NATIONAL KIDNEY FOUNDATION®

THE JOURNAL OF Nephrology Social Work

Case Presentations from the SLEEP-HD Trial: Extension of CBT-I to People with Kidney Failure Receiving Hemodialysis

Daniel Cukor, PhD, Associate Professor of Medicine, NYU Grossman School of Medicine, New York, NY; Susan M. McCurry PhD*, Research Professor Emeritus University of Washington, Seattle, WA; Carlyn Clark, MSW, University of Washington Medicine, Nephrology, Seattle, WA; Nisha Ver Halen, PhD, Integrative Medicine, Weill Cornell Medicine, New York, NY; Lori Linke, University of Washington Medicine, Nephrology, Seattle, WA; Mark L. Unruh, MD, MS, Chair and Professor of Medicine, University of New Mexico, Albuquerque, NM; Rajnish Mehrotra, MD, MS, Professor of Medicine, Belding H. Scribner Endowed Chair in Medicine, University of Washington School of Medicine, Seattle, WA*

ABSTRACT

People with kidney failure treated with hemodialysis are at higher risk for insomnia due an array of biological, treatment, and behavioral factors. The Short- and Long-term Effectiveness of Existing insomnia therapies for Patients undergoing HemoDialysis (SLEEP-HD) trial was a parallel-group, multicenter, placebo-controlled, randomized clinical trial that found no significant difference in the effectiveness of Cognitive Behavior Therapy for Insomnia (CBT-I) or trazodone, versus medication placebo in patients undergoing in-center hemodialysis. We now provide case reports from two of the participants treated in the trial to highlight both the challenges and successes of CBT-I in this population. Beyond the typical challenges with CBT-I implementation, we observed some unique difficulties faced by people with kidney failure trying to follow standard CBT-I recommendations, and we also found evidence that, for some, the intervention was quite impactful.

KEYWORDS: case report; CBT-I; HD; hemodialysis; kidney disease; Short- and Long-term Effectiveness of Existing insomnia therapies for Patients undergoing HemoDialysis (SLEEP-HD)

INTRODUCTION

There are more than 800,000 people in the United States living with kidney failure and, of those, about 70% are receiving ongoing in-center hemodialysis (HD) (USDRS., 2024). Although this therapy is lifesaving, it is associated with a high treatment and symptom burden, with treatment most commonly occurring 3 times weekly for 4-hour sessions. Among the many patient-reported symptoms, sleep disturbance is the most frequent and bothersome (Flythe et al., 2018; Roumelioti, 2020). Many patients with kidney failure fit a clinical diagnosis of insomnia, based on criteria that sleep difficulties occur despite adequate opportunities for normal sleep and daytime impairment resulting directly from poor sleep quality or duration. These insomnia symptoms are often chronic (occurring at least 3 times per week for more than 3 months) (Ohayon, 2002).

People with kidney failure receiving HD are at higher risk for insomnia, due to the known changes to the circadian rhythm, sleep architecture, and endogenous melatonin release which are endemic to kidney failure (Perl et al., 2006). Behavioral factors may also contribute to the higher rate of insomnia; people on HD report shorter total sleep time, more sleep fragmentation, and increased frequency of daytime napping, all of which are associated with dialysis days, compared to patients with kidney failure who are treated with other modalities (Maung et al., 2017). In addition to the direct distress, insomnia can be a contributor to other poor health outcomes in HD patients, including daytime sleepiness, fatigue, and worsened quality of life (Maung et al., 2017).

The SLEEP-HD (Short and Long-term Effectiveness of Existing insomnia therapies for Patients undergoing HemoDialysis) trial was a parallel-group, multicenter, placebo-controlled, randomized clinical trial that compared the effectiveness and safety of two commonly utilized methods to

Corresponding author: *Daniel Cukor, PhD, NYU Grossman School of Medicine, 550 First Avenue, New York, NY 10016 NYU; daniel.cukor@nyulangone.org*

treat insomnia in people on HD (cognitive behavior therapy for insomnia (CBT-I) delivered by telehealth, and trazodone) versus medication placebo in patients undergoing in-center hemodialysis (Mehrotra et al., 2024; Unruh et al., 2020). The study found no significant difference in the effectiveness of 6 weeks of CBT-I or trazodone, compared with placebo. It is the goal of this paper to provide case reports from two of the participants treated in the trial to highlight both the challenges and successes of CBT-I in this population, and to provide front-line clinicians, including nephrologists and social workers, insight into potential interventions.

METHOD

SLEEP-HD participants assigned to telehealth CBT-I were scheduled for 6 weekly 30-minute sessions. Study interventionists ("coaches") included a PhD-level psychologist and a Masters-level social worker. Coaches completed a one-day CBT-I training in study procedures led by experts in CBT-I (SMM) and psychosocial interventions in people with kidney diseases (DC), including use of a standardized treatment manual. Therapy sessions included standard components for treating insomnia: stimulus control, sleep scheduling and bed restriction, education about sleep stages and cycles, mindfulness, constructive worry, and changing beliefs and attitudes about sleep (McCurry et al., 2016; Vitiello et al., 2013). Recommendations for CBT-I were a priori adapted to address specific behaviors within this population, such as napping during hemodialysis (see **Table 1**). All participants provided written consent and as per the University of Washington IRB-approved protocol, all sessions were video-recorded, and a random sampling was reviewed to ensure fidelity to the intervention.

Case 1

This participant was a 49-year-old male who enrolled in the CBT-I intervention. At the start of treatment, he reported he had experienced poor sleep for about two years, had started dialysis about 10 months ago, and his sleep had worsened over the past 6 months. He indicated it was very difficult for

Table 1. CBTI Session Content, Challenges, and SLEEP-HD Modifications

Week	Specific Session Content	Challenges	Modifications
1	Sleep changes with kidney failure; rationale for CBT-I approach; stimulus control instructions	Medical sequelae associated with kidney failure affecting sleep (e.g., systemic persistent inflammation, anemia, pain, disrupted hormone levels, inadequate dialysis clearance, etc.) Post-hemodialysis (HD) treatment fatigue makes it difficult to not nap during the day or during HD sessions. Some living environments are not conducive to getting up to go to a different room when awake at night.	Include education about changes in sleep due to kidney failure and hemodialysis. Allow short daily naps in late a.m./early p.m. in bed, if needed. Brainstorm behavioral activation strategies for staying awake during midday dialysis sessions. Sit up in chair in bedroom or upright in bed if going to another room is impossible/unsafe.
2	Sleep scheduling/ bed restriction	Early- and late-shift dialysis schedules that overlap with recommended bed and rising times	Set in-bed recommended schedule, based on non-HD days; allow sleep at early/late HD shifts to compensate for sleep time cut out of recommended bed window
3	Sleep stages and cycles	Confounding impacts of kidney failure on sleep and increased risk of comorbid sleep disorders (e.g., sleep apnea, restless legs syndrome)	Education about changes in sleep patterns due to kidney failure, pain, and primary sleep disorders
4	Constructive worry; mindfulness exercise	Illness perceptions in HD patients can increase worry and anxiety, which negatively affect sleep.	Mindfulness can be used during dialysis sessions to help stay relaxed, and at other times to reduce health-related anxiety.
5	Changing beliefs and attitudes about sleep; sleep hygiene	Cognitive distortions about sleep and HD that lead to reduced independence and quality of life. Kidney failure dietary preferences/medications could affect sleep. Residential care or homeless clients may not have control over environmental factors negatively impacting sleep.	Facilitate realistic expectations about sleep, reduce catastrophic thinking, and enhance motivation to follow sleep plan recommendations. Avoid caffeine, stimulating meds at night. Brainstorm alternative ways to ensure sleeping environment supports sleep.
6	Maintenance/ relapse prevention plan	Kidney disease is a progressive disease with replacement therapy required indefinitely.	Education about the importance of maintaining good sleep routines and practices, and how to modify sleep plan as needed over time.

him to fall asleep, sometimes taking hours, and he often had prolonged awakenings through the night, such that he would "give up" and start his day, hours before his schedule required it. On his dialysis treatment days, he would typically return home at about 9:30-10 p.m. He expressed feeling extremely frustrated with his sleep pattern and seemed highly motivated to make improvements.

This participant's baseline sleep diary at the first session showed a sleep efficiency of only 34%. He spent on average 15 hours in bed, with less than 6 of those hours asleep. He described routine habits of playing video games, watching TV, and reading in bed. He said the sound of the TV helped calm his "busy brain." He reported that he tried to not nap during the day, but often felt so tired it was unavoidable, and he regularly slept during dialysis. He said that he had been prescribed a continuous positive airway pressure (CPAP) for use at night for his sleep apnea, but that it had been broken for three years. His initial treatment goals included avoiding non-sleep activities in the bedroom, limiting daytime sleep, and setting a consistent rise time.

Unfortunately, this participant did not show for his next scheduled session, and did not respond to calls and texts requesting a reschedule. Eventually he agreed to meet, though almost a month had passed since the first session. He reported that he had tried to work toward some of the initial agreed-upon goals, but had not been consistent. He did not complete any additional sleep diaries. He indicated that pain was impacting his sleep, and he was routinely using tramadol and occasionally OxyContin® at night. He was also occasionally taking Ambien® for sleep.

At the second session, the CBT-I content normally delivered over three weeks was combined into a single session to complete the intervention within the research protocol treatment timeline. The therapist attempted to cover the CBT-I information without overwhelming the participant with didactic material and behavior change requests. Following a client-centered approach, the participant was encouraged to choose which recommendations they felt were most relevant and realistic. The lack of diaries made it difficult to make bed restriction recommendations, but the participant did agree to keep to a set "window" of maximal time in bed, which initially was 1-8:00 a.m., but was reduced to 2-8 a.m. the following session. He said it was hard to stay awake during dialysis but would continue to try. The therapist acknowledged any small successes to encourage confidence and build rapport. He practiced a mindfulness exercise during the session and was enthusiastic to try it at home, saying he was hopeful this strategy might mitigate the anxiety that kept him awake most nights. He was hopeful that the constructive worry tool might also be helpful in this regard.

CBT-I content from two sessions was combined in the third and final session. The participant stated he had found mindfulness and constructive worry helpful but was still experiencing extreme difficulty falling asleep. Adhering to a consistent rise time was incredibly challenging. It was revealed that he consumed moderate to heavy amounts of coffee daily; the therapist reviewed and emphasized the negative impacts of caffeine on healthy sleep patterns, within a larger discussion of sleep hygiene. He noted that the discussion of cognitive distortions related to perfectionism and sleep catastrophizing resonated for him. He set monitoring and reframing of his self-talk as goals to focus on after the conclusion of the intervention. He did complete one sleep diary prior to the final session, which showed a sleep efficiency score of 36%, only a 2% improvement from his previous baseline diary. Despite his poor overall sleep efficiency, essential lack of improvement, and multiple missed sessions, he appeared engaged and motivated during those sessions he did attend and seemed to appreciate the content provided.

Case 2

This CBT-I participant was a 76-year-old male who had been on in-center hemodialysis for about 2 years. In the first session, he indicated that he had difficulty falling asleep, had frequent and prolonged awakenings in the middle of the night, and would occasionally wake too early and be unable to fall back asleep. This was especially true on nights after he dialyzed, typically returning home about 7:00 p.m. He was highly motivated toward change. He sought improvement in his mental acuity during the day. He also hoped to increase his physical endurance and opportunities for social interaction. The patient's goals for treatment were discussed and he expressed expectations that were both reasonable and achievable.

The participant's first sleep diary revealed a sleep efficiency of 67%. A review of his sleep behaviors indicated that he spent approximately 13 hours per day in bed, during which he would engage in a variety of non-sleep activities. He also reported that he often took naps lasting 1.5 to 2 hours in the middle of the day. In session one, several behavior changes were recommended, including reducing nap times, moving non-sleep activities to another space in his room, and setting a regular morning rise time. The participant was initially resistant to committing to a consistent rise time because he feared that, if his sleep was poor, getting up rather than sleeping in would leave him feeling "like a zombie." The patient's motivation for doing CBT-I was reviewed and the rationale for the recommended rise time was further explained.

In the second session, his sleep diary information was reviewed and he was presented with a suggested bed restriction schedule to reduce nightly time in bed. Initially, the participant was hesitant, again expressing worry about being "tired and zombie-like." The therapist utilized positive rapport and

collaboration to develop an in-bed window of 11:45 p.m. to 9:45 a.m., which was amenable to the patient. He ultimately agreed, based on the rationale that his sleep time would not be changing as much as his time spent in bed.

Throughout treatment, the participant completed his sleep diaries in a thorough and consistent manner. These data were reviewed each week and the participant indicated that he appreciated being able to observe changes in his behavior through his diary entries. Within 3 weeks, the participant had reduced his nap duration and his mid-night awakenings had decreased from 1.5 hours to 20 minutes per night. This produced a noticeable change in daytime energy. The participant was bolstered by his progress. In session 4, a mindful meditation exercise was practiced and the participant immediately expressed a liking for the tool. He reported feeling "relaxed and sleepy" while listening to the guided visualization exercise. The participant indicated that he planned to use meditation on a regular basis, and he even thought it could be helpful for staying relaxed during dialysis.

In session 5, the participant was invited to examine his cognitions about getting a "good night's sleep" that caused him considerable anxiety. As he had already alluded to, the participant was particularly worried that a short night of sleep would be followed by a lethargic and unproductive day. These beliefs were discussed and examples from the previous four weeks were offered as evidence to encourage him to consider alternative ways of thinking about these concerns.

In the final, sixth session the participant's progress was reviewed. His subjective experience of improved sleep was reflected in his diary. His sleep efficiency had improved from 67% to 78%. He felt good about moving his TV watching and other activities from his bed and he appreciated no longer needing naps every day. He had met all the goals he had set for the treatment and said that the changes had produced improvements in several areas of his life. Most notably, he felt "sharper" and "more energetic." Overall, the participant indicated that he found the treatment to be very helpful, and he felt optimistic about being able to use the tools he learned if he faced additional sleep difficulties in the future.

DISCUSSION

This report provides clinical insight into the use of CBT-I to improve sleep in people with kidney failure undergoing hemodialysis. While CBT-I and trazodone group means in the randomized trial did not differ from the placebo control condition, examination of the two presented cases highlights some of the challenges experienced in utilizing CBT-I in this population, but also provides indication that, for some, the intervention was quite impactful.

Some of the challenges the SLEEP-HD study faced were like those with any CBT-I client, particularly issues around motivation, commitment, and effort. In the first case example, the participant did not keep his daily sleep log, nor did he follow most treatment homework recommendations. His attendance was erratic, forcing the CBT-I content to be delivered in a few compressed sessions, which was not ideal for implementing behavioral change. While such problems are common to all patient care, it may be that having CBT-I treatment offered in the context of a research study, an as opposed to treatment that participants had sought on their own, allows the less motivated access to treatment. Another general issue may be the telehealth intervention delivery. There were frequent technical challenges due to participants' poor computer skills, inadequate internet access, and difficulty finding a quiet time and private locations for sessions.

Beyond the typical challenges with CBT-I implementation, we observed some unique difficulties faced by people with kidney failure trying to follow standard CBT-I recommendations. The long dialysis treatment sessions promoted daytime napping, and the very common experience of post-dialysis fatigue, which promoted napping after dialysis, both contributed to excess time in bed for many participants. Conversely, some people reported feeling "wired" after dialysis and required a substantial "cool-down" period before they felt ready for sleep. As evidenced by both of the cases presented, individual sleep plans for most people included recommendations to spend less time in bed at night, and to move behaviors such as reading, watching TV, or using one's phone to other locations whenever possible. Primary sleep disorders, such as sleep apnea, are common in persons with kidney failure, but as Case 1 illustrated, not all participants were being adequately treated.

Some treatment challenges faced in this study were related to the severity of medical illness experienced by many participants. Unexpected adverse health events associated with kidney failure, ranging from minor problems to hospitalization, occurred. We observed negative impacts on motivation, commitment, and follow-through with treatment which were recommended in response to each medical setback. Common medications (e.g., for pain) may affect patients' ability to sleep, get up in the morning, and/or to reduce daytime napping. As both cases demonstrated, the timing of dialysis treatments cannot be easily modified to accommodate sleep cycles, as patients need to stay up late 3 nights a week for treatments. This can greatly upset their diurnal (24-hour) sleep/wake patterns. Anxiety is a prominent component of the insomnia experience for many people, but for people being treated with hemodialysis, severe comorbid health problems, possible increased debilitation, and possible mortality may be felt more acutely and cause more intractable sleep anxiety problems.

Frequent patient medical complications superimposed on an already demanding treatment schedule contributed to prob-

lems with consistent weekly sessions for some participants. In actual clinical practice, CBT-I sessions can be scheduled over a longer period of time, but that was not an option within the bounds of the randomized trial. Lastly, while we screened to rule out participants with gross cognitive impairment from the study; mild cognitive impairment is common in people being treated with dialysis and that might have made remembering or following through with treatment recommendations more difficult.

There were limitations to the interpretation of these findings. The cases presented in this paper were selected purposefully, and were not intended to be representative of the overall effectiveness of behavioral interventions for sleep problems in people with kidney failure. From these reports, there are insufficient data to know whether the effect size or amount of change reported for insomnia patients in the general population being treated with CBT-I is possible for patients with kidney failure being treated with hemodialysis, given their complex medical comorbidities.

CONCLUSION

It may be that sleep interventionists, unit social workers, and patients need to have more modest expectations, but there certainly seems to be some indication that CBT-I can have a positive impact on sleep quality, at least for some people treating with hemodialysis.

ABBREVIATION LIST

CBT-I	Cognitive Behavior Therapy for Insomnia
CPAP	Continuous Positive Airway Pressure
HD	Hemodialysis
IRB	Institutional Review Board
SLEEP-HD	Short and Long-term Effectiveness of Existing insomnia therapies for Patients

REFERENCES

Flythe, J. E., Hilliard, T., Castillo, G., Ikeler, K., Orazi, J., Abdel-Rahman, E., Pai, A. B., Rivara, M. B., St Peter, W. L., Weisbord, S. D., Wilkie, C., & Mehrotra, R. (2018). Symptom prioritization among adults receiving in-center hemodialysis: A mixed methods study. *Clin J Am Soc Nephrol, 13*(5), 735–745. https://doi.org/10.2215/CJN.10850917

Maung, S., Sara, A. E., Cohen, D., Chapman, C., Saggi, S., & Cukor, D. (2017). Sleep disturbance and depressive affect in patients treated with haemodialysis. *J Ren Care, 43*(1), 60–66. https://doi.org/10.1111/jorc.12188

McCurry, S. M., Guthrie, K. A., Morin, C. M., Woods, N. F., Landis, C. A., Ensrud, K. E., Larson, J. C., Joffe, H., Cohen, L. S., Hunt, J. R., Newton, K. M., Otte, J. L., Reed, S. D., Sternfeld, B., Tinker, L. F., & LaCroix, A. Z. (2016). Telephone-based cognitive behavioral therapy for insomnia in perimenopausal and postmenopausal women with vasomotor symptoms: A MsFLASH randomized clinical trial. *JAMA Intern Med, 176*(7), 913–920. https://doi.org/10.1001/jamainternmed.2016.1795

Mehrotra, R., Cukor, D., McCurry, S. M., Rue, T., Roumelioti, M. E., Heagerty, P. J., & Unruh, M. (2024). Effectiveness of existing insomnia therapies for patients undergoing hemodialysis: A randomized clinical trial. *Ann Intern Med, 177*(2), 177–188. https://doi.org/10.7326/M23-1794

Ohayon, M. M. (2002). Epidemiology of insomnia: What we know and what we still need to learn. *Sleep Med Rev, 6*(2), 97–111. https://doi.org/10.1053/smrv.2002.0186

Perl, J., Unruh, M. L., & Chan, C. T. (2006). Sleep disorders in end-stage renal disease: 'Markers of inadequate dialysis?' *Kidney Int, 70*(10), 1687–1693. https://doi.org/10.1038/sj.ki.5001791

Roumelioti, M. E., Argyropoulos, C. P. & Unruh, M. L. (2020). Sleep Disorders. In D. Cukor, Cohen, S., & Kimmel, P (Eds.), *Psychosocial aspects of chronic kidney disease* (pp. 183–212). Academic Press. DOI: 10.1681/ASN.2007030345

Unruh, M., Cukor, D., Rue, T., Abad, K., Roumelioti, M. E., McCurry, S. M., Heagerty, P., & Mehrotra, R. (2020). Sleep-HD trial: Short and long-term effectiveness of existing insomnia therapies for patients undergoing hemodialysis. *BMC Nephrol, 21*(1), 443. https://doi.org/10.1186/s12882-020-02107-x

United States Renal Data System (USRDS). (2024). 2024 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases. https://usrds-adr.niddk.nih.gov/2024

Vitiello, M. V., McCurry, S. M., Shortreed, S. M., Balderson, B. H., Baker, L. D., Keefe, F. J., Rybarczyk, B. D., & Von Korff, M. (2013). Cognitive-behavioral treatment for comorbid insomnia and osteoarthritis pain in primary care: The Lifestyles randomized controlled trial. *J Am Geriatr Soc, 61*(6), 947–956. https://doi.org/10.1111/jgs.1227