

SUPPLEMENT 1

Title: *Protocol for a multi-center randomized controlled trial of digital cognitive behavior therapy for insomnia compared with digital patient education about insomnia in individuals referred to secondary mental health services in Norway.*

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World Health Organization Trial Registration Data Set

Data category	Information
Primary registry and trial identifying number	ClinicalTrials.gov: NCT04621643
Date of registration in primary registry	November 9, 2020
Secondary identifying numbers	Regional Committees for Medical and Health Research Ethics in South East Norway (125068).
Source(s) of monetary or material support	The Norwegian Research Council, grant number 273623
Primary sponsor	St. Olavs University Hospital (stolav.no)
Secondary sponsor(s)	None
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Public title	A digital intervention for insomnia for outpatients in mental health care.
Scientific title	A multi-center randomized controlled trial of digital cognitive behavior therapy for insomnia compared with digital patient education about insomnia in individuals referred to secondary mental health services in Norway.
Countries of recruitment	Norway
Health condition(s) or problem(s) studied	Mental Disorders, Insomnia
Intervention(s)	Active treatment: Digital Cognitive Behavior Therapy for Insomnia (Sleep Healthy Using The internet, SHUTi). Comparator: Digital patient education about insomnia
Key inclusion and exclusion criteria	Inclusion: Age \geq 18 years old. Score on the Insomnia Severity Index \geq 12. Willing and able to provide consent. Exclusion criteria: Individuals scoring \geq 13 on the Epworth Sleepiness Scale (ESS), and/or answering that they usually or every day snore and stop breathing (i.e., they positively endorse pre-selected indicators of sleep apnoea); self-report of the presence of any medical conditions where a fully automated CBT-I may be contra-indicated (e.g. epilepsy, recent heart surgery); and/or participating in shift work; and/or pregnancy; and/or having inadequate opportunity to sleep; and/or currently receiving psychological treatment for insomnia, and/or not registered at or under the care of any of the trial centers
Study type	Interventional Allocation: Randomized intervention model. Parallel assignment model: Blind (subject) Primary purpose: Intervention
Date of first enrolment	December 2020
Target sample size	800
Recruitment status	Recruiting
Primary outcome(s)	The Insomnia Severity Index
Key secondary outcomes	Sleep Diaries, Mental health, Physical Health, Nocturnal mentation, Cognitive function, Diurnal preference, Work productivity, Sick leave, Medication use, Health resource use.