Sleepless in the 21st Century: Rethinking Chronic Insomnia Care

Prof Colin A. Espie
PhD, DSc, FMedSci, FBPsS, FRCGP (Hon), FAASM
Professor of Sleep Medicine, Nuffield Dept of Clinical Neurosciences Founding Director of Experimental & Clinical Sleep Research Founding Clinical Director of Sleep Medicine Training
Fellow, Somerville College
HSRF, Dept of Psychiatry
University of Oxford
Honorary Consultant Clinical Psychologist
OUH NHS Trust and NHS Lanarkshire
Emeritus Professor of Clinical Psychology University of Glasgow
Honorary Fellow, BABCP

18th Annual Sleep Medicine CME Course

Conflict of Interest Disclosures: Dr Colin Espie

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Grant/Research Support	Wellcome Trust, NIHR/ HTA, NIMH
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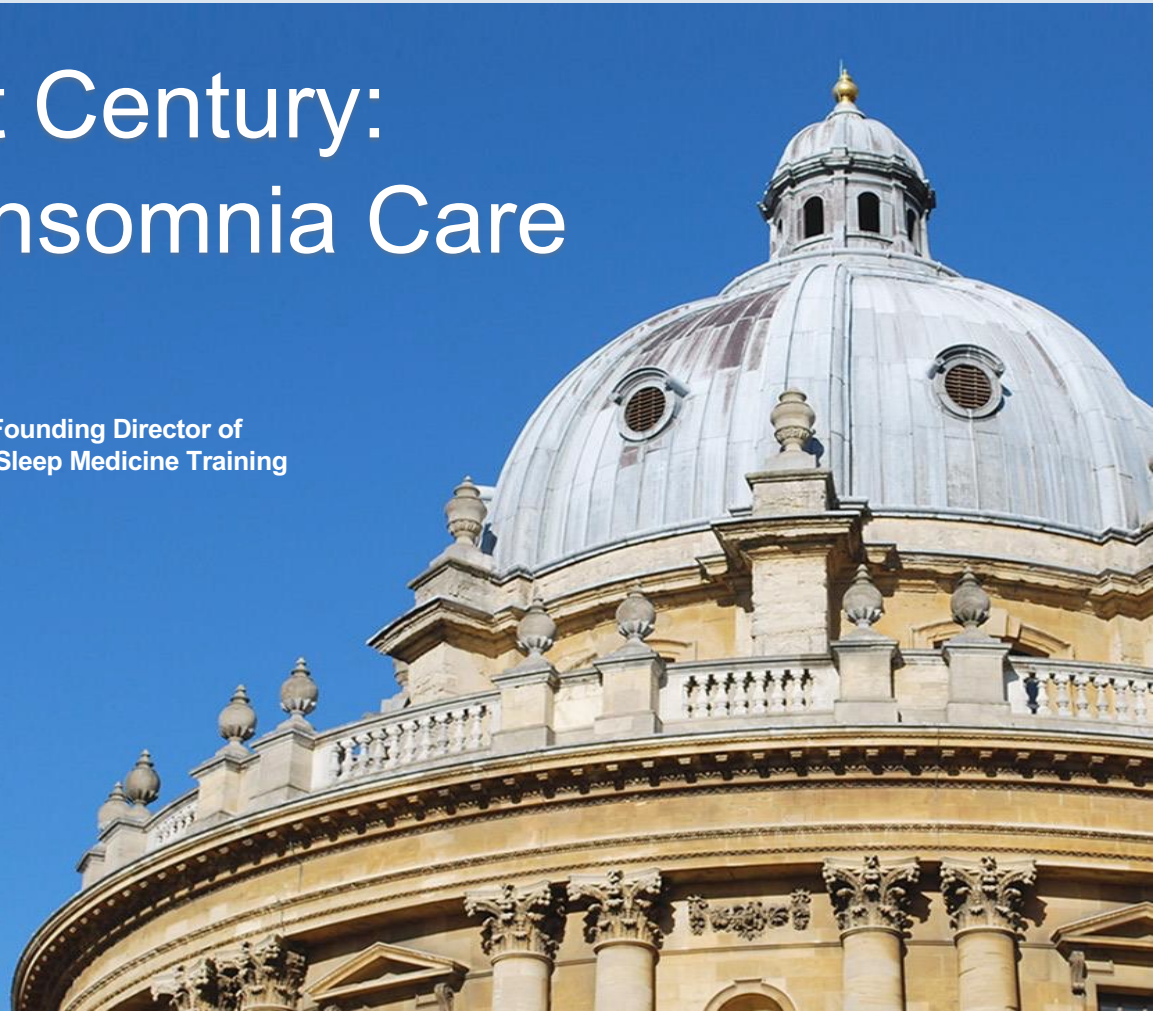
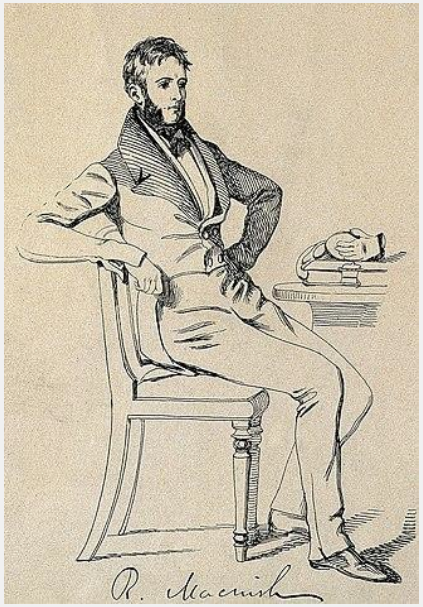


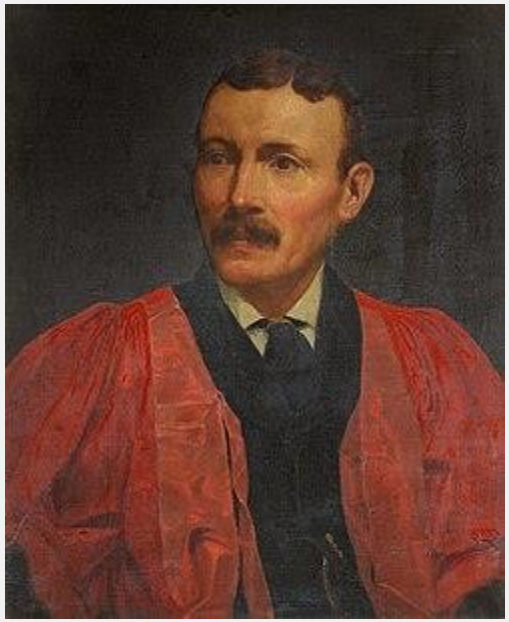
There have always been two ways of addressing insomnia



In some cases of restlessness, sleep may be procured by the person getting up, and walking for a few minutes about the room. It is not easy to explain on what principle this acts, but it is certain, that by such means sleep sometimes follows, where previously it had been solicited in vain. It is a com-

Robert McNish, The Philosophy of Sleep (1830, p. 186)

There have always been two ways of addressing insomnia



John Buckley Bradbury, Professor of Medicine, Cambridge University, 1899 Lecture to the Royal Society

"The reason [for insomnia] is that the cerebral cells have assumed an irritable condition and it is necessary to depress their activity to bring them back to a more natural state…it is here that hypnotics are of such great value"

Paraldehyde, chloral amide, chloralose (immobilizing agent), chloral hydrate, sulphonal (sulphon methane), potassium bromide were seen to be the least harmful

Horne JA Insomnia – Victorian style. *The Psychologist,* 22 October 2008

There have always been two ways of addressing insomnia - there still are

Medication	CBTx
• Drug formulary ○ Pharmacotherapy utilises pharmaceuticals ○ Multiple transporters	• CBTx formulary ○ Psychological treatment utilises cognitive and behavioural therapeutics ○ Multiple transporters

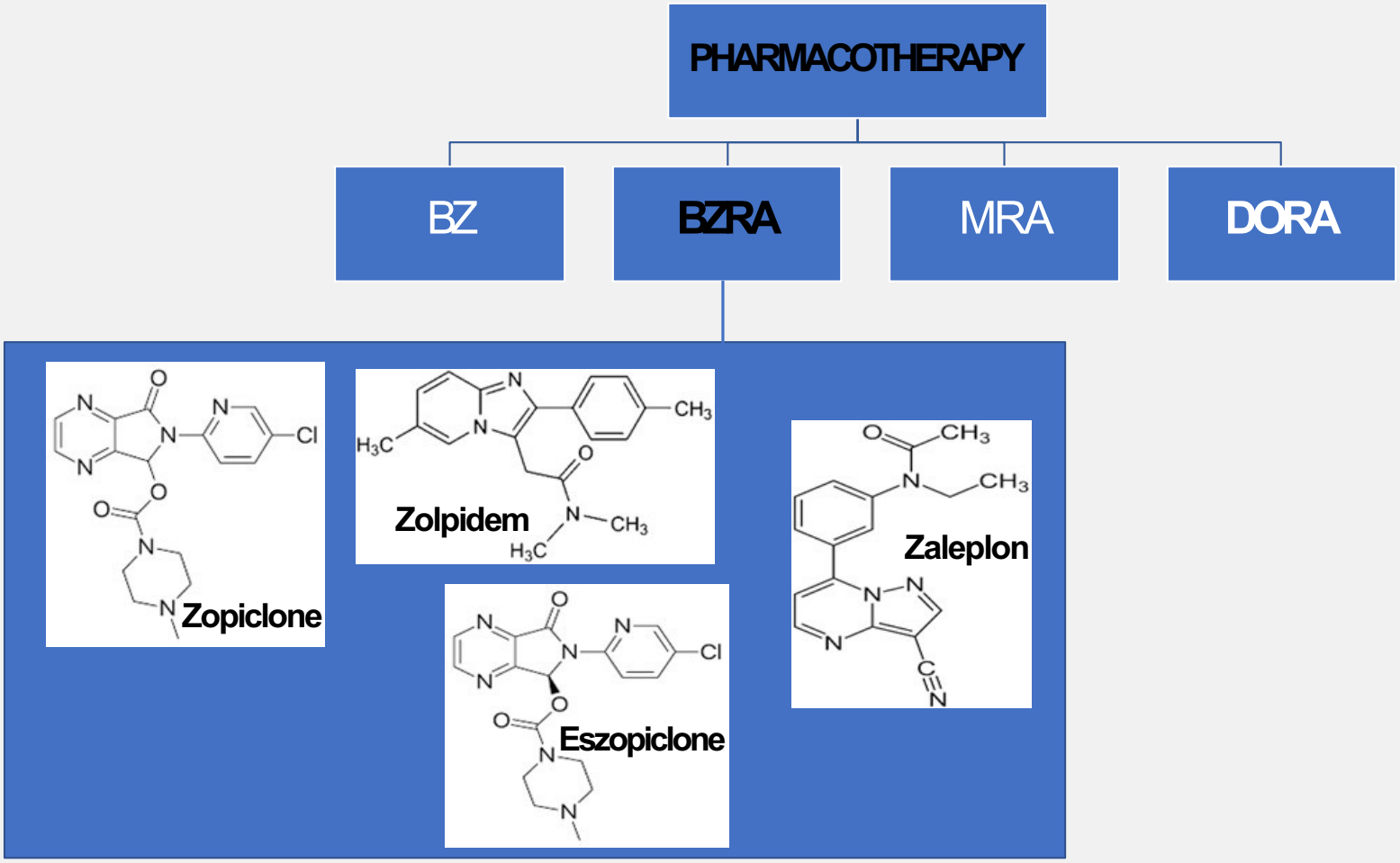


Figure 5.2: BZRA 'z' drug treatment options for insomnia
Espie, C.A. (2025) *A Clinician's Guide to Cognitive and Behavioural Therapeutics (CBTx) for Insomnia*. Cambridge University Press, UK

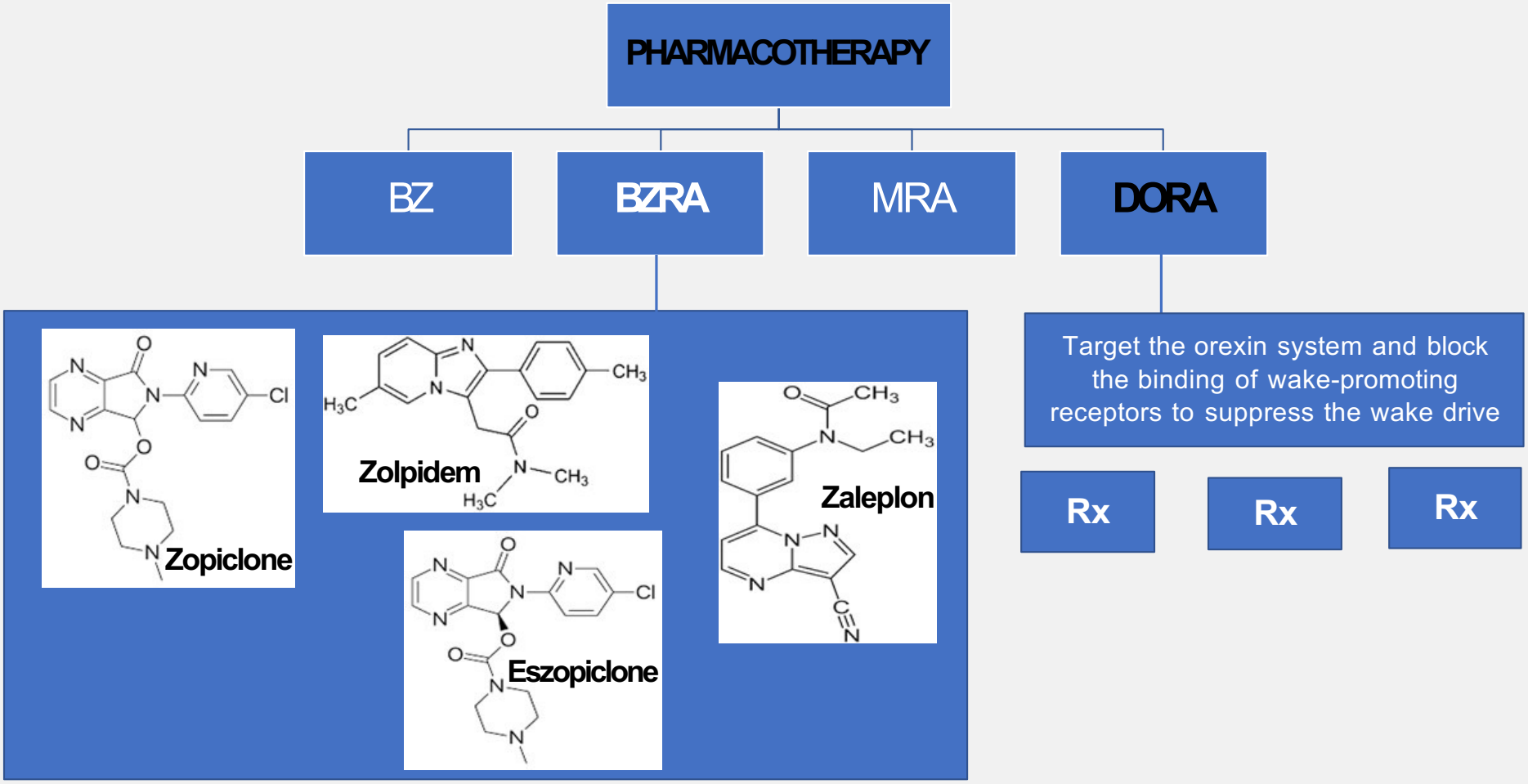


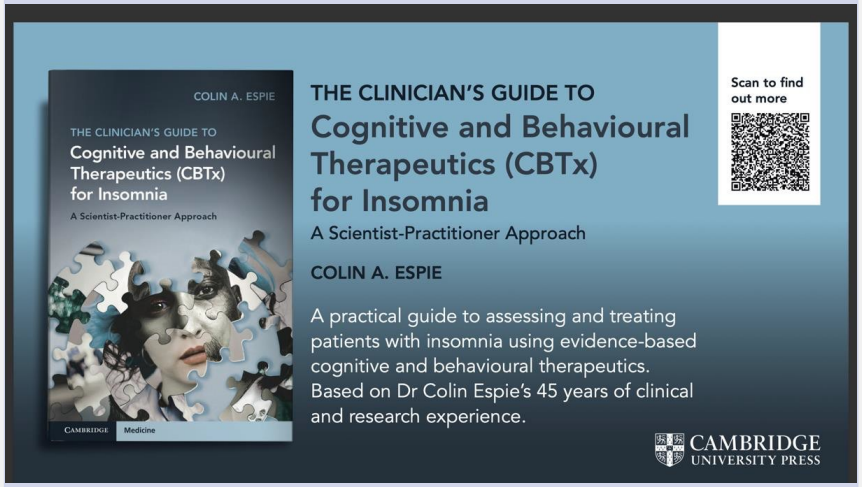
Figure 5.2: BZRA 'z' drug treatment options for insomnia
Espie, C.A. (2025) *A Clinician's Guide to Cognitive and Behavioural Therapeutics (CBTx) for Insomnia*. Cambridge University Press, UK

Therapeutic Formularies

Medication

- Drug formulary
  - Pharmacotherapy utilises pharmaceuticals
  - Multiple transporters

CBTx



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REVIEW ARTICLE

The European Insomnia Guideline: An update on the diagnosis and treatment of insomnia 2023

Dieter Riemann[1,2] | Colin A. Espie[3] | Ellemarije Altena[4] |
Erna Sif Arnardottir[5,6] | Chiara Baglioni[7] | Claudio L. A. Bassetti[8] |
Celyne Bastien[9] | Natalija Berzina[10] | Bjørn Bjorvatn[11] | Dimitris Dikeos[12] |
Leja Dolenc Groselj[13] | Jason G. Ellis[14] | Diego Garcia-Borreguero[15] |
Pierre A. Geoffroy[16] | Michaela Gjerstad[17] | Marta Gonçalves[18] |
Elisabeth Hertenstein[19] | Kerstin Hoedlmoser[20] | Tuuliki Hion[21] |
Brigitte Holzinger[22] | Karolina Janku[23] | Markus Jansson-Fröjmark[24,25] |
Heli Järnefelt[26] | Susanna Jernelöv[24,25] | Poul Jørgen Jennum[27] |
Samson Khachatryan[28] | Lukas Krone[3,8,19] | Simon D. Kyle[3] |
Jaap Lancee[29] | Damien Leger[30] | Adrian Lupusor[31] |
Daniel Ruivo Marques[32,33] | Christoph Nissen[34] | Laura Palagini[35] |
Tiina Paunio[36] | Lampros Perogamvros[34] | Dirk Pevernagie[37] |
Manuel Schabus[20] | Tamar Shochat[38] | Andras Szentkiralyi[39] |
Eus Van Someren[40,41] | Annemieke van Straten[42] | Adam Wichniak[43] |
Johan Verbraecken[44] | Kai Spiegelhalder[1]

- Stimulus control and sleep restriction are the most active ingredients of CBT

Meta-Analysis > J Clin Sleep Med. 2021 Feb 1;17(2):263-298. doi: 10.5664/jcsm.8988.

Behavioral and psychological treatments for chronic insomnia disorder in adults: an American Academy of Sleep Medicine systematic review, meta-analysis, and GRADE assessment

Jack D Edinger [1 2], J Todd Arnedt [3], Suzanne M Bertisch [4], Colleen E Carney [5], John J Harrington [6], Kenneth L Lichstein [7], Michael J Sateia [8], Wendy M Troxel [9], Eric S Zhou [10], Uzma Kazmi [11], Jonathan L Heald [11], Jennifer L Martin [12 13]

- Cognitive behavioural therapies
- Brief behavioural therapies
- Stimulus control
- Sleep restriction therapy
- Relaxation training
- Sleep hygiene
- Biofeedback
- Paradoxical intention
- Intensive sleep retraining
- Mindfulness

Four enormous changes in the insomnia landscape

Four enormous changes in the insomnia landscape

Recognition that insomnia is a disorder in its own right; and that it should be actively treated

‘Insomnia Disorder’

The Sleep Condition Indicator

Espie, C.A., et al.
BMJ Open 2014; JOSR, 2017

Luik A.I., et al.
BJGP, 2019

Appendix: The Sleep Condition Indicator

	Score		DSM-5		
Item	4	3	2	1	0
Thinking about a typical night in the last month … 1) … how long does it take you to fall asleep?	0 – 15 min	16 – 30 min	31 – 45 min	46 – 60 min	≥ 61 min
2) … if you then wake up during the night … how long are you awake for in total? (add all the wakenings up)	0 – 15 min	16 – 30 min	31 – 45 min	46 – 60 min	≥ 61 min
* 3) … how many nights a week do you have a problem with your sleep?	0 - 1	2	3	4	5 - 7
4) … how would you rate your sleep quality?	Very good	Good	Average	Poor	Very poor
Thinking about the past month, to what extent has poor sleep … 5) … affected your mood, energy, or relationships?	Not at all	A little	Somewhat	Much	Very much
6) … affected your concentration, productivity, or ability to stay awake	Not at all	A little	Somewhat	Much	Very much
* 7) … troubled you in general	Not at all	A little	Somewhat	Much	Very much
Finally … 8) … how long have you had a problem with your sleep?	I don’t have a problem / < 1 mo	1 – 2 mo	3 – 6 mo	7 – 12 mo	> 1 yr

Four enormous changes in the insomnia landscape

Recognition that insomnia is a disorder in its own right; and that it should be actively treated

Guidelines that CBT is the best evidenced treatment; and that CBT should be first line clinical care

CBT is the guideline treatment for chronic insomnia; not medication

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Review > J Sleep Res. 2023 Dec;32(6):e13841. doi: 10.1111/jsr.13841. Epub 2023 Feb 6.

Revisiting the Psychobiological Inhibition Model: a conceptual framework for understanding and treating insomnia using cognitive and behavioural therapeutics (CBTx)

Colin A Espie [1]

Four enormous changes in the insomnia landscape

Recognition that insomnia is a disorder in its own right; and that it should be actively treated

Guidelines that CBT is the best evidenced treatment; and that CBT should be first line clinical care

Evidence that treating insomnia effectively may alleviate comorbid mental and physical conditions

Comorbidity is the norm; not the exception

Original Investigation FREE

January 2019

Effect of Digital Cognitive Behavioral Therapy for Insomnia on Health, Psychological Well-being, and Sleep-Related Quality of Life: A Randomized Clinical Trial

Colin A. Espie, PhD[1,2]; Richard Emsley, PhD[3]; Simon D. Kyle, PhD[1]; et al

Author Affiliations | Article Information

JAMA Psychiatry. 2019;76(1):21-30. doi:10.1001/jamapsychiatry.2018.2745

n=1,771
77%F, mean age = 48yr

Health		
BMI, mean (SD)	25.3 (6.0)	25.1 (5.1)
Medical diagnosis, No. (%)		
Heart disease or high blood pressure	106 (12.4)	106 (12.4)
Diabetes	18 (2.1)	18 (2.1)
Stroke or other neurological problems	8 (0.9)	16 (1.9)
Cancer	41 (4.8)	39 (4.6)
Arthritis/other joint problems	90 (10.5)	87 (10.2)
Digestive disorders	121 (13.9)	123 (14.4)
Depression or anxiety	333 (38.8)	317 (37.2)
Hormonal problems	57 (6.6)	70 (8.2)
Other comorbidity	115 (13.4)	127 (14.9)
Any diagnosis	570 (66.4)	561 (65.8)

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Australasian sleep Association

JOURNAL ARTICLE CORRECTED PROOF

PRO: CBT-I for insomnia treatment can be delivered by a range of healthcare providers

Get access

Colin A Espie ✉, Michael A Grandner, Christopher L Drake

Sleep, zsaf124, https://doi.org/10.1093/sleep/zsaf124

Published: 21 May 2025 **Article history** ▾

JOURNAL ARTICLE CORRECTED PROOF

CON: CBT-I for insomnia treatment can be delivered by a range of healthcare providers

Get access

Christina S McCrae ✉, Ashley F Curtis, Melanie A Stearns

Sleep, zsaf123, https://doi.org/10.1093/sleep/zsaf123

Published: 21 May 2025 **Article history** ▾

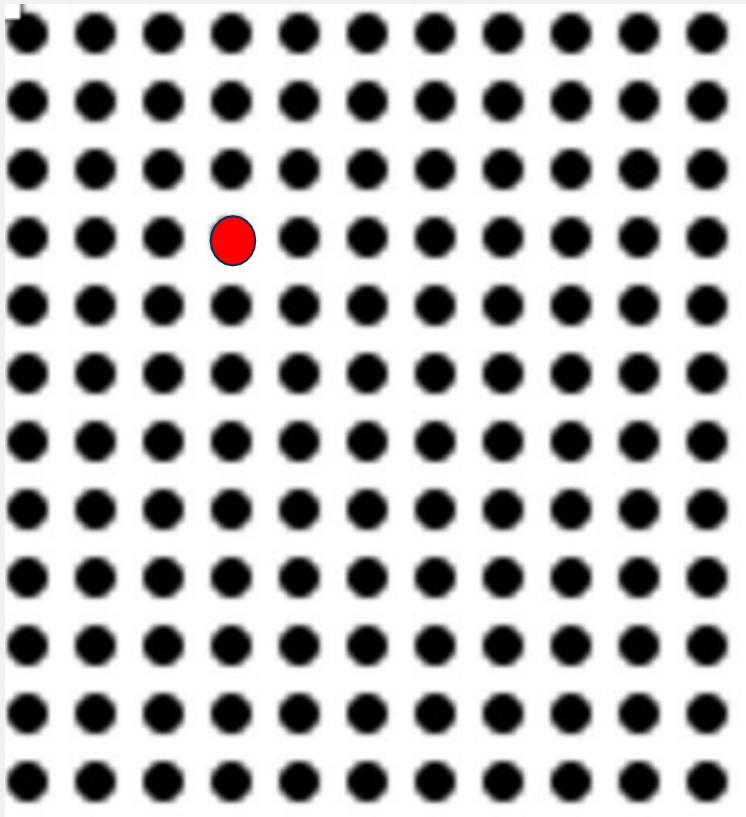
PRO: CBT for insomnia treatment can be delivered by a range of healthcare providers

1. A diverse range of professionals provides CBT (e.g. psychologists, nurses, therapists, physicians, social workers)
2. All health care systems require both generalists and specialists to meet population need
3. Who may deliver CBT is a generic matter of clinical governance
4. Professionals need to have a license to practice comprising core statutory registration
5. Licensing and other credentials/ expertise must be in the public domain, and open to scrutiny
6. Professionals must operate safely and effectively, within the limits of qualifications and expertise
7. Core licensing and training bodies must ensure/ police standards of training /supervision/ practice
8. Models like stepped care can
    a. efficiently manage populations of patients,
    b. make best use of professional skill-mix, and
    c. provide clinical governance to ensure best treatment and best practice

SOLVING the gap in meeting insomnia guidelines

? 1000:1

1:1
immediate availability today



The CBTx gap is currently bridged by pharmacotherapy

Four enormous changes in the insomnia landscape

Recognition that insomnia is a disorder in its own right; and that it should be actively treated

Guidelines that CBT is the best evidenced treatment; and that CBT should be first line clinical care

Evidence that treating insomnia effectively may alleviate comorbid mental and physical conditions

Regulatory clearance of dCBT products that make guideline treatment possible at population scale

What is the fundamental reason for CBT not being available, compared with medication

? Cultural practices reinforce medical management
? Practitioners are overprescribing medication
? Drug industry use aggressive marketing
? Patients want a quick fix
? CBT is too hard
? There is a lack of clinicians and therapists
? We don‘t have an efficient stepped care model
? Not enough funding goes into psychological care

What is the fundamental reason for CBT not being available, compared with medication

? Cultural
? Pra
? Dru
? Patie
? CBT is
? There
? We do
? Not enc ological care

Drugs may be administered by several routes

- Injected intravenous, intramuscular
- Sublingual (under tongue), between gums and cheek (buccally)
- Nasal, inhaler, nebuliser
- Placed in rectum (rectally), the eye (ocular), ear (otic)
- Topical, transdermal (skin patch)
- Intrathecal (spinal cord), or beneath the skin (subcutaneous)
- Oral

CBT may be administered by several routes

- Individual therapy
- Group therapy
- Large group therapy
- Teletherapy (text, phone, online)
- Bibliotherapy
- Digitally enhanced/ supported

Drugs may be administered by several routes

- Injected intravenous, intramuscular
- Sublingual (under tongue), between gums and cheek (buccally)
- Nasal, inhaler, nebuliser
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- **Oral**

CBT may be administered by several routes

- Individual therapy
- Group therapy
- Large group therapy
- Teletherapy (text, phone, online)
- Bibliotherapy
- Digitally enhanced/ supported
- **Fully automated digital (dCBT)**

Drugs may be administered by several routes

- Injected intravenous, intramuscular
- Sublingual (under tongue), between gums and cheek (buccally)
- Nasal, inhaler, nebuliser
- Placed in rectum (rectally), the eye (ocular), ear (otic)
- Topical, transdermal (skin patch)
- Intrathecal (spinal cord), or beneath the skin (subcutaneous)
- **Oral**

CBT may be administered by several routes

- Individual
- Group
- Large group
- Teletherapy (online, text, phone)
- Bibliotherapy
- Digitally enhanced/ supported
- **Fully automated digital (dCBT)**
- **Virtual reality**
- **Avatar**
- **Generative AI**

Drugs may be administered by several routes

- Injected intravenous, intramuscular
- Sublingual (under tongue), between gums and cheek (buccally)
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- **Oral**

CBT may be administered by several routes

- Individual therapy
- Group therapy
- Large group therapy
- Teletherapy (text, phone, online)
- Bibliotherapy
- Digitally enhanced therapy
- **Fully automated software as a medical device (SaMD)**

These transporter routes are scalable …and self-administered

HEALTH AFFAIRS FOREFRONT

RELATED TOPICS:
MENTAL HEALTH | PHARMACEUTICALS | REGULATION | QUALITY OF CARE | HEALTH CONDITIONS | QUALITY IMPROVEMENT | PATIENT HARM | PATIENT CARE | BEHAVIORAL HEALTH CARE

Digital Therapeutics Should Be Regulated With Gold-Standard Evidence

Colin A. Espie, John Torous, Troyen A. Brennan

FEBRUARY 28, 2022

10.1377/forefront.20220223.739329

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Letter to the Editor | Free Access

Evidence-informed is not enough: digital therapeutics also need to be evidence-based

Colin A. Espie, Joseph Firth, John Torous

First published: 07 May 2022 | https://doi.org/10.1002/wps.20993

PDF TOOLS SHARE

We are witnessing exponential growth in a heavily capitalized digital health industry which promises to transform behavioral and mental health care[1, 2]. Consequently, it is critical that

Digital Mental Health Treatments (DMHTs)

- **DMHTs (Digital Mental Health Treatments)** are a new treatment class defined by Centers for Medicare & Medicaid Services (CMS).
  - Must be **FDA-cleared under 21 CFR 882.5801**.
    - FDA review assesses clinical evidence, software quality, and cybersecurity.
    - Approval requires meeting **quality, security**, and **clinical efficacy** standards
- DMHTs include both **patient-facing interventions** and **provider dashboards** for insights/feedback.
- Can be prescribed by both **traditional and non-traditional licensed prescribers** (e.g., psychologists, LCSWs, LMFTs, LPCs).

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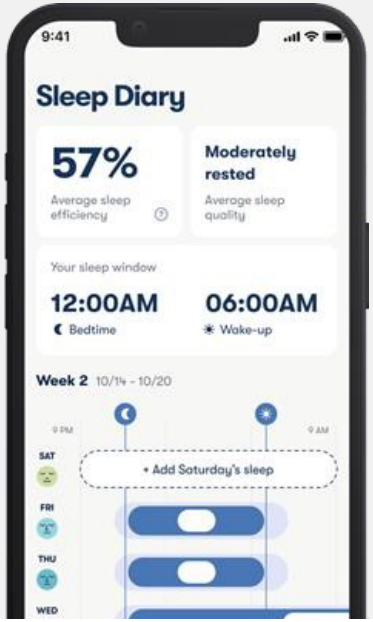
FDA Cleared Digital CBT-I

- To date, two digital CBT-I treatments have been cleared by FDA, SleepioRx (Big Health) and Somryst (Nox)
- Digital treatments for psychiatric disorders must be formally reviewed and cleared by FDA prior to market authorization. This is achieved through a detailed review of clinical evidence, technological characteristics and software quality over a 6-month period.

Sleepio Rx



SleepioRx: FDA cleared for the treatment of insomnia disorder in patients aged 18+

- Rx only
- Available for use by clinicians and patients today

SleepioRx is a digital therapeutic intended for the treatment of chronic insomnia/insomnia disorder as an adjunct to usual care in patients aged 18 and older. SleepioRx is a prescription device delivering Cognitive Behavioral Therapy for Insomnia (CBT-I) and can be made available on the order of a licensed healthcare provider. Patients should read the indications for use.

Somryst

Somryst: FDA cleared for the treatment of insomnia disorder in patients aged 22+

- Rx only
- Not available for use as of 2025

Somryst is a prescription-only digital therapeutic intended to provide a neurobehavioral intervention (Cognitive Behavioral Therapy for Insomnia – CBT-I) in patients 22 years of age and older with chronic insomnia. Somryst treats chronic insomnia by improving a patient's insomnia symptoms.

How to level the playing field

1. Overprescribing is not the core problem …it is massive under-provision of alternatives
2. The evidence-based care we need to scale into population provision… is CBT
3. We have approached this challenge incrementally …by solving for the wrong problem
4. CBTx has not scaled …because it has lacked a scalable transporter system
5. Scaling CBT is feasible …but we need to influence and adopt how healthcare procurement works
6. Successful scaling will require …development and execution of an accountable CBT industry

Key alliances to transform CBTx services

Key alliances to transform CBTx services

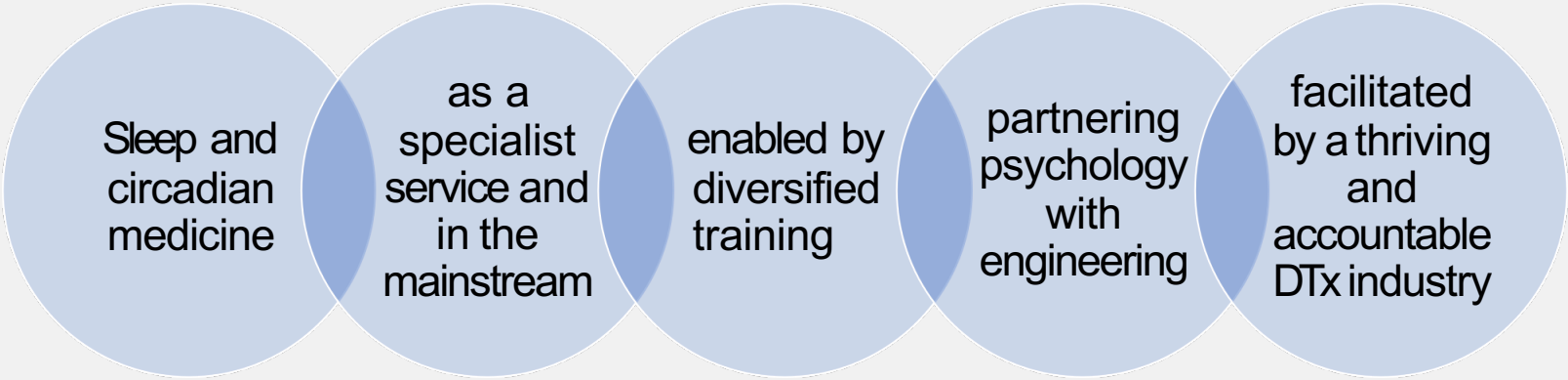


Figure 14.6 Alliances that will enable CBTx for insomnia to prosper and scale
from Espie (2025) *The Clinicians Guide to CBTx for Insomnia*. CUP, UK

There has always been sleep hygiene
(…or head hygiene?!)

"Soap your head with the ordinary yellow soap; rub it into the roots of the hair until your head is just lather all over, tie it up in a napkin, go to bed, and wash it out in the morning. Do this for a fortnight"

"Take no tea after 6pm. I did this and have never been troubled with sleeplessness since. I have lost sleep on an occasion since, but one or two nights of the soap cure put it right. I have conversed with medical men, but I have no explanation from any of them"

Cited in The Glasgow Herald reported in British Medical Journal, 29 September 1894 (p.279)

Comment by Jim Horne

"The editorial wisely ends with the comment that …"

'We can not help thinking that some of our sleepless readers would prefer the disease to the cure. But if any should like to try it, may we advise that they should first, at any rate, follow that part of the advice which relates to the tea, and leave the soap part as a last resource'

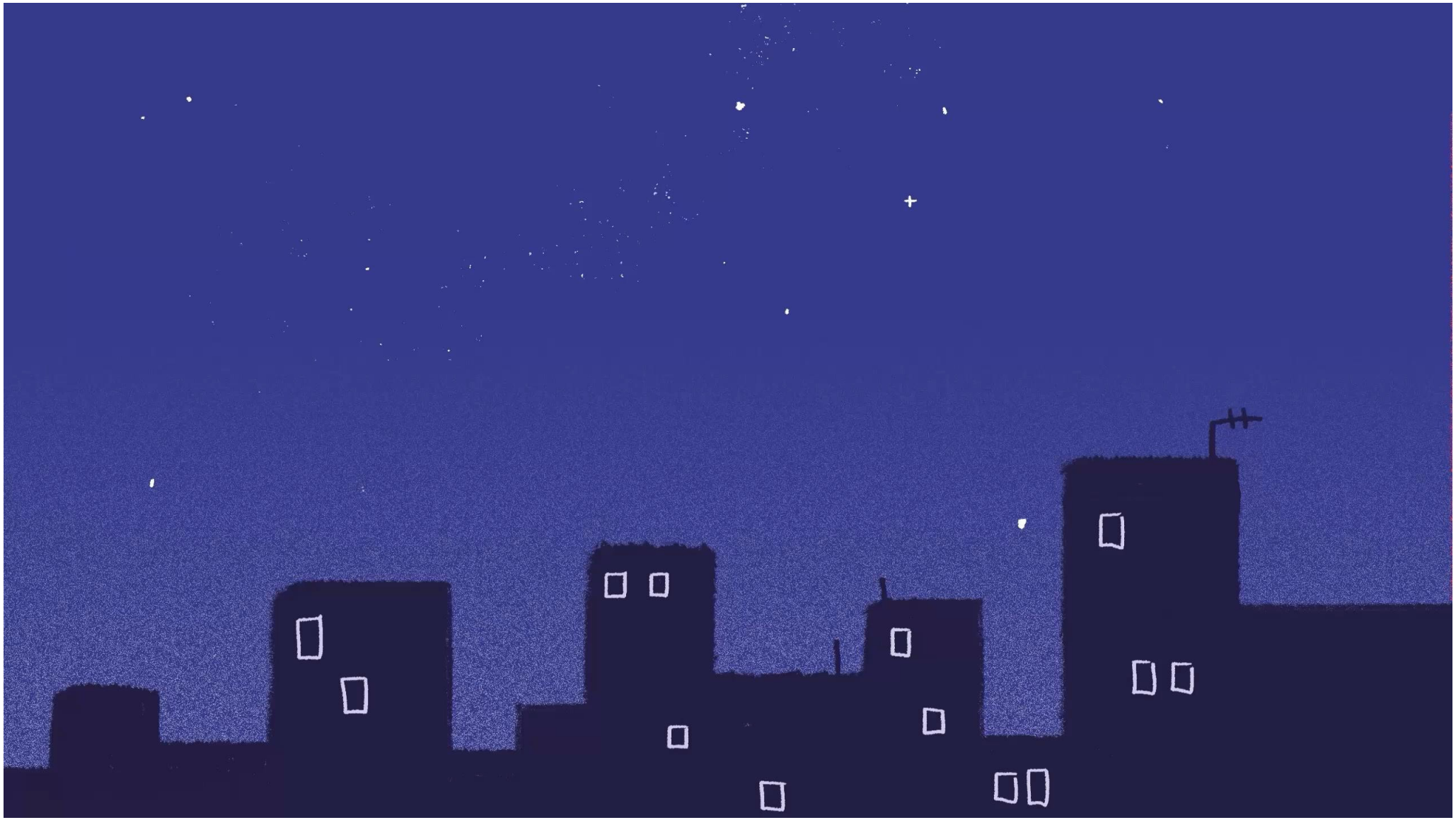
Horne JA Insomnia – Victorian style. *The Psychologist,* 22 October 2008

The 5 Principles of Good Sleep Health

Professor Colin Espie, University of Oxford

Sacha Baron Cohen

Scriberia



The 5 Principles of Good Sleep Health

Impact

https://thesleepcharity.org.uk/the-5-principles-of-good-sleep-health/

https://www.youtube.com/watch?v=xAcvD3n-Ghw

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Sleepless in the 21st Century: Rethinking Chronic Insomnia Care

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