Irritable bowel syndrome in adults: diagnosis and management of irritable bowel syndrome in primary care

NICE guideline

Draft for consultation, October 2014

If you wish to comment on this version of the guideline, please be aware that all the supporting information and evidence for the 2015 recommendations is contained in the addendum of the 2015 guideline. Evidence for the 2008 recommendations is in the full version of the 2008 guideline.

Contents

Introduction
Recommendations about medicines4
Patient-centred care5
Strength of recommendations
Update information
Key priorities for implementation9
1 Recommendations12
1.1 Diagnosis of IBS12
1.2 Clinical management of IBS15
2 Research recommendations19
2.1 Low-dose antidepressants19
2.2 Psychological interventions20
2.3 Refractory IBS21
2.4 Relaxation and biofeedback21
2.5 Herbal medicines
3 Other information
3.1 Scope and how this guideline was developed
3.2 Related NICE guidance23
4 Committee members and NICE staff24
4.1 Committee members24
4.2 Clinical Guidelines Update Team26
4.3 NICE project team27
4.4 Declarations of interests
Appendix A: Recommendations from NICE guideline CG61 (2008) that have
been changed

Introduction

Recommendations on dietary and lifestyle advice and pharmacological therapy have been added to and updated in sections 1.2.1 and 1.2.2. The addendum to NICE guideline CG61 [hyperlink to be added for final publication] contains details of the methods and evidence used to update these recommendations.

Irritable bowel syndrome (IBS) is a chronic, relapsing and often life-long disorder. It is characterised by the presence of abdominal pain or discomfort, which may be associated with defaecation and/or accompanied by a change in bowel habit. Symptoms may include disordered defaecation (constipation or diarrhoea or both) and abdominal distension, usually referred to as bloating. Symptoms sometimes overlap with other gastrointestinal disorders such as non-ulcer dyspepsia or coeliac disease. People with IBS present to primary care with a wide range of symptoms, some of which they may be reluctant to disclose without sensitive questioning.

People with IBS present with varying symptom profiles, most commonly 'diarrhoea predominant', 'constipation predominant' or alternating symptom profiles. IBS most often affects people between the ages of 20 and 30 years and is twice as common in women as in men. Prevalence in the general population is estimated to be between 10% and 20%. Recent trends indicate that there is also a significant prevalence of IBS in older people. IBS diagnosis should be a consideration when an older person presents with unexplained abdominal symptoms.

Key aspects of this guideline include establishing a diagnosis; referral into secondary care only after identification of 'red flags' (symptoms and/or features that may be caused by another condition that needs investigation); providing lifestyle advice; drug and psychological interventions; and referral and follow-up. The guideline refers to NICE's <u>referral guidelines for suspected cancer</u> in relation to appropriate referral to secondary care.

Irritable bowel syndrome in adults: NICE guideline DRAFT (October 2014) Page 3 of 36

The main aims of this guideline are to:

- provide positive diagnostic criteria for people presenting with symptoms suggestive of IBS
- provide guidance on clinical and cost-effective management of IBS in primary care
- determine clinical indications for referral to IBS services, taking into account cost effectiveness.

Recommendations about medicines

The guideline will assume that prescribers will use a medicine's summary of product characteristics to inform decisions made with individual patients.

This guideline recommends some medicines for indications for which they do not have a UK marketing authorisation at the date of publication, if there is good evidence to support that use. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. The patient (or those with authority to give consent on their behalf) should provide informed consent, which should be documented. See the General Medical Council's <u>Good practice in prescribing and managing medicines and devices</u> for further information. Where recommendations have been made for the use of medicines outside their licensed indications ('off-label use'), these medicines are marked with a footnote in the recommendations.

Patient-centred care

This guideline offers best practice advice on the care of adults with IBS.

Patients and healthcare professionals have rights and responsibilities as set out in the <u>NHS Constitution for England</u> – all NICE guidance is written to reflect these. Treatment and care should take into account individual needs and preferences. Patients should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If the patient is under 16, their family or carers should also be given information and support to help the child or young person to make decisions about their treatment. Healthcare professionals should follow the <u>Department of Health's advice on consent</u>. If someone does not have capacity to make decisions, healthcare professionals should follow the <u>code of practice</u> <u>that accompanies the Mental Capacity Act</u> and the supplementary <u>code of</u> <u>practice on deprivation of liberty safeguards</u>.

NICE has produced guidance on the components of good patient experience in adult NHS services. All healthcare professionals should follow the recommendations in <u>Patient experience in adult NHS services</u>.

Strength of recommendations

Some recommendations can be made with more certainty than others. The Committee makes a recommendation based on the trade-off between the benefits and harms of an intervention, taking into account the quality of the underpinning evidence. For some interventions, the Committee is confident that, given the information it has looked at, most patients would choose the intervention. The wording used in the recommendations in this guideline denotes the certainty with which the recommendation is made (the strength of the recommendation).

For all recommendations, NICE expects that there is discussion with the patient about the risks and benefits of the interventions, and their values and preferences. This discussion aims to help them to reach a fully informed decision (see also 'Patient-centred care').

Interventions that must (or must not) be used

We usually use 'must' or 'must not' only if there is a legal duty to apply the recommendation. Occasionally we use 'must' (or 'must not') if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

Interventions that should (or should not) be used – a 'strong' recommendation

We use 'offer' (and similar words such as 'refer' or 'advise') when we are confident that, for the vast majority of patients, an intervention will do more good than harm, and be cost effective. We use similar forms of words (for example, 'Do not offer...') when we are confident that an intervention will not be of benefit for most patients.

Interventions that could be used

We use 'consider' when we are confident that an intervention will do more good than harm for most patients, and be cost effective, but other options may be similarly cost effective. The choice of intervention, and whether or not to

have the intervention at all, is more likely to depend on the patient's values and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the patient.

Recommendation wording in guideline updates

NICE began using this approach to denote the strength of recommendations in guidelines that started development after publication of the 2009 version of 'The guidelines manual' (January 2009). This does not apply to any recommendations shaded in grey and ending **[2008]** (see 'Update information' box below for details about how recommendations are labelled). In particular, for recommendations labelled **[2008]**, the word 'consider' may not necessarily be used to denote the strength of the recommendation.

Update information

This guideline is an update of the NICE guideline on <u>irritable bowel syndrome</u> <u>in adults</u> (published February 2008) and will replace it.

New recommendations have been added for the clinical management (dietary and lifestyle advice, and pharmacological therapy) of people with IBS.

You are invited to comment on the new and updated recommendations in this guideline. These are marked as:

- [new 2015] if the evidence has been reviewed and the recommendation has been added or updated
- [2015] if the evidence has been reviewed but no change has been made to the recommended action.

Where recommendations end **[2008]** and/or are shaded in grey, the evidence has not been reviewed since the original guideline. We will not be able to accept comments on these. Where recommendations are shaded in yellow, wording changes have been made for the purpose of clarification only. Recommendations labelled **[2015]** have been edited into the direct style (in line with current NICE style for recommendations in clinical guidelines) where possible and are listed in appendix A.

The original NICE guideline and supporting documents are available here.

Key priorities for implementation

The following recommendations were identified as priorities for implementation in the 2008 guideline and have not been changed in the 2015 update.

Initial assessment

- Healthcare professionals should consider assessment for IBS if the person reports having had any of the following symptoms for at least 6 months:
 - Abdominal pain or discomfort
 - Bloating
 - Change in bowel habit. [2008]
- All people presenting with possible IBS symptoms should be asked if they have any of the following 'red flag' indicators and should be referred to secondary care for further investigation if any are present:¹
 - unintentional and unexplained weight loss
 - rectal bleeding
 - a family history of bowel or ovarian cancer
 - a change in bowel habit to looser and/or more frequent stools persisting for more than 6 weeks in a person aged over 60 years. [2008]
- All people presenting with possible IBS symptoms should be assessed and clinically examined for the following 'red flag' indicators and should be referred to secondary care for further investigation if any are present:¹
 - anaemia
 - abdominal masses
 - rectal masses
 - inflammatory markers for inflammatory bowel disease.

Measure serum CA125 in primary care in women with symptoms that

¹ See NICE's <u>referral guidelines for suspected cancer</u> for detailed referral criteria where cancer is suspected.

suggest ovarian cancer in line with the NICE guideline on ovarian cancer.² [2008]

- A diagnosis of IBS should be considered only if the person has abdominal pain or discomfort that is either relieved by defaecation or associated with altered bowel frequency or stool form. This should be accompanied by at least two of the following four symptoms:
 - altered stool passage (straining, urgency, incomplete evacuation)
 - abdominal bloating (more common in women than men), distension, tension or hardness
 - symptoms made worse by eating
 - passage of mucus.

Other features such as lethargy, nausea, backache and bladder symptoms are common in people with IBS, and may be used to support the diagnosis. **[2008]**

Diagnostic tests

- In people who meet the IBS diagnostic criteria, the following tests should be undertaken to exclude other diagnoses:
 - full blood count (FBC)
 - erythrocyte sedimentation rate (ESR) or plasma viscosity
 - c-reactive protein (CRP)
 - antibody testing for coeliac disease (endomysial antibodies [EMA] or tissue transglutaminase [TTG]). [2008]
- The following tests are not necessary to confirm diagnosis in people who meet the IBS diagnostic criteria:
 - ultrasound
 - rigid/flexible sigmoidoscopy
 - colonoscopy; barium enema
 - thyroid function test
 - faecal ova and parasite test
 - faecal occult blood

² This recommendation was updated in September 2012 in line with more recent guidance on the recognition and management of ovarian cancer in the NICE guideline on <u>ovarian cancer</u>.

hydrogen breath test (for lactose intolerance and bacterial overgrowth).
 [2008]

Dietary and lifestyle advice

- People with IBS should be given information that explains the importance of self-help in effectively managing their IBS. This should include information on general lifestyle, physical activity, diet and symptomtargeted medication. [2008]
- Healthcare professionals should review the fibre intake of people with IBS, adjusting (usually reducing) it while monitoring the effect on symptoms. People with IBS should be discouraged from eating insoluble fibre (for example, bran). If an increase in dietary fibre is advised, it should be soluble fibre such as ispaghula powder or foods high in soluble fibre (for example, oats). [2008]

Pharmacological therapy

- People with IBS should be advised how to adjust their doses of laxative or antimotility agent according to the clinical response. The dose should be titrated according to stool consistency, with the aim of achieving a soft, well-formed stool (corresponding to Bristol Stool Form Scale type 4). [2008]
- Consider tricyclic antidepressants (TCAs) as second-line treatment for people with IBS if laxatives, loperamide or antispasmodics have not helped. Start treatment at a low dose (5–10 mg equivalent of amitriptyline), taken once at night and review regularly. Increase the dose if needed, but not usually beyond 30 mg.³ [2015]

³ At the time of consultation on the guideline update (October 2014), TCAs did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's <u>Good practice in prescribing and managing medicines and devices</u> for further information.

1 Recommendations

The following guidance is based on the best available evidence. The <u>full</u> <u>guideline</u> [hyperlink to be added for final publication] gives details of the methods and the evidence used to develop the 2008 recommendations. The <u>guideline addendum</u> [hyperlink to be added for final publication] gives details of the methods and the evidence used to develop the 2015 recommendations.

Diagnosis and management of irritable bowel syndrome (IBS) can be frustrating, both for people presenting with IBS symptoms and for clinicians. Both parties need to understand the limitations of current knowledge about IBS and to recognise the chronic nature of the condition.

1.1 Diagnosis of IBS

Confirming a diagnosis of IBS is a crucial part of this guideline. The primary aim should be to establish the person's symptom profile, with abdominal pain or discomfort being a key symptom. It is also necessary to establish the quantity and quality of the pain or discomfort, and to identify its site (which can be anywhere in the abdomen) and whether this varies. This distinguishes IBS from cancer-related pain, which typically has a fixed site.

When establishing bowel habit, showing people the Bristol Stool Form Scale (see appendix I of the full guideline) may help them with description, particularly when determining quality and quantity of stool. People presenting with IBS symptoms commonly report incomplete evacuation/rectal hypersensitivity, as well as urgency, which is increased in diarrhoeapredominant IBS. About 20% of people experiencing faecal incontinence disclose their incontinence only if asked. People who present with symptoms of IBS should be asked open questions to establish the presence of such symptoms (for example, 'tell me about how your symptoms affect aspects of your daily life, such as leaving the house'). Healthcare professionals should be sensitive to the cultural, ethnic and communication needs of people for whom English is not a first language or who may have cognitive and/or behavioural problems or disabilities. These factors should be taken into

consideration to facilitate effective consultation.

1.1.1 Initial assessment

- 1.1.1.1 Healthcare professionals should consider assessment for IBS if the person reports having had any of the following symptoms for at least 6 months:
 - Abdominal pain or discomfort
 - Bloating
 - Change in bowel habit. [2008]
- 1.1.1.2 All people presenting with possible IBS symptoms should be asked if they have any of the following 'red flag' indicators and should be referred to secondary care for further investigation if any are present:⁴
 - unintentional and unexplained weight loss
 - rectal bleeding
 - a family history of bowel or ovarian cancer
 - a change in bowel habit to looser and/or more frequent stools persisting for more than 6 weeks in a person aged over 60 years. [2008]
- 1.1.1.3 All people presenting with possible IBS symptoms should be assessed and clinically examined for the following 'red flag' indicators and should be referred to secondary care for further investigation if any are present:⁴
 - anaemia
 - abdominal masses
 - rectal masses
 - inflammatory markers for inflammatory bowel disease.

⁴ See NICE's <u>referral guidelines for suspected cancer</u> for detailed referral criteria where cancer is suspected.

Measure serum CA125 in primary care in women with symptoms that suggest ovarian cancer in line with the NICE guideline on ovarian cancer.⁵ [2008]

- 1.1.1.4 A diagnosis of IBS should be considered only if the person has abdominal pain or discomfort that is either relieved by defaecation or associated with altered bowel frequency or stool form. This should be accompanied by at least two of the following four symptoms:
 - altered stool passage (straining, urgency, incomplete evacuation)
 - abdominal bloating (more common in women than men), distension, tension or hardness
 - symptoms made worse by eating
 - passage of mucus.

Other features such as lethargy, nausea, backache and bladder symptoms are common in people with IBS, and may be used to support the diagnosis. **[2008]**

1.1.2 Diagnostic tests

- 1.1.2.1 In people who meet the IBS diagnostic criteria, the following tests should be undertaken to exclude other diagnoses:
 - full blood count (FBC)
 - erythrocyte sedimentation rate (ESR) or plasma viscosity
 - c-reactive protein (CRP)
 - antibody testing for coeliac disease (endomysial antibodies [EMA] or tissue transglutaminase [TTG]). [2008]
- 1.1.2.2 The following tests are not necessary to confirm diagnosis in people who meet the IBS diagnostic criteria:

⁵ This recommendation was updated in September 2012 in line with more recent guidance on the recognition and management of ovarian cancer in the NICE guideline on <u>ovarian cancer</u>.

- ultrasound
- rigid/flexible sigmoidoscopy
- colonoscopy; barium enema
- thyroid function test
- faecal ova and parasite test
- faecal occult blood
- hydrogen breath test (for lactose intolerance and bacterial overgrowth). [2008]

1.2 Clinical management of IBS

1.2.1 Dietary and lifestyle advice

- 1.2.1.1 People with IBS should be given information that explains the importance of self-help in effectively managing their IBS. This should include information on general lifestyle, physical activity, diet and symptom-targeted medication. [2008]
- 1.2.1.2 Healthcare professionals should encourage people with IBS to identify and make the most of their available leisure time and to create relaxation time. [2008]
- 1.2.1.3 Healthcare professionals should assess the physical activity levels of people with IBS, ideally using the General Practice Physical Activity Questionnaire (GPPAQ; see appendix J of the full guideline). People with low activity levels should be given brief advice and counselling to encourage them to increase their activity levels. [2008]
- 1.2.1.4 Diet and nutrition should be assessed for people with IBS and the following general advice given.
 - Have regular meals and take time to eat.
 - Avoid missing meals or leaving long gaps between eating.
 - Drink at least eight cups of fluid per day, especially water or other non-caffeinated drinks, for example herbal teas.

- Restrict tea and coffee to three cups per day.
- Reduce intake of alcohol and fizzy drinks.
- It may be helpful to limit intake of high-fibre food (such as wholemeal or high-fibre flour and breads, cereals high in bran, and whole grains such as brown rice).
- Reduce intake of 'resistant starch' (starch that resists digestion in the small intestine and reaches the colon intact), which is often found in processed or re-cooked foods.
- Limit fresh fruit to three portions per day (a portion should be approximately 80 g).
- People with diarrhoea should avoid sorbitol, an artificial sweetener found in sugar-free sweets (including chewing gum) and drinks, and in some diabetic and slimming products.
- People with wind and bloating may find it helpful to eat oats (such as oat-based breakfast cereal or porridge) and linseeds (up to one tablespoon per day). [2008]
- 1.2.1.5 Healthcare professionals should review the fibre intake of people with IBS, adjusting (usually reducing) it while monitoring the effect on symptoms. People with IBS should be discouraged from eating insoluble fibre (for example, bran). If an increase in dietary fibre is advised, it should be soluble fibre such as ispaghula powder or foods high in soluble fibre (for example, oats). [2008]
- 1.2.1.6 People with IBS who choose to try probiotics should be advised to take the product for at least 4 weeks while monitoring the effect. Probiotics should be taken at the dose recommended by the manufacturer. [2008]
- 1.2.1.7 Healthcare professionals should discourage the use of aloe vera in the treatment of IBS. [2008]
- 1.2.1.8 If a person's IBS symptoms persist while following general lifestyle and dietary advice, offer advice on further dietary management.
 Such advice should:

Irritable bowel syndrome in adults: NICE guideline DRAFT (October 2014) Page 16 of 36

- include single food avoidance and exclusion diets (for example, a low FODMAP [fermentable oligosaccharides, disaccharides, monosaccharides and polyols] diet)
- only be given by a healthcare professional with expertise in dietary management.⁶ [new 2015]

1.2.2 Pharmacological therapy

Decisions about pharmacological management should be based on the nature and severity of symptoms. The recommendations made below assume that the choice of single or combination medication is determined by the predominant symptom(s).

- 1.2.2.1 Healthcare professionals should consider prescribing antispasmodic agents for people with IBS. These should be taken as required, alongside dietary and lifestyle advice. **[2008]**
- 1.2.2.2 Laxatives should be considered for the treatment of constipation in people with IBS, but people should be discouraged from taking lactulose. [2008]
- 1.2.2.3 Consider linaclotide for people with IBS only if:
 - they have had severe constipation for at least 12 months and
 - optimal or maximum tolerated doses of previous laxatives from different classes have not helped. [new 2015]
- 1.2.2.4 Loperamide should be the first choice of antimotility agent for diarrhoea in people with IBS. **[2008]**
- 1.2.2.5 People with IBS should be advised how to adjust their doses of laxative or antimotility agent according to the clinical response. The dose should be titrated according to stool consistency, with the aim of achieving a soft, well-formed stool (corresponding to Bristol Stool Form Scale type 4). **[2008]**

⁶ This recommendation has been updated. However, only the low FODMAP diet was included in the evidence review. The shaded text was not reviewed for this update and so we will not be able to accept comments on this.

- 1.2.2.6 Consider tricyclic antidepressants (TCAs) as second-line treatment for people with IBS if laxatives, loperamide or antispasmodics have not helped. Start treatment at a low dose (5–10 mg equivalent of amitriptyline), taken once at night and review regularly. Increase the dose if needed, but not usually beyond 30 mg.⁷ [**2015**]
- 1.2.2.7 Consider selective serotonin reuptake inhibitors (SSRIs) for people with IBS only if TCAs are ineffective.⁷ [2015]
- 1.2.2.8 Take into account the possible side effects when offering TCAs or SSRIs to people with IBS. Follow up people taking either of these drugs for the first time at low doses for the treatment of pain or discomfort in IBS after 4 weeks and then every 6–12 months.⁷
 [2015]

1.2.3 Psychological interventions

1.2.3.1 Referral for psychological interventions (cognitive behavioural therapy [CBT], hypnotherapy and/or psychological therapy) should be considered for people with IBS who do not respond to pharmacological treatments after 12 months and who develop a continuing symptom profile (described as refractory IBS). [2008]

1.2.4 Complementary and alternative medicine (CAM)

- 1.2.4.1 The use of acupuncture should not be encouraged for the treatment of IBS. [2008]
- 1.2.4.2 The use of reflexology should not be encouraged for the treatment of IBS. [2008]

⁷ At the time of consultation on the guideline update (October 2014), TCAs and SSRIs did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's <u>Good practice in prescribing and managing medicines and devices</u> for further information.

1.2.5 Follow-up

1.2.5.1 Follow-up should be agreed between the healthcare professional and the person with IBS, based on the response of the person's symptoms to interventions. This should form part of the annual patient review. The emergence of any 'red flag' symptoms during management and follow-up should prompt further investigation and/or referral to secondary care. **[2008]**

2 Research recommendations

In 2008, the Guideline Development Group made the following recommendations for research, based on its review of evidence, to improve NICE guidance and patient care in the future.

As part of the 2015 update, the Committee made 3 additional research recommendations on the clinical and cost effectiveness of a low FODMAP diet, low-dose TCAs and SSRIs in primary care, and computerised CBT and mindfulness therapy. These can be found in the <u>addendum</u> [hyperlink to be added for final publication].

2.1 Low-dose antidepressants

Are low-dose TCAs, SSRIs and serotonin and norepinephrine reuptake inhibitors (SNRIs) effective as first-line treatment for IBS, and which is the most effective and safe option?

Why this is important

Reviews have shown that TCAs and SSRIs have each been compared with placebo in the treatment of IBS, but not at low doses. In practice, TCAs are used at higher doses, and concordance with treatment is poor because of side effects. The Guideline Development Group clinicians believe that at low doses (5–10 mg equivalent of amitriptyline), TCAs could be the treatment of choice for IBS, but there is a lack of evidence to support this. A newer type of antidepressant, SNRIs, may also be useful in the treatment of IBS-associated pain. A large randomised trial is proposed, comparing an SSRI, a TCA and an

SNRI with placebo. Participants should be adults with a positive diagnosis of IBS, stratified by type of IBS and randomised to treatments. The type of IBS is defined by the predominant bowel symptom: diarrhoea, constipation or alternating symptoms. The primary outcome should be global improvement in IBS symptoms. Health-related quality of life should also be measured, and adverse effects recorded. Study outcomes should be assessed 12, 26 and 52 weeks after the start of therapy.

2.2 Psychological interventions

Are the psychological interventions CBT, hypnotherapy and psychological therapy all equally effective in the management of IBS symptoms, either as first-line therapies in primary care, or in the treatment of people with IBS that is refractory to other treatments?

Why this is important

Reviews show some evidence of effect when comparing psychological interventions with a control group, with the greatest effect shown in people who have refractory IBS. Many trials are small in size. Certain psychological interventions – namely, CBT, hypnotherapy and psychological therapy – are thought to be useful in helping people with IBS to cope with their symptoms, but it is unclear at what stage these should be given, including whether they should be used as first-line therapies in primary care. A large randomised trial is proposed, comparing CBT, hypnotherapy and psychological therapy (in particular, psychodynamic interpersonal therapy). Participants should be adults with a positive diagnosis of IBS, and they should be stratified into those with and without refractory IBS and then randomised to treatments. The primary outcome should be global improvement in IBS symptoms. Health-related quality of life should also be measured, and adverse effects recorded. Study outcomes should be assessed 12, 26 and 52 weeks after the start of therapy.

2.3 Refractory IBS

What factors contribute to refractory IBS?

Why this is important

Most people with IBS experience symptoms that are relatively short-lived or that only trouble them on an intermittent basis. Some people, however, develop chronic and severe symptoms that are difficult to treat. There are relatively few prospective studies that have investigated this problem.

A large, prospective, population-based cohort study is proposed, which would evaluate people in the community with IBS symptoms according to measures of bowel symptomatology, physical symptom profile, psychological symptoms, childhood adversity, psychiatric history, social supports, quality of life and other relevant potential predictors. Participants would be re-evaluated 12 and 24 months later using similar measures. Baseline variables would be used to predict chronicity of symptoms, quality of life and healthcare utilisation at 12 and 24 months.

2.4 Relaxation and biofeedback

What is the effect of relaxation and biofeedback therapies on IBS symptoms and patient-related outcomes?

Why this is important

Reviews of biofeedback and relaxation therapies suggest a positive effect on the control of IBS symptoms, but evidence is limited and not sufficient to make recommendations. Patient representation in the Guideline Development Group supports this view, from a personal and anecdotal perspective.

Recent developments in computer-aided biofeedback methods merit investigation. A large randomised trial is proposed to compare relaxation therapy, computer-aided biofeedback therapy and attention control in primary care. Participants should be adults with a positive diagnosis of IBS, and they should be stratified into those with and without refractory IBS and then randomised to treatments. The primary outcome should be global improvement in IBS symptoms. Health-related quality of life should also be measured, and adverse effects recorded. Study outcomes should be

assessed 12, 26 and 52 weeks after the start of therapy. Qualitative data should be generated relating to how people with IBS perceive their condition.

2.5 Herbal medicines

Are Chinese and non-Chinese herbal medicines safe and effective as first-line therapy in the treatment of IBS, and which is the most effective and safe option?

Why this is important

Reviews of herbal medicines suggest a positive effect on the control of IBS symptoms, but evidence is limited and not sufficient to make recommendations (eight comparisons from the six trials provide heterogeneous data, which are very difficult to interpret). A large randomised placebo-controlled trial is proposed, comparing Chinese and non-Chinese herbal medicines (both single and multiple compounds) that are available in the UK as standard preparations. Participants should be adults with a positive diagnosis of IBS, and they should be stratified by type of IBS and then randomised to treatments. The primary outcome should be global improvement in IBS symptoms, with symptom scores recorded using a validated scale. Health-related quality of life should also be measured, and adverse events recorded. Study outcomes should be assessed 12, 26 and 52 weeks post-intervention.

3 Other information

3.1 Scope and how this guideline was developed

The <u>scope</u> for the 2008 guideline covers the recommendations labelled **[2008]**. The recommendations labelled **[2015]** have been produced during the update.

The guideline covers adults (18 years and older) who present to primary care with symptoms suggestive of IBS, and the care that is provided by primary healthcare professionals, indicating where secondary care referral is appropriate. It does not cover:

- people with other gastrointestinal disorders such as non-ulcer dyspepsia or coeliac disease
- children and young people under 18 years
- inflammatory bowel disease.

How this guideline was developed

The 2008 guideline was developed by the National Collaborating Centre for Nursing and Supportive Care, which is based at the Royal College of Nursing. The Collaborating Centre worked with a Guideline Development Group, comprising healthcare professionals (including consultants, GPs and nurses), patients and carers, and technical staff, which reviewed the evidence and drafted the recommendations. The recommendations were finalised after public consultation.

NICE's Clinical Guidelines Update Programme updated this guideline in 2015. This guideline was updated using a Committee of healthcare professionals, methodologists and lay members from a range of disciplines and localities, as well as topic experts.

The methods and processes for developing NICE clinical guidelines can be found <u>here</u>.

3.2 Related NICE guidance

Details are correct at the time of consultation on the guideline (October 2014). Further information is available on <u>the NICE website</u>.

Published

General

- Patient experience in adult NHS services (2012) NICE guideline CG138
- Medicines adherence (2009) NICE guideline CG76

Condition-specific

- Irritable bowel syndrome with constipation in adults: linaclotide (2013) NICE advice ESNM16
- <u>Bile acid malabsorption: colesevelam</u> (2013) NICE advice ESUOM22
- <u>Faecal calprotectin diagnostic tests for inflammatory diseases of the bowel</u> (2013) NICE diagnostics guidance 11
- <u>Physical activity: brief advice for adults in primary care</u> (2013) NICE guideline PH44
- SeHCAT (tauroselcholic [75 selenium] acid) for the investigation of diarrhoea due to bile acid malabsorption in people with diarrhoeapredominant irritable bowel syndrome (IBS-D) or Crohn's disease without ileal resection (2012) NICE diagnostics guidance 7
- <u>Colonoscopic surveillance for prevention of colorectal cancer in people with</u> <u>ulcerative colitis, Crohn's disease or adenomas</u> (2011) NICE guideline CG118
- Prucalopride for the treatment of chronic constipation in women (2010)
 NICE technology appraisal guidance 211
- Depression in adults (2009) NICE guideline CG90
- Faecal incontinence (2007) NICE guideline CG49
- <u>Physical activity</u> (2006) NICE guideline PH2
- Referral guidelines for suspected cancer (2005) NICE guideline CG27

4 Committee members and NICE staff

4.1 Committee members

The Committee members listed are those for the 2015 update. For the composition of the previous Guideline Development Group, see the <u>full</u> <u>guideline</u>.

Standing Committee A members

Catherine Briggs

GP Principal, Bracondale Medical Centre, Stockport

John Cape

Director of Psychological Therapies Programme, University College London

Alun Davies

Professor of Vascular Surgery and Honorary Consultant Surgeon, Charing Cross and St Mary's Hospital and Imperial College NHS Trust

Alison Eastwood

Senior Research Fellow, Centre for Reviews and Dissemination, University of York

Sarah Fishburn

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Consultant Neonatologist, Staffordshire, Shropshire and Black Country Newborn Network, Royal Wolverhampton Hospitals Trust

Nick Screaton

Radiologist, Papworth Hospital NHS Foundation Trust

Lindsay Smith

Principal in General Medical Practice, Somerset PCT

Irritable bowel syndrome in adults: NICE guideline DRAFT (October 2014) Page 25 of 36

Philippa Williams

Lay member

Sophie Wilne

Paediatric Oncologist, Nottingham Children's Hospital

Topic-specific Committee members

Mark Follows

GP with a Special Interest in gastroenterology, St James' Medical Practice, Norfolk

Elspeth Guthrie

Professor of Psychological Medicine and Medical Psychotherapy, Manchester Royal Infirmary

Yvonne McKenzie

Dietician, specialist in Gastrointestinal Nutrition, Clinical Lead in IBS for the Gastroenterology Specialist Group of the British Dietetic Association

Marion Saunders

Lay member

Simon Smale

Consultant Gastroenterologist, York Hospitals NHS Foundation Trust

Peter Whorwell (non-voting topic-specific member)

Professor of Medicine and Gastroenterology, University Hospital of South Manchester

4.2 Clinical Guidelines Update Team

Phil Alderson Clinical Adviser

Emma Banks Co-ordinator

Paul Crosland Health Economist

Nicole Elliott Associate Director

Cheryl Hookway Technical Analyst

Jenny Kendrick Information Scientist

Susannah Moon Programme Manager

Rebecca Parsons Project Manager

Charlotte Purves Administrator

Toni Tan Technical Adviser

4.3 NICE project team

Mark Baker Clinical Lead

Christine Carson

Guideline Lead

Barbara Meredith (until September 2014)

Public Involvement Adviser

Katie Prickett Editor

Beth Shaw Technical Lead

Louise Shires Guideline Commissioning Manager

Lyndsey Unwin Communications Lead

Jennifer Wells Guideline Coordinator

Erin Whittingham (from September 2014)

Public Involvement Adviser

Katie Worrall

Implementation Lead

4.4 Declarations of interests

The following members of the Committee made declarations of interest. All other members of the Committee stated that they had no interests to declare.

Committee	Interest declared	Type of	Decision taken
member		interest	
Damien Longson	Family member employee of NICE	Personal family non- specific	Declare and participate
Damien Longson	Director of Research and Innovation, Manchester Mental Health and Social Care NHS Trust	Personal non-specific pecuniary	Declare and participate
Catherine Briggs	Husband is a Consultant Anaesthetist at the University Hospital of South Manchester.	Personal family non- specific	Declare and participate
Catherine Briggs	Member of the Royal College of Surgeons, the Royal College of General Practitioners, the Faculty of Sexual and	Personal non-specific pecuniary	Declare and participate

John Cape	Reproductive Health and the British Medical Association. Trustee of the Anna Freud Centre, a child and family mental health charity which applies for and receives grants from the Department of Health and the National Institute for	Personal non-specific non- pecuniary	Declare and participate
John Cape	Health Research. Member of British Psychological Society and British Association for Behaviour and Cognitive Psychotherapists who seek to influence policy towards psychology and psychological therapies.	Personal non-specific non- pecuniary	Declare and participate
Alun Davies	Research grant funding: Commercial: Vascular Insights; Acergy Ltd; Firstkind; URGO laboratoire; Sapheon Inc (terminated 2013). All administered by Imperial College London as Sponsor and Professor Davies as CI.	Personal non-specific pecuniary	Declare and participate
Alun Davies	Non-commercial: National Institute for Health Research, British Heart Foundation, Royal College of Surgeons, Circulation foundation, European Venous Forum.	Personal non-specific pecuniary	Declare and participate
Alun Davies	Non-commercial: Attendance at numerous national and international meetings as an invited guest to lecture where the organising groups receive funding from numerous sources including device and pharmaceutical manufacturers. Organising groups pay expenses and	Personal non-specific pecuniary	Declare and participate

	occasionally honoraria – the exact source of funding is often not known.		
Alun Davies	Non-commercial: Received travel expenses to attend the Veith Meeting NY 2013 November to give lectures by Vascutek.	Personal non-specific pecuniary	Declare and participate
Alison Eastwood	Member of an independent academic team at Centre for Review and Dissemination, University of York commissioned by NICE through National Institute for Health Research to undertake technology assessment reviews.	Non-personal non-specific pecuniary	Declare and participate
Sarah Fishburn	Organises workshops for physiotherapists treating pelvic girdle pain. Paid for this work.	Personal non-specific pecuniary	Declare and participate
Sarah Fishburn	Receives payment and expenses from the Nursing and Midwifery Council as a lay panellist of the Fitness to Practise Investigating Committee.	Personal non-specific pecuniary	Declare and participate
Sarah Fishburn	Lay reviewer with the Local Supervising Authority auditing supervision of midwives – receives payment and expenses for this work.	Personal non-specific pecuniary	Declare and participate
Sarah Fishburn	Lay reviewer for the National Institute for Health Research; has reviewed a number of research proposals being considered for funding. Paid for carrying out these reviews.	Personal non-specific pecuniary	Declare and participate
Sarah Fishburn	Chair of the Pelvic Partnership, a support group for women with pregnancy-related pelvic	Personal non-specific pecuniary	Declare and participate

	girdle pain. This is a voluntary position.		
Sarah Fishburn	Trained as a chartered physiotherapist and qualified in 1988 but has not been in clinical practice since 1997. Remains a non-practicing member of the Chartered Society of Physiotherapy.	Personal non-specific pecuniary	Declare and participate
Sarah Fishburn	Recently appointed by Mott MacDonald to carry out reviews as a lay reviewer on behalf of the Nursing and Midwifery Council of local supervising authorities and universities providing courses for nurses and midwives. This is paid work.	Personal non-specific pecuniary	Declare and participate
Jim Gray	None		No action
Nuala Lucas	Member, Obstetric Anaesthetists' Association Executive Committee	Personal non-specific non- pecuniary	Declare and participate
Nuala Lucas	Member, NICE Intrapartum care Guideline Development Group	Personal non-specific non- pecuniary	Declare and participate
Nuala Lucas	Member, Editorial Board, International Journal of Obstetric Anesthesia	Personal non-specific non- pecuniary	Declare and participate
Kath Nuttall	None		No action
Tilly Pillay	None		No action
Nick Screaton	Attended Thorax meeting – travel expenses paid.	None specific personal pecuniary	No action
Lindsay Smith	None		No action
Philippa Williams	None		No action
Sophie Wilne	Recipient of NHS Innovation Challenge Award for clinical awareness campaign to reduce delays in	Personal non-specific non- pecuniary	Declare and participate

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	diagnosis of brain tumours in children and young adults. Award will be used to develop the campaign.		
Sophie Wilne	Co-investigator for Research for Patient Benefit grant to undertake systematic reviews in childhood brain tumours.	Personal non-specific non- pecuniary	Declare and participate
Sophie Wilne	Co-investigator for grant awards from charity to evaluate impact of brain tumour awareness campaign.	Personal non-specific non- pecuniary	Declare and participate
Sophie Wilne	Speaker at conferences to talk about TS – invited by Novartis – travel expenses only.	Personal non-specific non- pecuniary	Declare and participate
Sophie Wilne	Presented at educational meetings sponsored by drug companies – not paid for educational events.	Personal non-specific non- pecuniary	Declare and participate
Topic-	Interest declared	Type of	Decision
specific member		interest	Decision
-	None		No action
member			
member Mark Follows Elspeth	None		No action

	recommendations on FODMAPs, currently pre draft stage. Will go out for full peer review, likely to be in early 2015. This review will be transferred to the Practice-based Evidence in Nutrition (PEN) database, a global dietetic resource for dietitians. Small amount of funding by PEN and honorarium will be received at the end. May gain funding to cover some of the personal time for writing up this guideline document. Travel, meeting refreshments and telephone expenses paid by the Gastroenterology Specialist Group.		
Yvonne McKenzie	Developing dietetic outcomes for IBS management. Travel, meeting refreshments and telephone expenses paid by the Gastroenterology Specialist Group.	Personal non- pecuniary	Declare and participate
Yvonne McKenzie	Developing an IBS key fact sheet that will provide guidance on the value of the role of the dietitian in IBS management, for GPs, therapy management, Clinical Commissioning Groups.	Personal non- pecuniary	Declare and participate
Yvonne McKenzie	Wrote a chapter on IBS for the Manual of Dietetic Practice. Published in June 2014 5 th Edition	Personal non- pecuniary	Declare and participate
Yvonne McKenzie	Presentation to be filmed 'Can probiotics help with IBS-type gut problems?' Yakult HCP study day at Royal College of Physicians. Stand alone paid educational work.	Personal non- pecuniary	Declare and participate

Yvonne McKenzie	Part of editorial panel for Dietetics Today, the British Dietetic Association's official magazine.	Personal non- pecuniary	Declare and participate
Yvonne McKenzie	Write articles on IBS for clinical dietetic practice and continuing professional development purposes (on FODMAPS – issued January 2013 and further article due October 2014)	Personal non- pecuniary	Declare and participate
Yvonne McKenzie	Planning to write further article to encourage dietitians who are British Dietetic Association members to have stronger leadership roles in gastroenterology, may include sections on supporting dietetic-led IBS management in the community	Personal non- pecuniary	Declare and participate
Marion Saunders	Patient member on the Psychological Therapies/Gastrointestinal advisory group at BUPA	Personal non- pecuniary	No action
Simon Smale	None		No action
Peter Whorwell (non-voting expert)	Advisory board member for Almirall	Specific personal non- pecuniary	Excluded from recommendation drafting part of Committee meeting. Required to leave for the laxatives question as Almirall are involved with linaclotide.
Peter Whorwell (non-voting expert)	Research grants from Almirall, Danone, Salix (published on hypnotherapy, acupuncture, probiotics)	Specific personal non- pecuniary	Required to leave for the laxatives question as Almirall are involved with

	linaclotide.

Appendix A: Recommendations from NICE guideline CG61 (2008) that have been changed

Changes to recommendation wording for clarification only (no change to meaning)

Recommendation numbers in current guideline	Comment
1.2.2.6 1.2.2.7 1.2.2.8	Recommendations have been edited into the direct style (in line with current NICE style for recommendations in clinical guidelines) where possible. Yellow highlighting has not been applied to these changes.