

# Randomized Controlled Study of the Effectiveness of Stepped-Care Sleep Therapy In General Practice

NCT03532282

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Data Analysis Plan for Primary AIM 1 (as originally proposed in the NIH grant application)

All analysis will be for the intent to treat sample.

For the primary outcomes we hypothesized that, compared to ONLN, participants in STEP would have greater reductions in the two co-primary outcomes, insomnia severity (Hypothesis 1a) and use of prescription sleep medications (Hypothesis 1b). Together these two hypotheses test whether the triaged stepped care strategy is superior to having access to only dCBT-I over one year.

Repeated measures mixed-effects linear model will be used with experimental group (STEP or ONLN) and time (6 assessments: at baseline and at months 2, 4, 6, 9, &12), and their interactions as fixed effects. Of interest for these analyses are the effects of these factors on the trajectory of individual responses. The group effect size on the slope (Group X Time) is the average group effect, ignoring strata, testing whether there is a difference in the response trajectories between the STEPPED CARE and ONLINE ONLY approaches. For hypothesis 1a the dependent variable is the ISI and for hypothesis 1b the dependent variable is use of prescription sleep medications.

For the secondary outcomes we hypothesized that, compared to ONLN, participants in STEP would have greater reductions in sleep related impairment (hypothesis 2a) and psychological distress (hypothesis 2b).

Repeated measures mixed-effects linear model will be used with experimental group (STEP or ONLN) and time (6 assessments: at baseline and at months 2, 4, 6, 9, &12), and their interactions as fixed effects. Of interest for these analyses are the effects of these factors on the trajectory of individual responses. The group effect size on the slope (Group X Time) is the average group effect, ignoring strata, testing whether there is a difference in the response trajectories between the STEPPED CARE and ONLINE ONLY approaches. For hypothesis 2a the dependent variable was the PROMIS sleep related impairment and for hypothesis 2b the dependent variable was PHQ-4.