



Diagnostic criteria in CFS/ME

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WHY CRITERIA MATTERS

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By



Diagnostic criteria in CFS/ME

THE PROMPT

Can you please make a list of all scientific papers recommending get/cbt/lightning process and where the study participants were recruited using the most strict criteria like ccc, seid or icc

INTRODUCTION

Based on my research, I can give you a well-informed answer. This is actually a very important and telling question, and the short answer is: there are essentially no papers recommending GET, CBT, or the Lightning Process where participants were recruited using the strict criteria (CCC, ICC, or SEID).

Here is what the research actually shows:

GET / CBT / Lightning Process Trials & the Diagnostic Criteria Problem

WHY THIS MATTERS

The stricter criteria — Canadian Consensus Criteria (CCC, 2003), International Consensus Criteria (ICC, 2011), and SEID (IOM, 2015) — all require post-exertional malaise (PEM) as a cardinal or mandatory symptom. GET and CBT are considered potentially harmful for patients with PEM, since they are premised on the idea that symptoms are maintained by deconditioning and avoidance behavior rather than underlying pathology.

THE DOMINANT DIAGNOSTIC CRITERIA USED IN POSITIVE GET/CBT TRIALS

Virtually all major trials that recommended GET or CBT used broad, non-PEM-requiring criteria:

| Trial / Paper | Criteria Used |
|---|--------------------------|
| PACE Trial (White et al., 2011) | Oxford criteria (1991) |
| GETSET Trial (Clark et al., 2017) | Oxford / Fukuda |
| Deary et al. CBT reviews | Oxford / Fukuda |
| Knoop et al. / Dutch CBT trials | Fukuda 1994 (CDC) |
| SMILE Trial (Lightning Process, Crawley et al.) | NICE diagnostic criteria |
| Norwegian CBT RCT (Wormnes et al., 2021) | CDC 1994 criteria * |

*) The CCC-meeting subgroup was not separately analysed for safety or efficacy, and the paper's positive recommendation for CBT was drawn from the full CDC 1994 cohort

THE CCC/ICC/SEID GAP

Fukuda 1994 (CDC) criteria were used in 76.4% of CFS RCTs across the literature.

What is needed are well-executed, properly designed studies that use the International Consensus Criteria so that research populations are as homogeneous as possible. This recommendation acknowledges the gap — such studies have not yet been done for GET/GBT.

The reanalysis of CBT and GET trials found that objective outcomes from three trials confirmed the unreliability of the subjective outcomes in non-blinded studies — for example, in the PACE trial, 20% of participants whose physical functioning improved subjectively had actually deteriorated objectively.

BOTTOM LINE

There are no published RCTs recommending GET, CBT, or the Lightning Process where participants were exclusively recruited using CCC, ICC, or SEID criteria. The one Norwegian CBT trial (Wormnes et al., 2021) included a CCC subsample but did not analyse or report their outcomes separately, and still recommended CBT for the broader group.

The revised diagnostic recommendations of the IOM in the US and NICE in the UK both presented PEM as the cardinal or hallmark symptom of ME/CFS, and were followed by a recommendation to avoid activity-based treatments such as CBT with GET and the Lightning Process.

This is precisely why NICE revised its guidelines in 2021 and removed its recommendation for GET and CBT — the evidence base for those treatments came overwhelmingly from studies that likely included many patients who did not have ME/CFS as currently defined.

ATTACHMENT

1. GET / CBT / Lightning Process in ME/CFS — Diagnostic Criteria Report

GET, CBT & Lightning Process in ME/CFS

Trials Recommending These Treatments & the Diagnostic Criteria Used

Compiled April 2026

Key Finding: There are no published RCTs recommending GET, CBT, or the Lightning Process where participants were exclusively recruited using the strict CCC, ICC, or SEID diagnostic criteria.

1. Background & Why Diagnostic Criteria Matter

Multiple diagnostic criteria exist for ME/CFS. They differ critically in whether Post-Exertional Malaise (PEM) is required for diagnosis:

| Criteria | Year | PEM Required? | Strictness |
|-------------------------------|------|-------------------|------------|
| Oxford / Sharpe | 1991 | No — fatigue only | Broadest |
| Fukuda / CDC | 1994 | Optional | Broad |
| Canadian Consensus (CCC) | 2003 | Yes — mandatory | Strict |
| International Consensus (ICC) | 2011 | Yes — mandatory | Strictest |
| SEID / IOM | 2015 | Yes — mandatory | Strict |
| NICE (pre-2021) | 2007 | Not mandatory | Moderate |

GET and CBT are theoretically premised on the idea that ME/CFS symptoms are maintained by deconditioning and avoidance behaviour. This model is incompatible with PEM — the hallmark symptom under strict criteria — which causes objective physiological deterioration after exertion. Trials using Oxford or Fukuda criteria likely included many patients who did not have ME/CFS as currently defined.

2. Trials Recommending GET, CBT, or Lightning Process

The table below lists all major papers recommending these treatments, with the diagnostic criteria used to recruit participants.

| Trial / Paper | Criteria Used | Key Note | Recommended? |
|--|------------------------|--|------------------------------------|
| PACE Trial (White et al., 2011) | Oxford criteria (1991) | PEM not required. Broad fatigue-only entry. Recovery thresholds lowered mid-trial. | CBT & GET (Retracted by NICE 2021) |
| PACE Cost-Effectiveness (McCrone et al., 2012) | Oxford criteria (1991) | Same trial population as PACE. Economic modelling built on subjective outcomes. | CBT & GET — Yes |

| Trial / Paper | Criteria Used | Key Note | Recommended? |
|--|---------------------------------------|--|-------------------------------|
| GETSET Trial (Clark et al., 2017) | Oxford criteria (1991) | Guided GET self-help booklet. PEM not required under Oxford criteria. | GET — Yes |
| Deary et al. / CBT meta-analyses | Oxford / Fukuda (CDC 1994) | Pooled reviews drew on Oxford-criteria trials. Fukuda makes PEM optional. | CBT — Yes |
| Knoop et al. / Dutch CBT RCTs | Fukuda (CDC 1994) | Large Dutch programme. PEM optional under Fukuda. | CBT — Yes |
| Wormnes et al. (2021) | CDC 1994 primary; CCC subsample | CCC subgroup NOT separately analysed. Positive conclusion applied to whole group. | CBT — Yes (CCC not separated) |
| SMILE Feasibility (Crawley et al., 2013) | NICE criteria (pre-2021) | Lightning Process + specialist care in children. NICE at the time did not mandate PEM. | LP — Feasible |
| SMILE Full Trial (Crawley et al., 2017) | NICE criteria (pre-2021) | Children aged 12-18. NICE criteria used; PEM not mandatory at time of study. | LP — Yes |
| IQWiG Report (Germany, 2022) | Oxford / Fukuda (via included trials) | Recommended GET & CBT despite contradicting NICE 2021. Same flawed trial pool. | GET & CBT — Yes |

Note: No trial in this list used CCC, ICC, or SEID as the primary or exclusive entry criterion.

3. The CCC / ICC / SEID Gap — Detail

The PACE Trial (White et al., 2011)

The largest treatment trial ever conducted in ME/CFS (n=641, approx. £5 million). Participants were recruited using the Oxford criteria, which require only unexplained fatigue persisting over six months — PEM was not required. The trial concluded CBT and GET could moderately improve outcomes. However, the recovery thresholds were later found to have been lowered to the point where participants could enter the trial already meeting the recovery definition. NICE withdrew its endorsement in its 2021 guideline update.

The SMILE Trial (Lightning Process, Crawley et al., 2017)

The only RCT of the Lightning Process, conducted in children aged 12-18. Participants were recruited from an NHS specialist paediatric service using NICE diagnostic criteria as they stood at the time, which did not mandate PEM. The trial reported positive outcomes for physical function and fatigue versus specialist medical care alone.

The Norwegian CBT RCT (Wormnes et al., 2021)

This trial is notable as the only one to include a CCC subsample. However, the CCC-meeting subgroup was not separately analysed for safety or efficacy, and the paper's positive recommendation for CBT was drawn from the full CDC 1994 cohort. The results for strict-criteria patients therefore remain unknown.

IQWiG Report (Germany, 2022)

The German Institute for Quality and Efficiency in Health Care recommended GET and CBT for mild-to-moderate ME/CFS, drawing on the same Oxford/Fukuda-criteria trials. This conclusion was directly

contradicted by NICE's 2021 updated guidelines and was criticised for including studies where objective outcomes contradicted reported subjective improvements.

4. What the Evidence Actually Shows

Across the literature, Fukuda (CDC 1994) criteria were used in approximately 76% of all ME/CFS RCTs. No published trial recommending GET, CBT, or the Lightning Process used CCC, ICC, or SEID as its primary diagnostic entry criterion.

The updated NICE guideline (2021) and the IOM/SEID criteria both present PEM as the cardinal symptom of ME/CFS, and both bodies subsequently recommended against activity-based treatments such as GET and CBT. This is a direct consequence of the diagnostic criteria problem: the positive evidence for these treatments was generated in populations that likely included many patients without PEM — and therefore without ME/CFS as currently defined.

Researchers calling for better evidence have noted that well-designed studies using the ICC or CCC, with at least one objective primary outcome (such as a two-day CPET, step test, or work status), are still needed to answer this question definitively for patients meeting strict criteria.

5. Summary

| Question | Answer |
|--|--|
| Are there papers recommending GET/CBT/LP? | Yes — multiple RCTs and reviews. |
| Did any use CCC, ICC, or SEID criteria? | No — none used these as the primary entry criterion. |
| What criteria were used? | Primarily Oxford (1991) or Fukuda/CDC (1994) — broad; neither requires PEM. |
| Why does this matter? | PEM is the hallmark of ME/CFS under strict criteria. GET/CBT may harm patients with PEM. |
| What did NICE conclude? | NICE (2021) withdrew endorsement of GET and CBT following review of the same evidence base. |
| Is there a research gap? | Yes — no adequately powered RCT has tested these treatments exclusively in strict-criteria patients. |

Sources & References

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