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 disorders[1] are common among renal transplant (RTx) recipients[2].
- Sleep rhythm disorders mainly disrupt sleep onset and/or sleep maintenance, resulting in daytime sleepiness[3].
- 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 sleepiness[3].

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

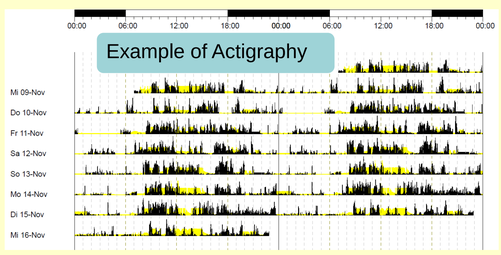
Intervention: Philips Energy Light (10000 Lux) for 30 minutes in the morning according to chronotype (“Morning-Evening-Questionnaire”)

Daqtix Actimeter

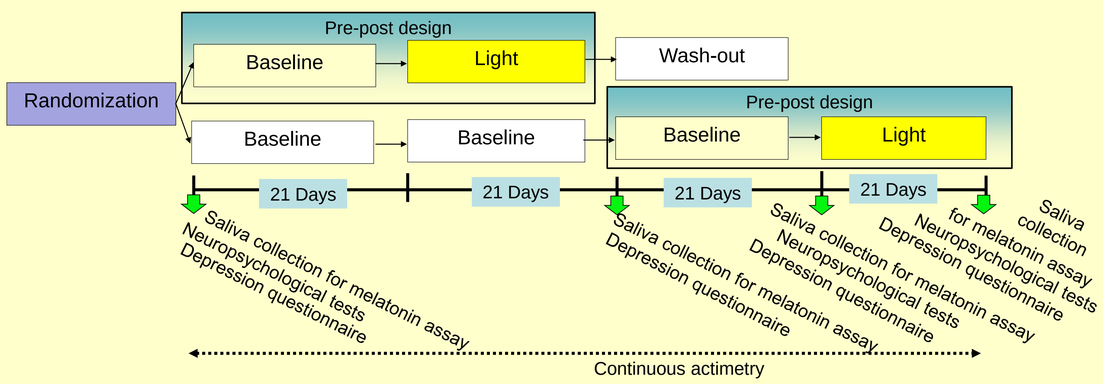
Philips Energy Light

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 symptomatology [7]
- Stroop color-word interference test: cognitive functional performance [8]



Study design

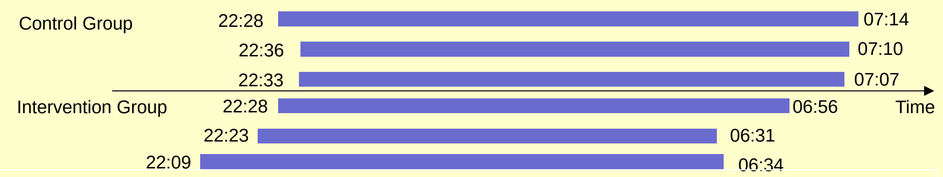


Statistical analysis

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
Post-Hoc analysis	Controlling for β-blockers, low-dose acetylsalicylic acid and BMI
	Outcome measures were standardized to compare the effect
	Interaction coefficient and Δtime 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.

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