NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Centre for Clinical Practice

Review of Clinical Guideline (CG53) – Chronic fatigue syndrome/ myalgic encephalomyelitis (or encephalopathy): diagnosis and management of chronic fatigue syndrome, myalgic encephalomyelitis (or encephalopathy) in adults and children.

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

1. 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

2. 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. In total, 59 studies were identified through the focused searches however, no identified new evidence contradicts current guideline recommendations.

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

4. 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 and behavioural insomnia therapy for CFS/ME. 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.

Guideline Development Group and National Collaborating Centre perspective

5. 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 (Fatigue intervention by nurses evaluation) and PACE (Comparison of adaptive pacing therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome) trials as emerging new evidence.

6. 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.

7. Seven 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

8. 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.

9. 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

10. NICE guidance related to CG53 can be viewed in Appendix 1.

Summary of Stakeholder Feedback

Review proposal put to consultees:
The guideline should not be updated at this time.
The guideline will be reviewed again according to current processes.

11. In total 25 stakeholders commented on the review proposal recommendation during the 2 week consultation period.

12. Nine stakeholders agreed with the review proposal recommendation that this guideline should not be updated at this time, and 5 did not respond to this question.

13. Eleven stakeholders disagreed with the review proposal on the basis that the guideline should focus on the aetiology and pathogenesis of CFS/ME, and that treatments/interventions recommended should be driven by aetiological/biomedical models. However, current literature relating to the aetiology and pathogenesis of CFS/ME is inconsistent and inconclusive whilst interventions recommended in the original guideline, such as CBT and GET, were described as the interventions for which there is the clearest evidence-base of benefit. This is supported by the recently published PACE trial (comparison of adaptive pacing therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome among 641 patients, published February 2011). The review of literature undertaken to inform the review proposal also did not identify any research which would invalidate or change the direction of current guideline recommendations,

14. Literature was submitted through stakeholder consultation relating to:
    - A survey of illness management requirements for people with CFS/ME and their carers
    - Multidimensional programmes for management of CFS/ME
    - Biomedical and vascular aspects of paediatric CFS/ME
    - CBT and GET for management of CFS/ME
    - GP attitudes and knowledge of CFS/ME
    - The biology and pathophysiology of the retrovirus XMRV

15. During consultation, areas to consider for review in any future update of the guideline were highlighted including:
    - Diagnosis of CFS/ME (in particular relating to case definitions, clinical utility of diagnostic tests and recommended blood tests)
    - Management of CFS/ME
    - Practical guidance on pacing for CFS/ME

16. During consultation, new areas to consider in any future update of the guideline were highlighted including:
    - Aetiology and pathogenesis of CFS/ME
    - Inclusion of the World Health Organization's ICD10 classification
    - Diagnosis of postural orthostatic tachycardia syndrome (POTS) in association with CFS/ME
    - The inclusion of ferritin as a marker in basic blood screening for CFS/ME
    - An emphasis on the multidisciplinary approach for CFS/ME management and rehabilitation
    - The use of mindfulness therapy for people with CFS/ME
    - The inclusion of the new blood donation policy for ME/CFS patients which was introduced from 1st November 2010

17. Because of comments received at consultation the review decision on this guideline was suspended until the PACE trial (Comparison of adaptive pacing therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome ([PACE]: a randomised trial) reported on the 18th February 2011. The data presented in this study was taken into account to inform the final review decision. In the study, patients were randomly allocated to standard medical care (SMC) alone or SMC plus cognitive behavioural therapy (CBT), graded exercise therapy (GET) or adaptive pacing therapy (APT). Assessments of fatigue and physical function, social adjustment scores, sleep disturbance, anxiety, depression and adverse events were undertaken at baseline, 12 weeks (mid-therapy), 24 weeks (post-therapy) and 52 weeks after randomisation. The results of the study indicated that either CBT or GET, when added to SMC, are moderately effective treatments for CFS. The results of the study are in line with current NICE guideline recommendations on the management of CFS/ME.

Anti-discrimination and equalities considerations

18. 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.

19. The following equalities issues were highlighted during stakeholder consultation. These issues should be taken into consideration during the scoping process for any future update of this guideline:
    - Equal access to healthcare for all patients with CFS/ME

Conclusion

20. 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.

Relationship to quality standards

21. This topic is not currently being considered for a quality standard.

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Centre for Clinical Practice
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Appendix 1

Guidance	Review date
CG27: Referral for suspected cancer, 2007.	Currently scheduled for an update.
CG23: Depression: management of depression in primary and secondary care, 2004.	The guideline was updated in 2009 (CG90) and was published alongside 'Depression in adults with a chronic physical health problem: treatment and management' (CG91), 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: October 2012.
CG61: Irritable bowel syndrome in adults: Diagnosis and management of irritable bowel syndrome in primary care, 2008.	This guideline was not published at the time of CG53 publication although was alluded to in the guideline. 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.