A Pilot Randomized Controlled Study of Light Therapy for Sleep-Wake Disturbances in Renal Transplant Recipients

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Introduction

- Insomnia and other circadian sleep-wake disorders1 are common among renal transplant (RTx) recipients.
- Sleep rhythm disorders mainly disrupt sleep onset and/or sleep maintenance, resulting in daytime sleepiness3.
- About one-third of RTx recipients report poor sleep quality and/or poor daytime functioning (34.1%)4.
- More than half say they suffer from daytime sleepiness3.

Objectives

- To evaluate the efficacy of morning light therapy in RTx recipients diagnosed with sleep-wake disturbances.
- Primary outcome: Earlier bedtime
- Secondary outcomes: Circadian and sleep parameters, depressive symptomatology and cognitive performance.

Methods

Design: Non-blinded, 1:1 randomized controlled wait-list pilot and feasibility trial

Randomization
- Sequence generation: Block with max. block size of 4, created with “Random number generator”
- Allocation concealment mechanism: Sequentially numbered opaque envelopes
- Implementation: Random allocation sequence was generated by an external researcher
- Blinding: No blinding

Sample/Setting: 30 home-dwelling RTx recipients (aged 59.6±12.6y) with sleep-wake disturbances, identified in a previous research study

Intervention: Philips Energy Light (10000 Lux) for 30 minutes in the morning according to chronotype (“Morning-Evening-Questionnaire”)

Variables and Measurements:
- Demographics and treatment regimen: patients charts
- Actigraphy (edited with diary records)
- Primary outcome: Sleep parameter (Bedtime)5
- Secondary outcomes: circadian (IS, IV, RA) & sleep parameters (Getup time, sleep latency, sleep efficiency)6
- Depression, Anxiety and Stress Scale: Depressive symptomatology7
- Stroop color-word interference test: cognitive functional performance8

Statistical analysis

RCT
- Descriptive statistics and linear mixed regression modeling
- Estimated effect sizes were calculated first overall with interaction analysis and with contrasts

Pre-post analysis
- Linear mixed regression modeling
- Controlling for β-blockers, low-dose acetylsalicylic acid and BMI
- Outcome measures were standardized to compare the effect
- Interaction coefficient and A.time were used as an effect size.

Results

RCT
- RCT findings showed that light therapy induced earlier (phase advance) bedtime (ES:-0.25; 95%CI -0.41; -0.09) and get-up time (ES:-0.23; 95%CI -0.42; -0.03).

Pre-post analysis
- The pre-post analysis showed a phase advance in get-up time (ES:-0.21; 95%CI -0.32; -0.11).

Post-hoc analysis
- Post-hoc analysis revealed that light therapy significantly increased sleep efficiency (ES:-0.28; 95%CI -0.45; -0.10) and decreased sleep latency (ES:0.42; 95%CI 0.20; 0.65) in RTx recipients taking neither β-blockers nor acetylsalicylic acid.
- Light therapy improved depression, not cognitive function.
- Light therapy induced a non significant phase advance in bed time only in normal BMI patients (ES:-0.002; 95%CI -0.02.0.02).
- Light therapy increased sleep efficiency only in those with normal BMI (ES:-0.02; 95%CI -0.03; -0.003).

Conclusions

- This is first evidence suggesting that light therapy might be beneficial as synchronizer for some RTx recipients with sleep-wake disturbances, also to improve mood.
- Post-Hoc analysis conclusion: Prior to initiating light therapy, factors on the metabolic level (BMI) such as possible inhibitory factors of melatonin production (β-blockers) and the presence of insulin resistance need to be taken care to have the desired effect.

References


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