



LONGITUDINAL COGNITIVE BEHAVIORAL EFFECTS ON SUBJECTIVE SLEEP OUTCOMES IN WOMEN WITH GYNECOLOGY MALIGNANCIES AND INSOMNIA



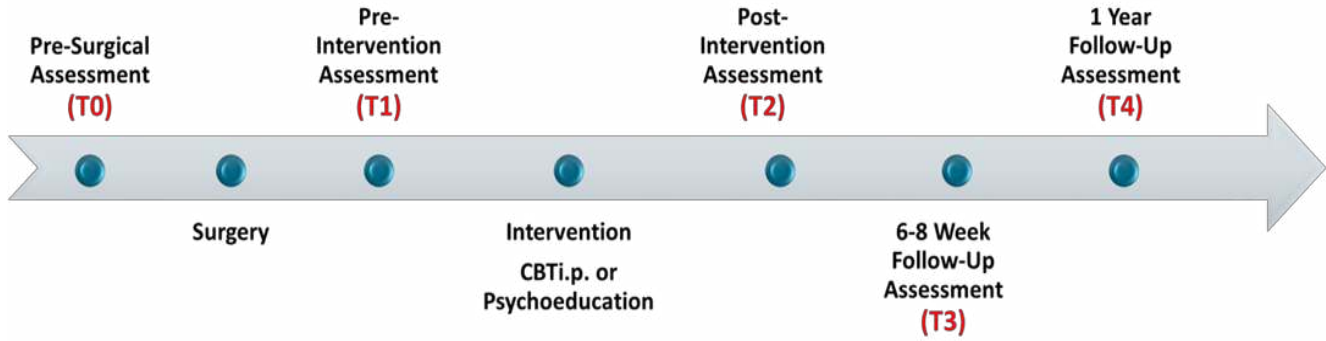
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INTRODUCTION

- Over 100,000 new cases of gynecologic cancers are expected to be diagnosed in 2019, with an estimated mortality rate of 33,000 (ACS, 2019)
- Sleep disturbance is a critical cancer outcome associated with depression, diminished quality of life, and mortality (Garnder et al., 2012)
- Empirical evidence corroborates the effectiveness of Cognitive Behavioral Therapy for insomnia (CBTi) in breast cancer (Johnson et al., 2016)
- Apart from preliminary studies demonstrating reductions in Total Wake Time (TWT), there is limited empirical evidence on the efficacy of cognitive behavioral interventions for insomnia and pain (CBTip) on subjective sleep variables within gynecologic malignancies
- This study examined the effects of CBTi.p on Sleep Efficiency (SE), Sleep Quality (SQ), Sleep Onset Latency (SOL), and Wake After Sleep Onset (WASO) while controlling for age and advanced disease (stage III-IV)

PARTICIPANTS & METHODS

- Study design:** Parallel-group Randomized Clinical Trial (RCT)



Inclusion Criteria

- Confirmed Primary GYN Cancer
- Clinically significant sleep difficulties
- Undergoing surgical treatment
- English proficiency
- Age 18 and older

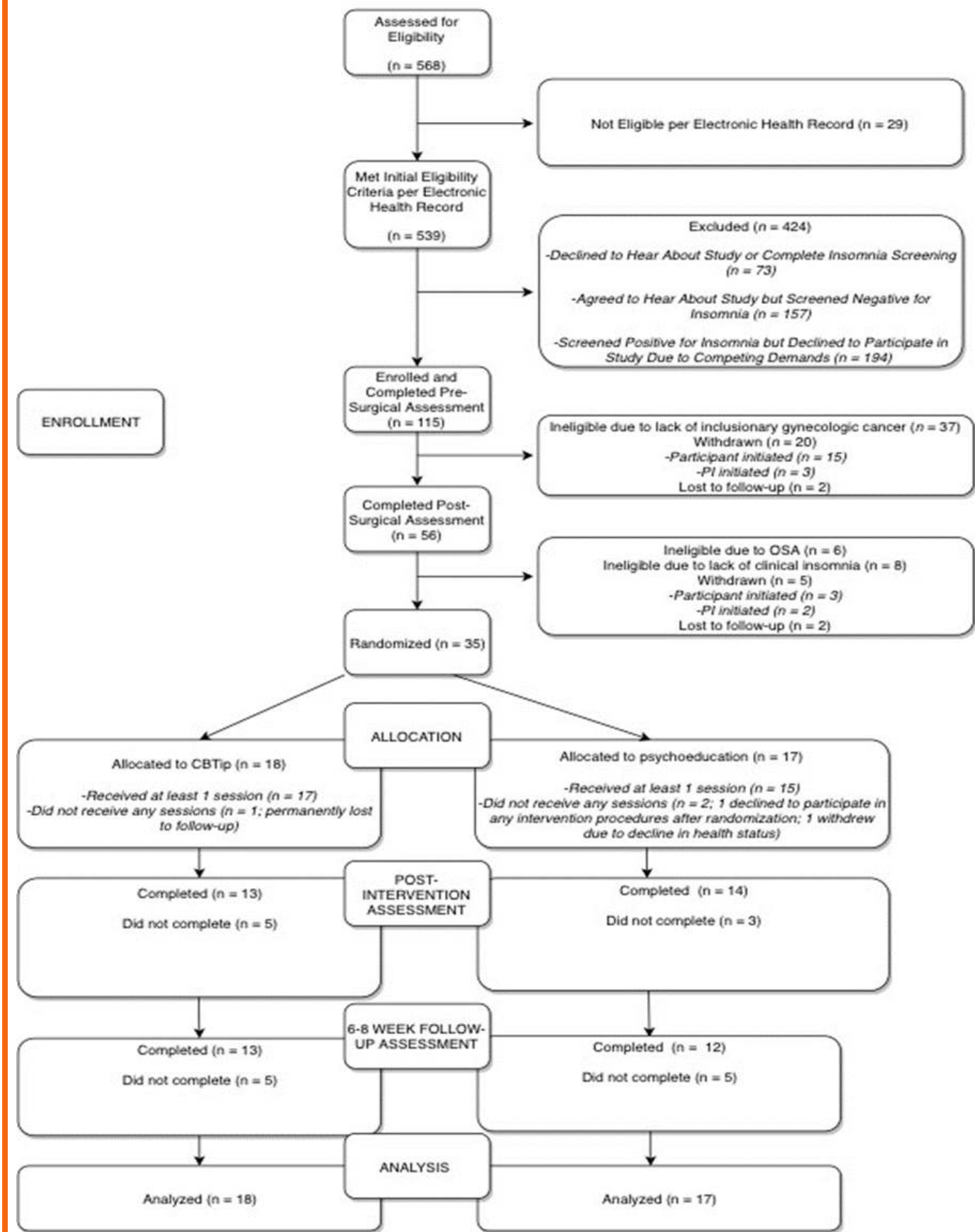
Exclusion Criteria

- Participation in behavioral sleep tx
- Diagnosis of sleep apnea
- History of seizures
- Current suicidal ideation
- Hx/current severe psychopathology

Variable Name	Total Sample (N=35)	Psychoeducation Program (N=17)	CBTi.p. (N=18)
Demographic Characteristics [N (%)]			
Age [years; M(SD)]	59.4(11.2)	59.9(10.3)	58.9(12.2)
Education (years)	14.1(2.4)	14.7(2.4)	13.4(2.4)
Marital Status (married)	23(65.7)	10(58.8)	13(72.2)
Race (Caucasian)	31(88.6)	16(94.1)	15(83.3)
Ethnicity (Non-Hispanic)	33(94.3)	15(88.2)	18(100.0)
Physiological Characteristics [N (%)]			
Chemotherapy (yes)	14(40.0)	7(41.2)	7(38.9)
Radiotherapy (yes)	7(20.0)	5(29.4)	2(11.1)
Invasive Surgery (yes)	17(48.6)	10(58.8)	7(38.9)
Surgical Complications (yes)	6(17.1)	4(23.5)	2(11.1)
Cancer Stage			
Stage I	20(57.1)	9(52.9)	11(61.1)
Stage II	3(8.6)	2(11.8)	1(5.6)
Stage III	9(25.7)	4(23.5)	5(27.8)
Stage IV	1(2.9)	1(5.9)	0
Unknown Stage	2(5.7)	1(5.9)	1(5.6)
Tumor Site			
Endometrial	26(72.3)	14(82.4)	12(66.7)
Ovarian	4(11.4)	2(11.8)	2(11.1)
Fallopian Tube	1(2.9)	2(11.8)	1(5.6)
Cervical	1(2.9)	0	1(5.6)
Vulvar	3(8.6)	0	2(11.1)

- Methods:** Subjective sleep variables were assessed via 14 days of sleep diaries, administered at: (1) baseline/post-surgery, (2) post-intervention, and (3) 2-month follow-up

CONSORT FLOW DIAGRAM



RESULTS

- Mixed linear modeling (MLM) was conducted to examine longitudinal group differences on subjective sleep variables across weeks 0-14
- Analyses controlled for possible confounding effects of age and advanced disease
- There were significant fixed effects of time/condition on SE and SOL
 - CBTip group had higher SE (9.68, $p < 0.01$) and lower SOL (-17.53, $p = 0.01$) compared to the Psychoeducation group
- Despite significant fixed effects of time on WASO, effects of condition on WASO and those of time and condition on SQ were not significant
- The study lacked power to demonstrate individual differences in rates of change

Figure 1. Effects of CBTi.p. on Sleep Efficiency (SE) Controlling for Age and Advanced Cancer

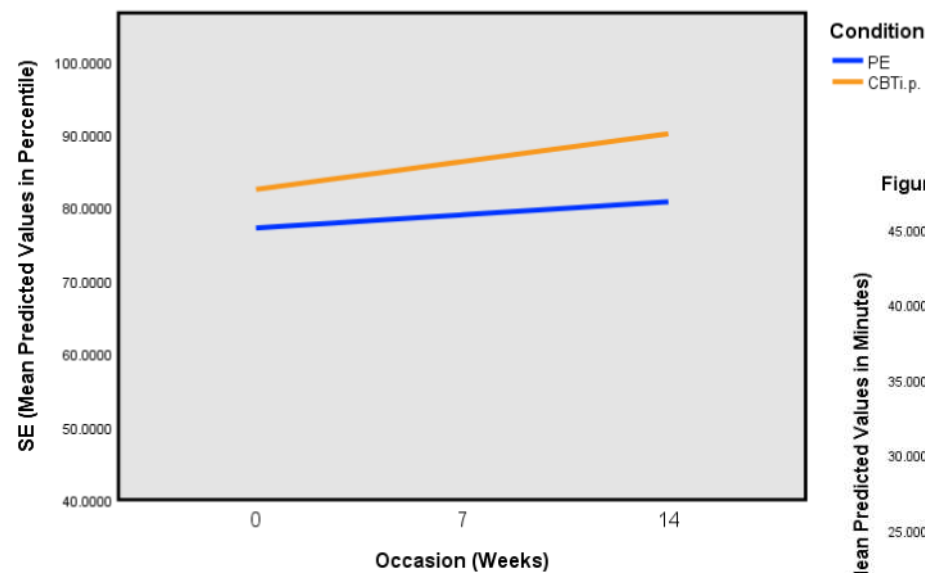
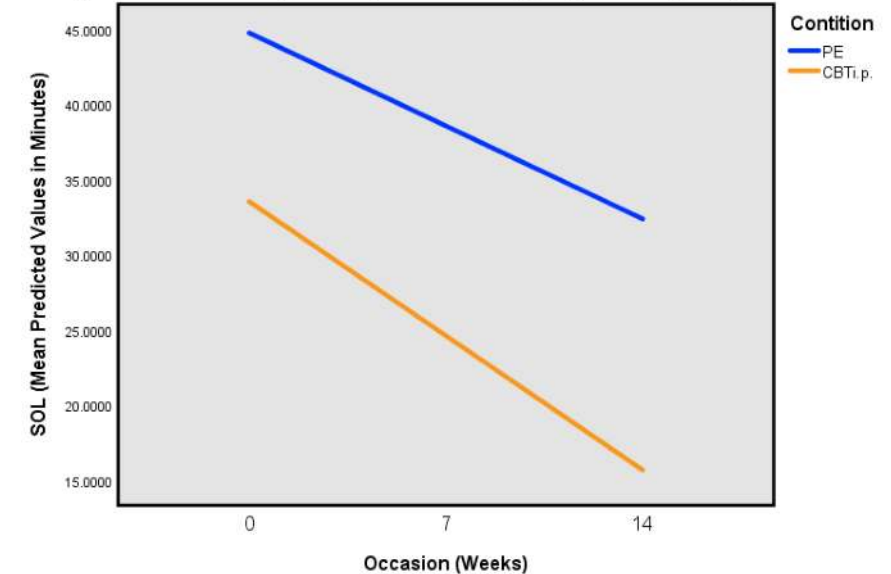


Figure 2. Effects of CBTi.p. on Sleep Onset Latency (SOL) Controlling for Age and Advanced Cancer



CONCLUSION

- Patients randomized to CBTi.p had higher SE and lower SOL compared to those randomized to PE during acute post-operative treatment phase
- CBTip may be an efficacious psychological intervention in improving sleep disturbance in women with gynecologic malignancies and insomnia
- Future research will focus on the effects of CBTi.p on subjective and objective pain variables