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A cluster randomized controlled trial of a theory-based sleep hygiene intervention for adolescents

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Abstract

Objective

To use theory to design and evaluate an intervention to promote sleep hygiene and health among adolescents.

Methods

The Theory of Planned Behavior (TPB) and the Health Action Process Approach (HAPA) were used to develop an intervention, which was then evaluated in a cluster randomizedtrial. Participants were high school students (N = 2,841, M age = 15.12, SD = 1.50). Adolescents in the intervention group received four face-to-face sessions providing behavior change techniques targeting the theoretical determinants of sleep hygiene. Adolescents in the control group only received educational material at the end of the study. The primary outcome was sleep hygiene measured at one and six months post intervention. A number of secondary outcomes were also measured, including beliefs about sleep, self-regulatory processes, and outcomes related to health and wellbeing.

Results

Sleep hygiene was improved in the intervention group as compared to the control group at both follow-up points (coefficients = 0.16 and 0.19, 95% CIs = 0.12-0.20 and 0.15-0.23 at one month and six months, respectively, for scores on the Adolescent Sleep Hygiene Scale), as were psychosocial and general aspects of health. Mediation analyses suggested that beliefs about sleep hygiene as specified by the TPB, along with self-regulatory processes from HAPA, both mediated the effect of the intervention on outcomes. In turn, the effects of the intervention on sleep hygiene mediated its impact on general health.

Conclusions

Healthcare practitioners might consider intervention programs based on the TPB and the HAPA to improve sleep among adolescents.

Keywords

Adolescent; Behavior; Clustered randomized trial; Health; Sleep

Clinical Trial Registration: Clinicaltrials.gov (NCT02551913) https://clinicaltrials.gov/ct2/show/NCT02551913

Statement of significance

Adolescents commonly have sleep problems that are often caused by poor sleep hygiene (e.g., using electronic devices before sleep). Several intervention programs have been designed to tackle such problems; however, they lack a solid theoretical background and so may fall short of promise. This manuscript describes a randomized controlled trial which provides evidence that two theoretical frameworks – namely, the Theory of Planned Behavior and the Health Action Process Action Approach – can be used to develop an intervention that is effective in promoting sleep hygiene in adolescents both one and six months following the intervention. The findings are significant because they suggest how to tackle the serious consequences of poor sleep.

Introduction

A good night's sleep is vital to effective cognitive and emotional processing, physical and mental health outcomes, and to overall quality of life (QoL).[1-4] The importance of sleep is particularly apparent in adolescence, where sleep plays a vital role in the development of cognition and emotion.[1,2] Indeed, evidence suggests that difficulties getting to sleep (i.e., sleep onset latency or SOL) and / or difficulties staying asleep (i.e., wake after sleep onset or WASO) are associated with poorer learning, school performance, higher levels of depression and anxiety, poor somatic/psychosocial health, and risk behaviors in adolescents.[2,3] Furthermore, evidence suggests that interventions that aim to improve sleep can improve daily performance, including working memory and capacity for learning.[4] Sufficient sleep also reduces daytime sleepiness[4] and improves mental health.[5-8] Unfortunately, adolescents tend to have a later bedtime as compared with their bedtime in childhood[9], and estimates suggest that nearly 30% of adolescents intentionally delay their sleep onset time.[10] Evidence also supports a rising trend of sleep problems in adolescents (e.g., insomnia, short and disrupted sleep patterns, tiredness/fatigue, and short sleep duration[11]). In short, finding ways to improve sleep, especially among adolescents, is a public health priority.

Sleep hygiene in adolescence

Sleep hygiene is the collective term used to refer to behaviors and habits that can either facilitate sleep (e.g., creating an environment that is conducive to sleep, having a consistent routine, avoiding caffeine before bed etc.), or inhibit/interfere with sleep (e.g., using technology before bed, a bedroom that is too hot/hold etc.). Evidence suggests that not getting enough sleep is often the result of poor sleep hygiene. For example, Kor and Mullan[13] found that three behaviors were particularly relevant for University students: (i) avoiding going to bed hungry and thirsty, (ii) avoiding activities that provoke anxiety and stress before bed, and (iii) making the bedroom and sleep environment restful. These three behaviors have therefore been recommended as the target of interventions designed to improve sleep among university students or adolescents.[14,15] We would also note that many adolescents live at home with their parents, who are likely to influence routines and the nature of the sleep environment. Like the adolescents themselves, parents may not be aware of the importance of sleep hygiene, suggesting that interventions might profitably target parents alongside adolescents.[16-18]

Current intervention approaches

Intervention programs using motivational interviewing, bright light therapy, psychoeducation, and cognitive behavior therapy (CBT) have been developed to improve sleep among adolescents, and significant effects of such interventions have been found on

outcomes such as knowledge about sleep, SOL, and sleep duration.[19-25] However, to date, researchers do not seem to have capitalized on the potential advantages of using theory to inform intervention (e.g., for selecting intervention components, evaluating why interventions work, and providing a conceptual framework that is replicable in similar contexts).[26,27] Unfortunately, while evidence suggests that using theory to develop interventions tends to result in larger effects on outcomes (for a review, see [28]), only about half of interventions are based on theory, and only 10% describe links between BCTs and targeted theoretical constructs.[29] We propose that two commonly used theories that have had promising effects on behavior change in other domains - namely, the Theory of Planned Behavior (TPB) and the Health Action Process Approach (HAPA) – may inform effective interventions for improving sleep hygiene behaviors among adolescents, and thus sleep and health more generally.

The Theory of Planned Behavior

The TPB proposes that the most salient and proximal predictor of behavior is behavioral intention – defined as self-instructions to perform particular behaviors or to obtain certain outcomes (e.g., "I intend to get enough sleep"). In turn, the TPB proposes that three beliefs (attitude, subjective norms, and perceived behavioral control) predict behavioral intention.[30] Attitudes are the person's cognitive and affective evaluations of the respective behavior (e.g., "Getting enough sleep would be worthwhile, but boring"); subjective norms reflect the extent to which individuals or groups that are important to the person agree that they should perform the respective action (e.g., "My parents would like me to go to sleep earlier") and how much an individual wants to comply with these referents. Finally, perceived behavioral control indicates the extent to which an individual can control the respective behaviors (e.g., "I have little control over when I wake up"). The TPB has beenfound to provide an adequate account of self-reported sleep;[13,31-33] however, the TPB is rarely used to develop interventions designed to improve sleep. We argue that this is a missed opportunity. If BCTs are identified that can modify the putative theoretical determinants of sleep-related behavior, then healthy sleep is likely to follow through more precise targeting of the active ingredients of change.

The Health Action Process Approach

The TPB is, however, limited in that it does not consider the process(es) by which intentions are translated into action. Given the widely cited gap between intention and action (for reviews, see [34,35]) models such as the HAPA build on the motivational constructs specified by the TPB to consider self-regulatory processes like action and coping planning that might help to explain why some intentions are translated into action, while others are not. Specifically, the HAPA suggests that changing behavior (e.g., improving sleep hygiene in an effort to get more sleep) involves two consecutive phases: (i) a motivational phase; and (ii) a self-regulatory phase.[36] While the TPB provides a reasonable account of the motivational factors that influence behavior, the self-regulatory phase of the HAPA suggests that action planning and coping planning are likely to be important in determining whether intentions are translated into action. That is, after an individual forms the intention to perform a health behaviors (e.g., "I will try to go to sleep at the same time each evening"), action planning helps him or her to plan when, where, and how to perform such behaviors (e.g., "I will go to bed after I watch the 10pm news") and coping planning helps him or her to design strategies to overcome anticipated barriers to performing such behaviors (e.g., "If I am tempted to look at Facebook before bed, then I will tell myself that it will still be there in the morning!")[37,38]

The present research

The TPB and the HAPA are commonly used to inform interventions designed to promote changes in various behaviors across different populations[39,40]. Furthermore, the two models have been previously combined to help to understand sleep hygiene among adolescents.[33] However, almost no studies to date have explored whether the TPB and the HAPA can inform interventions designed to *change* sleep hygiene behaviors, sleep quality, or sleep patterns. To our knowledge, only one study has used part of the TPB in an effort to promote sleep hygiene behaviors among students (i.e., targeting only intentions, but not other components of the TPB).[25] Similarly, one other study used the HAPA to improve the sleep quality of older patients with obstructive sleep apnea syndrome.[41] With this in mind, the present research aimed to examine the effects of an intervention informed by the TPB and the HAPA on sleep hygiene and sleep-related outcomes, including health, in a large sample of adolescents. Additionally, given that most adolescents live at home with their parents, and parents can influence adolescents' sleep hygiene and respective determinants,[18] parents were included in the first session of the intervention and asked to monitor their children's progress and provide feedback for evaluation. All of the outcomes were assessedone and six months following the intervention to understand the longitudinal effects of the intervention.

Methods

Design and population

A two-arm (wait-list control group vs. intervention group) clustered randomized trial with three assessment time points (baseline, one month, and six months post intervention) was conducted between September 2015 and July 2017. The protocol was approved by the ethics committee at Qazvin University of Medical Sciences (ref: IRQUMS.REC.1394.107) and the trial was registered on a World Health Organization (WHO) approved clinical trials database (ClinicalTrials.gov, NCT02551913). All of the study procedures were carried out in compliance with the Helsinki Declaration and all of the adolescents and at least one of their parents provided written informed consent. Adolescents and their schools were eligible if they located in Qazvin city, were not involved in another sleep education program and agreed to participate in the study.

A two-stage sampling approach was used to recruit adolescents. At the first stage, a list of high schools in Qazvin was obtained from the Organization for Education at Qazvin and assessed for eligibility. Nine schools were excluded because they had already participated in a sleep hygiene program or did not agree to participate, leaving seventy schools. Forty-eight high schools were randomly selected from the seventy remaining schools. At the second stage, two classes were randomly selected from each school and the adolescents were excluded if they were identified as having autism spectrum disorder or attention deficit hyperactivity disorder (as assessed by the Autism Diagnostic Interview-Revised and the Autism Diagnostic Observation Schedule-Generic) or IQ disability (as assessed by Wechsler intelligence scale) based on routine testing conducted by the participating schools. Given that the intervention sessions were carried out within the regular curriculum, all of the adolescents in the intervention group attended all of the intervention sessions. Figure 1 summarizes the flow of participants through the trial.

(Insert Figure 1 here)

Sample size

Power analysis based on a medium-sized improvement in sleep hygiene (i.e., a change from 14 to 16 on the Sleep Hygiene Behaviors Scale[42]), a standard deviation (*SD*) of 8.80 between the study groups six months after the intervention, an intracluster correlation coefficient (ICC) of 0.05, 20% drop-out rate and a significance level (α) of 0.01, suggested that 1,330 adolescents would be needed in each group.

Randomization and blinding

Randomization was conducted by an independent statistician using a random sequence generator in STATA 13 (StataCorp LLC, College Station, TX). Iran only has gender specific schools; therefore, the adolescents in each high school were randomly assigned in a 1:1 ratio, stratified by gender, to either the intervention group or the control group. Due to the nature of intervention, it was not feasible for participants to be blind to condition. However, those who collected and analyzed the data were masked to the randomization status.

Intervention

The intervention consisted of four group face-to-face sessions with the adolescents and one with their parents, each lasting around 60 minutes. Except for 73 dyads (5.12%) who missed one session of the intervention and 62 dyads (4.35%) who missed two sessions, the majority of participants (90.53%) attended all four of the sessions. The sessions were scheduled at approximately 2-week intervals across 2 months. The content of each session was designed in accordance with the BCTs as defined by Michie et al.[27] Examples include providing information about health consequences, pros and cons, comparative imagining of future outcomes, problem solving skills, and self-monitoring of behavior. Table 1 provides a more detailed description of the BCTs, as well as the putative theoretical determinant of behavior that they were designed to target. Although self-monitoring is not a part of the TPB or HAPA, self-monitoring was included in the present intervention as it forms a core part of many interventions for promoting sleep[14,43] and other frameworks for understanding self-regulation, including control theory.[44] The intervention was delivered by two trained facilitators in the schools. Both of the facilitators had Master's level degrees in a relevant discipline and at least 10 years' experience of working with children and young people. The facilitators were trained in the delivery of the BCTs prior to the start of the main study.

The BCTs were divided across the four sessions as follows. In the first session, the adolescents and their parents received information about the importance of sleep, a definition of sleep and sleep cycles as well as a description of common sleep problems, sleeping needs for adolescents, factors associated with poor sleep in adolescents, and how poor sleep affects school performance and other outcomes. In the second session, the pros and cons of sleep hygiene behaviors, as well as getting up earlier on weekends were discussed. In the third session, the adolescents were encouraged to reconstruct their physical environments (e.g., their bedrooms) to facilitate sleeping. At the end of this session, the adolescents were provided with a planning sheet and asked to indicate when, where, and how they would perform sleep hygiene behaviors every night. The adolescents were then asked to formulate three strategies for each sleep hygiene behavior. In addition, the adolescents were provided a second planning sheet and asked to anticipate potential barriers that could interfere with performing sleep hygiene behaviors. They were asked then to provide strategies to overcome anticipated barriers to performing each sleep hygiene behavior. In the final session, the adolescents' parents were asked to monitor their children's progress and provide feedback. In addition, the adolescents were provided a daily sleep dairy based on the Pittsburgh Sleep Diary.[45]

Adolescents in the control group did not receive any intervention and continued with their usual school curriculum. However, at the end of the study, adolescents in the control group received educational material related to sleep hygiene. None of the participants received any incentives during the study period.

Primary Outcomes

Adolescent Sleep Hygiene Scale. The ASHS[42,46] contains 32 items designed to measure aspects of sleep hygiene among adolescents. The ASHS assesses how often adolescents have done a series of things related to sleep (e.g., "During the hour before bedtime, I do things that make me feel very awake [e.g., playing video games, watching TV, talking on the telephone]") during the past month on a six-point Likert scale (1 = *never*; 6 = *always*). Cronbach's alpha indicated that the ASHS was internally reliable (α = 0.86, 0.82, and 0.88 for baseline, 3-, and 6-month follow-ups, respectively) and so total scores were computed for use in the analysis.

Sleep duration. Sleep duration was calculated using four items that asked participants to report the time that they fell asleep and woke up, respectively, during week days and weekend days. Sleep duration was estimated by computing the difference between wake-up time and time fallen asleep separately for week days and weekend days.[47] We then used this information to compute the average sleep duration over 7 nights using the following equation: Sleep duration = (5 x weekday sleep duration) + (2 x weekend sleep duration) /7.

Secondary Outcomes

Pediatric Daytime Sleepiness Scale. The PDSS[48] contains 8 items designed to measure daytime sleepiness – e.g., "How often do you fall asleep or get drowsy during class periods?" Adolescents were asked to respond on a five-point Likert scale (0 = *Never*; 4 = *Always*). The internal consistency (α) for this scale was found to be 0.91, 0.93, and 0.89 for baseline, 3-, and 6-month follow-ups, respectively. A summated total score was used for the PDSS in this study.

Pittsburgh Sleep Quality Index. The PSQI[49] contains 19 items designed to measure sleep quality and disturbance – e.g., "During the past month, how often have you had trouble sleeping because you had bad dreams?" Adolescents were asked to respond on a four-point Likert scale from *Not during the past month* to *Three times a week or more* such that higher scores indicate poorer sleep quality. The internal reliability of this scale was satisfactory (α = 0.83, 0.84, and 0.79 for baseline, 3-, and 6-month follow-ups, respectively). A summated total score was used for the PDSS in this study.

Sleep Disturbance Scale for Children. The SDSC[50] is a questionnaire that parents complete to assess the sleep quality of their child during the past six months. The SDSC contains 27 items (e.g., "The child feels anxious or afraid when falling asleep") that the parent was asked to rate on a five-point Likert scale from *Never* to *Always*. The reliability of the SDSC scale was found to be satisfactory (α = 0.88, 0.87, and 0.82 for baseline, 3-, and 6-month follow-ups, respectively). A summated total score was used for the PDSS in this study.

Secondary outcomes

Sleep knowledge. Knowledge about aspects of sleep was measured using the 15-item Sleep Knowledge Questionnaire, which was developed by Gallasch and Gradisar[51] and an extension of the Sleep Hygiene Awareness and Practice Scale[51] (e.g., "Going to bed hungry benefits sleep"). Participants were asked to indicate whether each item was true or false. Two marks were given to a correct answer, a "don't know" answer received 0 marks, while an incorrect answer resulted in 2 marks being deducted. The scores on each item were summed to provide a score ranging from -30 to 30, where a higher score indicates better knowledge about sleep. The internal consistency (α) for this scale was 0.87, 0.78, and 0.84 for baseline, 3-, and 6-month follow-ups, respectively.

General Health Questionnaire. The 12-item version of the GHQ (e.g., "You are able to concentrate") validated for use with Iranian samples[52] was used in the present study. The GHQ measures the health, especially the psychiatric well-being, of an individual. Adolescents were asked to respond on a four-point Likert scale from *Less than usual* to *Much more than usual*, and a higher score

indicates poor health. The internal consistency (α) for this scale was 0.81, 0.85, and 0.91 for baseline, 3-, and 6-month follow-ups, respectively. A summated total score was used for the PDSS in this study.

Health-related quality of life. The child-reported Pediatric Quality of Life Inventory[53,54] was used to assess QoL. The PedsQL contains 23 items that assess physical (e.g., "It is hard for me to walk more than one block"), emotional (e.g., "I feel afraid or scared"), social (e.g., "Other teens tease me"), and school (e.g., "It's hard to pay attention in class") aspects of QoL. Adolescents were asked to respond on a five-point Likert scale from *Never a problem* to *Almost always a problem*; then, all the item scores are linearly transformed into a 0-100 scale. Two summary scores were computed – physical health and psychosocial health – and higher scores on each indicate a better QoL. The internal consistency (α) was 0.86, 0.89, and 0.92 for baseline, 3-, and 6-month follow-ups, respectively (physical health); 0.88, 0.76, and 0.84 for baseline, 3-, and 6-month follow-ups, respectively (psychosocial health).

TPB variables. The four beliefs specified by the TPB – attitude, subjective norm, perceived behavioral control, and (behavioral) intention[30] – were each measured using a series of items to which participants responded on five-point Likert scales. The items reflecting each belief were combined such that higher scores indicate more positive attitudes (12 items; sample item: "Making my bedroom/sleep environment restful would make me feel rested in the morning", α = 0.93, 0.90, and 0.91 for baseline, 3-, and 6-month follow-ups, respectively), more favorable subjective norms (3 items; sample item: "People who are important to me think I should not have anxiety-provoking activity before bedtime", α = 0.85, 0.80, and 0.83 for baseline, 3-, and 6-month follow-ups, respectively), greater perceived behavioral control (3 items; sample item: "I am confident that every day I can prevent anxiety-provoking activity before bedtime" , α = 0.84, 0.89, and 0.85 for baseline, 3-, and 6-month follow-ups, respectively), and stronger intentions to perform the respective behaviors (6 items; sample item: "Over the next week, I intend to make my bedroom restful", α = 0.90, 0.93, and 0.96 for baseline, 3-, and 6-month follow-ups, respectively).

Action planning and coping planning. Action planning was measured by asking adolescents whether they had specified "when", "where", "how", and "how often" they would perform the focal sleep hygiene behaviors. Participants responded to each item on a five-point Likert-type scale (where 1 = *totally disagree* and 5 = *totally agree*), and the items were combined such that higher scores indicate better action planning. Coping planning was assessed using fiveitems reflecting whether adolescents had planned how to resolve potential barriers to performing sleep hygiene behaviors.[33] The internal consistency (α) for action planning was 0.88, 0.85, and 0.86 for baseline, 3-, and 6-month follow-ups, respectively; for coping planning scales w 0.86, 0.83, and 0.90 for baseline, 3-, and 6-month follow-ups, respectively

All of the primary and secondary outcomes were assessed three times: at baseline and at one and six months after the end of the intervention. The measures were administered to groups in a classroom setting where two research assistants were available to answer any questions that the participants had.

Data analysis

All of the analyses were conducted using MLwiN (version 2.27, Multilevel Model Project, Institute of Education, University of Bristol). Multilevel linear hierarchical models with three levels (clustered in schools and repeated measures in person) were constructed to examine the effects of the intervention on the outcomes at one month and six months post-intervention. A restricted iterative generalized least square (RIGLS) estimation was used to estimate unbiased coefficients for the random parameters. Intention-to-treat (ITT) analyses were used as the multilevel linear hierarchical models can impute the missing values through multiple

imputation. In addition to the intervention, potentially confounding variables (including age, gender, and father's level of education) were included in the models as previous findings suggest that these variables can influence sleep and factors that are related to sleep. For example, Gallasch and Gradisar[51] found that older people as compared with younger people had more consistent relationships among their sleep knowledge, sleep behavior, and sleep quality. Other studies have found that daytime sleepiness increased with age in early adolescence.[55-57] Mallampalli and Carter[58] summarize several differences in sleep between men and women (e.g., that sleep latency tends to be longer in women than men) and similar gender differences have been found in adolescents: For example, Galland et al. found that girls had poorer sleep quality and sleep hygiene (e.g., taking hot caffeinated drinks; longer sleep latency) than did boys.[59]

We also conducted meditation analyses following Krull and MacKinnon's recommendations;[60] which involve; (i) assessing the direct effect of the intervention on outcomes; (ii) assessing the effects of the intervention on the potential mediators; and, finally, (iii) computing the effects of the changes in the mediators on the outcomes. We conducted two mediation analyses. The first examined whether changes in beliefs and self-regulatory processes mediated any effects of the intervention on sleep hygiene. Therefore, we used ASHS scores measured at six-month post-intervention as the dependent variable and variables specified by TPB and HAPA measured at one-month post-intervention as potential mediators. The second mediation analysis examined whether changes in sleep hygiene behavior mediated any effects of the intervention on health. Therefore, we used PSQI and GHQ measured at six-month post-intervention as the dependent variables and ASHS score measured at six-month post-intervention as the mediator. The mediation analyses controlled for age, gender, and baseline measures of the outcome and mediators (i.e., TPB and HAPA variables, ASHS, PSQI and GHQ), where relevant.

Results

The control and intervention groups had similar demographic characteristics (see Table 2). Specifically, the mean age of the adolescents in the control group was 15.12 years (SD = 1.50) and the mean age of the adolescents in the intervention group was 15.51 years (SD = 1.08; $p < 0.001$). Slightly less than half of the participants were male in each of the conditions (48.0% in the control group and 45.1% in the intervention group; $p = 0.11$).

(Insert Table 2 here)

Table 3 describes the sleep patterns, sleep hygiene, sleep quality, and health status of both groups at baseline, 1-month, and 6-month follow-ups.

(Insert Table 3 here)

Effects of the intervention on primary outcomes

The intervention had promising effects on all of the primary outcomes. Specifically, sleep hygiene was improved among adolescents in the intervention group as compared with adolescents in the control group at both follow-ups, as suggested by scores on the ASHS ($p < 0.001$ for both 1 and 6 months). Similar improvements were shown in daytime sleepiness (i.e., adolescents in the intervention group were significantly less sleepy than adolescents in the control group both 1 and 6 months following the intervention, $p < 0.001$), sleep quality (i.e., PSQI scores, $p < 0.001$), sleep disturbance (i.e., SDSC scores, $p < 0.001$), and sleep duration ($p < 0.001$). Table 4 shows the findings of the three-level hierarchical linear models predicting primary outcomes on between two groups when their demographic characteristics were controlled.

(Insert Table 4 here)

Effects of the intervention on secondary outcomes

In terms of secondary outcomes, the analyses indicated that adolescents in the intervention group had increased knowledge about sleep ($p < 0.001$ for both 1 and 6 months), were more likely to have formed relevant action and coping plans ($p < 0.001$ for both 1 and 6 months), and had improved psychosocial QoL ($p < 0.001$ for both 1 and 6 months), and general health (i.e., GHQ scores, $p = 0.012$ for 1 month and $p < 0.001$ for 6 months) relative to adolescents in the control condition. However, there were no differences between the conditions in physical QoL ($p = 0.51$ for 1 month and $p = 0.74$ for 6 months; Supplementary Table 1). Supplementary Table 2 shows that all of the putative predictors of behavior as specified by the TPB (i.e., attitudes, normative and control beliefs, and intentions) were improved at both 1 month and 6 months among adolescents in the intervention group relative to adolescents in the control condition (all ps < 0.001).

Mediation analyses

In order to investigate whether the effects of the intervention on the primary outcomes were mediated by changes in relevant beliefs about sleep hygiene behaviors as specified by the TPB, along with self-regulatory processes as specified by the HAPA, we conducted mediation analyses (see Supplementary Table 3). Subjective norms ($p = 0.008$), perceived behavioral control ($p < 0.001$), behavioral intention ($p < 0.001$), action planning ($p < 0.001$), and coping planning ($p < 0.001$) all mediated the relationship between intervention and sleep hygiene. However, attitude did not mediate the relationship between intervention and sleep hygiene ($p = 0.32$).

Finally, we conducted additional mediation analyses to investigate whether the effects of the intervention on the primary outcomes (e.g., sleephygiene) at one month mediated the impact of the intervention on secondary outcomes reflecting general health and sleep quality at six months post-intervention. Consistent with this idea, sleep hygiene (i.e., scores on the ASHS) mediated the relationship between the intervention program and two secondary outcomes (GHQ and PSQI; ps < 0.001, see Supplementary Table 4).

Discussion

The present research found that a theory-based intervention improved sleep outcomes among adolescents, as evidenced by improved sleep patterns, sleep quality, knowledge about sleep, and performance of sleep hygiene behaviors. These beneficial effects were mediated by changes in the putative determinants of behavior, as specified by the TPB (i.e., attitude, subjective norms, perceived behavioral control, and intention) and the HAPA (i.e., action and coping planning). Furthermore, as a consequence of the improvements in sleep, the intervention also had positive effects on adolescents' health and QoL. The implication is that researchers and practitioners interested in improving sleep, particularly among adolescents, might draw on the insights provided by the TPB and HAPA in order to design effective interventions to improve sleep among adolescents.

The finding that the improvements in sleep following the intervention accrued (in part) from changes in motivational variables specified by the TPB support the findings of previous studies, which suggest that the TPB is an effective model for understanding the performance of sleep hygiene behaviors.[32,33] However, the present findings go beyond these (correlational) studies to show that *changes* in the putative determinants of action lead to *changes* in the respective behaviors (and, as a consequence, outcomes). Consequently, the present research provides experimental support for the TPB as a framework for improving sleep.

The present findings also support the idea that it is important for interventions to target self-regulatory process, such as those specified in the HAPA, in addition to motivational variables (i.e., those specified by the TPB). That is, adolescents in the intervention condition were prompted to form plans specifying when, where, and how they would perform sleep hygiene behaviors, as well as how

they would deal with potential obstacles. As a result, they evidenced better action and coping planning as compared to adolescents in the control condition and, again, these changes mediated the effect of the intervention on outcomes. These findings support those of correlational studies that point to the importance of self-regulatory processes in predicting sleep hygiene and related outcomes[33] and also the findings of Deng et al.[41] who found that an intervention based on the HAPA improved sleep quality among patients with obstructive sleep apnea. Taken together then, the present research suggests that targeting the motivational and self-regulatory processes that are specified by the TPB and HAPA can lead to changes in the respective behaviors.

As a consequence of the improvements in sleep, the present research also found that the intervention improved the health of the adolescents, particularly in psychosocial aspects; that is, scores on the GHQ and PedsQL psychosocial health were improved among adolescents in the intervention,relative to those in the control condition at both one- and six-month follow-ups; while scores on the PedsQL physical health were similar at both follow-ups. Other studies have also found that sleep hygiene is associated with psychosocial health,[33,61] perhaps because good sleep hygiene improves sleep quality and helps adolescents to recover from daily physical and psychological exertions.[62] The present research did not, however, find any improvement in physical health as a consequence of the improvements in sleep found among adolescents in the intervention condition. One possible reason is that physical health may need longer than psychosocial health to improve. Another possibility is that physical health cannot be improved through an intervention targeting sleep hygiene. Future studies using a longer timeframe are warranted to examine whether physical health can be improved using a theory-based intervention targeting sleep hygiene.

Limitations and future directions

The present research employed a cluster RCT methodology, and used advanced analytical methods appropriate to the design (i.e., multilevel and longitudinal analyses). The follow-up period (i.e., 6 months) was longer than in most previous studies, and we recruited a relatively large sample of adolescents in a field context. There are, however, some limitations to the present work that warrant discussion. First, the outcome measures were based on self-reports (or in one case, parents' reports). Although the measures used in the present research have been validated in previous work, and we have no reason to doubt the validity of the measures of cognitions, self-regulatory processes, behavior or outcomes such as health or QoL, there is evidence that self-reported and objective measures of sleep quality can differ.[6,63] Interestingly, evidence suggests that self-reported sleep, rather than objectively recorded sleep, is more strongly associated with health related outcomes,[6] suggesting that, although objective measures of sleep may help to further elucidate the effect of changes in sleep hygiene behaviors, the (self-report) measures employed in the present work may actually have captured the aspects of sleep that influence outcomes.

Second, we recognize that the present research was limited to one cultural context – namely Iranian adolescents. Studies have found that Iranian adolescents typically sleep for longer (7.7 hours) than Korean and Japanese adolescents (5.4 and 6.3 hours, respectively), and for less time than Finish and Swiss adolescents (8.5 and 9 hours, respectively).[64] Hence, care should be taken in generalizing the findings of the present study to other cultures. Furthermore, all of the outcome measures used in the present study were developed in Western countries. However, they have been validated for use in Iranian adolescents[42,46,48-54] suggesting that the measures were valid and reliable and also allowing the present findings to be compared with those of studies in other cultures.

Another issue that warrants discussion is that, although age was not significantly related to sleep hygiene, it was inversely associated with sleep quality such that older adolescents in our sample had poorer sleep quality as compared with their younger

counterparts. One possible explanation for this finding is that older adolescents may have felt higher levels of academic pressure or experienced more mental health difficulties than did young adolescents.[65] Therefore, although older and younger adolescents had similar sleep hygiene behaviors, these may not have been sufficient to buffer the impact of the additional stress that older adolescents may have felt and resulted in poorer sleep quality. However, as we did not measure (perceived or actual) academic pressure (or other stresses), future studies are warranted to test our postulation.

Finally, although the present intervention included parents in some aspects of the intervention, the influence of the intervention on parents and whether and how they influenced the beliefs and behaviors of their adolescent children was not assessed (beyond the examination of adolescents' normative beliefs, which may have included the views of their parents). The effect of including parents in sleep interventions is therefore not clear and future research might consider factorial designs that systematically manipulate key components of the intervention (e.g., inclusion versus exclusion of parents), in order to isolate the impact of different components of the intervention on outcomes. It will also be important to explore the best way to deliver this (or similar) interventions outside of the context of a research study. One possibility is that the intervention could be delivered in the form of an elective for students and families in a school setting.

Abbreviations

Adolescent Sleep Hygiene Scale; ASHS.

Behavior change technique; BCT.

General Health Questionnaire; GHQ.

Health Action Process Approach; HAPA.

Intention-to-treat; ITT.

Theory of Planned Behavior; TPB.

Pediatric Daytime Sleepiness Scale; PDSS.

Pediatric Quality of Life Inventory; PedsQL.

Pittsburgh Sleep Quality Index; PSQI.

Quality of life; QoL.

Restricted iterative generalized least square; RIGLS.

Sleep Disturbance Scale for Children; SDSC.

Sleep onset latency, SOL.

Wake after sleep onset, WASO.

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Figure caption

Figure 1. Flow of participants through the study.

Captions for Supplementary materials

Supplementary Table 1. Three-level hierarchical linear models predicting secondary outcomes
Supplementary Table 2. Three-level hierarchical linear models predicting variables specified by the Theory of Planned Behavior
Supplementary Table 3. Mediation analyses testing whether the impact of the intervention on scores of the Adolescent Sleep Hygiene Scale (ASHS) at six months post-intervention were mediated by variables specified by the TPB and HAPA at one month post-intervention.
Supplementary Table 4. Mediation analyses testing whether the impact of the intervention on (1) sleep quality and (2) general health is mediated by changes in sleep hygiene behaviors

Table 1

Behavior Change Techniques (BCTs) employed in the intervention and the outcome(s) that they target

Behavior change technique (BCT)	**Brief description**	**Targeted outcome(s)**
BCT 5.1: Information about health consequences	Explain that adolescents need between 9 and 10 hours of sleep every day to function best, According to the World Health Organization as well as the National Sleep Foundation. Less sleep (specifically, less than 7 hours per night) may have effects on the cardiovascular, endocrine, immune, and nervous systems, including anxiety, depression, obesity, Diabetes and impaired glucose tolerance.	Attitudes towards and intentions to perform sleep hygiene behaviors
BCT 9.2: Pros & cons	Outline the potential risks of insufficient sleep (e.g., blood pressure, stroke, diabetes, and cardiovascular diseases). The adolescents were asked to list the potential risks of poor sleep and the potential benefits of good sleep (e.g., 'If I sleep enough daily, then I will have a healthier life')..	Attitudes toward and intentions to perform sleep hygiene behaviors
BCT 12.1: Reconstructing the physical environment	Recommendations for making the bedroom more comfortable for sleeping (e.g., keep the temperature in your bedroom comfortable).	Perceived behavioral control
BCT 3.2: Social support	Encourage parents to attend the face-to-face sessions with the adolescents. In addition, encourage parents to provide feedback and monitor their adolescent's plans and use of a sleep diary.	Subjective norms
BCT 1.4: Action planning	Ask adolescents to create two plans specifying what (sleep hygiene behaviors), when (day), and where (place) they would sleep.	Action planning
BCT 1.2: Problem solving	Ask adolescents to identify barriers that they might encounter when trying to sleep and generate strategies to overcome them. e.g., 'If I cannot sleep because I am worried about an exam the next day, then I will take a warm bath'	Coping planning
BCT 2.3: Self-monitoring of behavior	Provide adolescents with a dairy and ask them to indicate length and timing of their sleep, times woken during the night, and reasons for waking each day for a month.	Self-monitoring[a]

Note. The labels and numbers of the BCTs are from Michie et al's[22] taxonomy.

[a] Self-monitoring was included in the present intervention as it forms a core part of many interventions for promoting sleep (Maris & Mullan;[37] Todd & Mullan[14]) and other frameworks for understanding self-regulation, including control theory (Carver & Scheier[38]).

Table 2
Demographic characteristics by condition (n = 2,841)

	Control (n = 1,416)[a]	Intervention (n = 1,425)[b]	p-value for the comparison

School characteristics			
Number of schools recruited	26	26	
Number of students per class; mean (*SD*)	27.23 (3.21)	27.40 (3.19)	
Individual characteristics			
Age in years; mean (*SD*)	15.12 (1.50)	15.51(1.08)	< 0.001
Number of males; *n* (%)	680 (48.0%)	642 (45.1%)	0.11
Father's education (year); mean (*SD*)	7.94 (2.35)	7.72 (3.24)	0.04
Mother's education (year); mean (*SD*)	6.98 (4.11)	6.73 (2.69)	0.06
Monthly family income; *n* (%)			< 0.001
High (>US$1000)	405 (28.6%)	456 (29.8%)	
Intermediate (US$500- US$1000)	581 (41.0%)	661 (41.9%)	
Low (<US$500)	430 (30.4%)	308 (26.4%)	

Table 3

Descriptive statistics for all outcome measures by condition and time

	Control (*n* = 1,416)			Intervention (*n* = 1,425)		
Outcome	Baseline	Month 1	Month 6	Baseline	Month 1	Month 6
Time asleep at weekdays (hour: min)	24:14 (0.34)	24:09 (0.28)	24:13 (0.20)	24:10 (0.45)	23:56 (0.31)	23:29 (0.32)
Wake time at weekdays (hour: min)	7:21 (0.26)	7:12 (0.22)	7:05 (0.18)	7:29 (0.12)	7:24 (0.11)	7:14 (0.13)
Sleep duration at weekdays (hours)	7.07 (0.28)	7.03 (0.19)	6.52 (0.20)	7.19 (0.21)	7.30 (0.15)	7.45 (0.14)
Time asleep at weekends (hour: min)	1:02 (0.11)	24:55 (0.21)	1:06 (0.24)	24:52 (0.27)	24:29 (0.19)	24:27 (0.17)
Wake time at weekends (hour: min)	10:47 (0.31)	10:18 (0.28)	10:39 (0.33)	10:25 (0.20)	10:20 (0.34)	10:26 (0.30)
Sleep duration at weekends (hours)	9.45 (0.16)	9.23 (0.14)	9.33 (0.12)	9.33 (0.24)	9.51 (0.23)	9.59 (0.28)
PDSS	10.46 (4.68)	10.83 (4.84)	10.81 (4.11)	10.82 (5.31)	8.13 (3.92)	8.02 (3.64)
GHQ	18.80 (3.14)	18.84 (3.38)	18.86 (3.52)	18.66 (3.07)	18.52 (3.23)	17.44 (3.50)
ASHS	3.67 (0.34)	3.66 (0.55)	3.64 (0.42)	3.76 (0.44)	3.90 (0.51)	3.91 (0.33)
PSQI	6.13 (2.07)	6.16 (2.30)	6.22 (2.58)	6.08 (2.90)	4.60 (2.20)	4.57 (2.43)
SDSC	62.37 (9.01)	62.61 (9.79)	63.39 (9.61)	62.39 (10.04)	49.18 (9.41)	48.14 (10.15)
PedsQL physical health [a]	60.31 (12.80)	60.51 (15.26)	60.08 (12.83)	60.77 (12.21)	61.07 (14.65)	62.55 (14.45)
PedsQL psychosocial health [a]	74.08 (15.75)	70.06 (15.49)	68.19 (0.17.67)	74.43 (16.52)	78.28 (13.82)	81.25 (14.72)
Sleep knowledge	7.03 (2.57)	7.06 (2.11)	7.02 (2.29)	7.11 (2.70)	10.02 (3.17)	10.07 (3.46)
Attitude	4.07 (0.57)	4.03 (0.52)	3.96 (0.78)	4.15 (0.50)	4.70(0.47)	4.69 (0.56)
Subjective norms	3.31 (0.67)	3.27 (0.54)	3.25 (0.64)	3.37 (0.63)	3.80 (0.50)	3.81 (0.61)
Perceived behavioral control	3.61 (0.76)	3.58 (0.69)	3.55 (0.71)	3.74 (0.79)	4.12 (0.78)	4.09 (0.68)
Intention	3.73 (0.81)	3.71 (0.73)	3.70 (0.66)	3.84 (0.59)	4.31 (0.69)	4.32 (0.61)
Action planning	2.75 (0.62)	2.69 (0.71)	2.67 (0.68)	2.80 (0.75)	3.30 (0.67)	3.31 (0.71)
Coping planning	2.71 (0.79)	2.67 (0.73)	2.59 (0.79)	2.78 (0.73)	3.52 (0.81)	3.53 (0.74)

Note. Standard deviations are in parentheses.

[a] The PedsQL scores were transformed into a 0-100 scale using the suggestions from PedsQL manual:raw score of 0=100; 1=75; 2=50; 3=25; 4=0.

PDSS = Pediatric Daytime Sleepiness Scale

GHQ = General Health Questionnaire

ASHS = Adolescent Sleep Hygiene Scale

PSQI = Pittsburgh Sleep Quality Index

SDSC = Sleep Disturbance Scale for Children, reported by parents

PedsQL = Pediatric Quality of Life Inventory

Table 4

Three-level hierarchical linear models predicting sleep hygiene behaviors, sleep quality, and duration

	ASHS	PDSS	PSQI	SDSC	Sleep duration at	Sleep duration at

									weekdays		weekend	
	B (*SE*)	*p* (95%CI)	*B* (*SE*)	*p* (95%CI)	*B* (*SE*)	*p* (95%CI)	*B* (*SE*)	*p* (95%CI)	*B* (*SE*)	*p* (95%CI)	*B* (*SE*)	*p* (95%CI)
Intervention (vs. control)	0.07 (0.04)	0.08 (-0.01, 0.15)	0.01 (0.04)	0.80 (-0.07, 0.09)	0.15 (0.34)	0.659 (-0.52, 0.82)	-.02 (0.04)	0.617 (-0.06, 0.1)	0.08 (0.04)	0.045 (0.001, 0.16)	0.10 (0.24)	0.677 (-0.37, 0.57)
Month 1 (vs. baseline)	0.13 (0.12)	0.279 (-0.11, 0.37)	-0.31 (0.01)	<0.001 (-0.33, -0.29)	0.03 (0.03)	0.317 (-0.03, 0.09)	-0.63 (0.02)	<0.001 (-0.67, -0.59)	-0.03 (0.03)	0.317 (-0.09, 0.03)	0.21 (0.03)	<0.001 (0.15, 0.27)
Month 6 (vs. baseline)	0.14 (0.01)	<0.001 (0.12, 0.16)	-0.30 (0.02)	<0.001 (-0.34, -0.26)	0.07 (0.03)	0.020 (0.01, 0.13)	-0.41 (0.04)	<0.001 (-0.49, -0.33)	0.53 (0.03)	<0.001 (0.47, 0.59)	0.12 (0.03)	<0.001 (0.06, 0.18)
Intervention (vs. control at 1 month)	0.16 (0.02)	<0.001 (0.12, 0.20)	-0.39 (0.02)	<0.001 (-0.43, -0.35)	-0.52 (0.05)	<0.001 (-0.62, -0.42)	-0.64 (0.02)	<0.001 (-0.68, -0.60)	0.14 (0.04)	<0.001 (0.06, 0.22)	0.40 (0.05)	<0.001 (0.30, 0.50)
Intervention (vs. control at 6 months)	0.19 (0.02)	<0.001 (0.15, 0.23)	-0.38 (0.02)	<0.001 (-0.42, -0.34)	-0.59 (0.05)	<0.001 (-0.69, -0.49)	-0.73 (0.03)	<0.001 (-0.79, -0.67)	0.48 (0.03)	<0.001 (0.42, 0.54)	0.38 (0.07)	<0.001 (0.24, 0.52)
Age	0.01 (0.01)	0.317 (-0.10, 0.03)	0.15 (0.03)	<0.001 (0.09, 0.21)	0.18 (0.04)	<0.001 (0.10, 0.26)	0.05 (0.01)	<0.001 (0.03, 0.07)	-0.25 (0.02)	<0.001 (-0.29, -0.21)	-0.21 (0.02)	<0.001 (-0.25, -0.17)
Female (vs. Male)	-0.14 (0.15)	0.351 (-0.43, 0.15)	0.18 (0.14)	0.198 (-0.09, 0.45)	0.16 (0.15)	0.289 (-0.13, 0.45)	0.11 (0.13)	0.395 (-0.14, 0.36)	-0.14 (0.22)	0.525 (-0.57, 0.29)	0.38 (0.28)	0.175 (-0.17, 0.93)
Father Education	0.25 (0.14)	0.074 (-0.02, 0.52)	0.20 (0.14)	0.153 (-0.07, 0.47)	0.05 (0.15)	0.741 (-0.24, 0.34)	0.02 (0.12)	0.865 (-.22, 0.25)	0.08 (0.21)	0.703 (-0.33, 0.49)	0.13 (0.17)	0.445 (-0.20, 0.46)
Intercept	0.74 (0.02)	<0.001 (0.70, 0.78)	2.30 (0.22)	<0.001 (1.87, 2.73)	0.44 (0.11)	<0.001 (0.22, 0.66)	0.52 (0.20)	0.009 (0.13, 0.91)	2.17 (0.21)	<0.001 (1.76, 2.58)	1.63 (0.22)	<0.001 (1.20, 2.06)
$\hat{\sigma}^2_{st}$ (student)	0.87 (0.03)	<0.001 (0.81, 0.93)	0.80 (0.2)	<0.001 (0.76, 0.84)	0.92 (0.03)	<0.001 (0.86, 0.98)	0.68 (0.02)	<0.001 (0.64, 0.72)	0.70 (0.02)	<0.001 (0.66, 0.74)	0.78 (0.02)	<0.001 (0.74, 0.82)
$\hat{\sigma}^2_{sc}$ (school)	0.11 (0.002)	<0.001 (0.11, 0.11)	0.12 (0.002)	<0.001 (0.11, 0.12)	0.07 (0.001)	<0.001 (0.07, 0.07)	0.21 (0.004)	<0.001 (0.20, 0.22)	0.59 (0.01)	<0.001 (0.57, 0.61)	0.19 (0.004)	<0.001 (0.18, 0.20)

PDSS = Pediatric Daytime Sleepiness Scale
ASHS = Adolescent Sleep Hygiene Scale
PSQI = Pittsburgh Sleep Quality Index
SDSC = Sleep Disturbance Scale for Children