

The PACE Trial Study in a Nutshell

Comparison of adaptive pacing therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome (PACE): a randomised trial

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Summary

76.4% / 70.9% / 41%,
79.9% / 70.1% / 41%,
64.7% / 49.0% / 31%, resp.
63.6% / 57.1% / 25% of
people with “disabling chronic fatigue”
(of which 47% suffered from psychiatric disorder and
±35% used antidepressants during treatment)
improved by CBT, GET, APT resp. SMC
based upon the subjective measures of
“fatigue”, “physical functioning” and “general health”.

The placebo effect for psychological interventions on ME/CFS is 14% [4].

Only 30% “recovered” from “CFS”
(based upon cut-off scores for “fatigue” and “physical functioning”,
largely insufficient for a CFS diagnosis according to the Fukuda criteria [5]).

The participants were also “atypical patients” when looking at their attitude:
71% of the participants considered CBT to be a logical therapy for “CFS” and
57% was confident about CBT treatment and
84% considered GET to be a logical treatment and
70% was confident about GET therapy.

Participants:
All people with “chronic fatigue”

Excluded

- In advance (various groups)
 - All people with severe ME/CFS (unable to participate).
 - People unable to comply with the protocol (many people with less severe ME/CFS).
 - ME/CFS patients and other participants with medical needs making participation inappropriate.
- As a result of the Oxford criteria [1]:
 - ME/CFS patients with “medical conditions” as a result of ME/CFS.
 - ME/CFS patients with proven neurological disease.

Included

- As a result of the Oxford criteria [1]:
all people with “disabling chronic fatigue”.
(of which just 51% met the London criteria [3]).
- People with psychiatric disorders (depressive disorders and anxiety disorders, phobias, obsessive-compulsive disorder, and post-traumatic stress disorder etc.): 47% of the participants (use of antidepressants: 40,6%)
- The patient seems very atypical in their view on CBT and GET:
71% of the participants considered CBT to be a logical therapy for ME/CFS and 57% was confident about CBT treatment. 84%! considered GET to be a logical treatment for ME/CFS and 70%! was confident about GET therapy.

Dropouts and adverse effects

- Dropouts: CBT 11%, GET 6% (APT 7%, SMC 9%)
- Serious deterioration: CBT 9%, GET 6% (APT 8%, SMC 9%)

Intervention:

Pacing (APT), CBT, GET and standard medical care (SMC)

- **SMC: 3 sessions**
Explanation, generic advice, such as to avoid extremes of activity and rest, specific advice according to the approach chosen by the participant, and symptomatic pharmacotherapy (especially for insomnia, pain, and mood).
- **CBT: 15 sessions (week 1, 2, 3, 4, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 36)**
Based upon the idea that "CFS" is reversible and that thoughts (fear of engaging in activity) and behavioural responses (avoidance of activity) are linked and interact with physiological processes to perpetuate "fatigue".
- **GET: 15 sessions (week 1, 2, 3, 4, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 36)**
Based upon the idea that "CFS" is perpetuated by reversible physiological changes as a result of deconditioning and avoidance of activity. Start level: 30 minutes of light exercise five times a week, intensity and aerobic nature of exercise gradually increased.
- **APT: 15 sessions (week 1, 2, 3, 4, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 36)**
Based upon the envelope theory/"pacing" and the idea that "CFS" is not reversible by behaviour. Patients were advised not to undertake activities demanding more than 70% of participants' perceived energy envelopes.

Results:

Small improvements, not much better than SMC/APT, “recovery”: 30%

“Improvement” (group averages)

Fatigue

	N	Base-line Score *	Score after 1 yr *	Improvement	Number improved	Percentage improved
APT	153	28.5	23.1	5.4	99	64.7%
CBT	148	27.7	20.3	7.4	113	76.4%
GET	154	28.2	20.6	7.6	123	79.9%
SMC	151	28.3	23.8	4.5	98	64.9%

* Normal score: 14.2, Cut-off Score Normal: <18.8

Physical function

	N	Baseline Score *	Score after 1 yr *	Improvement	Number improved	Percentage improved
APT	153	37.2	45.9	8.7	75	49.0%
CBT	148	39	58.2	19.2	105	70.9%
GET	154	36.7	57.7	21	108	70.1%
SMC	151	39.2	50.8	11.6	88	58.3%

* Normal Score: 84, Cut-off Score “Normal”: 60

Overall Health

	N	Positive Change	Minimum change	Negative change
APT	153	31%	63%	7%
CBT	148	41%	52%	6%
GET	154	41%	53%	7%
SMC	152	25%	66%	9%

Placebo effect for psychological interventions on ME/CFS: 14% [4].

“Recovery” (on an individual basis)

Success rate for CBT and GET

based upon cut-off scores for 2 subjective criteria (fatigue and physical function),

by large insufficient for a diagnosis CFS according to the Fukuda criteria [5]:

30%.

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