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Cognitive Behavioural Therapy for Insomnia (CBT-I)

CBT-I is supported by an unusually broad research base for a behavioural therapy approach, ranging from guidelines and meta-analyses to randomised comparative studies. The most interesting finding: the efficacy question is considered largely settled; research has shifted to the question of the format and implementation fidelity with which it can be achieved.

1,731

STUDIES IN
TOTAL

1,335

IN HUMANS

914

OF WHICH
CONTROLLED

8

IN ANIMALS

0

IN THE LAB

Figures from the IHR study database · Last updated 2026-10-15

How to Read This Dossier

ESTABLISHED

measured in humans, with a comparison group

PLAUSIBLE

supported by mechanism, animal studies or observation

HYPOTHESIS

a likely connection that still needs to be tested

Cognitive Behavioural Therapy for Insomnia (CBT-I) at a Glance

ORIGIN:

CBT-I is not a single measure, but a structured, usually multi-session treatment programme for chronic insomnia.

EVIDENCE BASE:

1,731 evaluated works · 914 controlled human studies · 421 observational studies · 160 review articles · 8 animal studies · 0 cell-culture studies

STRONGEST EVIDENCE:

- Cognition and psyche, proven: The American College of Physicians recommends cognitive behavioural therapy as first-line treatment for adults with chronic insomnia (strong recommendation, moderate quality of evidence).
- Cognition and psyche, proven: A meta-analysis of 20 randomised studies on self-help CBT reports effect sizes of 0.80 for sleep efficiency, 0.66 for sleep-onset latency and 0.55 for wake time after sleep onset.
- Cognition and psyche, proven: A meta-analysis of 33 studies shows a reduction in the Insomnia Severity Index of 5.00 points immediately after the intervention for the digital variant.
- Inflammatory processes: In 123 older adults, CBT-I was superior to the Tai Chi and seminar groups for insomnia remission; after 16 months the risk of CRP above 3.0 mg/L decreased (odds ratio 0.26).
- Cognition and psyche: In 45 adults with post-traumatic stress disorder, 41 % achieved complete remission after eight weekly individual CBT-I sessions versus 0 % on the waiting list.

LIMITATIONS:

- The methodological challenge is comparability: different programmes and control groups, predominantly self-reported endpoints; a GRADE assessment explicitly notes this heterogeneity.
- The starting point is comparison with other procedures: the non-inferiority studies versus Tai Chi Chih and mindfulness-based stress reduction are based on 90 and 111 participants respectively.
- The present material contains no CBT-I studies on the gut microbiome or viral infections; the requisite investigative work is still outstanding.

CLASSIFICATION:

CBT-I is regarded in several meta-analyses and two guidelines as first-line treatment for chronic insomnia in adults.

1. What CBT-I Is

CBT-I is not a single measure, but a structured, usually multi-session treatment programme for chronic insomnia. Typical components include sleep logging in a sleep diary, sleep restriction and stimulus control, cognitive work on the appraisal of insomnia, and relaxation techniques. It is delivered in individual or group settings, as self-help programmes and increasingly via digital applications. The procedure is anchored in sleep-medicine and internal-medicine guidelines; controlled studies examine it both against waiting lists and against active comparators such as Tai Chi or mindfulness meditation.

For the evaluation of all studies, what is measured is decisive. Many works rely on sleep diaries and questionnaires, others on objective recordings; the two do not coincide. Second, the formats are hardly comparable: the evaluation includes personally delivered, internet-based, automated and guided self-help programmes, each with its own session volume and contact intensity. Third, the control groups differ substantially, ranging from waiting lists through placebo web applications to active procedures. A dedicated systematic review has examined treatment fidelity, showing that the amount of the application protocol itself has become a research topic.

2. What the Studies Show in Detail

The key human studies and the most important reviews — by application area, with population, duration, preparation, measure and result as reported in the original works. Numbers appear only where the work states them.

Distribution of **controlled human studies** by application area — the numbers are not additive, as one work may be assigned to several areas:

APPLICATION AREA	CONTROLLED STUDIES
Fatigue and stress	823
Cognition and psyche	800
Safety and tolerability	225
Oncology	97
Gut and microbiome	50
Musculoskeletal system	46
Inflammatory processes	26

APPLICATION AREA	CONTROLLED STUDIES
Metabolism	23

Cognition and Psyche

PROVEN

The American College of Physicians bases its recommendation on a systematic review of randomised controlled trials published in English between 2004 and September 2015. It recommends cognitive behavioural therapy as first-line treatment for all adult patients with chronic insomnia (strong recommendation, moderate quality of evidence) and advises that additional pharmacological therapy should be considered only in a shared decision-making process if CBT-I alone is unsuccessful¹. As early as 2006, stimulus control, relaxation training and cognitive behavioural therapy were regarded as individually effective procedures for chronic insomnia (standard)²⁴.

A review compared CBT-I with prescription and non-prescription medications; five studies met the criteria. Evidence of low to moderate quality supports long-term superiority of CBT-I over benzodiazepines and non-benzodiazepines, very low-quality evidence supports short-term superiority of the benzodiazepines⁴. Both approaches work in the short term, yet the psychological and behavioural approaches show longer-lasting effects after discontinuation of active treatment⁷.

A meta-analysis of 20 randomised studies on self-help CBT reports effect sizes of 0.80 for sleep efficiency, 0.66 for sleep onset latency and 0.55 for wake time after sleep onset immediately after treatment; the dropout rate was 14.5 % compared with 16.7 % for therapist-led CBT²⁹.

A meta-analysis of 22 randomised studies examined CBT-I in adults with comorbid insomnia and mental disorder; the comorbidities were depression (eight studies, 491 patients), post-traumatic stress disorder (four studies, 216 patients), alcohol dependence (three studies, 79 patients), bipolar disorder (one study, 58 patients), psychosis (one study, 50 patients) and mixed comorbidities (five studies, 189 patients)⁸. In 45 adults (31 women, mean age 37 years) with post-traumatic stress disorder, an eight-session weekly individual CBT-I was superior on all sleep diary endpoints and polysomnographically measured total sleep time; 41 % achieved full remission compared with 0 % in the wait-list group¹⁰. In 28 patients with chronic neck and back pain (CBT-I n = 19, control n = 9) sleep onset latency, wake time after sleep onset and number of awakenings decreased over eight weeks, sleep efficiency increased, and the Insomnia Severity Index improved ($p = 0.05$)²⁷. A case series of 127 men and 174 women referred for insomnia compared seven group sessions of CBT-I at low and high depressive symptom load (cut-off 14 on the Beck Depression Inventory); improvement in insomnia severity, energy, productivity, self-esteem and treatment satisfaction did not differ ($p > 0.14$), while the high symptom load group reported lower adherence to fixed rise time, time in bed restriction and changed sleep expectations ($p < 0.05$)²⁶. A meta-analysis of ten studies on internet-based CBT-I yielded effect sizes of -0.35 (95 % CI -0.46 to -0.25) for anxiety and -0.36 (95 % CI -0.47 to -0.26) for depression³⁰. For the question of which CBT-I component contributes the largest share of the effect, the dismantling study is still outstanding.

Inflammatory Processes

A randomised controlled comparative study with 123 older adults with chronic and primary insomnia compared cognitive behavioural therapy, Tai Chi Chih and a sleep seminar control over four months with two-hour group sessions per week and follow-ups at 7 and 16 months; insomnia diagnosis, patient questionnaires, polysomnography and high-sensitivity C-reactive protein were recorded⁹. Cognitive behavioural therapy was superior to the Tai Chi and seminar groups for clinically confirmed remission of insomnia ($p < 0.01$) and showed stronger and longer-lasting improvements in sleep quality, sleep parameters, fatigue and depressive symptoms (all $p < 0.01$)⁹.

Compared with the sleep seminar control, cognitive behavioural therapy at 16 months was associated with a reduced risk of elevated CRP values above 3.0 mg/L (odds ratio 0.26; 95 % CI 0.07 to 0.97; $p < 0.05$); remission of insomnia at 16 months was associated with lower CRP values ($p < 0.05$)⁹.

HYPOTHESIS

The association between insomnia remission and lower CRP suggests that the inflammatory markers follow the sleep course and not vice versa; however, the study is not designed to separate this direction. Whether the CRP effect is confirmed in larger samples and at other baseline CRP values is an open question that would require its own controlled study.

Oncology

A randomised, partially blinded non-inferiority study with 111 of 327 screened cancer patients with insomnia (CBT-I n = 47; MBSR n = 64) compared mindfulness-based stress reduction with CBT-I; the non-inferiority margin was 4 points on the Insomnia Severity Index, measured at baseline, after the programme and after three months¹¹.

In the sleep diary, sleep onset latency decreased at follow-up by 22 minutes in the CBT-I group and by 14 minutes in the MBSR group; total sleep time increased by 0.60 hours under CBT-I and by 0.75 hours under MBSR¹¹. Cognitive behavioural therapy improved sleep quality ($p < 0.001$) and dysfunctional sleep beliefs¹¹.

A randomised study with 255 breast cancer survivors with clinically significant sleep disturbance (iCBT-I n = 133; wait-list n = 122) tested a fully automated, six-part internet-based CBT-I programme; insomnia severity, sleep quality and fatigue were recorded at baseline, after nine weeks and after 15 weeks, with sleep diaries over two weeks each before and after the intervention. A randomised, partially blinded non-inferiority study with 90 of 145 screened breast cancer survivors (CBT-I n = 45; Tai Chi Chih n = 45) over three months yielded a response rate at 15 months of 43.7 % under CBT-I and 46.7 % under Tai Chi Chih; Tai Chi Chih was non-inferior to CBT-I¹⁵. For cancer patients with tumour types other than breast cancer and for direct comparison with pharmacological options, the examining study is still outstanding.

Fatigue and Stress

A randomised study with 54 adults with chronic insomnia compared mindfulness-based stress reduction, a mindfulness-based insomnia therapy and eight-week self-monitoring; total wake time from sleep diaries, the Pre-Sleep Arousal Scale and the Insomnia Severity Index as well as polysomnography and actigraphy were recorded¹². The meditation-based procedures reduced total wake time by 43.75 versus 1.09 minutes, the Pre-Sleep Arousal Scale by 7.13 versus 0.16 and the Insomnia Severity Index by 4.56 versus 0.06 from baseline to after treatment compared with self-monitoring; no significant differences emerged between the two meditation procedures¹².

A review on comorbid insomnia and obstructive sleep apnoea reports that approximately 30 to 50 % of patients with sleep apnoea report clinically significant insomnia symptoms and 30 to 40 % of patients with chronic insomnia meet the diagnostic criteria for sleep apnoea; the review summarises epidemiological research, case studies, single-arm treatment studies and randomised controlled treatment studies ¹⁷.

A review on the reciprocal relationship between exercise and sleep describes that exercise has long been associated with better sleep and evidence is accumulating for exercise as a non-pharmacological treatment option for disturbed sleep, while conversely poor sleep can contribute to lower physical activity ²⁸. Whether CBT-I sustainably changes physical activity and resilience to fatigue is an open question that would require its own controlled study.

Gut and Microbiome

A narrative review evaluated 51 articles found on 11 January 2018 in PubMed, PsycINFO and Embase and examined barriers to access to CBT-I as well as attempts to increase its use ²⁵. Three categories of barriers were described: system barriers with limited access to CBT-I and to behavioural sleep medicine specialists, barriers among general practitioners through inadequate screening and referral behaviour, and barriers among patients through lack of knowledge, treatment beliefs and limited access ²⁵.

HYPOTHESIS An association between CBT-I and the gut microbiome is not examined in this work; the assignment of the topic to this area is not supported by the evaluated work. Whether CBT-I influences the gut microbiome or inflammatory bowel processes via sleep is an open question for which a dedicated study is lacking.

Viral Infections

A review on childhood sleep summarises studies of the past two decades from PubMed, SCOPUS and PsychInfo and lists as consequences of sleep deprivation and other sleep problems in children physical consequences such as obesity, neurocognitive consequences such as memory, attention, intelligence and academic performance as well as emotional and behavioural consequences such as internalising and externalising behaviours and behavioural disorders ³¹.

As current prevention and intervention approaches the review names nutrition, exercise, cognitive behavioural therapy for insomnia, aromatherapy, acupressure and mindfulness and places these in the context of coronavirus disease 2019 ³¹. **Hypothesis:** The work treats CBT-I only as one of several approaches and does not examine any effect on viral infections; a direct link between CBT-I and viral infections cannot be derived from it. Whether CBT-I is effective in children with sleep problems in the context of viral infections is an open question that would require its own controlled study.

Overall Picture

Across the areas, several meta-analyses and guidelines position cognitive behavioural therapy for insomnia as first-line treatment: the American College of Physicians issues a strong recommendation at moderate evidence quality ¹, the American Academy of Sleep Medicine bases its recommendations on 124 included studies ¹³, and the digital variant shows in a meta-analysis of 33 studies a reduction in the Insomnia Severity Index of 5.00 points immediately after the intervention ⁵. Even with comorbid mental disorders and in breast cancer survivors, controlled studies show improvements in sleep and partly in fatigue and depressive symptoms ^{8, 10, 14}.

Research begins where CBT-I is tested against other procedures: the non-inferiority studies on Tai Chi Chih and on mindfulness-based stress reduction are based on 90 and 111 participants respectively ^{11, 15}, and the comparative study on inflammatory markers comprises 123 older adults ⁹. For assignment to gut microbiome and viral infections the present material provides no dedicated CBT-I studies; the examining work is still outstanding here ^{25, 31}. It remains open how the effect behaves at follow-up beyond one year and whether adherence at high depressive symptom load alters the results ²⁶.

Methodology of the evidence base

Typical treatments comprise six to eight sessions over several weeks, partly as group therapy, partly internet-based ^{3, 10, 26}. Usually recorded are sleep diaries, the Insomnia Severity Index, polysomnography and actigraphy as well as questionnaires on mood and quality of life ^{2, 12}. What is still systematically lacking is the dismantling into individual components and testing over follow-up periods of more than one year.

The bottleneck lies in implementation, not in efficacy

The large number of controlled studies obscures the fact that the intervention tested in each work is a different one. A programme with six sessions, a self-help book and an automated web application bear the same name but examine different amounts of guidance and contact. A systematic review on adherence has addressed precisely this point and established dropout and implementation fidelity as an independent research field.

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therefore is that part of the variation between study results stems from implementation and not from the procedure.

For practice it follows that the guideline recommendation carries a condition that is not stated in the recommendation itself: that the programme is actually implemented. The comparative studies in the field support this view. In one randomised study in older people with insomnia, CBT-I was tested against Tai Chi; in another in cancer patients it was tested against mindfulness-based stress reduction in a non-inferiority design. The fact that active behaviour-based procedures are used at all as comparator groups shows how strongly the finding depends on structure, guidance and regularity. The contribution of the individual programme components has not yet been determined.

3. How Robust the Research Is

Controlled human studies dominate the evaluation; observational studies and basic research recede behind them. Thematically, two areas rank far ahead: fatigue and cognition, that is the immediate consequences of sleep deprivation. These are followed by safety and oncology as well as physical application areas such as gut, musculoskeletal system, inflammation, metabolism, cardiovascular system and bone, each represented by individual studies. The captured works range from 1994 to 2026; the most cited originate predominantly from the 2010s and 2020s and are guidelines, meta-analyses and systematic reviews.

Proven is the efficacy of CBT-I for chronic insomnia in adults at the level of several meta-analyses and two guidelines that list the procedure; the most cited work in the field is a clinical guideline, the second a systematic review with meta-analysis. One meta-analysis of randomised studies examines the digital variant separately. The methodological difficulty of the field lies less in the number of studies than in their comparability: different programmes, different control groups, predominantly self-reported endpoints. A review by the American Academy of Sleep Medicine explicitly addresses this heterogeneity in a GRADE assessment.

4. What Is Frequently Claimed — and What the Data Support

CLAIM	EVIDENCE BASE
CBT-I as first-line treatment for chronic insomnia	Proven: Two guidelines include the procedure, including one from the American College of Physicians. Several meta-analyses and systematic reviews support
Digital CBT-I works like personally delivered CBT-I	A meta-analysis of randomised studies on digital CBT-I is available, as is a randomised study on an automated web application versus placebo. The program
CBT-I also helps in comorbid insomnia	For mental disorders, a systematic review with meta-analysis is available, for post-traumatic stress disorder a randomised controlled study, for cancer a non-i
CBT-I acts beyond sleep on inflammation, metabolism and the cardiovascular system	For these areas, the evaluation yields individual controlled studies, including a comparative study in older people with an inflammation-related endpoint. This i

5. The Most Robust Studies

Ordered by strength of evidence, not by prominence. The complete evaluation comprises substantially more studies; the most robust are listed here.

Controlled Human Studies

- ¹ Management of Chronic Insomnia Disorder in Adults: A Clinical Practice Guideline From the American College of Physicians (2016)
- ² Cognitive Behavioral Therapy for Chronic Insomnia: A Systematic Review and Meta-analysis (2015)
- ³ A randomized, placebo-controlled trial of online cognitive behavioral therapy for chronic insomnia disorder delivered via an automated media-rich web ... (2012)
- ⁴ Comparative effectiveness of cognitive behavioral therapy for insomnia: a systematic review (2012)
- ⁵ Efficacy of digital cognitive behavioural therapy for insomnia: a meta-analysis of randomised controlled trials (2020)
- ⁶ Effect of Digital Cognitive Behavioral Therapy for Insomnia on Health, Psychological Well-being, and Sleep-Related Quality of Life: A Randomized ... (2019)
- ⁷ The treatments of chronic insomnia: a review of benzodiazepine receptor agonists and psychological and behavioral therapies (2009)
- ⁸ Cognitive behavioral therapy for insomnia in patients with mental disorders and comorbid insomnia: A systematic review and meta-analysis (2022)
- ⁹ Cognitive behavioral therapy vs. Tai Chi for late life insomnia and inflammatory risk: a randomized controlled comparative efficacy trial (2014)
- ¹⁰ Cognitive behavioral therapy for insomnia in posttraumatic stress disorder: a randomized controlled trial (2014)
- ¹¹ Mindfulness-based stress reduction compared with cognitive behavioral therapy for the treatment of insomnia comorbid with cancer: a randomized ... (2014)
- ¹² A randomized controlled trial of mindfulness meditation for chronic insomnia (2014)

- Co-Morbid Insomnia and Sleep Apnea (COMISA): Prevalence, Consequences, Methodological Considerations, and Recent Randomized Controlled Trials (2019)
- ¹³ Behavioral and psychological treatments for chronic insomnia disorder in adults: an American Academy of Sleep Medicine systematic review ... (2021)
- ¹⁴ Internet-Delivered Cognitive-Behavioral Therapy for Insomnia in Breast Cancer Survivors: A Randomized Controlled Trial (2018)
- ¹⁵ Tai Chi Chih Compared With Cognitive Behavioral Therapy for the Treatment of Insomnia in Survivors of Breast Cancer: A Randomized, Partially Blinded ... (2017)
- ¹⁶ The assessment and management of insomnia: an update (2019)
- ¹⁷ Bi-directional relationships between co-morbid insomnia and sleep apnea (COMISA) (2021)
- ¹⁸ Prevention of Incident and Recurrent Major Depression in Older Adults With Insomnia: A Randomized Clinical Trial (2022)
- ¹⁹ Nonpharmacological Treatments of Insomnia for Long-Term Painful Conditions: A Systematic Review and Meta-analysis of Patient-Reported Outcomes in ... (2015)
- ²⁰ Components and Delivery Formats of Cognitive Behavioral Therapy for Chronic Insomnia in Adults: A Systematic Review and Component Network ... (2024)
- ²¹ Efficacy of Cognitive Behavioral Therapy for Insomnia in Adolescents: A Randomized Controlled Trial with Internet Therapy, Group Therapy and A ... (2015)
- ²² Acupuncture Versus Cognitive Behavioral Therapy for Insomnia in Cancer Survivors: A Randomized Clinical Trial (2019)
- ²³ Efficacy of Digital Cognitive Behavioral Therapy for the Treatment of Insomnia Symptoms Among Pregnant Women: A Randomized Clinical Trial (2020)

6. Summary

The efficacy of CBT-I for chronic insomnia in adults is considered proven at the level of several meta-analyses and two guidelines that recommend the procedure. The American College of Physicians issues a strong recommendation with moderate evidence quality, the American Academy of Sleep Medicine bases its recommendations on 124 included studies, and a meta-analysis of 33 studies shows a reduction in the Insomnia Severity Index of 5.00 points immediately after the intervention for the digital variant.

A link between CBT-I and inflammatory markers is plausible: in a randomised comparison study with 123 older adults, remission of insomnia after 16 months was associated with lower CRP values ($p < 0.05$). **Hypothesis:** The association suggests that the inflammatory markers follow the sleep course and not vice versa; however, the study is not designed to separate this direction. It could follow that CBT-I is co-examined in fields in which only related approaches such as Tai Chi, mindfulness meditation or exercise have been investigated so far. The assignment to the gut microbiome and viral infections, by contrast, is not based on own CBT-I studies in the present material.

What remains to be clarified is how the effect behaves in follow-up beyond one year. In a case series with 127 men and 174 women referred for insomnia, improvement in insomnia severity, energy, productivity, self-esteem and treatment satisfaction did not differ between low and high depressive symptom load ($p > 0.14$), while the group with high symptom load reported lower adherence to fixed rising time, bed-time restriction and changed sleep expectations ($p < 0.05$). It is also open which CBT-I component carries the largest share of the effect; the decomposing study is still outstanding. Whether CBT-I influences the gut microbiome or inflammatory bowel processes via sleep and whether it works in children with sleep problems in the context of viral infections would have to be clarified by a separate controlled study.

7. What Remains Open

- **Programme components:** Which share sleep restriction, stimulus control and cognitive work contribute to the effect would be clarified through comparison studies with individual components.
- **Format:** Whether automated, guided and personally delivered CBT-I are equally effective under comparable baseline conditions would be decided by a randomised equivalence test.
- **Comorbidity:** For the co-occurrence of insomnia and sleep apnoea (COMISA) a review describes the field; whether CBT-I needs to be adapted here remains an open question for examination.

Frequently Asked Questions

How does CBT-I differ from sleep hygiene advice?

Plausible: Sleep hygiene advice is one component, but not the procedure itself. CBT-I is structured and multi-session, using a sleep diary, sleep restriction, stimulus control and cognitive work on sleep appraisal. Controlled testing refers to the overall programme; individual components were not examined separately in the present evaluation.

Can CBT-I be used in the presence of psychiatric comorbidity?

A systematic review with meta-analysis is available for patients with psychiatric disorders and comorbid insomnia, and a randomised controlled trial for post-traumatic stress disorder. Both studies examine CBT-I in the respective population. Whether the results are transferable to other comorbid constellations has not been decided.

What indicates in practice whether implementation is effective?

The systematic review on adherence treats dropout and implementation fidelity as separate variables. For evaluation this means recording the actual scope completed and regularity, not only assignment to the procedure. Which threshold of implementation is required for benefit cannot be derived from the present evaluation.

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Research, put in context. Every statement leads to the original paper; the decision in the individual case rests with the treating professional.
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