

**There is level 1a evidence that for every two adults with chronic fatigue syndrome treated with cognitive behaviour therapy one additional person will avoid a decrease in physical function.**

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**CLINICAL SCENARIO:** Chronic fatigue syndrome (CFS) is a disabling illness that affects the individual's ability to engage in everyday activities. Cognitive behaviour therapy (CBT) is a rehabilitation approach that combines a graded increase in activity with a psychological approach. The overall aim is to change thoughts and beliefs about CFS, which may impair recovery. CBT has been widely used in the treatment of CFS. What is the effectiveness of CBT for reducing the negative effects of CFS and improving function?

**FOCUSSED CLINICAL QUESTION:** Does cognitive behaviour therapy (**I**) improve physical function (**O**) in people with chronic fatigue syndrome (**P**) compared to no cognitive behaviour therapy (**C**)?

**SUMMARY of Search, 'Best' Evidence' appraised, and Key Findings:**

- 24 citations were found that met the inclusion criteria.
- One systematic review and one recent RCT (level 1a) were located and reviewed to determine quality.
- The systematic review by Price and Couper (1998), which synthesised three RCTs was deemed to be highest level of evidence and was critically appraised.
- This systematic review reported that CBT lessened the decline in physical functioning in adults with CFS more than relaxation therapy or routine medical care, after six to seven months of follow up.
- CBT was found to be effective in improving physical function and preventing adverse outcomes in adults with CFS.

**CLINICAL BOTTOM LINE:** People with chronic fatigue syndrome who receive CBT are more likely to experience improved physical functioning, 3.8 times more likely than those receiving routine relaxation therapy, and 2.8 times more likely than those receiving routine medical care.

**Limitation of this CAT:** This critically appraised paper has not been externally peer-reviewed.

**SEARCH STRATEGY:**

Using the levels of evidence defined by the Oxford Centre for Evidence-based Medicine (Phillips et al., 1998), searching aimed to locate the following study designs:

- Systematic reviews and meta-analyses of randomised controlled trials (level 1a);
- Systematic reviews and meta-analyses of lower level/quality randomised and non-randomised controlled trials (level 2a);
- Randomised controlled trials (level 1b or 2b);
- Controlled trials, cohort (level 2b) or case-control studies (level 3b);
- Case series (level 4);
- Expert opinion including literature/narrative reviews, consensus statements, descriptive studies and individual case studies (level 5).

A search was also conducted for clinical practice guidelines.

**Terms used to guide Search Strategy:**

- **P**atient/Client: patients with chronic fatigue syndrome
- **I**ntervention: cognitive behaviour therapy
- **C**omparison: no cognitive behaviour therapy
- **O**utcome(s): improvement in physical function

Databases/ sites searched	Search Terms	Limits
New Zealand Guidelines Group; Scottish Intercollegiate Guidelines Network (SIGN); National Health & Medical Research Council	Nil	Published from January 1990 to May 2005 = Nil
National Guidelines Clearinghouse	..... Disease/condition: <i>Chronic fatigue syndrome</i> Treatment/Intervention: <i>Cognitive behaviour therapy</i> Guideline Categories: <i>Management</i> Sort Order: <i>Relevance</i> .....	Nil
National Institute for Clinical Effectiveness (NICE)	(Chronic fatigue syndrome) AND (cognitive behaviour therapy)	Nil
Centre for Clinical Effectiveness (Monash University)	(Chronic fatigue syndrome) AND (cognitive behaviour therapy)	Nil
Cochrane Library	Chronic fatigue syndrome	Nil
PubMED	1. chronic fatigue syndrome 2. cognitive behavior?r therapy 3. #1 AND #2 4. Physical function 5. #3 AND #4	Nil
OTseeker; PEDro; Joanna Briggs Institute	(Chronic fatigue syndrome) AND (cognitive behaviour therapy)	Nil
CINAHL – Pre CINAHL, Arts Abstracts, PsycARTICLES, PsycINFO	(Chronic fatigue syndrome) AND (cognitive behaviour therapy) AND (physical function)	Language: English
Science Direct	(Chronic fatigue syndrome) AND (cognitive behaviour therapy)	Humans, English, 1995- present
Proquest- Social Science Journal	(Chronic fatigue syndrome) AND (cognitive behaviour therapy)	Nil

## INCLUSION and EXCLUSION CRITERIA

### Inclusion:

- Studies published in English
- Cognitive behaviour therapy as an intervention versus control group or other intervention
- Adults with chronic fatigue syndrome
- Physical function as the primary outcome

### Exclusion:

- People with conditions other than chronic fatigue syndrome
- Studies including children and adolescents
- Studies comparing CBT to exercise

## RESULTS OF SEARCH

- 24 relevant studies were located and categorised as shown in Table 1 (based on Levels of Evidence, Centre for Evidence Based Medicine, 1998)

**Table 1:** Summary of Study Designs of Articles retrieved

Level of Evidence	Study Design/ Methodology of Articles Retrieved	No. Located	Source(s)
	Evidence Based Clinical Practice Guidelines	2	- National Guideline Clearinghouse (25) - Royal Australasian College of Physicians (27) – Citation appeared in PEDro
<b>1a</b>	<b>Systematic Reviews and meta-analyses of randomised controlled trials</b>	<b>1</b>	Citation appeared in Cochrane Library (1), OTseeker (1), PEDro (1), PubMed (1)
2a	Systematic reviews and meta-analyses of randomised and non-randomised controlled trials	0	
1b	Randomised controlled trials	3	Citation appeared in Proquest (2,3,4), PubMed (2,4), OTseeker (3,4), PEDro (3,4), PsycINFO (2,3), CINAHL (4)
2b	Low quality randomised controlled trials, controlled trials and cohort studies	3	Citation appeared in PubMed (6), PEDro (5,6), OTseeker (5,6), Proquest (5), Science Direct (5), PsycINFO (7)
3b	Individual Case-Control Studies	2	Citation appeared in PsycINFO (8,9)
4	Case Series or poor quality cohort and case-control series	5	Citation appeared in PsycINFO (10,11,12,13,14,15) and Proquest (13)
5	Expert Opinion	11	Citation appeared in PsycINFO (15,17,18,19,22,23), PubMed (19,21), CINAHL (16,20,24), Science Direct (19, 21), Proquest (20, 21)

## BEST EVIDENCE

The systematic review by Price and Couper (1998) was identified as the 'best' evidence and selected for critical appraisal. Reasons for selecting this review were:

- The primary outcome in this review was physical function in adults with CFS, which best matched the clinical question.
- The review used sound methodology in search strategy, data collection and statistical analysis.

## SUMMARY OF BEST EVIDENCE

**Table 2:** Description and appraisal of systematic review by Price and Couper (1998)

### ***Aims of the Study***

To examine the efficacy of CBT in increasing physical functioning for adults with CFS. Additionally, to test the hypothesis that CBT is more effective than routine medical care or other interventions.

### ***Methodology***

Data Sources: Electronic databases including MEDLINE, EMBASE, PsycLIT, Biological Abstracts, SIGLE. The Trials Register of the Depression, Anxiety and Neurosis Group as well as citation lists were also searched as well as authors of relevant studies were contacted (p.4)

Design of included studies: Randomised controlled trials

Study Inclusion criteria: For studies to be included both reviewers had to agree that the following inclusion criteria were met: participants were over age 16, participants had disabling fatigue that was medically unexplained and lasted longer than six months, intervention was CBT, having both elements of psychological treatment that attempted both modification of thoughts and beliefs as well as behavioural responses to symptoms of CFS, individual or group intervention, physical functioning as primary outcome, trials had minimum of one month follow up (pp.4-6).

Study Exclusion Criteria: studies that included more than 10% of participants with disorders other than CFS, studies using drug therapy (i.e. Antidepressants) or self-help as part of intervention (pp.4-6).

Number of Studies screened: 13. Number of Studies included: 3

Patient Population: adult outpatients with CFS, patients received individual CBT. CBT attempted to increase activity and reduce rest time for participants (p.6).

Quality of RCTs Included in Systematic Review: The reviewers independently allocated the RCTs in three quality categories. Two studies (Deale, 1997; Sharpe, 1996) were rated as being of 'high' methodological quality with adequate randomisation methods, baseline comparability and intention-to-treat analysis. One study (Lloyd, 1993) was rated as being of 'moderate' methodological quality with randomisation 'probably adequate', no report of baseline comparability, and no intention-to-treat analysis (pp.6-7).

Analysis: Full data extraction, using standardised data extraction sheet, was performed on the included studies. Results were synthesised using the Review Manager software. The initial analysis of dichotomous outcomes used the odds ratio (OR)\*\*. When appropriate, ORs were combined across studies using Peto's fixed effect method\*\*\* to give pooled OR with 95% confidence intervals. The number needed to treat (NNT)\*\*\*\* was also calculated with 95% confidence intervals. Since the studies included in the systematic review each compared different interventions, they were analysed separately. No attempt at quantitative integration of data (meta-analysis) has been made (p.5, 7). Follow up: Ranged from three to seven mths (p.5).

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 \*\***Odds Ratio** – Describes the odds (probability) of an experimental patient (receiving CBT) suffering an adverse event relative to a control patient (not receiving CBT).

\*\*\***Peto's fixed effect method** – A statistical method to combine results from individual studies.

\*\*\*\***NNT** – Helpful statistic that expresses the number of clients that need to receive the treatment (CBT) before an additional client receives a clinically important result (prevention of unsatisfactory physical outcome)

### ***Interventions Investigated***

Interventions consisted of individual CBT sessions, once or twice per week, with the goal of increasing activity and reducing rest time. The three studies each compared CBT to three different control interventions, being relaxation training, routine medical care, or routine medical care plus placebo injections. The amount of CBT received by study participants ranged from six to approximately 15 hours. The duration of studies ranged from four to six months (p.6).

### ***Outcome Measures (Primary and Secondary), (p.6 and tables on pp.12-14)***

**Primary Outcome Measure:** The primary outcome measure was physical functioning as measured in one study (Deale, 1997) via three self-reports (Physical Functioning dimension of Medical Outcomes Study SF-36 Score; Work & Social Adjustment Scale; Long-term goals rating) and observer rating of lack of improvement in physical functioning. Physical functioning in the other two studies was measured using the Karnofsky scale (Lloyd, 1993; Sharpe, 1996) as well as activity diaries (Lloyd, 1993), self-rated Pain Disability Index, improvement in employment status, days in bed per week as well as a timed walking test (Sharpe, 1996) as outcome measures.

#### **Secondary Outcome Measures:**

- **Fatigue** was measured via self-rated fatigue problem rating, self-rated Fatigue Questionnaire and also by an assessor (Deale, 1997). Fatigue was self-rated in Sharpe, 1996.
- **Mood** was measured via the General Health Questionnaire, Beck Depression Inventory, Hospital Anxiety and Depression Scale (outcome measures varied between studies).
- **Other secondary outcomes** included self-rated global improvement, satisfaction with treatment, usefulness of treatment and quality of life (again varied across studies).

### ***Results***

#### **Effect of CBT on physical function at final follow up (four to six months)**

In the original studies, pre-determined criteria of 'unsatisfactory' functional outcomes were used and the results were presented as odds ratios (OR), which *measured the prevention of unsatisfactory physical outcomes for individuals receiving CBT*. Original results were stated as follows:

**Deale (1997): CBT vs Relaxation** (adverse outcomes at 6 months post treatment): as in Figure 1, p.18)

<b>CBT (n/N)</b>	<b>Relaxation</b>	<b>Peto OR (95% CI)</b>
11/30	25/30	0.15 (0.05 to 0.41)

**Sharpe (1996): CBT vs Routine medical care** (adverse outcomes at 7 months post treatment): as in Figure 21, p.28)

<b>CBT (n/N)</b>	<b>Routine Medical Care</b>	<b>Peto OR (95% CI)</b>
8/30	22/30	0.16 (0.06 to 0.44)

**Number needed to treat (NNT)**, (based on data from Deale (1997) and Sharpe (1996): 2.1 (1.5 to 4.1). For every two patients treated with CBT rather than relaxation or routine medical care, one additional 'unsatisfactory' physical outcome (based on pre-determined criteria) may be avoided. Or expressed differently – two people need to receive CBT for another third person to avoid an adverse outcome. This suggests a very effective treatment.

The effect on physical function in the study by Sharpe (1993) was not statistically significant. Due to missing data, calculation of effect size was difficult in the Lloyd study (1993).

### **Original Authors' Conclusions**

The trials included in this review demonstrated that 'CBT significantly benefits physical functioning in adult outpatients with CPS when compared to orthodox medical treatment or relaxation. It is necessary to treat two patients to prevent one additional unsatisfactory physical outcome about six months after treatment end. CBT appeared highly acceptable to patients in these trials' (Price & Couper, 1998, p.1).

### **Critical Appraisal:**

#### **Validity** (*Methodology, rigour, selection, bias*)

- The reviewers addressed a clearly focussed clinical question.
- A thorough search of the literature was conducted including several electronic databases and use of multiple search terms. Additional studies were located by searching citation and reference lists of relevant studies and reviews as well as contacting researchers in the field. It is not evident from the review whether the search was restricted by language or included English studies only.
- Pre-defined criteria were used to determine which studies were included in the review. The studies were categorised according to three quality criteria ('high', 'moderate' or 'low'). Only randomised controlled trials were included in the review. Of thirteen studies that were initially identified, three studies met the inclusion criteria. Both reviewers worked independently and had to agree on whether trials met the inclusion criteria; disagreements were resolved through discussion. This process aimed to reduce bias in the selection of studies. However, the reviewers were not blinded to the names of the authors, institutions, journal of publication and results of individual trials (p.4). This lack of blinding could have contributed to a selection bias, but would also have been time consuming to operationalise.
- Both reviewers independently extracted data from all included studies using a standardised data extraction sheet. Trial authors were contacted if any detailed information on participants, intervention, outcome measures and results was not available in the published trial. There was missing information on the study by Lloyd (1993), (p.7).

#### **Results** (*Favourable or unfavourable, specific outcomes of interest, size of treatment effect, statistical and clinical significance; minimal clinically important difference*)

- Since the three included studies compared different interventions, each study was analysed separately and meta-analysis was not performed (p.7).
- The two high quality trials in this review found a statistically significant effect of CBT on physical function for people with CFS. This outcome was established by using pre-determined criteria of 'unsatisfactory' functional outcomes. Odds ratios (OR) were used to express the outcome, the prevention of an adverse physical outcome for individuals with CFS. ORs prove to be difficult to interpret and translate into a practical interpretation of results and relate to the prevention of an adverse outcome rather than gaining a positive improvement in function. Therefore, it would have been better to present the outcomes in terms of relative risk (or 'relative benefit'), which gives an indication of the *probability of improvement of physical function in people receiving CBT* versus relaxation or routine medical care (as addressed in clinical question). Therefore:

<b>Deale (1997): CBT vs Relaxation (improvement in function at 6 months)</b>		
<b>CBT (n/N)</b>	<b>Relaxation (n/N)</b>	<b>Relative risk</b>
19/30	5/30	3.8

<b>Sharpe (1996): CBT vs Routine Medical Care (improvement in function at 6 months)</b>		
<b>CBT (n/N)</b>	<b>Routine Medical Care (n/N)</b>	<b>Relative Risk</b>
22/30	8/30	2.8

People with CFS treated with CBT are 3.8 times more likely to gain an improvement in physical function than those receiving relaxation therapy (Deale, 1997).

People with CFS treated with CBT are 2.8 times more likely to gain an improvement in physical function than those receiving routine medical care (Sharpe, 1996).

**Number needed to treat (NNT)**, (from Deale, 1997 and Sharpe, 1996):  
NNT= 2.14 (95% CI 1.5 to 4.1)

For every two patients treated with CBT rather than relaxation or routine medical care, a third person will gain improvement in physical function (same as for OR). This suggests a very effective treatment.

- One study (Lloyd, 1993) could have several biases as it did not report sufficiently on randomisation methods, did not use an intention-to-treat-analysis and blinding of assessors was unclear. Additionally, baseline characteristics were not specifically reported and might have lead to a selection bias. Statistical analysis was difficult for this study, as important data were not presented (ie. absence of standard deviations), (p.6).
- A possible intervention bias can be found in the Deale (1997) and Sharpe (1996) studies. Antidepressant use appeared to be higher in the control group of the Deale study while in the Sharpe study the experimental group seemed to use more antidepressants. The authors state that they are unclear how this might have influenced the results (p.7).
- It is unclear from the review whether the assessors in the individual studies were blinded. In Sharpe (1996), the assessor clearly was not blinded to treatment status. Relevant outcomes were measured either by self-report (Deale, 1997) or by an observer (Sharpe, 1996), (p.6).
- Good compliance with CBT is suggested since few participants dropped out of included studies (p.9).
- Cost effectiveness of CBT was not addressed in this systematic review.

## IMPLICATIONS FOR PRACTICE/ APPLICABILITY

- The results of this systematic review demonstrate that cognitive behaviour therapy is effective in improving physical function in adults with chronic fatigue syndrome.
- It would be more beneficial to present the effects of CBT for people with CFS in terms of **improvement** in physical function rather than in a prevention of 'unsatisfactory' physical outcomes (ie. RR vs OR). Reinterpretation of the data shows that the proportion achieving a positive outcome (an improvement in physical function) in the CBT group was 19/30 (Deale, 1997) and 22/30 (Sharpe, 1996) versus 5/30 (Deale, 1997) and 8/30 (Sharpe, 1996) in the non-CBT groups. Therefore, therapists need to treat two people with CFS in order for one additional person to gain improvement in function. Also, people with CFS are 3.8 times more likely to improve in function when receiving CBT as opposed to relaxation or routine medical care. This suggests CBT as a very effective treatment for adults with CFS.
- Although psychologists commonly administer CBT, it is important to consider its use in occupational therapy practice especially as CFS significantly influences functioning in everyday life. Through applying the principles of CBT in treatment and primarily client education, individuals can be empowered to change the thoughts and beliefs that are underlying their illness (ie. the belief that activity should be avoided) and consequently modify their behaviours.
- CBT in occupational therapy practice is likely to be most effective if used in conjunction with grading and pacing of activity (Cox, 1999; Friedberg, 2002). The therapist and client work together to break the link between the spiral of increasing fatigue and stopping and reducing activity. People with CFS are commonly deconditioned and sensitive to activity. Programs that examine people's daily activities, identify problem areas and gradually increase engagement in occupations balanced by rest can be employed by occupational therapist as an effective way to increase previously avoided behaviours. By giving clients homework and enabling them to substitute negative thoughts with positive ones behaviour can be modified (Cox, 1999). The client's family also needs to be educated on CBT and pacing in order to ensure a consistent approach at home.
- Training in CBT for occupational therapists is recommended in order to maximise the effectiveness of its use in therapy with clients (Sharpe, 1998).
- It is suggested that clients rate their performance as a consequence of applying the principles of CBT in terms of improvement in function rather than in prevention of unsatisfactory outcomes (as outlined in the studies included in the systematic review).
- Helpful outcome measures for use with clients with CFS may include activity diaries, the Canadian Occupational Performance Measure, questionnaires about attitudes and beliefs about activity (ie. Dutch Chronic Fatigue Syndrome-Activities and Participation Questionnaire (CFS-APQ), by Nijs et al., 2002). Fatigue rating scales (ie. Checklist Individual Strength (CIS) by Vercoulen et al., 1994) as well as Depression and Anxiety scales. These measures may be beneficial in demonstrating and tracking improvement as a result of applying CBT principles and pacing to their daily activities. Rating is suggested after clients perform daily activities such as sleeping, cooking, shopping and work activities.

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### Related Articles (not individually appraised)

Levels 1a / 2a = Nil

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