THE PREVALENCE AND CORRELATES OF INSOMNIA AMONG MIDDLE AGED PEOPLE IN KURUKSHETRA DISTRICT, HARYANA, NORTH INDIA.

DR. AAYAM GUPTA

Dissertation submitted in partial fulfillment of the

requirement for the award of the degree of

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ACHUTHA MENON CENTRE FOR HEALTH SCIENCE STUDIES

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES & TECHNOLOGY

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DEDICATION

The work embodied in this dissertation is dedicated to my father Prof. Vinod Kumar Gupta, my wife Dr. (Mrs.) Sandhya Gupta, my children Miss. Bhaumika and Master Jivitesh Gupta. They have sacrificed their time and comforts for me and their unconditional support and encouragement made this work possible.

This work is also a humble homage to my mother late Mrs. Manju Gupta who was an accomplished teacher herself.

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DECLARATION

I hereby declare that this dissertation titled, "The prevalence and correlates of insomnia among middle aged people in Kurukshetra District, Haryana, North India" is the bonafide record of my original research. It has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

DR AAYAM GUPTA

Achutha Menon Centre for Health Science Studies (AMCHSS)

Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST)

Thiruvananthapuram, Kerala, India

October, 2015

CERTIFICATE

Certified that the dissertation titled "The prevalence and correlates of insomnia among middle aged people in Kurukshetra District, Haryana, North India" is a record of the research work undertaken by DR. AAYAM GUPTA, in partial fulfillment of the requirements for the award of the degree of "Master of Public Health", under my guidance and supervision.

DR. BIJU SOMAN

Additional Professor

Achutha Menon Centre for Health Science Studies (AMCHSS)

Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST)

Thiruvananthapuram, Kerala, India – 695011

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GLOSSARY OF ABBREVIATIONS

APL	Above poverty line
ASPS	Advanced sleep phase syndrome
BPL	Below poverty line
BC/OBC	Backward class
CPS	Cycles per second
DSM	Diagnostic and statistical manual of mental disorders
DSPS	Delayed sleep phase syndrome
EDS	Excessive daytime sleepiness
ESS	Epworth sleepiness scale
GABA	Gamma-amino butyric acid
ISI	Insomnia severity index
MCH	Melanin concentrating hormone
MN	Mono-aminergic nuclei
Naps	Intentional day-time sleep
NCDs	Non communicable disease/s
NFHS	National family health survey
NREM	Non-rapid eye movement
ORX	Orexin/hypocretin
PSQI	Pittsburgh sleep quality index
PSG	Polysomnography
REM	Rapid eye movement
SC	Scheduled caste
SDB	Sleep disordered breathing
SWS	Slow wave sleep
TST	Total sleep time
VLPO	Ventro-lateral pre-optic nucleus

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ABSTRACT

Background

With the fast adoption of modern life styles, sleep wake disorders have emerged as a major health concern in the world; although not much researched in India. This study explores the community prevalence of insomnia based on Insomnia Severity Index score (ISI) in a district in Haryana, North India.

Methods

A household cluster survey was done at random geo-locations by the principal investigator using structured interview schedules. The data were collected on demographic characteristics, sleep schedule, sleep hygiene, self-perceived insomnia severity and comorbidity. The Hindi version of the Insomnia Severity Index scale (ISI) that is standardized and validated in India was used to measure self-perceived insomnia severity.

Results

Average age of study subjects is 43.8 years (N=299, range 35-54) and roughly half were males. The prevalence of insomnia (based on ISI cut off of 10) is 18.7(95% CI, 14.3-23.2), which is similar to the previous estimate from South India. Insomnia prevalence is more in females and those from lower socioeconomic strata, those with lower education, people with comorbidity and those with low sleep hygiene scores. No significant difference is seen among rural and urban residents. On multivariate analysis only three risk factors namely 'low socioeconomic status' (OR4.1, 95% CI, 1.7-10.1), 'sleep related co-morbidities' (OR 2.9, 95% CI, 1.5-5.6) and 'other medical co-morbidities' (OR 3.5, 95% CI, 1.7-7.2) are found to be significantly associated with insomnia.

Conclusion

The prevalence of clinical insomnia in Kurukshetra district in North India is found to be 18.7%. Among the factors studied, low socioeconomic status, sleep related comorbidity and other comorbidity were significantly associated with insomnia. The prevalence estimate based on ISI score is found to be higher compared estimate using stringent and recent diagnostic criteria like DSM-5.

Chapter-1: Introduction

1.1 Background

Adequate sleep is considered important even in traditional health systems practiced globally. Sleep is considered as one of the three pillars (traya-upastambhas) of health in the traditional texts (Charak Samhita) of Indian medicine. Various modalities are being used in complementary and alternative medicine (CAM) to manage sleep disorders. (Baldwin & Ornelas 2011) Inadequate sleep is associated with serious personal and public health consequences.(Ozminkowski et al., 2007; Léger and Bayon, 2010; Fineberg et al., 2013; Hillman and Lack, 2013; Ford et al., 2014) Modern life-style need for survival and related problems (work pressure, work schedule, unemployment, competition, apathy, fear, solitude, lack of social security) has caused changes in sleep duration and sleep characteristics in the population over time. The philosophy of sleep and its understanding differ among masses due to the influence of cultural beliefs and practices. (Redeker, 2011) Hence, an understanding of what is normal sleep (developmental changes) and what is abnormal sleep (pathological changes) is important. There is also an imminent need to bridge the gap between sleep research, sleep medicine and public health in order to align the sleep research more closely with local, regional and global healthcare objectives. The conceptual framework of 'Sleep Health' looks into various dimensions of sleep wake function and its mediating role in relation to distal health outcomes and in the context of improving population health.(Buysse, 2014; Irish et al., 2015)

1.2 Rationale for the study

The Centre for Disease Control and Prevention (CDC, Atlanta) has declared sleep insufficiency as a 'public health epidemic' as it is linked with motor vehicle crashes, industrial disasters, and medical and other occupational errors. Insomnia is a common public health problem, and the prevalence and impact of insomnia on middle age group is not well documented in Haryana. The outcome of this study is expected to contribute to the existing knowledge on prevalence of insomnia as we did not came across the reference of any study on middle age people (35-54 years) in Haryana.

Chapter-2 Review of Literature

The content of this chapter is a result of the systematic literature review that was done through an extensive search on PubMed, Science Direct and Google Scholar using MESH terms and keywords for articles published within the last ten years. Finally, more than fifty key articles including the paid ones were selected. The paid articles were retrieved directly from the authors by requesting them through emails. The reference books were also procured from other institutions through personal contacts. All the citations are included in the references section.

2.1 Sleep

Sleep is a biological necessity. It is a natural and restorative behaviour that involves temporary disengagement of the perception and unresponsiveness to the environment around us. It is not an unconscious state and it alternates with a period of wakefulness (state of arousal), wherein, one is alert and conscious of one's surroundings. (Bliwise, 2011; Landis, 2011) Short habitual sleep (<6-7 hours) is a risk factor for increased blood pressure, decreased anabolic hormone level and reduced tissue repair (e.g. growth hormone and prolactin), higher levels of inflammatory cytokinins and increased levels of cortisol during evening hours, when it is usually low. (Mullington et al., 2009; Knutson, 2011) Therefore, insufficient sleep makes one susceptible to chronic diseases such as hypertension, diabetes, depression, and obesity, cancer and is associated with increased mortality, and reduced quality of life and productivity. (Bin et al., 2012) Excessive daytime sleepiness (EDS) caused due to inadequate sleep leads to reduced performance and ability to handle work pressure, increase in alcohol intake, drowsy driving among adults. (Colten and Altevogt, 2006)

2.2 Sleep and Rest

'Rest' is a behaviour that resembles sleep and may involve less or no sleep (Landis, 2011). Sleep is necessary for physiological homeostasis, immunity and repair mechanisms. It serves both psychological and neurological functions. During sleep, memory stabilization and consolidation occurs, which affects learning. (Perogamvros et al., 2013) It is an important determinant of recovery from infection. (Imeri, 2010) Good quality sleep is a known marker of neurological and behavioural development and healthy aging. (Mindell et al., 2009; Landis, 2011).

2.3 **Sleep Health**

'Sleep health' is a multidimensional pattern of sleep-wakefulness, adapted to individual, social and cultural environmental demands, that promotes physical and mental well-being. Good sleep health is characterised by subjective satisfaction, appropriate timing, and adequate duration. (Buysse, 2014; Morgenthaler et al., 2015)

2.4 **Sleep architecture and sleep cycle**

Sleep has two distinct stages namely the stage of 'rapid eye movement' (REM) and of 'non-rapid eye movement' (NREM). NREM has further sub-stages (N_1, N_2 and N_3). A typical sleep cycle in a young healthy adult consist of one episode of NREM wherein 'N_1' is 2%-5%, 'N_2' is 45%-55% and 'N_3' is 13%-23% of total sleep time (TST) followed by one episode of REM (20-25% of TST). The sleep cycle varies in terms of number and duration from person to person and in different developmental stages across the life span of an individual (Table 2.1) but each individual has a consistent pattern of sleep from night to night in a particular developmental stage. One enters in sleep through the stage of NREM (Stage 1 - 2 - 3 - 2 and into REM) as follows: (Landis, 2011)

Awake (Relaxed wakefulness, Low voltage Theta waves (4-8 Hz))
Vertex sharp waves (absence of signs of other sleep stages)
↓
Drowsy - Alpha waves (8-12 CPS)
↓
Stage-1 (N1) - Theta waves (3-7 CPS)
↓
Stage-2 (N2) - Sleep spindles and K-complexes (12-14 CPS)
↓
Stage-3 (N3) /Delta sleep/ slow wave sleep (SWS)
Delta waves (1/2-2 CPS, >75µV), SWS depends on prior period of wakefulness.
↓
REM (tonic and phasic)
Dreamy state with saw-tooth waves (low voltage, random, fast)
Occurs in discrete periods throughout night

2.5 R**egulation of wake and sleep**

The wake sleep mechanisms mediated through wake and sleep promoting neurons are mutually inhibitory and are understood by the 'flip-flop model' of sleep state transitions, also known as 'two process model' of sleep regulation. (Saper et al., 2010) The term 'two process' refers to the circadian rhythm (process-C) and sleep wake homeostasis (process-S). The processes act in opposition to each other for maintaining alternate wake and sleep condition. The process-C is influenced by the dark and light periods and thus it affects the daily sleep cycle or the timing of sleep through circadian clock (in the hypothalamus). The disturbance in circadian rhythm leads to disorders of advanced sleep phase syndrome (ASPS) and delayed sleep phase syndrome (DSPS). The process-S regulates sleep intensity through homeostatic sleep drive (pressure to sleep). It depends upon the level of adenosine, sleep history and need of sleep. The intensity of sleep has inverse relationship with sleep duration and that some 'clock' genes also directly influence sleep intensity and duration such as hPer2, hPer3 and Per2 enzyme genes. (Landis, 2011) The sleep-wake transitions are very much affected not only by physiological changes but also by external environment. (Saper et al., 2010)

2.6 **Normal sleep in various developmental stages of human life**

It is difficult in everyday practice for a non-sleep specialist, researcher and the study subject to differentiate between what is normal and abnormal sleep. There are some controversies in scientific fraternity also on whether napping is harmful or beneficial (as a coping mechanism to inadequate sleep), duration of sleep to be labelled as healthy/unhealthy, the effects of habitual short-sleep and long sleep etc. Table 2.1 highlights the normal sleep pattern in various stages of human development. (Redeker, 2011)

Table 2.1: Stages of human development and normal sleep patterns

Stage of Development	Normal Sleep Time	Normal Sleep Pattern	Normal Sleep Stage	Normal Sleep Cycle	Factors Influencing Sleep (sleep hygiene)
Normal full term new-born	16-18 hours per day	Polyphasic (3-4 hours of sleep and wake distributed in day time)	Active (50%), quiet (14%) and indeterminate sleep	50-60 minutes	Parental involvement, cultural and ecological factors affect sleep initiation, continuity and duration.
2-3 months age	-	More sleep at night. Beginning of circadian rhythm	REM and NREM	-	
6-9 months age	-	More organized and consolidated sleep at night	-	-	
End of 1st year of age	Sleep for 50-55% of 24 hour period	Progressive increase in night sleep. Most sleep at night and 1-2 naps in the day	Most of time in quiet sleep	-	

Stage of Development	Normal Sleep Time	Normal Sleep Pattern	Normal Sleep Stage	Normal Sleep Cycle	Factors Influencing Sleep (sleep hygiene)
Toddlers and pre-schoolers	Decrease in day-time sleep and overall sleep duration upto age of 4 years.	Decrease in napping during the day but frequent night time awakening	Large amount of SWS and REM Sleep compared to adults. Females- higher levels of sleep efficiency and more Stage-3 sleep in 3-7 years of age	-	In Asian cultures the child's ability is generally decreased to initiate sleep on its own due to sharing of bed/room with parents and parental involvement.
School age	9-10 hrs per day (US Children)	Cross cultural consistency in day time sleep and napping (suggestive more of physiological than cultural practices)	Sleep latency & efficiency does not change up to adolescence. Females- More N_1 sleep among 6-7 years old	-	Gender, ethnicity, environment, light exposure (from TV, PC etc). Need monitoring for excessive daytime sleepiness (EDS).
Adolescents	7-8 hours (estimated need may vary e.g. 9.2 hours in US)	-	Increase in REM; decrease in latency to REM & SWS. Little change in sleep latency & efficiency	Circadian changes or sleep phase delays leads to preferences for delayed bed time and morning wake time. Excessive daytime sleepiness (EDS) is common.	Parental sleep pattern, climate, bedtime sleep rituals, socio-economic status, Gender, family meal patterns (regular/irregular) parental work, day care, school schedules (early school time), home-work activities, social activities, Pubertal status (gonadal hormones affecting maturation of circadian pacemaker), excessive exposure to light causes delays in sleep phase.

Stage of Development	Normal Sleep Time	Normal Sleep Pattern	Normal Sleep Stage	Normal Sleep Cycle	Factors Influencing Sleep (sleep hygiene)
Young and Middle Age Adults	6-9 hours (vast cultural and ethnic differences in TST, sleep latency and behaviours performed at bed time)	One long night sleep period with minimal or no day-time napping (reported by 36% - 80% persons). Night time sleep reduced linearly by 10 minutes per decade over the adult life span. Morbidities arising during middle age (NCD's, SDB etc)	Women- longer TST & sleep latency. Less N2 sleep, More SWS and more self-reported complaints of sleep associated with menstrual cycles, pre- and peri – menopause.	REM - 20-25%, NREM - 75% - 80% SWS (N3) maximum during first third of the night and REM predominantly at the end of the night. Incremental changes with age such as decrease in TST, sleep efficiency, SWS and REM (0.6% per decade) up to 75 yrs age and increased waking after sleep onset (by approx 10 min in each decade from 30-80 yrs), increased sleep latency (<10 min. between young and older adults)	Genetics, preferences, lifestyle, environment, work schedule, relationships, gender, race, ethnicity, morbidities.

Stage of Development	Normal Sleep Time	Normal Sleep Pattern	Normal Sleep Stage	Normal Sleep Cycle	Factors Influencing Sleep (sleep hygiene)
Older Adults	Little change in median sleep duration (60-75 yrs),	Day time napping common and increase with age (estimated 10% people nap in 55-64 yrs; 25% in 75-84 yrs & 69% in >75 yrs)	Healthy older women>75 yrs more TST, better sleep efficiency, more SWS than healthy older men.	Age related deterioration of circadian pacemaker (supra-chiasmic nucleus), Flattened circadian rhythm, circadian phase advance (ASPS considered normal development pattern in elderly) and increase sleep latency with age, decrease in sleep continuity (more in 85+), REM & SWS (upto and not later than 60 yrs age), more frequent arousals.	Retirement, lifestyle changes, gender, social interactions, cultural beliefs (wrong beliefs regards sleep disturbances in elderly leading to neglect of sleep hygiene), preferences, parenting, work, family, exposure to day-light, napping, EDS, depression, obesity and cognitive impairment.

Source:(Redeker, 2011). Developmental aspects of normal sleep. In: Redeker, N.S., McEnany, G.P. (Eds.), Sleep Disorders and Sleep Promotion in Nursing Practice. Springer Publishing Company, New York, pp. 19–32.

2.7 **Measurement of sleep**

The sleep is measured both subjectively (through sleep logs, validated questionnaires, sleep history interviews) and objectively (by polysomnography for physiological assessment and through actigraphy or observation methods (videos, etc.) for sleep behaviour assessment. (Moul et al., 2004; Lomeli et al., 2008; Mai and Buysse, 2008; Tremaine et al., 2010; Chokroverty, 2010) Insomnia assessment is usually done using subjective measures. Almost 81 various types of insomnia scales are available for use in

various regions of the world. (Monk et al., 2003; Moul et al., 2004; Lomeli et al., 2008; Schutte-Rodin et al., 2008; Tremaine et al., 2010; Espie et al., 2014)

2.8 **Sleep wake disorders**

Sleep disorders are now called as sleep-wake disorders according to the fifth version of Diagnostic and Statistical Manual of Mental Disorders (DSM-5). Sleep wake disorders are under-researched and under-diagnosed. (Colten and Altevogt, 2006) According to Stanford Centre for Sleep Sciences and Medicine, currently there are over 100 different types of sleep wake disorders. Eighty one sleep wake disorders were listed in the second version of International Classification of Sleep Disorders (ICSD-2). (Michael, 2011) There is an increasing emphasis on an independent clinical attention of a sleep wake disorder regardless of co-morbidities (mental or medical problems) due to their interactive and bidirectional nature.(Ohayon, 2002; Xiang et al., 2008) DSM-5 has adopted a 'lumping approach' to the classification of insomnia focusing on mental health and general medical clinicians. Insomnia is now considered as a separate diagnosable entity and therefore, the terms 'primary' and 'secondary' insomnia are no longer in use. Insomnia has been classified under following coding standards and the common defining characteristics are "repeated difficulty with sleep initiation, duration, consolidation or quality that occurs despite adequate opportunity and circumstances for sleep and results in some form of daytime impairment".

a. The International Classification of Sleep Disorders—Third Edition (ICSD-3, 2014)
b. International Statistical Classification of Diseases and Related Health Problems (ICD-10: 2015 online version), WHO – is used worldwide. Insomnia is classified under non-organic type sleep disorders (F51.-) under the category of sleep disorders (G47) in chapter VI entitled, 'Diseases of the nervous system (G00-G99)'.

c. Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), DSM-5 (American Psychiatric Association, 2013) – a US classification system for mental disorders that uses the official ICD statistical codes. DSM-5 is a major revision over DSM-4TR in terms of the diagnostic criteria and classification since 1994. (Gupta et al., 2014)

d. NANDA International Nursing Diagnoses: Definitions & Classification, 2015–2017: Insomnia (Code 00095) has been covered in the domain of activity/rest and defined as *"a disruption in amount and quality of sleep that impairs functioning"*. (NANDA International, Inc., 2014)

e. Systematized Nomenclature of Medicine Clinical Terms (SNOMED-CT) developed by international health terminology standards development organization (IHTSDO), Denmark**.** According to National Information Board of United Kingdom (UK), SNOMED-CT is a single clinical terminology system that is proposed to be adopted in UK in all primary care systems by the end of December 2016. SNOMED classifies insomnia as 'initial insomnia', 'middle insomnia' and 'terminal insomnia'.

2.9 **Insomnia: An abnormality in the wake arousal system**

Recent advances in sleep research have shown that insomnia is a state of hyper-arousal that is present 24 hours each day. (Nofzinger et al., 2004; Bonnet and Arand, 2010; Riemann et al., 2010) There is a physiological dysfunction causing inability to turn off the wake-promoting influences of the 'flip-flop switch' resulting in extended periods of time in transitional states and a prolonged state of wake. This patho-physiological dysfunction may be multi-factorial and may involve -

a. Neurophysiologic hyper-activation of the sympathetic nervous system, which may be due to modification of the sympathovagal balance. (de Leon-Lomeli et al., 2014)

b. Neuroendocrine dysregulation of hormones associated with arousal such as increased levels of adrenocorticotropic hormone (ACTH) and cortisol among chronic insomniacs with history of insomnia for more than six months (Vgontzas et al., 2001) and
c. The cognitive/behavioral responses directed toward sleep that perpetuate arousal. (McGinty and Szymusiak, 2011)
d. The state of hyperarousal has been objectively measured through biomarkers such as elevations in heart rate and heart rate variability, increased glucose metabolism causing sleep disturbance and consequent day time fatigue etc.(Nofzinger et al., 2004; de Leon-Lomeli et al., 2014)

2.10 **Insomnia: A public health issue**

Insomnia is the most common sleep-wake disorder. (Chung et al., 2015) If untreated, insomnia often results with significant negative health related consequences such as suicides in adolescents. (Morin et al., 2009; Woznica et al., 2014) There are many challenges to face in conducting epidemiological studies on insomnia. The cross cultural differences across various regions within and between countries, differences in study populations, methodologies, time frames, and sleep nosologies does affect the study outcomes and make them non-comparable. (Chung et al., 2015; Xiang et al., 2008) Defining insomnia itself is a complex task, because insomnia can occur as a symptom of another disorder, an independent disorder, or both. It can start as a symptom, but evolve into a disorder and its nature is heterogeneous. Measuring insomnia is even a more difficult task.

2.11 **Burden of Sleep wake disorders**

According to the American Academy of Sleep Medicine, 15% of world's population suffers from diagnosable sleep disorders. The estimated burden of sleep disorders in US

general population is 10-30% of population. (Ford et al., 2015) There is marked difference in prevalence of insomnia across various regions of the globe and it ranges from 6% - 76.3%. (Xiang et al., 2008) In India, the health system research output in general has been unsatisfactory and not in keeping with the trends of burden of disease. (Dandona et al., 2009) Though, a need to focus on emerging public health challenges has been acknowledged by Indian researchers also, few studies have been done in the area of 'sleep epidemiology'. (Shah et al., 2010) Indian ethnicity (OR 1.79; 95% CI, 1.28-2.49), has been quoted as one of the many independently associated factors in the manifestation of chronic Insomnia with daytime consequences. (Zailinawati et al., 2012) There is a need to devise appropriate people friendly sleep policies for the workplace, home and healthcare facilities and education of sleep hygiene. (Mindell et al., 2009) Improper sleep hygiene is one of the important causative factors for Insomnia. Chronic insomnia adversely affects work efficiency, learning capacity, academic performance and costs much in terms of non-medical costs (Mai and Buysse, 2008; Léger and Bayon, 2010; Leger et al., 2012; Hillman and Lack, 2013) Adults in low socioeconomics strata are much more affected.(Piccolo et al., 2013) There is growing evidence of association and strong influence of deprivation of sleep and sleep disorders on the manifestation and/or worsening of non-communicable diseases.(Grunstein, 2012) The sleep duration may influence breast cancer in women through effects of melatonin levels, which were 42% higher in those with more than hours versus those with less than or equal to six hours of sleep. (Wu et al., 2008) Insomnia is associated with depression and is a risk factor for development of anxiety. (Neckelmann et al., 2007)

2.12 **Identified research gaps**

There are very limited studies on insomnia in India. Studies generating 'normative data' would be a value addition to the existing knowledge of sleep disorders. No study on insomnia was found among middle aged people in Kurukshetra, Haryana.

Chapter-3 Methodology

3.1 **Research Hypothesis**

The prevalence and pattern of insomnia in North India could be different from that in South India.

3.2 **Research questions**

a. What is the prevalence of insomnia among middle aged people in North India?
b. What are the correlates of insomnia that affect the prevalence of insomnia among the middle aged in North India?

3.3 **Objectives**

3.3.1 Major Objective

To estimate the prevalence of insomnia among middle aged (35-54 year old) people in Kurukshetra district of Haryana using Insomnia Severity Index (ISI).

3.3.2 Minor Objective

To study the correlates affecting the prevalence of insomnia among middle aged (35-54 year old) people in Kurukshetra district of Haryana in North India.

3.4 **Study type**

The present study is a community based household survey focussing on the age group of 35-54 years.

3.5 **Study Design**

The study was conducted using a cross sectional survey design.

3.6 **Study setting**

Haryana is in the heartland of North India. Kurukshetra is a typical district among the 21 districts in Haryana, selected purposively. Out of the three tehsils in the district, Thanesar Tehsil being the largest one was purposively selected for the study.

3.7 **Study population**

a. **Target population:** This study aimed to generalize the study findings to residents of all the households in Kurukshetra district.
b. **Source population:** The study subjects were drawn from households in the rural and urban regions of Thanesar Tehsil of Kurukshetra district.
c. **Study population:** The study included only those subjects (35-54 years) who were residents of Kurukshetra for at least last six months at the time of the survey.

3.8 **Time frame**

The data was collected between June 23, 2015 and September 1, 2015.

3.9 **Sample size estimation**

With an assumed prevalence of 18.6% (Panda et al., 2012); absolute precision of 5%; design effect of 1.2; sample size at 95% confidence was estimated to be 280 from total population of 9,64,655 in Kurukshetra district (Govt. of Haryana, 2015). Assuming a non-response rate of 5 %, the final sample size arrived at was 294, rounded up to 300. OpenEpi version 3 was used to calculate sample size for proportion (Dean et al., 2015)

$$\text{Sample size } n = [\text{DEFF}*\text{Np}\ (1\text{-p})]/\ [(d^2/Z^2_{1-\alpha/2}*(\text{N-1}) + p*(1\text{-p})]$$

3.10 **Sampling strategy**

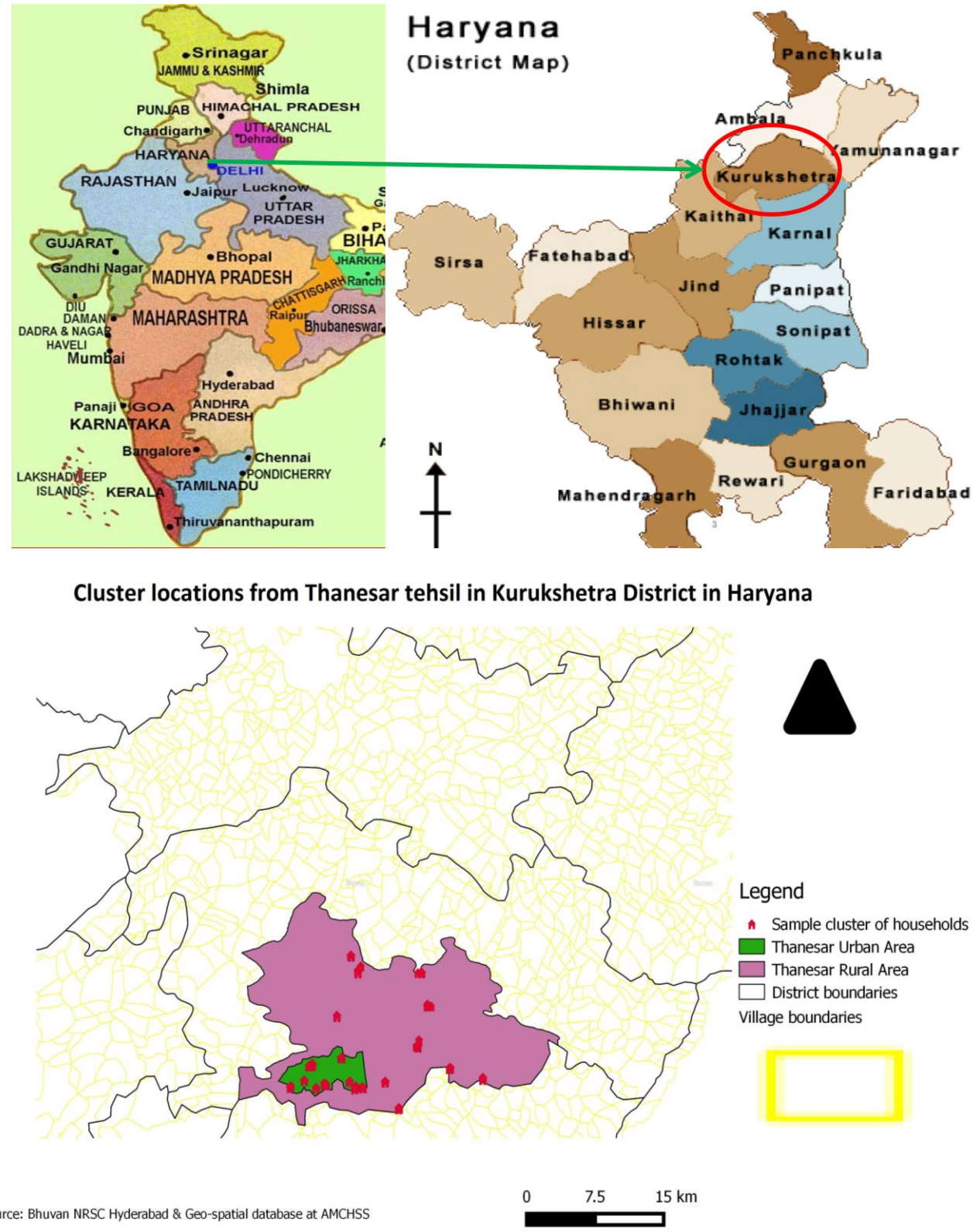
Tehsil Thanesar of Kurukshetra district, Haryana, India was selected using purposive sampling. Cluster sampling was adopted for subject selection within the selected Tehsil. The cluster locations were identified by the random location generating feature of the free and open source desktop Geographic Information System application known as QGIS. (QGIS Development Team, 2015) Ten such locations were identified in the rural area and another ten in the urban area. In each cluster the investigator started the survey by visiting the nearest household to the random location. The second house was the house to the right of the first one, and this continued until the desired sample of 15 eligible subjects was achieved from the locality. From each household only one individual was interviewed. If more than one eligible participant was present in a household at the time of the survey, male was chosen from the first household, female from the second household, male from the third household and so on. In case a household had more than one eligible participant in each sex category, youngest one was considered in the selection.

3.11 **Inclusion criteria**

Only those subjects who were residents of Kurukshetra for at least last six months at the time of the survey were enrolled as per the standard protocol of the study from age group 35-54 years.

3.12 **Exclusion criteria**

Anyone suffering from a debilitating condition and hence, unable to comprehend/respond to the questions was excluded.



Cluster locations from Thanesar tehsil in Kurukshetra District in Haryana

Source: Bhuvan NRSC Hyderabad & Geo-spatial database at AMCHSS

Figure 3.1: Map of the study setting

3.13 **Replacement plan for non-responders**

Those who were not available even after three consecutive visits or refused to participate were considered as non-responders. In the study we have not foreseen deaf and dumb people but we came across two such persons and excluded them. Similarly one person with a recent history of debilitating Illness was excluded after looking at his medical records (cerebral infarct & hemiplegia).

3.14 **Study variables and related definitions**

3.14.1 **Outcome variable: insomnia**

Insomnia was estimated using ISI score. A cut off score of 10 was used as per the recommendation of Morin et al. for assessing insomnia in a population-based sample. This cut off score has found to achieve an optimal balance between sensitivity (86.1%) and specificity (87.7%) (Morin et al., 2011) The four classical categories of insomnia severity index namely 'not clinically significant (ISI score 0-7)', 'sub-threshold insomnia (ISI score 8-14)', 'clinically significant insomnia-moderate (ISI score 15-21)' and 'clinically significant insomnia-severe (ISI score 22-28)' were also used for descriptive purpose.

3.14.2 **Predictor variables**

3.14.2.1 **Socio-demographic variables**

These following variables are based on questions in section 1 & 2 of interview schedule (Appendix-V) and used in univariate analysis. They were recoded into binary (dichotomous) variables for use in bivariate and multivariate analysis. The reference category was given value label=0

a. **Location** (code *S3)*: two categories were recoded as 'urban' (reference), and 'rural'

b. **Make of House** (code *S4)*: original three categories of 'kaccha', 'kaccha-pakka' and 'pakka' were clubbed into two categories 'pakka' (reference) and 'kaccha-pakka' under heading 'Type of house'

c. **Gender** (code *S5)*: The original categories were 'male', 'female' and 'others'. But no subject belonged to 'other' category. Hence they were recoded as 'male' (reference) and 'female'

d. **BPL card** (code *S6)***:** The original two categories 'No=2' and 'Yes=1' were recoded under heading 'BPL status' as 'No' (reference) and 'Yes'

e. **Age** (code *D1)*: The documented age was regrouped into four categories '35-39 years', '40-44 years', '45-49 years', and '50-54' years to see the variation of outcome variable with advancing age. Later two categories were formed '35-44 years' and '45-54 years' (based on the median=44) for bivariate and multivariate analysis. Many discrepancies were observed with regards to the documented 'age' of the subjects during data collection. There was no problems in recording age in urban region but in rural region, there was a mismatch of age in the government documents of the same subject such as ration card, aadhar card and driving license. The aadhar cards had recorded the first day of the month (notably January 1/April 1) in most cases. Hence, passport, ration card, PAN card and driving license were preferred in most cases. Wherever, there was a mismatch between old and new ration cards, the old one was considered authentic. In the absence of ration card, license was preferred.

f. **Highest level of education** (code *D2):* was used as an indicator for literacy status and thus five categories used in data collection were clubbed into two broad categories under heading 'Highest education above class 8' as 'Yes' (reference) and 'No'

g. **Religion** (code *D3)***:** The data was collected using nine options but was later grouped into two categories 'Hindu" (reference) & 'Others'

h. **Caste** (code *D4)*: The original four categories were 'SC', 'BC/OBC', 'general class' and 'others' but no subject belonged to 'other' category. Hence recoding was done into three categories. The reservation for 'Jats' in 'BC' category is no more valid due to a judgment by the Supreme Court. Hence, all the 'Jats' were included in 'general class' category.

i. **Marital status** (code *D5)*: During data collection, the data were collected using four options but were later regrouped as 'currently married' (reference) and 'others'

j. **Work status** (code *D6)*: The data was collected using nine options that were later re-grouped into four categories for univariate analysis namely 'unemployed', 'self-employed' (capturing entrepreneurs), 'employed' and 'retired'. For bivariate and multivariate analysis, these four categories were further clubbed into two categories 'earning' (reference) and 'non-earning'.

k. **Ease of managing monthly household expenditure** (code *D7)*: The data was collected using six categories which were later recoded into two categories 'not difficult' (reference) and 'difficult'

l. **Shift work and work related travel** (code *D8-D13)*: The original value labels in two questions (code *D8, D12)* were recoded as 'No' (reference) and 'Yes'.

m. **Socio economic status:** This composite variable was computed using the variables 'education' (code *D2)*, 'type of house' (code *DS4)*, 'work status' (code *D6)*, 'BPL status' (code *S6)* and 'ease of managing monthly household expenses' (code *D7)*. Those subjects who belong to the non-reference category of two or more variables mentioned above were grouped as having 'low' socio-economic status and others were grouped as having 'high' socio-economic status (reference). The clubbing was done as many people complained of irregularities in the issue of or cancellation of

BPL card. It was also observed that in spite of having 'pakka' house and other assets, many subjects were holding BPL cards.

3.14.2.2 **Variables related to 'sleep health'**

Three variables were computed by recoding the questions in section 2 and 3 (Appendix- V) namely 'sleep satisfaction' (codes *D15, D16, IS4)*, 'sleep adequacy' (codes *D14, D18 & D19*) and 'sleep hygiene (codes *D21-D30*). The coding into these broad categories was done keeping in mind the binary outcomes following the similar procedure as used to compute comorbidities.

'Sleep hygiene' refer to those behavioural and environmental practices/personal habits/ that have a positive influence on initiating and maintaining sleep resulting in good quality sleep and full day time alertness.

3.14.2.3 **Composite variables related to comorbidity**

The following composite variables with binary outcome were recoded based on the questions in the interview schedule (section 4, Appendix-V). The prefix 'suspected' was used during the analysis for such variables (wherever applicable) because the computations are based on self-reported events, and are not supported by laboratory investigations like polysomnography or actigraphy.

A. **Suspected obstructive sleep apnoea (OSA)**

Five questions (codes *MH2-MH6)* were included in the questionnaire (Appendix-V) to diagnose OSA from the field based data. Those five questions were re-codified in reference and non-reference category and presence of snoring was considered as mandatory among other optional conditions. Those who satisfied the following conditions were considered having OSA.

a. Self-reported snoring and someone reported episodes of breath holding while in sleep. (codes *MH2*=1 & *MH3*=1) Or
b. Self-reported snoring and frequent headache. (codes *MH2*=1 & *MH4*=1 & *MH5*=1) Or
c. Self-reported snoring and excessive sleepiness. (codes *MH2*=1 & *MH4*=1 & *MH6*=1) Self-reported napping or sleeping for at least two hours or more was considered as a proxy indicator of excessive sleepiness during daytime.

The question on frequency of morning headache had four categories 'never', 'daily', 'monthly' and 'weekly'. Those who reported 'daily' or 'weekly' were considered as having 'frequent' headache (value label=1) and others as having it 'rarely' (reference category, value label=0). Those who did not satisfy any of the aforementioned conditions were considered as normal.

B. **Suspected anxiety**

Three questions (codes *MH7, MH8 & MH12*) were included in the questionnaire (Appendix-V) to diagnose anxiety from the field based data. They were re-codified in reference and non-reference category and 'remaining awake at night/during sleep due to feeling anxious with sweating' was considered as mandatory condition among other optional conditions. Those who satisfied the following conditions were considered as having anxiety -

a. Remaining awake at night/during sleep due to feeling anxious with sweating and taking sleep medication (codes *MH7*=1 & *MH8*=1) or
b. Remaining awake at night/during sleep due to feeling anxious with sweating and feel helpless, hopeless and worthless (codes *MH7*=1 & *MH12*=1).

Those who did not satisfy any of the aforementioned conditions were considered as normal.

C. **Suspected depression**

Six questions (codes *MH8-MH13*) were included in the questionnaire (Appendix-V) to diagnose depression from the field based data. They were re-codified in reference and non-reference category and 'disturbed sleep due to feeling sad' was considered as mandatory condition among other optional conditions. Those who satisfied all the following five conditions were considered as having depression –

a. Disturbed sleep due to feeling sad and taking sleep medication (codes *MH9*=1 & *MH8*=1) or
b. Disturbed sleep due to feeling sad and prefer staying alone avoiding social contacts (codes *MH9*=1 & *MH10*=1) or
c. Disturbed sleep due to feeling sad and cry often (codes *MH9*=1 & *MH11*=1) or
d. Disturbed sleep due to feeling sad and feel helpless, hopeless and worthless. (codes *MH9*=1 & *MH12*=1) or
e. Disturbed sleep due to feeling sad and ever thought of ending one's life (codes *MH9*=1 & *MH13*=1) or

Those who did not satisfy any of the aforementioned conditions were considered as normal.

D. **Suspected restless leg syndrome (RLS)**

RLS computation was done based on five essential diagnostic criteria (revised 2012) of International restless legs syndrome study group (IRLSSG) and five questions from the interview schedule (codes *MH14-MH17 & MH19*) were used for this purpose. The mandatory condition was 'presence of abnormal sensations in legs with an urge to move

the limbs' among other optional conditions. Those who satisfied the following conditions were considered as having RLS –

a. Presence of abnormal sensations in legs with an urge to move the limbs (*MH14*=1) and
b. Presence of restlessness to relieve symptoms (*MH15*=1) and
c. Symptoms occur or worsen when at rest (*MH16*=1) and
d. Maximum level of symptoms experienced at night and is related to sleep onset (*MH17*=1) and
e. 'Measures involving movement' (walking) gives relief to the complaints (*MH19*=1)

If any of the above conditions were not met, the subject was considered as normal. Questions *MH17-MH19* were re-coded into two categories. Question (*MH17*) on time of experiencing maximum level of symptoms was recoded as 'both daytime and night' (reference category, value label=0) and 'at night/related to sleep onset' (value label =1). Question (*MH18*) on 'areas of body affected' was recoded as 'both hands and legs' (reference category, value label=0) and 'legs' (value label =1). Question (*MH19*) on relief measures was recoded as 'measures without movement' (reference category, value label =0) and 'measures involving movement' (value label =1).

E. **'Sleep related comorbidity (SRC)'**

For bivariate and multivariate analysis the binary values of variables 'suspected OSA', 'suspected anxiety', 'suspected depression' and 'suspected RLS' were clubbed through summation and categorized as 'No SRC' and 'Any SRC'. Those having summated score of '0' were considered normal 'No SRC' (reference) and others were categorized as ''any SRC'.

F. **'Other medical comorbidity (OMC)'**

For bivariate and multivariate analysis the binary values of variables 'hypertension', 'diabetes', 'asthma/chronic lung disease', 'heart problem', 'kidney problem', 'seizures', 'thyroid problem' and 'any other medical problem' were clubbed and re-codified into two categories ('no OMC'=0 and 'any OMC'= 1) following the same procedure as used for coding SRC.

G. **Insomnia Disorder (DSM-5)**

This composite variable has a more restricted definition compared to our outcome variable (clinical insomnia) that is based on ISI scores. This variable was computed to know the differences in estimates based on ISI and DSM-5. The following conditions were considered mandatory for computation -

a. Current complaint of sleep dissatisfaction in spite of adequate opportunity to sleep.
b. The sleep difficulty is ≥ 3 nights/weeks for ≥ 3 month, with adequate opportunity to sleep.
c. Complaint of difficulty initiating sleep for greater than 30 minutes.
d. Complaint of difficulty maintaining sleep, due to frequent awakenings or problems returning to sleep after awakenings and the added time of multiple awakenings between the sleep periods is greater than 30 minutes;
e. Early-morning awakening with inability to return to sleep (final awakening) greater than 30 minutes prior to actual rise time.

3.15 **Study tools**

3.15.1 **Data collection**

The data was collected using a pretested, structured interview schedule that was translated in Hindi (Appendix-V).

3.15.2 **The interview schedule**

The interview schedule (Appendix-V) has four sections as follows-

a. The first and second sections captured 'demographic data and personal details' (sleep need, sleep preference, person type, sleep opportunity in the past one year, sleep hygiene in the past three months and sleep pattern in the past one month).
b. The third section was meant to assess the type of insomnia and 'self-perceived insomnia severity' using a scale known as Insomnia Severity Index (ISI).
c. Fourth section captured informant on sleep and medical history to deduce information on sleep related morbidities and other medical morbidities.

3.15.3 **The scale used in the study**

No specific and universally applicable tool is available for measuring insomnia. We chose Insomnia Severity Scale (ISI) as this tool has been translated and validated in many languages and used widely for assessing the self-perceived severity of insomnia. It has seven items (questions) scale from 0 to 4 to assess nature, severity, and impact of insomnia in the past month. If the total score of all seven items is greater than 14, it indicates a clinically significant insomnia disorder. The tool has been validated in Hindi in 2011. (Bastien et al., 2001; Lahan and Gupta, 2011; Morin et al., 2011) The scale was procured from the authors directly. Permission has been granted by the authors to use ISI in this study.

3.16**Data entry**

The data entry was done using EpiData Manager software (Lauritsen and Christiansen, 2015)

3.17 **Data cleaning**

Data cleaning was done in three stages. First stage was concurrent to data collection in the field. The second stage was manual re-checking of all records just before digitization of records and the study subjects were contacted telephonically for any clarifications needed. In the final stage just after data entry in computer using epidata software the digitized records were checked for wrong entries and the errors were rectified. After validation, the data was exported to 'IBM SPSS Statistics' software version 21 for further analysis. (IBM Corp., 2012)

3.18 **Data analysis and statistical methods**

The analysis was done using IBM SPSS Statistics software version 21 to study the sample characteristics and to estimate the prevalence and correlates of insomnia among the middle aged (35-54 years). The p value of <0.05 was considered as significant with 95% confidence interval (CI).

3.18.1 **Univariate analysis**

It was done with all variables assessing the measures of central tendency, frequency and proportions in the sample to deduce information of sample characteristics. The outcome variable (insomnia) was computed based on ISI scores.

3.18.2 **Bivariate analysis**

Both predictor and outcome variables as mentioned in section 3.14 were recoded into binary (dichotomous) variable with reference category (value label=0) and non-reference category (value label=1) before doing bivariate and multivariate analysis. The bivariate analysis was done by cross tabulation of various categorical variables with the outcome variable (clinical insomnia) using Chi-square test and Fishers exact test (wherever chi-square test was not applicable) to identify significant associations between independent

and outcome variable (insomnia). The p-value of <0.05 was considered as significant. The independent samples t-test was done to compare the mean age of those with insomnia and of those without insomnia.

3.18.3 **Multivariate analysis**

Some of the variables used in the bivariate analysis were further clubbed into composite variables and re-coded into broader categories. (Sections 3.14.2 and 3.14.3) An adjusted analysis was finally done to find the key variables that have a strong influence on the outcome variable. Odds ratios, 95% CI of which do not include unity, were used as indicators of association in the analysis.

3.19 **Data storage**

The hard copies of the filled interview schedule and consent forms are being kept in a locked chamber under the custody of the principal investigator. A respondent identity number has been assigned to each participant to maintain the confidentiality and privacy of the data collected. Access to this number is restricted to the principal investigator and his research guide only. The personal details of any research subject were not shared with anyone at any stage. The data, other than the subject's personal identifiers were used for analysis. The hard copies shall be kept safe with the principal investigator for next five years from the date of data collection and afterwards the entire set of the hard copies will be destroyed.

3.20 **Ethical considerations**

The ethical clearance was obtained from the Institutional Ethics Committee (IEC) of SCTIMST vide letter no SCT/IEC/753/JUNE-2015 (Appendix-VI). An information sheet was provided to the prospective subjects and their queries were addressed (Appendix-II). After they agreed to participate in the study, their signatures were taken on the informed

consent form (Appendix-III). Those who denied were requested to sign a non-participation form but all non-responders refused to sign it (Appendix-IV). Those subject who were found facing the consequences of sleep deprivation and needed help from an expert were referred to the nearest health facility for appropriate intervention, investigations and management (such as Department of Psychiatry, LNJP civil hospital, Kurukshetra; Sleep Disorder Clinic, Govt. Medical College and Hospital, Sector-32, Chandigarh; Dept. of Pulmonary Medicine and Sleep Disorders, AIIMS, New Delhi and Department of Sleep Medicine, Sir Ganga Ram Hospital, New Delhi). Information about the Comprehensive Centre for Sleep Disorders of SCTIMST was also given. A unique respondent serial number was allotted to each subject (001-299) to maintain the anonymity and confidentiality of the data. These unique identifiers are being used for analysis.

3.21 **Dissemination of results**

The results of this study would be disseminated through publication of papers in research journals.

Chapter-4 Results

4.1 **Sample characteristics**

The sample characteristics are presented in Table 4.1. The overall response rate is 97.5%. Five out of six non-responders are replaced with other eligible subjects of the same gender except in one case where the non-responder is from the last house in that locality. Finally, the data of 299 subjects is analysed wherein 49.8 % (n=149) are urban residents and the rest are rural residents. Half of the study subjects (55.5% of 299) are males and rest are females. The average age of the study subjects is 43.8 years (43.8 ±5.6). There is no gender difference in terms of mean age.

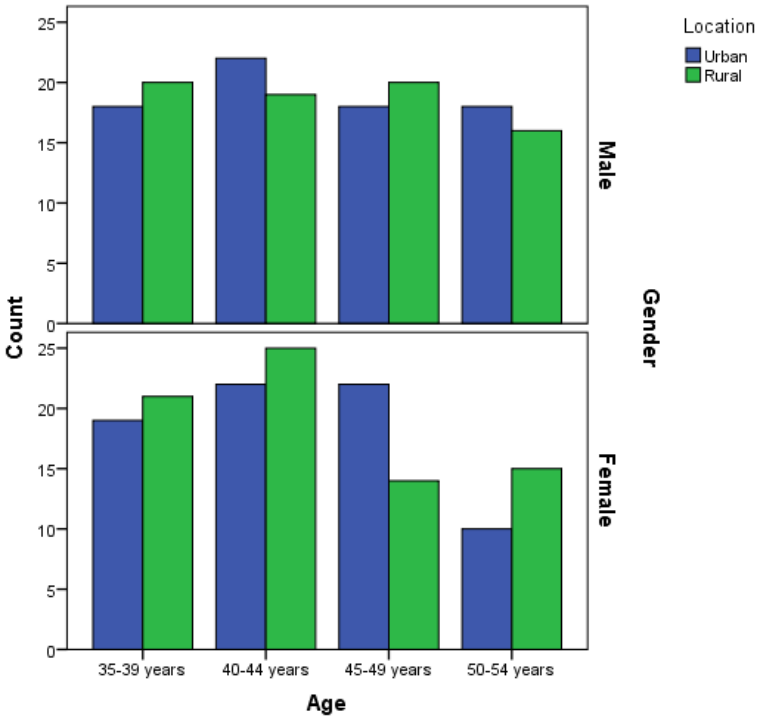


Figure: 4.1 Age-sex distribution in the sample by location

Majority of study subjects are currently married (95.7%, n=286) and their religious denominations is (a) Hindus (90%, n=269), (b) Sikh (7.3%, n=22) and (c) Muslims (2.7 %, n=8). Overall reported literacy level (class 1 and above) among the study subjects

is 76.6% (n=229). Among literates, more proportion of females (73.0 %, n=108) has highest education up to class 8, whereas more proportion of males (58.3%, n=88) has education beyond class 8.

4.2 **Socioeconomic status** (Table 4.1)

Just above half of the study subjects (56.2%, n=168) are employed/earning and rest are unemployed A large number of subjects in earning category (57.4%, n=105) express difficulty in managing monthly household expenditure compared to those unemployed (42.6 %, n=78).

A segregated analysis by gender reveals that among 151 males, 90.1% (n=136) are earning and engaged in full time (33.1%, n=50) or part-time (16.6%, n=25) employment. Among 148 females, only 21.6% (n=32) are earning and majority are homemakers (77.0%, n=114). More proportion of male earners (87.8%, n=79) have difficulty in managing monthly household expenditure compared to female earners (28.0%, n=26). Maximum proportion of subjects reside in 'pakka' houses (78.6%, n=235) and currently have APL status (80.9%, n=242). Overall 63.2% (n=189) are having low socio-economic status and the rest were having high socio-economic status.

4.3 **Shift work and work related travel**

The shift work in the last three months is reported by only 4% (n=12) subjects with an average of approximately 10 night shifts per month (mean=9.7±10.5, median=6). These numbers are inadequate to comment on this variable and its impact on sleep. The average work related travel of approximately 10 days per month (9.5 ± 8.8, median=6 days, range 1-30) is reported by just 20.1% (n=60) of the study subjects.

Table: 4.1 Demographic and socioeconomic characteristics of the sample

Variable	Category	Frequency (%) N=299
Age in years (mean 43.8 , SD 5.6)		
	35-39 years	78 (26.1)
	40-44 years	88 (29.4)
	45-49 years	74 (24.8)
	50-54 years	59 (19.7)
Age in years (clubbed by median)		
	35-44 years	166 (55.5)
	45-54 years	133 (44.5)
Gender		
	Male	151 (50.5)
	Female	148 (49.5)
Marital Status		
	Currently married	286 (95.7)
	Others	13 (4.3)
Location of Residence		
	Urban	149 (49.8)
	Rural	150 (50.2)
Make of House		
	Kaccha	6 (2.0)
	Kaccha - pakka	58 (19.4)
	Pakka	235 (78.6)
Make of residence (clubbed category)		
	Kaccha-pakka	64 (21.4)
	pakka	235 (78.6)
Below poverty line (BPL) status		
	No	242 (80.9)
	Yes	57 (19.1)
Religion		
	Hindu	269 (90.0)
	Sikh	22 (7.3)
	Muslim	8 (2.7)

Variable	Category	Frequency (%) N=299
Religion (clubbed categories)		
	Hindu	269 (90.0)
	Others	30 (10.0)
Caste		
	Scheduled caste	62 (20.7)
	Backward class (BC/OBC)	103 (34.5)
	General class	134 (44.8)
Highest level of education		
	Illiterate	70 (23.4)
	Elementary (class 1-8)	101 (33.8)
	Secondary (class 9-12)	72 (24.1)
	Tertiary level education	56 (18.7)
Literacy status (clubbed category)		
	Literate (Class ≥1)	229 (76.6)
	Illiterate	70 (23.4)
Work status in last 12 months		
	Unemployed	131 (43.8)
	Self-employed	59 (19.7)
	Employed	107 (35.8)
	Retired	2 (0.7)
Work status (clubbed category)		
	Earning	168 (56.2)
	Non-earning	131 (43.8)
Ease of expenditure*		
	Not difficult	116 (38.8)
	difficult	183 (61.2)
Socio-economic status (clubbed category)		
	High	110 (36.8)
	Low	189 (63.2)

* Ease of managing monthly household expenditure

4.4 **Sleep hygiene in the past three months**

The level of 'Sleep hygiene' based on the 'activities performed at bed time', 'sleep environment' and 'sleep routine'. (Table 4.2) Based on the median score of 14 (range 6-18), 55.2 % subjects (n=165) are having low sleep hygiene.

4.5 **Sleep pattern in the past one month**

Usual sleep time of 83.6% (n=250) subjects is between 8 pm and 12:30 am. Those who sleep before 8 pm (0.3%, n=1), after 12:30 am (0.3%, n=1) and have no fixed time of sleep (15.8%, n=47) are categorized as 'erratic sleepers'. Usual time to wake up is between 3 am and 8 am for 93.4% (n=279) subjects. Those who wake up before 3 am (0.3%, n=1), after 8 am (0.3%, n=1) and have no fixed time to wake up (6%, n=18) are also categorized as erratic sleepers. Only 19.7 % (n=58) persons have abnormal sleep latency period (more than 30 minutes) and 22.5% (n=67) have abnormal total awakening period at night (more than 30 minutes).

Table 4.2: Sleep Hygiene of the sample population in the past 3 months from the date of data collection

Variable		Frequency (N=299)	Percent (100%)
Activities performed at bed time (at least within 2 hours before sleeping at night)			
Alcohol Consumption			
	Always	14	4.7
	Sometimes	36	12.0
	Never	249	83.3
Tobacco/Smoking			
	Always	65	21.7
	Sometimes	5	1.7
	Never	229	76.6

	Variable	Frequency (N=299)	Percent (100%)
	Caffeine (tea/coffee)		
	Always	18	6.0
	Sometimes	49	16.4
	Never	232	77.6
	Light exposure before sleep		
	Always	111	37.1
	Sometimes	61	20.4
	Never	127	42.5
Sleep Environment			
	Uncomfortable bedding		
	Always	7	2.3
	Sometimes	17	5.7
	Never	275	92.0
	Uncomfortable bed-room		
	Always	9	3.0
	Sometimes	69	23.1
	Never	221	73.9
	Sleep disruption at night (due to bed partner/child/animals)		
	Always	34	11.4
	Sometimes	59	19.7
	Never	206	68.9
Sleep routine			
	Irregular Sleep Time		
	Always	46	15.4
	Sometimes	139	46.5
	Never	114	38.1
	Irregular wake up time		
	Always	29	9.7
	Sometimes	94	31.4
	Never	176	58.9

Variable	Frequency (N=299)	Percent (100%)
Sleep Hygiene distribution (based on percentile)		
Lower third (score of 6-12)	77	25.8
Middle third (score of 13-15)	140	46.8
Upper third (score of 16-18)	82	27.4
Sleep Hygiene distribution (based on median)		
High sleep hygiene (>14)	134	44.8
Low sleep hygiene (≤14)	165	55.2

4.5.1 **Sleep need**

The average self-reported sleep need (in hours) in the study sample is 6.9 ± 1.3 hours (median=7, range 4-12 hours). Maximum proportion (81.6%, n=244) of subjects have a sleep need of at least 6-8 hours, which is recommended level of core sleep to be fresh and remain active next day.(Banks and Dinges, 2011)

4.5.2 **Opportunity to sleep**

A majority of subjects (95.3%, n=285) have enough opportunity to sleep as per their sleep need. As many as 81.9% (n=245) subjects are 'morning type' persons (can work more and feel more active or alert in the morning than evening).

In the sample, 4.7% (n=14) have no opportunity to sleep. Out of these subjects no one has sleep problem less than one month, 21.4% (n=3) have sleep problem less than three months and rest 78.6% (n=11) have sleep problem for three months or more.

Table 4.3 – Sleep adequacy, sleep satisfaction and insomnia symptoms

Variable	Category	Frequency (N=299)	Percent (100%)
Sleep adequacy			
	Less sleep during night	38	12.7
	Adequate sleep (+/- one hour)	192	64.2
	More sleep during night	69	23.1
Sleep satisfaction			
	Fully satisfied	109	36.5
	Moderately Satisfied	152	50.8
	Dissatisfied	38	12.7
Difficulty initiating sleep			
	No problem	213	71.2
	Moderate problem	55	18.4
	Severe problem	31	10.4
Difficulty maintaining sleep			
	No problem	145	48.5
	Moderate problem	117	39.1
	Severe problem	37	12.4
Waking up too early			
	No problem	193	64.6
	Moderate Problem	64	21.4
	Severe problem	42	14.0

4.5.3 **Sleep adequacy**

'Sleep adequacy' refers to a combination of sufficient sleep duration and sleep quality. A mismatch in self-reported 'sleep need' and 'sleep preference' was observed during the field work. Therefore, 'sleep adequacy' was computed by subtracting 'sleep need' (core sleep) from 'preferred night sleep hours'. Likewise, the variable 'preferred night sleep hours' is computed by subtracting the variable 'preferred time to wake up' from the variable 'preferred time to bed'. Among the study subjects, 35.8% subjects (n=107) are having inadequate sleep.

4.5.4 **Sleep satisfaction**

Sleep satisfaction is reported by 87.3% (n=261) subjects in the sample (Table 4.3). No effect of any sleep disturbance in terms of impairing the quality of life is reported by 73.9% (n=221) subjects. Interestingly, many express satisfaction with their current sleep pattern in response to the fourth question in ISI scale (section 3, Appendix-V, *code IS4*) in spite of having difficulty in falling asleep, staying asleep, waking up too early and/or having an inadequate opportunity to sleep. Hence, they are considered normal (not suffering from insomnia).

4.6 **Prevalence of insomnia**

4.6.1 **Prevalence of insomnia based on ISI score (Table 4.4)**

The prevalence was estimated to be 18.7 (95% CI, 14.3-23.2) using Morin's cut off of 10. The prevalence in rural residents was slightly more (19.3%) compared to urban residents (18.1%). Table also shows the classical categories of Insomnia based on ISI score. Moderate insomnia was found to be 8.7% and severe insomnia was found to be only 2%.

4.6.2 **Prevalence of insomnia using more stringent criteria of DSM-5**

Dissatisfaction with sleep is regarded as one of the essential criteria for establishing insomnia by DSM-5. In our subjects sleep dissatisfaction was reported by only 12.7% (n=38) subjects (Table 4.3). Only those who are dissatisfied with sleep in spite of having adequate opportunity to sleep and have any of the insomnia symptoms (difficulty initiating or maintaining sleep or early awakening) for at least three nights per week and for at least three months are categorized as having insomnia disorder. The overall prevalence of insomnia disorder is 8.4% (n=25). The prevalence among urban residents is 7.4% (n=11) as compared to 9.3% (n=14) among rural residents.

Table 4.4 – Prevalence of insomnia: estimation using various methods

Variable	Category	Frequency (N=299)	Percent (100%)
Insomnia (based on ISI Morin's cut off of 10 (Morin et al., 2011)			
	No	243	81.3
	Yes	56	18.7
Insomnia (based on ISI classical category)			
	Not clinically significant (0-7)	218	72.9
	Sub-threshold insomnia (8-14)	49	16.4
	Clinical insomnia-moderate (15-21)	26	8.7
	Clinical insomnia-severe (22-28)	6	2.0
Insomnia (based on DSM-5 classification)			
	No	274	91.6
	Yes	25	8.4

4.6.3 **Severity of Insomnia symptoms (based on ISI scale)**

The first four questions of ISI scale in the interview schedule (section 3, Appendix-V, *code IS1-IS4)* relates to the insomnia symptoms. Approximately 28.8% (n=86) of study subjects have difficulty in initiating sleep; 51.5% (n=154) have difficulty in maintaining sleep and 35.5% (n=106) are waking up too early (Table 4.3). When all these four are clubbed the prevalence of insomnia symptoms came out to be 12% (n=36). Based on this method of estimation, we found that 18.7% subjects have insomnia.

4.6.4 **Duration of sleep problems**

Currently, 75.6% subjects (n=226) have sleep problem less than three months and 24.4% (n=73) have sleep problem for more than three months.

4.6.5 **Excessive daytime sleepiness**

As many as 41.1% (n=123) subjects nap 'sometimes' or 'always' for two hours or more during daytime. Among them, the habitual day-time sleepers ('always' sleep more than two hours) are 13% (n=39).

Table: 4.5 Sleep associated medical comorbidity

Variable		Frequency (N=299)	Percent (100%)
Hypertension	No	259	86.6
	Yes	40	13.4
Diabetes	No	281	94.0
	Yes	18	6.0
Asthma/Chronic lung disease	No	287	96.0
	Yes	12	4.0
Heart problem	No	298	99.7
	Yes	1	0.3
Kidney problem (renal calculus)	No	280	93.6
	Yes	19	6.4
Seizure disorder	No	297	99.3
	Yes	2	0.7
Hypothyroidism	No	292	97.7
	Yes	7	2.3
Any other medical problems	No	199	66.6
	Yes	100	33.4

4.7 **Sleep and medical history**

Looking at the overall sample, a small proportion 3% (n=9), have history of sleep problems in childhood also. A higher proportion of subjects 86.6% (n=259) have single morbidity and 13.4% (n=40) have multiple morbidity. Approximately 3% (n=9) subjects are taking sleep medication. Most of them are not having prescriptions. The medicines used are cetirizine and alprazolam, which are not strictly sleep medicines, but subjects express positive effects of these medicines on sleep. Hence, an affirmative response to the question on use of ‘sleep medicines’ (as perceived by the user) is used as one of the criteria for computing ‘suspected anxiety’ and ‘suspected depression’. Among study subjects 21.7% (n=65) have ‘suspected OSA’; 14.7% (n=38) have ‘suspected anxiety’, 17.1 % (n=51) have ‘suspected depression’ and 2.0% (n=6) have ‘suspected RLS’.

4.8 **Correlates of insomnia**

There is a difference between the mean age of those without insomnia (43.6±5.6) and those with insomnia (44.3±5.5) and on performing an independent sample's t-test, it is found to be non-significant ($p>0.05$). So age is not associated with clinical insomnia in this sample. For other variables a bivariate analysis using chi-square and Fisher's exact test is done to see the association between predictor variables and outcome variable. No significant association of clinical Insomnia is found with age, location, type of house, marital status, shift work, intake of alcohol within two hours before sleep, intake of caffeine after dinner & before going to bed, light exposure that is watching TV/mobile application/laptop sitting in bed before sleep at night, irregular sleep time, irregular wake time, suspected OSA, suspected RLS, asthma/chronic lung disease, heart problem, kidney problem and seizure problem.

Among the predictor variables (significantly associated with clinical insomnia), more proportion of clinical insomnia is found among non-Hindus. Among non-Hindus, 50.0% Muslims and 31.8% Sikhs have insomnia. Table 4.6 below, shows that more proportion of insomnia is found among those 'facing difficulty in managing monthly household expenditure' (44%); 'taking less or more than recommended core sleep' (25.5%); 'evening type personality' (29.6%); 'consuming tobacco after dinner and before going to sleep' (30.0%); 'having low sleep hygiene' (23.6%); have 'suspected anxiety' (48.1%), 'suspected depression' (49%) and 'hypertension' (32.5%). The prevalence of insomnia is also higher (50%) among those who have abnormal sleep latency period, which is the period between switching off the light/going to bed and initiation of sleep after switching off lights and going to bed'. Similarly 41.6%, (n=37) subjects with problems of early awakening (wake up more than 30 minutes before up time) have insomnia. An association

of insomnia is observed among the diabetics (38.9% having insomnia) compared to non-diabetics (17.4% having insomnia) but this association is not found clinically significant. The prevalence of insomnia, 38.9% (n=7) have insomnia but in this sample. All the cases with thyroid problems have been diagnosed with hypothyroidism. Almost (57.1%) of these have insomnia. Among those with other medical comorbidities, 56% have insomnia. Other self-reported medical problems were mainly skin allergies, painful musculoskeletal disorders (such as gouty arthritis, cervical and lumbar spondylosis, prolapsed intervertebral disc problems etc. One subject is having bipolar affective disorder and is currently taking mood stabilizing drug (lithium carbonate). Three persons have history of depression but currently are not taking any drugs, but no medical records are available. Among composite variables, a significant association is found between 'sleep related comorbidity (SRC)' and 'clinical insomnia' (chi square =22.4, df =1, $p<0.01$); between 'other medical comorbidity' (OMC) and 'clinical insomnia' (chi square = 19.5, df =1, $p<0.01$) and between 'socioeconomic status' and 'clinical insomnia' (chi square = 17.481, df=1, $p<0.01$).

Table: 4.6 Correlates of Insomnia

Predictors		Insomnia		
		No n (%)	Yes n (%)	N (%)
Religion χ^{**}				
	Hindu	224 (83.3)	45 (16.7)	269 (100.0)
	Others	19 (63.3)	11 (36.7)	30 (100.0)
	Total	243 (81.3)	56 (18.7)	299 (100.0)
Caste χ^{*}				
	Scheduled caste (SC)	46 (74.2)	16 (25.8)	62 (100.0)
	Backward class (BC/OBC)	79 (76.7)	24 (23.3)	103 (100.0)
	General class	118 (88.1)	16 (11.9)	134 (100.0)
	Total	243 (81.3)	56 (18.7)	299 (100.0)

Significance levels - *p≤ 0.05, **p< 0.01; F- Fisher's exact test p value; χ - Chi square p

Predictors		Insomnia		
		No	Yes	N (%)
		n (%)	n (%)	
Highest education above class 8 χ**				
	Yes	116 (90.6)	12 (9.4)	128 (100.0)
	No	127 (74.3)	44 (25.7)	171 (100.0)
	Total	243 (81.3)	56 (18.7)	299 (100.0)
Ease of managing monthly expenditure χ**				
	Not difficult	104 (89.7)	12 (10.3)	116 (100.0)
	difficult	139 (76.0)	44 (24.0)	183 (100.0)
	Total	243 (81.3)	56 (18.7)	299 (100.0)
Socioeconomic status χ**				
	High	103 (93.6)	7 (6.4)	110 (100.0)
	Low	140 (74.1)	49 (25.9)	189 (100.0)
	Total	243 (81.3)	56 (18.7)	299 (100.0)
Type of person χ*				
	Morning type	205 (83.7)	40 (16.3)	245 (100.0)
	Evening type	38 (70.4)	16 (29.6)	54 (100.0)
	Total	243 (81.3)	56 (18.7)	299 (100.0)
Intake of tobacco between dinner and sleeping χ**				
	No	194 (84.7)	35 (15.3)	229 (100.0)
	Yes	49 (70.0)	21 (30.0)	70 (100.0)
	Total	243 (81.3)	56 (18.7)	299 (100.0)
Sleep Hygiene Status (cut off by median) χ*				
	High Sleep Hygiene(>14)	117 (87.3)	17 (12.7)	134 (100.0)
	Low Sleep Hygiene (<=14)	126 (76.4)	39 (23.6)	165 (100.0)
	Total	243 (81.3)	56 (18.7)	299 (100.0)
Suspected Anxiety χ**				
	No problem	202 (91.8)	18 (8.2)	220 (100.0)
	Suspected anxiety	41 (51.9)	38 (48.1)	79 (100.0)
	Total	243 (81.3)	56 (18.7)	299 (100.0)
Suspected Depression χ**				
	No problem	217 (87.5)	31 (12.5)	248 (100.0)
	Suspected depression	26 (51.0)	25 (49.0)	51 (100.0)
	Total	243 (81.3)	56 (18.7)	299 (100.0)

Significance levels - *p≤ 0.05, **p< 0.01; F- Fisher's exact test p value; χ - Chi square p

Predictors		Insomnia		
		No	Yes	N (%)
		n (%)	n (%)	
Hypertension χ^{*}				
	No	216 (83.4)	43 (16.6)	259 (100.0)
	Yes	27 (67.5)	13 (32.5)	40 (100.0)
	Total	243 (81.3)	56 (18.7)	299 (100.0)
Diabetes mellitus (F-value not significant)				
	No	232 (82.6)	49 (17.4)	281 (100.0)
	Yes	11 (61.1)	7 (38.9)	18 (100.0)
	Total	243 (81.3)	56 (18.7)	299 (100.0)
Thyroid problem ^{F*}				
	No	240 (82.2)	52 (17.8)	292 (100.0)
	Yes	3 (42.9)	4 (57.1)	7 (100.0)
	Total	243 (81.3)	56 (18.7)	299 (100.0)
Other problems χ^{**}				
	No	170 (85.4)	29 (14.6)	199 (100.0)
	Yes	73 (73.0)	27 (27.0)	100 (100.0)
	Total	243 (81.3)	56 (18.7)	299 (100.0)
Sleep related comorbidity (SRC) χ^{**}				
	No SRC	169 (89.4)	20 (10.6)	189 (100.0)
	Any SRC	74 (67.3)	36 (32.7)	110 (100.0)
	Total	243 (81.3)	56 (18.7)	299 (100.0)
Other medical comorbidities (OMC) χ^{**}				
	No OMC	136 (91.3)	13 (8.7)	149 (100.0)
	Any OMC	107 (71.3)	43 (28.7)	150 (100.0)
		243 (81.3)	56 (18.7)	299 (100.0)

Significance levels - *p≤ 0.05, **p< 0.01; F- Fisher's exact test p value; χ - Chi square p value

4.9 **Adjusted multivariate analysis**

A test for co-linearity is done to test association among those variables that are significantly associated with Insomnia before doing multivariate binary logistic regression modelling using method 'enter' (Table 4.7). In the selection of variables used in the model, the biological plausibility and impression that the investigator got from the

field were used. Many of the variables that had shown significant association on bivariate analysis turned out to be non-significant where adjusted for other variables. Table 4.7 gives the results of the multivariate analysis.

Table 4.7 Results of multiple logistic regression analysis

Variables	Insomnia					
	Unadjusted Odds Ratio			Adjusted Odds Ratio		
		95% CI*			95% CI*	
	OR#	Lower	Upper	OR#	Lower	Upper
Age	1.06	1.0	1.13	1.00	0.95	1.07
Gender						
Male	1			1		
Female	1.56	0.74	3.30	1.47	0.73	2.96
Socio-economic status						
High	1			1		
Low	4.61	1.57	13.52	4.08	1.65	10.08
Sleep related comorbidities (SRC)						
No SRC	1			1		
Any SRC	5.29	2.35	11.91	2.91	1.51	5.59
Other medical comorbidities (OMC)						
No OMC	1			1		
Any OMC	5.0	2.0	12.54	3.53	1.73	7.20

Note: The model is adjusted for age as a continuous variable

The multivariate analysis adjusting for age and gender shows that having low socioeconomic status and comorbidities (either sleep related or other medical comorbidities) is a risk factor for insomnia.

a. Those in the lower socio-economic strata has 4.08 times higher odds of suffering from clinical insomnia compared to those from the high socio-economic strata.
b. Those suffering from any sleep related comorbidity (anxiety, depression, RLS and OSA) have 2.91 times higher odds of having clinical insomnia compared to those without any sleep related comorbidities.

c. Those with any other medical co-morbidities (hypertension, diabetes, thyroid problem etc.) have 3.53 times higher odds of having clinical insomnia compared to those without any co-morbidities.

Chapter-5 Discussion

The objective of this study was to estimate the prevalence of insomnia in Kurukshetra district. Most of the prevalence studies on insomnia have been based on subjective assessment. The factors affecting sleep health such as work factors (work schedule), family and social factors (usual sleep routine), perpetuating behavioral factors, health practices and environmental factors (under sleep hygiene) and cognitive factors (sleep worry) were looked into. While focusing on the correlates, the due consideration was given to the onset of sleep problem in childhood or adulthood, as prior complaints of insomnia is one of the risk factors for current sleep problems.(Klink et al., 1992).

The prevalence (18.7%) of insomnia among adult residents of Kurukshetra (age group 35-54 years) is higher compared to that reported by a survey on adults (5.7%) in Germany, (Schlack et al., 2013) higher than the estimates from recent studies in Australia (10.1%, age group 35-49 years) (Hillman and Lack, 2013) and in China (9.2%). (Xiang et al., 2008) but comparable to the estimate from South India (18.6%) (Panda et al., 2012), France (18.6%) (Ohayon and Lemoine, 2004) and Brazil (21%). (Hirotsu et al., 2014) Our findings also match well with other studies with respect to no difference in the prevalence of insomnia among rural and urban subjects. (Xiang et al., 2008)

The variations in prevalence could be due to difference in socioeconomic and cultural characteristics of the populations, which are discussed in details below. We have reasons to believe that our estimate is more precise. The cross sectional study by Panda et al. was conducted in a hospital set up for a time frame of one year and apparently healthy study subjects accompanying the patients were requested to participate. Around 1035 subjects were recruited from all states in the southern region of India. Of these, 86% were from

Karnataka and rest were from other states. They used a pretested questionnaire incorporating standardized tools namely modified Epworth Sleepiness Scale (ESS) and Pittsburgh Sleep Quality Index (PSQI). Even though we used different yardsticks, our estimates are almost same. Both PSQI and Insomnia Severity Index-ISI are widely used in the context of insomnia. ISI is a better indicator of clinical insomnia for use in population research as compared to PSQI. ISI has been validated by Morin et al. and at a cut off score of 10, it is found to have a sensitivity of 86.1% and specificity of 87.7% for detecting insomnia cases (Morin et al., 2011) whereas PSQI lacks specificity (Espie et al., 2014)

The regional differences in the prevalence of insomnia within the same country does exist. (Ohayon and Lemoine, 2002; Hirotsu et al., 2014) We anticipated the difference in prevalence of insomnia in Haryana (northern region) compared to Karnataka (southern region) due to the following reasons. The National Family Health Survey (NFHS-3) data on wealth index (an indicator for socio-economic status of households in India based on 33 housing assets and characteristics) shows that in most of the states of South India approximately 11% and 20% of population comes under the lowest wealth quintile and highest wealth quintile respectively (except in Kerala where just 1% of population is in lowest wealth quintile and 44.8% in highest wealth quintile) In contrast, in Haryana the lowest wealth quintile is 4.1 % and highest wealth quintile is 31.0% This shows that the general population in Haryana has a better socioeconomic status than most of Southern states. In our study, we found that low socioeconomic status is a risk factor for clinical insomnia. Low socioeconomic status (income, education) and racial disparities are frequently associated with the reduced opportunities of sleep (sleep deprivation) and adversities affecting sleep quality. We also found that that more proportion of subjects

who are facing difficulty in managing monthly household expenditure (13.7%, n=25) have clinical insomnia compared to those who have no difficulty (6.0%, n=7) It is known that the financial standing or income (one of the key indicators of socioeconomic status) has a bearing on both mental and physical health and is mediated by sleep quality and not sleep quantity. (Hirotsu et al., 2014; Piccolo et al., 2013; Talala et al., 2012) the possible explanation could be that in the adult age group of 35-54 years, people are at the peak of vocational and domestic engagements and therefore working people tend to suffer more. In the Brazilian population, more working people complained about insomnia and the key correlates were low socioeconomic status (low income and education levels less than eight years). (Hirotsu et al., 2014) There is minimal difference in mean age among insomniacs and normal subjects in our study but this difference is not significant. A similar evidence is given by the study of Ohayan wherein, the sleep dissatisfaction and insomnia diagnosis had minimal variation with increasing age. (Ohayon, 2002) We also found that comorbidities are a risk factor for insomnia. The negative health outcomes of insomnia are likely to be mediated by the associated comorbidities (related or associated with insomnia) and not by insomnia itself. (Pandey and Phillips, 2015) Hence, in our study, data was analyzed using two composite variables on co-morbidities. We found an association between sleep related comorbidities and insomnia, which is in line with other studies (Garcia-Borreguero et al., 2006; Neckelmann et al., 2007; Sheaves et al., 2015; Taylor et al., 2007). The use of sleep medication (3%) in Kurukshetra, was found similar to another study in Delhi. (Suri et al., 2008) A very high proportion of insomniacs have psychiatric disorders (Ohayon, 2002; Ohayon and Lemoine, 2002; Xiang et al., 2008) Similarly they have higher medical morbidity (vascular diseases, painful conditions and musculoskeletal diseases, cardiac diseases) compared to good sleepers and more socio-professional consequences (Léger et al., 2002; Grunstein, 2012) Studies have shown a

high burden of Non-communicable disease risk factors in Southern regions of India. (Gupta, 2012; Lipska et al., 2007; Thankappan et al., 2010) Diabetes and alcohol consumption is more in Southern regions and chronic lung diseases is more in Northern regions of India. Considering all these facts we can safely assume that Panda et al might have underestimated the prevalence of Insomnia in South India and that our estimates are valid. During our analysis, we also estimated the prevalence of insomnia using more stringent criteria (DSM-5 classification), which came out to be 8.4% (lesser prevalence compared to ISI scale (based on DSM-4). This finding corroborates with the work of Chung et al (Chung et al., 2015)

5.1 **Strengths and limitations**

5.1.1 **Strengths**

a. The principal investigator himself has done all the community interviews and so there is no inter-observer bias in the results.
b. Standard and established tool (ISI) validated in local language (Hindi) is used in the survey. The estimation of prevalence using the more recent DSM-5 criteria is also done. Only few studies in India have estimated the community prevalence of insomnia using different scale.
e. A high response rate (97.5%) is achieved, even though it necessitated up to three visits to a household.

5.1.2 **Limitations**

The presence of co-morbidities as reported by the participants could not be verified through laboratory or clinical examinations. However medical prescriptions and other medical documents were cross checked for confirmation wherever possible.

5.2 **Conclusion**

The prevalence of clinical insomnia in Kurukshetra district is similar to the estimates based on earlier studies in South India. Insomnia is found to be associated with low socioeconomic status, sleep related comorbidities and other medical comorbidities.

5.3 **Implications of the study**

This study reveals that insomnia is a notable entity in North India. So clinical and health services should take cognizance of this factor in future health planning. Health promotional and education related activities should include methods for increasing awareness regarding sleep disorders and sleep hygiene. The data generated from this study might encourage others to take up similar studies in North India. Further research is needed to understand the mediating role of associated comorbidities in the context of distal health outcomes attributed to insomnia.

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Chapter-6 APPENDICES

ANNEXURE-I

Achutha Menon Centre for Health Science Studies, SCTIMST, Thiruvananthapuram, Kerala
"Estimation of Prevalence of Insomnia among middle-aged people in Kurukshetra, Haryana, India"

Checklist (Cluster ID: XX)

Sr. No.	Respondent Code (RC)	Name	Age (in yrs)	Sex (Male-M, Female-F Other-O)	No. of household visits of Principal Investigator for interview	Status Interview Completed/ Non-participation/exclusion/withdrawal from interview	Date of Interview	Geo-Coordinates	Accuracy

Signature of PI _____

ANNEXURE-II

ACHUTHA MENON CENTRE FOR HEALTH SCIENCE STUDIES
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES & TECHNOLOGY
Thiruvananthapuram, Kerala, India – 695011

RESEARCH SUBJECT INFORMATION SHEET

Namaskar! I am XXXX, a resident of XXXX. I am doing my Masters in Public Health course at Achutha Menon Center for Health Science Studies (AMCHSS), Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Trivandrum. As a part of this course, I am doing a study on the sleep problems affecting the middle aged people (35-54 years) in Kurukshetra district of Haryana.

Purpose of the Study

The purpose of this study is to generate information on the number of middle aged men and women (age 35-54 years) who are suffering from a common disorder of disturbed/inadequate sleep, what doctors call as insomnia. Insomnia is associated with many other physical and mental disorders.

Description of the Study

The results of this study may act as an eye-opener for both people and healthcare professionals and may serve as one of the evidences for giving importance to sleep hygiene and important referral services for sleep disorder management. You have been chosen through a process of random selection from among the residents of the Kurukshetra district. A total of about 300 participants will be included and interviewed as part of this study in both rural and urban regions of the district. The study is conducted under the guidance of XXXXXXXX AMCHSS, SCTIMST (office contact no - XXXXXX)

Your contribution

If you agree to participate in this study, the entire process would take about 30-40 minutes. This includes the time of reading this information sheet, signing of the consent forms and the interview. The information given by you will be recorded. After the interview you may be contacted again only if it is found that information documented is either incomplete or any further clarification is needed.

Benefits

There may not be any direct benefit for you from this study but the information collected from you and from other participants will help in assessing the extent of the sleep problems in the community in Kurukshetra district. The results of the study will be helpful in further research & policy making, which will benefit the society as a whole. There will be no incentive in any form for participating in the study but in case during the course of the interview it is found that you may have a sleep problem and need further investigation and help, you would be advised to seek consultation from a nearest health facility, preferably having a sleep expert/sleep lab.

Risks and Discomforts

Participation in this study imposes no risk to your health. However, you would be asked questions which you may find personal in nature such as those related to your social and economic status, occupation, daily routine, and questions that would elicit information related to your normal sleep time and wake time, and habits that might be affecting or had affected your sleep in the recent past. This collected data will be used for research purposes only. Some questions may sound uncomfortable. In such case you are free to take time to answer or if you are not willing to answer, you can ask me to skip the question. If still you are not willing to answer further, you will be free to terminate the interview without any obligation.

Confidentiality of your data

You will be interviewed in private. It is hereby assured to you that whatever information you share will be kept highly confidential. A respondent identity number will be assigned to each participant that will help in maintaining the confidentiality of the data collected. Access to this number will be restricted to me and my research guide only. Your personal details will not be shared with anyone at any stage. The data other than your personal identifiers will be used for analysis of the study & results of the study will be published and presented.

Contact Information

Is there any query or doubt you want to ask? I will try to clarify it to best of my ability. If you have any doubt/query on the authentication of this study, or wish to verify my credentials, you may contact XXXX at the following address:

XXXXX Investigator (MPHXXX), Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Thiruvananthapuram – 695011 Kerala, India E-Mail: XXX Mobile : XXX (Kerala),	XXX Member Secretary, Institutional Review Board, Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Thiruvananthapuram – 695011 Kerala, India E-Mail –XXX Office: XXX

Voluntary Participation

Your participation in this study will be completely voluntary which means you can decide whether to participate in the study or not. You are free and have right to withdraw from participating at any time. There will be no penalty for withdrawal or not participating in the study. If you have decided to participate, kindly sign the enclosed informed consent form. If you donot want to participate kindly fill the non-participation form for academic purpose.

Date: Signature of Investigator

ANNEXURE-III

ACHUTHA MENON CENTRE FOR HEALTH SCIENCE STUDIES
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES & TECHNOLOGY
Thiruvananthapuram, Kerala, India – 695011

Informed Consent

I _____have read/heard and understood all the information provided in the 'research subject information sheet' dated _____. By signing/putting thumb impression I confirm my voluntary participation in this study. I agree to be contacted again if any missing information or further clarification is needed. I understand my right to withdraw from the interview anytime without any obligation.

Signature of the respondent/Thumb impression
(if unable to sign) : _____

Date : _____/ _____/_____
Place : _____

Witness (if needed): I confirm that the Principal Investigator (XXX) has explained all the information in the research subject information sheet to Mr./Mrs./Miss _____ and this person has voluntarily agreed to participate in this study.

Signature of the witness : _____

Name of the witness : _____

Date : _____/ _____/_____
Place : _____

Consent obtained: Yes / No Type of consent: Written / Oral

Signature of the Principal Investigator : _____

Name of the Principal Investigator : XXX
Date : _____/ _____/_____
Place : _____

ANNEXURE-IV

ACHUTHA MENON CENTRE FOR HEALTH SCIENCE STUDIES
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES & TECHNOLOGY
Thiruvananthapuram, Kerala, India – 695011

NON-PARTICIPATION FORM

If you are not willing to take part at this time, thank you for your time, but could you please fill in this non-response sheet for academic purposes? This information would be used for assessing overall non-participation rate while conducting the study. Confidentiality and anonymity would be strictly maintained.

Gender : Male Female Other

Age : _____years

Any reason for not participating : _____

Any health problem : _____

Any Sleep Problem : _____

Name : _____

Address : _____

Contact No : _____

Time : _____
Date : _____
Place : _____

Signature of the respondent

ANNEXURE-V INTERVIEW SCHEDULE

Respondent Id .....

S. No	Section-1: SURVEY INFORMATION		Code
1.1	Cluster Name/Id	_____	S1
1.2	Time of start of interview (12 hour clock)	_____ ☐ am/ _____ ☐ pm	S2
1.3	Are you residing in rural or urban location?	☐ 1 = Rural ☐ 2 = Urban	S3
1.4	What is the make of your house?	☐ 1 = Kachha ☐ 2 = Kaccha-pakka ☐ 3 = Pakka Hint: Kachha (raw or impermanent/ mud house) , Pakka (Solid and permanent/ brick house), Kaccha-pakka (built with high quality material such as brick/cement and also low quality material such as mud)	S4
1.5	What is your gender?	☐ 1 = Male ☐ 2 = Female ☐ 3 = Other	S5
1.6	Do you have a BPL card?	☐ 1 = Yes ☐ 2 = No	S6

S. No	Section-2 PERSONAL AND DEMOGRAPHIC INFORMATION Now I will be asking some general questions about your age, education, work schedule, etc.			Code
2.1	How old are you?	_____(years)	(If not known to the participant, researcher will help the participant to recollect widely known major events close to the time of his/her birth).	D1
2.2	What is the highest level of education you have attained?	☐ 1 = Illiterate ☐ 2 = Class 1 – 8 (elementary) ☐ 3 = Class 9 – 10 (lower secondary)	☐ 4 = Class 11 – 12 (higher secondary) ☐ 5 = UG/PG/Doctorate ☐ 88= Refused to answer	D2
2.3	What is your religion?	☐ 1 = Hindu ☐ 2 = Christian ☐ 3 = Sikh ☐ 4 = Muslim ☐ 5 = Jain	☐ 6 = Buddhist/Neo-Buddhist ☐ 7 = Jewish ☐ 8 = Parsi/Zoroastrian ☐ 9 = No Religion ☐ 10= Other :_____	D3
2.4	What is your caste?	☐ 1 = Scheduled caste ☐ 2 = General Class	☐ 3 =Backward class-BC/OBC ☐ 4 = Other :_____	D4
2.5	What is your marital status?	☐ 1 = Never married/Single ☐ 2 = Currently married ☐ 3 = Separated/ Widowed/ Divorced	☐ 4 = Other :_____ ☐ 88 = Refused to answer	D5
2.6	What have you been doing for most of the time over the last 12 months?	☐ 1 = Full-time student ☐ 2 = Full time homemaker or carer ☐ 3 =Volunteer (unpaid work) ☐ 4 = Retired ☐ 5 = Employed full time	☐ 6 = Employed part-time ☐ 7 = Unemployed & looking for work ☐ 8 = Unable to work/ ill/ handicapped ☐ 9 = Other :_____ ☐ 88= Refused to answer	D6
2.7	With how much ease do you manage your monthly household expenditure?	☐ 1 = Quite easy to manage ☐ 2 = Neither easy nor difficult ☐ 3 = Slightly difficult	☐ 4 = Very Difficult ☐ 77 = Do not know ☐ 88 = Refused to answer	D7
2.8	Are you involved in some kind of shift work? (change of work time in day and night)	☐ 1 = Yes ☐ 2 = No (Go directly to D12)		D8
2.9	How frequently is the change of shifts?	☐ 1 = Less than weekly ☐ 2 = Weekly	☐ 3 = Every 15 days ☐ 4 = Monthly	D9

2.10	How many night shifts you have done in the last three months?	Average of _____night shifts per month.	Hint: Give the average of the three months.	D10
2.11	How does your shift work affect your sleep schedule?	☐ 1 = To a great extent ☐ 2 = To some extent	☐ 3 = Not at all.	D11
2.12	Does your work related activities involves travelling?	☐ 1 = Yes ☐ 2 = No (Go to D14)		D12
2.13	How many times in a month you need to travel due to any work related reasons (and not for leisure)?	_____times/month		D13
2.14	How many hours of daily sleep do you normally need to feel refreshed/remain active for the next day?	_____hours		D14
	Please answer the following questions <u>THINKING ABOUT THE PAST 12 MONTHS</u>			
2.15	Did you face any difficulty to sleep well for at least three days or more in a week?	☐ 1 = Yes, Since _____month/s	☐ 2 = No	D15
2.16	Did you have enough time (opportunity) to sleep as per your daily need?	☐ 1 = Yes	☐ 2 = No, Since _____month/s	D16
2.17	One hears about morning and evening types of people. Which of these types do you consider yourself to be?	☐ 1= Definitely a morning person ☐ 2= More a morning than an evening type	☐ 3= More an evening than a morning type ☐ 4= Definitely an evening type	D17
2.18	If you could set your own schedule, what time would you go to bed for sleep at night?	_____pm / am		D18
2.19	If you could set your own schedule, what time would you get up in the morning?	_____am/ pm		D19
2.20	Did your daily routine activities affect your usual bed time or cause any disturbance in sleep (such as you wake up in the middle of the night)?	☐ 1 = Yes, always ☐ 2 = Yes, sometimes ☐ 3 = Never	Yes, because of ☐ 1 = Terminal illness of a family member/s (child/ adult/ elderly) ☐ 2 = A child/adult/ elderly in the family needs special care due to his/her physical/ mental disability. ☐ 3 = healthy child/children under 12 months of age ☐ 4 = healthy child/ children of 1-5 years of age ☐ 5 = Other reasons: _____	D20

	Now I am going to ask some questions related to your normal sleep behaviour and sleep environment. **Please answer the following questions <u>THINKING ABOUT THE PAST THREE MONTHS</u>**			
2.21	Do you take alcohol after dinner and before going to sleep?	☐ 0 = Always ☐ 1 = Sometimes	☐ 2 = Never	D21
2.22	Do you smoke/take any tobacco products after dinner and before going to sleep?	☐ 0 = Always ☐ 1 = Sometimes	☐ 2 = Never	D22
2.23	Do you take tea/coffee (caffeine) after dinner and before going to sleep?	☐ 0 = Always ☐ 1 = Sometimes	☐ 2 = Never	D23
2.24	How many cups of tea/coffee you have in a day?	0= _____cup of tea 1= _____cup of coffee	☐ 2 = Not Applicable	D24
2.25	Do you use your bed for things like watching TV, reading or study, eating, and using mobile phones etc during bed time?	☐ 0 = Always ☐ 1 = Sometimes	☐ 2 = Never	D25
2.26	Do you sleep on an uncomfortable bed? (Hint: E.g. poor mattress/ pillow, too much/ not enough blankets).	☐ 0 = Always ☐ 1 = Sometimes	☐ 2 = Never	D26
2.27	Do you sleep in an uncomfortable bedroom? (Hint: too bright/ hot/ cold/ noisy etc.).	☐ 0 = Always ☐ 1 = Sometimes	☐ 2 = Never	D27
2.28	Is your sleep disrupted by your bed partner/child or some pet?	☐ 0 = Always ☐ 1 = Sometimes	☐ 2 = Never	D28
2.29	Do you go to bed at different times from day to day?	☐ 0 = Always ☐ 1 = Sometimes	☐ 2 = Never	D29
2.30	Do you get out of bed at different times from day to day?	☐ 0 = Always ☐ 1 = Sometimes	☐ 2 = Never	D30
	Please answer the following questions <u>THINKING ABOUT THE PAST ONE MONTH</u>:			
2.31	What is your usual time to sleep?	☐ 1 = before 8 p.m ☐ 2 = between 8 pm –12.30 am Specify (Hint): _____ ☐ 3 = After 12.30 am ☐ 4 = No fixed time	<u>Hint:</u> 8.00 pm/ 8.15 pm/ 8.30 pm/ 8.45 pm/ 9.00pm/ 9.15 pm/ 9.30 pm/ 9.45 pm/ 10 pm/ 10.15 pm/ 10.30 pm/ 10.45 pm/ 11.00 pm/ 11.15 pm/ 11.30 pm/ 11.45 pm/ 12 midnight/ 12.15 am/ 12.30 am	D31
2.32	What time do you usually switch off the lights to sleep?	☐ 1 = before 8 p.m ☐ 2 = between 8 pm –12.30 am Specify (Hint): _____ ☐ 3 = after 12.30 am ☐ 4 = No fixed time	<u>Hint:</u> 8.00 pm/ 8.15 pm/ 8.30 pm/ 8.45 pm/ 9.00pm/ 9.15 pm/ 9.30 pm/ 9.45 pm/ 10 pm/ 10.15 pm/ 10.30 pm/ 10.45 pm/ 11.00 pm/ 11.15 pm/ 11.30 pm/ 11.45 pm/ 12 midnight/ 12.15 am/ 12.30 am	D32
2.33	How long does it normally take you to fall asleep?	☐ 1 = _____ ☐ 77= Do not know	<u>Hint:</u> 0 min/ 5 min/ 10 min/ 15 min/ 30 min/ 45 min/ 1 hr/ 1hr-15min/ 1hr-30 min/ 1 hr-45 min/	D33

			2 hrs/ 2 hrs-30 min/ 3 hrs/ 3hrs-30 min/ 4 hrs/ 4 hrs-30 min/ 5 hrs/ 5 hrs-30 min/ 6 hrs	
2.34	If you wake up once/more during the night, how long are you awake for, in total? (Add all the periods of wakening up in the middle of a typical night)	1 = _____ ☐ 77= Do not know	Hint: 0 min/ 5 min/ 10 min/ 15 min/ 30 min/ 45 min/ 1 hr/ 1hr-15min/ 1hr-30 min/ 1 hr-45 min/ 2 hrs/ 2 hrs-30 min/ 3 hrs/ 3hrs-30 min/ 4 hrs/ 4 hrs-30 min/ 5 hrs/ 5 hrs-30 min/ 6 hrs	D34
2.35	What is your usual time to get out of bed?	☐ 1 = between 3 am – 8.00 am Specify (Hint): _____ ☐ 2 = After 8am ☐ 77= No fixed time	Hint: 3.00 am/ 3.15 am/ 3.30am/ 3.45 am/ 4.00 am/ 4.15 am/ 4.30 am/ 4.45 am/ 5.00 am/ 5.15 am/ 5.30 am/ 5.45 am/ 6.00 am/ 6.15 am/ 6.30 am/ 6.45 am/ 7.00 am/ 7.15 am/ 7.30 am/ 8.00 am	D35
2.36	If your wake up time occurs before you intend to wake up, how much earlier is this?	1 = _____ ☐ 2= No such problem is there ☐ 77= Do not know	Hint: upto 15 minutes early/ 16-30 min/ 31-45 minutes/ 46-60 minutes/ 1-2 hours/ 2-3 hours / more than 3 hours early	D36

Section 3: INSOMNIA SEVERITY INDEX SCALE

S. No	Sleep problems (within last two weeks)	None	Mild	Moderate	Severe	Very Severe	Code
3.1	Difficulty falling asleep	0	1	2	3	4	IS1
3.2	Difficulty staying asleep	0	1	2	3	4	IS2
3.3	Problems waking up too early	0	1	2	3	4	IS3
3.4	How SATISFIED/dissatisfied are you with your current sleep pattern? Very satisfied (0) Satisfied (1) Moderately Satisfied (2) Dissatisfied (3) Very Dissatisfied (4)						IS4
3.5	How NOTICEABLE to others do you think your sleeping problem is in terms of impairing the quality of your life? Not at all (0) A little (1) Somewhat (2) Much (3) Very much (4)						IS5
3.6	How WORRIED/DISTRESSED are you about your current sleep problem? Not at all (0) A little (1) Somewhat (2) Much (3) Very much (4)						IS6
3.7	To what extent do you consider your sleep problem to INTERFERE with your daily functioning? CURRENTLY? (Hint: E.g. daytime fatigue, ability to function at work/daily chores, concentration, memory, mood etc) Not at all (0) A little (1) Somewhat (2) Much (3) Very much (4)						IS7
	Total Score (Q4.1+Q4.2+Q4.3+Q4.4+Q4.5+Q4.6+Q4.7) =.....						TotISI

S. No.	Section-4: SLEEP AND MEDICAL HISTORY			Code
4.1	Have you slept well during childhood?	☐ 1 = Yes	☐ 2 = No	MH1
4.2 a	Do you snore while sleeping?	☐ 1 = Yes	☐ 2 = No	MH2
b	Had anyone observed and reported to	☐ 1 = Yes	☐ 2 = No	MH3

	you that you stop breathing for few seconds while in sleep?			
c	Do you have morning headache?	☐ 1 = Yes	☐ 2 = No	MH4
d	How often do you wake up with morning headaches?	☐ 1 = Never ☐ 2 = Daily	☐ 3 = Monthly ☐ 4 = Weekly	MH5
e	Do you take daytime naps (total sleep spells) lasting two or more hours?	☐ 0 = Always ☐ 1 = Sometimes	☐ 2 = Never	MH6
4.3	Do you remain awake at night /during your sleep time due to feeling anxious with sweating?	☐ 1 = Yes	☐ 2 = No	MH7
4.4	Have you been taking any medicine to sleep?	☐ 1 = Yes, _____days/week	☐ 2 = No	MH8
4.5 a	Do you have disturbed sleep due to feeling sad?	☐ 1 = Yes	☐ 2 = No	MH9
b	Do you prefer staying alone and avoid social contacts?	☐ 1 = Yes	☐ 2 = No	MH10
c	Do you cry often?	☐ 1 = Yes	☐ 2 = No	MH11
d	Do you feel hopeless/helpless/worthless?	☐ 1 = Yes	☐ 2 = No	MH12
e	Have you ever thought of ending your life?	☐ 1 = Yes	☐ 2 = No	MH13
4.6 a	Do you have abnormal sensations (pins and needles, burning, pain) in legs with an urge to move the limbs?	☐ 1 = Yes	☐ 2 = No (Go to MH20)	MH14
b	Do you feel restless to relieve these symptoms?	☐ 1 = Yes	☐ 2 = No	MH15
c	Do these symptoms occur /worsen when at rest?	☐ 1 = Yes	☐ 2 = No	MH16
d	What time do you experience these symptoms to the maximum level?	☐ 1 = Daytime ☐ 2 = At night	☐ 3 = Related to sleep Onset	MH17
e	What areas of the body are affected?	☐ 1 = Legs ☐ 2 = Hands	☐ 3 = Both	MH18
f	What gives relief to the complaints?	☐ 1 = Walking ☐ 2 = Rubbing	☐ 3 = Pressing ☐ 4 = Tying with cloth	MH19
g	Have you or your bed partner noticed increased movements of toes at night?	☐ 1 = Yes	☐ 2 = No (Go to MH22)	MH20
h	Do these symptoms delay sleep onset?	☐ 1 = Yes	☐ 2 = No	MH21
i	Do you awaken yourself by kicking your legs during the night?	☐ 1 = Yes	☐ 2 = No	MH22

Now I would like to get information related to your medical problems and related treatment/s. Please answer in 'YES', if you are CURRENTLY suffering from any of these problems and/or CURRENTLY taking any ALLOPTHIC medicines for treatment as prescribed by a qualified medical practitioner.

	Disease		**Currently taking allopathic medicines?**	
4.7	High Blood Pressure	☐ 1 = Yes ☐ 2 = No	☐ 1 = Yes ☐ 2 = No	MH23
4.8	Diabetes	☐ 1 = Yes ☐ 2 = No	☐ 1 = Yes ☐ 2 = No	MH24
4.9	Asthma/Chronic lung problem	☐ 1 = Yes ☐ 2 = No	☐ 1 = Yes ☐ 2 = No	MH25

4.10	Heart problem	☐ 1 = Yes ☐ 2 = No	☐ 1 = Yes ☐ 2 = No	MH26
4.11	Kidney problem	☐ 1 = Yes ☐ 2 = No	☐ 1 = Yes ☐ 2 = No	MH27
4.12	Seizure disorder (convulsions)	☐ 1 = Yes ☐ 2 = No	☐ 1 = Yes ☐ 2 = No	MH28
4.13	Thyroid related problem (Please specify):_____	☐ 1 = Yes ☐ 2 = No	☐ 1 = Yes ☐ 2 = No	MH29
4.14	Any other disease (Please specify): _____	☐ 1 = Yes ☐ 2 = No	☐ 1 = Yes ☐ 2 = No	MH30

THANK YOU FOR YOUR TIME

	Time of completing the interview (12 hour clock)	_____ ☐ am/ _____ ☐ pm	TCI

ANNEXURE-VI

श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान

तिरुवनन्तपुरम - 695 011, केरल, भारत

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY

THIRUVANANTHAPURAM - 695 011, INDIA

(An Institute of National importance under Govt. of India)

Institutional Ethics Committee

(IEC Regn No. ECR/189/Inst/KL/2013)

SCT/IEC/753/JUNE -2015 10-06-2015

Dr. Aayam Gupta
MPH Scholar, AMCHSS,
SCTIMST, Thiruvananthapuram

Dear Dr. Aayam Gupta,

The Institutional Ethics Committee reviewed and discussed your application to conduct the study entitled "The prevalence and correlates of insomnia among middle aged people in Kurukshetra district, Haryana, North India" (IEC/753) on 2nd June, 2015.

The following documents were reviewed:

Original submission

1) *Research Proposal (P1-30)CV of Principal Investigator (Page 4 & 5) &*
2) *Appendix-1 (P31-35) which includes - Research subject information sheet (page 31-33), Informed consent and non-participation form in English (page 34-35)*
3) *Appendix-2 (P36-39) Hindi versions of Research subject Information sheet & Consent form*
4) *Appendix-3 (P40-46)Interview Schedule Revised (Eng)*
5) *Appendix-4 (P47-53)Interview schedule (Hindi)*
6) *Appendix-5 (P-54)Permission to use Insomnia Severity Index from the author- Prof. Charles M. Morin*

Revised submission

1. *Covering letter addressed to the Chairperson, IEC, SCTIMST dated 08.06.2015.*
2. *Modified IEC Application Form was submitted.*
3. *Modified Proposal was submitted.*

तार : चित्रमेट Grams : Chitramet | फोन Phone : 2443152 | फाक्स Fax : (91)471-2446433 2550728 | ई-मेइल E-mail : sct. @sctimst.ac.in वेबसाईट Website : www.sctimst.ac.in

The following members of the Ethics Committee were present at the meeting held on 2nd June, 2015 at G. Parthasarathi Board Room, AMCHSS, SCTIMST.

SL. No.	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation with Institution(s)
1.	Dr. R.V.G. Menon	PhD	Male	Lay Person	No
2.	Smt. Sathi Nair	MA	Female	Lay Person	No
3.	Dr. Kala Kesavan. P	MD	Female	Pharmacologist	No
4.	Dr. Mala Ramanathan	MSc, PhD, MA	Female	Ethicist/Social Scientist (Member Secretary)	Yes

IEC Decision

The IEC approved the conduct of the study in the present form.

Remarks:

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

There was no member of the study team /guide who participated in voting / decision making process. The ethics committee is organized and operated according to the requirements of Good Clinical Practice and the requirements of the Indian Council of Medical Research (ICMR).

Sincerely,

Mala Ramanathan
Member Secretary, IEC