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Brief title: The Effects Of Kiwifruit Consumption On Sleep Quality, Fatigue And BMI Of Saudi Adults

Official title: The Effects Of Kiwifruit Consumption On Sleep Quality, Fatigue And BMI In Saudi Students With Poor Sleep Quality: A 6-Week Pilot Randomized Controlled Trial

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Brief summary

Hypothesis: Kiwifruit contains antioxidants and serotonin which may be beneficial in the treatment of sleep disruption. Aim: to assess the effects of daily intake of kiwifruit on sleep quality, fatigue, and BMI among Saudi adults with poor sleep quality. Methods: Twenty-six female participants (14 cases, and 12 controls) were included. All participants were aged ≥18 years and were Saudi and had poor sleep quality. Pregnant, lactating and participants with any chronic diseases such as cardiovascular or neurological diseases, and history of using herbal or medications for inducing sleep for the last two months were excluded. Participants in the case group consumed 2 kiwifruits 1 hour before bedtime nightly for 6 weeks and the control group did not consume kiwifruit. The Pittsburgh Sleep Quality Index (PSQI) questionnaire was used to assess sleep quality before and after kiwi consumption (score ≥ 5 indicates poor sleep quality), Fatigue Severity Scale (FSS) was used to assess fatigue and anthropometrics were measured based on the WHO guidelines. After 6 weeks, sleep quality, fatigue and BMI were compared between cases and controls. Kiwifruit consumption may improve sleep quality in adults with self-reported poor sleep quality. Further investigation of the sleep promoting properties of kiwifruit is required.

Introduction

People spend almost one third of their lives in sleep and it is one of the main contributors to our life and wellbeing [1]. Sleep quality has several components including sleep duration, timing, efficiency (time in bed spent asleep) and latency (the amount of time it takes to fall asleep). Sleep disruption may be defined as any change in the components of sleep quality [2]. A cross-country comparative analysis reported the economic cost of insufficient sleep from 62,000 people in UK, US, Canada, Germany, and Japan. Insufficient sleep costs $411 billion annually for the US, $138 billion for Japan, £40 billion for UK, $60 billion for Germany, and $21 billion for Canada [3]. No study has measured the economic cost of sleep disruption in Saudi Arabia. This may be due to the fact that sleep medicine is relatively a new specialty in the medical community [4].

The National Sleep Foundation recommends different sleep durations for individuals according to age. Adults aged between 18–64 years are recommended to sleep 7–9 h/day [5]. In Saudi Arabia, 33.8% of adults sleep less than 7 hours, and this was shown in women more than men [6]. In meta-analyses, short sleep duration has been associated with an increased risk of obesity [7] [8]. Sleep disruption has been shown to increase the risk of cancer [9][10], type 2 diabetes mellitus [7], cardiovascular disease and coronary heart disease [11]. Furthermore, sleep disruption has been associated with an increased risk of mortality [7,12,13]. Collectively, sleep disruption has detrimental economic and health consequences and identifying the factors that may improve it is a public health priority. Thus, using interventions to improve sleep quality may help reduce disease risk and occurrence.

Nutritional research studied the effects of micro and macronutrients and whole foods on sleep measures. Micronutrients studied in relation to sleep included tryptophan, zinc, B-vitamins and polyphenols [14]. A recent systematic review explored the effects of macronutrient manipulation on sleep outcomes. Manipulating carbohydrate intake appeared to alter sleep outcomes in healthy individuals [15]. Several food items were studied in relation to sleep outcomes including fish [16] tart cherry juice and products[17–20] and kiwi fruit [21,22]. Despite these studies, nutritional advice that can be recommended for sleep hygiene is inconclusive due to limited interventional studies.

Recently, kiwifruit has gained interest in regards to sleep outcomes [23]. This may be due to the potential mechanisms of kiwifruit on sleep. Kiwifruit contain melatonin [24] which is important for regulating the circadian rhythms and sleep cycles [25]. Another potential mechanism is the high content of polyphenols, antioxidants, flavonoids, carotenoids, and anthocyanins that may decrease oxidative stress in people with sleep disorders or poor sleep quality. Furthermore, polyphenols may influence sleep through their effects on circadian rhythms, clock gene expression, and peripheral clocks [2]. Kiwifruits contain a protein named actinidin which is involved in precursors of neurochemicals required for sleep-wake regulation. In addition, kiwifruit is rich in folate and vitamin c which are essential in the metabolism of amino acids into neurochemicals [23]. Regardless of the potential mechanisms of kiwifruit on sleep, only two interventional studies were conducted [21,22] to explore this relationship. However, the study conducted by Lin *et al.* did not include a control group [21] and the intervention period in Nødtvedt *et al.* study was only 4 weeks [22].

Therefore, we designed the study with the purpose of replicating the study with a control group and a longer intervention period to investigate whether kiwi has beneficial properties on sleep. We conducted a randomized, controlled trial addressing whether intake of kiwifruit would improve sleep parameters in a Saudi student population with poor sleep quality.

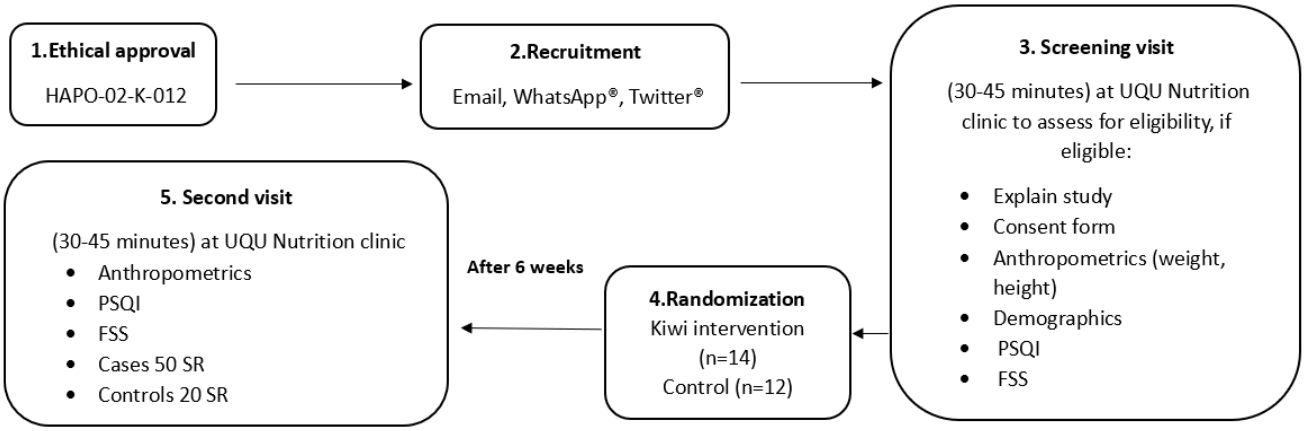
This study aims to 1) compare between sleep, fatigue and BMI in cases and controls at the start of the study and after 6 weeks in Saudi adults 2) Study the effects of kiwifruit consumption on sleep quality, fatigue, and BMI in Saudi adults.

Study Hypothesis: Kiwifruit intake may improve sleep quality, fatigue and decrease BMI

Materials and methods

Study design: a pilot randomized controlled trial (Figure 1.)

Figure 1. Methodology and study design



Legend: FSS: Fatigue Severity Scale, PSQI: The Pittsburgh Sleep Quality Index, SR: Saudi Riyal, UQU: Umm Al-Qura University

Participants*:* The study included university students aged ≥ 18 years with poor sleep quality from Umm Al-Qura University, Makkah, Saudi Arabia. Ethical approval was obtained from the Biomedical Research Ethics Committee at Umm Al-Qura University. No. HAPO-02-K-012. This study was carried out in accordance with the principles of the Helsinki Declaration. Participants were recruited through email and several social media platforms including WhatsApp™ and Twitter™ by a flyer between January-February 2022. Participants were invited to a screening visit (30-45 minutes) at Umm Al-Qura University Nutrition clinic to assess eligibility. In the screening visit, researchers explained the study aims and provided participants with a consent form and a kiwifruit consumption diary if eligible (Figure 1.).

Recruitment status: Completed

Inclusion/exclusion criteria: Eligibility to participate in the study; aged ≥ 18 years, have poor sleep quality that was assessed in the screening visit by the PSQI (a score of at least 5) (Kim et al. 2020; Tsai et al. 2005). Pregnant and lactating women were excluded due to their poor sleep quality [26],[27]. In addition, participants with any chronic diseases such as cardiovascular or neurological

diseases, and history of using herbal or medications for inducing sleep for the last two months were excluded.

Eligible participants signed a consent form for their agreement to participate and they were informed that their participation will be anonymous. After that, they were asked by the researchers a group of questions including demographic, fatigue questions, sleep quality and their height and weight were measured. Eligible participants were randomized by a lottery-based method to randomize the participants into two groups: a case or control group. After 6 weeks, eligible participants (cases and controls) attended a second visit.

Questionnaires:

A questionnaire was created to be filled in by the participants in both visits (Figure 1). The questionnaire included a brief introduction and a consent statement "I agree to participate in this study. Before finishing the trial, I can freely and without consequences terminate my participation". In addition, it included demographic questions, sleep quality questionnaire (PSQI) and the Fatigue Severity Scale (FSS).

Sleep quality

Sleep quality was assessed using the validated Pittsburgh Sleep Quality Index (PSQI) [28], which is an 18-item questionnaire. Two language versions of the PSQI were used; English [28], and the Arabic version that was translated by 10 Arabic bilingual translators was used [29]. The PSQI is a subjective measure that assesses seven factors of sleep: sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication and daytime dysfunction. Each dimension scored between 0–3, with a total score ranging from 0–21. Higher scores indicate lower sleep quality. A global PSQI score higher than 5 points indicates poor sleep quality [28]. Moreover, to analyze variables not considered by the PSQI, we included in the survey questions of stability of participants usual sleep/wake patterns and if they differ on weekends and how often they had naps.

The Fatigue Severity Scale (FSS)

Fatigue was assessed using the Fatigue Severity Scale (FSS) which is a self-administered questionnaire with 9 items (questions) investigating the severity of fatigue in different situations during the past week. Grading of each item ranges from 1 to 7, where 1 indicates strong disagreement and 7 strong agreements, and the final score represents the mean value of the 9 items [30]. The researchers independently translated the original version of the questionnaire from English to Arabic. Prior to use in this study, the questionnaire was initially administered to 10 bilingual subjects, who completed both the Arabic version and the English version to determine the test–retest reliability. Fatigue was independent of the version.

Study intervention

Eligible participants were randomly assigned to either a non-kiwifruit feeding group (controls) or consumed two medium-size kiwifruit group [21] (cases) 1 hour before bedtime every night for 6 weeks (42 days in total). Randomization was performed by giving participants a note identifying the condition to which they were randomized; the note was placed in a sealed envelope. Blindness was not applicable since cases received kiwifruit and controls did not receive. Total number of kiwis consumed should be (14 kiwis (number of kiwis in one week) x 6 (number of weeks) = 84 kiwis in total. Participants consuming the kiwifruit were asked to keep a diary to record if they consumed them every day. During the 6-week intervention period, participants received their kiwifruit every week on the first day of the week (Sunday) that is adequate for a week (14 kiwi fruits brand name: Sharbatly Co. Ltd, variety: Hayward, country of origin: Italy). The kiwifruits were supplied at optimum ripeness for consumption and were instructed to keep the kiwi in the fridge to prevent damage.

Anthropometric measurements

Participants' weight and height were measured via (GIMA Pegaso Digital Scale) on both visits to calculate their body mass index (BMI). WHO guidelines were used to take physical measurements of participants [31]and BMI categorization was based on WHO [32].

Statistical Analysis

Data analysis was performed using Statistical Package for the Social Sciences, SPSS 23rd version. Frequency and percentages were used to display categorical variables. Mean and standard deviation were used to present numerical variables. The Shapiro-Wilk test was used to test normality. Independent t-test and paired t-test were used to test associations for normally distributed variables (age, duration of nap, BMI at both start and end of the study, fatigue score at both start and end of the study, PSQI at end of the study). While the Mann-Whitney U test and Wilcoxon Signed-Rank test were used for non-normally distributed variables (PSQI at start of the study). Pearson's correlation was also used to test for associations between numerical variables. The level of significance was set at 0.05.

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Informed Consent form

Consent statement I hereby confirm that all aspects related to the study have been explained to me including aims and procedures and that the study (does/does not) include any experimental therapies and that my participation is voluntary with no extra-expenses and there (is/is no) payment offered to me for participation. I have been given a copy of data related to the study and a copy from this consent**.**
Signature of the participant:
Date of consent*(To be personally dated by the participant)*
Date of the consent*(personally dated by the participant's guardian if applicable)*
Name of the Principal Investigator *(or delegate)*
Signature of the Principal Investigator *(or delegate)*
Date of the consent *(To be personally dated by the Principal Investigator or delegate)*
Name of the witness *(if applicable)*
Signature of the witness*(if applicable)*
Date of the consent *(To be personally dated by the witness)*