



ผลของชาใบกัญชาต่อระยะเวลาตั้งแต่เข้านอนถึงเริ่มหลับ ระยะเวลานอนหลับรวม และระยะเวลาดื่นในช่วงนอนหลับ ติดตามด้วยสมาร์ตวอตช์

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Effects of Cannabis Leaf Tea on Sleep Onset Latency, Total Sleep Time, and Wake after Sleep Onset Tracked by a Smartwatch

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บทคัดย่อ

หลักการและวัตถุประสงค์: กัญชามีคุณสมบัติทางการแพทย์หลายประการ ผลการศึกษาที่ผ่านมาบ่งชี้ว่ากัญชามีศักยภาพในการช่วยนอนหลับ การทดลองทางคลินิกนี้มุ่งศึกษาผลของชาใบกัญชาต่อระยะเวลาตั้งแต่เข้านอนถึงเริ่มหลับ ระยะเวลานอนหลับรวม และระยะเวลาดื่นในช่วงนอนหลับในบุคลากรทางการแพทย์ที่ใช้สมาร์ตวอตช์ติดตามการนอนหลับ

วิธีการศึกษา: การศึกษาเป็นการศึกษาแบบกึ่งทดลอง 1 กลุ่มวัดผลก่อนและหลัง อาสาสมัครที่ผ่านเกณฑ์การคัดเลือกเข้าร่วมการวิจัย 4 วันโดยมีระยะห่างในแต่ละวันเท่ากับ 1 สัปดาห์ วันแรกอาสาสมัครใส่สมาร์ตวอตช์เข้านอนเพื่อข้อมูลพื้นฐานการนอนหลับ ในวันที่ 2, 3 และ 4 อาสาสมัครดื่มชาใบกัญชามีความเข้มข้น ต่ำ ปานกลาง และสูง ตามลำดับ ก่อนเข้านอน 30 นาที การวิเคราะห์ใช้สถิติทดสอบลำดับที่โดยเครื่องหมายของวิลค็อกซัน

ผลการศึกษา: อาสาสมัคร 63 ราย พบว่า ระยะเวลาตั้งแต่เข้านอนถึงเริ่มหลับในวันแรกที่ไม่มีการดื่มชาแตกต่างจากวันที่ดื่มชา ความเข้มข้นต่ำ ปานกลาง และสูงอย่างมีนัยสำคัญทางสถิติ (95%CI: 0.00-5.79, p = 0.005, 95%CI: 0.00-8.79, p = 0.002 และ 95%CI: 3.21-12.79, p < 0.001 ตามลำดับ) ระยะเวลานอนหลับรวมในวันแรกที่ไม่มีการดื่มชาแตกต่างจากในวันที่ดื่มชา ความเข้มข้นปานกลางอย่างมีนัยสำคัญทางสถิติ (95%CI: 9.76-42.00, p = 0.037) นอกจากนี้ ไม่พบความแตกต่างอย่างมีนัยสำคัญทางสถิติระหว่างระยะเวลาดื่นในช่วงนอนหลับในวันแรกที่ไม่มีการดื่มชาและวันที่มีการดื่มชาทั้งสามความเข้มข้น

สรุป: ชาใบกัญชาทั้งสามความเข้มข้นลดระยะเวลาตั้งแต่เข้านอนถึงเริ่มหลับ แต่อย่างไรก็ดี ชาความเข้มข้นปานกลางทำให้ระยะเวลานอนรวมลดลง นอกจากนี้ ชาทั้งสามความเข้มข้นไม่ลดระยะเวลาดื่นในช่วงนอนหลับ

คำสำคัญ: ชาใบกัญชา, ระยะเวลาตั้งแต่เข้านอนถึงเริ่มหลับ, ระยะเวลานอนหลับรวม, ระยะเวลาดื่นในช่วงนอนหลับ, สมาร์ตวอตช์

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Abstract

Background and Objective: Cannabis possesses many medicinal properties. Recent studies reported positive results using cannabis derivatives as a sleep aid. This study investigated the effects of cannabis leaf tea on sleep onset latency (SOL), total sleep time (TST), and wake after sleep onset (WASO) in medical personnel using a smartwatch as a sleep tracker.

Methods: This study was designed as a single-arm quasi-experimental trial. The eligible volunteers wore Fitbit Inspire 2 to track their sleep at home for four days, one week apart. On the first day, SOL, TST, and WASO were recorded as baseline data. On the second, third, and fourth days, the volunteers drank low, medium, and high concentrations of cannabis leaf tea approximately 30 minutes before bedtime. The statistical analysis was the Wilcoxon Matched-pairs Signed-rank test.

Result: Sixty-three volunteers were eligible for the trial. The findings revealed that the SOL baseline was different from the SOL of low concentration, the SOL of medium concentration, and the SOL of high concentration with statistical significance (95%CI: 0.00-5.79, $p = 0.005$, 95%CI: 0.00-8.79, $p = 0.002$ and 95%CI: 3.21-12.79, $p < 0.001$, respectively). Only the TST of medium concentration significantly differed from the TST baseline (95%CI: 9.76-42.00, $p = 0.037$). There was no significant difference between the WASO baseline and the WASO of the three concentrations.

Conclusion: All concentrations of cannabis tea shortened the SOL. However, the medium concentration decreased TST. In addition, all three concentrations could not reduce WASO.

Keywords: cannabis leaf tea, sleep onset latency, total sleep time, wake after sleep onset, smartwatch.

Introduction

Sleep plays a vital role in maintaining overall health and daily performance.¹ However, approximately 30% of adult population experience sleep difficulty once through their lifetime.² Difficulty in initiating sleep, difficulty in maintaining sleep, and early morning awakening are common sleep problems.³ Certain professions, such as medical personnel, are prone to sleep deprivation. Recent studies in Thailand showed that the prevalences of poor sleep quality reported by nurses were relatively high (64.2%³ and 85.5%⁴). Poor sleep quality also relates to poor physical health, fatigue in daytime, impaired immunity, poor memory, loss of focus and irritability.² Different approaches, both pharmaceutical and nonpharmaceutical treatments, have been invented to manage sleep difficulty. Recently, studies using natural-based sleep aids such as cedrol, valerian root extract, kava root extract, and Panax ginseng root extract, showed positive results in improving sleep.¹

The Thai Government Gazette by the Ministry of Public Health (MOPH) announcement on Category 5 Narcotic Substances (2565 B.E.) has had a substantial impact on cannabis use in Thailand.⁵ Cannabis, according to ancient Thai traditional medicine, has been used as an ingredient in sleeping pill formulas.⁶ Delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD) are among the most studied cannabinoids.⁷ In general, THC is a psychoactive substance, whereas CBD is an anxiolytic and sedative agent. These cannabinoids involve the mechanics of sleep by binding to the cannabinoid receptor 1 (CB1) and interacting with orexin in the hypothalamus region.⁸

Previous studies also reported promising results of cannabis in patients with cancers, chemotherapy-induced nausea and vomiting, chronic pain, multiple sclerosis, and sleep difficulty.⁹ A randomized controlled clinical trial reported that sublingual cannabinoid extracts improved sleep quality.¹⁰ Although THC might provide sleep advantages, prolonged use of THC is related to poor sleep habits.¹¹ Even though cannabis has medicinal benefits, it possibly causes undesirable effects. A recent study reported that nausea, vomiting, and behavioral changes were the most common presenting symptoms of hospitalized patients exposing to cannabis.¹²

In certain parts of the world, cannabis tea is widely used as a remedy for fever, cold, and stress.¹³ Since cannabinoids are more accumulated in flowers than in the leaves, cannabis leaf tea may cause less harm compared with other cannabis administrations. Besides, oral cannabinoid absorption is relatively poor compared with inhalation or sublingual route due to the low water solubility.¹⁴ The most common administrations of hospitalized patients exposing to cannabis were sublingual route and smoking.¹²

Recently, a guidebook on cannabis for health and safety use by the Thailand MOPH suggested using cannabis leaf tea as a sleep aid.¹⁵ However, the scientific-based data supporting the hypnotic effect of cannabis tea is limited. During sleep, a person can cycle through five stages of sleep: wake, light sleep (N1), deeper sleep (N2), deepest sleep (N3) and REM (rapid eye movement).¹⁶ Cannabis leaf tea may induce sleep by shortening the first stage because CBD, as a sedative agent, may slow down the brain activity. However, there is a limited evidence base for the effects of phytocannabinoids on human sleep cycles. This trial, therefore, aimed to investigate the effects of cannabis leaf tea on three sleep parameters. The first parameter is sleep onset latency (SOL) which refers to the time it takes when a person to fall asleep after getting on the bed. The second parameter is total sleep time (TST) which refers to the amount of time a person spends from falling asleep till awaking. The last parameter is wake after sleep onset (WASO) which refers to the amount of time a person awakes during sleeping.

Methods

The population of this one-arm quasi-experimental trial was 195 medical personnel¹⁷ working in eight healthcare government facilities in Khaosuanwang district, Khon Kaen, Thailand. The sample size, calculated by G*Power, was 63. Taking part in this trial was voluntary. The recruitment flyer was distributed in the facilities one month before recruitment. The trial commenced after approval by Khon Kaen Public Health Provincial Office Ethical Committee (COE 025/2565, REC 049/2565). The trial was registered with the Thai Clinical Trial Registry (TCTR20221001008). Medical personnel were eligible if they were 25 to 60 years old. Other inclusion

criteria were non-smoker, non-alcoholic drinker, and having a history of sleep difficulty. The exclusion criteria were cannabis allergy, cardiovascular diseases, mental disorders, liver diseases, kidney disease, warfarin use, pregnancy, and breastfeeding. The discontinuation criteria applied when the volunteers demanded to leave the trial, had significant side effects or were unable to complete the trial. After eligibility screening, the volunteers signed the consent form. Personal information, namely medical history, drug allergy history, date of birth, gender, height, and body weight, was recorded. Then, the volunteers were sent to meet a physician for evaluation. Since there was no standardized test to diagnose cannabis allergy, this study set up a test for evaluation. Each volunteer drank a cup of 200 ml of cannabis leaf tea, equivalent to 0.36 – 0.52 g of dried cannabis leaf, and stayed in an observation room for an hour. Two pharmacists interviewed the volunteers and assessed any adverse effects.

Cannabis leaf tea

Thai Stick was planted in Khaosuankwang hospital. The seeds were prepared for germination in paper towels soaked with distilled water for 24 hours in a dark container. After roots emerged, they were moved to be planted in a tray with sphagnum peat moss. The seedlings were moved to be planted in 2x6-inch planting bags for a month and then moved in 12-inch plastic pots. The planting materials were soil and chopped coconut husks in a 1:1 ratio. The planting area was exposed to sunlight for 10 hours daily. The cannabis was watered with tap water once a day in the morning. Cannabis leaf was harvested when the plant reached two months old. Cannabis leaves 2-3 centimeters in width and 15-20 centimeters in length were cut. Cannabis leaf tea preparation in this trial was adapted from the MOPH guidebook.¹⁵ The cannabis leaves were prepared for decarboxylation in a dried heat oven at 130-150 degrees Celsius for 12 minutes. Dried cannabis leaves were weighed and put into tea bags for low (0.72 to 1.43 grams), medium (1.44 to 2.15 grams), and high (2.16 to 2.87 grams) doses for three concentrations.

The tea preparation kit was composed of an electric kettle, a bottle of 250 ml of fresh water, a 200-ml paper cup, a cannabis leaf tea bag, and an

instruction sheet. The tea preparation was demonstrated individually to make sure the volunteers would perform it correctly at home. Half an hour before bed, the 200 ml tea was freshly prepared. The tea was left to cool down for 15 minutes before drinking.

Smartwatch

The smartwatch used in this trial was Fitbit Inspire 2. By collecting body movement and heart rate variability, the smartwatch automatically tracks sleep¹⁸ and offers valid sleep parameters.¹⁹ Eight smartwatches were purchased from a local department store. To determine functional error, one of the smartwatches was randomly selected as a master device while the others were assigned as unit under test (UUT) devices. The test was carried out by comparing the three sleep parameters (SOL, TST, and WASO) between the master and the UUT devices. One of the researchers wore the master one on the left hand and the UUT devices on the right hand, one by one, for five nights. There was no significant error in SOL, TST, and WASO between the master and the UUT devices.

Four-day trial

The trial took four days separated by a 1-week washout period. On the first day, the personal information of the volunteers was synced to the smartwatch. The volunteers wore the smartwatch before bedtime. On the other three days, the volunteers wore the smartwatch and drank cannabis leaf tea approximately 30 minutes before bedtime. The volunteers drank low, medium, and high concentrations of cannabis leaf tea on the second, third, and fourth days respectively. The volunteers were advised to monitor and record certain activities which might affect their sleep in a journey. They were asked to keep similar daily habits for all four trial days.

Statistical analysis

Primary outcomes were SOL, TST, and WASO. Since the assumption of a normal distribution was violated, the Wilcoxon Matched-pairs Signed-rank test was performed, using STATA 14.0 (StataCorp. Statistical Software, College Station, TX), to test the hypothesis that the distribution of differences has a median of zero.

Results

The recruitment began on October 4, 2022. Eighty medical personnel volunteered to participate in this trial. A cannabis tea-drinking test was carried out, and no major adverse effect was observed. However, 17 volunteers were illegible and excluded. Two were underage, one had underlying diseases, nine were unwilling to continue, and five could not complete the trial. After obtaining the data of the 63rd volunteer, the recruitment ended on December 30, 2022. There was no serious adverse event caused by cannabis leaf tea in this trial. The trial flow is shown in Figure 1.

Effect of cannabis leaf tea on sleep onset latency

The medians of SOL were shown in Table 2. The baseline SOL was 12 minutes. The SOL of low, medium, and high concentrations of cannabis leaf tea were 8, 7, and 2 minutes, respectively. The SOL of all three concentrations of cannabis leaf tea was significantly shorter than the baseline SOL. A decrease in SOL was clearly observed.

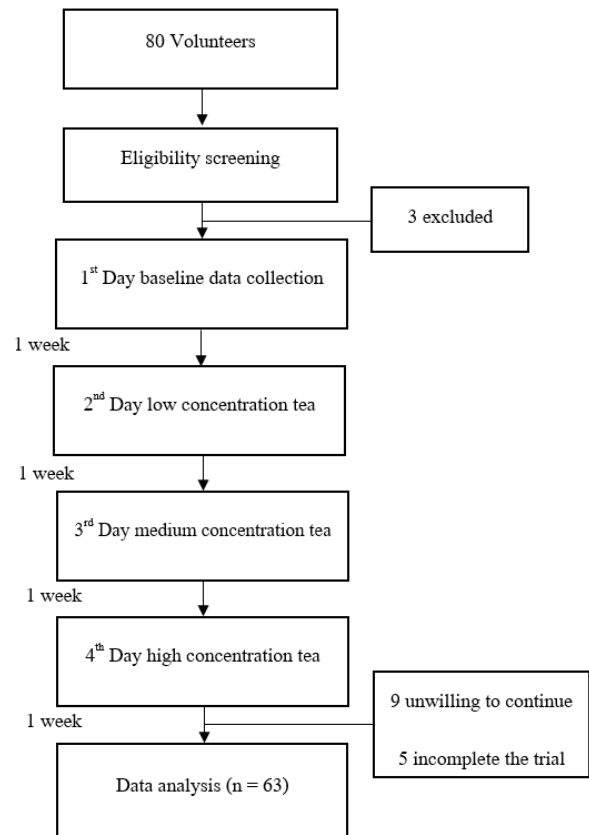


Figure 1 The trial flow

As shown in Table 1, most volunteers were female. The average age was in the early middle-age range. The average BMI of the volunteers was classified as overweight.

Table 1 Characteristics of the volunteers

Characteristics of the volunteers	Number (%) (n= 63)	Mean±SD
Gender		
Female	44 (69.84)	
Male	19 (30.16)	
Age (Min 23, Max 58)		39.38±7.54
Body Mass Index		24.21±3.92

Table 2 The differences in median of sleep onset latency

Cannabis leaf tea	Sleep onset latency (minutes)	Wilcoxon signed-rank test Z	95% CI	p-value
Baseline	12			
Low concentration	8	2.79	0.00-5.79	0.005
Medium concentration	7	3.04	0.00-8.79	0.002
High concentration	2	5.26	3.20-12.79	< 0.001

Effect of cannabis leaf tea on total sleep time

The medians of TST were shown in Table 3. The baseline TST was 366 minutes. The effects of cannabis leaf tea on TST were not in the same manner. The TST of the low concentration (384 minutes) was longer than the baseline TST; nevertheless, the difference was not statistically significant. The TST of the medium and high concentrations (361 minutes and 346 minutes, respectively) was shorter than the baseline TST. However, only the difference between the TST of the medium concentration and the baseline TST was statistically significant.

Effect of cannabis leaf tea on wake after sleep onset

The medians of WASO were shown in Table 4. The baseline WASO was 55 minutes. The effects of cannabis leaf tea on WASO were not in the same pattern. The WASO of medium concentration (55 minutes) was indifferent from the baseline WASO. On the other hand, the WASO of the low and the high concentrations (53 minutes and 51 minutes, respectively) was slightly lower than the WASO baseline. However, the differences were not statistically significant.

Table 3 The differences in median of total sleep time

Cannabis leaf tea	Total sleep time (minutes)	Wilcoxon signed-rank test Z	95% CI	p-value
Baseline	366			
Low concentration	384	0.05	22.17-28.55	0.954
Medium concentration	361	2.08	9.76-42.00	0.037
High concentration	346	1.26	3.38-48.76	0.207

Table 4 The differences in median of wake after sleep onset

Cannabis leaf tea	Wake after sleep onset (minutes)	Wilcoxon signed-rank test Z	95% CI	p-value
Baseline	55			
Low concentration	53	-0.56	4.79-10.00	0.575
Medium concentration	55	-0.21	5.79-7.00	0.832
High concentration	51	0.36	4.79-5.79	0.714

Discussion

There were limitations in this trial. Firstly, as a one-arm design, the trial lacked a control group for comparison. Secondly, there was no statistical approach for covariate adjustment. Thirdly, the amounts of cannabinoids in the cannabis leaf tea were unknown. The standardization was done by the weighting of dried cannabis leaf. Fourthly, in the context of a real-life setting, some uncontrollable factors might affect the causal relationship between cannabis leaf tea and sleep parameters. Lastly, sleep parameters were obtained by the sleep tracking function of the smartwatch, not medical equipment.

Rich in cannabinoids, terpenes, and flavonoids, cannabis leaves are the most used part for medicinal purposes.²⁰ Nevertheless, the extent of knowledge is minimal concerning cannabis tea preparation or composition.¹⁰ Focusing on the effect on sleep, the cannabis leaf tea in this trial was divided into three concentrations. The low concentration contained two cannabis leaves weighing approximately 0.72 to 1.43 grams. The medium concentration contained four leaves (1.44 to 2.15 grams), whereas the high concentration contained six leaves (2.16 to 2.87 grams). In addition, cannabinoid bioaccessibility can be increased by consuming cannabis with high-fat food.²¹ Moreover, some substances have interactions

with cannabis, for example, alcohol and opioids whereas some medications are contradictions, for example, warfarin and theophylline.²² During the trial, there was no significant adverse event or hospital-acquired condition.

In this trial, a commercial smartwatch tracked three sleep parameters, namely, SOL, TST, and WASO. With sleep tracking function, the smartwatch automatically tracks sleep and offers valid sleep parameters.^{18,19} An important part that makes smartwatches continuously increase their ability to track sleep is the development of sensor technology.²³ A small gyro sensor, a technology detecting rotational angle changes over time, effectively tracks body movements while sleeping.²⁴ Another technology used in sleep-tracking smartwatches is photoplethysmogram (PPG) which measures the signals of changes in blood volume in blood vessels that are reflected by light-emitting diodes.²⁴ A systematic review and meta-analysis pointed out that the smartwatches with sleep tracking function showed promising performances, especially in differentiating sleep from awake, estimating sleep parameters and reporting sleep times.²⁵

The SOL of three concentrations of cannabis leaf tea was shorter than the SOL baseline. This was in line with some previous studies. A randomized clinical trial using sublingual cannabis extract also reported that self-report SOL was significantly shortened.¹⁰ A study using 20 mg THC, around the around-the-clock for seven days, concluded that there were significant relationships between THC and reduced sleep onset latency, increased sleepiness, and increased daytime sleep of the next day.²⁶ A study using cannabis flowers in two groups, with and without sleep difficulty, also concluded that self-report SOLs were significantly shorter.²⁷ However, a double-blind, placebo-controlled trial concluded that 15 mg THC without CBD had no effect on nocturnal sleep.²⁸

The medium concentration of cannabis leaf tea significantly reduced the TST. Previous studies exploring the effect of cannabis and cannabinoids on TST provided mixed results. A clinical trial found that there was no significant difference in TSTs between the placebo group, 15 mg THC group, 5 mg THC and

5 mg CBD group, and 15 mg THC and 15 mg CBD group.²⁸ However, a study reported that 20 mg of THC significantly reduced sleep time.²⁶ In addition, a pre-post design study in subjects with posttraumatic stress disorder concluded that the sleep hours after taking nabilone were significantly longer than the sleep hours before taking this synthetic cannabinoid CB1 receptor agonist.²⁹

In this trial, cannabis leaf tea did not reduce the WASO. The previous studies on WASO also reported mixed results. A study using sublingual cannabis extract reported that the WASO of the experimental group, measured by actinography, was significantly different from the WASO of the control group.¹⁰ A study in young adults found that the administration of 15 mg THC and 15 mg CBD increased awake time²⁸. Additionally, a study on recreational cannabis users found that the regression model was not statistically significant for WASO³⁰.

As mentioned earlier, previous studies of the effects of cannabis, cannabis extracts, or synthetic cannabinoids on SOL, TST, and WASO delivered mixed results. The conclusion remained unclear as the studies explored various types of cannabis compounds, different routes of administration, different measurement approaches, and unlike populations.

Conclusion

Cannabis leaf tea could reduce the time needed to sleep. Nevertheless, the medium concentration of the tea seemed to reduce the time the volunteers spent asleep. This effect requires further investigation since it might cause insufficient sleep. Besides, the tea failed to reduce the time the volunteers woke after falling asleep. In this trial, there was no major adverse event which may imply the safety of cannabis leaf tea. However, a person should not drink the tea for an extended time since the long-term consumption has not been thoroughly studied. The findings showed both promising and questionable outcomes of cannabis leaf tea on sleep. Therefore, more studies should be conducted to clarify and support the current knowledge.

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