

National Institute for Health and Clinical Excellence

**CHRONIC FATIGUE SYNDROME / MYALGIC ENCEPHALOMYELITIS (CFS/ME) GUIDELINE**

**Stakeholder Comments**

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Please insert the **Page number (given at the bottom of the page)** in the 2<sup>nd</sup> column and the **Line Number** (given at the far left of the document). If your comment relates to the document as a whole, please put ‘**general**’ in this column. **Please refer page numbers not section numbers.**

<b>Name:</b>			
<b>Organisation:</b>		<b>Action for M.E.</b> Please also see executive summary attached.	
<b>Document.</b>	<b>Page Number</b>	<b>Line Number</b>	<b>Comments</b>
Indicate if you are referring to the <b>Full version</b> , or the <b>NICE version</b> .	Indicate <b>Page number</b> or <b>'general'</b> if your comment relates to the whole document	Indicate <b>Line number</b>	<p><b>Please insert each new comment in a new row.</b></p> <p><b>Please note that we offer an overarching analysis first, followed by comments on the full and then the shorter guidelines. We ask that comments made in relation to the full guidance are also noted for the shorter version, although disparities between the two have been noted where possible.</b></p> <p><b>As part of our consultation process with our constituents we undertook an online survey on the NICE guidelines, which ran from 30<sup>th</sup> October 2006 to 13<sup>th</sup> November 2006, with 335 responding (full details are attached). Where relevant we have incorporated data from this survey into our comments.</b></p> <p><b>We also undertook a focus group with those members who undertook NICE’s own survey, as a part of the guideline development process. Their views have also been incorporated into our responses, where relevant.</b></p>

<p>NICE Full and shorter guidelines</p>	<p>General</p>		<p>Action for M.E. believes that effective guidelines are required to ensure that M.E./CFS is properly diagnosed, treated and managed. We recognise that these draft guidelines are still a work in progress and further work needs to be done. We commend some aspects of the document, in particular the points addressing patient-centred care, partnership with patients and individually tailored management approaches. However, we have deep concern at the lack of emphasis on the physicality of the illness and the promotion of CBT and GET as the first treatments of choice at the expense of a comprehensive and individually tailored package of symptom management.</p> <p>We wish to work collaboratively to facilitate the development of a robust and workable document that incorporates the views of people affected by the illness, is usable for practitioners, and offers best practice advice on the care of people with M.E./CFS.</p> <p>The guideline's general principles of care are to be welcomed and we note the following as useful and appropriate recommendations.</p> <ul style="list-style-type: none"> <li>• The patient-centred approach at the heart of the guidelines</li> <li>• The emphasis on an individually tailored management approach to healthcare (e.g. Full section 6)</li> <li>• The need for partnership between the patient and the healthcare professional in the management of the illness (e.g. Full 5.4.5.1)</li> <li>• A clear commitment to the patient being in charge of their goals and pace of treatment</li> <li>• Regular contact between the health professional and the patient (e.g. p137 Full)</li> <li>• Regular and frequent reviews are good practice. (e.g. Full P195 6.3.6.28)</li> <li>• The recommendation for multidisciplinary working</li> <li>• The recommendation to healthcare professionals to aim to establish a supportive and collaborative relationship with the patient, their family and</li> </ul>
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			<p>carers (e.g. Full 4.3.6.2)</p> <ul style="list-style-type: none"> <li>• The explicit acknowledgement that patients can withdraw from or refuse suggested treatment or management techniques “without detriment to the provision of other aspects of care” (e.g. Full 4.1.1.1)</li> <li>• The recognition of the positive role of special services and also the vulnerability of their status (Note given in Full guidelines p37 and omitted in short – which we would like to see amended)</li> <li>• Recommendations re. healthcare practitioners: communications and activities reflect those given in the GMC’s Good Medical Practice booklet.</li> <li>• The need for schools and employers to be better educated about M.E./CFS but with information provided with ‘informed consent’ (e.g. Full P21 22-26).</li> <li>• That a designated healthcare professional should be identified as responsible for coordinating care for each adult or child with M.E./CFS (e.g. Short P10 1.1.1.2)</li> <li>• The commitment to continuity of care (e.g. Short P10 1.1.1.2)</li> <li>• We welcome the recommendation that assistance should be provided in negotiating the healthcare, benefits and social services systems</li> <li>• Much of the information presented in the key priorities sections of the guidelines is useful and the assumptions outlined in P208 6.44 establish the parameters of the guidelines and a best practice perspective. However, these need to be placed at the beginning of a final document</li> </ul> <p>There are, however, deep concerns about the following points, which should be addressed as part of the consultation process.</p> <ul style="list-style-type: none"> <li>• The guidelines should be placed clearly within the context of the National Framework for Long-term Conditions.</li> <li>• The context developed and expressed by the</li> </ul>
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			<p>CMO report has not been properly reflected in the guidelines.</p> <ul style="list-style-type: none"> <li>• The guidelines are too long and cumbersome to be effective for the average practitioner and that it is doubtful that GPs will have a clear understanding of the research context on which recommendations are based.</li> <li>• The discrepancies between the long and the short versions are confusing. For example, the implicit rejection of the psychosomatic viewpoint given in the full guidelines (P202) is not included in the shorter version. This should be addressed.</li> <li>• The guidelines need to stress that no individual therapy is proven effective for all patients and that there needs to be a portfolio of treatments and symptom control available appropriate to need.</li> <li>• The guidelines tend to place CBT and GET in isolation, and not as part of a comprehensive and individually tailored management package incorporating a range of necessary treatment relief. This is despite the commentary in the full guidelines executive summary (P2220-21).</li> <li>• A comprehensive and individually tailored management package regarding treatment and symptom control needs to be developed.</li> <li>• The recommendation for CBT and GET as first therapies of choice for the mild and moderately affected implies a “one size fits all” management approach and negates other symptom management. Our survey found 51% strongly disagreed and 27.6% disagreed with the statement that CBT and GET should be therapies of first choice for those with mild to moderate M.E.</li> <li>• The statement in the full guidelines (P202) – that CBT is not directed at illness beliefs, the underlying disease process or is regarded as curative is omitted from the shorter guidelines.</li> <li>• The scientific study of M.E./CFS is a rapidly developing field where little is known at present. There is a paucity of research across the field with available evidence limited and focused on</li> </ul>
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			<p>particular areas .The recommendation of CBT and GET as therapies of first choice suggests that, of a range of possible therapeutic approaches, they are the two which emerge as being most effective, whereas the reality is that there has been very little clinical trial activity involving other treatment or management approaches. There is, therefore, no basis for comparison. In our survey 46.9% strongly disagreed and 29% disagreed with the statement that there is ‘clear evidence’ supporting GET and CBT as therapies of first choice.</p> <ul style="list-style-type: none"> <li>• The research used as a basis for the recommendations did not include individuals who are severely affected.</li> <li>• Diagnostic Criteria remains a contentious issue, with many questioning the omission of the Canadian criteria and noting the need to develop a more focused and mutually acceptable definition for patients and healthcare practitioners.</li> <li>• Sub groups are inadequately dealt with – e.g. mild and moderate are ‘packaged’ together.</li> <li>• There is an implicit assumption that most people will recover or improve relatively quickly, yet we know that a significant number have been ill for ten years or more. 49.6% of respondents to our survey have had M.E./CFS for over 10 years and 25.6% have been ill for 5-10 years.</li> <li>• The extent of how badly impacted the severely affected are by this illness is not clearly articulated in either the long or the short guidelines, and information relating to their treatment is limited. This falls short of the stated aims of the guideline (Full P21). 68% of those who responded to our survey defined their illness as ‘severe’ when it was at its worst. And when asked if they thought there were sufficient outreach services for the severely affected, 68.2% strongly disagreed and 18.7% disagreed.</li> <li>• There are not the available resources – specialist services, trained staff etc. – to ensure the guidelines are properly implemented. In our survey 76.8% strongly disagreed and 12.9%</li> </ul>
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			<p>disagreed with the statement that there are sufficient specialist services for the treatment of M.E./CFS.</p> <ul style="list-style-type: none"> <li>• There is a recommendation that if specialist services exist in a region, financial cost does not seem to be a good reason for keeping someone with an uncertain diagnosis in primary care. (P115 2-5). How realistic is this recommendation given PCTs' financial resources and planning processes?</li> <li>• The training required for healthcare professionals to establish a suitable level of expertise in caring for people with M.E./CFS must be much more clearly delineated. Inexperience in this area can have a profoundly damaging effect. In our survey 75.6% strongly agreed and 20.6% agreed that training requirements for health professionals caring for people with M.E./CFS should be clearly defined.</li> <li>• Many of our constituency were distressed by certain terms and language used in the documentation, as they felt that this indicated a lack of understanding of the illness and/or an unhelpful view of it. One example can be found in the Full Executive summary, P21. This is ironic, given the emphasis the guidelines give regarding a universally accepted terminology.</li> <li>• While the emphasis on provision of information has been welcomed, our recent survey has shown that the vast majority of respondents (85%) self-sourced requisite information, rather than it being provided by healthcare practitioners. The role of the voluntary sector in information dissemination has not been properly noted in either the full or shorter guidelines (Short P6)</li> <li>• Both the long and short versions of the guidelines presented the M.E./CFS community with issues - the timeframe for response was limited for people experiencing extreme fatigue - they simply cannot do things as quickly as most groups.</li> <li>• Please note that not everyone has access to the Internet. We are also very aware - partly as a consequence of developing on-line surveys for our membership – that many people with</li> </ul>
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			M.E./CFS have trouble using PCs for any significant length of time. It is, therefore, not a particularly appropriate mode of communicating lengthy or complex material. (See P 259 7.4.1).
Full, Appendix 1	P17		It is stated that, "No studies were able to establish the superiority of one existing case definition over another". Our constituents have queried the omission of the Canadian guidelines in the development of diagnostic criteria.
Full Exec Summary	P21	9	<p>With regard to "...influencing practice in the real world", sufficient specialist services should be available, along with suitably trained health professionals, otherwise false hopes and expectations are raised.</p> <p>In addition, of particular concern is the lack of knowledge and expertise in Primary Care. In our survey, 36.5% disagreed and 19.6% strongly disagreed with the statement that Primary Care professionals could identify M.E./CFS. In a recent study, 811 GPs (77%) responded to a questionnaire intended to obtain baseline data and identify the factors associated with GPs' attitudes and knowledge of M.E./CFS. 48% of GPs did not feel confident with making a diagnosis of M.E./CFS; and 41% did not feel confident in treatment (Ref: Primary healthcare provision and Chronic Fatigue Syndrome: a survey of patients' and General Practitioners' beliefs. BMC Family Practice. 6:49, 2005).</p>
"	P21	13	There is a limited amount of detailed information in the guideline on support for the severely affected, although the full guidelines do contain more information.
"	P21	17	A key problem in facilitating communication between practitioners and patients is the fact that terminology still lacks clarity. For example, the phrase and definition of Graded Exercise Therapy concerns many of our constituents. Unfortunately, the use of ambiguous language has led to concern and confusion amongst our constituents as we note below.
Full	P21	19	Priority Recommendation, 'when the main goal is to return to normal activity'. Many constituents found this an insensitive comment as they felt it implied that they didn't

			want to return to normal. This needs to be rewritten.
Full	P22	14	Some of our constituents have noted that they have been advised not to engage with self-help groups, as this encourages 'sick beliefs'. Such issues need to be addressed.
Full, Research Reccs	P28		<p>The scientific study of M.E./CFS is a rapidly developing field where little is known at present.</p> <p>The guidelines are inconsistent with the phrase “there is little good research evidence for most aspects of CFS/M.E.” being used, which contradicts the claim made in both the full and short guidelines that there is 'clear evidence' for the effectiveness of CBT and GET. A transparent representation of the research context is needed.</p> <p>No explicit recommendation for biomedical research is made – which we consider essential. In our survey, 73.6% strongly agreed and 14.9% agreed that the most important research for people with M.E./CFS is biomedical.</p> <p>No mention is made of the M.E. Research Observatory, which will look at epidemiological issues.</p> <p>No rigorous evaluation of Pacing was identified, though patient experience supports this technique and this was clearly supported by the CMO report (A RCT on Pacing is now taking place in specialist services and is due for completion in 2009).</p> <p>Research into symptom management as part of a portfolio approach to the illness needs to be undertaken. In our survey 68.1% strongly agreed and 22.4% agreed with the need for such research.</p> <p>We would wish to see a recommendation for research into case definition. Research into sub group analysis was also supported by our constituents; 57.9% strongly agreed and 34.5% agreed that such research is required to see how effective different management methods are with different groups.</p> <p>A recommendation for research into the information needs of patients and practitioners would also be welcomed.</p>

			All of the above should be recommended as future and/or on-going research activity and noted as opportunities for future development in diagnosis and treatment.
Full	P28	6	The research question stated here is itself open to question.
Full	P37	13-16	The principles of pain management should be highlighted in both guidelines and should be more detailed, as it is often a significant feature of M.E./CFS.
Full	P37	1.6	There is a considerable difference in the comments made here, in lines 21–25, and those in the shorter guidelines (p161.2.3.3). The shorter guidelines should reflect the more comprehensive understanding of the illness given in the full guidelines.
Full	P38, 39		The limited availability and vulnerability of services is noted... this needs to be highlighted further to ensure that the guidelines can be properly met. This does not appear to be referred to in the short guidelines.
Full	P44	20-21	Identifying the evidence: we were unable to obtain the technical manual on-line and were informed in a follow-up phone call that hard copies would not be mailed. Some reference to its contents would have been helpful in your guide to explaining how the guidelines are drafted.
Full	P45		Formal consensus methods are welcomed in the development of this guideline. However, it was noted with some concern that there were areas where the disagreement of the wider group appeared to be ignored. This is particularly evident in relation to the use of GET for moderately affected (see P150 full guidelines).
Full	P45	8-12	The phrase “there is little good research evidence for most aspects of CFS/M.E.” contradicts the claim made in both the full and short guidelines that there is 'clear evidence' for the effectiveness of CBT and GET. A

			transparent representation of the research context is needed.
Full	P50	19-21	The small sample size was noted by constituents and unfavourably compared with voluntary organisations' membership surveys. The construction and distribution of the survey was also problematic for people with M.E., particularly for those who were severely affected.
Full	P55	3.2.1 – 3.2.12	As noted, patient responses have not been integrated into the guideline recommendations.
Full	P78	4.1.1.1	Shared decision-making - this section was welcomed and recognised as best practice.
Full	P78	4.1.1.2	The term “appropriate skills and expertise” needs to be more fully defined throughout both the full and the short guidelines. Particular concern was expressed that, given the shortage of expertise in properly qualified CBT practitioners, qualifications and experience in this field would need to be clearly delineated. It has also been suggested that, if GET is used, it should be obligatory for multi-disciplinary teams to include a suitably trained practitioner.
Full	P79/80		Research on the type of information required by patients, carers and healthcare professionals is extremely important to ensure that one of the key recommendations of the guidelines - shared decision-making - can be properly implemented.
Full	P81	4.2.6.1	“Universally understood definitions....” Further guidance on this is needed with an awareness of patient sensitivity.
Full	P81.	4.2.6.5	A clear delineation of what “informed consent” should mean should be provided.
Full	P83	4.2.6.7	We would like the importance of a written record to be highlighted, as this can be very helpful. It is also one of the components of providing good clinical care in the GMC's Good Medical Practice.

Full	P83		The points raised re. loss of work or education are important, as long as undue pressure is not placed on the patient.
Full	P86	4.3.6.1	We support the intention of the guidelines to help get the patient to return to as normal a life as possible, which would need to be undertaken with great sensitivity.
Full	P86	4.3.6.4	We welcome the recommendation that assistance should be provided in negotiating the healthcare, benefits and social services systems.
Full	P86-87	4.3.6.4- 4.3.6.6	Hospitals should be made aware of some patients' multiple chemical sensitivity and sensitivity to light etc. The guidelines need to note that hospital care may not be acceptable for all patients and domiciliary care should be available. However, in other cases respite care might be a real need and the guidelines should comment on this.
Full	P104	5.2.8	<p>"Primary healthcare professionals should be familiar with the presenting features of CFS/ME..." recent research indicates that this is not the case. Some reference to primary healthcare training would be helpful. (Ref: Primary healthcare provision and Chronic Fatigue Syndrome: a survey of patients' and General Practitioners' beliefs. BMC Family Practice. 6:49, 2005)</p> <p>The list of symptoms does not delineate all of those which can be experienced by people with M.E./CFS, particularly by those with severe M.E.</p> <p>Pain is a significant problem for many people with M.E./CFS and this needs to be noted (in both sets of guidelines). We would like to see the healthcare provider be required to direct the patient to an appropriate form of pain management.</p>
Full	P106	5.2.8	Risks of prolonged bed rest: while this is accepted wisdom, constituents, particularly those with severe M.E., felt this was unhelpful, if not dangerous, to their condition. Indeed, some constituents with milder forms of M.E. have also expressed concern that the guidelines emphasise the need for exercise without necessary

			<p>provisos (in relation to need, appropriately qualified practitioners etc.).</p> <p>In response to our online survey, 34.3% strongly agreed and 37.2% agreed that rest and minimal activity - at levels well below full capacity - help people with severe M.E./CFS to manage their illness. And when asked, during a setback, Activity Management should be maintained but not include prolonged rest unless absolutely necessary, 46.3% strongly disagreed and 27.8% disagreed with this statement. These differing views need to be addressed.</p>
Full	P107		The number of recommended tests is limited. For example, it seems illogical that the test for Creatinine Kinase is limited to children only.
Full	P110	5.3.1.1- 5.3.1.3	<p>Criteria: The guidelines state "No studies have established the superiority of one case definition over another". Given this, there is patient support for the Canadian Guidelines; and many have felt dismayed at the wider definition of M.E./CFS used. While we acknowledged an understandable desire to ensure no one falls through the net, there is a need for clearer case definition.</p> <p>Given that recent research has indicated that GPs are not confident about making a diagnosis, greater detail re. diagnosis would seem logical.</p> <p>It would also be helpful if there were a recommendation for research into case definition.</p>
Full	P116	5.3.4 In7	The assumption that the patient can refuse treatment without compromising the therapeutic relationship needs to be stated as a requirement in all guidelines.
Full	P124	5.3.6	We appreciate the concerns of the GDG re. ensuring an early diagnosis and the accompanying problem of a false diagnosis. This would lead one to presume that a recommendation of biomedical research and research into subsets would be appropriate (see P28 full guidelines).
Full	P126	4-6	Sleep apnoea merits prompt investigation and referral -

			This is not expressed as clearly or with the same urgency in the shorter guidelines (see short guidelines P27, 1.3.2.4)
Full	P132	5.4.5.1	The partnership approach between patients and healthcare professionals is welcomed.
Full	P132	5.4.5.2	These recommended timeframes for referral were generally well received. Our survey found that 44.3% strongly agreed, and 35.9% agreed, that adults and children with mild M.E./CFS should be referred within 6 months. This rose to 58% strongly agreeing and 29.3% agreeing that the moderately affected should be referred within 3-4 months; and increased to 69.8% strongly agreeing and 19.1% agreeing that the severely affected should be referred immediately.
Full	P133 – 135	5.5	<p>We expected reference to the WHO definition, or the Department of Health's classification of M.E. as a long-term, neurological illness to be made.</p> <p>NICE's implicit rejection - given here - of the psychosomatic viewpoint is extremely important. This position needs to be made crystal clear and included in the short guidelines.</p> <p>The emphasis on using appropriate language and sensitivity in dealing with patients is welcomed. Feedback we have received, however, indicates that there are still major problems in terms of how health practitioners relate to people with M.E./CFS. Some reference to training in relation to this would be helpful.</p> <p>Our constituents would welcome a clearer acknowledgement by health professionals that: a) the illness is a real, physical illness; and b) M.E./CFS is not a somatic condition. Again, a clear statement by NICE is required here.</p>
Full 6.Mgmt	P 137		<p>Many aspects of this are welcomed. These include: an integrated and tailored approach to care; regular contact between the health professional and the patient; and the stated need for an appropriate level of training for health professionals.</p> <p>Concerns have been raised regarding what is considered</p>

			'appropriate levels' of training and some clarification of this description is required.
Full	P138	6.3.1.1	<p>A more straightforward explanation of CBT within the current research context is required. Ambiguity in language such as referring to CBT as a treatment, while placing it under a section entitled 'Management', creates confusion and exacerbates concerns. Similarly, the view that it is not curative should be elucidated. We believe it to be a useful management strategy for some people and should be seen as part of a whole management package.</p> <p>There are few examples of longitudinal studies to determine the long-term benefits of CBT, therefore the statement "CBT is well understood and well researched." is not accurate.</p> <p>The use of CBT has been hotly debated among constituents and, while we consider that it can be useful for some individuals if appropriately applied by experienced practitioners, we must note the concerns of our members and those of the wider M.E. community. CBT must not be 'oversold'. A number of respondents have found it helpful but others are worried that it might be used to replace treatment for more immediate problems, such as the proper management of pain, which is often a significant symptom of M.E.</p>
Full	P 139	6.3.1.2	<p>GET remains a controversial treatment. NICE have clearly striven to provide a clear definition of this management process. However, further and emphasised acknowledgement of the fear and damage this procedure has created in a considerable number of people with M.E./CFS is required.</p> <p>We noted the recognition that this technique has sometimes been implemented with significant adverse responses and that it is essential that agreement and negotiation be at the very centre of a GET programme. This detailed comment is not reproduced in the shorter guidelines, thereby omitting its full context.</p> <p>The limitations of the research on GET – small studies with ill-defined levels of severity of participants – causes concern, particularly when aspects of it are being recommended in the guidelines for the severely affected.</p>

			<p>Many people with M.E./CFS strenuously rejected the use of aerobic exercise, even for people with initially moderate M.E./CFS. A considerable number of our constituents believe the balance of advice of activity and rest must be reconsidered, and that the guidelines should err on the side of safety. This view needs to be addressed.</p> <p>Clearly delineated criteria for the evaluation of the level of professional expertise is required, and it has been suggested that an appropriately qualified practitioner should be a compulsory member of the multi-disciplinary teams. Practitioners in primary care should always seek expert advice before recommending any aspect of a GET programme.</p>
	P139	7-8	<p>The explanation of GET given here is much clearer than that outlined in the short guidelines and, presumably, provides a better understanding to health professionals. We suggest it be included in the short guidelines.</p>
Full	P141	6.3.1.3	<p>Activity Management seems to link strongly to Pacing in all but name. Pacing is the favoured method of management shown by patient evidence.</p>
Full	P 141	6.3.1.6	<p>There needs to be delineation between a 'setback' and a 'relapse', with 'setback' referring to a very brief period of time with limited symptom impact.</p> <p>Many of our constituents consider that the uniform use of the term 'relapse' fails to acknowledge the duration and severity of symptoms which can occur. In our survey, 91.9% compared to 8.1% considered the term relapse to be more accurate than setback.</p>
Full	P 142	7-9	<p>While some delineation of the cause of 'setbacks' is given in the full guidelines, they do not appear in the shorter version, and many of our constituents have commented on this omission.</p>
Full	P 142 – 143		<p>A considerable number of constituents noted how they felt obliged to undertake activity which increased the severity of their relapse. Consequently, it would be appropriate to emphasise that the degree of severity in the setback must be defined by the patient and</p>

			respected by the health professional. Even for 'mild' setbacks some respondents argue that cessation of activity may be required for a short period. The crux of this is listening to the individual patient.
Full	P 145	6.3.2.1	This is a questionable statement and does not aid transparency of communication.
Full	P 146	6.3.2.8	Research undertaken this year by Dr Hazel O'Dowd indicates that group CBT is less effective than a one-to-one approach.
Full	P 146	6.3.2.10	Computerised CBT would reduce the person-centred approach that is required, particularly with an illness such as M.E./CFS, where personally validating human interaction is often limited.
Full	P146		<p>It was noted that the sample sizes were small. In the interests of transparency and building good will and understanding, reiteration of the limitations of the research available would be helpful.</p> <p>Understanding would be improved if this were placed in the context of 'currently available research'.</p>
Full	P147	7-9	This illustrates one of the problems of offering CBT as a 'one size fits all' approach. Management of this illness requires a portfolio of symptom management and treatments.
Full	P 147		The sample sizes in support of GET are very small. The patient voice is overwhelmingly against what they perceive as GET.
Full	P156	6.3.4.6	The importance of patient input is not made clear in lines 17-19.
Full	P158	1 - 3	These are assumptions about resources which could be stated earlier to ensure that a realistic assessment of the current context for the treatment of M.E./CFS is fully appreciated. Such transparency would be welcomed.

Full	P181	6.3.6.2	We welcome this statement and would recommend that this be implemented across Government Departments.
Full	P 181	6.3.6.3	Many constituents found the line ‘main goal is to return to normal activities’ an unacceptable expression implying that they may not want to get better.
Full	P181	6.3.6.4	The evidence is limited to the current research context and needs to be specified.  Pain is a significant symptom for a significant number of people with M.E. and needs to be listed here.
Full	P184		A significant number of our constituents – particularly those with the more severe forms of M.E. – have found the second bullet point in this section (i.e. that there is no evidence for the benefits of complete rest) untrue. Indeed, many found the implicit tone of this section to imply that the patient voice should be disbelieved. In response to our survey question “During a setback, activity management should be maintained but NOT include prolonged rest....” 46.3% strongly disagreed and 27.8% disagreed.
Full	P185	6.3.6.13	“Challenging cognitions which may adversely affect rehabilitation and/or symptom management....fear of activity and perfectionist beliefs”. Significant comment has been received regarding this statement. Constituents have argued that this reinforces an underlying psychological analysis which directs management approaches and a fundamental understanding of the illness. This passage needs to be rewritten to clarify its implicit and explicit meanings.
Full	P185		“Decreasing somatic attributions and addressing over-vigilance...” See comments made above ( P185 6.3.13).
Full	P192	6.3.6.20	Comments regarding the use of the word ‘relapse’ rather than ‘setback’ and issues relating to cessation of activity have already been commented on.
Full	P195	6.3.6.25	Many severely affected people were disturbed by this

			suggestion – its inclusion needs to be accompanied by a reiteration of the fact that the patient needs to be in charge of their goals.
Full	P195	6.3.628	Regular and frequent reviews are welcome
Full	P199	6.3.6.36	This should precede recommendations for the management of setbacks/relapses, to ensure the proper context is provided.
Full	P 202		A clearer definition of what constitutes a ‘suitably trained CBT therapist’ needs to be provided. We recently investigated a university-linked course for certificates and diplomas in CBT. We were informed that, following a course lasting a few days, we would be able to promote ourselves as a CBT therapist. Some assurance of quality control is necessary.
Full	P202	6.3.6.39	Again ‘appropriately trained’ needs further detail.
Full	P202	6.3.7	Does this mean the guidelines recommend 13-16 CBT sessions? There are linked issues here regarding number and availability of services  A number of constituents have expressed the view that the effectiveness of therapy depends primarily on the personal effectiveness of the therapist, rather than the specific therapeutic technique.
Full	P202 – 203	15 - 11	This statement is welcome and we would like to see it more prominently located within the guidelines and in any information dissemination regarding them. It should be noted, however, that this statement is omitted from the short guidelines and needs to be included.  However, there are some ambiguities elsewhere (e.g. p 185 ‘fear of activity and perfectionist beliefs’).
Full	P203	17	The evidence is questionable. A more appropriate comment would be to state that it is regarded as showing the most significant evidence - according to NICE - in the context of current research.

Full	P203	20-22	This recognition is very welcome but needs to be highlighted in both the long and the short versions of the guidelines.
Full	P203	27-29	<p>It is significant that patients did not support gradual increases in aerobic exercise. In our survey, 58% of those with mild to moderate M.E.; 76% of those with moderate M.E.; and 82% of those with severe M.E. strongly agreed that aerobic exercise could be damaging. A further 20% (mild), 15% (moderate), and 11% (severe), agreed. Again, there is need for greater understanding in this area.</p> <p>The lines referring to Healthcare professionals are confusing and should be made clear in the directions for implementing this management technique.</p>
Full	P204	1-10	Patient control of goal-setting and pace of progress as a core feature of GET needs to be highlighted in all relevant sections, to establish the proper context and confront patient fears.
Full	P204	11-14	We received extensive general comment from constituents stating that GET was entirely inappropriate for people with severe M.E./CFS. In addition, in our survey we asked people to respond to the question: 'Aerobic exercise can be damaging for people with M.E./CFS'. For those with mild M.E./CFS 58% strongly agreed and 20% agreed with the statement. In relation to the moderately affected, 76% strongly agreed and 15% agreed. And in relation to how this might impact on the severely affected, 82% strongly agreed and 11% agreed.
Full	P204	15-23	The concern of the GDG is understandable and supported by the accepted research evidence. However, this issue relates to the integration of the patient voice and underlines the fact that a 'one size fits all' approach to M.E./CFS is ineffective. Again, emphasising the tailoring of management programmes for the individual would be helpful.
Full	P205	6.4	Recommendations for pharmacological interventions are limited. Given the range of symptoms occurring with M.E./CFS a menu of treatment approaches is required.

Full	P207	4-8	The extremely limited research re. the severely affected has been noted by our constituents.
Full	P233	9-11	There are inconsistencies between the full and shorter guidelines. The full guidelines say that melatonin might be considered. In the shorter guidelines this is limited to children. We have had feedback from patients that melatonin is useful in the treatment of sleep disorders.
Full	P248	6.5.5.3	Many constituents find a tailored diet extremely helpful, so the input of a dietician as part of a multidisciplinary approach would be welcomed. In our survey, 42.7% strongly agreed and 41.2% agreed that diet and nutrition are important in the management of M.E./CFS.
Full	P256	7	Many of the severely affected are physically unable to access services; so domiciliary visits become an essential requirement and should be noted as such.
Full	P258	7.3.1.3	Telephone support for the severely affected – 76.5% of respondents to our survey thought this was a useful resource for the severely affected.
Full	P259	7.4.1	‘Access to DWP and other benefits may be an issue and this should be discussed and help provided if appropriate’. This is warmly welcomed but we would like to see it further emphasised – and perhaps related to the issue of a patient refusing a particular component of treatment.
Full	P259	22-23	Regular home monitoring is welcome – human contact alone would be beneficial. In many cases, home visits from specialists would also be welcome.
Full	P260	7.4.3	These comments regarding the position of carers are welcomed. These do not appear in the full guidelines, which would be useful.
Full	P262		Is this note about the skin sensitivity of people with M.E. included in the shorter guidelines? We have not been able to find it.

Full	P 262 – 263	27 – 2	“At first it should aim to control pain...”needs to be highlighted in the short guidelines.
Short	P 1		It would be helpful to insert the word ‘physical’ into the first sentence and to add that it is defined by WHO and classified by the Department of Health as a long-term neurological condition.
Short	P3		“CBT is an evidence-based treatment...”  We have already commented on concerns r. the level of research evidence available and the importance of noting that this statement is true within the current research situation.
Short	P 6	Bullet 1	We have already mentioned concerns re. the phrase ‘therapies of first choice’. M.E./CFS is not a ‘one size fits all’ illness.
Short	P 6	Bullet 2	Comments regarding shared decision-making are welcome but it would be appropriate to add that patients are in control of goals and pace of management programmes. This is so important it must be reiterated whenever necessary.
Short	P7	Bullet 5	“When an acute infection is followed by...”. As so many of our constituents have a problem with pain management this should be included as a requirement for special focus.
Short	P7	Bullet 7	“Referral to specialist care should be based on needs and symptoms...” An acknowledgement of the limited geographical spread and the vulnerability of the specialist services is made in the full guidelines but not in the short guidelines. What can the primary healthcare worker do if there are no services in their area or they cannot refer out?
		Bullet 8	“In the absence of a specialist diagnosis...” Who will provide this advice and symptom management? There is concern regarding the level of expertise amongst GPs and other primary healthcare providers.

Short	P9		The statement regarding the patient being in charge of their goals and pace of treatment should be included under General Principles of Care.
Short	P10	1.1.1.2	Again, appropriate skill and expertise needs to be clarified.
Short	P10	1.1.2.2	This comment re. continuity of care is welcomed.
Short	P11	1.1.3.5-6	Concern has been expressed in relation to how any refusal of a management component may be used in relation to employers or benefits. It should also be noted that the healthcare professional needs to properly understand the illness and its impact on daily life and take the patient view into account.
Short	P12	1.1.1.4	Particularly welcome here is support negotiating the healthcare, benefits and social services systems.
Short	P12	1.1.4.4	The listing under a line referring to it as a support that 'should be considered' is inappropriate and contradicts a key recommendation that all those with M.E./CFS should have equity of access to treatment.
Short	P13	1.2.1.2	There is significant concern that primary healthcare professionals are not familiar with the presenting features of M.E./CFS.
Short	P14	1.2.1.7	A timeframe relating to this discussion with a specialist should be provided? There are also resource issues to be considered here.
	P15	1.2.11	Reference to the patient being in control of goals and timeframe, as per our previous comments.
Short	P16	1.2.3.3	A prognosis of cautious optimism was generally welcomed. However, it should be noted that when we asked respondents to our survey to indicate which definition they agreed with - 'People with M.E. can go into remission' OR 'people with M.E. can recover' - 84.1% considered 'remission' the more accurate

			description (comments have already been made regarding the disparity between this section and the full guidelines).
Short	P17	1.2.4	This recommendation was welcomed but people wondered if it would be possible to implement, given lack of resources. Our survey showed that 76.8% strongly disagreed and 12.9% disagreed with the statement that there are sufficient specialist services available.
Short	P17	1.2.4.3	While clarification of waiting times for a referral have generally been welcomed, a concern has been raised. A GP may wait the recommended time for the referral but then an additional wait is required to see a specialist, which could exacerbate diagnosis in a condition where early diagnosis can be crucial. It is important that treatment is provided as soon as possible within the primary care setting (See also Action for M.E.'s 'Guidance on the management of M.E./CFS').
Short	P17	1.3.1	Much of this section is welcome but 1.1.1.3 is not. CBT is not necessarily the first choice of people with even mild or moderate M.E./CFS (although we would not argue that many would gain benefits from it).
Short	P19	1.3.1.11	A clearer understanding of CBT would be provided if comments re. the research context were provided.
Short	P19	1.3.1.10	General feedback which we have received via our survey indicates that this statement is regarded as particularly contentious when it has been compared to the overall lack of research data and clear evidence.
Short	P21	Bullet 2	<p>Many of our constituents were extremely disturbed by the phrase "somatic attributions and symptoms over-vigilance," which is regarded as patronising and ignores the patient voice.</p> <p>An expressed concern for over-exertion is understandable given how some with this illness have been affected by exercise regimes. Though we understand the necessity of moving people away from self-limiting beliefs, this statement could be better expressed.</p>

Short	P23	1.3.1.20	Constituents have noted that both guidelines have a dominant tone emphasising the need for exercise and to challenge patients' fear of it. Many people over extend themselves and yet there is only one reference to it (P20 1.3.1.3). This imbalance in the document could lead to misinterpretation.
Short	P23	1.3.1.21	The guidelines need to clarify what sort of support might be made available to enable the patient to reinforce learning and lifestyle changes.
Short	P31	1.3.4.	Pharmacological interventions should include some reference to helping with pain and offer a toolkit or portfolio of interventions to suit patient needs.
Short	P31	1.3.4.4	The warning re. lower tolerance and potential impact of medication is welcomed.
	P33	1.3.6	While there is little available research into complementary medicine or the benefits of supplements, a number of constituents feel they have derived benefits from both. Research is needed in this area and more detailed information on balancing individual benefits and cost. In our survey, 53% of respondents found a complementary therapy useful in managing M.E./CFS.
	P33	1.3.6.2	How this could link into specialist clinics should be considered.  Patient feedback at individual clinics, in relation to this issue, should be considered.
Short	P35		Summary of each consultation: this would be best practice, whatever the degree of severity.
Short	P37	4	The research recommendations are not to be found in section 5 of the full guidelines.
Short	P36-P37		The implementation process was outlined during the NICE Implementation Planning Meeting. A number of issues were raised relating to the need for tailored

			information for a variety of audiences. Unfortunately, this useful discussion was not reported in any detail in relation to the feedback notes, as certain comments raised would have been useful in making further comment on this section.
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