

EVIDENCE REVIEW

Cognitive Behavioural Therapy, Graded Exercise Therapy & the Lightning Process in the Treatment of ME/CFS

A Knowledge Review and Quality Assessment of the Scientific Literature

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By



1. Background

ME/CFS (Myalgic Encephalomyelitis/Chronic Fatigue Syndrome) is a complex, debilitating, multisystem chronic illness characterised by profound fatigue, post-exertional malaise (PEM), cognitive dysfunction, unrefreshing sleep, and autonomic dysregulation. Its treatment has been one of the most contested areas in modern medicine.

Three interventions have dominated the clinical and research landscape over the past three decades: Cognitive Behavioural Therapy (CBT), Graded Exercise Therapy (GET), and the Lightning Process (LP). All three are rooted in psychological or behavioural models of illness, and all three have attracted both vigorous academic support and equally vigorous criticism — particularly from patient organisations and researchers who regard ME/CFS as a biological rather than a psycho-behavioural condition.

Key contextual note: A central tension in this literature is the diagnostic criterion used to select participants. Many older trials used the Oxford criteria, which require only persistent, unexplained fatigue — and thus likely enrolled a heterogeneous population including patients with primary depression or other fatigue conditions. More recent and restrictive criteria (e.g. the Canadian Consensus Criteria, International Consensus Criteria, or the IOM 2015 criteria) require post-exertional malaise as a cardinal symptom, identifying a more specific ME/CFS population.

2. Cognitive Behavioural Therapy (CBT)

2.1 Theoretical Basis

CBT for ME/CFS operates from a cognitive-behavioural model positing that illness perpetuating factors — such as unhelpful beliefs about activity, fear-avoidance, and deconditioning — maintain symptoms. The treatment aims to challenge these cognitions and gradually increase activity. Critics argue this model is empirically unsupported for ME/CFS and is inappropriate for a disease with demonstrable biological abnormalities.

2.2 Findings from Key Studies

Meta-analyses and systematic reviews

The CBT evidence base is the largest of the three interventions reviewed here. Multiple meta-analyses have been conducted, though their conclusions diverge considerably depending on methodological standards applied.

- A 2023 meta-analysis reported a large effect size for CBT in reducing fatigue. A 2024 meta-analysis by Maas genannt Bermpohl et al. found a moderate effect across multiple RCTs using PRISMA 2020 guidelines.
- A 2024 individual patient data (IPD) meta-analysis by Kuut et al. (Psychological Medicine) pooled data from eight RCTs (n=1,298). It found significant reductions in fatigue severity, functional impairment, and physical functioning, and argued these

results did not vary significantly by whether patients met criteria including post-exertional malaise.

- A 2025 *Frontiers in Psychiatry* meta-analysis (Kolala et al.) excluded Oxford-criteria-defined cohorts entirely and still found statistically significant fatigue reduction, though with more modest effect sizes than earlier reviews.

The PACE Trial (White et al., 2011)

The PACE trial remains the most prominent and most contested study in this field. It enrolled 641 adults with CFS diagnosed by Oxford criteria and compared CBT, GET, adaptive pacing therapy (APT), and specialist medical care alone.

- The investigators originally reported that both CBT and GET were 'moderately' effective.
- However, post-hoc changes to the recovery definition — made after data collection — resulted in inflated recovery rates. Under the original pre-specified protocol, significant effects were not found.
- An analysis of individual PACE data estimated that only 3.7% of CBT participants and 6.3% of GET participants showed objective improvement, with the vast majority of 'improvements' not matched by any objective measure.

2.3 Methodological Quality Concerns

Summary of recurring methodological flaws in CBT trials: (1) Non-blinded design with subjective primary outcomes, creating high risk of performance and detection bias. (2) Use of Oxford criteria, which likely selected patients without true ME/CFS. (3) Outcome switching and endpoint changes after data collection. (4) Failure to include objective outcome measures alongside self-report. (5) No consistent reporting of adverse events.

A professor of medicine commented that PACE researchers failed to address the key design flaw of an unblinded study with subjective outcome measures — noting this demonstrated a lack of understanding of basic trial design requirements, and that a major overhaul of quality control in this field is needed.

A 2019 systematic review by Ahmed et al. concluded its findings did not support the claim that CBT and GET are effective treatments for ME/CFS due to methodological flaws and biases. PACE was found to suffer from performance bias, detection bias, and selective reporting.

The absence of objective improvement is particularly significant. Studies examining objective fitness measures (VO₂ peak, timed step tests, maximal aerobic capacity) consistently found no objective improvement despite self-reported fatigue reduction in CBT and GET arms.

2.4 Current Guideline Status

Following its 2021 review, NICE concluded the evidence of benefit from CBT was of low or very low quality. CBT is now recommended only as a tool to manage symptoms and distress, not as a route to recovery. This position has been contested by a group of over 50 international specialists

who published a critique arguing the NICE review process had eight significant shortcomings and that the guideline deviates from the scientific evidence.

3. Graded Exercise Therapy (GET)

3.1 Theoretical Basis

GET rests on a deconditioning model of ME/CFS: that patients have become physically deconditioned through activity avoidance, and that a structured, gradually increasing exercise programme can reverse this. Like CBT, this model is fundamentally challenged by the biological evidence for ME/CFS, and specifically by the existence of post-exertional malaise (PEM) — a hallmark feature in which exertion causes a delayed and disproportionate worsening of symptoms.

3.2 Findings from Key Studies

GET was recommended by NICE from 2007 to 2021 based predominantly on the PACE trial and earlier smaller RCTs. The evidence base largely overlaps with that for CBT, as PACE tested both arms simultaneously.

- A 2025 systematic review (Journal of Bodywork and Movement Therapies) found current guidelines suggest pacing therapy is superior to GET and CBT, and that GET can harm people with ME/CFS.
- Multiple studies measuring objective outcomes (VO2 peak, fitness tests) showed no objective improvement in the GET arms despite self-reported improvements.
- The PACE trial, GET arm: under the original protocol recovery criteria, significant effects were not found. A reanalysis of the trial data concluded GET is both ineffective and potentially unsafe when objective outcomes are applied.

3.3 Methodological Quality Concerns

GET trials share the same quality problems as CBT trials — non-blinding, subjective outcomes, Oxford criteria selection, and outcome switching — but carry an additional concern: harm.

- Most RCTs of GET did not systematically measure or report adverse events, meaning absence of documented harm is not the same as absence of actual harm.
- Safety issues often arise outside RCT settings and long after trials conclude. The PACE trial screened 3,158 patients but enrolled only 641 (20.3%), suggesting significant cherry-picking that may have excluded the most severely affected patients.
- Large-scale patient surveys have consistently documented that GET causes significant and sometimes permanent worsening of symptoms in a substantial proportion of those with ME/CFS.

3.4 Current Guideline Status

GET is no longer recommended by NICE (2021), nor by the American Institute of Medicine (2015), the Dutch Health Council (2018), the Superior Health Council of Belgium (2020), or the German IQWiG (2021). This represents a broad international consensus against GET as a treatment for ME/CFS, grounded in the conclusion that the biological reality of ME/CFS — particularly PEM — makes incrementally increasing exercise not merely ineffective but actively harmful for most patients.

4. The Lightning Process (LP)

4.1 What it Is

The Lightning Process is a trademarked commercial programme developed by Phil Parker, combining osteopathy, life coaching, and neuro-linguistic programming (NLP). It is delivered over three consecutive days in small groups or, more recently, via video technology. It frames illness through a neurological self-regulation model and teaches participants a set of physical and verbal techniques to interrupt unhelpful physiological states.

Important note: NLP (neuro-linguistic programming), on which the LP is substantially based, is not recognised by mainstream psychology or medicine as an evidence-based practice and is widely regarded as scientifically discredited.

4.2 Evidence Base

The LP evidence base is the thinnest of the three interventions reviewed here. There is only one published RCT — the SMILE trial — and it was conducted exclusively in a paediatric population.

The SMILE Trial (Crawley et al., 2018)

- Enrolled 100 participants aged 12–18 with mild-to-moderate CFS/ME at a specialist paediatric clinic.
- Compared specialist medical care (SMC) alone versus SMC plus the LP.
- Reported significant improvements in physical function at 6 and 12 months in the LP arm, along with improvements in fatigue, anxiety, depression, and school attendance.
- A feasibility pilot (SMILE feasibility, 2014) preceded the full trial and informed its design.

A systematic review of LP evidence (ScienceDirect, 2020) found variance in reported patient outcomes but identified an emerging body of evidence supporting LP efficacy across fatigue, physical function, pain, anxiety, and depression, concluding that more RCTs were needed.

4.3 Methodological Quality Concerns

The SMILE trial has attracted serious criticism from independent researchers and the academic community.

- The trial was open-label (not blinded), relying entirely on subjective self-reported outcomes — a design highly vulnerable to bias, particularly in a commercially promoted intervention with strong participant expectation effects.
- An investigation revealed undisclosed outcome-swapping between the feasibility trial and the full trial: the primary outcome was changed from fatigue (Chalder Fatigue Scale) to physical function (SF-36) without pre-registration of this change.
- An open letter signed by Dr David Tuller and over twenty academics was sent to Archives of Disease in Childhood citing serious anomalies. An editorial correction was subsequently published, though the journal declined to retract the paper.

- The trial was conducted by researchers within the specialist clinic delivering the LP, raising concerns about independence.
- There is no published RCT of the LP in adults with ME/CFS.

Academic critics have also raised concerns about the LP's theoretical underpinnings, the absence of scientific plausibility, and anecdotal reports of psychological harm in participants who attributed non-improvement to personal failure — a risk inherent in programmes that frame illness as self-maintained.

4.4 Current Guideline Status

The LP is not recommended by NICE or any major national clinical guideline body. It is not endorsed by the ME Association or most patient organisations. Its use remains commercially active, primarily outside NHS settings.

5. Summary Evidence Quality Table

Intervention	No. of RCTs	Evidence Quality	Current NICE Status	Key Concerns
CBT	8+ (in meta-analyses)	Low to moderate	Adjunctive only (not curative)	Subjective outcomes; unblinded design; Oxford criteria bias; no objective improvement shown
GET	Multiple	Low to very low	NOT RECOMMENDED	PEM risk; patient-reported harms; no objective improvement; safety rarely measured in trials
Lightning Process	1 (SMILE; paediatric only)	Very low	Not recommended	Outcome swapping; open-label; NLP pseudoscience base; no adult RCT available

6. Overall Assessment

6.1 Cross-Cutting Methodological Weaknesses

The body of evidence for all three interventions shares a set of serious, recurring methodological weaknesses:

- Reliance on subjective, self-reported outcome measures in non-blinded trials — a combination that maximises the risk of bias and placebo-response contamination.
- Use of overly broad diagnostic criteria (especially the Oxford criteria) that likely enrolled patients with primary depression or general fatigue conditions rather than ME/CFS, inflating apparent treatment response.
- Failure to measure or report adverse events systematically, meaning trials cannot be used to assess safety.
- Post-hoc changes to outcome definitions and primary endpoints in several key trials.
- Absence of objective outcome measures (e.g. actimetry, VO2 peak, return to work data) as co-primary endpoints alongside self-report.

6.2 The Biopsychosocial vs. Biomedical Debate

These methodological issues are not merely technical; they are deeply connected to the contested conceptual model of ME/CFS. CBT, GET, and LP all presuppose a psycho-behavioural perpetuation model of illness. If this model is incorrect — and the emerging biological evidence (immune dysfunction, mitochondrial abnormalities, neurological changes, autonomic nervous system dysregulation) increasingly suggests it is at least incomplete — then the theoretical rationale for these therapies is undermined regardless of the trial results.

The diagnostic criterion problem is central here: a trial using Oxford criteria may legitimately find that CBT helps fatigued patients without ME/CFS. But this cannot be extrapolated to demonstrate benefit in patients with biologically defined ME/CFS, particularly those with significant PEM.

6.3 Conclusions

The current scientific consensus, as reflected in the 2021 NICE guideline and multiple international bodies, is that: GET should not be used (potential for harm); CBT may be offered only as supportive symptom management, not as curative treatment; the Lightning Process lacks sufficient evidence for recommendation. However, a vocal and academically credentialled group of researchers disputes the NICE interpretation, arguing the RCT evidence does support CBT and GET. This debate remains live and unresolved, with the quality and interpretation of the underlying evidence at its heart.

What is not in dispute is that all three interventions share an evidence base that is, at best, of low to moderate quality — characterised by non-blinded designs, subjective outcomes, heterogeneous patient populations, and inadequate safety reporting. Future research should prioritise: (1) strict ME/CFS diagnostic criteria including PEM; (2) objective co-primary outcome measures; (3) systematic adverse event reporting; and (4) long-term follow-up beyond trial completion.

7. Key References

The following sources were drawn upon in the preparation of this review:

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