

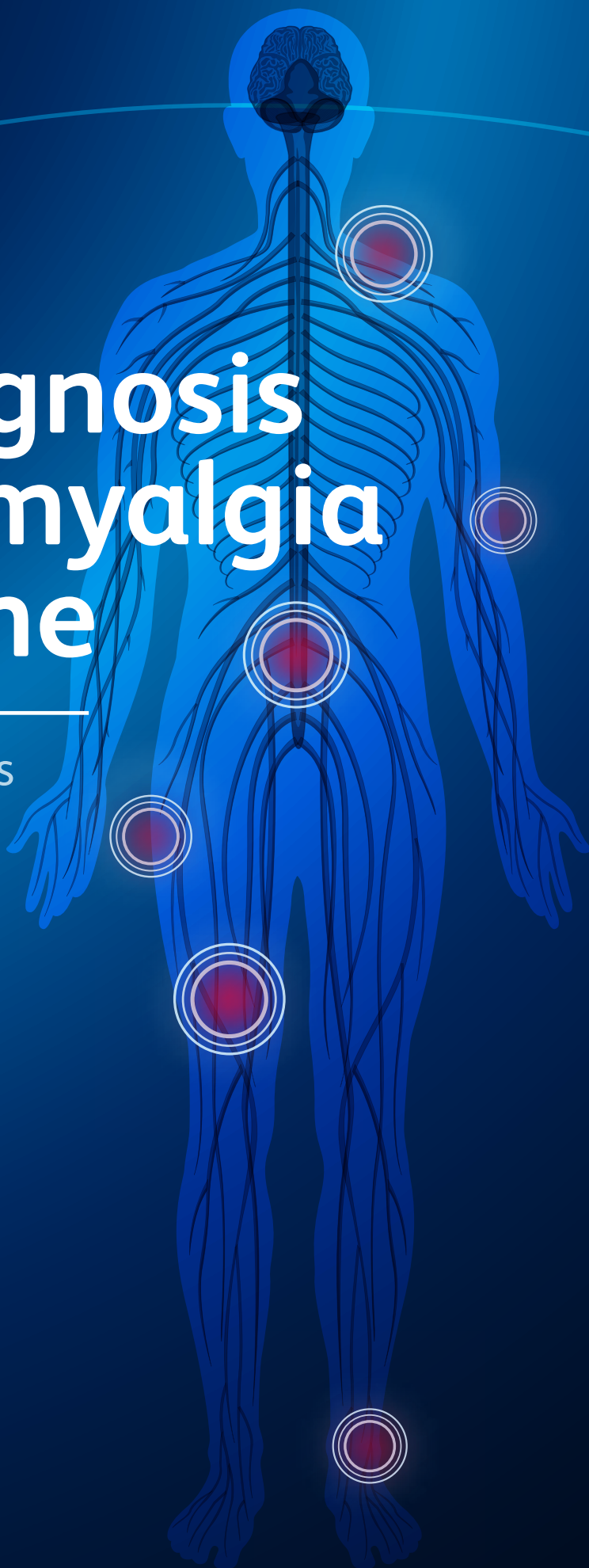


Royal College
of Physicians

The diagnosis of fibromyalgia syndrome

UK clinical guidelines

Consensus document from
a UK working party



The Royal College of Physicians

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Working party remit

The objective of this working party was to create a guideline for the diagnosis of fibromyalgia syndrome (FMS), particularly for clinicians who regularly encounter chronic pain presentations in their clinical practice. The guideline further aims to facilitate up to date understanding about this condition amongst clinicians and to provide tools allowing satisfactory patient information, leading to earlier diagnosis and better care. It is recognised that research in this field is rapidly advancing; this document reflects the best understanding in the UK currently (August 2021).

What the guideline covers

- > A brief overview of the current pathophysiological evidence in FMS
- > The diagnosis of FMS in the community and non-specialist setting
- > How to approach screening for other conditions
- > When a diagnosis is uncertain
- > Diagnosis in surgical practice
- > Patient and clinician information about FMS

Guideline Development Group

The multiprofessional Guideline Development Group (GDG) included representation from patients and carers of those with FMS, together with a wide range of stakeholders and professionals involved in the diagnosis and management of people with FMS.

GDG representation included those in community, secondary and tertiary care and those in academia. Some members of the GDG represented royal colleges or professional bodies.

The GDG engaged in preparatory work to define the scope of the document and met on one occasion. Further work and consultation were completed via telephone, email and virtually (partly determined by the COVID-19 outbreak).

The Royal College of Physicians provided a meeting room and refreshments. The Pain Relief Foundation supported the meeting with a restricted grant and booked travel and accommodation for those members of the GDG who needed it.

Members of the GDG

Fahim Anwar	British Society for Rehabilitation Medicine
Ased Ali	British Association of Urological Surgeons
Chris Barker	Royal College of General Practitioners and co-chair of the GDG
Anne Begley	British Association of Oral and Maxillofacial Surgeons
Richard Berwick	Trainee in pain medicine; systematic reviewer
Alison Bradshaw	Royal College of Occupational Therapists
Felicia Cox	Pain Nurse Network
Debra Dulake	Patient
Richard Dulake	Partner/carer
Mark Edwards	Association of British Neurologists
Marcia Glanvill	Patient
Andreas Goebel	Guideline lead and co-chair of the GDG
Nicholas Haden	Society of British Neurological Surgeons
Dharani Hapangama	Royal College of Obstetricians and Gynaecologists
Natalie Lane	British Psychological Society
Nadia Loftus	Chartered Society of Physiotherapy
Ann Lyons	Colorectal surgeon
Zoey Malpus	British Pain Society
Candy McCabe	Pain nursing/research
Andy Molloy	Foot and ankle surgeon
Robert Moots	British Society of Rheumatology
Donal O'Donoghue*	Royal College of Physicians
Francis O'Neill	British Association of Oral Surgeons
P Julian Owen	British Orthopaedic Association
Nick Phillips	Royal College of Surgeons
Helen Robinson	Patient
Martin Robinson	Partner/carer
Nick Shenker	British Society for Rheumatology Pain Interest Group
Manoj Sivan	British Society of Rehabilitation Medicine
Lynne Turner-Stokes	Northwick Park Professor of Rehabilitation Medicine, King's College London

*Professor Donal O'Donoghue was involved in the early stages of the guideline development until his death in January 2021. Dr Cathryn Edwards was appointed as RCP registrar in May 2021 and supported the review and final publication of the guidelines.

Administration

Hayley McCullough, Pain Research Institute, University of Liverpool.

Drafting the report

Dr Andreas Goebel (guideline lead and co-chair) and Dr Chris Barker (co-chair) were responsible for drafting the guideline. The members of the GDG contributed to the progress of the draft through various iterations.

Acknowledgements

The GDG authors would like to thank the participating patients/carers and professionals who kindly gave their time, insight and experience to the development of these guidelines.

Thanks to the Royal College of Physicians who provided a meeting venue and offered the support of their guideline development expertise and graphic design, the Pain Relief Foundation in Liverpool who provided support through administration and funding for the face-to-face meeting and publication.

Thank you also to the following individuals and organisations who generously offered advice and suggestions: Ernest Choy, Daniel Clauw, Gayathri Delanerolle, Mohammed Patel, Asim Suleman, John Wiles, Fibromyalgia Action UK.

Stakeholder organisations

These guidelines are endorsed by the following organisations:

British Association of Oral Surgeons
British Association of Oral and Maxillofacial Surgeons
British Association of Urological Surgeons
British Pain Society
British Orthopaedic Association
British Society of Rehabilitation Medicine
Chartered Society of Physiotherapists
Pain Nurse Network
Royal College of Obstetricians and Gynaecologists
Royal College of Occupational Therapists
Royal College of Surgeons
Society of British Neurological Surgeons



These guidelines have also been approved by the Association of British Neurologists and are also supported by the British Society for Rheumatology.

Methodology and guideline development process

The guidelines have been developed in accordance with the principles of the AGREE collaboration:

Scope and purpose

Overall objective of the guidelines

To inform clinicians who regularly encounter people with widespread persistent pain in their clinical practice, about:

- i) Fibromyalgia syndrome (FMS)
- ii) FMS recognition
- iii) FMS diagnosis
- iv) Recognition of differentials and multiple health conditions

The guideline also aims to provide easily digestible material to use in a consultation, both for the clinician and patient.

The patient group covered

Adults (16 years and over) with symptoms indicative of FMS.

Target audience

- > Clinicians
- > Patients and carers
- > Healthcare providers

Clinical areas covered

- > Aetiology of FMS
- > Assessment of pain
- > Factors raising the probability of FMS
- > Making a diagnosis of FMS
- > Considering and screening for alternate or concomitant diagnoses
- > Communicating knowledge around FMS

Stakeholder involvement

The GDG

The Guideline Development Group consisted of a multiprofessional group of patient/family representatives, primary, secondary and tertiary care clinicians, and academics.

Consultation

Members of the GDG circulated draft versions for comment to the organisations they represented; the GDG additionally invited a UK FMS patient organisation to comment, as well as additional clinicians and academics with significant involvement in the development of international guidelines for the management of FMS or in evidence-based medicine.

Funding and support

Central publishing and design support, a meeting room and general guideline development expertise was provided by the RCP. The Pain Relief Foundation provided a grant to cover travel and overnight accommodation expenses, administrative support pre-/post-meeting and other development costs.

Editorial independence

All members of the GDG declared any conflicts of interest.

Rigour of development

Evidence gathering

A formal systematic review was not undertaken for these guidelines as this was not considered suitable for the purpose (following the rationale outlined in Appendix 1 of [Spasticity in adults: management using botulinum toxin](#)) with two exceptions i) a systematic review on FMS diagnostic criteria was undertaken (See Appendix 3), and ii) a systematic review on perioperative management of FMS, and surgical outcomes in patients with FMS was initiated (see [Section 3](#) for details).

Review process

Evidence emerging from pertinent literature searches by GDG members was evaluated by the guideline lead and other members of the GDG using the National Service Framework (NSF) for Long Term Conditions typology.

Links between evidence and recommendations

NSF typology was used to describe and grade the evidence for each recommendation, and associated referenced articles (See Appendices 1 and 2)

Piloting and peer review

The penultimate draft of the guidelines were circulated to the endorsing/collaborating organisations. Feedback was considered and used to create the final guidance.

Quick reference resources

Single page information sheets for clinicians and patients/carers are included in Appendix 4 and also available to download separately from www.rcp.ac.uk/fibromyalgia-guidelines

Review date

These guidelines will be reviewed in 2027.

Foreword

Fibromyalgia syndrome (FMS) is common, with a worldwide prevalence of 2%.¹ Its nature has historically sometimes been misunderstood, or the condition even thought of as ‘not real’. Recent research has revealed important evidence for changes in central and peripheral nervous system functions and immunological activity. The International Classification of Diseases most recent iteration (ICD-11) includes fibromyalgia as a ‘third level diagnosis’ under the grouping MG30.01 – chronic widespread pain, which is a subgroup of chronic primary pain² (SNOMED code 203082005, Read code X75rx).

The diagnosis of FMS can be challenging; there are no known clinical laboratory investigations to confirm or refute its presence. Symptoms are commonly multiple, can fluctuate and may not easily sit within established medical diagnostic categories. It can often be difficult for patients to articulate their array of symptoms, and for both patients and healthcare professionals to fully make sense of the complexities of the condition. Due to these factors, patients may be diagnosed inaccurately with alternative conditions, only receive an FMS diagnosis after years of delay, or sometimes be inaccurately diagnosed with FMS.

These guidelines aim to support clinicians in the diagnosis of FMS. They are not intended to summarise the management of FMS or treatment pathways – other evidence-based guidelines are available to cover these areas. However, notably where conducted well, a consultation that leads to a diagnosis can have therapeutic and reassuring effects which should not be underestimated. These guidelines aim to provide succinct, relevant information for patients, relatives/carers and clinicians about what FMS is, and what it is not. The hope is that through better understanding, awareness of FMS will increase, enabling timely diagnosis and management.

The Guideline Development Group (GDG) took a pragmatic approach to evaluating the evidence. Literature searching, review and appraisal were conducted by expert GDG members familiar with pertinent outputs, and the evidence was assessed using National Service Framework (NSF) for Long Term conditions typology.³ Published diagnostic criteria for FMS, and evidence about perioperative care were systematically reviewed (see Appendices 1–3).

These guidelines are especially for patient-facing clinicians who are specialists in areas other than complex pain conditions. They neither aim to dictate the setting in which FMS should be diagnosed, nor who should make the diagnosis. Traditionally, rheumatologists have been involved in diagnosis, however, there is no need for this to be the case. Any diagnostician (eg GP or physiotherapist) is well-placed to consider a diagnosis of FMS. It is self-evident that such clinicians should not only understand how to interpret the diagnostic criteria, but also recognise when the pattern of symptoms suggests relevant coexisting or alternate medical pathology; this should not however preclude the appropriate diagnosis of FMS even when such conditions coexist.

The science of fibromyalgia is a rapidly developing landscape, and it can be challenging to keep a guideline current in such environments. It is hoped that this publication provides a foundation for best current practice; further iterations will be necessary as evidence develops.

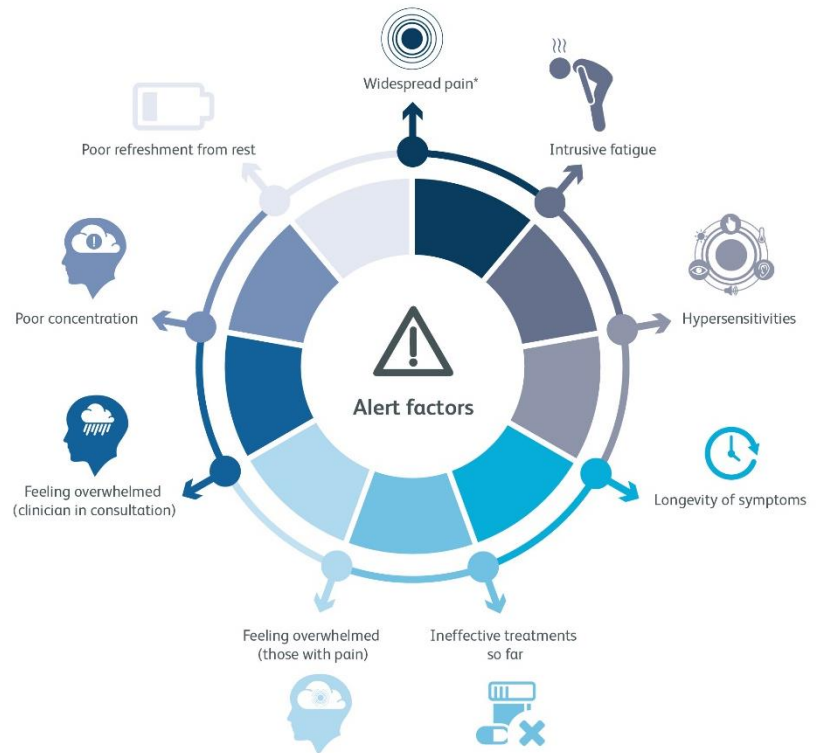
Dr Andreas Goebel, guideline lead and co-chair of the GDG
Dr Chris Barker, co-chair of the GDG

Executive summary

This diagnostic guideline aims to support clinicians when considering a diagnosis of fibromyalgia syndrome (FMS). In both highlighting potential symptoms that may indicate a diagnosis and guiding the clinician to interpret symptoms accurately, it is hoped this guideline will contribute to more timely diagnosis.

Be alert!

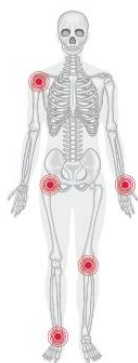
FMS symptoms are common and wide-ranging. When such symptoms are described, be curious and try to explore the presence of any other FMS-related symptoms.



*although only localised pain may be reported

Know pain types

All pains are painful! Not all pains mean damage or disease. Spending time understanding this can help choose the correct treatment or procedure. It may also prevent unnecessary treatments from taking place. FMS pain is 'nociplastic'.



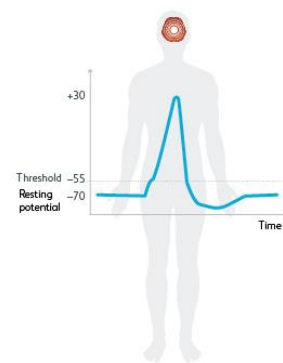
Nociceptive pain*

- > caused by harmful stimuli which activate pain receptors, eg osteoarthritis
- > may be alleviated by conventional treatments, eg medicines, or surgery to repair the damage



Neuropathic pain*

- > caused by a lesion or disease directly affecting the body's pain-sensing nerves, eg carpal tunnel syndrome, disc prolapse
- > may sometimes be alleviated by medicines or surgery, eg nerve decompression

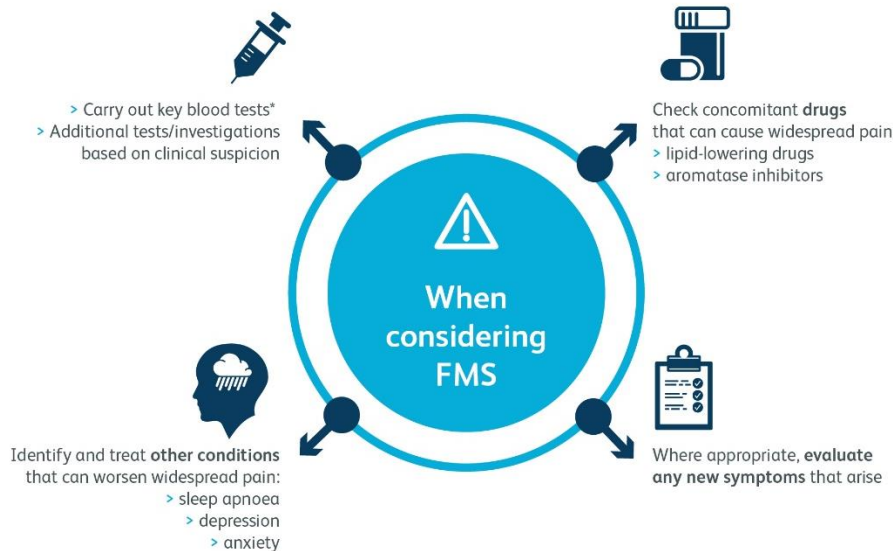


Nociplastic pain*

- > caused by a disturbance in peripheral and/or central nervous system pain processing, eg fibromyalgia
- > cannot be alleviated by surgery

* Note that in some patients experiencing more than one type of pain, it is unknown whether medical or surgical treatment of nociceptive or neuropathic pain associated with lesions has any effect on nociplastic pain. More research is needed, and MDT assessment will be useful in this situation.

Know how to exclude other conditions



* Blood tests should include: full blood count, erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP), creatine kinase (CK), liver function tests (LFT), thyroid stimulating hormone (TSH), glucose, urea and electrolytes (U&Es).

FMS is not a diagnosis of exclusion. Other conditions can present with some symptoms similar to FMS. FMS can also coexist with other established medical conditions (eg rheumatoid arthritis, depression etc.)

The diagnostician's role will be to navigate these symptoms and investigate where appropriate.

Use diagnostic criteria

The American College of Rheumatologists (ACR) 2016 diagnostic criteria can help clinicians decide more accurately whether to diagnose FMS.

[Fig 4](#) has more information on the ACR diagnostic criteria and a scoring tool for calculating pain using a widespread pain index and symptom severity scale.

Share resources and refer for uncertainties

Many evidence-based resources exist to help make sense of FMS symptoms. Know where and how to access these (see [Appendix 5](#)). They can also be used in the consultation to inform discussion and start conversation regarding constructing a management plan.

FMS symptoms may be equivocal, especially in the presence of multiple health conditions or when other conditions are considered diagnostically. Know when and where to refer for help.

Section 1: Fibromyalgia syndrome

1.1 What is fibromyalgia syndrome?

Fibromyalgia syndrome (FMS) is a condition characterised by persistent and widespread pain that is associated with intrusive fatigue, sleep disturbance, impaired cognitive and physical function and psychological distress. It is classified in the International Classification of Diseases ICD-11 as Chronic Primary Pain.^{2*} FMS has previously been called *fibrositis*, or *fibromyositis*. It has long been accepted that these names are inaccurate as they imply inflammatory activity within muscle as the primary cause of pain. Advances in research have shown that the predominant mechanism for pain is changes in pain processing that occur within the nervous system.⁴

1.2 What FMS is not

FMS is not^{5,6}

- > a condition caused by a tendency to experience psychological distress as pain ('somatisation')
- > driven by inflammation within muscles and/or joints
- > a reflection of poor coping†
- > a maladaptive reaction to trauma or distress
- > deconditioning or poor fitness
- > 'all in the head'.

1.3 Current evidence regarding the aetiology of FMS

Central nervous system sensitisation

Although the precise cause of FMS remains unknown, the central issue is proposed to be abnormal pain processing within the nervous system.⁷ Pain processing is complex and multiple components of the nervous system are involved. The exact mechanisms are unclear. Functional MR brain imaging studies comparing healthy individuals to those with FMS have shown similarity in pain-related brain activity; differences however occur in response to pressure-pain thresholds. Those with FMS experience pain from innocuous pressure and this is reflected in increased pain-related activity in the brain.⁸ Hypersensitivity (termed 'central and peripheral sensitisation') of the nervous system to external stimuli can explain many of the sensory symptoms associated with FMS.

Peripheral nervous system sensitisation

Recent studies have also shown that the peripheral nervous system may be affected in FMS, including as a result of immune effects,⁹ although to date the number of available studies that have investigated this is relatively small. Small pain nerve fibres in FMS display abnormal electrical signalling to standard stimuli¹⁰ and often their number in the skin is reduced.¹¹

Distress

There is good evidence that experiencing a stressful life-course or life events such as major physical or psychological trauma, increases the risk of developing FMS. The mechanisms by which severe

* Chronic primary pain is pain in one or more anatomic regions that persists or recurs for longer than 3 months and is associated with significant emotional distress or significant functional disability (interference with activities of daily life and participation in social roles) and that cannot be better explained by another chronic pain condition.

† FMS is sometimes compounded by poor pain management skills requiring appropriate treatment (see [Section 2.5](#) on clinical management).

distress triggers persistent symptoms are as yet unknown. However, while this may be important for some patients, many develop FMS without experiencing such triggers.¹²

Genetics

FMS can run in families and it is likely that variants of people’s genetic information increase the risk of developing the condition.¹³

1.4 The biopsychosocial assessment of pain

The term ‘biopsychosocial’¹⁴ refers to the understanding of biological, psychological, and social manifestations of a condition (in this case, pain) and their interactions. Given the multidimensional nature of pain, it has been recognised in many guidelines and publications that the full assessment of pain requires a biopsychosocial approach.¹⁵ To accomplish this, a knowledge of these key areas and allowing sufficient time to conduct such an assessment are required. The Faculty of Pain Medicine has produced further guidance on [conducting quality consultations](#).

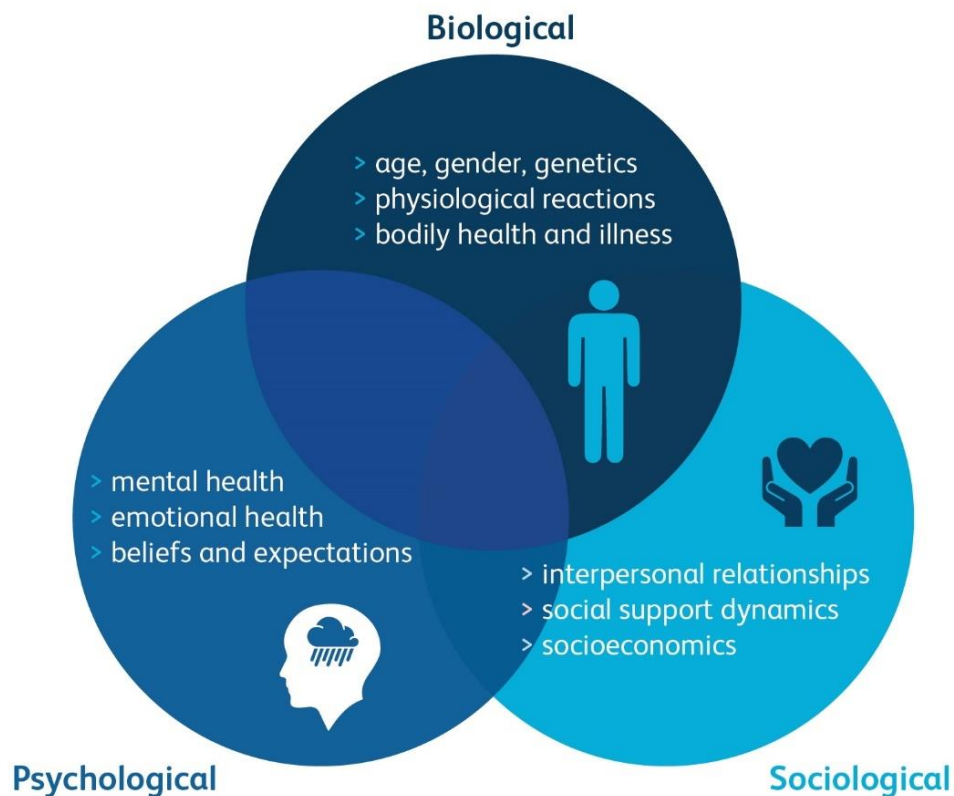


Fig 1. Biopsychosocial factors

Biological

Within the context of pain this is often considered to mean understanding diagnoses, disease processes or other biological functions that are responsible for the sensory elements of pain. This could mean for example, inflammation in an injured joint or altered neurological function in the peripheral or central nervous systems.

Psychological

There are many descriptions of how the human brain applies meaning to the sensory information it receives. Thoughts, feelings and previous experiences all influence the resultant sensory experience and, by the same token, unpleasant sensory input such as nociception[‡] will affect these psychological parameters.

Social

The social manifestations of pain are concerned with an individual's interactions with their family, social circle, work and wider society. For example, appropriate support from family and others can improve coping, reduce stress and enhance concordance with medical regimens.¹⁶ The experience of environmental stress can change the sensory biology, rendering peripheral nerves abnormally active and change the paths in which central neurons communicate with each other (central neuronal plasticity).¹⁷ Patients often report that they have changed their social interactions due to their pain.

[‡] Nociception: the neuronal processing of actually or potentially harmful stimuli; this is distinct from 'pain', which is the brain's conscious perception of such stimuli.

Section 2: The FMS diagnostic consultation

2.1 What factors should alert for the presence of FMS in the clinical consultation?

Certain key elements exist, which should alert the clinician (Box 1). In short consultations the opportunity for exploring wider information is limited, however, a brief enquiry about any of the following is informative:

Widespread pain: pain in multiple regions of the body

Patients with FMS **may not report** widespread pain and when asked about it may only report focal pain.¹⁸ It is therefore important to directly ask about the presence of pain elsewhere in the body (see Fig 4). There may be several reasons why patients do not describe widespread pain. It can be challenging to make sense of it. Patients may report their current *most prominent* regional pain. Or they may report regional pain which *appears to make sense*, such as back pain in the region of a known 'slipped disc'.

Recurrent consultations about regional pains may additionally hint at the presence of widespread pain.¹⁸

The use of a body chart either electronically or on paper can be useful in further understanding pain distribution (Fig 4).

Intrusive fatigue

This includes physical (reduced energy or exhaustion), cognitive (inability to concentrate, poor recall, 'fibro-fog') and emotional (reduced motivation) fatigue. These variants may be experienced simultaneously.¹⁹

Hypersensitivities

Increased sensitivity to sound, light or fluctuations in ambient temperature can represent changes in peripheral or central nervous system sensory processing.

Widespread tenderness on clinical examination and report of disproportional pain during or following hands-on physiotherapy may indicate abnormal mechanical hypersensitivity.

Longevity of symptoms

Pain that has been present or recurrent for longer than 3 months is considered 'chronic'⁵ or 'persistent'. This definition is well recognised internationally. It is consistent with normal tissue healing usually taking place within this time, but note FMS frequently arises without any tissue injury.

⁵ 'Chronic' as used here does not relate to symptom severity.

Ineffective treatments so far

Drug treatments for chronic primary pain are often ineffective, ** both in clinical trials and in the lived experience of those with FMS.²⁰

Rehabilitation focusing solely on manual therapy, including mobilisation or soft tissue techniques (for example massage) or vigorous exercises can be ineffective and may even increase pain.^{21,22}

Poor effect from pain medication and standard rehabilitative approaches can suggest that abnormal pain processing in the nervous system predominates, as opposed to structural, inflammatory, or psychological mechanisms.

Feeling overwhelmed (patients)

Multiple symptoms²³ and their consequences such as disability and/or distress can be difficult to understand and may lead to a patient feeling overwhelmed. This can be articulated in many ways. Clinicians should be mindful that such a complex presentation may represent FMS.

Feeling overwhelmed (clinicians)

Healthcare professionals often reflect on the interaction between themselves and their patient and how it makes them feel. It is not unusual for consultations to invoke feelings of being overwhelmed, even for the most experienced clinician. This can also be useful information in itself and point towards FMS.^{††}

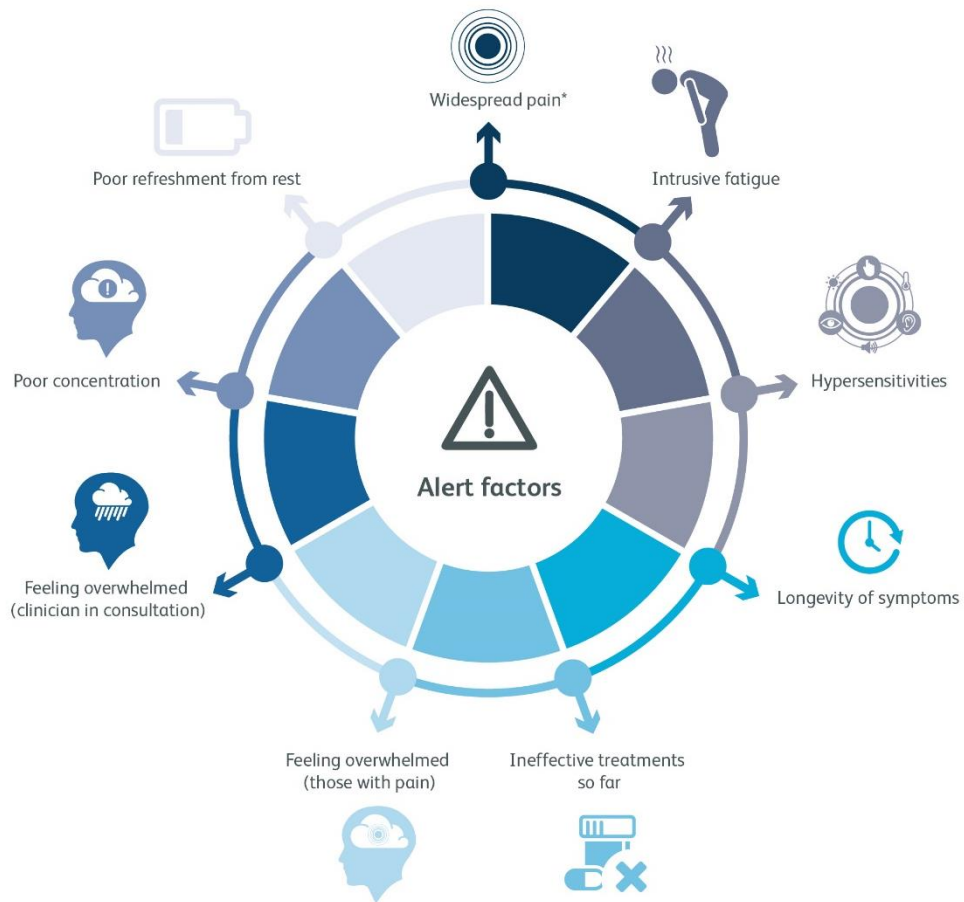
A two-question screening tool for use in consultations has been developed to identify those at risk of either developing or having complex pain such as FMS.^{‡‡}

** Some pain medications can be effective for weeks or months before tolerance develops and they become ineffective. Massages can sometimes be effective for short periods of time (minutes or hours), although vigorous exercise typically increases pain (for details see [Section 2.5 Clinical management](#)).

†† These are examples of symptoms that are commonly reported. Each of these symptoms can also suggest other diagnoses or the need for further investigation. In FMS the following symptoms can occur concomitantly: pain in upper abdomen, constipation, depression, insomnia, dizziness, numbness/tingling, pain/cramps in abdomen, headache, muscle weakness, thinking or remembering problems, fatigue/tiredness, muscle pain, nausea, nervousness, chest pain, blurred vision, fever, diarrhoea, dry mouth, itching, wheezing, hives/welts, ringing in ear, vomiting, heartburn, oral ulcers, loss/change in taste, seizures, dry eyes, shortness of breath, loss of appetite, rash, sun sensitivity, hearing difficulties, easy bruising, hair loss, frequent urination, painful urination, bladder spasms.²³

‡‡ [Ask2Questions](#):

- 1 Over the past 2 weeks has your pain been bad enough to interfere with your day-to-day activities?
- 2 Over the past 2 weeks have you felt worried or low in mood because of this pain?



*although only localised pain may be reported

Fig 2. Fibromyalgia syndrome alert factors

Box 1. FMS alert factors

Recommendation	Evidence
Clinicians should be alert to the possible presence of fibromyalgia syndrome if the following factors occur either in isolation or in combination:	
Widespread pain (although only regional pain may be reported) ^{23,24,26,27}	E1+E2, RA
Poor refreshment from sleep ^{23,24,25}	E1+E2, RA
Hypersensitivities ^{24,28,29}	E1+E2, RB
Intrusive fatigue ^{23,24,25,26}	E1+E2, RA
Pain longevity ^{23,24,25}	E1+E2, RA
Ineffective treatments so far	E2
Feeling overwhelmed (patients)	E2
Feeling overwhelmed (clinicians)	E2
Poor concentration and poor short-term memory	E2

Key for evidence evaluation: E1=user or carer opinion; E2=professional or stakeholder opinion; RA/RB/RC=research grading based on published evidence. For details see [Appendix 1](#).

Box 2: Conceptual shift from regional pain

Recommendation	Evidence
Healthcare professionals should be aware that patients presenting with <i>persistent or recurring regional pain</i> (eg spinal pain) may have coexisting pain in other areas.	E2
Healthcare professionals should recognise the challenge of <i>shifting focus</i> – from a regional structural abnormality to a widespread pain condition, where the patient’s pain may be more about how the nervous system has changed into a sensitised state. This change can also result in a normal stimulus (eg walking) now evoking pain.	E2

See [Appendix 1](#) for description of evidence evaluation.

2.2 Factors involved when making a diagnosis of FMS

Receiving a diagnosis of FMS can have a major impact on patients’ lives. The following factors are therefore relevant:

i) Who can diagnose FMS?

The responsibility for the diagnosis of FMS has moved away from the domain of a medical subspecialist except in cases of uncertainty (see also ‘diagnostic criteria’ in [Section 2.3](#)).

Box 3: Timing and communication of the FMS diagnosis

Recommendation	Evidence
Diagnosis of FMS should be made as early as possible for those patients who meet the diagnostic criteria.	E2
The diagnosis of FMS should be made by any clinician adequately experienced to make this diagnosis.	E1+E2
The diagnosis should be communicated to the patient and supported by written information, and/or links to websites etc.	E1+E2

See [Appendix 1](#) for description of evidence evaluation; and [Appendix 2](#) for rating of benefits, harms, costs and overall strength of recommendations.

ii) Setting the scene

Key points in the assessment of pain in the non-specialist setting:

Acknowledge your patient’s life situation

Chronic pain is a serious reality for most patients. They may previously have encountered lack of awareness and disbelief; unhelpful communications commonly encountered by FMS patients are summarised in Box 10c. Patients want reassurance that healthcare professionals are listening and understanding the breadth and relevance of their symptoms in a non-judgemental fashion.³⁰

Allow sufficient time

The complex symptoms of FMS may take more time than is available at a first appointment. In some settings, eg primary care, arranging a longer (or double) appointment or an agreed series of appointments with specific goals may be appropriate. In other settings, new referrals with the lead

symptom of chronic pain may routinely be given adequate time.^{§§} If there is no possibility to allow sufficient time for a diagnostic consultation, onward referral to a facility or clinic where this is possible will be necessary; the rationale for such referral should be explained.

Allow an in-person appointment (face-to-face is best)

Ideally, FMS should be diagnosed in a face-to-face consultation. Remote consultations may be appropriate.^{***} Important cues and information could be missed in audio-only consultations.

FMS should not be diagnosed solely using patient self-completed diagnostic forms (eg ACR diagnostic criteria self-completed).

Communication with patients

Examples of helpful and unhelpful communication phrases are provided in Box 10.

Box 4: Setting the scene when making the FMS diagnosis

Recommendation	Evidence
Acknowledge the patient’s life situation	E2
Allow sufficient time	E1+E2
Arrange additional appointments or refer where needed, and explain the arrangement	E2
Allow for a face-to-face diagnostic consultation if possible	E2

See [Appendix 1](#) for description of evidence evaluation; see [Appendix 2](#) for rating of benefits, harms, costs and overall strength of recommendations.

iii) Appreciate symptom fluctuation

The degree of widespread pain and other symptoms associated with FMS is a continuum,³¹ which is thought to relate to the degree of abnormal nervous system sensitisation. This continuum is best ranked using the ACR 2016 score (see [Section 2.3 Diagnosing fibromyalgia syndrome](#)).²⁵ Above threshold count qualifies for FMS diagnosis (Figs 3 and 4); however, lower counts can still indicate abnormal nervous system sensitisation.

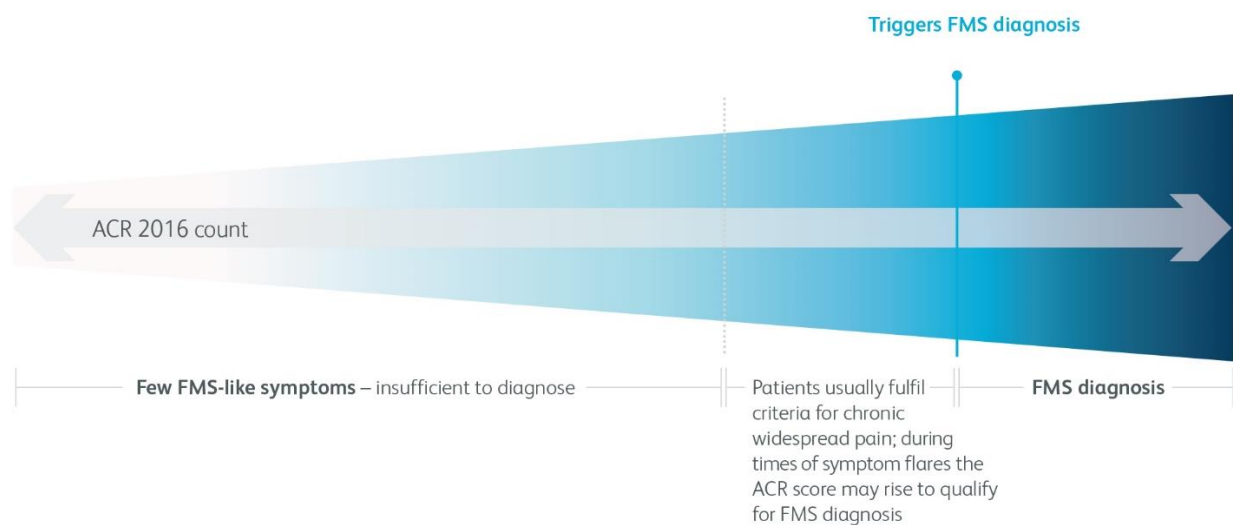


Fig 3. The trigger threshold for diagnosing fibromyalgia syndrome

§§ Cognitive symptoms and stress of getting to and from the appointment can compromise how patients present information, so that use of a 7–10 day diary where patients enter their symptoms may support high-quality assessment.

*** Guidance for arrangements during the COVID-19 pandemic is available from the [RCGP website](#)

The FMS diagnostic threshold is determined by the ACR 2016 count (Fig 3). As symptoms can vary over time, patients who have a count just below the threshold may cross the FMS diagnostic threshold at times of symptom flares. The position of the dotted line is arbitrary but crossing the diagnostic threshold during pain flares becomes less likely with lower ACR counts.

Patients' symptoms may fluctuate between above and below threshold counts. Furthermore, the distribution of pain and other symptoms can change from day to day, even with stable counts.

Patients can be puzzled and worried about their fluctuating symptoms. An open and clear discussion should take place to explain that fluctuating symptoms are typical for persistent pain conditions.

Most patients scoring below but close to the threshold will qualify for the alternative diagnosis of chronic widespread pain (CWP).³² Details of CWP are outside the scope of this document. While there is ongoing debate about CWP criteria, pragmatically, patients would have pain in at least three body quadrants (quadrants are upper-lower/left-right) and additionally 'axial pain' (either in the neck, back, chest or abdomen).²

iv) When a diagnosis is not certain

- > Reasons for diagnostic uncertainty may include:
 - symptoms just below the ACR diagnostic threshold; interpretation in the context of fluctuating symptoms can be challenging as there may be reports of 'above ACR diagnostic threshold' symptoms from recent assessments that are not present when the current assessment is made (see also Fig 3).
 - multiple health conditions (eg inflammatory conditions or depression) that may have an independent impact on the ACR widespread pain index or symptom severity score. In these cases, it is worth considering whether the coexisting condition(s) require optimisation for a more informed interpretation of FMS diagnostic symptoms (see [Section 2.4](#)).
- > Frequently symptoms evolve and it is appropriate to share any diagnostic dilemma with the patient, formulate a working diagnosis and apply a 'watchful waiting' strategy.³³
- > 'Safety netting' may be employed, which describes sharing important clinical symptoms or signs with the patient that may indicate alternate significant diagnoses.
- > Although a diagnosis of chronic widespread pain (CWP) is possible when widespread symptoms are below the ACR diagnostic threshold (Fig 3), in light of the fluctuating nature of both FMS and CWP, provision for reassessment should be made. Some patients may find the diagnosis of CWP less specific than the diagnosis of FMS, potentially causing frustration.
- > Sensitisation does not have temporal linearity, ie there is no evidence that sub-threshold symptoms will always progress to an FMS diagnosis.¹
- > Diagnostic uncertainty should not preclude agreeing a shared plan using the best evidence for the management of chronic widespread pain and any associated symptoms (see FMS management).

2.3 Diagnosing fibromyalgia syndrome

This section aims to support correct diagnosis. In consultation, patients may feel that they are fully being listened to for the first time. The diagnostic consultation can therefore have a therapeutic effect, which should not be underestimated.

Box 5: Use of the ACR checklist

Recommendation	Evidence
Diagnosing FMS should not become a tick-box exercise – the scoring tool provided in this section (Fig 4) should be used to ensure the validity of the FMS diagnosis ³⁴ , as an adjunct supporting the clinician’s consultation. ^{23,24,26,27,34}	E1+E2, RA
A diagnosis of FMS should not be made on self-completion of ACR criteria without a clinician present (either face-to-face or remotely) to provide reassurance and consider possible alternatives ^{23,25,27}	E1+E2, RA

See [Appendix 1](#) for description of evidence evaluation.

Diagnostic criteria

Over the past 30 years, various iterations of FMS diagnostic criteria have been developed. The consensus of the GDG is that the best evidence-based guideline is the American College of Rheumatologists (ACR) 2016 diagnostic criteria (see Fig 4, and [Appendix 3](#) for a systematic review of alternative criteria).²⁵

These criteria rely upon the presence of pain within body regions (WPI – widespread pain index, maximal score = 19) taken together with an evaluation of associated symptoms (SSS – symptom severity scale: fatigue, concentration, refreshment from rest, overall symptomatology – maximal score = 12). These factors are combined in a formula to aid in the diagnosis of FMS at time of assessment.

To make a diagnosis using the ACR 2016 criteria the following need to be present (Fig 4):

- 1 Widespread pain index (WPI) ≥ 7 and symptom severity scale (SSS) score ≥ 5 OR WPI 4–6 and SSS score ≥ 9 .
- 2 Generalised pain, defined as pain in at least 4 of the 5 body regions, is present (definition of body regions, see Fig 4).
- 3 Symptoms have been present at a similar level for at least 3 months.

Patients with symptoms just below this threshold may be diagnosed with FMS if the above threshold symptoms are documented from a recent assessment (see *iv*) *When a diagnosis is not certain* in [Section 2.2](#)).

Independently, if a patient presents with an established diagnosis of fibromyalgia, it is the diagnostic clinician’s role to ensure this is robust.

In case of uncertainty referral to a specialist with experience in diagnosing fibromyalgia (usually a pain specialist or a rheumatologist) is recommended for clarification of the diagnosis (see *Onward referral* in [Section 2.4](#)).

Symptom severity scale (SSS)

Have your problems with the symptoms below been present for 3 months or more? Yes No

If yes, using the following scale, indicate the severity of each symptom over the past week by circling the appropriate number.

	No problem	Mild	Moderate	Severe
Fatigue	0	1	2	3
Trouble thinking or remembering	0	1	2	3
Waking up tired (unrefreshed)	0	1	2	3

During the past 6 months, have you had any of the following symptoms?

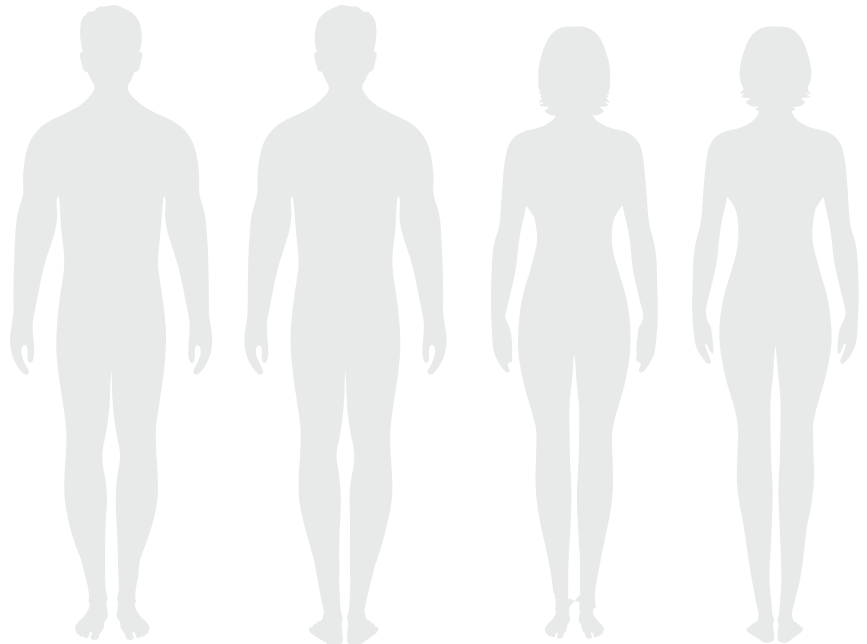
Pain or cramps in lower abdomen Yes No
 Depression Yes No
 Headache Yes No

Total score* for the SSS _____

*The sum of the three scaled symptoms plus one point each for the other symptoms (pain or cramps, depression, headache). The total will be between 0 and 12.

Body map

Use the figures to record where pain occurs in detail. Shade the areas of your body where you have felt persistent or recurrent pain for the past 3 months or longer (chronic pain).



Calculating the WPI score

Use this checklist to calculate the widespread pain index (WPI) score. Tick the areas where you have had chronic pain for 3 months or longer.

Region 1: left upper

- L jaw
- L shoulder girdle
- L upper arm
- L lower arm and/or L wrist/hand, L elbow

Region 2: right upper

- R jaw
- R shoulder girdle
- R upper arm
- R lower arm and/or R wrist/hand, R elbow

Region 3: left lower

- L hip and/or L buttock
- L upper leg and/or L groin
- L lower leg and/or L ankle/foot, L knee

Region 4: right lower

- R hip and/or R buttock
- R upper leg and/or R groin
- R lower leg and/or R ankle/foot, R knee

Region 5: axial

- Neck
- Upper back
- Lower back
- Chest (L and/or R)
- Abdomen

Total score[†] for the WPI _____

[†]The total will be between 0 and 19.

L=left; R=right

A diagnosis requires widespread pain >3 months duration with currently either i) widespread pain index (WPI) ≥7 and symptom severity scale (SSS) score ≥5, or ii) WPI 4–6 and SSS score ≥9, with pain in 4/5 body regions.

Fig 4: Fibromyalgia syndrome diagnostic worksheet

2.4 Considering and investigating differentials and multiple health conditions

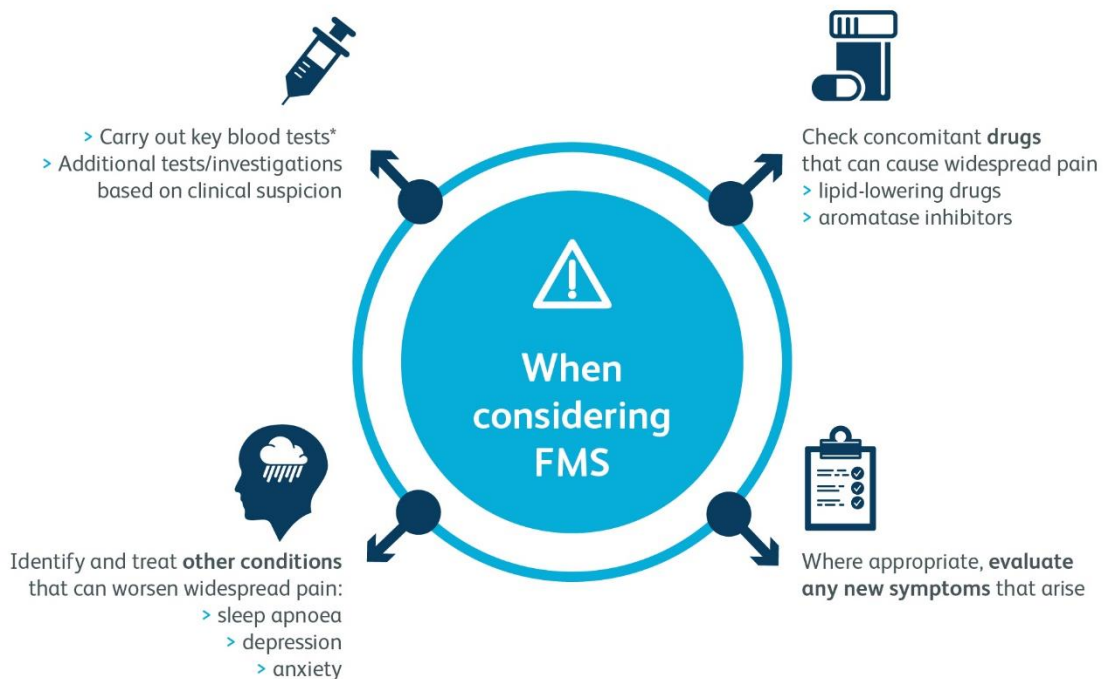
Healthcare professionals should be aware that:

- > FMS is not a diagnosis of exclusion.
- > There are no specific diagnostic tests for FMS.
- > Patients with other medical conditions may additionally have FMS (this is common in rheumatological conditions, eg rheumatoid arthritis (RA), systemic lupus erythematosus (SLE), ankylosing spondylitis).

Box 6: Validity of the FMS diagnosis when associated with other disorders

Recommendation	Evidence
A diagnosis of FMS is valid irrespective of other diagnoses. A diagnosis of FMS does not exclude the presence of other clinically important illnesses. ^{23,24,26,27}	E2, RB

See [Appendix 1](#) for description of evidence evaluation.



* Blood tests should include: full blood count, erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP), creatine kinase (CK), liver function tests (LFT), thyroid stimulating hormone (TSH), glucose, urea and electrolytes (U&Es).

Fig 5. Considering and investigating differentials and multiple health conditions

The relationship between evident FMS symptoms and another diagnosed condition in the same patient can be complex because FMS symptoms may:

- > not typically resolve by the treatment of the other condition,^{35,36} an example is rheumatoid arthritis, which is often a condition experienced alongside FMS.
- > sometimes resolve with appropriate treatment for that condition, eg steroid treatment in polymyalgia rheumatica.

Box 7: Diagnosis, multiple health conditions and differentials**Recommendation**

Diagnosing clinicians should consider conditions that may complicate the diagnosis of FMS because they may mimic some aspects of FMS and/or be experienced alongside it:

Endocrine disease (hypothyroidism). ^{24,27}	E2
Rheumatic conditions (eg ankylosing spondylitis, SLE, RA, polymyalgia rheumatica) ^{24,27}	E2
Neurological disease (neuropathies, myopathies, multiple sclerosis) ^{24,27}	E2
Drug-induced conditions (lipid-lowering drugs, aromatase inhibitors, high-dose opioids causing opioid-induced hyperalgesia). ^{24,27}	E2
Sleep disorders such as sleep apnoea ²⁴	E2
Chronic fatigue syndrome	E1+E2
Depression	

To help differentiate and/or identify other possible diagnoses, the following screening tests should be arranged: †††

Full blood count ^{24,27}	E2
Erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) ^{24,27}	E2
Creatine kinase (CK) ²⁷	E2
Liver function tests (LFT) ²⁴	E2
Thyroid stimulating hormone (TSH) ^{24,27}	E2
Blood glucose ²⁴	E2
U&Es ²⁴	E2

The following processes apply:**Evidence**

Any further tests in addition to those listed above should be based on clinical suspicion. ^{24,27}	E2
Clinicians who do not have direct access to arranging blood screening tests (eg physiotherapists) should refer to the primary physician involved in a patient's care. In most cases this will be the GP.	E2
Repeating of investigations after diagnosis should be avoided unless driven by the onset of new symptoms or signs on physical examination. ²⁷	E2
<i>New symptoms</i> in a patient with an <i>established</i> diagnosis of FMS should be evaluated according to appropriate clinical standards, with the understanding that FMS, as with any other illness, can be accompanied by additional, unrelated disease. ²⁷	E2

See [Appendix 1](#) for description of evidence evaluation; [Appendix 2](#) for complete listing of benefits, harms, costs and overall strength of recommendations.†††

These *neurological and psychiatric conditions* are sometimes considered as possible differentials by patients or clinicians:

- > Very rarely **multiple sclerosis (MS)** can cause generalised pain and fatigue without focal neurological deficit. Typically, patients have focal neurological deficits *as well as* pain and

††† Some members of the GDG felt that vitamin B12 deficiency should be a differential diagnosis to fatigue and pain associated with FMS.³⁷ On balance, however, the GDG considered that more evidence is required before a recommendation for testing can be made, and that measurement methods may also require attention.³⁸ Vitamin D deficiency is probably more common in patients with FMS than in the general population, but results on symptom control following replacement therapy are conflicting and screening tests for vitamin D are not recommended.³⁹

fatigue. Arrangement of investigations such as MRI scan, or referral for neurological opinion is not recommended unless there is specific suspicion or concern.

- > **Functional neurological disorder** (FND – also termed conversion disorder) is a common cause of neurological symptoms but is by definition not painful – further information is provided in [the glossary](#).⁴⁰
- > **Somatic symptom disorder** (SSD) (with predominant pain) is a psychiatric diagnosis in DSM 5 – further information is provided in [the glossary](#).^{41,†††}

Symptoms of chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME) can overlap with FMS. Details are outside the scope of this guidance. Pragmatically, where fatigue and/or excessive sleep is the predominant patient complaint, the patient should also be assessed for CFS.⁴² Some patients may fit criteria for both FMS and CFS.

Patients with hypermobile Ehlers-Danlos syndrome/hypermobility spectrum disorder (HSD) often report widespread pain and their clinical presentation can overlap with FMS. Details are outside the scope of this guidance and separate guidance is available.^{§§§}

After recovery from an episode of acute infection with coronavirus SARS-CoV-2 some patients experience symptoms similar to or resembling FMS and CFS. Details are outside the scope of this guidance and advice is available.^{****}

Onward referral

- > In situations where symptoms and signs for FMS are unequivocal, it is not necessary to refer for specialist opinion for confirmation of diagnosis.
- > Onward referral to a specialist service for diagnostic reasons is appropriate:
 - if FMS symptoms are continually equivocal
 - if there is clear diagnostic uncertainty (eg complicated by inflammatory rheumatological or neurological symptoms, see above)
 - in the presence of complex multiple health conditions
 - if there are symptoms that need investigating but are outside the clinician’s scope of practice
- > Referral options for confirmation of a patient’s diagnosis and/or for exclusion of other diagnoses typically include rheumatology or pain medicine services. For exclusion of neurological disease refer to neurology services. Availability of services and typical pathways vary within the UK.

2.5 Clinical management

The management of FMS is outside the scope of this document. However, several evidence-based resources have been published, see below (NSF typology was not applied to these references, except those used in Box 8).

It is important to acknowledge that:¹⁵

- > Any discussion regarding treatment should be a shared decision between patient and healthcare provider.
- > Clinicians offering advice should aim to do this with a knowledge of the current evidence.
- > It is appropriate to offer treatments based on a working diagnosis, even in the case of diagnostic uncertainty. However, some patients will find it challenging to accept treatment in that situation.

††† This diagnosis requires specialist assessment (eg by a psychiatrist, psychologist or neurologist).

§§§ <https://www.rcgp.org.uk/clinical-and-research/resources/toolkits/ehlers-danlos-syndromes-toolkit.aspx>

**** See section 6.3 of [Long Covid-19: Proposed primary care clinical guidelines](#) *Int J Environ Res Public Health* 2021;18:4350.

- > Interventions around education, self-management, and connection with support groups for non-clinical support are important; treatments may include:
 - signposting to local or virtual resources
 - advice on gentle rehabilitation (aerobic exercises)⁴³
 - group-based treatments in the community (eg pain-appropriate Pilates, mindfulness etc⁴⁴)
 - 1:1 professional treatment, eg pain-specialised physiotherapy (see also Section 2.1 on ineffective treatments), psychology, occupational therapy^{45,46}
 - pain management programmes
 - medication (considering current evidence base).²⁰
- > Upon referral to any surgical care the patient’s diagnosis of FMS should be included in the referral. Patients with FMS should be encouraged to share their diagnosis with the surgical team, and importantly, with the anaesthetist [prior to surgery](#).

Box 8: Clinical management and essential information

Recommendation	Evidence
Management of pain, including management with information, rehabilitative methods, and connect with non-clinical support groups can reduce suffering. This should be done in parallel to waiting for expert opinion and/or investigating potentially relevant pathology that may be contributing to the pain.	E1+E2
Established pain medications or normal musculoskeletal physiotherapy are often not effective or can even cause harm – the patient should be advised accordingly. ^{15,20,27,48}	E1+E2, RA
FMS is a long-term condition, sometimes requiring planned reviews in primary or secondary care. Thus, the primary or secondary care team should support and facilitate the development of a therapeutic relationship. This is crucial if expertise from both clinician and patient is to be effectively utilised in a shared management plan. ^{27,47}	E1+E2, RB

See [Appendix 1](#) for description of evidence evaluation; and [Appendix 2](#) for rating of benefits, harms, costs and overall strength of recommendations

2.6 Diversity and FMS

Although most common in women aged 40 to 60, FMS can also affect men, young people and older people. This guidance applies equally to all these groups.^{1,46}

Work on how fibromyalgia and chronic pain affect different ethnicities is ongoing. Most research into different ethnicities has taken place in the USA and involves people from African-American and Hispanic backgrounds. There is a lack of research into how fibromyalgia affects the South-Asian population in the UK.

Research suggests that people from ethnic minority backgrounds may be less likely to receive a diagnosis of fibromyalgia than White individuals. Patients with FMS from ethnic minority backgrounds may also be more affected by mood disturbances including depression, and sleep disturbances than White patients with FMS.⁴⁹

There is some evidence suggesting that there are different coping strategies and illness perceptions between White and Black, Asian and minority ethnic populations. Average self-efficacy, fear avoidance beliefs, locus of control and pain attitudes may also differ.⁵⁰

Acculturation (assimilation to a different culture) has been shown to be strongly negatively associated with widespread pain in a UK South Asian population; more integrated members of that

population had lower rates of chronic pain, although not all differences with the White European population are explained by acculturation.⁵¹

Language differences and lack of cultural awareness can contribute to poor communication between healthcare professionals and those in pain.⁵² Therefore, improved awareness of how cultural practices may contribute to the pain experience are essential and may assist health professionals in communicating with and treating patients from ethnic minority backgrounds.^{52,53}

Recommendations

- > Ask about mood – how the pain makes them ‘feel’.
- > Ask about beliefs about the onset of the pain.
- > Ask about the expectations they have from your consultation/service.
- > Develop some cultural awareness of the patient’s background.
- > If possible, provide patient information which is language and culture specific.
- > Be careful not to stereotype – there may be commonalities within a culture but be careful not to generalise (especially due to acculturation).
- > Use a translator to explain the meaning of words and concepts in the native language of the patient.
- > Involve family members in consultation and assessments if appropriate.

Section 3: FMS diagnosis and perioperative care specific to surgical practice

3.1 About this section

This section was compiled by a subgroup of the GDG which included representation from surgeons, anaesthesiologists, patients and members of the general GDG. It was subsequently reviewed by the whole GDG.^{††††}

Surgical involvement in FMS diagnosis and patient care typically concerns considerations about operative management. This surgical section addresses FMS recognition, communication and perioperative management. More information about diagnosing FMS is provided in [Section 2.3](#).

3.2 FMS pain versus surgically amenable pain

FMS is a common condition. The mechanisms causing FMS pain are unknown. FMS pain is not surgically amenable (Fig 6).

To clarify, surgically amenable pain is typically ‘nociceptive’. This means that a patient’s pain receptors are being excited through mechanical or inflammatory stimuli which may be remedied by surgery (Fig 6). Occasionally, surgically amenable pain may also be ‘neuropathic’, ie caused by damage to a nerve. Surgery can sometimes improve such pain, for example through nerve decompression.

Most chronic human pains are *neither* nociceptive nor neuropathic. Their mechanism is termed *nociplastic*.^{4,54}



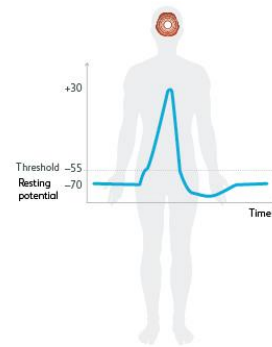
Nociceptive pain*

- > caused by harmful stimuli which activate pain receptors, eg osteoarthritis
- > may be alleviated by conventional treatments, eg medicines, or surgery to repair the damage



Neuropathic pain*

- > caused by a lesion or disease directly affecting the body’s pain-sensing nerves, eg carpal tunnel syndrome, disc prolapse
- > may sometimes be alleviated by medicines or surgery, eg nerve decompression



Nociplastic pain*

- > caused by a disturbance in peripheral and/or central nervous system pain processing, eg fibromyalgia
- > cannot be alleviated by surgery

* Note that in some patients experiencing more than one type of pain, it is unknown whether medical or surgical treatment of nociceptive or neuropathic pain associated with lesions has any effect on nociplastic pain. More research is needed, and MDT assessment will be useful in this situation.

Fig 6. Surgical treatment of chronic pain

†††† Members of the GDG subgroup: Ased Ali, Anne Begley, Debra Dulake, Marcia Glanvill, Andreas Goebel, Nicholas Haden, Dharani Hapangama, Ann Lyons, Andy Molloy, Robert Moots, Francis O’Neill, P Julian Owen, Nick Phillips, Manoj Sivan

FMS-related pain is *nociplastic*. In nociplastic pain, the patient’s nervous system abnormally processes painful signals; mechanisms are not understood. Good evidence exists indicating that nociplastic pain is not *caused* by psychological distress.⁵⁵ Nociplastic pain, however, is typically *associated* with psychological distress, and in subgroups may originally be *triggered* by a distressing experience.¹² More detail is given in [Section 1.3](#). Identification of FMS pain is expected to help surgeons improve operative outcomes.

Box 9: FMS alert factors in surgical practice

Recommendation	Evidence
Surgeons should be alert to possible presence of FMS if any of the following factors are evident:	
a) Pain	
> Pain out of proportion to pathology now, or in the patient’s history, either in the currently painful- or in other body regions	E2
> (note severe pathology does not protect from FMS)	
> Chronic pain in more than one location ¹	RC
b) Effectiveness of treatment for pain	
> Pain <i>not improving</i> with prior surgeries for this or other problems. This includes pain recurrence both immediately – or months after surgery	E2
> History of <i>repeated surgeries</i> for this or other painful problems	E2
> Medication treatment or physiotherapy not effective or even worsening pain ^{20,48}	E2, RC
c) Other factors	
> Presence of fatigue, non-refreshing sleep, psychological distress and cognitive decline (such as short-term memory problems or problems with thinking) ²⁵	E2, RC
> High perioperative pain, and high analgesia requirements in earlier operations ^{56,57,58}	E2, RB

See [Appendix 1](#) for description of evidence evaluation

Surgical alert factors for FMS

Recognition of FMS may be poor.⁵⁹ Appreciation of the alert factors summarised in Box 9 may improve recognition; for full diagnostic criteria see [Section 2.3](#).

3.3 Communicating with patients

Guidance on what is appropriate for a surgeon to say to their patient if their pain is not surgically explained, and what should be written in the clinic letter when FMS is suspected is given in Box 10.

Box 10: Communication with your patient and other healthcare professionals

Recommendation	Evidence
a) What to say to your patient	
> State the reason for the referral (why is the patient here)	E1+E2
> State that you can exclude the surgical cause, and explain why	E1+E2
> State that this does not mean that there is no reason for their pain	E1+E2
> If you suspect that this could be nociplastic pain, then explain this to the patient and provide them with a nociplastic pain information leaflet (see Appendix 4)	E1+E2
b) What to include in the surgical clinic letter	
> Mention suspected nociplastic pain or FMS within the clinic letter. This will provide important information to other healthcare professionals	E2
> Clarify that the specific surgical cause for their pain has been excluded.	E1+E2
c) What <i>not</i> to say to your patient	
> 'There is no reason for your pain'	E1+E2
> 'There is nothing wrong with you' or 'I can't find anything wrong with you'	E1+E2
> 'It is all in your head'	E1+E2
> 'It is psychological'	E1+E2
> 'There is nothing we can do', without providing further information	E1+E2
> 'There is nothing anyone can do'	E1+E2

See [Appendix 1](#) for description of evidence evaluation

3.4 Where should surgeons refer a patient with FMS?

If nociplastic pain or FMS is suspected, then the direction of any referral after surgical assessment will depend on the local situation, and may include back to the GP, pain clinic and others. There is a national move toward reducing referral to rheumatology for confirmation of FMS, but in some regions, this is still the recommended pathway.

If a surgeon suspects that their patient may fit **the very rare, exceptional case** of consciously exaggerating then it is appropriate to refer to a pain clinic for further assessment and advice. The surgeon should feel reassured that such a referral will not lead to excessive resource use, rather referral will help diagnosis and reduce further resource use.

3.5 Operating on someone with FMS

A systematic review of the literature was ongoing at the time of publication of this guidance; updated recommendation boxes 9–11 incorporating the results will be [available online](#). Patients with FMS often respond to surgical interventions differently to patients without FMS with a similar lesion and their management may benefit from involvement of a multidisciplinary team. Factors that will need to be considered both at consent stage and later are listed in Box 11; these factors should also be communicated to the patient.

It should be noted that failure to relieve pain with surgery may often only become apparent several months after surgery, because i) surgery by itself provides a potent stimulus for the internal placebo system, and ii) some types of anaesthetic may temporarily reduce nociplastic pain by reducing central sensitisation.⁶⁰

The true long-term effect of surgery on pain is impossible to gauge outside clinical trials because of these three effects and the long-term effect of regression on the mean. Independently, pain increase in the months after surgery in patients with FMS may not be due to surgery; they may also reflect a surgery-independent FMS pain flare.

Box 11: Decision to operate, and perioperative care

Recommendation	Evidence
FMS pain is not surgically amenable, but patients with FMS may be scheduled for surgical management of chronic pain attributed to a regional lesion or change, such as osteoarthritis. If relief from regional chronic pain is the primary indication for surgery in a patient with FMS (<i>particularly for repeated interventions</i>), then the decision to operate should generally be discussed by the multidisciplinary team which may involve a pain specialist, anaesthetist, pain-physiotherapist and pain psychologist as appropriate.	E1+E2
The following recommendations are valid both where surgery aims to primarily relieve regional pain, and also where surgery is planned for other reasons	
<i>The following risks should be discussed with the patient:</i>	
> Risk of failure to relieve pain is likely higher in FMS than in patients without FMS, and the degree of risk may be associated with the severity of FMS ^{61,62,63}	RB
> Risk of pain increase, including permanent pain increase , as the result of surgical trauma to the already-sensitised nerves, may be higher in FMS than in patients without FMS.	E2
<i>The following factors regarding perioperative care and discharge planning should be discussed within the perioperative care team, including recovery nurses and anaesthetists:</i>	
> Long-term pain medications should typically be continued through the perioperative period. Where the appropriateness of continuation of long-term pain medications is unclear a pain specialist should be involved in decision making.	E2
> In common with patients experiencing other chronic pain conditions, FMS patients often have higher and prolonged perioperative drug requirements to treat nociceptive pain, and despite this they often experience higher than average postoperative pain, although this does not occur in every patient with FMS. ^{56,57,58} Failure to communicate this can lead to patients experiencing increased pain and from a sense of not being believed.	E2, RB
> Those involved in perioperative care planning for a patient with FMS should consider whether involvement of a pain specialist may facilitate successful negotiation of the perioperative management plan with the patient. This will not be required in all cases.	E2
> Patients may experience increased fatigue/less strength in the perioperative period, potentially leading to longer stays in hospital.	E1+E2
> A clear pathway should be outlined to reduce postoperative opioids back to baseline level (none or low doses) as appropriate.	E2

See [Appendix 1](#) for description of evidence evaluation; [Appendix 2](#) for rating of benefits, harms, costs and overall strength of recommendations

3.6 Patients without a formal diagnosis of FMS

Surgeons should be aware that patients who have some features of FMS – even if these do not trigger a formal diagnosis of FMS – may achieve poorer pain relief from surgery.^{31,64}

Patients *with mostly regional pain* such as from painful knee osteoarthritis, *without or with only few additional chronic pains* may have symptoms akin to FMS such as fatigue, hypersensitivity to touch/pressure/optic or olfactory stimuli, poor sleep, poor memory, psychological distress, without fulfilling the criteria for FMS²³ (see also the footnote on symptoms on p16). The causes for these symptoms are unknown and they are not considered psychological, although many patients present with psychological distress.

The degree of such symptoms (intensity and number) is thought to relate to the degree of nervous system sensitisation; it can be measured with the ACR 2016^{***} symptom severity score (see Fig 4: symptom severity index). A continuous composite score (Fig 3) can be derived from both the degree of these non-painful symptoms and the number of painful body sites (Fig 4: calculating the WPI score).⁶⁴

Above a certain threshold, most patients with high scores will meet the criteria for FMS, but research indicates that even below that threshold surgical outcomes may be affected: as a group, patients with high scores are likely to be at risk for reduced pain improvement after surgery.⁶¹

Conversely, the response to surgery among patients with high sensitisation scores is diverse and many patients may have good outcomes. Six months after knee or hip replacement surgery, two-thirds of patients who preoperatively had *high sensitisation scores, but not FMS*, reported not only improvement in regional pain but also a reduction of generalised symptoms such as fatigue and poor sleep;⁶⁵ this suggests that regionally painful osteoarthritis may sustain more generalised symptoms in some patients. This is balanced, though, by the outcome in the remaining one-third of patients, who had either no improvement or even reported pain increases following their operation.

As yet, no reliable tool exists to predict good/poor responders within the group of patients with mostly regional pain and high sensitisation scores. In patients with osteoarthritis of the knee, pain at truly remote sites (such as neck, shoulder and arms) rather than nearby sites (such as buttocks and lower back) may be one such predictor, but more research is needed.⁶⁵

*** Other tools are also available.

Appendices

Appendix 1: Details of methodology

The Guideline Development Group (GDG) used a previously developed methodology for a pragmatic evaluation of evidence base and consensus, with minor adaptations and permission from the developers.⁶⁶ A ‘top-down’ approach was employed in which i) the recommendations were drawn up by consensus based on professional experience and expert knowledge of the literature. ii) Literature searches were then conducted by GDG members to assemble the strongest available literature.

For the assimilation of evidence, we used the typology of evidence that was developed for the UK National Service Framework for Long Term Conditions.³

For the overall strength of recommendations, we used a simplified GRADE^{66,67} approach, based on the overall evidence (including research and expert opinion) and three of the 11 questions used in the full GRADE system: These were:

- a) **Benefits:** Is there important uncertainty about how much guideline users value the recommendation?
- b) **Harms:** Are the desirable effects large, relative to any undesirable effects?
- c) **Costs:** Is the incremental cost small relative to the net benefits?

Process of application

There were three steps to the process

- 1 Identification and agreement of the key recommendations in the FMS guidance
- 2 Assimilation of the best-quality evidence to underpin the recommendation using the NSF typology
- 3 Grading the strength of the recommendation by consensus of the group, based on the three questions above

Separately, support for key recommendations in existing international guidance publications was indicated by citation of the respective international guidance document(s).

Step 1: was done by the whole GDG. The whole GDG submitted best quality evidence, which was then assimilated (second part of Step 2) using NSF typology, and graded (Step 3) by a subgroup of five GDG group members with prior expertise in this method or after training.

Step 2: valuation of the best quality evidence using the NSF typology

Each piece of evidence is reviewed and given an E rating *and* an R rating, if possible.

- > E: reflects user /carer/ professional opinion
- > R: reflects research-based evidence.

Expert evidence (E) is expressed through consultation or consensus processes rather than formal research designs and is classified as follows:

E1	User and/or carer opinion
E2	Professional or other stakeholder opinion

Research evidence (R) is categorised for each piece of evidence on three levels: a) Design, b) Quality and c) Applicability, by two or more evidence reviewers.

a) Design**Primary research-based evidence**

P1	Primary research using quantitative approaches
P2	Primary research using qualitative approaches
P3	Primary research using mixed methods (qualitative and quantitative)

Secondary research-based evidence

S1	Meta-analysis of existing data analysis
S2	Secondary analysis of existing data.

Review-based evidence

R1	Systematic reviews of existing research;
R2	Descriptive or summary reviews of existing research

b) Quality assessment: based on five simple questions

Each quality item is scored as follows: 2 = Yes, 1 = In part, 0 = No

	Score
Are the research question/aims and design clearly stated?	
Is the research design appropriate for the aims and objectives of the research?	
Are the methods clearly described?	
Is the data adequate to support the authors' interpretations/ conclusions?	
Are the results generalisable?	
Total	10

c) Applicability to the recommendation

- > Direct – ie evidence from the same population/condition
- > Indirect – ie extrapolated evidence from a different population/condition

Thus, a high-quality cohort study might be assigned **P1 High direct**, and moderate quality narrative review in a related field might be assigned **R1 Medium indirect**.

Assimilation of research evidence

A single grade of recommendation was derived from the above evaluations:

Research grade A (RA):

- > More than one study of high-quality score ($\geq 7/10$) *and*
- > At least one of these has direct applicability

Research grade B (RB):

- > One high-quality study *or*
 - > More than one medium quality study (4-6/10) *and*
 - > At least one of these has direct applicability
- or
- > More than one study of high-quality score ($\geq 7/10$) of indirect applicability

Research grade C (RC):

- > One medium-quality study (4–6/10) *or*
- > Lower quality (2–3/10) studies *or*
- > Indirect studies only

In summary

Each evidence-based statement was given the following ratings according to the strength of supporting evidence:

- > Expert: E1 and/or E2 (if applicable)
- > Research: RA, RB or RC – if there is research-based evidence to support it

For example:

A diagnosis of FMS should not be made on self-completion of ACR criteria without a clinician present (either face-to-face or remotely) to provide reassurance and consider possible alternatives (E1+E2, RA).

Step 3: Having assimilated the evidence to support each statement, *where appropriate* the consensus process to determine the overall strength of the recommendation was applied as summarised below. This step was applied to recommendation Boxes 3, 4, 7 and 12; results are provided in Appendix 2

Evidence	What is the level of evidence for the benefits of this approach?*	Descriptive User/professional opinion only: (E1/E2) * +/- Research grade A, B, or C
Benefits	1. Is there important uncertainty about how much people value the recommendation? **	<ul style="list-style-type: none"> > Important uncertainty or variability > Possibly important uncertainty or variability > Probably no important uncertainty of variability > No important uncertainty of variability > No known undesirable
Harms	2. Are the desirable effects large, relative to the undesirable effects? **	<ul style="list-style-type: none"> > No > Probably not > Uncertain > Probably yes > Yes > Varies
Costs	3. Is the incremental cost small relative to the net benefits? **	<ul style="list-style-type: none"> > No > Probably not > Uncertain > Probably yes > Yes > Varies
Overall strength of the recommendation		<ul style="list-style-type: none"> > Strong > Moderate > Weak

* Rated according to NSF typology ** Extracted from the GRADE process

Appendix 2: Benefits, harms, costs, analysis, and overall strength of recommendations

Box 3: Timing and communication of the FMS diagnosis

Recommendation	Evidence	Benefits	Harms	Costs	Overall strength recommendation
Diagnosis of FMS should be made as early as possible for those patients who meet the diagnostic criteria.	E2	No important uncertainty	Yes	Probably yes	Strong
The diagnosis of FMS should be made by any clinician adequately experienced to make this diagnosis.	E1, E2	No important uncertainty	Yes	Yes	Strong
The diagnosis should be communicated to the patient and supported by written information, and/or links to websites etc.	E1, E2	Probably no important uncertainty	Probably yes	Probably yes	Moderate to Strong

Box 4: Setting the scene when making the FMS diagnosis

Recommendation	Evidence	Benefits	Harms	Costs	Overall strength recommendation
Acknowledge the patient's life situation	E2	No known undesirables	Yes	Yes	Strong
Allow sufficient time	E1, E2	No important uncertainty	Yes	Probably yes	Strong
Where needed arrange additional appointments or refer, explain the arrangement	E2	No important uncertainty	Yes	Variable	Moderate to strong
Allow for a face-to-face diagnostic consultation if possible	E2	Probably no important uncertainty	Probably yes	Variable	Moderate to Strong

See [Appendix 1](#) for description of evidence evaluation.

Box 7: Diagnosis, multiple health conditions and differentials

Recommendation	Evidence	Benefits	Harms (little)	Costs (small)	Overall strength recommendation
<i>Diagnosing clinicians should consider conditions that may complicate the diagnosis of FMS, because they may mimic some aspects of FMS and/or coexist:</i>					
Endocrine disease (hypothyroidism) ^{24,27}	E2	No known undesirable	Yes	Yes	Strong
Rheumatic conditions (eg early inflammatory arthritis, polymyalgia rheumatica) ^{24,27}	E2	No known undesirable	Yes	Yes	Strong
Neurological disease (neuropathies, myopathies, multiple sclerosis) ^{24,27}	E2	No known undesirable	Yes	Yes	Strong
Drug-induced conditions (lipid-lowering drugs, aromatase inhibitors, high-dose opioids causing opioid-induced hyperalgesia) ^{24,27}	E2	No known undesirable	Yes	Yes	Strong
Sleep disorders, such as sleep apnoea ²⁴	E2	No known undesirable	Yes	Yes	Strong
Chronic fatigue syndrome	E1, E2	No known undesirable	Yes	Yes	Strong
<i>To help differentiate and/or identify other possible diagnoses, the following screening tests should be arranged:</i>					
Blood tests					
Full blood count ^{24,27}	E2	No known undesirable	Yes	Yes	Strong
Erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) ^{24,27}	E2	No known undesirable	Yes	Yes	Strong
Creatine kinase (CK) ²⁷	E2	No known undesirable	Yes	Yes	Strong
Liver function tests (LFT) ²⁴	E2	No known undesirable	Yes	Yes	Strong
Thyroid stimulating hormone (TSH) ^{24,27}	E2	No known undesirable	Yes	Yes	Strong
Blood glucose ²⁴	E2	No known undesirable	Yes	Yes	Strong
U&Es ²⁴	E2	No known undesirable	Yes	Yes	Strong
The following processes apply:					Evidence
Any further tests in addition to those listed above should be based on clinical suspicion. ^{24,27}					E2
Clinicians who do not have direct access to arranging blood screening tests (eg physiotherapists) should refer to the primary physician involved in a patient's care. In most cases this will be the GP.					E2
Repeating of investigations after diagnosis should be avoided unless driven by the onset of new symptoms or signs on physical examination. ²⁷					E2
<i>New symptoms</i> in a patient with an <i>established</i> diagnosis of FMS should be evaluated according to appropriate clinical standards, with the understanding that FMS, as with any other illness, can be accompanied by additional, unrelated disease. ²⁷					E2

Box 8: Clinical management and essential information

Recommendation	Evidence	Benefits	Low risk of harm?	Low cost	Overall strength
Management of pain can reduce suffering. This should be done in parallel to waiting for expert opinion and/or investigating potentially relevant pathology that may be contributing to the pain.	E1+E2	No important uncertainty	Yes	Yes	Strong
Unfortunately, established pain medications are often not effective or can even cause harm – the patient should be advised accordingly. ^{15,27,47,48}	E1+E2, RB	No important uncertainty	Yes	Yes	Strong
FMS is a long-term condition, sometimes requiring regular reviews in primary care. Thus, the primary care team should invest time in building an empathic, therapeutic relationship. This is crucial if expertise from both clinician and patient is to be effectively used in a shared management plan. ^{27,47}	E1+E2, RB	No important undesirables	Yes	Probably yes	Strong

See [Appendix 1](#) for description of evidence evaluation.

Box 11: Decision to operate, and perioperative care

Recommendation	Evidence	Benefits	Harm	Costs	Overall strength	Comments*
FMS pain is not surgically amenable, but patients with FMS may be scheduled for surgical management of chronic pain attributed to a regional lesion or change, such as osteoarthritis. If relief from regional chronic pain is the primary indication for surgery in a patient with FMS (particularly for repeated interventions), then the decision to operate should generally be discussed within a multidisciplinary team which may involve pain specialist, anaesthetist, pain-physiotherapist and pain-psychologist as appropriate.	E1/E2	No important uncertainty	Probably yes*	Probably yes	Strong	Dependent on any excessive delay with MDT
The following recommendations are valid both where surgery aims to primarily relieve regional pain, and also where surgery is planned for other reasons						
<i>The following risks should be discussed with the patient:</i>						
Risk of failure to relieve pain is likely higher in FMS than in patients without FMS, and the degree of risk may be associated with the severity of FMS ^{48,51,3}	RB	No important uncertainty	Probably yes*	Yes	Strong	Placebo effects possibly reduced
Risk of pain increase, including permanent pain increase , as result of surgical trauma to the already-sensitised nerves, may be higher in FMS than in patients without FMS.	E2	No important uncertainty	Yes	Yes	Strong	
<i>The following factors regarding perioperative case and discharge planning should be discussed within the perioperative care team, including recovery nurses and anaesthetists:</i>						
Long-term pain medications should typically be continued through the perioperative period. Where the appropriateness of continuation of long-term pain medications is unclear a pain specialist should be involved in decision making.	E2	No important uncertainty	Probably yes	Yes	Strong	
In common with patients suffering from other types of chronic pain conditions, FMS patients often have higher and prolonged perioperative drug requirements to treat <i>nociceptive</i> pain and, despite this, they often experience higher than average postoperative pain, although this does not occur in every patient with FMS. ^{56,57,58} Failure to communicate this can lead to patients suffering from increased pain and from a sense of not being believed.	E2, RB	No important uncertainty	Probably yes*	Yes	Strong	Postoperative complications might be wrongly attributed to FMS

Recommendation	Evidence	Benefits	Harm	Costs	Overall strength	Comments*
Those involved in perioperative care planning for a patient with FMS should consider whether involvement of a pain specialist may facilitate successful negotiation of the perioperative management plan with the patient. This will not be required in all cases.	E2	No important uncertainty	Yes	Yes	Strong	
Patients may experience increased fatigue/less strength in the perioperative period, potentially leading to longer stays in hospital	E1/E2	No important uncertainty	Yes	Yes	Strong	
A clear pathway should be outlined to reduce postoperative opioids back to baseline level (none or low doses) as appropriate.	E2	No important uncertainty	Yes	Yes	Strong	

Appendix 3: Systematic review of diagnostic criteria in fibromyalgia

Search strategy

An electronic literature systematic review was performed to identify the current and historical methods of diagnosing fibromyalgia syndrome (FMS). The primary outcome was to find diagnostic criteria for FMS. The secondary outcome was to identify screening tools used currently or previously. Databases interrogated were: MEDLINE (via OVID), EMBASE (via Scopus), PubMed, Web of Science, ScienceDirect and CINAHL. The searches were limited to the English language from inception and conducted in December 2020.

Search terms were developed iteratively and included the following:

“(Diagnostic criteria)

AND

(fibromyalgia **OR** fibromyositis **OR** fibrositis **OR** muscular rheumatism)”

All the search results were combined using Endnote (X9) and duplicates were removed. Reference lists of the primary and secondary literature were manually browsed to identify any additional studies.

Inclusion and exclusion criteria

Papers were included that: (a) first described a means of diagnosing fibromyalgia, (b) or first described a means of screening fibromyalgia and (c) were reported as full-text publications or book chapters. Studies were excluded if they: (a) were not in humans, (b) were not in adults aged >18 years, (c) were not reported in English. There were no publication cut-off dates to capture all relevant literature. Study populations of non-English speaking countries were also included provided the article text was in English.

All article titles and abstracts were then screened. Articles meeting the inclusion criteria were selected for full-text analysis. Articles that mentioned a screening technique or diagnostic method for FMS were analysed to identify the reference originally describing the methodological technique or process. Irrelevant articles were removed following screening and a shortlist of articles was compiled for full-text analysis.

Data extraction

The article first author/tool name, date of publication, diagnosis/screening methodology and the documented sensitivity and specificity were extracted.

Analysis

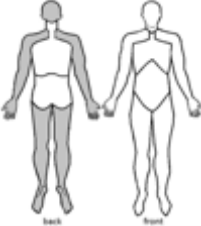
The results are presented in a table ordered by date of publication. There were 2,085 hits in total from MEDLINE (via OVID) [337], EMBASE (via Scopus) [21], PubMed [1,384], Web of Science [63], Science Direct [123] and CINAHL [158]. When combined and duplicates removed there were 1,538 hits. Twenty-five articles were excluded at this stage for non-English text, 21 were excluded for studying a paediatric population. There were 1,492 article titles and abstracts screened initially, yielding 13 for full-text analysis. Another six articles were added to this number following analysis of the primary hits’ content and references.

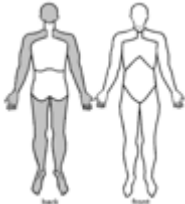
Results

The results of the systematic review are given in the table below.

Criteria	Assessor test type	Year	Sensitivity and specificity	Method of diagnosis or screening
Traut ⁶⁸	Physician	1968	NA	'Muscular fibrositis' or 'non-articular rheumatism' consists of generalised pain, tiredness, sleep disorders, and palpation pain in trigger areas, including the soft tissues of the neck, shoulder, elbow, carpal tunnel, palms and lower back area
Smythe ⁶⁹	Physician DIAGNOSTIC	1972	NA	A diagnosis is made with: > Local tenderness, stiffness and fatigue in the absence of abnormal laboratory tests results
Smythe and Moldosky ⁷⁰	Physician DIAGNOSTIC	1977	NA	A diagnosis is made if the following conditions are met: a) Unrefreshed sleep, fatigue, and widespread pain* b) 12 of 14 anatomic sites be positive for tenderness *No definition or assessment methods were recommended for these conditions.
Smythe ⁷¹	Physician DIAGNOSTIC	1979	NA	A diagnosis is made if the following conditions are met: 1 Widespread aching of more than three months duration 2 Local tenderness at 12 of 14 specified sites 3 Skin-roll tenderness over the upper scapular region (upper border of the trapezius) 4 Disturbed sleep, with morning fatigue and stiffness 5 Normal erythrocyte sedimentation rate, serum glutamic oxaloacetic transaminase, rheumatoid factor test, antinuclear factor, muscle enzymes and sacroiliac films
Yunus ⁷²	Physician DIAGNOSTIC	1981	NA	A diagnosis is made if conditions A, B & 3 of C OR A, 3 of B & 5 of C are met a) Generalised aches and pains or stiffness, at three anatomic sites, for 3 months and absence of secondary causes, eg traumatic, rheumatic (including degenerative), infective, endocrine or malignant; with normal laboratory tests (CRP, ESR, rheumatoid factor, ANA, muscle enzymes) and roentgenograms b) Major criteria: Presence of at least five typical and consistent tender points c) Minor criteria: Modulation of symptoms by physical activity, (B) modulation of symptoms by weather factors, (C) aggravation of symptoms by anxiety or stress, (D) poor sleep, (E) general fatigue or tiredness, (F) anxiety, (G) chronic headache, (H) irritable bowel syndrome, (I) subjective swelling, and (J) numbness
American College of Rheumatology Diagnostic Criteria (1990) ⁷³	Physician DIAGNOSTIC	1990	Sensitivity 88.4% Specificity 81.1%.	A diagnosis is made if conditions A and B are met: a) History of widespread pain: Pain on right and left and above and below the waist and axial skeleton for 3 months b) Pain in 11 of 18 tender point sites on digital palpation (4 kg): (Occiput, bilateral; low cervical, bilateral; trapezius, bilateral; supraspinatus, bilateral; second rib, bilateral; lateral epicondyle, bilateral; gluteal, bilateral; greater trochanter, bilateral knee, bilateral)
London fibromyalgia screening questionnaire (LFESSQ) ⁷⁴	Physician SCREENING	1999	NA	A positive screen for FMS is made in one of the two following ways: (a) meeting the pain criteria alone (LFESSQ-4), or (b) meeting both the pain and the fatigue criteria (LFESSQ-6) <u>Pain criteria</u> In the past 3 months: 1 Have you had pain in muscles, bones, or joints, lasting at least 1 week?

				<p>2 Have you had pain in your shoulders, arms, or hands? On which side? Right, left, or both?</p> <p>3 Have you had pain in your legs or feet? On which side? Right, left, or both?</p> <p>4 Have you had pain in your neck, chest or back?</p> <p><i>Meeting the pain criteria requires “yes” responses to all 4 pain items, and either (1) both a right- and left-side positive response, or (2) a both sides positive response.</i></p> <p>Fatigue criteria</p> <p>1 Over the past 3 months, do you often felt tired or fatigued?</p> <p>2 Does tiredness or fatigue significantly limit your activities?</p> <p><i>Screening positive for chronic, debilitating fatigue requires a ‘yes’ response to both fatigue items.</i></p>
American College of Rheumatology Diagnostic Criteria (2010) ²³	Physician DIAGNOSTIC	2010	NA	<p>A diagnosis is made with A & B & C</p> <p>a) Widespread pain index (WPI) 7 and symptom severity (SS) scale score 5 or WPI 3–6 and SS scale score 9</p> <p>b) Symptoms have been present at a similar level for at least 3 months</p> <p>c) The patient does not have a disorder that would otherwise explain the pain</p> <p>WPI:</p> <p><i>No of areas pain felt in last week of: right shoulder girdle, left shoulder girdle, right upper arm, left upper arm, right lower arm, left lower arm, right hip, left hip, right upper leg, left, upper leg, right lower leg, left lower leg, right jaw, left jaw, chest, abdomen, upper back, lower back, neck.</i></p> <p>Score out of 19.</p> <p>SS:</p> <p><i>Sum of severity of fatigue, waking unrefreshed, cognitive symptoms & severity of somatic symptoms*. Out of 12. (Severity is scored: 0 = no problem, 1 = mild problems, 2 = moderate problems, 3 = severe problems).</i></p> <p><i>*Based on the number of symptoms, patients are included in one of four score ranges: 0 symptoms (score of 0), 1 to 10 symptoms, (score of 1), 11 to 24 symptoms (score of 2), and 25 or more symptoms (score of 3).</i></p>
Fibromyalgia rapid screening tool FiRST ⁷⁵	Patient SCREENING	2010	Sensitivity 90.5% Specificity 85.7%	<p>The screen is positive for FMS with 5/6 of the following sentiments:</p> <p>1 ‘I have pain all over my body’</p> <p>2 ‘My pain is accompanied by a continuous and very unpleasant general fatigue’</p> <p>3 ‘My pain feels like burns, electric shocks or cramps’</p> <p>4 ‘My pain is accompanied by other unusual sensations throughout my body, such as pins and needles, tingling or numbness’</p> <p>5 ‘My pain is accompanied by other health problems such as digestive problems, urinary problems, headaches or restless legs’</p> <p>6 ‘My pain has a significant impact on my life, particularly on my sleep and my ability to concentrate, making me feel slower generally’</p>
Association of the Medical Scientific Societies in Germany (AWMF) criteria ⁷⁶	Physician DIAGNOSTIC	2010	NA	<p>A diagnosis is made if the following conditions are met:</p> <p>1 Widespread pain assessed by medical history and/or pain drawing including</p> <p>a) Axial pain and</p> <p>b) Pain in all four extremities</p> <p>2 The report of sleep disturbances and fatigue and feeling of swelling or stiffness of the hands or feet or face in the past 3 months with a score scale $\geq 1/10$ on a numeric rating scale</p>

<p>REVISIONS to American College of Rheumatology Diagnostic Criteria (2010)⁷⁷</p>	<p>Physician DIAGNOSTIC</p>	<p>2011</p>	<p>Sensitivity 96.6% Specificity 91.8%</p>	<p>A diagnosis is made if conditions A, B & C are met (as with 2010):</p> <p>a) Widespread pain index (WPI) 7 and symptom severity (SS) scale score 5 or WPI 3–6 and SS scale score 9 b) Symptoms have been present at a similar level for at least 3 months c) The patient does not have a disorder that would otherwise explain the pain</p> <p>The modification consisted of substituting the physician’s estimate of the extent of somatic symptoms with the sum score of three specific self-reported symptoms (0-3).</p> <p>a) Headaches b) Pain or cramps in the lower abdomen c) Depression symptoms (including depressive symptoms, feelings of depression, or depressed mood) *</p> <p>* <i>Depression in this context does not indicate a psychiatric diagnosis of depression</i></p>
<p>Fibromyalgia Diagnostic Screen Physician Assessment⁷⁸</p>	<p>Physician SCREENING</p>	<p>2012</p>	<p>Sensitivity 68% Specificity 69%</p>	<p>The screen is positive for FMS with 5/5 of the following:</p> <ol style="list-style-type: none"> 1 At least mild pain in at least 1 site within at least 3 out of 5 areas of the body 2 Duration of pain 3 months or longer 3 Pain gets worse with physical activity or exercise 4 Sum of 8 or more in symptom severity 5 At least 2 out of 8 positive tender points
<p>Fibrodetect⁷⁹</p>	<p>Physician SCREENING</p>	<p>2014</p>	<p>Sensitivity 90% Specificity of 67%</p>	<p>The screen is positive for FMS with 6/9 of the following:</p> <p>(A body map is given to mark. A point is given for each of the following answers)</p> <ol style="list-style-type: none"> 1 At least one body part of upper body ticked (head, neck, shoulders) 2 At least one body part of upper limb ticked (right and left arms) 3 At least one body part of lower limb ticked (right and left legs) 4 Frequency of the pain: ‘Every day or almost every day’ 5 At least 3 kinds of pain ticked * 6 Frequency of tiredness: ‘Every day’ 7 Impact of physical effort on tiredness: ‘Much more tired’ 8 At least 7 symptoms ticked ** 9 Extent to which patients recognise themselves in the questions being asked: ‘Absolutely’ <ul style="list-style-type: none"> • Among 8 kinds of pain: muscle aches, cramps, pins and needles, stabbing, shooting pain, burning, pulling and pain that moves from one place to another. <p>** Among 17 symptoms: stiffness, headaches, tiredness, tiredness on waking up, exhaustion, insomnia, disrupted or disturbed sleep, sensitive to cold or heat, sensitive to smells, sensitive to noise, sensitive to touch, problems remembering things, problems concentrating, nausea, diarrhoea, constipation and problems with urination.</p> 
<p>American Rheumatology Association Diagnostic Criteria (2016)²⁵</p>	<p>Physician DIAGNOSTIC</p>	<p>2016</p>	<p>NA</p>	<p>A diagnosis is made if conditions A, B, C & D are met:</p> <p>a) Widespread pain index (WPI) ≥ 7 and symptom severity (SS) scale score ≥ 5 or b) Widespread pain index (WPI) 4-6 and symptom severity (SS) scale score ≥ 9</p>

				<p>c) Generalised pain: Pain must be present in at least 4 of 5 regions. Jaw, chest, and abdominal pain are not included in generalised pain definition</p> <p>d) Symptoms have been generally for at least 3 months</p> <p>A diagnosis of fibromyalgia is valid irrespective of other diagnoses. A diagnosis of fibromyalgia does not exclude the presence of other clinically important illnesses.</p> <p>WPI (No areas in which the patient has had pain over the last week) Score out of 19</p> <p>1 Region 1: Left upper region Jaw, left* / Shoulder girdle, left / Upper arm, left / Lower arm, left</p> <p>2 Region 2: Right upper region Jaw, right* / Shoulder girdle, right / Upper arm, right / Lower arm, right</p> <p>3 Region 3: Left lower region Hip (buttock, trochanter), left / Upper leg, left / Lower leg, left</p> <p>4 Region 4: Right lower region Hip (buttock, trochanter), right / Upper leg, right / Lower leg, right</p> <p>5 Region 5: Axial region Neck / Upper back / Lower back / Chest* / Abdomen*</p> <p>* Not included in generalised pain definition</p> <p><i>The fibromyalgia severity (FS) scale is the sum of the WPI and the SS scale</i></p>
Jones et al. ⁸⁰	Physician SCREENING	2017	Sensitivity 64% Specificity 86%	<p>The screen is positive for FMS with both A & B:</p> <p>a) The patient confirms that they ‘have a persistent deep aching over most of my body’.</p> <p>b) Pain is elicited by pinching the Achilles tendon with approximately 4 kg/pressure over 4 seconds.</p>
AAPT criteria ²⁴	Physician DIAGNOSTIC	2019		<p>A diagnosis is made if Dimension 1 criteria are met:</p> <p>Dimension 1: Core Diagnostic Criteria</p> <p>a) Multisite pain (MSP) defined as 6 or more pain sites from a total of 9 possible sites (see Fig .1)</p> <p>b) Moderate to severe sleep problems OR fatigue</p> <p>c) MSP plus fatigue or sleep problems must have been present for at least 3 months</p> <p>Dimension 2: Common features</p> <p>a) Tenderness</p> <p>b) Dyscognition</p> <p>c) Musculoskeletal stiffness</p> <p>d) Environmental sensitivity or hypervigilance</p> <p><i>The presence of another pain disorder or related symptoms does not rule out a diagnosis of FMS. However, a clinical assessment is recommended to evaluate for any condition that could fully account for the patient’s symptoms or contribute to the severity of the symptoms.</i></p> 
The ABC fibromyalgia indicators ⁸¹	Physician DIAGNOSTIC	2019	Sensitivity 88.3% Sensitivity 62.3%	<p>A diagnosis may be made if all three indicators are present:</p> <p>a) Indicator A: Allgesia (hyperalgesia operationalised through pain pressure algometry),</p> <p>b) Indicator B: Bilateral, multilocular, axial-symmetric pain distribution pattern (operationalised through pain drawings or clinical examination), and</p>

				<p>c) Indicator C: Chronic distress symptoms (operationalised through standardised questionnaires or SSS 2011)</p> <p><i>Clinical examination and serological or radiological screens for the verification/exclusion of lesion-based or inflammatory components of coexisting conditions (according to rheumatology standards).</i></p>
<p>Modified Fibromyalgia Assessment Status (FAS 2019 modCr)⁸²</p>	<p><i>Patient</i></p> <p><i>SCREENING</i></p>	<p>2019</p>	<p>Sensitivity 84.2%</p> <p>Specificity 89.0%</p>	<p>The screen is positive for FMS with a combined score ≥ 20 out of 39 of the following:</p> <ol style="list-style-type: none"> 1 Score fatigue and unrefreshing sleep during the past week on an NRS from 0 (no problem) to 10 (severe problems). The scores are summed with a maximum score of 20. 2 A regional pain scale assessing 19 areas of the body. Pain is assessed over the past week. The number of separate pain sites are summed from a maximum of 19 body sites (score 0–19)
<p>Simple Fibromyalgia Screening (SIFIS)⁸³</p>	<p><i>Patient</i></p> <p><i>SCREENING</i></p>	<p>2020</p>	<p>Sensitivity 89.4%</p> <p>Specificity 77.5%</p>	<p>The screen is positive for FMS with 4/6 of the following sentiments:</p> <ol style="list-style-type: none"> 1 'I have a persistent deep aching over most of my body' 2 'I have frequently long periods of fatigue' 3 'I feel unrefreshed and tired in the morning' 4 'I have frequently problems with memory or ability to concentrate on a task' 5 'My pain is accompanied by other health problems such as headaches, abdominal pain, urinary problems, cramps and feeling of restlessness in my legs at night' 6 'I feel anxious and depressed'

Appendix 4: Patient and clinician information sheets



Royal College
of Physicians

Fibromyalgia syndrome: the essentials

For patients



What is fibromyalgia syndrome?



- > Fibromyalgia syndrome (FMS) is real
- > It causes pain from typically non-painful things
- > It is a condition that changes the way the nervous system processes sensory signals; pain can result from this
- > It is not a degenerative, age-related or psychological condition

What can I expect to feel?

You are likely to experience some, but not necessarily all of these symptoms:

- > Widespread pain without an injury
- > Old or healed injuries can hurt
- > No energy or struggling to recharge
- > Difficulty with getting to sleep or staying asleep
- > Trouble concentrating or remembering things
- > Frustrated, worried or low in mood
- > Changeable symptoms – things can worsen or improve, sometimes without warning



How is it diagnosed?

- > There are no X-rays, scans or blood tests that can check for fibromyalgia
- > Your clinician will decide with you whether you need tests to rule other things out
- > There are detailed criteria used to help diagnose FMS – your clinician will share these with you
- > A diagnosis can be made when a pattern of symptoms occur



What can I do?



- > Get to know about the condition – find and use as many good resources as you can – share them with those around you to help them understand too
- > Be really honest with yourself – ask yourself ‘How do I know my pain medicines are helping?’ and ‘How can I do the best I can to look after myself physically and mentally?’
- > Develop your support team – get to know what you need from people around you, and keep those you know help you close
- > Be open with people about what you need from them
- > Be curious about what helps – your toolbox is yours and no one else’s
- > Be focused and realistic with healthcare professionals to make the best use of your time together – plan ahead what you want from the consultation and discuss this at the start



Royal College of Physicians

Fibromyalgia syndrome: the essentials

For clinicians



What is fibromyalgia syndrome (FMS)?

- > FMS is a medical condition that causes widespread pain, fatigue and difficulty concentrating
- > It is multifactorial with neurophysiological, immunological and cognitive elements
- > It responds poorly to conventional treatments, including medicines and injections
- > It is best managed with an individualised multi-element support plan



What to look for

- > Pain treatment is ineffective – ‘nothing works’
- > Significant distress
- > Multiple symptoms over time
- > Other conditions such as IBS, headache, abdominal or pelvic pain
- > Pain out of proportion to what would usually be expected



Screen for other pathologies

- > History and examination:
 - rheumatological, endocrine or neurological conditions
 - obstructive sleep apnoea
 - chronic fatigue syndrome/ME
 - depression
- > Review and examine medication
- > Lab tests based on clinical suspicion, but should include:
 - full blood count
 - ESR/C-reactive protein
 - urea and electrolytes (U&Es)
 - liver and bone profile
 - creatinine kinase
 - blood glucose
 - thyroid stimulating hormone
- > Remember: FMS is not a diagnosis of exclusion; it can also coexist with other conditions



How to diagnose

- > Ideally, carry out a face-to-face assessment
- > Symptoms should be present for >3 months
- > Use ACR (American College of Rheumatology) criteria to aid diagnosis
- > Use symptom severity index (SSI)* to score fatigue, concentration, refreshment from rest and presence of abdominal pain, depression and headache
- > Use widespread pain index (WPI)* to score pain in four body quadrants plus axial region
- > Does it sound right? ie not unilateral or upper/lower body pain only
- > Symptoms cannot be explained by any other conditions



What to say

- > First of all, listen, supportively
- > Share information and signpost to links
- > Share decisions on management and support planning
- > Help coordinate an individualised support plan based on goals and skills

*FMS diagnosis requires a WPI score ≥ 7 and SSI score ≥ 5 or WPI 4–6 and SSIS ≥ 9 , with pain in 4/5 body regions

Appendix 5: Online resources

Help and support

[NHS information on fibromyalgia](#) – NHS website providing information on fibromyalgia and links to further advice and support.

[Fibromyalgia Action UK](#) – registered charity administered primarily by unpaid volunteers, the majority of whom have fibromyalgia syndrome. It was established in order to provide information and support to people with FMS and their families. It maintains a list of registered support groups that meet in person or online around the UK and has publications on FMS available to download.

[Versus Arthritis](#) – large UK charity dedicated to supporting research and providing patient information in the field of musculoskeletal disorders and pain.

[Pain Relief Foundation](#) – UK charity dedicated to supporting research into the causes and new treatments for chronic pain. The PRF supported the development process for these guidelines.

[Flippinpain](#) – public health campaign designed to change the way we all think about, talk about, and treat, persistent pain. It helps improve understanding of how the brain has a key role in pain and recovery.

[Pain Toolkit](#) – a general pain information and management resource for people with chronic pain.

Mindfulness resources

These websites offer information and education about mindfulness and provide links to meditation exercises:

- > [Breathworks](#) – managing fibromyalgia with mindfulness
- > [Mindfulness](#) – finding peace in a frantic world
- > [Free Mindfulness Project](#) – downloadable meditation exercises
- > [Be Mindful](#) – web-based therapeutic course

Employment/education advice

- > [Job Centre Plus](#) – assistance and advice on returning to the workplace by speaking to a work coach
- > [Worksmart](#) – information on disability rights in the workplace
- > [Disability Rights UK](#) – a network of disability organisations providing information on getting work, education and skills
- > [Access to Work](#) – a self-referral service that provides support and adaptations in the workplace
- > [Turn2us](#) – includes a free and easy-to-use benefits calculator and grants search tool
- > [UCAS](#) – universities and colleges have well-developed systems and procedures for admitting disabled students and making sure they progress in their studies.
- > [FMA UK publications](#) – includes employment booklets to download

Pain education websites for patients

- > www.retrainpain.org
- > www.tamethebeast.org

Resource for children to understand chronic pain in someone they know

- > [Do you know someone whose body always hurts?](#)

Glossary

Autoimmune

Where the body's immune system reacts against something that belongs to the body.

Biopsychosocial

A term used to combine 'biological', 'psychological' and 'social' factors when describing something. It may be used, for example, in relation to assessing, or even thinking about a medical condition that is influenced by each of these factors.

Chronic

In relation to pain this is a measure of the persistence of pain and not its severity. People with fibromyalgia may have persistent pain at a low or high intensity.

Chronic primary pain

This is defined by IASP (International Association for the Study of Pain) as:
Pain in 1 or more anatomical regions that persists or recurs for longer than 3 months and is associated with significant emotional distress or significant functional disability (interference with activities of daily life and participation in social roles) and that cannot be better explained by another chronic pain condition.

Chronic widespread pain

Chronic widespread pain (CWP) is characterised by long-lasting pain in multiple body regions.

Fibromyalgianess⁸

Is a new term used to describe the amount of or intensity of symptoms associated with fibromyalgia syndrome or chronic widespread pain (eg 'the amount of fibromyalgianess').

Functional neurological disorder (FND)

FND is where the nervous system 'software' doesn't function correctly, causing changes to how the brain works, or how the body moves or feels. Its diagnostic classification covers symptoms of

- i) motor dysfunction (weakness, movement disorders such as tremor and dystonia),
- ii) sensory loss,
- iii) episodes that resemble epileptic seizures (eg loss of awareness with limb shaking), and
- iv) cognitive symptoms.

Pain is not included in current diagnostic criteria.³² Pain, however, is commonly experienced by people with FND. There is also often overlap between FMS and FND although FMS is not an FND. Some experts believe that pain should be part of the FND diagnosis, but currently it is not. The FND/conversion syndrome diagnosis is based on the presence of specific symptoms and physical signs, with tailored electrophysiological investigations sometimes added. FND can be considered as a disorder of impaired control or access of the brain to the body that occurs in the presence of normal will and motivation and normal structural integrity of the nervous system. Those patients with chronic pain and FND might benefit from techniques used in treatment of chronic pain alongside those used to treat FND.

Functional magnetic resonance imaging (fMRI)

fMRI is a type of MRI scan that looks at activity within the part of the body being scanned (usually the brain) rather than the structure of it. It gives a good idea of brain activity moment-to-moment and can show how areas of the brain change in activity depending on stimulus.

Hypersensitivity

When the level of sensitivity in an area (of the body) is more than normal.

Inflammatory

When the body's immune system becomes active.

Nociplastic pain

Pain that arises from altered nociception (ie altered activity of that part of the nervous system which senses harmful signals) despite no clear evidence of actual or threatened tissue damage causing the activation of peripheral nociceptors (ie peripheral nerves that sense harmful signals) or evidence for disease or lesion of the somatosensory system causing the pain.

Somatic symptom disorder^{§§§§}

Where *excessive thoughts, feelings and behaviours* regarding physical symptoms (including pain) result in additional disability over and above the symptoms themselves. Levels of anxiety tend to be very high and notable time and energy is spent focusing on the physical symptoms. It is possible for an individual to be diagnosed with both FMS and SSD. This is a diagnosis that requires careful psychiatric expertise and familiarity with typical pain presentations, and which, where present, would suggest the need for additional treatment. It is clearly a difficult judgement as to the degree to which thoughts and worries might be 'excessive' – specific expertise is necessary but experts may well disagree between each other when assessing this.⁴¹

^{§§§§} 'Somatisation' is a term that underpinned the now-abandoned diagnostic entity of 'somatisation disorder', a disorder characterised by a presumed mechanism whereby distress is experienced as a somatic symptom, such as pain, breathlessness, or urinary urgency.

Declaration of interests

Any conflicts of interest were fully declared and are available from the RCP. A 'declaration of interests' form was completed by all GDG members.

- > Ased Ali is a member of the medical advisory panel for the charity Bladder Health UK. He is an elected member of the British Association of Urological Surgeons (BAUS) Executive Committee for the Section of Female, Neurological and Urodynamic Urology.
- > Chris Barker has been paid by Connect Health Ltd to act as adviser on the steering group for their public health campaign 'Flippinpain'. He represents the Royal College of GPs nationally for pain (an honorary position) and is co-opted to the council of the British Pain Society. He has received honoraria from media companies for authoring articles in the medical press.
- > Andreas Goebel is a member of the Pain Relief Foundation (PRF) Scientific Committee and is in receipt of research and infrastructural funding support from the PRF, a research charity. He is director of the Pain Research Institute at the University of Liverpool, supported by the PRF. On behalf of the University of Liverpool, he has provided consultancy to Novartis about the use of their drugs in chronic pain, as well as to UCB on a potential drug trial for fibromyalgia. He is a member of the British Pain Society (BPS), an organisation for practitioners working in acute or chronic pain, and chairs the BPS Science Committee. He writes medico-legal reports for the Court about chronic pain after injury/medical intervention; these sometimes involve patients who have fibromyalgia. Ann Lyons, a colorectal surgeon and member of the GDG, is his wife.
- > Robert Moots has undertaken consultancy work and/or received support to attend or present research at academic meetings from AbbVie, Amgen, Eli Lilly, Galapagos, Gilead, Novartis, Pfizer, as well as research grant support from Novartis.
- > Donal O'Donoghue was chair of trustees of Kidney Care UK (patient charity), immediate past president of the Renal Association (RA) and a trustee of the RA.
- > Nicholas Shenker receives unrestricted educational paid work from Eli Lilly and has previously received from Roche. He is chair of the CRPS UK Network and Registry.
- > Manoj Sivan is president-elect of the British Society of Rehabilitation Medicine (an unpaid role).
- > Lynne Turner-Stokes leads the Upper Limb International Spasticity study, a 10-year programme of research sponsored by Ipsen PLC. From time to time, she has received honoraria in relation to that work. She co-chaired the RCP spasticity in adults guidelines which make recommendations about the use of botulinum toxin for spasticity. Ipsen manufactures one of the three current botulinum toxin products licensed in the UK for managing spasticity.
- > **All other contributors have no interests to declare.**

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This guideline aims to support clinicians in the diagnosis of fibromyalgia syndrome (FMS). It is not intended to summarise the management of FMS or treatment pathways; other evidence-based guidelines are available to cover these areas. However, notably where conducted well, a consultation that leads to a diagnosis can have therapeutic and reassuring effects which should not be underestimated. The guideline aims to provide succinct, relevant information for patients, relatives/carers and clinicians about what FMS is, and what it is not. The hope is that through better understanding, awareness of FMS will increase, enabling timely diagnosis and management.

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