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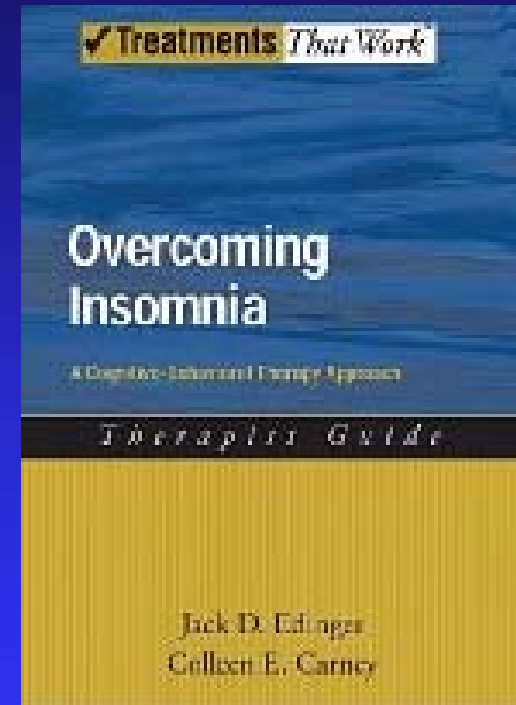
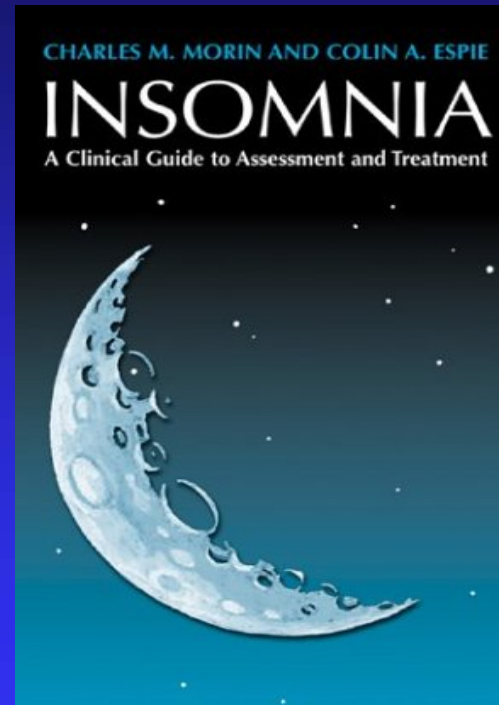
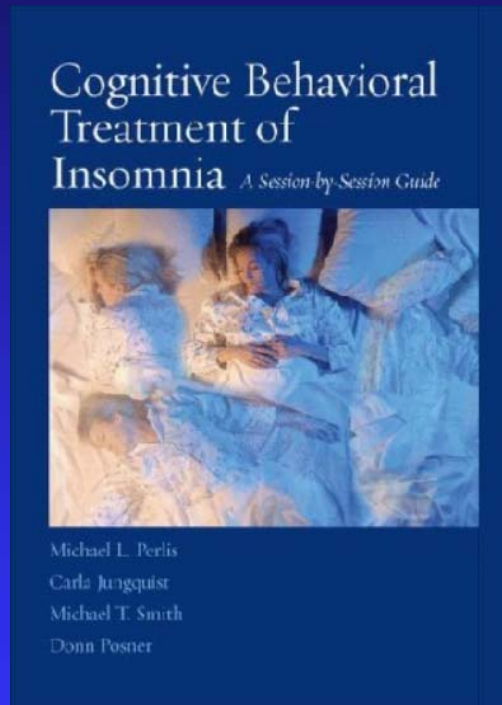
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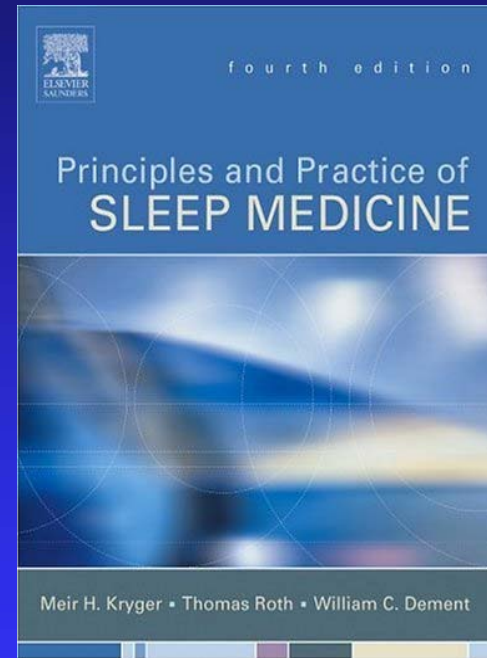
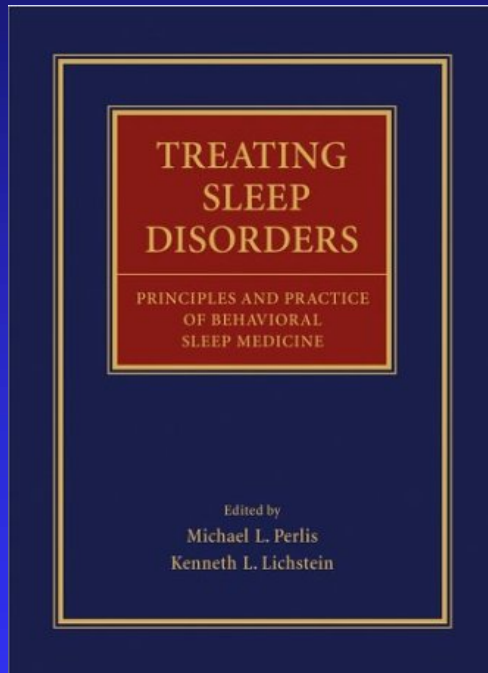
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INSOMNIA

Recommendations for a Standard Research Assessment of Insomnia

Daniel J. Buysse, MD¹; Sonia Ancoli-Israel, PhD²; Jack D. Edinger, PhD³; Kenneth L. Lichstein, PhD⁴; Charles M. Morin, PhD⁵

¹Department of Psychiatry, University of Pittsburgh School of Medicine, Pittsburgh, PA; ²Department of Psychiatry, University of California San Diego and Veterans Affairs San Diego Healthcare System, San Diego, CA; ³Department of Psychology, Veterans Administration Hospital and Duke University, Durham, NC; ⁴Department of Psychology, University of Alabama, Tuscaloosa, AL; ⁵Department of Psychology, Université Laval, Québec, QC

Study Objectives: To present expert consensus recommendations for a standard set of research assessments in insomnia, reporting standards for these assessments, and recommendations for future research.

Participants: N/A.

Interventions: N/A.

Methods and Results: An expert panel of 25 researchers reviewed the available literature on insomnia research assessments. Preliminary recommendations were reviewed and discussed at a meeting on March 10-11, 2005. These recommendations were further refined during writing of the current paper. The resulting key recommendations for standard research assessment of insomnia disorders include definitions/diagnosis of insomnia and comorbid conditions; measures of sleep and insomnia, including qualitative insomnia measures, diary, polysomnography, and

actigraphy; and measures of the waking correlates and consequences of insomnia disorders, such as fatigue, sleepiness, mood, performance, and quality of life.

Conclusions: Adoption of a standard research assessment of insomnia disorders will facilitate comparisons among different studies and advance the state of knowledge. These recommendations are not intended to be static but must be periodically revised to accommodate further developments and evidence in the field.

Keywords: Insomnia, diagnosis, polysomnography, sleep diary, actigraphy, questionnaires

Citation: Buysse DJ, Ancoli-Israel S, Edinger JD et al. Recommendations for a standard research assessment of insomnia. *SLEEP* 2006;29(9):1155-1173.

INTRODUCTION

INSOMNIA IS THE MOST COMMON SLEEP COMPLAINT IN THE GENERAL POPULATION. RECENT RESEARCH HAS ADDRESSED A WIDE RANGE OF ISSUES related to this condition, including epidemiology, consequences, pathophysiology, and treatment. However, understanding the results of the research and translating these results into clinical practice have been hindered by the absence of standardized definitions, assessments, and reporting standards. For instance, a recent review of epidemiologic studies showed that the reported prevalence of insomnia in the general population can range from 2% to 48%, depending on the definition of insomnia.¹ Studies examining the clinical and physi-

ologic characteristics of insomnia have used definitions ranging from the very broad (e.g., self-defined "good vs poor sleepers"), to the very narrow (e.g., individuals with "sleep-state misperception," which can only be defined with polysomnography^{2,3}).

Reviews of treatment studies demonstrate similar problems. For instance, Nowell and colleagues identified 198 studies comparing drug therapy with placebo in insomnia, but only 22 could be included in a final meta-analysis.⁴ The authors needed to make several inferences regarding the diagnosis of primary insomnia because most studies failed to specify insomnia duration, clinically significant distress, or the means by which psychiatric or medical causes of insomnia were excluded. Holbrook and colleagues⁵ identified 89 double-blind trials for their meta-analysis but excluded half of these, noting, "the methodologic quality of the studies was not uniform... The diversity in outcomes used and the methods of summarizing... prevented the pooling of many trials." Likewise, Smith and colleagues initially identified 194 treatment studies of primary insomnia but included only 21 in their final meta-analysis. Many primary sources were excluded because means, standard deviations (SD), and test statistics were not reported. A recent review of behavioral and psychological treatment studies for insomnia⁶ also identified a wide range of diagnostic methods, specific diagnoses, and specific outcomes, with 16 of 33 eligible studies excluded from the review for reasons including the failure to document an insomnia diagnosis. In summary, consistent diagnostic, baseline, and outcome measures have not been used in published insomnia studies. Inconsistency of reporting methods and outcome data has further limited the ability to compare findings across studies.

This paper reports the findings of an expert consensus process to develop recommendations for standard assessments and reporting standards in insomnia research studies. This process included a conference held on March 10-11, 2005, in Pittsburgh, Penn., with 25 experts in insomnia research in attendance. The specific aims of this process and the accompanying conference, reflected

Disclosure Statement

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Accepted for publication April 1, 2006

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SLEEP, Vol. 29, No. 9, 2006

1155

Standard Research Assessment of Insomnia—Buysse et al

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EDITORIAL

How can we make CBT-I and other BSM services widely available?

Michael L. Perlis, Ph.D.¹; Michael T. Smith, Ph.D.²

¹University of Rochester, Sleep & Neurophysiology Research Laboratory, Rochester, NY; ²Johns Hopkins University, Behavioral Medicine Research Laboratory and Clinic, Baltimore, MD

Following several presentations and discussion panels regarding cognitive-behavior therapy for insomnia (CBT-I) during the 2007 annual meeting of the Associated Professional Sleep Societies in Minneapolis, it seems to many of us that the budding field of behavioral sleep medicine (BSM) is at a critical juncture.

Six events have occurred that bring us to the present crossroads. First, as result of the vision and generosity of the American Academy of Sleep Medicine (AASM), there is (as of 2004), a credentialing board for BSM that is underwritten and administered by the academy.¹ Second, the research literature regarding CBT-I has matured to a point where the 2005 NIH State of the Science panel acknowledged that this form of BSM is to be considered a first-line therapy for chronic insomnia.² Third, sleep medicine (with the change in the board-certification process from the American Board of Sleep Medicine to the American Board of Medical Specialties) has recently been redefined as a medical subspecialty and, as a result, BSM is not formally a part of sleep medicine. Fourth, with the revamping of AASM sections to be aligned with disease states (vs areas of specialty), BSM is no longer identified as a section within the Academy. Fifth, the recent AASM Comprehensive Academic Sleep Programs of Distinction initiative does not reference BSM nor require that centers within this program have BSM services.³ Sixth, and finally, it now appears that there is a substantial push to alter who should provide CBT-I (non-BSM "physician extenders" vs BSM specialists) and how treatment should be conducted (fewer and shorter sessions). Although each of the last 4 events is relevant for the continued growth of BSM as an allied

field and an interdisciplinary component of sleep medicine, the last and most recent event urgently needs to be addressed.

The push to make CBT-I more available by diversifying who can provide it and how it is provided is largely based on the following beliefs: (1) There are not enough credentialed BSM specialists to provide treatment for the millions of patients with insomnia, (2) reimbursement for BSM services is complicated and garners too low a level of reimbursement, (3) CBT-I can be conducted by anyone with a minimal amount of training, and (4) BSM specialists have little to offer sleep disorders centers beyond the treatment of insomnia (which can hardly keep one busy enough to justify a part-time equivalent or full-time equivalent salary).

Before addressing these issues specifically (and providing a series of recommendations), it is worth addressing the global perspective. Twenty to 30 years ago, sleep medicine itself was faced with many of the same daunting issues (e.g., too few specialists, problems with reimbursement, and a lack of evidence that sleep medicine alone could sustain a dedicated clinical enterprise). Yet, at that time, there was no call to populate the field with non-MDs to conduct polysomnography studies and evaluations (although this was allowed via the American Board of Sleep Medicine) nor was there a call to make polysomnography assessment studies half or one-third night studies to reduce the burden of the assessment process. Instead it was recognized that these issues required time and work to resolve and that only in this way could a clinical specialty be established. What has changed? Why is there such a sense of urgency and a rush toward solutions that can only diminish the effort to establish BSM as a subspecialty of sleep medicine (and behavioral medicine). Whatever the answer, it cannot be one that accepts that sleep medicine is, and should continue to be, a multidisciplinary field.

THERE ARE NOT ENOUGH CREDENTIALLED BSM SPECIALISTS TO PROVIDE TREATMENT FOR THE MILLIONS OF PATIENTS WITH INSOMNIA.

First, while it is estimated that 10% to 15% of the population suffers from chronic insomnia, it is unclear what proportion of this population is actively seeking help. Thus, the assumption that the demand far exceeds the supply remains to be formally documented. What is clear is that most accredited sleep disorders centers do not have full-time or part-time clinicians who special-

Disclosure Statement

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Accepted for publication October, 2007

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Journal of Clinical Sleep Medicine, Vol. 4, No. 1, 2008

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The screenshot shows a webcast player interface. On the left is a video window showing a man in a suit, identified as Kenneth Lichstein, PhD. Below the video is a progress bar at 0:26 / 33:20 and a 'CONTINUE' button. The main content area is titled 'Update on Behavioral Therapy for Insomnia' and 'Relaxation'. It lists topics: Quiet Self-inquiry, Relaxation Response (with sub-points: Quiet environment, Object to dwell upon (monotonous stimulation), Passive attitude, Comfortable position), and Methods (with sub-points: Progressive muscle relaxation, Autogenic training, Biofeedback, Meditation). At the bottom, there is a copyright notice and a Purdue University logo.

SMEI
Sleep Medicine Education Institute

Update on Behavioral Therapy for Insomnia

Relaxation

- Quiet Self-inquiry
- Relaxation Response
 - Quiet environment
 - Object to dwell upon (monotonous stimulation)
 - Passive attitude
 - Comfortable position
- Methods
 - Progressive muscle relaxation
 - Autogenic training
 - Biofeedback
 - Meditation

0:26 / 33:20

Kenneth Lichstein, PhD

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The Importance of Recognizing Insomnia in the Aged and in Other Special Populations

Donald Bliwise, PhD
Phyllis Zee, PhD

The Changing Landscape of Effective Pharmacotherapy for Insomnia

Wallace Mendelson, MD
Gary Zammit, PhD

Update on Behavioral Therapy for Insomnia

Arthur Spielman, PhD
Kenneth Lichstein, PhD

Diagnosis and Assessment of Insomnia:

Co-morbid Conditions
Michael Perlis, PhD
Ruth Benca, MD, PhD

Critical Review of the Epidemiology and Pathophysiology of Insomnia

Thomas Roth, PhD
Michael Bonnet, MD

Fundamentals of Normal Sleep

Mary Carskadon, PhD
Gary Richardson, MD

Insights in Insomnia for Pharmacists

Andrew Krystal, MD
Julie Dopheide, PharmD

Key Concepts in the Diagnosis and Assessment of Insomnia

Daniel Buysse, MD
James Walsh, PhD

<http://sleepmeded.org>

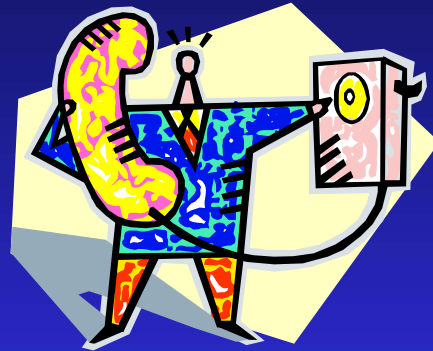
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Sara Matteson

Brown University
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Michael Smith
Phil Gehrman

Johns Hopkins University
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For more than 30 years the American Academy of Sleep Medicine (AASM) has helped both medical professionals and sleep centers and labs excel in the rapidly growing field of sleep medicine.


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Certified Behavioral Sleep Medicine Specialists

The American Academy of Sleep Medicine (AASM) administers an annual certification examination in behavioral sleep medicine. Individuals who pass the exam earn the designation of C.B.S.M. (Certified in Behavioral Sleep Medicine).

To pass the exam an individual must display a comprehensive understanding of the diagnosis and treatment of the full range of sleep disorders. Certification also confirms an individual's expertise in the application of behavioral and cognitive methods of prevention and treatment.

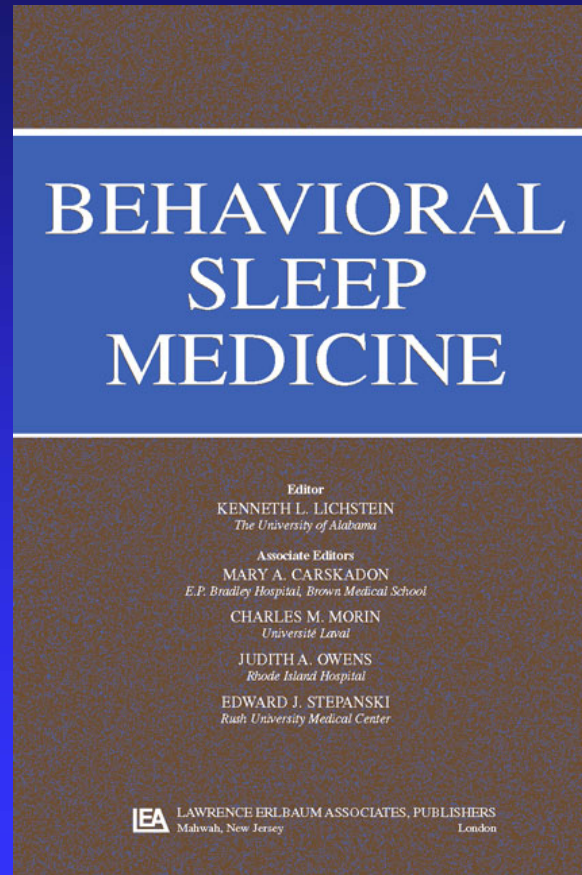
These individuals have earned certification from the AASM in behavioral sleep medicine:

NAME	CITY	STATE	COUNTRY	DATE
Sunoj Abraham, M.D., FCCP, D, ABSM, FACP	Hernando	FL		June 18, 2006
Mark S. Aloia, Ph.D.	Providence	RI		June 18, 2006
Sonia Ancoli-Israel, Ph.D., D, ABSM	San Diego	CA		June 4, 2003
Michael W. Anderson, Ph.D., D,ABSM	Prairie Village	KS		June 4, 2003
Carolyn Andrews, Ph.D.	Skokie	IL		June 8, 2008
J. Todd Arnedt, Ph.D.	Providence	RI		June 4, 2003
Amy Aronsky, DO, FAASM	Kelso	WA		June 8, 2008
Kristin Avis, Ph.D.	Birmingham	AL		June 18, 2006
Erin K. Baehr, Ph.D.	Woodbine	M.D.		June 19, 2005
Anne D. Bartolucci, Ph.D.	Decatur	GA		June 10, 2007

www.aasmnet.org/BSM.aspx

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CONSIDER SUBSCRIBING TO THE BSM JOURNAL



“BUT WAIT – THERE’S MORE !”



FAQS AND REFERENCES

1. How Efficacious is CBT-I (i.e., what's the clinical trial data)? - Very.

Morin C.M., et al. (1994) Non-pharmacological interventions for insomnia: a meta-analysis of treatment efficacy. *Am. J. Psychiatry* 151, 1172-1180.

Murtagh D et al. (1995) Identifying Effective Psychological Treatments for Insomnia - A Meta-analysis. *JGCP*, 63, 79-89.

2. How Effective is CBT-I (i.e., is there case series data in "real" patients)? - Very.

Lichstein K.L. et al. (2000) Psychological treatment of secondary insomnia. *Psychology of Aging* 2, 232-240.

Perlis M., et al. (2000) Behavioral treatment of insomnia: A clinical case series study. *J. Behav. Med.* 23, 149-161.

3. How does CBT-I compare to Pharmacotherapy? – The therapies are comparable.

Morin C.M., et al. (1999) Behavioral and pharmacological therapies for late-life insomnia: a randomized controlled trial *JAMA* 281, 991-999.

Smith M.T., et al. (2002) Behavioral treatment vs pharmacotherapy for insomnia - a comparative meta-analysis. *Am. J. Psychiatry* 159, 5-11.

Jacobs G.D. et al. (2004) Cognitive behavior therapy and pharmacotherapy for insomnia - A randomized controlled trial and direct comparison. *Arch. Intern. Med.* 164, 1888-1896.

Sivertsen B., et al. (2006) Cognitive behavioral therapy vs zopiclone for treatment of chronic primary insomnia in older adults - A randomized controlled trial. *Journal of the American Medical Association* 295, 2851-2858.

4. Does the NIH have a position on what's the best for the treatment of insomnia? – Yup.

<http://consensus.nih.gov/2005/2005InsomniaSOS026.html.htm>

This is available on web cast. <http://videocast.nih.gov/PassEvents.asp?c=1&s=81>

5. Does the AASM have a position on what's the best for the treatment of insomnia? – Yup.

Chesson A.L., et al. (1999) Practice parameters for the non-pharmacologic treatment of chronic insomnia. An American Academy of Sleep Medicine report. Standards of Practice Committee of the American Academy of Sleep Medicine Sleep. 22, 1128-1133.

Chesson A., et al. (2000) Practice parameters for the evaluation of chronic insomnia. An American Academy of Sleep Medicine report. Standards of Practice Committee of the American Academy of Sleep Medicine Sleep. 23, 237-241.

Morgenthaler T. et al. (2006) Practice parameters for the psychological and behavioral treatment of insomnia: An update. An American Academy of Sleep Medicine Report. Sleep. 29, 1415-1419.

Morin C.M., et al. (2006) Psychological and behavioral treatment of insomnia: Update of the recent evidence (1998-2004). Sleep. 29, 1398-1414.

6. How does one know who is an appropriate candidate for CBT-I? See for example.

Smith M.T. et al. (2006) Who is a candidate for cognitive-behavioral therapy for insomnia? *Health Psychol.* 25, 15-19.

7. Are there books me and mine can read on how to do CBT-I - Yup.

Insomnia: A Clinician's Guide to Assessment and Treatment Eds. Morin & Espie. Plenum Pub Corp. 2000
Cognitive Therapy for Insomnia: A session by session guide. Perlis, Jungquist, Smith & Perlis, Springer-Verlag. 2005.

8. Are there training courses available on CBT-I? - Yup.

General: <http://www.aasmnet.org/SleepEdSeries.aspx>

Specific: www.urmc.rochester.edu/cpa/CBT-I/

9. Is it possible to arrange for peer supervision for one's first CBT-I cases. Yup.

It is likely that any of the individuals with the CBSM would be willing.

See, <http://www.aasmnet.org/BSMSpecialists.aspx>

10. Is it possible to be credentialed in CBT-I Yup.

There is a certification exam. See, <http://www.aasmnet.org/BSMExam.aspx>

11. How does reimbursement work for CBT-I. Ask:

Donn Posner at Brown → DPosner@Lifespan.org

Sara Matteson at UR → Sara_Matteson@URMC.Rochester.edu



The University of Pennsylvania



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mperlis@upenn.edu