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A randomized controlled trial of the Transdiagnostic Intervention for Sleep and Circadian Dysfunction (TranS-C) to improve serious mental illness outcomes in a community setting

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Abstract (250 words)

Objective: To determine if the Transdiagnostic Intervention for Sleep and Circadian Dysfunction (TranS-C) improves functional impairment, disorder-focused symptoms and sleep and circadian functioning.

Method: Adults diagnosed with serious mental illness (SMI) and sleep and circadian dysfunction (*N*=121) were randomly allocated to TranS-C (*n*=61; 8 individual weekly sessions) or 6-months of Usual Care followed by Delayed Treatment with TranS-C (UC-DT; *n*=60). SMI was defined as the presence, for 12 months, of at least one Diagnostic and Statistical Manual-defined mental disorder. Blind assessments were conducted before and immediately following treatment and 6 months later (6FU). The location was the Alameda County Behavioral Health Care Services (ACBHCS), the Community Mental Health Center (CMHC) for Alameda County, California.

Results: TranS-C, relative to UC-DT, was associated with reduction in functional impairment (*b*=-3.18, *p*=0.025), disorder-focused symptoms (*b*=-5.88, *p*=0.001), sleep disturbance (*b*=-5.55, *p*<0.0001) and sleep-related impairment (*b*=-9.14, *p*<0.0001) from pre-treatment to post-treatment. These effects were maintained to 6FU, except for functional impairment. TranS-C, relative to UC-DT, was associated with improvement in sleep efficiency and the Sleep Health Composite score from pre-treatment to post-treatment and to 6FU. TranS-C was also associated with reduced sleep diary measured total wake time and waketime variability from pre-treatment to post-treatment, as well as reduced hallucinations and delusions, sleep diary measured bedtime variability, and actigraphy measured activity count variability from pre-treatment to 6FU.

Conclusions: This trial provides evidence that a novel transdiagnostic treatment, delivered within a CMHC setting, improves selected measures of functioning, symptoms of the comorbid disorder, and sleep and circadian outcomes.

Trial Registration: ClinicalTrials.gov Identifier: NCT02469233, registered 9 June 2015.

Keywords. Transdiagnostic, sleep, circadian, serious mental illness, dissemination, community mental health.

A randomized controlled trial of the Transdiagnostic Intervention for Sleep and Circadian Dysfunction (TranS-C) to improve serious mental illness outcomes in a community setting

Sleep and circadian dysfunction contributes to vicious cycles of escalating vulnerability in persons diagnosed with a serious mental illness (SMI). A range of sleep and circadian problems, including insomnia, hypersomnia, advanced and delayed phase, sleep continuity problems and irregular sleep-wake schedules, are commonly comorbid with SMI (1, 2). These problems often persist even when the SMI is treated (3) and they predict and predate SMI symptom onset and exacerbation (4, 5). Moreover, insufficient sleep exacerbates emotion regulation difficulty, poor problem solving, difficulty with cognitive functioning, and behaviors like impulsivity (6). Taken together, there is a need for treatment approaches that address the complexity of real life sleep and circadian problems in mental illness. The Transdiagnostic Sleep and Circadian Intervention (TranS-C) (7) has been proposed to address the need for one short protocol to address the broader range of sleep and circadian dysfunction experienced by SMI patients. TranS-C is grounded in basic science and draws from cognitive behavior therapy for insomnia (CBT-I)—the first-line treatment for insomnia (8), which effectively treats insomnia across psychiatric disorders and often the comorbid disorder (9, 10)—along with Interpersonal and Social Rhythm Therapy (11), Chronotherapy (12) and Motivational Interviewing (13). TranS-C is transdiagnostic in two ways: It aims to address a range of sleep and circadian problems and to be useful across SMI.

TranS-C is likely to be highly disseminable due to the substantial cost advantage to training providers in one treatment protocol that covers multiple problems (14). Further, an important gap in knowledge is the performance of treatments in routine practice settings as most treatment research is conducted in research settings. CBT-I has been effectively delivered in a range of real world settings (15-17). The present study was conducted to extend these findings by delivering TranS-C in CMHCs. CMHCs are critical settings as they are major, publicly funded providers of treatment for SMI. They provide for the poorest and most underserved members of the community who experience high rates of comorbidity and complexity (18, 19). As such, transdiagnostic treatments like TranS-C are appropriate as they target processes that underpin multiple disorders and afford treatment for a

greater heterogeneity of clinical presentations.

As described in the study protocol (20), the aim of this study was to evaluate the effects of TranS-C vs. Usual Care followed by Delayed Treatment with TranS-C (UC-DT) on *functional impairment, disorder-focused symptoms* and *sleep and circadian function* in participants receiving treatment for SMI in a CMHC. The hypothesis tested is that TranS-C will be superior to UC-DT at post-treatment and 6-month follow-up (6FU) for *functional impairment, disorder-focused symptoms* and *sleep and circadian function*.

Method

Study Design

Adults (N = 121) who met inclusion and exclusion were randomly assigned, in a 1:1 parallel group design, to TranS-C (n = 61) or Delayed Treatment with TranS-C following 6-months of Usual Care (UC-DT; n = 60) (see Figure 1 in the online supplement for the CONSORT diagram). Randomization was stratified by psychosis (yes, no) and age (49 and under, and then 50+). Participants received a battery of outcome measures pre-treatment, and again at post-treatment (i.e. 9-14 weeks later) and at 6FU. UC-DT received two additional assessments: 9-14 weeks and 6 months into UC-DT. Assessors were blinded to treatment allocation. A project coordinator conducted randomization after each eligibility assessment was completed. The Committee for the Protection of Human Subjects approved the study.

Participants and Setting

Adults who met criteria for SMI and sleep and circadian dysfunction were recruited from multiple sites within Alameda County Behavioral Health Care Services (ACBHCS), the Community Mental Health Centers (CMHC) for Alameda County, California. Participants were referred via ACBHCS case managers and psychiatrists, and recruited via advertising in clinic waiting rooms and giving presentations. SMI was operationalized according to Public Law 102-321 and previous research (21) as the presence, for 12 months, of at least one Diagnostic and Statistical Manual-defined mental disorder that leads to substantial interference with one or more major life activities (22).

To enhance representativeness and generalizability, the inclusion and exclusion criteria were kept to a minimum. The inclusion criteria follow: 1) Age 18+ years; 2) English language fluency; 3) presence of at least one DSM-5 mental disorder for 12 months; 4) one or more of the following sleep or circadian problems for 3 months assessed with the Sleep and Circadian Problems Interview: taking ≥30 mins to get to sleep 3 or more nights per week, waking in the middle of the night for ≥30 minutes 3 or more nights per week, obtaining <6 hours of sleep per night 3 or more nights per week, obtaining >9 hours of sleep per 24 hour period (i.e., nighttime sleep plus daytime napping) 3 or more nights per week, having more than 2.78 hours of variability in sleep-wake schedule across one week, sleeping at a bedtime later than 2 am on 3 or more nights per week; 5) having a guaranteed bed to sleep in for 3 months; 6) receiving care for SMI at ACBHCS; and 6) consenting to regular communications between research team and psychiatrist and/or case manager.

The exclusion criteria follow: 1) presence of an 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 (assessed by our staff, a case manager or psychiatrist); 3) night shift work >2 nights per week in the past 3 months; 4) pregnancy or breast-feeding; 5) not able/willing to complete the pre-treatment assessments. Individuals with sleep apnea and periodic limb movement disorder often have comorbid insomnia and poor sleep habits, and can benefit from CBT-I (23, 24). Hence, these individuals were included in this study. Participants' SMI medications often need to be changed. Excluding on this basis is neither feasible nor representative of clinical practice. Medication use and changes were recorded.

Measures

The assessors were blind to treatment allocation. In addition to demographics, the following measures were administered.

Primary Outcomes. Functional Impairment was assessed with the *Sheehan Disability Scale* (SDS) (25) which is a widely used brief measure. The DSM-5 Cross-Cutting Measure was included as a measure of disorder-focused symptoms. Sleep and circadian function was assessed with the *PROMIS–Sleep Disturbance (PROMIS–SD)* (26) and the *PROMIS–Sleep-Related Impairment (PROMIS–SRI)* (26), which are brief, comprehensive and well validated.

Secondary Outcomes. Disorder-focused symptoms were assessed by the *Quick Inventory of Depressive Symptoms (QIDS)* (27), *Alcohol, Smoking and Substance Involvement Screening Test (ASSIST)* (28) and/or the *Psychotic Symptoms Rating Scales (PSYRATS)* (29). Impairment was assessed by the self-administered version of the *World Health Organization Disability Assessment Schedule (WHODAS) 2.0* and the 4-question *'Healthy Days'* core module developed by the Centers for Disease Control and Prevention (30). Sleep and circadian function was assessed with the *daily sleep diary* and *actigraphy* (GT9X Link, ActiGraph), collected for 7 days at each assessment point. The daily sleep diary was typically collected via a daily phone call with a member of the research team. The outcomes analyzed from the sleep diary are the mean and variability in sleep efficiency (total sleep time/time in bed X 100), total sleep time (TST), total wake time (TWT), bedtime and waketime. The outcomes analyzed from actigraphy are the mean and variability for TST and TWT, as well as the daytime activity count. In addition, we calculated a Sleep Health Composite score (31). This is defined as the sum of scores on 6 sleep health dimensions (each dimension was dichotomized such that 1 = good; 0 = poor): Regularity (Midpoint fluctuation across the 7-day sleep diary), Satisfaction (Sleep quality question on PROMIS-SD), Alertness (Daytime sleepiness question on PROMIS-SRI), Timing (Mean midpoint across the 7 day sleep diary), Efficiency (Sleep efficiency based on the 7-day sleep diary) and Duration (TST based on 7-day sleep diary). Higher scores on the sleep health composite indicate better sleep health. Following Dong et al. (32), the cut-off used for each dimension is presented in Table 1. This measure is proposed to capture the complexity of the sleep problems covered by TranS-C.

Measures included at pre-treatment assessment only. The diagnostic measure for mental disorders was the Mini-International Neuropsychiatric Interview (MINI) (DSM-5, Version 7.0.0 including Schizophrenia and Psychotic Disorders). The MINI was included as an evaluation of the presence of current and past SMI. The MINI was developed to meet the need for a simple, short yet accurate structured psychiatric interview. The diagnostic measure for sleep disorders was the *Duke Structured Interview for Sleep Disorders (DUKE)* (33).

Sleep/insomnia history was obtained with the *Sleep and Circadian Problems Interview*, to assess inclusion/exclusion criteria. To improve our ability to identify obstructive sleep apnea, we supplemented the DUKE assessment with the *STOP-BANG* (34), which is an 8-item screen for obstructive sleep apnea. Both measures are well validated and widely used. Those suspected to have another sleep disorder were referred for non-study evaluation/treatment and were *not* excluded.

The Medication Tracking Log was used to record the medications patients were receiving at each assessment.

Treatment credibility/expectancies was administered after Session 2 via the *Credibility/Expectancy Questionnaire* (35).

Treatments.

TranS-C was administered by masters' level (and one doctoral level) therapists, hired within the University of California, Berkeley for this study, who traveled between the ACBHCS clinic sites. Clinicians attended a one-day workshop, used a treatment manual, and received weekly supervision to standardize treatment administration.

TranS-C was provided in 8 weekly individual 50-minute sessions. Underpinned by the Sleep Health framework (31), TranS-C includes 4 cross-cutting interventions featured in every session; 4 core modules that apply to the vast majority of participants; and 7 optional modules used less commonly, depending on the presentation (See Table 2). The modular design of

TranS-C as well as the personalized behavioral “prescriptions,” are responsive to the calls to ‘develop a *personalized approach* to the diverse needs and circumstances of people with mental illness’ (36).

Weekly supervision was conducted by AGH, MD or EF. Sessions were audio recorded. TranS-C treatment integrity was evaluated by AGH, MD or EF with the Cognitive Therapy Rating Scale (CTRS), on which a score of ≥40 is generally regarded as competent delivery (37). A checklist of TranS-C elements was used to rate the presence/absence of treatment elements for a random subset of tapes (38).

Usual Care followed by Delayed Treatment with TranS-C (UC-DT) within ACBHCS involved a case manager who co-ordinates care and refers each client for a medication review and to various rehabilitation programs (e.g., health care, housing, nutrition, physical activity, vocational, meditation group, tobacco cessation group, peer monitoring, ‘hearing voices’ group). The content of usual care was monitored using the Medication Tracking Log. As depicted in Figure 1, after 8 months in UC-DT, the participants received 8 sessions of TranS-C.

Trial Registration

We report the primary and secondary outcomes listed in the ClinicalTrials.gov protocol (NCT02469233). The update to the ClinicalTrials.gov protocol on December 19, 2019 was to remove nap timing and duration via sleep diary because naps were inconsistently reported and these data were poor quality.

Data Analysis

The sample size (N = 120) was determined by power analysis, assuming a medium effect for the average effect size across outcomes based on prior literature (15, 16, 39), a significance of 0.05, and power of 80%. The final sample size for analysis was 121 because during the final weeks of recruitment, there was one eligible participant already in the ‘assessment pipeline’. Prior to the analysis presented here, there was one analysis conducted

for the purpose of a grant application and conference presentation in July 2018, when over 75% of the data had been collected and entered.

Data were analyzed using Stata 15. All analyses were adjusted for age and whether or not the participant had a psychotic disorder, which were the stratification factors used during randomization. Intent-to-treat analysis was performed. Multilevel modeling with maximum likelihood estimation with the assumption of missing at random was used to examine the outcome variables, all modeled as continuous outcome variables. The fixed component of the model included stratification factors, dummy-coded indicator for time (0 = pre, 1 = post, 2 = 6FU), an indicator for treatment condition (0 = UC-DT, 1 = Immediate TranS-C), and a time-by-treatment interaction term. The random part of the model included a subjective-specific random intercept and a time- and subject-specific error term. A significant treatment-by-time interaction is the treatment effect of interest, as it is interpreted as the difference in mean change (for a given outcome variable) from pre-treatment to post-treatment and to 6FU contrasting TranS-C vs. UC-DT. The Benjamini-Hochberg procedure (40) was used to correct for multiple testing for confirmatory analyses on the primary outcomes (41, 42) (i.e., TranS-C effects on each of the 4 primary outcomes from pre-treatment to post-treatment and to 6FU). Assuming a 5% false discovery rate, all *p* values remain significant compared to the corresponding Benjamini-Hochberg critical values.

Results

Participant Characteristics

Figure 1 illustrates participant flow. Among randomized participants, dropout rates were 1.7% between randomization and Session 1, 9.9% through the post-treatment assessment, and 1 participant dropped out before 6FU. Attrition rates were significantly higher in TranS-C than UC-DT during the treatment phase (X^2=7.89, df=1, p=0.005), but not significantly different at 6FU (X^2=2.41, df=1, p=0.12). Relative to completers, participants who did not begin treatment or who dropped out were not significantly different on gender (X^2=0.09, df=1, p=0.76), age group

(above or below 50 years; X^2=2.15, *df*=1, *p*=0.14) or psychosis status (X^2=0.01, *df*=1, *p*=0.94). Table 3 shows the demographic and clinical characteristics of participants. The two treatment conditions did not differ on any of these variables.

Primary Outcomes

Descriptive statistics of all outcome variables are presented in Table 4. Multilevel modeling results are presented in Table 5. There was no group difference between TranS-C and UC-DT on any of the outcome variables at pre-treatment.

Among the primary outcomes, from pre-treatment to post-treatment, TranS-C had significant effects on all four primary outcomes, relative to UC-DT. Specifically, participants in TranS-C, relative to UC-DT, exhibited a significant reduction in SDS (*b*=-3.18, *p*=0.025), DSM-5 cross-cutting symptoms (*b*=-5.88, *p*=0.001), PROMIS-SD (*b*=-5.55, *p*<0.0001), and PROMIS-SRI (*b*=-9.14, *p*<0.0001). The treatment gains for TranS-C, relative to UC-DT, were maintained through 6FU for DSM-5 cross-cutting symptoms (*b*=-3.90, *p*=0.03), PROMIS-SD (*b*=-4.92, *p*<0.0001), and PROMIS-SRI (*b*=-5.37, *p*=0.027), but not for SDS.

Secondary Outcomes

Relative to UC-DT, participants in TranS-C had significantly reduced PSYRATS scores from pre-treatment to 6FU (*b*=-17.52, *p*=0.02). Among the sleep diary outcomes, participants in TranS-C had significantly improved sleep efficiency from pre-treatment to post-treatment (*b*=5.68, *p*=0.03) and 6FU (*b*=5.89, *p*=0.03), relative to UC-DT. Relative to UC-DT, TranS-C participants showed significantly reduced total wake time (*b*=-39.33, *p*=0.04) and reduced wake time variability (*b*=-0.39, *p*=0.047) from pre-treatment to post-treatment, and significantly earlier bedtime from pre-treatment to 6FU (*b*=-0.71, *p*=0.04). Among the actigraphy outcomes, participants in TranS-C showed significantly reduced variability in daily activity count (*b*=-0.27, *p*=0.02) from pre-treatment to 6FU. TranS-C did not show advantage over UC-DT on other outcomes.

For the Sleep Health Composite, TranS-C exhibited significantly improved sleep health from pre-treatment to post-treatment (b=0.91, p=0.002) and to 6FU (b=0.64, p=0.03), relative to UC-DT.

Treatment Integrity, Credibility and Fidelity

CTRS (n=203 recordings, M=51.08, SD=5.66, 98.5% 40 or over) indicate that TranS-C was delivered with fidelity. A checklist of TranS-C elements (38) (Table 2) was used to rate the presence/absence of treatment elements and non-TranS-C elements for a random subset of patients with no missing recordings (n=19; 31.15% of TranS-C participants). All 8 sessions of recordings for each patient were coded (n=152 sessions). 94.74% of patients received all 4 cross-cutting modules (100% received functional analysis, education, and motivational enhancement). 36.84% received all 4 core modules (100% Core Module 1, 68.42% Core Module 2, 57.89% Core Module 3, 100% Core Module 4). 100% received at least 1 optional module. No non-TranS-C elements were coded.

Medications

At study entry, 90/121 participants (74.4%) were taking prescription SMI medications and 16/121 participants (13.2%) were taking sleep medications. The mean±SD (median) number of medications per participant was 2.80±1.41 (3).

When considering each medication for each participant separately, the doses of 51.2% of SMI medications and 71.4% of sleep medications remained stable across the treatment phase. When considering all medications for a particular participant, 22.8% of participants remained on stable doses of all SMI medications and 68.4% remained on stable doses of all sleep medications across the treatment phase.

The percentage of TranS-C compared to UC-DT participants taking SMI medications was statistically similar at baseline (75.4% vs. 73.3%), post-treatment (73.8% vs. 66.7%), and 6FU (73.8% vs. 66.7%). There was no significant difference in the percentage of participants

discontinuing at least one SMI medication at some point during the treatment phase (0% vs. 0%) or during the 6FU (0% vs. 0.03%).

The percentage of TranS-C compared to UC-DT participants taking sleep medications was statistically similar at baseline (11.5% vs. 15.0%), post-treatment (13.1% vs. 13.3%), and 6FU (16.4% vs. 13.3%). There was no significant difference in the percentage of participants discontinuing at least one sleep medication at some point during the treatment phase (0% vs. 0%) or during the 6FU (0% vs. 0%).

Discussion

Relative to UC-DT, TranS-C was associated with improvement from pre-treatment to post-treatment for all primary outcomes. This finding confirms our hypothesis that, at post-treatment, TranS-C was superior to UC-DT for functional impairment, disorder-focused symptoms, and sleep and circadian function. These findings were retained at the 6FU for all outcomes except functional impairment, although the mean values were in the hypothesized direction. These findings replicate prior research showing that sleep treatments improve functioning, symptoms of comorbid mental health conditions as well as sleep and circadian functioning (9, 10). In addition, these findings extend prior research by testing a transdiagnostic treatment designed to address a range of sleep and circadian problems experienced by a mixed diagnosis SMI sample in a community setting. CMHC settings are critically important as they treat the poorest and most under-served members of our community, as evident from the demographics in Table 3.

Secondary outcomes were included to index three disorder-focused symptoms: depression, substance use, and hallucinations and delusions. Reduced hallucinations and delusions were observed for TranS-C, relative to UC-DT, from pre-treatment to 6FU. This finding is consistent with prior epidemiological (43) and treatment research (44) showing a tight coupling of psychotic symptoms and sleep. While the total score for depression did not yield a significant difference between the treatments, an inspection of the mean values suggests a non-

significant advantage on depression for TranS-C, relative to UC-DT. Also, the mean QIDS score for both groups started in the 'moderate depression range'. First, this level of depression may constitute a floor-like effect. Second, at the post-treatment and 6FU assessments, the UC-DT group stayed in this range. In contrast, at post and 6FU the mean QIDS score moved to the 'mild range' for the TranS-C group. These non-significant findings are in line with multiple prior studies showing an improvement to depression following sleep treatment (45). The total score for the measure of alcohol, smoking and substance use also did not yield a significant difference between the treatments. Substance abuse/dependence was exclusionary if it made study participation infeasible. This may have contributed to a restricted range of substance use in the sample. Importantly, the time frame for the ASSIST is the past 3 months or lifetime. At the post-treatment assessment, we assessed the past 2 weeks so the timeframe did not cover the pre-treatment timepoint. For this reason, the mean of the ASSIST is lower at the post-treatment assessment, relative to the pre-treatment or 6FU assessments. This may have contributed to the null results.

Before discussing the sleep diary and actigraphy outcomes, it is important to note that these variables suffer from wide inclusion gates inherent to transdiagnostic research. For example, TST that is too long *and* too short is indicative of poor sleep health (31). Hence, reducing TST *and* increasing TST can both be treatment goals within TranS-C. Therefore, mean TST does not accurately reflect treatment change. This is also the case for WT. Within TranS-C, the treatment goal for some participants is to wake earlier (e.g., a patient who sleeps until noon), while for others the goal is to wake later (e.g., a patient who wakes at 4:30am). Again, the mean WT value will not provide an index of the impact of treatment for a transdiagnostic sample. To address these problems, we have developed a new outcome measure called the Sleep Health Composite (32). This is derived from the Sleep Health Framework (31) which encourages sleep improvement along six dimensions that have been linked to mental and physical health outcomes. The Sleep Health Composite combines sleep diary and global indices

of sleep for the six dimensions: *regularity* of sleep and waking up; *satisfaction* with sleep or sleep quality; *alertness* during waking hours or daytime sleepiness; appropriate *timing* of the patient's sleep within the 24-hour day; *sleep efficiency,* or the ability to sleep for a large percentage of the time in bed, as indicated by ease of falling asleep at the beginning of the night and ease of returning to sleep after awakenings across the night; and *sleep duration,* which is the total amount of sleep obtained per 24 hours. On this novel metric, TranS-C exhibited improved sleep health from pre-treatment to post-treatment to 6FU, relative to UC-DT.

For the daily sleep diary outcomes, relative to UC-DT, TranS-C was associated with improved sleep efficiency at all assessment timepoints. Also, relative to UC-DT, TranS-C participants showed reduced total wake time and reduced wake time variability from pre-treatment to post-treatment, and significantly earlier bedtime from pre-treatment to 6FU. Interestingly, an inspection of the mean values for sleep diary suggests a non-significant advantage to TranS-C for TST (which increased by 33 mins from pre-treatment to 6FU, relative to 13 mins for UC-DT) and TWT (which decreased by 40 mins from pre-treatment to 6FU, relative to 13 mins for UC-DT). Among the actigraphy outcomes, participants in TranS-C showed significantly reduced variability in daily activity count from pre-treatment to 6FU. TranS-C did not show an advantage over UC-DT on other outcomes. Given the problem of the wide transdiagnostic inclusion gates discussed above, we were perhaps not surprised that some of the traditional sleep diary and actigraphy sleep parameters were not significant. Future research is needed to update sleep diary and actigraphy reporting standards (46) for transdiagnostic samples. There are two other possible contributors to the lack of treatment effects for actigraphy. The GT9X Link from ActiGraph doesn't have an event marker which may have reduced validity (47). Also, anecdotally many participants in this sample reported spending substantial periods engaging in motionless behaviors (e.g., watching television), which may have been incorrectly recorded as sleep.

There are several limitations to this study that warrant consideration. Fidelity to the core modules was lower than expected. While there was 100% fidelity to Core Module 1 (Irregular sleep-wake times, difficulty winding down, difficulty waking-up) and Core Module 4 (Maintenance of behavior change), only 68% of cases received Core Module 2 (Daytime impairment) and 58% received Core Module 3 (Unhelpful beliefs about sleep). These modules may be harder to identify. It is also possible that, due to the severity of impairment present for some individuals, the provider focused on the very basic building blocks of sleep health (i.e., Core Modules 1 and 2). In addition, despite substantial racial-ethnic and socioeconomic diversity in the study population, recruitment from a single site may limit potential generalizability.

In summary, this study adds to the evidence that dysregulated sleep and circadian rhythms in SMI are important and understudied maintaining mechanisms. The findings are consistent with the conceptual model that sleep and circadian dysfunction contribute to vicious cycles of escalating symptoms, vulnerability, and risk in SMI (48). The findings also underscore the potential of a transdiagnostic treatment designed to treat a wide range of sleep and circadian problems experienced by adults with a wide range of SMI and suggests the viability of a novel outcome measure: the Sleep Health Composite. Importantly, this study was conducted in a community mental health setting. This represents a step toward bridging the large gap between research and routine practice. The encouraging results reported raise the possibility that TranS-C is a candidate for dissemination to improve SMI outcomes in community settings. Given that the providers for this study were employed, trained and supervised within a university setting, an important next step is to determine if similar results are obtained by community-based providers.

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Table 1. Sleep Health Composite Score Cut-Off

Dimension	Measure	Definition/Cut-off
Regularity	Midpoint fluctuation across the 7-day sleep diary	Poor (coded 0) = *SD* of midpoint sleep >= 1 hour Good (coded 1) = *SD* of midpoint sleep < 1 hour
Satisfaction	Sleep quality question on PROMIS-SD: item 8 "My sleep quality was: very poor, poor, fair, good, very good"	Poor (coded 0) = "very poor" or "poor" or "fair" Good (coded 1) = "good" or "very good"
Alertness	Daytime sleepiness question on PROMIS-SRI: Item 13: "I was sleepy during the day time: not at all, a little bit, somewhat, quite a bit, very much"	Poor (coded 0) = "somewhat" or "quite a bit" or "very much" Good (coded 1) = "good" or "very good"
Timing	Mean midpoint across the 7-day sleep diary	Poor (coded 0) = Midpoint <= 2 am or >= 4 am Good (coded 1) = Midpoint between 2 am and 4 am
Efficiency	Sleep efficiency based on the 7-day sleep diary	Poor (coded 0) = SE < 85% Good (coded 1) = SE >= 85%
Duration	Total Sleep Time based on 7-day sleep diary	Poor (coded 0) = TST <7.0 or > 9.0 hours Good (coded 1) = TST between 7 and 9 hours

Table 2. Summary of TranS-C

Cross-Cutting Modules				Common Sleep-Circadian (S-C) Problems experienced by SMI Clients	Treatment Module
Functional Analysis	Education	Motivational Enhancement	Goal Setting	Irregular sleep-wake times	Core Module 1
				Difficulty winding down	Core Module 1
				Difficulty waking up	Core Module 1
				Daytime impairment	Core Module 2
				Unhelpful beliefs about sleep	Core Module 3
				Poor sleep-efficiency	Optional Module 1
				Too much time in bed	Optional Module 2
				Delayed or Advanced phase	Optional Module 3
				Sleep-related worry	Optional Module 4
				Promoting compliance with CPAP/ Exposure Therapy for claustrophobic reactions to CPAP	Optional Module 5
				Negotiating sleep in a complicated environment (e.g., group home)	Optional Module 6
				Nightmares	Optional Module 7
				Maintenance of behavior change	Core Module 4

Table 3. Baseline Demographic and Clinical Characteristics of Patients in Both Treatment Conditions

	UC-DT (n = 60)		TranS-C (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
Education				
High school or below	22	36.67	19	31.14
Vocational school	2	3.34	9	14.76
Some college or completed college	34	56.67	30	49.18
Graduate school	2	3.34	3	4.92
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
MINI Diagnosis at pre-treatment (current or past)[b]				
Schizophrenia spectrum disorder	29	49.15	26	43.33
Bipolar disorder	13	22.03	21	35.00
Major depressive disorder	17	28.81	11	18.33
Any anxiety disorder	27	45.76	30	50.00

Obsessive compulsive disorder	13	22.03	9	15.00
Post-traumatic stress disorder	12	20.34	6	10.00
Substance Use Disorder	20	33.90	19	31.67
Psychotic symptoms/features	42	71.19	39	65.00
DUKE diagnoses at pre-treatment (current)[b]				
Insomnia disorder	49	81.67	52	85.25
Hypersomnolence disorder	14	23.33	17	27.87
Circadian Rhythm Disorder				
Delayed sleep phase type	5	8.33	3	4.92
Advanced sleep phase type	0	0.00	2	3.28
Irregular sleep-wake type	0	0.00	1	1.64
Restless leg syndrome	3	5.00	2	3.28
Periodic limb movement disorder	4	6.67	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. [b] Comorbidity was common.

Table 4. Descriptive statistics of outcome variables.

	Pre				Post				FU			
	UC-DT		TranS-C		UC-DT		TranS-C		UC-DT		TranS-C	
Variable	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*
Primary Outcomes												
SDS	14.30	8.51	12.03	6.20	11.76	7.57	6.57	7.07	10.51	8.36	7.00	6.41
DSM5 Cross-Cutting Measure	25.57	10.72	25.05	9.75	23.53	10.59	17.00	11.23	23.07	9.78	18.67	11.38
PROMIS-SD	29.02	6.57	28.26	6.06	27.33	7.22	20.88	8.91	26.40	8.00	20.87	8.50
PROMIS-SRI	51.02	14.09	47.93	11.80	47.22	14.14	35.16	14.01	44.30	15.22	35.65	13.83
Secondary Outcomes												
QIDS	12.50	4.71	12.03	5.15	10.55	5.54	8.88	5.70	10.67	4.58	8.46	5.03
ASSIST	33.68	25.87	39.70	26.68	14.62	17.15	15.35	17.13	32.58	25.25	34.60	24.10
PSYRATS	36.60	5.13	39.60	14.29	41.73	11.39	36.00	14.82	42.58	9.44	25.80	11.23
WHODAS	81.53	25.56	76.48	21.38	81.48	26.80	68.93	25.53	73.45	26.14	66.63	23.17
Healthy Days Overall Health	3.57	1.17	3.44	1.03	3.40	1.26	3.37	1.27	3.40	1.26	3.37	1.27
Sleep Diary												
SE mean	77.61	11.89	77.39	13.52	78.93	14.50	84.31	10.07	79.54	12.88	84.78	10.86
SE variability	12.52	7.63	11.92	6.71	11.86	8.49	10.01	7.95	11.25	6.71	9.24	7.87
TST mean	452.42	101.37	431.06	111.47	459.09	100.16	450.71	92.77	465.23	115.13	464.90	106.54
TST variability	109.59	55.14	103.96	46.37	123.59	79.11	96.50	97.84	99.30	52.38	90.87	58.77
TWT mean	131.89	80.47	124.84	75.03	131.29	116.57	84.37	49.45	118.92	77.55	83.55	65.53
TWT variability	77.85	54.92	74.04	46.48	82.07	77.64	61.33	62.27	73.27	47.70	52.69	52.56
Bedtime mean	22.20	1.95	22.17	2.36	22.39	1.56	22.00	1.65	22.41	1.88	21.96	2.13
Bedtime variability	1.39	1.06	1.28	0.79	1.41	1.07	1.01	0.93	1.55	1.32	1.00	0.68
Waketime mean	7.90	1.83	7.31	2.02	8.26	2.25	7.31	1.82	7.95	1.83	7.33	1.74
Waketime variability	1.42	0.88	1.34	1.00	1.61	1.11	1.10	1.08	1.22	0.69	1.26	0.95
Actigraphy												
TST mean	421.35	126.92	453.65	147.28	411.82	108.28	427.23	135.85	443.24	119.47	437.69	137.88
TST variability	132.08	75.83	132.34	79.71	135.38	75.05	140.06	95.02	144.86	88.72	134.43	96.75
TWT mean	91.06	41.52	94.95	55.18	91.39	48.65	90.80	44.85	92.73	41.87	84.51	45.84
TWT variability	55.65	51.16	54.46	48.26	60.36	68.61	51.72	41.86	56.22	48.70	41.41	30.65
Day time activity count mean	1309.74	532.79	1280.09	607.46	1361.19	532.36	1257.82	680.06	1362.37	598.01	1281.35	667.83
Day time activity count variability	379.69	211.65	394.04	256.07	393.58	223.01	371.08	310.24	447.29	257.81	354.96	212.71
Sleep health composite	2.28	1.29	2.54	1.60	2.34	1.33	3.45	1.39	2.53	1.39	3.38	1.64

Table 5. Multilevel Modeling Results for Primary and Secondary Outcomes

	Treatment Effect at Baseline			Treatment Effect on Change from Pre to Post			Treatment Effect on Change from Pre to FU6		
	Coef.	*SE*	*p*	*Coef.*	*SE*	*p*	*Coef.*	*SE*	*p*
Primary Outcomes									
SDS	-2.18	1.34	0.10	-3.18	1.42	0.025	-1.52	1.40	0.28
DSM5 Cross-Cutting Measure	-0.25	1.89	0.89	-5.88	1.81	0.001	-3.90	1.79	0.03
PROMIS-SD	-0.85	1.33	0.52	-5.55	1.31	<0.0001	-4.92	1.30	<0.0001
PROMIS-SRI	-2.92	2.49	0.24	-9.14	2.44	<0.0001	-5.37	2.42	0.027
Secondary Outcomes									
QIDS	-0.62	0.92	0.50	-0.95	0.95	0.32	-1.67	0.94	0.08
ASSIST	0.26	0.24	0.26	-0.09	0.24	0.72	-0.08	0.23	0.74
PSYRATS	0.87	5.84	0.88	-2.46	7.08	0.73	-17.52	7.54	0.02
WHODAS	-4.87	4.42	0.27	-7.19	4.18	0.09	-1.13	4.16	0.79
CDC Healthy Days: Overall Health	-0.12	0.20	0.55	0.16	0.21	0.46	-0.34	0.21	0.10
Sleep Diary									
SE mean (min)	-0.46	2.35	0.85	5.68	2.67	0.03	5.89	2.64	0.03
SE variability (min)	-0.33	1.45	0.82	-1.45	1.86	0.43	-1.55	1.84	0.40
TST mean (min)	-24.98	19.33	0.20	24.85	20.60	0.23	34.31	20.36	0.09
TST variability (min)	-3.08	12.89	0.81	-19.90	15.23	0.19	-1.76	15.07	0.91
TWT mean (min)	-6.18	15.62	0.69	-39.33	18.83	0.04	-28.56	18.64	0.13
TWT variability (min)	-2.20	11.18	0.84	-17.57	14.11	0.21	-16.05	13.97	0.25
BT mean	0.06	0.36	0.87	-0.55	0.34	0.10	-0.71	0.34	0.04
BT variability	-0.08	0.19	0.68	-0.31	0.25	0.20	-0.45	0.25	0.07
WT mean	-0.57	0.35	0.11	-0.33	0.38	0.39	-0.02	0.38	0.96
WT variability	-0.10	0.18	0.59	-0.39	0.20	0.047	0.20	0.20	0.30
Actigraphy									
TST mean (min)	36.92	23.14	0.11	-12.68	23.42	0.59	-28.33	23.30	0.22
TST variability (min)	0.15	15.44	0.99	4.65	18.72	0.80	-7.57	18.63	0.68
TWT mean (min)	4.16	8.48	0.62	-4.42	10.14	0.66	-13.34	10.09	0.19
TWT variability (min)	-0.005	0.13	0.97	-0.05	0.17	0.77	-0.22	0.17	0.20
Daytime activity count mean	-41.19	107.66	0.70	-76.85	80.83	0.34	-87.15	79.93	0.28

Daytime activity count variability	0.01	0.10	0.95	-0.15	0.11	0.18	-0.27	0.11	0.02
Sleep health composite	0.26	0.26	0.32	0.91	0.30	0.002	0.64	0.30	0.03

Note. SDS = Sheehan Disability Scale. DSM 5 DSM-5 Cross-Cutting Measure. PROMIS-SD = Patient-Reported Outcomes Measurement Information System–Sleep Disturbance. PROMIS-SRI = Patient-Reported Outcomes Measurement Information System– Sleep-Related Impairment. QIDS = Quick Inventory of Depressive Symptoms. ASSIST = Alcohol, Smoking and Substance Involvement Screening Test. PSYRATS = Psychotic Symptoms Rating Scales. WHODAS = World Health Organization Disability Assessment Schedule 2.0. CDC Healthy Days: overall health question from the 4-question healthy days core module developed by the Centers for Disease Control and Prevention. SE = sleep efficiency (total sleep time/time in bed × 100). TST = total sleep time. TWT = total wake time. BT = bedtime, WT = wake time. All the *p*-values in bold are the exact *p*-values and remained significant after applying the Benjamini-Hochberg procedure with a 5% false discovery rate assumed.