NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guideline scope

Myalgic encephalomyelitis (or encephalopathy)/chronic fatigue syndrome: diagnosis and management

The Department of Health and Social Care in England has asked NICE to develop guidance on diagnosing and managing myalgic encephalomyelitis (or encephalopathy)/chronic fatigue syndrome (ME/CFS).

The guideline will be developed using the methods and processes outlined in developing NICE guidelines: the manual.

This guideline will replace the NICE guideline on chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy) (CG53).

1 Why the guideline is needed

This guideline scope uses the term 'ME/CFS' but this is one of a number of names that have been used to describe this illness. It is recognised that there are people who need care but who may not meet existing clinical or research criteria.

ME/CFS is a disabling and distressing illness characterised by extreme and debilitating fatigue, particularly after exertion. Clinically, ME/CFS is heterogeneous and multifactorial and people experience the illness differently. Common symptoms include chronic pain, disordered sleep, digestive problems and cognitive difficulties. For most people with ME/CFS, everyday life is severely disrupted and a complete recovery is unusual, although this can vary depending on the age of onset.

The causes of ME/CFS are unknown but there are thought to be many contributing factors. One commonly reported trigger is the onset of a viral
illness and post-viral malaise, although the reasons for this being a trigger for ME/CFS are not understood. The lack of understanding of the aetiology of the condition has contributed to a number of different symptom-based definitions being used in research and in clinical care. Ongoing research into the causes and pathological processes underlying the symptoms of ME/CFS includes examination of immune function, autonomic function, neuroendocrine disorders and gene expression.

The estimated minimum prevalence rate of ME/CFS in the UK was 0.2% for people meeting either the Centers for Disease Control and Prevention (CDC) or Canadian case definitions in a UK primary care cross-sectional study. People with ME/CFS report delays in diagnosis, and research has highlighted that many GPs lack the confidence and knowledge to diagnose and manage ME/CFS. However, a review of diagnoses at a referral centre found that 40% of people referred did not have CFS but had fatigue associated with another chronic disease; a primary sleep disorder; a psychological or psychiatric illness; or a cardiovascular disorder. In the same review, 5.2% of all the people referred did not have a clear cause identified to explain their fatigue.

People with ME/CFS have reported a lack of understanding among health and social care professionals about their illness and related problems. There are added issues for children, young people and their carers when illness makes school attendance difficult and families come to the attention of educational and social care services.

The previous NICE guideline (CG53) made recommendations on the use of cognitive behavioural therapy (CBT) and graded exercise therapy (GET). The evidence supporting these interventions has been challenged and some people with ME/CFS report being pressured to participate in exercise programmes, leading to a worsening of symptoms. There is therefore a need to review the evidence for these and other interventions.

2 Who the guideline is for

This guideline is for:
• All health and social care professionals including those working or providing input into educational and occupational health services
• Commissioners
• People with suspected or diagnosed ME/CFS, their families and carers and the public

It may also be relevant for:

• education services
• occupational health services
• voluntary sector organisations

NICE guidelines cover health and care in England. Decisions on how they apply in other UK countries are made by ministers in the Welsh Government, Scottish Government, and Northern Ireland Executive.

Equality considerations

NICE has carried out an equality impact assessment during scoping. The assessment:

• lists equality issues identified, and how they have been addressed
• explains why any groups are excluded from the scope.

The guideline will look at inequalities relating to ethnic origin.

3 What the guideline will cover

3.1 Who is the focus?

Groups that will be covered

• People with suspected or diagnosed ME/CFS
• Specific consideration will be given to:
  – children and young people
  – people with severe symptoms.
3.2 **Settings**

**Settings that will be covered**

All settings where NHS or social care is provided or commissioned, including health services related to education and occupational health.

3.3 **Activities, services or aspects of care**

**Key areas that will be covered**

We will look at evidence in the areas below when developing the guideline, but it may not be possible to make recommendations in all the areas.

1. Identification and assessment before diagnosis
2. Diagnosis of ME/CFS
3. Management of ME/CFS
4. Monitoring and review
5. Information, education and support for people with suspected and diagnosed ME/CFS, and their families and carers
6. Information, education and support for health and social care professionals.

Note that guideline recommendations for medicines will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a medicine’s summary of product characteristics to inform decisions made with individual patients.

**Areas that will not be covered**

1. The specific management of symptoms where NICE guidance already exists (see below for related NICE guidelines) and management is not expected to be different in ME/CFS

**Related NICE guidance**

**Published**

- Lyme disease (2018). NICE guideline NG95
• **Neuropathic pain in adults: pharmacological management in non-specialist settings** (2013). NICE guideline CG173

• **Headaches in over 12s: diagnosis and management** (2012). NICE guideline CG150

• **Common mental health problems: identification and pathways to care** (2011). NICE guideline CG123

• **Irritable bowel syndrome in adults: diagnosis and management** (2008). NICE guideline CG61

**In development**

• **Thyroid disease: assessment and management**. NICE guideline. Publication expected November 2019

• **Chronic pain: assessment and management**. NICE guideline. Publication expected January 2020

**NICE guidance that will be replaced by this guideline**

• **Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy): diagnosis and management** (2007) NICE guideline CG53

**NICE guidance about the experience of people using NHS services**

NICE has produced the following guidance on the experience of people using the NHS. This guideline will not include additional recommendations on these topics unless there are specific issues related to ME/CFS:

• **Medicines optimisation** (2015) NICE guideline NG5

• **Patient experience in adult NHS services** (2012) NICE guideline CG138

• **Service user experience in adult mental health** (2011) NICE guideline CG136

• **Medicines adherence** (2009) NICE guideline CG76

**3.4 Economic aspects**

We will take economic aspects into account when making recommendations.
We will develop an economic plan that states for each review question (or key area in the scope) whether economic considerations are relevant, and if so
whether this is an area that should be prioritised for economic modelling and analysis. We will review the economic evidence and carry out economic analyses, using an NHS and Personal Social Services perspective.

3.5 Key issues and draft questions

While writing this scope, we have identified the following key issues and draft question related to them:

1. Identification and assessment before diagnosis
   1.1 In whom should ME/CFS be suspected?
   1.2 What is the most clinically and cost effective method of assessing people with suspected ME/CFS?
   1.3 Can disability or assessment scales aid the identification of people with ME/CFS?
   1.4 What are the barriers and facilitators to the identification of ME/CFS?
   1.5 What are the precautionary management strategies that should be adopted before diagnosis?

2. Diagnosis of ME/CFS
   2.1 What tests are clinically and cost effective in making a diagnosis of ME/CFS?
   2.2 In people with suspected ME/CFS, what are the criteria used to establish a diagnosis?
   2.3 What are the barriers and facilitators to the diagnosis of ME/CFS?

3. Management of ME/CFS
   3.1 What is the clinical and cost effectiveness of pharmacological interventions for people with ME/CFS?
   3.2 What is the clinical and cost effectiveness of non-pharmacological interventions for people with ME/CFS?
   3.3 What is the clinical and cost effectiveness of self-management strategies for people with ME/CFS?
   3.4 In people with ME/CFS, what is the clinical and cost effectiveness of different models of multidisciplinary team care, including team composition?

4. Monitoring and review
4.1 What is the most clinically and cost effective method of monitoring people with ME/CFS?

4.2 What is the most clinically and cost effective method of reviewing people with ME/CFS?

4.3 What are the barriers and facilitators to the care of people with ME/CFS?

5 Information, education and support for people with suspected and diagnosed ME/CFS, and their families and carers

5.1 What information, education and support do people with ME/CFS and their families and carers need?

6 Information, education and support for health and social care professionals

6.1 What information, education and support do health and social care professionals who provide care for people with ME/CFS need?

3.6 **Main outcomes**

The main outcomes that may be considered when searching for and assessing the evidence are:

1 Quality of life (for example, EQ-5D, SF-36)

2 Pain

3 Fatigue

4 Physical and cognitive functioning (a person’s ability to do everyday tasks and activities)

5 Psychological wellbeing

6 Care needs

7 Sleep

4 **NICE Pathways**

When this guideline is published, we will update the NICE Pathway on ME/CFS. NICE Pathways bring together everything we have said on a topic in interactive flowcharts.
5 Further information

This is the draft scope for consultation with registered stakeholders. The consultation dates are 21 June to 19 July 2018.

The guideline is expected to be published in October 2020.

You can follow progress of the guideline.
https://www.nice.org.uk/guidance/indevelopment/gid-ng10091

Our website has information about how NICE guidelines are developed.