1. Background information

Guideline issue date: 2007
3 year review: 2010
National Collaborating Centre: National Clinical Guidelines Centre (formally NCC Primary Care)

2. Consideration of the evidence

Literature search
From initial intelligence gathering and a high-level randomised control trial (RCT) search clinical areas were identified to inform the development of clinical questions for focused searches. Through this stage of the process 25 studies were identified relevant to the guideline scope. The identified studies were related to the following clinical areas within the guideline:

- Case definitions of CFS/ME
- Information and support needs of CFS/ME patients, carers and healthcare professionals
- Management of CFS/ME
Three clinical questions were developed based on the clinical areas above, qualitative feedback from other NICE departments and the views expressed by the Guideline Development Group, for more focused literature searches. The results of the focused searches are summarised in the table below. All references identified through the initial intelligence gathering, high-level RCT search and the focused searches can be viewed in Appendix I.
## Clinical area 1: Case definitions of CFS/ME

<table>
<thead>
<tr>
<th>Clinical question</th>
<th>Summary of evidence</th>
<th>Relevance to guideline recommendations</th>
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<tbody>
<tr>
<td>What are the existing case definitions for chronic fatigue syndrome in adults and children and what evidence exists to substantiate or validate these case definitions?</td>
<td>Through the focused search 19 studies relevant to the clinical question were identified. Literature relating to case definitions for CFS/ME generally included observational studies with small sample sizes. Some studies provided a description of symptoms however, no conclusive evidence providing a definitive case definition was identified. Therefore, no new evidence relating to case definitions for CFS/ME was identified which would warrant an update of the current guideline recommendations.</td>
<td>No conclusive evidence was identified that would invalidate current guideline recommendations.</td>
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### Clinical area 2: Information and support needs

<table>
<thead>
<tr>
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<tr>
<td>What are the support needs of healthcare professionals, patients and carers?</td>
<td>Eight studies were identified through the focused search relating to this clinical question.</td>
<td>No new evidence was identified which would change the direction of current guideline recommendations.</td>
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<td></td>
<td>In terms of information and support needs of CFS/ME patients, carers and healthcare professionals, most identified studies focused on educational interventions to improve knowledge of CFS/ME among healthcare professionals. Identified evidence included small observational studies which added no new area or contradictory information to current guideline recommendations.</td>
<td></td>
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Clinical area 3: Management of CFS/ME

<table>
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<tr>
<th>Clinical question</th>
<th>Summary of evidence</th>
<th>Relevance to guideline recommendations</th>
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<tr>
<td>Does the evidence show that any particular intervention or combination of interventions is effective in treatment, management or rehabilitation of adults and children with a diagnosis of CFS/ME?</td>
<td>Through the focused search 32 studies relevant to the clinical question were identified. Most identified studies were related to interventions for management of CFS/ME. The majority of studies focused on cognitive behavioural therapy (CBT) however, identified studies reported results that were in line with current guideline recommendations. No new evidence was identified specifically related to graded exercise therapy (GET) or pacing. Although the protocol for the PACE trial (an RCT of adaptive pacing, CBT, and graded exercise, as supplements to standardised specialist medical care) was identified, the results of this study were not published at the time of this review (publication date unknown). In addition, a study (FINE trial) of pragmatic rehabilitation, supportive listening and General Practitioner treatment as usual reported inconclusive results.</td>
<td>There is currently no new published evidence that would invalidate current guideline recommendations.</td>
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</table>
In terms of pharmacological and dietary interventions, new evidence was identified however this was not contradictory to current guideline recommendations.

Similarly, evidence related to complementary therapies remains limited in quantity and quality. As such, no evidence was identified which would warrant an update of the guideline recommendations at this time.
Several ongoing clinical trials (publication dates unknown) were identified focusing on the effectiveness of group CBT for patients with CFS/ME; the efficacy of internet-based CBT for adolescents with CFS/ME; behavioural insomnia therapy for CFS/ME and the efficacy of pacing/graded exercise therapy/CBT plus specialist medical care. The results of these trials have not been published at this time but may contribute towards the evidence base relating to management of CFS/ME in the next update review.

No evidence was identified that was relevant to research recommendations in the original guideline.

In conclusion, no identified new evidence contradicts current guideline recommendations.

**Guideline Development Group and National Collaborating Centre perspective**

A questionnaire was distributed to GDG members and the National Collaborating Centre to consult them on the need for an update of the guideline. Ten responses were received with respondents highlighting the FINE and PACE trials as emerging new evidence (results of the PACE trial have not been published at this time) and new research on therapy (therapy not specified). Conflicting evidence on the association between retrovirus and CFS/ME were also highlighted. However, this is considered outside the remit of the original guideline. No published literature relating to the scope of the guideline was specified through the questionnaire which contradicted current guideline recommendations.

The majority of respondents felt that there is insufficient variation in current practice supported by adequate evidence at this time to warrant an update of the current guideline.
Implementation and post publication feedback

In total 104 enquiries were received from post-publication feedback, most of which were routine. Key themes emerging from post-publication feedback included enquiries relating to CBT, GET, dietary supplements, complementary therapies and immunoglobulin therapy. This feedback contributed towards the development of clinical question 3 as described above.

No new evidence was identified through post publication enquiries or implementation feedback that would indicate a need to update the guideline.

Relationship to other NICE guidance

The following NICE guidance is related to CG53:

<table>
<thead>
<tr>
<th>Guidance</th>
<th>Review date</th>
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<tr>
<td>CG27: Referral for suspected cancer, 2007</td>
<td>Currently scheduled for a consideration for an update (Dec 2010).</td>
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<tr>
<td>CG23: Depression: management of depression in primary and secondary care, 2004</td>
<td>The guideline was updated in 2009 and was published alongside 'Depression in adults with a chronic physical health problem: treatment and management' (NICE clinical guideline 91), which makes recommendations on the identification, treatment and management of depression in adults aged 18 years and older who also have a chronic physical health problem. Expected review date: TBC.</td>
</tr>
<tr>
<td>CG61: Irritable bowel syndrome in adults: Diagnosis and</td>
<td>This guideline was not published at the time of CG53 publication although was alluded to in the guideline.</td>
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Guidance | Review date
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management of irritable bowel syndrome in primary care, 2008 | Expected review date March 2011.
TA97: Depression and anxiety - computerised cognitive behavioural therapy (CCBT), 2006 | The recommendations in this technology appraisal relating to the treatment of depression have been updated and replaced by recommendations in the two Depression clinical guidelines (CG90 and CG91) published in October 2009.
PH19: Management of long-term sickness and incapacity for work, 2009 | This guideline was not published at time of CG53 publication although was alluded to in the guideline. Expected review date: TBC.

**Anti-discrimination and equalities considerations**

No evidence was identified to indicate that the guideline scope does not comply with anti-discrimination and equalities legislation. The original scope is inclusive of diagnosis, treatment and management of mild, moderate or severe CFS/ME in children (aged 5 years and upwards, including young people in transition to adulthood) and adults. The guideline covers care in primary and secondary care, and in specialist centres/teams.

**Conclusion**

Through the process no additional areas were identified which were not covered in the original guideline scope or would indicate a significant change in clinical practice. There are no factors described above which would invalidate or change the direction of current guideline recommendations. The CFS/ME guideline should not be updated at this time.
3. Review recommendation

The guideline should not be updated at this time.

The guideline will be reviewed again according to current processes.

Centre for Clinical Practice
27.10.10
Appendix I


White, P.D., Sharpe, M.C., Chalder, T., DeCesare, J.C., & Walwyn, R. 2007. Protocol for the PACE trial: A randomised controlled trial of adaptive pacing, cognitive behaviour therapy, and graded exercise as supplements to standardised specialist medical care versus standardised specialist medical care alone for patients with the chronic fatigue syndrome/ myalgic


