of the GI tract are responsible for monitoring the physiologic condition of the organs in concert with the nervous system [100]. Endocrine cells are dispersed throughout the epithelium and generate two types of effects: 1) rapid-transient – involving behaviour, sensation, secretion, metabolism, absorption, and motor functioning and 2) prolonged – involving cell growth, morphogenesis, and differentiation. The importance and variety of these effects has earned the GI's endocrine function the name 'brain in the gut', which is not to be confused with the brain-gut axis described earlier.

The GI's immune system defends the body via gastric acid, mucus, bile, and numerous immune cells (including T cells and mast cells) located throughout the epithelium and lamina propria (Figure 2.6) [100]. The organ level response initiated by the GI system to impending danger is increased motility and mucus secretion, resulting in an effort to 'flush' potentially harmful materials from the body. Cellular level response is initiated by activation of immune cells, which in turn recruit more immune cells to the GI tract causing inflammation. Chemicals released by immune cells affect neurons, smooth muscle, and various other cells along the GI tract. During inflammation, mast cells release histamine and serotonin into the surrounding tissue, which stimulates the silent afferents involved in the pain pathway (Section 2.4.1). Histamine release, which is elevated in IBS patients along with increased serotonin, causes prolonged neuronal excitation, inhibition of histamine blockers, and inhibition of secretomotor blockers [102]. The inhibition of secretomotor blockers allows the uncontrolled release of water and mucus, which may be associated with abdominal cramping, pain, and diarrhoea [111]. In addition to their presence during inflammation, the increase in mast cells correlates with the severity and frequency of abdominal pain [112]. Although histamine and serotonin are not biomarkers for IBS, the influence of these chemicals on IBS symptoms makes them an attractive subject for acupuncture research discussed in Chapter 3.

In concert with the nervous system, the immune system participates in intricate communications that influence IBS signs and symptoms. Communications may be disrupted or exacerbated in the various tissue layers shown in Figure 2.6 including: elevations in mast cells, T cells, and or lymphocytes, which in turn release inflammatory chemicals; hypertrophy in the longitudinal muscle; and abnormal pace maker cells [104, 113]. The disrupted or exacerbated communications affect the endocrine system and may be described as a type of stress.

2.4.3 Endocrine & Stress Response

Each of the previous subsections describes a type (e.g. pain) or creator (e.g. excess serotonin) of interoceptive stress (Figure 2.5) that threatens homeostasis. The colon is particularly susceptible to stress as evidenced by increased colonic motility, decreased transit time, and induction of faecal excretion [114]. Both physical and

psychological stress can elicit these effects; however, psychological effects are prolonged [115]. As indicated by Figures 2.4 and 2.5, our response to stress heavily influences the development and propagation of IBS symptoms. Additionally, Figure 2.4 includes the factors genetics, early life events, and pathological factors which contribute to the uniqueness of each person's stress response [95]. Severe and/or chronic stress damages the fluidity of the homeostatic mechanism, which ultimately leads to exacerbation of an illness or predisposition to a new illness. With regard to the endocrine system, chemicals released by the mast cells activate the hypothalamus-pituitary-adrenal (HPA) axis alone or in combination with corticotrophin releasing hormone (CRH) [116]. The HPA axis is a fundamental component of the endocrine system that when activated causes an increase in glucocorticoid secretion, negative feedback control of the response, and suppression of GI inflammation [117]. Collective functioning of these mechanisms constitute the EMS introduced in Section 2.3 [96]. Generally speaking, the EMS co-ordinates emotionally motivated behaviour, specifically relating to homeostasis, including responses to hunger, pain, and stomach cramps [106, 118]. As indicated by Figure 2.5, dysregulation of the EMS and subsequent malfunctioning of the HPA axis is a possible mechanism of IBS. Specifically, IBS patients may exhibit an exaggerated HPA response to stress through elevated levels of cortisol and adrenocorticotrophin hormone, and/or decreased levels of CRH [117, 119]. A malfunctioning HPA axis response may contribute to fatigue, prolonged inflammation, and emotional disturbances, which in turn trigger IBS symptoms.

2.4.4 Signs & Symptoms Summary

IBS patients may suffer from a variety of symptoms including: bloating, nausea, wind, mucus, belching, diarrhoea, constipation, and/or muscle pain [90, 120]. Abdominal pain is the one symptom consistently described by patients, which may be derived from excessive release of inflammatory cytokines, neuronal damage, or hypersensitivity [102, 104]. Although abdominal pain is consistently reported by IBS patients, the pains as well as other symptoms fluctuate in their frequencies and intensities [68]. The variety of signs and symptoms as well as their inconsistencies among patients may make finding an effective treatment difficult. Furthermore, patients perceive the impact of their symptoms from a minor inconvenience to a

profound interference in their lives [65]. The differences in the impact of symptoms on patients' lives and fluctuations in intensity and frequency may contribute to their perceived severity and health care seeking behaviour.

2.5 Severity & Health Care Seeking

Due to the lack of a biomarker [68], patients' IBS symptoms are not only used in diagnosis but also to establish severity and design treatments. Considering that abdominal pain is one symptom consistently reported across IBS patients, it features prominently in discussions about IBS severity. Other symptoms such as diarrhoea and constipation may affect severity, but are not applicable to all patients [121], thereby illustrating the difficulty in capturing the relevant aspects of severity for a heterogeneous population. Furthermore, the differences in symptoms and severities present a treatment challenge as evidenced by the lack of an effective treatment for the overall IBS population. In addition to their influence on treatment decisions, IBS severities may influence health care seeking and be used as an outcome measure in clinical trials. This section describes the inter-relatedness of IBS severity, comorbidity, and health care seeking.

Both patients and practitioners estimate IBS severity, and patients use their perceptions of severity in decisions about medication, time off work, and/or health care seeking [120]. Reviews by Spiegel *et al* and Drossman *et al* identified a variety of factors patients' considered important to their severity including: pain, bloating, urgency, straining, myalgia, dietary restrictions, and limited social activities [122, 123]. Drossman *et al* also suggest that patients' severities may be determined by the number of these factors they report. Although the number of factors may influence severity, I consider the themes drawn from patients' interviews such as unpredictability, shame, frustration, loss of freedom, and isolation [91, 120] to be important factors as well. Specifically, the unpredictable nature, both in terms of symptom triggers and severity, disrupts daily routines and initiates a vicious cycle of perceived loss, frustration, shame and embarrassment [90, 92, 120]. For example a patient with unpredictable symptoms may worry about the location of toilets, be embarrassed about using a public toilet, and therefore stay home and feel a loss of freedom and frustration. Additionally, these feelings may contribute to isolation and

the search for a role in health care. Isolation goes beyond limiting activities to an unwillingness to discuss IBS and maintaining it as a 'guilty secret' [91, 92]. The themes convey strong emotions that appear to affect patients' behaviours; therefore the list of factors, which emphasise specific GI symptoms, may underestimate or not reflect the impact of those symptoms.

In comparison to the patient's perspective, practitioners evaluate IBS severity through various questionnaires and/or their experiences with patients. Similar to diagnosis, the lack of a standard measure means that a patient's severity may be considered mild by one instrument or GP and moderate by another. Table 2.1 illustrates how interpretations of severity vary by instrument, perspective (e.g. GP or patient), and source of recruitment (e.g. primary care). Similar to the variation in prevalence, severity varies based on the target sample. For example, patients receiving secondary and tertiary care have more severe GI symptoms, poorer quality of life, and more anxiety than patients in primary care [124]. Although the cases may be more severe in tertiary care than in primary care, the possibility that severity estimates will vary based on the instrument or perspective remains. The Functional Bowel Disease Severity Index (FBDSI) and the IBS Symptom Severity Scale (IBS-SSS) are two practitioner derived questionnaires commonly used in clinical trials (Appendix A). As indicated by the questions, both severity measures emphasise pain, which as mentioned previously is the only symptom consistently reported across IBS patient groups. According to the patients' perspectives mentioned previously, pain only accounts for a portion of their perceived severity. Furthermore, neither of these questionnaires is validated from the patient's perspective [122]. Thus there is a possibility that the practitioner derived instruments may not reflect the patient's perceived severity. With regard to the experiential estimates, practitioners are better able to identify patients with the least and most severe symptoms, but underestimate patients' pain intensities [125]. Since neither the practitioner derived instruments nor experiential estimates present an ideal measure of IBS severity, study outcomes may be misinterpreted as discussed in Chapter 4. Considering that the second research question addresses the effectiveness of acupuncture for IBS and that the IBS-SSS is the primary outcome, it is appropriate to further explore severity interpretations.

Chapter 7 analyses the validity and reliability of the IBS-SSS, while Chapter 8 compares the patients' perceptions of severity with their IBS-SSS categories.

Study	Diagnostic criteria	Patients	Scale	Mild %	Moderate %	Severe/very severe %
Coffin [126]	Rome II	GI clinic	IBS-SSS	8.3	41.3	50.4
Drossman [127]	Rome I	3° & GI clinic	GP rating	26	55	19
Drossman ‡ [123]	GP	Ads	IBS-SSS			55
			FBDSI			20
			Self-report			35
Francis [128]	GP	GI clinic	GP rating	16.4	42.6	40.9
Hahn [129]	Rome I	3°	Bowel symptom checklist	6	25	69
Hillila [130]	Manning	Community	Likert pain scale		73	27
	Rome I				56	44
	Rome II				56	44
Johansson ‡ [131]	Rome II	1°	Activity/frequency	36	52	12
Longstreth [132]	Rome I	1°	Pain/discomfort	29.6	45.7	24.7
Longstreth [133]	Rome I	1°	Severity question*		87	13
		Ads			97	3
		GI clinic			77	23
Ricci [134]	Rome II	1° & GI clinic	GP rating	15	23	62
Sach [135]	Rome I	3° & Ads	IBS-QoL	5	38	56
Whitehead ‡ [136]	Rome II	1° & GI clinic	IBS-SSS	21.4	42.3	36.3

Table 2.1 Variations in IBS severity. From Lembo *et al* [121] with the addition of recent papers (‡). *Patients were only allowed to classify their symptoms as moderate or severe.

In addition to differences in severity categorisations assigned by patients and questionnaires, GPs also dispute the relationship between psychological comorbidities and severity. Approximately 50% of diagnosed IBS patients suffer from a variety of comorbid conditions and symptoms (Table 2.2) [74, 137]. Anxiety and depression in particular receive special attention, yet studies report conflicting findings as to whether they are related to IBS severity and patients' health care seeking behaviours [129, 138]. However, evidence does not support a causal relationship between the psychological conditions and IBS [138]. Regardless of the relationship to diagnosable conditions (e.g. depression) the patients' emphases on shame, embarrassment, and frustration suggest that psychosocial well-being may play an important role in severity. Furthermore, differences in psychosocial well-being may distinguish patients who seek health care and are diagnosed with IBS from non-patients [138]. While the dispute over the relevance of psychological

comorbidities is likely to continue *ad infinitum*, the introduction of comorbidities and health care seeking presents two as yet unexplored aspects of IBS.

Conditions	Symptoms
Depression	Urinary dysfunction
Anxiety	Headaches
Fibromyalgia	Backaches
Tempromandibular joint disorder	Dyspareunia
Myalgic encephalomyelitis or Chronic fatigue syndrome	Muscle aches
Chronic pelvic pain	Tiredness
Cystitis	Sleep problems
Asthma	Allergies

Table 2.2 Non-gastrointestinal comorbidities. Compiled from Halpert *et al* and Whitehead *et al* [77, 139].

Although researchers dispute the relationship between severity and psychological comorbidities, patients with a diagnosed psychological comorbidity are likely to have additional comorbidities in comparison to IBS patients without a psychological comorbidity [139]. In addition to psychological comorbidities (e.g. depression) IBS patients exhibit a variety of other non-gastrointestinal comorbidities and symptoms (Table 2.2), that although are the most common in the general population have a higher incidence rate among IBS patients. However, none of the non-gastrointestinal comorbidities has a unique pathophysiological link to IBS. Diagnosed IBS patients also commonly exhibit multiple FGIDs (Box 2.1), particularly gastroesophageal reflux disease (GERD) and dyspepsia [77]. The comorbid existence of those conditions is possibly due to the fact that they have overlapping symptoms such as abdominal pain. Overall, gastrointestinal comorbidities are more common than non-gastrointestinal comorbidities, and have a shared pathophysiology with IBS [139]. With regard to severity, a study by Speigel *et al* reports that IBS patients health related quality of life (HRQoL) is strongly associated with chronic stress and exhaustion including: poor sleep, low sex drive, and fatigue, but is not related to patients' gastrointestinal symptoms [79]. The repetitive use of the 'diagnosed' tag highlights the fact that these findings are representative of subsets of patients who have an IBS diagnosis, which accounts for approximately 30 – 40% of IBS suffers in the community [74]. In general, these findings raise more questions about the applicability of the severity measures described previously.

Based on the previous paragraphs a picture of the different IBS populations has begun to emerge, which is illustrated in Figure 2.7. Throughout the chapter, I have mentioned that approximately 33 – 90% of people with IBS symptoms do not seek health care and may be undiagnosed [74]. Non-consulters (or non-patients) report not seeking health care because their symptoms were mild or under control, they had asked a family member for advice, they used a non-biomedical intervention for treatment, or they feared the diagnosis [124]. Additionally, non-consulters are less likely to be diagnosed, have less comorbidity, have greater coping abilities, and have better HRQoL than consulters [124, 140]. According to Bertram, IBS patients initially seek treatment for abdominal cramping and diarrhoea in their teens to mid thirties [91]. Many patients consider this a diagnostic phase of health care seeking, which ends for some due to a lack of remedy or empathy. This group of patients comprises the sporadic consulters group and find themselves somewhere in between the other groups with regard to symptom severity, comorbidity, and ability to cope. Alternatively, frequent consulters are likely to have psychological comorbidities, poor social support, more severe IBS symptoms, and poorer HRQoL in comparison to sporadic and non-consulters [124, 140].

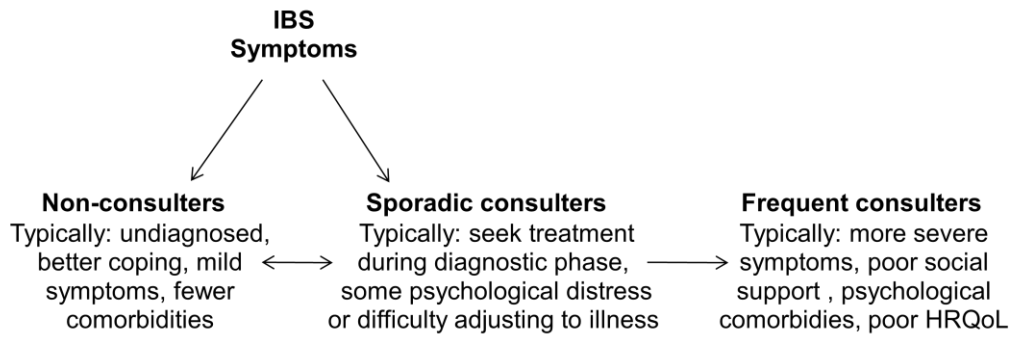


Figure 2.7 Health care seeking of IBS population from Koloski [140].

Similar to the discussion on prevalence variation, consultation rates also vary according to the criteria used to define IBS. For example, a study by Badia *et al* reports that 42% patients identified by Rome I and 68% of patients identified by Rome II were consulters [141]. One other notable remark about the study was that consultations were recorded regardless of complaint. In comparison, a study by Sandler reports that 62% of the patients who met the IBS study criteria did not

consult for their abdominal problems [142], while a study by Akehurst *et al* reports that GP diagnosed patients meeting the Rome I criteria used significantly more resources than non-patients [143]. Although the diversity of findings is confusing, they suggest two important concepts: 1) patients diagnosed with IBS are likely to consult more frequently, although not necessarily for IBS related symptoms, than non-consulters, and 2) patients' comorbidities influence their health care seeking behaviours.

For research purposes, the differences in severity and health care seeking have several important implications. First, patients with mild symptoms are more likely to report symptom relief but have smaller score changes than more severe patients who are less likely to report symptom relief, despite higher baseline scores and larger score changes [136]. Furthermore, the impact of comorbidities, in particular exhaustion and psychosocial well-being, are not currently reflected in IBS severity measures. Both of these discrepancies highlight the importance of collecting quantitative severity outcomes such as the IBS-SSS as well as qualitative outcomes that capture other aspects of well-being and patients' perceptions of improvement. Second, the site of recruitment determines the relative severity of patients' IBS symptoms and level of comorbidity in an increasing fashion from community to primary care to tertiary care. Therefore, studies that plan to generalise findings to a broad IBS population would need to recruit from multiple sites. Third, the finding that the majority of IBS consulters continue to seek health care for their comorbid conditions, suggests that treatments should target both to improve quality of life and reduce resource use [131]. Given that IBS currently lacks an effective treatment, as discussed in the following section, this finding presents an imposing challenge that simply improving IBS symptoms may not be sufficient to decrease the overall health care burden of IBS. Although imposing, the challenge may make complex interventions such as acupuncture an attractive option to investigate.

2.6 Treatment

As discussed previously, biomedicine currently lacks an effective treatment for IBS, which may be influenced by the variations in symptoms and severities. Since IBS lacks an effective treatment, the most recent guidelines advise GPs to employ

empathetic listening and offer advice on lifestyle, stress, diet, and symptom management [74].With regard to diet, treatments may encourage an increase or decrease in fibre intake based on the patient's current intake; however, the guidelines acknowledge that there is not sufficient evidence to support this recommendation. Other dietary recommendations are a trial of wheat and/or lactose exclusion or dietary modification that identifies intolerance. GPs are recommended to offer psychological treatment (such as CBT or psychotherapy) based on the patient's preference or if the GP suspects marked psychological symptoms. Pharmacological treatment of IBS is recommended to be based on the patient's predominant symptom. Since single drugs are not globally effective, treatments may involve multiple drugs. Specifically, there is some beneficial evidence for some antispasmodics for abdominal pain; however, there is no clear evidence for the use of antidepressants or bulking agents for IBS [144]. The authors of this review conclude that there is weak evidence supporting IBS drug efficacy. Considering that the recommendations read as a black box of possibilities, it is not surprising that some GPs have described the treatment of IBS as frustrating or trial and error [66]. Furthermore, the lack of an effective biomedical treatment facilitates the use of pluralistic therapies (Figure 1.1) and provides an opportunity for those therapies to establish effectiveness.

One potential alternative to pharmacological treatment is the use of probiotics or 'good' bacteria to support digestion. As mentioned previously, damage to good bacteria in the gut may occur during gastritis or pro-longed inflammation. A systematic review by McFarland *et al* demonstrates that probiotics may improve IBS symptoms but carries a disclaimer that there is insufficient evidence for a recommendation [145]. A second potential alternative is acupuncture, which the World Health Organisation describes as an area for further research with regard to IBS [146]. A systematic review by Lim *et al* suggests that the acupuncture studies to date are of poor quality and do not provide sufficient evidence to support a decision on the effectiveness of acupuncture for IBS [29]. Therefore, good quality studies, such as the clinical trial within which this work is based, are needed to generate evidence that may support a decision on the effectiveness of acupuncture for IBS.

In comparison to the recommendations and possible treatments, patients typically self-regulate treatments based on their IBS symptoms [91]. For example, patients are likely to take an anti-diarrhoeal during a diarrhoea episode. Although IBS symptoms may be associated with frustration and a loss of freedom, some patients find empowerment in developing their own treatments incorporating: vitamins, herbs, massage, exercise, and hot baths [92]. Despite the empowerment derived from developing their own treatments, some patients value a teamwork approach between themselves and doctors, which may influence the patient's willingness to try multiple therapies. According to Harris and Roberts, IBS patients' high acceptability of a variety of therapies such as yoga and suppositories corresponds to the unmet need for an effective treatment [147]. In comparison to the GP recommendations which give generic, if not confusing, dietary advice, patients perceive diet to be a key aspect of treatment [90]. Nonetheless, both the GPs and patients describe a trial and error approach to treatment that may incorporate a variety of modalities. Here it is important to reiterate that patients actively seeking care may only represent one third of people with IBS symptoms. Furthermore, the literature favours the treatment strategies of those patients with an IBS diagnosis; however, this is not particularly problematic because those patients are more likely to seek treatment. The patients' willingness to try multiple therapies and specifically CAM therapies suggests that patients may respond favourably to recruitment for this study.

2.7 Summary

IBS is a heterogeneous condition not just in terms of the variations in signs and symptoms but also in terms of the different populations identified by diagnostic criteria. Adding further complexity to the issue are the variations in symptom severities and comorbidities. Given the amount of heterogeneity, it is unsurprising that researchers such as Whitehead *et al* [77] have questioned whether IBS is a single condition. As mentioned previously, diagnostic understanding evolves over time, so it is possible that the future definition of IBS may identify a more homogenous population. Based on the emerging physiological evidence and the emphasis on targeting treatment to particular symptoms, I agree that patients are likely to be classified into different diagnoses and that IBS will identify a smaller more homogenous population in the future. Today researchers should address the

challenges presented by questionable IBS outcomes and recruitment constraints discussed in Chapter 4. Furthermore, as indicated by Johansson *et al*, researchers should address both IBS specific symptoms as well as comorbid symptoms to maximise the patient's potential treatment benefits [131]. The effectiveness design of the trial portion of this study allows practitioners to deliver treatments that potentially target multiple areas. Before discussing the methods used to collect and analyse data (Chapter 4), the following chapter explores the fundamental concepts of TCM and the TCM interpretation of IBS including associated diagnoses and treatments.

Chapter Three

IBS Background: Chinese Medicine Perspective

Chapter highlights

- TCM utilises observations of the natural world to explain the onset and aetiology of disease, and emphasises balance among the elements as the key to wellness
- As an intervention, TCM provides complex treatments that may include acupuncture, herbs, and/or additional therapies
- With regard to IBS, the literature suggests that patients may manifest a variety of TCM diagnoses and that each of those diagnoses may be related to a unique treatment that is also influenced by the practitioner
- Mechanistically, acupuncture may alleviate IBS symptoms based on its ability to regulate cytokine and hormone levels and affect impaired neuronal communication

3.1 Introduction

The previous chapter reviews the IBS background from the biomedical perspective and highlights the heterogeneity of symptoms, comorbidities, and severities that create a diverse IBS population. One key aspect of the diversity is that the majority of information on IBS only applies to a subset of patients who are likely to be diagnosed and seeking health care. Additionally, IBS currently lacks a globally effective biomedical treatment [144]. As illustrated in Figure 1.1, a variety of factors such as the lack of an effective biomedical treatment and the perceived ambiguity of some biomedical diagnoses augmented the popularity of pluralistic therapies. The increase in pluralistic therapies such as TCM has the potential to alter the dominant-ancillary symbiotic dynamic between the medical practices. However, it is unclear as to whether acupuncture is an effective treatment for IBS [29]. The lack of an effective biomedical treatment and the uncertainty around acupuncture provide the impetus to conduct further research on TCM-based acupuncture for IBS. Particular to this thesis, the need for further research provides an opportunity to explore the relative importance of TCM diagnosis differentiation and treatment individualisation. Before proceeding to the data chapters that address this question, this chapter reviews the TCM understanding of IBS.

In comparison to the uncertain aetiology and heterogeneity among IBS diagnoses, the TCM understanding of IBS may be depicted as uncertain and heterogeneous regarding diagnosis and treatment (Figure 3.1). The foundational concepts of yin-yang and the five elements depicted in the first image of Figure 3.1 allow for the complex interaction of multiple aetiologies to produce various symptoms that may be related to multiple diagnoses. Although a variety of TCM diagnoses may be associated with IBS (Figure 1.2), there is a lack of empirical evidence about the identity of those diagnoses and their associated treatments, which may incorporate a variety of acupuncture points, herbs, or additional therapies. The heterogeneity of treatments elicits a question about whether the effectiveness of acupuncture should be assessed by treatment according to specific points' prescriptions, biological efficacy (Section 3.3), or practitioners' pragmatic selection. Before reviewing the TCM and trial literature of associated diagnoses and treatments for IBS, the following sections introduce the fundamental concepts of TCM, a mechanistic

explanation of how acupuncture works, patients' understandings and experiences with acupuncture, and the difficulty in measuring acupuncture outcomes.

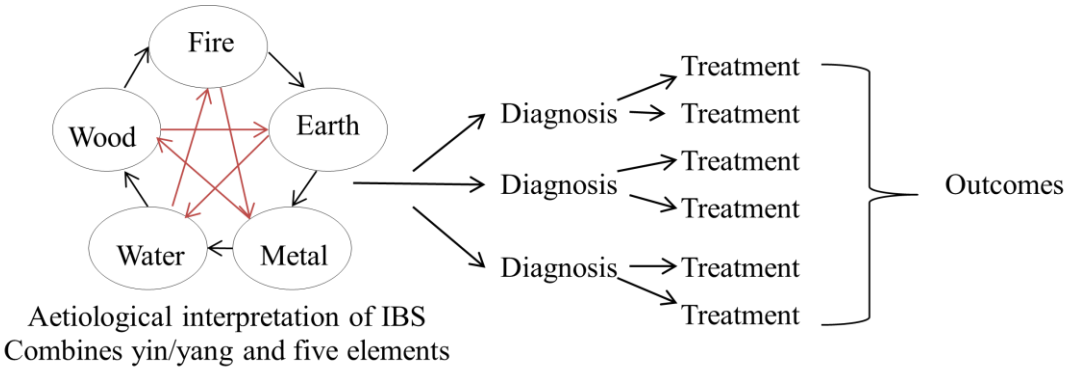


Figure 3.1 Chinese medicine understanding of IBS. IBS symptoms are interpreted by yin/yang and five elements theories to generate TCM diagnoses that may be used in treatment to produce outcomes.

3.2 TCM concepts

As mentioned in the previous section, TCM language may be unfamiliar to some readers; therefore this section provides a brief overview of important concepts to enable readers to engage with the data particularly in Chapters 5 – 6. The fundamental concepts of TCM lie in the complex interactions between yin and yang as well as the five elements. Yin and yang serve as a platform for observing and analysing the material world and represent two inter-related, opposing, and continuously transforming aspects [148]. Historically yang is related to the sunny side of a hill, fire, and men, while yin is related to the shady side of a hill, water, and women. Beyond the simple dichotomy, theory suggests everything in existence is comprised of these two aspects. In TCM, yin-yang underpins physiology and pathology as well as guides diagnosis and treatment. Information is also classified according to the five elements (Table 3.1), which is a similar, yet more complex model than yin-yang [23]. The primary cycles generate and control the development of the elements, creating positive and negative feedback loops (Figure 3.2). In healthy individuals, the body maintains a harmonic balance between yin-yang and the five elements. As a biomedically trained microbiologist and a TCM practitioner, I appreciate that the initial introduction to these concepts may be difficult to grasp. To facilitate your understanding of these concepts, you may substitute the more familiar concept of homeostasis (mentioned in Chapter 2).

Element	Tissue	Season	Colour	Taste	Organ	Emotion
Water	bones	winter	black	salty	kidney, bladder	fear
Fire	vessels	summer	red	bitter	heart, small intestine	joy
Earth	muscles	late summer	yellow	sweet	spleen, stomach	worry
Metal	skin	autumn	white	pungent	lung, large intestine	melancholy
Wood	sinews	spring	green	sour	liver, gall bladder	anger

Table 3.1 The TCM theory of five elements

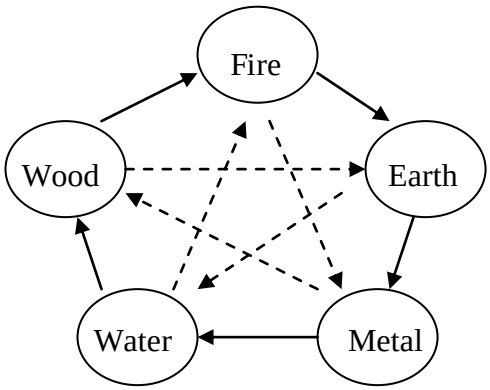


Figure 3.2 Five element diagram of primary cycles. Black arrows indicate the generating cycle. Dashed arrows indicate the controlling cycle

3.2.1 Qi

While the universe is infinitely divided into yin-yang aspects, the entity responsible for producing matter and phenomena is qi (pronounced chee). Qi exists as an essential substance within the body as well as drives the body's functions including: growth; development and physiological activity; warming the body; defence; and nourishment [148]. Additionally, qi manifests as a person's 'shen' or spirit/consciousness [23]. Shen is comprised of five spirits each relating to a different virtue that when functioning well correlate with healthy relationships, self awareness, and pursuit of goals [149]. Imbalances of shen may manifest as confusion, boredom, passiveness, or mental illness. Considering the emphasis on the psychological component of IBS, described in Chapter 2, and its association with anxiety and/or stress, the possibility exists that shen may play a role in the TCM understanding of IBS (Chapters 5 – 6). In addition to shen, the state of a person's qi may be reflected in his/her energy, pulse, and appetite.

Qi traverses the body along the meridian system known as 'jingluo', which consists of fourteen principle pathways and numerous branches [150]. Transportation of qi

throughout the meridians connects the internal organs and tissues with the exterior surface of the body. Each of the principle meridians is associated with an organ (e.g. heart) and may manifest an imbalance or be used in treatment of its associated organ. The organs, collectively known as the 'zang-fu', each correspond to an aspect of yin or yang and to an organ of the opposite aspect (e.g. spleen-yin partners stomach-yang). Both biomedicine and TCM associate the large intestine with water absorption and excretion; however, TCM also links the large intestines with the emotional ability to let go and to the functions of the spleen and liver [33]. The interdependent relationship between these three organs is clarified by Figure 3.2 where the liver – wood controls the spleen – earth, which controls the large intestine – metal which completes the circle by controlling the liver. Consequently, bowel problems in TCM are commonly associated with a spleen or liver imbalance as described in Section 3.5.

3.2.2 Causes of illness and diagnosis

According to TCM, health is maintained by free flowing qi and blood throughout the body, which may stagnate when acted upon by external, internal or miscellaneous influences shown in Table 3.2 [33]. As indicated by Table 3.2, emotional, physiological and environmental influences interact to cause disease. Emotions are considered a necessary part of healthy functioning; however, they may cause disease when they are chronically excessive or deficient, or when they are suddenly extreme [149]. The Huang Di Nei Jing, a classic TCM text, states that the various influences were able to cause disease because people "no longer knew the correct way to live and disregard the principles of healthful living." Consequently, "illness came more easily and are more complex" [56]. Surprisingly this excerpt, which is over 2000 years old, is applicable today. As people struggle to get enough exercise and to eat a balanced diet, they increasingly suffer from chronic and/or complex disorders (e.g. IBS). The comment from the Huang Di Nei Jing simply summarises the concept of dual emphasis in that illness arises from a combination of factors that are related to the patients' attributes and behaviours as well as the environment and the nature of the illness. Although not identical, this concept is similar to the biopsychosocial model (Figure 2.5) of IBS that incorporates stress, physiological dysfunction, and patients' behaviours. Furthermore, this similarity may represent an aspect of the

symbiotic relationship that biomedicine and Chinese medicine could exploit for their mutual benefit.

Classification	Causative agent
External	Wind, cold, damp, heat, fire, dryness
Internal	Joy, anger, fear, fright, sadness, worry, pensiveness
Miscellaneous	Overwork, excessive sex, improper diet, trauma, weak constitution

Table 3.2 TCM causes of disease

TCM diagnoses attempt to identify the underlying disharmony producing disease manifestations, by determining the nature and character of a disease, location, and treatment principle [33]. There are various disease differentiation methods including: eight principles, qi-blood, zang-fu, six channel, five element, and four levels. Analyses in Chapters 5 – 6 discuss the most commonly used differentiation methods in this study; therefore, they are briefly defined here. The eight principles framework classifies disease according to heat/cold, yin/yang, exterior/interior, and excess/deficiency, and may be applied to any disease (e.g. common cold – cold, yin, excess, exterior). The qi-blood framework identifies imbalances among the essential substances, and may be integrated with the eight principles or zang-fu frameworks (e.g. menstrual pain – qi and blood stagnation). By applying the concepts of the eight principles and qi-blood frameworks to the organs, the zang-fu framework determines the affected organ (e.g. kidney yin deficiency), thereby making it the most important framework in clinical practice [33]. Differentiation methods may be used individually or in combination giving rise to an array of possible diagnoses for a particular condition as seen in Figure 1.2, Section 3.5, and Chapters 5 and 6.

3.2.3 Treatment

One of the primary means through which TCM practitioners may attempt to treat a condition is through acupuncture. Acupuncture points are categorised as either channel points, lying along one of the principle meridians; extra or non-channel points; or ashi points, defined by pain upon pressure [151]. Points are characterised by both their actions (e.g. clear heat) and their indications (e.g. sore throat) [33]. With regard to treatment, points may be selected based on empirical understanding, point categories, channel, and/or sensitivity to palpation. Acupuncture's effectiveness

is derived from its ability to manipulate qi and blood through the functions of moistening, drying, warming, cooling, unblocking, augmenting, depleting, raising, and lowering [149, 152]. Collectively these functions promote self-healing and restore balance. Figure 3.3 depicts the most commonly used acupuncture points for GI disorders based on reviews by Diehl and Ouyang [153, 154]. The variety of points illustrates the diversity in treatment design that may combine local (e.g. St 25), distal (e.g. P 6), and/or organ specific (e.g. UB 18) points.

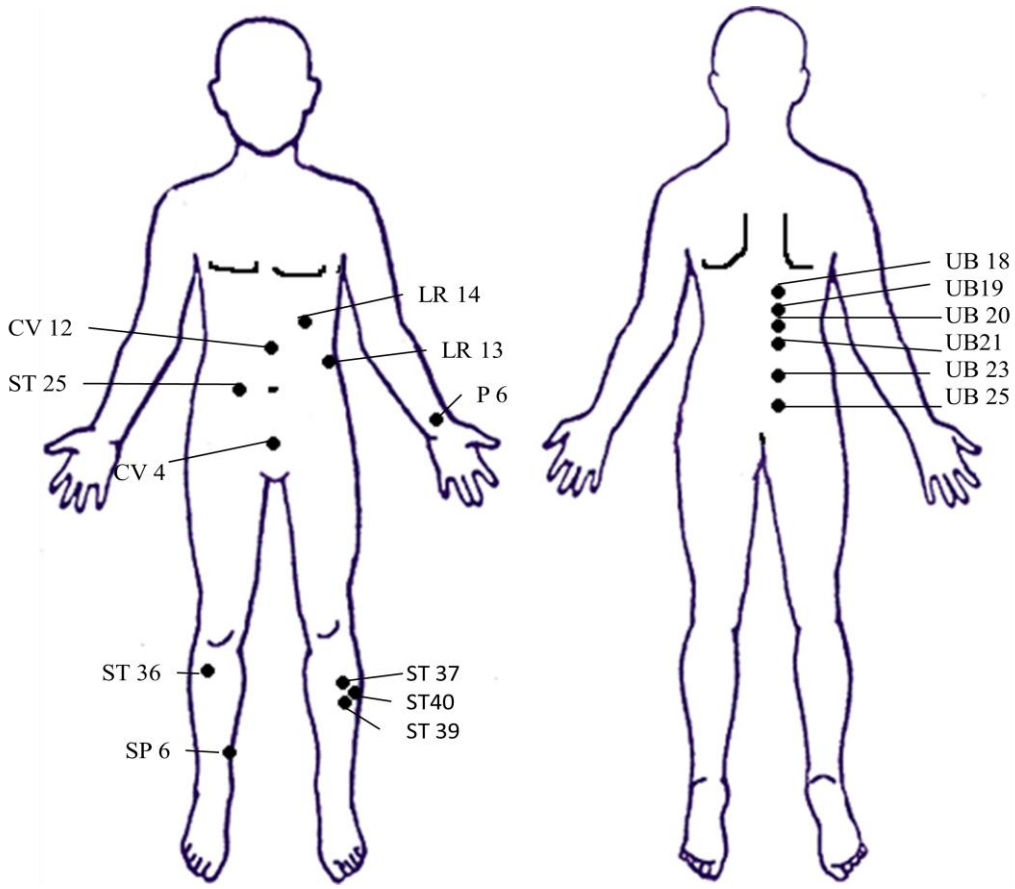


Figure 3.3 Most commonly used acupuncture points for GI disorders

In addition to acupuncture, TCM practitioners may use a variety of adjunct modalities to amplify treatment effects. For example, moxibustion (aka moxa) applies the herb *Artemisia vulgaris*, a species of chrysanthemum, to needles or skin to heat a particular area [148]. Moxa travels through all the principle meridians and is associated with the ability to expel cold, stop bleeding, expel damp, regulate qi, and augment yang. Similarly, cupping is an adjunctive therapy that creates a vacuum between the skin and a glass jar. By creating a vacuum, cupping augments local circulation, decreases swelling, expels cold damp, and unblocks stagnation. As

discussed in Chapter 4, the effectiveness nature of the study allowed practitioners to use these adjunct therapies as they deemed appropriate. The use of additional therapies, either in conjunction with acupuncture or separately provides an example of how acupuncture behaves as a complex intervention [155]. Furthermore, the complexity of acupuncture manifests in its ambiguous definition, variety of styles (e.g. TCM, five element, trigger point), and multiple modalities (e.g. moxa, cupping). Strategies to research complex interventions and accommodate the inter-dependent functioning of their components are discussed in Chapter 4.

3.2.4 TCM concepts summary

According to TCM theory, imbalance in yin-yang or the five elements may be used to interpret illness. The interpretations may incorporate the concept of qi or various mundane causative factors such as overwork, and may be applied to a variety of diagnostic frameworks. To treat illnesses, practitioners may use a variety of modalities, which in themselves may be composed of a variety of delivery options. All these variations as well as the potential importance of the practitioner who delivers the treatment contribute to intervention complexities. Therefore, this thesis attempts to determine the relative importance of TCM diagnoses and treatment individualisation from a complex intervention applied to a complex disease.

Although both TCM and biomedicine epitomise balance, have defined diagnosis and differentiation procedures, and utilise a variety of treatment modalities, their language is different. Biomedicine's literal explanations of anatomy and physiology, as seen in Chapter 2, sharply contrast with TCM's figurative explanations. That is not to say that biomedicine is devoid of figurative language; metaphors are commonly used in clinical practice to explain technical (i.e. scientific) concepts [156]. For example, IBS may be literally explained as the over secretion of histamine and serotonin which prevents the absorption of water and mucus causing diarrhoea (Section 2.4.2). Figuratively, a healthy colon absorbs water like a sponge thereby producing solid faecal material. In IBS patients, the sponge's pores are blocked, which prevents water absorption. In contrast, TCM employs figurative language to explain natural (i.e. observed) concepts that are fundamental to TCM theory. For example, the description that the large intestine is the transportation official [56] or

toll booth operator explains the observation that faecal material passes through the large intestine. Although our everyday language may be filled with figurative expressions, scientific disciplines tend to associate such expressions with untruth and literal language with truth [157]. Therefore, TCM's use of figurative language at the foundational level may be a source of tension between the practices and compound difficulties in interpreting different cultural expressions. According to Gibbs, unfamiliar figurative language may hinder communication and foster misunderstanding [157]. Given the differences in language and potential for misunderstandings, Wolpe's suggestion that biomedicine endeavoured to change the language of Chinese medicine so as to incorporate it into practice [7] seems plausible. In addition to the poor understanding of Chinese medicine's figurative language, biomedicine was also concerned by the lack of a literal explanation for acupuncture's mechanism. The following section explores some of the scientific explanations for the mechanism of acupuncture, which may also serve as comparisons for the third research question 'how do patients, acupuncturists, and GPs understand acupuncture to work'.

3.3 Acupuncture's scientific mechanism

The scientific description of acupuncture's mechanism serves two purposes. First, in addition to the question of relative importance of TCM diagnosis and treatment individualisation is the question of the impact of a patient's attitudes, experiences, and expectations on outcome. Specifically, does a person's understanding of how acupuncture works play a role in his/her outcome. Therefore, the descriptions in this section may be important to some patients and possibly influence their treatment outcome. Second, the descriptions demonstrate how biomedicine's dominant influence has shaped TCM research and incorporation of scientific language. Although TCM practitioners may be content with the traditional explanation of how acupuncture works, some researchers have claimed that "such fanciful metaphysical theories [are] obsolete" [158]. Thus begins the quest to identify a biochemical mechanism of acupuncture and the co-optation of biomedical language. During the quest, researchers have been puzzled by: the existence of acupuncture points; the inconsistency of acupuncture point distribution with nerves, vessels, and lymphatics; the non-specific stimulation (e.g. needle, temperature, pressure) of acupuncture

points; and the long-lasting effects attributed to transient stimulation [159]. A review by Moffet *et al* estimated that 50% of acupuncture studies provide a rationale for how acupuncture works, and that most papers cite neurochemical responses [160], indicating popularity, at least among researchers, of the biochemical mechanism. The elusiveness of a comprehensive scientific mechanism favours an efficacy approach to research and suggests that the studies described in this section are likely contributory pieces to the mechanistic puzzle.

Possibly influenced by the excitement over acupuncture anaesthesia, early research concentrated on the mechanism by which acupuncture modulates pain. The gate control theory proposed that impulses travelling from the periphery to the brain and back to the periphery pass through 'gates' along the spinal nerves [161]. The ability of the gates to modulate the descending impulses could influence pain perception, thus it was inferred that acupuncture manipulated the gates and decreased pain. Subsequently, acupuncture points were related to motor points, "points which elicit maximum muscular contraction when stimulated", and their ability to stimulate peripheral nerves [18, 162]. Based on the premise that acupuncture points should be adjacent to nerves or simulate motor points to affect manipulations, Ulett categorised 80 of the known 365 plus points as medically relevant [21]. Consequently, some researchers concluded that the meridian system did not exist and that the nervous system was the sole mediator of acupuncture's effect. A more recent study by Birch contradicts the earlier work by demonstrating a correlation between motor points and ashi points, and not with channel or extra points [151]. Several inferences can be drawn from these studies including: some acupuncture points are adjacent to nerves and may stimulate nervous responses; proximity to nerves and/or motor points does not describe the location of all acupuncture points; and the points not located near nerves may mediate their effects via alternative mechanisms. The following subsections describe two of the more recent scientific explanations of the acupuncture mechanism.

3.3.1 Neurophysiology model

The first explanation explores cellular behaviour at the site of needle insertion and its broader effects. Langevin *et al* propose that the acupuncture meridian network is

representative of interstitial connective tissue, which connects organs and tissues of the body [163]. Their studies determined that needle grasp (binding needle to tissue) was due to connective tissue stimulation not muscle contraction, and that the stimulation was not unique to acupuncture points but was enhanced at those sites. Binding needle to tissue via needle manipulation, induces a change in cellular architecture and mechanosignal transduction [164], which I illustrated in Figure 3.4. These signals may elicit cellular responses in the form of cytoskeleton remodelling or changes in cell shape, and/or molecular responses in the form of altered gene expression, cell signalling, and/or matrix adhesion [165, 166]. Furthermore, their studies determined that acupuncture channels typically intersected with intermuscular or intramuscular connective tissue planes [163]. These studies support the case for the existence of both acupuncture points and meridians, and demonstrate the ability of acupuncture to elicit responses independent of neuronal involvement.

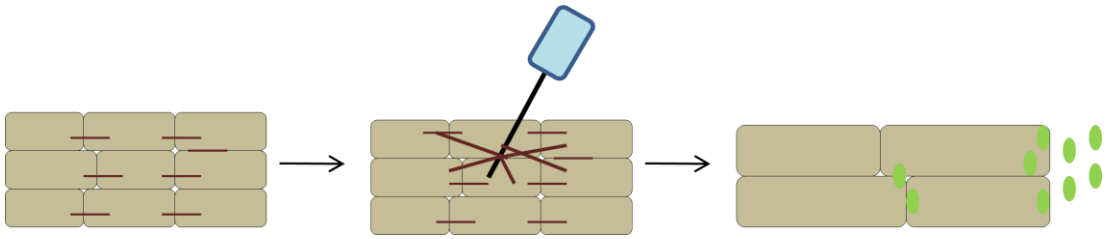


Figure 3.4 Mechanosignal transduction cartoon. Depicts a) normal tissue layer, b) binding needle to tissue, and c) cellular responses

While the evidence from Langevin and colleagues indicate that acupuncture may elicit a variety of cellular responses, Table 3.3 highlights biochemical studies that investigated specific effects of those responses in relation to acupuncture points or meridians used to treat FGIDs. Recall from Chapter 2 that mast cells and various cytokines (e.g. serotonin) are elevated in some IBS patients, and that elevations contribute to pain, hypersensitivity, and altered bowel habits. Additionally, CRH, adrenocorticotrophin hormone, and cortisol all participate in the HPA axis and EMS, which contribute to prolonged inflammation and emotionally related behaviour. According to Table 3.3, approximately fifteen different acupuncture points may successfully regulate the levels of those cytokines and hormones, thereby alleviating IBS symptoms.

Study	Points	Mediators	Effect
Kim [167]	P 6, SJ5	↑ c-fos	Reduced stress response
Jin [168]	P 6, St 36, UB 20	↑ somatostatin, β endorphin, ↓ gastrin	Inhibits gastric acid secretion
Lin [169]	P 6, ST36	↑ gastric slow waves	Normalize gastric arrhythmia
Liu [170]	ST25, ST37	↓ serotonin	Increased pain threshold
Liu [171]	GB14, ST2, ST6	↑ c-fos	Infer decrease in abdominal distension and pain
Lux [172]	CV12, ST36, UB21	Unknown	Inhibits gastric acid secretion
Ma [173]	Du, UB, P channels	↑ NO, nNOS	NO may serve as messenger for sympathetic nerve activation
Ma [174]	ST25, ST37	↓ CRH, mast cells, substance P	Infer decrease in hypersensitivity and stress response
Tougas [175]	ST36	Possibly opioid pathway	Inhibits gastric acid secretion
Wen [176]	Ear vagus	↓ ACTH, cortisol	Infer vagus activation
Wu [177]	ST25, CV6	↓ cytokines, TNFα, ↑neutrophil apoptosis	Infer decreased inflammation
Wu [178]	ST25	↓ mast cell, c-fos	Infer decreased hypersensitivity
Zhou [179]	Du 26	↓ serotonin	Increased pain threshold

Table 3.3 Biochemical effects of acupuncture related to FGIDs.

In addition to the biochemical effects, recent research has revealed more detail about acupuncture's effect on the nervous system (Table 3.4). Recall from Chapter 2 that IBS patients may suffer from a variety of nerve impairments including: vagal nerve dysregulation, exaggerated HPA axis response, and neuronal degeneration in the GI tract. According to Table 3.4, sixteen acupuncture points have demonstrated effects on nerve stimulation providing evidence that acupuncture may improve nerve dysfunction. Several studies in particular, Yuan *et al* [180], Kong *et al* [181] and Tatewaki *et al* [182] demonstrated dichotomous effects of acupuncture points. Each of these studies used different acupuncture points (UB20, UB21; LI4; ST35 respectively) indicating that dichotomous effects may be a general characteristic of acupuncture points. Importantly, the finding provides empirical evidence to support the traditional concepts that acupuncture promotes self-healing, and that acupuncture points have multiple functions. The affirmation of these traditional concepts may subsequently affect the acceptance of other concepts such as the importance of treatment individualisation.

Study	Points	Effect	Outcome
Fang [183]	LR2, LR3, ST44	Deactivation of limbic-paralimbic-neocortical area	Demonstrated effect on limbic system
Haker [184]	LI4, ear lung 1	↓ distress, ↑ calmness	Demonstrated effect on parasympathetic pathway
Huang [185]	P6	↓ heart rate, ↑ peristalsis	Altered modulation of cardiac vagal complex
Knardahl [186]	LI4, LI11	↑ tooth pain thresholds	Demonstrated effect on sympathetic pathway
Kong [181]	LI4	↑ signals ↓ signals	Difference between manual and electrical needling on brain effects
Li [187]	ST36	Modulation of gastric motility	Increased vagus activity and inhibition of sympathetic
Li [188]	ST36, ST37, P5, P6	↓ pressor response	Infer inhibition of cardio reflex response and endorphin activity
Napadow [189]	ST36	↓ signal to corticolimbic region of brain	Demonstrated effect on limbic system
Schneider [190]	LR3, ST36, SP6, CV12, ST21, ST25, HT7, Du20	↓ salivary cortisol, ↑ parasympathetic tone	Infer that overactive HPA in IBS is related to change in parasympathetic tone
Tatewaki [182]	ST36	Dual effects on gastric motility	Stimulation via vagal efferent & opioid pathway
Wang [191]	ST36, ST37	Regulate gastric activity	Demonstrated changes in dorsal vagal complex
Yuan [180]	UB20, UB21	Sympathetic – parasympathetic regulation	Increase gastric peristalsis in patients with low gastric motility and suppression in those with high motility

Table 3.4 Neuronal stimulation effects of acupuncture related to FGIDs.

Based on the studies in Tables 3.3 and 3.4 and the work by Langevin *et al* the neurophysiology model supersedes earlier work on gate control and motor points by establishing acupuncture's ability to elicit extracellular, intracellular, and neurologic responses in a range of acupuncture points. Furthermore, the studies in this section indicate that acupuncture may be a promising treatment for IBS. With regard to the question posed in Section 3.1, the method by which these studies were conducted on single points looking at specific effects favours a points' prescription approach to treatment.

3.3.2 Growth control model

While the neurophysiology model utilises relatively common biomedical concepts and terminology, the growth control model incorporates physics to probe the origin and function of points and channels. The growth control model is comprised of two distinct aspects blended together in the biofield hypothesis. The first aspect proposed by Yung states that meridians behave like electromagnetic transmission lines[2] upon which qi travels as a standing wave[3] due to the variation in resistance between meridians and the surrounding tissue (Figure 3.5) [192]. Along the meridian, acupuncture points act as nodes that can be "charged" to restore resonance or energy levels, which may be altered during illness. The studies by Langevin *et al* [163], from the neurophysiology model, also highlight variations in tissue composition by suggesting that there is something unique at acupuncture and/or meridian sites. A systematic review by Ahn *et al* confirmed that acupuncture meridians possess decreased electrical impedance; however, the review concluded that the studies were too poor in quality to provide conclusive evidence [193]. To summarise the first aspect, energy travels through the meridians differently than the surrounding tissue due to variations in their physical properties.

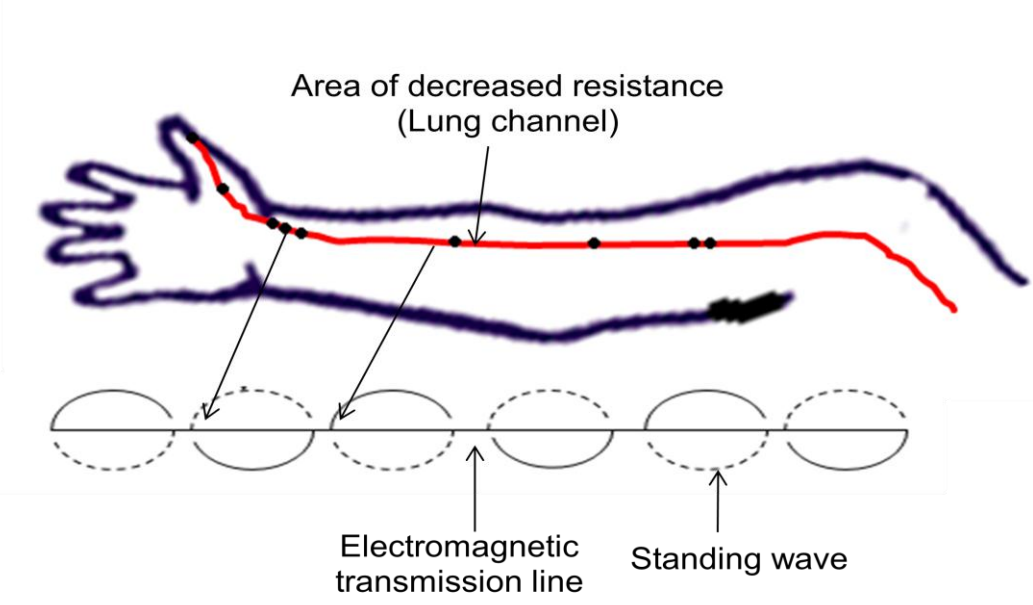


Figure 3.5 Channels and resistance from Yung [192]. Dots represent acupuncture points along the Lung channel. Qi moves along the Lung channel (transmission line) as a standing wave that can be affected by acupuncture point stimulation.

[2] Electromagnetic transmission lines are paths along which electromagnetic energy is transmitted.
[3] Standing wave is a wave that remains in a constant position.

The second component of the growth control model proposes that acupuncture points and meridians are generated during embryogenesis, wherein regional body development is controlled by small groups of cells [194]. These small groups, known as organising centres (OCs), have high electrical conductance, current density, and numbers of gap junctions, which facilitate intracellular communication. At the macroscopic level, OCs demarcate transitions from one state to another and tend to be located at extreme points of curvature on the body's surface. OCs give rise to the body's growth control system, which coordinates the nervous, circulatory, immune, and various other bodily processes. As seen in Tables 3.3 and 3.4, acupuncture points are capable of stimulating the nervous and immune systems in particular. Further similarities between OCs and acupuncture points including: high conductance, high density gap junctions, and response to non-specific stimuli (such as temperature or pressure) suggest that acupuncture points are derived from OCs. The idea that the body engineers specific clusters of cells to co-ordinate diverse processes is congruent with the traditional theory that stimulating acupuncture points recalibrates the body and promotes self-healing.

The ideas that energy traverses the meridian system in a unique fashion due to tissue resistance and that the travelling energy may be acted upon at OCs are combined in the biofield hypothesis. The biofield hypothesis postulates that the mechanism of acupuncture embodies the particle-wave duality from quantum physics, which assumes that organisms are complex, non-linear, dynamic, self-organising, and continuously exchanging information with themselves and their surroundings [195]. Specifically, the biofield is an electromagnetic field (EMF) created by the super-positioning of multiple EMFs, which radiate from all objects and interact with the EMFs of other objects. Thus, the EMF of an acupuncture needle interacting with the EMF of an individual may generate a biological response thereby stimulating steady-state healing or instability. The nature of the response is part of an organism's homeodynamics[4], which encompass physiological and biochemical processes to maintain equilibrium. Although the growth control model is based in science and mathematics, the concepts may evoke an alien or abstract feeling similar to the concept of qi. On the other hand the neurophysiological model conveys familiarity

[4] Homeodynamics consists of the normal physiologic and biochemical functions of the body as well as the capacity to respond to stress so as to maintain equilibrium [194].

and confidence through biomedical terminology. Both of the models demonstrate how acupuncture researchers have embraced scientific and investigative methods that employ biomedical language. While researchers may describe the mechanism of acupuncture in terms of physics and biochemistry, and TCM explanations may describe the importance of balance and the movement of qi, the following section introduces the patients' explanations as well as their experiences.

3.4 Patients' understanding & outcome

The previous sections describe the mechanism of acupuncture in both simplistic terms such as balance, and complex terms such as neurophysiological effects. Patients' interpretations and explanations of how acupuncture works which potentially incorporate these ideas may shape their treatment experience and thereby influence outcome. Furthermore, patients' attitudes may also have an influential effect on their outcomes. As introduced in Chapter 2, IBS patients typically self-regulate their treatments through trial and error [91], and have a high acceptability of pluralistic therapies [147]. Additionally, their perceptions of severity differ from GP derived measures, which poses a challenge to interpreting outcome. Therefore, in-depth patient interviews (Chapter 8) analyse the patients' attitudes and understandings of how acupuncture works, and how their experiences influence outcome. With regard to the literature in this section, the patients' expectations, attitudes, explanations, and outcomes relate to routine acupuncture patients who are typically women, aged 30 - 65, pay for their treatments, and consult for musculoskeletal conditions and/or general well-being [196, 197].

According to Richardson, CAM patients expect treatment to provide symptom relief, a holistic approach, an improved quality of life, self-help advice, and reduced risk in comparison to other treatments [198]. Based on the findings Richardson classified the expectations as high; however, I question the classification. Apart from the holistic approach, which may distinguish these expectations as CAM, the expectations appear reasonable for many forms of therapy particularly in light of the health movements introduced in Chapter 1. Since the 1960s, a variety of movements influenced patients to actively participate in their care and seek natural or safer treatments, whether they were related to biomedicine or a pluralistic therapy.

However, I agree that the expectations may be high depending on the degree to which they must be met. For example, two IBS patients who suffer from chronic diarrhoea may both expect symptom relief, yet one may expect reduction and the other may expect cure. In comparison, a review by Linde *et al* reports that patients' expectations significantly impact outcome for chronic pain and specifically that patients with high expectations report better outcomes [199]. On one hand, patients with high expectations may engage more readily with treatment and hold practitioners to a high standard making them ideal patients. Alternatively, high expectations may be problematic if they are unrealistic such as the IBS patient who expects a cure. Despite the findings by Linde *et al*, the effect of patients' expectations on outcomes is debatable. Two studies on low back pain, by the same group, report contradictory findings and suggest that answer may be complicated by people who have previously received acupuncture [200, 201]. Whether or not the patients' expectations are high or influence outcome, Hull *et al* report that 68% of acupuncture patients felt that treatments met or exceeded their expectations and that 75% experienced improvements [202] suggesting that the majority of patients are satisfied with treatment. In contrast to expectations, researchers have reported consistent findings that a patient's attitude toward and/or belief in CAM does not affect his/her treatment outcome for chronic pain conditions [203-205]. In addition to attitudes and expectations that may affect outcome, researchers have also begun to explore the role of patients' acupuncture understandings.

As mentioned in Sections 3.2 and 3.3, there are a variety of ways to describe how acupuncture works such as balancing qi or stimulating cytokine production. A study by Cassidy asked patients 'what does Chinese medicine do' which generated the themes: alleviates symptoms; improves physiological coping; improves psychological coping; provides close patient-practitioner relationships; and treats the whole person [206]. The findings suggest that the net effect of acupuncture increased energy, self-awareness, and calm as well as decreased symptoms. Although the comments reflect familiar ideas from the fundamental concepts of TCM (Section 3.2) they describe the 'end' but not the 'means' of how outcomes were achieved. Based on their comments Cassidy concludes that patients may not be familiar with or consider TCM language relevant because they did not employ TCM language in their

comments. However, I contend that the research question is not designed to predict patients' knowledge of TCM language any more so than the question 'what does biomedicine do' predict patients' knowledge of pharmacological language. Nonetheless the Cassidy study initiates an interesting discussion on patients' perceptions of what acupuncture does and whether those perceptions are related to how it works.

A more recent study by de Lacy *et al* asked patients how they perceived acupuncture to work [207]. Patients described their perceptions of how acupuncture works through metaphorical responses emphasising machine tune-ups, specifically acupuncture made things 'flow better' and improved 'balance'. Although there is no discussion about the use of TCM language, the comments appear to describe the 'means' of acupuncture similar to the fundamental concept of restoring balance. Alternatively, some patients may prefer biomedical terms such as those discussed in Section 3.3. In contrast to these descriptions, Paterson and Britten note that some people have no interest in understanding acupuncture and are content to trust the practitioner [208]. These studies demonstrate that patients employ a variety of descriptions to understand how acupuncture works and its effects. While some patients prefer no explanation, the question remains as to whether patients' understanding and/or explanations of acupuncture influence their outcome. Chapter 8 explores how patients in this study understand acupuncture to work and their perceptions of the impact of those understandings on their outcome.

Although expectations and explanations of how acupuncture works may or may not influence outcome, multiple studies report that patients experience relaxation. Some acupuncture patients have reported that the relaxing effect of acupuncture made them feel uncomfortable driving after treatment; however, their overall experience was enjoyable and made them look forward to treatment [209]. Similarly, patients in a study by Hughes, noted that the environment, acupuncturist's demeanour, and perception that the treatments were extensive contributed to a 'relaxing and pleasurable' experience [210]. In addition to relaxation, patients have also reported their experiences with needle insertion as a range from not feeling them at all to aching and tingling sensations [208]. On the whole, these studies indicate that

patients perceive acupuncture treatment to be a positive experience that is bolstered by a sense of relaxation, caring therapeutic relationship, and skillful practitioner. The various aspects that contribute to patients' acupuncture experiences may all contribute to their outcomes.

According to Verhoef *et al*, patients' outcomes are embedded in their context; perception of the healing process; and experiences, which are influenced by multiple factors [211]. In addition to the multiple factors affecting outcome, Verhoef *et al* also report that patients may perceive changes in multiple domains including: physical well-being, emotional well-being, connectedness, and personal transformation. Similarly, patients in the Cassidy study, previously mentioned, reported a broad range of outcomes including: increased energy, increased self-awareness, less pain, reduced dependence on prescription drugs, faster healing, and reduced irritation by chronic complaints [206]. Verhoef *et al* and Cassidy illustrate that multiple factors contribute to patients' outcomes and that the outcomes themselves are multidimensional, thereby creating difficulties in measurement (Chapter 4). Patient reported outcomes beyond the resolution of his/her main complaint have been termed 'unexpected outcomes' [212]. For example, rheumatoid arthritis patients not only experienced less pain and more mobility ('expected'), they also reported improved sleep, less fatigue, and less depression ('unexpected') [210]. Furthermore, it was the 'unexpected outcomes' such as the ability to relax and cope, change in emotion, and increased body awareness that patients considered important outcomes not captured by standard measures [213].

With regard to IBS, there is a potential for patients to report multiple expected and unexpected outcomes. Based on the description of IBS in Chapter 2, patients may report expected outcomes related to abdominal pain, bowel habit, and/or wind. Patients may also report unexpected outcomes related to their comorbidities that may be indirectly affected by treatment. Moreover, the literature in this section suggests that patients may report unexpected outcomes related to relaxation or self-awareness. In order to capture the range of potential outcomes, it is important that this study collect disease specific and global health outcomes as well as patient accounts (in-depth interviews) of IBS specific and non-specific outcomes. Before transitioning to

the discussion on methodology and methods (Chapter 4), the following section explores the TCM understanding of IBS and associated treatments.

3.5 TCM & IBS

Having reviewed various treatment and background aspects of TCM, this section introduces the TCM interpretation of IBS. Perhaps the easiest way to explore the TCM interpretation of IBS is through patterns associated with the chief symptoms. According to Chapter 2, the chief symptoms associated with IBS are abdominal pain, bloating, and abnormal bowel habits (e.g. diarrhoea). Table 3.5 lists possible patterns associated with the chief IBS symptoms, their accompanying signs and symptoms, and their recommended treatments. I identified patterns from the Mao-Liang [150] and Xinnong [148] texts based on the literature and my TCM training; however, neither of these texts refers to IBS specifically. On the other hand, Lewis [214] and Maciocia [215] specifically refer to IBS and potentially related patterns. The gradual appearance of biomedical diagnoses such as IBS in TCM texts is another illustration of how the ancillary discipline TCM has adapted to biomedicine's dominant influence.

According to Mao-Liang, Xinnong, and Maciocia the patterns most commonly associated with IBS may be caused by improper diet, cold attack, over work, constitutional weakness, dampness (either heat or cold), heat attack, improper emotion, or a combination of these [148, 150, 215]. From Figure 3.2, the reader can visualise how the bowel may be affected by these causal agents. For example, an improper diet can directly damage the spleen (earth) and disrupt the generating cycle, which fails to promote the large intestine (metal) causing abnormal bowel habits.

	Pattern	Signs/symptoms	Points
Mao-Liang [150]	Abdominal pain: accumulation of cold	Violent pain, better w/ warm, loose stool, cold limbs	CV12, CV8, CV4, ST36, SP4 (moxa)
	Abdominal pain: spleen yang deficiency	Intermittent dull pain, relief w/ pressure, loose stool, listless, aversion to cold	UB20, UB21, CV12, CV6, LR13, ST36 (moxa)
	Abdominal pain: food retention	Distension, fullness, worse w/ pressure, reflux, anorexia, alleviated by passing stool	CV12, UB25, CV6, ST36, inner neiting (moxa & cupping)
	Acute diarrhoea: a) cold damp attack, b) damp heat attack	a) borborygmi, pain, no thirst, aversion to cold, prefer warm b) hot yellow foul stool, pain, burning, scant dark urine	CV12, ST25, ST37, SP9 (a – moxa)
	Diarrhoea: a) spleen qi deficiency b) kidney yang deficiency	a) sallow face, listless, weak, poor appetite b) morning pain, aversion to cold, cold limbs	UB20, LR13, CV12, ST25, ST36, Du 4, CV4 (cupping & moxa)
	Constipation: excess	Feverish, thirst, foul breath, prefer cold, distension, pain, belching, loss of appetite	UB25, ST25, SJ6, ST37 (+LI4, LI11), (+CV12, LR2), (+UB20, UB21), (+CV8, CV6)
	Constipation: deficiency	Pale complexion, dizzy, palpitations, listless, cold pain, prefer warm	
Xinnong [148]	Abdominal distension: spleen deficiency	better w/ pressure, borborygmi, loose stools, loss of appetite, lassitude, listless, clear urine	CV12, ST25, ST37, LI4, CV6, SP9, CV4, SP3, ST36 (moxa)
	Abdominal distension: irregular food intake	Fullness, worse w/ pressure, pain, belching, foul breath, dark urine, constipation, possible fever, vomiting	
Lewis [214]	Liver qi stagnation	Spastic pain, worse w/ pressure, constipation, distension, incomplete emptying	LR3, LR13, LR14, ST25, ST27, ST37, ST39, GB34, SJ6, P6, CV4, CV6, UB18, UB25, UB27
	Spleen qi deficiency	Loss appetite, lassitude, fatigue, diarrhoea, mucus, mild pain better w/ pressure	SP3, SP6, SP9, SP15, ST25, ST36, ST37, ST42, CV12, UB20, UB21, UB25, UB27
	Combined: liver qi stagnation & spleen qi deficiency (poss. also lung qi deficiency)	Mixture of symptoms	LR3, LR13, LR14, GB34, CV6, CV12, ST25, ST36, ST37, SP6, Lu7, UB18, UB20, UB21, UB25, UB27
Maciocia [215]	Diarrhoea: Liver qi stagnation invading spleen	Diarrhoea alternating w/ constipation, distension, belching, poor appetite, depression, moody, irritable	CV12, UB20, LR13, GB34, ST36, SP6, ST39
	Abdominal pain: liver qi stagnation	Pain related to emotion, bloating, constipation, irritable, belching, borborygmi, poss. fatigue	CV6, P6, P7, SJ6, GB34, LR3, UB18, SP6
	Epigastric pain: stomach pathology	variable	variable

Table 3.5 TCM patterns related to IBS

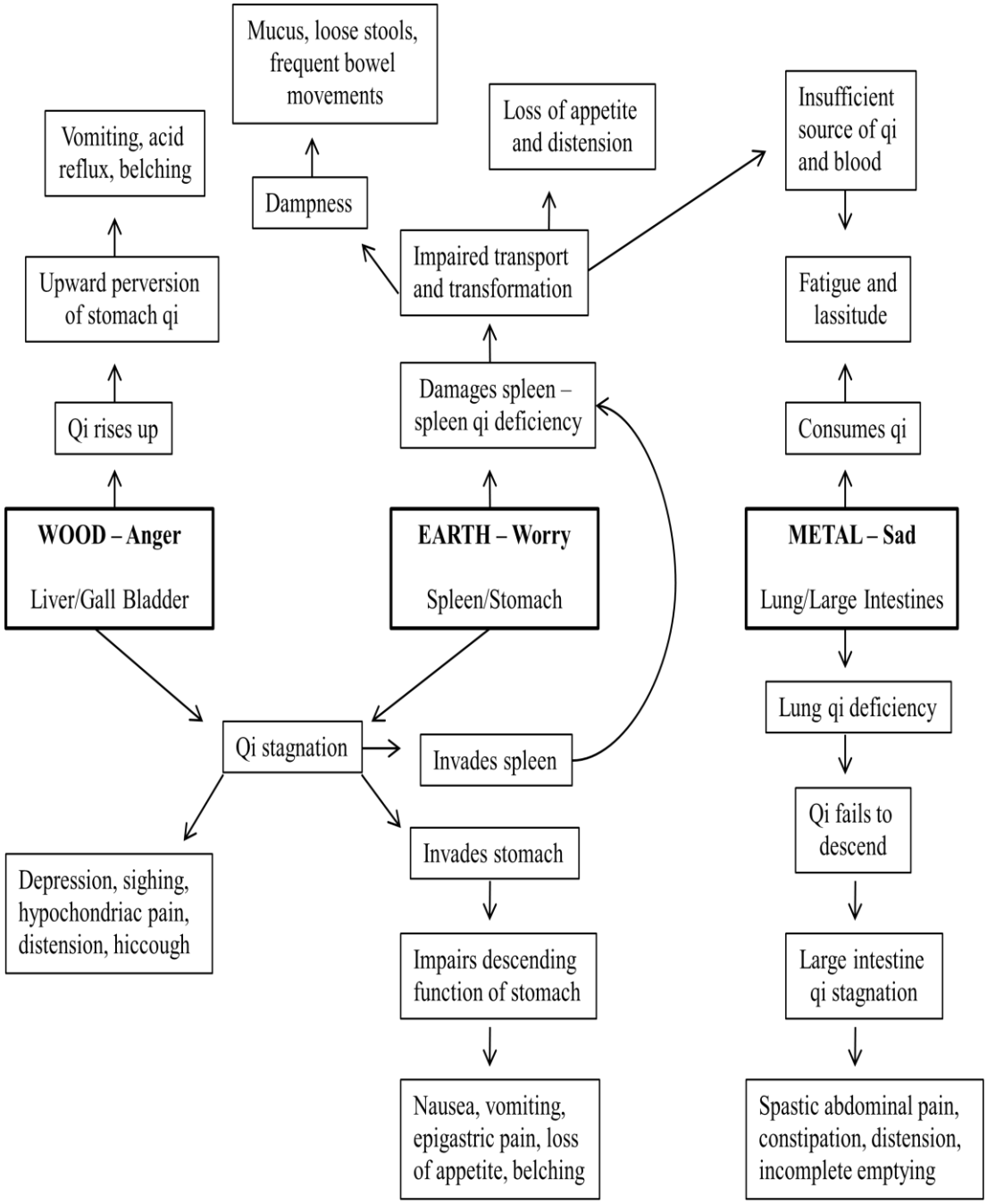


Figure 3.6 Role of emotion in TCM related to IBS from Lewis [214].

With regard to emotion, Lewis depicts the role of improper emotions in the development of IBS in Figure 3.6. For example, excessive sadness damages qi and may result in fatigue, distension and constipation. Although TCM concepts may be different from biomedicine, both disciplines describe multiple causative factors that may contribute to the development of IBS symptoms particularly regarding emotion and/or stress.

According to Table 3.5, there are at least eleven TCM patterns potentially related to IBS that each has its own recommended treatment. Furthermore, the complexity diagram in Chapter 1 (Figure 1.2) illustrates how each of the TCM diagnoses is related to IBS as well as other biomedical diagnoses. One study has attempted to establish an empirical relationship between IBS and the TCM patterns: liver qi stagnation, spleen qi deficiency, and a combination of stagnation and deficiency [216]. The authors asked practitioners to differentiate IBS patients according to the three patterns, from which they concluded that those patterns are associated with IBS. The primary weakness of this study lies in the pre-determined nature of the patterns and the expectation for practitioners to classify accordingly. By pre-determining patterns, the researchers negate variation in the differentiation process described earlier. In comparison, the trial literature (Table 1.1) indicates that only two studies allowed practitioners to make an unrestricted diagnosis. Forbes *et al* state that IBS "corresponded to a wide range of TCM patterns, making individual diagnosis essential" but did not list the TCM patterns diagnosed [39]. The other study delivered five element acupuncture, which employs a different diagnostic framework than TCM and therefore does not provide comparable diagnoses to Table 3.5 [47]. Three studies employed between four and eight TCM diagnoses (that were pre-determined to be potentially relevant) to design their interventions (Table 3.6), which supports the assertion that the three diagnoses identified by Tan *et al* may be too limited. Nonetheless the pre-determined nature of all of these diagnoses means that empirical evaluation is necessary to establish the correlation between TCM patterns and IBS.

	Study		
Diagnosis	**Anastasi** [35]	**Lembo** [41]	**Schneider** [34]
Spleen yang deficiency	x		x
Kidney yang deficiency	x		x
Liver qi stagnation	x	x	x
Cold damp	x		
Damp heat	x	x	
Food stagnation	x	x	
Spleen qi deficiency w/ damp	x	x	
Spleen/stomach qi deficiency	x	x	x
Blood stasis		x	
Cold accumulation		x	

Table 3.6 TCM diagnoses used in design of acupuncture trial interventions

With regard to the recommended treatments, a total of thirty-four different acupuncture points as well as moxa and cupping are indicated (Table 3.5). Only six of the points, designated as the core group[5], are recommended for ≥ 50% of the patterns including: CV 4, CV6, CV 12, St 25, St 36, and St 37. Each of the points in the core group was investigated by studies in Tables 3.3 or 3.4, thereby establishing a connection between the pedagogical and empirical knowledge. The variations in treatment recommendations highlight two important concepts 1) there are multiple point combinations that may be used to treat a particular pattern owing to the concepts that points have multiple functions and that multiple points share overlapping functions and 2) point combinations are influenced by the practitioner and diagnosis.

In comparison to the recommended points, Table 3.7 lists the acupuncture points used in IBS trials and the reason for their selection. Only one study allowed for an unrestricted points' selection [47], while three other studies used a combination of pre-selected fixed and optional points [35, 39, 41]. A fixed plus optional point's combination refers to an intervention that specifies one set of points for all patients and a second set which the acupuncturists may or may not needle. Based on the translations of papers by Liu [43] and Liu [45], it appears that acupuncturists could use any of the points in the defined set, which is slightly different from the other studies. The selection of points is important because, as seen in Table 3.5, the points vary according to the practitioner and TCM pattern. Of the studies that gave explanations, eight based their selection on the points' functions consistent with TCM principles (e.g. tonify spleen), and two studies based their selection on physiological data such as described in Tables 3.3 and 3.4. None of the trials used the same combination of points, contributing to at least sixteen different combinations and the use of more than thirty-nine points. In comparison to the six core points from Table 3.5, the trials had two (St 25 & St 36), which in conjunction with the sentence above reiterates the importance of preference. Treatment complexity is further complicated by the use of additional therapies such as moxa, massage, and transcutaneous electrical nerve stimulation (TENS) either in combination with acupuncture or at acupuncture sites. The diversity within factors such as point

[5] The core group refers to my classification of acupuncture points that were recommended in ≥ 50% of the patterns in Table 3.5.

selection, preference and additional therapies that may influence treatment design generates a question about the appropriateness of comparing effectiveness across trials with flexible and fixed treatments, which may be addressed by establishing the relative importance of treatment individualisation.

Study	Points Used	Explanation of Selection
Anastasi [35]	Fixed: CV12, CV6, ST25, UB23, UB25 plus moxa Optional: 2-6 other points	Semi predetermined list with some variability for different diagnoses
Chan [36]	LR 3, Sp 6, St 36, St 25, St 27, LI 4, LI 11, Lu 5	Based on easily identified and repeatable points which are traditionally associated with treating abdominal conditions and soothing
Chu [37]	UB18,UB 20, UB21, UB23	No clear explanation
Fireman [38]	LI 4, UB 60	No clear explanation
Forbes [39]	Used 8 – 16 needles but does not specify which points	Based on manipulation and movement of qi
Huang [40]	CV 12, ST 25, ST 36, SP 4, SP 6, LR 2, UB 20, ST 43, SP 9 UB25, SJ 6, ST 40 (optional)	No clear explanation
Lembo [41]	Fixed: CV10, ST25, LR3, SP4, P6, ST37 Optional: ST36, CV4, LI4, LR14, ST40, LI11, ST27, CV12, SP10, GB34, SP6	Used mix of fixed and optional points Fixed were for general GI problems and the optional were to vary for differentiated diagnoses
Liao [42]	ST25, P6, LR3, ST36, UB21, UB23	Tonify spleen and improve liver function
Liu [43]	St36, P6, CV12, ST25, LR3, UB20, UB23, Du 4, CV8 - moxa	No clear explanation
Liu [45]	Ear – stomach, shenmen, sympathetic, subcortex, liver	Balance nervous system, calm shen, stop pain, and move qi
Liu [44]	ST25, ST37	Regulate sp/st and LI
Reynolds [47]	St 36, P 6, LI 4, Sp 6, Sp 8, K 3, CV 12, LR 3, LI 11	Pragmatic trial – points selected at practitioners' discretion
Rohrböck [48]	UB 27, UB 30	Selected b/c commonly used for colon conditions and b/c allowed for blinding
Schneider [34]	LR 3, St 36, Sp6, CV 12, St 21, St 25, Ht 7, Du 20	Selected points that would likely strengthen spleen and promote digestion
Xiao [49]	TENS - LI 4, St 36, UB 57	Physiological effect on nerves & endogenous peptides, known use for GI problems
Xing [50]	TENS - ST36, P6	Physiological effect on acid secretion, known use for GI problems

Table 3.7 Acupuncture points used in IBS trials. TENS – transcutaneous electrical stimulation

Descriptions of the patterns and treatments recommended by the literature and used in trials provide background information on TCM diagnoses and treatment

individualisation that were introduced in Chapter 1. With regard to the diagnosis, Tables 3.5 and 3.6 begin to clarify the range of diagnoses acupuncturists may encounter, which consequently manifests in treatment variations. The variations highlight disease-specific and individualised (from the acupuncturist's perspective) approaches to treatment. Although variability contributes to the complexity of acupuncture as an intervention and to the difficulty in evaluating it via clinical trials (Chapter 4), whether or not the variability is overly attributed to patient individualisation is debatable. The variability in diagnoses and treatments, and the extent to which they impact outcome is currently underreported and/or unknown, which is why Chapters 6 and 7 provide detailed accounts of the trial diagnoses, treatments, and outcomes. Furthermore, the indirect introduction to the TCM interpretation of IBS, provided me with the opportunity to explore the contextualisation of IBS from the acupuncturists' perspective (Chapter 5).

3.6 Summary

The foundational concepts of TCM highlight natural observations of the world that are used to explain body functions and disease pathology. In comparison, the mechanism of acupuncture may be explained using the foundational concepts or neurophysiology. With regard to IBS, TCM interpretation begins with the component symptoms such as abdominal pain. Based on the component symptoms IBS may be differentiated into a variety of TCM patterns that are treated by combinations of acupuncture points and possibly additional therapies, which are influenced by the practitioner. Similar to biomedicine, the TCM aetiology of IBS involves a complex mixture of physiological and emotional factors.

As discussed in Chapter 1, biomedicine's dominant symbiotic position has influenced the conduct of TCM research through biomedical diagnoses. Moreover, the majority of acupuncture trials for IBS, to date, utilised an efficacy approach that incorporated the assumptions that TCM diagnosis differentiation and treatment individualisation are not important (Box 1.1 & Table 1.1). By making these assumptions, the trials created a gap in the literature regarding the relative importance of differentiating among patterns and delivering individualised treatments. Therefore, an objective of this thesis addresses this gap and develops

knowledge about the relative importance of diagnosis differentiation and treatment individualisation. In addition to this objective, this thesis also assesses the role of patients' attitudes toward treatment and their explanations of how acupuncture works with regard to outcome. As indicated by the treatment variations and diversity in patients' expected and unexpected outcomes, there are a number of challenges for acupuncture research. The following chapter explores the challenges to acupuncture and IBS research as well as describes the methods used to accomplish the thesis's objectives.

Chapter Four

The Methodology & Methods

Chapter highlights

- Both acupuncture and IBS research studies face a variety of challenges such as heightened placebo response, recruitment, population, and intervention complexities
- A mixture of methodological approaches and methods including qualitative and quantitative were used to address the research questions
- A pragmatic theoretical perspective provided the flexibility necessary to combine the mixture of methodologies and methods

4.1 Introduction

As introduced in Chapter 1, biomedicine and traditional Chinese medicine (TCM) co-exist in a dynamically fluctuating dominant-ancillary symbiosis. The symbiosis influences compromises and adaptations that may affect clinical practice and research in both disciplines. Because biomedicine is the dominant discipline and this study revolves around IBS patients and treatment, Chapter 2 provides a detailed framework of IBS. From this, the reader has learned that IBS is a heterogeneous condition comprised of patients with varying signs, symptoms, severities, and comorbidities. Transitioning from the IBS background, Chapter 3 introduces the fundamentals of TCM and describes a TCM interpretation of IBS. From this, the reader has learned that IBS may be associated with a variety of TCM diagnoses, that TCM treatments incorporate multiple modalities including acupuncture, and that patients may experience expected (i.e. related to main complaint) and unexpected (i.e. beyond main complaint) outcomes. Given that IBS is a complex condition and TCM-based acupuncture is a complex intervention, it is not surprising that the previous chapters raise several challenges to research. Therefore, the purpose of this chapter is to address these challenges, and then discuss the methodology and methods used to answer the research questions (Box 4.1).

Overarching aim – formulate a hypothesis about the relative importance of TCM diagnosis and treatment individualisation from the data collected to address the following questions.

4. How do TCM acupuncturists treat IBS in routine practice and how do the treatments compare with treatments in a pragmatic study?
    a. What (if any) are the distinguishing features of treatment?
    b. How is IBS contextualised?
        i. Are treatments individualised?
5. Is there a difference in outcome for particular TCM diagnoses?
    a. Is the IBS Symptom Severity Scale (IBS-SSS) a valid and reliable measure of severity?*
    b. Can the acupuncturists' prognoses predict patient outcome?*
6. How do patients, acupuncturists, and GPs understand acupuncture to work?*
    a. Does the patient's understanding affect his/her perceived treatment outcome?*
    b. Do acupuncturists perceive their explanations to affect patients' outcomes?*
    c. Do GPs consider acupuncture a valid treatment modality?**

Box 4.1 Research questions. *Subsidiary questions asked to address the controversy around IBS and acupuncture outcomes. ** Subsidiary question asked to address potential integration and referral barriers that may affect clinical practice.

4.2 Research challenges

Before discussing the methods used to answer the questions, this section reflects on some of the challenges for acupuncture and IBS research. As discussed in Chapter 1, one aspect of biomedicine's strategy to address the growing popularity of acupuncture was to encourage acupuncture research that assumed a biomedical model [7]. Specifically, biomedicine encouraged a systematic (condition → needles → outcome) approach that emphasised progression from efficacy to effectiveness to treatment promotion [217]. In other words, determine the active components of an intervention and that it works under ideal circumstances. Then, establish that the intervention works under practical circumstances and promote it as a health care option. Although this approach may be practical for new treatments such as pharmacological interventions, it may be impractical for treatments already in use such as acupuncture [217]. Furthermore, some TCM practitioners and researchers criticise the ability of the efficacy approach (or restricted protocols) to reflect the complexity of acupuncture [60, 218, 219].

As discussed in Chapter 3, acupuncture derives some of its complexity from the use of additional therapies, practitioners' preferences for particular points, and a range of outcomes described by patients. Therefore, efficacy studies that restrict intervention complexities such as the addition of moxa; variation in practice such as point prescriptions; and individuality in delivery limit these challenges to research and may determine if they are active elements of the intervention. The majority of acupuncture for IBS trials listed in Table 3.7 employs an efficacy approach. For example, the study by Lembo *et al* explores the effects of an augmented patient-practitioner interaction and its effects, in addition to the efficacy of acupuncture for IBS [41]. Although the study reveals that patients with an augmented encounter experienced better outcomes, Glasgow *et al* suggest that the success or failure of a complex intervention in an efficacy study does not guarantee the same outcome in an effectiveness study [217]. A difference in outcomes may arise from the fundamental differences in study design, wherein effectiveness studies may account for patients' attributes, preferences, and behaviours and be delivered across a range of settings, conditions and populations. In contrast, the limited applicability of efficacy studies may be one reason why efficacious interventions are not successfully implemented in

the population. The assertion that acupuncture is a relatively safe intervention [220], and the nature of the research questions to address the relative importance of diagnosis and treatment in routine practice support an effectiveness approach for this study.

In addition to allowing for the delivery of acupuncture under routine circumstances, effectiveness studies are also advantageous because they may recruit a sample that is representative of the condition's population. However, locating a sample that is representative of the population may be rather difficult for an IBS study. As discussed in Chapter 2, criteria used to diagnose IBS all identify different IBS populations, although there is a trend from primary to tertiary care of increasing case severity. Further complicating the issue, are the findings that only a portion of the IBS population seeks care (from their GP) and are diagnosed. Therefore, to study a representative sample of the IBS population, patients should be recruited from all three areas of care to capture a range of diagnostic styles and severities, and from the general population to capture undiagnosed patients. While advertisements may identify potential participants in the general population, a patient's diagnosis whether made by his/her GP or consultant should be recorded on the patient's electronic record (hypothetically). Therefore, researchers may access the database from a GP's surgery to identify a list of potential participants from all three areas of care. A study that comprises a sample of IBS patients from these different sources should be generalisable to the IBS population. The recruitment of IBS patients to the trial portion of this study is further discussed in Section 4.3.4b.

Although emphasis on recruiting a representative sample of IBS patients is important for an effectiveness study, it is a challenge for TCM. As indicated by Table 1.1, all of the acupuncture for IBS studies recruited patients based on their IBS diagnosis. The practice of recruiting patients with the same biomedical diagnosis to a study for a non-biomedical intervention illustrates biomedicine's successful implementation of the research strategy described by Wolpe [7] in Chapter 1 and highlights biomedicine's dominant symbiotic influence. The complexity diagram (Figure 1.2) and the variety of patterns listed in Table 3.5 underline one problem with recruitment to a TCM trial by biomedical diagnosis, which is that patients may all have different

TCM diagnoses. Thus from baseline, the patients may represent a heterogeneous group. Unlike in Chapter 1, where a heterogeneous sample in an effectiveness study refers to a group of patients who are more representative of the population than a homogeneous sample in an efficacy study, heterogeneity introduced by differences in TCM diagnoses may incur a Type II error [221]. Since most trials of acupuncture for IBS employ an efficacy approach that assumes the TCM diagnoses are unimportant (Box 1.1), they overcome this potential problem. For effectiveness studies to overcome the potential problem, acupuncture researchers recommend recruiting patients by TCM subgroups or recruiting sufficient numbers to perform subgroup analyses based on TCM diagnoses to account for potential differences in TCM diagnoses [219, 222]. For this study, I elected to explore subgroup analyses based on TCM diagnoses (Chapter 7).

In addition to recruitment challenges, acupuncture and IBS studies also face criticism over the placebo effect, which may be defined as "that aspect of treatment not attributable to specific pharmacologic or physiologic properties" [223]. According to Dorn *et al* the placebo response estimates for biomedical treatments of IBS range from 16% - 71%, and for complementary and alternative medicine (CAM) treatments average 43% [224]. The findings illustrate similarity across disciplines in their conclusion that a similar percentage of patients exhibit a placebo response regardless of the intervention. However, the controversy around the placebo response also questions whether acupuncture treatment has any effect beyond the placebo response [225]. Emerging data on the biochemical effects of acupuncture related to the gut (Tables 3.3 & 3.4) and the studies by Dorn *et al* [224] and Kaptchuk *et al* [226] suggest that acupuncture treatment elicits both biological and placebo effects. Nevertheless, the effectiveness approach overcomes the challenge of determining which aspect (biological or placebo) influences outcome more in acupuncture studies. For IBS studies, Spiller recommends that clinical trials for IBS should run a minimum of three to six months to overcome placebo effects [227]. The protocol for the trial portion of this study overcomes the challenges by conducting a pragmatic trial that ran for twelve months.

Although an effectiveness approach may enable an acupuncture and/or IBS study to overcome many of the challenges to research, it does not address the issue of outcomes. As discussed in Chapter 3, acupuncture patients may report expected outcomes related to their main complaint and unexpected outcomes related to other aspects of their well-being [212]. Additionally, some researchers have expressed concerns that standard outcome measures do not capture the range of benefits [218], and suggest that studies of complex interventions collect textual and interview based outcomes [228, 229]. In general, qualitative studies may enhance trials by providing meaning to: the patient about the intervention; the patient's context; the event process; and the different perspectives of various stakeholders. The addition of qualitative outcomes may be particularly important for this acupuncture study because IBS patients experience a variety of symptoms and comorbidities that may be affected by treatment. The addition of qualitative outcomes is also important due to the lack of consensus on clinically significant improvement for IBS [230]. Recall from Chapter 2 that the lack of an IBS biomarker contributed to the development of practitioner derived severity measures such as the Functional Bowel Disorder Severity Index (FBDSI) and IBS Symptom Severity Scale (IBS-SSS). Moreover, a review by Camilleri *et al* questions the validity of these instruments [231], and a review by Whitehead *et al* suggests that IBS patients with severe scores are less likely to report improvement despite larger score changes than patients with mild scores and smaller score changes [136]. Given the controversy around IBS outcomes and the expectation that as acupuncture recipients the IBS patients may report expected and unexpected outcomes, the inclusion of qualitative data was important for this study. In addition to providing information on outcomes, qualitative data provided input on the appropriate treatment protocol; established a basis for pragmatic treatment comparison; and captured the patients' experiences and understandings of acupuncture as well as their impact on outcomes.

In summary, there are a number of challenges facing both acupuncture and IBS study designs. Some challenges, such as study duration, are more easily addressed than others such as incorporating qualitative research. As indicated throughout this section, both the trial team and I addressed these particular challenges in the design phase and established that an effectiveness approach and the incorporation of

qualitative research were appropriate. The following section makes transparent the research process as it relates to the thesis.

4.3 The research process

An effectiveness approach and the inclusion of qualitative research are two strategies that address some of the challenges to acupuncture and IBS research. Furthermore, the aims and objectives discussed in Chapter 1 suggest that a flexible approach to diagnosis and treatment, and a study design that captures the patient's perspective are necessary to assess the relative importance of TCM diagnosis differentiation and treatment individualisation. Therefore, the methodology and methods operationalize the research challenges to address the aims and objectives of the thesis. The following sections elaborate on the methodological choices and methods used to answer the research questions (Box 4.1).

According to Crotty, there are four inter-related elements that inform the research process (Figure 4.1) [232]. In addition to providing a methodological overview, the diagram illustrates the importance of fluidity in that the elements may be practically employed in a circular manner. Explanation of the theoretical approach establishes the foundation upon which methodological choices were made, and initiates the reflexive process. Reflexivity acknowledges how the researcher and the research process may affect data collection and outcomes [233], and is further discussed in subsequent sections that elaborate on the research elements and the methods used in this thesis.

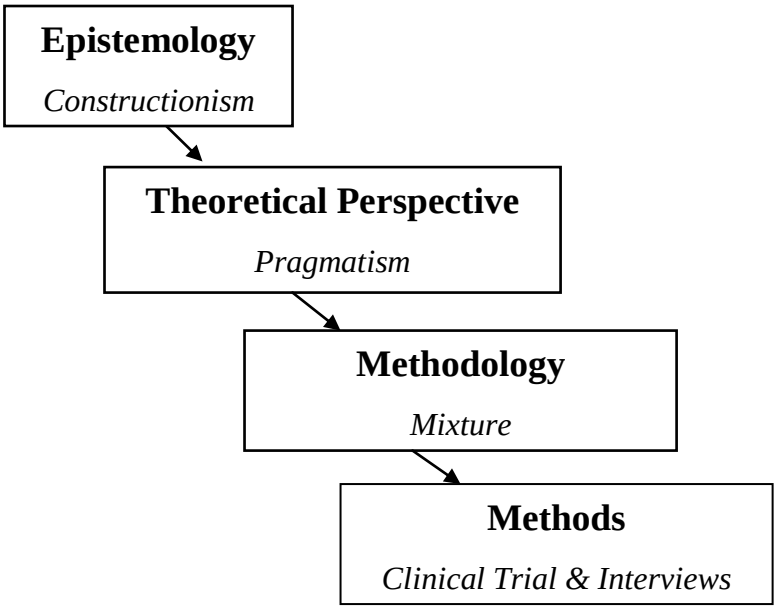


Figure 4.1 The four elements of research. From Crotty [232] with the positions used in this thesis in italics

4.3.1 Epistemology

The first element of research, from which the others emerge and cyclically influence the first, is epistemology, the all encompassing study of the generation of knowledge [232]. The what and how of knowledge alone is a thesis, therefore, I only state and justify my stance as it relates to this thesis. People acquire knowledge through experience, which is coloured by the context surrounding the experience. In other words, people construct knowledge based on their interactions with each other and the world around them [232]. According to Creswell, constructionism assumes that [234]:

- Meaning is developed through interactions with the world
- Social and historical perspectives shape the context of those interactions
- Meanings are subjective, multiple, and varied, which creates complexity
- The researcher identifies her role in the interpretation of meaning
- The research process is generally inductive and may generate theories

The first three assumptions manifest in the different interpretations of IBS described in Chapters 2 and 3. Patients are likely to construct their understanding of IBS through direct physical and emotional experiences, while, in comparison, GPs and acupuncturists may construct their understanding through indirect experiences via

their patients and their training. Therefore, it is not surprising that the understanding of IBS varies with perspective. Constructionism allows for these multiple realities based on differences in context, consequently making constructionism a logical perspective for this thesis. The fourth assumption alludes to the importance of transparency in that the research process is clear and/or easy to follow, and reflexivity [235]. As mentioned previously, both the researcher and the research process may affect data collection and analysis. From my perspective, my background as an acupuncturist shapes my constructionist epistemology and may therefore influence my interpretation of data. With regard to the research process, methods such as individual interviews generate different types of data than other methods such as surveys. Lastly, the fifth assumption implies that a constructionist approach employs observations of specific events such as an effectiveness study to generate a theory about the relative importance of TCM diagnosis differentiation to the treatment of IBS.

4.3.2 Theoretical Perspective

While the theoretical perspective provides context for the ensuing decisions on methodology and methods, it also provides a way of looking at and making sense of the world [232]. By providing a way of looking at and making sense of the word, the theoretical perspective links itself with the creation of knowledge and epistemology. The constructionist epistemology allows for people to obtain knowledge through their experiences, which in turn allows for multiple and subjective meanings [234]. Given that epistemology embeds itself in the theoretical perspective and that people may construct knowledge differently, pragmatism is a logical theoretical perspective for this thesis. According to Creswell, pragmatism assumes [234]:

- Variability in philosophical positioning
- Unrestricted research methods
- A problem-centred approach based on what works for a particular social, historical, and political context

Although pragmatism acts as the dominant theoretical perspective, the first assumption implies that a pragmatic perspective may incorporate multiple perspectives. Additionally, the engagement with variability in philosophical positioning and unrestricted research methods allows for the use of both empirical

and descriptive observations. The unrestricted research methods and problem-centred approach assumptions foster the idea that pragmatism deems the research question/s superior to both the methods and philosophical perspective [236]. The complex objective of this thesis, to assess the relative importance of TCM diagnosis differentiation and treatment individualisation necessitated the use of three research questions listed in Box 4.1. Considering that biomedicine and TCM evolved in unique social contexts, pragmatism provides the liberty necessary to allow the research questions to dictate the study methodology so as to discern the answers.

4.3.3 Methodology

Proceeding on from the theoretical perspective, the next element in the process, methodology, provides the rationale for selecting particular methods [237]. Complex research objectives, as mentioned previously, often necessitate the use of multiple research questions, which in turn necessitates the use of multiple methods [236]. Quantitative and qualitative methods anchor opposite ends of the research continuum [238]; wherein, the quantitative end represents deductive, theory driven methods that examine the relationships between variables to generate generalisable findings, and the qualitative end represents inductive, meaning driven methods that examine individuals to generate theories [239]. Mixed methods exemplify the application of quantitative or qualitative methods as dictated by the research question/s. By varying methods, a mixed methods strategy can answer questions deemed to be unanswerable by other means [240]. After reflecting on these ideas, the research questions, and the challenges to IBS and acupuncture research, I decided that a mixture of mixed methods, quantitative, and qualitative methodologies was necessary to answer the research questions.

Table 4.1 clarifies the methodological element via a typology adapted from Teddlie and Tashakkori [239]. The methodological approach is designated by qualitative (QUAL), quantitative (QUAN), and mixed methods (MM) instead of QUAL and QUAN to emphasise that the research incorporates a mixture of methodologies and is not an exclusively mixed methods approach. Although Teddlie and Tashakkori argue that the priority of methods approach cannot be determined until after data collection, I chose to define the priority of approach in terms of time and to include it in the

typology. Both the complexity of the research objectives and the research challenges demonstrate the appropriateness of a pragmatic mixture of methodologies. How the various methodological approaches were employed is discussed in the following section.

Criterion	Used	Value
Number of methodological approaches	Yes	QUAN & QUAL & MM
Number of strands	Yes	Multiple strands
Type of implementation process	Yes	Combination: parallel & sequential, conversion
Stage of integration of approaches	Yes	Across stages
Priority of approach	Yes	Qual → qual + quan → qual
Theoretical/Ideological perspective	Yes	Pragmatism

Table 4.1 Typology of methods. From Teddlie and Tashakkori [239].

4.3.4 Methods

With the understanding that the research questions engage the constructionist paradigm and a pragmatic approach that incorporates a mixture of methodologies, this section introduces the methods used to answer the research questions. First, the proposal for a pragmatic randomised controlled trial (RCT) of acupuncture compared to usual care for IBS with a built-in economic evaluation was written prior to my participation (Appendix B 1). Pragmatic refers to a study design that produces evidence on the benefits of an intervention, delivered in routine care that may be utilised by health care decision makers [241]. The use of a pragmatic RCT reflects the effectiveness approach that addresses the various challenges posed by a complex intervention and illness described in Section 4.2. Additionally, the pragmatic RCT provided the optimal means from which to collect data for the first two research questions. After the proposal was awarded funding, I worked with the trial team to incorporate a pre-trial study and a nested qualitative study. By incorporating these studies, I was able to answer all three questions and address the challenge of capturing patients' outcomes. As mentioned in Chapter 1, the research questions were designed to collect data that could be used to address the underlying question about the relative importance of TCM diagnosis differentiation and treatment individualisation. For clarity of purpose, the following subsections present the methods used according to each research question.

4.3.4a Question 1

How do TCM acupuncturists treat IBS in routine practice and how do the treatments compare with treatments in a pragmatic study?
- a. How is IBS contextualised?
- b. What (if any) are the distinguishing features of treatment?
  - i. Are treatments individualised?

To answer the first question, it was necessary to employ a sequential mixed methods (QUAL → QUAL) strategy. A sequential strategy conducts phases of research in chronological order, thereby allowing the initial phase to give rise to the latter [239]. The sequential strategy utilised pre-trial interviews and trial treatment logs to generate data. Specifically, the pre-trial interviews were designed to explore how acupuncturists envision treating IBS in routine practice, how acupuncturists contextualise IBS, and strategies to capture treatment information. In particular, the strategies for capturing treatment information were used to inform the design of treatment log books used for the sequential phase of research.

Because the RCT was to be carried out in North Yorkshire, I adopted a purposive sampling strategy for recruiting practitioners in the area. A purposive strategy seeks participants based on specific criteria so as to ensure the intended topic will be covered in detail [242]. Recruiting acupuncturists from the same area as the trial ensured an accurate description of treatments that may be delivered to trial patients as well as created an opportunity to involve potential trial acupuncturists in the development of trial instruments. The criteria for inclusion in the study were that the acupuncturists be members of the British Acupuncture Council (BAcC) and practice TCM as their primary style of acupuncture. The rationale for selecting these criteria was derived from the practitioner's requirements for the trial. Acupuncturists were excluded if they did not meet the two inclusion criteria. Potential participants were contacted via their postal address and/or email address listed in the BAcC membership register.

The information pack sent to potential participants contained a cover letter, information sheet, and consent form (Appendix B 2). Emails sent to potential participants simply contained the information sheet and an invitation to contact me

with any queries. Acupuncturists who returned the consent form were contacted to schedule an interview. Recruitment was time dependent on the number of participants I could recruit, interview, and analyse in time for use in the trial. From the time ethics gave their approval (Section 4.4) until the trial started, I had approximately three months to complete this phase of research. Details about the response rates and participants' characteristics are discussed in Chapter 5.

The primary means of collecting data to map the treatment of IBS was paired in-depth interviews. Note that 'paired' simply refers to a two person interview and not 'matching' which refers to pairing based on specific criteria [243]. I chose this method because the nature of the topic was relatively detailed, and it was important not only to extract answers but also a description of how the acupuncturists arrived at those answers. Paired interviews ensured that interplay between acupuncturists could stimulate discussion, while the intimate numbers ensured that each participant received adequate time to thoroughly express his/her ideas. The term paired interviews was chosen instead of focus group because the interviews intentionally involved only two participants, making the term focus group misleading. Nevertheless, Morgan defines a focus group as a means by which to determine the nature and quality of data via observing the communication process [244]. Based on this definition the paired interviews can technically be categorised as focus groups because observations were made as to how the communication process influenced dialogue.

The interviews were conducted using a flexible topic guide, which I constructed with input from KA and HM[6] (Appendix B 3). The topic guide presented in the appendix not only lists the interview questions, but it also provides the reason each question was asked. In general, the opening questions were designed to introduce the topic and promote practitioners' self-reflections, which focused their attention on a particular illness and their experiences. For example, I asked the acupuncturists how many patients they treat per month with irritable bowel symptoms. Subsequent questions emphasised the treatment process and particular aspects of treatment. The responses were used to map the treatment of IBS and also identify potentially problematic and/or significant areas of treatment that would require attention in the

[6] KA – Karl Atkin and HM – Hugh MacPherson provided supervisory input on the topic guide.

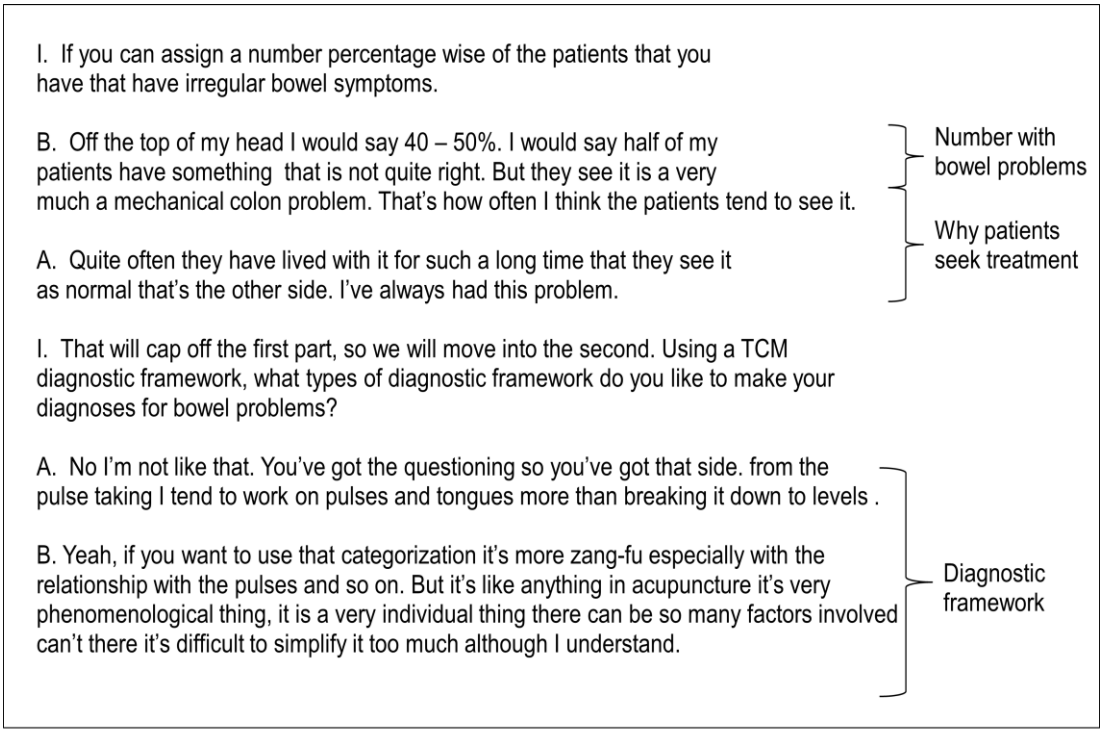
treatment protocol and log book. The topic guide's flexibility is demonstrated in the use of open-ended questions that are not restricted by order. Therefore, the paired interviews could be shaped by particular topics that the practitioners most readily engaged with, yet each interview covered the same topics [245]. Several probes were built into the topic guide regarding the points used and practitioners' needling techniques; however, I interjected additional probes to clarify some practitioners' comments or to encourage further discussion around emerging themes. For example, one acupuncturist stated that she gave exercise advice and I prompted her to explain that in more detail.

Once the topic guide was drafted, I piloted it with an acupuncturist who had research experience but was not involved with the trial. Piloting the topic guide served two purposes: 1) it provided me (a new researcher) with an opportunity to practice my interview skills with someone who could provide constructive feedback and 2) it clarified questions with problematic wording. Specifically, the piloting experience taught me how to improve the way in which I asked questions, which probably improved my ability to engage the practitioners and establish rapport.

After the topic guide was piloted and the participants were recruited, I conducted the interviews. Interviews were scheduled at the acupuncturist's convenience and held either at their clinic or nearby location. In total, seven interviews were conducted of which five were paired as intended. The two individual interviews were carried out despite being unpaired so as to collect as much data as possible. Although two of the participants were interviewed individually, the content of the topic guide was identical to the one used for the paired interviews. Thus, the individual interviewees only lacked the interplay with another practitioner. Prior to the beginning of the interview I engaged the acupuncturists in a general chat wherein we introduced ourselves and I explained the purpose of the interviews and how the information would be used. By engaging in this process, maintaining eye contact, limiting my interruptions when participants were speaking and listening attentively by providing reassuring comments such as 'I see' or summarising their comments I established rapport [245]. The interviews lasted between one to one and a half hours. All of the interviews were audio recorded with the exception being due to equipment

malfunction. I transcribed the interview tapes verbatim, and analysed them together with field notes, which were a particularly useful backup for the recording failure. To protect the acupuncturists' anonymities, each participant was assigned a pseudonym and each interview was randomly assigned a Greek letter.

To analyse the data, I employed two strategies described by Morgan as the mechanical and interpretive phases of analysis [244]. First, the transcripts were mechanically organised into segments via code mapping. During this process, I indicated the emergence of major categories in the margins of each transcript. Names for the categories were derived from, but not limited to the questions in the topic guide as evidenced by Box 4.2. Once the interviews were coded, the comments from each category were collated thereby completing the mechanical phase of analysis. I began the interpretive phase of analysis by identifying the emergent themes and subthemes for each category. Once the themes and subthemes were identified, they were re-analysed to generate theories that would provide meaning [1]. Additionally, I created an overview grid [244] to assess the degree of agreement between participants and to assess how data were generated in paired interviews (Appendix B 4). To enhance credibility and limit bias (particularly since I am an acupuncturist), the data were reviewed by a second analyst (KM) [245]. Details of the findings are discussed in Chapter 5 and were published last year [246].



Box 4.2 Example of code mapping. Excerpt from interview *Tau* with Holly (A), Sam (B) and the interviewer (I). Brackets identify particular codes.

On the whole, my first experience conducting and analysing interviews was enjoyable. As an acupuncturist, I was familiar with the role of interviewer, but in a different context. The experience taught me patience when waiting for responses to develop and the importance of neutrality in keeping my tone consistent whether I agreed or disagreed with a response [245]. Feedback from the pilot interview proved useful in that the questions were well received. Based on the acupuncturists' comments they appeared to enjoy the experience and were challenged to think about their practices from a different perspective. With regard to the analyses, I was most challenged and inspired by the discussion on context. Although the literature provides a variety of articles on the research controversies and pattern associations (e.g. Tan *et al* [216]), I was unable to find any studies on the contextualisation of biomedical conditions from a TCM perspective. Therefore, I used the interview findings to develop a hypothesis about the contextualisation of biomedical conditions from a TCM perspective, which is summarised in Chapter 5.

Although paired in-depth interviews were appropriate for collecting data to answer the first aspect of question one, they were not ideal for collecting data to analyse the

trial treatments. Iterative inquiry aptly formed the basis for the second aspect of question one, in that data gathered from the interviews guided the collection of data from the trial [235]. Because an objective of question one was to compare pre-trial to trial treatments, it was imperative that the treatment log capture similar information to the interviews. Using the feedback from the pre-trial interviews, information from the pilot, and input from HM, I designed the treatment protocol for the RCT and the treatment logs (Appendix B 5). As mentioned previously, one advantage of the pre-trial interviews was that they identified potentially problematic areas of treatment. Specifically, several of the acupuncturists indicated that they prescribed herbal remedies in conjunction with acupuncture to treat bowel disorders. The inclusion of herbal remedies was beyond the scope of the trial; therefore, the treatment protocol specified their exclusion. Apart from prohibiting the use of herbal remedies and magnets, the protocol encouraged the acupuncturists to provide treatments that were otherwise representative of routine practice. The emphasis on routine practice is important because it embodies the effectiveness approach and pragmatic nature of the study, which have practical implications. With regard to the treatment logs, the acupuncturists described a variety of sections in their patients' charts that they considered important such as history. From the sample charts we discussed, I was able to construct a treatment log that captured the information they considered important as well as the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) recommendations [247]. The STRICTA recommendations outline acupuncture specific reporting criteria that should enhance transparency of treatment delivery. The items in Box 4.3 describe the components of the treatment log that correspond to the data collected from the interviews.

Chief complaint: For interview purposes, this question was broad so as to determine why people sought treatment and if that reason related to IBS symptoms. For trial purposes, all patients had a diagnosis of IBS, yet IBS is not a chief complaint. Therefore it was important to ascertain which aspect of IBS was the most distressing (e.g. pain, bloating, constipation). Note that in TCM, the chief complaint influences how questions are asked during intake, and may influence the diagnosis and treatment plan.

Framework: The diagnostic framework was a direct comparison, in that practitioners were asked to plainly state which framework they used in both instances.

Diagnosis: During the interview, the practitioners were asked to list hypothetical diagnoses relating to IBS. The treatment log utilised a primary diagnosis table derived from the TEAMSI [1] with variations for IBS to incorporate interview data and current literature. Practitioners indicated the presence of particular patterns, as well as, what influenced that conclusion. The secondary diagnosis table created an opportunity to collect more detailed information so as to address the lack of evidence about which TCM pattern/s are related to IBS. There was also a free text area, which was designed to capture any relevant diagnosis not included in the table.

Treatment principle: Similar to the treatment framework, the treatment principle was a direct comparison to the interview in the form of free text.

Points used: In the interviews, practitioners listed points that were used to treat TCM patterns hypothetically related to IBS. Space was provided in the treatment logs to list the points, as well as, needle technique used for each treatment. Space was also provided to allow the acupuncturists to write why they chose specific points. Special attention was paid here to ascertain the uniqueness and/or commonality of points.

Additional therapies: As part of the treatment, the practitioners were asked about the types of additional therapies, specifically related to TCM, they used in conjunction with acupuncture. The treatment log asked this question in two ways 1) what therapies were used and 2) whether or not the additional therapy was applied to specific acupuncture points.

Lifestyle advice: Acupuncturists were asked what type of lifestyle advice they gave patients with IBS-like conditions. The treatment log contained a similar question with a free text response.

Box 4.3 Treatment log components

In addition to information on the diagnoses and points used, the log books captured information on adverse events and the practitioners' experiences. Once drafted, I

emailed copies of the treatment log to each of the interviewees for comment. The responses served as a form of analytical triangulation, whereby the interviewees' responses to the treatment log provided an estimate on the credibility of the analysis [248]. Although the interviewees' comments about the treatment log were generally positive, comments made during the trial suggest that the tick box diagnosis question was particularly confusing.

Analysis of the treatment logs acted as the sequential part of the mixed methods process employed to fully answer question one. Each treatment log represents the story of a patient in an atypical narrative format. The narrative presentation allowed the data to be processed using content analysis, whereby text is organised into comparable units then described or statistically reviewed [249]. Extraction of text from the treatment logs was influenced by interview data, which allowed the formation of categorical variables. The points used and the additional therapies categories were the most straightforward to analyse, in that I created a spreadsheet that identified the points and therapies, and their frequencies. In contrast, the chief complaint, diagnosis, treatment principle, and lifestyle advice categories posed an analytical challenge. One advantage of qualitative analysis is the absence of strict rules allowing the researcher to be creative and in this case use a phrase inventory [245]. I created separate phrase inventories for each of the challenging categories, which allowed me to condense a variety of similar terms into comparable units. For example, Box 4.4 lists a variety of primary diagnosis phrases from the free text section of the treatment logs. Without the phrase inventory one may report that each acupuncture patient received a unique primary diagnosis, which is only partially correct given that practitioners may use different language to describe the same diagnosis and/or phrases may describe different levels of the same diagnosis. The liver qi stagnation phrases illustrate this concept in that the three phrases describe different aetiologies of the same diagnosis. Similarly, a study by Coeytaux *et al* reports condensing free text diagnoses for headaches in a similar manner [250]. In total, I analysed all 1,016 treatments from three perspectives including: the overall trial, diagnosis, and acupuncturist. Although the overall trial data is the most readily comparable to other trials such as those listed in Table 3.7, the other two perspectives are more important to the thesis's objective. Details of the findings from the

treatment logs, a comparison to the pre-trial interviews, and examples of the spreadsheets are presented in Chapter 6.

Liver Qi Stagnation	Combined
Liver qi stagnation	Liver qi stagnation & spleen qi deficiency
Liver qi stagnation with fire	Liver qi stagnation with heat & spleen qi deficiency
Liver qi stagnation with liver invade spleen & stomach	
	Yin/Blood Deficiency
Damp Heat	Blood deficiency
Damp heat	Liver blood deficiency
Damp heat in spleen	Stomach & kidney yin deficiency
Damp heat in large intestine	Stomach yin deficiency
Damp heat in lower jiao	Spleen & stomach yin deficiency
	Spleen Qi Deficiency
Cold Damp	Spleen qi deficiency
Cold damp in middle jiao	Spleen & stomach qi deficiency
Stomach cold & damp	Spleen & heart qi deficiency
Yang Deficiency	
Kidney yang deficiency	
Spleen & kidney yang deficiency	

Box 4.4 Phrase inventory for diagnosis category

While the treatment logs were analysed via content analysis, the acupuncturists who completed the logs were conveniently recruited from the platform of the pre-trial interviews. Acupuncturists participating in the interviews received information regarding the trial prior to the interview, and were invited to ask questions about the trial following the interview. Potential participants were contacted via the post with an information sheet (Appendix B 6), honorary contract, and criminal record background check. In addition to the criteria above, the acupuncturists were required to have three years of clinical experience and professional liability insurance. Twelve acupuncturists were considered optimal for the treatment portion of the trial, allowing an average of ten to twelve patients to be allocated to each acupuncturist. Seven of the nine acupuncturists who participated in the trial completed a pre-trial interview. The other two acupuncturists were not recruited in time to complete an interview. Details about the acupuncturists who delivered the trial intervention are presented in Chapter 6.

In contrast to the convenient recruitment of trial acupuncturists, patients were purposively recruited via database searches of GP practices in York and Harrogate.

As mentioned previously, the pragmatic nature of this study encouraged the recruitment of a representative sample of diagnosed IBS patients. With regard to database recruitment, I have published on the strengths and weaknesses of this technique [251] and will therefore only highlight details related to this study. Database search criteria were derived from the trial protocol, which specified that patients be eighteen or older; have a diagnosis of IBS or be prescribed medication to treat IBS symptoms; consulted their GP within the previous two years regarding their symptoms; and have no history of cancer or haemophilia. The trial co-ordinator (HC) and I piloted the database search at York Medical Group and modified the criteria with guidance from Dr. Mark Roman to identify patients diagnosed with IBS who had no history of psychosis and who were not pregnant. The search for patients based on medication was not performed because GPs were unwilling to hand-search medications, such as mebeverine, because they have multiple indications. Additionally, the two year limitation on consultation was omitted because it significantly reduced the pool of potential participants from 524 to ~150, and the database search could not specify consultations for IBS symptoms after the diagnosis was made. In terms of advantages, the searches identified patients who had been diagnosed with IBS and who may be receiving care from primary, secondary, or tertiary providers. Recruitment as such captured a range of severities and diagnoses made with different criteria, thereby providing a representative sample of diagnosed patients including those actively seeking care and those who Bertram *et al* describe as given up due to lack of remedy or empathy [91] (Chapter 2). In terms of disadvantages, the recruitment strategy did not identify representatives from the undiagnosed portion of the IBS population, which may contribute 50% of IBS cases identified in population surveys [80]. Therefore, the findings are limited to those patients who are diagnosed.

After identifying a list of potential participants, GP practices sent the individuals information packs containing an information sheet, consent form, and baseline questionnaire (Appendix B 7). Calculations from the pilot study estimated that 220 patients were needed for the trial, accounting for attrition [47]. Patients who returned a consent form and baseline questionnaire were assessed for eligibility by HC and

HT[7]. In addition to the criteria used to design the database search, the patients had to score ≥ 100 on the IBS-SSS (Sections 2.5 & 4.3.4b) to be eligible. Eligible patients were then allocated to either usual care or usual care plus up to ten sessions of acupuncture using a simple concealed randomisation scheme [252] that was computer generated. For the purpose of this study, usual care refers to routine treatment provided by a GP. With regard to the ten sessions of acupuncture, I understand that the authors of the protocol considered the number to be reasonable for NHS support if the intervention was cost effective. Although I appreciate the rationale, it undermines the effectiveness approach to some extent and may foster unrealistic patients' expectations further discussed in Chapter 5. Once randomised, the patients allocated to acupuncture were telephoned by SB[8] to schedule their initial appointment. Patients were allowed to choose the location of the practice and the time of their session. Having recruited acupuncturists (TS), patients (TS, HT, HC), and made appointments (SB), data collection on the trial treatments began. Findings from the analyses described previously are presented in Chapter 6.

4.3.4b Question 2

Is there a difference in outcome for particular TCM diagnoses?
- a. Is the IBS Symptom Severity Scale (IBS-SSS) a valid and reliable measure of severity?
- b. Can the acupuncturists' prognoses accurately predict patient outcome?

Although qualitative methods were appropriate to answer question one, the answer to question two was derived from a quantitative approach. The pragmatic mixed methodological approach that I adopted for this thesis allowed me to transition between different types of methods to answer the research questions. Given the pragmatic nature of the RCT, the variety of TCM diagnoses potentially associated with IBS, and the objective to assess the relative importance of the TCM diagnoses, question two asked whether there was a difference in outcome for particular TCM diagnoses. Before I answered this question, I addressed the challenge to IBS outcomes specifically related to the primary outcome measure used in the trial, the IBS-SSS. As mentioned previously, the IBS-SSS is a five question instrument

[7] HC – Helen Cox & HT – Helen Tilbrook were the trial co-ordinators of the RCT.
[8] SB – Sally Brabyn was the trial support officer on the RCT.

(Appendix A) that monitors changes in patients' IBS symptoms and estimates their IBS severity [128]. IBS-SSS scores range from 0 – 500 and indicate remission (< 75), mild (75 – 175), moderate (176 – 300), and severe (> 300) symptoms. However, as discussed in Chapter 2, a review of IBS endpoints suggests that the IBS-SSS lacks sufficient evidence to support its validity [231]. Considering the review by Camilleri *et al*, my own confusion by the wording of some questions, and the limited representation of the symptoms described by patients (Chapter 2), I decided to further analyse the validity and reliability of the IBS-SSS. To determine the validity and reliability of the IBS-SSS, I conducted a factor analysis and Cronbach's alpha calculation using the baseline data for all trial participants in SPSS 17.0.2. Details of the exact methods such as principal axis factoring, appropriateness, hypothesis, and findings are discussed in Chapter 7, Section 7.3.

After I assessed the validity and reliability of the IBS-SSS, I was able to analyse the IBS-SSS and the global outcome measure (i.e. SF-12) for differences in outcomes specific to TCM diagnoses. The SF-12 is a simplified version of the SF-36 that measures eight different domains of health including: pain, vitality, general health, social functioning, role emotional, physical functioning, role physical, and mental health [253]. Additionally, component scores for physical and mental health can be calculated. Scores for the SF-12 may be compared across groups in their raw form, or be compared to the population as mean adjusted scores. The SF-12 scores are potentially important because patients' IBS symptoms may manifest in multiple health domains some of which are not reflected in the condition specific measure.

Initially, data on all patients who were allocated to acupuncture and received a TCM diagnosis were analysed to determine whether a patient's TCM diagnosis was related to his/her age, IBS severity, and/or IBS duration. Based on the heterogeneous nature of IBS (Chapter 2) and fundamental differences between TCM and biomedicine I hypothesised that the factors would not be related to TCM diagnoses. To test the hypothesis, the factors were descriptively compared then analysed by multi-nomial logistic regression in SPSS 17.0.2. Analyses of the descriptive statistics provided an opportunity to become familiar with the data, while the multi-nomial logistic regression provided the appropriate means to explore the relationship between the

factors (continuous independent variables) and a non-ordinal categorical variable with seven categories [254]. Details of the findings are discussed in Chapter 6, Section 6.5.3.

Similar to the methods used to determine the relationship between TCM diagnoses and age, duration of IBS, and IBS severity, descriptive statistics and linear regressions were used to determine the differences in outcome among TCM diagnoses. Descriptive analyses compare the mean score changes for the different TCM diagnoses across the IBS-SSS and SF-12. Linear regression was deemed the appropriate method to determine the difference in outcome among TCM diagnoses because it assesses the ability to predict one variable (outcome) from another (diagnosis) [254]. I elected to run linear regressions on the IBS-SSS and the SF-12 because they were the primary and global outcome measures. To determine if the data were appropriate for linear regression, I assessed the distribution of the dependent variables. Next, the models were run with the TCM diagnoses and baseline scores as independent variables and the three and six month outcomes as dependent variables. The hypothesis and findings are further discussed in Chapter 7, Section 7.4.

In addition to the primary aspect of question two, a sub-question asked whether the acupuncturists' prognoses predicted outcome. To address the question of the acupuncturists' prognoses, I included a question about their perception in the treatment log. The acupuncturists could assign a 'good', 'poor', or 'don't know' prognosis to each patient. Once collected, the data were descriptively analysed to determine the frequency of each prognosis. Second, I performed a cross tabulation and chi-square test to determine the relationship between the prognoses and acupuncturists as well as a cross tabulation and chi-square test to determine the relationship between the prognoses and TCM diagnoses. This method was deemed appropriate because it assesses the relationship between two categorical variables [254]. Third, the prognoses were entered into a linear regression model to determine whether they were predictive of outcome. The hypothesis and findings related to the relationship between prognosis and outcome are further discussed in Chapter 7, Section 7.5.

4.3.4c Question 3

3. How do patients, acupuncturists, and GPs understand acupuncture to work?
    a. Does the patient's understanding affect his/her perceived treatment outcome?
    b. Do acupuncturists perceive their explanations to affect patients' outcomes?
    c. Do GPs consider acupuncture a valid treatment modality?

Similar to the methodology employed to answer question one, question three employed a qualitative strategy. To address the patients' aspect of question three, I conducted in-depth interviews nested within the RCT. I also conducted in-depth interviews with acupuncturists and GPs; however, those participants were not specifically recruited from the RCT. As such, the variety of approaches used to answer the questions reaffirms the appropriateness of a pragmatic mixture of methodologies for this thesis.

The primary means of collecting data to answer question three was individual in-depth interviews. I chose this method because like the pre-trial interviews the nature of the topic was relatively detailed; however, the personal nature of the questions and potentially uncomfortable topics made individual interviews appropriate. For example, patients may be less likely to speak about their bowel habits in front of other people particularly considering the embarrassment associated with IBS [90, 92, 120]. Each set of interviews was conducted using a flexible topic guide that I constructed with input from KA and HM (Appendix B 8). Similar to the topic guide previously discussed, these topic guides are presented with questions and the reasons they were included. All three topic guides contained questions about how acupuncture works and the potential impact of how the mechanism is understood, for example does it affect patients' treatment outcomes. The patients were also asked about their experiences with acupuncture, while the acupuncturists and GPs were asked about the role of acupuncture in health care and its acceptance. I used probes and established rapport in the same manner as with the pre-trial interviews. After drafting the topic guides, I piloted each of them to identify potentially problematic questions and/or wording.

With regard to recruitment, the acupuncturists were recruited by a purposive sampling strategy similar to the pre-trial strategy. One exception was that those

acupuncturists participating in the trial were excluded from contact. Trial acupuncturists were excluded to ensure that the topics covered in the interview did not alter treatment delivery. On the other hand, recruitment of GPs employed a convenience sampling strategy of practitioners whose surgeries were participating or had expressed an interest in the trial. The reason for adopting a convenience approach was to increase the likelihood of recruiting participants from a hard to reach group. Potential participants were sent an information sheet and consent form (Appendix B 9). Details of the response rates and characteristics of the acupuncturists and GPs are presented in Chapter 9.

Patients were recruited from the pool of trial participants allocated to acupuncture, using a purposive sampling matrix selecting for sex, IBS severity, and treatment preference (Table 4.2) indicative of a maximum variation sample [245]. Given the heterogeneous nature of IBS symptoms and comorbidities, the factors such as sex and preference may further stratify the IBS experience. Interviewing patients with diverse characteristics creates an opportunity to identify shared and divergent experiences. The target was three to four participants from each group for an overall sample of 24 – 32 participants. Due to staggered trial recruitment, interview recruitment was staggered over six months. Recruitment continued until the target sample for each group was reached or the potential sample was exhausted. Participants who returned the consent form were contacted to schedule an interview. Details of the response rates and the patients' characteristics are presented in Chapter 8.

Severity	**Prefer Acupuncture**		**Prefer Either**		**Total**	
	Male	Female	Male	Female	Male	Female
Mild/Moderate	3-4	3-4	3-4	3-4	6-8	6-8
Severe	3-4	3-4	3-4	3-4	6-8	6-8
Total	6-8	6-8	6-8	6-8	12-16	12-16

Table 4.2 Patient interview recruitment matrix

Once the topic guides were constructed and the participants were recruited, I conducted the interviews at the convenience of the participant. All the interviews were conducted at a location convenient for the participant, most commonly at home for patients and acupuncturists, and at the surgery for GPs. In total, I conducted fifty-

five interviews (33 patients, 11 GPs, & 11 acupuncturists). The interviews lasted between thirty minutes to one hour, and all were audio recorded. Each interview was transcribed verbatim and analysed together with field notes. Two of the participants (1 GP & 1 acupuncturist) agreed to participate and act as the pilot, which meant that they not only answered the questions but also identified problematic questions or wording. Because these participants contributed to both processes I analysed their transcripts with the other interviews. To protect the participants' identities, each person was assigned a pseudonym.

Upon reflection, the interviews were both my least and most favourite aspects of data collection. Specifically, the patients' interviews were my favourite probably because of the patients' enthusiasm and expressions. For example, one woman said she was normally jet propelled (by wind) when she walked her dog. Overall, the patients seemed pleased to be interviewed and to receive acupuncture whether it helped or not. On the other hand, the GPs, as a group, were my least favourite because they were the most difficult to recruit and schedule interview times. I also felt rushed during the interviews, which was sometimes exacerbated by flippant responses. The difference in interview locations (i.e. patients – home & GPs – work) potentially contributed to the harried atmosphere. Although the in-depth interviews captured useful data, I may seek a different way to collect data from GPs in the future.

Each set of interviews was analysed according to the mechanical and interpretive strategies described by Morgan [244]. First, each transcript was organised into categorical segments derived from, but not limited to its respective topic guide. As indicated in Box 4.2, the emergent categories were noted in the margin of each transcript. After the initial coding, comments from the same category were collated. Next, I identified the themes and subthemes that emerged from each category as indicated by the example in Box 4.5. I compared the themes and subthemes that emerged within a particular category, and compared them across different categories. This process allowed me to explore the similarities and differences among particular cases as well as contextualise the themes in relation to the broader dataset [234]. Additionally, I conducted a comparative analysis using methods triangulation of the patients' transcripts and the questionnaire data. Triangulation aspires to uncover the

complexity of reality and consistency in findings by co-analysing data from multiple methods, but does not aim to describe the same results from different sources [245]. Furthermore, triangulation can strengthen the credibility of qualitative data. The findings are presented in Chapters 8 and 9 with representative quotations from the participants identified by pseudonyms.

Rose: You'll try anything when you're fed up with something won't you. Anything. It can't do any harm. I know it can't do any harm so I just went with it.	• Try anything • Not harmful
Patricia: It was a case of I'll try anything. In the hope that it would prove to be a solution.	Try anything
Lucas: I just saw if it helps and it stops me taking so much stuff to make me go I'll try it and if it helps then it's got to be better than taking something everyday.	Alternative to medication
Nick: I'm quite interested in alternative treatments because the treatments I've been given medical the prednisolone these are serious interventions and they do have very serious side effects particularly prednisolone so any alternative which would treat me in a different way without having side effects and I don't think things like acupuncture have side effects as such I'd be interested in trying	• Alternative to medication •Not harmful
Gina: I was just willing to try anything cause I'm sick of pumping myself full of drugs all the time and not really knowing what they are doing and if they are making any difference.	•Try anything •Alternative to medication

Box 4.5 Example of identifying themes and subthemes. Excerpt from the reason to participate category

4.4 Ethical Considerations

Ethical approval to conduct the pre-trial interviews was obtained from the Ethics Committee at the University of York. Ethical approval to conduct the RCT of acupuncture for IBS with a nested qualitative study was obtained from the York Research Ethics Committee (# 08/H1311/66). I prepared the ethics application with assistance from HM, HT, and KB, and attended the ethics board meeting.

With regard to the interviews, each potential participant was assured that expressing an interest in the study did not obligate him/her to participate. Participants were notified that interviews would be audio recorded prior to the interview and a second time before the recording began. All participants agreed to be recorded. Each interview and interviewee was assigned a code name so that participants may only be identified by their consent form.

The primary ethical concern with the pre-trial interviews was asking questions in a non-threatening manner, so that acupuncturists did not become defensive about their style of treatment. According to Kruger, people are more likely to provide candid answers in a comfortable and non-judgemental environment [255]. Questions were designed to be open and encouraging to a broad range of responses. Additionally, I facilitated a dialogue to explore why conflicting answers occurred and supported the idea that this was a learning opportunity.

The primary ethical concern with the trial portion was ensuring that the identities of patients and acupuncturists remained anonymous. Each patient and acupuncturist was given an identity code to be used on all documentation with the exception of consent forms and contracts, respectively. Only those persons working directly on the trial had access to the database carrying the identity codes. All paper documentation was stored in locked cabinets.

4.5 Quality in Qualitative Research

While the previous sections emphasise qualitative methods, this section introduces the concepts I consider important to addressing quality. According to Mays and Pope, there is some debate about how to judge quality in qualitative research that is part of a broader debate on the contributions produced by qualitative studies [233]. Moreover, the quality debate has been going for many years and has led to multiple term translations such as external validity to transferability [256]. The subjective/creative methods and analyses associated with qualitative research contributed to the debate and development of various checklists for assessing the quality. Since it is not practical to utilise all the checklists, I based my interpretation of quality on the works by Mays and Pope and Teddlie and Tashakkori.

To improve quality, Mays and Pope recommend that researchers 1) present findings in such a way that another researcher may analyse the data and draw a similar conclusion and 2) present a reasonable explanation of the topic being studied [257]. The previous sections provide a transparent explanation about the data collection process such as the collation of comments into particular categories to identify emergent themes. Additionally, the following chapters provide multiple sample

quotations that allow the reader to gauge the appropriateness of the findings. Beyond addressing these two quality questions, Mays and Pope suggest that validity (i.e. the extent to which the explanation accurately reflects the topic) may be questioned with regard to reflexivity, context and sampling [233].

Section 4.3 introduces reflexivity as the researcher's acknowledgement and consideration of how he/she affects the research process. I acknowledge that I am a TCM trained practitioner, which potentially influenced data collection and analysis. Based on my background and potential influence on the study it was prudent to incorporate a second analyst with a non-CAM background to ensure reliability of the findings. Reliable refers to the Teddlie and Tashakkori concept that the intended topic was consistently measured [239]. With regard to context and sampling, the participants are described in sufficient detail to allow the reader to interpret adequacy as well as to determine if the findings are transferable to other populations. As mentioned in Section 4.3.4a, I also asked the acupuncturists to comment on the treatment log designed based on their interviews as a form of analytic triangulation.

Based on my reflections over the course of this project I consider the second analyst strategy a more practical method of ensuring quality than the analytic triangulation using practitioners. As the reader will see in Chapter 6, despite using analytic triangulation to clarify questions in the treatment log book several of the questions were misinterpreted. However, the log books generated a large volume of useful data. With regard to the second analyst, I was challenged to continually review and defend my interpretations as well as learn how the data may be interpreted by another researcher, which I think made for an overall more robust discussion and evaluation of the data.

4.6 Summary

Studies of acupuncture and IBS present a number of research challenges including: placebo effect, recruitment, population, intervention complexities, and outcomes. An effectiveness approach, wherein researchers employ a flexible protocol and deliver pragmatic treatments in routine settings, is one means to overcome many of the challenges. An effectiveness approach is not only advantageous for acupuncture and

IBS studies, but it also provides the flexibility necessary to answer the research questions and accomplish the objectives of this thesis. The complexity of the research questions necessitated the use of a pragmatic mixed methodological approach that incorporates mixed, quantitative, and qualitative methods. Chapters 5 – 9 present findings to answer each of the research questions, while Chapter 10 synthesises the findings from each question to assess the relative importance of TCM diagnosis differentiation and treatment individualisation from multiple perspectives.

Chapter Five

Mapping the routine TCM treatment of IBS

Chapter highlights

- TCM acupuncturists contextualise IBS based on the biomedical characteristics they deem relevant, and overall consider it to be an un-useful diagnosis
- Although the majority of patients seek acupuncture for reasons other than their bowels, the acupuncturists estimated that 40-50% of patients describe abnormal bowel habits
- The acupuncturists' descriptions of point selection corresponds with the three approaches identified by Unschuld as pragmatic, disease specific, and individualised
- The implementation of different treatment aspects such as point selection, additional therapies, and lifestyle advice are influenced by similar factors but to different degrees

5.1 Introduction

The previous chapters provide a background on IBS, which depicts a complex heterogeneous condition, and explore the traditional Chinese medicine (TCM) interpretation and treatment. From the descriptions, the reader has learned that both biomedicine and TCM agree that IBS is a heterogeneous condition and although they differ in the treatments, both practices use a variety to alleviate symptoms. Additionally, Chapter 4 introduces several challenges to TCM and IBS research many of which may be overcome by an effectiveness approach. Although the effectiveness approach may overcome some research challenges, it is also the appropriate approach for this thesis because it allows for the flexibility necessary to answer the research questions.

According to Chapter 3, multiple TCM diagnoses may be associated with IBS, and the acupuncture points used to treat IBS may be based on the diagnosis and practitioner's preference. While Chapter 3 refers to textual recommendations and clinical trials, the lack of literature about how acupuncturists treat IBS in routine practice forms the underlying rationale for undertaking this aspect of research. Additionally, whether the treatments delivered during the trial will mimic those described in routine practice is unknown. Therefore this chapter presents findings related to the first aspect of question one, which asks how do acupuncturists contextualise and treat IBS in routine practice. The interviews included questions about contextualisation, TCM diagnosis, and treatments of IBS to generate data that may be used to address the first aspect of question one. With regard to the overarching aim to develop a hypothesis about the relative importance of TCM diagnosis and treatment individualisation, the interviews provide data from the acupuncturists' perspective about how they diagnose and treat patients in routine practice. The following sections present the aims and objectives, methods summary, participants, findings and discussion about the interviews.

5.2 Aims & Objectives

The aim of this chapter is to map how acupuncturists treat IBS in routine practice. The objectives are to establish:

- How the acupuncturists contextualise IBS

- The type of treatments delivered in routine practice
- The processes involved in treatment design, which influenced treatment guidelines (Appendix B 5)
- An effective way to capture treatment information, which influenced treatment log design (Appendix B 5)
- A basis for comparing treatments delivered during the trial (Chapter 6)

Capturing a detailed map of how the acupuncturists treat IBS in routine practice is slightly misleading. In order to be reflexive and transparent, it is necessary to elaborate on this statement. As indicated by the TCM texts reviewed in Chapter 3, an acupuncture treatment plan is inextricably linked to the diagnosis, which is formed in accordance with TCM diagnostic frameworks. Therefore, the question of how a TCM practitioner treats IBS is an oxymoron. Valuable information can still be gleaned from asking the question as long as the answers are put into context. The practitioners described real treatments for particular TCM diagnoses that hypothetically correspond to IBS.

5.3 Methods summary

As described in Chapter 4, data for this chapter were collected as part of the primary phase of a sequential mixed methods strategy to answer the first research question. I conducted seven in-depth interviews, of which five were paired as intended, to generate data. Each interview began with a reminder about informed consent and a general overview of the structure of the interview. Since IBS is not a TCM diagnosis, it was essential that the acupuncturists were not restricted to the biomedical definition of IBS. When answering questions, interviewees were encouraged to answer based on their personal experiences with patients whom they considered to have irritable bowel symptoms and on patients who claimed to have IBS. The topics covered during the interviews included (Appendix B 3):

- The number of patients treated with IBS or IBS like conditions
- Whether IBS is a primary complaint or reason for seeking acupuncture treatment
- Commonly used diagnostic frameworks and diagnoses of IBS patients
- How points are selected and which points are used

- What additional therapies are used
- What lifestyle advice is provided
- How best to capture the information they have provided

At the end of the interview, the acupuncturists were given drafts of treatment logs to be used in the trial and asked to comment on suitable changes. The acupuncturists' responses to the sample logs along with information from the literature and pilot study were used to design the treatment log and treatment guidelines for the trial, which represent the sequential phase of research. Data were analysed through mechanical and interpretive familiarizations with the transcripts [244] as illustrated by the sample coding in Box 4.2. Data are displayed as direct quotes from the acupuncturists according to their pseudonym. The following sections present the findings and a discussion on the implications of this study.

5.4 Response Rates

Despite my willingness to be flexible with times and locations only sixteen acupuncturists agreed to be interviewed, with twelve actually completing the interview. Of the four who initially responded with interest but did not participate, one was ineligible because she did not practice TCM and the other three had multiple scheduling conflicts. Thus twelve of the sixteen people who replied with interest completed an interview. Table 5.1 lists the complete response rates. As discussed in Chapter 4, I had approximately three months to recruit, conduct, and analyse the interviews. Given more time it may have been possible to schedule additional interviews; however, the consistency among the findings suggests that additional interviews would not have contributed ample new data.

Response	People	Percent
Replied with interest	16	40%
Replied not interested	8	20%
No Reply	16	40%
Total	40	100%

Table 5.1. Paired in-depth interview response rates.

5.5 Characteristics of Participants & Pairs

The participating acupuncturists averaged 11.2 years in practice and were predominantly female (10/12) (Table 5.2). Each of the interviews is referred to by a

Greek letter and each participant is referred to by a pseudonym to protect the identities of the participants. A brief description of the participants and paired interviews is provided in Box 5.1, while a comprehensive account of the interaction between the participants is provided in Appendix B 4.

Acupuncturist	Sex	Yrs practice	Speciality
Beth	F	25	Internal medicine
Cindy	F	17	
Lisa	F	10	
Jill	F	10	Gynaecology
Holly	F	4.5	
Ellen	F	5	
Sue	F	17	Paediatrics
Amy	F	2	
Janet	F	10	Pain
Michelle	F	3	Pain
Sam	M	21	
Alex	M	10	

Table 5.2 Acupuncturists' characteristics

Delta: Sue and Amy have an employee-employer relationship that is relatively new. Sue answered questions as if the interview was a teaching opportunity, while Amy seemed conscious about justifying her answers. There is not as much dialogue between the two as there could be; both seem to have an individual agenda for answering questions. The agreement between the two is overshadowed by the teacher-student dynamic.

Omega: Janet and Michelle are friends but do not work together. Although this pair was comfortable talking about acupuncture in general, neither had much experience treating bowel conditions. They had a free flowing dialogue, but it was not always directed toward the topic.

Kappa: Beth and Cindy are co-workers who do not have an obvious power dynamic. Cindy frequently gave vague answers, whereas Beth gave direct quantifiable answers. They discuss things about the individual in an open way, but not about specific cases, which was dissimilar from the other groups.

Rho: Lisa and Jill studied together but do not work together. There was an excellent dialogue between the two even though Jill tended to dominate the conversation.

Tau: Sam and Holly recently started working together. Although Sam was newer to the office, he was more experienced and dominated the conversation to the point of interrupting Holly. Despite the fact that Sam dominated the conversation there was still a good exchange of ideas.

Gamma: Ellen completed an individual interview and brought notes with her about her experiences. This interview was not audio recorded due to equipment malfunction; however, detailed field notes were made.

Lambda: Alex completed an individual interview. He often used metaphors to explain his reasoning.

Box 5.1 Summary of acupuncturists' interactions

The descriptions in Box 5.1 and characteristics in Table 5.2 suggest that there was a range of clinical experience and practice styles such as multi-practitioner or individual settings, which is important because it reflects the diversity of routine care settings. Patients seeking routine acupuncture care may encounter a variety of practice styles and experience on the BAcC register. Additionally, the descriptions highlight the fact that each pair of interviewees knew each other, which influenced their dialogue. For example, Lisa and Jill were friends and former classmates who had a natural conversational rhythm. Although the interviews were not designed to intentionally pair acupuncturists who knew each other, I think the result was an unexpected benefit. Specifically, it allowed the practitioners to openly discuss differences in a way that either would not or may not occur if the interviews were individual or focus groups. With regard to the two individual interviews, they provided useful information but without the additional layer of detail.

5.6 Findings

Having introduced the acupuncturists and reflected on their interactions, the following sections present the findings. The findings are divided into three components: 1) IBS in context, 2) background information on how many and the reason why patients seek acupuncture, and 3) a step-wise explanation of the treatment process. A mind map (Appendix C) summarises the treatment process as it explores making a diagnosis, diagnostic patterns, treatment principles, point selection, points used, additional therapies, and lifestyle advice. The following subsections describe the emergent themes and interpretations related to these categories as well as details about the role of emotion, counselling, and patient follow-up.

5.6.1 IBS in context

As discussed in Chapters 2 and 3, the definition, understanding, and causes of IBS vary according to perspective. Due to the variations and consideration that IBS is a biomedical diagnosis, the interviews began by contextualising the acupuncturist's perspective of IBS. Primarily, the acupuncturists contextualised IBS according to symptoms as illustrated by Sam and Janet.

> Sam: "[patient] who has been very stressed with stress symptoms but has really poor bowel habits and severe constipation and lots of associated problems."

> Janet: "On waking in the morning he goes six times with chronic diarrhoea before about nine o'clock. Then he's fine for the rest of the day."

Within the symptom theme, two subthemes, variability and emotion, emerged. Acupuncturists indicated that IBS symptoms vary widely, which contributed to a sense of non-diagnosis and need for clarification.

> Lisa: "You always have to ask them what they mean by IBS because they will have either self-labelled or been labelled and it is immensely variable what they mean by that."

> Alex: "Generally speaking when they come in with IBS, IBS is a junk diagnosis, it's a non-diagnosis. So really what you are left with then is this person has this group of symptoms."

The tone and language expressed by Lisa and Alex not only associate IBS with variability, but also indicate that the diagnosis as a label is not particularly helpful. Effectively, these comments illustrate that TCM practitioners may be familiar with biomedical diagnoses, but only incorporate them into practice insomuch as the symptoms the patient expresses. In an emotional context, the acupuncturists associated IBS with inappropriate expressions of emotion and stress.

> Jill: "There's the anxiety that goes with it and the palpitations and just not feeling emotionally anchored along with the anxiety and 'I might need the loo kind of thing'."

> Holly: "There is a lot of held emotion and it manifests wherever there is a weakness and digestion is a very common place."

Secondarily, the acupuncturists contextualised IBS by identifying meaningful biomedical characteristics of IBS.

> Cindy: "IBS is episodic."

> Beth: "Whatever the reason they take antibiotics then our bowel is in trouble after this."

> Holly: "You kind of know they've got a functional problem but you don't know the underlying cause."

Acupuncturists contextualised IBS in terms of symptoms, particularly abnormal bowel movements and stress. Stress was identified as an aspect of 'held' emotions,

which was not considered unique to IBS patients, but rather a manifestation of 'held' emotions in a system with an underlying weakness. Additionally, the symptom variability and sense of non-diagnosis encouraged contextualisation according to biomedical characteristics the acupuncturists considered relevant; however, the IBS diagnosis itself was not considered useful. With regard to the literature, I was unable to find supporting or contradictory studies; therefore, I asked a group of practitioner-researchers about the context of biomedical diagnoses. The impact of the findings and highlights from the practitioner-researchers' discussion are presented in Section 5.8.

5.6.2a Reasons People Seek Treatment

As indicated by Figure 1.1, there are many factors encouraging the uptake of pluralistic therapies. Furthermore, the reason people seek treatment and/or their primary complaint is arguably the most influential factor in treatment plan design. Exploring the reasons people seek treatment served to engage the acupuncturists in thinking about their patients' primary complaints and whether or not those complaints were related to irritable bowel symptoms. The primary theme that emerged from this category was the importance of the acupuncturist's speciality. Accordingly, acupuncturists responded with the following comments regarding the primary reason people seek treatment.

> Michelle: "I find most people only come to me for pain."
>
> Jill: "I think it depends on your practice because mine is mostly gyneo/obstetric."
>
> Holly: "Anything and everything. I don't specialise at all."

Importance of speciality can be distilled from the observations made by Jill, in that her patients primarily seek treatment for gyneo/obstetric problems, and by Holly who does not specialise in that she treats a wide variety of primary (i.e. chief) complaints. Therefore, it can be reasoned that patients are less likely to have a primary complaint differing from the acupuncturist's speciality (if applicable), and in the case of no speciality primary complaints are broad ranging.

The first subtheme that emerged in this category was the notion that patients with bowel problems do not seek treatment for their bowel problems because the patients often consider the problem to be 'normal', as illustrated by the following statements.

> Amy: "Lots of people in the initial consultation will say 'I've always had constipation or I've always had loose stools' and not realise."

> Jill: "They don't think about that bit at all until you ask them what is your usual bowel habit and they go 'well normal for me' you really have to tease it out and how often is that 'once every three days' then it comes out that there is bloating and pain."

> Holly: "Quite often they have lived with it for such a long time that they see it as normal. 'I've always had this problem.'"

The second subtheme that emerged in this category was that patients with bowel problems do not state bowel problems as their primary complaint because they often do not think it is treatable.

> Sue: "I get a lot of bloating type. I get a lot of people who say 'well I just live with it because I didn't think anything could be done'."

> Michelle: "IBS is seen as incidental because they don't think they can get treatment. They are very surprised."

> Sam: "Someone who came in this morning who has been very stressed with stress symptoms but has really poor bowel habits and severe constipation and lots of associated problems and it never occurred to her that maybe acupuncture could help that as well."

The secondary theme that emerged in this category was the idea that people seek acupuncture treatment when they are dissatisfied with biomedicine and/or other treatments are ineffective. The following examples provide evidence for this finding.

> Alex: "A lot of people come to acupuncture having been through a lot of other interventions and treatments and not got very far. So they are already feeling like it is the end of the road, which is a shame but it tends to be that acupuncture is perceived often by people as a last resort."

> Holly: "They come to us with this whole list of treatments they've had. Most people's first port of call is the GP to have tests done. They come to us when they have had all the tests and told nothing is wrong."

These comments were conveyed with a strong sense of frustration, in terms of how acupuncture is utilised by the public. According to Smart *et al*, IBS patients are more likely to seek alternative medical treatment if biomedical treatments are ineffective [258], which reaffirms the acupuncturists' frustrations that acupuncture is a last

resort. Based on the acupuncturists' comments, patients' primary complaints are influenced by the practitioner's speciality and by what the patients think acupuncture can treat. Furthermore, bowel problems are not commonly the primary complaint because patients often consider the problem 'normal' and/or untreatable. One possible reason why patients may not consider acupuncture a treatment option is that the UK guidelines for IBS do not mention acupuncture as an option, and the WHO guidelines only mention that it is an area for research (Chapter 2) [74, 259]. Alternatively, the patients who consider their problem to be 'normal' may represent the group of IBS patients in the general population who are undiagnosed and do not seek medical care for their bowels. Ultimately, the reason patients seek treatment guides the consultation and diagnostic processes, which in turn influences the treatment principle and delivery [33] as discussed in subsequent sections.

5.6.2b Number of Patients with Bowel Problems

Considering the uncertainty around the number of people who suffer IBS (Chapter 2) and the two million annual GP consultations for functional abdominal symptoms [84], it was important for the acupuncturists to estimate the number of patients they treat with irritable bowel symptoms. The estimates were to be determined regardless of whether the patients' primary complaints were bowel problems.

> Amy: "When I think about the number of people who have come in specifically for digestive problems that's small compared to the number of people I treat for digestive problems."
>
> Janet: "A lot of them have bloating, like 40% and with bowel probably 20% say they have differences."
>
> Sam: "I would say 40 – 50%. I would say half of my patients have something that is not quite right but they see it as very much a mechanical colon problem."

There is consistency among the responses that the percentage of people with digestive and/or bowel problems is approximately 40 – 50% of the patient population. Additionally, there is a noticeable disparity between the number of people being treated for bowel conditions and the number seeking treatment for bowel conditions. The small number who present with bowel problems as a primary complaint corresponds with a UK national survey, which indicates only 5% of patients seeking acupuncture site gastrointestinal disorders as their primary

complaint [197]. From the previous section, we may infer that the disparity is influenced by whether a patient thinks his/her condition is 'normal' and/or treatable as well as what information is collected during the consultation. Hence, it is more likely that a bowel condition will become the focus of treatment after consultation for another problem, when it is determined that the patient's bowel function is abnormal and potentially treatable.

5.6.3a Making a Diagnosis

As discussed in Chapter 3, there are a variety of primary diagnostic frameworks from which to make a TCM diagnosis that is typically based on patients' primary complaints. Acupuncturists in this study were asked to consider which framework they would most likely use when diagnosing bowel conditions. Two themes emerged from the line of questioning about making a diagnosis 1) the diagnostic framework chosen and 2) the aspects that influence selection of the diagnostic framework. In terms of the diagnostic framework chosen, acupuncturists responded:

> Beth: "Probably like eight principles and zang-fu diagnosis."
>
> Sam: "If you want to use categorisation it's more zang-fu especially with the relationship with the pulses and so on. But it is like anything in acupuncture it's very phenomenological thing, it is very individualised.

The acupuncturists agreed in favour of using the zang-fu framework and to a lesser extent eight principles for diagnosing bowel conditions. The statements also unveil the subtheme that diagnosis is an individualised process. Based on the idea that diagnosis is individualised, the acupuncturists reserved the right to employ any diagnostic framework according to the needs of the individual. Emphasis on the individual appeared for the first time in this category and frequently reappeared in subsequent categories. As discussed in Chapter 1, reference to the importance of the individual commonly appears in TCM literature and teachings; however, Unschuld criticises the references as an over-emphasis on a particular treatment approach that may obscure the combination of approaches used in routine practice [52]. To assess the criticism, Chapter 6 explores whether the acupuncturists' emphasis on the individual manifests in practice as well as in their rhetoric.

The second theme regarding factors that influence selection of diagnostic framework generated responses such as:

> Jill: "I suppose it's layering. I think the discussion often gives me a sense of the zang-fu involved and the body fluids and blood and qi and then you get to the palpation and pulses feeling the channels and the abdomen and that gives you the channels that are most likely affected."

> Lisa: "It depends on the patient who comes in and when they start talking. Sometimes it can be first impression of them one of those (diagnostic frameworks) will seem more appropriate route at the time during the process than another."

> Holly: "I think it (tongues and pulses) is a way of confirming whether it is acute or chronic as well. I suppose that's where I start with it and then bring everything else around whether it's the actual source of the digestive problem."

Acupuncturists state that the appearance of a patient, palpation, tongues and pulses, and responses to questions are all influential in making a diagnosis. The acupuncturists weight the importance of each of these factors differently according to their training and confidence in that factor. Combining information from the various factors leads to the selection of a diagnostic framework and diagnosis that is representative of the individual. With regard to irritable bowel symptoms, the acupuncturists are more likely to diagnose patients using the zang-fu or eight principles framework. As mentioned in Chapter 3, the zang-fu framework incorporates the concepts of the eight principles and qi-blood frameworks, making it the most important and broadly applicable framework in clinical practice [33]. Information regarding the diagnostic framework chosen provides insight into how acupuncturists visualise a condition, and foreshadows the treatment strategy.

5.6.3b Diagnostic Patterns

Once the acupuncturists explored what influenced their diagnoses and what framework they were likely to use, they described commonly encountered diagnostic patterns in patients with irritable bowel symptoms. As seen in Figure 1.2 and Table 3.5, there are multiple TCM diagnoses that may be related to IBS. The theme that emerged was that a malfunctioning liver and/or spleen were the likely culprit as indicated by the following statements:

> Sue: "I get a lot of spleen issues plus damp. A lot of them have excess mucus – can be lung related. Combined lung and large intestine situation."
>
> Jill: "I always think in terms of the liver. I would go for liver qi stagnation as that kind of core and everything else coming out of that being invading spleen or something heart or affecting kidney. So I tend to see liver qi as that kind of root."
>
> Alex: "It tends to be liver invading stomach and/or spleen. Other one that commonly present occasionally there is some large intestine pattern or gall bladder influence but generally it tends to be stomach, spleen, and liver that are the organs you are looking at."

There is particular emphasis on the zang organs (e.g. liver, spleen, kidney), which is consistent with earlier statements that the acupuncturists favour zang-fu diagnoses for bowel related conditions. These statements are also consistent with the theory discussed in Chapter 3 in that bowel problems may be reflected in liver and/or spleen imbalances [215] as well as studies by Tan *et al* [216] and Schneider *et al* [34] which emphasise related patterns. As discussed in Chapter 3, the empirical correlation between the TCM diagnoses and IBS remains to be established. Data collected from the treatment logs and analysed in Chapter 6 aims to establish the correlation between the conjecture and empirical data.

The first subtheme that emerged in this section was a discussion on the nature of the pattern in terms of excess and deficiency, which relates to the eight principles framework. The following statements suggest that the acupuncturists were attempting to determine the sequence and/or predominance of certain aspects of pattern development.

> Michelle: "Kidney yang shu. Probably quite a lot of stomach heat. It's hard to tell which came first for most of them."
>
> Beth: "Very rarely I see spleen deficiency. Generally I see excess conditions than the deficiency. There is some stress related cause the liver say invading the spleen and cause a problem and stagnation."
>
> Holly: "I guess the majority of the patients I treat are on the deficient side rather than excess."
>
> Sam: "Majority of people it is due to deficiency of digestion as opposed to heat or excess that's just my client base."

There is an obvious dichotomy in responses here, which suggests that each acupuncturist based the prevalence of excess and deficiency on his/her experience resulting in conflicting responses. Additionally, whether or not a liver problem contributed to a spleen problem or vice versa is also determined on the basis of each acupuncturist's experiences. The mixture of organ patterns and eight principles illustrates how the zang-fu framework combines multiple frameworks.

The second subtheme that emerged from this segment reintroduced the importance of the individual. When discussing diagnostic patterns of irritable bowel symptoms, the acupuncturists readily identified several common diagnoses, while maintaining that generalisations may not be helpful.

> Amy: "Something like stomach yin shu won't come out until you've actually looked at the tongue. It changes a lot when you are treating digestive problems."
>
> Cindy: "With IBS specifically I would probably emphasise liver patterns more than damp heat, but it depends very much on the patient."
>
> Lisa: "It really depends on the individual. You might get some damp or damp heat related to liver qi."

The acupuncturists' comments regarding diagnosis indicate that IBS may be related to a variety of TCM diagnoses through an individualised process. Their emphasis on organ involvement demonstrates the use of the zang-fu framework described in the previous section. Additionally, the acupuncturists noted blood deficiency, heat, and dampness as important contributors to the primary diagnoses.

5.6.3c Treatment Principles

Directly related to the diagnosis is the treatment principle. Acupuncturists were asked what treatment principle they would typically employ for irritable bowel symptoms and what factors would influence their decisions. While the importance of the individual recurs as a subtheme in previous categories, it emerges as the prominent theme in this category as indicated by the following statements.

> Amy: "I guess it's what we've been talking about is each individual is different and it is really hard isn't it unless you are speaking about a specific patient. I've never treated two the same."
>
> Michelle: "It depends on the individual case really. If the patient is more deficient and looks flabby and tired that is more nourishing and tonifying."

> Sam: "I think as acupuncturists we know that we get people with IBS they are all going to be slightly different. You can't give them all the same treatment or if you do it limits results. There's got to be some flexibility in the treatment. Tailor the program to suit the individual."

Using individuals as the cornerstone for treatment principle development, two subthemes appeared to be influential in delivery. The first subtheme is alleviation of symptoms. Several acupuncturists stated that alleviating symptoms as soon as possible influences their treatment principle.

> Alex: "In the first few treatments I tend to work on the symptoms rather than the underlying causes because my rationale is if people don't feel better more or less immediately they won't come back."

> Sam: "It depends on where the priority is. If it is a primary symptom let's say the main symptom this person has come with you need to alleviate that symptom as soon as possible. You can add constitutional stuff but the primary is to alleviate symptoms."

The second subtheme depicts the linear relationship between the diagnosis and treatment principle. For example, a diagnosis of damp heat would inspire a treatment principle that aims to eliminate damp heat. Another way to describe this relationship is that the treatment principle rephrases the diagnosis.

> Amy: "I'd obviously be treating the liver, strengthening the spleen and removing any stagnation."

> Beth: "If you think the liver causes aggravation and a lot of stress makes the intestines not function well then you could use liver points usually in combination but partially to relax and strengthen body energy and partly clear excess condition."

Similar to diagnosis, selecting a treatment principle is an individualised process. More specifically the treatment principle is likely to address the alleviation of an individual's symptoms and rephrase his/her diagnosis. With regard to the literature, an example of this can be found in a study by Schneider *et al*, wherein the authors incorporate the treatment principles: calm the liver, strengthen the spleen and stomach, remove stagnation, and calm the mind based on a diagnosis of spleen qi deficiency and liver qi stagnation [34]. The authors state that this type of standardised approach violates the rules of TCM in that individual therapeutic schemes are compromised [34], which makes the effectiveness approach of the clinical trial (allowing for pragmatic treatments) advantageous because it allows us to determine if or the extent to which the individualised scheme is routinely employed.

5.6.3d Point Selection

After determining the treatment principle, the acupuncturists were asked how they selected the acupuncture points to be needled. Two prominent themes emerged with various subthemes. The following comments illustrate the first theme that emerged, which was that point selection was based on the treatment principle.

> Cindy: "You make your diagnosis. Let's say your diagnosis is damp heat in the bowel and liver qi stagnation. You'd extract your treatment principles which are clear damp heat and move liver qi stagnation and then choose points that do that."
>
> Lisa: "It depends on the treatment principles obviously. So if your primary treatment principle is to move liver qi then it depends on exactly where the liver qi is stuck."

Three subthemes emerged within the treatment principle theme including the selection of points based on: **a)** the point's actions, **b)** a core/favourite set of points (practitioner specific), and **c)** a generic group of points (condition specific).

> **a)** Amy: "Mine would be mainly the point's actions and what they are used for."
>
> **a)** Alex: "There are points which are going to be more likely to be used. I'd be thinking about points to subdue the liver. I am selecting points on the point's actions.
>
> **b)** Michelle: "I have a common set of points I use on almost all my patients."
>
> **c)** Sam: "If you took it mechanistically there would be certain points that you could do whoever the people. Where you might use LI 4 and things like that might be a classic point for the colon but it is not quite as simple as that."

Here it should be noted that the treatment principle and action of the point are conveying the same idea in two formats. In other words, how acupuncturists select acupuncture points can be explained using either the treatment principle or the point's actions. Additionally, several acupuncturists acknowledged that they have a set of favourite points that they like to use on all patients regardless of their condition. For example, Michelle prefers to use St 36 and Sp 6 on the majority of her patients, and varies treatments using additional points based on the patient's condition. The third subtheme is similar to pragmatic point selection based on a point's usefulness for a particular condition. For example, Sam suggests that LI 4 may be part of a group of points that could be needled for any bowel condition;

however, his suggestion that such a practice may not be useful for all patients reintroduces the importance of the individual.

The second theme that emerged was that point selection was based on the individual.

> Sue: "I will use point combinations if I feel that it is the most appropriate and I choose that on the basis of how they (the patients) are each time they come."
>
> Jill: "I think the beauty of acupuncture is that they are multifaceted points so the ones you choose become much more relevant depending on the person and what you are feeling."
>
> Sam: "You find that when you are an acupuncturist that some people have points that work a lot better for them than they work for other people, the same point."

Here the emphasis on the individual is highlighted by the subtheme that exploration (e.g. palpation, feeling the pulse, etc.) influences point selection.

> Amy: "With this particular patient all around the epigastrium was so tender and so painful I was trying to needle points close to the actual site of pain."
>
> Jill: "Where it is tender. I think for a lot of people there is a lot of discomfort and it is working where things are holding. Depending on what is holding that will guide me as to what points to use."
>
> Lisa: "Particularly if you palpate during treatment, which I do and do pulses during treatment. I'll modify according to what's happening and maybe more local points or more nourishing points."

To summarise, the acupuncturists select points based on the treatment principle, which integrates the points' actions and their preferences. Additionally, point selection is based on the patient and his/her tender areas. The acupuncturists' identification of a generic or pragmatic group of points for bowel conditions was followed by a caveat that those points alone may not be sufficient or appropriate depending on the individual. In comparison, the majority of acupuncture for IBS studies (Table 3.7) uses a fixed group of points that were generally selected on the basis that they improve bowel function or are indicated for abdominal conditions. In other words, the studies emphasised the points' actions. The emphasis on a fixed group of points is typical of the efficacy approach, and provides a basis for comparison of why these interventions may not transfer in routine practice. For

example, delivering the fixed intervention would require acupuncturists to sacrifice their point preferences and guidance from patients' tender areas.

5.6.3e Points Used

Noting the emergent theme emphasising the importance of the individual for point selection, I asked the acupuncturists to name points they would recommend for irritable bowel symptoms. Even with the prompt to consider points in general, the acupuncturists remained adamant that the individual dictated the points used stating:

> Cindy: "It's very individual and it does depend on the diagnosis and on the people, it's not one condition."
>
> Jill: "Every time you imagine a different patient you come up with a slightly different set of points."

In addition to reiterating the theme from point selection regarding the importance of the individual, the discussion on points used also reiterated the idea that points are used because of a particular action and/or they are the practitioner's favourites.

> Sue: "Stomach 36 is always a lovely one to do. It's such a basic point that people can really benefit from especially on the first visit because it's relaxing, tonifying, grounding."
>
> Michelle: "If there is fire or food stagnation I will use other points LR 13 and UB 22. A lot depends on the case."
>
> Beth: "GB 34 to clear damp heat and it is also for the liver and gall bladder. GB 20 is my favourite one. Everyone get because there is so much tension there."
>
> Jill: "I probably go more for GB 41 and SJ 5 especially if I think there is dampness something like GB 28 that's that kind of feeling that there is dampness."
>
> Alex: "I think there would be some core ones ST 36, Sp 6, Sp15, St 25, LR 3, LI 4. It really depends on what I am presented with."

In terms of themes, points used mirrors point selection, which is important because it allows for mapping the thought processes and actions of the acupuncturists. There is variation between the acupuncturists in terms of which points they favour or recommend for irritable bowel symptoms. Only one point (St 36) was mentioned in every interview, while St 25, LR 3, LI 4, Sp 6, GB 34, and CV 12 were mentioned in at least half of the interviews. Figure 5.1 identifies the most common points, while Table 5.3 lists their unique features and primary functions to illustrate why they may

be so popular. For example, St 25 is the master point of the large intestine thereby making it a potentially appropriate point for any bowel condition. As discussed in Chapter 3, empirical evidence supports the traditional teaching about points' multi-functionalities [180-182], which provides an explanation for why St 25 may be effective for both diarrhoea and constipation. The responses to this question reinforce the ideas that acupuncturists rely on individualised point selections that incorporate their personal preferences and the point's actions. Section 5.8 provides a further comparison to the literature.

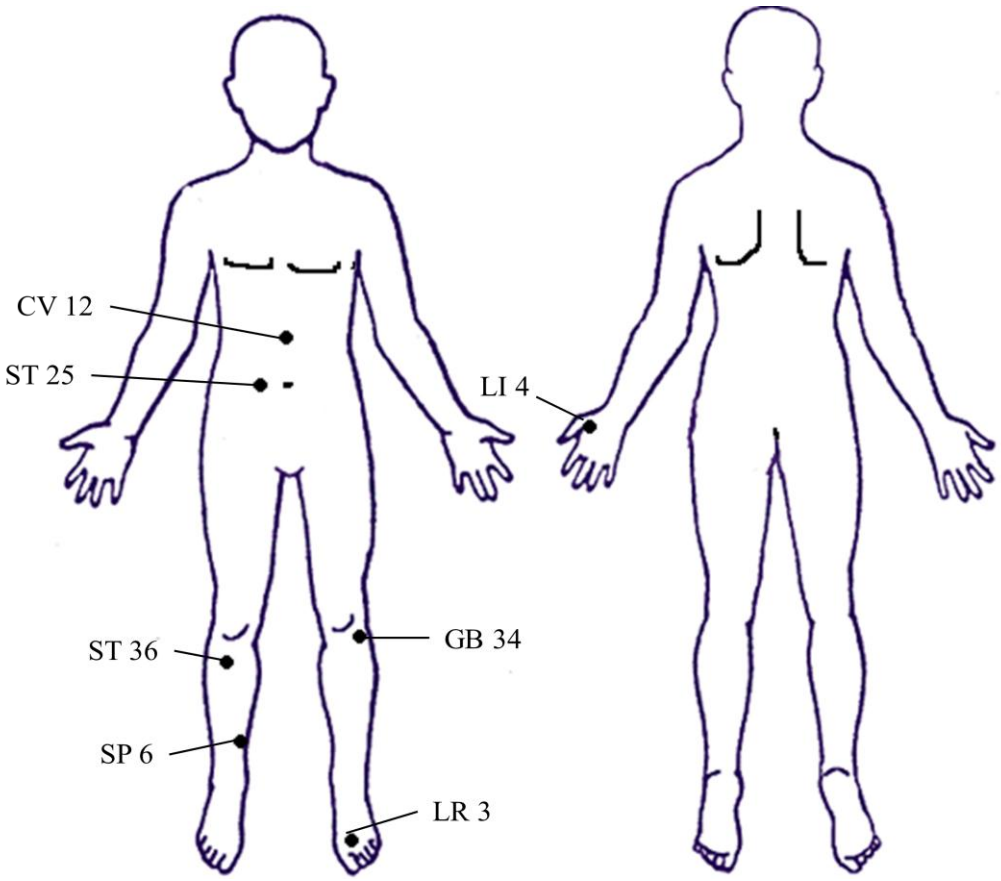


Figure 5.1 Commonly used acupuncture points to treat irritable bowel symptoms according to acupuncturists' interviews.

Acupuncture point	Unique Feature	Primary Function
ST 36	Sea of food	Tonify qi and blood, promote stomach and spleen function
ST 25	Front mu of large intestine	Regulates intestine, stomach, spleen function; clears damp heat
LR 3	Yuan primary point, 4 gates	Calms liver, regulates qi flow, clears damp
GB 34	Master point of tendons	Regulates qi flow, clears damp heat
CV 12	Front mu of stomach, yang channels meeting point	Tonify spleen and stomach, regulates qi flow, clears damp
LI 4	Yuan primary point, 4 gates	Release exterior, relieve pain, promotes smooth qi flow
SP 6	3 yin meeting point	Tonify spleen, kidney, liver; clears damp; relieve pain

Table 5.3 Characteristics of commonly used acupuncture points for irritable bowel symptoms. For more detailed information see Maciocia [33].

5.6.3f Additional Therapies

As mentioned in Chapter 3, TCM additional therapies may be used in conjunction with acupuncture as a means of augmenting treatment effects. Therefore, I asked the acupuncturists about the types of additional therapies they used to complement acupuncture. Two themes emerged 1) the therapies used and 2) why those therapies were chosen. The most common additional therapies used were acupressure, herbs, massage, and moxa/heat lamp. Other therapies mentioned were colours, cupping, ear seeds, and magnates. The choice of which therapy to use was based on two familiar subthemes 1) the patient and 2) the practitioner.

> Beth: "With damp heat in the bowel I have to use herbs. When somebody has got acute gastric flu, vomiting, diarrhoea I may use cupping."
>
> Jill: "I love heat so heat lamp, moxa essence especially if there is cold and the kidney is not driving. Even with blood deficiency I use moxa to nourish everything and warm things."
>
> Lisa: "I would use whatever feels appropriate to the patient."

With regard to the practitioner, his/her training appeared to be a decisive factor as to the additional therapy used. Acupuncturists trained in herbs strongly favoured prescribing herbs for bowel conditions, and were of the opinion that chronic and/or severe bowel conditions were not necessarily treatable without herbs. Acupuncturists with less training in certain therapies, for example ear seeds, simply would not use

them for that reason. Therefore, the use of additional therapies depends on what is best suited to a particular patient based on the acupuncturist's repertoire. Note that when discussing the patient attention to his/her diagnosis is implied.

5.6.3g Lifestyle Advice

Beyond the additional therapies, I asked the acupuncturists about the type of lifestyle advice, if any, they provided to patients with irritable bowel symptoms. Two themes emerged in this category the first of which was the advice itself. Along that line, several acupuncturists specified providing patient's information sheets to remind them about the advice. Acupuncturists stated they most commonly gave advice about diet, breathing, meditative exercise, relaxation, and stress management. Within these generic categories the acupuncturists provided some specific examples such as diet advice may involve a discussion on dairy, sugar, alcohol, and/or caffeine. The acupuncturists emphasised the generic categories over the specific examples possibly because they did not want to insinuate that only one type of advice (e.g. avoid dairy) would be appropriate for all patients as indicated by the second theme.

The second theme that emerged was the reasoning behind why they gave particular advice. The reasons why acupuncturists gave certain lifestyle advice included: **a)** it was seen as an important adjunct to treatment, **b)** it was appropriate to the individual, and **c)** it was influenced by the practitioners' preferences. The following statements illustrate these reasons.

> **a)** Sam: "I think patients are receptive normally very good at it (lifestyle changes) and it can make a big difference to them as well."
>
> **a)** Cindy: "It's support and positive feedback they are doing things for themselves because that's what is going to keep them well when they finish treatment and will stop them needing to come back."
>
> **a)** Beth: "They have a treatment here and they go away and continue to do something about it the effect is a lot better."
>
> **b)** Janet: "When to eat. I have one of Legget's charts which I get them to look at and what sort of TCM pattern they've got. I find people who are eating and drinking things that they think are good for them and they are actually not."
>
> **b)** Cindy: "It depends on the individual and what's going to suit them best and what they are going to keep up."

> **b)** Jill: "I will get a sense of what sort of change is acceptable to them (patient) because some people will feel very protective of the way they do things and they are not comfortable at all with the idea at the moment."
>
> **c)** Sue: "Remind them of what they know. Remembering when they felt well and how they felt and if they can get that feeling of what they need to do to get there in terms of making changes. It's not me telling them, it's coming to that understanding."
>
> **c)** Alex: "I'm very gentle with changes. So get them to cut down in an easy way. I think if you are too prescriptive with it, it is too difficult for people and they are set up to fail.
>
> **c)** Beth: "I'm tough when patient comes first time. I tell them that they are not supposed to eat this and that and you can eat something else – start them crying."

Although the acupuncturists suggest that lifestyle advice is an important adjunct to treatment, they also suggest that advice may not be appropriate for all patients. For example, both Cindy and Jill explain that their decision to give advice is based on whether or not they think the patient is receptive. A patient who they perceive to be unreceptive may not be given advice, or they may be given advice at a future session. Practitioner's preference was also expressed in the type of advice they were most likely to provide such as Amy who favoured yoga for meditative exercise. Furthermore, the final three comments demonstrate sharp contrasts in practice styles such as recommending aggressive, subtle, or passive changes. The different styles of practice reflect an important feature of routine practice, which may be more attractive to some patients than others.

In general, the acupuncturists agreed that regulating diet is supremely important to alleviate irritable bowel symptoms; however, as mentioned before, the type of diet advice depends on the individual. Unlike previous categories, there appears to be a disjointed relationship between the advice given and the diagnosis. Of all the statements on lifestyle advice, only two indicated a relationship with the diagnosis, yet the majority of comments continued to emphasise the importance of the individual. One possible reason for the disparity is that acupuncturists may not explain things to their patients in TCM terms. Another possible explanation is that some of the advice is not related to the patient's TCM diagnosis, and is instead influenced by biomedicine (e.g. food intolerance) or the acupuncturist's personal

preference and experiences. For example, one acupuncturist explained that she would provide advice on stress management that involved the use of Flower Essences, which was directly related to her personal experience with the product. Based on the responses I hypothesise that the lifestyle advice forms an independent aspect of treatment (to some extent), wherein practitioners may readily apply additional training such as nutrition, homeopathy, or reflexology that incorporate theories unrelated to TCM.

5.6.3h Follow-up

Regarding lifestyle advice, the acupuncturists were asked how they monitored and/or followed-up the advice they provided. The emergent theme indicates that acupuncturists follow-up their lifestyle advice with 'gentle' questions at subsequent treatments.

> Michelle: "I ask how they are getting on."
>
> Alex: "I will check in with them and say how have you been getting on."

Most acupuncturists agreed that being overbearing and/or nagging patients about lifestyle changes was generally unhelpful. An interesting sidebar developed within this category, which highlighted follow-up frustrations for the acupuncturists.

> Jill: "They often still come back and say 'I've had one session of acupuncture and you know I'm still not better' and I say really [sarcastic]."
>
> Lisa: "They drift off. They get better enough. It's a cause of constant frustration. The cost of it starts coming in they feel better enough and they think they have reached what they can afford to pay."

Although these particular comments do not specifically address the question, they provide meaningful context around the follow-up process. First, at follow-up appointments patients may be anxious about their rates of improvement. Jill's comment illustrates how instant gratification is generally unrealistic, which is frustrating both for the patient and practitioner. As discussed in Chapter 3, the literature reports conflicting findings about the influence of expectations on outcomes [199-201]; however, patients' expectations on the rapidity of improvement do appear to influence the number of treatments recommend by practitioners (Section 5.6.3i). Second, Lisa's comment highlights a frustration with patients who improve and/or reach tolerable discomfort then discontinue treatment. The premature

stoppage of treatment, whether or not due to financial concerns, captures a common frustration that reappears in the treatment logs and in the acupuncturists' interviews in Chapter 9. Although the acupuncturists may feel frustrated by patients' premature stoppage of treatment, it is a common phenomenon across medical disciplines for various reasons. For example, a Cochrane review by Haynes *et al* reports that poor adherence is a common for prescribed treatments [260]. The consistency marks patients' fickleness over treatment, which the acupuncturists perceive to be exacerbated due to the out-of-pocket expense for treatment. In general, the follow-up process involves explicit routine questions with implicit cautionary undertones about the rapidness of improvement and patient retention.

5.6.3i Number of Treatments

As indicated by Jill's previous comment, patients' IBS symptoms are not likely to abate after one treatment. Therefore, I asked the acupuncturists how many treatments were necessary to effect a change, but not necessarily cure irritable bowel symptoms. One theme that emerged was that changes in bowel habit can be rapid. An initial change in bowel habit may occur in as little as two treatments, but the consensus was that six treatments are more realistic.

> Amy: "Anything from one to six certainly one to see a change and quite dramatic changes often. Digestive things I find are quite quick."

Although the bowels may respond quickly, the emergent subtheme was that acupuncturists do not want to foster false expectations about the rapidity of improvement.

> Sue: "Four to six treatments before you are going to feel any better, but it could happen sooner or take longer. I don't want to build up expectation. With most people you can tell look it took awhile to get like this, you just didn't suddenly develop IBS you've got to expect that it is going to take awhile."
>
> Jill: "I usually give people an idea of how many sessions I think I need to be sure that we are making a difference or not and it's never usually one or two. I rarely say just a couple will do it. It's been six years but hey two sessions of acupuncture and you're cured."
>
> Holly: "I would also say to the patient that we will review it in five to six so that their expectations aren't so high that they won't think they will be cured on the second treatment."

The second subtheme to emerge was that the actual response time varies depending on the patient and how fully he/she engages with the treatment.

> Cindy: "It can depend a lot on people's lifestyle and what their diet and consumption of alcohol and whether or not they change that. Some people respond quite quickly to acupuncture and some don't."

> Alex: "If you are dealing with older people or the longer they have had the problem the more treatment they are going to need possibly slower the progress might be. The younger and more acute problem tend to respond quicker."

Cindy's comment illustrates the subtheme and reintroduces the importance of diet and life style changes to some patients' outcomes. In comparison, Alex's comment introduces a distinction in response rate based on the nature of the illness such as acute or chronic, and the age of the patient. Thus, although bowels may respond quickly to acupuncture, the overall number of treatments necessary to effect change is influenced by multiple factors. The general consensus suggests that irritable bowel symptoms should be improving by six treatments, and that early changes indicate effectiveness.

5.6.3j Frequency & Duration

Knowing that the practitioners recommend a minimum of six treatments, they were asked the typical frequency of the treatments. All the practitioners responded that their standard protocol is to provide weekly treatments. As patients improve, the treatments are spread out over longer intervals. Most treatments last an hour with 20 – 30 minutes of needle retention; however, retention time may vary depending on the patient. The following statements exhibit these findings.

> Lisa: "Weekly. I want to see you weekly for at least four weeks and probably for six. Then we will think about spreading it out."

> Amy: "If they come for a digestive complaint and you've sorted it and it's stable and you treat it six to seven treatments then say to them we should go to two weekly and then three weekly and then monthly because then you give them a top-up and once they have had treatment for a little longer they can go away for a little bit and whey they see signs again they will come back."

> Sam: "Leave the needles fifteen to twenty minutes. Occasionally if I think it is appropriate put the needle in tonify – needle out just to open that point up, just to set something moving."

The combined analysis of the number of treatment and frequency categories illustrates an important aspect of acupuncture treatment particularly with regard to chronic illness. The acupuncturists prefer to provide approximately six treatments, depending on the rate of improvement, on a weekly basis. Once symptoms are under control the treatments are spread out and patients may return for on-going maintenance or to treat flare-ups. The variability around the six treatments necessary to detect improvement and on-going maintenance treatments contrasts with the ten treatments over three months defined in the treatment protocol, which undermines the effectiveness approach (Chapter 4). Although evaluating the effectiveness of a certain number of treatments over a specified time may be beneficial to decision makers, it may foster unrealistic expectations among patients, which as noted in the interviews is a concern for some acupuncturists. According to Birch, the adequacy of treatments administered in a trial is a defining feature of trial equity [261]. Assuming the ten treatment protocol is effective, researchers, including myself, should advise decision makers that patients may require maintenance sessions over the long term in addition to the initial intensive phase of treatment.

5.6.3k Emotional Issues

Since both anxiety and depression are common IBS comorbidities [137], the acupuncturists were asked if they noticed a trend regarding emotional issues and irritable bowel symptoms. Based on the responses, this question was apparently interpreted in two different ways. The first interpretation conveyed the theme that acupuncture itself can stimulate an emotional response and/or release.

> Amy: "I was thinking about one time when I put in needles and this man just started crying so I just sat there holding GB 14 and I just said we'll let the needles work."
>
> Janet: "You do find in practice you do certain things which unleash emotions and somebody will start crying."

According to the acupuncturists, an emotional release such as crying during treatment may be considered therapeutic and/or a positive sign that the treatment is working.

The second interpretation conveyed the theme that a positive relationship exists between patients with irritable bowel symptoms and emotional issues, although there

was a possibility that this was a characteristic of the acupuncturists' patient populations in general.

> Sue: "A lot of these people are not grounded terribly well. I find that I need to do an earth kind of approach to get them back grounded because they have been stressed."
>
> Jill: "It's an emotional lack of anchor self-control thing that is becoming the real problem of quality of life."
>
> Holly: "I think we have a real problem with expressing appropriate emotions in our culture so there is a lot of held emotion and it manifests wherever there is a weakness and digestion is a common place."
>
> Sam: "That's a problem with society I think bottling up emotions a lot of liver qi stagnation. I think those who hold those in more are certainly susceptible to one of the things that will happen is that the bowel will stop moving. It is very linked to holding on process."

The comments suggest that emotional issues are a common problem related to peoples' interactions with society, and that those issues negatively impact quality of life and may exacerbate or cause bowel problems. Figure 3.6 illustrates several examples of how emotion may impact the bowels such as when a person worries excessively or over studies for an extended period of time. These emotions can damage the spleen, which disrupts qi flow, causing abdominal distension and constipation. In comparison to biomedicine (Chapter 2), whose aetiological understanding of IBS moved from a predominantly psychological to a biopsychosocial model, these comments highlight a similarity between the practices. Specifically, patients with an underlying digestive problem and who lack groundedness or self-control and/or are stressed and struggle to express emotions are more likely to exhibit irritable bowel symptoms.

5.6.3l Counselling

As mentioned in Chapter 3, some patients perceive acupuncture treatments to provide a close patient-practitioner relationship [206]. Because of the time intensive nature and potential closeness of the relationship, I asked the acupuncturists whether they associated their role with counselling. The first theme that emerged was that acupuncturists do not provide counselling based on the strict definition.

> Cindy: "You listen if somebody is talking about their stress and what triggers them and so on. You do supportive listening. A counselling role is much more difficult than that."
>
> Lisa: "I listen but I'm not a counsellor."
>
> Sam: "A counsellor might not necessarily call it counselling. I think in the open sense of the term counselling yes in a very general way talking through issues."

The second theme that emerged was that the amount contact time and probing to find out what is wrong with the patient creates an opportunity for patients to discuss multiple aspects of their lives in detail. The opportunity is particularly beneficial for patients who may not otherwise speak about their health.

> Michelle: "I think it is one of the only opportunities for most of them to find someone who will listen."
>
> Jill: "I think because you create a safe space for people and you hope for them to see the link up of all aspects of their life in the way that the impact of emotional stuff on the way the physical body is responding. I try to help them understand the relationship rather than trying to help them solve the problem."
>
> Beth: "It's just like when you give a patient treatment you have a general chat in a very relaxed atmosphere and something comes up and you see what might do best."

There is a consensus that the acupuncturists are not trained counsellors, but they are trying to determine what is wrong with their patients and create a picture that integrates all aspects of their lives. The amount of contact time and probing to find underlying conditions creates an opportunity for patients to talk in a 'safe' environment. The idea that acupuncturists create a 'safe' environment for patients to talk about their conditions may be particularly important for IBS patients given their emphases on shame and embarrassment from Chapter 2.

5.7 Recording Treatment Information

As indicated by the previous sections, treatments may consist of a variety of different points, additional therapies, and lifestyle advice, and be based on a variety of patterns. At the end of the interviews, the acupuncturists were shown drafts of a log book that combined questions from the pilot and standard patient intake forms. The purpose of this was to generate a discussion on the structure of treatment log that

would be used in the trial. Several acupuncturists offered me copies of their own log books to illustrate particularly useful sections. The general consensus among the acupuncturists was that although tick box questions were useful, they preferred free text questions particularly regarding diagnosis, treatment principle, and signs and symptoms. The acupuncturists also suggested including a space for describing why they chose particular points.

> Sam: "When you're analysing the results you'll know what these points are doing, you know what they do. I suppose it is quite nice to know why they were done and the practitioner can explain that."

Based on the interviews and pilot I designed a log book for the trial that contained a mixture of tick box and free text questions (Appendix B 6). Furthermore, the comment by Sam implies that the acupuncturists knew that I was an acupuncturist and that specialist knowledge would benefit the trial analyses. As described in Chapter 6, some of the free text data from the log books were transformed into quantitative data, which would not be possible without specialist knowledge. Therefore, I was able to design a log book that potentially captured a comprehensive description of patients' treatments as well as one that was more challenging to analyse.

5.8 Discussion

Quotations in the previous sections illustrate findings from acupuncturists' interviews about the routine treatment of IBS, and suggest that a large number of acupuncture patients suffer from abnormal bowel habits. The findings also suggest that the acupuncturists perceive patient individualisation to be a key factor in treatment design. Based on the acupuncturists' references to their preferred acupuncture points and additional therapies, I suggest that the acupuncturist's preference is also a key factor in treatment design. However, it is unclear from their references to preferred points and additional therapies whether the acupuncturists would describe themselves as a key factor in treatment design. This section addresses how the findings answer the question about contextualisation and routine treatment and compare to the literature.

The answer to the question, 'how do TCM acupuncturists treat IBS in routine practice' lies in the acupuncturists' comments about diagnoses, point selections, additional therapies, and lifestyle advice. Individualisation thematically recurs across the categories thereby distinguishing itself as the acupuncturists' perceived cornerstone of routine treatment. The findings also suggest that the individual practitioner's training and preferences as well as pragmatic and condition specific decisions influence routine treatment. The influence of the individual patients and practitioners gives rise to diversity in diagnoses, point selections, additional therapies, and lifestyle advice, which creates a heterogeneous collection of routine treatments.

As introduced in Chapter 1, there is some controversy around the emphasis on individualisation (specific to the patient) in TCM treatment. Studies by Coeytaux *et al* and Sherman *et al* analysed pragmatic treatments for headaches and low back pain respectively, which allowed them to observe similarities and differences in the acupuncturists' approaches to routine treatment [53, 250]. Based on their data the authors report that the treatment process is idiosyncratic and may be more related to the practitioner than the patient. Practitioners' idiosyncrasies highlight the need to identify the subject of individualisation given that it has two key components (i.e. patients and practitioners). Although the acupuncturists in this study acknowledged their preferences for certain acupuncture points, their repeated emphasis on the patient suggests that they perceive individualisation (based on the patient) to be the predominant influence on treatment design. One possible explanation for the difference in findings is the difference in perspectives. Acupuncturists in this study describe what they perceive to be influences on treatment based on their clinical experience, while researchers in the Coeytaux *et al* and Sherman *et al* studies interpret what they perceive to be influences on treatment based on practitioners' logs. With regard to the criticism by Unschuld (Chapter 1), that some TCM literature (e.g. The Web That Has No Weaver [149]) over-emphasises individualisation and discounts the role of other treatment approaches [52] the acupuncturists may be perpetuating an idealised stereotype that is not necessarily an accurate description of the treatment approaches they actually utilise. Analyses of the treatment logs (Chapter 6) provide a means to explore the difference in findings from another

perspective and to further assess the role of various treatment approaches including individualisation.

In contrast to the interviews and studies by Sherman *et al* [53] and Coeytaux *et al* [250], the majority of studies in Table 3.7 employed an efficacy approach that restricted the idiosyncratic treatment process. Therefore, the most common points derived from Table 3.7 identify the points typically used in fixed point prescriptions. Although the core points may be used to test a hypothesis in an efficacy study, they may not reflect routine treatments or enable practitioners to better treat IBS. Table 5.4 compares the core points for IBS from the recommendations, efficacy studies, and pragmatic studies, and identifies that only one point was used in ≥ 50% of efficacy studies. In terms of enablement, the revelation that the most common points (St 25, St 36, CV 12) are the master points for the large intestine and abdominal problems is unremarkable, and therefore not likely to better enable practitioners to treat IBS. What may enable practitioners to better treat IBS is a discussion around point variability such as what points are less commonly used and what is their role in treatment. Specifically, are the other points related to particular diagnoses or practitioners' preferences, and do they have an impact on outcome. To answer this question, a trial would need to compare acupuncture interventions that provided both fixed and pragmatic point selections. The pragmatic nature of this study allowed me to explore the similarity between the treatments described in the interviews and delivered during the trial (Chapter 6) as well as assess the relative importance of treatment individualisation (Chapter 10).

Source	Core Points
Recommendations (Table 3.5)	CV 4, CV 6, CV 12, St 25, St 36, St 37
Efficacy studies (Table 3.7)*	St 25
Pragmatic (Pilot & interviews)*	CV 12, St 36, Sp 6, LR 3, LI 4

Table 5.4 Comparison of core points. *Reports a comparison of studies that identified the points used – one study did not report a comprehensive list and was therefore excluded.

In addition to how acupuncturists treat IBS in routine practice, question one also asks about the contextualisation of IBS. The acupuncturists contextualised IBS in terms of symptoms and biomedical characteristics they perceived relevant. Based on their contextualisation IBS was not perceived to be a useful diagnosis, which suggests that

it does not influence treatment design. One potential explanation for the use of biomedical characteristics and symptoms in contextualizing biomedical diagnoses is the influence of biomedicine on TCM education. As discussed in Chapter 1, the increased popularity of pluralistic therapies led to the development of TCM schools [23, 24]. However, the symbiotic pressure from biomedicine and TCM's need to adapt itself fostered the incorporation of biomedical classes into the TCM curricula. Studying basic biomedicine and TCM allows acupuncturists to be 'bilingual' and may encourage TCM practitioners to contextualise biomedical diagnoses from a biomedical perspective. Comparatively, I think my presence and the knowledge that the interviews were being used to design a trial may have influenced the tone and language of the comments. Specifically, the tone and language of the interviewees' responses were critical and/or negative, which influenced the conclusion that they perceived IBS to be an un-useful diagnosis that would not influence treatment design. The interviewees' knowledge about me perhaps created a measure of solidarity that allowed them to be openly critical (e.g. junk diagnosis); however, they may have made the same comments to a non-acupuncturist interviewer.

Considering the controversy around recruitment to TCM studies by biomedical diagnoses (Chapter 4), I was surprised to find a gap in the literature around acupuncturists' contextualisation of biomedical diagnoses. Given the gap in the literature this finding may be developed into a hypothesis that can be used in future studies. I intend the hypothesis to encourage practitioners and researchers to investigate if and how biomedical diagnoses are utilised by TCM practitioners so that more reliable and better informed research may be conducted. I hypothesise that TCM practitioners contextualize biomedical diagnoses according to the biomedical characteristics they consider relevant, which influences how/whether a particular diagnosis is incorporated into TCM treatment [262].

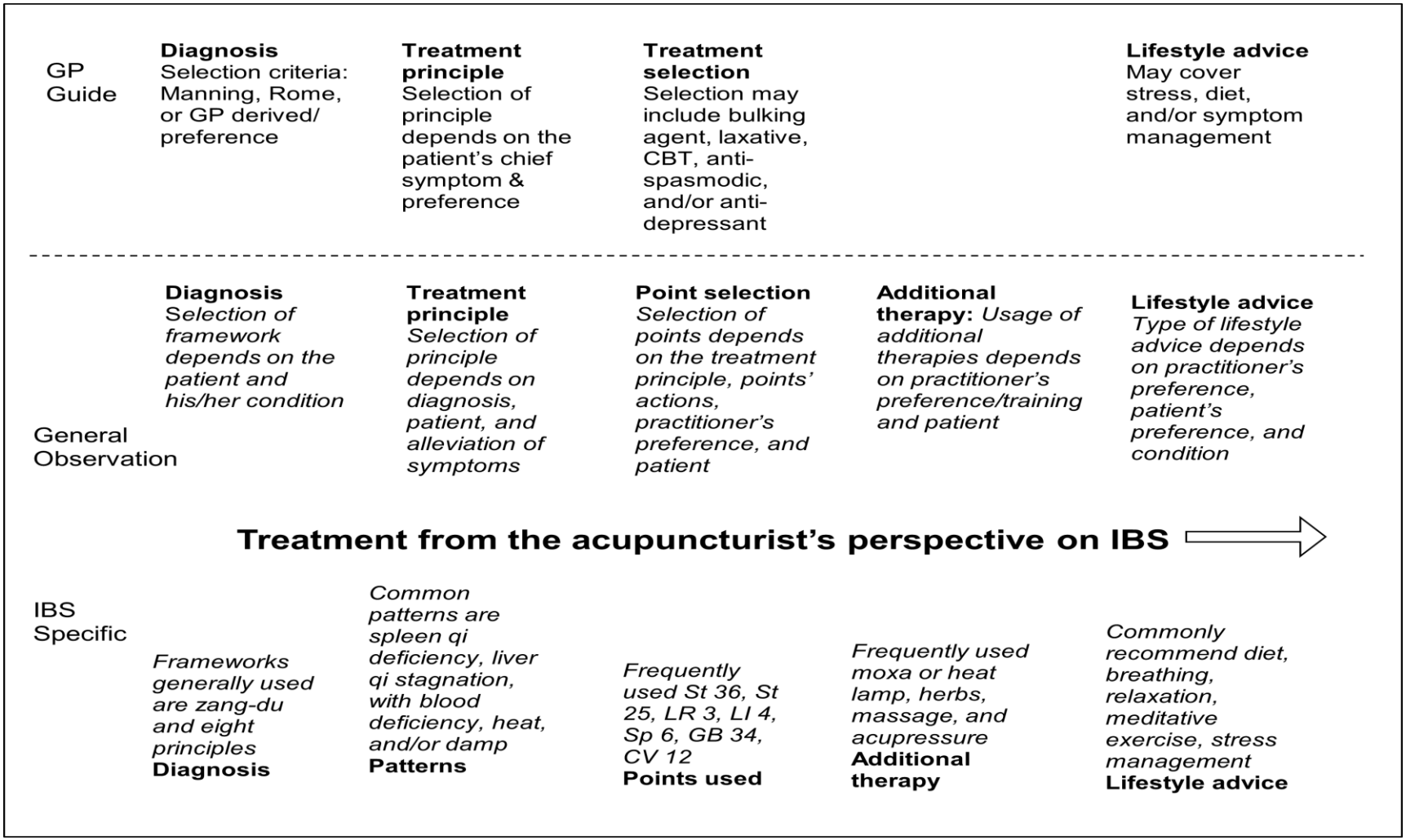
In addition to individualisation and contextualisation, the estimated 40 – 50% of acupuncture patients that suffer from abnormal bowel habits is noteworthy. Although the 40-50% estimate may seem inflated, the proportion is not restricted to patients with a known IBS diagnosis, and may reflect the impact of generally poor diets across Britain. According to the acupuncturists, the patients' perceptions that they

have a 'normal' or untreatable condition is the likely cause for the disparity between the small number of patients identifying bowel problems as their primary complaint versus the 50% of patients being treated for bowel problems. I consider this to be noteworthy because it suggests that bowel problems are commonly treated in routine acupuncture practice, thereby strengthening the case for a pragmatic trial of acupuncture for IBS to determine effectiveness. Furthermore, if the percentage is a reflection of generally poor diet, it supports investment in public education and prevention, which in the long term may provide cost savings.

Finally, Figure 5.2 illustrates a comparison of the findings with the GP recommendations for treating IBS from Chapter 2. In general, the GP recommendations and findings from the acupuncturists' interviews are similar. For example both groups of professionals use various frameworks or criteria to diagnose irritable bowel symptoms. Additionally, their selection of treatment principles both derive from the patient and alleviation of symptoms. A difference lies in the treatment, which for GPs is likely to involve pharmacological interventions and for acupuncturists involves needling and possibly an additional therapy. GP guidelines on lifestyle advice are also similar to the acupuncturists' descriptions wherein Spiller suggests discussing diet, stress, and symptom management [74]. While advice categories are similar, more research is necessary to determine if the advice itself (e.g. increase fibre intake) is similar. As discussed in Chapter 1, the symbiotic nature of the relationship between Chinese medicine and biomedicine often casts the disciplines in parasitic and/or beneficial roles that over time reshape the dominant-ancillary boundaries. The GP recommendations such as active listening and lifestyle advice may be a reflection of how the boundaries have been shifted by CAM influences. Recognising the need for more effective interventions to treat chronic complex conditions, provides an opportunity for both practices to embrace a mutually beneficial co-existence that acknowledges similarities. Acknowledging similarities may increase dialogue that enables the practices to work together to ultimately provide better patient care.

Having established that the acupuncturists perceive the patient to be a prominent factor in treatment design, the following chapter examines the treatments delivered in the trial and the factors that influenced them.

Figure 5.2 Comparison of routine acupuncture treatments with GP recommendations for IBS



Chapter Six

Trial Treatment Delivery

Chapter highlights

- The acupuncturists identified seven primary and eight secondary TCM diagnoses whose combinations produced unique diagnoses for 95/113 IBS patients
- Diagnosis-specific analyses suggest that the patient's diagnosis plays a more influential role in the selection of acupuncture points than the use of additional therapies or lifestyle advice
- The use of additional therapies and lifestyle advice are more influenced by the practitioner and patients' characteristics beyond the diagnosis than the diagnosis itself
- Overall the treatments incorporated a variety of approaches including disease-specific, individualised, and pragmatic whose influences varied depending on the treatment aspect and the practitioner

6.1 Introduction

The previous chapter explores how acupuncturists treat IBS in routine practice and reveals that treatments are likely to reflect the importance of the individual patient as well as individual practitioner's training, skills, and preferences. Additionally, the interviews reveal that the acupuncturists contextualise IBS as an un-useful diagnosis due to symptom variation and the nebulous connotation. Overall, these findings answer the first aspect of question one and denote two areas (individualisation and treatment diversity) that may require special attention when answering the second aspect of question one – 'how do acupuncturists treat IBS in a pragmatic trial'. In comparison to the paired interview format (Chapter 5), data regarding the pragmatic trial were collected in an atypical narrative fashion (i.e. log books). While variations in data collection and analyses demonstrate the advantage of using a pragmatic mixed methodological approach, the pre-trial interviews provide a means to compare routine practice with trial treatments.

The material presented in this chapter addresses the second aspect of question one by emphasising diagnoses identified, points used, additional therapies used, and advice provided as part of the acupuncture treatments delivered in the trial. The answer to the question about trial treatment delivery is important because, unlike efficacy studies with pre-determined treatments, pragmatic treatments are a mystery until analysed. Furthermore, considering that the majority of studies in Table 3.7 are efficacy based, the trial provided the first pragmatic data on TCM treatment of IBS. In addition to addressing the second aspect of question one, the analyses provide findings that may be used to address the overarching aim to develop a hypothesis about the relative importance of TCM diagnosis and treatment individualisation. Specifically, the analyses identified whether/how the diagnoses influenced treatment design and whether treatments were individualised.

6.2 Aims and Objectives

The aim of this chapter is to provide a detailed analysis of the treatments delivered during the trial and to compare the findings with the routine treatment data from Chapter 5. The objectives are to determine:

- A comprehensive picture of the treatments delivered during the trial: including the treatment principle, acupuncture points used, additional therapies, and lifestyle advice
- Acupuncturist and diagnosis specific treatments, so as to assess individualisation
- Whether and to what extent routine treatments (Chapter 5) correlate with the treatments delivered during the trial

6.3 Methods summary

To answer the first research question, I adopted a sequential mixed methods (QUAL→QUAL) strategy (Chapter 4). Acupuncturists' interviews provided data for the first phase of research and together with information from the pilot were used to design the treatment protocol and log book (Appendix B 5). The treatment protocol encouraged the acupuncturists to administer treatments as they would in routine practice with exceptions to the use of herbs or magnets. Restrictions on the use of herbs and magnets distort the pragmatic nature of the study as further discussed in Sections 6.5.6 and 6.6. With regard to the treatment logs, the questions contained a mixture of tick box and free text answers that covered categories similar to the interviews. Additionally, the acupuncturists were encouraged to provide their rationale for selecting particular points, additional therapies and advice. While I consider the analysis of all 113 log books and 1,016 treatments to be a strength of this study, the volume and variety of questions posed an analytical challenge. As discussed in Chapter 4, some of the data were transformed into frequencies (e.g. the number of points used), while other data were condensed into phrase inventories. Several of the acupuncturists commented that they struggled with the tick box diagnosis section; therefore, I concentrated the diagnostic analysis on the free text answers. Apart from the diagnosis question, the acupuncturists suggested that the log book and guidelines were clear and easy to use. To address the question of treatment individualisation, treatment log data were analysed from multiple perspectives. The patients' background data presented in Sections 6.4 and 6.5.3 were derived from their baseline questionnaires and analysed in SPSS 17.0.2.

6.4 Characteristics of Participants

Of the 233 trial participants, 116 were allocated to receive a maximum of ten acupuncture sessions. According to the treatment logs, 113 participants received a total of 1,016 acupuncture sessions, with an average of nine sessions per participant. Two of the participants that did not receive acupuncture withdrew from the study prior to treatment, the other participant failed to attend her appointment (HT[9]). Baseline characteristics of the acupuncture participants are presented in Table 6.1. The proportion of women to men (4:1) is fairly consistent with the diagnosed IBS population described in Chapter 2. Recall from Chapter 4 that the recruitment strategy targeted patients diagnosed with IBS, therefore this group is comprised of patients from primary to tertiary care as well as those who were actively seeking and not seeking treatment.

	Female (n = 95)	Male (n = 21)	Total (n = 116)
Age Avg. (range)	43.2 (21 – 78)	45.3 (29 – 71)	43.6 (21 – 78)
Severity Avg. (range)	291.5 (160 – 460)	222.4 (152 – 435)	279.0 (152 – 460)
Duration Avg. (range)	13.9 (0.2 – 48)	13.6 (4.2 – 30)	13.6 (0.2 – 48)

Table 6.1 Characteristics of acupuncture patients at baseline. Severity was measured by the IBS-SSS on a 0 – 500 scale where higher scores indicate more severe IBS. Age and duration of IBS are in years.

The nine acupuncturists participating in the trial averaged 11.2 (range 3 – 25) years of clinical experience and each treated an average of 12 (range 3 – 22) trial patients. Characteristics of individual acupuncturists are listed in Table 6.2. Patients were allocated to an acupuncturist on the basis of their preferred treatment location and appointment times, hence the unequal distribution. Of the nine acupuncturists participating in the trial, seven participated in a pre-trial interview. Pseudonyms from Chapter 5 are maintained to facilitate comparability.

[9] HT – Helen Tilbrook was the trial co-ordinator who recorded withdrawal and non-attendance data

Acupuncturist	Sex	Yrs practice	Patients (%)
Beth – *i*	F	25	3 (3)
Cindy - *i*	F	17	16 (14)
Lisa – *i*	F	10	22 (19)
Jill – *i*	F	10	10 (9)
Holly – *i*	F	4.5	8 (7)
Ellen - *i*	F	5	11 (10)
Marie	F	5	17 (15)
Sam - *i*	M	21	16 (14)
John	M	3	10 (9)
		Avg. 11.2	113 (100)

Table 6.2 Characteristics of acupuncturists (n = 9), *i = interviewed*

6.5 Treatment Log Components

Data from the treatments were extracted from all 113 log books and included all 1,016 treatments. Data were arranged so as to mimic the step-wise journey through the treatment process outlined in Chapter 5. The purpose of presenting data in a similar manner is to facilitate comparability and illustrate the chronology of treatment leading to a discussion on outcome (Chapter 7). Subsections describe the data that emerged in relation to the primary complaints, diagnoses, treatment principles, point selection and usage, additional therapies, and lifestyle advice. Furthermore, the subsections describe the data according to the relevant perspective(s) (i.e. general trial, diagnosis, acupuncturist) and make comparisons to the pre-trial interviews. With regard to the pilot [47], the style of acupuncture delivered (i.e. five elements) is dissimilar to TCM in several ways such as diagnosis, limiting the comparability of findings.

6.5.1 Primary Complaint

As stated in Chapter 5, a patient's primary complaint is integral to the diagnosis and treatment plan. For example, as a primary complaint, abdominal pain influences the consultation process by prompting questions about location, duration, and quality, ultimately contributing to the diagnosis. Similar to the diagnoses, the patients' primary complaints were organised into a phrase inventory (Appendix D 1). Given that 15% of the logs list IBS as the primary complaint (Table 6.3), it appears that there was some misinterpretation of the question. I suggest misinterpretation because all of the patients had an IBS diagnosis, and a chief complaint should be the primary symptom(s) identified as the most problematic. Further analysis revealed that one

acupuncturist listed IBS as the primary complaint for each of her patients, thereby contributing ten of the seventeen complaints (Table 6.4). I had anticipated that analytic triangulation of the treatment log (Section 4.3.4a) would pre-empt misinterpretations; however, further clarification may be required for future studies.

In contrast the other acupuncturists appeared to answer the question as intended, and noted that patients were most bothered by pain and their bowel habit. Within the pain category, specific complaints ranged from dull aches to gnawing, stabbing pain. The added detail foreshadows possible diagnoses, which for dull pain is commonly associated with deficient conditions, while stabbing pain is usually associated with excess and/or stagnant conditions. Among complaints in the 'other' category were phrases such as incomplete evacuation and inflammation. Additionally, bloating and wind were commonly listed in conjunction with the primary complaints overall affecting 42% of patients. As mentioned in Chapter 2, studies by Drossman *et al* [120] and Kennedy *et al* [90] identified similar primary complaints such as pain, bloating, diarrhoea, constipation, nausea, and incontinence, which suggests that the trial participants are similar to the diagnosed IBS population in the UK and USA.

Primary complaint	**Frequency**	**W/ bloating**	**W/ wind**
Alternating bowel movement	20	6	3
Pain	19	11	3
Diarrhoea	18	7	2
IBS	17	0	0
Constipation	15	5	0
Indigestion	9	7	1
Urgency	6	1	2
Other	4	1	2
Fatigue	4	1	0
Total	112	39	13

Table 6.3 Patients' primary complaints (n = 112). The table shows the frequency of patients' primary complaints and how many patients complained of accompanying bloating and/or wind.

Acupuncturist	Alternating bowel habit	Pain	Diarrhoea	IBS	Constipation	Indigestion	Urgency	Fatigue	Other
Beth	0	1	1	0	0	0	0	1	0
Cindy	1	1	0	2	4	2	1	3	1
Lisa	3	5	4	0	3	4	3	0	0
Jill	0	0	0	10	0	0	0	0	0
Holly	1	2	1	0	0	3	0	0	1
Ellen	4	1	3	1	1	0	1	0	0
Marie	3	2	5	3	3	0	0	0	1
Sam	6	3	3	1	2	0	0	0	1
John	2	4	1	0	2	0	1	0	0
Total	20	19	18	17	15	9	6	4	4

Table 6.4 Primary complaints according to acupuncturist. The table shows the number of patients each acupuncturist associated with a particular primary complaint.

6.5.2 Diagnostic Frameworks

Using the patient's primary complaint and history the acupuncturist selected a diagnostic framework from which to make a diagnosis. Table 6.5 lists all the frameworks that contributed to the diagnostic process and the number of acupuncturists who used them. Ninety-nine percent of diagnoses employed the zang-fu framework, which categorises disease based on the affected organ; however, only 33% of these cases appeared to use the zang-fu framework in isolation. As mentioned in previous chapters, the zang-fu framework incorporates concepts from both the eight principles and qi-blood frameworks. Taking this into consideration, I repeated the analysis by removing the qi-blood and eight principles frameworks marked in tandem with zang-fu. The adjusted column in Table 6.5 displays a potentially more accurate account of the zang-fu framework's popularity, and supports the claim that it is the most important framework in clinical practice [33]. The adjusted analysis also indicates that the acupuncturists, as a group, employed multiple frameworks on 23% of patients, which contrasts with the 67% of patients with multiple frameworks from the unadjusted analysis. More research is necessary to determine how to better phrase the framework question to reflect a representative account of framework usage.

Framework	Frequency used (%)	Used by Acupuncturist	Frequency used Adjusted (%)	Used by Acupuncturist
Zang-fu	110 (99)	9	110 (99)	9
Qi-blood	53 (48)	8	1 (0.9)	1
8 Principle	48 (43)	6	0 (0)	0
5 Element	14 (13)	1	14 (13)	1
Pathogen	11 (10)	5	11 (10)	5
4 Level	3 (3)	1	3 (3)	1
6 Channel	1 (0.9)	1	1 (0.9)	1

Table 6.5 Diagnostic frameworks (n = 111 treatment logs, n = 9 acupuncturists). The table shows the number of patients whose diagnoses were derived from a particular framework and the number of acupuncturists that used a particular framework. The adjusted column shows the frequency each framework was used after removing qi-blood and eight principles frameworks marked in conjunction with zang-fu.

Detailed analysis of the acupuncturists' selection patterns, omitting duplicate frameworks, revealed that practitioners' training and preference influenced framework selection (Appendix D 2). For example, Sam used four different framework combinations, and was the only practitioner to use the five elements framework, highlighting a difference in his training. Appendix D 2 also reflects the use of multiple frameworks on a single patient introduced previously (23%).Thus, patient individuality debuts in this category, but its importance is overshadowed by the practitioner's training and preference. Differences in framework selection do not indicate rightness or wrongness, but rather variations in symptom interpretation. In comparison, acupuncturists in the pilot most commonly used the causative factor framework, which is fundamental to five element acupuncture [263]. The comparison highlights the difference in acupuncture practices and the necessity to define the style of acupuncture.

According to Chapter 5, the acupuncturists anticipated favouring the zang-fu framework, and demonstrating the importance of the individual. The following comment, by Lisa, captures this idea, which she delivered in the trial by using three different frameworks and three different combinations.

> Lisa: "Zang-fu and kidney stuff, but you might get somebody coming in for an infectious disease so that going through levels or stages."

In contrast to using a framework, Holly stated

> "I don't think that [framework] when I am actually working with the patient I would rely totally on the pulses and tongues."

Each of Holly's treatment logs indicates that she used the zang-fu framework, despite a section to write 'pulses and tongues', which appears to be a deviation in practice. However, when a practitioner examines the pulse and tongue she is determining the function/vitality of the organs (e.g. red-tipped tongue may indicate heart heat). Therefore, the apparent deviation between practice and discussion may be a product of different contexts, wherein during treatment decisions are made according to what is seen and felt, and in the treatment log are described in terms of theory. Alternatively, Holly's answers may be indicative of an assumed trial behaviour discussed in Section 6.6.

6.5.3 TCM Diagnoses

Incorporation of six diagnostic frameworks illustrates the complexity of the TCM diagnostic process. The complexity stems from placing primary complaints in the context of other signs and symptoms to create a picture of the predominant pattern as well as its origin, development and relationship with other patterns [33]. Analysis revealed a variety of patterns associated with IBS, which were condensed into seven different primary diagnoses (Box 4.3 & Table 6.6). For example, one acupuncturist diagnosed damp heat and another diagnosed damp heat in the large intestine. Combining these diagnoses into a single category allowed for comparisons to be made across treatments. Six of the seven diagnoses directly correspond to patterns listed in Table 3.5 with the exception of yin deficiency, which falls under the collective heading 'stomach patterns' defined by Maciocia [215]. The only pattern in Table 3.5 not mentioned as a primary diagnosis is food stagnation/improper diet; however, it is mentioned among the secondary diagnoses. The strong degree of consistency between the diagnoses and text book patterns further establishes the link between pedagogy and practice, and justifies their comparison. On the other hand, the variety of diagnoses reflects the complexity depicted in Figure 1.2, which may be described as one biomedical diagnosis corresponding to multiple Chinese medicine diagnoses and vice versa [33].

Primary diagnosis	Patients # (%)	Sex M	F
Liver qi stagnation	28 (24.8)	7	21
Damp heat	20 (17.7)	7	13
Cold damp	17 (15.0)	0	17
Liver qi stagnation & spleen deficiency	17 (15.0)	2	15
Blood/Yin deficiency	13 (11.5)	2	11
Spleen qi deficiency	10 (8.8)	1	9
Yang deficiency	8 (7.1)	2	6
Total	113 (100)	21	92

Table 6.6 Primary diagnoses. The table identifies the overall frequency of the seven primary diagnoses observed in the trial (n = 113).

Considering the underlying question about the relative importance of TCM diagnosis (Chapter 10) and the acupuncturists' emphases on individuality, I analysed the predictability of diagnosis based on the quantifiable indicators: age, IBS severity, and/or IBS duration. Based on the heterogeneous nature of IBS (Chapter 2) and fundamental differences between TCM and biomedicine I hypothesised that the factors would not predict TCM diagnoses. To test the hypothesis, I descriptively compared the potential predictors (Table 6.7) then performed an ANOVA and multi-nomial logistic regression. The descriptive comparison in Table 6.7 suggests that patients with spleen qi deficiency may differ in terms of age, and that patients with damp heat may differ in terms of IBS severity. However, the significance values calculated by the ANOVA suggest that the mean scores are similar across the groups (Table 6.7). Following the ANOVA, I designed a regression model to determine the relationship between the factors and TCM diagnoses (Appendix D 3). The regression analysis reveals that severity is predictive of damp heat ($p = 0.02$) with reference to liver qi stagnation; however, none of the variables are capable of accurately predicting TCM diagnoses collectively. Essentially, the finding supports the hypothesis that the factors (i.e. age, IBS severity, and IBS duration) are not predictive of a patient's TCM diagnosis; however, the model was poorly fitted to the data ($p = 0.09$). Reasons for the poor model fit include small sample sizes across the diagnoses and the non-normal distribution of the data (Appendix D 4). Age and duration were positively skewed for the overall group of acupuncture recipients and variably skewed among the specific diagnoses. Although data transformation may overcome the problem of non-normally distributed data, error bar charts indicate that transformation would not alter the outcome (Appendix D 5). Therefore, further

research with robust sample sizes is necessary to determine if any of the factors are predictive of TCM diagnosis.

Diagnosis	**Age Avg. (SD)**	**Duration Avg. (SD)**	**Severity Avg. (SD)**
Liver qi stagnation	46.8 (13)	15.3 (10.1)	276.9 (80.4)
Damp heat	46.6 (14.6)	17.7 (13.4)	238.7 (65.6)
Cold damp	40.2 (13.3)	12.3 (11.3)	303.6 (85.7)
Liver qi stagnation & spleen deficiency	48.3 (18.5)	12.6 (10.5)	262.0 (63.7)
Blood/Yin deficiency	41.0 (11.9)	14.0 (10.7)	304.9 (78.6)
Spleen qi deficiency	33.6 (9.8)	9.2 (5.3)	277.7 (107.3)
Yang deficiency	41.6 (13.4)	11.1 (9.0)	308.9 (93.5)
ANOVA	$F = 1.83$, $p = 0.10$	$F = 1.65$, $p = 0.44$	$F = 0.98$, $p = 0.14$

Table 6.7 Patients' characteristics at baseline according to TCM diagnosis. The table also shows the F statistic and significance of the ANOVA.

As mentioned previously, diagnosis involves the identification of both primary and secondary patterns. Table 6.8 lists the most common secondary/concomitant patterns identified in the study according to patients' primary patterns. The most common primary pattern, liver qi stagnation, is also among the most common secondary patterns, overall affecting 67% (76/113) of patients. Spleen qi and yin deficiencies were the other prominent secondary patterns that combined with their primary numbers affected 55% and 53% of patients respectively. Although the terms may be unfamiliar, Table 6.8 illustrates the complexity of TCM diagnoses and how 'heterogeneous' is an appropriate description of the patients from both the TCM and biomedical perspectives.

Primary Diagnoses	Secondary Diagnoses							
	Liver qi stagnation	**Damp heat**	**Cold damp**	**Spleen qi deficiency**	**Yin/Blood deficiency**	**Yang Deficiency**	**Food stagnation**	**Phlegm**
Liver qi stagnation	0	9	0	13	12	6	2	5
Damp heat	17	0	0	14	7	3	1	4
Cold damp	10	0	0	13	10	2	1	1
Combined	0	3	3	0	9	5	0	2
Spleen qi deficiency	10	1	0	0	7	2	0	4
Yin deficiency	7	0	0	8	0	2	0	5
Yang deficiency	4	1	3	4	2	0	1	0
Total	48	14	6	52	47	20	5	21

Table 6.8 Secondary diagnoses. The table shows the frequency that secondary diagnoses were identified in the trial and are arranged by primary diagnoses.

Rotating the analytic perspective to the acupuncturist allows for the exploration of diagnostic tendency. I attempted a comparative analysis of the relationship between primary diagnoses and acupuncturists in both SPSS 17.0.2 and STATA 10; however, neither programme could determine the Fisher's exact test due to sample size constraints. Descriptive analysis revealed that the four acupuncturists who diagnosed six or seven primary patterns treated the most patients, suggesting a positive relationship between the number of diagnoses and the number of patients (Table 6.9). Additionally, the comparison demonstrates the importance of practitioner's preference, for example 55% of Ellen's patients were diagnosed with liver qi stagnation. With regard to individuality, the acupuncturists made a unique primary diagnosis for approximately 12% of their patients. When accounting for secondary diagnoses, the average percentage of patients receiving a unique diagnosis climbed to 84% (Appendix D 6). The reason for the exponential jump in unique diagnoses may be attributed to the variety of different diagnoses. For example, application of only seven primary diagnoses limits uniqueness; however, combinations with eight secondary diagnoses, of which patients may have more than one, creates a minimum of forty-eight diagnostic combinations. Combined analysis of primary and secondary diagnoses highlights patient individualisation, which is a recurring theme in the interviews as well as other literature mentioned in Chapter 5 [56, 149].

Acupuncturist	Primary Diagnosis							
	Yang Deficiency	**Spleen qi deficiency**	**Blood deficiency**	**Damp Heat**	**Cold damp**	**Combined**	**Liver qi stagnation**	**# Patients**
Beth	0	0	0	1	1	0	1	3
Cindy	1	2	1	4	2	1	5	16
Lisa	3	3	0	4	1	7	4	22
Jill	2	0	0	2	0	2	4	10
Holly	2	0	2	1	0	1	2	8
Ellen	0	0	0	3	0	2	6	11
Marie	0	4	5	3	2	1	2	17
Sam	0	1	2	1	7	3	2	16
John	0	0	3	1	4	0	2	10
Total	8	10	13	19	17	17	29	113

Table 6.9 Diagnosis according to acupuncturist. The table shows the frequency each acupuncturist used particular primary diagnoses.

Interview statements mentioned each of the primary diagnoses identified in the trial with the most common (liver qi stagnation, spleen qi deficiency, and kidney yang deficiency) accounting for 56% of the trial diagnoses. Although the acupuncturists identified all the diagnoses used in the trial, some differences emerged between what was anticipated and what was diagnosed. For example, Beth anticipated:

> "Damp heat or heat more because if you say somebody with bad constipation that is more heat rather than damp. If somebody has more loose stools and smelly stools and mucus that's damp heat condition."

Yet only one of her patients had a primary diagnosis of damp heat and one had a secondary diagnosis of damp heat. The difference may be related to the fact that she only treated three patients, and as mentioned earlier a positive relationship may exist between the number of patients and number of diagnoses. It also reaffirms the multitude of statements about diagnosis being an individualised process. In contrast Jill anticipated:

> "Liver qi stagnation as that kind of core and everything else coming out of that being invading spleen or something heart or affecting kidney. So I would tend to see liver qi as that kind of root."

Which was reflected in 60% of her patients being diagnosed with primary liver qi stagnation and 50% being diagnosed with spleen and/or kidney patterns. Overall, the

interviews demonstrated accuracy in identifying the diagnoses that were present, but not necessarily the prevalence.

In summary, the diagnostic process utilises multiple frameworks to describe multiple primary and secondary patterns. Neither age, duration of IBS, nor baseline severity appears to be a reliable predictor of TCM diagnosis; however, diagnosis does appear to be associated with practitioner's preference and number of patients. A comparison to the TCM literature (Chapter 3) and interviews (Chapter 5) implies consistency in the most common diagnosis, liver qi stagnation, further discussed in Section 6.6.

6.5.4 Treatment Principles

Themes from Chapter 5 introduce the idea that treatment principles rephrase the diagnosis, which is also an idea found in TCM texts (e.g. [33]). Although treatment principles overlap with diagnoses, the advantage of analysing them is that the acupuncturists wrote treatment principles for most treatments thereby allowing for longitudinal comparisons in treatment emphasis, which may be used to answer the question of relative importance in Chapter 10. The phrase inventory in Appendix D 7 displays the diversity of statements used to describe the treatment principles that were condensed into eleven categories. Table 6.10 displays the treatment principle categories and suggests that the most common, regardless of diagnosis, were tonify spleen qi, clear damp (heat or cold), move stagnation, and calm shen. As mentioned in Chapter 3, shen corresponds to a person's spirit/mind that when imbalanced may manifest as depression or confusion [33]. With regard to treatment individualisation, the less frequent principles such as 'stop pain' and 'release exterior' provide the most readily identifiable examples. For instance, Jill used the 'release exterior' principle in combination with others on a patient who complained of a sore throat at one treatment session. Drawbacks to presenting data in this manner are the lack of representation of secondary diagnoses and treatment sequences. To address the question of sequence emphasis, examples are given in conjunction with points used in the subsequent section. Considering the entwined nature of the diagnosis and treatment principle, it is unsurprising that diagnosis-specific analyses did not produce any particularly noteworthy findings (Appendix D 8). For example, move stagnation

was a more common treatment principle for patients with liver qi stagnation than yin deficiency.

Treatment principle	Patients	Percent
Tonify spleen/qi	96	91
Tonify yin	33	31
Tonify yang	29	27
Move stasis	66	62
Regulate bowel	32	30
Soothe liver	34	32
Calm shen	57	54
Clear damp/phlegm	39	37
Clear damp/heat	39	37
Stop pain	4	4
Release exterior	6	6

Table 6.10 Treatment principles (n = 106). The table shows the number of patients whose treatments incorporated each principle.

While diagnosis specific analyses are unremarkable, the acupuncturist's perspective reiterates the importance of practitioner's preference (Table 6.11). Table 6.11 illustrates each practitioner's preferred treatment principle. For example, Lisa favoured tonify spleen qi and calm shen, while Ellen favoured tonify spleen qi and move stasis. Overshadowing the practitioners' preferences is the apparent importance of the individual as implied by the overall diversity of treatment principles used by each acupuncturist. On average, the acupuncturists assigned unique treatment principles to 84% of their patients. The example in Box 6.1outlines the treatment principles for four patients, three of whom have different primary diagnoses, treated by the same acupuncturist. The tonify spleen principle anchors each patient's treatment, while the other principles vary with the diagnosis and patient. Box 6.1 is important because it demonstrates the advantage of integrating data from multiple categories to interpret findings and generate hypotheses.

Treatment Principle	Acupuncturist									Total
	Beth	**Cindy**	**Lisa**	**Jill**	**Holly**	**Ellen**	**Marie**	**Sam**	**John**	
Tonify spleen/qi	3	10	16	10	7	11	15	14	10	96
Tonify yin	0	5	4	2	2	2	9	3	6	33
Tonify yang	0	3	13	3	4	4	0	1	1	29
Move stasis	3	12	12	4	6	11	5	9	4	66
Regulate bowel	0	1	2	3	0	7	5	13	1	32
Soothe liver	0	0	1	6	1	0	10	13	3	34
Calm shen	1	1	16	6	1	5	10	11	6	57
Clear damp/phlegm	1	6	3	2	2	5	8	5	7	39
Clear damp/heat	3	3	5	8	1	7	6	4	2	39
Stop pain	0	0	1	3	0	0	0	0	0	4
Release exterior	0	0	0	1	2	0	3	0	0	6

Table 6.11 Treatment principle usage according to acupuncturist

Patient 1: Diagnosis – Liver qi stagnation
Treatment principle – Tonify spleen, soothe liver, regulate bowel, clear damp heat, calm shen
Patient 2: Diagnosis – Liver qi stagnation
Treatment principle – Tonify spleen, soothe liver, move qi, clear damp heat
Patient 3: Diagnosis – Damp heat
Treatment principle – Tonify spleen, stop pain, move qi, clear damp heat
Patient 4: Diagnosis – Yang deficiency
Treatment principle – Tonify spleen, tonify yang, calm shen, release exterior

Box 6.1 Comparison of patients' treatment principles

In general, importance of the diagnosis and the patient were prominent themes related to treatment principles in the pre-trial interviews as indicated by Cindy.

> "I would probably emphasise liver patterns more than damp heat, but it depends very much on the patient."

She demonstrated this in the trial by using treatment principles that emphasised liver patterns in twelve out of thirteen of her patients, while maintaining unique treatment principle combinations for eleven out of thirteen of her patients. Referring back to the difference between Beth's anticipation of damp heat and its presence among her patients, her use of the clear damp heat principle for all her patients clearly highlights the importance of practitioner's preference.

6.5.5 Point Usage & Selection

Following the diagnoses and treatment principles, the acupuncturists identified the points used in each treatment. Approximately 126 different acupuncture points, with an average of seven points per treatment, were stimulated by the 7,185 needle insertions delivered during the trial (Appendix D 9). Four points comprise the core group (LR3, LI 4, ST 36, SP 6), as defined by use in ≥ 50% of treatments, and their combined use accounts for 36% of the total needle insertions. However, none of these points was used in more than 75% of treatments. Five points comprise the supporting group (CV12, GB 34, K 3, SP 9, ST 25), as defined by use in 25% - 49% of treatments, and their combined use accounts for 21% of the total needle insertions. Besides the core and supporting groups, the remaining 117 (93%) points comprise the variable group, as defined by use in < 25% of treatments. Among those points, forty-three (37%) were only used on one patient. The finding that the majority of points belong to the variable group and that 37% of those points were only used on one patient reinforce the idea, from Chapter 5, that treatment summaries emphasising the core group may over-simplify the treatments delivered. To address the question of individualisation, and understand the role of the variable group and the differences in point usage, the points were further explored in relation to diagnoses and acupuncturists. Comparisons to the pilot and other literature are discussed in Section 6.6.

In contrast to the overall trial findings, diagnostic analyses revealed that as many as six or as few as two acupuncture points comprised the core and supporting groups (Table 6.12). Moreover, eleven points (58%) only appear in one or two core and/or supporting groups indicating that diagnosis is an important feature of point selection. Core and support points were identified by dividing the number of treatments in which a particular point was used by the number of treatments for patients with a particular diagnosis. For example, KD 3 was used in forty-eight treatments of patients with yang deficiency (48/77 = 0.62). Effectively, data in Table 6.12 illustrate the combination of pragmatic and disease-specific treatment approaches described by Unschuld [52]. As such, the data provide useful information about the relative importance of differentiating TCM diagnoses further discussed in Chapter 10, and

generate questions about the variations in size and composition of core and support groups on treatment outcome.

Point	Primary diagnosis						
	Yang Deficiency	**Spleen qi deficiency**	**Blood deficiency**	**Damp Heat**	**Cold damp**	**Combined**	**Liver qi stagnation**
LR 3	X	X	X	X	†	X	X
LR 8			†				
LI 4	†	X	X	X	†	X	X
LI 11				†			
ST 25	†	†		†		X	†
ST 36	X	X	X	X	X	X	X
SP 3	†				†		
SP 6	†	X	X	X	X	X	X
SP 9	X			X			
SP 15		†					
LU 7			X				
CV 6	†					†	
CV 12	X	†		†		X	†
KD 3	X		†	†			
KD 6			†				
GB 34	†			†		†	†
SJ 6		†					
HT 7			†				
PC 6					†		

Table 6.12 Point usage based on diagnosis. X – core group used in ≥ 50% treatments. † - supporting group used in 25 – 49% treatments.

Having established diagnosis as an influential factor on the selection of core and supporting points, Table 6.13 attempts to determine the relationship among the number of patients, number of treatments, number of acupuncturists, and the total number of points. A cursory glance at Table 6.13 suggests positive relationships between the total number of points, number of patients, number of treatments, and the number of acupuncturists; however, a closer examination reveals that none of these factors maintains a consistent relationship. Therefore, I suggest that other

factors, such as practitioners' preferences and secondary diagnoses, may contribute to variations among the total points used. Table 6.13 also reveals that > 75% of the points for each diagnosis belongs to the variable group. This finding is important because it illustrates that sole emphasis on the core and supporting groups disregards a substantial amount of treatment data. Additionally, the variable group, as its name implies, provides specific information on treatment diversity and suggests that diversity is an important aspect of treatment design. What is unknown and requires further research is whether or not variability impacts outcome.

Primary diagnosis	**Patients (#)**	**Sessions (#)**	**Acupuncturists (#)**	**Total points**	**Group**	**Points # (%)**
Liver qi stagnation	28	252	9	79	CG SG VG	4 (5) 3 (4) 72 (91)
Damp heat	20	191	9	84	CG SG VG	5 (6) 5 (6) 74 (88)
Combined	17	154	7	63	CG SG VG	6 (9) 2 (3) 55 (87)
Cold damp	17	152	6	41	CG SG VG	2 (5) 4 (35) 35 (85)
Blood deficiency	13	107	5	40	CG SG VG	5 (12) 4 (10) 31 (77)
Spleen qi deficiency	10	83	4	50	CG SG VG	4 (8) 4 (8) 42 (84)
Yang deficiency	8	77	4	47	CG SG VG	5 (11) 6 (13) 36 (76)

Table 6.13 Point variety based on diagnosis. CG – core group, SG – support group, VG – variable group

In addition to analysing the acupuncture points by overall and diagnosis frequency, the points were also analysed from the acupuncturist's perspective. Of the 126 different acupuncture points used, fifty-five (44%) were only used by one acupuncturist. Table 6.14 summarises a wealth of information about the

acupuncturists' treatment patterns, while specific details on the acupuncturists' core and supporting groups are provided in Appendix D 10. The variety of points the acupuncturists selected was not dependent on their number of patients or their number of diagnoses (Table 6.9), instead Table 6.14 and Appendix D 10 highlight the importance of practitioners' preferences and individual patients. For example, the variation in size and composition of the acupuncturists' core groups illustrates how Holly is more likely to provide similar treatments to her patients than Cindy, and that Beth is more likely to select GB 20 than any other practitioner. Not only is Holly more likely to provide a similar treatment to her patients than other acupuncturists, her limited use of patient specific points is markedly irregular. Whether the irregularity is a true difference in treatment style, or a deviation for trial purposes is unknown. With regard to individualisation, the 'number of points used on one patient' column provides some information about how treatments were individualised. For example, of the fifty-seven different points Lisa used, twenty of those points were only used on one patient. The variation among practitioners' point selections and use of the individualised approach may offer an explanation of why efficacy based fixed points' prescriptions do not transfer well into routine practice.

As mentioned in the previous section, the acupuncturist-specific analyses allowed for the longitudinal comparison of treatments and principles. Table 6.15 provides examples of the three distinct approaches to point selection that emerged from the analyses. The most common approach identified in 50% of the treatment logs utilised a fixed nucleus of points with moderate variations in additional points. Alternatively, 21% of patients received very diverse treatments that lacked a consistent nucleus, and 29% received repetitive points with minimal variations. Although each of the acupuncturists employed the fixed nucleus approach, it was more popular among the more experienced practitioners (Appendix D 11). As such, this finding portrays a distinction between practitioners' years of experience and raises a question as to whether the less experienced practitioners will alter their treatment approaches over time. With regard to the treatment principles, Table 6.15 illustrates how their change in emphasis over time influenced point variations. For example, the repetitive points approach was modified by the addition of LI 4 and Lu 7 to expel cold when the patient complained of flu-like symptoms. Combined analysis of the point

modifications and treatment principles also demonstrates how treatments targeted concomitant symptoms or conditions in addition to bowel problems. The acupuncturists noted that they targeted concomitant symptoms such as headaches, cold and flu symptoms, night sweats, low back pain, coughing, and emotional issues. The broader importance of Table 6.15 is that it illustrates the complexity of practitioners' and patients' influences on treatment delivery and the difficulty in presenting a comprehensive account of the treatments.

Acupuncturist	**Patients**	**Treatments delivered**	**Total points**	**PPT (avg.)**	**Diff PPP (avg.)**	**Points used on 1 patient**	**Usage (%)**
Beth	3	30	33	6	16	18	CG – 3 (9) SG – 5 (15) VG – 25 (76)
Cindy	16	124	71	6	14	34	CG – 4 (6) SG – 7 (10) VG – 60 (85)
Lisa	22	205	57	8	15	20	CG – 6 (11) SG – 4 (7) VG – 47 (82)
Jill	10	97	56	9	20	23	CG – 8 (14) SG – 6 (11) VG – 42 (75)
Holly	8	74	18	8	11	2	CG – 7 (39) SG – 3 (20) VG – 8 (53)
Ellen	11	103	46	7	19	11	CG – 5 (11) SG – 2 (4) VG – 39 (85)
Marie	17	143	38	7	11	11	CG – 3 (8) SG – 8 (21) VG – 27 (71)
Sam	16	156	31	5	13	11	CG – 3 (10) SG – 4 (13) VG – 24 (77)
John	10	84	24	7	10	10	CG – 6 (25) SG – 2 (8) VG – 16 (67)

Table 6.14 Acupuncturists' points used. Abbreviations: PPT – points per treatment, Diff PPP – number of different points per patient, CG – core group, SG – support group, VG – variable group

Treatment	Points used	Treatment principle
	Approach: Repetitive points for multiple treatments	
1	Sp 6, St 36, Ht 7, SJ 6, CV 12, yintang	Soothe liver, tonify for treatments 1 - 6
2	Sp 6, St 36, Ht 7, SJ 6, CV 12, yintang	
3	Sp 4, St 36, Ht 7, SJ 6, CV 12, yintang	
4	Sp 4, St 36, Ht 7, SJ 6, CV 12, yintang	
5	Sp 4, St 36, Ht 7, SJ 6, CV 12, yintang, LR 8	
6	Sp 4, St 36, Ht 7, SJ 6, CV 12, yintang, LR 8	
7	St 36, Ht 7, CV 12, yintang, LR 3, LR 8, LI 4, Lu 7	Soothe liver, expel cold, calm shen for treatments 7 - 10
8	St 36, Ht 7, CV 12, yintang, LR 3, LR 8, LI 4, Lu 7	
9	St 36, Ht 7, CV 12, yintang, LR 3, LR 8, LI 4, Lu 7	
10	St 36, Ht 7, CV 12, yintang, LR 3, LR 8, LI 4, Lu 7	
	Approach: Fixed nucleus with moderate variation	
1	GB 20, UB 13, UB 18, UB 20, UB 23, GB 34, Sp 6	Move qi, clear damp heat, tonify
2	GB 20, UB 18, UB 23, UB 25, GB 34, Sp 9	Move qi, clear damp heat
3	GB 20, UB 18, GB 34,Sp 6, LI 4	Move qi
4	GB 20, UB 18, Sp 6, LI 4, Huatuo T3 – T4	Move qi
5	GB 20, UB 18, UB 60, LI 4, LI 5	Move qi, clear damp heat
6	GB 20, UB 18, GB 34, Sp 6, LI 4	Clear damp heat
7	GB 20, UB 18, GB 34, Sp 6, LI 4, LI 5	Move qi, tonify spleen
8	GB 20, UB 18, GB 34, Sp, 6, LI 4	
9	GB 20, UB 18, GB 34, Sp, 6, LI 4	
10	GB 20, UB 18, UB 21, GB 34, Sp 6, LI 4, LI 5	Move qi, dry damp
	Approach: Inconsistent nucleus with lots of variation	
1	CV 12, Sp 6, SJ 6, LI 4, LR 3, LI 11	Move qi, clear heat, tonify spleen/stomach
2	CV 12, S 6, LR 3, LI 11, St 25, St 36, St 37	Clear damp heat, tonify spleen/stomach
3	CV 12, Sp 3, LR 3, St 25, St 36, Kd 7	Move qi, tonify kidney/spleen
4	Sp 6, LR 3, St 25, St 36, Kd 7, GB 34, P 6	Move qi, clear damp, tonify kidney
5	Sp 6, Sp 15, LR 3, LI 4, St 36, Kd 7, P 6	Move qi, clear damp, calm shen
6	CV 6, Sp 3, St 25, St 40, Kd 7	
7	CV 12, Sp 6, SP 15, LR 3, LI 4, St 36	
8	CV 12, Sp 6, SJ 6, LR 3, St 36, UB 20, 21, 23, 25	
9	CV 12, Sp 3, Sp 9, Sp 15, St 36, Kd 7, P 6	
10	CV 4, Sp 6, LR 3, St 36, Kd 9, Ht 7	

Table 6.15 Acupuncturists' approaches to point usage

According to the pre-trial interviews, acupuncturists select acupuncture points based on their preferences, the treatment principle, the patient, and the point's actions. In other words, the diversity of points selected by the acupuncturists represents different approaches to treating IBS symptoms. The data described in this section reflect each of these themes. For example, the acupuncturists' acknowledgement of their preferences, such as Beth:

> "GB 20 is my favourite one everybody gets cause there is so much tension."

was demonstrated in her use of GB 20 on each patient and in twenty-seven of the thirty treatments she delivered.

Furthermore Sam's comment:

> "If you took it almost mechanistically there would be certain points that you could do whoever the people where you might use LI 4 and things like that might be a classic point for the colon obviously but it's not quite as simple as that."

provides an insight and/or a rational for the popularity of the fixed nucleus approach to treatment and the diverse composition of the practitioners' supporting and variable groups. The consistency between the pre-trial themes and trial data confirms that routine acupuncture treatments are diverse and integrate an acupuncturist's preferences, patient specific considerations, and the diagnosis.

6.5.6 Additional Therapy

Additional therapies include techniques that may be applied to acupuncture needles and/or points, and are a means of supplementing treatment. The pragmatic nature of the trial allowed the acupuncturists to incorporate additional therapies as they deemed appropriate with restrictions on the use of herbs and magnets. Overall twenty-five patients (22%) received one or more additional therapies in 11% of the treatments (Table 6.16). The acupuncturists indicated that they used sixteen different points for moxa with the majority applying moxa at ST 25 and ST 36 (Appendix D 12), which as mentioned in Chapter 5 are the master points for the large intestine and abdominal problems. In comparison to the 12% of trial participants who received moxa, 70% of patients in the pilot received moxa [263]. One possible explanation for the variation is that the two styles of acupuncture may emphasise the use of additional therapies differently. Alternatively, some acupuncturists may be substituting moxa with heat lamps to reduce potential side effects such as burns and/or odour.

Additional therapy	Patients (%)	Treatment (%)	Avg.* Stimulation	Avg.† Stimulation
Moxa	14 (12)	37 (4)	2.6	0.33
Tui-na (massage)	11 (10)	45 (4)	4.1	0.40
Acupressure	6 (5)	23 (2)	3.8	0.30
Ear seed	4 (4)	8 (1)	2.0	0.07
Breathing	3 (3)	4 (0.4)	1.3	0.04
Cupping	2 (2)	11 (1)	5.5	0.10

Table 6.16 Additional therapies (n = 113 patients, n = 1,016 treatments). * Mean number of stimulations per participant receiving that additional therapy. † Mean number of stimulations per participants receiving acupuncture.

Rotating the analytic perspective to the diagnosis revealed that diagnoses are a minor contributing factor to additional therapy usage. For example, moxa was used on fourteen patients with various diagnoses (Table 6.17). By incorporating the secondary diagnoses, the number of patients suffering from cold patterns increases to ten out of fourteen. I consider diagnosis to be a minor contributing factor because only ten of the forty-three patients with either a primary or secondary cold pattern received moxa. Furthermore, a study by Cassidy reports that moxa is the most commonly used additional therapy regardless of diagnosis [196]. Thus, the key to additional therapy usage may lie in the acupuncturist and/or patient.

	Additional Therapy					
Primary diagnosis	**Moxa**	**Tuina**	**Acupressure**	**Ear seeds**	**Breathing**	**Cupping**
Liver qi stagnation	4	4	2	1	1	0
Damp heat	3	4	1	0	1	1
Cold damp	2	1	0	0	0	1
Combined	3	2	2	2	0	0
Blood/Yin deficiency	0	0	1	1	0	0
Spleen qi deficiency	0	0	0	0	1	0
Yang deficiency	2	0	0	0	0	0
Total	14	11	6	4	3	2

Table 6.17 Primary diagnosis versus additional therapy

The third perspective analysed the acupuncturists, eight of whom delivered an additional therapy (Table 6.18). Acupuncturists' preferences are borne out in the type

of therapies used, and the number of patients receiving an additional therapy. For example, Beth delivered two types of additional therapies, one of which was only used by her, to each of her patients. In contrast, Sam delivered one type of additional therapy, which was used by five different acupuncturists, on one patient. One can infer that some acupuncturists are more comfortable delivering additional therapies and/or place more importance on them. Combined analysis of diagnosis, acupuncturist, and additional therapy reinforces the supremacy of acupuncturist's preference over diagnosis as illustrated by Jill's use of moxa on four patients with three different diagnoses. Despite accounting for the acupuncturist and diagnosis, some potentially important factors including patients' characteristics (e.g. willingness) and length of treatment remain unexplored.

Acupuncturist	Therapies	Patients	Avg. * Stimulation	Frequency†
Beth	cupping, massage	3/3	8.0	80%
Cindy	moxa, ear seed, breathing	5/16	0.65	9%
Lisa	ear seed	2/22	0.09	1%
Jill	moxa	4/10	2.2	23%
Holly		0/8	0	0
Ellen	moxa, acupressure, massage	8/11	5.5	59%
Marie	moxa	1/17	0.24	3%
Sam	moxa	1/16	0.06	1%
John	acupressure	1/10	0.30	4%

Table 6.18 Acupuncturist perspective of therapies delivered. The table shows the therapies each acupuncturist used and the number of patients on which they used them. *Mean number of stimulations per participant receiving treatment from that particular acupuncturist. †Percentage of treatments in which each acupuncturist used an additional therapy.

According to the pre-trial interviews, the acupuncturists preferred using herbs, moxa, and massage to treat bowel conditions with the caveat that the therapy chosen would depend on the patient. Lisa stated that:

> "If there is damp heat stuff I would use herbs because they are quicker, providing they have enough spleen qi to be able to cope."

Since acupuncturists were not allowed to provide herbs in this study, it is possible that Lisa's sparing use of additional therapies (Table 6.18) may be attributed to the fact that her preferred additional therapy was disallowed. Additionally, Lisa's comment highlights the finding that additional therapy usage is related to the acupuncturist's training and confidence in particular therapies.

Alternatively, Holly stated that she:

> "Occasionally put some moxa box if there is cold. I don't use a lot of moxa. I tend to use the lamp which I find is really useful and it is easier for me because I am doing other things."

Holly's comment refers to the idea that some acupuncturists may substitute moxa with heat lamps. The acupuncturists' use of heat lamps was not specifically recorded in this study; however, in light of the findings it should be considered in future studies. Holly's comment also reiterates an earlier idea that the use of additional therapies may be associated with time and/or length of treatment.

6.5.7 Lifestyle Advice

As discussed in Chapter 3, improper diet is a potential cause of disease that may contribute to IBS symptoms, and data from Chapter 5 indicate that lifestyle advice may be an important adjunct to treatment. The treatment protocol (Appendix B 6) instructs acupuncturists to describe their advice and the rationale for why it was given. Analysis of the treatment logs revealed that 68% of participants received lifestyle advice typically regarding their diet (Table 6.19). Seven patients (6%) received advice outside the scope of the trial regarding probiotics, herbs, and/or colonic irrigation. Advice classified as 'other' included comments such as 'warm abdomen with a hot water bottle' and 'decrease smoking'. Of the patients who received advice, 47% received advice from multiple categories. In comparison to the pilot, patients received advice in similar categories such as diet, exercise, and relaxation; however, they were less likely to receive advice than pilot patients [47]. Possible reasons that patients were less likely to receive advice include: differences in sample size, number of acupuncturists, and style of acupuncture. Additionally, data from the pre-trial interviews indicate that acupuncturists selectively give advice, and base their selectively on whether or not they perceive the patient to be receptive.

Lifestyle advice	Patients (%)	Acupuncturists
Diet	64 (57)	9
Stress/relaxation	25 (22)	5
Exercise	18 (16)	6
Probiotics/herbs	5 (4)	3
Additional therapy at home	3 (3)	3
Colonic irrigation	2 (2)	1
Referred to GP	2 (2)	2
Sleep	2 (2)	2
Other	6 (5)	3

Table 6.19 Lifestyle advice provided (n = 113 patients, n = 9 acupuncturists). The table identifies the number of patients who received a particular type of advice and the number of acupuncturists who provided a particular type of advice.

Diagnosis-specific analyses revealed that patients with a primary diagnosis of spleen qi deficiency, yang deficiency, or liver qi stagnation were the most likely to receive advice. However, all patients had > 50% chance of receiving advice. Diagnosis-specific analysis also revealed that the three most common types of advice (diet, stress/relaxation, exercise) remained consistent across diagnoses (Appendix D 13). Analysis of advice by diagnosis also allowed for the exploration of differences among the categories. For example, diet advice for patients with yang deficiency typically involved eating warm/cooked foods and avoiding cold/raw foods; however, this was the only diagnosis with a distinct pattern. Diet advice for the other diagnoses included a mixture of eating warm/cooked foods; avoiding wheat, sugar, dairy; meal times/portions; and alcohol consumption, but lacked a distinct pattern. The apparent lack of pattern by primary diagnosis may be related to the complexity of the diagnostic process and/or practitioners' preferences. Alternatively, the lack of pattern may indicate that advice is more related to general well-being rather than specific diagnoses, which was also found in the interviews (Chapter 5).

Acupuncturist-specific analyses revealed that four acupuncturists gave advice to ≥ 90% of their patients, three of whom gave advice to all of their patients (Table 6.20). For example, Ellen gave each of her patients a diet sheet about non-damp foods and healthy eating (Appendix D 14), and provided additional advice based on the patient, such as how to perform an abdominal massage. On the other hand, Sam demonstrated advice selectivity by indicating when advice was not appropriate for example: the amount/type of medication a patient is taking or the patient already has a healthy lifestyle. The other acupuncturists gave advice to 40 – 69% of their

patients. The analysis reveals a distinction among acupuncturists' use of advice as an adjunct to needling and illustrates how the composition of the acupuncturist's group affects study findings. Furthermore, the analysis provides additional support for the importance of practitioner's preference and training, particularly in additional modalities such as colonic irrigation.

	Lifestyle advice									
Acupuncturist	**Diet**	**Stress/ relaxation**	**Exercise**	**Probiotics/ herbs**	**At home therapy**	**Colonic irrigation**	**GP referred**	**Sleep**	**Other**	**Patients**
Beth	x			x						2/3
Cindy	x	x	x							9/16
Lisa	x		x							9/22
Jill	x	x	x							10 /10
Holly	x	x			x		x	x	x	8/8
Ellen	x		x	x	x	x	x		x	11/11
Marie	x			x						8/17
Sam	x	x	x		x			x	x	11/16
John	x	x	x						x	9/10

Table 6.20 Lifestyle advice according to acupuncturist. The table identifies the type of advice each acupuncturist provided and the total number of patients he/she provided advice to.

Based on the pre-trial interviews the acupuncturists were keen to provide advice regarding diet, stress, and exercise with an overarching theme of individuality. The comment below illustrates this finding and alludes to the patient's general well-being.

> Sam: "Certainly try and take them off things like red wine, alcohol, coffee, sugar, and classic things that we have to look at and many of them are just not aware that they take dairy or just how much dairy they consume. How much activity they do – do they have a stagnate job or do any type of particular exercise. There are all sorts of things like that are crucial not only looking at diet and lifestyle but looking at the strategies of dealing with certain issues."

Chapter 5 describes this general approach to health, although individualised, as a deviation from other categories that appear strongly related to diagnosis. I suggest that the combination of advice on general well-being with needles focusing on the diagnosis displays the complex utilisation of multiple treatment approaches described

by Unschuld [52]. As such, treatment aspects such as advice and needling may utilise different approaches and/or employ them to various extents. Lifestyle advice may emphasise the diagnosis approach less than needling because it is the treatment aspect wherein acupuncturists may most readily apply additional training such as colonic irrigation, homeopathy, or reflexology. Therefore, advice lends itself to a pragmatic and/or individualised approach.

The interviews also provide a potential explanation for why some practitioners were more likely to give advice than others. Jill states:

> "I think the lifestyle stuff makes a difference. I think if they are really good at bringing the lifestyle stuff on board they can start getting much more empowered to cope on their own."

Her comment suggests that some practitioners perceive advice to be an integral part of treatment that may enable patients to better manage their conditions. Therefore, the relative importance acupuncturists attribute to advice may explain the difference in the frequency it is given. Overall, the treatment logs demonstrate consistency with the interview findings; however, the acupuncturists' advice rationales conflict to some extent as further discussed in the following section.

6.6 Discussion

Data in the previous sections present findings across a range of perspectives, and suggest that both the TCM diagnosis and practitioner's preference are important to treatment delivery. Additionally, the data illustrate the complex combination of treatment approaches that incorporate pragmatic, disease-specific, and individualised aspects. By comparison, the selection of acupuncture points appears more influenced by the diagnosis than other treatment aspects such as additional therapies and lifestyle advice. The latter two aspects appear more influenced by the pragmatic and individualised approaches particularly regarding practitioners' preferences. This section discusses how the findings address the second aspect of question one, compare to the literature, and the strengths and limitations of this study.

The answer to the question, 'how do acupuncturists treat IBS in a pragmatic study' incorporates multilayer approaches, practitioners' preferences and training, and

patients' characteristics (e.g. diagnosis), which manifests in the diverse application of acupuncture points, additional therapies, and lifestyle advice (Tables 6.21 & 6.22). Therefore, 'complex' is an appropriate description of the influences and approaches contributing to the treatment of IBS, and is consistent with the interview findings. Specifically, Table 6.21 illustrates the consistency of core groups across diagnoses and the diversity in supporting and variable groups, while Table 6.22 highlights the importance of practitioners' preferences and how they contribute to diagnostic and treatment differences.

Although the effectiveness approach overcomes several challenges to TCM research, the resultant treatment diversities pose a challenge to the thorough presentation of treatments delivered. Currently, acupuncture studies are encouraged to report their protocols or treatments according to the standards for reporting interventions in clinical trials of acupuncture (STRICTA) guidelines [264]. Efficacy studies, in particular, benefit from the guidelines because they typically evaluate specific acupuncture points that other studies may choose to replicate. Box 6.2 compares STRICTA information for this study to a fictitious efficacy study. Although the guidelines derive useful information from both types of studies about the style of acupuncture and the acupuncturists, effectiveness studies employ flexible protocols that encourage pragmatic treatment delivery, which may result in the use of 'variable' or generic descriptions of points and techniques. Furthermore, the information is not intended for strict repetition, unlike efficacy studies, because pragmatic treatment by definition differs according to the acupuncturist. As such, the information should provide researchers and practitioners with a sense of the similarity between the pragmatic trial and routine treatments.

Liver qi stagnation (28)	
Acupuncture pts	Avg. stimulations
LR 3	7.1
LI 4	6.9
ST 36	7.0
SP 6	5.8
ST 25	2.8
CV 12	3.8
GB 34	2.4
72 other pts	29.9
Total	1838

Cold Damp (17)	
Acupuncture pts	Avg. stimulations
ST 36	8.0
SP 6	6.9
LR 3	2.6
LI 4	2.4
SP 3	2.2
PC 6	2.8
35 other pts	27.1
Total	888

Spleen qi deficiency (10)	
Acupuncture pts	Avg. stimulations
LR 3	5.6
LI 4	5.3
ST 36	5.3
SP 6	4.2
ST 25	3.8
SP 15	2.4
CV 12	3.5
SJ 6	2.2
42 other pts	24.0
Total	563

Combined (17)	
Acupuncture pts	Avg. stimulations
LR 3	7.2
LI 4	6.6
ST 36	6.8
SP 6	5.5
ST 25	4.5
CV 12	5.5
CV 6	2.4
GB 34	3.3
55 other pts	25.4
Total	1142

Yang Deficiency (8)	
Acupuncture pts	Avg. stimulations
LR 3	4.6
ST 36	7.6
SP 9	5.6
CV 12	5.1
Kd 3	6.0
LI 4	3.5
ST 25	4.5
SP 3	2.6
SP 6	3.1
CV 6	4.3
GB 34	3.3
36 other pts	25.5
Total	606

Blood Deficiency (13)	
Acupuncture pts	Avg. stimulations
LR 3	4.6
LI 4	4.2
ST 36	5.4
SP 6	6.5
Lu 7	4.2
LR 8	2.9
Kd 3	2.4
Kd 6	2.5
Ht 7	2.5
31 other pts	22.4
Total	750

Damp Heat (20)	
Acupuncture pts	Avg. stimulations
LR 3	5.1
LI 4	5.3
ST 36	6.8
SP 6	5.5
SP 9	4.8
LI11	3.4
ST 25	2.8
CV 12	3.9
Kd 3	2.7
GB 34	3.3
74 other pts	26.7
Total	1398

Table 6.21 Summary of treatments by diagnosis. The number of patients with each diagnosis is in parentheses. Core (in bold) and support points as previously defined and the mean number of stimulations per participant.

Beth (3)		**Cindy (16)**		**Lisa (22)**		**Jill (10)**	
Primary dx* - 3 **Secondary dx* – 3** **Additional therapies* – 2** **Advice† - 67%**		**Primary dx* - 7** **Secondary dx* – 8** **Additional therapies* – 3** **Advice† - 56%**		**Primary dx* - 6** **Secondary dx* – 6** **Additional therapies* – 1** **Advice† - 41%**		**Primary dx* - 4** **Secondary dx* – 8** **Additional therapies* – 1** **Advice† - 100%**	
Acupuncture pts	Avg. stimulations	Acupuncture pts	Avg. stimulations	Acupuncture pts	Avg. stimulations	Acupuncture pts	Avg. stimulations
SP 6	8.3	**St 36**	5.9	**LR 3**	6.7	**LR 3**	6.4
GB 20	9.0	**LR 3**	3.9	**St 25**	5.5	**LI 4**	6.7
GB 34	5.0	**LI 4**	4.4	**St 36**	8.9	**ST 25**	6.2
LI 4	4.3	**Sp 6**	4.4	**GB 34**	5.8	**Sp 6**	6.1
St 25	3.0	St 25	2.1	**LI 4**	5.4	**CV 6**	7.1
St 36	4.0	Sp 9	2.6	**CV 12**	7.9	**CV 12**	5.6
UB 18	4.0	Sp 15	2.4	Sp 9	2.5	**GB 41**	5.1
Du 20	3.0	CV 4	2.2	CV 6	4.2	**SJ 5**	5.1
		CV 6	2.0	Kd 3	4.4	St 36	4.3
		CV 12	2.6	LR 13	3.3	St 37	4.5
		GB 34	2.3			Sp 9	3.3
						Sp 15	3.7
						GB 28	3.7
						GB 34	3.8
25 other pts	19.3	60 other pts	15.8	47 other pts	18.7	42 other pts	23.6

Table 6.22 Summary of treatments by acupuncturist. Each acupuncturist's number of patients is in parentheses. Core (in bold) and support points as previously defined and the mean number of stimulations per participant. * Refers to the number of different diagnoses and/or therapies used. † Indicates the percentage of the practitioner's patients receiving advice.

Ellen (11)		**Holly (8)**		**Marie (17)**		**Sam (16)**		**John (10)**	
Primary dx* - 3 **Secondary dx* – 6** **Additional therapies* – 3** **Advice† - 100%**		**Primary dx* - 5** **Secondary dx* – 6** **Additional therapies* – 0** **Advice† - 100%**		**Primary dx* - 6** **Secondary dx* – 6** **Additional therapies* – 1** **Advice† - 47%**		**Primary dx* - 6** **Secondary dx* – 6** **Additional therapies* – 1** **Advice† - 69%**		**Primary dx* - 4** **Secondary dx* – 4** **Additional therapies* – 1** **Advice† - 90%**	
Acupuncture pts	Avg. stimulations	Acupuncture pts	Avg. stimulations	Acupuncture pts	Avg. stimulations	Acupuncture pts	Avg. stimulations	Acupuncture pts	Avg. stimulations
LR 3	8.2	**LR 3**	9.3	**LI 4**	5.7	**St 36**	8.3	**St 36**	7.9
St 36	7.3	**LI 4**	8.4	**Sp 6**	7.7	**Sp 6**	6.1	**Sp 6**	8.1
Sp 6	7.2	**St 36**	8.4	**LR 3**	4.9	**PC 6**	5.3	**Kd 7**	7.1
LI 4	5.5	**Sp 6**	6.8	LR 8	3.4	LI 4	3.3	**Ht 7**	7.8
CV 12	5.3	**Sp 9**	6.0	St 25	2.9	Sp 3	3.5	**LR 3**	4.8
LI 11	4.3	**Lu 7**	6.6	St 36	3.6	LR 3	2.9	**LI 4**	4.4
St 25	3.5	**Kd 3**	8.1	Sp 9	3.5	PC 7	3.2	Kd 3	3.9
		LI 11	4.4	Sp15	2.9			LR 8	2.9
		St 40	3.3	Lu 7	4.2				
		Lu 9	3.6	Kd 6	3.7				
				SJ 6	2.8				
39 other pts	22.5	8 other pts	9.9	27 other pts	15.5	24 other pts	14.1	16 other pts	7.9

Table 6.22 continued

STRICTA item	ACIBS	Example efficacy
1. a) Style	TCM	TCM
b) Reason for treatment	Systematic review by Lim [29]	Systematic review by Lim [29]
c) Variation	Individualised	Same for all sessions
2. a) # needles per treatment	14 needles (4 – 23)	9
b) Names	Variable (~126 different pts)	St 25, St 36, LR 3, LI 4, CV 12
c) Depth of insertion	Variable	0.25 – 0.5 cun
d) Response sought	Variable	De qi
e) Needle stimulation	Manual	Manual
f) Retention	Variable (sec. to 30 minutes)	25 minutes
g) Needle type	Variable	Serin No. 3 (0.20) x 30mm
3. a) # sessions	10	10
b) Frequency & duration	Usually 1x wk over 12 wks	2x wk for 5 wks
4. a) Other interventions	Variable Restricted herbs & magnets	Moxa CV for 10 minutes No other interventions allowed
5. Participating acupuncturists	BAcC members ≥ 3 yrs experience Predominant style TCM	BAcC members ≥ 3 yrs experience Predominant style TCM

Box 6.2 Comparison of effectiveness and efficacy studies by STRICTA reporting. ACIBS – acupuncture for IBS is the acronym for this trial.

According to Glasgow *et al*, the routineness of a trial treatment has practical implications in that trial treatments that are not similar to routine practice are unlikely to transition beyond the trial phase [217]. For this reason, I suggest that the guidelines should encourage practitioners participating in effectiveness studies to assess the 'variable' treatment aspects (Box 6.2 Item 2) and to report their perceived routineness. For example, pragmatic studies may employ process evaluation to explore treatment delivery, whereby a mixture of quantitative and qualitative methods assesses the routineness of delivery [265]. The pre-trial interviews and log book question about treatment limitations, discussed in the following paragraph, are an initial attempt at process evaluation that may be strengthened by a quantitative measure. One possible method of measuring routineness is a VAS (Figure 6.1); however, psychometric analyses are necessary to determine the usefulness of this type of question. Based on the potential practical implication of perceived

routineness, I suggest studies encourage acupuncturists to rate the overall routineness of their pragmatic treatments. By reporting the routineness of treatment, researchers may make trial findings more accessible to practitioners.

Figure 6.1 VAS of pragmatic trial treatment routineness

Analysis of the treatment logs and the acupuncturists' comments about the protocol provide some indication about the 'routineness' of the trial treatments. First, the acupuncturists' comments about the protocol suggest that treatment delivery was affected by the restriction on herbs and probiotics. Specifically, two practitioners indicated that they would recommend an herbal supplement or probiotics to some of their patients under normal circumstances. Moreover, three practitioners recommended them (Table 6.19) despite the restrictions. Based on these comments I suggest that the protocol limited the routineness of treatment with regard to additional therapies (i.e. herbs) and lifestyle advice (i.e. probiotics).

Second, two acupuncturists indicated that they felt restricted by the number of sessions. As mentioned previously (Chapter 5), the number of sessions is a controversial subject, and while the acupuncturists suggest that symptoms may improve quickly they are also wary of predicating a number that may foster unrealistic expectations among patients. Under routine circumstances, patients may attend as many sessions as they choose, which according to the interview is sometimes influenced by finances. Patients in this study received ten free sessions of acupuncture, after which 26/33 continued or planned to continue with additional treatments as can be seen in Chapter 8. Therefore, researchers and decision makers should pay special attention to this area when offering and/or designing an intervention.

Another indication of routineness may be interpreted from a critical examination of the treatments. As mentioned in Section 6.5.5, data suggest that one acupuncturist's treatments may be irregular in comparison to the other acupuncturists' treatments.

While Holly used a similar variety of diagnoses and treatment principles as the other acupuncturists, she used markedly fewer points and the least number of unique points per patient (Table 6.14). Additionally, Table 6.15 and Appendix D 10 indicate that she heavily favoured the repetition of points for multiple treatments. Therefore, it seems probable that she either modified her behaviour for the trial and gave each of her patients very similar repetitive treatments, or, since John's approach is similar, her behaviour is indicative of the routine practice of less experienced acupuncturists. An audit of treatment logs from routine practice may provide data to address this question. With regard to the overall routineness of the pragmatic treatments, the data suggest that practitioners were partially limited by the protocol and delivered relatively routine treatments.

In addition to the question of routineness, Holly's treatment irregularity introduces the subject of trial behaviour. Generally, this topic is associated with patients' understanding of their role in the research process, which affects their characterisation of self as volunteer or patient [266]. With regard to acupuncture, studies such as McManus *et al* [267] have explored the acupuncturist's role in providing sham interventions. According to McManus *et al*, some acupuncturists felt hypocritical or deceitful about delivering sham acupuncture. In contrast, some of the acupuncturists' comments in the log books state that they enjoyed the trial experience; however, their answers to questions about advice rationale suggest that they altered their behaviour to some extent. As discussed in Chapter 4 and seen in the treatment log (Appendix B 6), the acupuncturists were asked to list the lifestyle advice they provided and the rationale for that advice. Data in Section 6.5.7 suggest that advice is related to general well-being, practitioner's preference, and the patient. Diagnosis only appeared important in reference to patients with yang deficiency who were given consistently similar dietary advice such as avoid raw food. In contrast, the authors of a low back pain study report that practitioners' advice whether generic or not was related to patients' diagnoses [268]. The difference in findings may be related to the difference in data collection methods which subsequently influenced different question interpretations and responses. However, the lack of transparency in that no data are presented to allow the reader to assess the relationship between the advice and diagnosis, and the lack of reflexivity on potential biases makes it difficult

to judge the reliability of the finding. As discussed in the following paragraph, analysis of the acupuncturists' advice rationales highlights the potential influence of response bias.

While the diagnosis and acupuncturist-specific analyses suggest that advice is related to a combination of influences including the practitioner, patient and to a lesser extent diagnosis, analysis of the acupuncturists' rationales suggest that diagnosis plays a larger role. Box 6.3 provides an example of the acupuncturists' advice and rationales. Specifically, Beth advised two patients (with different diagnoses) to try probiotics. Her rationales for this advice differ in that one response supports the benefit of 'good' bacteria, while the other response supports the patient's secondary diagnosis of spleen qi deficiency. Beth's interview comments (Chapter 5) ground her preference for probiotics in the assumption that the overuse of antibiotics damages the GI tract. Considering that her first rationale is consistent with her interview comments, the deviation for the second rationale raises a question about potential response bias due to observation. If the deviation is due to response bias, it is unfortunate because Beth's initial comments demonstrate how acupuncturists integrate biomedical information within their treatments and/or the importance they assign that information as discussed in Chapter 5 (Figure 5.2). Additionally, Ellen gave advice to all of her patients, and one component of that advice was identical (i.e. diet sheet). The four patients in Box 6.3 have three different primary diagnoses. Similar to Beth, Ellen gave advice outside the scope of the trial and provided two different rationales one of which correlates with her treatment principles. Based on the analysis of the acupuncturists' advice rationales and advice given, I suggest that the acupuncturists may have modified their rationales because they were being observed. As mentioned previously, lifestyle advice is a unique aspect of treatment, wherein practitioners may apply various aspects of additional training and preferences not related to TCM. Therefore, it is also an area where practitioners may feel pressured to modify their behaviour or rationales for research.

Acupuncturist	Patient	Advice	Rationale
Beth	1	Eat live yoghurt (probiotics) Avoid wheat, sugar, dairy	Replace good bacteria Avoid damp forming foods
	2	Eat live yoghurt (probiotics) Reduce sugar & dairy	Help spleen function Reduce damp forming foods
Ellen	1	Diet sheet Massage abdomen Colonic irrigation	Warm easy to digest food Move wind Think it's a good idea
	2	Diet sheet Colonic irrigation	To not overwork system Regulate bowel
	3	Diet sheet Warm foods & eat breakfast	Help digestion
	4	Diet sheet Avoid raw & cold food Avoid ice drinks	Tonify spleen & clear damp

Box 6.3 Lifestyle advice versus rationale

With regard to diagnosis, Figure 1.2 and Table 3.5 identify a variety of TCM patterns potentially related to IBS, and Table 6.6 lists the seven primary patterns diagnosed in the trial. As mentioned previously, I am sceptical of a previous attempt to establish an empirical relationship between IBS and TCM patterns due to the pre-determined nature of the study, wherein acupuncturists were asked to classify patients as either liver qi stagnation, spleen qi deficiency, or a combination of the two [216]. Although I agree that these diagnoses are important, data from this study reveal that they may only account for 50% of primary diagnoses when practitioners are unrestricted. As indicated by the findings, patients' primary diagnoses played a role in the practitioner's selection of treatment principles and points used contributing to treatment diversities. Therefore, restrictions on a practitioner's diagnostic freedom may consequently alter treatment principles, the selection of acupuncture points, and potentially a patient's treatment outcome. However, as introduced in Chapter 1, there is a lack of information about the role of TCM diagnosis differentiation in treatment design and potential impact on outcome. Only one acupuncture for IBS study employed an unrestricted approach to TCM diagnosis, but does not list the diagnoses identified [39]. Nonetheless, Forbes *et al* do suggest that the diagnoses were used to select different treatment principles and acupuncture points. In contrast, a study by Sherman *et al* reports a lack of consistency among diagnoses and treatments for low back pain, and attributes the treatment variations to practitioners' idiosyncratic

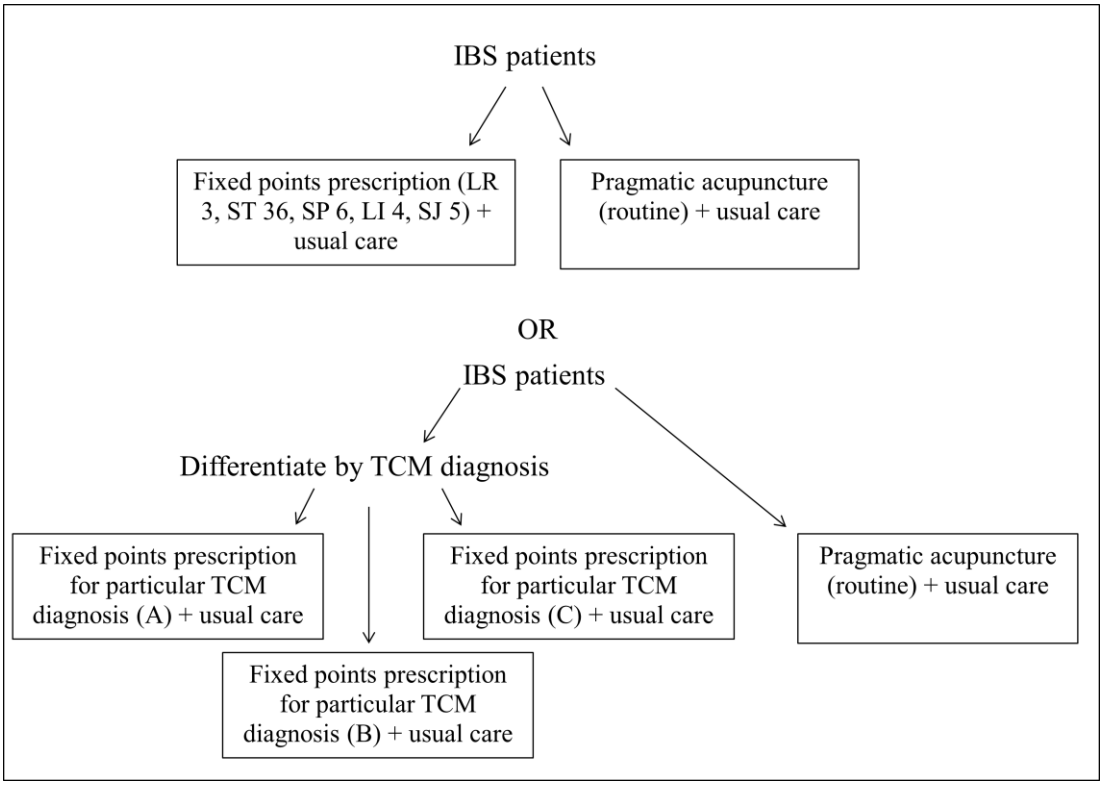
approaches [53]. The authors suggest that the lack of consistency may reflect the unimportance of the diagnosis to treatment design. A third paper that reviews pragmatic treatments, by Napadow *et al*, identifies a core set of points that are used across a variety of diagnoses as well as disease specific points [54]. From these papers, it is difficult to determine the relative importance of TCM diagnosis differentiation. Additional information from this study suggests that treatments may also be described as idiosyncratic relative to the practitioner; however, the contrast between this study and the low back pain study may reflect a notable distinction between the relative importance of diagnoses. Similar to the discussion on context in Chapter 5, wherein some biomedical diagnoses may be more 'important' than others to TCM practice, so too may certain TCM diagnoses be more 'important' to treatment design than others. Alternatively, the consistency in treatment or lack thereof may be related to patients' chief complaints. Low back pain may be related to multiple diagnoses, yet patients may report similar chief complaints. In contrast, IBS is associated with multiple diagnoses and a range of potentially unrelated chief complaints (Table 6.3). Further research is necessary to determine whether particular diagnoses and/or chief complaints are more important to treatment design than others.

Considering that the acupuncturists used a variety of points based on their preferences, diagnoses, and patients' characteristics, a comparison to the literature is somewhat complicated. Table 6.23 presents a comparison of the core points from the trial, the recommended points from Table 3.5, the efficacy studies from Table 3.7, and the pragmatic studies from Table 3.7. In comparison to the most commonly recommended points from Table 3.5, only one point (St 36) is among the core points for the trial, while the most common points among efficacy studies is among the supporting points for the trial. The inconsistency among the current study, efficacy studies and recommendations illustrates a comment by Birch that point recommendations (Table 3.5) and treatment plans (i.e. efficacy studies) are not typically based on empirical evidence, and are subject to possible translation bias and practitioners' preferences [261]. The comment and inconsistencies also support the use of pragmatic studies and pre-trial research such as expert panel reviews to design treatment plans for efficacy studies.

Source	Core Points
ACIBS	St36, Sp 6, LR 3, LI 4
Recommendations (Table 3.5)	CV 4, CV 6, CV 12, St 25, St 36, St 37
Efficacy studies (Table 3.7)*	St 25
Pragmatic [47], [39]*	CV 12, St 36, Sp 6, LR 3, LI 4

Table 6.23 Comparison of core points. *Reports a comparison of studies that identified the points used – study did not report a list and was therefore excluded.

In contrast, the trial's core group is identical to the pragmatic studies, apart from CV12 which is a support point. Furthermore, the trials' core group of points are identical to the core group of points identified by Napadow *et al* (LR 3, LI 4, ST 36, SP 6, SJ 5) with exception to SJ 5 [54]. The authors note that the most commonly used points have multiple indications and may be used for a variety of conditions thereby contributing to their popularity. In addition to multiple indications, I suggest that the points may also be popular because of their locations and accessibility. For example, both LI 4 and SJ 5 are located on the hand and just below the wrist (respectively), which allows them to be needled without the removal of clothes and with the patient seated, prone, supine, or on her side. The fact that four of the five core points are the same for multiple studies reaffirms Napadow *et al*'s conclusion that a small core of points may be used to treat a variety of conditions and that those points are supplemented by an idiosyncratic group of points. Nevertheless, I should reiterate that only St 36 was a core point for all seven trial diagnoses, and that the other points were either core or supporting points (Table 6.12). Future studies may explore whether the core group, the idiosyncratic group, or the combination of the two drives outcome. Box 6.4 provides examples of possible trial designs, wherein all the participants receive usual care. The first example allocates patients to receive either fixed acupuncture treatments that employ five or six core points or fully pragmatic treatments. The second example allocates patients to receive fixed acupuncture treatments deemed relevant to a particular TCM diagnosis or to fully pragmatic treatments. The emphasis on 'fully' pragmatic treatments refers to the earlier comment about the routineness of treatments in this study being limited by the restriction to herbs and probiotics. Therefore, to be more routine/fully pragmatic future studies should allow TCM practitioners to deliver combinations of acupuncture and herbs; acupuncture, herbs, and additional therapies, or acupuncture and additional therapies as they deem appropriate. To my knowledge, this degree of flexibility has not been attempted in an RCT setting.



Box 6.4 Possible trial designs

With regard to the strengths and limitations of this study, I have discussed the particular limitations throughout this section. Therefore, this paragraph highlights the strengths. Missing and/or incomplete data are often a problem for quantitative studies [269], and although the treatments logs technically collected qualitative data, missing log books would have been problematic. Thus, a key strength of this study is that all 113 log books and all 1,016 treatments were analysed to create a robust dataset. An additional strength of the study was the methods, including data triangulation, used throughout this chapter. As mentioned in Chapter 4, the purpose of triangulation is not to capture the same data from different sources but to improve the credibility of qualitative research and explore the differences in data collected from different sources. Lastly, the analyses from multiple perspectives allowed for a broad exploration of the motivations and factors that contribute to treatment delivery.

In summary, the pragmatic trial treatments of IBS incorporated a variety of approaches including diagnosis-specific, individualised, and pragmatic that were each influenced by the practitioner. The findings address the second aspect of question one, and the related discussion raises several suggestions for future

research. Most notably research studies should address the importance and overall contribution of core and variable points to patients' outcomes. The following chapter explores the patients' outcomes in this study with particular attention to the TCM diagnoses.

Chapter Seven

The TCM Diagnosis & Outcome

Chapter highlights

- The items comprising the IBS-SSS represent a single factor that accounts for less than half of the variability in patients' IBS symptom severities
- Exploratory regression analyses suggest that TCM diagnosis may be predictive of outcome and that patients with deficient diagnoses report worse outcomes in comparison to patients with excess diagnoses
- Regression analyses also suggest that patients' prognoses are predictive of outcome and that patients with good prognoses report better outcomes in comparison to patients with poor prognoses

7.1 Introduction

Data presented in the previous two chapters provide an answer to the first research question that is the TCM treatment of IBS is on one hand categorically individualised based on the individual practitioner and patient, and is on the other hand an intricate blend of pragmatic and disease-specific approaches. The diversity of influences and blending of approaches gave rise to a heterogeneous selection of points, additional therapies, and lifestyle advice. Recall from Chapter 4 that one criticism of acupuncture research is its inattention to TCM diagnoses [219, 222, 270], which in addition to the diversity of diagnoses identified in Chapter 6 and the objective to assess the relative importance of TCM diagnoses provide the rationale for the second research question, 'is there a difference in outcome for patients with particular TCM diagnoses'.

While the question about the difference in outcome for particular TCM diagnoses is a primary research question, the use of a controversial outcome measure in the analyses prompted the inclusion of a subsidiary question about the validity and reliability of the IBS symptom severity scale (IBS-SSS). The chapter also includes data relating to the subsidiary question regarding prognoses. The purpose of including this question is to assess the ability of practitioners' prognoses to predict patients' outcomes. Findings related to outcome associated with patients' TCM diagnoses contribute to the hypothesis development about the relative importance of diagnosis differentiation by providing evidence as to whether diagnosis may predict outcome (Chapter 10).

Data for this chapter were primarily derived from patients' questionnaires, and supplemented by the treatment logs (Appendices B 6 & 8). Unlike the previous chapters, data in this chapter are quantitative, and for that reason require a different presentation. The following sections describe the aims and objectives, validity and reliability of the IBS-SSS, patients' outcomes, and the relationship between prognosis and outcome.

7.2 Aims & Objectives

The aim of this chapter is to quantitatively explore patients' outcomes according to their TCM diagnoses and the relevance of practitioners' prognoses to outcome. The objectives are to determine:

- The validity and reliability of the IBS-SSS
- The patients' outcome by analysing the IBS-SSS and SF-12 according to TCM diagnoses
- Whether there is a correlation between patients' pre-trial beliefs and the acupuncturists' prognoses
- The correlation between the acupuncturists and prognoses and outcome
- Whether the prognoses were a significant predictor of outcome

To accomplish the objectives, data were analysed in SPSS 17.0.2 or STATA 10. Since accomplishing each of the objectives required slightly different analyses the purpose, hypothesis, method, and result for each objective is discussed in a separate section.

7.3 IBS-SSS Construction & Reliability

As discussed in Chapter 2, IBS is a heterogeneous condition that manifests as a variety of symptoms, which fluctuate along a continuum from asymptomatic to severe. These two characteristics pose a challenge to measuring IBS severity and outcomes related to treatment. The IBS-SSS is a practitioner-derived questionnaire comprised of five items that each measure 0-100 (Appendix A) [128]. Total scale scores range from 0-500 and indicate remission (< 75), mild (75-175), moderate (176-300), and severe (> 300) symptoms. Although Francis *et al* suggest that the IBS-SSS is a valid questionnaire, a review by Camilleri *et al* suggests that there is a lack of sufficient evidence to support this claim [231]. In particular, Camilleri *et al* were critical of the questionnaire's construct validity; inconsistencies in the instructions that refer to a patient's current symptoms and symptoms over the past ten days; and the lack of psychometric data that could support the scoring algorithm, factor structure, or internal consistency of the questions. Table 7.1 lists the analyses Francis *et al* conducted on IBS-SSS and highlights the use of small sample sizes particularly given the diversity of IBS symptoms and intensities. Additionally, the qualitative comparison of the patients' classifications by GPs (mild, moderate,

severe) to the questionnaire's classification used different categories in that the questionnaire includes a fourth classification (i.e. remission). Lastly, the sensitivity to change assessment was based on before and after data, which is potentially biased by regression to the mean (i.e. initially extreme measurements appear more average on the second measurement [271]).

With regard to the current study, I noticed that all of the potential participants (both included & excluded) scored ≥ 135 on the IBS-SSS during recruitment, which means that no one was excluded from the trial for a failure to meet the minimum severity score of 100. As mentioned in Chapter 4, database recruitment from primary care should potentially capture a range of severities; therefore the absence of scores < 135 is noteworthy. The noteworthiness of this baseline data became apparent during the patients' interviews and is further discussed in Chapter 8. The recruitment data combined with the questions raised by Camilleri *et al* prompted further analysis of the questionnaire. Further analysis was also considered appropriate in lieu of the research questions that address the importance of diagnosis and outcome, discussed in subsequent sections.

Assessment	Patients	Comparison
Reliability	61 – IBS 40 – control	GP classification (mild, moderate, severe) qualitative comparison to questionnaire score
Reproducibility	40 – IBS 15 – control	Re-test administered 6 – 24 hr after original test
Sensitivity to change	40 – IBS (undergoing hypnotherapy)	Baseline and 3 month follow-up scores

Table 7.1 IBS-SSS validation. Data extracted from Francis *et al* [128]

The purpose of analysing the IBS-SSS was to assess the structure and reliability of the questionnaire and to determine the overall validity of the study findings. With regard to structure, the analyses emphasise construct validity, which is the extent to which the questionnaire measures what it is intended to measure (i.e. IBS severity) [272]. The construct validity of a questionnaire contributes to the internal validity or degree to which the research provides a true picture of the people being studied. With regard to IBS severity, capturing a true picture may be difficult given the heterogeneity of the population and the variations in factors that GPs and patients

perceived to be contributing to severity (Chapter 2). The internal validity (or true picture of people being studied) differs from external validity which is a measure of the generalizability of study findings to a broader population. In addition to assessing the validity of the IBS-SSS, it is also necessary to address whether the questionnaire reliably measures IBS severity. Reliability in this analysis refers to whether the questions measure the same thing, which is reflected in their correlations [273]. This is different from inter-rater reliability and test-retest reliability, which measure the degree of agreement between two or more individuals and the consistency of a questionnaire for a particular person at different points in time respectively [254]. To measure the validity and reliability of the IBS-SSS, I conducted factor and Cronbach's alpha analyses.

Factor analysis was deemed the appropriate method to assess the structure of the IBS-SSS because it determined whether certain variables were related to latent factor/s (e.g. IBS severity) by describing the relationship of covariance among multiple variables [274]. There are two underlying assumptions to address before conducting factor analysis. First, we must assume that an underlying structure exists [275]. The applicability of this assumption is not statistically measurable; therefore, I interpreted the face validity (i.e. the relevance, clarity and presentation [272]) of the questionnaire. Second, we must assume that the population is homogeneous from the standpoint that we have not administered the questionnaire to people who are known to respond differently [275]. Given that IBS is a heterogeneous condition, I interpreted this assumption to mean that it would be inappropriate to conduct factor analysis on a population that included both IBS patients and controls (i.e. non-patients).

The IBS-SSS has five variables including pain intensity, pain frequency, distension intensity, satisfaction with bowel movement, and symptom effect on daily life. A box-plot was created for each variable to check for outliers (Figure 7.1). Due to the presence of outliers in the satisfaction with bowel movement and symptom affect on daily life variables, I conducted a principal axis analysis, which can detect structure and account for outliers [275]. In addition, the Cronbach's alpha of the scale was calculated to determine the internal consistency of the questionnaire. Based on the

relatively small sample sizes, limited initial assessments (Table 7.1), and the variety of IBS symptoms potentially related to severity including those mentioned by patients (e.g. embarrassment), I hypothesised that the IBS-SSS does not capture a broad range of aspects contributing to IBS severity and has limited reliability.

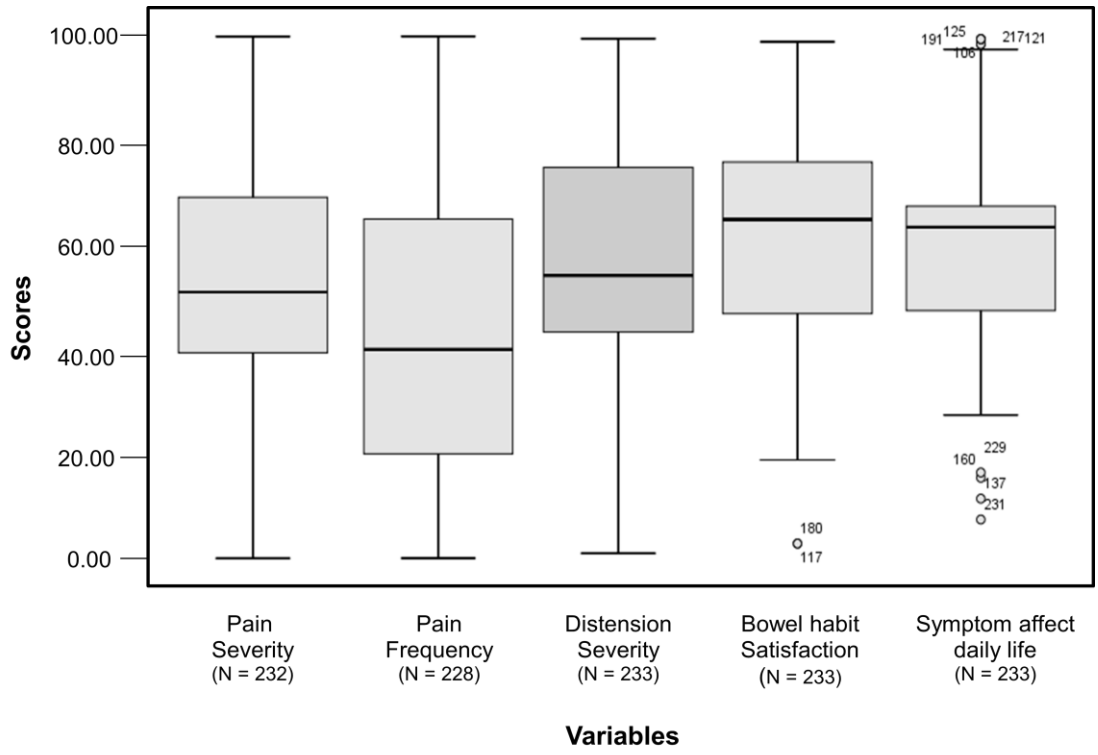


Figure 7.1 Box plots of IBS-SSS variables

Prior to conducting the factor analysis I determined that the data were suitable for the analysis. To determine the sample size and the appropriateness of including each of the IBS-SSS items, the data were initially assessed for factorability via descriptive analysis and correlation matrix (Appendix E 1). According to the descriptive analysis, the sample size is 228 and the determinant of the correlation matrix is 0.41, which suggests that each of the items may be included in the analysis because there is no risk of multicollinearity (i.e. an analytic complication created by the interrelationship between variables [254]). If multicollinearity was present, one or more of the items would be removed from the analysis. Next, the sample size was analysed for adequacy based on the rule of thumb that there should be a minimum of ten observations for each item, and the Kaiser-Meyer-Olkin (KMO) measure. The KMO measure of sampling adequacy ranges from 0-1 and for an adequate sample

size should be > 0.60. The sample size of 228 satisfies the rule of thumb, and the KMO measure (0.753) also indicates the sample size is adequate. Additionally, the Bartlett's test for sphericity was significant ($p < 0.001$), which suggests that there is adequate correlation among the variables to detect clusters that measure the same thing and that factor analysis is appropriate.

After establishing that factor analysis was appropriate, the sample size was adequate, and that each of the items in the IBS-SSS should be included, I ran the principal axis analysis (Appendix E 2). Initially, the analysis was run unrotated to determine the appropriate number of factors to extract. Based on the scree plot (Figure 7.2) and the Kaiser method of retaining factors with Eigen values > 1 only one factor was considered extractable [254, 276]. However, some researchers argue that neither of these methods is sufficient to determine the number of factors, so I also based the decision to extract one factor on the factor loadings (Table 7.2). According to Stevens, for a sample size > 200 a factor loading > 0.364 is significant [277]. All of the factor loadings for factor one are > 0.50, therefore only one factor was extracted and subsequent rotations were not required. The factor analysis indicates that the extracted factor accounts for 47% of the variation in symptom severity. Although in a large questionnaire a single factor accounting for 47% of the variation may be considered robust, in this case, as the only factor it reveals that the IBS-SSS is unable to detect approximately 53% of the variation in symptom severity. Given the diversity of symptoms and variability in the frequencies and intensities within those symptoms, one can appreciate the limited ability of the five IBS-SSS items to capture variations. With regard to the hypothesis, the finding supports the hypothesis that the IBS-SSS is limited in its ability to measure the range of symptoms contributing to IBS severity.

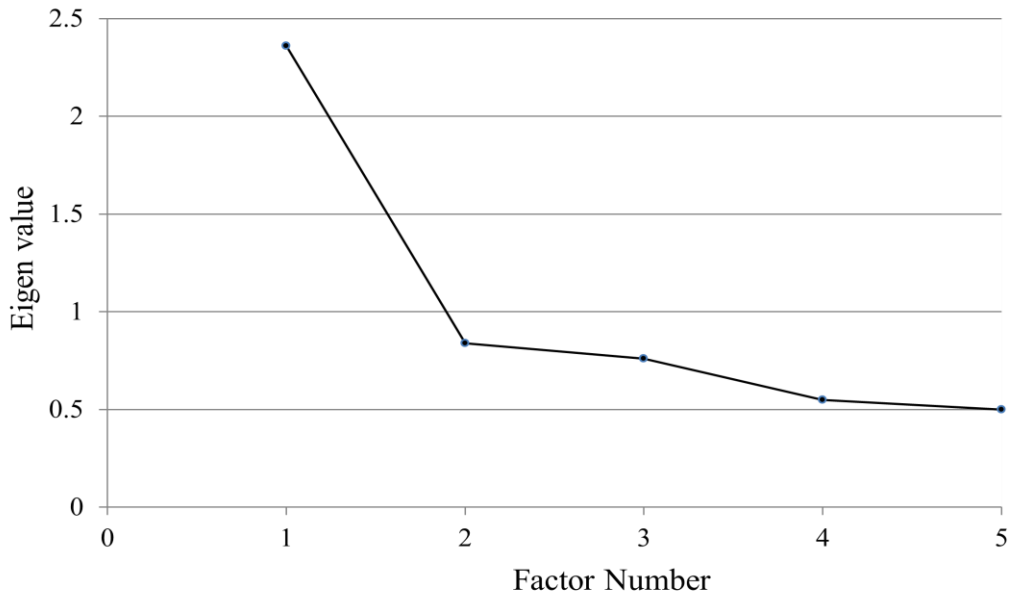


Figure 7.2 Scree plot of IBS-SSS factors

	Factor 1	**Factor 2**	**Factor 3**
Pain severity	0.61	0.22	-0.27
Pain frequency	0.52	0.36	0.13
Distension severity	0.61	-0.26	-0.22
Bowel habit satisfaction	0.56	-0.13	0.22
Symptom affect daily life	0.71	-0.12	0.15
Variance explained (%)	47.1	16.7	15.2

Table 7.2 Factor matrix. The table shows the factor loadings of each IBS-SSS item onto three factors of the IBS-SSS and their percent of variance explained.

Although the IBS-SSS may capture a limited picture of symptoms contributing to severity, the question remains as to whether or not it reliably measures those particular symptoms. Cronbach's alpha is a reliability coefficient that ranges from 0-1 and determines whether items in a questionnaire measure the same thing [273]. Bland and Altman suggest that a questionnaire with an alpha score between 0.70-0.80 is satisfactory for research purposes, but should be ≥ 0.90 for clinical purposes. The proposed guideline creates an interesting dilemma for the IBS-SSS because its alpha value is 0.702, wherein each of the items should be retained (Table 7.3). As mentioned previously, the IBS-SSS is a practitioner derived questionnaire designed for use in the clinic. Therefore, an alpha of 0.702 indicates that the IBS-SSS is not a satisfactory instrument, yet one could argue that it does meet the minimum research requirement. Given the limited nature of the variation captured and the low alpha value, I suggest that clinicians and researchers should exercise prudence when

interpreting the IBS-SSS. If researchers continue using the IBS-SSS, they should modify the questionnaire to achieve greater reliability and to capture more variation. Suggestions for how this may be accomplished are discussed in Section7.6 along with the limitations and implications of these analyses.

IBS-SSS Item	Scale mean if item deleted	Cronbach's α if item deleted
Pain severity	225.7	0.65
Pain frequency	234.4	0.69
Distension severity	222.0	0.66
Bowel habit satisfaction	214.4	0.68
Symptom affect daily life	217.9	0.62

Table 7.3 IBS-SSS item Cronbach's alpha statistics. Scale mean is 278.6, $\alpha = 0.702$

7.4 TCM Diagnosis and Outcome

Findings in the previous section suggest that the primary outcome measure (IBS-SSS) only partially captures the variation in patients' symptom severities and that it does so with limited reliability. Therefore, the answer to the second research question, 'is there a difference in outcome for patients with particular TCM diagnoses' should be interpreted with caution. Nonetheless, the exploratory nature of the analyses in this section may still generate useful hypotheses. The purpose of this section is to assess patients' outcomes in relation to their TCM diagnoses, which may provide information on the relative importance of TCM diagnosis differentiation (Chapter 10). I hypothesised that patients with excess patterns such as liver qi stagnation or damp heat would be more likely to report improvements than patients with mixed patterns such as cold damp or combined liver qi stagnation and spleen qi deficiency, or deficient patterns such as spleen qi deficiency, yang deficiency, and yin deficiency. I based the hypothesis on the premise that excess patterns are commonly associated with the acute, short phase of a disease [278]. Furthermore, deficient patterns are associated with chronic illness and slow recovery. To assess the patients' outcomes with regard to their diagnoses, the data were descriptively compared then analysed by linear regression. The descriptive analyses compare the mean score changes on the IBS-SSS and SF-12 across the different TCM diagnoses, while the linear regression models analyse whether differences in TCM diagnosis are predictive of different outcomes.

7.4.1 Descriptive Statistics

The descriptive comparisons provide an opportunity to become familiar with the data and to identify any peculiarities that may highlight a particular diagnosis. Table 7.4 compares the seven TCM diagnoses in terms of the mean score changes for the IBS-SSS. As mentioned in Chapter 4, the IBS-SSS is scored from 0 – 500 and a fifty point decrease is considered clinically significant [128]. Furthermore, analyses in Chapter 6 suggest that patients' IBS-SSS baseline scores were not predictive of their TCM diagnosis. Data in Table 7.4 indicate that the mean IBS-SSS scores decreased at least fifty points for each diagnosis over a six month period, and that the majority of changes occurred during the treatment phase of the study (0 – 3 months). Because these scores only represent the acupuncture patients and the three month follow-up was the first data collection point after baseline, some of the change may be attributed to regression to the mean. Figure 7.3 depicts the difference in change more clearly, in that the diagnoses with the highest baseline scores (yang deficiency, spleen qi deficiency, yin deficiency, and cold damp) had the largest mean decreases and the diagnosis with the lowest baseline score (damp heat) had the smallest mean decrease. With regard to the hypothesis, the mean scores suggest that deficient conditions improve the most supporting the null hypothesis. However, a study by Whitehead *et al* reported similar findings wherein IBS patients with the most severe symptoms showed the largest quantitative improvement, yet they were less likely to classify themselves as experiencing adequate symptom relief [136]. Therefore, the differences in outcome may be related to higher baseline scores for patients with those diagnoses.

TCM Diagnosis	Baseline (SD)	3 month (SD)	6 month (SD)
Yang deficiency	308.9 (93.5)	268.3 (74.0)	214.9 (92.8)
Spleen qi deficiency	277.7 (107.3)	185.7 (107.8)	171.8 (122.6)
Yin deficiency	304.9 (78.6)	221.1 (139.2)	196.6 (126.9)
Damp heat	238.7 (65.6)	190.5 (107.5)	184.7 (90.9)
Cold damp	303.6 (85.7)	215.2 (111.8)	198.1 (97.3)
Combined	262.0 (63.7)	233.4 (53.8)	204.9 (63.1)
Liver qi stagnation	276.9 (80.4)	217.4 (70.7)	212.6 (70.4)
All Diagnoses	279.0 (81.7)	215.5 (95.6)	198.6 (89.5)

Table 7.4 IBS-SSS mean score changes by TCM diagnosis. The table shows the mean IBS-SSS scores (and standard deviations) for each TCM diagnosis at baseline, three months and six months.

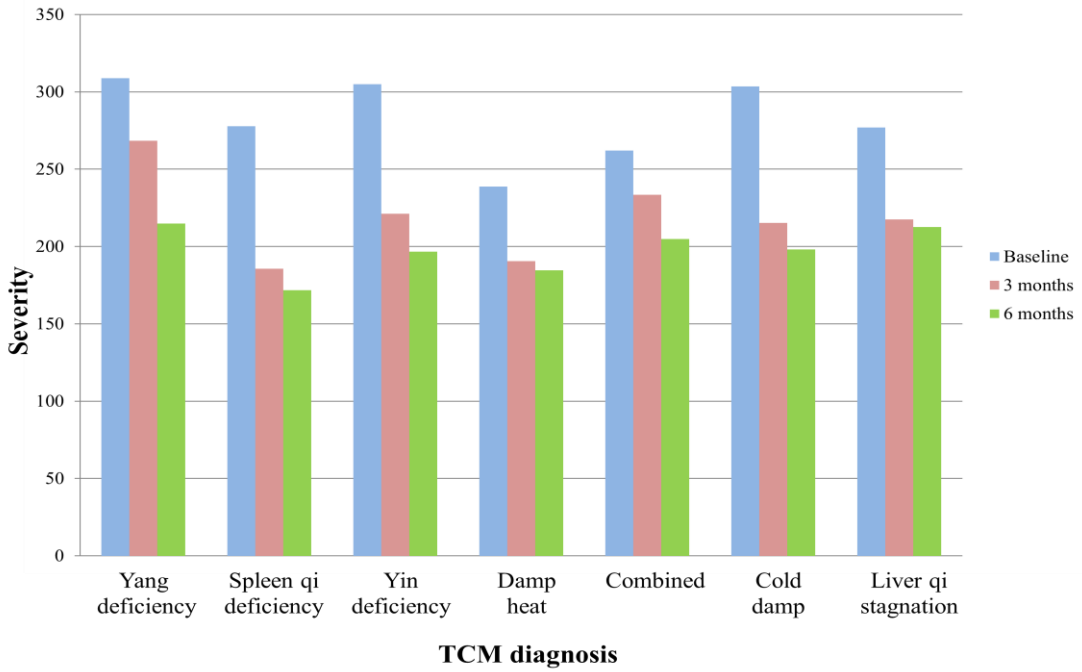


Figure 7.3 IBS-SSS mean score changes by TCM diagnosis

Having compared the mean score changes for the condition specific measure, Table 7.5 compares the mean scores for the global outcome measure. As described in Chapter 4, the SF-12 may be presented as raw scores to facilitate within group comparisons (Appendix E 3), or as norm scores to facilitate population comparisons [253]. One notable feature of Table 7.5 is that patients in five of the seven TCM diagnoses scored lower in the mental health component (MCS) than the physical health component (PCS) at baseline. The MCS scores are not only lower than the PCS, but fall 8 – 15 points below the population norm (i.e. 50), while the PCS scores only fall 0 – 7 points below. Figure 7.4 illustrates the change in vitality scores, which appear to be an influential contributor to the low MCS averages, with raw scores in the 30s, and a key health domain where patients improved. The apparent lack of vitality corresponds to the description of fatigue as one of the patients' primary complaints (Table 6.3) and an area of improvement (Chapter 8). Similar to the improvements in the IBS-SSS, the patients in particular diagnoses were likely to improve the most in domains they scored the lowest or which were lower than the other diagnoses. With regard to the hypothesis, data from the SF-12 indicate that the hypothesis may be false.

		Norm Score					Norm Score		
Dx	**Scale**	**BL**	**3 mo**	**6 mo**	**Dx**	**Scale**	**BL**	**3 mo**	**6 mo**
Yang deficiency	GH	39.6	37.7	43.5	**Combined**	GH	44.6	44.6	47.3
	PF	51.1	51.6	50.3		PF	53.4	50.6	53.0
	BP	42.2	44.3	48.7		BP	49.7	49.2	48.6
	VT	41.5	37.7	43.4		VT	44.2	45.9	44.4
	SF	43.9	39.3	46.5		SF	46.5	46.5	47.1
	MH	49.3	41.9	48.9		MH	42.7	41.7	42.6
	RE	51.9	41.7	50.5		RE	47.5	48.4	46.0
	RP	44.5	47.3	49.9		RP	51.2	52.9	49.8
	PCS	43.0	47.9	48.1		PCS	52.4	51.3	52.4
	MCS	48.2	37.4	47.3		MCS	42.2	43.8	42.1
Spleen deficiency	GH	44.1	43.3	42.4	**Liver qi stagnation**	GH	44.4	46.3	45.7
	PF	52.2	47.9	52.2		PF	51.7	51.7	51.5
	BP	48.3	50.6	54.4		BP	46.1	48.1	47.6
	VT	39.7	45.5	43.7		VT	43.1	47.0	48.2
	SF	38.4	45.3	46.5		SF	45.7	49.3	48.8
	MH	38.3	44.2	42.6		MH	41.9	45.8	46.0
	RE	41.5	44.9	46.6		RE	44.7	49.6	48.6
	RP	45.7	49.0	49.8		RP	49.1	50.9	49.9
	PCS	51.4	50.0	52.5		PCS	50.2	50.4	50.1
	MCS	35.4	42.0	41.7		MCS	41.6	46.6	46.1
Yin deficiency	GH	43.2	47.1	39.1	**Cold damp**	GH	39.4	43.1	42.3
	PF	47.9	50.7	50.0		PF	49.0	48.9	49.4
	BP	41.8	45.6	44.7		BP	44.3	47.3	45.3
	VT	43.9	47.8	44.0		VT	41.3	47.8	47.8
	SF	41.8	41.4	38.9		SF	42.9	46.5	46.5
	MH	41.6	40.2	36.3		MH	45.5	43.7	47.4
	RE	42.7	44.0	40.7		RE	48.2	51.1	51.5
	RP	48.0	47.6	48.5		RP	47.2	46.6	48.3
	PCS	47.2	50.6	49.8		PCS	45.7	46.9	46.0
	MCS	40.8	40.4	35.8		MCS	45.7	47.0	48.8
Damp heat	GH	40.7	40.9	42.8	**Total**	GH	42.5	43.8	43.9
	PF	47.0	45.6	46.5		PF	50.5	49.6	50.4
	BP	43.2	45.6	43.5		BP	45.3	47.4	47.3
	VT	42.7	45.1	46.2		VT	42.5	46.1	46.1
	SF	42.9	43.3	43.3		SF	43.8	45.5	46.1
	MH	41.1	44.0	43.0		MH	42.6	43.6	44.4
	RE	43.8	44.3	45.5		RE	45.4	47.2	47.5
	RP	45.9	46.8	48.0		RP	47.9	49.1	49.2
	PCS	46.7	45.7	46.3		PCS	48.6	49.0	49.2
	MCS	41.3	43.6	43.7		MCS	41.9	44.1	44.4

Table 7.5 Mean comparisons of SF-12. Domains of health: GH – general health, PF – physical health, BP – body pain, VT – vitality, SF- social function, MH – mental health, RE – role emotional, RP – role physical, PCS – physical component score, MCS – mental component score. The population norm is 50.

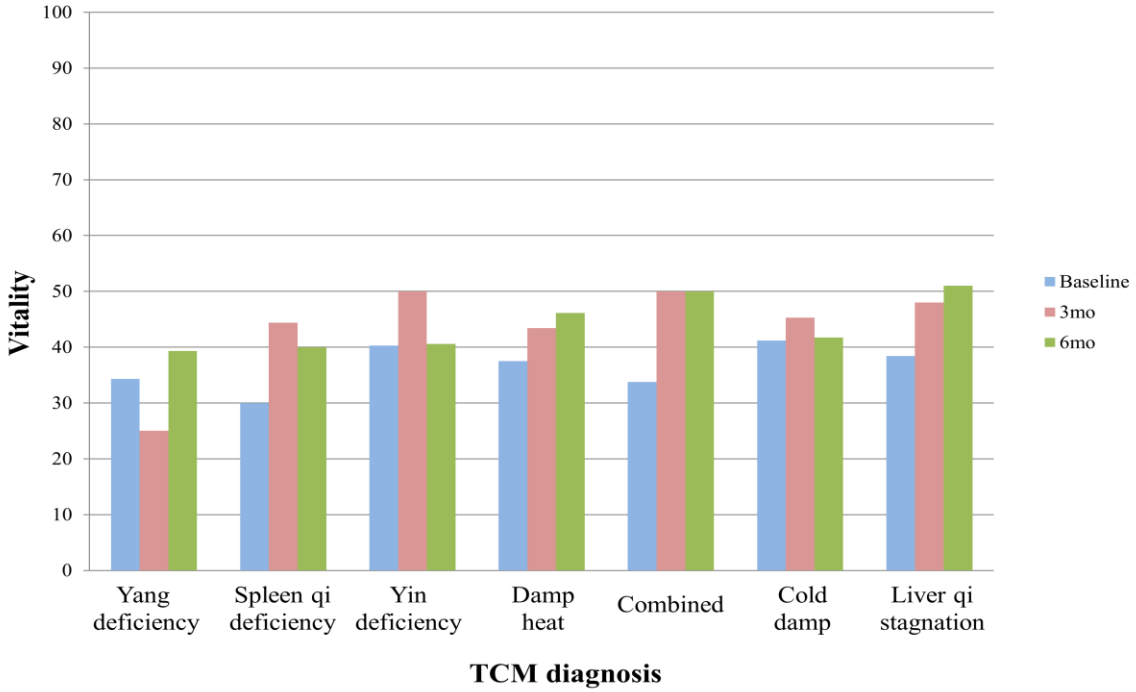


Figure 7.4 Vitality domain mean raw score changes by TCM diagnosis

In general, the descriptive statistics suggest that patients' IBS symptoms improved at clinically significant levels irrespective of their TCM diagnosis. Although Figure 7.3 suggests that patients with particular diagnoses such as yang deficiency had higher baseline scores (more severe IBS), the analyses in Chapter 6 indicate that the differences among baseline means are insignificant. Whether or not the mean scores at three and six months are significantly different is discussed in the next section. Additionally, the SF-12 comparison perhaps provides the most interesting data that suggests patients physical functioning is similar to the population norm, while their mental functioning falls much lower. Based on the comparisons it appears that patients had a better chance of improving in their MCS than PCS irrespective of diagnosis further analysed in the following section. With regard to the hypothesis that patients with excess patterns would be more likely to improve than patients with deficient patterns, the descriptive comparisons indicate that it may be false.

7.4.2 Linear Regression

While descriptive analyses suggest that patients with deficient diagnoses may improve more than others, further analyses were necessary to determine if the differences in outcome were significant. Multiple linear regression was used to determine the predictive ability of patients' baseline scores, TCM diagnoses, age, sex, and duration of IBS (i.e. independent variables) on their outcomes at three and six months (i.e. dependent variables). Before running the regression analyses, there are several key assumptions to address. First, we must assume that the data for the dependent variables are normally distributed (Figure 7.5). Plots of the standardised dependent residuals were also produced and support the assumption (Appendix E 4). Second, we must assume that the observations are independent of each other. Third, the assumptions regarding homoscedasticity (i.e. there is a constant variance among the residuals of the predictor variables), collinearity (i.e. no linear relationship exists between two or more of the predictors), and linearity (i.e. a linear relationship exists between the outcome and predictor variables) were all examined post hoc [254]. Specifically, I plotted the standardised residuals against the standardised predicted values of the dependent variable, which shows randomly dispersed dots around zero when data meet the homoscedasticity and linearity assumptions. To address collinearity, I assessed the variance inflation factor (VIF) and tolerance statistics of each model. Models may have a problem with collinearity if the largest VIF is > 10 or if the tolerance is < 0.2 [254]. The results of the tests regarding the assumptions are discussed in the following sections.

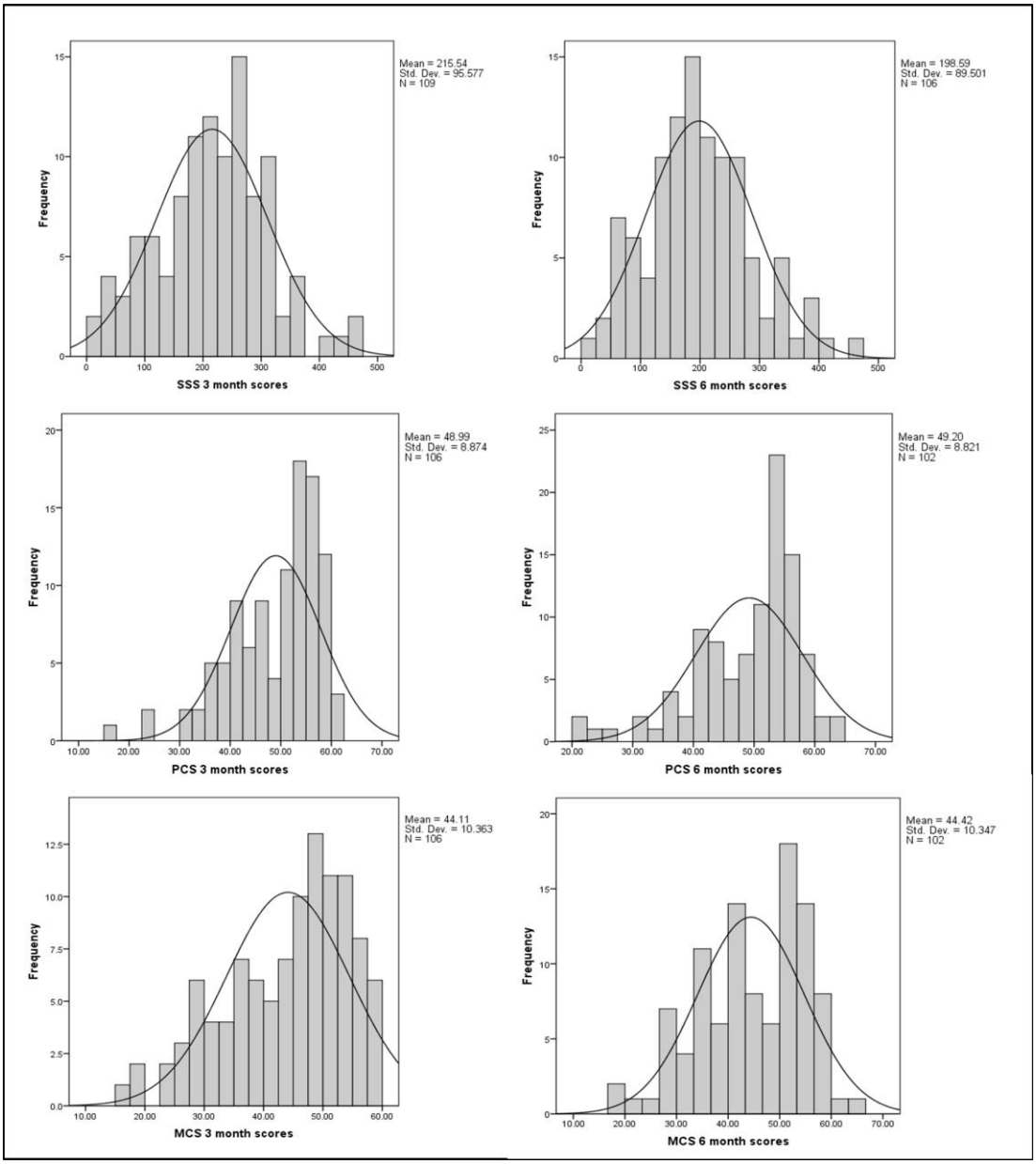


Figure 7.5 Distribution of dependent variables

The first set of models assessed the IBS-SSS and TCM diagnoses at three and six months. As mentioned previously, the hypothesis was that patients with excess patterns would report better outcomes than patients with deficient or mixed patterns. Because TCM diagnosis is a categorical variable, I coded the diagnoses as dummy variables and used liver qi stagnation as the reference category throughout this section. According to the first set of models, baseline severity is a significant predictor of outcome at both time points, but the TCM diagnoses are non-significant in comparison to liver qi stagnation (Table 7.6a). With regard to the goodness-of-fit, the F statistics ($F = 6.6$, $p < 0.001$; $F = 4.2$, $p < 0.001$) suggest that the models are a

good fit [254]. Additionally, Figure 7.6 illustrates that both the assumptions for homoscedasticity and linearity were met as evidenced by the random display of dots around zero. With regard to the post hoc test for collinearity, the tolerance values ranged from 0.67 – 0.91 and the VIF ranged from 1.26 – 1.49, which suggests that there is no collinearity in the models [254]. See Appendix E 5 for details of the post hoc tests.

	3 month			6 month		
Covariate	**Beta**	**95% CI**	**Sig.**	**Beta**	**95% CI**	**Sig.**
SSS baseline	0.64	0.44, 0.85	*	0.54	0.33, 0.75	*
Yin deficiency	-19.0	-72.7, 41.8		-21.4	-79.7, 36.9	
Yang deficiency	37.0	-28.9, 110.2		-4.17	-73.2, 64.9	
Spleen deficiency	-33.6	-90.5, 30.9		-37.0	-97.3, 23.2	
Damp heat	-9.28	-49.2, 49.3		-3.59	-53.4, 46.2	
Cold damp	-20.5	-68.0, 34.2		-26.4	-78.1, 25.3	
Combined	29.4	-18.7, 85.5		9.01	-42.9, 60.9	

Table 7.6a Models of IBS-SSS outcome at three and six months by TCM diagnosis. Three month: $\beta = 42.5$, $R^2 = 0.32$. Six month: $\beta = 59.1$, $R^2 = 0.23$. * $p < 0.001$.

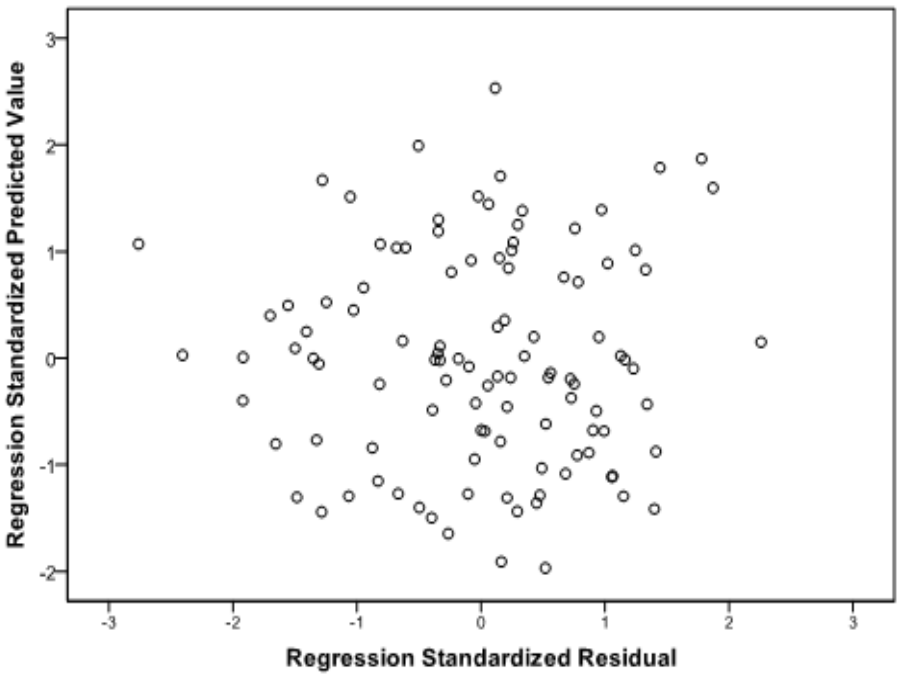


Figure 7.6 Residual plot of IBS-SSS 3 month scores. Shows homoscedasticity and linearity assumptions are met. See Appendix E 5 for 6 month plot.

Considering that IBS is more likely to be diagnosed in women (in the West) [82], be more severe in patients under the age of 50 [121], and is a chronic condition, the patient specific characteristics age, sex, and duration of IBS were added to the

model. According to the F statistics ($F = 5.5$, $p < 0.001$; $F = 3.0$, $p = 0.003$), the models are a good fit. At three months, age was a significant predictor of outcome regardless of sex, baseline severity, duration of IBS, and TCM diagnosis; however, the significance was not maintained at six months (Table 7.6b). Specifically, a one year increase in age is associated with a higher score (worse outcome) on the IBS-SSS (i.e. SSS 3 month score = (1.58*Age) – 40.3). As with the previous models, I examined post hoc tests for the regression assumptions. To not be overly repetitive, these data are available in Appendix E 6 and show that the assumptions were met.

	3 month			6 month		
Covariate	**Beta**	**95% CI**	**Sig.**	**Beta**	**95% CI**	**Sig.**
SSS baseline	0.72	0.49, 0.94	**	0.48	0.23, 0.72	**
Age	1.58	0.16, 3.0	*	-0.34	-1.85, 1.17	
Sex	-12.9	-56.9, 31.1		7.27	-40.9, 55.5	
Duration	-0.63	-2.49, 1.22		1.26	-0.66, 3.19	
Yin deficiency	-6.42	-63.1, 50.2		-10.9	-73.2, 51.4	
Yang deficiency	42.6	-26.1, 111.3		2.19	-68.8, 73.2	
Spleen deficiency	-9.09	-71.1, 52.9		-33.1	-97.7, 31.4	
Damp heat	-3.31	-54.5, 47.9		-8.74	-62.8, 45.3	
Cold damp	-5.27	-57.0, 46.5		-23.3	-77.7, 31.2	
Combined	40.6	-12.6, 93.9		12.9	-42.4, 68.1	

Table 7.6b Adjusted models of IBS-SSS outcome at three and six months by TCM diagnosis. Three month: $\beta = -40.3$, $R^2 = 0.37$. Six month: $\beta = 66.4$, $R^2 = 0.25$.
* $p \leq 0.05$, ** $p < 0.001$

The second set of models assessed the PCS and TCM diagnoses at three and six months. According to the F statistics ($F = 17.7$, $p < 0.001$; $F = 12.5$, $p < 0.001$), the models are a good fit. Similar to the previous models, homoscedasticity, collinearity, and linearity were assessed post hoc (Appendix E 7). The results suggest that the data met each of these assumptions. Additionally, the models indicate that baseline PCS is a significant predictor of outcome at both time points, but TCM diagnosis is not (Table 7.7a).

Subsequently, the models were adjusted for age, sex, and duration of IBS. Although the models were a good fit ($F = 13.1$, $p < 0.001$; $F = 9.4$, $p < 0.001$), none of the additional factors were significant predictors of PCS outcome (Table 7.7b). Detailed model outputs including tests for the assumptions are in Appendix E 8 show that the assumptions are met.

	3 month			6 month		
Covariate	**Beta**	**95% CI**	**Sig.**	**Beta**	**95% CI**	**Sig.**
PCS baseline	0.74	0.60, 0.87	**	0.67	0.52, 0.83	**
Yin deficiency	2.34	-1.73, 6.41		0.94	-4.15, 6.03	
Yang deficiency	3.26	-1.77, 8.29		3.12	-2.35, 8.59	
Spleen deficiency	-1.47	-5.95, 3.00		1.86	-2.82, 6.54	
Damp heat	-0.47	-4.15, 3.22		-1.01	-4.97, 2.95	
Cold damp	2.09	-1.75, 5.92		1.12	-3.13, 5.38	
Combined	-0.07	-3.76, 3.63		1.33	-2.76, 5.41	

Table 7.7a Models of PCS outcome at three and six months by TCM diagnosis. Three month: $\beta = 13.1$, $R^2 = 0.57$. Six month: $\beta = 16.0$, $R^2 = 0.50$. ** $p < 0.001$

	3 month			6 month		
Covariate	**Beta**	**95% CI**	**Sig.**	**Beta**	**95% CI**	**Sig.**
PCS baseline	0.75	0.60, 0.89	**	0.69	0.53, 0.85	**
Age	0.02	-0.08, 0.12		0.02	-0.09, 0.14	
Sex	1.24	-1.79. 4.27		3.24	-0.21, 6.69	
Duration	-0.06	-0.20, 0.07		-0.10	-0.25, 0.05	
Yin deficiency	1.91	-2.14, 5.96		0.42	-4.70, 5.54	
Yang deficiency	2.85	-2.12, 7.81		3.05	-2.43, 8.53	
Spleen deficiency	-2.24	-6.79, 2.31		1.03	-3.83, 5.89	
Damp heat	0.15	-3.61, 3.91		-0.35	-4.47, 3.77	
Cold damp	1.32	-2.61, 5.25		0.13	-4.27, 4.54	
Combined	-0.10	-3.89, 3.69		-0.04	-4.29, 4.21	

Table 7.7b Adjusted models of PCS outcome at three and six months by TCM diagnosis. Three month: $\beta = 12.2$, $R^2 = 0.60$. Six month: $\beta = 13.2$, $R^2 = 0.53$. ** $p < 0.001$

The third set of models assessed the MCS and TCM diagnoses at three and six months (Appendix E 9). The F statistics ($F = 5.9$, $p < 0.001$; $F = 6.2$, $p < 0.001$) of these models suggest that they are a good fit. The models indicate that baseline MCS is a significant predictor of outcome at both time points, and that patients with yang deficiency (at 3 months) and yin deficiency (at 6 months) reported a significantly different outcome than patients with liver qi stagnation (Table 7.8a). Based on the regression equations (e.g. MCS 3 month score = (-13.0*Diagnosis) + 28.1) patients with yang deficiency and yin deficiency had a worse outcome (lower scores) than patients with liver qi stagnation.

Similar to the previous models, these models were adjusted for age, sex, and duration of IBS. The F statistics ($F = 4.3$, $p < 0.001$; $F = 4.3$, $p < 0.001$) of these models suggest that they are a good fit. Although the significant differences between liver qi stagnation and yin and yang deficiencies remained, none of the additional factors

were predictive of outcome (Table 7.8b). See Appendix E 10 for post hoc tests that indicate the assumptions were met.

	3 month			6 month		
Covariate	**Beta**	**95% CI**	**Sig.**	**Beta**	**95% CI**	**Sig.**
MCS baseline	0.46	0.29, 0.62	**	0.44	0.27, 0.60	**
Yin deficiency	-5.76	-12.1, 0.58		-8.69	-15.9, -1.45	*
Yang deficiency	-13.0	-20.7, -5.12	**	-1.82	-9.52, 5.87	
Spleen deficiency	-2.77	-9.82, 4.37		-1.76	-8.48, 4.96	
Damp heat	-4.73	-10.4, 0.95		-2.46	-8.05, 3.14	
Cold damp	-2.34	-8.28, 3.59		1.28	-4.70, 7.27	
Combined	-4.38	-10.2, 0.62		-4.93	-10.8, 0.89	

Table 7.8a Models of MCS outcome at three and six months by TCM diagnosis. Three months: $\beta = 28.1$, $R^2 = 0.31$. Six months: $\beta = 28.1$, $R^2 = 0.33$. * $p \leq 0.05$, ** $p \leq 0.001$

	3 month			6 month		
Covariate	**Beta**	**95% CI**	**Sig.**	**Beta**	**95% CI**	**Sig.**
MCS baseline	0.47	0.30, 0.64	**	0.45	0.28, 0.62	**
Age	-0.09	-0.25, 0.06		-0.05	-0.21, 0.11	
Duration	0.15	-0.06, 0.37		0.06	-0.16, 0.28	
Sex	-1.07	-5.95, 3.81		-0.09	-5.15, 4.97	
Yin deficiency	-5.76	-12.2, 0.70		-8.71	-16.2, -1.33	*
Yang deficiency	-12.6	-20.4, -4.72	*	-1.85	-9.71, 6.00	
Spleen deficiency	-2.48	-9.83, 4.86		-1.93	-9.03, 5.18	
Damp heat	-5.63	-11.6, 0.32		-2.64	-8.57, 3.30	
Cold damp	-1.93	-8.16, 4.31		1.16	-5.18, 7.50	
Combined	-4.24	-10.3, 1.82		-3.60	-9.75, 2.55	

Table 7.8b Adjusted models of MCS outcome at three and six months by TCM diagnosis. Three months: $\beta = 30.2$, $R^2 = 0.33$. Six months: $\beta = 28.9$. $R^2 = 0.34$. * $p \leq 0.05$, ** $p \leq 0.001$

In general, the regression analyses suggest that the differences in outcome observed in the descriptive comparison were not related to sex or the duration of IBS. However, age appears to be a significant predictor of outcome on the IBS-SSS at three months with older patients reporting worse outcomes. In comparison, a recent study by Witt *et al* reports that patients under fifty experienced better outcomes from acupuncture for chronic pain than older patients [279]. Although there is some consistency between the studies, the controversial reliability and limited ability of IBS-SSS to capture symptom variation suggest that the IBS-SSS analyses should be interpreted with caution.

None of the factors was associated with changes in the PCS, which is unsurprising because patients averaged relatively normal scores at baseline. Therefore, a larger sample size would be necessary to detect a difference in outcome. In contrast, patients averaged poor scores on the MCS at baseline. The differences in patients' outcomes on the MCS provide the first empirical evidence that patients with deficient conditions may not experience the same degree of improvement as patients with excess conditions. The evidence supports statements from both the pre-trial interviews (Chapter 5) and the nested acupuncturist interviews (Chapter 9) regarding the slow improvement of older and/or deficient patients. Since the analyses are exploratory and involve small sample sizes across the diagnoses, the findings need to be verified by subsequent studies. In addition to analysing the patients' TCM diagnoses, this chapter investigates the relationship between patients' outcomes and the acupuncturists' prognoses.

7.5 The Acupuncturists' Prognoses

While data from the previous section highlight a possible difference in outcome related to TCM diagnosis, this section explores the relationship between the acupuncturists' prognoses and patients' outcomes. The influence of the acupuncturist's belief in the likelihood of a particular outcome may be a latent factor not reflected in the diagnosis or treatment design, while their prognoses may provide information on the type of patients likely to benefit from acupuncture. Additionally, there may be a relationship between the acupuncturist's prognosis and the patient's belief that acupuncture may work. As mentioned in Chapter 3, studies report conflicting findings as to whether patients' attitudes toward acupuncture influence their treatment outcomes [199, 203, 280]. Initially, data on the prognoses and beliefs were descriptively compared (Figure 7.7 & Table 7.9). The comparison of acupuncturists' prognoses suggests that patients were roughly split between the prognoses 'good' and 'don't know'. Comparing the patients' beliefs posed a challenge because the baseline questionnaire asked two questions: 1) do you think acupuncture can work and 2) do you think acupuncture may help your IBS. As indicated by Table 7.9, thirty-four patients gave different responses most commonly 'yes, acupuncture can work' and 'don't know if it will help my symptoms'. The difference in responses highlights the importance of a question's wording and offers

a potential explanation for the difference in findings about patients' beliefs mentioned above. Because patients appear to believe that acupuncture can work, but are unsure if it will affect their IBS, both questions were included in subsequent analyses. The following subsections evaluate the relationship between prognosis and belief; prognosis and acupuncturist; and prognosis and outcome.

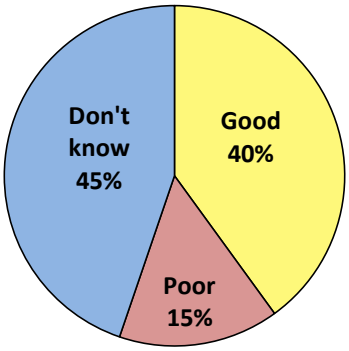


Figure 7.7 Patients' prognoses (n = 105)

Can acupuncture work?				Will acupuncture help my IBS?			
	Men	Women	Total (%)		Men	Women	Total (%)
Yes	8	53	61 (52%)	Yes	4	27	31 (27%)
No	1		1 (1%)	No	1		1 (1%)
Don't know	12	42	54 (47%)	Don't know	16	68	84 (72%)

Table 7.9 Patients' beliefs derived from baseline questionnaires (n = 116)

7.5.1 Prognosis Versus Belief

As indicated by the descriptive comparison, the acupuncturists assigned 85% of patients a 'good' or 'don't know' prognosis, while only 15% were assigned a 'poor' prognosis. The patients' beliefs are more complex and suggest that many patients believed acupuncture may work but not necessarily relieve their IBS symptoms. The purpose of analysing the patients' beliefs and the acupuncturists' prognoses was to determine their relationship. I hypothesised that the patients' beliefs and the acupuncturists' prognoses would positively correlate.

To test the hypothesis, data were analysed via cross tabulation and chi-squared test. The methods were deemed appropriate on the basis that cross tabulation and chi-square determine the significance of a relationship between categorical variables

[254]. Before conducting the analyses, we must make two assumptions. First, each of the prognoses may only contribute to one cell of the contingency table, and second each cell should have an expected count greater than five [254]. According to the baseline questionnaire, the patients could answer 'no', 'yes', or 'don't know' to both questions about belief. Since only one patient answered 'no', that category was combined with 'don't know' to eliminate the problem of cells with too few observations (Tables 7.10a & 7.10b). The analyses revealed that there is no significant association between patients' beliefs that acupuncture can work and their prognoses, or between their beliefs that their IBS symptoms may improve and their prognoses. The finding supports the null hypothesis that there is no relationship between these variables.

			Belief acupuncture can work		
			Yes	**Don't know**	Total
Prognosis	**Good**	Count	23	19	42
		Percent	42.6	37.3	40.0
	Poor	Count	8	8	16
		Percent	14.8	15.7	15.2
	Don't know	Count	23	24	47
		Percent	42.6	47.1	44.8
Total		Count	54	51	105
		Percent	100.0	100.0	100.0

Table 7.10a Cross tabulation: Prognosis vs. Belief acupuncture can work (n= 105)
$\chi^2 = 0.32$, $p = 0.85$

			Belief acupuncture will help IBS		
			Yes	**Don't know**	Total
Prognosis	**Good**	Count	14	28	42
		Percent	53.8	35.4	40.0
	Poor	Count	2	14	16
		Percent	7.7	17.7	15.2
	Don't know	Count	10	37	47
		Percent	38.5	46.8	44.8
Total		Count	26	79	105
		Percent	100.0	100.0	100.0

Table 7.10b Cross tabulation: Prognosis vs. Belief Acupuncture helps IBS (n = 105)
$\chi^2 = 3.25$, $p = 0.20$

7.5.2 Prognosis Versus Acupuncturist

Although patients' beliefs and prognoses do not appear to be related, the importance of practitioners' preferences on treatment design (Chapter 6) warrants analysis of prognosis preferences. The purpose of analysing the relationship between the acupuncturist and prognosis was to determine whether the acupuncturists routinely assign the same prognosis. Establishing a correlation would support the inference that the practitioners have preferred prognoses and may imply a limited usefulness of this information. Moreover, if practitioners routinely specified the same prognosis, it may explain the lack of association between the prognoses and the patients' beliefs. Based on the descriptive comparison in Table 7.11, which suggests the acupuncturists do have a preferred prognosis, I hypothesised that the acupuncturists would have a positive association with the prognoses.

	Prognosis		
Acupuncturist	Good	Poor	Don't know
Beth	1	1	0
Cindy	3	2	7
Lisa	1	7	13
Jill	9	1	0
Holly	4	0	4
Ellen	2	2	6
Marie	5	2	9
Sam	12	0	4
John	5	1	4
Total	42	16	47

Table 7.11 Acupuncturists' prognoses. The table shows the frequency each acupuncturist used each prognosis.

Similar to the previous section, the categorical nature of the data necessitated the use of a cross tabulation. A chi-square could not be accurately calculated because there were too many cells with counts below the minimum level; therefore, I used a Fisher's exact test. A Fisher's exact test can determine the significance of a relationship between categorical variables with small sample sizes [281]. The analyses revealed that there is a significant association ($p < 0.001$) between the acupuncturist and the prognosis (Appendix E 11). Considering that the qualitative data in Chapter 6 suggest that there is a association between the acupuncturist and diagnosis, and that previous analysis indicates a significant association between the acupuncturist and prognosis, the data were further analysed to determine the

relationship between the prognosis and diagnosis. Based on the findings, I hypothesised that the prognoses would not be associated with particular diagnoses. The cross tabulation and Fisher's exact reveal that there is not a significant association ($p = 0.20$) between the prognosis and diagnosis (Appendix E 11). In light of the previous finding, the non-significance adds to the importance of the acupuncturist's preference in making a prognosis. This finding contrasts with the interview comments that suggest patients with deficient conditions experience poorer outcomes, and the exploratory finding that deficient patients' experience less improvement than patients with the excess diagnosis liver qi stagnation. However, the low power of the Fisher's exact test [281] and small sample size limit the usefulness of these findings.

7.5.3Prognosis Versus Outcome

Although the prognoses appear to be related to the acupuncturists, the question remains as to whether they are predictive of outcome. As discussed in Section 7.4.2, multiple linear regression is an appropriate method to determine the predictive ability of patients' baseline scores, prognoses, age, sex, and duration of IBS (i.e. independent variables) on their outcomes at three and six months (i.e. dependent variables). Because prognosis is a categorical variable, I coded the prognoses as dummy variables and used 'poor prognosis' as the reference category throughout this section. Recall that the histograms in Figure 7.5 and the plots of the residuals for previous models demonstrate that the three and six month outcomes for the IBS-SSS and SF-12 composite scores (i.e. PCS & MCS) were normally distributed. Post hoc tests for the assumptions regarding homoscedasticity, linearity, and collinearity are presented in the appendix. Based on the finding that prognoses appear to be related to the acupuncturists I hypothesised that they would not be predictive of outcome.

The first set of models analysed prognoses and the IBS-SSS at three and six months. Similar to the regression models in Section 7.4.2, these models are a good fit ($F = 14.9$, $p < 0.001$; $F = 10.7$, $p < 0.001$). At three months, both 'don't know' and 'good' prognoses are significant predictors of outcome in comparison to 'poor' prognoses, but the significance is only maintained at six months by the 'don't know' prognosis (Table 7.12a). Patients with these prognoses reported outcomes that were 59 – 64

points lower (i.e. better) than patients with a poor prognosis. See Appendix E 12 for post hoc tests.

Age, sex, and duration of IBS were subsequently added to the model to analyse individual characteristics. The models are a good fit (F = 8.38, p < 0.001; F = 5.35, p < 0.001). Both 'good' and 'don't know' prognoses remain significant in comparison to 'poor prognoses' and age is also significant (Table 7.12b). Similar to the model in Section 7.4.2 (Table 7.6b), a one year increase in age is associated with a higher score (worse outcome) on the IBS-SSS in this model. Details of the post hoc tests are presented in Appendix E 13.

	3 month			6 month		
Covariate	**Beta**	**Sig.**	**95% CI**	**Beta**	**Sig.**	**95% CI**
SSS baseline	0.57	**	0.37, 0.77	0.437	**	0.23, 0.64
Prognosis – good	-58.6	*	-106.9, -10.4	-46.9	*	-97.2, 3.36
Prognosis – don't know	-63.9	*	-112.6, -15.3	-67.3	*	-118.3, -16.2

Table 7.12a Models of IBS-SSS outcome at three and six months by prognosis. Three months: β = 106.8, R^2 = 0.32. Six months: β = 127.5, R^2 = 0.26. * p ≤ 0.05, ** p < 0.001

	3 month			6 month		
Covariate	**Beta**	**Sig.**	**95% CI**	**Beta**	**Sig.**	**95% CI**
SSS baseline	0.68	**	0.45, 0.90	0.38	*	0.13, 0.63
Age	1.67	*****	0.25, 3.10	-0.51		-1.96, 0.95
Sex	-16.8		-61.8, 28.3	2.06		-46.3, 50.4
Duration	-0.90		-2.73, 0.94	1.42		-0.44, 3.27
Prognosis – good	-54.8	*****	-104.7, -4.78	-40.3		-93.9, 13.3
Prognosis – don't know	-54.7	*****	-104.9, -4.43	-63.2	*****	-118.1, -8.31

Table 7.12b Adjusted models of IBS-SSS outcome at three and six months by prognosis. Three months: β = 26.9, R^2 = 0.36. Six months: β = 140.6, R^2 = 0.27. * p ≤ 0.05, ** p < 0.001

The second set of models analysed the patients' PCS scores and prognoses. The models were a good fit (F = 42.2, p < 0.001; F = 30.0, p < 0.001) at three and six months respectively. Additionally, the models indicate that a 'good' prognosis is a significant predictor of outcome at three months (Table 7.13a). Patients with a good prognosis reported a 4.6 point increase on the PCS in comparison to patients with poor prognoses. Similar to the models above, the PCS models were subsequently

adjusted for age, sex, and duration of IBS (Table 7.13b) and were a good fit (F = 21.3, p < 0.001; F = 16.2, p < 0.001) at three and six months respectively. While a good prognosis continued to be a significant predictor of outcome, age, sex, and duration of IBS were not significant. Details of the post hoc tests are presented in Appendices E 14 – 15.

	3 month			6 month		
Covariate	**Beta**	**Sig.**	**95% CI**	**Beta**	**Sig.**	**95% CI**
PCS baseline	0.66	**	0.53, 0.79	0.66	**	0.51, 0.80
Prognosis – good	4.60	*	0.71, 8.49	4.15		-0.33, 8.63
Prognosis – don't know	2.96		-0.81, 6.74	3.70		-0.69, 8.09

Table 7.13a Models of PCS outcome at three and six months by prognosis. Three months: β = 14.3, R^2 = 0.59. Six months: β = 14.3, R^2 = 0.51. * p ≤ 0.05, ** p < 0.001

	3 month			6 month		
Covariate	**Beta**	**Sig.**	**95% CI**	**Beta**	**Sig.**	**95% CI**
PCS baseline	0.65	**	0.52, 0.79	0.65	**	0.50, 0.80
Age	0.02		-0.08, 0.12	0.01		-0.10, 0.12
Sex	1.18		-1.81, 4.17	2.78		-0.64, 6.19
Duration	-0.05		-0.18, 0.08	-0.08		-0.23, 0.07
Prognosis – good	4.51	*	0.63, 8.39	3.90		-0.54, 8.33
Prognosis – don't know	3.23		-0.54, 7.01	3.27		-1.08, 7.63

Table 7.13b Adjusted models of PCS outcome at three and six months by prognosis. Three months: β = 13.5, R^2 = 0.60. Six months: β = 12.9, R^2 = 0.55. * p ≤ 0.05, ** p < 0.001

The third set of models analysed the patients' MCS scores and prognoses. According to the F statistics (F = 10.3, p < 0.001; F =12.0, p < 0.001), these models are a good fit at three and six months respectively. A good prognosis remained significant across three and six months, indicating that patients with a good prognosis scored approximately seven points higher on the MCS in comparison to patients with a poor prognosis (Table 7.14a). Patients with a 'don't know' prognosis also reported an increase in their MCS scores; however, the difference was only significant at six months. The MCS models were subsequently adjusted for age, sex, and duration of IBS, and were a good fit (F = 5.32, p < 0.001; F = 6.43, p < 0.001) at three and six months respectively. However, age, sex, and duration of IBS were not significant

predictors of outcome (Table 7.14b). Details of the post hoc tests for these models are presented in Appendices E 16 – 17.

	3 month			6 month		
Covariate	**Beta**	**Sig.**	**95% CI**	**Beta**	**Sig.**	**95% CI**
MCS baseline	0.38	**	0.21, 0.55	0.40	**	0.23, 0.56
Prognosis – good	6.86	*	0.52, 13.2	8.14	*	1.60, 14.7
Prognosis – don't know	5.18		-1.01, 11.5	6.53	*	0.04, 13.0

Table 7.14a Models of MCS outcome at three and six months by prognosis. Three months: $\beta = 22.5$, $R^2 = 0.26$. Six months: $\beta = 21.3$, $R^2 = 0.30$. * $p \leq 0.05$, ** $p < 0.001$

	3 month			6 month		
Covariate	**Beta**	**Sig.**	**95% CI**	**Beta**	**Sig.**	**95% CI**
MCS baseline	0.39	**	0.22, 0.56	0.41	**	0.25, 0.58
Age	-0.08		-0.24, 0.08	-0.04		-0.20, 0.12
Sex	0.21		-4.73, 5.15	-0.47		-5.49, 4.55
Duration	0.14		-0.07, 0.36	0.08		-0.13, 0.30
Prognosis – good	6.95	*	0.53, 13.4	8.12	*	1.56, 14.7
Prognosis – don't know	4.78		-1.57, 11.1	6.84	*	0.31, 13.4

Table 7.14b Adjusted models of MCS outcome at three and six months by prognosis. Three months: $\beta = 23.7$, $R^2 = 0.28$. Six months: $\beta = 21.6$, R^2 0.32. * $p \leq 0.05$, ** $p < 0.001$

Overall, the regression analyses indicate that a good prognosis is predictive of a better outcome in comparison to a poor prognosis on both the IBS-SSS and the SF-12 composite scales. As such, this is the first study to provide empirical evidence that suggests the acupuncturists' prognoses may be a useful predictor of outcome.

7.6 Discussion

The previous sections present a variety of findings that are intended to address the second research question 'is there any difference in outcome for patients with particular TCM diagnoses'. Additionally, the findings address the sub-questions related to the validity and reliability of the IBS-SSS, and the ability of the acupuncturists' prognoses to predict patients' outcomes. In general, the exploratory regression analyses suggest that there may be a difference in outcome between patients with deficient TCM diagnoses (e.g. yin deficiency) and excess TCM diagnoses (e.g. liver qi stagnation). The regression analyses also suggest that age is a

potentially important predictor of outcome, but that sex and a patient's duration of IBS are not predictive of outcome. With regard to the sub-questions, the exploratory factor analysis suggests that the IBS-SSS captures approximately 47% of the variation in symptom severity and does so with limited reliability, while the acupuncturists' prognoses appear to be predictive of patients' outcomes. Beyond recapping the main findings, this section places them in the context of the literature, discusses implications, and reviews the strengths and limitations of the different analyses.

As discussed in Chapter 2, a patient's IBS severity is difficult to determine and may be interpreted differently depending on the perspective (e.g. patient or GP) or instrument used to evaluate severity. The IBS-SSS is a practitioner derived severity instrument that is valid according to its authors [128], but has questionable validity according to reviewers [231]. As such, the factor analysis and Cronbach's alpha provide useful information on the structure and reliability of the questionnaire. Considering that the IBS-SSS was designed as a clinical tool, the alpha value ($\alpha = 0.702$) suggests that it is not reliable for use in practice [273]. However, one could argue that the alpha value is sufficient for research purposes. A study by Kelley *et al* also evaluated the reliability of the IBS-SSS on a group of patients ($n = 289$) in an acupuncture study and reported a poorer reliability ($\alpha = 0.65$) [282]. Taken together the findings suggest that the IBS-SSS has limited reliability and may not be suitable for use in practice or research. The implications of this finding are that outcomes related to the IBS-SSS should be interpreted with caution, and that future studies should either employ an alternative questionnaire or re-design the IBS-SSS to improve reliability.

The development of a valid and meaningful IBS severity measure is an on-going project in the gastroenterology community [283]; therefore, the findings and suggestions have practical implications that may contribute to the design of a new severity measure. In terms of re-designing the questionnaire, the factor analysis data and severity discussion in Chapter 2 provide a useful starting point. Since the questionnaire items account for 47% of the variation in symptom severity, similar variables related to pain, frequency, and affect on daily life should be retained.

Variables that contribute to the remaining 53% of variation in symptom severity may include: dietary restrictions, fatigue, shame, embarrassment, and restrictions to social activities. Each of these areas was perceived to be important to patients and/or emerged from patients' interviews [91, 120, 122, 123]. Based on the variety of areas that patients and GPs perceive to be related to severity, I suggest that a re-designed questionnaire should emphasise two domains (i.e. physical and emotional) and allow for subcategories to form within the domains. Box 7.1 lists two examples of potential questions that may contribute to the different domains. The questionnaire development process may begin with 20 – 30 questions similar to those in Box 7.1 and through analyses determine which questions are the most appropriate. In contrast to the visual analogue scales (VAS) and binary questions listed in the IBS-SSS, the questions in Box 7.1 adopt a Likert format. I selected a different format for several reasons. First, a consistent style of question may improve clarity and face validity. Second, Guyatt *et al* suggest that the Likert format is more user-friendly than VAS and is easier for practitioners to interpret particularly regarding clinically significant changes [284]. Simply increasing the number of items in a questionnaire may increase reliability [254]; therefore, it is important that each item and/or factor be assessed for reliability. In addition to statistical psychometric and reliability testing, the questions should be qualitatively assessed by patients to establish content validity (i.e. how well patients perceive the questions to measure the various aspects of their condition) [285]. Content validity may be particularly important for a new IBS measure and may narrow the gap between patients and GPs perceptions of severity as discussed in Chapter 2.

How often do you experience abdominal pain?

1	2	3	4	5
Never	A little bit of time	Sometime	Most of the time	All the time

Do you feel embarrassed and/or ashamed about your IBS?

1	2	3	4	5
Never	A little bit of time	Sometime	Most of the time	All the time

Box 7.1 Example questions for re-designed IBS severity instrument

With regard to the strengths and limitations of the factor analysis, the large sample size (n = 228) is a key strength, while the variety of methods and subjective nature of the analysis are key limitations [275]. As mentioned in Section 7.3, I based my decision to extract factors and interpret the findings on multiple rather than a single source to overcome this limitation. Another limitation is that the findings from principal axis factoring may not be extrapolated to the entire population of IBS patients [254]. A separate factor analysis on another dataset is necessary to confirm the findings.

Considering the factor analysis and Cronbach's alpha data, the findings related to the regression analyses using the IBS-SSS should be interpreted with caution. Moreover, the exploratory nature of the regression analyses supports cautious interpretation. The collapsed categories of TCM diagnoses (Box 4.3) are a potential limitation because another researcher may interpret the diagnoses differently and create different categories. The relatively small sample sizes of each diagnostic category are also a potential limitation because they may reduce the power of the calculations. To detect a real difference between groups, the analyses should have a power ≥ 0.8 [254]. Post hoc power calculations indicate that sample size of the intervention group (n = 116) was adequate to detect a significant difference (power > 0.80) in the baseline and three month scores on the IBS-SSS (Appendix E 18). With regard to the subgroup analyses, the power calculations suggest that the six month models have better power than the three month models. Another potential limitation is that subgroup analyses may be criticised as a form of multiple testing, which increases the possibility of false positive findings (i.e. finding a significant difference between one or more subgroups when no difference actually exists) [286].

Since the patients participated in an individually randomised controlled trial (iRCT), analyses may assume that outcomes are independent. However, the findings may be limited by clustering attributed to particular acupuncturists. According to Walters, interventions delivered by individual practitioners may have effectiveness beyond the treatment effect dependent on the skill of the practitioner [287]. Therefore, the patients treated by each acupuncturist may for a unique cluster whose outcomes reflect differences in the effectiveness of acupuncture [288]. If analyses assume that

outcomes are independent, when they are actually clustered, the power of the study is reduced and the p-values are inflated. One acupuncture study, by Thomas et al, explored the potential effects of clustering on outcome and reported that differences between the acupuncturists did not significantly impact the findings [205].

Future studies that attempt to confirm the findings in this chapter should account for potential clustering and obtain adequate power. As opposed to linear regression, which does not account for clustering, an iRCT with clusters may be analysed by cluster level analysis, a random effects approach, or a population averaged approach [287]. Cluster level analysis compares the mean outcomes for all patients in each cluster, but does not allow the analyses to account for individual level covariates. Given the potential impact of age and sex on outcome, the cluster level analysis may be less robust than the random effects approach and population averaged approach which use individual level data. Although both use individual level data, the random effects approach explores multiple forms of clustering and produces generalisable findings, which makes it more advantageous than the population averaged approach.

In terms of importance, the regression analyses suggest that patients with deficient diagnoses report a worse outcome in comparison to patients with excess diagnoses. Regarding the controversy around the importance of TCM diagnosis differentiation discussed in Chapters 1 and 6, the finding provides empirical evidence that suggests a patient's TCM diagnosis is potentially important information that may predict his/her outcome. Although TCM diagnoses may be predictive of outcome, this data does not address the observation made by Sherman *et al* about the diagnosis' apparent lack of impact on treatment design [53]. As such, the findings support the calls for the inclusion of TCM differential diagnosis and/or subgroup analyses in acupuncture trials [51, 219, 222]; however, studies should consider concurrently evaluating the role diagnosis differentiation plays in treatment design. A potential implication may be that future studies place more emphasis on the TCM rather than the biomedical aspect of patients' conditions, thereby influencing a shift the symbiotic relationship between biomedicine and TCM. Additionally, the acupuncturists' prognoses, which are not correlated with particular diagnoses, are predictive of outcome. A potential implication of this finding is that acupuncturists'

prognoses may be used to assist the referral of patients to acupuncture. In particular, patients with poor prognoses may be better suited to a different intervention, while patients with deficient diagnoses may require additional treatment sessions, longer follow-up to detect improvement, and/or a different intervention.

In summary, the quantitative analyses provide useful insight into the importance of TCM diagnosis differentiation and subgroup analysis. As such, the findings support further research into these areas and suggest that the acupuncturists' prognoses may be a useful tool in clinical decision making. Having addressed the second research question, the following chapter presents the patients' perceptions of outcome and treatment experience.

Chapter Eight

The patient's experience with acupuncture & perception of outcome

Chapter highlights

- Patients grasp basic TCM concepts and explain the mechanism of acupuncture through three main themes including: channels and energy, anatomy and physiology, and needle sensations
- Approximately half of the patients considered the explanation of how acupuncture works to have impacted their treatment outcome
- In addition to the explanation, other factors including the patient-practitioner relationship, treatment experience, and attitude also appeared to affect the patients' perceived outcome

8.1 Introduction

Findings from the previous chapters suggest that the treatments the patients received incorporated pragmatic, disease-specific, and individualised approaches. Within the individualised approach treatment variations arose from patients' characteristics and practitioners' idiosyncrasies. Additionally, the findings in Chapter 7 suggest that the practitioners' prognoses are predictive of outcome and that there is a difference in outcome related to patients' traditional Chinese medicine (TCM) diagnoses. As these findings address the first two research questions, this chapter transitions to the third question 'how do patients understand acupuncture to work and do their understandings influence treatment outcome'. As discussed in Chapter 3, there are a variety of traditional and scientific explanations for the mechanism of acupuncture with which the patients may be familiar. There are also a variety of factors that may influence their outcome including: the needling aspect, environment, nature of the condition, and practitioner.

The third research question, included as a subsidiary question, addresses the call in the literature for the inclusion of qualitative work to explore patients' outcomes [228, 229], particularly in CAM studies where quantitative measures may not capture the range of outcomes patients' experience. As mentioned in Chapter 3, a variety of studies suggest patients' attitudes, expectations, and/or beliefs may affect their treatment outcome. Therefore, question three was also included to explore another potential factor influencing outcome (i.e. patients understanding of acupuncture). With regard to the overarching aim to develop a hypothesis on TCM diagnosis and treatment individualisation, the emphasis on understanding how acupuncture works limits the contribution of the findings. However, the material provides valuable context about patients' perceptions of acupuncture treatment and outcome.

Although the third research question is relatively well defined, the broad scope of potentially important factors necessitated the exploration of the multiple treatment aspects. Moreover, the diversity of IBS symptoms, severities, and comorbidities prompted an in-depth discussion on IBS to help define the study population. As such, the patients' interviews generated a wealth of information. The following sections

review the aims and objectives and methods, and present the patients' characteristics, study findings and discussion.

8.2 Aims & Objectives

The aim of this chapter is to explore patients' understandings of how acupuncture works and the effect that understanding has on treatment outcome as well as to capture detailed descriptions of treatment experiences. The objectives are to determine:

- The similarity of this group with other diagnosed IBS patients
- Patients' motivations for participating in the study
- Patients' beliefs about and prior experiences with acupuncture
- How patients understand acupuncture to work and how they make sense of acupuncture
- The influence acupuncture had on the patients' understanding of the body
- The impact of the understanding on outcome

As mentioned in Chapter 4, the patients' interviews were my favourite part of this thesis probably due to the patients' enthusiasm and candour when discussing their condition. Exploring the patients' experiences and perceptions accomplished the objectives above, which inform the structure of the chapter.

8.3 Methods Summary

As described in Chapter 4, I adopted a qualitative strategy that employed in-depth interviews with patients receiving acupuncture to accomplish the objectives. Patients were recruited to participate based on a purposive sampling matrix selecting for sex, IBS severity, and treatment preference (Table 4.2). All thirty-three interviews were conducted following the same topic guide (Appendix B 8), and lasted an average of one hour each. I recorded and transcribed all of the interviews. The topics covered during the interviews included:

- IBS onset and severity
- Management strategies and triggers
- Pre-trial acupuncture attitude and experience with acupuncture
- Reason for participating in the trial
- Explanation of how acupuncture works and how the explanation developed

- How the explanation makes sense
- Experience with trial treatments and compliance
- Perceived improvement and the impact of the explanation
- Role of the practitioner
- Changes in behaviour and/or body awareness

As indicated by the list of topics, the interviews collected a variety of information. Boxes 8.1a and 8.1b provide excerpts from two interviews to provide the reader with examples of the interview process. To reduce bias and improve validity, I analysed the transcripts and field notes in conjunction with BC[10]. Similar to the previous interviews, the patients' comments were initially organised by categories then analysed for emergent themes. Relevant categories were also triangulated with data from the patients' questionnaires. For example, I compared the patients' baseline severity scores on the IBS Symptom Severity Scale (IBS-SSS) with their perceived baseline severities. To contrast patients' outcomes and to interpret the data from a different perspective, I arranged excerpts from two patients' transcripts into poems (Section 8.13.2) [289]. Although unusual, the technique is advantageous because it allows the reader to engage with multiple prominent themes from an interview in a few lines of text.

To adequately present the breadth of data, the findings are separated into three sections: background, pre-trial, and trial. Throughout the chapter representative statements are denoted by patients' pseudonyms and illustrate how particular themes emerged. Additionally, each pseudonym is represented by initials on various continuums used to explain the findings.

[10] BC - Baltica Cabieses is a colleague with qualitative research experience who independently coded transcripts as a form of analyst triangulation to reduce the risk of bias.

I. We'll talk a bit about the acupuncture. Before the trial did you have any experience with acupuncture?

Lucas: No I've been I was having problems with both my shoulders a few months back well for the last year my shoulders have been giving me grief up until when I got laid off cause I was a joiner I think with the rest it seems to sort itself out but there was a Chinese shop in town and it said free acupuncture session and I went into see about my shoulders and I did actually think it kind of did something but it was the hard sell they tried to give me when I come out was the only reason that I didn't go back for any more they tried getting like five hundred pound off me in one payment for so many treatments and they were giving me a hard sell but hadn't they done that they would have had more business from me. But that's the only experience I've had with it before.

I. So what then made you want to participate in the trial?

Lucas: I just saw if it helps and it stops me taking so much stuff to make me go I'll try it and if it helps then it's got to be better than taking something every day. I'm open to it working. I'm not of these who says aw no that can't work its only a few needles. I sort of understand when she explains it to me it makes a lot of sense but when I try and explain it to other people it sounds like jargon you know and to be honest I do think it has helped the few days I usually go four o'clock on a Wednesday then through the weekend the past few weeks she was on holiday last week but the past few weekends before that I was not taking any molical at all up until the last couple of days I went to see her again and every time it went on a little longer but she had a week off last week not last week the week before I went last week and I'm due to see her again tomorrow.

Box 8.1a Example of interview process. Excerpt from interview with Lucas.

I. How would you describe your experience with the treatments?

Irene: I've had about I don't know maybe eight or so now. The first four there wasn't a huge difference probably by about maybe I've had seven by about number five I noticed a great improvement in that it's I said to my therapist it's amazing I'm going to the toilet everyday I'm not needing any laxatives I'm not having any bloating I can eat without any discomfort. The only hiccup is last week he did something slightly different and things aren't quite as good but I'm seeing him again today so I just mention what he did last week wasn't quite as good just in that I've not felt as comfortable going to the loo because the symptom I had was I'd go to the loo and even though I'd open my bowels it didn't feel as if I'd opened them properly I still felt that as if I needed to go perhaps that's crept in a little bit this week but I'm quite surprised and I'm very aware of the placebo effect and I'm not jumping into this is fantastic and I want it to work I'm very sceptical and you know making sure that it is working and I'm pleasantly surprised really cause I think it is and then I was speaking to him last week and saying to him how long do the effects last because I don't want everything to go back to 'normal' after a few months which I suppose they might do.

I. Specifically tell me a bit the treatments themselves.

Irene: Right I mean there's not for example I lye on the couch and he's been putting some needles in my hand he started off putting one in my web space and my thumbs as a calming type needle then he put another couple in my hands and he put some in my lower leg then he put one in my big toe and sometimes he changes them slightly when he did something halfway up my leg I don't particularly look because I don't sit up and have a quick look at where he's putting them to be fair I know where he's putting them so I don't particularly look and count them and all the rest I don't mind needles at all and when he did the one that he said is for sluggish bowel that was just amazing that worked so well and sometimes as I say he'll change them slightly he did say he was going to try and improve my discomfort with the fibroids at the same time but that's not been affected at all but I'm not hugely that wasn't the remit really and they don't hurt he just sort of jabs them in quickly they don't hurt sometime when he is moving one around it really aches and I can feel it it's obviously catching something and sometimes I again link it to catching a nerve cause it makes my leg twitch for example and some of them ache like mad and one time I flexed my foot and my leg just ached so much but it's not unpleasant at all and then I sort of lye afterwards once he's got all the needles in place have a lye down and relax for twenty minutes usually fall asleep and then usually straight away that day I can go to the loo then it just continues from there.

I. That started from about treatment four?

Irene: Yeah I think prior to that after the first say four treatments I was trying very hard not to use any laxatives and I wasn't using them as much but I still was needing to use them once or twice a week but what I would do was I wouldn't take any by the fourth day I'd think this is ridiculous I've not been to the loo yet so I'm going to have to take something and then by about four or five I just didn't need to.

Box 8.1b Example of interview process. Excerpt from interview with Irene.

8.4 Response Rates

Fifty-nine patients were invited to participate in an in-depth interview based on the sampling matrix (Table 8.1). The target of three to four patients was achieved in six of the eight categories. Of the two categories not achieving target, one had no potential participants meeting the criteria and the other exhausted the potential sample. Overall, thirty-three patients who responded with interest completed an interview. The three patients who replied with interest but were not interviewed were 'too busy' to schedule an interview. Roughly double the number of patients that preferred acupuncture was contacted due to a 45% response rate, in contrast to the 79% response rate among patients that preferred either intervention. According to a review by the Preference Collaborative Review Group, patients who receive their preferred intervention are likely to improve more than patients who prefer either intervention [290]. Therefore, the variation in recruitment rates may represent another difference between these groups of patients. Table 8.2 summarises the response rates.

	Prefer Acupuncture		**Prefer Either**		**Total**	
Severity	Male	Female	Male	Female	Male	Female
Mild/Moderate	11 (5)	12 (5)	6 (5)	6 (5)	17 (10)	18 (10)
Severe	3 (1)	14 (7)	0*	7 (5)	3 (1)	21 (12)
Total	14 (6)	26 (12)	6 (5)	13 (10)	20 (11)	39 (22)

Table 8.1 Interview recruitment. Each box shows the number of patients contacted and the number interviewed (in parentheses). * There were no participants in the trial, allocated to acupuncture, who met these criteria.

Response	**Patients**	**Percent**
Replied with interest	36	61
Replied not interested	3	5
No reply	20	34
Total	59	100

Table 8.2 In-depth interview response rates

Background

8.5 Characteristics of Participants

Characteristics of the thirty-three patients who completed an interview are presented in two formats: 1) quantitative data from baseline questionnaires and 2) qualitative data from the interviews. Presenting the background information in this manner provides numeric and narrative pictures of the participants, so that the reader engages

with the multidimensionality of the data. The data also provide a basis for comparison to the other trial participants as well as the diagnosed IBS population. The quantitative data listed in Table 8.3 are highlighted by below average mental health and average physical health scores on the SF-12 and moderate IBS severity similar to the data in Chapter 7. Additionally, none of the patients preferred usual care, and one patient did not believe acupuncture would work. Baseline details of those patients who participated in an interview are similar to those who did not participate (e.g. age – 40, severity – 281, duration – 12.5), and to the overall group of patients receiving acupuncture. One difference is a greater representation of patients who preferred either intervention, which is potentially important because these patients may improve less than those patients who preferred acupuncture.

Table 8.4 summarises the quantitative baseline data according to the recruitment matrix. Patients who preferred either intervention were more likely to think that acupuncture can work but less likely to believe that it would relieve their IBS in comparison to people who preferred acupuncture. Additionally, patients who prefer either intervention appear to have suffered a shorter duration of IBS, which may favour a rapid recovery in comparison to chronic cases who are likely to recover slowly [278]. With regard to sex, women (15/22) were more likely to believe that acupuncture could work than men (3/11); however, neither sex was confident that acupuncture could improve their IBS symptoms (2/11, 8/22). Having constructed a quantitative picture of the interviewees, the following subsections provide a qualitative picture through their IBS onset, chief complaints, perceived severity and comorbidities.

	Interviewees‡		**Acupuncture Patients***	
Age Avg. (range)	45.7 (21 – 73)		43.6 (21 – 78)	
Sex	Female 22 Male 11		Female 95 Male 21	
Duration Avg. (range)	15.9 (1.6 – 48)		13.6 (0.5 – 48)	
IBS-SSS Avg. (range)	263.1 (159 – 396)		279.0 (152 – 460)	
SF-12	Norm Base	Raw	Norm Base	Raw
	PF 49.7	80.3	PF 50.5	82.5
	RP 49.6	79.2	RP 47.9	74.7
	BP 47.6	75.8	BP 45.3	70.0
	GH 43.5	57.1	GH 42.5	54.7
	VT 42.6	37.1	VT 42.5	36.9
	MH 42.7	55.3	MH 42.6	55.0
	RE 44.7	74.6	RE 45.4	76.2
	SF 44.3	69.7	SF 43.8	68.3
	MCS 41.4	--	MCS 41.9	---
	PCS 49.7	--	PCS 48.6	---
Belief # (%) Acupuncture works Acupuncture doesn't work Don't know	 18 (54.5%) 1 (3%) 14 (42.4%)		 61 (52.6%) 1 (1%) 54 (46.6%)	
Belief # (%) Acupuncture will help IBS Acupuncture won't help Don't know	 9 (27.3%) 1 (3%) 23 (69.7%)		 31 (26.7%) 1 (1%) 85 (73.2)	
Preference # (%) Acupuncture & usual care Usual care Either	 18 (54.5%) 0 15 (45.4%)		 90 (77.6%) 0 26 (22.4%)	

Table 8.3 Baseline characteristics of interviewees and all patients receiving acupuncture in the trial. ‡ (n = 33) * (n = 116)

	Prefer Acupuncture	**Prefer Either**
Mild/ Moderate	Severity – 216 Age – 44 Duration – 14.7 4/10 think acupuncture can work 3/10 think acupuncture can help IBS	Severity – 186 Age – 49 Duration – 12.3 6/10 think acupuncture can work 1/10 think acupuncture can help IBS
Severe	Severity – 345 Age – 47 Duration – 27.4 4/8 think acupuncture can work 5/8 think acupuncture can help IBS	Severity – 336 Age – 41 Duration – 5.9 4/5 think acupuncture can work 1/5 think acupuncture can help IBS

Table 8.4 Baseline data summary by interview recruitment

8.5.1 IBS Onset

To begin the qualitative background, this section explores the patients' IBS onsets, which from a biomedical perspective (Chapter 2) is possibly triggered by a combination of factors such as GI infection, immune and/or nervous dysregulation,

and/or hypersensitivity. Patients were asked to identify the origin of their IBS, which generated five onset classifications identified by frequency and sex in Table 8.5. Additionally, Box 8.2 presents a sample of representative statements to illustrate how those particular onset classifications emerged.

Onset Classification	Frequency
Pain	9F 1M (10)
Life event	6F 1M (7)
Travel/illness	0F 4M (4)
Always had it	3F 2M (5)
Don't know	4F 3M (7)

Table 8.5 IBS onset classifications

Patricia: "My mother died and I had a breakdown and I've been ill ever since and the IBS seemed to develop at the same time." [Life event]

Alistair: "I was careful what I was eating and drinking [abroad] cause I was using chlorine tablets but on one occasion I couldn't have been careful enough and I ended up with very bad intestinal problems. The discomfort has never totally gone away." [Travel/illness]

Catherine: "I actually had to go to the hospital because they thought I had appendicitis and I was in hospital for a week before they diagnosed what it was." [Pain]

Emma: "I've always had problems in that area ever since being a baby and it's just kind of got to the point where it's becoming painful and uncomfortable recently." [Always had it]

John: "I noticed that on the medical that I had to have getting the job actually referred to IBS and nobody had ever told me I had IBS before so I must have been having some symptoms around that time but it is difficult to remember." [Don't Know]

Box 8.2 Illustrative statements of patients' onset classifications

As indicated by the statements, some patients were able to pinpoint an approximate time when their symptoms began, while others were rather vague. Although comments in both the 'pain' and 'always had it' themes mentioned pain, 'always had it' comments described the pain as chronic and part of a larger problem whereas 'pain' comments described an acute, often severe episode of pain. Patients such as Alistair may be representative of a post-infectious case of IBS [86], while patients such as Emma may be representative of the IBS patients who associate onset with being colicky babies or childhood constipation [91]. In contrast, the patients' responses differ from a study by Kennedy *et al* (except food poisoning) wherein comments suggested genetics or environmental causes of IBS [90]. I contend the

difference in responses may be due to a difference in question 'What caused your IBS' versus 'When did your IBS start'. With regard to the 'always had it' or 'don't know' categories, the comments support the acupuncturists' statements in Chapter 5 that some IBS patients may not consider their bowel habits to be abnormal. In general, the patients' comments about their IBS onset are relatively consistent with the literature.

8.5.2 Chief Complaint & Triggers

As mentioned in Chapter 5, a patient's treatment plan may hinge on his/her chief complaint, which according to the treatment logs (Table 6.3) was most commonly alternating bowel movements. During the interviews, patients said they were most bothered by bloating and the often accompanying pain and wind, as explained by Betsy.

> "The bloating and the pain that goes with that obviously. You're trying to fit into your skinny jeans with a bulging belly that hurts."

Although it may appear that the chief complaints as identified by the acupuncturists and patients differed, bloating and wind were listed in 42% of the logs in combination with the other symptoms and as such bloating was the most common symptom reported. The difference between the patients and the acupuncturists is that the acupuncturists interpreted bloating as a feature of pain or bowel movement, while the patients interpreted pain as a feature of bloating.

The subtheme that emerged was a feeling of embarrassment, which often affected patients' decisions about activities. Feelings of embarrassment were consistent across age groups and sex as demonstrated in the following statements.

> Lucas: "It's hard if you're somewhere, say a young lady's house or something you don't want to be doing it [passing wind] and you try to hold it and you get even more uncomfortable. It's mainly the embarrassment about that really." [age 29]

> Ashley: "It's embarrassing sometimes when you're out when you start passing wind. When you're out in shops and it starts you try and get out of the way." [age 60]

Lucas' and Ashley's comments provide a potential explanation for why patients scored higher (closer to norm) on the PCS component of the SF-12 than the MCS

(Table 8.1). Additionally, the vitality domain, which had the lowest raw score, was reflected in patients' references to fatigue as a chief complaint. Fatigue, as Matthew describes below, was indicated as the primary complaint in 4% of treatment logs (Table 6.3).

> Matthew: "Incredibly tired to the point that everything is an absolute chore when the IBS is flaring up. It really is a hassle to do anything."

With regard to chief complaints, abdominal pain is a well known feature of IBS as indicated by its prominence in the definition of IBS [64], and in its frequent indication as a chief complaint both by patients and acupuncturists. However, the interviews revealed that the associated aspects of pain such as bloating, wind, and embarrassment have important implications. For example, one patient was so ashamed about her IBS that she had not told her husband about her condition. The interviews imply that pain is problematic more for its restrictive factors with regard to social activities, posture, and clothing, and contributory effects such as embarrassment than the actual pain itself. Hiding symptoms and feeling alone may contribute to patients' unwillingness to participate in social events and sense of a lack of freedom [91, 120]. Additionally, the patients' identification of fatigue as an important symptom and the low vitality scores represent an underexplored area of potential patient improvement. In addition to the symptoms, patients also experience uncertainty with regard to their triggers.

Patients explained that their symptoms were most commonly triggered by stress, food, menstruation, and/or clothing. Within the stress theme patients specifically attributed symptom triggers to travel (e.g. Matthew), deviation in routine, a lack of control, or a nervous personality (e.g. Kelley).

> Matthew: "I find my IBS is at its worst big time when I travel even just going to Kent. I went [away] at the weekend, weekend before last shocking [symptoms]."

> Kelley: "I'm quite a nervous sort of person that's probably half the problem so that might be part of it. I get a bit wound up about things so that might not help."

In addition to stress, some patients reported specific food triggers including: wheat, dairy, spicy foods, rich/fatty food, alcohol, raw food, sugar, greens, and caffeine. Most patients such as Diana, made discoveries by trial and error, although a few

underwent food allergy testing. Patients such as Rob also explained that their food triggers varied over time.

> Diana: "I've completely cut bread out of my diet cause I think gluten is a big problem in our diet so I've stopped all bread and I have started to notice a difference."
>
> Rob: "Initially when the problem first developed it was any solid food then it turned into dairy products."

Although some triggers were well defined, many patients expressed frustration and/or uncertainty about the variation over time and the unpredictable nature of particular triggers to 'always' produce symptoms. Approximately half of the patients indicated that both stress and food sensitivities triggered symptoms. Recall from Chapter 2 (Section 2.4.3 and Figures 2.4 and 2.5) that the colon is particularly susceptible to both interoceptive and exteroceptive stress and that susceptibility contributes to symptom manifestations. The willingness of these patients to discuss the impact of stress on their IBS deviates from the discussions portrayed in Chapter 2 in that those patients resented the association of IBS and stress [90]. However, patients from various studies including this one are similar in their recognition of stress as an important symptom trigger [90-92, 291]. Overall, the patients' reported chief complaints and triggers are similar to those reported in the treatment logs and in other studies.

8.5.3 Severity & Treatment

As discussed in Chapters 2 and 4, IBS severity is difficult to determine, and data from Chapter 7 indicate that the IBS-SSS only captures 47% of the variation. However, clinicians maintain that severity impacts on medication, work, and healthcare seeking decisions [120]. The interviews provided an opportunity to compare patient-assessed severity and a practitioner derived severity measure. The first theme to emerge suggests that the relapsing-remitting nature of IBS causes IBS sufferers to slide along a continuum between asymptomatic and severe symptoms as indicated by the following comments.

> Richard: "In terms of what I know about IBS if I was to put it on a scale of 1 to 10, I would say I varied across all points on the scale."
>
> Philip: "I'd say over the last five years it was probably a seven or an eight and occasionally it would go up to a nine. It was beyond pain for me. That's definitely progressed down to a three or four."

Not only do both comments reflect the idea that severity slides along a continuum, described in the literature as the 'wax and wane' of symptoms [68], they also provide another dimension to Matthew's comment about triggers from the previous section. Patients' day-to-day severities may increase when they are subjected to particular triggers such as travel, and may decrease when they are subjected to particular treatments and/or behaviours such as those described later in this section. In addition to symptom fluctuation, the self-classification of seventeen (17/33) patients differed from their IBS-SSS baseline classification (Figure 8.1). For example, statements by Rob and Elloise illustrate how patients who were quantitatively classified as severe or moderate often described themselves as mild.

> Elloise: "Only really mild. I never thought myself as suffering like I know some people have and do just general flare-ups if I ate certain types of foods." IBS-SSS baseline = severe
>
> Rob: "The odd thing is that you probably wouldn't know that I had the problem now. I can't remember the last time I had to be treated for it." IBS-SSS baseline = moderate

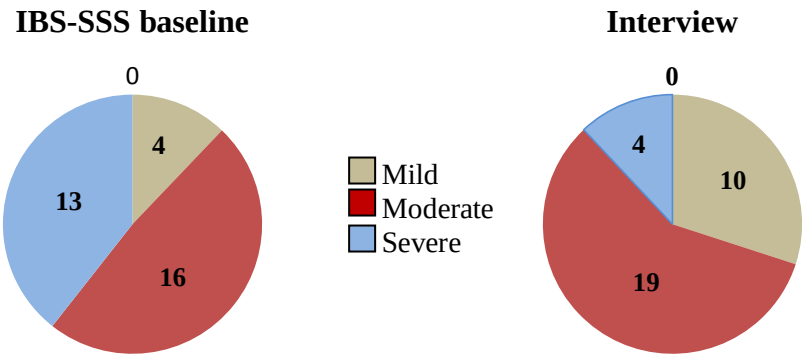


Figure 8.1 IBS severity comparison

Only one of the four people who was originally classified with mild IBS symptoms identified a different classification during the interview compared with eight of the sixteen classified as moderate and eleven of the thirteen classified as severe. In comparison, the baseline IBS-SSS scores for all trial participants classify 37% of

patients' symptoms as severe, 55% as moderate, and 8% as mild. The interview finding supports the inference that the IBS-SSS may favour or too readily elicit high scores. The ideas that patients' symptoms continually slide along a severity continuum and that their perceptions of severity may differ from questionnaires presents a challenge to establishing the effect of acupuncture as well as other treatments. The challenge is particularly important given the findings by Whitehead *et al* that patients who score high at baseline are less likely to report adequate relief of symptoms despite greater reductions in scores [136]. The difference between patients' and the IBS-SSS interpretations of mild, moderate, and severe symptoms favours the use of qualitative data such as these interviews to establish the benefit of treatment.

In addition to different interpretations of severity, IBS patients also approach treatment differently. The patients primarily described self-management strategies which were either patient initiated and/or GP encouraged. The following examples illustrate this theme, and the subtheme that IBS is a condition to be 'tolerated' not cured.

> Rose: "[speaking with GP] 'It's just you've got a sluggish gut and you just have to make it.' End of conversation go away and live with it, so that's it."
>
> Nick: "I have managed it myself basically you get used to the fact that you've got it and you take precautions."

To 'make it' and 'take precautions' as Rose and Nick suggest, patients explained that they typically manage their IBS symptoms via diet, which reinforces the variety of comments about dietary triggers from Section 8.5.2 and potentially the willingness of patients to accept diet advice from the acupuncturists (Section 8.13.2). Recall that some of the diet advice was from GPs (e.g. Catherine), but was mostly trial and error and for some patients made no difference (e.g. Nathan).

> Catherine: "I did this food diary which was really helpful actually. I cut out everything then introduced things slowly back in and we realised it was dairy. So I did that. Now it's more of a self-management thing for me I just know I'll try and stay away [from triggers]."
>
> Nathan: "I cut out different foods at different times and found that in the long run it didn't seem to make any difference."

In addition to diet, patients also modified their posture, exercise, and stress management to alleviate their IBS symptoms.

> Emma: "I hula-hoop. My theory behind it was that if I make my stomach area work then it might help it inside so I got myself a hula-hoop."

> Brooke: "Whether its habit or I do rub my stomach if it has been playing up. I rub it in circular motions trying to ease the food down through my gut."

> Brenda: "I sort of talk to myself a lot and say right you know just relax if you feel some tension or something you don't need to feel like that cause it won't develop."

Each of these comments illustrates different strategies that patients adopted to manage their IBS symptoms. Additionally, the comments illustrate the idea that these patients not only take an active role in their health, but also assume that their actions may influence their symptoms. The active versus passive approach to health is potentially important based on the acupuncturists' comments (Chapters 5 & 9) that patients who are motivated to engage with treatment and make changes have better outcomes. The active approach and awareness re-emerge in subsequent sections related to the patients' perceptions of how the body works and integration of acupuncture.

With regard to medication, approximately half of the patients (16/33) had taken various prescription medications, and half of those achieved symptom improvement. Yet even when a prescription worked, patients were likely to alter doses. Victoria explains that a fear of side effects is one reason patients alter their prescribed medication. An additional eleven patients such as Irene and Lucy used over-the-counter medicine or herbal products.

> Victoria: "I don't take it and you know the reason I don't take it is because when you read the caution and all that side effects that it could have now I know I may not have side effects but when I read it it frightens me and I think I'll just leave that off and cope with it."

> Irene: "In the past I've tried things like colefac I can't remember the other name for it and I've tried all sorts of different molbicol prescriptions and cenna and all the sort of laxatives that you can get over-the-counter and stuff."

> Lucy: "I'll take things like aloe vera to help my stomach and I've read a lot about things that gradually help a little bit I think I have it quite well managed."

The patients' descriptions of their treatment strategies, particularly the self-management strategies, are consistent with those discussed in Chapter 2. Moreover, the patients' emphases on self-management may contribute to their perceptions of how the body works and their integration of acupuncture explanations as discussed in future sections. The medication comments highlight a common threat to the success of an intervention, adherence. According to a review by Haynes *et al*, non-adherence is influenced by side effects, poor instructions, poor memory, a disagreement with the need for treatment, an unaffordable treatment, and/or a poor patient-practitioner relationship [260]. Specifically, Lembo reports that diagnosed IBS patients suffer an average of three side effects from their IBS medications, which subsequently influences non-adherence [292]. Although the patients may not readily adhere to the medication component of their treatments, they attended an average of nine acupuncture sessions each. The strong adherence to acupuncture may be a by-product of the patient's trial behaviour as indicated by Thomas.

> "I did all ten yeah. I could have easily given up half way through probably but there's no point because I said it was something that I want to try and I got ten free sessions so I might as well."

As discussed in subsequent sections, Thomas reports that his symptoms initially worsened with treatment and gradually returned to a pre-trial level of discomfort. His comment above reflects the idea that his adherence was influenced by trial behaviour and the offer of something not normally available. In routine practice, patients such as Thomas who pay for acupuncture themselves may not adhere to treatment after the initial session, which is further discussed in Section 8.14.

The idea that IBS is a condition to be 'tolerated' may offer a potential explanation for the difference in patient-assessed and practitioner assessed severities. Patients who have learned to 'tolerate' their moderate or severe symptoms may report them as mild due to their tolerance or adaptation. Alternatively, the difference may reflect the perceived impact of the patients' symptoms (e.g. pain) versus the impact of their consequences (e.g. embarrassment). Comments in this section and 8.5.2 suggest that

symptoms may contribute less than consequences to a patient's assessment of his/her severity, yet contribute more to a practitioner's assessment.

8.5.4 Comorbidities

As discussed in Chapter 2, a number of comorbid conditions/symptoms are associated with IBS including: reflux disease, backaches, depression, anxiety and headaches [77, 117, 137]. Given the prevalence of comorbid conditions and the association of acupuncture with unexpected effects, I asked the patients about their concomitant health problems. Table 8.6 lists the comorbidities described by the interviewees, and Table 8.7 lists the comorbidities by recruitment matrix.

Condition	Patients	Symptom	Patients
Reflux	2M 6F	Headache/migraine	1M 5F
Anxiety	1M 3F	Tiredness	2M 2F
Depression	1F	Backaches	1M 2F
Chronic cough/ lung condition	1M 2F	Urinary dysfunction	2M 1F
Thyroid dysfunction	3F	Joint pain	2M 2F
Anaemia	2F	Sleep problem	2M
		Gynaecological problem	3F

Table 8.6 Comorbidities reported in patient interviews (n = 33)

	Prefer Acupuncture	Prefer Either
Mild/ Moderate	7/10 had ≥1 comorbidity 3 M, 4F	8/10 had ≥1 comorbidity 4M, 4 F
Severe	8/8 had ≥1 comorbidity 1M, 7 F	1/5 had ≥1 comorbidity 1 F

Table 8.7 Comorbidities based on recruitment matrix

Over half of the patients (20/33) indicated that they suffered from at least one of the comorbidities in Table 8.6. Furthermore, women typically suffered an average of two comorbidities, while men suffered an average of one. As discussed in Chapter 2, after diagnosis, IBS patients are more likely to seek care for their comorbidities rather than IBS symptoms. Therefore, to reduce the burden of IBS, treatments should account for IBS symptoms as well as comorbidities [131]. The comorbidities were considered important from an acupuncture perspective because, as seen in Chapter 6 (Table 6.15), some aspects of treatment targeted those symptoms. Patients who

preferred acupuncture and were classified as severe suffer from the most comorbidities and longest duration of symptoms potentially making them the most difficult to treat.

To summarise the background section, patients perceived themselves to be suffering mild/moderate IBS, had developed self-management strategies to limit flare-ups, and typically identified triggers through trial and error. Patients' onsets and comorbid conditions were consistent with other IBS literature and highlight the heterogeneous nature of IBS. In general, the background information suggests that this group is similar to other diagnosed IBS patients indicating that the findings may be relevant to a wider diagnosed IBS population.

Pre-Trial

8.6.1 Prior Experience & Attitude

While the previous section explores the patients' backgrounds and establishes similarities between the patients and the diagnosed IBS population, this section describes the patients' prior acupuncture experiences and attitudes. Ten participants (7F, 3M) received acupuncture prior to the trial for various conditions including: back pain, neck pain, shoulder pain, arthritis, tinnitus, headaches, and nausea. Seven of the ten reported an improvement in the condition being treated. These ten participants comprise a subset of patients whose pre-trial attitudes and knowledge about acupuncture was based on personal experience with the intervention, thereby potentially predisposing them to a different trial experience.

As discussed in Chapter 7, the baseline questionnaire asked patients if they thought acupuncture works and if they thought it would alleviate their IBS symptoms. Although patients were roughly split between believing acupuncture works and not knowing, the majority (23/33) were unsure that it would alleviate their symptoms. By asking patients about their attitudes towards acupuncture, the interviews provided information on both their attitudes and the associated influences. The patients' attitudes toward acupuncture prior to the trial based on their interview responses are depicted on a continuum (Figure 8.2). The initials on the continuum represent the pseudonym of each patient. Since the continuum is a useful tool for illustrating

differences in the patients' comments, it is used throughout this chapter. Overall, twenty-one patients were positive, six were ambivalent and five were negative toward acupuncture prior to treatment. Of the patients with a positive attitude, nine had prior experience with acupuncture.

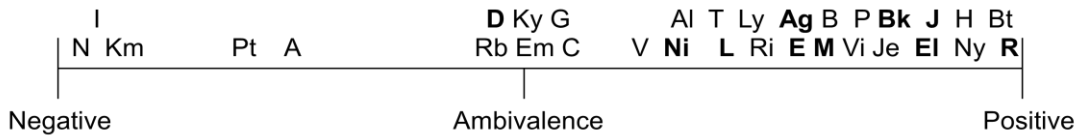


Figure 8.2 Acupuncture attitude continuum. Bold initials depict patients with prior acupuncture.

Attitude statements frequently contained the phrase 'open minded', which was usually associated with a positive connotation. Angela's comment:

> "I was quite open minded about it. I suppose reasonably maybe positive is the wrong word hopeful but I generally didn't know what it might do." (Ag)

places her on the positive end of the continuum. Factors that influenced a positive acupuncture attitude include: direct or indirect experience with acupuncture or other complementary and alternative medicine (CAM) therapy, and publicity.

> Nancy: "I go to an osteopath for a bad back and I know that that's worked brilliantly. I have a lot of faith in another alternative therapy so I thought well perhaps I'll have a go at this." (Ny)

> Philip: "You see it become more common or more apparent in today's society. If it's in a magazine talking about different therapies and what can help you. I just thought well I'll give it a go." (P)

> Rose: "I got my positive bit from his [husband] positive bit eighteen months ago and it worked wonderfully for him so why shouldn't it work for me." (R)

Comments by Nancy and Rose illustrate the positive influences of direct and indirect experiences with CAM, while Philip's comment illustrates the positive influences of publicity. In addition to key words such as 'positive', the tone of the patient's language helped determine his/her position along the continuum. The majority of patients (14/18) who indicated acupuncture works on the baseline questionnaire made a positive attitude statement.

In contrast to the baseline questionnaire, the interviews suggest that there was more than one person who did not believe acupuncture would work. Negative attitudes were influenced by apprehension about the treatment or a lack of confidence in the treatment to be beneficial and/or credible.

> Irene: "I've always been very sceptical about any sort of complementary type therapy because I've always said to my patients you can't rely on it it's not credible it's not been studied." (I)

> Ashley: "I didn't know a lot about it so I was a bit scared about it all these needles being stuck in. So I don't fancy that, if it's gonna be painful and things, cause you're not knowing anything about it before." (A)

Although both Irene and Ashley appear on the negative side of the continuum, Irene's comment is considered more negative because of her apparent lack of confidence in the intervention. Alternatively, Ashley's comment demonstrates treatment apprehension, which is less negative. The discrepancy between the number of negative attitudes in the questionnaires and interviews reflects an advantage of collecting detailed qualitative data. Four of the five negative answers replied 'don't know' in the questionnaire, with only Ashley answering 'acupuncture can work'. The only person to answer 'no' in the questionnaire gave an ambivalent response in his interview. Ambivalent attitudes (e.g. Emma) were related to a lack of information/experience about acupuncture.

> Emma: "I didn't have any go either way with it. It's just one of those things you hear about. I kind of had an idea in my head that it was gonna be. I was expecting it to be like huge needles like ten feet long and incense. I suppose it sounds a bit dumb but a little Chinese man. But other than that I didn't have any sways towards it or against or anything." (Em)

Nine of the ten patients with prior acupuncture experience had a positive attitude compared with twelve of the twenty-two patients who did not. In addition to direct experience with acupuncture, information from the media or friends who used CAM appeared to influence patients' attitudes. Whether the patients' attitudes influenced their perceived treatment outcome is further discussed in Section 8.13. With regard to recruitment, eight of the patients who had received acupuncture prior to the trial preferred either intervention in comparison to two patients who preferred acupuncture (Table 8.8). Thus, patients who preferred either intervention may be willing and/or able to pursue acupuncture regardless of allocation. Although more than half of the patients had positive attitudes, which may help explain their

willingness to participate in the trial, the following section explores why patients with positive and negative attitudes participated.

	Prefer Acupuncture	Prefer Either
Mild/ Moderate	1/10 tried acupuncture before 8/10 had positive attitude 3/10 acupuncture will help IBS (BL) 4/10 acupuncture can work (BL)	7/10 tried acupuncture before 7/10 had positive attitude 1/10 acupuncture will help IBS (BL) 7/10 acupuncture can work (BL)
Severe	1/8 tried acupuncture before 4/8 had positive attitude 4/8 acupuncture will help IBS (BL) 3/8 acupuncture can work (BL)	1/5 tried acupuncture before 3/5 had positive attitude 1/5 acupuncture will help IBS (BL) 4/5 acupuncture can work (BL)

Table 8.8 Pre-trial experience & attitude by recruitment. BL – baseline questionnaire

8.6.2 Reason for Participating

As discussed in the previous section, the majority of patients in this study had positive attitudes about acupuncture, which may explain why the RCT over-recruited and recruited faster than the projected time frame. To understand why the RCT recruited so well, I asked the patients why they volunteered for an acupuncture study. Four themes emerged in this category, the most prominent being desperation for symptom relief. Patients had a willingness to 'try anything' that was prompted by feelings of nothing to lose, acupuncture is not harmful, it is an unexplored option, intrigue, and potential success.

> Rose: "You'll try anything when you're fed up with something won't you. Anything. It can't do any harm. I know it can't do any harm so I just went with it."

> Thomas: "It was something I hadn't tried really it might be a possible treatment I thought I'd give it a go because it's unexplored."

Both Rose and Thomas share the same desire to try anything, but were influenced by different motivations. As depicted in Figure 1.1, there are multiple factors influencing patients' uptake of pluralistic therapies. The second theme illustrates another factor in Figure 1.1, the desire for an alternative to biomedicine, which involved a preference for less medication and a holistic approach to treatment.

> Gina: "I'm sick of pumping myself full of drugs all the time and not knowing what they are doing and if they are making any difference."
>
> Patricia: "I think the acupuncture approach is more holistic and that appealed to me because I've got so many things wrong with me. When I go to the doctor they tend to look at that or that rather than me – the whole person sort of thing."

Gina's and Patricia's comments highlight several factors influencing the increased popularity of pluralistic therapies (Figure 1.1) such as unmet needs, medical counterculture, and the consumer health movement.

Lastly, five patients emphasised the opportunity to try a normally unaffordable treatment or altruism as their reasons for participating.

> Betsy: "It's one of those things you want to try but when it's £35 a pop it's like can I really take that out of my budget. So I was really, really pleased to be able to give it a go."
>
> Elloise: "I think being able to help people that actually suffer worse than me and knowing whether there is something out there that can maybe help."

In comparison to the previous section, the patients' reasons for participating provide insight into why patients with negative or ambivalent attitudes toward acupuncture enrolled for treatment. All of the patients with negative or ambivalent attitudes toward acupuncture expressed a desperation for symptom relief and in doing so a willingness to try anything. Several of the patients were also keen to have an alternative to biomedicine. Therefore, the findings suggest that the desire for symptom relief outweighed patients' negative or ambivalent attitudes toward acupuncture in their decisions to participate. Although patients said they would 'try anything', the idea that they wanted alternatives to biomedicine may indicate a potential barrier to recruitment for other studies. In comparison, the desire for symptom relief and willingness to try anything reflect similar themes found in other acupuncture and IBS studies (e.g. [147, 293, 294]). The significance of these findings is that despite their level of symptom tolerance (Section 8.5.3), the patients are keen to improve their quality of life. Their keenness supports continued effectiveness research such as this study. Having explored the patients' backgrounds, attitudes, and prior experiences, the following sections explore their trial experiences, understanding of how acupuncture works, and perceived improvement.

Treatment Experience

8.7 The Acupuncture Experience

While the previous sections suggest that patients were generally positive about acupuncture prior to treatment and were desperate for symptom relief, thirty-one described a positive acupuncture experience regardless of outcome. Patients described the positive experiences in terms of value (helpful, useful), quality (good, lovely, amazing, pleasant), and fulfilment (fascinating, brilliant, enjoy). Only two patients appeared to have a negative experience described in terms of the needle sensations (ouch) and overall as alright. Although the comments are not blatantly negative, their sharp contrast with the positive comments portrays them as negative. The relative nature of the negative comments is similar to that of the attitude comments (Section 8.6.1), in that the words 'scared' and 'sceptical' appeared negative in comparison to the words 'hopeful' and 'positive'. The understated negativity of the patients' comments may be a by-product of the interview process, wherein patients who were willing to try anything did not want to appear unappreciative for the opportunity, even though the treatment did not meet their expectations or prove beneficial. As discussed in Section 8.8, patients' comments about their interactions with the acupuncturists strongly parallel the comments related to the overall experience, which offers insight into the difference between a positive and negative experience.

Patients' comments about their experiences typically incorporated multiple themes including: needle sensations, other treatment aspects, the response continuum, and relaxation. With regard to needle sensations, patients said:

> Rose: "You feel a dull ache if it's working, if it's in the right spot. If it's not, if it's sharp then that's wrong and she [acupuncturist] wants to know."

> Verne: "Feelings most of the time it was I wouldn't say pleasant but it wasn't unpleasant and sometimes there was a feeling of great warmth. Sometimes there was a twitchy like electric shock feeling."

Comments by Rose and Verne capture a variety of needle sensations commonly reported in the literature. For example, Paterson *et al* report that patients described needle sensations ranging from no sensation to aching, tingling, and shooting sensations [208]. Rose's comment also foreshadows the discussions on how acupuncture works and perceived outcome.

In addition to needle sensations, patients described their experiences with other aspects of the treatment such as advice, additional therapies, and the practitioner.

> Catherine: "She was very interested in my diet and what I was eating and about stress. It was quite nice to we would talk about the food and nutrition and what would benefit as well as acupuncture linked in as well."
>
> Ashley: "She not only did acupuncture she cupped my back. She did my back and then she did the acupuncture as well. That was very soothing as well."
>
> Kim: "I had quite an excellent I suppose like a chat first then obviously from each conversation he then chose which areas he wanted to treat."

As mentioned in Sections 8.5.2 and 8.5.3, diet plays an important role in patients' symptom triggers and treatments. Therefore, Catherine's comment reaffirms the importance of diet from previous categories and illustrates the potential benefit of an underexplored aspect of acupuncture treatments. Additionally, Kennedy *et al* suggest that IBS patients expect and/or want diet advice to be part of treatment [90]. Recall from Chapter 6 that the acupuncturists offered diet advice to 57% of patients, and that some considered advice to be an important adjunct to treatment; however, they selected the appropriateness of advice according to the individual patient (Chapter 5). The comments by Ashley and Kim highlight the patients' response to additional therapies and interaction with the practitioner respectively. Together these three comments illustrate the complexity of acupuncture as an intervention and imply that patients derive benefit from multiple aspects of treatment.

In comparison to the overall experience, several patients described the initial treatment effects. Specifically, their comments illustrate a range of effects from worse symptoms to no change to euphoria. Figure 8.3 depicts the diversity of responses on a continuum. Comments on the euphoric side of the continuum were either associated with symptom improvement or a sense of extreme, unanticipated relaxation. Emma (Em) and Nick (Ni) were unique in that they described an initially extreme euphoric or positive response that was followed by worse symptoms. The range of patients' experiences was reflected in their comments such as:

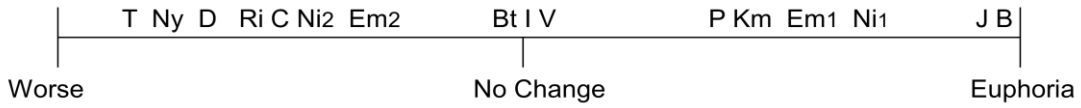


Figure 8.3 Initial treatment effect continuum

> John: "The effect afterwards that can be particularly strange. The first time I felt very peculiar. I felt as if I had been on some sort of drugs. I felt only half of me was there almost like an out of body experience really." (J)
>
> Nancy: "I came out of that acupuncture and I felt rotten the first time. Went to Tesco and I felt rotten which was quite a shock. It was a return to symptoms that I probably hadn't had like that in maybe three or four years." (Ny)

In addition to different initial responses, Nancy and John received different initial treatments. A comparison of the initial treatments in Box 8.3 suggests that there is not a consistent group of points that triggers either an initial worsening of symptoms or euphoria. Furthermore, the patients were treated by seven different acupuncturists, indicating that the initial treatment effect is not dependent on the acupuncturist. Based on this finding I hypothesise that a patient's initial response to acupuncture is largely influenced by his/her individual character. Similarly, Campbell provides an anecdotal report on a range of patients' responses to acupuncture including: unexplained laughter, tears, and euphoria [295]. Campbell hypothesises that acupuncture stimulates the limbic system[11] and that people who are hypersensitive to stimulation may react more strongly to treatment than others. This hypothesis is particularly interesting with regard to IBS because, as discussed in Chapter 2, it is associated with hypersensitivity and/or dysregulated communication between the brain and intestines in a subgroup of patients. More research on patients' responses to acupuncture and individual characteristics is necessary to address the hypothesis, and to establish the relationship between initial effects and outcome.

[11] The limbic system regulates emotional responses and contributes to the emotional motor system depicted in Figure 2.5.

Patient	First treatment
Irene†	Ht 7, Sp 6, KD 7, Kd 3, Sp 3, LR 8
Verne†	LI 4, LR 3, Sp 6, St 36, St 44, yintang
Betsy†	GB 40, P 6, Sp 6, St 36
Emma‡*	LI 4, LR 3, GB 34, LR 13, St 25, St 36, CV 12
Nick‡*	LI 4, LR 3, St 36, CV 12, Kd 6, Kd 3
Nancy*	LI 4, St 36, LR 3
Thomas*	GB 40, P 6, St 36, Sp 6
Dorothy*	LI 4, LR 3, St 36, CV 12, Kd 3, CV 6
Catherine*	LI 4, LR 3, GB 41, SJ 5, Sp 6, Sp 9, CV 12
Richard*	St 36, Sp 6, GB 40, LR 3
Philip‡	LI 4, LR 3, LI 11, St 36, Sp 6
Brenda‡	LI 4, LR 3, GB 34, CV 12, LR 13, St 36
Kim‡	St 36, Sp 6, Kd 7, Ht 7
John‡	GB 20, UB 13, UB 18, UB 20, UB 23, GB 34, Sp 6 + massage

Box 8.3 Acupuncture points and additional therapies used in initial treatment. † reported no change * reported worse symptoms ‡ reported euphoria or unanticipated improvement

Although the initial treatment produced a range of responses from worse symptoms to euphoria, twenty-two patients described the overall experience as relaxing. In addition to the relaxed experience, the patients' comments (e.g. Brooke & Alistair) revealed the factors that influenced their relaxation (Figure 8.4).

> Brooke: "You have that time. You know it is your time to have a treatment and they are focusing on you."
>
> Alistair: "I find it very relaxing. I find almost find it's going too far to say out of body but it's very relaxing and I find myself dreaming and in a sort of state of reverie. Very relaxed."

Figure 8.4 Factors that influence relaxation.

Figure 8.4 illustrates multiple influences that contribute to a patient's relaxation some of which are related to the environment and/or context effects associated with the treatment, while others are related to the treatment itself. The relaxation influences described by the patients, particularly those related to the environment and practitioner, are similar to the influences reported by Hughes (Chapter 3) [210]. As mentioned in Chapter 4, there is some controversy around the ability of acupuncture to deliver effects beyond the placebo response [225]. Therefore, the patient's comments are important because they demonstrate that patients' perceive both the contextual elements and the needling to be active components of treatment. As discussed in subsequent sections, some patients conceptualised the mechanism of acupuncture through physical needle sensations, which they often perceived to be an indication that the treatment was working.

In summary, the majority of patients described their treatment experience in positive terms. Factors that influenced the treatment experience included: needle sensations, additional therapies, advice, interactions with the practitioner, and responses to treatment such as relaxation and symptom exacerbation.

8.8 The Practitioner

As indicated by comments in the previous section, the acupuncturists played a role in many of the patients' treatment experiences. Following the question about treatment experience, the patients elaborated on the role the acupuncturists played in their perceived outcome. The majority of patients (26/30) described the acupuncturists in terms of positive characteristics such as: gentle, encouraging, approachable, friendly, inspiring, lovely, nice, warm, honest, astute, confident, welcoming, understanding, calm, and perceptive. Additional comments about the acupuncturists' abilities such as: put her heart into what she was doing; extremely diligent; skilled; took time; competent; obviously enjoys it; and had a passion for it, were also positive. The perceived characteristics and abilities fostered a sense of confidence, trust, assurance, faith, relaxation, ease, and freedom from embarrassment. In contrast to the positive descriptions, three patients described their patient-practitioner relationships in less enthusiastic terms such as: alright, just straightforward, and just professional. Similar to the comments in Sections 8.6.1 and 8.7, the minimalist tone of these comments in

relation to the exuberantly positive comments conveys negativity. Each of the patients who made relatively negative comments was treated by a different acupuncturist, which suggests that the dissatisfaction does not characterise a single practitioner. Furthermore, the emergence of the relative negativity theme in multiple categories links patients across their attitudes, experiences, and beliefs.

In addition to the positive and negative characterisations, patients assessed whether the patient-practitioner relationship and/or the acupuncturist's skills were influential in their outcome. Approximately twenty patients thought that their relationship with the practitioner and/or her skills were influential in their outcome (e.g. Jennifer), while four patients indicated it had no impact (e.g. Helen) and the others were unsure.

> Jennifer: "I think they would do because that kind of therapy is one to one and unless you develop a relationship with that person or unless you get on with them it could affect the outcome I would have thought."

> Helen: "I don't think any influence either way because I think if he had said more maybe but it wasn't. We only exchanged a few words sort of pleasantries and then had the treatment. "

The comments emphasise the importance of the relationship over patients' perceptions of the acupuncturists' skills; however, the prized aspects of the relationships such as 'confidence in her ability', 'easy to speak to', and 'makes me feel so relaxed' are likely to be related to the acupuncturists' skills. Furthermore, one may infer from Jennifer's comment that an unsatisfactory relationship may adversely affect outcome. In comparison, Helen's comment represents one of the three people who described a relatively negative patient-practitioner relationship. Analysis of her comments in this context implies that the relative negativity may be related to the acupuncturist's failure to meet her expectations. Other patients in the 'no impact' group implied that their symptoms were not likely to improve with acupuncture, despite a positive relationship and skillful practitioner. Although patients in the 'don't know' group were generally positive about their relationships with the practitioners, they had not considered how the relationships affected treatment or that it was part of the treatments.

As mentioned in Chapter 3, some researchers consider acupuncture patients to have high expectations that may be a potential barrier to improvement [198]. While a failure to meet expectations appears to be influential in at least two patients' negative descriptions of the acupuncturist and treatment experience, the overwhelming use of positive language in both categories suggests that most acupuncturists and treatment experiences met and/or exceeded patients' expectations.

8.9 How Acupuncture Works

As discussed previously, the patient's interpretation of how acupuncture works may influence his/her perceived outcome in conjunction with his/her attitude, experience, and patient-practitioner relationship. To investigate whether or not a patient's understanding of how acupuncture works impacts his/her perceived outcome, the interviews explored the origins of the explanations, patients' understandings of how acupuncture works, the context and development of the explanation, and the perceived impact. According to the patients, their explanations of how acupuncture works were largely derived from their acupuncturists and to a lesser extent by alternate information (e.g. internet, pamphlets, friends).

> Philip: "When I had my first appointment with [the acupuncturist] I just asked her outright how does this all work because I don't know."
>
> Alistair: "I didn't really do any reading beforehand because I thought I'll go into this with an open mind."
>
> Nick: "I looked up the acupuncture on Google so Googled acupuncture and did various sort of readings on it and talked to people about it."
>
> Gina: "I talked to people who had it done before so I didn't feel like I needed to go on to the internet and stuff. I looked at posters when I was there and how different parts of your body related to different parts of your insides and stuff."

Each of these statements represents a unique approach to collecting information. Although the comments made by Philip, Nick and Gina may reflect normal behaviour, Alistair's comment indicates that he and patients making similar comments intentionally altered their behaviour for the study. A study by Paterson *et al* describes similar behaviour among patients in a migraine study and suggests that by intentionally not seeking information the patients are 'playing their part' as research subjects [294]. The idea that some patients altered their behaviour for the

trial was previously mentioned with regard to treatment adherence in Section 8.5.3, and is further discussed in Section 8.14.

Participants described their understanding of how acupuncture works using several themes. First, thirteen (13/33) patients began their explanations by with phrases such as 'I don't know' or 'I don't fully understand' how acupuncture works. The comments about a perceived lack of knowledge on the subject were followed by inferences that acupuncture does or may work. Moreover, some patients (e.g. Matthew) explained that *how* was less important than *does acupuncture work.*

> Irene: "I guess I know that I don't really understand how these things work and to be fair I'm not hugely bothered about fully understanding. I know that therapists study for years so I can't possibly hope to understand things."
>
> Matthew: "I prefer to just get on with it. I've always been like that to be honest. If it works, it works. If it doesn't, it doesn't. Get the experts in to fix it."
>
> Rose: "To be honest I really don't know how it works. I'd just say it works, you've just got to go in with an open mind and trust it."

The perceived lack of knowledge may be important because it implies that the explanation does not influence treatment outcome for some patients. Recall from Chapter 3 that there is also a lack of consensus and on-going research into the mechanism of acupuncture that highlights a lack of scientific knowledge about acupuncture. The patients' emphases on trust in the therapy and/or practitioner's expertise as potentially important influences on treatment outcome correspond with comments in the previous section. However and perhaps most importantly, the patients' comments express a desire for an effective treatment over mechanistic understanding. I consider this 'most important' because, as discussed in the introductory chapters, effectiveness (or pragmatic) studies of acupuncture for IBS are less common than efficacy studies. Therefore, the patients' comments provide an additional rationale for conducting effectiveness research on acupuncture.

Aside from the initial comments, the patients described how acupuncture works in terms of channels and energy, anatomy and physiology, needle effects or a combination of themes. The channels and energy descriptions indicated that movement (i.e. flow), balance, and self-healing are the functional operators of

acupuncture. Twenty-five (25/33) patients described how acupuncture works, either primarily or secondarily through this theme.

> Betsy: "They put the needle in where the channel begins or part way down and that sets off a chain reaction around your body to balance everything and make things work more efficiently."
>
> Angela: "There are various energy channels through the body and that the needle points relate to those energy channels and the purpose is to try and get the body to be balanced or realign those energy lines."
>
> Brenda: "My understanding is that it is something about your own energies in your body and your own ability to heal yourself and that the acupuncture points that they use are very much related to the problems that you're having and it's something about releasing energy so that you can cure yourself or balance your own body."

The comments by Betsy and Angela reflect the explanation from Chapter 3 that the channel system provides the conduits through which qi circulates and connects various aspects of the body, while Brenda's comment reflects the idea of self-healing. In general, the comments suggest that patients are familiar with basic TCM concepts. Whether or not there is a correlation between explanation and acupuncturist is explored in Chapter 9 along with the idea that acupuncturists tailor explanations to individuals.

In contrast to the channel and energy descriptions, patients' anatomy and physiology descriptions of how acupuncture works incorporated words such as endorphins, nerves, and blood, and conveyed a sense of compatibility or incongruity.

> Verne: "It can release endorphins and things for pain relief. Chemicals and that. The acupuncture points are not necessarily anywhere near where you get the pain."
>
> Rob: "All the pins do is stimulate these areas of the central nervous system which produces a given response."
>
> Nathan: "One word springs to my mind that's 'gobbledy-gook'. The notion that I have six pulses in my wrist when I've only been able to find one is strange."
>
> Irene: "My thought is it's similar to the way nerves, so if you stimulate a nerve it might for example stimulate the bowel to move. I know it's not nerve pathways it's more energy pathway."

Of the ten (10/33) patients who made statements in this category, seven of them were men. Rob's comment highlights the idea that his understanding of how acupuncture

works is relatively feasible in the context of his anatomy and physiology knowledge, whereas comments by Irene and Nathan display various degrees of incongruity. For some patients the incongruity may be overcome, as seen in side-by-side comparison of Irene's earlier comment on the perceived lack of knowledge. On the other hand, the incongruity may be insurmountable for patients such as Nathan.

Transitioning from the theoretical and scientific explanations, the third theme patients (5/33) used to describe how acupuncture works was physical needling effects. As discussed in Section 8.7, patients associated physical needle sensations with the idea that something was happening, which contributed to their ability to relax. With regard to how acupuncture works, patients explained that:

> Elloise: "You can kind of feel when you're lying there with the needles in, you can feel something happening. You can feel something unravelling."
>
> Lucas: "The only way I can explain it when she's doing it when the needles are in I can actually feel my stomach. It sounds strange but my stomach rumbles as if things are moving as soon as she puts them in I can hear it rumbling sort of easing off."
>
> Diana: "When she goes off and leaves me with needles in there's definitely this problem area that I have on the right side – it starts to contract it's a weird feeling so they're doing something but what I have no idea."

The comments provide slightly different information than the previous comments, which emphasise the insertion and manipulation of needles. In this context, the patients provide detail about their interpretation of the body's response to needle retention and how that response, to them, characterises the mechanism of acupuncture. As with the channels and energy theme, the patients identify movement as a key component of the acupuncture mechanism. Similar to previous sections, the phrases such as 'easing off' foreshadow the patients' perceptions of outcome.

To summarise, approximately one third of patients made an initial comment that they did not know how acupuncture works and that how it works may not be as important as if it works and the practitioner's skill. Given the lack of consensus on a scientific mechanism and variety of explanations discussed in the TCM literature (Chapter 3), the patients' observations create a link between themselves, researchers, and practitioners. Although the comments imply that the explanation of how acupuncture works may not influence outcome, this topic is directly addressed in

Section 8.12. Additionally, patients repeated the phrase 'open minded', which they commonly used in positive attitude comments. The repetition of ideas and phrases highlights the importance of analysing themes across categories in addition to category specific interpretations. To explain how acupuncture works, all of the patients made comments using one or a combination of three themes: channels and energy, anatomy and physiology, and needle effects. Furthermore, the themes needle effects and anatomy and physiology explain both how acupuncture works and how patients contextualise the explanation in the following section. The similarities and differences these themes have with the literature are explored in the discussion (Section 8.14).

8.10 Making Sense of How Acupuncture Works

Having established that patients use a variety of themes to explain how acupuncture works, I subsequently asked if the explanations made sense and how they were contextualised. The complexity of this question generated a variety of interpretations and responses. Furthermore, the responses' inferences, more so than the themes, provide insight into how patients make sense of the explanations. For that reason, this section highlights how the patients' contextualisation is related to their beliefs and understandings, and briefly introduces the themes. Patients' comments about how they made sense of their acupuncture explanation involved five themes including: history, understanding, physical sensations, anatomy and physiology, and other CAM therapies.

> Brooke: "There is definitely something and if the Chinese have been using these alternative treatments for thousands of years there has got to be something in it." [history]
>
> Dorothy: "When my stomach starts churning and stuff like that it is actually working." [physical sensations]
>
> Lucy: "I think I'm open minded to the fact that things work that I don't understand. I can't explain electricity but I know if I put a plug in the socket it's gonna work. So I do have an open mind to the possibility something can work just because I can't see it." [understanding]
>
> Angela: "I think I understand it. I also do tai chi - its similar kind of principles about having the flow of energy so I could relate to it in that sense." [other CAM therapies]

> Irene: "I know that the body produces positive and negative ions that we are all very electrical based beings. We probably have some sort of energy field around us so certainly when my therapist said that when he was putting the needle in he can feel when he's hitting the energy flow I guess I just accept that we do have energy flows within us and the principle is you sort of try to maximize or smooth out these flows." [anatomy & physiology]

Each of these comments represents a different theme patients used to explore how they made sense of their acupuncture explanation from the previous section. The themes range from broad cross-cultural observations to person-specific observations. What is striking is that comments in all of the themes blend how patients make sense of acupuncture with their perception of effectiveness. For example, Dorothy makes sense of how acupuncture works through her body's physical response, which suggests that the treatment is effective. Although some patients were more emphatic than others, the majority of patients made positive inferences about effectiveness.

In addition to the positive inferences about effectiveness, the comments also reflect different combinations of beliefs and understanding. For example, Patricia's comment highlights her belief, but not necessarily her understanding, whereas Nathan's comment demonstrates his understanding and disbelief.

> Patricia: "I think acupuncture is such an old medicine, such an old approach. I don't think people as clever as the Chinese would have carried on with something that just didn't work."

> Nathan: "Well I like to understand what's going on. I'm understanding but not believing that's where I am, which is like I feel about Christianity really. I understand it and I've been involved in it all my life but I don't believe it and I think that is pretty well where I am."

While the comments illustrate different combinations of beliefs and interpretations that patients drew on, Lucy's comment from above suggests that understanding may be unimportant. Through her experiences with things that work despite her lack of understanding, Lucy suggests that acupuncture has the potential to work based on this premise.

Apart from combinations of beliefs and understanding, many of the comments contain references to the patients' perceptions of the body. In particular, they emphasise the perception that the body is intricately linked.

> Catherine: "I think right if acupuncture can just take that edge off – almost like if you massage a muscle. It's so tense and it pops out. That's how I see it in my mind. I believe in reflexology and stuff. I think that helps with bits. I think all the body is interlinked."
>
> Emma: "I'm quite open to that kind of stuff like reflexology and how the bottom of your foot might sort a headache out. That kind of thing so I kind of understand how, cause your body is all one."
>
> Alistair: "I do believe there is a close link between the mind and the body and I believe there are energy flows within the body. It just seems obvious to me that if the heart is a pump and its pumping blood around and obviously you can get blockages and cholesterol. So if there are points on the body which are key yeah why not like a stimulation or like a push which can assist the flow."

The emergence of the anatomy and physiology comments in this section as well as the previous, and the references to the body from other themes in this section prompted a more detailed question about the relationship between the body and acupuncture discussed in the next section.

As a category, the comments present a diverse spectrum of interpretations of how patients make sense of acupuncture. The diversity of responses illustrates constructionism in action, whereby the patients subjectively interpreted the question and provided responses using their historical and social interactions with the world. Patients' personal and cultural contextualisations suggest that acupuncture may work, and that patients apply concepts with which they are familiar (e.g. other CAM therapies) to new media (e.g. acupuncture).

8.11 Integrating How the Body Works

The appearance of anatomy and physiology comments in the previous categories, as well as the introduction of body perception, provided an opportunity to explore the relationship between acupuncture and the body in more detail. Initially, I asked patients to explain how the body works, which focused their attention to a particular context. Then I asked the patients how they integrated their explanations. Patients described how the body works using a combination of three themes from which they also integrated their acupuncture understanding. First, patients (9/33)[12] described that

[12] Parenthetical references denote the popularity of each theme, but do not total thirty-three due to the combination of themes.

the body works via a mind-body interaction encompassing either body control through brain and nerve pathways (e.g. Lucas) or body control though mental/emotional health states (e.g. Patricia).

> Lucas: "Your mind tells the nerves which then tells the muscles which then move. That's the only way I know about it."
>
> Patricia: "I certainly believe that your state of mind has a massive effect on your physical being."

Although Lucas' and Patricia's comments describe different perspectives of the mind-body interaction, both imply that the mind plays an important role in the body's function. Patients integrated their mind-body explanations with the channels and energy explanation of how acupuncture works. The abstract or literal integrations are best represented by the following comments.

> John: "Movements of the body that are basically all being triggered by the brain. Okay by putting these needles in, in maybe different parts of the body is that somehow affecting the signals that are constantly being given. Is it either encouraging this increasing stimulation or decreasing the stimulation of what of how my stomach and intestines are working."
>
> Erica: "I would think they integrate quite well – channels go up to my mind [laughs]."

John's comment reflects a more literal relationship between mind-body functioning and acupuncture than Erica's comment and suggests that a causal interaction allows acupuncture to manipulate that function. Comparatively, Erica's comment highlights a more abstract relationship that suggests the acupuncture channels may be a communication conduit for the mind-body interaction.

Second, patients (13/33) described how the body works as a function of self-care or self-awareness. The patients' comments define self-awareness as a perception that their behaviour influences the body's function as indicated by the comments below.

> Elloise: "You can't do one thing to one part of your body and not expect a reaction from another part. So for me it's very much you need to look after it otherwise you can't expect anything from it."
>
> Matthew: "I think it's easily abused, easily stuffed with the wrong food and wrong liquids. It's easily overworked. Now [since developing heart disease] I treat it with a bit more respect."

The self-awareness that the patients exert some degree of control over their bodies potentially enables them to self-manage their IBS symptoms through behaviour and diet as seen in Section 8.5.3. Patients integrated the self-care/awareness explanations of how the body works with their understanding of acupuncture using channels and energy (e.g. Helen), and a perception of heightened self-awareness as a treatment outcome (e.g. Brenda).

> Helen: "If your channels are blocked it's [the body] obviously not functioning properly as well as if I was gonna compare that to not getting a full night's sleep, not getting any sleep at all not being able to function properly. I suppose the answer to that solution would be getting some sleep and unblocking any channels."
>
> Brenda: "You just start to say to yourself don't expect to have pain maybe you've been having pain because you've been expecting to have pain but the acupuncture was the thing that helped me to change my thinking."

Both comments suggest that the relationship between acupuncture and the body's function involves an active participatory interaction. For example, Helen uses an analogy about sleep to compare her active participation in her health with acupuncture. In addition to reflecting the relationship between self-awareness and acupuncture, comments such as Brenda's also suggest that the heightened self-awareness affected the patients' abilities to recognise the importance of self-care, the impact of mental health/outlook on general health, and symptom triggers.

Lastly, patients (19/33) described how the body works in terms of anatomy and physiology (e.g. Victoria & Richard). Within this theme, a subset of comments provided figurative illustrations of the body as a machine (e.g. Nathan).

> Victoria: "Well your heart pumps the blood and the blood brings the nutrients to the different places and eliminates what you don't use and we have to take proper food to keep it going."
>
> Richard: "I guess we have vital organs inside our skin the skin being a vital organ as well and we have our brains and our personalities we have to feed our vital organs and brain with food and oxygen and water. It works optimally by trying to get the right balance between all those things."
>
> Nathan: "Well there is a lot of mechanical stuff and hydraulic stuff there's like electronic stuff which is the nerves all melded together in a fantastic incomprehensible way."

While the comments fuse multiple themes such as anatomy and physiology and self-care, they also suggest that balance and movement are important aspects of the body's mechanistic function, which corresponds with previous comments about acupuncture's mechanism. Patients integrated the anatomy and physiology explanations and their understanding of acupuncture using additional anatomy and physiology and/or channel comparisons.

> Nick: "As I said the human body is a functioning machine and as in any machine it needs servicing, it needs parts replacing occasionally or whatever. So acupuncture is like I would regard it as some sort of tuning system like in any engine getting the engine to run as efficiently as possible."
>
> Brooke: "The fact that you have your blood system, everything, you've got things running right the way through the body. They are channels themselves so there has to be a way of tapping into those channels. It's just a matter of opening those channels so that if you have impurities in your system they have a way of escaping."

Similar to the mind-body relationship with acupuncture, these comments highlight a facilitatory relationship, wherein acupuncture repairs or allows the body to repair itself.

In summary, the patients' comments suggest that there are a variety of relationships between the mechanism of acupuncture and how the body works including: causal, facilitatory, and active participatory. Linking the relationships are the common threads balance, movement, and self-care. From a practical perspective, acupuncturists may be able to use this information to engage with patients. For example, if the acupuncturist knows that a patient understands his/her body through active participation it may enable him/her to tailor explanations and lifestyle advice.

8.12 Impact of the Explanation

Based on the comments in previous sections, the patients' interpretations of their acupuncture explanations blended their beliefs and understanding, and overall conveyed a positive sentiment that acupuncture may work. Therefore, I asked the patients whether or not the explanation of how acupuncture works influenced their outcome. Patients were split roughly fifty-fifty between *yes/maybe* and *no/don't know* over this issue. Patients stating *yes/maybe* explained that understanding how acupuncture works enabled them to work with the treatment, relax, and establish rapport with the practitioner. Some patients indicated that it was not necessarily the explanation itself, but the overarching context, usefulness, experience, and possible placebo effect that influenced outcome, as illustrated in the following statements.

> Catherine: "Understanding what it is and what the whole method and type of treatment and where it has come from and what it can treat. I think I've seen so much stuff about it. Knowing about it has helped."

> Lucy: "It's possible that it would in the sense that if I believed it worked I wasn't going to do anything that would sabotage. I wanted to do everything to work with it."

> Angela: "I think having as much information as possible and a greater understanding helps to belay the apprehension, so possibly having the explanation I don't know actually it possibly has an impact on how I viewed how successful it is."

In contrast to the statements above, the comments below represent patients who said *no/don't know*.

> Thomas: "I don't know enough about how it works. I couldn't say whether that [explanation] helped me. I just don't know. I think it's one of those things where you've got to put your trust in the person that's doing it and in their experience and knowledge."

> Elloise: "I don't think it had any influence because when I was getting told it, it was after me actually saying x, y, z. It was just proving that what I was experiencing wasn't freakish or abnormal."

The comments illustrate that some patients who said *no/don't know* considered themselves to not have enough information or understanding of acupuncture for the explanation to impact their perceptions of outcome. It is unclear from the *no/don't know* comments whether patients perceived their lack of knowledge about acupuncture to limit their outcome, which contrasts with the *yes/maybe* comments (e.g. Angela) that indicate a lack of knowledge may impact the perception of

outcome. Alternatively, some patients indicated that the explanation did not impact outcome because they received it after experiencing a particular outcome, while other patients simply said that the explanation did not affect their perceptions of outcome.

Despite contrasting answers, comments in both groups suggest that an explanation of how acupuncture works may be clinically important. For example, if acupuncturists know that patients with treatment apprehensions, such as Angela, may be more likely to relax and engage with the treatment if they provide an explanation, it may alter their behaviour. In contrast, Lucy suggests that the explanation may negatively alter the behaviour of a patient who wants to sabotage treatment. For patients such as Elloise, who do not think that the explanation influenced outcome, it did contribute to her ability to distinguish between symptom variations and improvements.

In addition to perceived impact, some responses to this question provided insight into the negative treatment descriptions in Sections 8.7 and 8.8. Helen's comments about her acupuncture experience and patient-practitioner relationship were categorised as negative based on the suggestion that she found treatments painful and that the practitioner did not meet her expectations. With regard to impact of the explanation, Helen suggests that the explanation ameliorated her painful experience, which may also explain why her treatment description was relatively negative instead of caustic. Overall, the explanations appear to play an important role in treatment for some patients and therefore have the potential to influence relationships with practitioners, engagement with treatment, and outcome.

8.13 Perceived Outcome

Several themes from previous sections foreshadowed the patients' perceptions of outcome, which for twenty-seven patients was a positive perception. In terms of IBS specific effects, patients reported: less pain, bloating, cramps, and wind; more regular bowel movements; and improved appetite. Perceived improvements related to comorbidities and general health included: decreased back and joint pain, fewer headaches, less coughing, improved concentration, better sleep, willingness to engage in activities/socialize, less reflux, calmer, more energy, better mood, weight

loss, and decreased medication. The following quotes illustrate the range of improvements.

> Gina: "For my stomach stuff that hasn't made much difference. It did work for the pain. I felt better in myself because obviously my ankles then my hips work better so I think that did make a bit of difference to how I felt." (G)

> Lucas: "My stomach always feels that little bit better as well it's hard to put, I do think it's helping. I've gone out a bit more than I would normally and socialized a bit more." (L)

> Kim: "It has done me personally, mentally, and everything I just feel like a different person so as I say I can't praise it enough." (Km)

> Elloise: "Making me just want to be round friends and family that bit more because you're not feeling bloated and fat and in pain." (El)

These comments demonstrate the variety of outcomes that Schulman describes as the expected (related to main complaint) and unexpected (beyond main complaint) outcomes related to acupuncture treatment [212]. Elloise's comment about an increased willingness to socialize is a particularly noteworthy unexpected outcome given the emphasis on isolation, loss of freedom, and embarrassment associated with IBS (Chapter 2).

In contrast, Richard's comment represents the five patients who perceived no overall change and one patient (Vi) who was undecided at the point of interview.

> Richard: "Although I think it was a good experience and I quite enjoyed it and I'm sure it did have some effect to some degree but ultimately I've come out of it, I don't think I'm any different really than when I went into it." (Ri)

Of the five patients who perceived no change in their symptoms, four are men, which suggests that men and women may have different perceptions of outcome and/or respond differently to treatment.

Figures 8.5a and 8.5b illustrate the variety of responses on a continuum ranging from no change in symptoms to life changing improvements. Similar to previous continuums, the initials represent patients' pseudonyms. Unlike the initial response continuum, the overall outcome continuum does not include 'worse' because all of the patients reported that their symptoms had returned to their pre-trial severities (i.e.

no change) or they had improved. Two patients (G, H) perceived to have improved comorbid symptoms and not their IBS symptoms, while another patient (Km) perceived a life changing improvement. Figure 8.5a highlights the patients' who had prior experience with acupuncture, and indicates that they all had a positive perception of outcome. Therefore, it is possible that the patients with prior acupuncture experience are inflating the positive outcome perceptions.

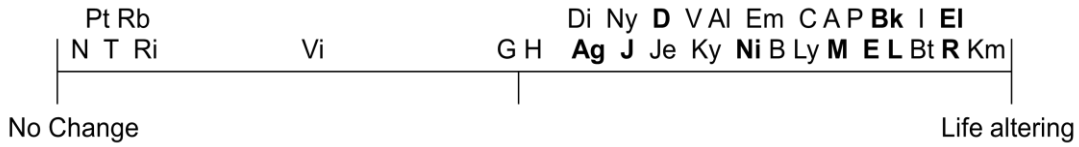


Figure 8.5a Outcome continuum. Bold initials indicate patients with prior acupuncture experience.

Figure 8.5b Outcome continuum highlighting pre-trial attitudes. Red – negative attitude. Blue – ambivalent attitude. Black – positive attitude.

Figure 8.5b depicts the patients' outcomes while highlighting their pre-trial attitudes about acupuncture discussed in Section 8.6.1. The mixture of attitudes on both ends of the continuum suggests that attitude alone is an insufficient indicator of perceived outcome. Examining patients' comments across a variety of categories indicates that different factors and/or combinations of factors were important to different patients. With regard to the recruitment matrix, Table 8.9a indicates that patients who prefer either intervention may be more likely to perceive improvement than patients who preferred acupuncture. However, quantitative analyses are necessary to confirm this finding. Additionally, Table 8.9b descriptively compares the mean score changes on the IBS-SSS and SF-12 composite scores. As mentioned previously, Whitehead *et al* report that although patients with more severe baseline scores improve more than milder patients, they are less likely to report perceived improvement [136]. The comparison of mean scores indicates that severe patients quantitatively improved more than mild/moderate patients; however, the data do not support Whitehead *et*

al's finding about perceived improvement. One reason for the difference may be the presentation of questions, wherein patients in this study were asked in person about a range of outcomes, related and unrelated to bowel symptoms, while patients in the Whitehead study were only asked about their bowel symptoms via questionnaire.

	Prefer Acupuncture	**Prefer Either**
Mild/moderate	Improved – 5F 3M No change – 2M	Improved – 5F 4M No change – 1M
Severe	Improved – 6F No change – 1F 1M	Improved – 4F Undecided – 1F

Table 8.9a Patients' perceived outcome according to recruitment

		Prefer Acupuncture			**Prefer Either**		
	Time	IBS-SSS	PCS	MCS	IBS-SSS	PCS	MCS
Mild/ Moderate	BL	216	54	42.4	186	46.4	40.2
	3 month	168.7	51.3	46.8	200	46.7	41.6
	6 month	134.6	53	49.3	199.8	45.2	42.2
Severe	BL	345	49.7	42.5	336	48.0	39.9
	3 month	251	49.2	44.8	197	47.7	46.0
	6 month	241	49	39.8	150.3	51.0	50.0

Table 8.9b Descriptive comparison of mean score changes according to recruitment. BL – baseline

8.13.1 Continuation & Recommendation

Having explored the patients' treatment experiences and perceived outcomes, the interviews concluded with a question about whether they would continue with and/or recommend acupuncture to other patients. Twenty-six patients stated that they have or would like to continue with acupuncture treatment, and all of the patients responded favourably to recommending acupuncture to friends or family. However, some patients indicated that additional treatments may be cost prohibitive (e.g. Gina). Other patients suggested they would wait for symptoms to return (e.g. Erica) or that they would try acupuncture for a different condition (e.g. Thomas & Philip).

> Thomas: "I think it would be worth it for aches and pains. I would definitely consider using acupuncture again because I'm convinced it does something and may well help me for that but not this particular thing."
>
> Philip: "It's something I have considered I would like to say yes. I've also considered it for other attributes that aren't to do with IBS and maybe doing other courses for other like stopping smoking."
>
> Erica: "If I did if I felt myself going back to constipation or any I would be straight back for another treatment."
>
> Gina: "She was really good actually definitely if I had the money and I had to have stuff like that done I would go back and see her again."

Although the majority of patients provided positive comments about continuation, three patients were not interested in additional acupuncture sessions (e.g. Rob), and four patients who had not completed treatment stated that they were undecided about additional sessions (e.g. Jennifer).

> Jennifer: "I would consider it but I'll have to wait and see what the end result is what the outcome is."
>
> Rob: "No probably not. I tend to look at it there would have to have been for me to take acupuncture seriously and actually invest in it in my own time and my own financial input I would have to have seen a much better and much more clearly defined improvement."

All of the comments highlight the importance of perceived outcome in the decision to continue with acupuncture, and the overall positive endorsement of acupuncture indicates that it is an acceptable treatment. However, the treatment is not suited or perceived to be effective 'enough' for everyone. The comments about cost re-introduce an important point from the patients' reasons to participate that the type of acupuncture delivered in this study was provided outside the NHS. Therefore, additional treatments would require self-funding. As mentioned in Section 8.5.3 and Chapter 5, cost is a potential barrier to adherence in routine practice. For that reason, patients may not adhere outside the trial setting if they do not perceive enough benefit to justify the expense or they cannot afford treatment. A recent study by Barlow *et al* reports a similar finding from patients in an osteoarthritis study who wanted to continue with acupuncture beyond the trial period but were unable due to the cost barrier [296]. From a policy perspective, decision makers should consider the effectiveness and patients' acceptability of treatments as well as options for both

acute phase and long term follow-up in their assessment of acupuncture as a potential treatment.

8.13.2 Case comparison

In comparison to the previous sections that present findings from individual categories, this section presents two cases to illustrate relationships among themes from multiple categories [297]. Comparing themes across multiple categories may be particularly important to understanding outcome because as Verhoef *et al* suggest a patient's outcome is embedded in his/her context, perception of the healing process, and experiences [211]. To explore patients' outcomes through the combination of context, perception of healing, and experiences, I ethnopoetically configured excerpts from two interviews. Traditionally, ethnopoetics refers to the analysis of linguistic structure in oral literature regarding how the performer captures the audience [289]. Coffey and Atkinson suggest that interviews are a type of performance whose data may be arranged into a poem to emphasise particular personal or emotional content. The two cases were selected on the basis that they represent patients whose outcomes gravitate to the extreme ends of the continuums (Figures 8.3 & 8.6a). Comparing patients with opposite outcomes may provide insight into factors that influenced the difference. To ensure quality in this phase of the project, I configured excerpts from the interviews into poems and subsequently had them reviewed by the second analyst BC. BC was familiar with the patients' interview transcripts and determined that the poems reflected the tone and content of the interviews.

> I never regarded myself as having IBS.
> The GPs nominated me as IBS.
> Pain, discomfort, writhing, and moving
> I've been and had investigations up and down.
> Scientific type background believe nothing that you hear and only half of what you see.
> I'm pragmatic and if something worked, what the hell.
> Words used in it – gobbledy-gook.
> Stuff feels like feeding back – I feel a little bit suspicious.
> The history taking was the best I've ever had.
> I just enjoyed the relaxation.
> That diagnosis, it's the gobbledy-gook.
> It's not working for me – not for IBS. ~Nathan

I was told nothing was the matter with me.
I have the symptoms, but I didn't really know what they were.
Quite a lot of pain all the time, queasiness, and sickness.
In my mind I've been confused – Is that caused by IBS?
I went into the treatment quite cynical.
How can having treatment change what's inside you?
It is a medicine, just a different sort.
The explanation that is was the balance had quite an impact.
Just lying there blissful, relaxing.
First I lost the tenseness in my shoulders.
The bloatedness got better, then you get weight loss.
God, why haven't I tried this before?
I can't praise it enough. It's been excellent! ~Kim

Both Kim and Nathan belong to the prefer acupuncture group (severe and mild severities respectively), and began the study with negative attitudes toward acupuncture. Nathan also explains that he did not consider himself to have IBS. Although both patients had some positive comments about their experiences, they perceived opposite outcomes. Exploring Nathan's outcome in the context of the poem reveals two key insights 1) he is somewhat disassociated from his diagnosis and 2) he expected to receive a diagnosis he could associate with from his acupuncture treatments. The comments indicate that symptom relief was a secondary objective, and that Nathan was unable to relate to the TCM diagnosis possibly due to his suspicion about how acupuncture works.

In comparison to Nathan's disassociation from IBS, Kim explains that she is confused and unable to differentiate between symptoms related to IBS and other health problems. Her confusion and desperation for symptom relief played a pivotal role in her trial participation. Unlike Nathan, Kim suggests that she engaged with the TCM explanation and that it clarified the confusion around her symptoms. Kim's transition to the positive end of the continuum was fostered by a perceived change in her symptoms. Overall, each patient's poem collectively reflects comments from multiple themes and illustrates how multiple factors such as attitude, explanation, interpretation, and experience interact and influence the patient's perceived outcome. The interaction of multiple themes also gives rise to latent themes. Specifically, an individual analysis of Kim's and Nathan's reason to participate suggests that they were desperate for symptom relief. However, in the context of other comments, it appears that they both sought information about their condition, which may be described as the latent theme 'consultation expectation: alternative diagnosis'.

As discussed in Chapters 5 and 6, there is a debate about the relative importance of TCM diagnoses to treatment design, yet there is a lack of research on how patients interpret and make use of TCM diagnoses and/or explanations[13] of their conditions. Based on the comparison across themes in this section, I hypothesise that a patient's TCM diagnosis (or explanation of his/her condition) is an influential factor on some patients' perceived outcomes, which may be further explored in future research.

8.14 Discussion

The quotations in previous sections provide illustrative examples that allow the reader to assess emergent themes across a broad range of topics. The emergent themes informed the findings, which suggest that the patients have a number of similarities with the broader IBS population (Chapter 2) including: self-regulated treatments, a variety of comorbidities, and desperation for symptom relief. Furthermore, the findings are consistent with other acupuncture studies mentioned in Chapter 3, wherein patients report outcomes related to both expected and unexpected improvements. Specifically, patients reported expected outcomes related to IBS such as more regular bowel movements, and unexpected outcomes related to comorbidities and/or general well-being such as less coughing. Apart from the reduction in bowel symptoms, the patients increased willingness to socialize is particularly noteworthy given that IBS patients often identify loss of freedom and isolation as attributes of severity. Considering the limitations of the IBS-SSS discussed in Chapter 7, the interviews are a particularly useful indicator that the majority of patients in this study perceive acupuncture to be an effective treatment for IBS. Several factors and/or combinations of factors appeared to influence the patients' perceptions of outcome including: explanation of how acupuncture works, TCM diagnosis, treatment experience, and relationship with the acupuncturist. How they made sense of acupuncture combined their perceived effectiveness and ideas on mechanism. In addition to recapping the main findings, this section discusses how the findings address the first aspect of question three and relate to the literature.

Patients derived the answer to the first aspect of question three, 'how do patients understand acupuncture to work' from the acupuncturists, internet, and pamphlets.

[13] Explanation in this sense refers to a description of the patient's condition as opposed to an explanation of how acupuncture works as seen in Section 8.9.

Their explanations incorporated descriptions about channels and energy, anatomy and physiology, and needle sensations, and often reflected perceptions of effectiveness. Moreover, the patients made sense of the explanations using similar themes that incorporated their experiences with other CAM therapies as well as historical and cultural references. The repetition of anatomy and physiology in multiple categories prompted an in-depth comparison of the patients' acupuncture and body function explanations. Figure 8.6 illustrates the relationships that emerged between the two explanations. For example, patients related their mind-body and channels and energy explanations through a causal inference that acupuncture manipulates body functions to exact a change in health. Similarly, the facilitatory relationship between anatomy and physiology explanations infers that acupuncture allows the body to heal itself. Lastly, the self-care and channels and energy explanations were related through patients' active participation wherein acupuncture presented a means to affect a change in health through partaking. The discussions on relationships and how patients make sense of their explanations make this study unique in comparison to the literature introduced in Chapter 3.

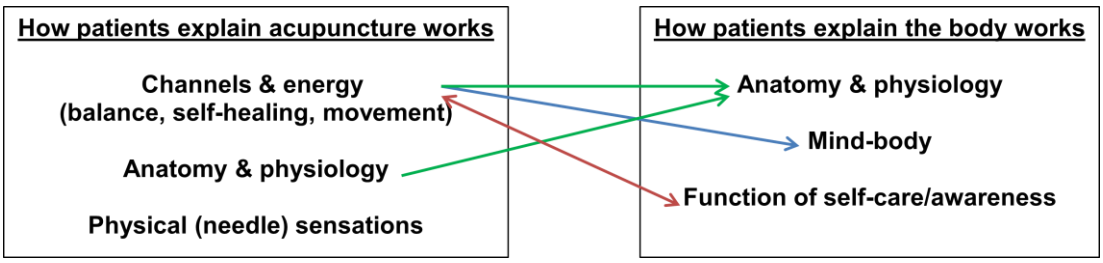


Figure 8.6 Relationship between how acupuncture and the body work. Blue – Causal/faciltiatory relationship. Red – active participatory relationship. Green – faciltiatory.

In addition to the question about how acupuncture works, the patients were asked about their perceived outcome and whether the explanation about acupuncture influenced their perception. Approximately half of the patients suggested that the explanation influenced their perceived outcome by enabling them to work with treatment, relax, and establish rapport with the practitioner. Additionally, some patients who perceived that the explanation did not influence outcome indicated that it did enable them to distinguish between symptom variations and improvements. Based on the responses to the third research question and the exploratory nature of

the interviews, I propose two hypotheses that may be explored in future research. First, I hypothesise that the explanation of how acupuncture works impacts patients' perceptions of outcome and therefore may influence clinical practice. Second, I hypothesise that by understanding how patients perceive the body to work acupuncturists may be able to tailor their acupuncture explanations.

Furthermore, patients' interest in an effective therapy over mechanistic information has potential research implications. As discussed in Chapters 1 and 3, there are many efficacy studies related to the biochemical effects of acupuncture as well as studies such as Lembo *et al* [41] that attempt to identify the active components of acupuncture. Considering that patients are the tax payers funding much of the research, their preferences may be used as a platform to encourage more effectiveness studies.

As mentioned, this study's emphases on impact and integration of ideas make it unique in comparison to studies by de Lacy *et al* and Cassidy. The studies by de Lacy *et al* and Cassidy emphasise the patients' explanations of what acupuncture does and how it works. De Lacy *et al* report that patients used metaphors to describe how acupuncture works, which emphasised flow and balance [207]. As such, both studies suggest that patients are familiar with TCM concepts, but do not necessarily use TCM terms. In comparison, Cassidy reports that patients explained 'what does Chinese medicine do' in terms of alleviates symptoms, improves psychological coping, improves physiological coping, provides close patient-practitioner relationships, and treats the whole person [206]. Specifically related to outcomes, treatments decreased symptoms, increased energy, self-awareness and calm. Cassidy concludes that patients may not be familiar with or consider TCM language relevant because it is not reflected in the comments. However, there is a distinct difference between the questions and findings from our respective studies. Although patients in this study rarely used words such as *yin*, *yang* or *qi*, their frequent use of channels and energy as well as explanations of balance and movement demonstrates their familiarity with basic TCM concepts. The difference between the questions 'how does acupuncture work' and 'what does acupuncture do' likely contributes to the difference in findings. Additionally, the following chapter explores the explanations

acupuncturists provide, which suggests that practitioners purposely substitute TCM language with more familiar words to explain TCM concepts. Therefore, this particular study has the added advantage of multiple perspectives.

Beyond addressing the third research question, the interviews generated several other discussion-worthy findings. One such finding is the patients' acceptability of and adherence to treatment. As previously mentioned, patients attended on average nine of the ten sessions offered, and most were interested in additional sessions and were likely to recommend acupuncture, which suggests strong acceptability and adherence. Strong adherence is important because it indicates that the findings reflect the perceived outcome of the intended intervention. Second, strong acceptability suggests that patients may respond favourably to the offer of acupuncture as a treatment option.

Although patients strongly adhered to treatment, comments by Thomas (Section 8.5.3) and Alistair (Section 8.9) suggest that some patients' approach to treatment and adherence was influenced by an assumed trial behaviour. According to a study by Heaven *et al*, patients assume a trial identity that falls along a continuum from volunteer to real patients [266]. Patients on the volunteer end are motivated by their potential contribution to knowledge and sense of responsibility similar to the altruism theme in Section 8.6.2. On the other end, real patients are motivated by the desire for personally relevant medical care. While a couple of patients identified with the extreme ends, most assumed hybrid or fluctuating identities. The authors report that identity affected the patients' perceptions of appropriate behaviour. Assessing the patients' trial identities was not an objective of this study; however, I can infer from the data that some patients identified with the volunteer end of the continuum and that their assumed responsibility influenced adherence to treatment. Therefore, the adherence rate may be artificially inflated by those patients who continued with treatment despite the lack of benefit such as Thomas.

While Thomas' comment highlights his association with the volunteer role and assumed trial behaviour regarding adherence, Alistair's comment highlights his association with the volunteer role and assumed trial behaviour regarding

information seeking. Specifically, Alistair suggests that he did not seek information about acupuncture prior to treatment because it may influence his experience. Paterson *et al* report a similar finding in that patients assume the role of research subject during a trial, which contributes to less information seeking and patient-practitioner discussion [294]. The reluctance to seek information may affect a patient's ability to operationalise explanations, which, according to Cartwright and Torr, enable patients to make sense of their illness and manage their health [298]. Therefore, the assumed trial behaviour may produce different outcomes than would be expected in routine practice.

Another discussion-worthy finding is that six patients (4M, 2F) stated that they did not suffer from IBS; instead, they claimed to have ulcerative colitis, Crohn's disease or trapped wind. The comments prompted a retrospective search of the patients' records to determine the validity of these claims, which revealed that one patient was diagnosed with ulcerative colitis. As mentioned in Chapter 4, database recruitment has many advantages; however, these comments identified an unanticipated disadvantage in that preliminary diagnoses are maintained in the computer system even when they are superseded by another diagnosis. Future studies should be aware of this potential limitation and adapt their database recruitment strategies accordingly. Although the comments highlight a potential limitation of database recruitment, they also demonstrate the benefit of combined qualitative research. With regard to the acupuncture intervention, the pragmatic nature of the treatment hypothetically compensated for differences in biomedical diagnoses.

In summary, the interviews suggest that patients construct their understanding of acupuncture with cultural and historical contexts, and their experiences with other CAM therapies. Beyond the constructs, the patients' understanding of how acupuncture works connects to their perceptions of how the body works through faciltiatory and/or participatory relationships with their health. Given the interest some patients expressed in their TCM diagnosis, as identified by the latent theme 'consultation expectation – alternative diagnosis' (Section 8.13.2), further research that employs direct questions about patients' TCM diagnoses may provide useful information about patients' interpretation and operationalisation of TCM diagnoses

as well as the commonality of this consultation expectation. The following chapter explores acupuncturists' and GPs' understanding of how acupuncture works and its acceptance as a treatment.

Chapter Nine

How Acupuncture Works: Interviews with Acupuncturists & General Practitioners

Chapter highlights

- Acupuncturists tailor their explanations of how acupuncture works to individual patients using TCM concepts and perceive that their explanations may influence patients' outcomes
- Acupuncturists perceive acupuncture to be gaining acceptance as a valid treatment; however, a lack of financial support and distinction in training may limit the integration of traditional acupuncturists into the NHS
- GPs are aware of the traditional acupuncture explanation; however, they prefer to explain the mechanism of acupuncture through biomedically oriented concepts such as the gate control theory
- Although acupuncture is relatively well accepted as a valid treatment, some GPs raised concerns around training and safety that limit their acceptance of traditional acupuncturists

9.1 Introduction

The previous chapter explores how patients understand acupuncture to work, their treatment experiences, and perceptions of outcome. Findings suggest that patients use a variety of explanations that integrate, to some extent, their understanding of how the body works, and that half of the patients perceived their explanations to influence treatment outcome. With regard to IBS, the patients bore many similarities to the literature (Chapter 2) including: desperation for symptom relief, willingness to try anything, self-regulated treatments, and multiple comorbidities. As introduced in Chapter 1, the lack of an effective biomedical treatment and unmet needs are two of a number of areas influencing the increase in pluralistic therapies (Figure 1.1) such as acupuncture. The increase in popularity generated a shift in the symbiotic dynamic between biomedicine and TCM that has affected research and practice. This final data chapter explores how GPs and acupuncturists understand acupuncture to work as well as the acceptance of acupuncture as a valid treatment modality and the integration of traditional acupuncturists into the health care community.

By addressing how GPs and acupuncturists understand acupuncture to work, the acceptance of acupuncture as a valid treatment modality, and the integration of traditional acupuncturists into the health care community, the material in this chapter answers the second aspect and associated subquestions of question three. The subquestions provide particularly pertinent context about the relationship between GPs and acupuncturists, and highlights perceived barriers to treatment delivery. Although practically important, this chapter contributes least to the hypothesis development about the relative importance of TCM diagnosis and treatment individualisation.

9.2 Aims & Objectives

The aim of this chapter is to address the second aspect of the third research question, ‘how do acupuncturists and GPs understand acupuncture to work’ and the sub-questions regarding potential affect on outcome and acceptance. The objectives are to determine:

- How acupuncturists explain acupuncture to work and how they explain it to patients

- Whether acupuncturists perceive their explanation to impact treatment outcome
- Which characteristics augment the likelihood that acupuncture will be effective or not for a particular patient
- How GPs understand acupuncture to work
- Whether GPs perceive acupuncture to be an accepted treatment modality
- The status of traditional acupuncturists in the medical community

9.3 Methods Summary

As discussed in Chapter 4, this phase of research employed a qualitative methodology and individual in-depth interview method. Acupuncturists were recruited to participate based on a purposive strategy selecting for acupuncturists registered with the British Acupuncture Council (BAcC) who practice traditional Chinese medicine (TCM) in North Yorkshire, excluding acupuncturists participating in the trial. GPs were recruited from a convenience sample of surgeries that expressed an interest or participated in the trial. In total, I conducted twenty-two interviews (11 acupuncturists & 11 GPs) based on flexible topic guides (Appendix B 8) that lasted between thirty minutes and one hour. The topics covered during the interviews included:

- The perceived uses of acupuncture
- How acupuncture works
- How acupuncturists describe acupuncture to patients
- Type of patient most likely to benefit from treatment (acupuncturists only)
- Whether the explanation influences outcome (acupuncturists only)
- General feelings about acupuncture (GPs only)
- The discussion of acupuncture with patients and in what context (GPs only)
- Acupuncture's role in the medical community

I audio recorded and transcribed all of the interviews, and together with the field notes analysed them via mechanical and interpretive strategies that uncovered themes and subthemes [244]. Similar to the previous chapter, I attempted to reduce bias and improve validity by analysing the data in conjunction with BC[14]. Since the

[14] BC - Baltica Cabieses is a colleague with qualitative research experience who independently coded transcripts as a form of analyst triangulation to reduce the risk of bias.

acupuncturists and GPs participated in slightly different interviews, the findings from each group are presented in separate sections. To protect anonymity, each participant is referred to by a pseudonym.

9.4 Response Rates

Fifty-five acupuncturists were invited to participate in an in-depth interview, of which eleven replied with interest and completed an interview. Table 9.1 lists the acupuncturists' response rates. Although 100% of the acupuncturists who replied with interest completed an interview, the percentage of interested responses dropped by half compared to Chapter 5. One reason for this may be that a number of those acupuncturists who may have been interested were already participating in the RCT and were therefore excluded from this study. The acupuncturists who were interviewed had an average 7.5 years in practice (range 1 – 28) (Table 9.2). Similar to the pre-trial interviews, the majority of acupuncturists were women (8/11).

Response	Acupuncturists	Percent
Replied with interest	11	20%
Replied not interested	8	15%
No reply	36	65%
Total	55	100%

Table 9.1 Acupuncturists' response rates

Acupuncturist	Sex	Yrs in practice
Frank	M	28
Henry	M	10
George	M	1
Sasha	F	6
Kayla	F	2
Danielle	F	6
Tori	F	3
Ruth	F	9
Caroline	F	13
Isabel	F	1
Whitney	F	3

Table 9.2 Acupuncturists' characteristics

Over one hundred GPs were invited to participate in an in-depth interview, of which twelve replied with interest and eleven completed an interview. Table 9.3 lists the GPs' response rates. The GP who did not complete an interview indicated that it was

too time intensive. The GPs who were interviewed had an average of 13.2 years in practice (range 1 – 28) (Table 9.4). Additionally, three completed acupuncture training provided by the British Medical Acupuncture Society (BMAS). In contrast to the acupuncturists, eight of the eleven GPs were men.

Response	GPs	Percent
Replied with interest	12	10%
Replied not interested	1	1%
No reply	109	89%
Total	122	100%

Table 9.3 GPs' response rates

GP	Sex	Yrs in practice	CAM training
Brad	M	18	Acupuncture
Norman	M	13	
Arthur	M	28	Hypnosis
Oliver	M	1	
Dennis	M	8	
Gilbert	M	22	
Jack	M	5	Acupuncture
Nelson	M	16	Acupuncture
Natalie	F	3	Reflexology
Lynn	F	10	
Emily	F	21	

Table 9.4 GPs' characteristics

9.5 Acupuncturists' Findings

Findings from the acupuncturists' interviews describe how they understand acupuncture to work, how they explain acupuncture to patients, whether the explanation impacts treatment outcome, who may benefit from acupuncture, and their perception of acceptance by GPs.

9.5.1 How Acupuncture Works

Before exploring the potential impact of explanations on patients' outcomes, I asked the acupuncturists to describe how acupuncture works. The explanations were dominated by TCM concepts from Chapter 3 including: yin-yang, self healing, smooth flow through channels, and balance. The following statements illustrate these ideas.

> Isabel: "It stimulates the body's own energy that runs through or as we see it runs through channels in the body just below the surface of the skin."
>
> Ruth: "Blockages of energy which cause disease or cause pain so by freeing the energy up or freeing the channels up that the pain is occurring in you can have free flow of energy that will, the body will heal itself."

Although all eleven acupuncturists explained how acupuncture works using TCM concepts, the degree to which they used TCM terminology varied. For example, the acupuncturists readily used the words *channels* or *meridians* as seen in the statements above, but rarely used the words *qi* or *yin/yang* in comparison to energy and balance. One possible reason why they use the word *channels* is because they are easy to visualise and may be associated with blood vessels or roadways, unlike *qi* which does not have a simple comparator. The blended use of terms suggests that language may be important.

In addition to using TCM concepts in their explanations, the acupuncturists recognised that how acupuncture works is not fully understood and that non-TCM explanations may contribute to the understanding.

> George: "I don't think anybody hand on heart can properly say they know how it works. There's something a little bit special that we can't fully explain. I find that particularly exciting."
>
> Tori: "I think that the action of the sort of release of endorphins and cortisol and things like that, that have been shown in studies to happen during the course of treatment makes people feel better."

Beyond illustrating the ideas that the mechanism of acupuncture is not fully understood and that the mechanism may incorporate biomedical explanations, the comments suggest that the unknown element is a positive attribute of acupuncture and that explanations have the potential to influence outcome. From a negative perspective, the unknown factor has been described as a challenge to acupuncture research, insomuch as it limits the development of an appropriate placebo comparator [299], which may limit the validity of studies using placebo controls. Another way of looking at the mysterious mechanism is through the constructionist perspective of this thesis. From the acupuncturists' perspective, the mysterious attribute is part of their knowledge about the mechanism of acupuncture, while the researchers' perspective (Chapter 3) suggests that the mystery outlines an area that

requires knowledge acquisition. Therefore, acupuncturists and researchers may have different interpretations and understandings of the same topic.

The acupuncturists' explanations of how acupuncture works emphasise TCM concepts, and introduce the ideas that the mystery around the mechanism and the incorporation of biomedical concepts are positive interpretations and/or adaptations. The mystery, TCM concepts, and biomedical explanations are similar to themes from the patients' interviews (Chapter 8), which for some patients influenced trust in the practitioner and/or compatibility of information. The similarity may reflect the influence of the acupuncturists' explanations on the patients' explanations or the possibility that they are using similar contexts to construct their explanations. Additionally, the findings are similar to Jackson and Scambler who report that acupuncturists (in London) understand acupuncture's mechanism through the Chinese notions of qi and regulating the body, and distinguish that apart from TCM explanations the mechanism is mysterious [300]. The consistency across these studies is important because it suggests that the findings may be relevant to the broader BAcC community.

9.5.2 Patient Explanation

According to the previous section, acupuncturists blend the use of TCM and non-TCM terms, which suggests that they may purposefully select language for their explanations. Similar to the recurring theme from Chapter 5, the acupuncturists explained that they tailor explanations to the individual.

> Frank: "I think you have to sort of fit your language and the level of explanation to the person in front of you to some extent. So I have I suppose developed a language."
>
> Whitney: "I've always explained things in terms that patients will understand. If you bamboozle them with technical stuff it goes way over their head and they don't understand and they don't gel with you."

The comments by Frank and Whitney flow through the process of recognising the importance of language, selecting the appropriate words, and delivering them in a comprehensible way. Whitney also notes that a failure to enact this process may result in a poor patient-practitioner interaction. Nathan's comments (Chapter 8) provide an example of incompatible language that possibly alienated him from

treatment or created a barrier in his patient-practitioner relationship. Additionally, the acupuncturists' efforts to 'fit their language to the patient' may explain why the patients grasp TCM concepts but make limited use of TCM terms.

To individualise explanations, the acupuncturists expressed a need to know the patient and be aware of those who do not want an explanation.

> Caroline: "Varies very much with the patient. I think during the consultation you can get an idea of whether they're interested in the explanation – some people aren't"

> Danielle: "Some have no interest in how it works at all, as long as it works. I think I have to gauge [that] with the patients cause some really don't they just don't want you to explain it and they just want you to get on with treatment."

The emphasis on gauging a patient's interest in an explanation reinforces the inference that the explanation is important. The comments also parallel the difference in the patients' keenness for explanations in that some actively sought an explanation while others were not interested (Chapter 8). The parallel creates a circular relationship between the patient and practitioner that is further discussed in Section 9.7.

With regard to language, some acupuncturists preferred to use analogies involving car maintenance, showers, or bank accounts as illustrated by Kayla.

> Kayla: "It's a bit like a bank account and if you're working really hard you are kind of going on credit and you know you get to a point where your over draft limit is maxed out. You're exhausted, so you need to eat, you need to rest, so that you can build up your reserves."

The use of analogies allows the acupuncturists, such as Kayla, to transform potentially unfamiliar TCM language into familiar concepts. As discussed in Chapter 3 and seen in previous comments, the TCM explanation of how acupuncture works relies on figurative language that describes observations of the natural world. Therefore, the acupuncturists' use of analogies reinterprets the figurative explanations. Although figurative language is common in everyday speech and provides a means to conceptualise experiences, it may foster miscommunication if it is unrecognisable [157]. Gibbs also notes that science typically grounds explanations in literal language and associates figurative language with distorted realties. This antagonistic view of figurative language may provide insight into the GPs use of

scientific acupuncture explanations (Section 9.6.3). Alternatively, the view may encourage acupuncturists to incorporate scientific language and/or familiar analogies.

Apart from analogies, the acupuncturists suggest that they typically provide patients with explanations that involve TCM concepts (e.g. Henry), which resemble explanations from the previous section.

> Henry: "The way that I explain it to patients is that I talk, the idea of energy flow through the body and when that energy is disrupted it's no longer flowing correctly and that the needles are used to manipulate the flow of energy."

The idea that acupuncturists explain how acupuncture works to patients through TCM concepts corresponds with the popularity of patients' descriptions of channels and energy (Chapter 8). One reason this finding is important is that the correlation implies that the acupuncturists did not alter their behaviour with regard to this aspect of treatment during the trial. In comparison, a study by Paterson *et al* reports that acupuncturists, in an efficacy study, provided less explanation to and discussion with patients as an assumed trial behaviour [294]. Considering that a number of patients and acupuncturists (Section 9.5.3) suggest that the explanation influenced treatment outcome, the routineness and/or alteration of the explanation is potentially important. Furthermore, the potential differences in behaviour and influence on outcome support the need for an assessment to evaluate the routineness of trial treatments as mentioned in Chapter 6.

Having established that the acupuncturists use TCM concepts and analogies to explain how acupuncture works, I asked the acupuncturists when they provided the explanations. The timing and detail of explanations varied according to the acupuncturist. Some acupuncturists preferred to provide an explanation if patients asked or if they felt it was appropriate (e.g. Isabel), while others preferred to provide a simple explanation to everyone and vary the amount of detail at follow-up treatments (e.g. Ruth).

> Isabel: "It may come into the conversation during the initial consultation and depending on the patient. Then as you go through follow-up treatments some will ask more as they go along."
>
> Ruth: "Explain to them how the blockages of qi can give the symptoms they've got and then I don't give them the explanation all in one go because it's too much to take in. You add in things as the weeks go on."

The comments by Isabel and Ruth reiterate the need to gauge patients' interest and highlight the importance of the practitioner's preference. Thus, the key to an explanation's timing, detail, and language resides in the practitioner's preference and his/her assessment of the patient, which includes distinguishing who does and does not want an explanation.

The acupuncturists provide explanations that reflect basic TCM concepts (Chapter 3), but do not necessarily incorporate TCM terms. Based on the attention paid to the language and gauging patients' interest, I infer that the explanation is an integral component of the treatment process.

9.5.3 Impact of Explanation

Building on the understanding that the acupuncturists modify their explanations for the individual, they were asked whether the explanation may influence treatment outcome. Two acupuncturists said *no/don't know* whether the acupuncture explanation influences outcome, but that it does facilitate an understanding of the treatment process. For example, an explanation could help a patient understand "why you put needles in their feet when they've said they got a headache" [Tori]. An additional two acupuncturists thought it was possible, and that it may influence outcome through suggestion or placebo as indicated by the following comment.

> George: "Possibly that could be part of building up a placebo effect and saying here's the rationale of how it can work, so that might work away in the head."

However, the majority of acupuncturists indicated that the explanation does impact outcome, specifically for some patients.

> Frank: "I personally think it is a significant part of the treatment and as I've said I think there is something about making sense of what's happening to you that people find empowering and reassuring."

> Henry: "It is useful for them to have an idea of what I'm trying to achieve when I treat, so for some patients it helps them to sort of visualise the change."

In addition to suggesting that the explanation impacts outcome, the comments also suggest that the explanation impacts outcome because it may influence a patient's ability to visualise treatment, provide reassurance and/or empowerment, or influence the patient-practitioner relationship. Empowerment appears in various literature related to this thesis including CAM, IBS, and the health care movement, and is therefore further discussed in Section 9.7.

Overall, the acupuncturists' comments are similar to the patients' comments, which indicate that the explanation may contribute to an ability to distinguish between fluctuations in symptoms and improvements, a placebo effect, the patient-practitioner relationship, relaxation, and an ability to work with the treatment. Comments regarding the lack of impact were also similar in that despite the potential lack of impact on outcome the explanation may affect the perception of treatment and/or symptoms. Therefore, the explanation is a potentially important aspect of treatment.

9.5.4 Who Does Acupuncture Work For

Based on the potential role of the practitioners' prognoses in predicting outcome (Chapter 7), the interviews asked them to distinguish patients' characteristics that they associated with positive and negative outcomes. Familiarly, the first theme to emerge was the importance of the individual. The acupuncturists were in agreement that a patient's outcome depends on the individual. Within this broad theme the acupuncturists identified some characteristics that may augment the likelihood of a positive outcome. For example, patients who were willing to make lifestyle or diet changes, commit to treatment, and have realistic expectations may be more likely to improve as indicated by the following statements.

> Sasha: "It's enough motivation to be prepared to come for treatment."

> Kayla: "They're keen. Number one they want to make a change. They want to make a change. They don't know how to make a change. That's number one."

In contrast, the acupuncturists perceived that patients who lacked commitment and/or did not participate, were impatient, or suggested acupuncture is 'not my choice' were not likely to improve.

> Kayla: "Most of them were sent, were told to come by someone close to them. It wasn't their choice. The other thing is again they honestly didn't want to make any changes."
>
> Sasha: "It's almost like they don't want to be involved with their care. I'm [the patient] not actually responsible for my health, it's your problem."

Although the comments depict different types of patients, both appeared to be a source of frustration for the acupuncturists. The opposing characteristics contrast the patients' and the acupuncturists' perceptions of outcome, and as such the comments collectively reflect a range of patient-practitioner encounters applicable to a broader context. For example, Lupton describes the opposing characteristics as 'active consumers' who are patients that seek information about their condition and want to be part of the decision making part of their care, and 'passive patients' who are not interested in an active role in their care [301]. While Kelley *et al* report that extraversion, agreeableness, and openness to experience are associated with improvement [282]. The comments also reflect similar statements about participation and motivation that the acupuncturists considered important in Chapter 5. The active or passive characteristic patients adopt may be influenced by their relationship with the practitioner as well as their sense of empowerment [301]. Therefore, the dynamic created among the interaction of these factors may influence outcome.

In addition to motivation and participation, the acupuncturists indicated that a patient's age (e.g. Ruth) and nature of the condition (e.g. Henry) were potential indicators of improvement.

> Ruth: "I suppose younger people do respond better, quicker."
>
> Henry: "People more or less do respond it depends on how long they've had it and the nature of the condition as to how they are going to respond."

In comparison to the idea that younger patients or more acute problems are more likely to improve, the acupuncturists noted that elderly patients or chronic conditions may be more difficult to treat (e.g. Whitney). They also hinted that sex may influence outcome (e.g. Danielle).

> Whitney: "If you've got a deficient patient, they are harder to treat. There is no question about it a deficient [patient] is harder."
>
> Danielle: "The women tend to be more patient, so they [men] are and sometimes I can sense they are just not really prepared to commit."

These two sets of comments identify a number of factors that the acupuncturists perceive as potential influences on outcome. Regression analyses, in Chapter 7, suggest that older patients reported less improvement on the IBS Symptom Severity Scale (IBS-SSS) than younger patients; however, there was no association between sex or the duration of IBS and outcome. In contrast, the patients' interviews reveal that four of the five patients who perceived no change in symptoms were men, which does suggest a difference in sex. The difference in findings may be related to the small number of men participating in the study in that the sample size was too small to detect a difference. Alternatively, the difference may be related to how men and women perceive health. A recent study by Witt *et al* reports that sex (i.e. female) and age under fifty characterise patients with better acupuncture outcomes [279]. With regard to deficient conditions, more research is necessary, but the exploratory analyses suggest that patients with yang or yin deficiencies improved less than patients with liver qi stagnation (excess). As such, the exploratory findings support the acupuncturists' comments.

Lastly two acupuncturists noted that the patient-practitioner relationship and practitioner's experience were important to outcome.

> Tori: "That relationship, a connection or you might meet somebody and that relationship just doesn't gel between you."

Tori's comment highlights a simple concept, people do not get along with everyone they meet, with complex consequences that impact outcome. Given the number of inferences about the importance of practitioners' preferences (Chapters 5 & 6), it is surprising that only two of the eleven acupuncturists perceived their skills and/or relationships with patients to potentially influence outcomes. However, the question was directed at patients' characteristics, which may explain the inattention to the importance of the practitioner.

Generally, the acupuncturists perceived the combination of a patient's willingness, motivation, age, sex, duration of illness, and nature of illness to be predictive of outcome. Based on the data and related literature, age and sex, in particular, appear to be important predictors of outcome. Nevertheless, the acupuncturists' emphases on the individual as the most important predictor of outcome suggest that over-reliance on a single characteristic such as age may inadequately predict outcome. Analysis of the practitioners' prognoses and patients' outcomes (Chapter 7) indicate that the acupuncturists are capable of differentiating between patients likely to experience positive and negative outcomes. The ability to differentiate patients in terms of positive and negative outcomes has potential practical implications that could be used in the referral process in primary care or in research.

9.5.5 Acupuncture's Acceptance

Transitioning from how acupuncture works to its role the in the wider health care community, the acupuncturists described their perceptions of acupuncture's acceptance by GPs. The first theme that emerged was that the acceptance of acupuncture varied by GP and more specifically his/her age.

> Isabel: "Variable – some are more open to it than others. Some I suppose it's a generational issue because I believe doctors in training now are more exposed to complementary medicine."

Beyond the variability in acceptance, Isabel's comment foreshadows the second theme that acceptance is shifting. Additionally, her comment provides insight into a potential explanation for acceptance among younger GPs in that their training likely exposes them to acupuncture. Therefore, the difference in acceptance may be a by-product of a difference in the GPs' curricula. A study by Lewith *et al* also notes the relationship between age and GPs' attitudes toward acupuncture and reports that acupuncture is one of the most commonly used CAM therapies in the NHS [302]. Since it is one of the most commonly used, one may infer that it is also more commonly accepted as a valid treatment than other CAM therapies.

The second theme highlights a shift towards gaining acceptance or recent acceptance by GPs. The acupuncturists identified a variety of factors potentially influencing the shift such as increased acupuncture research, National Institute for Health and Clinical Excellence (NICE) guidelines that mention acupuncture, and the BMAS.

> Danielle: "Changing – much more positive. I think the NICE guidelines a few months ago [re low back pain] has made a difference."
>
> Sasha: "What's shifting it and certainly the GPs that quote things to me almost without exception will say that's been published so it's the research projects."

Both Danielle's and Sasha's comments suggest that the shift in acceptance is an on-going process, which implies that they do not perceive acupuncture to be fully accepted. Along those lines, the acupuncturists indicated that GPs may only recognise the use of acupuncture for pain or infertility. This finding is supported by a survey that reports GPs perceive patients with pain as the most likely beneficiaries from CAM [303]. However, the positive implication assigned to the increase in research and guidelines contrasts with other literature as discussed in Section 9.7.

In addition to asking the acupuncturists about GPs' acceptance of acupuncture as a valid treatment, they were also asked about their acceptance. One word summarily describes the answers to this question – mixed – which is poignantly expressed by Kayla.

> Kayla: "Their attitude towards us again is quite mixed."

Kayla's comment captures the idea that some acupuncturists have positive relationships with GPs and therefore feel 'accepted' while others have had negative experiences. Despite the mixed responses there was an underlying sense of optimism, possibly related to the shift in acupuncture's acceptance, that their acceptance would change.

> Caroline: "I hope it's changing. I'm sure in the past it's been thought to be Mickey Mouse. I'm hoping that's changing because GPs are now seeing the evidence."

Caroline's comment succinctly combines a variety of themes about the shift in acceptance, role of evidence, and optimism that the shift will be positive. A shift in the acceptance of acupuncture whether positive or negative may alter or be the by-product of an alteration in the symbiotic dynamic between TCM and biomedicine. As discussed in Chapter 1, popularity, practice, and acceptance are some of the factors affected by and affecting the symbiotic dynamic. Section 9.7 presents further discussion on the findings and the symbiotic dynamic.

Aside from positive and negative experiences, the acupuncturists identified two areas that may inhibit their acceptance by GPs. First, some acupuncturists perceived money to be a limiting factor because many TCM trained acupuncturists currently work outside the NHS (e.g. Isabel). Second, some acupuncturists perceived a lack of distinction in training between traditional acupuncturists and BMAS trained providers to be a limiting factor (e.g. Frank).

> Isabel: "There is also the fact that we are in private practice and not funded through the NHS. In a way they [GPs] have their budgetary implications if we were to work with them at the moment it would have to come out of their budget."

> Frank: "You're going to have difficulty understanding the difference between a traditional practitioner and somebody who has done a few weekends training a dry needling approach to pain management. Its only I think if you have a bigger picture and have some sense of the holistic nature of the way we practice that maybe you can begin to make more distinctions."

Isabel's comment raises a potentially negative consequence of the positive shift in acupuncture's acceptance, whereby increased acceptance by GPs may not translate into work/referrals because they practice outside the NHS. The acupuncturists acknowledged that their position outside the NHS creates competition with less expensive providers such as BMAS trained physiotherapists and GPs inside the NHS. Issues over money, regarding treatment adherence, availability, and implementation, have been raised by acupuncturists (Chapters 5 and 9), patients (Chapter 8), and GPs (discussed in Section 9.6.5), the importance of which is further discussed in Section 9.7.

With regard to the second barrier, acupuncture lacks statutory regulation (Chapter 1); therefore anyone may use the title acupuncturist. Self-regulatory authorities such as the BMAS and the British Acupuncture Accreditation Board[15] (BAAB) established different training requirements that require a minimum of 24 hours and 3,600 hours of acupuncture training respectively [22, 304]. However, unless a person is familiar with these distinctions he/she may not be aware that there is a difference. As discussed in Section 9.6.5, GPs are unfamiliar with traditional acupuncture training,

[15] The BAAB provides accreditation for acupuncture programmes offered at schools such as the University of Westminster and is affiliated with the BAcC. Included in the 3,600 hours training are courses in biomedical anatomy, physiology and diagnosis.

which raises concerns about safety. In terms of importance, clarifying the distinction in training may provide traditional acupuncturists leverage to demonstrate their value and challenge the money barrier, and assuage safety concerns.

In addition to explaining how acupuncture works and identifying patients' characteristics that may influence their outcome, the acupuncturists' interviews generated several discussion-worthy themes around the integration of acupuncture and acupuncturists as well as the symbiotic dynamic between TCM and biomedicine.

9.6 GP Findings

To compare and contrast the acupuncturists' interviews, the GPs' interviews explore their general perceptions of acupuncture, what it is used for, how it works, acceptance by the medical community and acceptance of acupuncturists. The following sections present findings from the GPs' interviews related to their perceptions.

9.6.1 Acceptance of Acupuncture

At the beginning of the interviews, the GPs were asked about their general perceptions of acupuncture. Considering that three of the GPs had BMAS training, there was a potential for them to form a unique group. However, all of the responses about the acceptance of acupuncture revolved around three key ideas including: acupuncture's role, evidence, and effectiveness as illustrated by the comments below. The phrases 'right things' and 'situations' allude to answers for the subsequent question about what acupuncture treats (Section 9.6.2).

> Jack: "The situations in which I use it are situations which are, that there is established evidenced base especially for osteoarthritis of the knee." (Ja)
>
> Dennis: "I think it's one of those things that if people have tried it and got benefit from it then I've no worries about them continuing on with it." (Dn)
>
> Natalie: "It has a role I think. It's got to be like any treatment – it's got to be used for the right things, not just everything [be]cause nothing treats everything." (Na)

Although GPs have a positive perception of acupuncture's acceptance as a valid treatment, as illustrated in Figure 9.1, their emphasis on accepting acupuncture for certain conditions highlights a contrast between the practice styles of GPs and

acupuncturists. For example, GPs biomedically evaluate patients' conditions then decide whether acupuncture is a valid treatment option. Acupuncturists, on the other hand, evaluate patients according to a different paradigm such as TCM and may selectively incorporate a patient's biomedical information as they deem appropriate. Based on their evaluation the acupuncturist decides the appropriate acupuncture treatment. The difference in practice styles reintroduces contentions around the implementation barrier to statutory regulation regarding who should deliver acupuncture and for what conditions further discussed in Chapter 10.

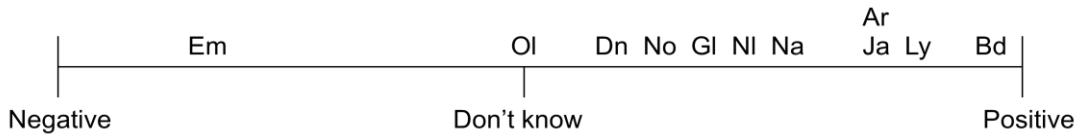


Figure 9.1 GPs' perception of acupuncture's acceptance. Initials represent the pseudonym of each participant.

Although the GPs' responses are weighted towards the positive end of the continuum (Figure 9.1), I did not infer that acupuncture was an accepted treatment. Therefore, a follow-up question specifically addressed whether acupuncture is considered a valid treatment modality. Similar to the acupuncturists, the GPs made statements with quantifiers that indicated a recent shift toward acceptance. For example the GPs used phrases such as 'more mainstream', 'more accepting', and 'accepted now' to convey the shift. With regard to what may be influencing this shift, the comments suggest the increase in evidence and BMAS training may be contributing factors. Even though acupuncture may be more accepted, one GP alluded to the idea that acupuncture may be less accepted if delivered by a traditionally trained acupuncturist rather than a medic.

Overall, the GPs had positive perceptions of acupuncture, which were likely to be influenced by patients' accounts and the evidence base. In turn, this contributed to the idea that acupuncture has a role in patient care for certain biomedical conditions. Therefore, findings from previous chapters have the potential to influence the GPs' acceptance of acupuncture from multiple levels including the patients' reports and empirical evidence. Section 9.7 includes a comparison to the literature, while Section

9.6.5 explores the idea that acupuncture may be less accepted when performed by a traditional acupuncturist in more detail.

9.6.2 What Acupuncture Treats

Following the discussion on the perceived acceptance of acupuncture, the GPs were asked to comment on the uses of acupuncture. As alluded to previously, the GPs mentioned particular conditions most commonly musculoskeletal and migraine. Other conditions that were mentioned include: nausea, vomiting, anxiety, menorrhagia, and IBS.

> Nelson: "I can see from the research that you lot have been doing menorrhagia, IBS looks like it is quite useful for that as well."

Nelson's comment indicates that the inclusion of menorrhagia and IBS may be attributed to awareness of and/or participation in those studies, which were conducted in York. Nevertheless, the GPs' comments are consistent with the BMAS, which suggests that acupuncture may treat pain conditions such as musculoskeletal, migraine, headache and arthritis, and might be helpful for a variety of other conditions [305]. Studies by van Haselen *et al* and Lewith *et al* also found that GPs most commonly used acupuncture for pain conditions [302, 303]. Given the consistency of findings among reports it is possible that the findings from the current study are relevant to a larger GP community.

9.6.3 How Acupuncture Works

After expressing the idea that acupuncture is gaining acceptance and has a role in treating certain conditions, the GPs explored how acupuncture works. Two themes emerged in this category, the first of which was 'don't know'. Similar to the patients (Chapter 8), who followed 'I don't know' with 'if it works, it works' the GPs concluded:

> Dennis: "I don't have to understand why it works, but if it works that's fine."

As such, the comments from both perspectives (i.e. GPs & patients) imply that effectiveness may be superior to defining mechanisms for certain therapies. Additionally, the idea that treatments should be safe debuts within this theme and appears frequently in comments about the acceptance of acupuncturists (Section 9.6.5). Therefore, the issue of safety is discussed more fully in that section.

The second theme to emerge was the distinction between the traditional and biomedical explanations of acupuncture, and within the biomedical explanations the GPs emphasised gate control theory. In distinguishing between the explanations, the comments suggest an underlying discomfort with the traditional explanation.

> Arthur: "I read quite a bit about it on the sort of Chinese ideas of meridians and all the rest of it and I must say I think I've largely forgotten all that now. I suppose I think of it in terms of pain physiology and pain gates."

> Gilbert: "I understand more is they act on trigger points and works through the kind of gate control. Pain, it can affect an area of the body apart from where you are putting in the needle but that's understandable medically understandable.

As introduced in Chapter 3, the gate control theory suggests that acupuncture affects the 'gates' controlling the flow of pain impulses to the brain [161]. One reason that the GPs may be more comfortable with the gate control explanation is that it utilises biomedical terms and provides a mechanism that is consistent with the biomedical understanding of the body, whereas the traditional explanation utilises potentially unfamiliar and figurative language related to a different paradigm. As mentioned previously, Gibbs suggests that science-based disciplines associate figurative explanations with distorted realties [157], which may consequently discourage GPs from utilising the traditional explanations and encourage them to seek a literal (i.e. biomedical) explanation. Consequently, the difference in training may contribute to the GPs' reluctance to accept traditional acupuncturists (Section 9.6.5).

9.6.4 Discussion with Patients

Given that the GPs considered acupuncture to be potentially useful for particular biomedical conditions, I asked them how they described and/or discussed acupuncture with patients. The three BMAS trained GPs were grouped together in this category because they potentially deliver treatments. The BMAS trained GPs favoured discussing acupuncture with patients who had particular symptoms or for whom previous treatments with other therapies were unsuccessful.

> Jack: "I suppose if I think that their set of symptoms might lend itself to acupuncture, so if I think there's a sort of myofascial component to their pain then I'm more likely to go for it or if they're on medication that is giving them side effects."

The consistency of the comments with those from previous categories informs the interpretation that the BMAS trained GPs selectively target their discussion about

acupuncture to particular individuals. Targeting individuals parallels a common theme from the acupuncturists' interviews. As such, patient individualisation and practitioner's preference appear to be important features of both disciplines. Wye and Adams report that GPs made CAM available for 'specific conditions' or patients deemed suitable for treatment [306, 307]. The similarity across studies reiterates that the findings may be relevant to a broader GP population.

The BMAS trained GPs also stated that they strictly limit their acupuncture appointments for two reasons. First, the comments imply that patients are so keen to use acupuncture that GPs could fill their appointment books, and second GPs restrict availability (at least in York) because they are not compensated for the appointments.

> Nelson: "Maybe one a week [acupuncture treatment] maximum. I restrict it otherwise you end up just filling them all up."
>
> Brad: "You don't get paid for it not because it's a problem with PCT, it's something you can't charge your own patients for, so that's the first thing. And it takes time out of me so I suppose there is a cost element for the practice."

The comments suggest that although GPs may receive acupuncture training, it is not necessarily convenient for them to provide acupuncture treatments. The issues raised by the BMAS trained GPs may have practical implications that alter the payment scheme for acupuncture or support the delivery of acupuncture by practitioners other than GPs. A study by Wearn *et al* reports a similar finding in that GPs reluctance to provide CAM is related to finance, time, and space [308]. The findings from our studies are important because they may contribute to the debate on the delivery of acupuncture and financial compensation by the NHS further discussed in Section 9.7.

In comparison, the non-BMAS trained GPs suggest that they typically discuss acupuncture with patients who initiate the conversation. However, they may initiate the discussion if other treatments are unsuccessful or if they refer a patient to physiotherapy for example. Reasons why they would not discuss acupuncture included a lack of evidence or their patient population.

> Dennis: "It tends to be something that if they [patient] bring it up as they're asking is it worth trying or they've mentioned they've tried it already. Then we will have a discussion about it in that way."

> Natalie: "Some patients come in and say you know I've got really bad pain and I think right I want to refer them to the pain clinic… and tell them that you know it's not just medicine that goes on there. There's all sorts of alternative therapies, there's acupuncture, there's physio there's all these other things."
>
> Lynn: "I work in a very deprived area… so no it isn't at all [something I discuss]. I imagine if I was in a different patient demographic then yes a lot."

Several interpretations may be drawn from the comments. For example, Lynn's comment may be interpreted to mean that it is appropriate to discuss acupuncture with affluent patients, but inappropriate to discuss it as a treatment option with less affluent patients. Another interpretation is that although the evidence base may be influencing a shift in acceptance it is not sufficient for GPs to actively promote acupuncture. In terms of implications, the comments illustrate how practitioners' preferences may contribute to differences in patient populations, wherein some are offered and/or exposed to CAM more readily than others. The findings are similar to the literature such as a study by Maha and Shaw who report that GP-initiated conversations about CAM are uncommon due to a lack of evidence, however, GPs discuss it if patients initiate the conversation [309]. Additionally, GPs who initiate conversations about CAM are more likely to provide it and likely to discuss it after biomedical options.

9.6.5 Acceptance of Acupuncturists

Although the GPs were relatively positive about the acceptance of acupuncture, their comments about the acceptance of traditional acupuncturists conveyed a degree of reservation, which was possibly a by-product of two themes. The first theme addresses the role of traditional acupuncturists in the NHS and an inability to refer to them because they are not affiliated with the NHS (e.g. Oliver). In contrast, GPs can refer to GPs or physiotherapists with acupuncture training who are part of the NHS. Furthermore, it may be more advantageous to have multi-trained providers (e.g. Natalie).

> Oliver: "If they were part of the NHS structure, then I think we'd be a bit more comfortable about it."

> Natalie: "I think acupuncture and acupuncturists won't necessarily get used to their full scope whereas someone that's got physio and acupuncture. We've got a cash-strapped NHS we can't develop a new [provider] we've got to use what skills we've got."

The comments suggest that the relationship between traditional acupuncturists and GPs is unlikely to change as long as the traditional acupuncturists remain outside the NHS; however, it may not be beneficial to incorporate them. As such, the comments highlight a paradox among the GPs comments whereby the BMAS trained GPs do not have time to deliver the number of acupuncture sessions sought yet they are somewhat unwilling to incorporate practitioners dedicated to delivering those sessions. Similar to the acupuncturists' comments about potential negative consequences of acupuncture's increasing acceptance, money appears to be a contributing factor to the GPs' paradox.

The second theme that emerged from the comments provides insight into the paradox that goes beyond money and position in the NHS. The second theme about the acceptance of traditional acupuncturists deals with training, regulation, and standards. Specifically, GPs note a need for clear qualifications and regulation accompanied by the subthemes safety and red flags. Overall, nine of the GPs provided comments such as:

> Norman: "I suppose actually I don't know very much about what a trained acupuncturist, what that means and what defines it and how that's regulated."

Which were often followed by comments such as:

> Norman: "I think probably more I feel more comfortable with a physio using acupuncture because that's part of, they are following the same kind of, they have a map in their head that determines practice."

Norman's comment highlights the concept of unfamiliarity. The GPs were unfamiliar with the type and amount of training that traditional acupuncturists receive as well as how the practice is regulated. Their unfamiliarity with these issues translated into a question about safety as explained below.

> Emily: "I don't know enough about the training to know whether the diagnosis [biomedical] is part of the process and knowing the limitations and the red flag signs and that sort of thing that I suppose are the things that give me reservations."

In addition to highlighting her unfamiliarity with traditional acupuncture training, Emily's comment illustrates how her unfamiliarity caused her to question the ability of traditional acupuncturists to recognise red flags. Red flags refer to sign/symptoms such as sudden, unexplained weight loss that are associated with biomedical conditions that require immediate attention (e.g. cancer). As such, the potential inability to recognise red flags makes traditional acupuncturists unsafe. The perception that traditional acupuncturists may be unsafe appears to influence the GPs reticent acceptance of traditional acupuncturists, which despite the growing popularity of acupuncture may limit interaction between the practices.

9.7 Discussion

The findings from the previous sections present two perspectives (i.e. acupuncturists & GPs) about how acupuncture works, its acceptance, and the acceptance of traditional acupuncturists. In addition to these topics, the findings also address who acupuncturists perceive may benefit from acupuncture and what conditions GPs perceive acupuncture to treat. According to the acupuncturists, patients who are younger, with less chronic conditions as well as those who adhere to treatment, have realistic expectations, and are willing to make lifestyle and/or diet changes are more likely to benefit from treatment. In contrast, patients who are impatient, non-adherent, or older are less likely to benefit. However, the acupuncturists prefer not to rely on a single characteristic to predict a patient's outcome, but rather the individual patient. In terms of conditions that may be suitable for acupuncture treatment, the GPs most commonly identified migraines and musculoskeletal. In addition to recapping the main findings, this section discusses how the findings address the second aspect of question three and relate to the literature.

The second aspect of the third research question asks 'how do acupuncturists and GPs understand acupuncture to work'. The acupuncturists responses suggest that they use TCM concepts including: channels, energy, balance, and self-healing to explain how acupuncture works. They also implied that the lack of a defined mechanism is a positive attribute. In their explanations to patients, acupuncturists tailor their language to the individual. In comparison, the GPs prefer to explain how acupuncture works through the biomedically oriented gate control theory. The GPs

selectively discuss acupuncture as a treatment option with patients who either initiate the conversation or who have not responded to other treatments. The individualisation of explanations and/or discussions with patients highlights a similarity wherein both groups of professionals incorporate their preferences and interpretations of patients' needs in their practice.

In addition to the question about how acupuncture works, the acupuncturists were asked whether they perceived their explanations to affect patients' outcomes. The majority of acupuncturists perceived that their explanations may influence outcome by augmenting empowerment, the patient-practitioner relationship, and/or treatment visualisation. As mentioned in Section 9.5.3, empowerment is a popular topic that appears across the literature spectrum. Several studies report that CAM practitioners include empowerment as a treatment goal and they suggest that CAM practitioners encourage a greater sense of responsibility for self-care and the adoption of healthy lifestyle changes among their patients [310-312]. Beyond the CAM literature, empowerment has been noted as important in the management of chronic conditions such as IBS and in the health care movement that influenced the increase in pluralistic therapies (Figure 1.1). For example, IBS patients in a study by Meadows *et al* suggest that they take active responsibility in developing their treatment strategies [92]. While in the broader sense, patients have gained empowerment through the increased availability of information and ability to participate in discussions about their health [9]. The emphasis on empowerment and the active role of the patient is important because active patients tend to seek information, be involved in their care, be more adherent to treatment and report better outcomes [301, 313]. Therefore, acupuncturists who provide an explanation that resonates with the patient may affect the dynamic between his/her beliefs, empowerment, and outcome to augment the response to treatment.

Given that the majority of acupuncturists and half of the patients (Chapter 8) perceive the explanation to affect outcome, I extrapolated the findings to the biopsychosocial consultation model. Recall that the biopsychosocial model incorporates biological, psychological, and social factors that may affect health and links the current biomedical understanding of IBS (Figure 2.5) with the TCM

understanding of illness. According to di Blasi, four domains of care (cognitive, behavioural, physical, emotional) comprise the biopsychosocial consultation [314]. In particular, cognitive care refers to a treatment aspect that affects patients' beliefs about the effects of treatment, while emotional care refers to a treatment aspect that reduces unhelpful emotions. Moreover, Thomas reports that patients are more likely to report an improvement in their condition when they receive treatments comprised of these domains [315]. Using the domain descriptions, I hypothesise that the explanation about how acupuncture works contributes to cognitive care and works in combination with empowerment, which contributes to emotional care, to affect patients' outcomes.

Combining the explanation, empowerment, and lifestyle advice with the needling or physical care aspect of acupuncture treatment, I developed an acupuncture-specific biopsychosocial consultation model (Figure 9.2). In addition to the four care domains, the figure highlights patients' characteristics that the acupuncturists in this chapter and in Chapter 5 indicated may influence treatment delivery and/or outcome. Given that the acupuncturists appear to tailor their explanations and advice, for example by determining a patient's interest, the circular illustration of the consultation process is appropriate. Further research, particularly regarding the role of the explanation, is necessary to determine the correctness of the model. One potential study design could compare the outcome of a group of patients who receive the acupuncturists routine explanations based on preference and interest to the outcome of a group who does not receive an explanation. Alternatively, the comparison group may all receive the same explanation

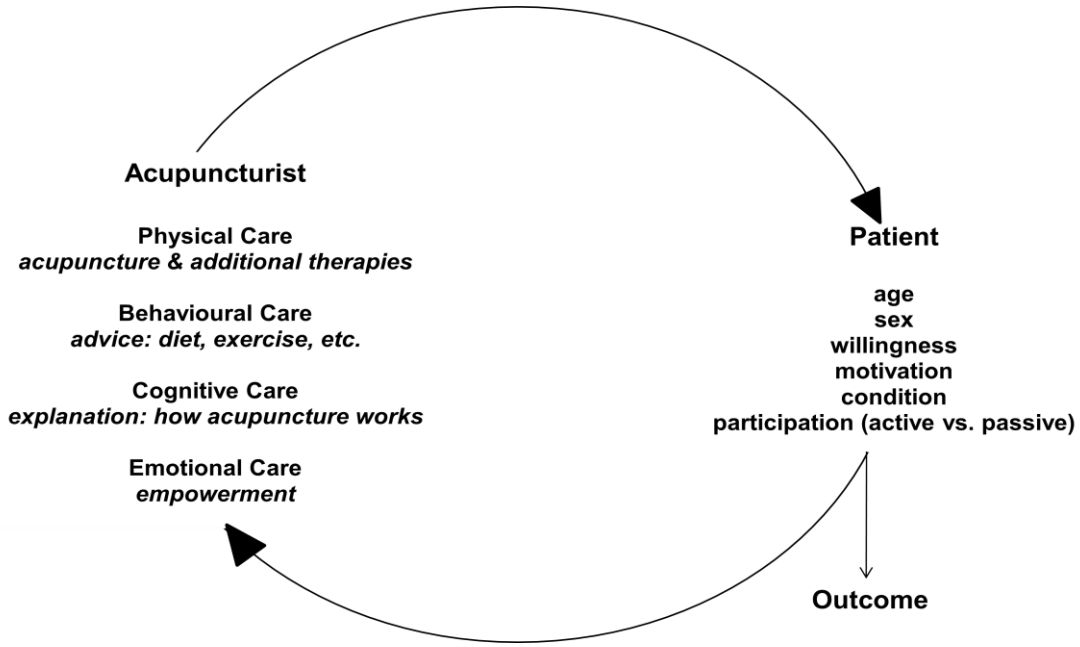


Figure 9.2 Acupuncturist biopsychosoical model of care. Developed as a hypothetical model based on the findings in this thesis and current literature.

Apart from the question about acupuncture explanations, the GPs and acupuncturists were asked whether they perceived acupuncture to be a valid treatment modality. The GPs' comments suggest a relatively recent shift toward the acceptance of acupuncture as a valid treatment. However, the shift in acceptance only applies to particular biomedical conditions such as musculoskeletal. The shift towards acceptance of acupuncture for particular conditions appears to be influenced by the increase in research, exposure during training, and patients' accounts. The acupuncturists also noted a recent shift towards acceptance and similar influential factors. Studies by Lewith *et al* and Hsiao *et al* also report that younger GPs have more positive attitudes toward CAM possibly due to their exposure [302, 316]. Maha and Shaw identified factors such as personal experiences for positive GPs, a lack of knowledge for undecided GPs, and the perception of false hope for negative GPs that appeared to influence acceptance [309]. While the shift in acceptance and increased exposure provide a useful overview, the findings and literature highlight several aspects of the relationship between acupuncture and GPs worthy of further discussion.

As discussed in Chapter 1, one of biomedicine's responses to the increased popularity of acupuncture was to encourage systematic research [7]. One review of

the literature suggests that the number of CAM articles increased by 340% since the early 1990s [31]. Although both the acupuncturists and GPs identified the increase in research as a factor in the shift in acupuncture's acceptance, the lack of evidence was a limiting factor to GPs discussion of acupuncture with patients. Similarly, a study by Maha and Shaw note the evidence base as a rationale for GPs acceptance of CAM [309], while a survey by Lewith *et al* suggests that more research is necessary [302] and the lack of evidence may limit integration [303]. In contrast, a study by Jackson and Scambler suggests that acupuncturists distrust and are fearful of research and its implications [300]. Specifically, the acupuncturists indicate that trials may not capture treatment individualisation, which as mentioned in this thesis (Chapters 5 & 9) as well as other studies (e.g. [51]) acupuncturists consider important. The acupuncturists also suggest that evidence based research may have negative implications such as 'an agenda to discredit acupuncture', practice restrictions (i.e. limited to treating particular conditions), or co-optation by biomedicine [300]. The negative sentiment may find justification in Kelner *et al's* report that GPs and nurses suggest biomedicine holds CAM to a double standard in research, wherein biomedicine does not have adequate evidence for all of its treatments, but expects CAM disciplines to provide such evidence [317]. Therefore, research appears to be advantageous to both practices, on one hand, solidifying a positive relationship, while on the other hand it appears non-advantageous augmenting tensions.

In addition to research, training requirements and money are two potentially key areas that may influence the relationship between GPs and traditional acupuncturists. The acupuncturists identified the lack of distinction in training as a barrier to the acceptance of traditional acupuncturists. Moreover, the lack of distinction in training appears to facilitate an estranged relationship in which GPs accept the practice but not the practitioner. As indicated by their comments, the GPs are unfamiliar with traditional acupuncturists' training particularly regarding red flags, which encourages their support for BMAS over traditional acupuncturists. Other studies have identified similar preferences for CAM to be delivered by 'safe therapists' (e.g. GPs) [303, 307]. However, BAcC registered practitioners are required to attend courses in basic biomedicine. Therefore, the lack of awareness or as the GPs suggest unfamiliarity about the incorporation of biomedical courses in traditional acupuncture training

appears to be a more pronounced barrier to acceptance than the distinction in training. Within the broader context, addressing the multiple calls for the statutory regulation of acupuncture (e.g. [318]), as discussed in Chapter 1, may overcome this barrier by establishing similar training standards for all acupuncture practitioners. Until this time, if traditional acupuncturists endeavour to work inside the NHS, they need to mount a campaign that asserts their safety. Currently, the combination of increased popularity, increased acceptance of acupuncture, and GPs' preference for 'safe therapists' may alter the symbiotic dynamic between biomedicine and TCM in favour of further co-optation of acupuncture by biomedicine.

Besides training requirements, the acupuncturists and GPs made comments about the financial barriers to acupuncture. First, all the acupuncturists who were interviewed work in private practice, therefore referral to them or their incorporation into the NHS would incur an added expense. Consequently, the acupuncturists suggest that BMAS trained practitioners represent less expensive competition. However, the GPs' comments suggest that they are not compensated for treatment and therefore restrict the number of sessions they provide. Other studies have reported similar findings that GPs provide relatively few treatments per week [302, 319], and that money, time, and space are barriers to the provision of CAM by GPs [306, 308]. Additionally, some patients (Chapter 8) identified cost as a barrier to their continuation with acupuncture after trial treatments ended. Given the agreement among the various stakeholders about cost as a barrier to acupuncture treatment both privately and on the NHS, further research offers one means of effecting change in coverage. A change though may exacerbate tensions around training, appropriate conditions for treatment, and treatment delivery (e.g. who & how long). Therefore, it may be important to address these issues simultaneously and highlight the strengths and capabilities of each discipline so as to maximise potential patient benefits.

In summary, the interviews highlight a shift in the relationship between TCM and biomedicine as well as several factors that may generate further shifts. Decisions about money and who will deliver treatments may further co-optation or integration of acupuncture. With regard to the explanation, the acupuncturists' perception that it potentially affects outcome necessitates further research on its role in treatment.

Having addressed the final research question, the following chapter summarises the findings from Chapters 5 – 9 and presents their contribution to the debates about the importance of TCM diagnosis differentiation and treatment individualisation.

Chapter Ten

Contributions & Conclusion

10.1 Introduction

According to the United States District Court for the Southern District of Texas,

> "Acupuncture has been practiced from 2,000 to 5,000 years. It is no more experimental than is the Chinese language as a mode of communication. What is experimental is not acupuncture, but Westerners' understanding of it and their ability to use it properly." [Andrews vs. Ballard 1980] [320]

Thirty years on from this landmark case, that found doctors do not have the knowledge to control access to health care that involves techniques and principles unknown to biomedicine, we (practitioners, researchers, and patients) are still trying to understand acupuncture and use it effectively. While the court clearly separates the roles of biomedicine and acupuncture, we have to recognise that in everyday practice (at least in the West) acupuncture occurs within a dominant-ancillary symbiosis with biomedicine. As such, TCM schools that train acupuncturists incorporate biomedical courses and research studies of TCM interventions often recruit patients by their biomedical diagnoses.

From the biomedical influences, particularly on research, two key implicit assumptions arise about the relative importance of TCM diagnosis differentiation and treatment individualisation (Box 1.1) that directly link with our ability to understand and use acupuncture. Given that the topics occur within a complex reality, it may be beneficial to gain a better understanding of the relative importance of TCM diagnosis differentiation and treatment individualisation through multiple stakeholders' perspectives. In particular, this thesis captured three stakeholders' perspectives as it undertook to explore how acupuncturists contextualise and treat IBS in routine practice compared to a pragmatic trial setting and to explore how patients, GPs, and acupuncturists understand acupuncture to work and the impact of those understandings. Findings related to these objectives, presented in previous chapters, have been building towards a climatic discussion on the relative importance of TCM diagnosis differentiation and treatment individualisation that endeavours to determine whether they become lost, retain, and/or alter their identity during the research process and if that is important. The following sections provide a summary of my contributions to the literature and their implications, discuss current debates in the literature around the use of TCM diagnosis differentiation and treatment individualisation, and review the strengths and limitations of my research.

10.2 Contributions to the literature & research implications

As the title of this thesis 'The relative importance of TCM diagnosis differentiation and treatment individualisation as seen through a study on IBS' suggests research into these topics may clarify our understanding and ability to use TCM. Before going into detail about the relative importance of TCM diagnosis differentiation and treatment individualisation (Section 10.3), the following subsections provide a summary of several original contributions to the literature (Section 10.2.1) and a discussion on their potential research implications (Section 10.2.2).

10.2.1 Original contributions

First, I found that TCM acupuncturists contextualise IBS based on the biomedical characteristics and symptoms they perceive to be relevant, which highlights the evolving hybrid character of TCM. By hybrid character, I am referring to acupuncturists' response and/or adaptation to the dominant symbiotic pressures of biomedicine through their use of biomedical concepts. The comments suggest that IBS is not a useful diagnosis to the practice of TCM and that it does not influence treatment design. Within this context, a patient's TCM diagnosis appears more important than his/her biomedical diagnosis. Therefore, while acupuncturists appear to have adapted to the use of biomedical concepts, their TCM diagnoses and subsequent treatments remain distinct. With regard to recommendations, further research is necessary to determine if the contextualisation and utilisation of other biomedical diagnoses is similar to IBS, and to determine whether the finding is representative of the broader population of TCM practitioners. I hypothesise that some TCM diagnoses are more important to treatment design than others, and that some biomedical diagnoses have a greater impact on TCM treatment design than others (Chapter 5) [262]. As mentioned in Chapter 1, biomedicine and TCM may augment the mutually beneficial aspect of their symbiosis and deliver more effective patient care by continually redefining patients' needs and their abilities to meet those needs. Additional studies that identify the context and utilisation of diagnoses between the practices provide a means of enacting this process.

In terms of the TCM diagnoses identified among the IBS patients, the seven primary and eight secondary diagnoses present the first empirical evidence on the TCM

diagnoses associated with IBS. While the diagnoses demonstrate the theory that a single biomedical diagnosis may be associated with multiple TCM diagnoses (Figure 1.2) [33], they contrast with the report by Tan *et al* that suggests only three TCM diagnoses are related to IBS [216]. As mentioned previously, the methods in the study by Tan *et al* indicate that the three TCM diagnoses (liver qi stagnation, spleen qi deficiency, and a combination of liver qi stagnation and spleen qi deficiency) were pre-determined and that acupuncturists were instructed to categorise patients into one of the three groups. Therefore, the seven diagnoses identified among patients in this study may be more reflective of diagnoses encountered in routine practice. Because the analyses indicate that TCM diagnoses are a key contributor to acupuncture point selection, fixed point prescriptions (e.g. Schneider *et al* [34], Table 3.7), based on pre-determined diagnoses, may be inadequate for such a broad ranging condition and therefore offer inconclusive evidence on the effectiveness of acupuncture. The implication of this finding may influence future trial design as discussed in Section 10.2.2.

Evidence from the acupuncturists' interviews (Chapters 5 and 9) and common TCM teachings (e.g. [278]) suggest that patients with excess TCM conditions may recover more quickly than patients with deficient conditions. Of the seven primary TCM diagnoses identified among the IBS patients, three may be classified as deficient (i.e. spleen qi deficiency, yang deficiency, blood/yin deficiency), two may be classified as excess (liver qi stagnation and damp heat), and two may be classified as a combination of excess and deficiency patterns (cold damp and liver qi stagnation with spleen qi deficiency). My findings are the first to provide quantitative data that patients with excess TCM diagnoses associated with IBS may report a better outcome than patients with deficient TCM diagnoses. Therefore, acupuncture may be a more favourable treatment option for IBS patients with excess TCM diagnoses as opposed to patients with deficient TCM diagnoses. However, I am reluctant to present this finding as a recommendation due to the limited number of treatments (i.e. 10) patients received, the acupuncturists' suggestions that patients with deficient conditions may require more treatments than patients with excess conditions, and because the difference in outcome was only detected on the MCS. As discussed in Chapter 5, acupuncturists are wary of designating a specific number of treatments

that may foster false expectations. Moreover, a recent review by White *et al* suggests there is an urgent need to define the adequate dose of acupuncture [321], to which I would add there is an urgent need to define the adequate dose by accounting for differences in patients' TCM diagnoses. After the adequate dose is determined, the finding from this study may be re-evaluated for applicability. One possible method of determining the appropriate number of treatments would be to allocate patients to study arms of a trial that provide different numbers of sessions.

In addition to the information that may be gleaned from a patient's diagnosis, the practitioners' prognoses also provided information that was predictive of outcome. Specifically, patients with a 'good' or 'don't know' prognosis reported better outcomes than patients with a 'poor' prognosis. The implication of this finding is that practitioners may provide useful information about whether patients are likely to benefit from acupuncture. Therefore, prognoses may serve a practical use in the referral process, and potentially provide more reliable information than patients' diagnoses given the uncertainty around the adequate dose of acupuncture. Further research is necessary to confirm this finding, at which point prognoses may also be used in research during allocation (Section 10.2.2).

With regard outcome, twenty-seven (27/33) patients indicated that they had a positive perception of outcome related to their acupuncture treatments. Moreover, sixteen (16/33) suggested that their understanding of how acupuncture works may have affected their perception of outcome. Figure 8.6 illustrates that patients integrated their understanding of how acupuncture works with their understanding of self-care, anatomy and physiology, and the mind-body interaction through facilitatory, causal, and/or active participatory relationships. As discussed in Chapter 8, this is the first study to assess the role of the explanation in relation to perceived outcome and the relationship between the patients' explanations and the understanding of body function. The potential impact on outcome associated with the acupuncture explanations may be relevant to other CAM therapies when comparing the findings to the broader literature. For example, Cartwright and Torr interviewed a mixture of CAM patients who suggested that the explanations they received influenced their abilities to make sense of their illness and manage their

health [298]. Broader still, the explanations may augment empowerment, which is perceived to be an important aspect of care for CAM patients and patients with chronic conditions such as IBS (Chapter 9).

In addition to the patients, the majority of acupuncturists perceived that their explanations may affect patients' outcomes and highlighted the need to tailor language appropriately. As such, findings from both sets of interviews imply that the explanation and patients' understanding of how acupuncture works are important treatment aspects. With regard to the biopsychosocial consultation and its four domains of care (cognitive, physical, behavioural, emotional) [314], I hypothesise that the explanation contributes to the cognitive care domain that in conjunction with the other domains may augment patients' outcomes (Figure 9.2). Further research, such as observational studies, is necessary to assess the relationship between the delivery of the explanation and its interpretation. Observational research may also be used to evaluate whether the patient's perception of the explanation affects clinical practice.

While acupuncturists and patients perceive their explanations may affect outcome, the heterogeneity of IBS symptoms and comorbidities introduce difficulties in measuring IBS severity, which is commonly used as an outcome measure in practice and clinical trials. Through factor analysis, I found that the IBS Symptom Severity Scale (IBS-SSS) captures less than half of the variability in IBS severity and does so with limited reliability. The analyses indicate that the IBS-SSS data should be interpreted with caution and support the review by Camilleri *et al* that suggests the questionnaire lacks validity [231]. For this study, the findings imply that the comparison of mean score changes across the TCM diagnoses (Table 7.4) does not necessarily demonstrate clinically significant improvement among patients. With regard to the controversy around the validity of the IBS-SSS, the findings may influence research and/or practice through the recommendation that clinicians and future studies should develop (and use) an IBS severity measure that is more reliable and captures more variability as well as one that reflects both patients' and GPs' perceptions of severity. As discussed in Chapter 7, questions that employ a Likert format, address both the physical and emotional factors of IBS, and are evaluated by

psychometric and qualitative analyses may provide a more reliable measure capable of capturing greater variability.

Although not an original finding *per se*, the attention paid to the symbiotic dynamic between TCM and biomedicine warrants mention among the contributions. While the controversy around the importance of diagnosis may cast a parasitic pallor on the relationship (Section 10.3.2a), that particular topic may provide the impetus to augment a mutually beneficial shift. First, TCM and biomedicine should embrace their use of diagnostic frameworks and aetiology to make sense of patients' conditions as a similarity that may open dialogue. Subsequently, symptoms may provide the clearest link between paradigm differences to facilitate the discussion. As part of the discussion, the practices should explore how diagnoses and/or symptoms are used by practitioners and patients. In doing so, the practices can identify ways in which they may already work together without knowing and identify areas that may benefit from collaboration. However, discussions may be unproductive if they do not also address ways to overcome barriers related to money and unfamiliarity with training (Chapter 9, [308, 309]) that currently obstruct integrative care. Considering the growing burden of chronic disease, a mutually beneficial symbiosis may provide the best means of delivering effective patient care.

In general, the findings provide several original contributions to the literature, some of which have been published and/or presented (Appendix F), while additional papers have been planned to disseminate the other contributions. Following this summary, Section 10.2.2 identifies possible implications the findings may have on future trial designs of TCM studies.

10.2.2 Implications for future research

First, the finding that seven different primary TCM diagnoses were identified among the IBS patients and that the exploratory analyses suggest there is a difference in outcome among the diagnoses, may influence recruitment and/or analytic strategies. In terms of recruitment, the variety of diagnoses identified and potential difference in outcome may encourage the recruitment of patients by their TCM diagnoses. Recruiting patients by a particular TCM diagnosis overcomes problems associated with subgroup analyses such as insufficient power, small samples, and data trawling.

However, researchers that choose to recruit by biomedical diagnoses may prefer TCM subgroup analyses and account for sample size limitations prior to recruitment. If trials employ subgroup analyses, they will also need to devise a strategy for categorising the TCM subgroups. As mentioned in Chapter 6 and paper by Coeytaux *et al* [250], subgroups may be formed by collating similar diagnoses. Future studies may compare different techniques for collating diagnostic categories to determine the impact on findings. Several papers have called for subgroup analyses and/or recruitment by TCM diagnosis (e.g.[219, 222]), and these findings provide empirical evidence that supports the potential benefit of including this in trials.

Regardless of whether trials recruit by TCM diagnosis or differentiate TCM diagnoses during treatment, the consistent finding that LI4, LR3, ST36, and SP6 are the most commonly used points may prompt the use of a treatment protocol that compares the effectiveness of those points to diagnosis specific or pragmatic treatments. As illustrated in Box 6.4, a comparison between the most commonly used points and diagnosis specific points may create a protocol with multiple treatment variations. Additionally, researchers should be aware that the diagnosis specific treatment may be one aspect of a more complex approach to treatment. For these reasons, I recommend that researchers assess the comparison between the most common points and a pragmatic approach.

Future trials that employ the pragmatic protocol and seek to assess the variety/combinations of treatment approaches will face analytic challenges. Researchers may consider the three-tiered analytic approach used in Chapter 6, which identifies influences on treatment design and evaluates treatment delivery. As I mentioned, the current STRICTA guidelines encourage researchers to report a limited view of pragmatic treatments that as indicated by the findings treatment delivery appears to be influenced by multiple factors including the diagnosis, practitioner, and patient. Moreover, these factors appear to play different roles for various aspects of treatment, which may influence future trials to incorporate analytic strategies that account for the variability. The second analytic change that future studies may be encouraged to make is addressing the routineness of treatments. Studies may incorporate a question in each patient's log about the routineness of care

delivered and the barriers to routine care. In terms of translating this research into practice this may be one of the most important questions to answer for practitioners. According to Glasgow et al, the lack of routineness is a key barrier for translating research into practice [217].

Another question that researchers may choose to incorporate in future studies relates to the patients' prognoses. By asking about prognoses researchers may identify patients that are likely to benefit from treatment and who may not benefit or require additional sessions/longer follow-up. This may be incorporated into future studies by designing a trial that allocates patients based on their prognosis. For example, patients with a good prognosis may be allocated to acupuncture while patients with a poor prognosis (for acupuncture) may be allocated to another treatment modality. The treatment arms may be compared to a non-treatment or usual care arm to establish whether utilising patients' prognoses identifies effective treatments for patients overall. Alternatively, patients with poor prognoses may be excluded from the study. Using patients' prognoses in treatment allocation may serve a practical purpose beyond TCM studies, in that patient may receive more effective care. Or other health care providers may explore whether their prognoses are predictive of outcome.

With regard to contextualisation, future trials may be inclined to incorporate a qualitative component that explores how practitioners contextualise and utilise TCM and biomedical diagnoses. In terms of importance, exploring how practitioners contextualise TCM and biomedical diagnoses may provide information on how TCM adapts itself to biomedicine. Or it may provide information on possible routes for integration. Studies may also choose to incorporate a qualitative component that explores how patients understand and utilise their TCM diagnosis, and whether they are actively seeking a TCM diagnosis as part of the treatment process or dissatisfaction with their biomedical diagnosis and whether these patients had a different outcome. Given the importance placed on biomedical diagnoses as the cornerstone of practice and a means of validating symptoms, understanding how/whether patients utilise and/or seek TCM diagnoses and whether the diagnosis affects outcome will provide a means of comparison.

Following this summary, Section 10.3 locates the findings within current debates on TCM diagnosis differentiation and treatment individualisation.

10.3 The current debates

As discussed previously, biomedicine and TCM co-exist in a dynamically fluctuating dominant-ancillary symbiosis. While the lack of effective treatments for and increases in chronic disease outline areas where TCM may augment its ancillary position, biomedicine's dominant influences on health care mandate adaptations to TCM research and practice. In particular, the adaptations have raised debates about the use of biomedical diagnoses in clinical trials of TCM interventions and the potential over-emphasis on treatment individualisation. To amplify these adaptations and evaluate their relative importance, this thesis situates TCM within the biomedical context of IBS. Beyond a simple summary, as in the previous section, it is necessary to collectively interpret the findings from Chapters 5 – 9 to understand the contribution they make to these debates. The following subsections provide background detail on the debates, an explanation about the collective interpretation of findings, and a discussion about what this adds to the literature.

10.3.1 Background on TCM diagnosis differentiation

According to Hammerschlag, patients are typically recruited to acupuncture trials based on their biomedical diagnoses [60], which has prompted questions about study validity and calls for studies to use TCM subgroup analyses [51, 219, 222]. Furthermore, the emphasis on biomedical diagnoses contributes to implicit assumptions about the relative importance of TCM diagnosis differentiation (Box 1.1). As such, the debate regarding TCM diagnosis differentiation in clinical trials stems from a convoluted layering of exchanges about the importance of diagnosis and the dominant-ancillary positioning of biomedicine and TCM. To appreciate the complexity around this somewhat simple debate, this section briefly introduces several layers of background.

The first layer involves the concept that diagnosis is the cornerstone of biomedicine as seen through its ability to act as a treatment, validate symptoms, and affect access to health care (Chapter 1). Comparatively, the common TCM teaching about the

fundamental importance of diagnosis differentiation, wherein inaccurate diagnosis prompts incorrect treatment and physician failure [56], has not been convincingly demonstrated. For example, Forbes *et al* suggest that pragmatic TCM diagnosis differentiation guides treatment design [39], while Sherman *et al* suggest that acupuncturists' preferences have a more important role in treatment design than patients' diagnoses [53]. While the inconsistency in findings necessitates further research that may clarify the relative importance of TCM diagnosis differentiation, it also represents a vulnerability of TCM that may succumb to pressure applied by the fundamental importance of biomedical diagnoses. As discussed in the next paragraph, the addition of biomedical courses to TCM training may illustrate this adaptation.

In its ancillary position in the symbiotic dynamic, TCM has been pressured to equip traditional acupuncturists with the skills and knowledge necessary to collaborate with the biomedically dominant health care community. As such, accreditation programmes in the UK (i.e. BAAB) and in the USA (i.e. NCCAOM) require traditional acupuncturists to receive basic instruction in biomedicine including diagnoses and red flags. Recall from Chapter 9 that GPs' unfamiliarity with traditional acupuncture training in red flags translated into a safety concern and referral barrier. Similarly, GPs interviewed in a study by Kelner *et al* suggest that they should diagnose patients prior to CAM treatment to assure patients that their condition does not require urgent biomedical care, and to prevent CAM practitioners from treating conditions that require urgent biomedical care practices [317]. The authors suggest that the emphasis on the need for a biomedical diagnosis may be used as a gatekeeping mechanism to control CAM practice, consequently creating another layer of complexity. Alternatively, gatekeeping may be interpreted through the concept that biomedical diagnoses are necessary to acquire resource allocation and progress through health services [57]. From this perspective, I suggest that the negative connotation associated with gatekeeping is replaced by the necessity for GPs to provide adequate care within a particular budget and to which there is access.

The idea that patients need a biomedical diagnosis before acupuncture revisits the dispute brought before the United States District Court, but poses the doctors' case

from a different perspective. Instead of controlling access through unknown principles and conditions, the emphasis on red flags and biomedical diagnoses firmly places control in principles that biomedicine has knowledge. However, the disparity between red flags and biomedical diagnoses highlights a problem with this scenario. Red flags refer to signs/symptoms that are associated with biomedical conditions that require immediate attention, while a diagnosis labels a group of signs/symptoms that may or may not include red flags. Furthermore, the implicit agreement among traditional acupuncturists, as well as other ancillary disciplines such as physiotherapy and chiropractic, to identify red flags and refer patients to biomedical care minimises the need for a biomedical diagnosis prior to CAM treatment. Therefore, requiring patients to have a biomedical diagnosis before acupuncture treatment overlooks the distinction that traditionally trained practitioners provide diagnoses based on a separate paradigm, and further subordinates TCM in its ancillary position.

As discussed in Chapter 1, implementation as to who will deliver acupuncture and for what conditions is perceived to be one of the primary barriers to statutory regulation [28]. Biomedicine's dominant influence on research has facilitated a shift toward defining biomedical conditions that acupuncture may effectively treat, which may consequently favour the implementation of acupuncture for biomedical conditions. Nevertheless, there have been calls from CAM researchers that studies should incorporate diagnosis differentiation to improve validity [51]. Additionally, some researchers advocate recruiting patients by TCM subgroups or recruiting sufficient numbers to perform subgroup analyses based on TCM diagnoses [219, 222]. Given that efficacy studies are less likely to incorporate TCM diagnosis differentiation than effectiveness studies, an implicit assumption arises about the relative importance of TCM diagnosis differentiation. As illustrated in Box 1.1, efficacy studies assume that TCM diagnosis differentiation is not important and effectiveness studies assume that it is important. Notwithstanding the fact that efficacy and effectiveness studies address different research objectives, the broad and narrow exchanges surrounding the inclusion of TCM diagnosis differentiation in clinical trials may be influenced by evidence that clarifies the role of TCM diagnosis in treatment design and patients' outcomes. As such, studies in this thesis produced findings that allow me to contribute to this debate.

10.3.1a Collective interpretation & contribution

To determine how data from multiple studies contribute to the debate on TCM diagnosis differentiation, I collectively interpreted findings across the datasets. Interpreting findings across different studies is advantageous because the studies addressed different aspects of TCM diagnosis differentiation and treatment individualisation (10.3.2), and collected data from different stakeholders such as patients and acupuncturists. Multiple perspectives are important because they reflect a more comprehensive picture of complex realities.

To inform the collective interpretation, I used a process similar to meta-ethnography described by Noblit and Hare as the 'synthesis of qualitative research' that involves extracting data, identifying a relationship, and translation [322]. Data related to TCM diagnosis differentiation were extracted from each of the studies presented in Chapters 5 – 9 and organised into a table (Table 10.1). Based on the methods explained by Noblit and Hare, I compared summaries of the findings to avoid problems with differences in the types of data. Once organised, the table provided a concise means through which to assess the relationship among the findings. Findings in Chapters 5, 6, and 9 are associated with the acupuncturists' perspective, while Chapter 8 is associated with the patient's perspective. Chapter 7 includes data that are related to both the patients and the acupuncturists. With regard to the relationship, the findings may be described in terms of perceived importance and practical application.

Having extracted the findings and assessed the relationship, the main ideas and concepts from each chapter were translated. According to Atkins *et al*, this process allows for refinement of the initial summary interpretations and merges summaries across studies [323]. Findings from the acupuncturists' interviews (Chapters 5 and 9) note the acupuncturists' perceptions about the role diagnosis plays in treatment and the information that may be gleaned from a diagnosis (e.g. potential outcome). Specifically, the acupuncturists perceived the diagnoses to play an integral role in treatment, and that patients with acute/excess diagnoses may improve more quickly than patients with chronic/deficient diagnoses. In comparison, the findings from the treatment logs (Chapter 6) highlight whether and to what extent the diagnoses were

employed in practice. As discussed, trial data were analysed according to general usage, diagnostic specificity, and acupuncturist specificity. Based on the analyses TCM diagnosis differentiation appears to play a key role in acupuncture point selection; however, it appears less important to the use of additional therapies and provision of lifestyle advice. In terms of collective interpretation, the acupuncturists' perceptions and the treatment log analyses both indicate that TCM diagnosis differentiation is fundamental to treatment design (particularly the acupuncture aspect).

With regard to the patients' perspective, analyses of the patients' outcomes (Chapter 7) suggest that patients with excess diagnoses reported greater improvement in comparison to patients with deficient diagnoses. Additionally, findings from patients' interviews (Chapter 8) suggest that some patients (Section 8.13.2) seek a TCM diagnosis and/or explanation of their condition due to dissatisfaction with the biomedical diagnosis and/or explanation of IBS. Moreover, their interpretation and/or acceptance of the TCM diagnosis/explanation of their condition may influence their perceptions of outcome. However, because these findings emerged through latent themes further research is necessary. Collective interpretation of these findings suggest that TCM diagnoses may serve similar functions as biomedical diagnoses by validating patients symptoms and identifying conditions that may be treated effectively, which may inform hypothesis development.

TCM Diagnosis Differentiation

Study	Main findings
Acupuncturists' interviews (Chapter 5)	• diagnosis is an individualised process • inextricably linked to the treatment principle • selection of acupuncture points based on the treatment principle, patient's condition, & practitioner's preferences • use of additional therapies accounted for the patient & his/her condition but was more related to the practitioner's preferences • lifestyle advice emphasises the individual & practitioner's preferences but not necessarily the diagnosis
Trial treatment delivery (Chapter 6)	• diagnosis differentiation is a complex process involving primary & secondary patterns • ~84% of patients had a unique diagnosis • treatment principles appeared to be related to the patients' diagnoses • patients' diagnoses appeared to be more important to the selection of acupuncture points than the use of additional therapies or lifestyle advice • analyses of the points used highlight common points used across the diagnoses, condition-specific points & practitioners' favourites • use of additional therapies & lifestyle advice appeared more related to the practitioner & a pragmatic approach
Trial outcomes (Chapter 7)	• regression analyses suggest that patients with deficient diagnoses reported a worse outcome than patients with excess diagnoses • the acupuncturists' prognoses are predictive of patients' outcomes & patients with good prognoses reported better outcomes • there is no correlation between the prognoses & TCM diagnoses
Patients' interviews (Chapter 8)	• some patients anticipated/sought an alternative diagnosis/explanation* to IBS and/or symptoms • for patients who sought an alternative diagnosis/ explanation their interpretation of the new diagnosis/explanation* appeared to influence their perception of outcome
Acupuncturists' interviews (Chapter 9)	• elderly and/or patients with deficient conditions may be more difficult to treat or improve less than younger and/or patients with excess conditions (acupuncturists)

Table 10.1 Data related to TCM diagnosis differentiation. *Explanation refers to an explanation of the patient's condition not how acupuncture works as discussed in Section 8.9.

Overall, each of the findings provides some information that may be used to develop a hypothesis on the relative importance o TCM diagnosis differentiation. The acupuncturists' interviews (Chapters 5 and 9) and the log book analyses (Chapter 6) provide stronger evidence than the quantitative analyses (Chapter 7) and the patients' interviews (Chapter 8). However, based on the collective interpretation of the data, I hypothesise that TCM diagnosis differentiation is an important component of TCM practice and in relative terms is more important to the selection of acupuncture points than other treatment aspects, impacts some patients' perceptions of outcome (particularly those seeking an alternative diagnosis), and distinguishes those patients more likely to benefit from acupuncture from those less likely to benefit.

With regard to the debate and layers of exchanges between biomedicine and TCM, the interpretation has several implications. For research purposes, the finding supports the use of TCM subgroup analyses or recruitment by TCM diagnosis, and suggests that trials that use TCM acupuncture without diagnosis differentiation may incur a Type II error. Furthermore, the role in validating patients' symptoms and identifying conditions that are treated effectively suggests that TCM diagnoses should 'control' access to TCM acupuncture in favour of biomedical diagnoses. Subsequently, this implication may affect the implementation question about who should deliver acupuncture in favour of TCM acupuncturists. Specifying TCM acupuncture and acupuncturists acknowledges that there are multiple styles of acupuncture and that this finding is not necessarily applicable to other styles. Regarding the inconsistency between the studies by Sherman *et al* [53] and Forbes *et al* [39], the finding supports the conclusion by Forbes *et al* that diagnosis differentiation is integral to treatment design. Although integral to the selection of acupuncture points, the findings that diagnoses do not appear to be (as) important to the provision of lifestyle advice or additional therapies supports the comment by Unschuld that practitioners utilise a combination of treatment approaches [52]. As discussed in the following section the diagnosis was only one of three approaches used in treatment design.

10.3.2 Background on TCM treatment individualisation

The debate on the importance of TCM diagnosis differentiation leads researchers and practitioners into the tangentially related debate about the emphasis on TCM treatment individualisation. As introduced in Section 1.3.2, the debate regarding treatment individualisation stems from the paper by Unschuld that suggests the emphasis on individualisation may be a by-product of TCM's efforts to distinguish itself from biomedicine, and discounts the inclusion of other treatment approaches (e.g. pragmatic and disease specific) [52]. Recall that pluralistic therapies were gaining popularity around the same time that biomedicine was facing criticism over its reductionist/disease-specific treatment approach. Although both TCM and biomedicine may employ disease-specific and individualised treatments, this line of argument infers that it would have been advantageous for TCM to downplay its disease-specific approach and emphasise individualisation.

With regard to research, TCM treatment individualisation is the subject of the second implicit assumption (Box 1.1) facing clinical trials, wherein efficacy studies assume it is not important by prescribing identical treatments and effectiveness studies assume that it is important by allowing it to occur. As with diagnosis differentiation, some researchers suggest that by allowing for treatment individualisation effectiveness studies are more valid [51]. Additionally, comments such as "the rules of TCM would have been best met if individual therapeutic schemes had been used" [34] appear to perpetuate the idea that individualisation is key to TCM treatment. However, a study by Napadow *et al* notes the popular use of four to five acupuncture points across a range of diagnoses [54]. While the authors refer to these points as the most common, I suggest they may also be described as pragmatic given their multiple indications. The authors also note the use of disease specific points such as the scalp speech points for aphasia. In comparison, Sherman *et al* report that practitioners' preferences drive treatment design [53]. Therefore, emerging data may challenge the individualisation assertion and/or necessitate clarification about how individualisation is defined. The controversy may benefit from further research about the role of treatment individualisation and clarification of the influence of the patient and practitioner. As such, the studies in this thesis allow me to contribute to this debate.

10.3.2a Collective interpretation & contribution

To determine how data from studies in Chapters 5 – 9 contribute to the individualisation debate, I collectively interpreted the findings related to treatment individualisation based on the Noblit and Hare recommendations for meta-ethnography [322] described in Section 10.3.1a. Findings from each chapter were extracted, compared across other studies to assess the relationship and translated to collectively interpret the overall finding. The extracted data are presented in Table 10.2. As previously mentioned, the findings represent different stakeholders' perspectives, specifically Chapters 5, 6, and 9 relate to acupuncturists and Chapter 8 relates to patients.

Although the studies by Sherman *et al* [53] and Napadow *et al* [54] discuss the use of most common and disease specific acupuncture points, to my knowledge, this thesis presents the first study to provide evidence about the combined use of multiple treatment approaches regarding their proportional influences on different treatment aspects. Findings from acupuncturists' interviews (Chapters 5 and 9) suggest that individualisation, specific to the patient, is the foundation of treatment. Nevertheless, the acupuncturists' acknowledgement of their preferences for particular acupuncture points and additional therapies highlights another important dimension of treatment individualisation. From the data, it is unclear whether the acupuncturists perceive their preferences to play a key role in treatment individualisation. In comparison, data from the treatment logs (Chapter 6) highlight whether and to what extent the treatments were individualised in a pragmatic trial setting. Acupuncturist individualisation was evident in all aspects of treatment, and was most prominent in the use of additional therapies and lifestyle advice. Similarly, patient individualisation was evident in all aspects of treatment but was most prominent in the selection of acupuncture points. With regard to the patients' perspective, findings from Chapter 8 suggest that patients perceived treatments to be individualised and that their perception of the treatment experience contributed to their perception of outcome.

Treatment Individualisation

Study	Main findings
Acupuncturists' interviews (Chapter 5)	• individualisation is the perceived cornerstone of routine treatment • as a theme individualisation recurs across multiple categories including diagnosis, point selection, lifestyle advice • selection of acupuncture points based on the treatment principle, patient's condition, & practitioner's preferences • use of additional therapies accounted for the patient & his/her condition but was more related to the practitioner's preferences • lifestyle advice emphasises the individual & practitioner's preferences but not necessarily the diagnosis
Trial treatment delivery (Chapter 6)	• three treatment approaches including pragmatic, individualised, and disease-specific were used in varying combinations • acupuncturist individualisation is apparent in the favourite acupuncture points, preferred additional therapies, and lifestyle advice • patient individualisation is apparent in the less frequently used acupuncture points & in unique lifestyle advice • patients' diagnoses appeared to be more important to the selection of acupuncture points than the use of additional therapies or lifestyle advice • use of additional therapies & lifestyle advice appeared more related to the practitioner & a pragmatic approach
Patients' interviews (Chapter 8)	• patients perceived treatments to be individualised and holistic • the patients' perceptions of their treatment experience appeared to contribute to their perceptions of outcome
Acupuncturist' interviews (Chapter 9)	• the language of the explanation about how acupuncture works should be tailored to the individual • need to identify which patients are interested in an explanation and which patients are not • failure to tailor the language appropriately may contribute to a poor patient-practitioner interaction

Table 10.2 Data related to TCM treatment individualisation

Based on the collective interpretation of the data, I hypothesise that the TCM literature over-emphasises treatment individualisation regarding the patient and under-emphasises the role of other influences on treatment design. However, when accounting for both types of individualisation (i.e. patient and acupuncturist), individualisation prominently features in treatment. With regard to the work by Unschuld [52], the findings support his claim that TCM treatment combines a variety of approaches. Taking the findings and comparison to the literature into account, I recommend future trials should designate the type of individualisation being assessed, and explore the role and application of multiple treatment approaches. In-depth analyses of pragmatic treatments, such as those presented in Chapter 6, may determine whether the combination of disease-specific, pragmatic, and individualised approaches is applicable to a wider practitioner population. Additionally, a mixture of observational and treatment log auditing studies may provide useful information on this topic.

10.4 Strengths & limitations

To understand the context in which the findings, discussed in the previous sections make sense, and to be reflexive about the methods used and my role as the researcher, this section discusses the strengths and limitations of the studies. Additionally, I briefly reflect on what I would do differently if I did the studies again.

First, generalisability may be a study limitation. The purposive samples of the qualitative studies in this thesis as well as elsewhere intentionally select the perspectives they choose to analyse [245]. Furthermore, purposeful samples are intended to collect detailed information from a particular group, and not emphasise generalisability. I specifically recruited acupuncturists (Chapter 5) from the trial area to ensure comparability between the interviews and the trial, particularly for those acupuncturists who participated in both studies. From a limitation perspective, the findings do not reflect a variety of acupuncture styles; however, this was not an objective.

The purposive matrix used to recruit patients to interivews (Chapter 8) was designed to capture a mixture of severities, preferences, and sexes. Although the sampling

matrix intended to select a variety of different cases and the patients described a mixture of experiences and outcomes, it is possible that the largely positive tone is not representative of all the trial participants allocated to acupuncture. The purposive sample may be criticised for its potential to elicit selection bias [324], wherein the patients represented a self-selected group of participants who had a positive treatment experience and/or perceived an improvement. Alternatively, the volume of positive language may be a by-product of the interview process, wherein the patients did not want to appear ungrateful for the opportunity to receive a treatment that is not normally offered.

Another potential qualitative limitation is interviewer bias [248]. Given my acupuncture background, my knowledge and training potentially influenced my interpretation of the data. Additionally, the trial acupuncturists (Chapters 5 – 6) knew that I was an acupuncturist, which potentially influenced their responses particularly regarding language. For example, an acupuncturist may not describe a patient as "livery" to a non-acupuncturist. To limit my potential bias, I introduced my background, provided a reflexive account of the studies and used analyst triangulation. In particular, the analysts participating in the analyst triangulation (KA and BC) were non-acupuncturists with qualitative expertise that independently contributed to the analysis. I also provided examples of the data analyses (e.g. Box 4.2 & 4.4) and displayed multiple quotations throughout Chapters 5, 8, and 9 to allow the reader to interpret the validity of the findings.

In terms of the quantitative analyses, the small sample sizes for the TCM diagnosis categories and subgroup analyses [286], and the subjective nature of factor analysis [275] are potential limitations. As discussed in Chapter 7, subgroup analyses may be criticised as a form of multiple testing and the relatively small sample sizes of each diagnostic category may reduce the power of the calculations. To limit the criticism, I reported my intention to conduct the analyses prior to the start of the trial and did not conduct analyses that were not decided *a priori*. I also conducted power calculations to determine the adequacy of the sample sizes (Appendix E 17).

Although the paired interview approach (Chapter 5) may be unusual and my specialist knowledge may be a potential limitation, I suggest they are also strengths of the studies. The paired approach allowed the acupuncturists to provide detailed answers in an intimate setting. Furthermore, the paired interviews highlighted differences in practice and practitioners' preferences. Instead of identifying a 'right' or 'wrong' treatment, the differences illustrate how the fundamental concepts of TCM give rise to diversity (Figure 3.1). Secondly, my specialist knowledge allowed the interviews and data analyses to be conducted in the acupuncturist's language. In other words, the acupuncturists did not have to alter their responses, and I did not have to translate sections of text. I suggest that my specialist knowledge allowed me to conduct more thorough and potentially more accurate interviews than would have been conducted without such knowledge.

The pragmatic mixture of methodologies that allowed for design and analytical flexibility is also a strength of this thesis. In particular, the pragmatic theoretical perspective underpinning the thesis allowed me to select the methodology and methods that were the most appropriate for each research question. Therefore, I was able to adjust my approach according to the different stakeholders, the use of which (i.e. multiple stakeholders) was also a strength. Interviews captured detailed information on a variety of complex topics including 'unexpected' acupuncture outcomes that may not be reflected in patient reported outcome measures/ questionnaires. Additionally, the pragmatic nature of the trial allowed for TCM diagnosis differentiation and relatively routine treatments without which it may not have been possible to establish the relationship among the various aspects of treatment and the difference in outcomes by diagnosis.

If I was to conduct the studies again, there are three things I would do differently. First, I would include an additional IBS outcome measure and/or pilot new severity questions. Including an additional outcome measure or new questions would provide an important compare/contrast aspect to the IBS-SSS that may further enable clinicians and researchers to determine the usefulness of the questionnaire. Second, instead of asking GPs how they perceive acupuncture to work, I would ask them how they perceive acupuncturists to use biomedical diagnoses and how do they interpret

TCM diagnostic classifications. Although the questions I asked provided interesting information, questions about biomedical and TCM diagnoses may connect more directly to the on-going debate about the importance of TCM diagnosis differentiation and the gatekeeping role of biomedical diagnoses. Third, I would reduce the number of questions to patients about IBS. While the information on IBS was very useful in establishing the similarity of the interviewees with the broader IBS patient population, I think they unnecessarily lengthened the interviews. Additionally, I think asking specific questions about the patients' TCM diagnoses would have provided a useful comparison to the explanation of how acupuncture works. Although in hind sight I can identify areas that I would change if I did the studies again, the studies that I conducted met the objectives set out in Chapter 1 and made several original contributions to the literature.

10.5 Concluding remarks

To generate data that could be used to develop a hypothesis on the relative importance of TCM diagnosis and treatment individualisation, this thesis undertook to answer two primary and a variety of subsidiary research questions that spanned two medical disciplines with distinct paradigms, employed a mixture of methodologies, and incorporated multiple stakeholders. Although TCM appears to have altered its identity in its symbiotic adaptation to biomedicine, particularly regarding the inclusion of biomedical concepts, TCM diagnosis differentiation and treatment appear distinct. Moreover, TCM diagnosis differentiation demonstrates its importance to practice through its impact on treatment design and potential ability to identify conditions that are treated effectively.

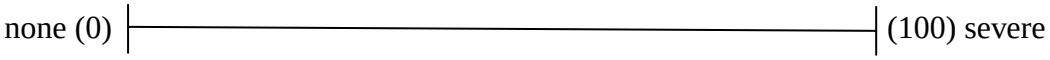
In addition to the inclusion of biomedical concepts, I support the observation that emphasis on TCM treatment individualisation appears to be another adaptation to the evolving symbiotic dynamic. Although TCM treatments employ an individualised approach that encompasses both the individual patient and practitioner, treatment design is also heavily influenced by disease-specific and pragmatic approaches. Questioning the extent to which the different approaches influence different aspects of treatment is a particularly noteworthy contribution of this thesis, and will hopefully encourage future research projects.

Appendix

Appendix A – Examples of IBS severity measures used in clinical practice and trials

Functional Bowel Disorder Severity Index (FBDSI) from Drossman *et al* [127]

1. On the line below, please place a vertical mark that indicates the amount of abdominal pain you feel today:



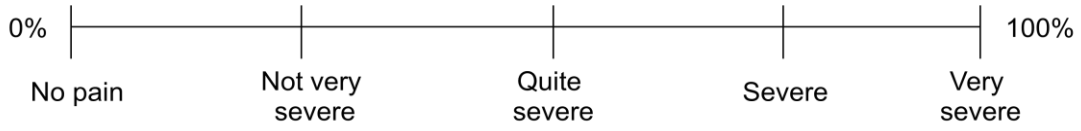
2. Diagnosis of chronic functional abdominal pain? Yes/No

3. How many visits have you made to your doctor for your bowel symptoms in the past six months? _____

IBS Symptom Severity Scale (IBS-SSS) from Francis *et al* [128]

1. a. Do you suffer from abdominal pain? Yes/No

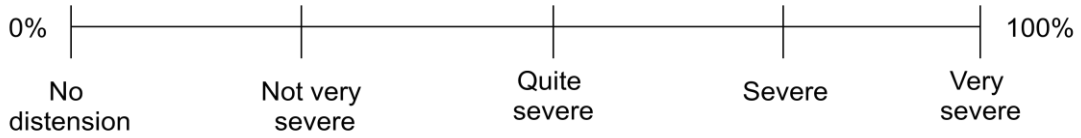
   b. If yes, how severe is your abdominal pain?



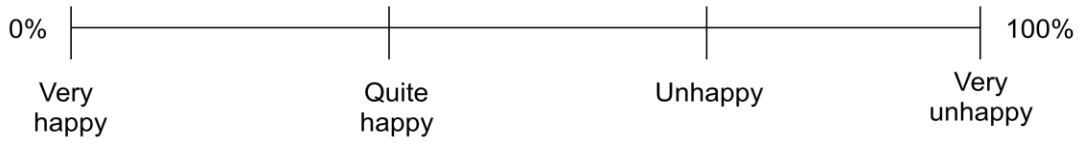
   c. Enter the number of days that you get the pain in every 10 days. _____

2. a. Do you suffer from abdominal distension? Yes/No

   b. If yes, how severe is your abdominal distension?



3. How satisfied are you with your bowel habit?



4. Please indicate with a cross on the line below how much your Irritable Bowel Syndrome is affecting and interfering with your life in general.

Appendix B 1 Trial protocol for pragmatic study on acupuncture for IBS (from original grant application)

RfPB Application: September 21, 2007

Ref # PB-PG-0407-13241

Authors: MacPherson, H., Bloor, K., Bland, M., Torgerson, D., Reynolds, J., Whorwell, P., Geddes, D.

Research plan & methodology section

Design.

We are proposing to undertake a two-group pragmatic randomised controlled trial. We will compare acupuncture plus usual GP care to usual GP care alone. The rationale for this open design is that it will best answer practical questions regarding the clinical and cost implications of offering an additional treatment option within primary care that will be adjunctive to conventional medical care (Roland & Torgerson 1998). This trial design will not ascertain the extent that "placebo" effects contribute to the overall outcome. The only feasible way of estimating both the pragmatic effects (the overall effect) and explanatory effects (separate effects of acupuncture and placebo) within a single trial is to undertake a four armed study with: sham acupuncture; true, but blinded, acupuncture; true and open acupuncture; and no acupuncture. The problem with this approach is that the study would have to be more than twice as large as a two armed study, which increases its costs as well as its complexity. In pragmatic terms, if some of the effect of the treatment process is due to 'placebo' effects then this may be worth paying for anyway, because if the placebo effect leads to an improvement in outcome for patients then, to the patient, the cause of this improvement is immaterial. In practical terms therefore, the pragmatic trial offers best value by providing results that are immediately applicable to patients, data of direct relevance to policy and decision-makers, and enabling a real-world comparison to be made for a cost-effectiveness analysis. Consequently we have decided to use a two armed pragmatic trial design to evaluate clinical and cost-effectiveness.

Participant recruitment criteria.

We plan to use the 'database' recruitment method, as we did for the pilot. Patients will be identified via the databases of GP practices in North Yorkshire and York Primary Care trust. Our inclusion criteria are that patients must be aged 18-80, with either a diagnosis of IBS from their GP or being given medications to treat IBS symptoms, and having consulted in primary care within the last two years. Patients will be screened for IBS symptoms according to the Rome III diagnostic criteria (Longstreth GF 2006). We will exclude patients who score less than 100 on the IBS Symptom Severity Score (SSS) (Francis et al. 1997), who have a current diagnosis of haemophilia or cancer, who have had major gastrointestinal surgery in the previous six months or who are receiving acupuncture at the time. In our pilot based in Birmingham, 32 eligible patients consented to participate from four GP practices that together had a registered list size of 20,300 (Reynolds et al. 2007). For the proposed research we estimate we will need to recruit the 220 patients (see below for sample size justification) from a total primary care list size of approximately 140,000 patients, equivalent to 28 to 30 GP practices with an average of 5,000 patients each. We plan to recruit GP practices in geographically contained groups, such that each group of practices is located near a clinic that provides acupuncture from qualified acupuncturists, and these groups are likely to be in the larger centres of population in the region. Based on our pilot in which we recruited 30 patients in one month (Reynolds et al. 2007), we estimate that recruitment will take eight months, however we have allowed a conservative 12 months for recruitment in our timetable (see Gantt chart).

Randomisation and blinding.

We will randomise patients to receive either a short course of traditional acupuncture plus usual GP care or usual GP care alone, using simple concealed randomisation, which is the most robust method of avoiding possible selection bias (Hewitt & Torgerson 2006). The randomisation sequence will be computer generated at the York Trials Unit, University of York, by an independent data manager and concealed from the researcher who will subsequently inform patients of their allocation. For those allocated to acupuncture, selection of acupuncture practitioner will be by availability of appointments and convenience to patients. As this is a pragmatic trial,

neither participants nor researchers will be blind to treatment assignment. Whilst randomisation eliminates selection bias, there are other sources of bias we need to avoid. To assess the impact of patient preferences we propose to ask participants at baseline for their treatment preferences, (Torgerson et al. 1996). To avoid bias due to attrition, participants in both groups will be followed up carefully. Participants will also be given an incentive to complete the final follow-up questionnaire in order to reduce attrition rates.

Interventions.

Acupuncture will be provided by professional acupuncturists who are registered with the British Acupuncture Council, and have at least three years experience. The acupuncture will be provided at independent clinics, and comprise up to 10 treatment sessions over a three month period. Acupuncturists will follow a treatment protocol adapted from one that has been devised previously and tested by acupuncturists taking part in the pilot trial of acupuncture for IBS (Reynolds et al. 2007). The treatment protocol allows sufficient standardisation to assist replication, yet is flexible enough to allow individualised treatments. In terms of compliance, we expect to obtain similar levels to those achieved in our pilot in which, on average, patients allocated acupuncture took up eight of the ten sessions offered. All patients will remain under the care of their general practitioner and will continue to receive their usual NHS treatment. Both groups will be able seek care elsewhere according to need. We will collect information from patients in both groups at three, six, nine and twelve months on all treatments they have received.

Outcomes measures.

Our primary outcome measure will be the IBS Symptom Severity Score (IBS SSS) (Francis et al. 1997) at three months. Scored from 0 to 500 (<75 = no IBS, 75-175 = mild case, 175-300 = moderate and 300+ = severe), this measure had been validated for use in IBS patients. Our secondary outcomes at three months will be the IBS Non-Colonic Symptom Score (which includes lethargy & tiredness, "wind", backache, and other symptoms). (Atkinson et al. 2004) We will also assess the Global Impact Score (question 4 of the IBS SSS: 'How much does your IBS affect and interfere with your life in general' scored 0-100) (Atkinson et al. 2004), the

Hospital Anxiety and Depression scale (Zigmond & Snaith 1983) and EQ-5D (Euroqol Group 1990). We will also collect data on medication use, health services use and days lost from work. Along with baseline data, all outcomes will be sought by postal questionnaire at three, six, nine and twelve months, and where this fails, the main outcome measure will be sought by telephone. Open text questions will be used to gather qualitative data on patient experiences of acupuncture, including adverse events. We will also collect data on safety and treatment processes from logs completed by the acupuncturists. Acceptability will be assessed through patient reports on satisfaction and willingness to try acupuncture again, as well as the uptake of acupuncture.

Sample size required.

The sample size required for a full-scale trial is based on a minimal clinical difference of 50 points on the primary outcome measure the IBS Symptom Severity Score (Francis et al. 1997). A residual standard deviation of 90 points was observed in our pilot (Reynolds et al. 2007), and taking into account potential sampling bias (Browne 1995) by using a one-sided 90% confidence interval for the variance, we estimate an adjusted standard deviation to be 105 points. Using this estimate, the sample size required to detect a difference at 90% power and 5% significance level is 188 patients in a two-arm trial. To allow for loss to follow up of a similar proportion observed in the pilot at three months (13%), our proposed trial requires 220 patients.

Data analysis.

We will use intention to treat analysis: all participants will be included in their randomised groups, whether or not they have received their allocated treatment. The primary outcome will be IBS Symptom Severity Score at three months, using multiple regression to adjust the treatment difference for baseline scores. Sensitivity to missing outcomes data will be addressed using multiple imputation. As a secondary analysis, analysis of covariance will be used to examine the interaction between the effect of acupuncture and three variables: participants' belief in acupuncture; belief that acupuncture will help their IBS (expectation); and patient treatment preference, as assessed prior to randomisation. Further secondary analyses will investigate the effects of variation between GP and between acupuncturists.

Cost effectiveness.

We will undertake a cost-effectiveness analysis at twelve months by combining resource use in the two groups with any treatment benefit in an incremental cost-effectiveness ratio. The primary analysis will use an NHS perspective, but this will be supplemented by a sensitivity analysis including non-NHS costs and benefits. We will collect data from patients and GPs about patients' resource use, such as visits to their GP, visits to other health providers, both within and outside the NHS and medication use, as well as their days off usual activities because of IBS. We will use EQ-5D to measure health-related quality of life and convert into quality adjusted life years (QALYs), in order to calculate an incremental cost effectiveness ratio (cost per QALY gained), after adjusting for baseline EQ-5D score (Manca et al.). We will also use a net monetary benefit approach to generate cost effectiveness acceptability curves (CEACs) exploring the probability that acupuncture will produce an acceptable cost per QALY at different cost-effectiveness thresholds. This approach accounts directly for uncertainty around the estimates of costs and effects (Fenwick et al. 2001), which is particularly important as this trial is powered on the basis of the clinical effectiveness measure (IBS SSS) rather than the economic outcome measure (EQ-5D).

Appendix B 2 Pre-trial interviews: potential participant (acupuncturist) information packet with cover letter, information sheet and consent form

THE UNIVERSITY of York

DEPARTMENT OF HEALTH SCIENCES
HYMS Building
2nd Floor, Postgraduate Area
Heslington, York YO10 5DD
Direct line: (01904) 431918
Email: tls504@york.ac.uk

3 July 2008

Dear Acupuncturist,

Thank you for expressing an interest in participating in a focus group discussion about irritable bowel syndrome (IBS). Because patients using acupuncture may not use the term IBS and/or IBS may not be their primary reason for seeking acupuncture, consider patients who present with abdominal pain or discomfort that is associated with defecation or change in bowel habit (generally patients with chronically irregular bowel habits).

The goal of the focus group will be to determine what the common TCM diagnoses are for patients with IBS and/or with irregular bowel habits. I would also like to map what acupoints you use, the number of sessions you recommend, and the general treatment plan you design for this condition.

Since this is detailed information, please feel free to bring notes with you to the discussion.

I will be in contact soon about meeting times. I look forward to working with you and appreciate your help.

Sincerely,

Tracy Stuardi
(Supervising Acupuncturist)

THE UNIVERSITY of York

NHS National Institute for Health Research

Acupuncture for Irritable Bowel Syndrome – Focus Group
Participant Information Sheet

This letter invites you to take part in a focus group exploring how acupuncturists treat Irritable Bowel Syndrome (IBS) and/or irritable bowel symptoms in routine practice. Your decision to participate is important, so we would like to take this opportunity to explain why the research is being done and what it will involve. We appreciate your taking the time to decide whether or not to participate.

The purpose of the focus group is to map how acupuncturists treat IBS in routine practice and to determine the most effective way to document that information, thereby providing a means to improve treatment reporting. We will use the information to design a survey to be sent to a randomly selected group of acupuncturists. Using the information from the focus groups and the survey we plan to develop treatment guidelines and a comprehensive practitioner's log that will be used in our full-scale trial of acupuncture for IBS.

The interview tape will be transcribed to protect your identity and all names will be changed to maintain anonymity. Once the tapes are transcribed, they will be destroyed. The only people who will have access to your identity will be the researchers who will ensure that steps are taken to maintain security and confidentiality.

Your participation in the focus group is entirely voluntary. If you decide to take part, keep this information sheet and sign and return one of the consent forms in the pre-paid envelope. If you decide to take part, you may withdraw from the study at anytime without giving a reason.

If you have any questions, please contact Tracy Stuardi at 01904 431918 or tls504@york.ac.uk.

We appreciate your participation.

Sincerely,

Tracy Stuardi
(Supervising Acupuncturist)

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PARTICIPANT CONSENT FORM
Acupuncture for Irritable Bowel Syndrome Focus Group

1. I confirm that I have read and understand the information sheet dated May 27, 2008 (version 1.0) for the above study. I have had the opportunity to consider the information, to ask questions and to have these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.

3. I understand that the interview will be audio recorded and that the tapes will be destroyed when transcription is complete.

4. I agree to take part in the study.

If you agree to the four points above, please complete the box below and return this form in the pre-paid envelope. Your contact information will be kept confidential and will only be used to contact you regarding the study. If you have any questions, contact Tracy Stuardi at 01904 431918 or tls504@york.ac.uk. Thank you for your interest in participating in this study.

Printed name: _____

Signature: _____

Address:
_____
_____

_____

_____

Post Code:

Time it is better to reach you: am/pm (circle one)

Day of the week most convenient for you: Mon/Tues/Wed/Thurs/Fri/Sat (circle any)

Telephone number:
_____ (with dialling code)

Email:_____@_____

Appendix B 3 Topic guide for pre-trial interviews with acupuncturists

Topic Guide for Paired Interviews

Objective: The objective of this topic guide is to help the interviewer gather information on how acupuncturists treat IBS in routine practice and what questions would produce the most usable answers in the treatment log.

Introduction

- How long have you been in practice?
- Approximately how many patients do you see per month with irregular bowel symptoms?
- Are the irregular bowel symptoms the primary reason he/she came for treatment?
- What percentage of your patients do they represent?

Reason – These questions were designed to collect background information on the participant and his/her practice. The questions were also designed to draw the acupuncturist's attention to a particular illness and his/her experience caring for those patients

Treatment of IBS

- Using TCM, which diagnostic framework do you use most commonly for patients with irregular bowel symptoms?
    - What are the most common diagnoses?
- What is the typical treatment framework you use for IBS patients?
- How do you select the points you use treat irregular bowel symptoms?
    - What are those points?
    - What type of needling technique/s do you prefer to use?
- How long does the typical treatment last?
- What is the average number of treatments necessary to regulate bowel functioning?
- What additional therapies do you use to treat irregular bowel symptoms?
- What lifestyle advice do you give as part of the treatment for irregular bowel symptoms?
    - How do you monitor the adoption of those practices?
- What kind of counselling do you provide these patients?

Reason – These questions were designed to capture various aspects related to the treatment process and the actual treatments themselves. The description of treatments may be important for designing the treatment protocol for the trial and these questions could identify potentially problematic areas.

Conclusion

- With regard to reporting IBS treatments, what other information do you think would be useful to capture?
- Are there any other comments you would like to make about how you treat IBS patients in routine practice or what you think are the best ways to capture that information?

Reason – The conclusion questions were designed to capture any information that the acupuncturists considered relevant that was not captured by the previous questions. Additionally the questions generated a discussion on how to report treatment information that was considered user friendly by the acupuncturists and data rich by the researcher.

Appendix B 4 Overview grid of pre-trial interviews with acupuncturists. The table identifies topics and ideas that were discussed and the relative agreement between the acupuncturists. Each group is represented by a Greek letter as in Box 5.1

Content	Group Delta	Group Omega	Group Kappa	Group Rho	Group Tau
Relationship	Co-workers, one is the boss and the other is relatively new employee	Acquaintances/ friends	Co-workers, non-apparent power dynamic	Friends; studied together	Co-workers, relatively new relationship
Time in practice	2 yrs. and 17 yrs.	10 years and 3 yrs	26 years and 19 yrs.	10 yrs. Each	4.5 yrs and 21 yrs.
Agreement				Joke about years gone by	
# Bowel problem	10/30-40 per month and the other is more 20% Mainly female.	20-40% only a few actually say they have IBS. Suspect there are others who are undiagnosed. Mainly female.	50% for one whose practice involves lots of abdominal cases. Other says 40% of which 10% is primary complaint	Initially say they are treating 3/20 per wk with bowel prob. If talking about primary cond. If talking about bowel prob. in general ~50% patients	One says 40-50% w/ digestive prob. The other focuses on liver invading aspect thinks the number may be higher
Agreement/ How idea was generated	Discuss how many patients they see per month in general. Ones that come in with other things who turn out to have bowel issues.	Discuss what symptoms they think would fit and who says they have it.	Discuss what they see as primary problem and what the patients come in with	Both seem to see it as part of a picture of sympt that but explain it differently. Feed off each other's comments until complete story unfolds	Discuss individual cases and how the patient sees the prob as 'normal'. Emphasize emotional aspect.
Reason for treatment	Headache, fertility, stress. Most patients are female.	Depends on uptake of alternative medicine and education. Mostly pain. Most patients are female.	(Not discussed)	One sees mostly gyne other is general pract. Wide variety	Wide variety although some come for digestive things, but not necessarily IBS per se.
Agreement/ How idea was generated	Generated from discussion of who has bowel problems and what they treat routinely	Discuss the idea that pain is seen as the only thing acupuncture can treat so they feel people don't know they can come for other reasons		Agree that bowels are not usu main complaint	Have a discussion about patients who've been in recently then turned out to have bowel things. Similar answers.
Patterns	Liver, spleen, stagnation issues. Dampness. Possible difference in gender regarding which pattern manifests.	Liver invading spleen, spleen deficiency, damp, poss liver yang rising, stomach heat	Damp heat or heat, liver qi stagnation, spleen deficiency	One very much in favor of liver predominating, the other thinks it is more complicated, back to the individual	One emphasizes liver, spleen, and kidney. The other contributes heat/ damp heat and liver qi stagnation.

Agreement	Disagreement about heat and whether they have seen heat pattern. Exp. Acupuncturist takes more of a teaching approach.	Discuss seasons and signs sympt that lead to identity of such patterns. Very good dialogue sharing ideas.	One emphasizes liver more than the intestines, while the other holds opposite view. They base this on experience and different cases they see.	Very good interplay in the dialogue feeding off each other. The two appear very comfortable speaking with each other.	Variation here as to how they decide – one predominantly zang-fu the other is pulse/tongue. But draw similar conclusions.
Treatment principles	Treat liver, strengthen spleen and remove stagnation. Tonify.	Depends on the individ case. If the individ is deficient they tonify and if excess they reduce. Influenced by tongue and pulse observation.	Depends on the pattern. If heat – clear heat.	Both use palpation to inform treatment. Very much in favor of moving things. Focus on individ	Treats based on primary symptom. Discuss excess and deficiency of patient population.
Agreement/ How idea was generated	Both give individual accounts of why they use certain approach.	Agree but don't discuss in detail.	Describe the variation in patterns seen and how the treatment principle would be adjusted.		One emphasizes the symptoms and the other constitution to guide principle.
Individual Accounts	Both give several individ examples relating to different topics to help explain why they do thing	One uses individ examples of why she does certain things or cases she is familiar w/	Discussed importance of individ, but did not actually refer to specific cases as I treated him/her in such a way	Note that one give individ examples, and the other focuses on the importance of the individ w/o examp.	Both give individual examples particularly about why people seek treatment and as justificat for why they do things
Point Selection	Based on points actions and how the patient is each time he comes. Also use palpation.	Have a common set of core pts that they will use. Will add other pts depending on the case.	Based on treatment principles and pts that do that. One emphasizes that she "just does it"	Depends on treatment principles. What is happening during treatment. "looks"	Based on priority for each patient. The other bases it on pulses.
Agreement/ How idea was generated	Each gives her own account. Not dialogue between.	Agree that there are just certain pts they really like using that they feel comfortable with.	Both describe a general session with patient coming in, make diagnosis, flows into treatment and pt choice	Open discussion of variation in pts used and one may try what the other does	Discuss the role of tongues and pulses in influencing treatment. Both agree they confirm diagnosis
Points Used	Ren 12, Lv 13, St 25, Sp 15, St 36, Lv 3, Sp 4, ashi, yin tang, si shen cong, P 6, Lu 5, Lu 9, bladder pts on back	Sp 6, St 36, Kd 3, St 40, Lv 3, St 25, Ren 12, Ren 4, Ren 6, GB34, Sj 6, LI 22, Lv 13, Sp 4, Back shu, P 6	GB34, GB 20, Lv 3, LI 11, St 25, Sp 6, St 36, Sp 10	Sp15, St 25, St 36, R 6, GB 34, St 37, Lv 3, H 7, P 6, LI 4, GB 41, SJ 5, Lv 13, GB 20-21	St 36, Sp 6, Sp 3, LI 4, Lu 7, Lu 9, Lv 3, Ren 12, P 6, Du 20, Ht 7
Agreement/	Noted that they were	Have a core set then discuss	One discusses why she	Good exchange of ideas and	Discuss which pts to use at

How idea was generated	thinking about individ cases. Again seems like there is a teaching aspect taken by older. Better dialogue though	the sympt that would prompt use of additional pts and why those pts. more detailed discussion here.	chose each of the pts and that others would be added based on the case. The other emphasizes more individ w/ core group	why those pts	which treatment b/c will vary. Feed off each other to cover the different organs.
Needle Technique	(not discussed)	Depends on the condition, do some manipulation.	(not discussed)	Depends – some gentle some stronger, feel qi	Depends – mostly tonification, shallow needling
Agreement		Not a lot of discussion here.		Yes	Yes
Lifestyle Adv	Diet, stress release, breathing, flower essence	Exercise, diet, sleep	Diet, stress management, exercise, meditation	Diet, exercise	Diet, stress release, exercise
Agreement/ How idea was generated		Discuss importance of IBS patients to move but not strenuous exercise	State that patients often ask what they can do which generates discussion	Explain to each other why they do certain things that are different and clearly agree others	Laugh about difficulty in getting patients to talk about diet. What are the causes of stress etc.
Additional Therapies	Heat, moxa, massage, holding pts, colors	Moxa, acupressure, ear seeds	Herbs, massage, cupping, probiotics	Moxa, heat, herbs, probiotics	Acupressure, herbs, moxa
Agreement/ How idea was generated	Parts seem instructional and part is a free dialogue where building on each other	Discuss what they are comfortable using and techniques they learned	Discussion of what they've used in past and what the clinic has to offer	Use different therapies debate on merit of which is better and why in educational manner	Discuss what they are trained to use and patterns they see
Emotional Aspect	Treatment can release emotions.	Treatment may unleash emotions.	Think there is often stress involved	"livery" people, stress, anxiety	See stress, anger, fear: bottling up of emotions
Agreement/ How idea was generated	Agree that its best to let the emotions come out but not actively ask what's wrong.	Generated from discussion about counselling and their role	Discuss one sees this aspect as secondary cond. and one think of it as more primary	Interesting discussion and laughing on what it means to be "livery"	Discuss societal role in emotional issues and its contribution to bowel prob
Follow-up	Ask how they are getting along. Non-challenging	Ask how they are getting on	Support and positive feedback	Gently ask and write things down for the patients.	Gently remind, not try to change too much at once
Agreement/ How idea was generated	Both keep notes on what the patient was recommended to do. No dialogue.	Some apparent frustration w/ ability to follow-up feels restricted by profession	Agree that they want the treatment to go well	Yes	Agree not trying to change the person but help them get on the right track
Counselling	Feel they are not counsellors. Just listen and are encouraging. Will refer	Feel important to listen. Is an opportunity for patient to speak in detail	Relaxed chat, nice relationship with the patient, not counselling Will refer is	Emphasize listening and that treatment is a safe space for people to express things	In a general way, talking through issues. Refer if it is too heavy

	if necessary		necessary		
Agreement /How idea was generated	More dialogue here and agree that it is not their role. Do talk about specific event that they reflect on.	Discussion on their role, when referral may be appropriate	Agree that it's not counselling. Discuss listening and talking to patients that they want to understand the "knot"	One express sense of importance in explaining how every thing is related in detail the other agrees but wants to move quickly on from this area	Agree that it's talking to patients and helping them look at issues. It is part of the treatment.
# treatments	About 6 before you see real changes.	Don't specify a number. Have had difficulty with treating this condition	One does not want to make a generality. The other says about 6.	Joke that patients think it should be 2, actually agree more 6-10	2-3 to see change review it at 5-6 make sure treatment is working
Agreement/ How idea was generated	Explain individ cases as to how many treatments are needed. Good exchange of stories.	One thinks can see results quickly based on 1-2 cases but the other is less confident. Discuss lack of experience treating this condition.	Discuss patient expectations and pract expectations at the start of treatment. Confidence as pract and individ cases are issues. Episodic nature.	Agree 4-6 to see a change then one brings up frustration about retention and is comforted by the other	Both agree that is important to see an early change and discuss w/ patient but it will take additional treatments
Frequency	Weekly	Weekly	(not discussed)	Weekly	Weekly
Agreement	Agree	Discuss people's expectations of how many treatments should have and the cost. Difficult in mind set of encouraging more than weekly		agree	agree
Duration	(both stay with their patients for an hour)	45min to an hour	50min to an hour, leave needles 20-30min.	45-50min. w/ 20-30min for retention	45 min to one hour, leave needles ~ 20min
Agreement	(not part of the recorded discussion)	No real discussion here	Agree	Slight variation and discussion as to why	Very similar answers
Diagnosis			Zang-fu, based on individual cases	One clearly states zang-fu the other more focused on the individual presentation	Zang-fu mostly but depends on individual
Agreement/ How idea was generated			Brief discussion on need to decide diagnosis based on individ	Doesn't generate disagreement just different ideas	See it differently. In terms of pulses and tongues or in terms of factors involved

Appendix B 5 Treatment protocol and log book used by acupuncturists in the pragmatic trial of acupuncture for IBS

Protocol

Introduction

Thank you for taking part in the University of York's trial of acupuncture for IBS. The primary objectives of this trial are to determine the clinical effectiveness and cost effectiveness of acupuncture as a treatment for IBS. This trial is designed to allow you to treat patients as closely to your normal practice as possible yet within a research framework. The following pages outline the treatment guidelines you will be expected to follow, provide instruction on how to use the treatment log, and provide you with some background information relating to previous research on acupuncture and IBS.

As part of the trial, we hope to refer to you 10 -12 patients diagnosed with IBS and screened by the University of York using the criteria listed on your information sheet. Each patient will be entitled to receive up to ten sessions of acupuncture as part of the trial, and these sessions should ideally be completed within three months (i.e. 13 weeks) of the first treatment. If you deem that the patient has improved sufficiently, you can formally end the series of treatments, and please explain to us the reason. Also if a patient decides to discontinue treatment of their own accord, please let us know the reason (if possible).

Completed treatment logs should be returned to the University of York in the pre-paid envelopes as each patient finishes his/her sessions. Because this is a research trial you may not photocopy any part of the treatment log. Any notes about treatment that you wish to retain must be made on separate paper.

Treatment Guidelines

The following is a list of processes intended to guide you in the treatment of trial patients. Please note that you should conduct the treatments in such a way as to mimic your normal practice as much as possible.

1. Take each patient's history including: past medical history, recent medical history, and detailed summary of his/her irritable bowel and related symptoms.

2. Examine each patient using the TCM diagnostic assessments you find appropriate (e.g. palpation, tongue, pulse).

3. Make a diagnosis based on the TCM pattern of differentiation you find appropriate (e.g. zang-fu, eight principles, four levels).

4. Select a treatment principle based on TCM theory (e.g. tonify yin, soothe the liver). Note that the treatment principle may vary for each treatment and that these guidelines allow for such variation.

5. Design a treatment strategy that incorporates the treatment principle and that aims to accomplish the treatment objective.

6. Select acupuncture points and additional therapies (see below) that are suitable for each patient's condition and treatment strategy. These may be modified at subsequent treatment sessions as appropriate.

Additional therapies that may be used are restricted to the following:

- Cupping
- Bleeding
- Tui-na (not more than 10 min)
- Ear seeds
- Electrical stimulation
- Moxa or moxa essence
- Heat lamp
- Gua sha
- Breathing
- Acupressure (not more than 10 min)

Note that the use of herbs and magnates are not permitted in the trial.

7. Use acupuncture needles that are of the appropriate length and gauge for the points selected and patient being treated.

8. Insert acupuncture needles using your chosen method of insertion and to the depth you determine is appropriate for the point location and patient.

9. Use needling techniques which correlate with the treatment principle and which elicit the desired response (e.g. deqi).

10. Retain the needles for an appropriate period of time according to the point location and the patient's condition.

11. Apply the relevant additional therapies (see point 5 above) that supplement each patient's treatment strategy according to the appropriate guideline or theory for that therapy.

12. Provide appropriate lifestyle advice according to each patient's needs and your clinical judgement.

13. Answer any questions the patients may have about what to expect from acupuncture treatment, their diagnoses, and their prognoses. Where appropriate – explain to each patient the necessary information about his/her condition from a TCM point of view.

14. Discuss the treatment plan with each patient being sure to include information about the number and frequency of treatments based on his/her needs. Keep in mind the number of treatments funded by the trial and the time frame in which they are to be delivered.

15. Discuss and agree reasonable expectations with each patient regarding his/her acupuncture treatment.

16. Record and interpret patients' reactions to acupuncture treatment (i. e. positive or negative) as well as any adverse reactions the patients experience.

17. Refer patients to their GP or appropriate health care professional if you become concerned about worsening of symptoms, the appearance of new symptoms, or if patients have questions about their prescribed medication.

18. Record the treatment process including background, diagnosis, points used, additional therapies, and lifestyle advice in the treatment log for each patient.

19. **Please note that pregnant women have been excluded from this trial. We have asked patients to inform one of the trial co-ordinators if they are pregnant. However, if a patient advises you that she is pregnant, please inform her that you are unable to treat her and ask the patient to contact one of the trial co-ordinators.**

Using the Practitioner's Log

Each patient will have his/her own treatment log for the trial. All information regarding treatment of trial patients must be recorded in the treatment log. Because this information is part of a confidential research trial, the treatment log may **NOT** be photocopied. If you would like to maintain a record of the patients' visits, you may make notes on your usual intake forms. During the trial, please keep all treatment logs in a secure (preferably locked) location.

Inside page – Write the patient's name, date of birth and your name. This will allow the researchers to double check the code on the cover to ensure the patient is correctly matched to the right book and practitioner. Do not write anything else on this page because it will be destroyed before analysis.

PARTS 1, 2, 3, 4 AND 5 OF THE TREATMENT LOG SHOULD BE COMPLETED FOLLOWING THE FIRST SESSION

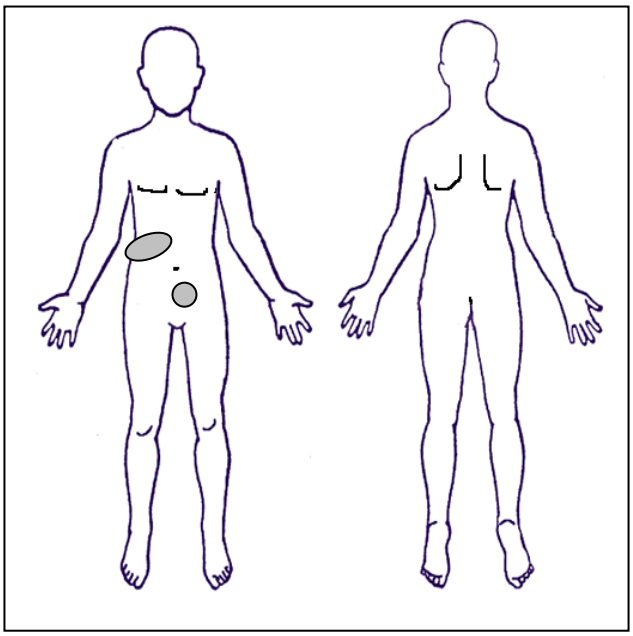
Part 1 - Background Information

Chief Complaint: Write the patient's chief complaint as it is described to you (i.e. abdominal pain and bloating).

Current Condition: Provide an overview of the case history of the patient. Describe relevant details that will provide insight into the patient's symptoms and overall condition.

Palpation: If you palpate as part of your routine assessment, briefly describe your findings.

Body Diagram: Mark on the diagram painful or tender areas. Additionally, you may mark areas you deem important based on palpation. See the example below.



Example: The patient complains of lower abdominal pain on the left side. The area is tender to palpation. Note that there is cold rigidity on right side hypochondriac region.

Pulse: Note your observation of the patient's pulse.

Tongue: Note your observation of the patient's tongue.

Part 2 – Primary Diagnosis

Use the differentiation table to denote which are the primary patterns affecting each patient. Mark the appropriate response in the **Presence** column based on your diagnosis. Mark how you came to this conclusion in the **Source** column.

Diagnostic Framework: Mark the diagnostic framework/s that you used to make your diagnosis.

Part 3 – Secondary Diagnosis

Use the differentiation table to denote which are the secondary patterns affecting each patient. You may mark more than one, but mark only those that are absolutely present.

Diagnosis: In your own words, write out the patient's complete diagnosis in the area below the table.

Part 4 – Treatment

Write the points used in treatment as channel # (i.e. Lv 3). If extra points, ear points, or scalp points are used, write out the name of the point (i.e. Si Shen Cong, ear heart, or scalp motor). Note whether the point was needled on one side (1x) or on both sides (2x). Note the amount of time the needles are retained. Note the technique used for each point as follows

T – tonify
R – reduce
E – even
O – other

Note the additional therapy used at particular points as follows

E – electrical stimulation
B – bleeding
A – acupressure
M – moxa

For research purposes we will be looking for trends in treatment as well as for variation, so please be as thorough as possible.

Treatment Principle: In 1 – 2 sentences, describe your treatment principle (i.e. Clear damp heat and move liver qi).

Point Selection: Briefly state why you chose this combination of points.

Additional Therapies: Mark all the boxes that apply. If you provide an additional therapy not listed in the table, please write it as other.

Note that herbs and magnates are **NOT** to be used in this trial.

Adverse Events:

According to the University of York guidelines, an adverse event is defined as any undesirable experience occuring to a patient, whether or not considered related to the treatment being used in the trial. A serious adverse event is defined as one that fulfills at least one of the following criteria: results in death, is life threatening, requires hospitalisation, results in disability, is a congenital anomaly or birth defect, or is otherwise considered medically significant by the investigator. If you become aware of a serious or minor adverse event, contact the trial co-ordinator **immediately**. The trial co-ordinators are:

Helen Tilbrook: 01904 321668 or het2@york.ac.uk
(hours of work, Mon – fri 9.30am to 1.45pm)
Helen Cox: 01904 321614 or hc18@york.ac.uk
(hours of work 7.30am – 3.30pm)

Please leave a message if no reply

Please note the trial co-ordinators only need to be notified of significant adverse events (serious or minor). These are events that are not expected to occur in normal clinical practice (for example pain or bleeding at the sight of needle insertion does not need to be reported). If you or the patient become concerned about an event, it should be reported.

In addition to contacting the trial co-ordinator, mark the appropriate box in the treatment log and write a brief description of the event. Please also mark whether you think the event is related to the acupuncture treatment or not.

Part 5 – Discussion

Prognosis: Based on your experience, note the prognosis for each patient in terms of whether or not he/she will respond well to acupuncture treatment.

Lifestyle Advice: Describe the lifestyle advice you provided each patient. Please write a rationale for this advice (this could be that it relates to the patient's TCM diagnosis, your clinical experience, or some other reason).

PART 6 OF THE TREATMENT LOG SHOULD BE COMPLETED FOLLOWING TREATMENTS 2 – 10

Part 6 - Follow-up

Treatment sessions 2 – 10 should follow your normal routine for subsequent visits. There is space for you to write pertinent comments about the patient's progress. If you palpate, please note any significant changes in pain/tenderness or heat/cold. Complete the treatment table using the same coding as given above. Also mark the use of additional therapies and presence of side effects in the same manner.

PART 7 OF THE TREATMENT LOG SHOULD BE COMPLETED FOLLOWING THE FINAL TREATMENT

Part 7 - Summary

This section allows you to provide feedback on the patient's overall experience and progress at the end of treatment. It is also a space for you to write comments about your experience with the trial, the treatment guidelines, and/or using the treatment log.

Note: Medication

Patients participating in this trial may be taking prescription and/or over-the-counter medication. Please respect the patient's decision regarding continuation of the medication. If the patient has questions about prescribed medication, refer them to the prescribing GP for advice. If the patient has questions about over-the-counter medication, use your best judgement when answering. Patient medication usage will be monitored by the University of York throughout the trial.

Claiming for your fees

Please claim for your fees for the treatment sessions on the **Casual Workers/Visitors Fees and Other Expenses** claim form. Please complete only the following sections:

- Your personal and bank details
- Date(s) Incurred – please enter the period you are claiming for (i.e. the date of the first treatment session and the date of the last treatment session you are claiming for).
- Details of the Claim – please enter the number of sessions you are claiming for alongside 'Fee'
- Sign and date the claim.

(Please do not complete the weekly timetable).

Please also complete and submit the document entitled '**Details of Claim (continued**)' which should be stapled to the claim form. On this form we require the details of the sessions you are claiming for please.

With your first claim, we require the **Casual Workers/Visitors - HESA Data form**. Please complete Section A and sign and date the form. (This form is required with you first claim only).

All the forms should be returned to us at the University of York in the pre-paid envelopes provided.

You can claim for your fees on a weekly basis or less often if you prefer.

<u>Notes about payment</u>

The payment is £34 per treatment. We are unable to make payment for cancelled appointments. However, we will endeavour to ensure that participants know that they need to give at least 24 hours notice when cancelling an appointment. National insurance contributions will be deducted on payment of over £105 per week. Tax will be deducted on payment of over £116 and per week. (Please note that if you are claiming for more than one week's fees it is important to ensure that you have put the date of the first treatment session and the date of the last treatment session on the main fees and expenses claim form)

Background Information

A systematic review of all available evaluative studies in 2006 states that there is too little information to determine whether acupuncture is an effective treatment for IBS. The results of this trial will provide evidence that contributes to determining whether acupuncture is effective in IBS. Please refer to the list below if you would like to read about the trials that have been conducted or relate to acupuncture and IBS.

1. Diehl, D. Acupuncture for gastrointestinal and hepatobiliary disorders. 1999.
J Alternative and Complementary Medicine. 5(1): 27-45.

2. Fireman, Z. et al. Acupuncture treatment for Irritable Bowel Syndrome. 2001. Digestion. 64: 100-103.

3. Forbes, A. et al. Acupuncture for Irritable Bowel Syndrome: a blinded placebo-controlled trial. 2005. World J Gastroenterology. 11 (26): 4040-4044.

4. Haker, E. Effect of sensory stimulation (acupuncture) on sympathetic and parasympathetic activities in healthy subjects. 2000. Journal of the Autonomic Nervous System. 79: 52-59.

5. Joos, S. et al. Use of Complementary and alternative medicine in Germany – a survey of patients with inflammatory bowel disease. 2006. BMC Complementary and Alternative Medicine. 6: 19-25.

6. Li, P. et al. Effect of electroacupuncture on pressor reflex during gastric distension. 2002. Am J Physiol Regul Integr Comp Physiol. 283: 1335-1345.

7. Lim, B. et al. Acupuncture for treatment of Irritable Bowel Syndrome. 2006. Cochrane Database of Systematic Reviews. Issue 4. Art No.: CD005111.

8. Reynolds, J. et al. Acupuncture for Irritable Bowel Syndrome – an exploratory randomised controlled trial. 2008. Acupuncture in Medicine. 26(1): 8-16.

9. Rohrbock, R. et al. Acupuncture has a placebo effect on rectal perception but not on distensibility and spatial summation: a study in health and IBS. 2004. Am J Gastroenterology. 99: 1990-1997.

10. Schneider, A. et al. Acupuncture treatment in irritable bowel syndrome. 2006. Gut. 55: 649-654.

11. Schneider, A. et al. Neuroendocrinological effects of acupuncture treatment in patients with Irritable Bowel Syndrome. 2007. Complementary Therapies in Medicine. 15: 255-263.

12. Takahashi, T. Acupuncture for functional gastrointestinal disorders. 2006. J Gastroenterology. 41: 408-417.

13. Wang, J. Electro-acupuncture of foot yang ming regulates gastric activity possibly through mediation of the dorsal vagal complex. 2007. American Journal of Chinese Medicine. 35(3): 455-464.

Contact Details

Trial Co-ordinators

Helen Cox:	01904 321614 or hc18@york.ac.uk
Helen Tilbrook	01904 321668 or het2@york.ac.uk

Supervising Acupuncturists

Tracy Stuardi	01904 321915 or tls504@york.ac.uk
Hugh MacPherson	01904 321394 or hm18@york.ac.uk

Administrative Support

Sally Brabyn	01904 321389 or sb43@york.ac.uk

Trial Acupuncturists

Annabelle Armitage	Malton Complementary Clinic	01439 788813
Jane Donnelly		
Alison Fletcher	Academy Spa	01423 779026
Liping Han	York Clinic	01904 709688
Tsering Jones	Derwent Surgery	01653 618737
Harriet Lansdown	York Clinic	01904 709688
Alison Longridge	York Clinic	01904 709688
Janice Ann Miller	Castle Clinic	01423 797800
Annie Milles	The Acupuncture Practice	01904 625578
Michael Stephenson	York Clinic/ Castle Clinic	01904 709688
Elaine Wilson	Clinic on the Green	01904 673050

Contact Address

York Trials Unit
Area 4 Seebohm Rountree Building
Heslington, York YO10 5DD

Treatment Log

Part 1. Background Information (to be completed at first appointment)
Chief Complaint:

_____

_____

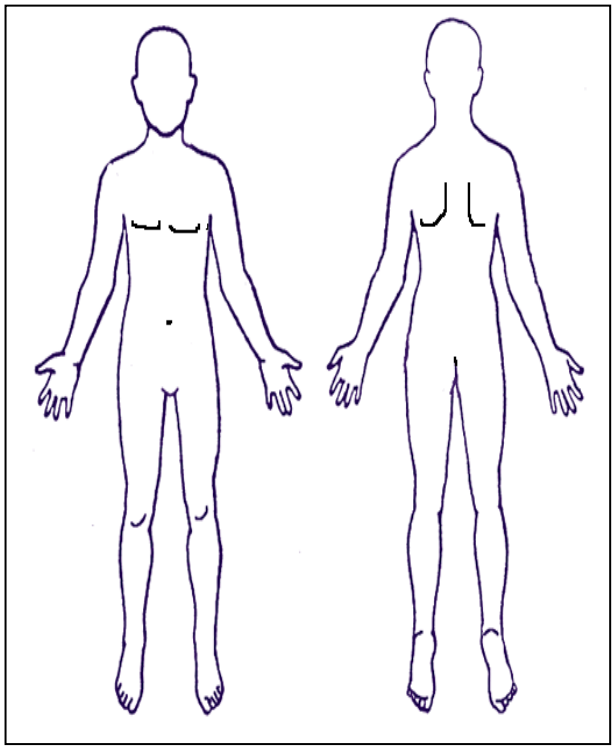
Current Condition: (provide an overview of the case history)

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

Palpation: _____
_____
_____
_____
_____
_____
_____

Pulse:_____
_____
_____
_____

Tongue: _____
_____
_____



Part 2. Primary Diagnosis

IBS: Primary Pattern Differentiation according to TCM.
Consider each pattern **as it relates to IBS,** a) for each pattern listed, mark "No", "Yes", or "Not sure" in the "Presence" column; and b) mark with an "**x**" in the "Source" columns if your decision on the pattern's presence is based on the: aetiology, generalized signs, bowel movement, or other source. You may select more than one source for each pattern.

	Pattern	Presence	Source					
			Aetiology	Description of Pain	Bowel Movement	Generalised Signs	Tongue & Pulse	Other
Excess	**Damp Heat**	☐ No ☐ Yes ☐ Not Sure						
	Cold Damp Accumulation	☐ No ☐ Yes ☐ Not Sure						
	Qi Stagnation/ Invasion	☐ No ☐ Yes ☐ Not Sure						
	Food Stagnation	☐ No ☐ Yes ☐ Not Sure						
Deficiency	**Yin Deficiency**	☐ No ☐ Yes ☐ Not Sure						
	Yang Deficiency	☐ No ☐ Yes ☐ Not Sure						
	Qi Deficiency	☐ No ☐ Yes ☐ Not Sure						
	Blood Deficiency	☐ No ☐ Yes ☐ Not Sure						
Mixed	**Excess & Deficiency**	☐ No ☐ Yes ☐ Not Sure						

Diagnositic Framework: (Mark the framework you used to make your diagnosis)

☐ Eight extra vessels ☐ Eight principles ☐ Six Channels

☐ Four levels ☐ Zang-fu ☐ Pathogenic Factors

☐ Qi, blood, body fluids ☐ Five elements: Shen/Ko cycles

☐ Other (specify): _____

Part 3. Secondary Diagnosis

IBS: Secondary Pattern Differentiation according to TCM

For each category, mark the underlying, constitutional, or secondary patterns that are most relevant in this patient. Please mark only those patterns that absolutely characterize this patient's clinical presentation.

Category	Pattern					
Qi	Deficiency ☐	Stagnation ☐	Counterflow ☐	Sinking ☐		
Blood	Deficiency ☐	Stagnation ☐	Blood Heat ☐	Blood Cold ☐	Blood Loss ☐	
Yin	Deficiency ☐	Deficiency with Deficiency Heat ☐	Deficiency with Fire ☐	Turbid Yin not Descending ☐		
Yang	Deficiency ☐	Hyperactivity ☐	Clear Yang not Ascending ☐			
Cold	Excess ☐	Deficiency ☐				
Damp	Stagnation ☐	Affecting the Spleen ☐	Affecting the Channels ☐	Transforming to phlegm ☐	Damp Heat ☐	Damp Cold ☐
Phlegm	Accumulating in the chest ☐	Affecting the Lung ☐	Phlegm Fire ☐	Disturbing the Mind ☐	Phlegm Cold ☐	Phlegm Heat ☐
Heat	Excess ☐	Deficiency ☐	Due to Hyperactive Yang ☐	Deficiency due to Yin Deficiency ☐		
Fire	Due to heat Transformation ☐	Yin Substance Accumulation ☐				

Diagnosis: (In your own words, write the complete diagnosis)

_____

_____

Part 4. Treatment 1

Points Used	Side	Time	Technique	Additional therapy

Points should be written as channel & pt (i.e. Lv 3). If extra point, ear point, or scalp point write out name (i.e. Si Shen Cong, ear heart, or scalp motor).

Side is either 1x for single side or 2x for bilateral.

Technique box should be coded as follows:
E – even R – reduce
T – tonify O – other

Additional therapy box should be coded as follows:
E – electrical M – moxa
B – bleeding
A - acupressure

Treatment Principle:

_____
_____
_____

Point Selection: (brief description of why these points)

_____
_____
_____
_____

Additional Therapies: (mark all that apply)

Cupping ☐ Electro-acupuncture ☐ Ear Seeds ☐
Bleeding ☐ Acupressure ☐ Moxa ☐
Tui-na ☐ Breathing ☐ Gua Sha ☐
Other (specify) _____

Adverse Events Treatment 1: (mark all that apply)

Serious adverse events* Did you notice an event that resulted in or could be considered significant such as:

Death	☐	Induced birth defect	☐	Life threatening condition	☐
Disability	☐	Hospitalisation	☐	Fits (convulsions)	☐

Other (specify)_____

Minor adverse events*: Did the patient complain of any of the following as a result of needling:

Fainting or severe dizziness	☐	Broken Needle	☐	Forgotten Needle	☐
Moxa Burn	☐	Unacceptable Bleeding	☐	Vomiting	☐
Unacceptable Pain	☐	Skin Infection	☐	Severe Dizziness	☐
Unacceptable Bruising	☐	Worsening of existing symptoms	☐		

Other (specify) _____

*Report any **serious** OR **minor** adverse events to the Trial Co-ordinator at the York Trials Unit **immediately**. (Helen Cox 01904 321614 or Helen Tilbrook 01904 321668)

Did the event occur: **during treatment** or **after treatment** (circle one). If after treatment, state how long after treatment the event occurred._____

With regard to the acupuncture treatment do you think the adverse event was:

☐ Unrelated	☐ Unlikely to be related
☐ Possibly related	☐ Probably related
☐ Definitely related	☐ Not able to determine whether related

Description of Event:

_____

_____
_____

Part 5. Discussion Treatment 1

Prognosis: (mark only one)

☐ Good ☐ Poor ☐ Don't Know

Lifestyle Advice: Provide a brief description of the advice relating to diet, exercise, rest, relaxation, work, and/or other aspect of lifestyle. Please state a rationale for why such advice was given (i.e. it relates to an aspect of the patient's TCM diagnosis or your clinical experience).

Advice Given	**Rationale**
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Part 6. Follow-up Treatments

Treatment 2

Comments:_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Points Used	**Side**	**Time**	**Technique**	**Additional therapy**

Points should be written as channel & pt (i.e. Lv 3). If extra point, ear point, or scalp point write out name (i.e. Si Shen Cong, ear heart, or scalp motor).

Side is either 1x for single side or 2x for bilateral.

Technique box should be coded as follows:
E – even R – reduce
T – tonify O – other

Additional therapy box should be coded as follows:
E – electrical M – moxa
B – bleeding
A - acupressure

Diagnosis:_____

_____

Treatment Principle: _____

_____

Point Selection: _____

_____

Additional Therapies: (mark all that apply)

Cupping	☐	Electro-acupuncture	☐	Ear Seeds	☐
Bleeding	☐	Acupressure	☐	Moxa	☐
Tui-na	☐	Breathing	☐	Gua Sha	☐

Other (specify) _____

Side Effects & Adverse Events: Treatment 2 (mark all that apply)
Serious adverse events* Did you notice an event that resulted in or could be considered significant such as:

Death	☐	Induced birth defect	☐	Life threatening condition	☐
Disability	☐	Hospitalisation	☐	Fits (convulsions)	☐

Other (specify) _____

Minor adverse events*: Did the patient complain of any of the following as a result of needling:

Fainting	☐	Broken Needle	☐	Forgotten Needle	☐
Moxa Burn	☐	Unacceptable Bleeding	☐	Vomiting	☐
Unacceptable Pain	☐	Skin Infection	☐	Severe Dizziness	☐
Unacceptable Bruising	☐	Worsening of existing symptoms	☐		

Other (specify) _____

*** Report any serious or minor events to the Trial Co-ordinator at the York Trials Unit immediately.**
Did the event occur: **during treatment** or after **treatment** (circle one). If after treatment, state how long after treatment the event occurred. _____

With regard to the acupuncture treatment do you think the adverse event was:

☐ Unrelated	☐ Unlikely to be related
☐ Possibly related	☐ Probably related
☐ Definitely related	☐ Not able to determine whether related

Description of Event: _____
_____
_____

Lifestyle Advice: (If you provided advice different from Treatment 1 please state it here).

Advice Given	**Rationale**
_____	_____
_____	_____
_____	_____
_____	_____

Treatments 3 – 10 used the same formatted pages as treatment 2.

Part 7. Summary (to be completed following last treatment session)

Total Number of Treatments: _____

Patient Outcome: _____
_____
_____
_____
_____

Your Experience: (with the trial and treatment guidelines) _____
_____
_____

Comments on the Treatment Log: _____
_____
_____
_____

Please provide information regarding the following needle details used for this patient during their treatment:

Depth of insertion (range in cm)_____
Needle length (range in mm)_____
Needle gauge or thickness (range in mm)_____
Response elicited (e.g. de qi)_____
Needle retention (range in minutes) _____
Needle stimulation methods _____

Thank you for participating!

Please return the completed treatment log to
the University of York in the pre-paid envelope.
York Trials Unit
Area 4 Seebohm Rountree Building
Heslington, York YO10 5DD

Appendix B 6 Trial acupuncturist: Potential participant information pack with cover letter and information sheet

THE UNIVERSITY of York

Department of
Health Sciences
HYMS Building
2nd Floor Postgraduate Area
Heslington
York YO10 5DD
Direct line: (01904) 321918
Email: tls504@york.ac.uk

September 1, 2008

Dear Acupuncturist,

I am contacting you to participate, as an acupuncturist, in the University of York's randomised controlled trial of acupuncture for IBS, which is sponsored by the National Institute for Health Research's Research for Patient Benefit programme. Enclosed is an information sheet about the trial and your role as an acupuncturist.

To comply with the standards set-out in the trial, all acupuncturists must be registered with the British Acupuncture Council and have at least three years of clinical experience. Additionally, all acupuncturists must obtain an honorary contract from the North Yorkshire Alliance Research & Development Unit. The University of York will assist you with this process by providing you with a copy of the contract, a CRB form, and we will forward your completed documents to the Research & Development Unit.

Please take time to consider your participation carefully as we may be referring you patients for three to twelve months, depending on the rate of recruitment. Also note that acupuncturists will be given preference on a first come first serve basis, until a maximum of twelve acupuncturists is recruited. With this in mind, we would like to recruit 1-2 acupuncturists from The Clinic on the Green.

If you would like to participate, please return the honorary contract, a copy of your CV, a copy of your professional liability insurance, and a copy of indemnity for your place of work, and the CRB form in the pre-paid envelope. If you have questions or would like more information, please contact Tracy Stuardi at 01904 321918 or tls504@york.ac.uk.

Thank you for your consideration. I look forward to working with you in the future and to producing exciting results for the acupuncture community with regard to IBS.

Sincerely,

Tracy Stuardi
(Supervising Acupuncturist)

THE UNIVERSITY of York

NHS National Institute for Health Research

Information for Acupuncturists
Randomised Controlled Trial of Acupuncture for Irritable Bowel Syndrome

Irritable bowel syndrome (IBS) is a commonly encountered functional bowel disorder in primary care. Although current treatments (such as antispasmodics) can relieve abdominal pain, an effective treatment modality that can improve a patient's global health remains elusive. Acupuncture offers a unique approach to the treatment of IBS in that it has the ability to address the multiple symptoms associated with IBS concurrently. The University of York has obtained funding from the National Institute for Health Research initiative Research for Patient Benefit Programme to carry out a multicentre randomised controlled trial to evaluate the clinical effectiveness and cost effectiveness of acupuncture in the treatment of IBS. Patients will be randomised by the York Trials Unit, University of York, to one of two treatments.

1. Acupuncture & usual care: As well as receiving the usual care provided by the patients' GPs, patients allocated to this group will be offered 10 sessions of acupuncture over 3 months. Each session will last approximately 60 minutes. We are recruiting acupuncturists who are registered with the British Acupuncture Council and have at least three years experience.

2. Usual care only: Patients allocated to this group will continue to receive treatment based on the usual care provided by the patients' GPs.

All eligible consenting patients will be randomised to one of the above treatments and will be asked to complete questionnaires at baseline, 3, 6, 9, and 12 months follow-up. All acupuncture sessions will be free of charge to participants.

Additionally, this trial contains a qualitative component to gain insight into the experiences of acupuncturists and their involvement with the healthcare community. We would appreciate your participation in an in-depth interview, but please note that if you are unwilling to be interviewed, your practice is still eligible to treat patients for the intervention portion of the trial.

What would be involved for you?

We have designed the trial so that each participating acupuncturist will treat between 8-12 patients and be compensated for each treatment provided as part of the study.

To compensate you for your time and cost of providing acupuncture, we propose a sum of £34 per treatment to be paid to your practice. We also propose a sum of £5 to be posted to all participants with their final questionnaire at the 12 month follow-up to thank them for their time and participation.

As part of the study, we have designed a treatment protocol, which is flexible enough for you to tailor treatments to each individual, but allows us to monitor treatments across the trial. You will be given instruction on how to use the treatment protocol, as well as, a treatment log to record activities. We would also like you to note any adverse events experienced by the patients.

Your responsibilities include:

- Treat patients according to the treatment protocol
- Complete a patient log for each treatment
- Return patient logs at the end of treatment (in pre-paid envelopes)

We are using the following eligibility criteria to recruit patients:

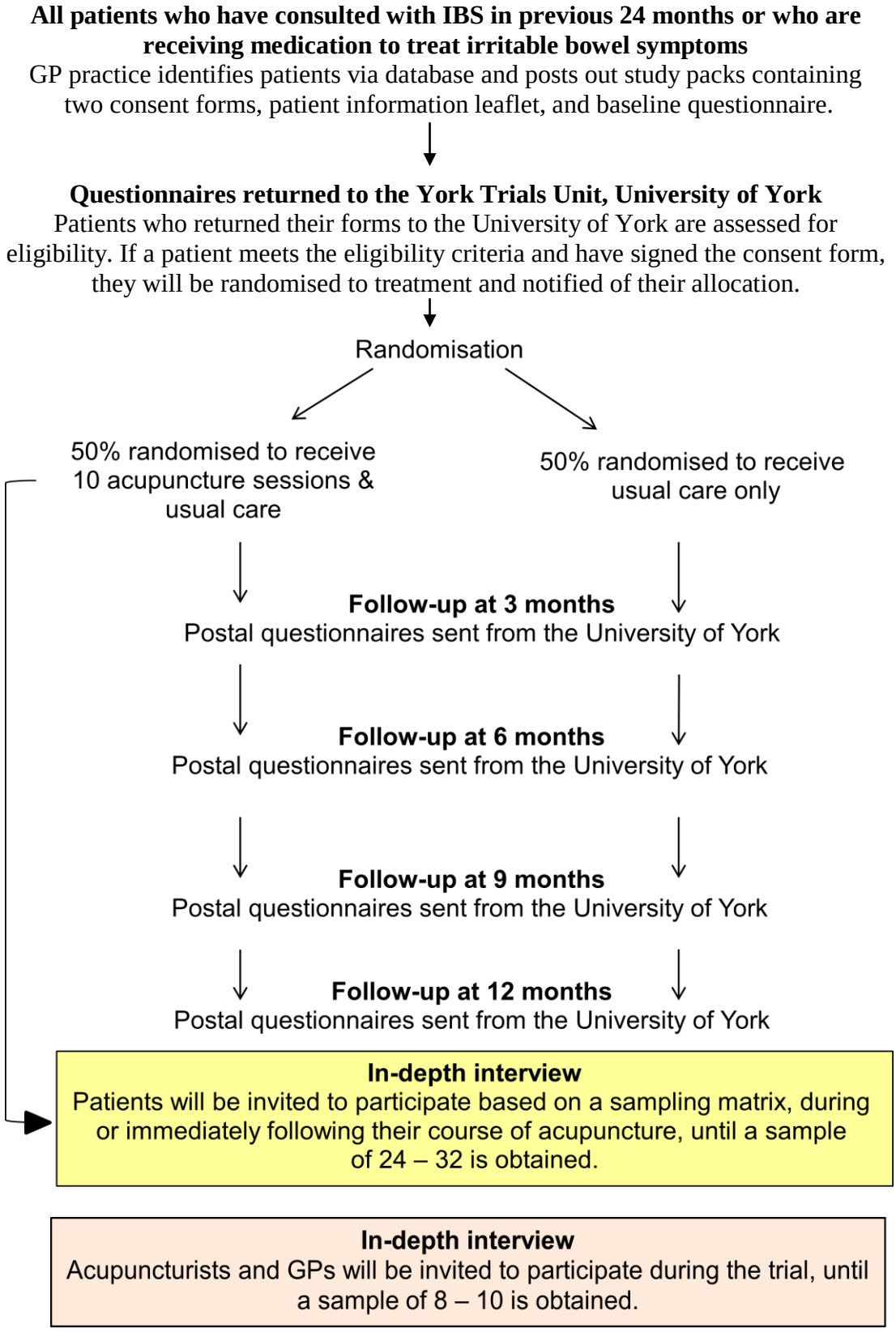
Screening Criteria

- Over 18 years of age
- Has a diagnosis of IBS or is being prescribed medication to treat IBS symptoms
- Has had a primary care consultation within the past two years for the above condition
- Not receiving cancer care

Eligibility Criteria

- No haemophilia
- No cancer
- Score more than 100 on the IBS Symptom Severity Score
- Have **not** had major gastrointestinal surgery within the past 6 months
- Are **not** currently receiving acupuncture

Flowchart of Trial Procedures



Appendix B 7 Trial: Potential participant (patient) information pack with cover letter, information sheet, consent form, and baseline questionnaire

Sample cover letter

Dear Patient
REF: A Randomised Study of Acupuncture for Irritable Bowel Symptoms

Our surgery, in collaboration with the University of York, is taking part in a research study exploring the use of acupuncture to treat irritable bowel syndrome (IBS) and its symptoms. The objective of this study is to see how effective acupuncture is in the treatment of IBS. The information collected during the research will be used to help medical professionals make decisions about treating irritable bowel symptoms in the future.

According to our records you have attended the surgery with irritable bowel symptoms or you are receiving medication to treat irritable bowel symptoms. The University of York and this practice would like to request your help by participating in this study if you still suffer with irritable bowel symptoms. There is an information sheet enclosed which describes the research and what to expect if you decide to become involved.

If after reading the information sheet you are interested in taking part in the study, please complete the enclosed questionnaire and complete the consent forms (one copy is for you to keep and one is to be returned to the University of York). We should be grateful if you would submit the forms in the pre-paid envelope provided to the University of York **within the next 2 weeks**. Upon receiving the forms, your eligibility will be assessed by the University and you will be informed of the decision made via a letter to your home address within 4 weeks.

If you would like to discuss the study in more detail before returning the forms, please do not hesitate to get in touch with one of the trial co-ordinators (Helen Cox on 01904 321614 or email hc18@york.ac.uk or Helen Tilbrook on 01904 321668 or email het2@york.ac.uk) at the University of York, who will be happy to answer your questions. If you would like more information about acupuncture, please contact one of the study's co-ordinating acupuncturists at the University of York (Hugh MacPherson on 01904 321394 or email hm18@york.ac.uk or Tracy Stuardi on 01904 431918 or email tls504@york.ac.uk).

While your help in this project would be greatly appreciated, it is completely voluntary. If you decide not to take part, it will not affect the care you receive at your doctor's surgery. **Your GP surgery has not given your name, personal or medical information to the University of York**, and the only information the University of York will receive will come from you if you decide to participate. All acupuncture sessions are free of charge and will be provided in your area.

Yours sincerely

YORK MEDICAL GROUP & THE UNIVERSITY OF YORK

THE UNIVERSITY of York

DEPARTMENT OF HEALTH SCIENCES
York Trials Unit
Seebohm Rowntree Building
Heslington
York YO10 5DD
Direct line: (01904) 321614/1668

PARTICIPANT CONSENT FORM
A randomised control trial of acupuncture for Irritable Bowel Symptoms

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to consider the information, to ask questions and to have these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, and my medical care and legal rights will not be affected. ☐

3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the University of York, from regulatory authorities, or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. I understand that my participation in this study is confidential and that no material which could identify me will be used in any reports of this study. ☐

4. I agree to my GP being informed of my participation in the study. ☐

5. I agree to take part in the above study. ☐

If you agree to the above five points <u>please initial each box</u> and <u>complete the information below</u>. Return this form with the questionnaire in the pre-paid envelope provided. Your contact information will be kept confidential and will only be used to contact you regarding the trial. If you have any questions, contact Helen Tilbrook at 01904 321668. Thank you for your interest in participating in this trial.

Date of Birth: ☐☐ ☐☐ ☐☐☐☐

Title: _____

Forename(s): _____ Signature:_____

Surname: _____

Address: _____ email:_____@_____

_____ Telephone number: _____
(including dialing code)

_____

_____ Mobile number: _____

POSTCODE:

☐☐☐☐ ☐☐☐☐

THE UNIVERSITY of York

NHS
National Institute for
Health Research

Acupuncture for Irritable Bowel Symptoms
Participant Information Sheet

This information leaflet invites you to take part in a research study exploring acupuncture as a treatment for irritable bowel symptoms. This study is being funded by the Department of Health's Research for Patient Benefit Programme, which is an initiative of the NHS National Institute for Health Research and sponsored by the University of York. Your decision to participate is important, so we would like to take this opportunity to explain why the research is being done and what it will involve. We encourage you to read the following information carefully and to discuss it with your family and friends if you find it helpful. We appreciate you taking the time to decide whether or not to participate.

Why have you been chosen?
You have been invited to take part in this research because you have been to see your GP within the past two years with irritable bowel symptoms.

What is the purpose of this research?
Irritable bowel syndrome (IBS) is the most common bowel disorder seen by GPs in the UK. However current treatments for IBS have been shown to be limited in treating its symptoms. Many people with IBS or irritable bowel symptoms try complementary and alternative medicine, including acupuncture, to manage their symptoms. Acupuncture is a technique of inserting very fine needles into specific points on the body to promote health. The goal for this study is to help regulate your digestive system and relieve your irritable bowel symptoms. However currently it is unclear how effective acupuncture is in treating irritable bowel symptoms and how it compares to standard treatments given by your GP. The purpose of this research is to determine how effective acupuncture is in treating irritable bowel symptoms when compared to standard treatments in normal GP care. We will also look at how the costs of the two treatments compare to each other.

The decision to take part
It is your decision whether or not to take part in this research project. If you decide to take part you may withdraw from the research at any time without giving a reason. The decision to withdraw at any time or the decision not to take part will not affect the standard of care that you receive.

If you decide to take part

If you agree to take part in this research project please sign the enclosed consent forms and fill out the questionnaire about your health which will take approximately 15 - 20 minutes. Return one consent form and the questionnaire to the University of York using the pre-paid envelope provided. Once we receive this information we will determine if you are eligible to participate. If you are eligible, you will be allocated to one of two groups:

1. Participants receive acupuncture plus continue with normal GP care.
2. Participants continue to receive normal GP care.

Our goal is to recruit 220 participants in total, out of which 110 will be offered acupuncture to treat their irritable bowel symptoms in addition to continuing with normal GP care, while the other 110 will continue to receive normal GP care. We cannot say which of the above treatments you will receive as this will be selected by a computer programme in a random way, so it will be down to chance. None of the researchers, clinicians, or participants will have any influence over this process. Each individual has a one in two chance of being selected for acupuncture.

We will inform you of whether or not you are eligible to take part in this research study via a letter to your home address. If you are eligible, we will also inform you of which treatment you have been allocated to receive.

1. Acupuncture treatment group

If you are allocated to this group, you will be referred for free acupuncture treatment at a private acupuncture clinic in your area. You will be provided with up to 10 sessions, which are expected to occur over a 3 month period. The researcher will offer to arrange the first appointment for you at a time that is the most convenient for you. The first appointment will last between one and two hours. Follow-up appointments will generally last up to one hour and be arranged directly between you and the acupuncturist. All acupuncture treatments that are part of this research are free of charge. In addition to the acupuncture treatments, you will continue to receive normal care from your GP as needed.

About the acupuncturists

All acupuncturists involved in this study have the equivalent of at least 3 years full-time training and a minimum of 3 years post-qualification clinical experience. They are also members of the British Acupuncture Council, which means that they observe Codes of Practice and Ethics and are insured for professional acupuncture practice.

Your first appointment

The acupuncturist treating you will take a full and detailed history. Questions will focus on your current symptoms, treatments you have received, and your medical history. There will also be questions about your digestion, energy levels, sleep patterns, and emotions. The acupuncturist will examine the colour and coating of your tongue, as well as, feel your pulse in each wrist. Using this information, the

acupuncturist will make a diagnosis and design a treatment specific to your needs. During the process feel free to ask questions.

The acupuncture treatment
The acupuncture treatment itself involves the insertion of very fine, sterile disposable needles into the skin. Needles will be placed at specific acupuncture points while you lie on a treatment couch. When the needles are inserted, the acupuncturist will ask you to describe the sensation you feel. The sensation should not be painful, but may feel like a dull ache or tingling. This sensation typically lasts a few seconds after insertion. Needles are typically left in place for twenty to thirty minutes, while you relax. At the end of the treatment, the needles are removed.

Over the following week, you should monitor how you feel and tell your acupuncturist at the next appointment. Please tell the acupuncturist if you change your medication during the course of the treatment sessions. The cost of the acupuncture treatments will be paid by the research project, although travelling expenses to and from the acupuncturist will not be provided.

2. Normal GP care treatment group
If you are allocated to this group you will continue to receive normal GP care. Your irritable bowel symptoms will be monitored at regular intervals throughout the trial. The results will be used to help determine the effectiveness of acupuncture as a treatment for irritable bowel symptoms when compared to your normal GP care.

What we need from you
In addition to completing the consent forms and questionnaire included with this letter, you will be asked to complete and return a questionnaire sent to you at 3, 6, 9, and 12 month intervals. We will enclose a stamped addressed envelope each time for this purpose. The questionnaires are designed to enable us to determine how useful the treatment was for you. Questions will cover your general health and well-being, how the treatments worked for you, and how the treatments affected your ability to work. A small number of patients allocated to the acupuncture group will also be asked to take part in an in-depth interview about their experience. The interview will be conducted by a University of York researcher and be scheduled for your convenience. The interviews will last approximately one hour. If you agree to participate in the trial you are still under no obligation to participate in the interview.

The possible disadvantages and risks
The risk of side effects with acupuncture is low, although, very rarely acupuncture can cause an unwanted health problem. Sometimes people feel a prick sensation when the needle is inserted. When the needle is withdrawn, it may cause minor bleeding (few drops) or a slight bruise. Some people feel tired after treatments, while others feel energised. Rarely people may feel sick or faint during treatment. Generally these reactions can be a sign that the treatment is working. These rarely pose a health risk, but if they concern you please talk to your acupuncturist, GP, or

you can discontinue treatment. We will include a comment section on the three month questionnaire for you to tell us about these experiences. ***Finally, it is essential that you tell the acupuncturist if you think you are pregnant.*** Your acupuncturist will provide further advice for your comfort and safety as necessary.

The possible benefits

As a result of treatment, it is expected that both groups (acupuncture and usual care) will experience some improvement in their IBS over the course of the study. However, it is not known to what extent the acupuncture group will benefit more (or less) than the usual care group.

When the study ends

After the study has ended, additional acupuncture treatments will not be funded by the research group or your GP. If you wish to continue acupuncture treatment, you will have to arrange it and pay yourself. You will still be entitled to continued normal GP care including prescription medication. Your GP will also be able to advise you on any other treatments that might be available.

Confidentiality

All information collected about you during the course of the study will be kept in strict confidence. The information, including your questionnaires, is subject to legal requirements and the Data Protection Act of 1998. Therefore, only your GP and the principal researchers at the University of York will know which patients have agreed to be included in the study. Your information will not be disclosed to anyone. Any information about you which is used in reports of the study will be made completely anonymous and used in such a way that you cannot be identified.

Results of the research study

The results of this research study will be available in December of 2011. We will publish the results in a healthcare journal to provide GPs and other healthcare practitioner's with information. You will be able to access the results of this study via the York Trials Unit's webpage:
www.york.ac.uk/healthsciences/research/trials.htm

Who reviewed the study

The study has been reviewed by the York Local Research Ethics Committee.

Contacts for further information

If you have any questions about any aspect of this study, please contact one of the researchers at the York Trials Unit, University of York.

Helen Cox: phone 01904 321614 or email hc18@york.ac.uk
Helen Tilbrook: phone 01904 321668 or email het2@york.ac.uk

If you would like more information about acupuncture, please contact one of the study's co-ordinating acupuncturists at the University of York.

Hugh MacPherson: phone 01904 321394 or email: hm18@york.ac.uk
Tracy Stuardi: phone 01904 431918 or email: tls504@york.ac.uk

Dissatisfaction with the study

If you are dissatisfied with any aspect of this study, you can file a complaint in one of two ways:

1. NHS complaints procedure (Tel: 0121 449 5725 or free phone: 0800 389 8391). Taking part in this study in no way affects your right to complain about any aspect of the way in which you have been treated during the course of this study.
2. British Acupuncture Council (Tel: 020 8735 0400 or email: ethics@acupuncture.org.uk). If you are in the acupuncture group, you can also use the normal British Acupuncture Council complaints procedure. Ask to speak with the Ethics Secretary who will give you further advice.

Further information about taking part in research

For independent information about participating in this study, contact your local Patient Advisory Liaison Service (PALS).

North Yorkshire & York PCT
York
YO31 7ZX
Tel: 0800 5870856
Email: pals-sy@nyypct.nhs.uk

Baseline questionnaire

PLEASE READ ALL THE INSTRUCTIONS BEFORE COMPLETING THE QUESTIONNAIRE

Thank you for showing an interest in taking part in this study and for taking the time to read the information sheet about the study. If you are willing to take part please fill out the following questionnaire and return it to us along with one of the consent forms in the pre-paid envelopes provided.

Please answer ALL the questions. Although it may seem that questions are asked more than once, it is still important that you answer every one. All information will be kept strictly confidential.

If you find it difficult to answer a particular question, please answer to the best of your ability.

When answering questions, use a cross rather than a tick, as if you are filling out a ballot paper. For example in the following question, if your answer to the question is yes, you should place a cross firmly in the box next to yes.

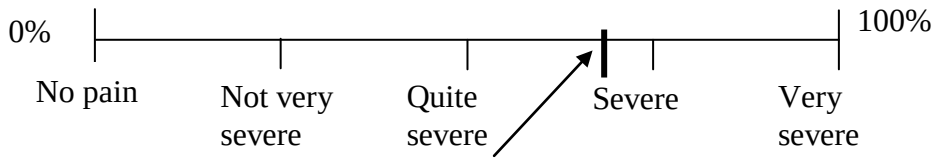
Do you have abdominal pain? Yes ☒ No ☐

If you are asked to write in an answer, please print clearly.

For example, what is your age? | 3 | 8 |

Some questions require you to mark a line, which enables us to judge the severity of a particular problem.

For example, how severe was your pain?



This mark indicates that the pain was approximately 73% severe.

Some questions require you to circle a number to indicate the level at which you experience something. For these questions, circle the number most appropriate to you.

For example, how often do you feel tired during the day?

Never	Sometimes	Often	Always
1	(2)	3	4

Please use a blue or black pen. This questionnaire is designed to assess your eligibility for entry into the study. We will write to you within the next four weeks to let you know whether you are eligible for the study.

Section 1. The following questions ask about general details and information related to your medical history, as well as, other issues that may affect you or

your health if you are to begin treatment in this study.

1. What is your date of birth?
(*Please write your date of birth)*

Day Month Year

2. What is your postcode?
(Please write your postcode)

3. Are you? ☐ Male ☐ Female

4. How old were you when you left full-time education? ☐☐ years

Or if you are still in full-time education cross this box ☐
and move onto question 6:

5. Are you currently working? ☐ Yes ☐ No

If yes, do you work full-time? ☐ Yes ☐ No

If no, please mark the following that applies to you.

☐ Currently looking for work
☐ Permanently unable to work
☐ Looking after home/family
☐ Retired
☐ Other

6. Are you currently receiving acupuncture treatment? ☐ Yes ☐ No

7. In general, do you think acupuncture can work? ☐ Yes ☐ No ☐ Don't know

8. Do you think acupuncture may help your bowel symptoms? ☐ Yes ☐ No ☐ Don't know

9. To which group would you prefer to be allocated if given the choice? *(Please cross one box). Please note this is for our information only, groups will be randomly assigned by computer.*

Acupuncture + Usual care ☐

Usual care ☐

Don't mind either ☐

10. How long have you had irritable bowel symptoms? ☐☐ Yrs ☐☐ Mns

11. Have you suffered from abdominal (tummy) discomfort or pain during the last 12 months? ☐ Yes ☐ No

If yes, have you had abdominal discomfort or pain for more than 12 weeks during the last year (the weeks need not be continuous weeks)? ☐ Yes ☐ No

12. About your abdominal (tummy) discomfort or pain:

a. Is it relieved by having a bowel movement? ☐ Yes ☐ No

b. Is its onset associated with a change in frequency of motion? ☐ Yes ☐ No

c. Is its onset associated with a change in form (appearance) of motion? ☐ Yes ☐ No

13. Have you had major gastrointestinal surgery in the last six months? ☐ Yes ☐ No

14. Do you have a current diagnosis of cancer? ☐ Yes ☐ No

15. Do you have a current diagnosis of haemophilia? ☐ Yes ☐ No

16. Do you have a current diagnosis of hepatitis? ☐ Yes ☐ No

17. Do you have a current diagnosis of HIV? ☐ Yes ☐ No

18. Are you pregnant? ☐ Yes ☐ No

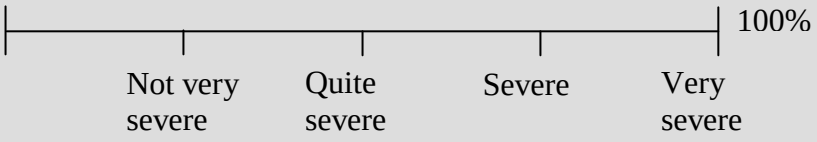
19. Have you experienced either of the following with your bowel symptoms?*

a. Unusual weight loss ☐ Yes ☐ No

b. Prolonged loss of appetite? ☐ Yes ☐ No

***Please note that if you answered "yes" to either part of Question 19, please contact your GP to make an appointment for a check-up if you have not already been to seen your GP with these symptoms.**

Section 2. The following questions are about your IBS. Some questions require you to mark a line, which enables us to judge the severity of a particular problem. For example, how severe was your pain?

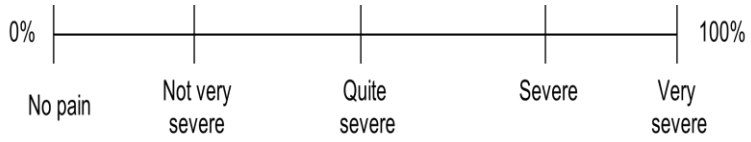


This mark indicates that the pain was approximately 73% severe.

For office use only

1. a. Do you suffer from abdominal (tummy) pain? Yes / No
(circle appropriate)

b. If yes, how severe is your abdominal (tummy) pain? (mark with an X)



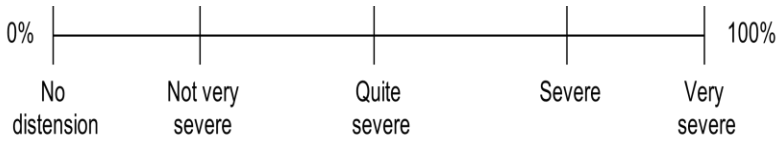
c. ***Please enter the number of days that you get the pain in every 10 days.***
For example, if you enter 4 it means that you get pain 4 out of 10 days.
If you get pain every day please enter 10.

10x

Number of days with pain

2. a. Do you suffer from abdominal distension? Yes / No
(bloating, swollen or tight tummy) (circle appropriate)

b. If yes, how severe is your abdominal distension? (mark with an X)

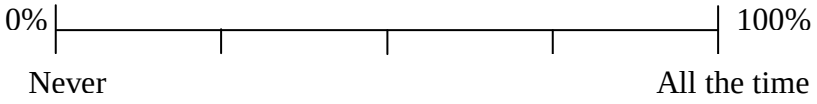


3. How satisfied are you with your bowel habit? (mark with an X)

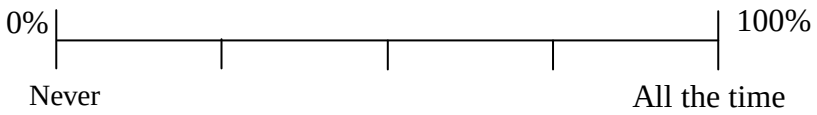
4. Please indicate with a cross on the line below how much your Irritable Bowel Syndrome is affecting and interfering with your life in general.

5. Do you suffer from the following? (mark with an X)

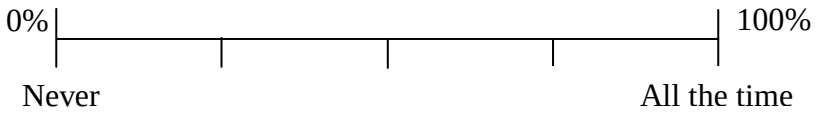
a. Nausea/vomiting?



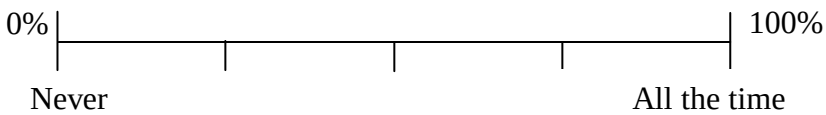
b. Difficulty finishing meals?



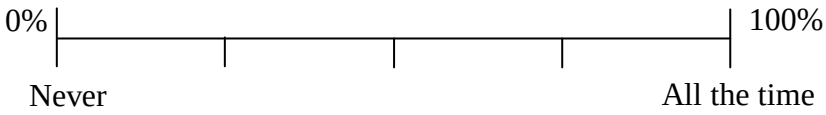
c. Headaches?



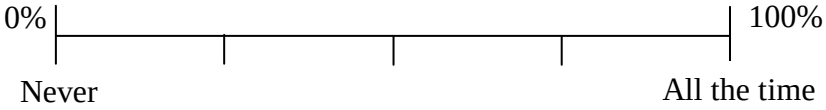
d. Backaches?



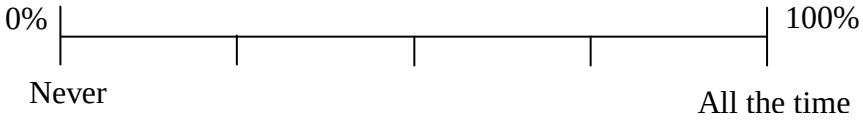
e. Lethargy or tiredness?



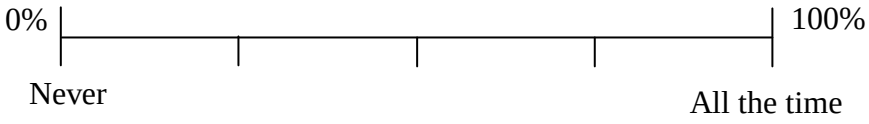
f. Excess wind (up or down)?



g. Heartburn?

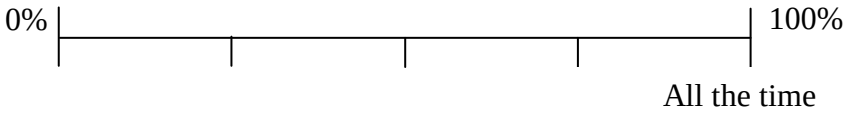


h. Having to pass urine frequently or with urgency?

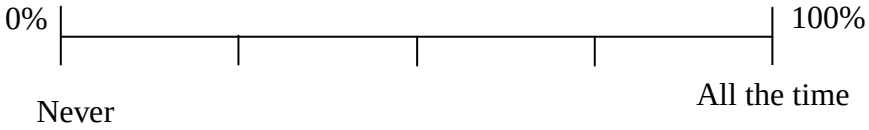


.

i Thigh pain?



j. Aches and pains in muscles and joints?



Section 3. The following set of questions is about your general health. Please mark one answer in each group that best describes your state of health today.

1. Mobility ***(mark one)***

- ☐ **I have no problems in walking about.**
- ☐ **I have some problems in walking about.**
- ☐ **I am confined to bed.**

2. Self-care ***(mark one)***

- ☐ **I have no problems with self-care**
- ☐ **I have some problems washing or dressing myself**
- ☐ **I am unable to wash or dress myself**

3. Usual Activities **(mark one)**

- ☐ **I have no problems with performing my usual activities (e.g.work, study, housework, family or leisure activities)**
- ☐ **I have some problems with performing my usual activities.**
- ☐ **I am unable to perform my usual activities.**

4. Pain/Discomfort **(mark one)**

- ☐ **I have no pain or discomfort.**
- ☐ **I have moderate pain or discomfort.**
- ☐ **I have extreme pain or discomfort.**

5. Anxiety/Depression **(mark one)**

- ☐ **I am not anxious or depressed.**
- ☐ **I am moderately anxious or depressed.**
- ☐ **I am extremely anxious or depressed.**

6. **In general,** would you say your health is: (please circle one number only) Excellent
Very Good Good Fair Poor
1 2 3 4 5

7. During a typical day does **your health** limit you **in moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf ? If so, how much?
(Please circle one number only)

Yes, limited a lot Yes, limited a little No, not limited at all
1 2 3

8. During a typical day does your health limit you in climbing several flights of stairs ? If so, how much? (Please circle one number only)

Yes, limited a lot Yes, limited a little No, not limited at all
1 2 3

9. During the **past 4 weeks,** how much time have you accomplished less than you would like in regular daily activities as a result of your physical health ? (Please circle one number only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5

10. During the **past 4 weeks,** how much time have you been limited in performing any kind of work or other regular daily activities as a result of your physical health? (Please circle one number only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5

11. During the **past 4 weeks**, how much time have you accomplished less than you would have liked in your work or any other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious) ? (Please circle one number only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5

12. During the **past 4 weeks**, how much time have you done work or other activities less carefully than usual as a result of any emotional problems (such as feeling depressed or anxious)? (Please circle one number only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5

13. During the **past 4 weeks**, how much did pain interfere with your normal work (both outside the home and housework)? (Please circle one number only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5

14. This question is about how you feel and how things have been with you during the **past 4 weeks.** Please give the one answer that comes closest to the way you have been feeling. How much of the time during the **last 4 weeks** have you felt calm and peaceful?
(Please circle one number only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5

15. This question is about how you feel and how things have been with you during the **past 4 weeks.** Please give the one answer that comes closest to the way you have been feeling. How much of the time during the **last 4 weeks** did you have a lot of energy? (Please circle one number only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5

16. This question is about how you feel and how things have been with you during the **past 4 weeks.** Please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks have you felt downhearted and low? (Please circle one number only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5

17. During the **past 4 weeks** how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives etc.)? (Please circle one number only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5

Section 4. The following questions are about your work and daily activities. The questions are designed to provide an overview of how your IBS symptoms (e.g. abdominal discomfort, abdominal pain, bloating, and constipation) affect the time you spend at work and the time you spend performing your daily activities.

1. During the **past 7 days**, how much did irritable bowel symptoms affect your ability to perform normal daily activities, **excluding your job?** *By normal activities, we mean the usual activities you perform, such as working around the house, shopping, childcare, exercising, studying, etc. Think about times you were limited in the amount or kind of activities you could perform and times you accomplished less than you would like. If irritable bowel symptoms affected your activities only a little, choose a low number. Choose a high number if irritable bowel symptoms affected your activities a great deal.*

Bowel symptoms had no effect on my daily activities **0 1 2 3 4 5 6 7 8 9 10** Bowel symptoms completely prevented me from doing my daily activities

2. Are you currently in paid employment? ☐ Yes ☐ No

If you are NOT currently in paid employment, please go to Question 7.

3. During the **past 7 days**, how many hours did you miss from work because of problems associated with your irritable bowel symptoms? *Include hours you missed on sick days, times you went in late, left early, etc., because of IBS symptoms. Do not include time you missed to participate in this study.* ☐☐ hrs

4. During the **past 7 days**, how many hours did you miss from work because of any other reason, such as annual leave, holidays, time off to participate in this study? ☐☐ hrs

5. During the **past 7 days**, how many hours did you actually work? ☐☐ Hrs

6. During the **past 7 days**, how much did irritable bowel symptoms affect your productivity while you were working? *Think about days you were limited in the*

amount or kind of work you could do, days you accomplished less than you would like, or days you could not do your work as carefully as usual. If irritable bowel symptoms affected your work only a little, choose a low number. Choose a high number if irritable bowel symptoms affected your work a great deal.

Bowel symptoms had no effect on my work	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10** Bowel symptoms completely prevented me from working

7. Please use the space below to write any comments on how irritable bowel symptoms have affected your life.

Section 5. The following questions refer to how you have been feeling over the past week. Please circle the number that most closely describes how you feel for each question.

1. I feel tense or wound up:

Not at all	Occasionally	A lot of the time	Most of the time
0	**1**	**2**	**3**

2. I get a sort of frightened feeling as something awful is about to happen:

Not at all	A little but it doesn't worry me	Yes but not too badly	Yes definitely and quite badly
0	**1**	**2**	**3**

3. Worrying thoughts go through my mind:

Only occasionally	From time to time, not too often	A lot of the time	A great deal of the time
0	**1**	**2**	**3**

4. I can sit at ease and feel relaxed:

Definitely	Usually	Not often	Not at all
0	**1**	**2**	**3**

5. I get a sort of frightened feeling like 'butterflies' in the stomach:

Not at all	Occasionally	Quite often	Very often
0	**1**	**2**	**3**

6. I feel restless as if I have to be on the move:

Not at all	Not very much	Quite a lot	Very much indeed
0	**1**	**2**	**3**

7. I get sudden feelings of panic:

Not at all	Not very often	Quite often	Very often indeed
0	**1**	**2**	**3**

8. I still enjoy the things I used to enjoy:

Definitely	Not quite so much	Only a little	Hardly at all
0	**1**	**2**	**3**

9. I can laugh and see the funny side of things:

As much as I always could	Not quite so much now	Definitely not so much now	Not at all
0	**1**	**2**	**3**

10. I feel cheerful:

Most of the time	Sometimes	Not often	Not at all
0	**1**	**2**	**3**

11. I feel as if I am slowed down:

Not at all	Sometimes	Very often	Nearly all the time
0	**1**	**2**	**3**

12. I have lost interest in my appearance:

I take just as much care as ever	I may not take as much care	I don't take so much care as I should	Definitely
0	**1**	**2**	**3**

13. I look forward with enjoyment to things:

As much as ever	Rather less than I used to	Definitely less than I used to	Hardly at all
0	**1**	**2**	**3**

14. I can enjoy a good book or TV programme:

Often	Sometimes	Not often	Very seldom
0	**1**	**2**	**3**

Section 6. This section is about health care you have received in the last three months. Please read each question carefully. For each question, if you have had no treatments or visits, please enter '0' as indicated. <u>We would like to know about visits to health professionals for any reason, not just IBS or bowel related symptoms</u>.

<u>Care from your GP's surgery</u>

1. In the **past 3 months** have you consulted a GP, practice nurse or other health professional at your GP practice?

☐ Yes
☐ No

2. If you have answered 'yes' to question 1 above, how often did you consult any of the following at your GP's surgery in the **past 3 months**? (if none please enter '0')

Your own GP or another GP	☐☐
Practise nurse	☐☐
Other (please specify) _____	☐☐
Other (please specify) _____	☐☐

3. How many of the above visits were related to your IBS or irritable bowel symptoms? ☐☐

Enter number of times

<u>Care from hospitals</u>

4. In the **past 3 months**, have you been admitted to a hospital **as an emergency?**

☐ Yes
☐ No

4a. If you have answered 'Yes' to question 4 above, please write the number of times you have been admitted to a hospital **as an emergency**. ☐☐

Enter number of times.

4b. How many of the emergency admissions to a hospital were related to your IBS or irritable bowel symptoms? ☐☐

Enter number of times.

5. In the **past 3 months**, have you been admitted to a hospital **NOT** as an emergency?

☐ Yes

☐ No

5a. If you have answered 'Yes' to question 5 above, please write the number of times you have been admitted to a hospital **NOT** as an emergency?

☐☐ Enter number of times.

5b. How many of the non-emergency admissions to a hospital were related to your IBS or irritable bowel symptoms?

☐☐ Enter number of times.

6. In the past **3 months,** how many times were you seen by a doctor at an **outpatient clinic** of a hospital?
(if none please enter '0')

☐☐ Enter number of times.

6a. If you have been seen by a doctor at a outpatient clinic, please write how many of these visits were related to your IBS or irritable bowel symptoms.

☐☐ Enter number of times.

Care from NHS hospitals

7. In the **past 3 months,** how often have you been seen by **any other health professionals** in a NHS hospital?

Acupuncturist ☐☐

Chiropractor or osteopath ☐☐

Other (please specify) _____ ☐☐

7a. If you have answered 'Yes' to question 7 above, please write how many of these visits were related to your IBS or irritable bowel symptoms.

☐☐ Enter number of times.

Private Treatments

7. In the **past 3 months**, how many times did you consult a **private healthcare professional**?

Doctor	☐☐
Acupuncturist	☐☐
Chiropractor or osteopath	☐☐
Other (please specify) _____	☐☐

7a. How many of the private treatments above were related to your IBS or irritable bowel symptoms? ☐☐

Medication

7. Over the past 3 months, have you used any prescription medication? ☐ Yes ☐ No

If yes, please list the name and daily dose of the prescription medication.

Name of prescription medication	**Daily dose (for example, 1 x 8mg tablet)**

8. Over the past 3 months have you used any non-prescription (over-the-counter) medication or supplements? ☐ Yes ☐ No

If yes, please list the name and daily dose of the non-prescription (over the counter) medication or supplements

Name of non- prescription medication or supplements	**Daily dose (for example, 1 x 8mg tablet)**

9. Please estimate the amount you have spent on non-prescription (over-the-counter) medication or supplements in the past 3 months. £_____

Thank you for completing this questionnaire. Please return this questionnaire and a consent form in separate pre-paid envelopes which are provided. Once we receive this questionnaire AND your consent form we will assess your eligibility for the study and inform you within four weeks via a letter to your home address. THANK YOU.

York Trials Unit
Area 4, Seebohm Rowntree Building
University of York
Heslington York YO10 5DD

Appendix B 8 Topic Guides for in-depth interviews with patients, acupuncturists and GPs

Topic Guide for IBS Patients

Objective: The objective of this topic guide is to help the interviewer gather information on how patients explain acupuncture to work, the impact of that explanation on treatment outcome, and how that explanation affects their perception of their body (health).

Introduction

- Summary of current activity and/or occupation
- What are your general feelings about IBS?

Reason – The purpose of the introductory questions was to collect background information on the patients and help them feel at ease with the interview process.

Disease History

- Age at onset
- What type of illness severity and/or pattern have your experienced
- Management strategies
    - Interventions used (including prescription medication, non-prescription medication, alternative therapies, other)
    - What has your experience been with these different therapies (effectiveness)
    - What is your perception on how these treatments have impacted your life in general
- What other health problems do you have?
    - Do these other problems or their treatments affect your IBS

Reason – These questions were designed to capture the heterogeneity of the IBS patients in the study, which could be used for a comparison to the broader IBS population to determine generalizability.

Perception of Acupuncture

- General feeling about acupuncture
- Reasons for being drawn to acupuncture intervention
- Describe your experience with acupuncture prior to the trial
    - Discussion with GP, family, friends
    - Did he/she try acupuncture before for IBS or other condition

Reason – These questions were asked to establish the patients' beliefs in acupuncture as well as their prior experience with acupuncture. These questions provided data that could be triangulated with the baseline questionnaire responses to establish the importance of and influences on belief.

Explanation of how Acupuncture Works

- Please explain how acupuncture works.
    - You may also illustrate how it works to assist your explanation (optional)
- How did the explanation evolve
    - Was it explained by an acupuncturist

    - Reading or the web
    - Completely extemporaneous
- Interpretation of explanation
    - Does the explanation make sense to you
    - How does the explanation make sense or not
    - In what type of context
    - Is there a deeper understanding that resonates in your life

Reason – These questions were designed to elicit answers that address the primary aspect of question 3 in that how does acupuncture work and how does patients make sense of their explanations.

Acupuncture Therapy

- How would you describe your current experience with acupuncture
- Do you believe that the therapy will work or has worked
- Compliance with treatment schedule
    - How many visits did you attend?
    - What influenced the number of visits you attended?
        - Is the number of visits you attended related to your improvement
        - Is the number of visits you attended related to your opinion of the practitioner
- Perceived improvement
    - Have you experienced improvement in your IBS symptoms?
        - What types of improvements have you experienced?
    - Have you experienced improvement in any other symptoms?
        - What types of improvements have you experienced?
- How does the explanation relate to perceived improvement?
    - Do you think that the explanation of how acupuncture works and your understanding of that explanation contributed to your improvement?
    - If yes, in what way did it contribute?
    - If no, what do you think contributed to your improvement?
- Opinion of practitioner
    - Do you think that the skills of the practitioner contributed to your improvement
    - If yes, in what way did they contribute
- Post study information
    - Will you continue with acupuncture after the trial has ended?
        - Why or why not?
    - Would you recommend the use of acupuncture to friends and/or family?
        - Why or why not?

Reason – This group of questions addressed a variety of sub-questions in terms of the patients' experiences and what influences those experiences as well as their perceptions of improvement and compliance.

Perception of Health/Body Related to Explanation

- How has the explanation of how acupuncture works influenced your perception of your body and health?
    - Have you experienced a change in body awareness?
        - Please describe the change
    - Have you made a lifestyle change?
        - Please describe the change
- Has the explanation of how acupuncture works impacted the way you view healthcare in general?
    - How has it impacted your view?
    - How are you incorporating this new view into your life?

Reason – Considering the literature discussed in Chapter 3, these questions were included to determine whether patients experienced unexpected outcomes that were directly related to their body awareness, lifestyle, and health care.

Conclusion

- Would you like to make a summary remark on how acupuncture works and how the explanation of how acupuncture works has influenced your treatment outcome?
    - Please summarize.
- Do you have any additional thoughts on acupuncture and/or how it works that you would like to share?

Reason – The purpose of the concluding questions was to provide patients an opportunity to address any aspect of the interview in more detail or add information they considered relevant that was not asked in the interview.

Topic Guide for Acupuncturists

Objective: The objective of this topic guide is to help the interviewer gather information from acupuncturists on how they explain acupuncture to work, how they describe this to their patients, and whether they think it influences patients' outcomes. Secondarily the topic guide explores how the explanation may influence the referral network in the medical community.

Introduction

- Background as an acupuncturist
    - Where did you train?
    - How long was the course?
    - How long have you practitioner?
    - What is your speciality?
- What do you think are the perceived uses for acupuncture?
- Based on your experience, what do you think acupuncture treats most effectively?

Reason – The purpose of the introductory questions was to collect background information on the acupuncturists. Additionally the questions were designed to put the acupuncturists at ease and emphasize their expertise because the subsequent questions were potentially threatening.

Explanation of how Acupuncture Works

- Please explain how acupuncture works.
    - You may illustrate your explanation. (optional)
- How did your explanation evolve?
- Interpretation of explanation
    - In general, what does the explanation mean
    - Specifically, do you experience a deeper understanding of how acupuncture works

Reason – These questions explore the acupuncturists' explanations of how acupuncture works, which is part of the objective.

Explanation Given to Patients

- What explanation of how acupuncture works do you describe to patients
    - Is it the same or different from previous the description
    - Do you explain how acupuncture works as part of an initial consultation or only provide one at a patient's request
    - Do you include any information that would be considered theoretical
        - Please describe what information you would include (i.e. yin-yang, five elements, relationship between the organs, etc.)
- How do patients respond to the explanation?
- In addition to the explanation of how acupuncture works, do you provide information that may influence the patient's understanding of his/her body and health
    - Beliefs about IBS
    - Diet and exercise

Reason – These questions address the second aspect of the objective, which is to determine how the explanation may differ when given to the patient. The comments could be compared to the answers above to determine the importance of language.

Relationship Between how Acupuncture Works & Patient Outcomes

- What type of patient is the treatment most likely to work for and why
    - Are there general assumptions about the types of patients who improve with acupuncture treatment
    - Is IBS a more treatable (or easily treatable) condition than others
- Does explaining how acupuncture works influence treatment outcome
    - If yes, elaborate on how the explanation influences outcome
    - If no, what are the key determinants of outcome
- Do patients with positive outcomes seek more information about acupuncture theory
    - What kind of information do they seek
    - Where do you direct them to find the answers
- What types of patients are likely to continue with acupuncture therapy?

Reason – These questions were designed to capture the practitioner's perception of the impact of their explanation as well as who generally benefits from acupuncture.

Relationship Between how Acupuncture Works & Healthcare Community

- In general, what is your experience with the healthcare community as an acupuncturist?
- How do you think the healthcare community perceives acupuncture to work?
    - What influence does this perception have on the healthcare community?
        - In its attitude toward acupuncturists
        - In its acceptance of acupuncture as a valid treatment modality
        - In its dissemination of information to patients
        - In its willingness to accept acupuncturists as part of the healthcare community
    - How does it influence your relationship with other healthcare practitioners?
    - How can the perception of how acupuncture works be altered?
        - What impact will this have on the healthcare community?
        - What impact will this have on patients?
- Do you have a recommendation network of healthcare practitioners?
    - What types of practitioners recommend patients for acupuncture?
    - Do these healthcare practitioners have a clear understanding of how acupuncture works or have you personally discussed acupuncture with them?
    - What do you think influences their decision to recommend patients for acupuncture
- What types of recommendation do you receive?
- What are the reasons why you do not have a recommendation network? (if needed)
    - Do you receive recommendation without a network?
    - Where do these patients come from and what type of patients are they?

Reason – These questions address the secondary objective, which is to explore the acupuncturist's relationship with the health care community and the role of acupuncture. These questions could establish the integration of acupuncture care in the community and future prosperity.

Conclusion

- Would you like to make a summary remark on how acupuncture works and how the explanation of how acupuncture works influences patient outcomes?
    - Please summarize.
- Do you have any additional thoughts on acupuncture and/or the topics we discussed that you would like to share?

Reason – The last questions provided an opportunity for the acupuncturists to discuss any aspect of the topics they felt were not covered or amend their answers.

Topic Guide for GPs

Objective: The primary objective of this topic guide is to help the interviewer gather information on how GPs explain acupuncture to work and whether or not this influences their discussion with patients about acupuncture and referral for acupuncture. Secondarily the topic guide explores how the explanation may influence recommendations in the healthcare community.

Introduction

- Background as a GP
    - How long practising
    - Speciality
    - Training

Reason – The purpose of the introductory questions was to collect background information on the participants and establish their willingness to be interviewed.

Perception of CAM

- General feelings about acupuncture
- Have you been exposed to acupuncture either personally or via friends and family
    - Describe your experience.
- What are the perceived uses for acupuncture

Reason – These questions were also designed to collect background information, but also focussed the participant's attention of the specific topic. They could help establish the participant's beliefs, attitude, and exposure, which could set the tone for the rest of the interview.

Explanation of how Acupuncture Works

- Please explain how acupuncture works
    - You may illustrate the explanation (optional)
- How did the explanation evolve
    - Explained by an acupuncturist
    - Reading or the web
    - Completely extemporaneous
- Interpretation of explanation
    - What does the explanation mean to you
        - Does it make sense
        - In what context does it make sense

Reason – These questions established the link across all sets of interviews by capturing how the GPs understand acupuncture to work.

Explanation given to patients

- Do you ever discuss acupuncture with your patients?
    - In what context do you discuss acupuncture with your patients
    - What conditions do patients have or what types of patients do you discuss acupuncture with
        - What is the explanation given to the patient on how acupuncture works
        - Is the explanation prompted by patient request

        - Is the description the same as the one given earlier
        - If no explanation is given, what do you generally say about acupuncture
    - If no, what are the reasons
- What is the perceived impact of your description on the patient's willingness to try acupuncture
- Do you experience a change in your relationship with patients who try acupuncture

Reason – These questions helped establish whether acupuncture was an intervention that GPs recommended to patients and if so whether it was a patient initiated discussion. The responses set the tone for the subsequent questions.

Relation Between how Acupuncture Works & Healthcare Community

- In general, how does the medical community perceive acupuncture to work
    - What influence does this perception have on the medical community
        - In its attitude toward acupuncturists
        - In its acceptance of acupuncture as a valid treatment modality
        - In its dissemination of information to patients
        - In its willingness to accept acupuncturists as part of the healthcare community
    - How does it influence your relationship with acupuncturists?
    - How can the perception of how acupuncture works be altered?
        - What impact will this have on the healthcare community?
        - What impact will this have on patients?
- Do you have a recommendation network of acupuncturists?
    - How do you decide which acupuncturists to recommend to?
    - What types of patients do you recommend?
    - What conditions do you recommend?
    - What do you think influences your decision to recommend patients for acupuncture
- What are the reasons why you do not have a recommendation network? (if needed)
    - What events would encourage you to develop a referral network?
- How do your colleagues regard GPs who refer/support acupuncture?

Reason – These questions were designed to determine how GPs perceived acupuncturists to fit into the health care community and the future role of acupuncture.

Conclusion

- Would you like to make a summary remark on how acupuncture works and how the explanation of how acupuncture works influences your discussions with patients and/or the healthcare community?
    - Please summarize.
- Do you have any additional thoughts on acupuncture and/or the other topics that you would like to share?

Reason – The concluding comments provided GPs the opportunity to discuss any of the topics in more detail or to amend their answers. It was also an opportunity for them to ask questions.

Appendix B 9 In-depth interviews: Potential participant (patients, acupuncturists, GPs) information pack with information sheet and consent form

THE UNIVERSITY of York

NHS
National Institute for
Health Research

Acupuncture for Irritable Bowel Syndrome – Study Interview
Participant Information Sheet

As part of the trial investigating acupuncture for Irritable Bowel Syndrome, we would like to invite you to take part in an in-depth interview exploring your explanation of how acupuncture works. We hope to gain a broader understanding of what influences patients' outcomes and the medical community. We are seeking the views of patients, acupuncture practitioners, and GPs to answer this question.

In the interview, we will ask about your experience with acupuncture, your understanding of how it works, and the broader impact that experience has had on your perception of health and the healthcare community. The interview will be audio recorded and will last approximately one hour. The interview will be conducted at a time and place convenient for you, either in your own home/clinic or at an agreed venue.

The interview tape will be transcribed to protect your identity and all names will be changed to maintain anonymity. Once the tapes are transcribed, they will be destroyed. The only people who will have access to your identity will be the researchers who will ensure that steps are taken to maintain security and confidentiality.

Your participation in the interview is entirely voluntary. If you decide to take part, keep this information sheet and sign and return one of the consent forms in the pre-paid envelope. If you decide to take part, you may withdraw from the study at anytime without giving a reason. The decision to withdraw or the decision to not take part will not affect your participation in future studies.

If you have any questions, please contact either Helen Tilbrook at 01904 321668 or het2@york.ac.uk or Tracy Stuardi at 01904 321915 or tls504@york.ac.uk.

We appreciate your participation.

Sincerely,

Helen Tilbrook
(Trial Co-ordinator)
Department of Health Sciences
2nd Floor, Area 4 Seebohm Rowntree Building
Heslington, York YO10 5DD

THE UNIVERSITY of York

DEPARTMENT OF HEALTH SCIENCES
York Trials Unit
Seebohm Rowntree Building
Heslington
York YO10 5DD
Direct line: (01904) 321614
Email: hc18@york.ac.uk

PARTICIPANT CONSENT FORM
Acupuncture for Irritable Bowel Syndrome Study Interview

1. I confirm that I have read and understand the information sheet dated May 19, 2008 (version 1.0) for the above study. I have had the opportunity to consider the information, to ask questions and to have these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to decline the offer to participate without giving any reason, and my medical care and legal rights will not be affected. ☐

3. I understand that the interview will be audio recorded and that the tapes will be destroyed when transcription is complete. ☐

If you agree to the above three points, please initial each box and complete the information below and return this form in the pre-paid envelope. Your contact information will be kept confidential and will only be used to contact you regarding the trial. If you have any questions, contact Helen Cox at 01904 321314 or Helen Tilbrook at 01904 321668. Thank you for your interest in participating in this trial.

Printed name:_____

Signature:_____

Address:
_____

_____

_____

Post Code:

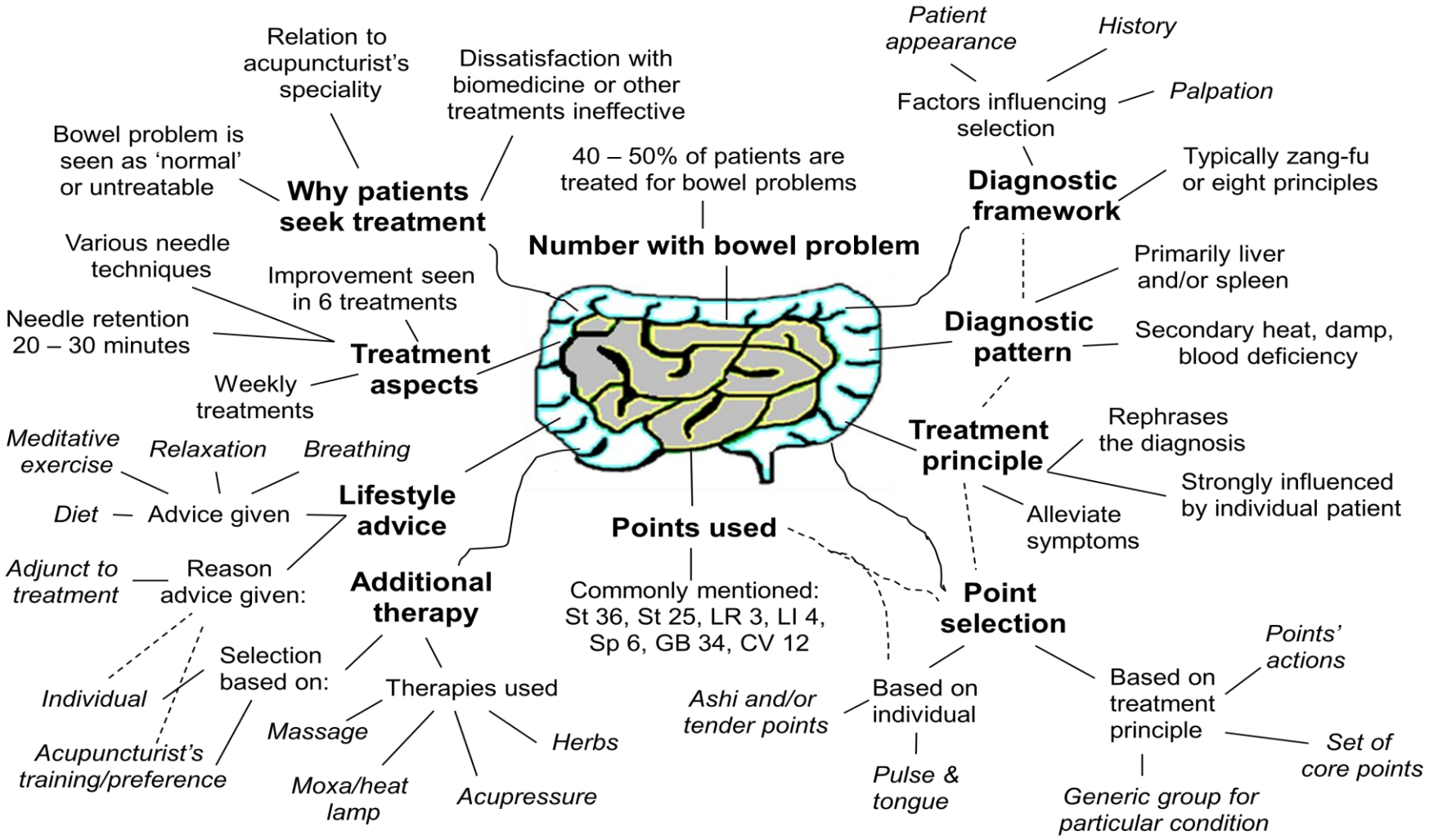
Time it is better to reach you: am/pm
(circle one)

Day of the week most convenient for you:
Mon/Tues/Wed/Thurs/Fri/Sat
(circle any)

Telephone number: _____
(with dialing code)

Email:_____@_____

Appendix C Mind map of treatment process discussed in pre-trial acupuncturists' interviews. Categories – bold, themes – not bold, subthemes - italics



Appendix D 1 Phrase inventory of chief complaints. Each of the underlined complaints represents a group of phrases, identified by treating acupuncturists, with similar meanings to allow for comparisons across groups.

Alternating bowel movement	Indigestion
Alternating bowel movement	Slow digestion w/ bloating
Alternating bowel movement w/ wind	Reflux w/ bloating
Alternating bowel movement w/ bloating	Indigestion w/ nausea
Erratic bowel movement	Indigestion w/ wind
Diarrhoea	Other
Diarrhoea	Incomplete evacuation
Sudden diarrhoea	Trapped wind
Diarrhoea w/ bloating	
Loose stool	Urgency
Loose stool w/ wind	Urgent stools
	Urgency frequency w/ wind
Constipation	
Constipation	Pain
Constipation w/ bloating	Episodic pain w/ severe bloating
	Abdominal pain
Fatigue	Abdominal pain w/ bloating
Lethargy & fatigue	Gripping pain
Tiredness	Gnawing pain
Lethargy w/ bloating	Stabbing pain w/ bloating
	Cramps w/ bloating
IBS	Burning pain

Appendix D 2 Adjusted analysis of acupuncturists' diagnostic frameworks. Adjusted refers to the analysis of frameworks that removed qi-blood and eight principles that were marked in tandem with zang-fu so as to avoid duplication.

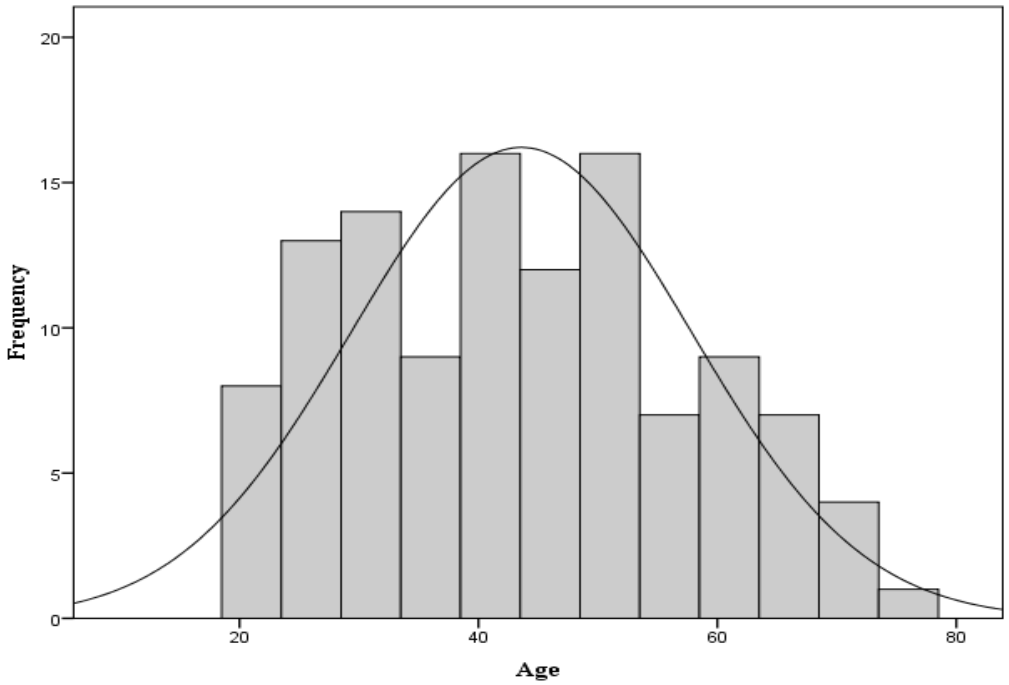
Acupuncturist	**Sam**	**Marie**	**Beth**	**Holly**	**Ellen**	**Lisa**	**John**	**Jill**	**Cindy**
Yrs exp	21	5	25	4.5	5	10	3	10	17
# Patients	16	16	3	8	11	22	10	10	16
Framework									
Zang-fu	15	16	3	8	11	22	10	10	15
Qi-blood	1	0	0	0	0	0	0	0	0
8 Principles	0	0	0	0	0	0	0	0	0
5 Element	14	0	0	0	0	0	0	0	0
Pathogen	0	3	2	0	0	4	1	0	1
4 Level	0	0	0	0	0	3	0	0	0
6 Channel	0	0	0	0	0	0	0	1	0
Combinations	4	2	2	1	1	3	2	2	2

Appendix D 3 Multi-nomial logistic regression

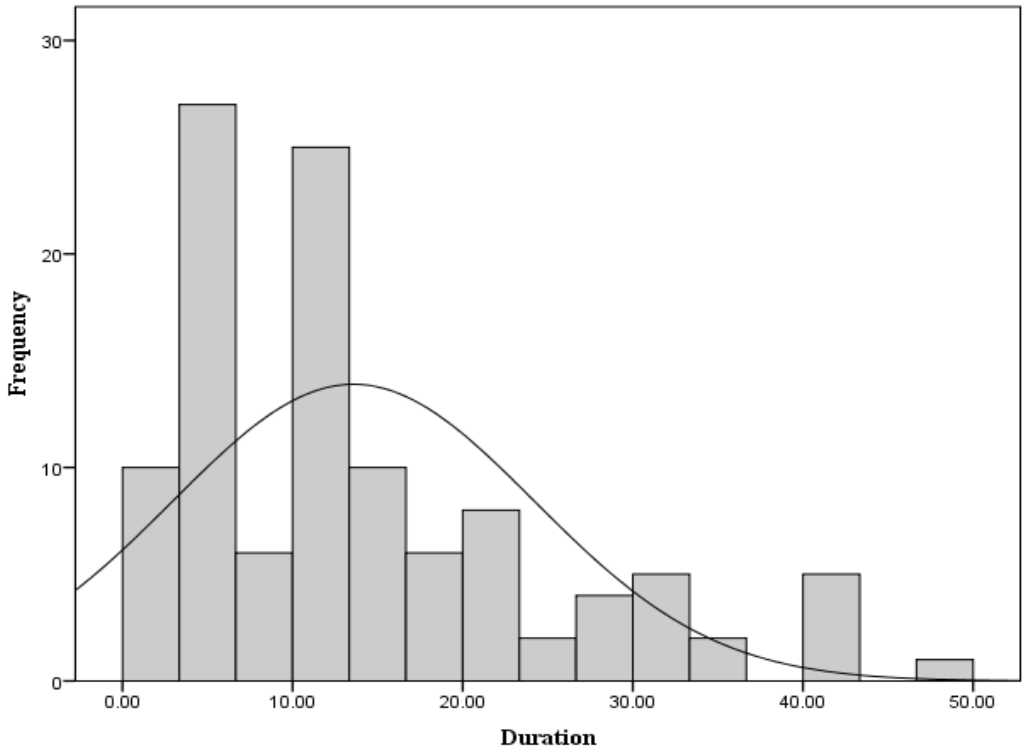
The table shows the Beta coefficient, significance, and 95% confidence intervals for the multi-nomial logistic regression model using TCM diagnosis as the non-ordinal categorical variable with seven categories, and age, severity, and duration of IBS as the continuous independent variables. The reference category is Liver qi stagnation.

				95% Confidence Interval	
TCM diagnosis		**Coefficient**	**Sig.**	**Lower**	**Upper**
Yang deficiency					
	Severity	0.01	0.34	1.00	1.02
	Age	0.00	0.99	0.93	1.07
	Duration	-0.05	0.34	0.86	1.05
Spleen qi deficiency					
	Severity	-0.00	0.66	0.99	1.01
	Age	-0.07	0.08	0.86	1.01
	Duration	-0.01	0.82	0.88	1.11
Blood/yin deficiency					
	Severity	0.00	0.43	1.00	1.01
	Age	-0.02	0.50	0.92	1.04
	Duration	-0.00	0.97	0.92	1.08
Damp heat					
	Severity	-0.01	**0.02**	0.98	1.00
	Age	-0.04	0.23	0.91	1.02
	Duration	0.06	0.09	0.99	1.15
Combined					
	Severity	-0.00	0.79	0.99	1.01
	Age	0.02	0.55	0.97	1.07
	Duration	-0.03	0.37	0.90	1.04
Cold damp					
	Severity	0.00	0.45	1.00	1.01
	Age	-0.02	0.48	0.93	1.04
	Duration	-0.02	0.62	0.91	1.06

Appendix D 4 Histograms of age (years) and duration of IBS (years) for acupuncture patients

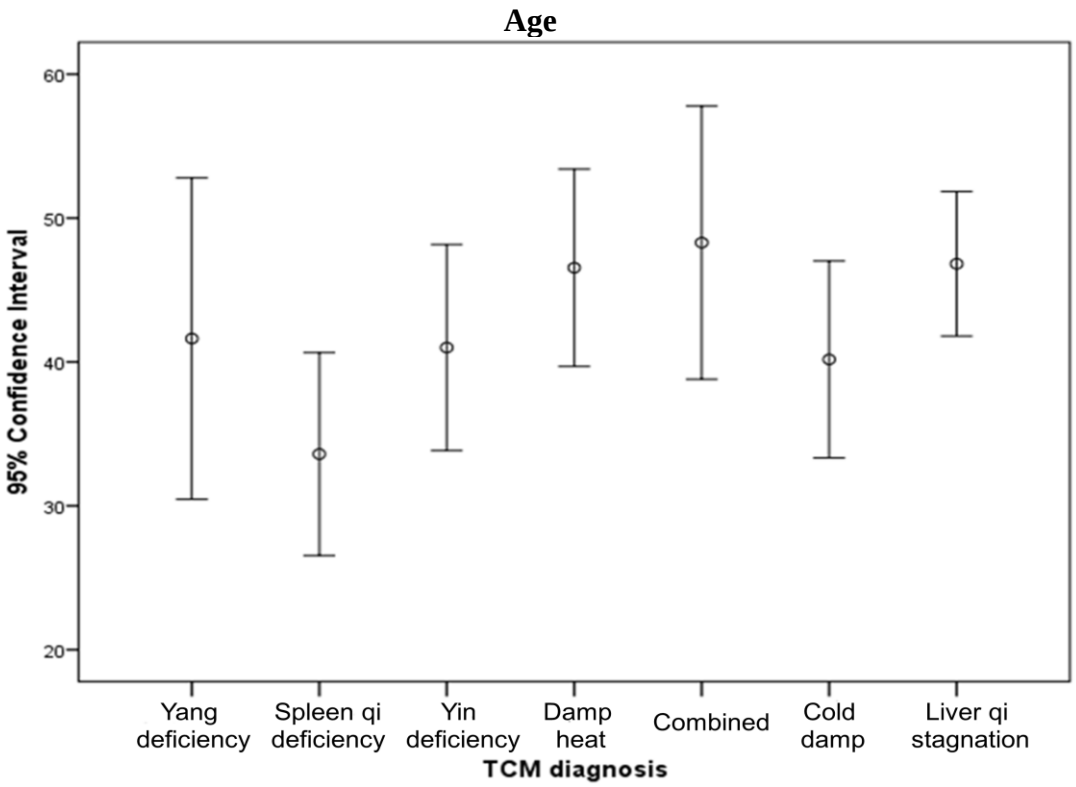


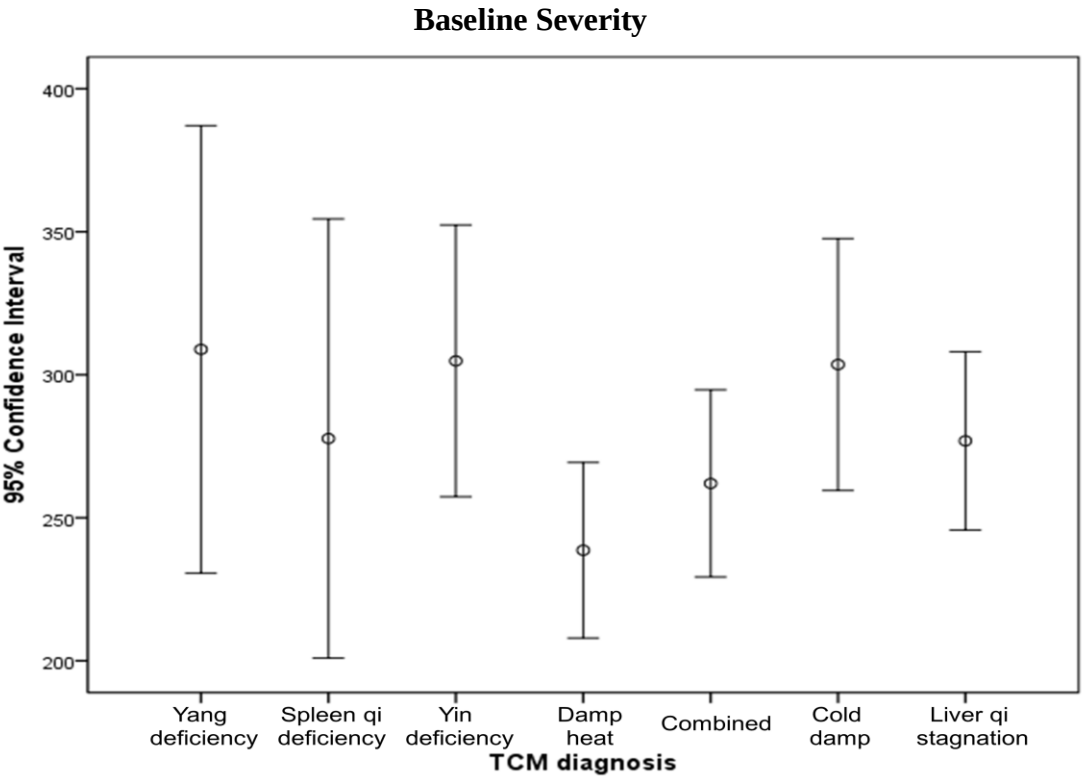
Age: mean 43.6 years (SD 14.3) n = 116

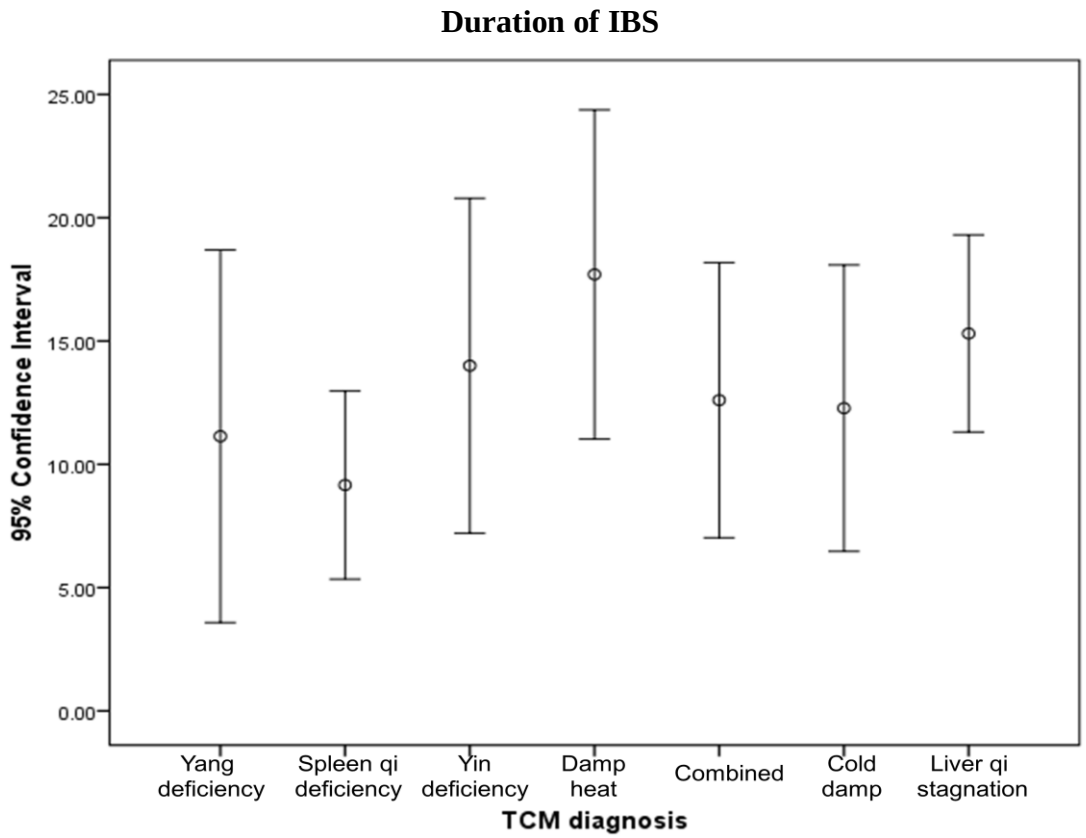


Duration: mean 13.6 years (SD 10.6) n = 111

Appendix D 5 Error bar charts of mean scores for age (years), severity (IBS-SSS), duration of IBS (years) among acupuncture patients according to TCM diagnosis.







Appendix D 6 Secondary diagnoses according to the acupuncturist. The table shows the frequency a particular diagnosis was used by a particular acupuncturist.

	Secondary Diagnoses							
Acupuncturist	**Liver qi stagnation**	**Damp heat**	**Cold damp**	**Spleen qi deficiency**	**Yin/Blood deficiency**	**Yang Deficiency**	**Food stagnation**	**Phlegm**
Beth	2	1	0	2	0	0	0	0
Cindy	7	3	1	5	7	1	1	2
Lisa	11	1	0	9	15	7	0	2
Jill	2	4	1	3	4	2	1	1
Holly	1	0	1	3	3	1	0	2
Ellen	3	5	1	5	1	7	0	0
Marie	13	0	0	11	4	2	1	9
Sam	5	0	2	6	9	0	2	2
John	4	0	0	8	4	0	0	3
Total	48	14	6	52	47	20	5	21

Number of diagnoses used per acupuncturist. The table compares the number of primary and secondary diagnoses used by each acupuncturist.

Acupuncturist	Primary diagnoses	Secondary diagnoses
Beth	3	3
Cindy	7	8
Lisa	6	6
Jill	4	8
Holly	5	6
Ellen	3	6
Marie	6	6
Sam	6	5
John	4	4

Appendix D 7 Phrase inventory of treatment principles. Each of the underlined treatment principles represents a group of phrases, used by the treating acupuncturists, with similar meanings to allow for comparisons across groups.

Tonify spleen/qi	Tonify yin	Clear damp/phlegm
Tonify spleen	Tonify yin	Clear phlegm
Tonify spleen & kidney	Tonify yin & blood	Clear damp
Tonify spleen & stomach	Tonify blood	Dissolve phlegm
Tonify qi	Moisten	Clear damp phlegm
Harmonize spleen & stomach		Clear cold damp
	Soothe liver	Dry damp
Release exterior	Soothe liver	
Expel cold	Harmonize liver	Clear damp/heat
Expel pathogen	Soothe qi	Clear damp heat
Expel wind		Clear heat
Release exterior	Stop pain	
	Reduce pain	Regulate bowel
Tonify yang	Reduce inflammation	Promote bowel
Warm stomach	Ease pain	Regulate bowel
Warm kidney		
Tonify yang	Move stasis	Calm shen
Tonify kidney yang	Move qi	Calm spirit
	Move liver qi	Clam mind
	Move stagnation	Calm shen
	Regulate qi	
	Move qi & blood stasis	

Appendix D 8 Diagnosis and treatment principles. The table shows the frequency a particular treatment principle was used in relation to a particular diagnosis.

Treatment principles	**Primary Diagnosis**							
	Yang Deficiency	**Spleen qi deficiency**	**Blood deficiency**	**Damp Heat**	**Cold damp**	**Combined**	**Liver qi stagnation**	**Patients**
Tonifysp/qi	4	9	9	17	16	16	25	96
Tonify yin	0	3	9	4	6	3	8	33
Tonify yang	4	2	1	8	3	5	6	29
Move stasis	1	6	5	12	8	13	21	66
Regulate bowel	1	2	4	4	7	6	8	32
Soothe liver	1	5	3	4	7	5	9	34
Calm shen	2	5	5	9	11	11	14	57
Clear damp/phlegm	1	1	5	5	12	4	10	39
Clear damp/heat	2	1	4	15	4	2	11	39
Stop pain	1	0	0	1	0	2	0	4
Release exterior	2	0	2	0	1	0	1	6

Appendix D 9 Acupuncture points used in the trial. The table shows the points that were used, the number of patients the points were used on (of a possible 113), and the number of treatments the points were used in (of a possible 1,016).

Acupuncture Point	# Patients	# Treatments	Acupuncture Point	# Patients	# Treatments	Acupuncture Point	# Patients	# Treatments
Lu 1	2	5	**St 25**	60	313	**Kd 3**	49	256
Lu 3	1	1	**St 26**	5	14	**Kd 4**	1	1
Lu 5	2	6	**St 27**	4	13	**Kd 6**	36	127
Lu 7	43	185	**St 28**	3	3	**Kd 7**	27	119
Lu 9	12	43	**St 29**	7	15	**Kd 9**	3	3
Lu 10	1	1	**St 36**	103	766	**Kd 14**	1	6
LI 4	104	587	**St 37**	56	84	**Kd 15**	2	3
LI 5	3	7	**St 40**	24	73	**Kd 16**	6	16
LI 10	2	8	**St 41**	1	3	**Kd 23**	1	3
LI 11	39	163	**St 42**	4	13	**Kd 25**	1	1
LI 20	1	2	**St 44**	7	19	**UB10**	1	1
LR 3	99	621	**Sp 3**	40	133	**UB 13**	5	7
LR 4	2	7	**Sp 4**	24	45	**UB 15**	4	5
LR 8	19	89	**Sp 5**	3	4	**UB 17**	4	12
LR 13	16	73	**Sp 6**	101	634	**UB 18**	9	29
LR 14	1	1	**Sp 8**	11	22	**UB 20**	13	22
St 3	1	1	**Sp 9**	51	273	**UB 21**	3	3
St 8	3	5	**Sp 10**	10	40	**UB 22**	3	3
St 9	1	3	**Sp 14**	2	2	**UB 23**	13	30
St 21	9	16	**Sp 15**	46	187	**UB 24**	1	2
St 23	1	2	**Kd 1**	1	1	**UB 25**	8	16
St 24	1	4	**Kd 2**	5	26	**UB 26**	1	1

Appendix D 9 continued

Acupuncture Point	Patients	# Treatments	Acupuncture Point	# Patients	# Treatments	Acupuncture Point	# Patients	# Treatments
UB 28	1	1	**GB 14**	2	2	**CV 13**	1	2
UB 31	2	6	**GB 20**	21	63	**CV14**	9	16
UB 32	3	7	**GB 21**	6	22	**CV 15**	3	6
UB 33	2	6	**GB 24**	1	1	**CV 17**	4	10
UB 34	1	2	**GB 26**	1	2	**Taiyang**	1	1
UB 40	1	2	**GB 28**	8	40	**Yintang**	17	51
UB43	1	1	**GB 29**	1	1	**Ashi**	8	18
UB 53	1	1	**GB 30**	2	4	**Zexie**	1	1
UB 54	4	6	**GB 31**	1	1	**Huatuo**	3	4
UB 58	1	1	**GB 33**	1	2	**Bitong**	1	1
UB 60	5	6	**GB 34**	54	261	**Xiyan**	1	5
UB 64	1	1	**GB 40**	17	44	**Shenmen**	1	1
P 4	1	1	**GB 41**	17	72			
P 6	56	197	**SI 3**	1	1			
P 7	17	56	**SI 4**	1	1			
Ht 5	1	1	**Du 2**	1	1			
Ht 6	6	8	**Du 20**	13	42			
Ht 7	27	130	**Du 22**	1	1			
SJ 4	10	24	**CV 3**	8	27			
SJ 5	24	83	**CV 4**	21	65			
SJ 6	22	81	**CV 6**	41	204			
SJ 14	1	1	**CV 9**	1	1			
SJ 15	1	1	**CV 10**	5	9			
SJ 17	2	3	**CV12**	67	388			

Appendix D 10 The acupuncturists' core points. The table identifies each acupuncturist's core and supporting acupuncture points. X core points (used ≥ 50% treatments) † support points (used 25-49% treatments)

Point	Beth	Cindy	Lisa	Jill	Holly	Ellen	Marie	Sam	John
LR 3		X	X	X	X	X	X	†	X
LR 8							†		†
LR 13			†						
LI 4	†	X	X	X	X	X	X	†	X
LI 11					†	†			
ST 25	†	†	X	X		†	†		
ST 36	†	X	X	†	X	X	†	X	X
ST 37				†					
ST 40					†				
SP 3								†	
SP 6	X	X		X	X	X	X	X	X
SP 9		†	†	†	X		†		
SP 15		†		†			†		
LU 7					X		†		
LU 9					†				
CV 4		†							
CV 6		†	†	X					
CV 12		†	X	X		X			
KD 3			†		X				†
KD 6							†		
KD 7									X
GB 20	X								
GB 28				†					
GB 34	X	†	X	†					
GB 41				X					
SJ 5				X					
SJ 6							†		
HT 7									X
PC 6								X	
PC 7								†	
UB 18	†								
Du 20	†								

Appendix D 11 Acupuncturists' treatment approaches. The table identifies the frequency each acupuncturist used a particular treatment approach: fixed nucleus – used a small group of points for multiple treatments with moderate variations to additional points; repetitive treatments – used the same points for multiple treatments with minimal variation; diverse treatments – lack a consistent nucleus and widely vary in points used. The frequencies are based on the number of patients each acupuncturist treated and a collective comparison of the treatments for each patient.

Acupuncturist	Fixed nucleus	Repetitive treatments	Diverse treatments	Patients
Beth	2	0	1	3
Cindy	8	3	5	16
Jill	6	2	2	10
Lisa	18	0	4	22
Marie	2	13	1	16
Holly	1	7	0	8
Ellen	6	0	5	11
Sam	9	1	6	16
John	4	6	0	10
Total	56	32	24	112

Appendix D 12 Points used for moxa during the trial. The table identifies the points that were used for moxa and the number of patients that received moxa at that particular point.

Point	Patients
CV 3	1
CV 4	1
CV 6	6
CV12	2
ST 25	7
ST 36	8
ST 37	2
ST 40	2
Kd 3	1
Kd 7	4
Sp 3	6
Sp 9	5
Sp 15	3
GB 28	2
UB 23	1
UB 25	1

Appendix D 13 Lifestyle advice and the diagnosis. The table identifies the frequency advice in a particular category was provided to patients with a particular primary diagnosis.

Advice	Liver qi stagnation	Damp heat	Cold damp	Spleen qi deficiency	Yang deficiency	Yin deficiency	Combined	Total
Diet	19	11	7	7	6	5	9	64
Stress/ Relaxation	7	3	4	1	2	3	5	25
Exercise	7	1	1	3	1	2	3	18
Probiotics/Herbs	2	3	0	0	0	0	0	5
Additional home therapy	1	0	0	0	0	1	1	3
Colonic irrigation	1	0	0	0	0		1	2
GP referral	1	0	0	0	0	1	0	2
Sleep	0	0	0	0	1	1	0	2
Other	0	0	0	1	3	2	0	6

Appendix D 14 Diet sheets used in trial treatments. The following are examples of three diet sheets from different acupuncturists that were given to trial patients.

Sheet # 1: Dietary advice sheet for patients with dampness

AVOID too much raw, cold, sweet or rich food and the over-consumption of fluid.

Cut down or avoid the following: Diary products (sheep and goat products are less dampening), pork and rich meat, roast peanuts, concentrated juices especially orange and tomato, wheat, bread, yeast, beer, bananas, sugar, and sweeteners and saturated fats. Also reduce intake of greasy and fried foods.

INCREASE your intake of:

Aduki beans	Alfalfa	Anchovy
Barley	Ginger	Celery
Corn	Horseradish	Garlic
Green tea	Kidney beans	Jasmine tea
Lemon	Mackerel	Marjoram
Mushrooms (button)	Mustard leaf	Onion
Parsley	Pumpkin	Radish
Rye	Scallion	Turnips

To reduce phlegm INCREASE your intake of the following:

Almond	Apple peel	Clams
Lemon peel	Garlic	Grapefruit
Mushrooms (button)	Liquorice	Marjoram
Olives	Onions	Orange peel
Pears	Black and white pepper	Peppermint
Persimmon	Shiitake mushrooms	Radishes
Seaweed	Weak tea	Thyme
Tangerine peel	Watercress	Shrimp
Walnuts		

Sheet # 2: Irritable bowel syndrome – dietary advice

Sugar often plays a role in weakening the spleen, acidifying the blood and causing fermentation in the digestive system. Beneficial food include most grains, squash and root vegetables which satisfy the spleen and pacify the liver; miso and sauerkraut which strengthen the digestion and protect the colon; carminative teas with herbs such as fennel, aniseed, dill, chamomile, and cardamom will also help; ginger tea can be excellent. Increasing fibre, drinking more fluid and cutting out fluoride – which is known to aggravate the colon are also important.

- Start the day with warm water (this relaxes the colon and helps defecation)
- Reduce coffee and/or substitute with tea (coffee is too aggravating whereas tea regulates digestion)
- Adopt a relaxation practice
- Eat regularly (this calms and strengthens the digestion)
- Eat more slowly, chewing well (to reduce the stress on the system)
- Eat a cooked lunch (this supports the spleen)
- Drink more water
- Cut out sweet snacks or improve their quality (to protect the spleen)
- Eat porridge for breakfast (this helps form the stool, stabilises energy levels and supports the spleen)

Olives – a sour flavour – regulate our sugar cravings
Mashed root vegetables are kind and nourishing to the spleen and provide the colon with fibre.

Carrot and ginger soup would be beneficial as would baked sweet potatoes and bakes bananas.

Follow each meal with organic fennel or fresh ginger tea. Flax seed is a good all around remedy for digestive aggravation found in European and Ayurvedic traditions and can be drunk over a long period with no side effects.

Liquorice root chewed during the day helps to reduce anxiety that often leads us towards sweet snacks or cigarettes.
Sheet #3: To support your acupuncture treatment

To improve your energy, focus on well-cooked, simple foods with relatively few components in each meal. Select fresh, good quality, local produce and enjoy the preparation of your meals as well as the eating of them. Choose long slow cooking methods such as soups, casseroles and stews.

Choose

- Neutral or sweet, warm flavours; light grains such as white rice, rice porridge, oats, barley, spelt, pumpkin, sweet potato, celeriac, squash, carrot, parsnip, chick peas, aduki beans, broad beans, black beans, peas, walnuts, stewed fruits, chicken, mackerel, tuna, anchovy
- Include bitter and pungent food such as onion, leek, garlic, turnip, pepper, fresh ginger, cinnamon, nutmeg, fennel, watercress, mustard, horseradish, white and black pepper, clove, cardamom, dill, coriander, oregano, thyme, basil, fresh ginger
- Small amounts of complex sweet flavours such as molasses, dates, rice syrup
- Try to have regular meal times, not to eat late in the evening and it is better for you generally to have a good breakfast, good lunch, and less in the evenings
- Try to eat the same amount of foods each day

Restrict or avoid

- Try to avoid dairy foods, particularly cow's milk
    - Where you would use cow's milk in drinks, on cereals or for cooking use soya milk/oat milk/almond milk/ rice milk instead, now easily available from both Tesco and Sainsbury
    - Try to cut down on using cheese and where you do want to use some, try goat's cheeses or sheep's cheeses instead (feta cheese is often made with sheep's cheese, and can usually be found in supermarkets; mozzarella from water buffalo milk; good cheese shops will have some non-cow's milk cheeses)
    - You can also buy soya milk yoghurt, cream and ice cream
    - Instead of butter or margarines which have milk in them, you can use non-dairy spreads which you can find in supermarkets or be continental and use olive oil/hemp oil/ Udo's oil instead
- Other mucus-generating foods such as sugar, chocolate, roasted peanuts, and peanut butters
- Excessive fluids with meals
- Cold, uncooked or raw foods including salads, raw fruits whether whole or juiced, especially citrus, raw vegetables, tofu, salt, too many sweet foods or concentrated sweeteners, brown rice, antibiotics, vitamin C (over 1 – 2 grams a day)
- Beer
- Wheat, salt, vinegar
- Deep fried and junk foods

Appendix E 1 Descriptive analysis and correlation matrix of the IBS-SSS

IBS-SSS item descriptive statistics. The table shows the statistics for each item based on the baseline scores for all patients in the trial (n = 233). Scores for each item range from 0 – 100.

	Item statistics	
IBS-SSS item	**Sample size**	**Mean (SD)**
Pain frequency	228	44.2 (27.7)
Pain intensity	232	52.7 (20.8)
Satisfaction with bowel habit	233	64.0 (21.3)
Distension intensity	233	56.6 (23.6)
Symptom affect on daily life	233	60.6 (18.6)

Correlation matrix of IBS-SSS items. The table shows the correlations among each of the IBS-SSS items based on the baseline scores for all patients in the trial (n = 233). The matrix has a determinant of 0.41 and the significance values for each of the correlations was $p < 0.001$.

IBS-SSS items	Pain intensity	Pain frequency	Distension intensity	Satisfaction w/ bowel habit	Symptom affect on daily life
Pain intensity	1.00	0.36	0.37	0.25	0.37
Pain frequency	0.36	1.00	0.19	0.27	0.35
Distension intensity	0.37	0.19	1.00	0.33	0.43
Satisfaction w/ bowel habit	0.25	0.27	0.33	1.00	0.45
Symptom affect on daily life	0.37	0.34	0.43	0.45	1.00

Appendix E 2 Factor analysis and Cronbach's alpha

IBS-SSS item statistics based on Principal Axis Factoring and Cronbach's alpha reliability test.

	Communalities		Cronbach's Alpha	
IBS-SSS Item	Initial	Extraction	Scale Mean if Item Deleted	α if Item Deleted
Pain intensity	0.25	0.32	225.7	0.65
Pain frequency	0.19	0.23	234.4	0.69
Distension intensity	0.26	0.33	222.0	0.66
Satisfaction w/ bowel habit	0.24	0.31	214.4	0.66
Symptom affect on daily life	0.35	0.54	218.0	0.62

Total Variance Explained by IBS-SSS factors.

	Initial Eigen values			Extraction Sums of Squared Loadings		
Factor	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	2.36	47.1	47.1	1.72	34.5	34.5
2	0.84	16.7	63.8			
3	0.76	15.2	79.0			
4	0.55	11.0	90.0			
5	0.50	10.0	100.0			

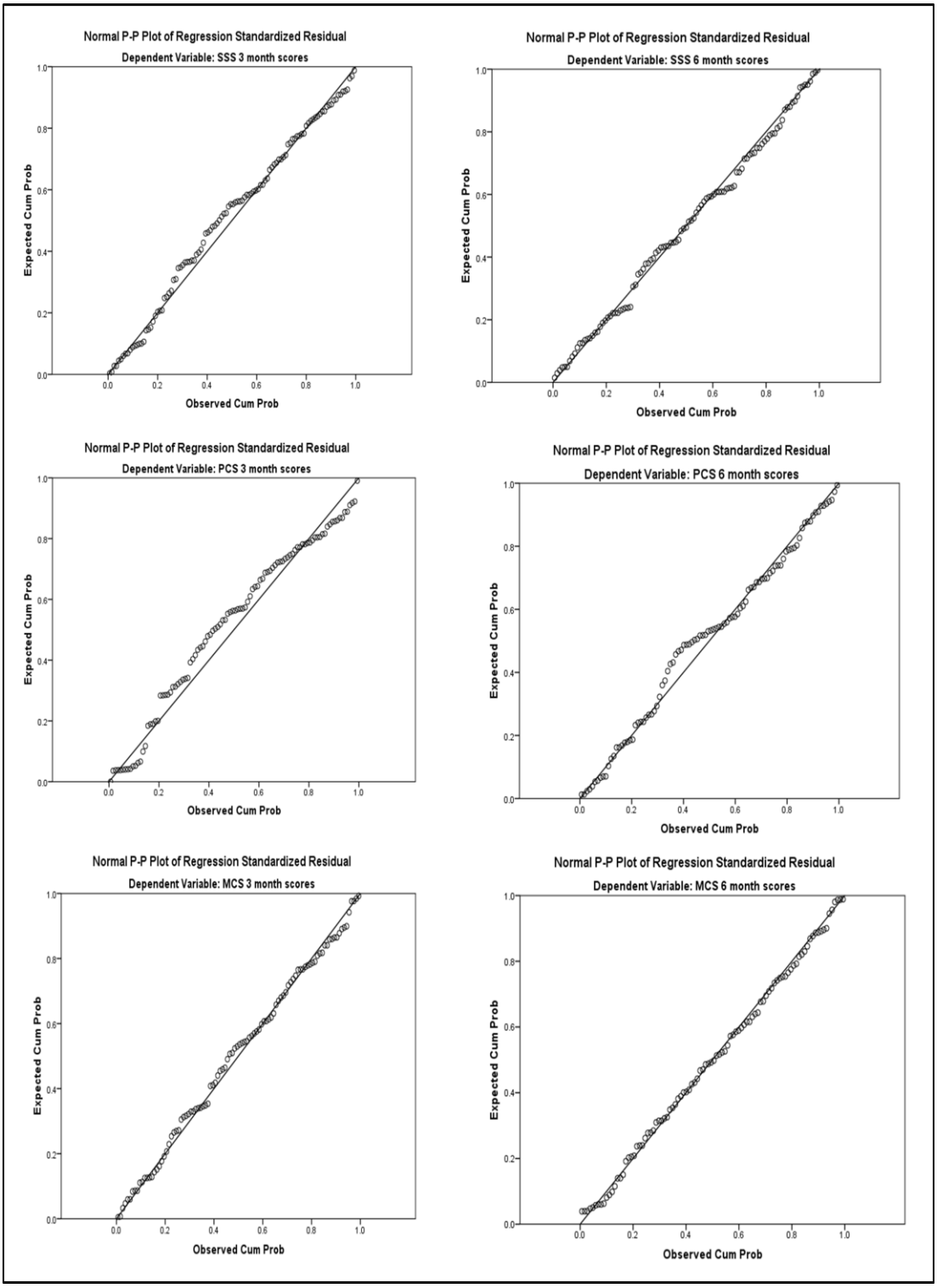
Appendix E 3 Raw scores of the SF-12

The table shows the mean score changes on the SF-12 sub-scales for different TCM diagnoses (includes only trial patients who received acupuncture) at baseline (BL), three months (3 mo) and six months (6 mo). Domains of health: GH – general health, PF – physical health, BP – body pain, VT – vitality, SF- social function, MH – mental health, RE – role emotional, RP – role physical.

		Raw Score					Raw Score		
Dx	**Scale**	**BL**	**3 mo**	**6 mo**	**Dx**	**Scale**	**BL**	**3 mo**	**6 mo**
Yang deficiency	GH	48.1	43.6	57.1	**Cold damp**	GH	47.6	56.2	54.4
	PF	84.4	85.7	82.1		PF	78.3	77.9	79.7
	BP	62.5	67.9	78.6		BP	66.2	75.0	70.3
	VT	34.3	25.0	39.3		VT	33.8	50.0	50.0
	SF	68.8	57.1	75.0		SF	66.2	75.0	75.0
	MH	68.8	53.6	67.9		MH	61.0	57.4	64.8
	RE	90.6	67.9	87.5		RE	82.4	89.0	89.8
	RP	65.6	73.2	80.54		RP	72.8	71.3	75.8
Spleen deficiency	GH	58.5	56.7	54.5	**Combined**	GH	59.7	59.7	66.0
	PF	87.5	75.0	87.5		PF	91.2	82.8	90.0
	BP	77.7	83.3	92.5		BP	80.9	79.7	78.3
	VT	30.0	44.4	40.0		VT	41.2	45.3	41.7
	SF	55.0	72.2	75.0		SF	75.0	75.0	76.7
	MH	46.3	52.8	55.0		MH	55.1	56.3	55.0
	RE	67.5	75.0	78.8		RE	80.9	82.8	77.5
	RP	68.8	77.8	80.0		RP	83.8	88.3	80.0
Yin deficiency	GH	56.5	65.4	46.9	**Liver qi stag**	GH	59.3	63.6	62.1
	PF	75.0	83.3	81.3		PF	86.1	86.0	85.6
	BP	61.5	70.8	68.8		BP	72.2	77.0	76.0
	VT	40.3	50.0	40.6		VT	38.4	48.0	51.0
	SF	63.4	62.5	56.3		SF	73.2	82.0	80.8
	MH	52.9	50.0	42.2		MH	53.6	61.5	59.6
	RE	70.2	72.9	65.6		RE	74.6	85.5	83.2
	RP	75.0	73.9	76.6		RP	77.7	83.0	80.3
Damp heat	GH	50.5	51.1	55.5	**Total**	GH	54.7	57.8	57.9
	PF	72.5	68.4	71.1		PF	82.5	80.0	82.4
	BP	65.0	71.1	65.8		BP	70.0	75.5	75.0
	VT	37.5	43.4	46.1		VT	36.9	45.8	45.8
	SF	66.3	67.1	67.1		SF	68.3	72.6	74.0
	MH	52.0	57.9	55.9		MH	55.0	57.1	58.1
	RE	72.5	73.7	76.3		RE	76.2	80.2	80.8
	RP	69.4	71.7	75.0		RP	74.7	77.9	78.4

Appendix E 4 Standardised plots of dependent residuals

The figure shows the standardised plots of dependent residuals for IBS-SSS scores at three and six months using the IBS-SSS baseline scores as the independent variable. It also shows standardised plots of the dependent residuals for the PCS and MCS at three and six months using their respective baseline scores as the independent variables.

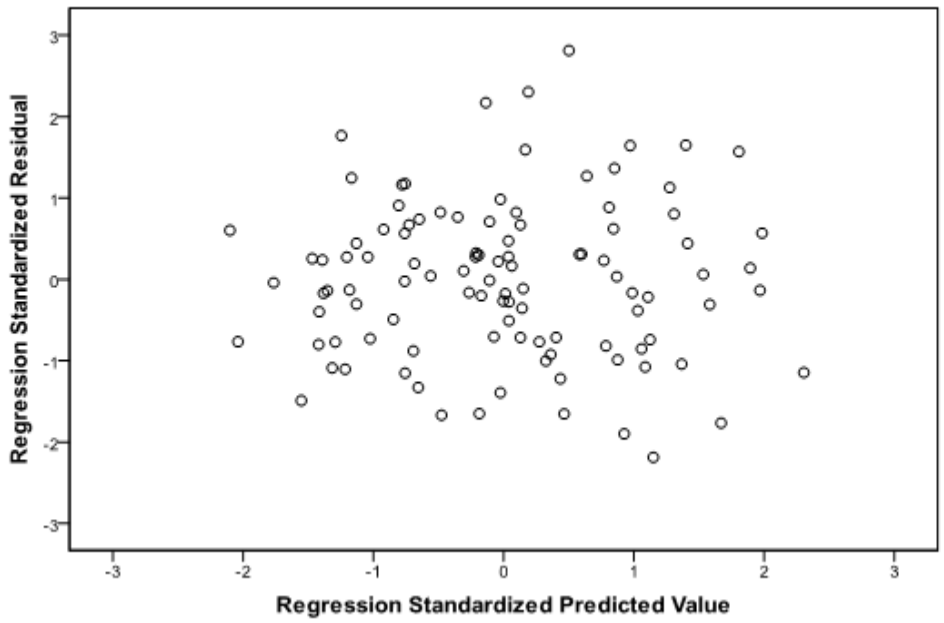


Appendix E 5 Post estimation tests for models of IBS-SSS outcome at three and six months by TCM diagnosis

The table shows the significance values and collinearity statistics for the three and six month models using TCM diagnoses and IBS-SSS baseline scores as independent variables and IBS-SSS three and six month scores as the dependent variable. Liver qi stagnation is the reference category.

	3 months			**6 months**		
		Collinearity Statistics			Collinearity Statistics	
Covariate	Sig.	Tolerance	VIF	Sig.	Tolerance	VIF
SSS baseline	< 0.001	0.71	1.41	< 0.001	0.91	1.09
Yang deficiency	0.29	0.72	1.39	0.91	0.84	1.19
Yin deficiency	0.51	0.84	1.19	0.47	0.78	1.28
Spleen deficiency	0.27	0.76	1.31	0.23	0.80	1.25
Damp heat	0.71	0.80	1.26	0.89	0.68	1.47
Cold damp	0.42	0.67	1.49	0.31	0.73	1.38
Combined	0.26	0.71	1.41	0.73	0.72	1.39

The figure shows the scatter plot of the standardised predicted values and residuals of IBS-SSS scores at six months. The random array of dots indicates that there is homoscedasticity and linearity.

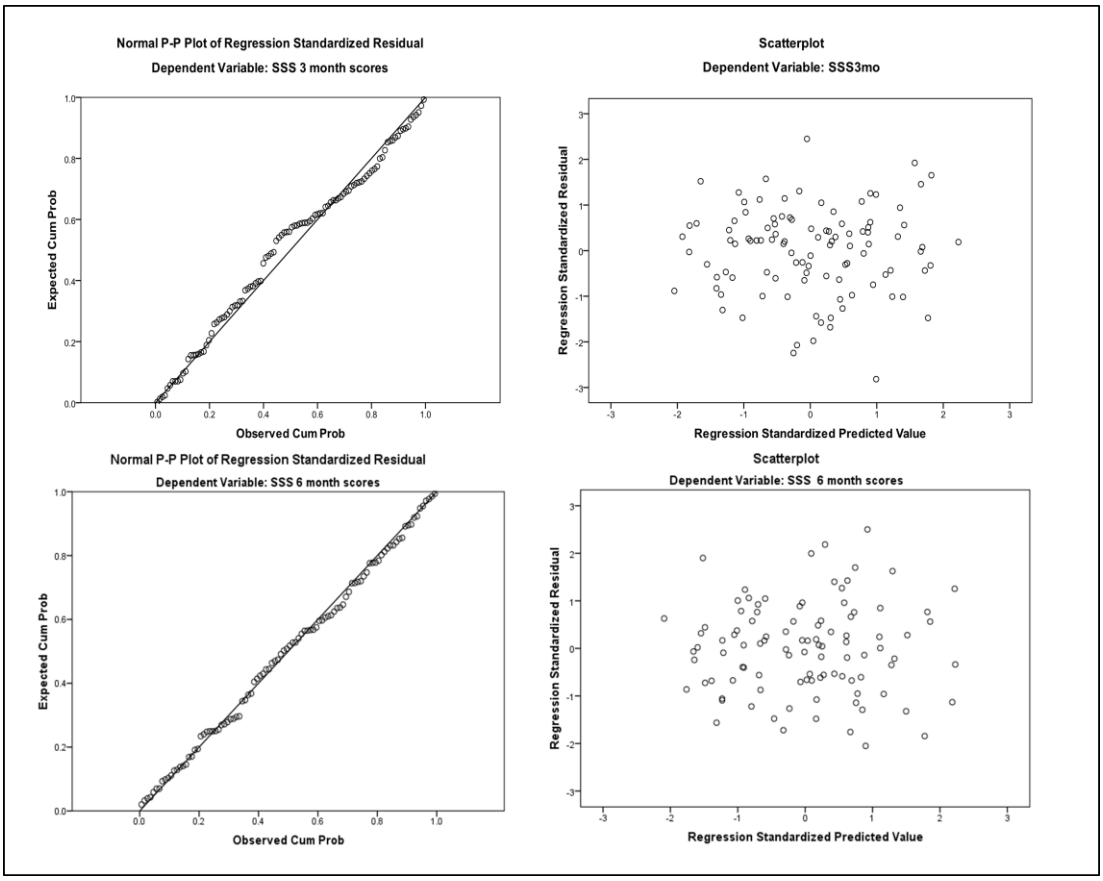


Appendix E 6 Post estimation tests for adjusted models of IBS-SSS outcome at three and six months by TCM diagnosis

The table shows the significance values and collinearity statistics for the three and month models using TCM diagnoses, IBS-SSS baseline scores, age, sex, and duration of IBS as independent variables and IBS-SSS three and six month scores as the dependent variable. Liver qi stagnation is the reference category.

	3 months			**6 months**		
		Collinearity Statistics			Collinearity Statistics	
Covariate	Sig.	Tolerance	VIF	Sig.	Tolerance	VIF
Yang deficiency	0.22	0.83	1.20	0.95	0.83	1.20
Yin deficiency	0.82	0.75	1.33	0.73	0.78	1.28
Spleen deficiency	0.77	0.74	1.36	0.31	0.73	1.37
Damp heat	0.90	0.66	1.53	0.75	0.66	1.51
Cold damp	0.84	0.67	1.49	0.40	0.69	1.46
Combined	0.13	0.70	1.42	0.64	0.70	1.42
Age	0.03	0.62	1.62	0.66	0.61	1.63
Duration	0.50	0.62	1.60	0.20	0.62	1.60
SSS baseline	< 0.001	0.73	1.37	< 0.001	0.69	1.46
Sex	0.56	0.82	1.22	0.77	0.77	1.31

The figure shows the post hoc tests for linearity and homoscedasticity in both the three and six month models.

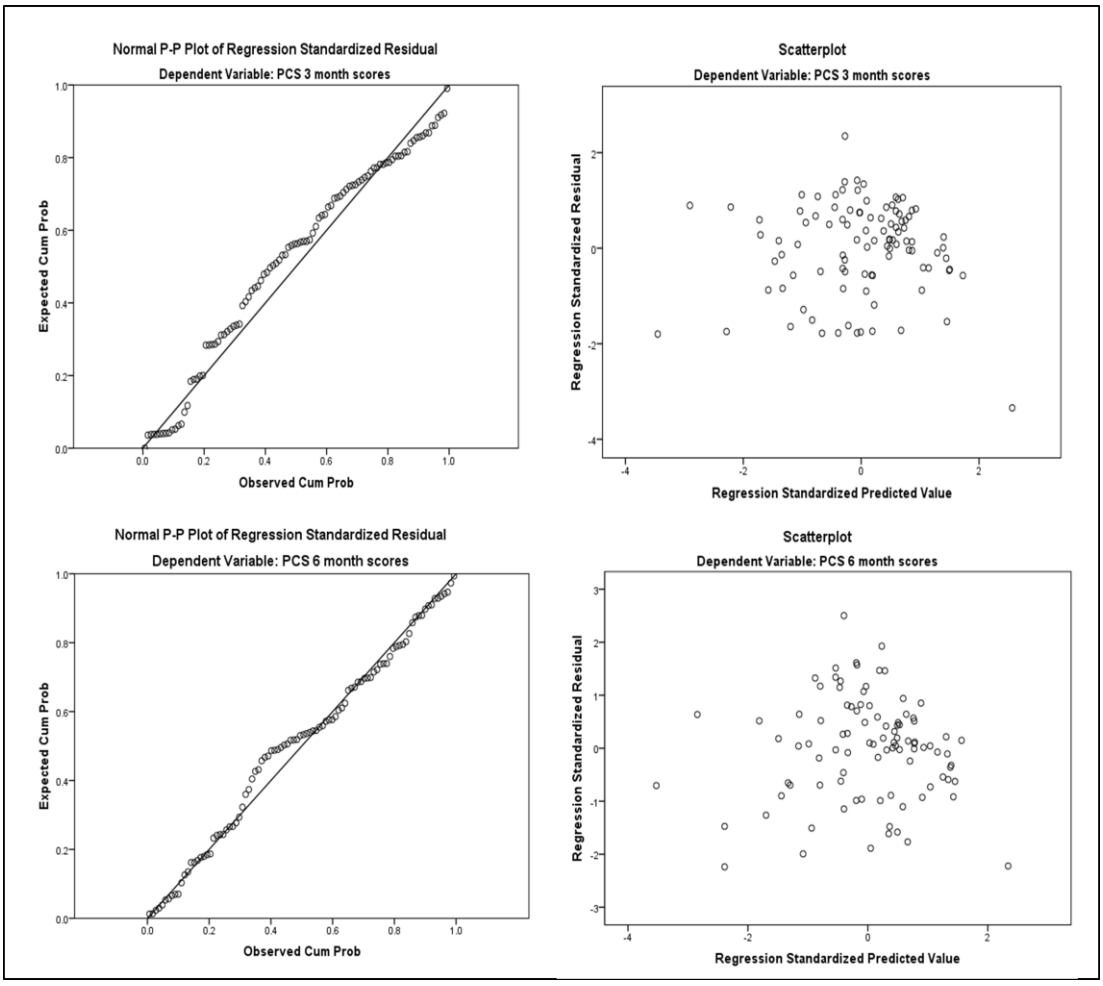


Appendix E 7 Post estimation tests for models of PCS outcome at three and six months by TCM diagnosis

The table shows the significance values and collinearity statistics for the three and six month models using TCM diagnoses and PCS baseline scores as independent variables and PCS three and six month scores as the dependent variable. Liver qi stagnation is the reference category.

	3 months			**6 months**		
		Collinearity Statistics			Collinearity Statistics	
Covariate	Sig.	Tolerance	VIF	Sig.	Tolerance	VIF
Yang deficiency	0.20	0.79	1.26	0.26	0.81	1.24
Yin deficiency	0.26	0.75	1.33	0.72	0.82	1.21
Spleen deficiency	0.52	0.80	1.25	0.43	0.80	1.26
Damp heat	0.80	0.68	1.46	0.61	0.71	1.40
Cold damp	0.28	0.70	1.43	0.60	0.72	1.39
Combined	0.97	0.71	1.40	0.52	0.74	1.35
PCS baseline	< 0.001	0.89	1.13	< 0.001	0.90	1.11

The figure shows the post hoc tests for linearity and homoscedasticity in both the three and six month models.

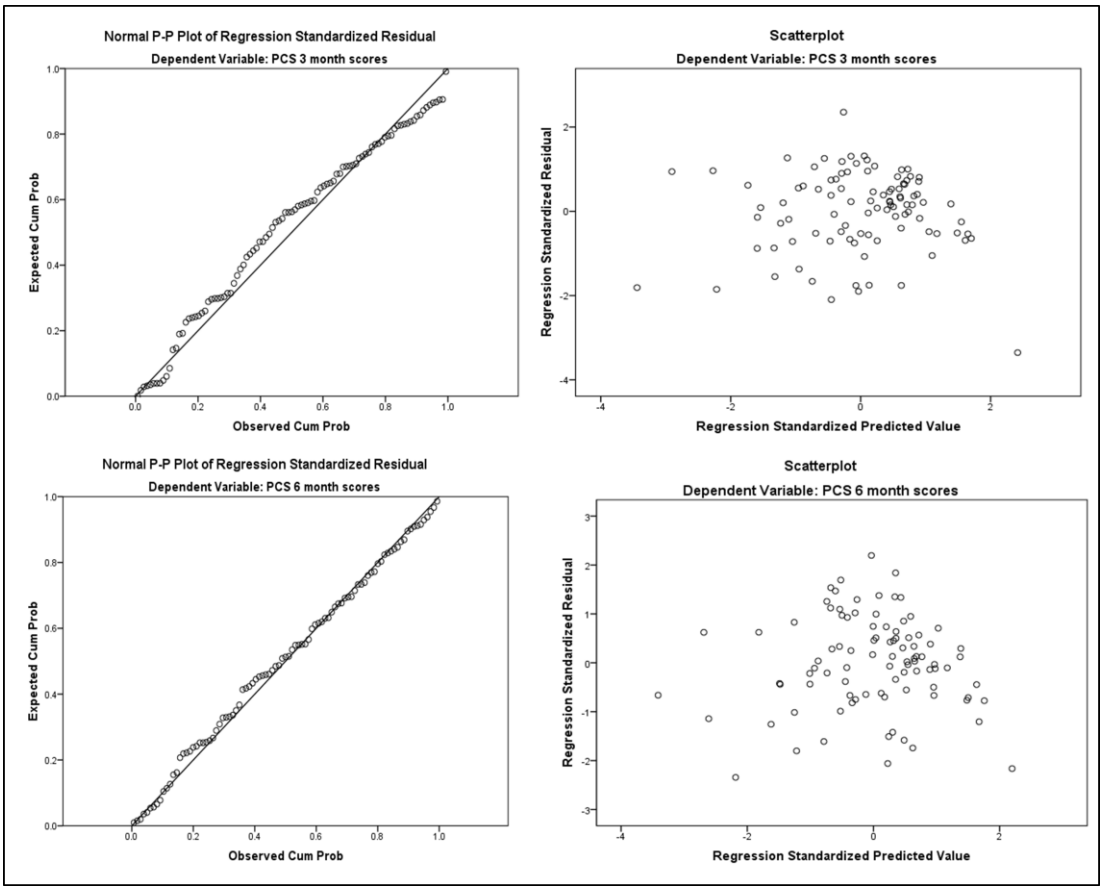


Appendix E 8 Post estimation tests for adjusted models of PCS outcome at three and six months by TCM diagnosis

The table shows the significance values and collinearity statistics for the three and six month models using TCM diagnoses, age, sex, duration of IBS and PCS baseline scores as independent variables and PCS three and six month scores as the dependent variable. Liver qi stagnation is the reference category.

	3 months			**6 months**		
		Collinearity Statistics			Collinearity Statistics	
Covariate	Sig.	Tolerance	VIF	Sig.	Tolerance	VIF
PCS baseline	< 0.001	0.79	1.27	<0.001	0.82	1.22
Age	0.73	0.62	1.63	0.67	0.64	1.56
Sex	0.42	0.86	1.16	0.07	0.86	1.17
Duration	0.35	0.68	1.47	0.20	0.71	1.41
Yang deficiency	0.26	0.78	1.28	0.27	0.79	1.26
Yin deficiency	0.35	0.73	1.38	0.87	0.80	1.24
Spleen deficiency	0.33	0.74	1.35	0.68	0.73	1.37
Damp heat	0.94	0.66	1.51	0.87	0.69	1.46
Cold damp	0.51	0.65	1.56	0.95	0.67	1.50
Combined	0.96	0.69	1.45	0.99	0.72	1.40

The figure shows the post hoc tests for linearity and homoscedasticity in both the three and six month models.

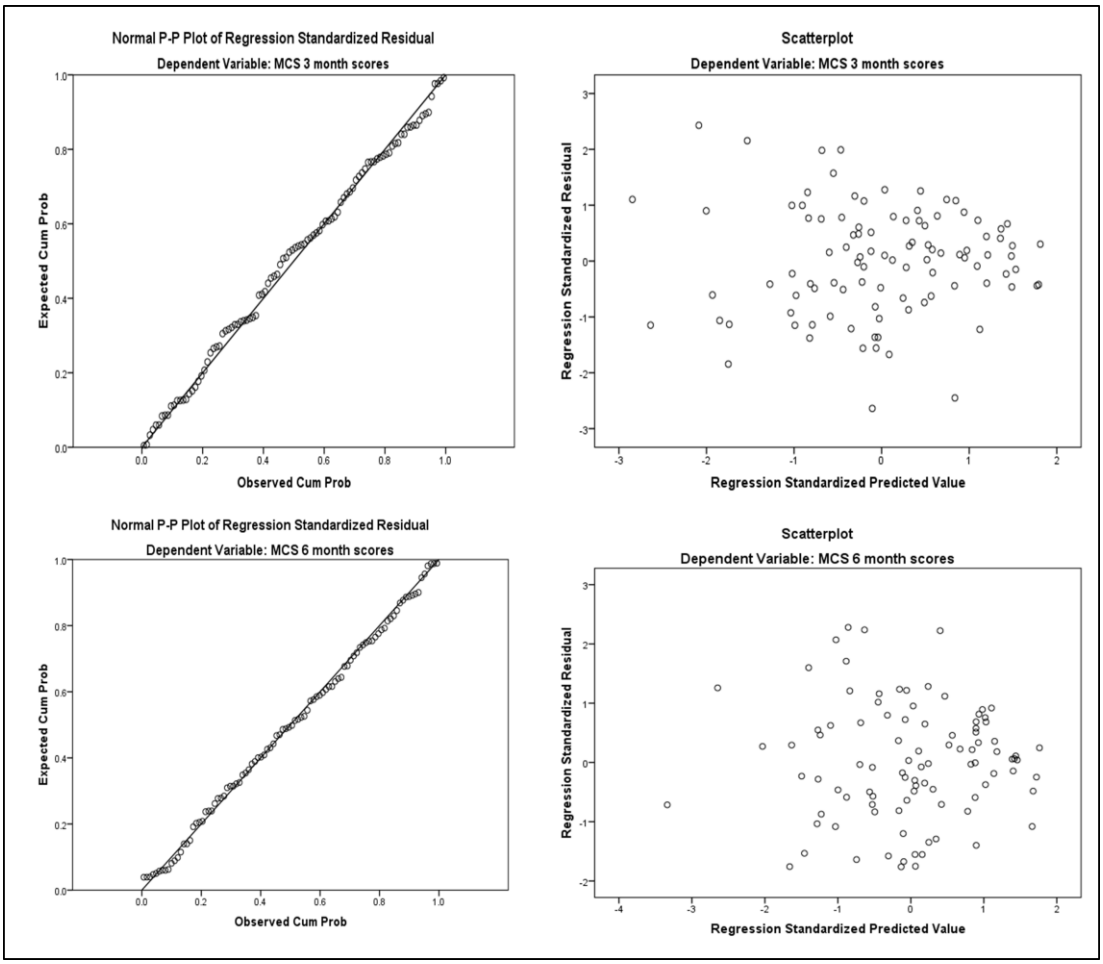


Appendix E 9 Post estimation tests for models of MCS outcome at three and six months by TCM diagnosis

The table shows the significance values and collinearity statistics for the three and six month models using TCM diagnoses and MCS baseline scores as independent variables and MCS three and six month scores as the dependent variable. Liver qi stagnation is the reference category.

	3 months			**6 months**		
		Collinearity Statistics			Collinearity Statistics	
Covariate	Sig.	Tolerance	VIF	Sig.	Tolerance	VIF
Yang deficiency	< 0.001	0.81	1.23	0.64	0.82	1.22
Yin deficiency	0.07	0.76	1.32	0.02	0.82	1.22
Spleen deficiency	0.44	0.79	1.27	0.60	0.78	1.28
Damp heat	0.10	0.71	1.42	0.39	0.72	1.38
Cold damp	0.44	0.71	1.40	0.67	0.74	1.35
Combined	0.14	0.71	1.41	0.10	0.74	1.36
MCS baseline	< 0.001	0.93	1.08	< 0.001	0.91	1.10

The figure shows the post hoc tests for linearity and homoscedasticity in both the three and six month models.

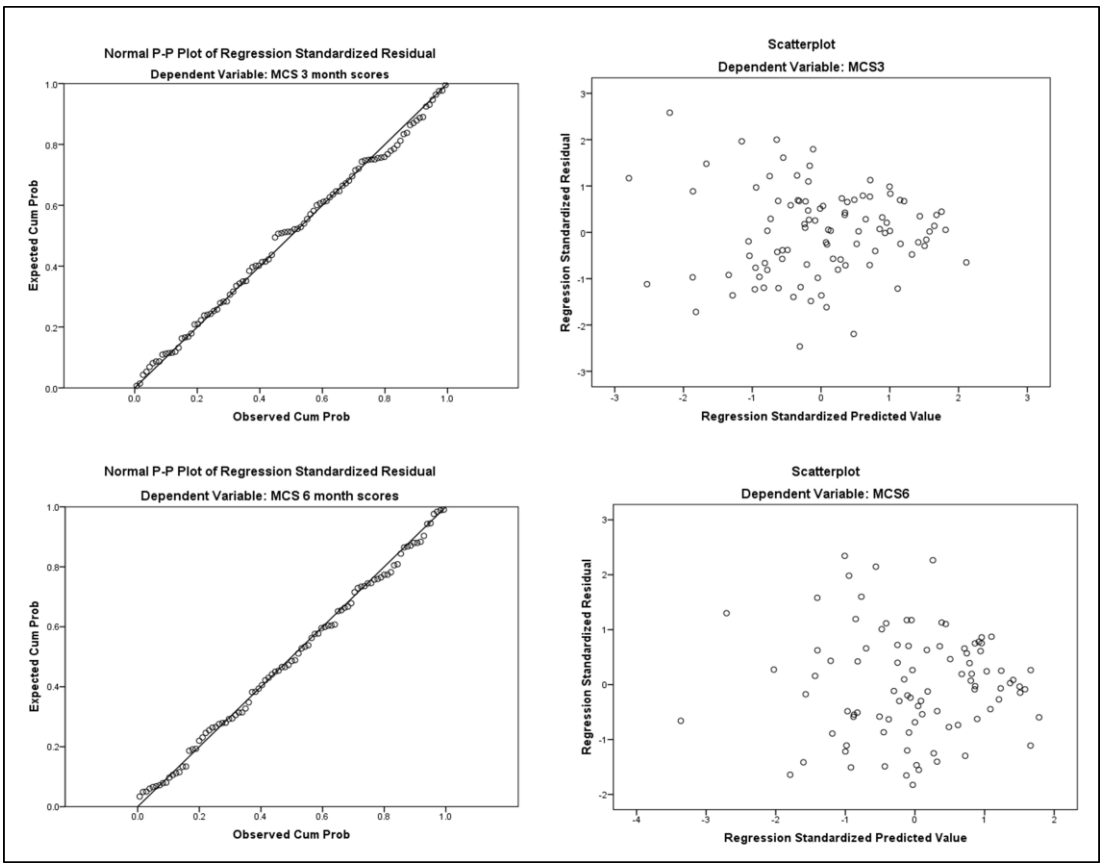


Appendix E 10 Post estimation tests for adjusted models of MCS outcome at three and six months by TCM diagnosis

The table shows the significance values and collinearity statistics for the three and six month models using TCM diagnoses, age, sex, duration of IBS, MCS baseline scores as independent variables and MCS three and six month scores as the dependent variable. Liver qi stagnation is the reference category.

	3 months			**6 months**		
		Collinearity Statistics			Collinearity Statistics	
Covariate	Sig.	Tolerance	VIF	Sig.	Tolerance	VIF
Yang deficiency	0.002	0.81	1.24	0.64	0.82	1.23
Yin deficiency	0.08	0.74	1.36	0.02	0.81	1.24
Spleen deficiency	0.50	0.73	1.37	0.59	0.72	1.38
Damp heat	0.06	0.68	1.47	0.38	0.70	1.43
Cold damp	0.54	0.66	1.53	0.72	0.68	1.47
Combined	0.17	0.69	1.44	0.25	0.72	1.38
MCS baseline	< 0.001	0.91	1.10	< 0.001	0.88	1.14
Age	0.24	0.67	1.50	0.55	0.68	1.47
Sex	0.66	0.85	1.17	0.97	0.84	1.19
Duration	0.16	0.68	1.47	0.57	0.71	1.41

The figure shows the post hoc tests for linearity and homoscedasticity in both the three and six month models.



Appendix E 11 Fisher's exact tests of prognosis

		Prognosis			
Acupuncturist		**Good**	**Poor**	**Don't know**	**Total**
1	Count	5	1	4	10
	Percent	11.9	6.25	8.51	9.52
2	Count	1	1	0	2
	Percent	2.38	6.25	0.00	1.90
3	Count	1	7	13	21
	Percent	2.38	43.8	27.7	20.0
4	Count	9	1	0	10
	Percent	21.4	6.25	0.00	9.52
5	Count	12	0	4	16
	Percent	28.6	0.0	8.51	15.2
6	Count	3	2	7	12
	Percent	7.14	12.5	14.9	11.4
7	Count	5	2	9	16
	Percent	11.9	12.5	19.2	15.2
8	Count	4	0	4	8
	Percent	9.52	0.00	8.51	7.62
9	Count	2	2	6	10
	Percent	4.76	12.2	12.8	9.52
Total	Count	42	16	47	105
	Percent	100.0	100.0	100.0	100.0

Cross tabulation: Prognosis vs. Acupuncturist (n = 105)
Fisher's exact = 40.24, $p < 0.001$

		Prognosis			
Diagnosis		**Good**	**Poor**	**Don't know**	**Total**
1	Count	4	0	3	7
	Percent	57.1	0.00	42.9	100.0
2	Count	4	1	5	10
	Percent	40.0	10.0	50.0	100.0
3	Count	3	0	9	12
	Percent	25.0	0.00	75.0	100.0
4	Count	4	7	7	18
	Percent	22.2	38.9	38.9	100.0
5	Count	6	2	9	17
	Percent	35.3	11.8	52.9	100.0
6	Count	9	2	5	16
	Percent	56.3	12.5	31.3	100.0
7	Count	12	4	9	25
	Percent	48.0	16.0	36.0	100.0
Total	Count	42	16	47	105
	Percent	40.0	15.2	44.8	100.0

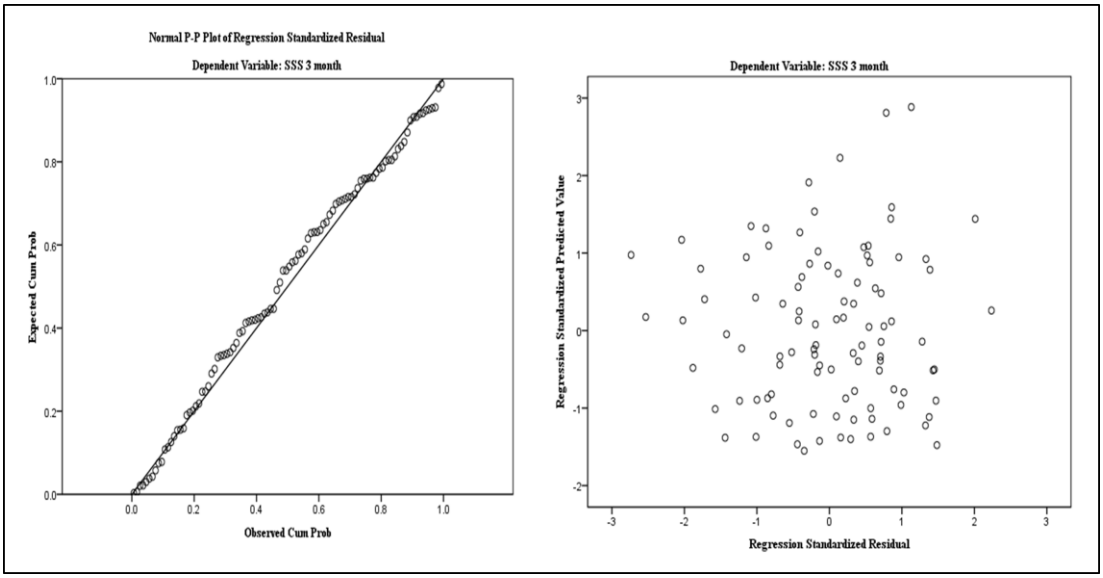
Cross tabulation: Prognosis vs. TCM diagnosis (n = 105)
Fisher's exact = 18.06, $p = 0.20$

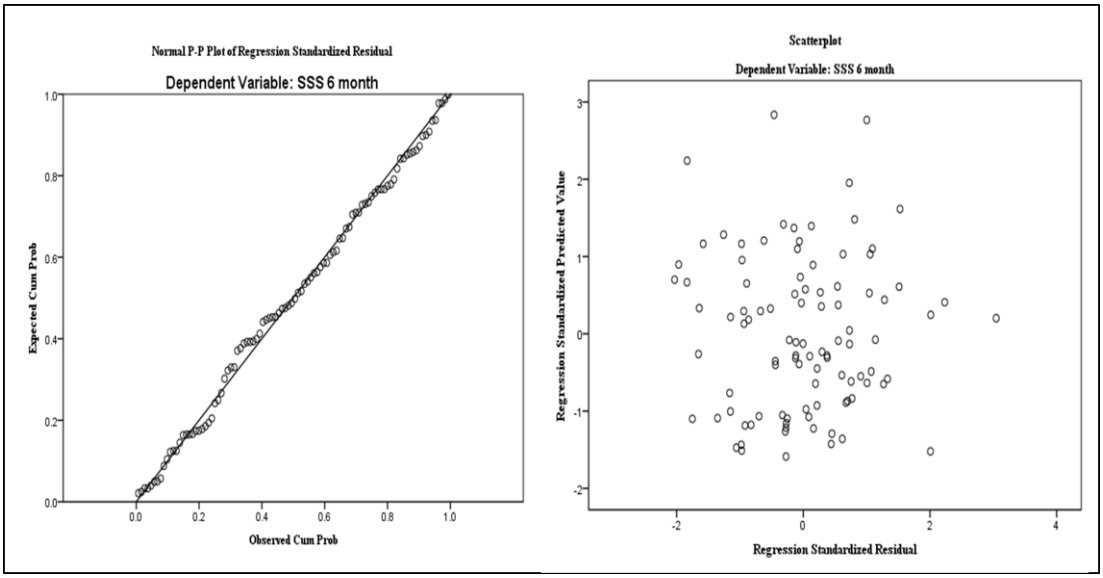
Appendix E 12 Post estimation tests for models of IBS-SSS outcome at three and six months by prognosis

The table shows the significance values and collinearity statistics for the three and six month models using the acupuncturists' prognoses and IBS-SSS baseline scores as independent variables and IBS-SSS three and six month scores as the dependent variable. Don't know prognosis is the reference category.

	3 month			**6 month**		
		Collinearity Statistics			Collinearity Statistics	
Covariate	Sig.	Tolerance	VIF	Sig.	Tolerance	VIF
SSS baseline	0.004	0.96	1.04	< 0.001	0.93	1.08
Good prognosis	< 0.001	0.45	2.21	0.07	0.41	2.41
Don't know prognosis	0.01	0.44	2.25	0.01	0.39	2.55

The figures show the post hoc tests for linearity and homoscedasticity in both the three and six month models.



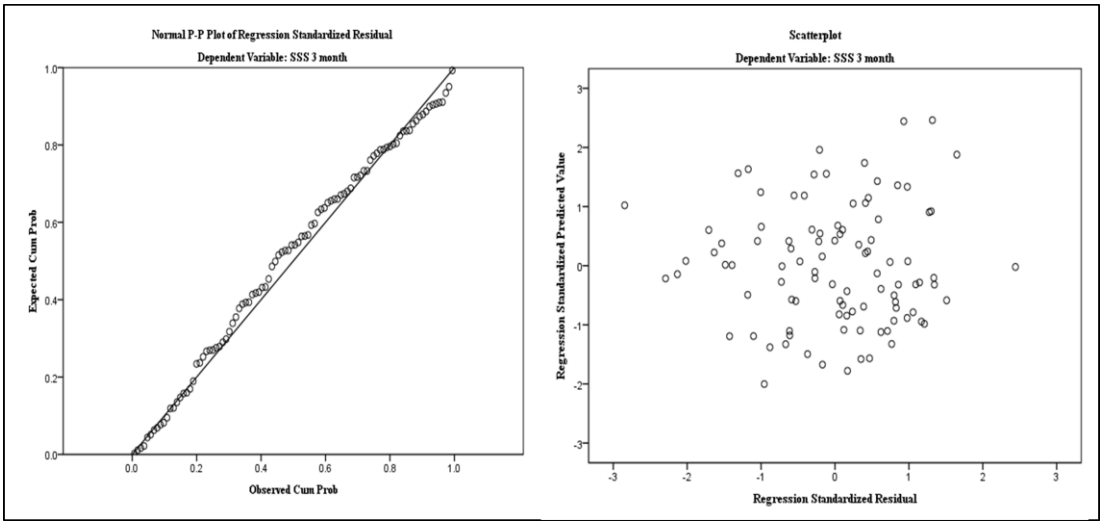


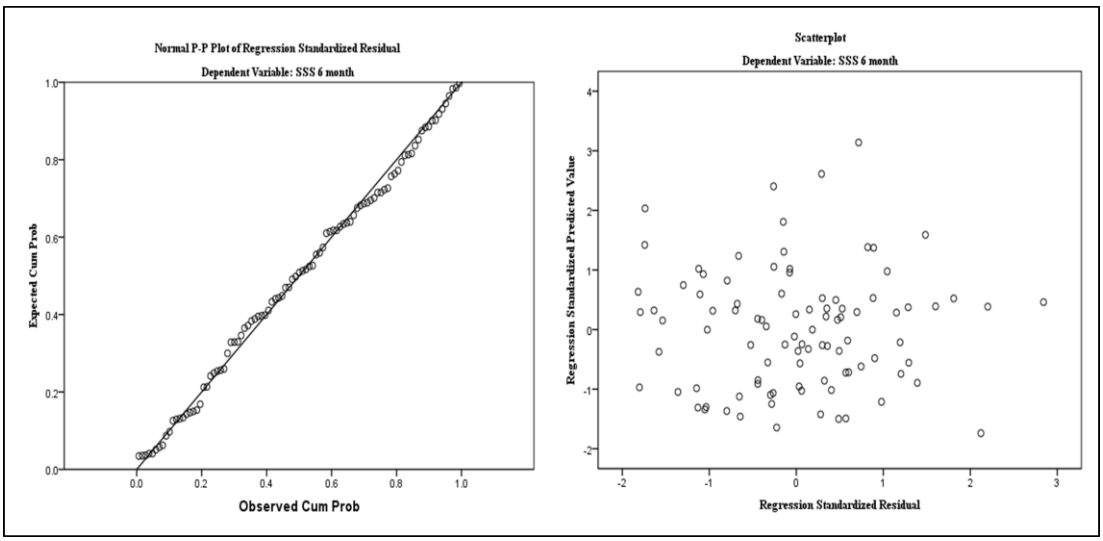
Appendix E 13 Post estimation tests for adjusted models of IBS-SSS outcome at three and six months by prognosis

The table shows the significance values and collinearity statistics for the three month model using the acupuncturists' prognoses, age, sex, duration of IBS and IBS-SSS baseline scores as independent variables and IBS-SSS three month scores as the dependent variable. Don't know prognosis is the reference category.

	3 month			**6 month**		
		Collinearity Statistics			Collinearity Statistics	
Covariate	Sig.	Tolerance	VIF	Sig.	Tolerance	VIF
SSS baseline	< 0.001	0.75	1.33	0.003	0.65	1.53
Good prognosis	0.03	0.42	2.37	0.14	0.38	2.63
Don't know prognosis	0.03	0.42	2.40	0.03	0.36	2.77
Age	0.02	0.64	1.56	0.49	0.63	1.58
Sex	0.46	0.89	1.13	0.93	0.82	1.22
Duration	0.34	0.64	1.57	0.13	0.63	1.58

The figures show the post hoc tests for linearity and homoscedasticity in both the three and six month models.



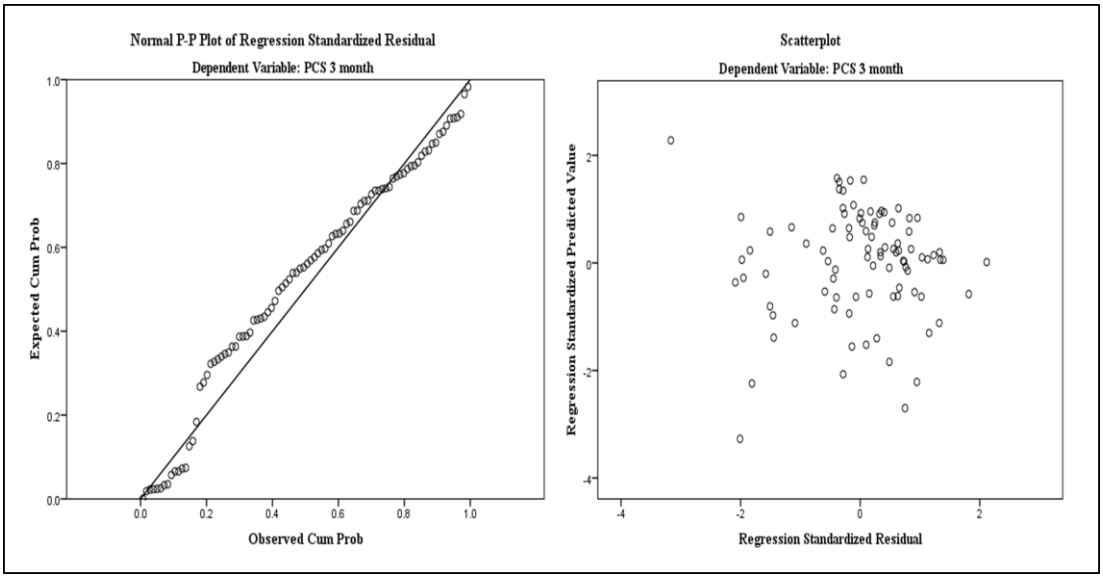


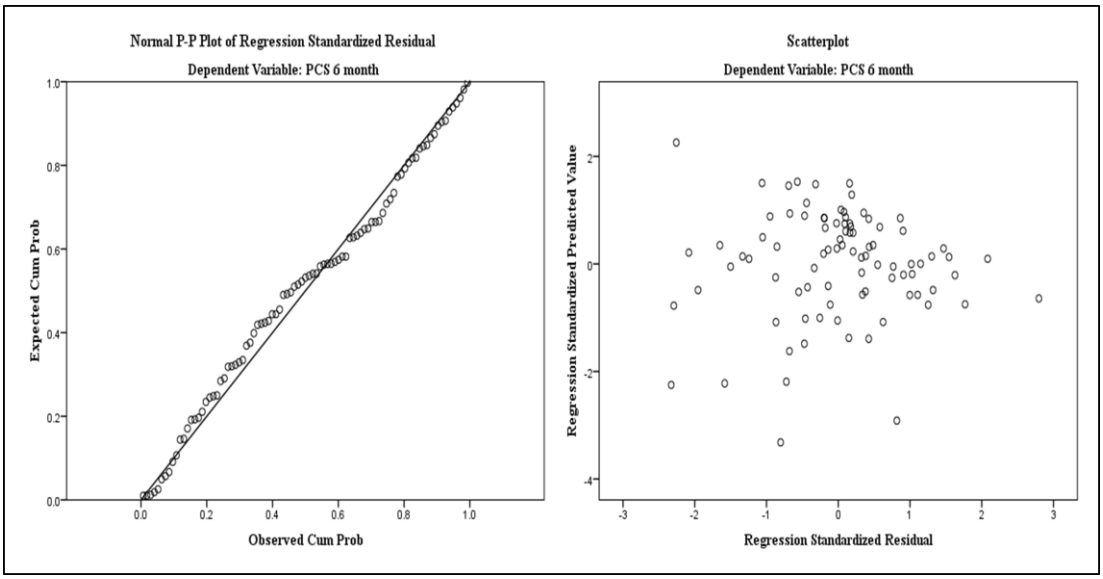
Appendix E 14 Post estimation tests for models of PCS outcome at three and six months by prognosis

The table shows the significance values and collinearity statistics for the three and six month models using the acupuncturists' prognoses and PCS baseline scores as independent variables and PCS three and six month scores as the dependent variable. Don't know prognosis is the reference category.

	3 month			**6 month**		
		Collinearity Statistics			Collinearity Statistics	
Covariate	Sig.	Tolerance	VIF	Sig.	Tolerance	VIF
Good prognosis	0.02	0.36	2.80	0.07	0.35	2.87
Don't know prognosis	0.12	0.37	2.68	0.10	0.36	2.80
PCS baseline	< 0.001	0.93	1.07	< 0.001	0.95	1.05

The figures show the post hoc tests for linearity and homoscedasticity in both the three and six month models.



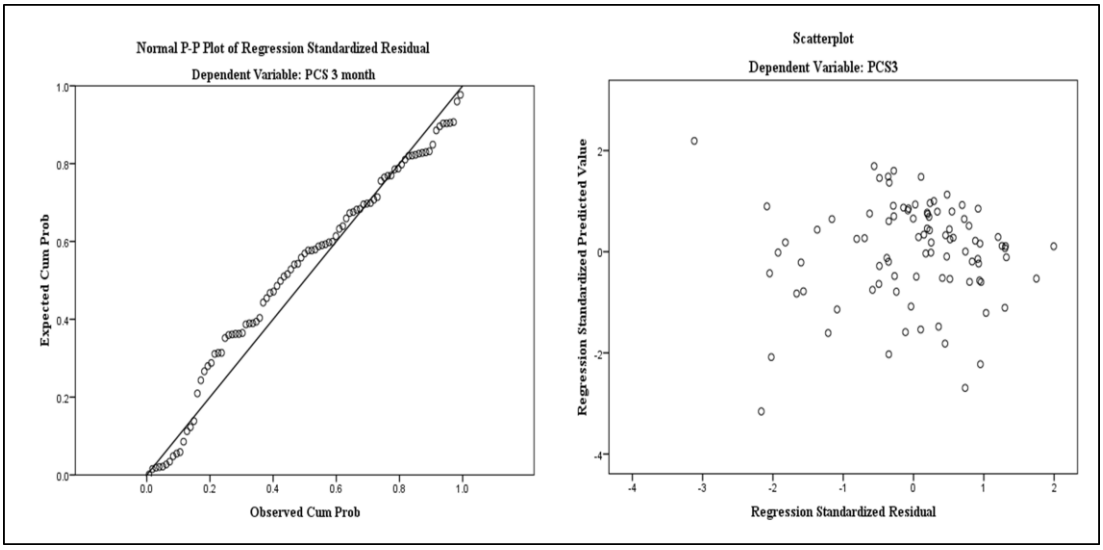


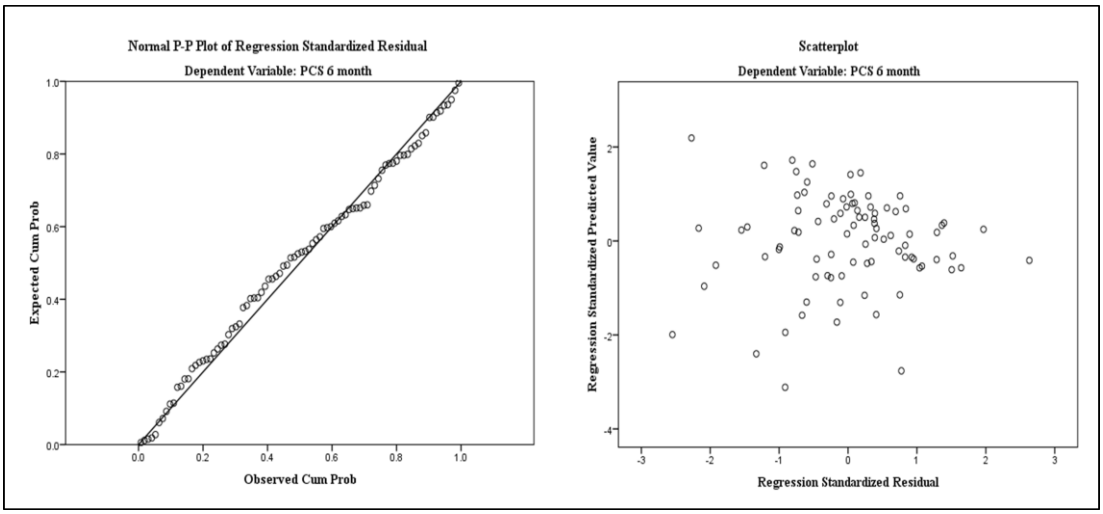
Appendix E 15 Post estimation tests for adjusted models of PCS outcome at three and six months by prognosis

The table shows the significance values and collinearity statistics for the three month model using the acupuncturists' prognoses, age, sex, duration of IBS and PCS baseline scores as independent variables and PCS three month scores as the dependent variable. Don't know prognosis is the reference category.

	3 month			**6 month**		
		Collinearity Statistics			Collinearity Statistics	
Covariate	Sig.	Tolerance	VIF	Sig.	Tolerance	VIF
Good prognosis	0.02	0.36	2.79	0.08	0.35	2.87
Don't know prognosis	0.09	0.38	2.67	0.14	0.36	2.79
PCS baseline	< 0.001	0.87	1.15	< 0.001	0.90	1.11
Age	0.74	0.67	1.49	0.84	0.69	1.45
Sex	0.44	0.97	1.03	0.11	0.97	1.03
Duration	0.43	0.70	1.42	0.27	0.72	1.38

The figures show the post hoc tests for linearity and homoscedasticity in both the three and six month models.



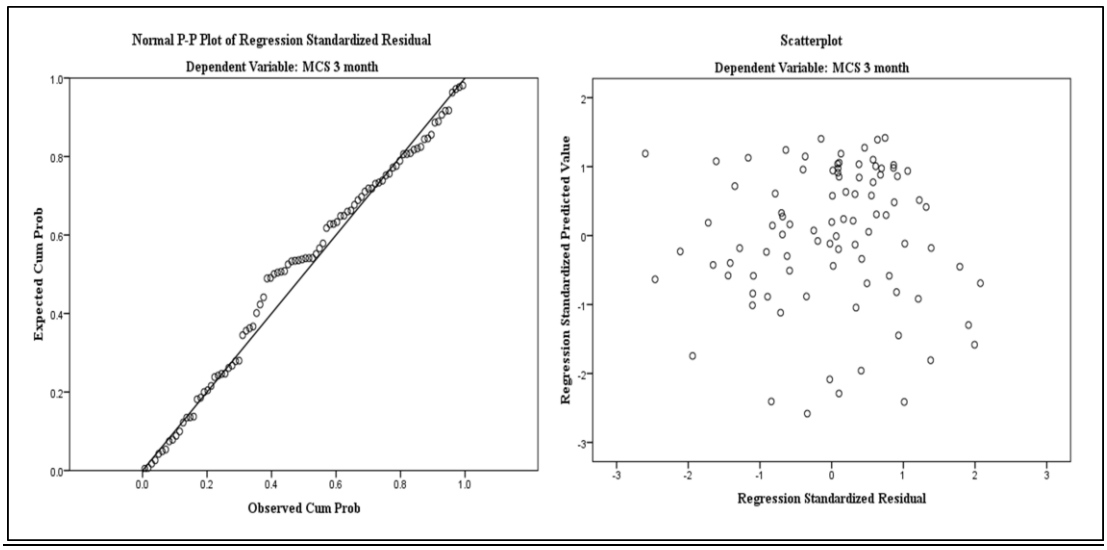


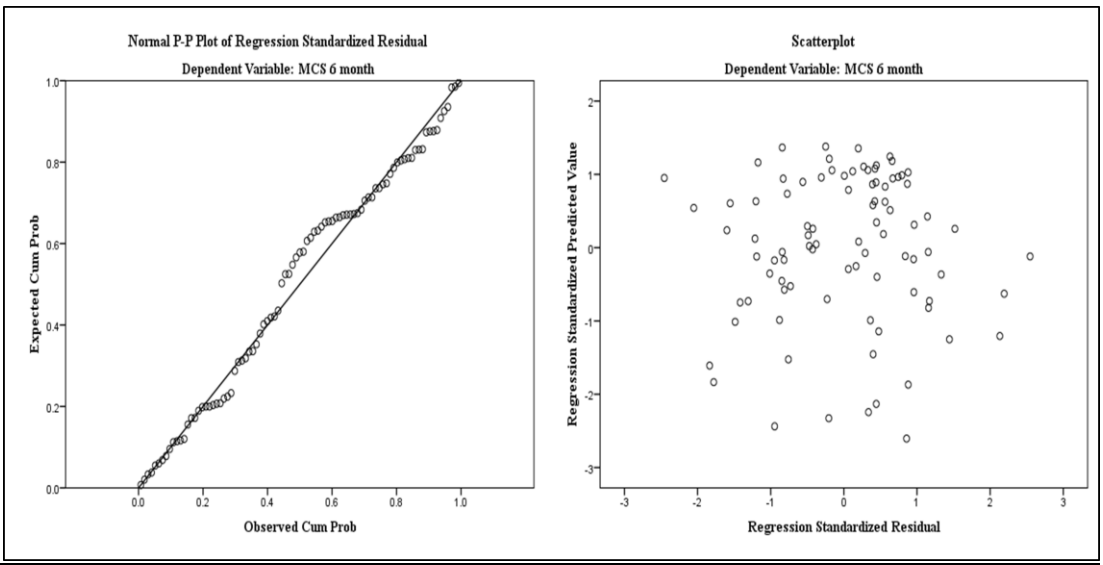
Appendix E 16 Post estimation tests for models of MCS outcome at three and six months by prognosis

The table shows the significance values and collinearity statistics for the three and six month models using the acupuncturists' prognoses and MCS baseline scores as independent variables and MCS three and six month scores as the dependent variable. Don't know prognosis is the reference category.

	3 month			**6 month**		
		Collinearity Statistics			Collinearity Statistics	
Covariate	Sig.	Tolerance	VIF	Sig.	Tolerance	VIF
Good prognosis	0.03	0.36	2.78	0.02	0.35	2.90
Don't know prognosis	0.10	0.36	2.76	0.05	0.34	2.90
MCS baseline	< 0.001	0.94	1.07	< 0.001	0.94	1.06

The figures show the post hoc tests for linearity and homoscedasticity in both the three and six month models.



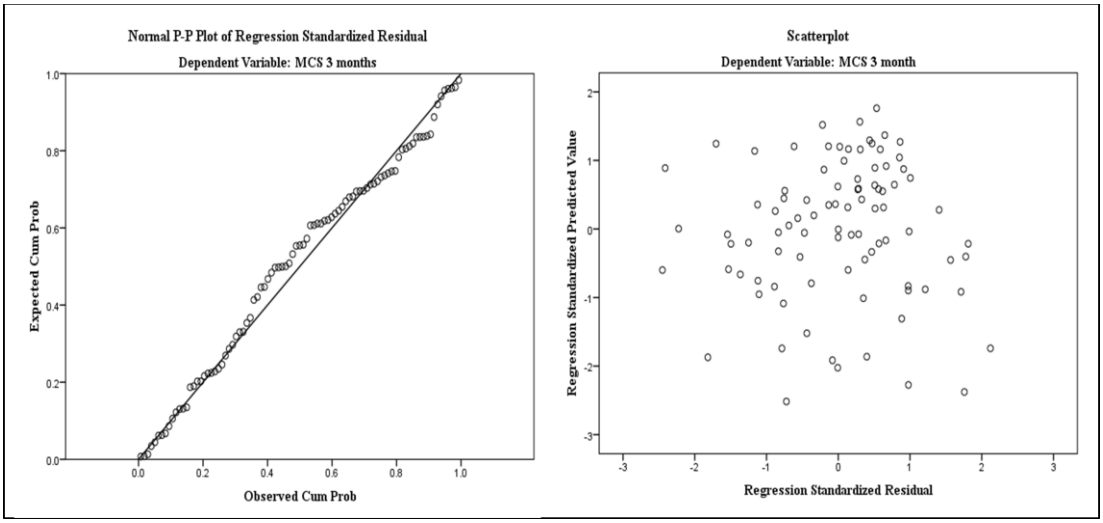


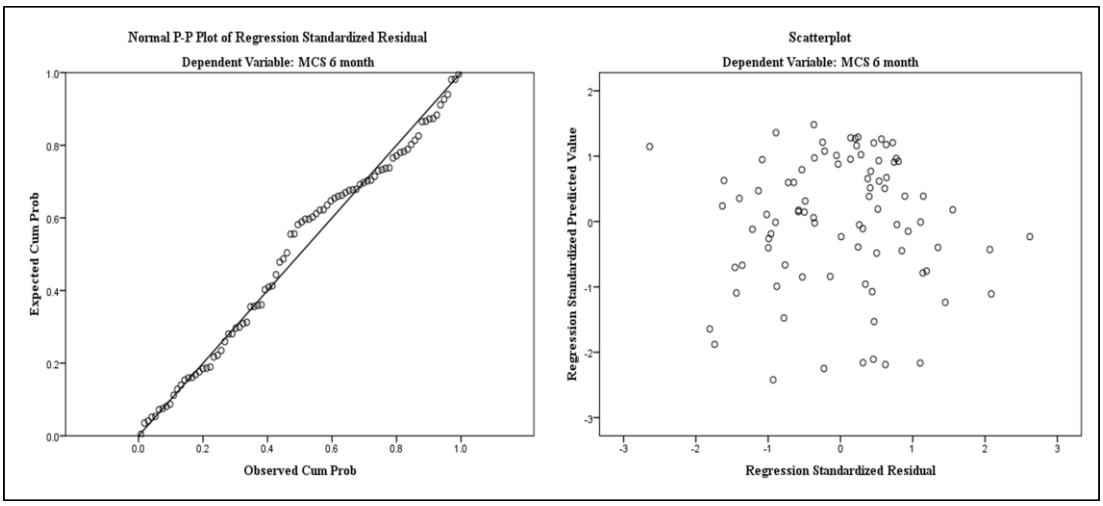
Appendix E 17 Post estimation tests for adjusted models of MCS outcome at three and six months by prognosis

The table shows the significance values and collinearity statistics for the three and month models using the acupuncturists' prognoses, age, sex, duration of IBS and MCS baseline scores as predictors (independent variables) and MCS three and six month scores as the dependent variable. Don't know prognosis is the reference category.

	3 month			**6 month**		
		Collinearity Statistics			Collinearity Statistics	
Covariate	Sig.	Tolerance	VIF	Sig.	Tolerance	VIF
Good prognosis	0.03	0.36	2.80	0.02	0.34	2.93
Don't know prognosis	0.14	0.36	2.77	0.04	0.34	2.93
MCS baseline	< 0.001	0.92	1.08	< 0.001	0.91	1.10
Age	0.31	0.70	1.44	0.62	0.70	1.42
Sex	0.93	0.97	1.03	0.85	0.96	1.04
Duration	0.19	0.70	1.43	0.43	0.72	1.39

The figures show the post hoc tests for linearity and homoscedasticity in both the three and six month models.





Appendix E 18 Power calculations

Acupuncture Intervention Group

	Baseline (n = 116)	3 month (n = 109)
IBS-SSS Mean (SD)	279.0 (81.7)	215.5 (95.6)

For a power = 0.80 the sample size required is 18

TCM Diagnosis Subgroups

	Baseline	**3 month**	**6 month**
Yang deficiency	n = 8	n = 7	n = 7
IBS-SSS Mean (SD)	308.9 (93.5)	268.3 (74.0)	214.9 (92.8)
For a power = 0.80 the sample size required is 27 at 3 months & 8 at six months			
Spleen qi deficiency	n = 10	n = 10	n = 10
IBS-SSS Mean (SD)	277.7 (107.3)	185.7 (107.8)	171.8 (122.6)
For a power = 0.80 the sample size required is 11 at 3 months & 11 at six months			
Yin deficiency	n = 13	n = 12	n = 11
IBS-SSS Mean (SD)	304.9 (78.6)	221.1 (139.2)	196.6 (126.9)
For a power = 0.80 the sample size required is 22 at 3 months & 11 at six months			
Damp heat	n = 19	n = 19	n = 18
IBS-SSS Mean (SD)	237.1 (67.0)	184.1 (106.5)	185.1 (93.5)
For a power = 0.80 the sample size required is 98 at 3 months & 26 at six months			
Cold damp	n = 17	n = 17	n = 7
IBS-SSS Mean (SD)	303.6 (85.7)	215.2 (111.8)	198.1 (97.3)
For a power = 0.80 the sample size required is 13 at 3 months & 7 at six months			
Combined	n = 17	n = 16	n = 16
IBS-SSS Mean (SD)	262.0 (63.7)	233.4 (53.8)	204.9 (63.1)
For a power = 0.80 the sample size required is 28 at 3 months & 10 at six months			
Liver qi stagnation	n = 29	n = 27	n = 27
IBS-SSS Mean (SD)	276.6 (79.0)	220.9 (71.7)	211.3 (69.4)
For a power = 0.80 the sample size required is 14 at 3 months & 9 at six months			

Appendix F Papers and presentations associated with this thesis

Papers

Stuardi, T., Kang'ombe, A. The IBS-SSS: An assessment of factor structure and reliability. Currently in draft

Stuardi, T., MacPherson, H. The diagnosis and treatment of patients with Irritable Bowel Syndrome in a pragmatic trial. *Acupuncture in Medicine*. Submitted 7/2011

Stuardi, T. A context hypothesis on biomedical diagnosis in TCM practice. *Journal of Alternative and Complementary Medicine*. Accepted 5/2011

Stuardi, T., Cox, H., Torgerson, D. Database recruitment: A solution to poor recruitment in randomised trials. *Family Practice*: 2011. 28(3): 329-333.

MacPherson, H., Bland, M., Bloor, K., Cox, H., Geddes, D., Kang'ombe, A. Reynolds, J., Stamuli, E., **Stuardi, T**., Tilbrook, H., Torgerson, D., Whorwell, P. Acupuncture for irritable bowel syndrome: A protocol for a pragmatic randomised controlled trial. *BMC Gastroenterology*. 2010. 10:63

Stuardi, T., Atkin, K. How acupuncturists envision treating irritable bowel syndrome: A pre-trial analysis. *Medical Acupuncture*. 2010. 22 (2): 1-10.

Presentations

05/11 American Association of Acupuncture & Oriental Medicine (Baltimore, MD) *Oral presentation: Cart before the horse: Discovering the importance of patient specific TCM diagnosis and treatment through a pragmatic study on IBS*. Video available at www.users.york.ac.uk/~tls504

05/10 5th International Conference on Complementary Medical Research (Tromso, Norway) *Oral presentation: 'If it works it works': A patient's perspective on how acupuncture works*

05/09 North American Research Conference on Complementary & Integrative Medicine (Minneapolis, MN) *Poster: How acupuncturists envision treating IBS*

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