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The Transdiagnostic Intervention for Sleep and Circadian Dysfunction (TranS-C) in community mental health: Comorbidity and use of modules under the microscope

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Abstract

Sleep and circadian problems are intertwined with serious mental illness (SMI). Thus, optimizing treatments that target comorbid sleep and circadian problems and SMI is critical. Among adults with sleep and circadian problems and SMI, the present study conducted a secondary data analysis of the Transdiagnostic Intervention for Sleep and Circadian Dysfunction (TranS-C). TranS-C targets a range of sleep and circadian problems and SMI with 15 modules, seven of which are optional. In a 'real world' sample recruited from a community setting (N=121, 52.07% female, 42.97% African American or Black), we aimed to (1) elucidate patterns of sleep and circadian problems that met criteria for full diagnoses and subdiagnostic symptoms across (a) the full sample and (b) SMI diagnoses, and (2) determine whether TranS-C optional modules were delivered as intended based on participants' sleep and circadian problems. Results indicated that most participants (> 85.0%) had full diagnoses or subdiagnostic symptoms of two or more sleep and circadian problems. Further, participants exhibited heterogenous comorbidities between sleep and circadian problems and SMI diagnoses. Specifically, participants with a schizophrenia spectrum disorder (n=50), bipolar disorder (n=35), and major depressive disorder (n=26) exhibited 25, 24, and 21 patterns of sleep and circadian comorbidity, respectively. Notably, most participants with insomnia, hypersomnia, and an advanced or delayed circadian rhythm phase disorder did *not* receive the intended TranS-C optional modules designed to target these problems. Results underscore sleep and circadian and SMI diagnostic complexity in the community. Additionally, findings reveal discrepancies between intended and 'real-world' use of treatment modules. Future research investigating clinician decision-making—particularly when treating patients with comorbidities or using modularized treatments—is needed.

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Keywords

comorbidity; transdiagnostic; sleep and circadian; serious mental illness

Introduction

Sleep and circadian problems are closely linked to serious mental illness (SMI). Sleep and circadian problems predict SMI onset and severity (Harvey et al., 2016; Hertenstein et al., 2019; Kivela et al., 2018; Manber & Chambers, 2009; Takaesu, 2018). Sleep symptoms are also included as key diagnostic criteria of several SMI diagnoses, including major depressive, persistent depressive, posttraumatic stress, bipolar, and generalized anxiety disorders (American Psychiatric Association, 2013). A recently developed treatment, the Transdiagnostic Intervention for Sleep and Circadian Dysfunction (TranS-C), seeks to target a range of sleep and circadian problems implicated in SMI with a single treatment protocol (Harvey & Buysse, 2017). Thus, TranS-C is transdiagnostic in two ways: it addresses a range of sleep and circadian problems—including insomnia, hypersomnia, advanced and delayed phase, sleep continuity problems and irregular sleep-wake schedules—that are commonly experienced by individuals diagnosed with a range of SMI (Baglioni et al., 2016).

TranS-C is underpinned by the Sleep Health framework, grounded in basic science, and draws on cognitive behavior therapy for insomnia, the first-line treatment for insomnia (Buysse, 2014; Edinger et al., 2021; Qaseem et al., 2016). Supporting the link between sleep and circadian problems and SMI, cognitive behavioral therapy for insomnia often improves symptoms of insomnia and comorbid SMI (Geiger-Brown et al., 2015; Taylor & Pruiksma, 2014). To further address SMI and sleep and circadian problems beyond insomnia, TranS-C also draws on Interpersonal and Social Rhythm Therapy (Frank et al., 2005), Chronotherapy (Wirz-Justice et al., 2009) and Motivational Interviewing (Miller & Rollnick, 2002). A recent randomized controlled trial (RCT) funded by the National Institute of Mental Health (R01MH105513; henceforth referred to as the ‘parent RCT’ for the present study), evaluated TranS-C plus usual care, relative to usual care followed by delayed treatment with TranS-C (UC-DT), in a community mental health center (CMHC) (Harvey et al., 2021). Promisingly, TranS-C relative to UC-DT was associated with reductions in functional impairment, SMI symptoms, sleep disturbance, and sleep-related daytime impairment.

TranS-C is comprised of eight modules that are used with all patients and seven optional modules (Harvey & Buysse, 2017). Use of the optional modules is guided by a combination of case conceptualization, patient goals, and provider judgment. Five of the optional modules target symptoms of specific sleep and circadian problems. Specifically, the module ‘Improving Sleep Efficiency’ targets insomnia, ‘Reducing Time in Bed’ targets hypersomnia, ‘Delayed or Advanced Phase’ targets delayed and advanced phase circadian rhythm disorders respectively, ‘CPAP Machine and Exposure’ targets obstructive sleep apnea, and ‘Reducing Nightmares’ targets nightmare disorder (Harvey & Buysse, 2017). The sixth optional module targets worry (i.e., ‘Reducing Sleep-Related Worry’), a transdiagnostic process implicated across SMI and sleep and circadian problems (Harvey et al., 2004). The seventh module ‘Negotiating Complicated Environments’ helps patients

navigate contextual challenges (e.g., noisy neighbors) that can exacerbate sleep and circadian problems.

Modular treatments, such as TranS-C, are gaining interest as a transdiagnostic approach (Sauer-Zavala et al., 2017). Research on modular treatments is still in its infancy, but initial outcomes are promising (Chorpita et al., 2017; Harvey et al., 2021; Murray et al., 2014). One key advantage is that modular treatments allow providers to personalize a single evidence-based treatment to a wide range of patient clinical presentations. Using TranS-C as an example, a provider treating a patient with hypersomnia and delayed phase circadian rhythm problems would deliver all the core TranS-C modules *and* the two optional modules that target the patients' presenting symptoms (i.e., 'Reducing Time in Bed' and 'Advanced or Delayed Phase').

A critical step to advance the modular approach involves improving our understanding of the transdiagnostic samples for which modular treatments, such as TranS-C, are designed. As noted above, sleep and circadian problems are closely linked to SMI. Even with this well-known link, very little research has unpacked comorbidity between sleep and circadian problems and SMI. This small body of research has primarily focused on investigating one or two sleep and circadian problems and SMI diagnoses at a time (e.g., insomnia and hypersomnia in a major depressive episode; Geoffroy et al., 2018; see also Ford et al., 1989), the incidence of comorbidity collapsing across sleep and circadian problems (e.g., Reeve et al., 2019), or the prevalence of comorbidities between SMI and common sleep symptoms assessed in isolation (e.g., Roth et al., 2006). One recent study reported the prevalence of comorbidities between sleep and circadian problems in a community sample. However, they did not detail *which* sleep and circadian disorders were comorbid, nor how sleep and circadian comorbidities intersected with SMI diagnoses (Hombali et al., 2019). This dearth of findings reflects the limited comorbidity research in clinical science, despite increasing evidence that comorbidity is the norm rather than the exception (Dalgleish et al., 2020).

A related limitation is that existing research on sleep and circadian problems has typically focused on patients who meet full diagnostic criteria. Put another way, research tends to ignore subdiagnostic symptoms, or core symptoms of a disorder in the absence of meeting full diagnostic criteria (Wolitzky-Taylor et al., 2014). This is troubling, because subdiagnostic symptoms are common, associated with significant impairment, and require treatment to facilitate optimal therapeutic outcomes (Bernatchez et al., 2018; Sarfan et al., 2021). Indeed, a recent study evaluated whether psychosocial and sleep and circadian functioning at baseline was associated with *number* of sleep and circadian problems or *diagnostic threshold* (full diagnosis versus subdiagnostic symptoms) of those problems (Sarfan et al., 2021). Number of sleep and circadian problems was associated with worse overall impairment, psychiatric symptoms, and sleep and circadian dysfunction at baseline, whereas diagnostic threshold was not. In other words, at baseline, impairment was as significant for participants with subdiagnostic symptoms as it was for participants who met full diagnostic criteria.

Furthermore, with the autonomy for providers to flexibly use modules, important questions arise. One important question is: are modules delivered as intended for specific clinical

presentations? In the parent RCT of TranS-C, providers were trained to deliver modules via a one-day workshop. They were also given a treatment manual and received weekly group supervision to discuss treatment progress and planning. Unfortunately, on its own, training in mental health treatment is often not associated with substantial gains in provider adherence and treatment skills (Beidas et al., 2012; Rakovshik et al., 2016). Additionally, although supervision and consultation can improve provider adherence and skill (Beidas et al., 2012; Rakovshik et al., 2016; Sholomskas & Syracuse-Siewert, 2005), the little existing research on supervision and provider enactment of *modular* treatments suggests that the effects of supervision content on provider practices are variable (Bearman et al., 2013).

The parent RCT offers the unique opportunity to elucidate (a) patterns of comorbidity between SMI and sleep and circadian problems (including full diagnoses and subdiagnostic symptoms), and (b) module use in a real-world context—specifically, a community mental health center (CMHC). CMHCs are important publicly funded providers of SMI treatment. Typically, CMHCs treat patients who present with high rates of comorbidity and are among the most socioeconomically disadvantaged in the community (Adashi et al., 2010; Drake et al., 2001). Taking this into consideration, the parent RCT purposefully limited inclusion and exclusion criteria to enhance representativeness and generalizability. Indeed, participants presented with a wide range of SMI and sleep and circadian problems, including subdiagnostic symptoms of sleep and circadian problems.

To help address the limited research on (a) comorbidity between full diagnoses and subdiagnostic symptoms of sleep and circadian problems and SMI, and (b) delivery of modularized treatments, the current report presents a secondary data analysis from the parent RCT of TranS-C. For Aim 1, we describe the patterns of non-comorbid and comorbid sleep and circadian problems that met criteria for full diagnoses or subdiagnostic symptoms across (a) the full sample and (b) each SMI diagnosis. For Aim 2, we evaluate whether the optional modules were delivered as intended for specific sleep and circadian problems. We hypothesized that participants with insomnia would receive the Improving Sleep Efficiency optional module; participants with hypersomnia would receive the Reducing Time in Bed optional module; and participants with delayed and advanced phase circadian rhythm disorders would receive the Delayed or Advanced phase module.

Method

Participants and Setting

Adults ($N = 121$) who met criteria for SMI were recruited from Alameda County Behavioral Health Care Services (ACBHCS), the CMHC for Alameda County, California. See Table 1 for participant demographics. SMI was operationalized based on Public Law 102–321 and previous research as the presence of at least one mental disorder, defined by the Diagnostic and Statistical Manual-5 (DSM-5), for at least 12 months that leads to substantial interference with one or more major life activities (Wang et al., 2002). To be eligible for the study, all participants needed to have carried an SMI diagnosis—according to this SMI definition—for at least 12 months. When participants were referred to the study by ACBHCS providers, the providers confirmed this timeframe on the initial participant referral

form. Similarly, participants were asked to confirm this timeframe when recruited for the study by research project coordinators.

Inclusion and exclusion criteria were kept to a minimum. Inclusion criteria included: 1) Age 18+ years; 2) English language fluency; 3) SMI as defined above; 4) guaranteed bed to sleep in for three months; 5) receiving care for SMI at ACBHCS; 6) consenting to regular communication between research team and providers; and 7) experiencing one or more sleep or circadian problems for at least three months, as assessed with the Sleep and Circadian Problems Interview (Morin, 1993). Sleep and circadian problems included: taking ≥30 mins to get to sleep on 3 or more nights per week, waking in the middle of the night for ≥30 minutes on three or more nights per week, obtaining <6 hours of sleep per night on three or more nights per week, obtaining >9 hours of sleep per 24 hour period (i.e., nighttime sleep plus daytime napping) on three or more nights per week, having more than 2.78 hours of variability in sleep-wake schedule across one week (Gruber et al., 2009), sleeping at a bedtime later than 2 a.m. on three or more nights per week.

Exclusion criteria included: 1) active and progressive physical illness or neurological degenerative disease and/or substance abuse/dependence making participation in the study infeasible; 2) current serious suicide or homicide risk; 3) night shift work >2 nights per week in past three months; 4) pregnancy or breast-feeding; and 5) not able/willing to complete pre-treatment assessments.

Study Design

Participants were randomly assigned to TranS-C ($n = 61$) or Usual Care followed by Delayed Treatment with TranS-C (UC-DT; $n = 60$) (see Supplement Figure 1). Randomization was stratified by lifetime presence of a psychotic disorder (yes, no) and age (49 and under, 50+). Participants completed a battery of measures at pre-treatment, post-treatment, and 6-month follow-up. Assessors were blind to condition. The Committee for the Protection of Human Subjects approved the study.

Measures

In addition to demographics, the following are reported in the current paper:

Mental disorders—Current and past presence of psychiatric diagnoses were assessed using the Mini-International Neuropsychiatric Interview (MINI) (DSM-5, Version 7.0.0), which is a short, structured interview. The MINI has demonstrated good test-retest reliability (kappa > .88) and validity (Lecrubier et al., 1997; Sheehan et al., 1998). MINI diagnoses for two participants were missing.

Our approach to determining SMI principal diagnosis consisted of a three-step process. First, the MINI was used to establish that severity, distress, and/or impairment of participants' symptoms were sufficient to qualify as a DSM-5 diagnosis. Second, from the MINI diagnoses, each participant's principal diagnosis was identified using the Clinician Severity Rating scale of the *Anxiety Disorders Interview Schedule – Revised* (Di Nardo et al., 1993; Summerfeldt & Martin, 2002). On this widely-used severity scale (e.g., Arteche et al., 2011; Summerfeldt & Martin, 2002; Tsao et al., 1998), each diagnosis is rated for level

of distress and/or functional impairment on a scale from 0 (absent) to 8 (severe). Using these ratings, principal diagnosis was defined as the disorder that was currently most distressing and/or impairing at the time of assessment. Third, as mentioned above, participants needed to have carried an SMI diagnosis for at least 12 months to be eligible for the study.

Sleep and Circadian Problems—Sleep and circadian problems were assessed using the *Duke Structured Interview for Sleep Disorders* (DSISD) (Edinger et al., 2006). The DSISD is a semi-structured interview designed to detect the presence of sleep and circadian problems. It was updated for the present study to assess criteria from both the International Classification of Sleep Disorders-3 (American Academy of Sleep Medicine, 2014) and the DSM-5 (American Psychiatric Association, 2013). Based on problems represented within the sample, the present study included the following assessed by the DSISD: insomnia, hypersomnia, circadian phase disorders (i.e., irregular, advanced, delayed), restless leg syndrome, and parasomnias (i.e., sleep walking, nighttime eating, night terrors, sexsomnia, nightmare disorder). Note that DSISD also assesses narcolepsy and periodic limb movement, and the parent RCT (NCT02469233) assessed sleep apnea via self-report; however, these problems were not included in the present study, because the gold standard assessment—namely, polysomnography—was not used (American Academy of Sleep Medicine, 2014; American Psychiatric Association, 2013). To our knowledge, psychometric properties of the DSISD have not been established for the DSM-5, although the DSISD has demonstrated discriminant validity and high reliability (kappa: .71 to .86) for the DSM-IV (Carney et al., 2009). Full diagnoses were clarified via a review of a 7-day daily sleep diary collected for the week preceding pre-treatment assessment.

To determine whether participants met criteria for subdiagnostic symptoms, core symptoms from the DSM-5 were pre-identified for each sleep and circadian problem. Core symptoms were defined as unique symptoms that would be required for a participant to meet full diagnostic criteria for a given sleep or circadian problem (e.g., endorsing nightmares for nightmare disorder). Participants were categorized as subdiagnostic if they endorsed one or more core DSM-5 symptoms assessed by the DSISD but did not meet full diagnostic criteria (see Supplement Table 1 for core DSM-5 symptoms and corresponding DSISD questions) (Bernatchez et al., 2018; Laborde-Lahoz et al., 2015).

Here we note two nuances regarding classification of subdiagnostic circadian rhythm problems. First, we did not assess the non-24-hour sleep-wake subtype because of the uncertainty and challenges involved in diagnosing this subtype among sighted individuals, even at the full diagnostic level, and the present sample did not include any participants with impaired vision (e.g., Malkani et al., 2018). Second, core symptoms of delayed, advanced, and irregular circadian rhythm subtypes were identified in the DSM-5 then assessed via corresponding items in the DSISD (see Supplement Table 1). Incidentally, all participants who endorsed the core symptom for a circadian rhythm subtype endorsed all three of the general DSM-5 criteria that are shared across the circadian rhythm problems (American Psychiatric Association, 2013). Together, with these general, shared symptoms and the sleep diaries, we had quite a bit more diagnostic data to inform our classification of each subtype of circadian rhythm problems beyond the core symptoms.

Therapy Modules—The Provider-Rated TranS-C Checklist (Gumport et al., 2020) was completed by providers after each session to identify which TranS-C modules were delivered. This measure assessed all TranS-C treatment modules, except the optional module focused on nightmares, which was excluded due to an administrative error. This measure has demonstrated adequate convergent validity (Gumport et al., 2020)

Treatment

TranS-C was administered by masters' and doctoral level therapists, hired within the University of California, Berkeley, who traveled to the ACBHCS clinic sites. Clinicians attended a one-day workshop, used a treatment manual, and received weekly supervision. TranS-C was provided in eight, weekly, individual 50-minute sessions. Modules are presented in Table 2.

Data Analysis

All analyses were completed in Excel 16.45. For Aim 1, sleep and circadian problems that met criteria for full diagnoses or subdiagnostic symptoms were identified for each participant. We then calculated how many participants had: a non-comorbid sleep and circadian problem, comorbid sleep and circadian problems, subdiagnostic symptoms, and comorbidities between full diagnoses only, full diagnoses and subdiagnostic symptoms, and subdiagnostic symptoms only. Next, the frequencies of sleep and circadian problems were calculated by collapsing across diagnostic status (i.e., full diagnosis, subdiagnosis), allowing us to take a more dimensional approach to examining patterns of sleep and circadian problems. Then, for each of the most common principal SMI diagnoses in the sample (i.e., schizophrenia, bipolar disorder, and major depressive disorder), the number of participants who met criteria for each pattern of sleep and circadian problem/s was calculated, again collapsing across full and subdiagnoses of sleep and circadian problems. Note that we did not evaluate patterns of sleep and circadian problems for principal diagnoses of posttraumatic stress disorder, anxiety disorders, obsessive compulsive disorder, and substance use disorders, because these principal diagnoses were only endorsed by one to three participants. In Aim 2, for participants who had full diagnoses and subdiagnostic symptoms of insomnia, hypersomnia, and circadian rhythm disorders, the percentage of optional modules administered was calculated. These percentages were calculated by dividing the participants with each sleep and circadian problem who received the module (assessed by the Provider-Rated TranS-C Checklist) by the number of participants with that sleep and circadian problem. Given that providers might prioritize optional modules differently depending on whether a patient has a single, comorbid, or subdiagnostic sleep and circadian problem, we present the results for participants with (a) a non-comorbid full diagnosis (i.e., just insomnia, hypersomnia, or delayed and advanced phase circadian rhythm disorders), (b) comorbid full diagnoses (i.e., comorbid diagnoses that included full diagnoses of insomnia, hypersomnia, or delayed and advanced phase circadian rhythm disorders), and (c) subdiagnostic symptoms (i.e., subdiagnostic symptoms of insomnia, hypersomnia, or delayed and advanced phase circadian rhythm problems). Additionally, to gather more information about module use, we identified the most commonly delivered optional TranS-C module for the most common sleep and circadian problems. Note that we did not evaluate the CPAP Machine and Exposure or Reducing Nightmare optional modules, because as

described above, sleep apnea was not included in the present study and the Reducing Nightmares data were excluded due to administrative error.

Results

Aim 1. Frequency of Full and Subdiagnostic Sleep and Circadian Problems with and without Comorbidities

See Supplement Table 2 for frequencies of non-comorbid and comorbid sleep and circadian problems, with subdiagnostic status indicated by italics.

Participants with a sleep or circadian problem that met full diagnostic criteria without a full or subdiagnostic comorbidity occurred in 9.9% of the sample. Thirteen participants (10.7%) were experiencing a sleep and circadian problem that met subdiagnostic criteria, but not full diagnostic criteria. Of those participants, only 4.1% endorsed subdiagnostic symptoms of a single sleep or circadian problem (i.e., without a comorbidity). Most participants had subdiagnostic symptoms of at least one sleep and circadian problem (81.8%).

When collapsing across diagnostic status, only 14.0% of the sample had a single full or subdiagnostic sleep or circadian problem (insomnia n=11, hypersomnia n=5, restless leg syndrome n=1). Stated another way, most participants presented with comorbid full or subdiagnostic sleep and circadian problems (86.0%). More specifically, 7.4% presented with comorbidities between sleep and circadian problems that met full diagnostic criteria only; 71.0% presented with comorbidities between full diagnoses and other subdiagnostic symptoms; and 6.6% presented with comorbidities between sleep and circadian problems that met subdiagnostic criteria only.

When collapsing across diagnostic status, participants exhibited 48 patterns of sleep and circadian problems. Of these 48 patterns, the most frequently occurring were: insomnia and hypersomnia (n=16); insomnia (n=11); insomnia, hypersomnia, and restless leg syndrome (n=11); insomnia, hypersomnia, and nightmares (n=10); and insomnia, hypersomnia, and delayed circadian rhythm (n=6). The other 43 patterns occurred in five or fewer participants. See Figure 1 for the frequency of each pattern of sleep and circadian problem/s, collapsing across diagnostic status.

SMI Diagnosis—Results in this subsection were calculated from frequencies presented in Supplement Tables 3, 4, and 5. Among participants with a principal diagnosis of schizophrenia (n=50), only 14.0% had a single full or subdiagnostic sleep or circadian problem (insomnia n=4, hypersomnia n=2, restless leg syndrome n=1), meaning that 86.0% had two or more sleep and circadian problems (see Figure 2 and Supplement Table 3). When collapsing across sleep and circadian diagnostic status, there were 25 patterns of sleep and circadian problems (see Figure 2). Of these 25 patterns, the most frequently occurring were: insomnia and hypersomnia (n=9); insomnia, hypersomnia, and restless leg syndrome (n=6); insomnia (n=4); and insomnia, hypersomnia, and nightmares (n=4). The other 21 patterns occurred in two or fewer participants.

Among participants with a principal diagnosis of bipolar disorder (n=35), only 20.0% had a single full or subdiagnostic sleep or circadian problem (insomnia n=4, hypersomnia n=3), meaning that 80.0% had two or more sleep and circadian problems (see Figure 3 and Supplement Table 4). When collapsing across diagnostic status, there were 24 patterns of sleep and circadian problems (see Figure 2). Of these 24 patterns, the most frequently occurring were: insomnia (n=4); hypersomnia (n=3); insomnia and hypersomnia (n=3); insomnia, hypersomnia, and nightmares (n=3); and insomnia, hypersomnia, and delayed circadian rhythm (n=3). The other 19 patterns occurred in one participant.

Among participants with a principal diagnosis of major depressive disorder (MDD) (n=26), only 7.7% had a single full or subdiagnostic sleep or circadian problem (insomnia n=2), meaning that 92.3% had two or more sleep and circadian problems (see Figure 4 and Supplement Table 5). When collapsing across diagnostic status, there were 21 patterns of sleep and circadian problems (see Figure 4). Of these 21 patterns, the most frequently occurring were: insomnia (n=2); insomnia and hypersomnia (n=2); insomnia, hypersomnia, and restless leg syndrome (n=2); insomnia, hypersomnia, and nightmares (n=2); and insomnia, hypersomnia, and delayed circadian rhythm (n=2). The other 16 patterns occurred in one participant.

Aim 2. Delivery of TranS-C Optional Modules by Intended Sleep and Circadian Problem

Results were calculated from frequencies in Supplement Tables 6 through 11, which present the number of participants who received each optional module by their sleep and circadian problem/s.

Insomnia and ‘Improving Sleep Efficiency’—Of the 9 participants with a non-comorbid full diagnosis of insomnia, 4 (44.4%) received the ‘Improving Sleep Efficiency’ optional module. Of the 92 participants with comorbid full diagnoses that included insomnia, 21 (22.8%) received the ‘Improving Sleep Efficiency’ optional module. Of the 11 participants with subdiagnostic symptoms of insomnia, 2 (18.2%) received the ‘Improving Sleep Efficiency’ optional module.

Hypersomnia and ‘Reducing Time in Bed’—Of the 4 participants with a non-comorbid full diagnosis of hypersomnia, 4 (100.0%) received the ‘Reducing Time in Bed’ optional module. Of the 26 participants with comorbid full diagnoses that included hypersomnia, 12 (46.2%) received the ‘Reducing Time in Bed’ optional module. Of the 54 participants with subdiagnostic symptoms of hypersomnia, 20 (37.0%) received the ‘Reducing Time in Bed’ optional module.

Advanced or Delayed Phase Circadian Rhythm Disorders and ‘Delayed or Advanced Phase’—The 1 participant with a non-comorbid full diagnosis of an advanced or delayed circadian rhythm disorder did not receive the ‘Delayed or Advanced Phase’ optional module (0%). Of the 10 participants with comorbid full diagnoses that included an advanced or delayed circadian rhythm disorder, 1 (10.0%) received the ‘Delayed or Advanced Phase’ optional module. Of the 27 participants with subdiagnostic symptoms

of an advanced or delayed circadian rhythm disorder, 4 (14.8%) received the ‘Delayed or Advanced Phase’ optional module.

TranS-C Optional Modules by Most Common Sleep and Circadian Problems— Last, we examined the most common optional modules delivered for the most common full and subdiagnoses of sleep and circadian problems. The most common diagnoses that met full diagnostic criteria were insomnia and hypersomnia. For the 101 participants with an insomnia diagnosis that met full diagnostic criteria, the most commonly delivered optional modules were: ‘Reducing Sleep-Related Worry’ (52.5%, n=53), ‘Reducing Time in Bed’ (39.6%, n=40), and ‘Improving Sleep Efficiency’ (24.8%, n=25). For the 31 participants with a hypersomnia diagnosis that met full diagnostic criteria, the most commonly delivered optional modules were ‘Reducing Time in Bed’ (51.6%, n=16), ‘Reducing Sleep-Related Worry’ (45.2%, n=14), and ‘Improving Sleep Efficiency’ (25.8%, n=8).

The most subdiagnostic symptoms were hypersomnia and nightmares. For the 54 participants with subdiagnostic symptoms of hypersomnia, the most commonly delivered optional modules were: ‘Reducing Sleep-Related Worry’ (57.4%, n=31), ‘Reducing Time in Bed’ (37.0%, n=20), and ‘Improving Sleep Efficiency’ (22.2%, n=12). For the 42 participants with subdiagnostic symptoms of nightmares, the most commonly delivered optional modules were: ‘Reducing Sleep-Related Worry’ (61.9%, n=26), ‘Reducing Time in Bed’ (45.2%, n=19), and ‘Negotiating Complicated Environments’ (26.2%, n=11).

Discussion

This study evaluated patterns of sleep and circadian problems—including those that met criteria for full diagnoses or subdiagnostic symptoms—and comorbidity with SMI diagnoses among individuals receiving care in a CMHC. We also assessed whether TranS-C optional modules were delivered as intended for specific sleep and circadian problems at the full diagnostic and subdiagnostic levels. At the outset, we emphasize that the gold standard assessment of sleep and circadian problems is no easy task and ideally requires multi-method assessments (Buysse et al., 2006; Vetter, 2020). Given the nature of the CMHC setting—particularly concerns about participant burden—we had limited tools to make full diagnoses; namely, a structured interview and one week of sleep diary. We acknowledge this limitation and highlight the need for replication.

The first aim of the present study was to report on the patterns of non-comorbid and comorbid sleep and circadian problems for the full sample, as well as for each principal SMI diagnosis. Interestingly, less than 10% of individuals met full diagnostic criteria for only one sleep or circadian problem and less than 5% had subdiagnostic symptoms of only one sleep and circadian problem. Instead, most participants (> 85.0%) met criteria for at least one comorbidity between sleep and circadian problems. This finding adds to growing evidence that comorbidity is the norm, rather than the exception (Dalgleish et al., 2020; Kessler et al., 2005), and has meaningful implications for RCTs. Specifically, because RCTs often exclude patients on the basis of comorbidities (e.g., Goldstein-Piekarski et al., 2016; Halvorson & Humphreys, 2015; Ronconi et al., 2014), they may be excluding many typical patients.

A related result from this aim was that most participants met criteria for subdiagnostic symptoms of at least one sleep and circadian problem (81.8%) at the start of treatment. Further, 10.7% of participants did not meet full diagnostic criteria for a sleep and circadian problem but were experiencing distress and sleep disturbance that was significant enough to seek treatment and meet the trial eligibility criteria. Each of these individuals had subdiagnostic symptoms of at least one sleep and circadian problem, and several had subdiagnostic symptoms of multiple problems. By extension, if we rigidly rely on full diagnostic criteria, we may not a) recognize individuals who need treatment and b) ensure our treatments are effective for those with subdiagnostic symptoms. Overreliance on full diagnostic criteria is particularly worrisome in light of evidence that subdiagnostic symptoms are common and often associated with significant impairment (Bernatchez et al., 2018; Li et al., 2014; Sarfan et al., 2021). Considering the results of the first aim together, providers may improve clinical care by evaluating and treating comorbidities and subdiagnostic symptoms, even in the absence of full diagnostic criteria, which aligns with dimensional approaches to psychopathology (Cuthbert & Insel, 2013; Dalgleish et al., 2020).

Further, among the participants who met criteria for at least one comorbidity, most of these participants (71.0%) presented with comorbidities between sleep and circadian problems that met criteria for full diagnoses *and* subdiagnostic symptoms, whereas 7.4% presented with comorbidities that met criteria for full diagnoses only, and 6.6% presented with comorbidities that met criteria for subdiagnostic symptoms only. Additionally, when collapsing across full diagnoses and subdiagnoses to examine patterns of sleep and circadian problems using a more dimensional approach, certain sleep and circadian problems appeared to “hang” together. The most frequently occurring patterns of sleep and circadian problems included: insomnia and hypersomnia; insomnia, hypersomnia, and restless leg syndrome; and insomnia, hypersomnia, and nightmare disorder. Similarly, when examining participants with each of the most common principal SMI diagnoses in the sample, some sleep and circadian problems occurred more frequently than others. For instance, among participants with schizophrenia, comorbid insomnia and hypersomnia occurred most frequently, followed by insomnia, hypersomnia, and restless leg syndrome, then insomnia, hypersomnia, and nightmares. For participants with bipolar disorder, the most common sleep and circadian problems were insomnia; hypersomnia; insomnia and hypersomnia; and insomnia and hypersomnia comorbid with either nightmares or delayed circadian rhythm subtype. For participants with MDD, no pattern of sleep and circadian problems occurred in more than two participants. However, the most frequently occurring patterns were insomnia; insomnia and hypersomnia; and insomnia and hypersomnia comorbid with either restless leg syndrome, nightmares, or delayed circadian rhythm. A related cluster of findings was the striking diversity in SMI and sleep and circadian comorbidities. Participants with a principal diagnosis of schizophrenia spectrum disorder (n=50) exhibited 26 patterns of sleep and circadian problems. Participants diagnosed with bipolar disorder (n=35) exhibited 25 patterns of sleep and circadian problems. Participants diagnosed with major depressive disorder (n=26) exhibited 21 patterns of sleep and circadian problems. To our knowledge, this is the most comprehensive characterization to date of comorbidity between sleep and circadian problems across SMI diagnoses. These findings add to the growing recognition of “massive heterogeneity within diagnoses” (Dalgleish et al., 2020, p. 181) and indicate

that there is also massive heterogeneity in *comorbidities*. From a clinical perspective, this heterogeneity underscores the utility of transdiagnostic treatments for sleep and circadian and SMI comorbidities in "real-world" settings. Moreover, although replication and extension with larger samples is warranted, these findings have additional clinical utility in offering clues about which sleep and circadian problems and SMI diagnoses may be more likely to occur together. Thus, for a given patient's clinical presentation, the results may help narrow down which sleep and circadian problems might merit further clinical assessment. For example, if a patient with schizophrenia presents to treatment with insomnia symptoms, these findings suggest that it might be important for the clinician to also assess for hypersomnia and restless leg syndrome. Similarly, when treating a patient with bipolar disorder and nightmares, it may also be important to assess for insomnia and hypersomnia.

The third aim was to report on whether TranS-C optional modules were delivered as intended for participants with specific sleep and circadian problems. In contrast to hypotheses, most participants with insomnia, hypersomnia, or an advanced or delayed phase circadian rhythm disorder did *not* receive the intended optional modules. This pattern was consistent when looking at non-comorbid full diagnoses, comorbid full diagnoses, and subdiagnostic symptoms. The one exception was that all four participants with non-comorbid full hypersomnia diagnoses did receive the intended module, 'Reducing Time in Bed.' These findings reveal discrepancies between intended module use and actual module use by providers. Importantly, these discrepancies were observed despite thorough training and supervision in TranS-C that included a full-day workshop, manuals, and weekly supervision. From an applied lens, the present results suggest that additional approaches may be needed to help providers deliver TranS-C with fidelity (i.e., delivering optional modules to patients with appropriate clinical presentations). Drawing from the supervision and treatment fidelity literatures, such approaches may include supervision that incorporates goal setting (e.g., fidelity goals, session content goals), is focused on delivery of optional modules, and integrates systematized strategies to help clinicians match presenting symptoms with intended modules (e.g., Bearman et al., 2013; Eiraldi et al., 2018; Murray et al., 2015). Similar to the emerging evidence-base for gold standard training in cognitive behavioral therapy (Rakovshik & McManus, 2010), these approaches may represent possible building blocks of evidence-based training and supervision for transdiagnostic treatments.

Alternatively, there are a few other possible explanations for these surprising findings. One possibility is related to TranS-C's role as a transdiagnostic treatment. Of the optional modules, Sleep-Related Worry was consistently one of the most commonly administered modules for the most common sleep and circadian problems. It is conceivable that use of this module reduced other symptoms (e.g., reducing sleep-related worry improved sleep efficiency), obviating the need for additional problem-specific modules. Similarly, it is possible that the core modules sufficiently addressed sleep problems targeted by the optional modules (e.g., regularizing sleep-wake times in Core Module 1 meaningfully improved sleep efficiency). Indeed, in a prior study with a different sample of individuals diagnosed with bipolar disorder, our group found that regularizing bed and wake times was sufficient for improving sleep efficiency (Kaplan & Harvey, 2013). Because the parent RCT only assessed outcomes at pre-treatment, post-treatment, and six-month follow-up, rather than session-by-

session outcomes, we are unable to test the direct, temporal relationships between module use and symptom reduction. However, research to dismantle the effect of each TranS-C module on outcomes at post-treatment and six-month follow-up is currently underway and will help clarify these possible explanatory hypotheses (e.g., Callaway et al., in preparation). Another possible contributor to the current findings was that a diagnosis of insomnia according to the DSM-5 or the DSISD does not require poor sleep efficiency, though individuals with insomnia often report sleep efficiency less than 85% (APA, 2013; Edinger et al., 2009; Schutte-Rodin et al., 2008). In the present sample, 22% of participants with a full diagnosis or subdiagnostic symptoms of insomnia had sleep efficiency of 85% or higher at baseline. In other words, these participants may not have needed the 'Improving Sleep Efficiency' module, which may have accounted for the some of the discrepancies between clinical presentation of insomnia and therapist use of the 'Improving Sleep Efficiency' module. Finally, an interesting pattern in the results was that the percentage of participants with insomnia and hypersomnia who received the intended modules was higher for non-comorbid diagnoses than comorbid diagnoses. Thus, perhaps the comorbid diagnoses complicate the decision-making process for providers. Together, these findings highlight that more research is needed on (a) the effects associated with each TranS-C module and (b) clinical decision-making for complex patients. In fact, with the growing influence of modular approaches (Sauer-Zavala et al., 2017), these areas of research (i.e., effects of individual modules and clinical decision-making) have been identified as priorities to enhance effectiveness and efficiency of transdiagnostic treatments (e.g., Becker et al., 2012; Martin et al., 2018; Sauer-Zavala et al., 2017).

Findings from the present study should be considered in light of several limitations. First, the study protocol did not include qualitative measures to assess therapist rationale for delivering TranS-C optional modules. Future studies might benefit from qualitative measures to assess the influence of provider preference and client symptoms on delivery of therapeutic modules. Second, criteria for subdiagnostic symptoms were determined after termination of the experimental treatment condition. It is unclear what influence, if any, these subdiagnostic symptoms had on client and/or therapist priorities during sessions. Third, findings reflect the complexity of sleep and circadian problems for individuals with SMI within a CMHC setting. Replication of these results in different settings and populations is warranted. Fourth, the nightmare module was not assessed due to administrative error and thus was not analyzed. Fifth, we did not assess subdiagnostic symptoms of the non-24-hour sleep-wake subtype of circadian rhythm problems, due to the uncertainty and challenges of diagnosing this subtype among sighted individuals even at the full diagnostic level, and the present sample did not include any participants with impaired vision (Malkani et al., 2018). Studies to clarify this diagnosis are reportedly underway (e.g., Garbazza, 2018), and these investigations may pave the way for assessing core subdiagnostic symptoms of the non-24-hour sleep-wake subtype. Sixth, the approach used to classify subdiagnostic sleep and circadian problems may need to be refined in future research. In particular, it was challenging to differentiate subdiagnoses of the circadian rhythm subtypes and insomnia using just the core symptoms for these sleep and circadian problems. Incidentally, in our sample, all participants who endorsed the core symptom of a circadian rhythm subtype also endorsed all three general DSM-5 circadian rhythm criteria, providing more diagnostic

clarity. However, 11 participants in our sample were classified with subdiagnostic insomnia, two of whom also endorsed full or subdiagnostic delayed or advanced circadian rhythm problem (see Supplement Table 2). For these participants, it is important for readers to consider that the subdiagnostic symptoms of insomnia may actually reflect subdiagnoses of advanced or delayed circadian problems. To clarify these issues in future research, revisions to the classification system may be warranted, such as delineating additional core symptoms for subdiagnostic insomnia and circadian rhythm problems, adding interview questions to help differentiate these sleep and circadian problems at the subdiagnostic level, and/or incorporating the recommendation to include assessment of physiological markers for circadian rhythm problems, such as dim light melatonin onset or biomarker panels (Duffy et al., 2021). Indeed, an important next step for future research will be to systematically evaluate the approach to classifying subdiagnostic sleep and circadian problems used in the present study. This would help confirm that the present results definitively reflect broad heterogeneity of clinical presentation rather than assessment limitations (e.g., incomplete assessment). Seventh, to our knowledge, the psychometric properties of the DSISD for the DSM-5 have not been published, and thus, the extent to which this measure validly and reliably assesses DSM-5 symptoms remains unclear. Eighth, we did not differentiate between too much total sleep and too much time in bed in assigning a diagnosis of hypersomnia. This is an important distinction to include in future research (Kaplan & Harvey, 2009). Finally, there are many ways to operationalize SMI (Martinez-Martinez et al., 2020). Notably, a recent systematic review yielded a “lack of unanimity in the variables considered necessary to identify SMI” (Martinez-Martinez et al., 2020, p. 229). It is important to acknowledge that use of other SMI definitions might result in different patterns of comorbidity between SMI and sleep and circadian problems than those identified in the present study.

In summary, findings from the present study add to the growing literature on diagnostic complexity by illustrating the substantial comorbidity between sleep and circadian problems, particularly when considering full diagnoses *and* subdiagnostic symptoms. Further, to our knowledge, this is the most comprehensive characterization to date of sleep and circadian comorbidities across SMI diagnoses. Results highlight the most common patterns of comorbidity in the present sample but also underscore striking heterogeneity in sleep and circadian and SMI diagnostic combinations. Given these high rates of comorbidity and heterogeneity, the findings support use of transdiagnostic treatments, such as TranS-C, in CMHC settings. However, optional modules were generally not delivered as intended, eliciting questions about module efficacy and clinical decision-making. Future research addressing these questions may enhance modularized approaches—an exciting next step for transdiagnostic treatments.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Highlights

- TranS-C is a modular treatment that targets sleep and circadian problems and SMI
- Analyzed comorbidity, subdiagnostic symptoms, and provider use of TranS-C modules
- 86.0% of sample had at least one comorbidity between sleep and circadian problems
- Comorbidity patterns between sleep and circadian problems and SMI varied widely
- Substantial discrepancies between intended and ‘real-world’ use of TranS-C modules

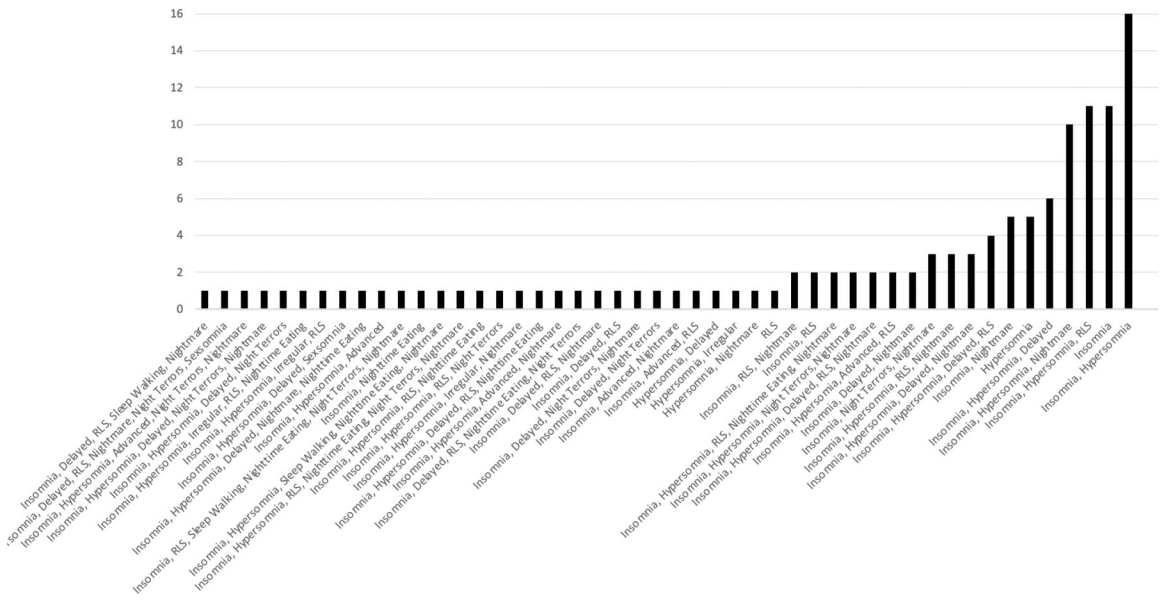

Figure 1.

Frequency of Each Pattern of Sleep and Circadian Problems

Note. RLS = Restless Leg Syndrome.

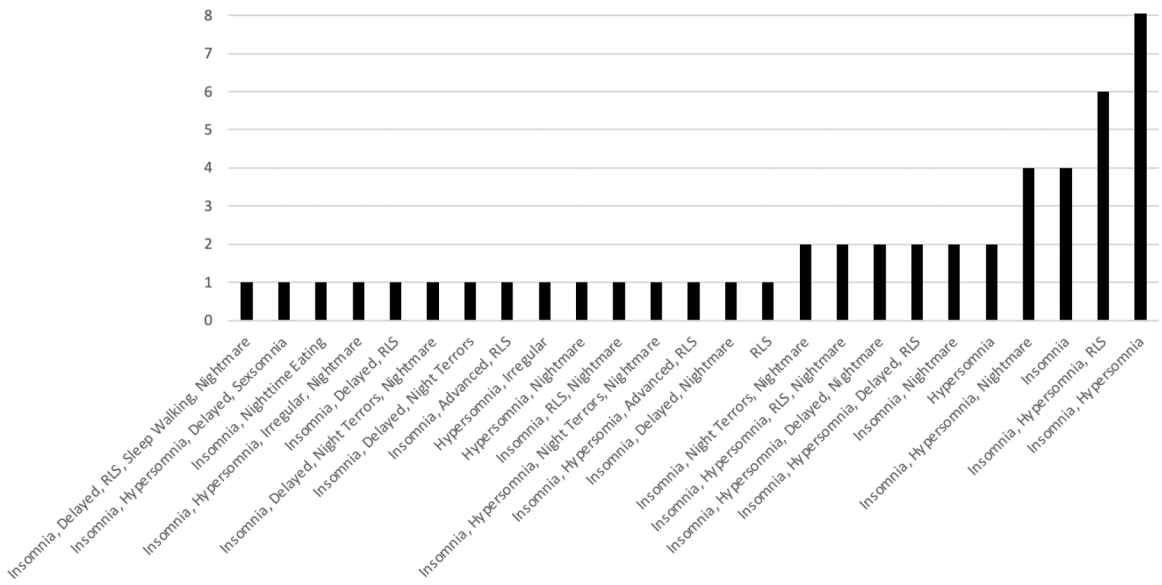

Figure 2.

Frequency of Each Pattern of Sleep and Circadian Problem/s Comorbid with Schizophrenia

Note. RLS = *Restless Leg Syndrome*.

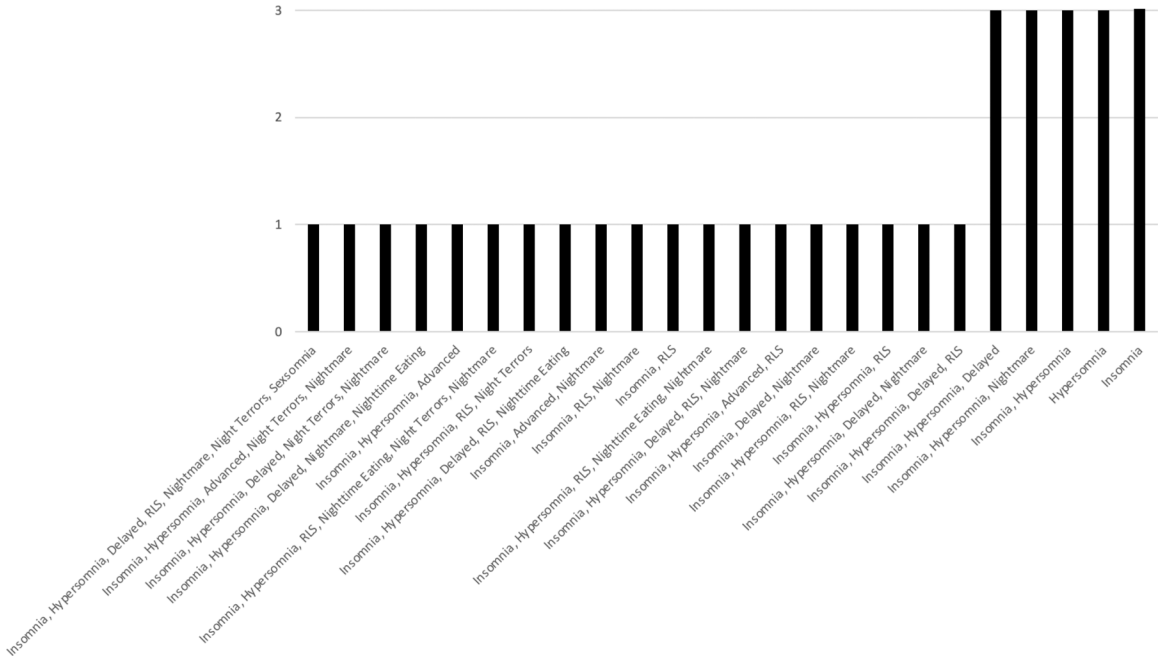

Figure 3.

Frequency of Each Pattern of Sleep and Circadian Problem/s Comorbid with Bipolar Disorder

Note. RLS = *Restless Leg Syndrome*.

Figure 4.

Frequency of Each Pattern of Sleep and Circadian Problem/s Comorbid with Major Depressive Disorder

Note. RLS = *Restless Leg Syndrome*.

Table 1.

Baseline Demographics of Participants in Both Treatment Conditions

	UC-DT (n = 60)		TranS-C+UC (n = 61)	
Characteristic	***n***	**%**	***n***	**%**
Female	33	55.00	30	49.18
Ethnicity				
Hispanic or Latino	9	15.00	10	16.39
Not Hispanic or Latino	51	85.00	50	81.97
Missing			1	1.64
Race				
White	21	35.00	25	40.98
African American/Black	26	43.33	26	42.62
American Indian or Alaskan Native	4	6.67	4	6.56
Asian	5	8.33	2	3.28
Native Hawaiian/Other Pacific Islander	2	3.33	1	1.64
Missing	2	3.33	3	4.92
Civil status				
Single	42	70.00	38	62.3
Married/common law partner	4	6.67	5	8.2
Separated/divorced/widowed	14	23.33	18	29.51
Employment				
Full-time	1	1.67	1	1.64
Part-time	6	10.00	9	14.75
Unemployed	49	81.66	49	80.33
Other	4	6.67	1	1.64
Missing			1	1.64
Living arrangement				
Alone	12	20.00	8	13.11
With family (spouse or children)	8	13.33	6	9.84
With friend or roommate or pet	11	18.34	11	18.03
Supported housing[a]	29	48.33	35	57.38
Missing			1	1.64
	M	**SD**	**M**	**SD**
Age (in years)	45.45	13.25	47.97	11.51
Education (in years)	13.38	3.89	13.80	3.05
Annual personal income	$12,429	$15,317	$12,636	$9,850
Annual household income	$24,091	$27,507	$26,537	$23,576

Note.

[a]Supported housing includes living in board & care homes, senior housing, transitional housing, and homeless shelter. Baseline variables did not differ between treatment conditions.

Table 2.

Common Problems and TranS-C Modules

Treatment Module	Common Sleep and Circadian Problems
Core Module 1	Irregularity, difficulty winding down/waking up
Core Module 2	Daytime Impairment
Core Module 3	Unhelpful beliefs about sleep
Optional Module 1	Poor sleep-efficiency
Optional Module 2	Too much time in bed
Optional Module 3	Delayed or advanced phase
Optional Module 4	Sleep-related worry
Optional Module 5	Promoting Compliance with CPAP
Optional Module 6	Disruptive environments
Optional Module 7	Nightmares
Core Module 4	Maintenance of behavior change

Note. All sessions included 4 cross-cutting modules: functional analysis, education, motivational enhancement, and goal setting.