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Protocol

Factors which affect the efficacy of hypnotherapy for IBS: Protocol for a systematic review and meta-regression

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ABSTRACT

Introduction: Hypnotherapy for the treatment of Irritable Bowel Syndrome (IBS) has accumulated a broad evidence base, resulting in its inclusion in the UK National Institute of Health and Care Excellence (NICE) Guidelines in 2008. Although several high quality systematic reviews and meta-analyses of hypnotherapy's efficacy have been conducted, subgroup analysis of factors which contribute to this are absent. The goal of this systematic review is to evaluate the current literature to identify factors which contribute to its effectiveness.

Methods and analysis: We will conduct searches in CINAHL, Cochrane library, Conference Citation Index (science & social science), Embase (excerpta medica), PubMed, PsycARTICLES, PsychINFO, Science Citation Index-expanded and Social Science Citation Index. Data will be included from randomised (RCTs) and non-randomised controlled trials with a concurrent comparator of hypnotherapy interventions for IBS, reported in English. Two authors will independently review studies for inclusion, with arbitration by a third reviewer if needed. We will assess for risk of bias using the Cochrane Collaboration's risk of bias tool for RCTs and the Robins-I tool for non-RCTs.

Where appropriate a meta-regression analysis of pre-defined subgroups will be conducted using a random effects model. Where quantitative analysis is not possible a narrative description will be given.

Discussion: These will be disseminated via peer review journals and at appropriate conferences. The results may be of use in establishing the most efficient formulation of services delivering hypnotherapy for IBS.

1. Introduction

Irritable Bowel Syndrome (IBS) is a chronic functional bowel disorder characterised by a high degree of variability in bowel movement frequency and composition accompanied by recurrent abdominal pain [1]. The disorder affects large numbers of people worldwide with prevalence figures around 11% often cited [2–5], however due to substantial variation between studies brought about by differences in who identifies the IBS [6], and the diagnostic criteria used [7] no universal prevalence rate can currently be agreed upon [8].

IBS consumes a substantial amount of primary [9,10] and secondary care time [10,11] and money, with an estimated £70 million being spent by the UK's National Health Service (NHS) on antispasmodics and laxatives specifically for the treatment of IBS [12]. In addition to physical symptoms, sufferers experience negative impacts on quality of life [13], frequently experience anxiety and depression [14] and express higher than average levels of suicidal ideation and behaviour [15].

Historically IBS has had a reputation as difficult to both diagnose [16,17] and treat [18], with traditional pharmacological approaches such as antispasmodics, anti-motility agents and bulking agents [19] being focused upon symptom control rather than cure. Sufferers sometimes have a low opinion of traditional medicines [20] and commonly turn to complementary and alternative therapies (CAM) for help [21]. The last few decades have seen the exploration of a raft of potential novel treatments, with some proving efficacious, albeit to varying degrees; these include peppermint oil [22], probiotics [23,24] and 5-HT antagonists [25]. Some of these treatments have sufficient evidence of efficacy to warrant inclusion in National Institute for Health and Care Excellence (NICE) guidelines [19], such as exercise [26], antidepressants [27], and the FODMAP diet [28]. One of these novel NICE approved approaches is hypnotherapy, which is specifically recommended for IBS sufferers 'who do not respond to pharmacological treatments after 12 months and who develop a continuing symptom profile', known as 'refractory' [19]. There is evidence that general practitioners may be open to hypnotherapy for IBS [29], although IBS sufferers themselves appear cautious, with one study finding that 36.3% of sufferers consider it an unacceptable treatment option [30].

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Hypnotherapy is hypnosis [31] used with the intention of generating a beneficial outcome. The earliest trials of hypnotherapy for the treatment of IBS date back to the early 1980 s [32,33] using a package of broadly similar techniques, the most well-known of which are the Manchester Model [18] and the North Carolina Protocol [34] which have been termed gut-directed hypnotherapy (GDH) [35]; these models were quickly adopted as the norm [36,37].

GDH is a multisession approach which combines general relaxation with gut specific suggestions and imagery to promote digestive calm, control and strength [38]. The mechanisms by which GDH improves outcomes are unclear [39,40]. There is evidence that suggests it may normalise rectal sensitivity [41], but this is not a universal finding [42]. Equally, there is evidence to suggest it may have an effect on digestive motility [43], but recent work has failed to confirm this [44]. Other factors which have been implicated as possible mechanisms of action of GDH include changes to bowel distention perception [45], cognitive alteration [46] and moderation of activity in the posterior insula region of the brain [47], an area associated with processing sensations from inside the body, which suggests that hypnotherapy may moderate the signals from the body in some way, although exactly how remains unclear.

Hypnotherapy for IBS has a demonstrable record of effectiveness [48,49], however older reviews lacked sufficient data to conduct meaningful subgroup analysis, [4,39], and those more recent reviews which have carried out subgroup analysis have focused upon symptoms such as pain and constipation [48–50]. One review did examine the difference between refractory sufferers' and non-refractory sufferers' responsiveness [48], however due to substantial heterogeneity in sample populations and symptom measures these findings cannot be considered conclusive. Heterogeneity is a consistent problem as studies do not use consistent interventions or outcome measures [48,49]. Beyond this, concerns exist that outcomes may be subject to a degree of variability dependent upon as yet unexamined factors [51]. Factors that might affect the outcome of hypnotherapy for IBS include the hypnotherapist's skill, training and experience [10,52]; patient demographics [51], with evidence suggesting that gender may be a factor [53,54], but no meta-analysis has assessed the validity of these findings over different populations. The clinical setting may be a factor [48,52] as may the nature of the hypnotherapeutic approach itself [51].

Hypnotherapy for IBS is notably time intensive, currently delivered for up to 12 h contact time per patient on a one-to-one basis [40]. Any findings which help to increase this treatment's efficacy, be that by identifying the most responsive populations, efficient dose, effective type of practitioner or clinical setting, are likely to reduce the costs of this NICE approved therapy [19].

1.1. Objectives

The review aims to assess the impact of different variables within and around the hypnotherapeutic treatment of IBS. Specifically, the review will address the following questions:

Are the outcomes of hypnotherapy for IBS affected by:

1 recruitment location: primary and community, secondary and tertiary care
2 delivery location: primary and community, secondary and tertiary care
3 hypnotherapist's characteristics such as gender, age and duration of training
4 number of sessions delivered
5 total therapy time
6 time between sessions
7 mode of delivery: individual or group treatment
8 population variables, such as gender, age, educational status
9 duration of symptoms
10 type of hypnotherapy: GDH approaches versus hypnotherapy with a distinctly different underlying philosophy such as hypnotherapeutically enhanced Cognitive Behavioural Therapy (CBT) [55]
11 Type of IBS: There are three main types of IBS as defined by the main symptom experienced, IBS-D where the person predominantly experiences diarrhoea, IBS-C where constipation is predominant, and IBS-A, the alternating type where both diarrhoea and constipation are frequent [56].

2. Methods

2.1. Study registration

This protocol review has been registered on PROSPERO CRD42018065533

2.2. Eligibility criteria

2.2.1. Type of study

Eligible studies include randomised, quasi-randomised or non-randomised studies comparing an intervention with a definable element of hypnotherapy to an explicit concurrent comparator, such as another treatment, or placebo such as sham therapy. Due to financial constraints only English language journals will be used. No limits will be placed on publication date.

2.2.2. Type of participant

No exclusion will be made on grounds of gender, ethnicity, duration of symptoms or socio-economic status. Studies of children ($\leq$17 years of age) will be excluded.

Participants will have received a diagnosis of IBS in line with one of the major criteria, Manning [57], Rome I [58], II [59], III [60] or IV [61]. Although these criteria have been superseded by each other, i.e. Rome I replaced Manning, Rome II replaced Rome I and so on, they were the definable criteria of their time and represent a recognised diagnosis, as such they will be accepted as a valid definition of IBS status which is consistent with previous reviews' practice [50,62].

2.2.3. Type of intervention

The intervention will contain some degree of hypnotherapy for the treatment of IBS. The work will be conducted by an individual identified as possessing hypnotherapeutic skill. To this end, therapy identified as guided imagery, relaxation or any other treatment which is not explicitly defined as hypnosis will be excluded.

2.2.4. Type of comparator

This group will be in receipt of an alternative treatment, which may include another hypnotherapeutic approach, treatment as usual or a placebo intervention.

2.2.5. Type of outcome measure

2.2.5.1. Primary. Any continuous measure of global gastrointestinal symptoms. Several of these exist, some of the most commonly used are presented below in preferential order for use if more than one is present in a single study.

1) IBS Symptom Severity Scoring System (IBS-SSS) [63].
2) The gastrointestinal symptoms rating scale (GRS-IBS) [64].
3) Functional Bowel Disorder Severity Index [65]
4) IBS Symptom Questionnaire [65]
5) Visceral Sensitivity Index (VSI) [66,67].
6) Other continuous measure of global gastrointestinal symptoms

2.2.5.2. Secondary. These are for specific symptoms, for example physical, mental or quality of life which cannot be combined within the study, as it is unlikely that studies will use more than one measure for these outcomes no preferential order has been specified;