Sleep Treatment for Teens (RCT Phase)

NCT07303959

Status	RECRUITING
Phase	Not Applicable
Sponsor	Rutgers, The State University of New Jersey
Enrollment	80 participants

Key Eligibility Criteria

Inclusion (4)

- Age 14-18 years old.
- Recent hospitalization due to suicide risk (i.e., suicide attempts, aborted/interrupted attempts, or suicide ideation with intent and/or a plan) using an abbreviated version of the semi-structured and well-validated Columbia Suicide Severity Rating Scale (C-SSRS; Posner et al., 2011). Regarding recency, adolescents will need to complete the baseline within three months (Study 1) or 45 days (Study 2) of discharge in order to capture the high-risk post-discharge period, which is up to 3 months following discharge from acute psychiatric hospitalization (Chung et al., 2017).
- Clinically significant insomnia symptoms: SCI scores d16 will be used to recruit a sample with clinically significant insomnia symptoms. The ISI will also be administered to gain additional information about the nature of adolescents' sleep problems in order to confirm primary insomnia. ISI scores may also be obtained via chart review when applicable
- Access to or willingness to use a compatible Smart Device. SleepioTM works with any internet connection (cellular or Wifi) on any iOS device running iOS 10.3 or later or on any Android device running Android OS 8.0 or later. Metricwire is compatible with all devices that SleepioTM is compatible with. If an interested adolescent does not have access to their own smart device, the research team will offer them a loaner device for the duration of the treatment/follow-up phase.

Exclusion (7)

- Prior CBT-I treatment, which would indicate lack of response to a prior reasonable dose of this treatment.
- Bipolar disorder given that certain components of CBT-I (e.g., sleep restriction) may be risky for this population.
- Substance use disorder that is primary to insomnia which would require alternative treatment.
- Presence of factors that may reduce participants' ability to consent or complete the study procedures (e.g., current psychosis, other-directed violence; severe cognitive impairment, non-English speaking).
- Unwillingness to wear wrist actigraphy or complete the EMA surveys.

... and 2 more (see full listing online)

Locations (2 total)

Rutgers University Behavioral Healthcare, Piscataway, New Jersey, United States
Children's Hospital of The King's Daughters, Norfolk, Virginia, United States