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Research Article

A pilot study of a brief intervention program (RECHARGE) to reduce sleep-wake and circadian rhythm disturbances in youth being treated for depression

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Abstract

Aim: Sleep-wake and circadian rhythm disturbances are linked to the emergence and persistence of depression in youth. However, few youth-specific interventions have been developed to address these problems in clinical settings. We aimed to test the efficacy of a novel program targeted at sleep-wake and circadian rhythm problems in youth with depression.

Methods: Adolescents and young adults with depression and sleep-wake disturbances were invited to join the 8-week RECHARGE program. Outcomes of interest were pre- to post-intervention changes in self-reported sleep-wake patterns and circadian preference, actigraphy recordings of circadian sleep rhythms, and depressive symptoms.

Results: 10 individuals completed the RECHARGE program showed modest improvements in self-reported sleep-wake patterns and circadian rhythmicity as measured by actigraphy; however these did not explain a significant portion of the variance in post-intervention

depression scores.

Conclusions: Modest trends for some sleep-wake and circadian parameters indicate that future investigation of a modified RECHARGE program is merited.

Keywords: Youth; Depression; Sleep-Wake; Circadian Rhythm; Intervention

Introduction

In adolescents and young adults, depression is ranked as the most burdensome disorder worldwide [1]. Early onset depression cases frequently have a poorer prognosis and greater illness burden than later onset cases, implying that targeted early intervention may be justified [2,3,4]. Potential targets that are of considerable interest to mood disorder researchers are sleep-wake and circadian rhythm disturbances, as disruptions in many of these phenomena may overlap with the symptoms of mood episodes or may trigger or prolong mood symptoms [5,6]. In youth with mood disorders, evidence shows that sleep-wake and circadian rhythm disturbances may adversely affect the course of depression, including slower response to treatment [7], as well as being associated with early recurrence of major depressive disorder (MDD) in recovered adolescents [8,9]. Thus targeting sleep-wake and circadian rhythm disturbances as an adjunct to treatment in youth with mood disorders could be an important avenue for research [10,11]

Currently available treatments that target sleep-wake and circadian rhythm disturbances include pharmacological (e.g. melatonin agonists), non-pharmacological (e.g. chronotherapies such as bright light therapy; BLT), and psychological (e.g. cognitive-behavioral therapy for insomnia; CBT-I) interventions. These interventions seek to stabilize sleep-wake and circadian systems by shifting the timing of sleep-wake behaviors and modifying light exposure. Some, but not all, of these interventions have been used as an adjunctive treatment for major depression as it is hypothesized that the improvements in sleep-wake patterns help to further reduce depression severity and symptoms [12]

However, the lack of well-tested non-pharmacological sleep-wake and/or circadian rhythm interventions for clinical youth has hindered research in this area. While results from several trials of sleep-wake and circadian rhythm interventions in improving sleep-wake and circadian disturbances in depressed adults are promising [13,14], developmental differences between youth and adult sleep-wake and circadian systems argue for youth-specific interventions [15]. This is most notable in the post-pubertal period where there are peak phase delays in sleep-wake cycles and circadian rhythms (Hagenauer et al., 2009), which importantly are more pronounced in youth with mood disorders [6,16].

Youth are also among the most difficult age group to engage in treatment, including high rates of skipping sessions and premature termination [10], where greater outcomes for this group could be expected if engagement in care is increased. Technology is one aspect of life with which young people are strongly engaged [17], and may offer an opportunity to enhance engagement in treatment for youth with mood disorders. Studies of interventions involving technology conducted with clinical youth

samples have shown increased program adherence and completion [18,19], low drop outs [20], and increased effect sizes compared to non-technological treatments [21].

Of the sleep-wake and circadian interventions that have been trialed in youth with mood disorders, most, surprisingly, have neglected to examine sleep-wake and circadian rhythms as outcome measures. The majority of studies have focused on measures of depression alone, which, although important, has restricted clarification of intervention specificity (i.e. whether the intervention effects are influenced by specific sleep-wake/circadian rhythm techniques and not common factors shared between interventions for mood disorders in general). Those that have attempted to assess sleep-wake cycles have extracted measures of sleep profiles, which provide limited information on sleep-wake cycles or circadian rhythms as distinctly different phenomena (i.e. representative of the entire 24 hour activity profile). A further difficulty is that studies have favored self-report measures (also primarily of sleep profiles) over objective assessments of sleep-wake and circadian rhythms. Only two studies have utilized actigraphy as an objective measurement tool [22,23]; however again sleep parameters were extracted from the output (e.g. sleep onset latency; waking after sleep onset, total sleep time).

There is a growing research literature on actigraphic measures of circadian rhythms in youth, however many researchers and/or clinicians are unfamiliar with the relevance of some measures and are uncertain how to select and interpret pertinent circadian parameters [24]. As such, it can be helpful to select easily interpretable circadian markers that have identified differences in young people with unipolar (UP) and bipolar disorder (BD), including amplitude, acrophase and circadian rhythmicity index. Studies report lower 24-hour activity rhythms (amplitude) for UP and BD youth [25-28], delayed timing of maximal activity within a 24 hr period (acrophase) [6,28,29], and that a longer duration of illness was correlated with reduced robustness of rhythms (circadian rhythmicity) [28]. These circadian parameters, and particularly circadian rhythmicity, could be an interesting avenue for sleep-wake and circadian rhythm intervention research. Indeed [28] recently demonstrated that rhythmicity was less robust in BP youth with more severe manic and depressive symptoms, and may represent an important intervention target for young people who are at a higher risk of severe depression illness course.

Given the findings outlined above, we decided to pilot a novel youth-specific intervention targeted at improving sleep-wake and circadian sleep disturbances in adolescents and young adults being treated for depression. The 8-week program, called RECHARGE, involved four sessions aimed at developing healthy sleep-wake and circadian rhythm patterns *via* a technological app called RECHARGE. We focused on change in sleep-wake and circadian sleep rhythms using established self-report measures and objective actigraphic assessment of three easily interpretable circadian parameters; amplitude, acrophase, and circadian rhythmicity. This paper reports the findings of the initial case series.

Methods

Participants

Study approval was obtained from the Human Research Ethics Committee

(HREC) of The University of Sydney (project number 2015/496). Individuals aged 16 to 30 years seeking professional help primarily for significant depressive symptoms were recruited from a youth-focused mental health service headspace; [30] located in Camper down in Sydney, Australia.

Inclusion criterion was a DSM-IV diagnosis of MDD [31] at intake determined by a standard clinical interview with a trained clinician at headspace. Individuals with comorbidities considered secondary to MDD were not excluded as sleep-wake disturbances and depression are commonly comorbid with a range of psychiatric disorders and exclusion would have reduced the representativeness of the sample.

Additional inclusion and exclusion criteria were determined in a further screening assessment with the program facilitator. This screening assessment included the Pittsburgh Sleep Quality Index PSQI [32], as well as study specific questions pertaining to sleep apnoea, alcohol and substance use disorders, shift work, and recent trans-meridian travel. Individuals self-reporting significant sleep-wake disturbance over the last month (indicated by a global PSQI score greater than 5) were considered eligible. Individuals were excluded if they identified as having sleep apnoea, comorbid alcohol or substance use disorder, engaged in shift work, or had evidence of recent travel across time zones. Individuals who met eligibility criteria and gave written informed consent were then invited to an appointment to complete the pre-intervention assessment.

Assessments

The following measures were collected at a pre- and post-intervention assessment interview with the program facilitator. The pre-intervention assessment was at the end of the initial actigraphy recording period (i.e. immediately before the commencement of RECHARGE), and the post-intervention assessment was at the end of the final actigraphy recording period (i.e. two weeks after the finish of RECHARGE).

Depression severity:

This was assessed using the self-rated Quick Inventory of Depressive Symptomology for Youth [33]. Questionnaire items are rated on a 4-point Likert scale and combined to provide total scores ranging from 0 to 27, with a score of 10-15 indicative of a moderately severe depression [33].

Sleep-wake cycles and circadian rhythm:

The PSQI [32] was repeated in the pre-intervention assessment as a subjective assessment of sleep-wake patterns across the last month. We assessed only the global score. A higher score is indicative of worse sleep-wake difficulties and a total score of ≥ 5 suggests significant sleep-wake problems. The Morning-Eveningness Questionnaire [34] assessed subjective circadian preference (chronotype). Total MEQ scores can range from 16 to 86, with a score of ≤ 41 indicative of “evening types”, scores between 42 and 58 indicative of “intermediate types”, and scores of ≥59 indicative of “morning types”.

Objective data on circadian rhythms was acquired every 30 seconds using an actigraphy watch (GENEactiv,

Activinsights Ltd, UK); a wrist-worn device that assesses patterns (rather than snapshots) of rest and activity across a 14-day period. Actigraphy recordings were collected for two weeks before program commencement and for the two weeks immediately following the completion of the program. To characterize the circadian profile of the activity-rest cycle, individual actigraphy datasets were fitted to an extended Cosinor model using GraphPad Software. For this study, we extracted three easily interpretable circadian rhythm parameters from the characterized circadian profile that have been highlighted as markers of circadian rhythm disturbance in UP and BP youth [25-29]:

1) Amplitude: a measure of the range of activity levels across the 24-h period. Higher scores indicate a higher level of activity.

2) Acrophase: a phase marker that can be used as a measure of an advance or delay in the peak of the activity rhythm. Scores indicate the timing of the peak, with later times indicating a more delayed phase.

3) Circadian rhythmicity: an indicator of the strength or robustness of circadian activity rhythms. The circadian rhythmicity index is a 'goodness of fit' measure and higher values indicate more robust rhythms.

Intervention

Following the pre-intervention assessment, the participant was asked to attend the RECHARGE program, which was delivered at the Brain and Mind Centre (BMC) in central Sydney. The RECHARGE program comprised of four sessions lasting between 1-2 hours each that were delivered at fortnightly intervals over the eight weeks, and were delivered in accordance with a program manual by a program facilitator with minimum four-year university qualification in psychology. The first session oriented participants to the problem of sleep-wake and circadian rhythm disturbance and its relationship to depression, followed by training on how to use the RECHARGE app to target these disturbances. Specifically, the RECHARGE app helps individuals to create a personalized sleep-wake and circadian rhythm schedule, and utilize the schedule to guide incremental shifts in wake timing, increases in morning light exposure, and increases in physical exercise. The following sessions focused on skill development for improving sleep-wake and circadian rhythms in accordance with the personalized schedule created by the RECHARGE app. The program then concluded with training to try to prevent the recurrence of sleep-wake cycle and circadian sleep disturbances (see Table 1 for a detailed overview of program content).

Table (1): RECHARGE program content

Session	Content
1	Psych education on sleep-wake cycles/circadian rhythm; visual exercises on identifying unhealthy behaviors; training on use of *Recharge* app and creating a healthy daily activity schedule.
2	Personalized analysis of *Recharge* app adherence; examination of efficacy/suitability of current behavioral regulation strategies; goal setting.
3	Personalized analysis of *Recharge* app adherence; examination of efficacy/suitability of current behavioral regulation strategies; goal review.
4	Personalized analysis of *Recharge* app adherence; examination of efficacy/suitability of behavioral regulation strategies; goal review and long term goal setting; psych education about lapses and relapses in sleep-wake cycles and circadian rhythm; structured problem solving exercises for relapse management and prevention.

Statistical Analyses

Statistical analyses were performed using SPSS version 22 (IBM SPSS Statistics, 2014). We report means (with standard deviations: S.D.) or frequencies (numbers or percentages) to describe the baseline characteristics of the sample and pre- and post-intervention scores for each measure. The statistical analyses proceeded in three steps:

1) Descriptive analysis: Paired t-tests were used to examine pre- to post-intervention changes in the QIDS, PSQI, MEQ, and circadian rhythm variables (acrophase, amplitude, and rhythmicity).
2) Magnitude of change: in order to evaluate whether our novel program impacted on outcomes in the pilot case series design, we estimated the effect sizes (ES) for any pre- to post-intervention variables that demonstrated a $p \leq 0.1$ in the univariate analyses (paired t-test), corrected for the within subject design and referred to as the ESr [35]. An ESr >.8 was regarded as large, and an ESr < 0.3 was regarded as small [36].
3) Identification of key markers of change: as some variables are known to be highly likely to share significant associations with each other (e.g. sleep-wake variables), we used Backward Stepwise Linear Regression (BSLR) to identify the amount of variance in depression severity at post-intervention (over and above baseline depression level) that was explained by changes in sleep-wake and circadian markers pre- to post-intervention. Given the small sample size, we only included variables in the equation that demonstrated a $p<0.1$ in the univariate analyses (paired t-test). Prior to undertaking the analysis, we confirmed that the data met the assumptions of regression analyses: normality, homogeneity of variance.

Results

Eleven of the 17 individuals referred to the study completed the consent procedure. However, one further individual dropped out prior to undertaking any pre-intervention assessments (see Figure 1).

The ten participants in the RECHARGE program were attending appointments with a clinician and 80% (n = 8/10) were being prescribed antidepressant medications. Sample means and SDs for demographic, depression severity, and sleep-wake cycles and circadian rhythm variables at pre-intervention are reported in (Table 2).

Figure (1): Participant flow

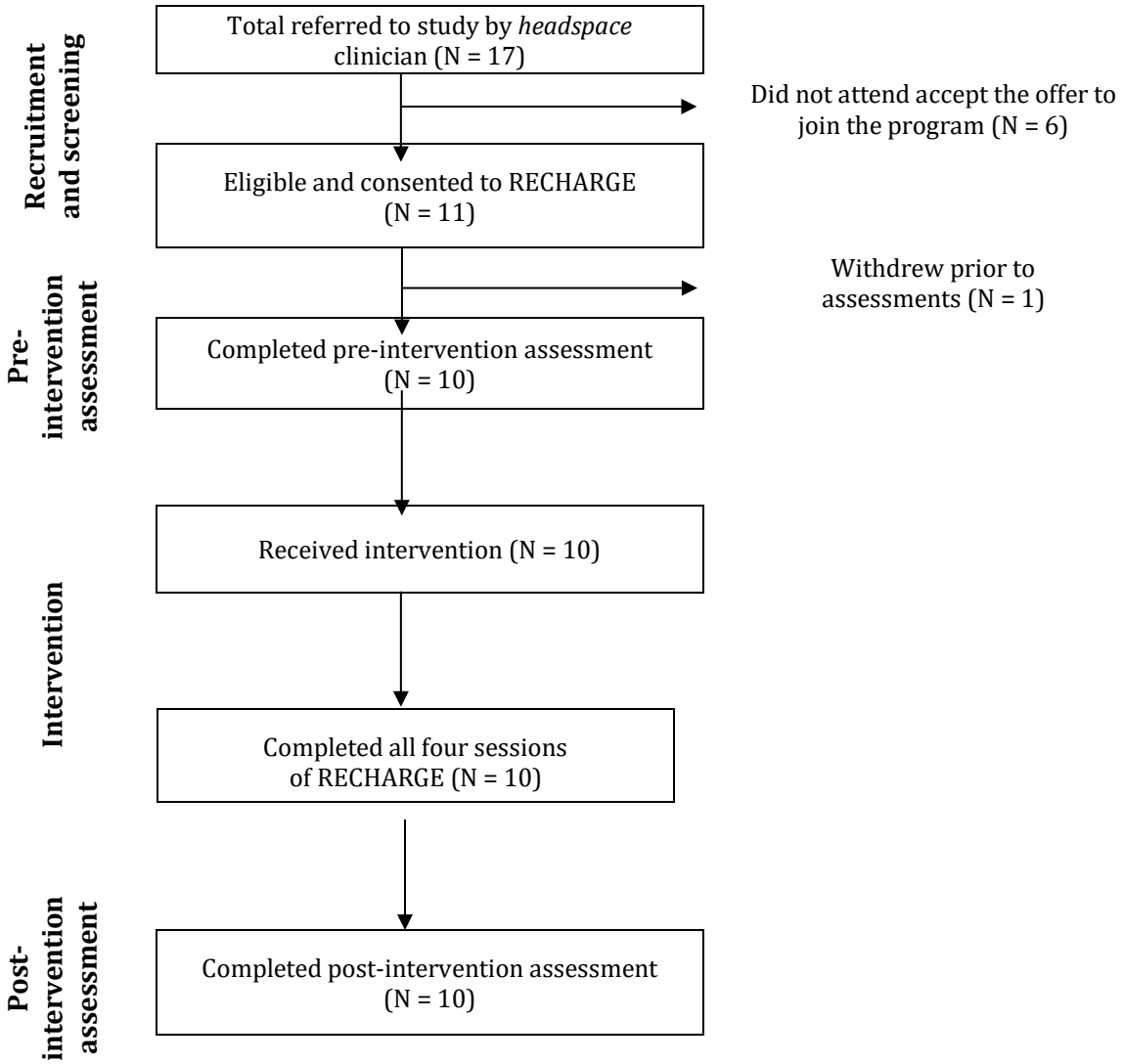

Table (2): Demographic and clinical characteristics of ten study participants

	***N* (%)**
Female	6 (60)
DSM-5 primary diagnosis of bipolar disorder	5 (50)
DSM-5 secondary diagnosis of an Axis I disorder	9 (90)
Medication use	
Antidepressants	8 (80)
Antipsychotics	2 (20)
Mood stablizers	5 (50)
Other	3 (30)
	M (S.D)
Age, years	22.81 (3.97)
Quick Inventory of Depression Scale (QIDS) score	15.2 (4.34)
Morning Eveningness Questionnaire (MEQ) score	42.2 (6.51)
Pittsburgh Sleep Quality Index (PSQI) score	9.4 (3.66)
Amplitude	.61 (.19)
Acrophase	15.89 (.86)
Rhythmicity	.30 (.16)

N = number of cases; % = frequency; M = mean; S.D. = standard deviation

Change in depression and sleep-wake

Cycles/circadian rhythms

Comparisons of pre- and post-intervention measures are shown in Table 3. The paired t-tests demonstrated statistically significant improvements pre-to post-intervention in self-rated depression ($p = .004$), and self-reported PSQI scores ($p = .005$). Pre- to post-intervention changes in rhythmicity showed a trend towards significant improvement ($p = .089$).

The magnitude of change was greatest for overall improvement in depression symptoms (ESr for QIDS = .56), with a moderate effect size improvement in PSQI (ESr = .31) and a small effect size improvement in rhythmicity (ESr = .14).

The BSLR analysis demonstrated that baseline QIDS score explained 20.2% of the variance in QIDS scores at post-intervention, whilst the combination of change in PSQI total score and in circadian rhythmicity (r^2) explained an additional 9.4% of the variance in post-intervention QIDS score. However, the overall model was non-significant.

Table (3): Mean scores on outcome measures at pre- and post-intervention assessment

		Pre-intervention		*Post-intervention*		Statistics		
Measures		*M*	*SD*	*M*	*SD*	*t (df 9)*	*p*	*ES r*
QIDS [a]		**15.2**	**4.34**	**9.30**	**4.21**	**3.85**	**.004**	**.56**
PSQI [b]		**9.40**	**3.66**	**7.10**	**3.31**	**3.74**	**.005**	**.31**
MEQ [c]		42.0	6.51	46.1	5.72	-1.82	.102	
Actigraphy								
Circadian rhythms	Amplitude	.61	.19	.67	.16	-1.45	.180	
	Acrophase	15:53	0:51	16:15	1:16	-1.59	.144	
	Rhythmicity	**.30**	**.12**	**.33**	**.09**	**-1.90**	**.089**	**-.14**

N = number of cases; M = mean; S.D. = standard deviation; *t* = paired t-test; df = degrees of freedom; ES r = effect size, corrected for the within subject design

[a] QIDS = Quick Inventory of Depression Symptomology
[b] PSQI = Pittsburgh Sleep Quality Index
[c] MEQ = Morning-Eveningness Questionnaire

Discussion

This was a small pilot study of a novel youth-specific program offered as an adjunct to usual treatment of depression in youth and young adults. To test any additional benefits from including the RECHARGE program, we attempted to identify individuals with concomitant sleep-wake difficulties that were a significant supplementary problem to their depression. Our findings demonstrated that this brief intervention produced modest changes in some key markers of sleep-wake and circadian sleep disturbances, in particular a moderate improvement in PSQI. However it should be noted that the post-intervention scores on the PSQI were still in the range for significant impairment, and PSQI and circadian rhythmicity did not explain a significant portion of the variance in post-intervention depression scores when controlling for pre-intervention depression scores.

The results of this pilot trial are important for three reasons. Firstly, the effect sizes obtained for our sleep-wake and circadian parameters are interesting and could be used to inform power calculations for a larger future study to more comprehensively assess the RECHARGE program. Secondly, once individuals began attending the program, they all remained engaged. One potential explanation for this is that our program was developed specifically for youth, including a large focus on age-appropriate content (e.g. focus on developmentally distinct delays in and lower robustness of rhythms) and language (information conveyed through pictures and cartoons), and included the use of contemporary technological applications that are highly interactive, personalized, and provide real-time feedback. Given that adolescents and young people with depression are among the most difficult to keep engaged in treatment, the current study provides the preliminary data that youth with mood disorders can be engaged in treatment by targeting sleep-wake cycles and circadian rhythm disturbances within the context

of a youth-specific intervention.

Thirdly, this pilot yielded important products that will facilitate future modifications to the RECHARGE program: the feasibility of technological application use; estimates of recruitment, retention, and attrition; capacity to detect changes in newly explored circadian parameters using actigraphy; and the magnitude of change of candidate outcome measures. In particular, we found that actigraphy, a frequently employed tool in circadian rhythm research but with limited use in sleep-wake and circadian rhythm interventions for youth with mood disorders, was able to detect modest trends in circadian sleep parameters previously unexplored in this area of research. One method of further improving circadian parameters as measured by actigraphy could be a lengthened program. Other interventions such as CBT-I that have found short-term advantages for actigraphy parameters in youth (ES *d*=1.12; [22]) are considerably longer and more intensive (i.e. 10 sessions over 12 weeks). Hence the current RECHARGE program could be extended to circadian actigraphy parameters whilst ensuring low attrition rates are retained (e.g. 6 sessions over 12 weeks).

We note also that the modest magnitude of change of sleep-wake and circadian rhythm parameters may suggest that other intervention targets may need to be explored. Other sleep-wake and circadian rhythm interventions such as CBT-I target cognitions and challenge unrealistic beliefs regarding consequences of sleep-wake disturbance, and consider cognitive coping styles that interfere with sleep-wake functioning as a key program component [22]. Maladaptive rumination is one coping style that is a known predictor of depression in youth [37,38] and importantly bidirectional linked to sleep-wake disturbance in adolescents with depression [39-41]. A modified RECHARGE program may need to integrate additional program components that address related cognitive coping styles like rumination to achieve larger and lasting improvements in outcome measures.

The current study has a number of limitations other than the small sample. Given that this was a pilot trial of a novel intervention, the majority of participants were concurrently using antidepressant medication. As there was no control group and all participants received the same program, no firm conclusions can be made about the efficacy of RECHARGE over and above treatment as usual. Additionally, the study had insufficient power to account for confounders, which increased the chances of type II errors e.g. in the regression analyses. Also, no long term assessments of outcome measures were undertaken, and researchers were not blinded to the hypotheses being tested. Cases were also selected according to significant sleep-wake disturbances as measured by the PSQI, where the program also sought to intervene with circadian rhythm (and not only sleep-wake) disturbances, and which may partially account for the difference in magnitude of change between PSQI and actigraphic parameters. Finally, in using established measures of sleep-wake and circadian rhythm (i.e. PSQI, MEQ) in their original form, the self-report assessments were out of phase with the objective actigraphy data. Actigraphy was undertaken over two weeks whilst the original PSQI and MEQ questionnaires asked participants to answer items based on their experiences,

on average, over the last month. Future studies should seek to synchronise these measures, and use actigraphy to help select for cases with circadian rhythm as well as sleep-wake disturbance.

In conclusion, the high program acceptability and modest trends for some sleep-wake and circadian parameters indicate that future investigation of a modified RECHARGE program is merited. An extension of the program to 12 weeks and inclusion of cognitive program components may offer advantages over the current RECHARGE program. In the meantime, it is our hope that our pilot work will encourage future development of sleep-wake and circadian rhythm interventions specific to the needs of clinical youth populations.

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