Promoting Improved Sleep Quality in the Geriatric Population

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Abstract

Melatonin is an over the counter medication that can be obtained without a prescription. Melatonin may be more tolerated than other sleep promoting medications such as trazodone, benzodiazepine, and other sedatives in the treatment of insomnia in the geriatric population. There have been many studies performed on the geriatric population that provide mixed reviews on whether melatonin, no matter the form, is a good sleeping aid for those experiencing persistent insomnia for over a month. The aim of this paper is to review current literature to create an evidence- based local community health promotion project related to the benefits of using 3mg of prolonged released exogenous melatonin to improve sleep quality in the geriatric population suffering from persistent insomnia. The Health Promotion Model created by Nola Pender is the theoretical approach that guides this health promotion project. The health promotion project will last one month, focusing on educating geriatric patients on the benefits of using 3mg of exogeneous melatonin to improve sleep quality. The Pittsburgh Sleep Quality Index will serve as the pre-survey and post-survey to evaluate the project benefits to each participant. A 7-to-14-point reduction in the post-survey when compared to the pre-survey would represent an effective health promotion through education on the benefits of taking sustained release melatonin to improve sleep quality. If positive results are obtained from the health promotion project, then neighboring geriatric facilities may implement the same steps and evaluate its' benefits to the participants.

Keywords: geriatric, elderly, insomnia, falls, benzodiazepine, and melatonin

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Section I: Introduction and Background

Persistent insomnia is the most common sleep disorder in ten percent of the U.S population. It affects people of all ages. Sleep deprivation on a consistent basis has been proven to impair short term memory, cause confusion, increase agitation— leading to aggressive behaviors— and misguide judgement in everyday activities (Huang, et al., 2014). The sleep and wake cycle is controlled by the release of a hormone called melatonin from the pineal gland. As people age, there is a chance that the calcification of the pineal gland or the decline in function of the suprachiasmatic nucleus that regulates the melatonin hormone, production quality is more likely to occur (Monti, Alvariño, Cardinali, Savio, & Pintos, 1999). The decrease in endogenous melatonin increases sleep latency, wake time after sleep onset, time in bed, and decreases total sleep time. In the elderly melatonin secretion may decrease as much as 80% (Huang, et al., 2014).

Since there are practice guidelines on the use or the recommended dose of melatonin that providers should use to guarantee improved sleep quality in their elderly patients, who are 65 years or older, physicians have resorted to using stronger medication such as benzodiazepines, trazodone, and other medications (Huang, et al., 2014). These medications' adverse effects have led to increased falls in the elderly, which resulted in fractures, skin tears, and or death. These serious adverse effects have made some providers cautious about using heavy sedative drugs as sleeping aids. As reported by the Centers for Disease Control and Prevention (CDC) website over 800,000 geriatric patients are treated in emergency departments each year due to falls resulting in a broken hip or head injury ("Home and Recreational Safety", 2016). Not all falls within the geriatric population are the result of someone taking benzodiazepines, but some are. The CDC reported in 2015, $50 billion dollars was the cost of falls alone in the geriatric

population ("Home and Recreational Safety", 2016). The lack of sleep may cause some elderly patients to experience increased agitation, memory loss, confusion, and falls, which can lead to disability and or death (Huang, et al., 2014).

Focus Population.

As a nation, insomnia is costing American workers an average of $63.2 billion, and as individual workers around $2,280 in lost productivity every year. It costs an average of $200 to $1200 a year to treat insomnia among individuals, depending on whether generic sleeping pills are used or behavioral therapy is utilized (Harvard Medical School, 2011). The population of interest to promote insomnia treatment and reoccurrence prevention is in the senior population, 65 years of age or older. About 38.0% to 44.1% of adults in Hawaii suffer from short sleep durations. Nearly half the geriatric population, 65 years or older, suffer from insomnia (CDC, 2016). Insufficient sleep in this population may lead to increased risk of cardiovascular disease, frequent strokes, depression, obesity, falls, and diabetes if left untreated (CDC, 2016).

The purpose of this project is to promote an effective method to using exogenous melatonin in the treatment of persistent insomnia in a geriatric population to reduce the adverse effects seen when using benzodiazepines and other narcotics to induce and maintain quality sleep.

Section 2. Review of Literature

PUBMED, CINAHL, and NCBI are the databases that were used to perform a literature review to establish a proper guideline for using exogenous melatonin while decreasing the use of narcotics such as benzodiazepines in the treatment of persistent insomnia. The search terms used were geriatric, elderly, insomnia, falls, benzodiazepine, and melatonin. To evaluate the efficacy

of the target-population medication administration method and efficacy, six research articles were reviewed (see Appendix I).

Wade, et al. (2010) conducted a study that used 2mg of prolonged released melatonin to treat persistent insomnia in geriatric study subjects, who were able to fall asleep within 58 minutes after taking the medication, while the placebo group took about 73 minutes to fall asleep, within the first week of the experiment. By week 15, the experimental group's sleep latency time was around 51 minutes while the placebo group took 68 minutes. In 21weeks, the experimental group's sleep latency was still around 50 minutes while the placebo group was measured to be around 74 minutes. The study also showed that the experimental group was able to go to bed two hours earlier than the placebo group by week three, and by week 13 they were able to go to bed 3.5 hours earlier than the placebo group. By week 29, the experimental group was able to go to bed five hours earlier than the placebo group. The same positive results could be seen in the experimental group waking up earlier with improved morning alertness and sleep quality.

Gehrman, et al. (2009) conducted a study that involved geriatric patients who presented with Alzheimer's disease and insomnia and were treated with a high dose of melatonin (10 mg) that contained 8.5 mg of instant release and 1.5 mg sustained release. The study showed that this treatment regime was ineffective in improving sleep quality. This study, like others, suggests that high doses of melatonin may have caused saturation and made the medication less effective.

Monti, et al. (1999) conducted a study with 10 geriatric patients suffering from chronic primary insomnia who were treated with three mg of melatonin. Five out of 10 of the participants showed a dramatic increase in total sleep time but in all the participants melatonin reduced wake time after sleep onset and increased total sleep time and quality during a two-week period.

Baskett, et al. (2003) conducted a study using 5 mg of instant release melatonin to treat 20 normal and 20 problem geriatric sleepers. There were no significant results suggesting that this form of melatonin did not improve sleep duration, quality, or any factors measured in either group. The researchers concluded that if the 5mg of instant release melatonin was the same as 2mg then it did not mimic normal physiologic secretory profiles and the peak levels would have been over 100 times normal biological levels after one hour.

Garfinkel, et al. (1995) conducted a study which included 12 geriatric patients who were on a variety of medications for chronic illnesses and who also suffered from chronic insomnia. The study findings showed 2mg of controlled- release melatonin over a three-week period had increased sleep efficiency while decreasing wake time after sleep onset significantly when compared to the placebo group. Total sleep time was not affected and sleep latency did not decrease significantly.

Valtonen, et al. (2005) study results from administering milk containing 10-40ng/l melatonin at night revealed that there was no significant increase or decrease in the sleep factors being measured. The study also revealed that the seasons had more of an effect on the geriatric population that was experiencing different levels of dementia. The shorter days experienced in the winter lead to increase night time activity, but during the summer or spring when the days were longer there was less activity at night and increase in sleep quality.

Support for Project

Upon literature review, treating persistent insomnia in the geriatric population with a control release melatonin around 2 to 3 mg was effective no matter if there were other chronic conditions present or if multiple treatment medications were being taken to treat those diseases.

As reported by Wade, et al. (2010), Monti, et al. (1999), and Garfinkel, et al. (1995) the administration of controlled release melatonin in geriatric participants suffering from persistent insomnia showed significant improvement in sleep latency, onset, quality, and morning alertness.

Section 3. Project Description

Need

As reported by the CDC, nearly half the geriatric population 65 years or older suffer from chronic insomnia which has led to decreased cognitive ability, increase in related chronic conditions, injuries and deaths ("Despite risks, benzodiazepine use highest in older people", 2014). The National Institutes of Health reported in 2008 that benzodiazepines prescriptions in patients ages 65 to 80 for treatment of long term insomnia was around 31.4 percent ("Despite risks, benzodiazepine use highest in older people", 2014). Prescriptions for short term use in the geriatric population was around 8.5% and may have risen since ("Despite risks, benzodiazepine use highest in older people", 2014).

Theoretical Framework.

The suitable theoretical frame work for this project is the Health Promotion Model (HPM) by Nola Pender because the focus of the HPM is positive motivation. It is believed that improving patient's quality of life is essential for the prevention of disease in the HPM. The model consists of three components: 1) individual's characteristics and experiences, 2) behavior-specific cognitions and affect, and 3) behavioral outcomes. The health promoting behaviors are the desirable behavioral outcome as they lead to improved health, better functional ability and quality of life in all developmental stages (Butts & Rich, 2015). Therefore, it frames the design of a health promotion treatment for persistent insomnia and reoccurrence prevention.

Proposed Intervention Activities

The participants will be selected by their Insomnia Severity Index (ISI) as scored by a nurse practitioner. The questions asked in this assessment tool are appropriate for the cognitively intact geriatric population and will allow the practitioner to select participants experiencing different levels of insomnia. The first three questions in the ISI survey assess how difficult it is for participants to fall and stay asleep, while waking up early the next day ("Insomnia Severity Index - My HealtheVet"). The fourth question gauges how satisfied participants are with their current sleeping patterns. The fifth question is aimed to see if the participants' social circles notice if their sleeping patterns are affecting their quality of life. The sixth question is to reveal the participants' own distress level due to the sleeping problem. The last question is to check the extent to what their sleeping problem interfering with their daily activity. Each question is scored on a 1-4 scale, with 4 indicating either very severe, very dissatisfied, very much worried, or very much interfering depending on the question being asked. A score of 8-14 suggests subthreshold insomnia, 15 – 21 equals clinical insomnia with moderate severity, and a score of 22 – 28 implies severe clinical insomnia.

To evaluate the effectiveness of education in using 3mg of controlled released melatonin in treating insomnia in the geriatric population, the Pittsburgh Sleep Quality Index (PSQI) will be used as a pre-survey and post-survey. The PSQI is based on seven questions that are used to assess subjective sleep quality, latency, duration, habitual efficiency, disturbances, use of sleep medication, and daytime dysfunction over the previous month. Each category may be given a score from zero, which represents no difficulty, to three, which specifies severe problems. A total score of zero represents normal sleep and 21 represents problems falling asleep, increase waking up after sleep onset, and decrease quality sleep. After the pre-survey, patients will be educated on

primary insomnia and its associated signs and symptoms. They will also be educated on how to achieve quality sleep through the promotional use of 3mg of controlled released melatonin. The benefits and adverse effects in using exogenous melatonin will also be explained through brochures at the end of each weekly visit over a one-month period. This brochure will also contain information on insomnia signs and symptoms. To participate each participant must provide written consent. At the end of the one-month period, the post-survey will be given. The pre-survey and post-survey of each participant will be compared, even if the sustained release melatonin was not taken on a constant nightly base or at all.

Goals, Objectives, Timelines

As a health care professional, it is vital to learn about insomnia, promote awareness, and to administer the most effective treatment with the least adverse effects in the geriatric population to increase or maintain quality of life. Since Honolulu currently observes Hawaii Standard Time (HST) and no longer daylight-saving time (DST), there will be no seasonal effects experienced by the participants as seen in the Valtonen, et al. (2005) study. The beginning of January 1st through 31st of 2019, in Hawaii will be adequate for implementation, including presurvey and postsurvey.

The goal of this project is to increase the quality of sleep experienced by the geriatric population in Hawaii's nursing homes who are experiencing insomnia by reducing the PSQI postsurvey scores by 7 to 14 points. The 7-to-14-point reduction would represent an effective health promotion through education on sustained release melatonin.

Community Assets and Resources

This project will be taking place at Aloha Nursing Rehab Center in Kaneohe. The facility is split into skilled nursing care on the 1st floor and long-term care on the second floor. There are five cognitively intact patients on the second floor and ten on the first floor who suffer from different levels of insomnia. The estimated number of participants in this study is 15.

Potential Barriers/Resolutions

The barrier of this project is participants having to take 3 mg of prolonged release melatonin 30 minutes to an hour before bed every night for one month. Based on the previously reviewed studies the positive effects of melatonin may be seen after one week of constant administration. To prevent individuals from giving up on taking melatonin after the first few days, two-day follow up visits will be made to the facility for the first week to provide reinforcement and encouragement in the benefits of melatonin. Then weekly visits will be made for the rest of the health promotion study.

Nurse Practitioner Role

The US Census Bureau most recent data on the population on the state of Hawaii shows that the geriatric population in 2016 was 81,361 in total and expected to keep growing ("Research & Economic Analysis", 2016). The United States Department of Labor showed that there are only 410 nurse practitioners (NPs) employed as of 2017 in the state of Hawaii in a variety of specialties ("Occupational Employment and Wages", 2018). This project will allow new graduates and a variety of NPs with different skill levels an opportunity to help promote and maintain individual geriatric patients a higher quality of life. Persistent insomnia experienced by the geriatric population is detrimental to the quality of life (Huang, et al., 2014). The role of the nurse practitioner is to acknowledge individuals who are suffering from persistent insomnia and

promote the most effective medication with fewest side effects, such as the use of exogeneous sustained release melatonin to achieve quality sleep.

Evaluation Plan (to assess impact)

After one month, the post-survey will be filled out face-to-face with the participants to evaluate sleep quality improvement, so as to reduce communication error. A pre-survey to post-survey score reduction between 7 to 14 in the PSQI would represent effective health promotion through education on the use of exogeneous sustain release melatonin.

Future Research

Future research is needed to find out the long-term outcomes for those geriatric participants after routine promotion in the use of 3mg of sustain released melatonin in treating insomnia, such as the number of people still experiencing decreasing quality of sleep, and sleep deprivation-related injuries or deaths. Moreover, a larger study consisting of participants from a variety of nursing homes must be conducted in order to conclude the promotion in the use of 3mg of sustain released melatonin in treating insomnia may be affective in providing improved sleep quality to geriatric patients in any nursing home setting.

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Appendix 1

Matrix

Author name/ date	Title	Level of Evidence	Brief description	Results
Alan G Wade , Lan Ford, Gordon Crawford, Alex McConnachie, Tali Nir, Moshe Laudon, Nava Zisapel. (2010)	Nightly treatment of primary insomnia with prolong release melatonin for 6 months: a randomized placebo-controlled trial on age and endogenous melatonin as predictors of efficacy and safety	Level II	A randomized, double-blind, and parallel group clinical trial, which lasted 33 weeks, consisting of 546 participants that received 2mg of prolonged- released melatonin (PRM) at different stages. The sample group was recruited from Glasgow and the surrounding areas of West of Scotland and were prescreened via telephone using the Sleep History Questionnaire (SHQ), which selected participants with poor sleep qualities in having trouble in falling asleep (Wade, et al., 2010). The exclusion criteria included the use of benzodiazepine or non-benzodiazepine hypnotics within two weeks prior to the study (Wade, et al., 2010). The data was collected through sleep dairies, which were reviewed by nurses. The participants' characteristics and variable data are represented in the form of percentages, mean, and standard deviation. The MMRM was also used as an analysis for the long-term period to calculate the values of the PSQI, CGI-I and the WHO-5 Index scores (Wade, et al., 2010). Moreover, reliability of the sleep diaries does not pose a threat to validity of the data, but the participants own perception of sleep quality does. Under reporting or even over reporting sleep qualities and other variables could be present with some participants (Wade, et al., 2010). The reliability of the sleep diaries to measure applicants sleep quality will always be accurate because the data would represent each participant own perception of sleep quality obtained the prior night (Wade, et al., 2010). The strength of this study is patients 65 years or older who present primary insomnia would likely benefit from melatonin therapy and the response could be maintained for over six months. The sleep quality, and latency components of the PSQI global score reported in the dairies were significantly lower in	Regardless of initial melatonin levels in the elderly participants, PRM had an intense effect in reducing sleep latency compared to the placebo trails. Over the six-month period there were no signs of tolerance. In addition, the improvements made from the administration of PRM was observed as extra sleep time and daytime boundaries were either maintained or enhanced over the six-month period. There were no differences between PRM and placebo adverse effects for any safety outcome. The adverse effects were all minor in severity.

			the PRM group in all the visits in the participants aged 65-80 years old (Wade, et al., 2010). The lack of tools such as an actigraphy or a polysomnography that could maintain validity provides the limitations of the study results (Wade, et al., 2010). It might not be possible to reproduce the same results in another population with the same sample requirements since it is based on individuals own sleep quality.	
Philip R. Gehrman, Donald J. Connor, Jennifer L. Martin, Tamar Schochat, Jody Corey-Bloom , Sonia Ancoli-Israel. (2009)	Melatonin fails to improve sleep or agitation in double blind randomized placebo-controlled trial of institutionalized patients with Alzheimer disease	Level II	A small, randomized, placebo-controlled trail that was meant to compare the effects of exogenous melatonin versus placebo on sleep and agitation in the elderly in a nursing home who suffered from Alzheimer's disease. Convenience sampling was used for this study, recruiting residents from a nursing home who had Alzheimer's disease (Gehrman, et al., 2009). There was no mention of exclusions in this study. The researchers used an actigraph reading to measure the sleep variables such as number of hours slept per day, percentage of sleep per day with time spent asleep during the day, length and number of daytime naps. Trained staff nurses also used the Agitated Behavior Rating Scale and the Cohen Mansfield Agitation Inventory to collect objective data from the participants for 20 seconds, every 15 minutes for a whole day, every other day from 0700 until 2000 (Gehrman, et al., 2009). The study presented the scores from the CMAI that represented the results of agitation during the day as 31.6, and 29.8 in the evening. The score of 27.4 at night showed a decrease in agitation as the day progressed (Gehrman, et al., 2009). An actigraph, the Agitated Behavior Rating Scale, and the CohenMansfield Agitation Inventory (CMAI) were used to collect data in the study and there were no internal threats to the reliability of the tools since they were designed to measure sleep time and agitation. The trained nurses who were familiar with the participants behaviors used the tools in collecting data which was the internal strength of the study to secure reliability of the tools. There was an internal threat to validity of the actigraph used in the study, since there was no mentioning of the tool being	The use of exogenous melatonin in the study did not yield any significant positive changes to sleep circadian rhythms or decrease agitation when compared to placebo use. This study, like others, suggests that high doses of melatonin may have caused saturation and made the medication less effective or even toxic.

			calibrated and tested against a polysomnography to conclude its accuracy. The lack of validity of the actigraph tool in this study is a limitation that would cause difficulties in reproducing the same results in any Alzheimer population in other nursing homes.	
J.M. Monti , F. Alvarino, D. Cardinali, I. Savio, A. Pintos. (1999)	Polysomnographic Study of the effect of melatonin on the sleep in elderly patients with chronic primary insomnia	Level II	A single-blind placebo-controlled study with the purpose of evaluating the effects of administering short and intermediate 3 mg of melatonin in eight women and two elderly male patients over 19 nights. All participants had to be between the ages of 66 and 86 years old and had to be experiencing chronic primary insomnia (Monti, Alvariño, Cardinali, Savio, & Pintos, 1999). The exclusions consisted of patients with acute and chronic pain, hepatic, renal, respiratory, cardiac, and neuropsychiatric disease. A polysomnography was used to collect baseline variables on the participants on the 2nd and 3rd night to compare to the results gathered in the sleep study lab on the 4^{th}, 5^{th}, 15^{th} and 16^{th} nights (Monti, Alvariño, Cardinali, Savio, & Pintos, 1999). The mean of each variable for placebo bassline, melatonin period, and the last placebo phase was tested using a one-way ANOV with variety of measures. Statistical differences worth noting between melatonin and placebo went through the Newman-Keuls post hoc method and expressed with overall F-values. Moreover, the EEG results were analyzed using the PASS PLUS spectral analysis software (Monti, Alvariño, Cardinali, Savio, & Pintos, 1999). Since a polysomnography which is the gold standard in measuring sleep variables was used in this study, there were no internal or external threats to reliability. There was no mentioning of the tool validity being verified against another polysomnography. Five out of the ten participants experienced significant decrease in wake time after sleep onset, which suggests that the interventions in this study will have a fifty percent chance of improving sleep quality in certain geriatric populations. The lack of male participants in the study has hindered the results	Five out of ten of the participants showed a dramatic increase in total sleep time but in all the participants the exogenous melatonin reduced wake time after sleep onset and increased total sleep time and quality during a two-week period.

			from being applied to the general population outside the sample group. Moreover, the step by step instructions on how the study was conducted, with having the sleep records coded and scored blind, and not by allowing patients or physicians to know who was receiving the placebo or melatonin, were all strengths in this study to secure the accuracy in the results.	
Jonathan J. Baskett, Joaana B. Broad, Philip C. Wood , John R. Ducan, Megan J, Pledger, Judie English, Josephine Arendt. (2003)	Does Melatonin improve sleep in older people? A randomized crossover trial.	Level II	A double blind, randomized placebo-controlled crossover trail in healthy geriatric volunteers, to conclude if 5mg exogenous melatonin would increase their quality of sleep that was being affected by age- related sleep maintenance problems. Participants were enlisted from urban part of Auckland, New Zealand via an initial verbal interview which consisted of meeting the Pittsburgh Sleep Quality Index questionnaire requirements, passing the Mini Mental Status Examination, and the Geriatric Depression Score (Baskett, 2003). Actiwatches were used to measure time in bed, sleep time, sleep latency, number of wakening's, and sleep efficiency. Sleep dairies contained the Pittsburgh Sleep Quality Index (PSQI), the Leeds Sleep Evaluation Questionnaire, a place to record number of daytime naps, time to bed, time lights out before sleep, time of actual sleep, wake up and final get up times (Baskett, 2003). The statistical analyses were performed using SAS Version 8.02, and S-PLUS200 professional edition. The medians of the baseline of sleep quality indicators were reported with a 95% confidence interval. The Medians and the P-values were also present for each sleep quality variable. The difference between the means of the seven variables of each participant while on melatonin or placebo represented the treatment effect (Baskett, 2003). The reliability and validity of the actigrapghy was confirmed when it was tested against a polysomnography which confirmed the intrasubject measurement of activity and immobility do to sleep were reported to be stable (Baskett, 2003). The reliability of the sleep dairy was effective since they recorded the participants	The results of the actigraphy, sleep diaries, and the Leeds Sleep Evaluation Questionnaire suggested that the administration of the 5mg of fast acting melatonin given before bedtime did not improve the sleep quality in geriatric population suffering from age –related sleep maintenance problems.

			perception sleep experienced the night before. Under reporting or even over reporting sleep qualities and other variables could be a possibility with some participants when using the sleep diaries, which posed an internal threat to validity. Even though guidelines were produce in the study on how to use the actiwatches, the researchers recognized a major limitation was one of precision. The researchers also realized it would have been useful to use the actiwatches and dairies in the prescreening process in order to compare pre-results and post-results. The actiwatches being used were the same brand, model and used on the same non-dominant limb to measure and compare the intra-subjects which made it reliable and a strength in the study. The actiwatches were non-invasive, allowed participants to be studied at home. The study concluded that 5 mg of instant release melatonin would not improve the sleep quality and duration of geriatric patients suffering from age related sleep maintenance problems.	
D Garfinkel, M Laudon, D nof, N Zisapel. (1995)	Improvement of Sleep Quality in Elderly People by Controlled- Release Melatonin	Level II	A randomized, double blind, crossover study where 12 elderly participants (seven males and five females) who presented with long term insomnia were treated for three-week with 2 mg of controlled-released melatonin per night before a 1-week washout period, and finally a three-week placebo period. A convenient sampling method was used to recruit participants 65 years or older who experienced long term insomnia in a assistant living residential center (Garfinkel, Laudon, Nof, & Zisapel, 1995). Volunteers were excluded if they presented dementia or had poor compliance. Data on the quality of sleep was collected objectively via a wrist actigraphy consecutively for 3 days at the end of each 3-week session. The data was used in an automatic scoring algorithm to determine sleep latency, total sleep time, sleep efficiency, and wake after sleep onset. Furthermore, the two-tailed t test on the dependent sample was used to view the different variable results that were produced during the melatonin and placebo phases (Garfinkel, Laudon, Nof, & Zisapel, 1995).	The results suggested that administering controlled- released melatonin in the elderly who suffer from insomnia due to low melatonin levels would benefit by experiencing a decrease time in wake after sleep onset and sleep latency. There will be no effect on total sleep time.

			In the study it was reported that the actigraph was designed to record wrist movement constantly for 72 hours. It also contained a software that differentiated between sleep-wake patterns. The wrist actigraphy was validated against a polysomnography which showed that the measured sleep variables association between both machines was high with a result of 0.82 – 0.90, p <0.0001, and confirmed its' reliability could be trusted (Garfinkel, Laudon, Nof, & Zisapel, 1995). On the other hand, validity may have been compromised through instrumentation since there were no specific instructions followed on how to use the actigraphs, such as whether it should be placed on the dominant or nondominant hand. The sample of the study was a true representation of the facility population. The strength of the study was that the same treatment methods could be applied to the rest of the community within the facility in order to achieve desired sleep quality. The population outside the facility may vary in certain characteristics which would not allow the same treatment to reproduce the same results seen in the convenient sample in the study.	
Maija Valtonen, Leo Niskanen, Anti-Pekka Kangas, Teuvo Koskinen. (2005)	Effect of melatonin-rich night-time milk on sleep and activity in elderly institutionalized subjects	Level II	A two long term double blind, placebo-controlled, crossover studies that observed the effects of administering milk containing 10 – 40 ng/l melatonin at night to institutionalized elderly. Each study had eight weeks of participants taking enriched melatonin milk, one-week washout period in-between, and eight weeks with regular milk. The first study contained 70 demented patients and the second contained 81 healthy people (Valtonen, Niskanen, Kangas, & Koskinen, 2005). The first study sample was selected from Harjula Hospital and the second study sample came from came from two nursing homes in the city of Kuopio. A Mini- Mental State (MMSE) tool on a scale from 1 (poor and restless) to 10 (normal and restful sleep) was use by nurses nightly to monitor the number of awakens and disturbances each subject experienced at night. In both studies the Wilcoxon test was used to monitor the differences in sleep quality between the	The first study which took place in the spring revealed seasonal effects on the participants sleep quality. Moreover, in the second study the seasonal effects were more apparent in the results as shown in increase sleep quality in all three groups after the winter solstice. Finally, administering milk containing 10-40ng/l melatonin at night revealed that there was no significant increase or decrease in the sleep factors being measured.

			groups. In the second study an additional pairwise t-test was used to compare morning and evening activities (Valtonen, Niskanen, Kangas, & Koskinen, 2005). The reliability of the Mini- Mental state tool used to exam the individual sleep quality presented no external or internal threats, but the validity of the tool did pose and internal threat to the study results. The results reported using the MMSE by the nurses could have been under or over reported, because it's the nurses' own perception of sleep quality based on the number of awakenings and disturbances which occurred at night and not the subjects view. The results of this study would not support the intervention of administering night time milk to any geriatric population outside the study groups since the quality of sleep was based on the nurses' own perception of sleep quality in the subjects. Having two different studies using the same enriched melatonin milk on two different elderly groups was a strength of this study. It allowed results to be collected from the demented and the fairly healthy.	

Appendix II

Insomnia Severity Index (ISI)

Instruction: Please rate each question from 0 (none), 1 (mild), 2 (moderate), 3 (severe), 4 (very sever).

Insomnia Problem

1.) Difficultly falling asleep
2.) Difficulty staying asleep
3.) Problems waking up too early

Instruction: Please rate question 4 from 0 (very satisfied), 1 (satisfied), 2 (moderately satisfied), 3 (dissatisfied), 4 (very dissatisfied)

4.) How satisfied/dissatisfied are you with your current sleep pattern?

Instruction: Please rate the following questions from 0 (not at all noticeable), 1 (a little), 2 (somewhat), 3 (much), 4 (very much noticeable)

5.) How noticeable to others do you think your sleep problem is in terms of impairing the quality of your life?
6.) How worried/ distressed are you about your current sleep problem?
7.) To what extent do you consider your sleep problem to interfere with your daily function (e.g. daytime fatigue, mood, ability to function at work/daily chores, concentration, memory, mood, ect.) currently?

Appendix III

Pittsburgh Sleep Quality Index (PSQI)

Instructions: The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

1. During the past month, when have you usually gone to bed at night? Usual bed time_____
2. During the past month, how long (in minutes) has it usually take you to fall asleep each night? Number of minutes____
3. During the past month, when have you usually gotten up in the morning? Usual getting up time_____
4. During the past month, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spend in bed.) Hours of sleep per night_____

Instructions: For each of the remaining questions, choose from 0 (not during the past month), 1 (less than once a week), 2 (once or twice a week), 3 (three or more times a week)

5. During the past month, how often have you had trouble sleeping because you……

(a)…cannot get to sleep within 30 minutes

(b)…wake up in the middle of the night or early morning

(c)…have to get up to use the bathroom

(d)…cannot breathe comfortably

(e)…cough or snore loudly

(f)…feel too cold

(g)…feel too hot

(h)…had bad dreams

(i)…have pain

(j)…other reason(s), please describe_____

How often during the past month have you had trouble sleeping because of this?

6. During the past month, how would you rate your sleep quality overall? Choose one, very good, fairly good, fairly bad, very bad

Instructions: Choose one answer for the next two questions. Choices: not during the past month, less than once a week, once or twice a week, three or more times a week

7. During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep?
8. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

Instructions: Choose one answer for the next question. Choices: no problem at all, only a very slight problem, somewhat of a problem, a very big problem

9. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

Instructions: If you have a roommate or bed partner, ask him/her to complete question 10 first then complete how often in the past month you have had…. Answer Choices: not during the past month, less than once a week, once or twice a week, three or more times a week

10. During the past month, how of a problem has it been for you to keep up enough enthusiasm to get things done?

(a)…loud snoring

(b)…long pauses between breaths while asleep

(c)…legs twitching or jerking while you sleep

(d)…episode of disorientation or confusion during sleep

(e)…other restlessness while you sleep; please describe

Appendix IV

What are the symptoms ?

- Daytime fatigue,
- Daytime sleepiness,
- Mood changes,
- Poor attention and concentration,
- Lack of energy,
- Anxiety,
- Poor social function,
- Headaches, and increased errors and mistakes.
- **Decreased quality of nighttime sleep.**

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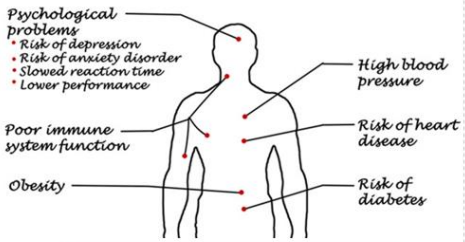
References

Retrieved from http://www .epocrates.com/mobile/iphone/insomnia.

Complications of Insomnia



Melatonin

Take 3mg of sustained release melatonin dose 30 minutes before be

- Turn off all electronics before goi to bed.
- Refrain from drinking caffeine before bed.
- Maintain a sleeping schedule.

Benefits

- Decreased sleep onset,
- Decrease night time awakenings after sleep onset,
- Increase daytime energy,
- Increase attention, and concentration.

Adverse Effects

- Abdominal cramps,
- Drowsiness,
- Diarrhea,
- Nausea/ vomiting,
- Itching,
- Headaches, and
- Depression.