

A Report on
1. Study of Correlation of Problematic Internet Use and Quality of
Sleep Among College Students During COVID-19 Pandemic
Lockdown in India
2. Introduction to Systematic Review and Meta-Analysis

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2019-2021



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ACKNOWLEDGMENT

To begin with, I am most grateful to my institute, **Indian Institute of Health Management Research, Jaipur** for providing me with this opportunity to conduct a research study in these difficult times of a global pandemic.

This project would not have been possible without the support and unfailing guidance of my academic mentor **Dr. Deepti Sharma, Associate Professor, IIHMR University** and **Mr. Abhishek Sharma**.

I also wish to express my sincerest gratitude to **Mr. Sharanraj Krishnan, PhD Scholar (Social Sciences), Jawaharlal Nehru University, New Delhi** for his constant guidance, encouragement and keeping me motivated throughout this study.

This summer project has been an important part of my career development and I would like to express my sincere and wholehearted thanks to all the individuals contributed to this study and taking me ahead in this journey. I shall endeavour all the skills and learning I procured while doing this study to the best of my abilities and will strive for improvement every step in my career.

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ABBREVIATIONS

COVID-19	Coronavirus disease 2019
EDS	Excessive Daytime Sleepiness
IAMAI	Internet And Mobile Association of India
IAT	Internet Addiction Test
PSQI	Pittsburgh Sleep Quality Index
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
SPIN	Social Phobia Inventory
SWLS	Satisfaction With Life Scale
WHO	World Health Organization

PART I

RESEARCH PROJECT REPORT

INTRODUCTION

“In late December 2019, Wuhan Municipal Health Commission, China reported a cluster of cases of pneumonia in Wuhan, Hubei Province.” (1) Chinese scientists soon identified the virus causing the disease a novel coronavirus and was initially named as 2019 coronavirus (2019-nCoV) later, the World Health Organization on February 11, 2020, announced a new name for the diseases as Corona Virus Disease (COVID-19). Also, the International Committee on Taxonomy of Viruses along with the WHO renamed the virus as “Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2).” (2) The initial outbreak in Wuhan spread in no time, affecting other cities of China. Cases were detected all around the world in 6 of the 7 continents. On January 20, 2020, World Health Organization declared that “COVID-19 is a public health emergency of international concern” and on March 11, 2020, declared it as a global pandemic. As of June 15, 2020; 7,690,708 cases have been reported globally and 427,630 deaths. (3) The cases are inevitably destined to grow more and more as a vaccine for such diseases takes a longer time. Contact tracing and social distancing are two strategies effective for containing the disease spread. (4)

Social distancing is one such technique to not just limit socialization but also promote physical distancing to prevent the risk of infection of COVID-19. (5) With these strategies in mind, nationwide lockdowns were implemented globally to flatten the curve. On 24 March, “the Government of India ordered a nationwide lockdown for 21 days, restricting outside movement of the whole 1.3 billion population of India” as a precautionary measure against the 2020 coronavirus pandemic in India. (6) This was Phase One lockdown. Since cases rose more and more, three more lockdown phases were implemented, viz. lockdown Phase Two- April 15, 2020, to May 3, 2020, Phase Three- May 4, 2020, to May 17, 2020, and Phase Four- May 18, 2020, to May 31, 2020. These lockdown restricted people from leaving their homes for non-essentials activities. With such restriction set in place, there is an impact on social habits and deleterious effects such as mental health problems, behavioural addiction disorders and physical inactivity (7, 8)

Since its inception in 1989, internet use has increased rampantly over these past twenty years in both developed and developing countries mainly because of easy and affordable access to the population. Internet is used for activities ranging from teaching, learning, research; exchanging email, business transactions, business meeting via video-conferencing, online gaming, shopping, pornography, gambling, watching movies and videos; social networking via texting, video calling, social websites and applications, etc. (9)

There are approximately 504 million internet users in India as of January 2020. (10) As the lockdown persists for a long period, online socialization is promoted rather than offline. People spend a great deal of time in surfing the internet, binge-watching of television, using social networking apps, online gaming etc to dawdle or kick the boredom. Thus increasing the chances of developing behavioural addiction disorder especially in the younger generation. (5) One such behavioural addiction disorder is the problematic internet use.

Problematic internet use can be defined as “Internet use that is risky, excessive or impulsive in nature leading to adverse life consequences, especially physical, emotional, social or functional impairment.” (11) Since the nationwide lockdown was first introduced, India’s internet consumption rose by 25-30%. (12) Various studies have shown to have pernicious effects of problematic internet use like low self-esteem, a poor coping mechanism, engaging in risky behaviour, cyber-bullying, pornography addiction, social exclusion, suicidal ideation, poor dietary habits, eye-strain, e-thrombosis, musculoskeletal disorders like low-back pain, carpal tunnel syndrome, mental health problems like obsessive-compulsive disorder, paranoia, psychoticism, depression, anxiety, stress, attention deficit hyperactive disorder. (9, 13, 14, 15, 16, 17, 18, 19, 20, 21)

Since there is no fixed routine to follow; lockdown will not only lead to behavioural addiction disorders but disrupt sleep schedules of individuals as well. Sleep plays a pivotal role in modulating of hormone release in the body, cardiovascular activities, and regulation of blood glucose levels, it has been proven that changes in sleep quality have significant implications on the physical health of an individual. (22, 23, 24, 25) Lack of sleep leads to various mood disorders, memory loss and affects the lifestyle of students as well. (26) Internet overuse has been linked with excessive daytime sleepiness and insomnia. (27, 28) Thus the assessment of sleep quality is of dire importance in such uncertain times. Hence, the purpose of this study was to investigate the correlation between problematic internet use and quality of sleep during the COVID-19 pandemic lockdown in India.

RATIONALE

An individual is unconstrained to socialize online, use internet to attend classes online, research purposes, learn new skills and pass their time. One can assume the period of lockdown lasting for a long time, the use of the internet is also likely to persist during these dire times which may later result in problematic internet use. Young people spend a disproportionate amount of time on the internet and tend to ignore sleep, thus, its consequences may lead to pernicious effects on one's physical and mental health. Hence, this study was taken to study the correlation between problematic internet use and quality of sleep among college students during the COVID-19 pandemic lockdown in India.

RESEARCH QUESTION

Is Quality of sleep affected due to problematic internet use among college students during COVID-19 pandemic lockdown in India?

OBJECTIVES

➤ BROAD OBJECTIVE

To determine the correlation between problematic internet use and quality of sleep among college students during COVID-19 pandemic lockdown in India

➤ SPECIFIC OBJECTIVES

- To assess problematic internet use among college students during COVID-19 pandemic lockdown in India
- To assess quality of sleep among college students during COVID-19 pandemic lockdown in India

LITERATURE REVIEW

- A study by **Krishnamurthy et al. (2015)** on “Internet addiction: Prevalence and risk factors: A cross-sectional study among college students in Bengaluru, the Silicon Valley of India.” in which 515 students of 8 colleges were analyzed to assess the risk factors, patterns and prevalence of internet addiction. With results reported to have no severely addicted users, 8% of moderately addicted users and 34% mildly addicted users with a marginally higher female representation of addicted users than males. She found male gender, peer influence, pornography, online relationships and socializing and prolonged use of the internet for coursework to be the risk factors for internet addiction. She concluded that college students were a vulnerable population to develop internet addiction.
- A study was done by **Sharma et al. (2018)** on “Internet addiction and psychological well-being among college students: A cross-sectional study from Central India.” He stated that with benefits of the internet comes a set of cons of excessive use of the internet and its negative implications on the mental health of young adults. He investigated the relationship between internet addiction and psychological well-being among 461 college students from the city of Jabalpur, Madhya Pradesh. He concluded that an inverse relationship exists between internet addiction and psychological well-being. Therefore, as internet use increased, the level of psychological well-being of a student decreased thus concluding that internet overuse had a negative impact on psychological well-being.
- A research study by **Choi et al. (2009)** on “Internet overuse and excessive daytime sleepiness in adolescents” in which high school students from South Korea were investigated for Internet Addiction and Excessive Daytime Sleepiness. He proposed that among high school students’ higher representation of male students were internet addicts than females. EDS was found to be higher in students with internet addiction, followed by students who were possible internet addicts and concluded a significant association between internet overuse and EDS and other sleep problems. It also concluded that the prevalence of alcohol consumption was higher among internet addicts. Thus, substance abuse playing a predominant role in internet addiction.
- A research study was done by **Jain et al. (2020)** on “Study of internet addiction and its association with depression and insomnia in university students” Internet overuse has been associated to many mental health problems including anxiety, depression, and insomnia. Influence of internet addiction has been seen on sleep patterns as well. He investigated the proposed depression and insomnia due to internet overuse among university students

among Indian setting. In his study, from 954 participants, postgraduate students were found to be addicted to the internet more than undergraduate students. In this study, Internet Addiction was significantly associated with alcohol consumption and smoking. 24.49% reported insomnia along with internet addiction and 55.15% were over users of the internet. Depression was reported 26.84% in internet addicts and 53.44% among over users. Hence, predicting alcohol consumption, smoking, male gender to be higher predictors of internet addiction. He concluded a significant association between internet addiction, depression and insomnia thus, inferring internet addiction, sleep and mental health problems to be a rising concern among the youths of India.

- A study by **Vadheri et al.** (2019) on “Predictors of problematic Internet use in school-going adolescents of Bhavnagar, India” This study was done to investigate the frequency and predictors of problematic internet use including social anxiety disorder, sleep quality and quality of life among school-going individuals. Various tests like IAT, PSQI, Social Phobia Inventory (SPIN), and Satisfaction with Life Scale (SWLS) were administered among the 1361 participants. Frequency of problematic internet users was found to be 16.7% and internet addiction as 3%. The study also reported that problematic internet users were likely to have higher SPIN and PSQI scores with strong association. There was also a significant correlation between the severity of problematic internet use and severity of social anxiety disorder. She concluded that adolescents with problematic internet use are likely to have a social anxiety disorder and adolescents with higher scores of PSQI were likely to be problematic internet users or internet addicts.

METHODOLOGY

STUDY SETTING AND PARTICIPANTS

The present study employs a cross-sectional descriptive study design. The data were collected from students pursuing college irrespective of their graduation courses across all the states of India during the period of the second lockdown. (April 15-May 3) Online collection of data methodology was chosen to bear in mind the restrictions put in place by the Government of India, for ease of access to larger sample size and fortuity to reach heterogeneous groups. As a mode of random sampling, the survey was emailed to various students of different colleges across India within the age group of 18-29 years, both male and female. Thus, a sample size of 252 was investigated for the study.

DATA COLLECTION TOOLS

At the beginning of the survey, all the participants were informed of the study, the nature of the study, the assurance of the confidentiality of the information. Prior consent was taken. The online survey was a self-administered questionnaire with three parts:

1. Socio-demographic Variables
2. Young's Internet Addiction Test
3. Pittsburgh Sleep Quality Index

1. Socio-demographic variables: A semi-structured questionnaire was constructed to document information about socio-demographic data (age, gender, qualification, the status of their internship, knowledge of coronavirus outbreak and lockdown measures taken by Government of India) and internet usage variables namely frequency of internet usage, duration, devices used, the purpose of the internet use, and the predominant time of day for internet use. The participants were asked to inform about their overall internet use and not differentiate between essential and non-essential use.
2. Young's Internet Addiction Test: The Internet addiction test (IAT) by Dr Kimberly Young was used to assess the prevalence of problematic internet use. It is a 20-item scale 5-point Likert scale ranging from 0 (does not apply) to 5 (rarely) that measures the severity of self-reported compulsive use of the internet. All the scores are added to obtain a total score. The maximum score is 100 points. The higher the IAT score, the greater level of severity of internet compulsivity. Total scores ranging from 0-30 points are considered a normal level of internet use; score range of 31-49 indicates the presence of mild level of compulsivity;

50-79 score range indicates the presence of a moderate level and 80-100 reflect a severe dependence of internet. (29) The rationale for using IAT for this study was good internal consistency reliability as well as concurrent validity and its good reliability on college students in Asia. IAT shows an overall Cronbach's alpha of 0.889 (95% CI 0.884-0.895). The standard deviation of the alpha was low at 0.049. (30)

3. Pittsburgh Sleep Quality Index: This scale was derived by Daniel J. Buysse used to assess the sleep quality and disturbances over 1 month. 19 individual items generate seven components score: "subjective sleep quality" (1 item), "sleep latency" (2 items), "sleep duration" (1 item), "habitual sleep efficiency" (3 items), "sleep disturbances" (9 items), "use of sleeping medication" (1 item), and "daytime dysfunction" (2 items). Items 1-4 in this scale are the free entry of usual "bed and wake times", "minutes of total sleep time", and "sleep latency" (minutes). Items 5-18 are 4-point Likert scale responses pertaining to problem frequency "not during the past month (0)"; "less than once a week (1)"; "once or twice a week (2)"; and "three or more times a week (3)." Item 19 is a 4-point Likert scale rating of overall sleep quality from 0 (very good) to 3 (very bad). All component scores range from 0 to 3. The sum of scores for the seven components yields one global score. The Global score ranges from 0 to 21. Higher global scores indicate poorer sleep quality. An empirically attained cutoff score of >5 distinguishes poor sleep quality. (31) The Cronbach's alpha of PSQI's 7 component scores is of 0.83 reflecting a high internal consistency. The sensitivity and specificity of PSQI are of 89.6% and 86.5% respectively. (32)

DATA ANALYSIS TOOL AND TECHNIQUE

Derived responses were entered into the Microsoft Excel worksheet. Descriptive statistics were used to describe the data, frequencies and percentages for categorical variables and mean values with standard deviations for continuous variables. Pearson's Correlation Coefficient was applied to study the correlation between Problematic internet use and Sleep quality.

RESULTS

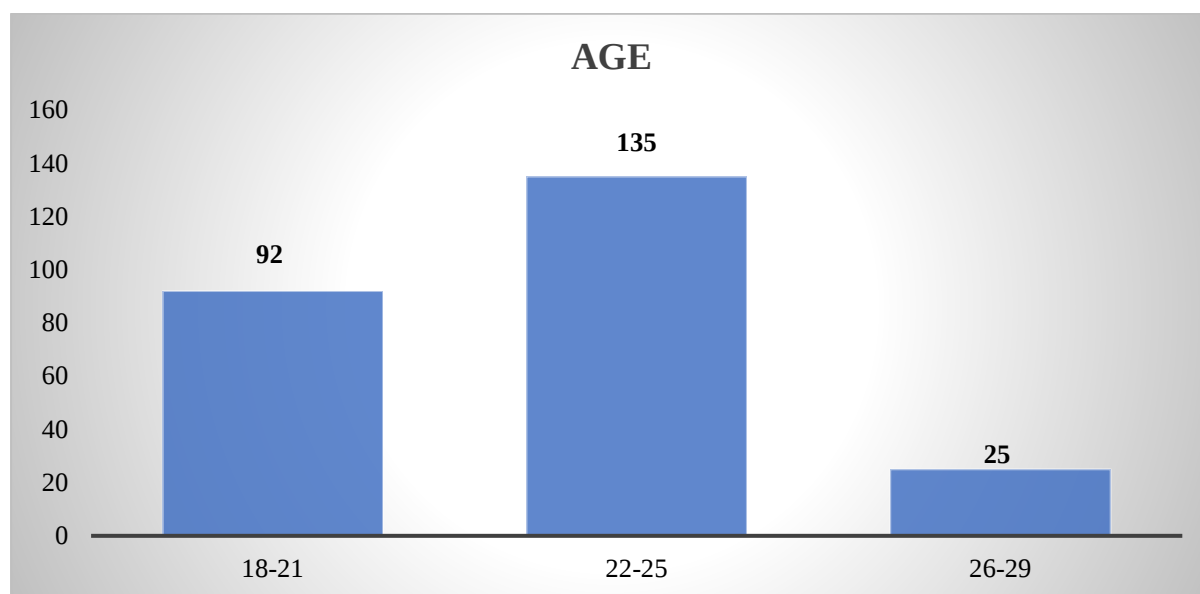


Figure: 1 Age of the Respondents

Table 1: Mean Age

Mean Age	SD
22.38	±2.24

Interpretation: 53% of respondents belonged in the age group of 22-25, while 37% were between 18-21 and 10% in the age group of 26-29.

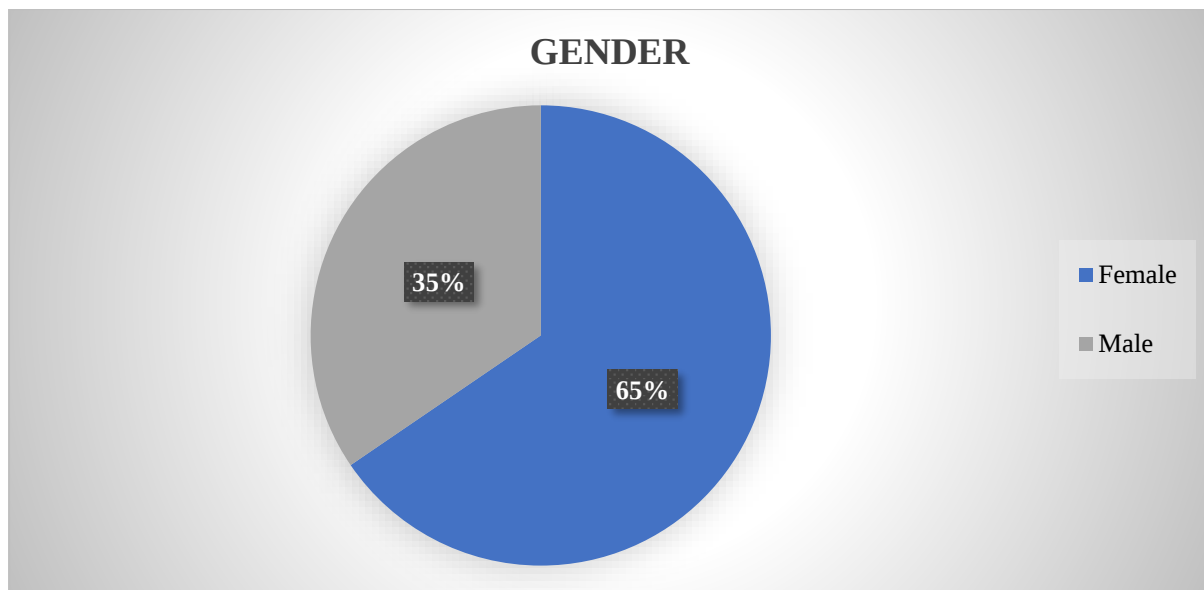


Figure 2: Gender of the Respondents

Interpretation: 65% of respondents were Females while 35% of respondents were Males.

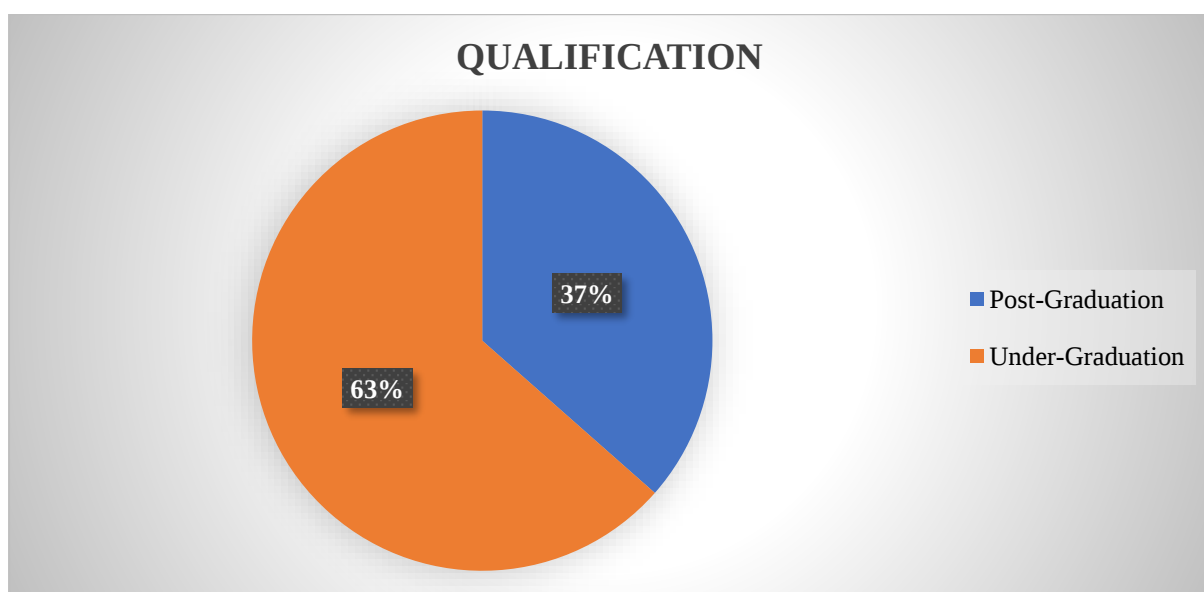


Figure 3: Qualification of the Respondents

Interpretation: 63% of respondents were pursuing Under-Graduation while 37% were pursuing Post-Graduation.

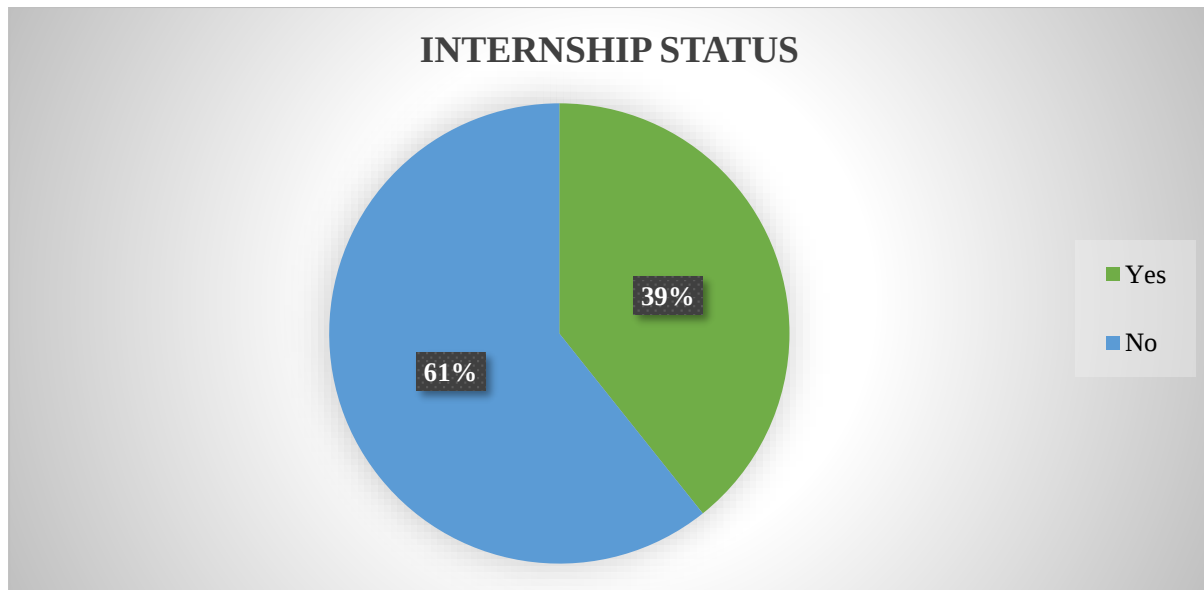


Figure 4: Internship Status of the Respondents

Interpretation: 61% of respondents were interning while 39% of respondents were not interning.

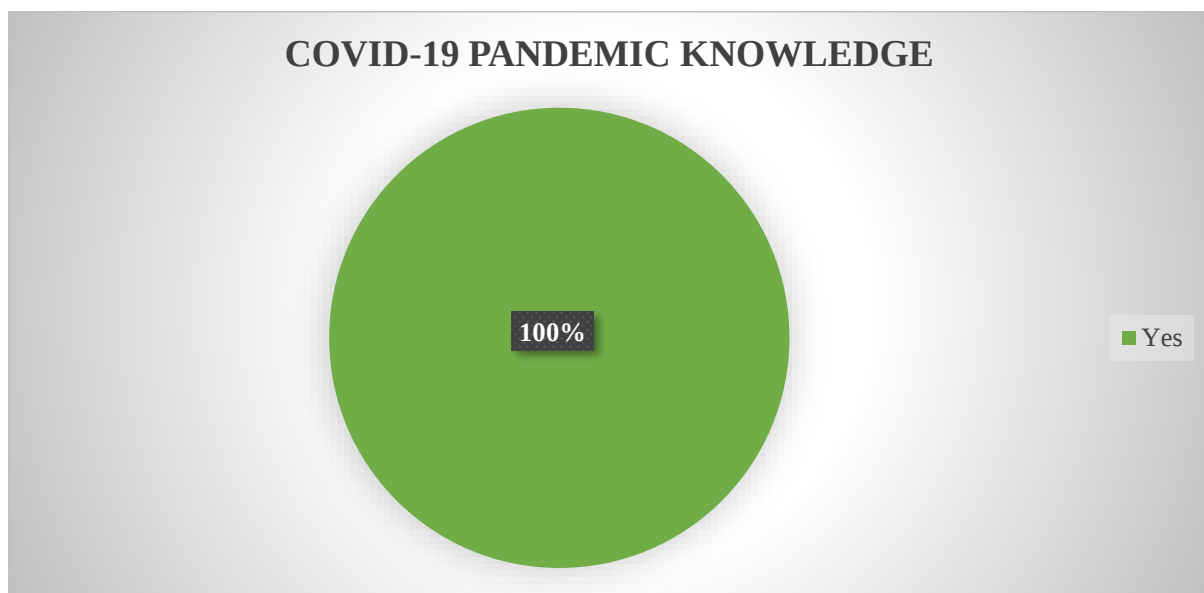


Figure 5: COVID-19 Pandemic Knowledge of the Respondents

Interpretation: All the respondents (100%) were about the COVID-19 outbreak.

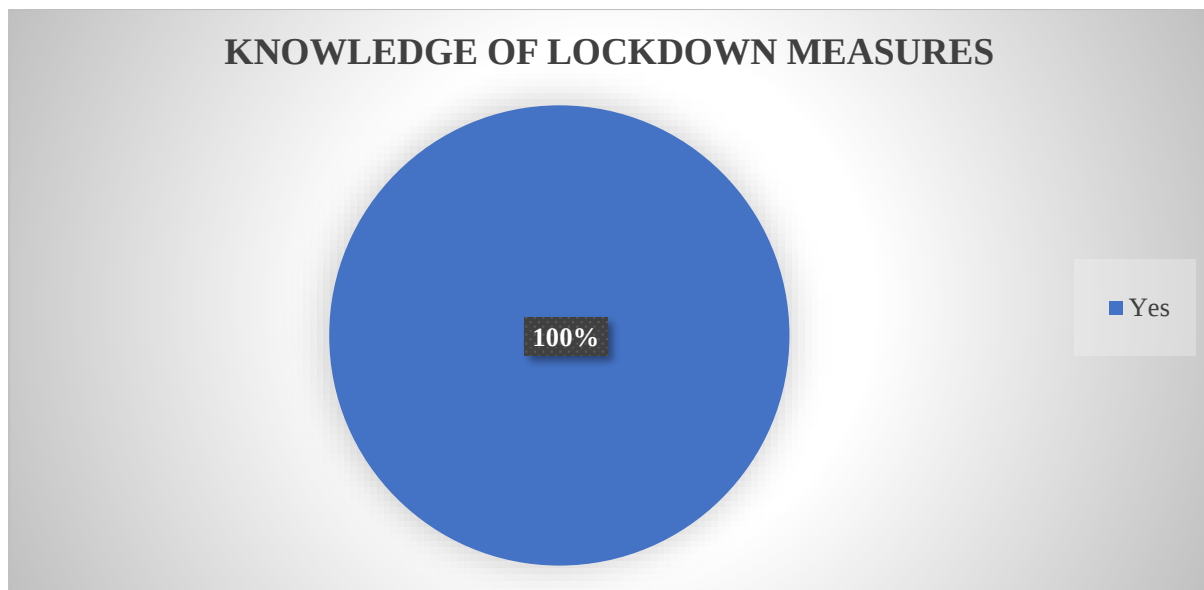


Figure 6: Knowledge of Lockdown Measures

Interpretation: All the Respondents (100%) had knowledge of the Lockdown measures taken by the Government of India.

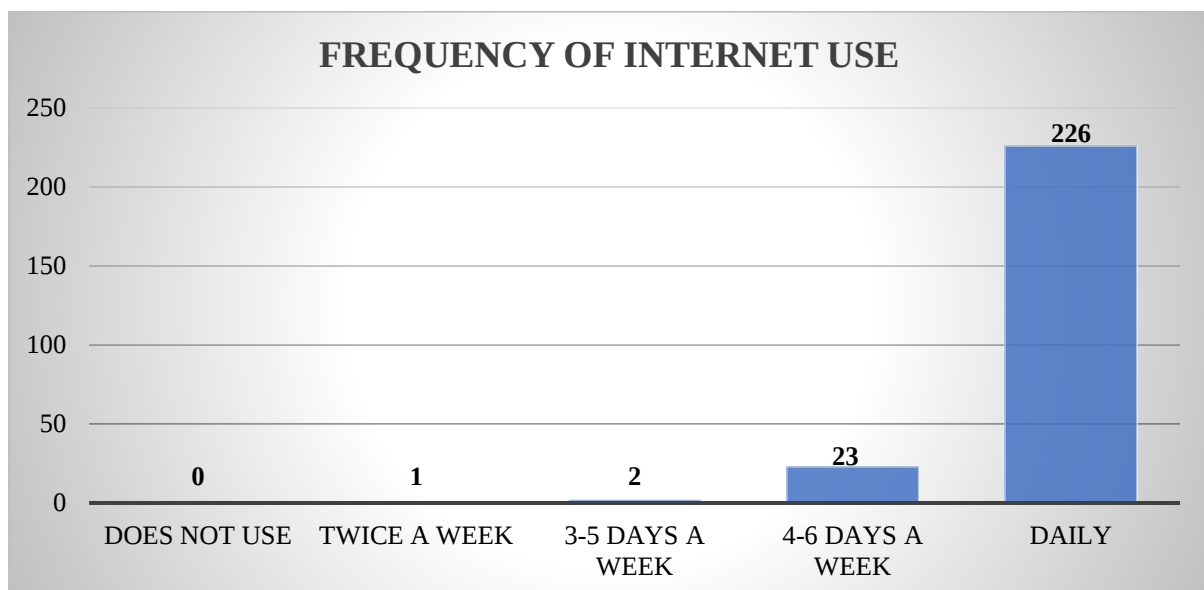


Figure 7: Frequency of Internet use

Interpretation: 89.68% of respondents accessed the Internet daily.

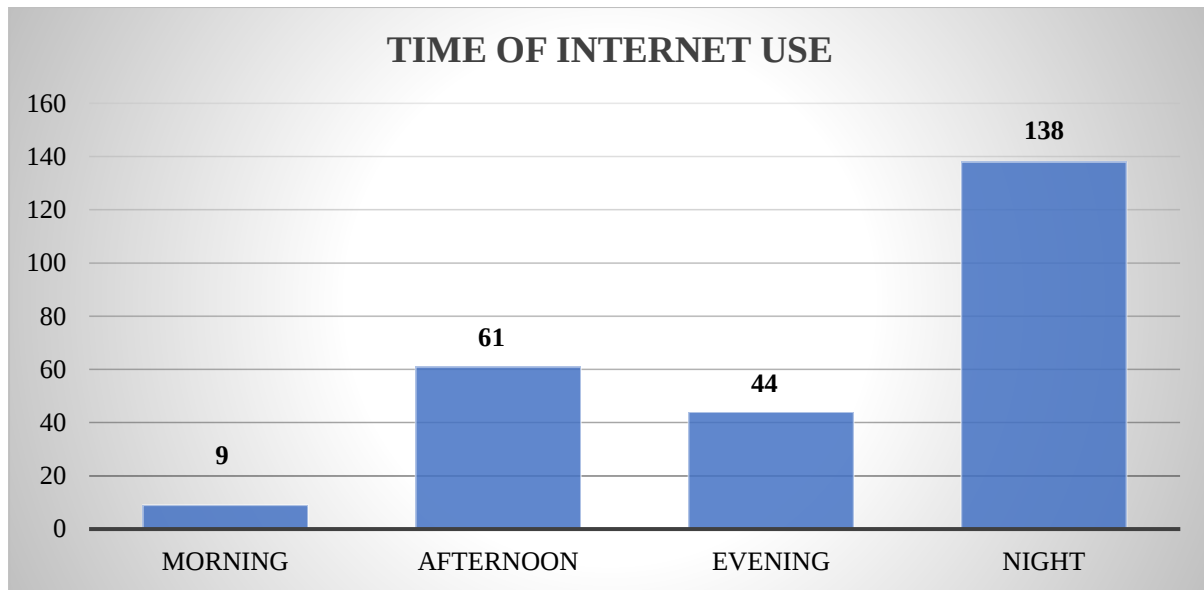


Figure 8: Time of Internet use

Interpretation: 54.76% of respondents accessed the Internet during night.

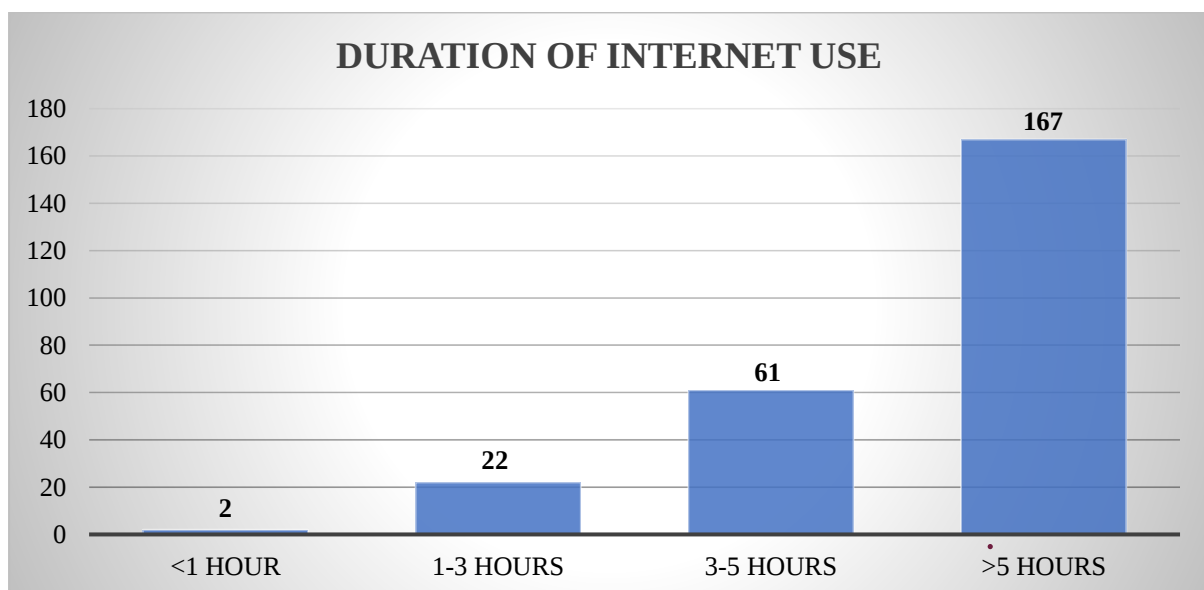


Figure 9: Duration of Internet use

Interpretation: 66.27% of respondents accessed the Internet for more than 5 hours a day.

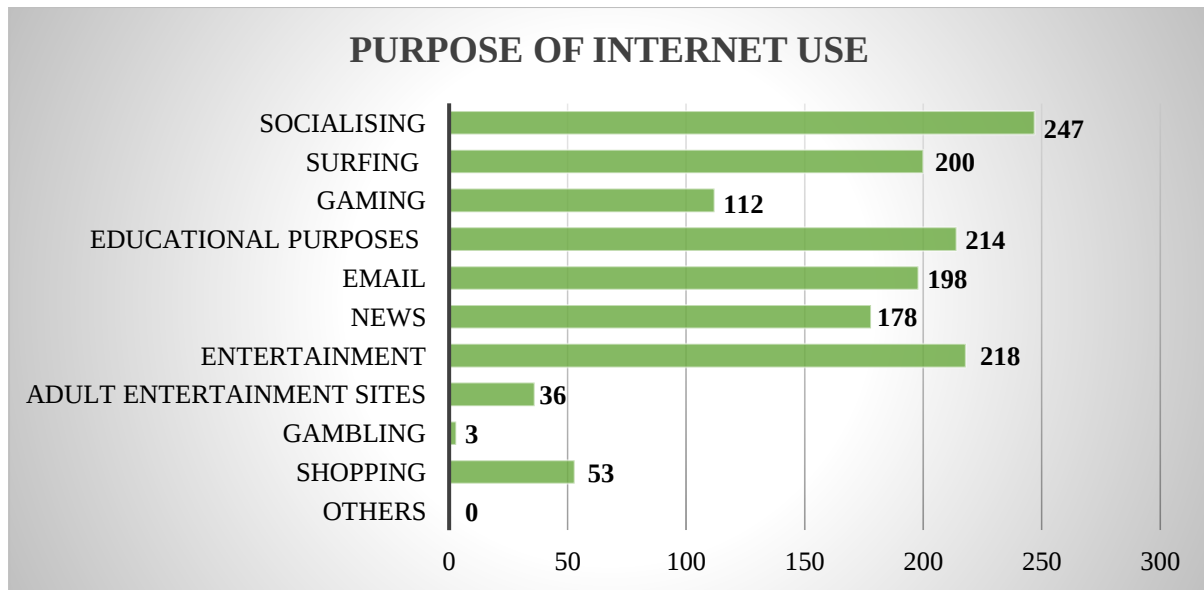


Figure 10: Purpose of Internet use

Interpretation: 98.02% of the respondents used the Internet for Socializing, 86.51% of respondents used the Internet for Entertainment purposes, and 84.92% of respondents for Educational purposes.

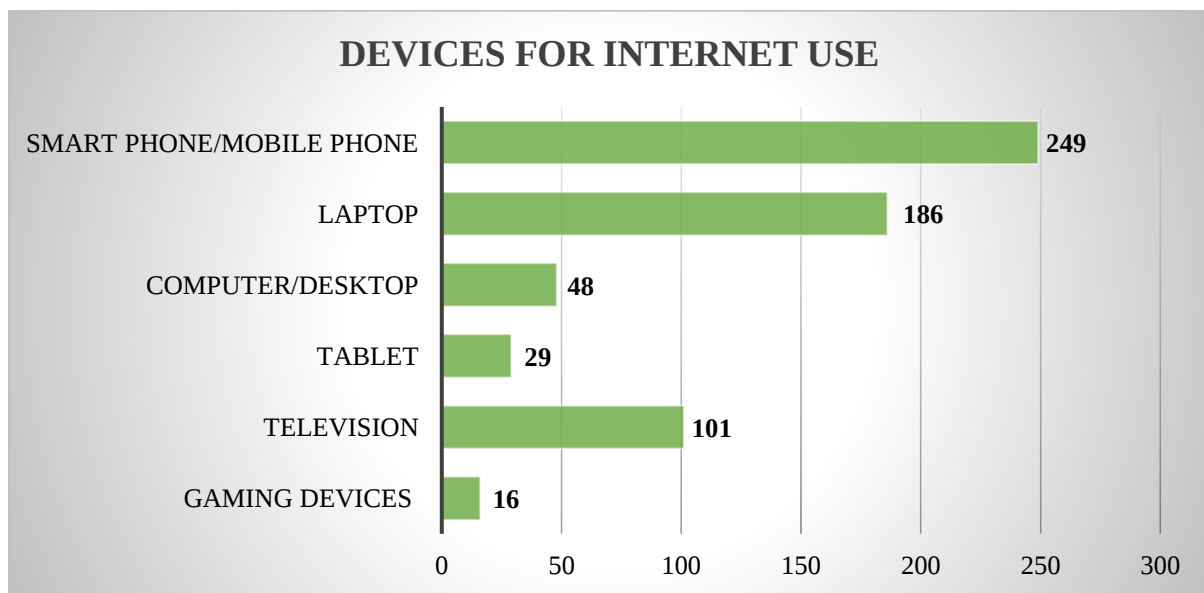


Figure 11: Devices used for Internet use

Interpretation: 98.81% of respondents used Mobile phones/Smartphones to access the Internet.

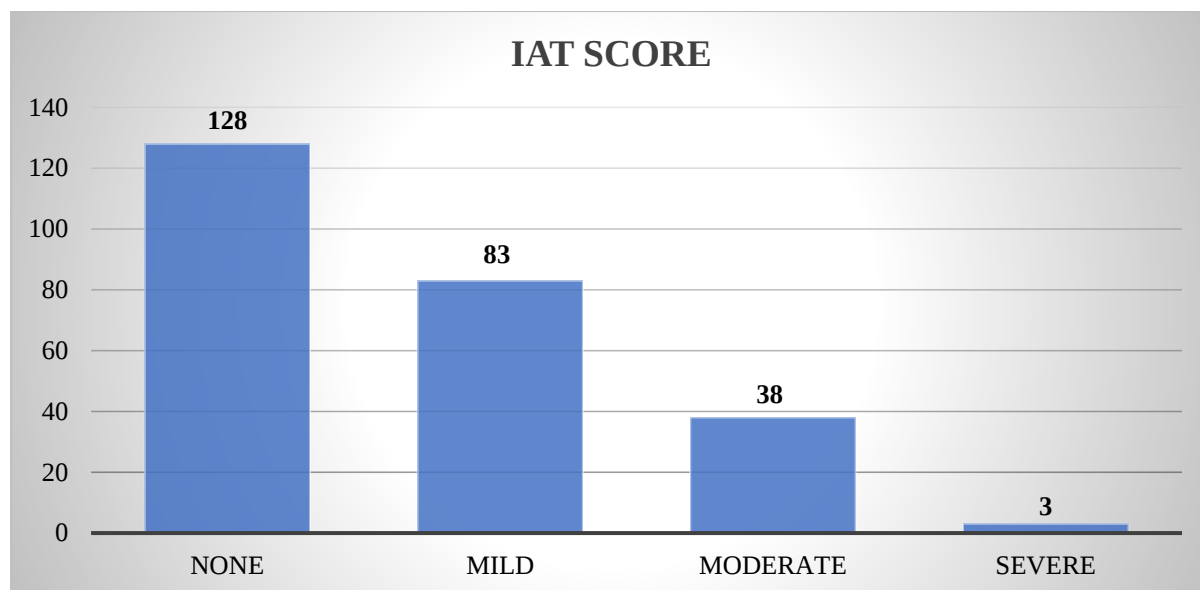


Figure 12: Internet Addiction Test Score

Table 2: Mean Internet Addiction Test Score

Total Score	Mean	SD
8134	32.28	±17.64

Interpretation:

- 1.19% of respondents were Severe Problematic Internet Users
- 15.08% were Moderate Problematic Internet Users
- 2.94% were Mild Problematic Internet Users
- 50.79% were found to be Normal Internet Users.

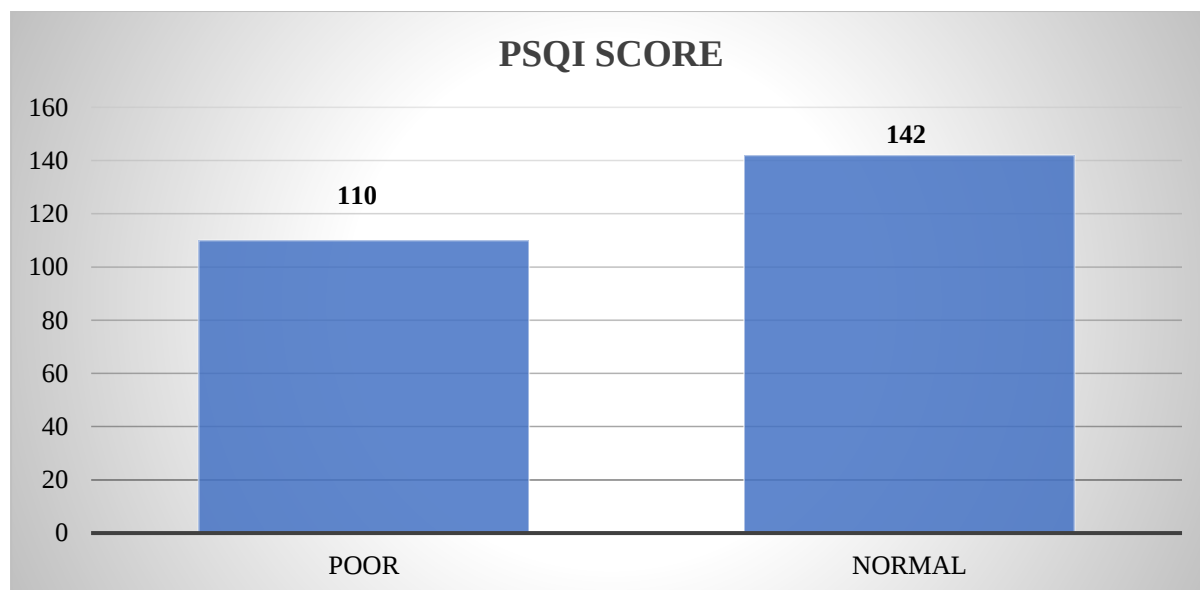


Figure 13: Pittsburgh Sleep Quality Index Score

Table 3: Mean Global Pittsburgh Sleep Quality Index Score

Global PSQI Score	Mean Global PSQI	SD
1381	5.48	± 2.81

Interpretation: 44% of respondents had Poor quality of sleep while 56% of respondents had Normal quality of sleep.

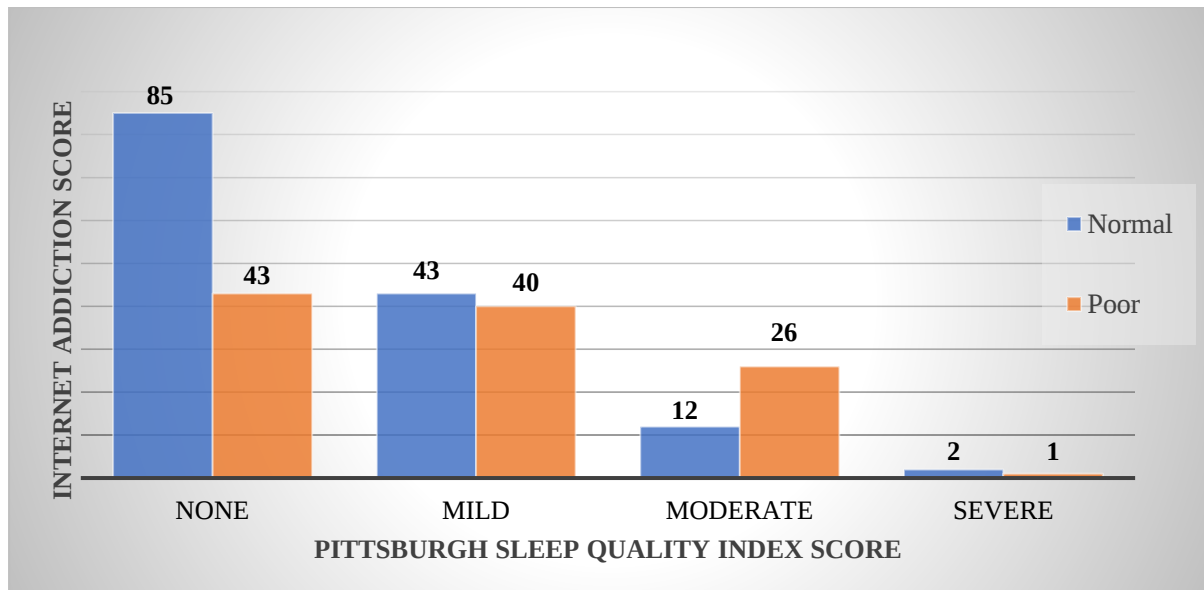


Figure 14: IAT Score with PSQI Score

Interpretation:

- 17.06% of respondents were Normal Internet users and had poor quality of sleep while 33.73% Normal Internet users with Normal sleep quality.
- 15.87% of respondents were Mild Problematic Internet users and had Poor sleep quality while 17.06% were Mild Problematic Internet users with Normal sleep quality.
- 10.32% of respondents were Moderate Problematic Internet users with Poor sleep quality while 4.76% were Moderate Problematic Internet users with Normal quality of sleep.
- 0.40% of respondents were Severe Problematic Internet users with Poor sleep quality while 0.79% were Severe Problematic Internet users with Normal sleep quality.

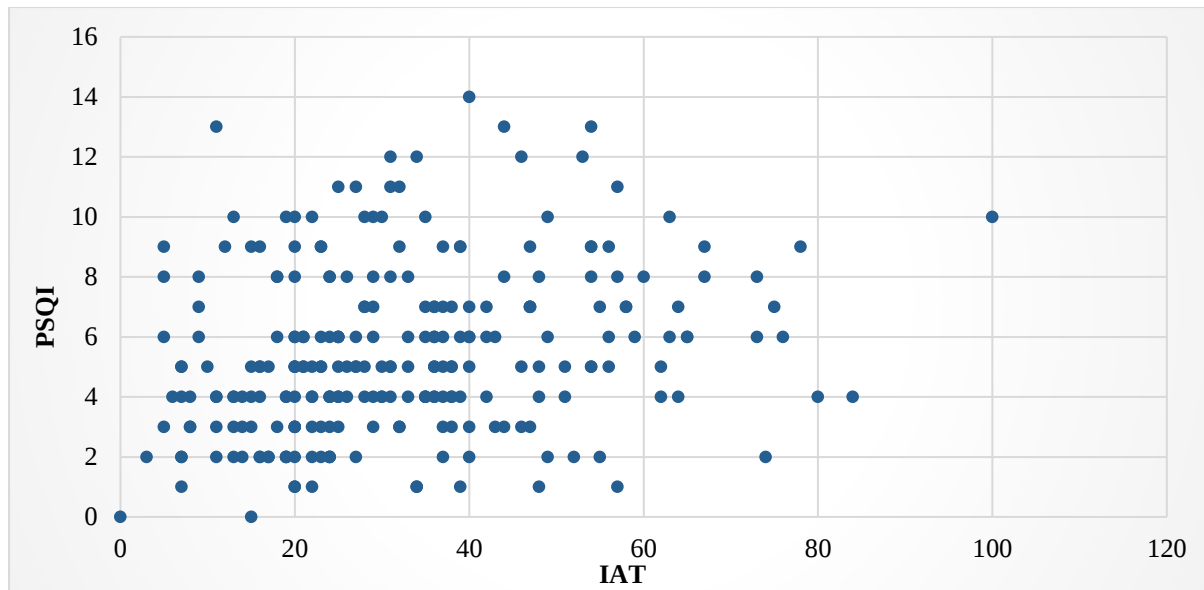


Figure 15: Scatter Plot of Correlation of Internet Addiction Test Score and Pittsburgh Sleep Quality Index Score

Interpretation: There is a positive weak correlation between problematic internet use and sleep quality among the 252 Respondents, $r=0.24$, $p<0.05$.

DISCUSSION

The present study aimed to investigate problematic internet use and its correlation with the quality of sleep among college students during COVID-19 pandemic lockdown in India. In this study, the prevalence of problematic internet use was 49.21% of students as per the criteria of IAT. The findings are greater than the previous studies done in India among college students which reported a range of problematic internet use from 37% to 42%. (33, 18, 35) However, a study done by **Vyjayanthi et al.** reported an overall prevalence of 8.8% which is very less than inferred in our study. (34) Students who had mild problematic internet use were 2.94% whereas moderate internet users were 15.08% and severe problematic internet users were only 1.19%. Thus, this study presents a higher representation of normal internet users of 50.79%

In the present study, sleep quality was assessed and reported 44% of students had poor quality of sleep which was higher in comparison to a study done by **Kaur & Sharma et al.** which associated sleep quality with general health reported 33.8% of students with poor sleep quality. (36) Both the studies supported a higher representation of the normal quality of sleep. A study done by **Ghrouz and Noohu et al.** on physical activity and sleep quality in relation to mental health among college students reported a higher prevalence of poor sleep quality i.e. 51% when compared to this study. (37)

There was a major gender difference in terms of problematic internet use. Females with problematic internet use were 30.95% with male problematic internet users being at 18.25%. The present study supported by other studies (18, 33) has shown a higher female representation of problematic internet use in contradictory to studies which have reported higher male representation of problematic internet use. (35, 38, 34)

With regards to sleep quality as well, female representation was higher than male representation in terms of poor quality of sleep – 28.97% and 14.68% respectively. This is in contradiction to the study done by **Kaur et al.** which reported to have a higher male representation of poorer sleep quality. (36)

Students who had problematic internet use with poor sleep quality were 26.59% and with normal sleep quality were 22.62%. Students who had no problematic internet use with poor sleep quality were 17.06% and with a normal quality of sleep were 33.73%.

Internet is ubiquitous and its dark reality of dependence requires further research and remedies. It is salient to emphasize that cause and effect relationship between problematic internet use and quality of sleep could not be established in the present study. A similar study was done on school-going population by **Vadher et al.**, reported the association of social anxiety disorder, sleep quality and quality of life with problematic internet use and concluded to have poor sleep quality a predictor of problematic internet use and vice versa. (39) Thus, it opens to the possible association of problematic internet use and quality of sleep with the hypothesis tested in the present study among the college-going population.

CONCLUSION

The present study concludes that there is a significant ($p < 0.05$) weak association between problematic internet use and quality of sleep ($r = 0.24$) among college students during COVID-19 pandemic lockdown in India. The Internet is ubiquitous that its excessive consumption concerns alarming physical and mental health-related problems. Hence, appropriate prevention and awareness should be made to protect the mental and physical health of the students during such difficult times.

RECOMMENDATIONS

- Despite numerous publications on the subject of problematic internet use, information about Internet use and its deleterious implications in the context of India remains largely unexplored despite unprecedented national usage. Thus, awareness should be made specially to the vulnerable age group as they thrive for career development and may use the internet in excess and sort maladaptive practices to achieve their goals.
- Education regarding sleep disorders and sleep medications should be made to the students.
- Clinical help should be sought if symptoms of either of the problems have been exhibited among the students during the lockdown and also when the lockdown is lifted.
- Further research needs to be done on this topic with a bigger sample size along with the assessment of depression, anxiety and social support.
- Prospective studies need to be done further on the topic as the lockdown is still ongoing and also to assess the extent to which quality of sleep is affected and how it is affected by the internet use.

LIMITATIONS

- The study findings have to be regarded as preliminary due to the small sample size.
- Socio-economic background of the students was not included in the study.
- Other factors like depressive episodes, anxiety issues, sleep apnea, etc. were not included in the study.
- No face-to-face interviews were conducted to explore the phenomenology of Problematic internet use and Sleep quality.
- The present study did not differentiate between the essential and non-essential of internet use.
- Data collected in this study were obtained from self-administered scales. The results may be meagre by the student's lack of openness. Hence, social desirability bias could be present.
- Since participants were asked to report details of past exposure and experiences of 1 month, recall bias cannot be ruled out.

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ANNEXURE

1.	Age in completed years	
2.	Gender	
	a. Male b. Female c. Other	
3.	Current place of residence	
4.	Education	
	a. Under-Graduation b. Post-Graduation	
5.	Are you aware of COVID-19 Pandemic?	
	a. Yes b. No	
6.	Are you aware of lockdown measures taken by the Government of India?	
	a. Yes b. No	
Following are some questions related to internet use during the last one month only. Your answers should indicate honest replies.		
7.	Have you used the internet in the past month?	
	a. Yes b. No	
8.	Which devices do you use to access the internet? (Multiple options)	
	a. Smart phone/Mobile phone b. Tablet c. Laptop d. Computer/Desktop e. Television f. Gaming Devices (Xbox, PS4, etc.)	
9.	Why do you the internet for? (Multiple options)	

	a. Social Media (Facebook, Twitter, Instagram, Whatsapp, etc.) b. Surfing (browsing websites) c. Gaming d. Educational purposes (Online courses, research, etc.) e. Email f. News g. Entertainment purposes (Watching videos/ TV shows/Movies) h. Adult Entertainment Sites i. Gambling j. Shopping k. Others	
10.	How long do you use the internet in a day?	
	a. <1 hour b. 1-3 hours c. 3-5 hours d. >5 hours	
11.	How often do you use the internet?	
	a. Does not use b. Daily c. Twice a week d. 3-5 days a week e. 4-6 days a week	
12.	When do you use the internet the most?	
	a. Morning b. Afternoon c. Evening d. Night	

13. Following are the statements, after reading each statement carefully please select the response which best describes you. If two choices seem to apply equally well, circle the choice that best represents how you are most of the time during the past month.

	Not Applicable	Rarely	Occasionally	Frequently	Often	Always
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Do you find that you stay online longer than you intended?						
Do you neglect household chores to spend more time online?						
Do you prefer the excitement of the Internet to intimacy with your partner?						
Do you form new relationships with fellow online users?						
Do others in your life complain to you about the amount of time you spend online?						
Do your grades or schoolwork suffer because of the amount of time you spend online?						

Do you check your email before something else that you need to do?						
Does your job performance or productivity suffer because of the Internet?						
Do you become defensive or secretive when anyone asks you what you do online?						
Do you block out disturbing thoughts about your life with soothing thoughts of the Internet?						

14. Following are the statements, after reading each statement carefully please select the response which best describes you. If two choices seem to apply equally well, circle the choice that best represents how you are most of the time during the past month.

	Not Applicable	Rarely	Occasionally	Frequently	Often	Always
Do you find yourself						

anticipating when you will go online again?						
Do you fear that life without the Internet would be boring, empty, and joyless?						
Do you snap, yell, or act annoyed if someone bothers you while you are online?						
Do you lose sleep due to being online?						
Do you feel preoccupied with the Internet when off-line, or fantasize about being online?						
Do you find yourself saying "just a few more minutes" when online?						
Do you try to cut down the amount of time						

you spend online and fail?						
Do you try to hide how long you've been online?						
Do you choose to spend more time online over going out with others?						
Do you feel depressed, moody, or nervous when you are off-line, which goes away once you are back online?						

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

15.	What time have you usually gone to bed at night?	
16.	How long (in minutes) has it usually taken you to fall asleep each night?	
	a. <15 minutes b. 16-30 minutes c. 31-60 minutes d. > 60 minutes	
17.	How many hours of actual sleep did you get at night? (Different than hours you spent in bed)	

18. During the past month, how often have you had trouble sleeping because you...				
	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
a. Cannot get to sleep within 30 minutes				
b. Wake up in the middle of the night or early morning				
c. Have to get up to use the bathroom				
d. Cannot breathe comfortably				
e. Cough or snore loudly				
f. Feel too cold				
g. Feel too hot				
h. Have bad dreams				
i. Have pain				
j. Other reason(s), please describe:				
19. How often have you taken medicine to help you sleep (prescribed or “over the counter”)?				
20. How often have you had trouble staying awake while driving, eating meals, or engaging in the social activity?				
	No problem at all	Only a very slight problem	Somewhat of a problem	A very big problem
21. How much of a problem has it been for you to keep up enough enthusiasm to get things done?				
	Very good	Fairly good	Fairly bad	Very bad

22. During the past month, how would you rate your sleep quality overall?				
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PART II

ONLINE COURSE REPORT

INTRODUCTION

Introduction to Systematic Review and Meta-Analysis is an online course offered by Johns Hopkins University on an online learning platform, Coursera. It is a 6-week graded course with 9 modules along with 2 peer reviewed assignments. The course has two instructors, Dr. Tianjing Li, an Assistant Professor of Epidemiology and Dr. Kay Dickersin, Professor of Epidemiology at John Hopkins University. The course introduces to methods for performing systematic review and meta-analysis of clinical trials.

OBJECTIVES OF THE COURSE

“An Introduction to Systematic Review and Meta-analysis” by John Hopkins University was created with three objectives,

1. “To learn the steps that comprise a systematic review and meta-analysis.”
2. “To be able to read critically in the future, read the literature of a systematic review and meta-analysis.”
3. “To be able to integrate the results of systematic reviews in research or clinical practice.”

COURSE CONTENTS

MODULE 1 – INTRODUCTION

Section A: Introduction to Systematic Review

A systematic review focuses on a specific question. It uses explicit, pre-planned scientific methods to identify, select, appraise and summarize similar but separate studies.

Not all review articles are systematic reviews. Four steps that differentiate a systematic review from a traditional narrative review are to identify all evidence on the topic, select them, appraise the quality of these evidences, and summarize them.

There are seven steps to perform a Systematic Review,

1. Establish a research team
2. Develop a protocol
3. Data collection, locating the studies and screening the results
4. Abstract data and appraise risk of bias in the individual studies
5. Synthesize findings, interpret, and assess overall body of evidence
6. Summarize in a Report
7. Update

Section B: Introduction to Meta-Analysis

By Glass (1976), “The statistical analysis of a large collection of analysis results from individual studies for the purpose of integrating the findings.” Meta-analysis is an optional component of a systematic review. A Meta-analysis can help in assess strength of evidence: to determine whether an effect exists in a particular direction. It can combine results quantitatively: to obtain a single summary result. It can investigate heterogeneity: to examine reasons for different results among studies.

Section C: Producers and Users of Systematic Reviews

More than 60% of the systematic reviews are done by independent authors, investigators, researchers, clinicians, professionals who are interested in a particular topic and the Cochrane Collaboration produces less than 40% of the systematic reviews.

“The Cochrane Library is a collection of databases that contain different types of high-quality, independent evidence to inform healthcare decision-making. The Cochrane Library is owned by the Cochrane and published by Wiley, Inc.” It is the single best place to find independent, high quality evidence for health care decision making.

It is a not for profit organization with collaborations from more than 120 countries. Working together to produce credible, accessible health information that is free from commercial sponsorship and other conflicts of interest.

Features of a Systematic Review:

- Facilitates efficient integration of information for rational decision making
- Provides a clear and transparent process
- Demonstrates where the effects of health care are consistent and where they vary
- Minimize bias (systematic errors) and reduce chance effects.
- Meta-analysis can provide more precise estimates than individual studies
- It can be readily updated as needed
- It allows decisions based on the totality of the available evidence.

MODULE 2 – FRAMING THE QUESTION

Section A: Resources for Framing the Question

There are various resources to follow for framing a question for a systematic review, they are:

- Finding What Works in Healthcare
- Cochrane handbook for Systematic Reviews of Interventions

Section B: Deciding the Type and Scope of the Question

They are different types of questions in a systematic review, they are:

Epidemiology Questions: Incidence, Prevalence, Etiology

Intervention: Therapy, Screening, Diagnostic Accuracy, Prognosis, Harm, Prevention

John Tukey, a well-known statistician in the 1960s said, “The most maxim for data analysis to heed, and one which many statisticians have shunned, is this. Far better an approximate answer to the right question, which is often vague, than an exact answer to the wrong question, which can always be made precise.”

A researcher has to decide whether a question is a broad or a narrow question.

Narrow Questions:

- May not be applicable to multiple settings, populations or exposures
- Can result in spurious or biased conclusions.

Broad Questions:

- May be valid
- Searches may be more time-consuming
- Difficult Synthesis and interpretation
- Difficult to maintain

Section C: Elements of the Question

Steps in the Practice of Evidence-Based Healthcare are,

1. Framing the question to be answered
2. Finding the best evidence
3. Critically appraise the evidence
4. Apply that evidence

Components of Well-Constructed and Answerable Clinical Questions,

P – Patients or populations

Define condition or disease, including explicit diagnostic criteria, population and setting of interest (age, race, sex, community, hospital, outpatient)

I – Interventions/Exposure

Timing of exposure, route of administration, dose intensity, duration of exposure or therapy.

C – Comparison group(s)

For trials: Placebo, standard therapy, no treatment.

For Epidemiological study: No exposure, non-cases (hospitals, neighbourhood, etc.)

O – Outcome

Criteria for defining, important to consumers, providers, unpublished data

Section D: Refining of the Question

clinicaltrials.gov defines five elements to every outcome. They are

1. Domain
2. Specific measurement(s)
3. Specific metric(s)
4. Method(s) of aggregation
5. Time point(s)

Refinement of Question: Generally not possible to formulate an answerable question without knowing a bit about what data are available. Need to guard against testing a hypothesis.

Section E: Examples of Framing the Question

The lecturer uses some examples for systematic reviews. One such example was, “Is a history of exercise training associated with falls in community dwelling and institutionalized people?”

Section F: Analytic Frameworks

An analytic framework is a logic model that links and defines clinical concepts, evidence, and populations as they relate to outcomes.

MODULE 3 – FINDING THE EVIDENCE - SEARCHING PRINCIPLES

This module is divided into 4 sections:

1. Introduction
2. Identify key sources and techniques for searching
3. Building a high-quality search strategy
4. Documenting the search and conclusions

Section A: Introduction

In this section, the lecturer Claire Twose explains about various of sources that is needed to use in order to do a comprehensive, unbiased search.

To develop a protocol for conducting the search:

- Source: Databases, hand-searching
- How it is searched: Dates, Strategies
- How to make decisions: Duplicate screening
- How to document: Dates and numbers included or excluded

Section B: Identifying Key Sources and Techniques for Searching

Major bibliographic databases for RCTs and observational:

- MEDLINE/PUBMED
- EMBASE
- Cochrane Central Register of Controlled Trials (CENTRAL)
- National and regional databases: LILACS
- Subject-specific databases: CINHALL, PsychINFO, OTSeeker

Citation databases: Web of Science, Scopus, Dissertation, thesis databases: ProQuest

Gray literature databases: OpenGrey or SIGLE

Almost all of the large, bibliographic databases, at least the ones that are subject specific, include something called a Controlled Vocabulary. It is a standardize list of terminology that's used in indexing information to facilitate retrieval.

Other techniques used for sources are: Hand-searching and “snowballing”

Finding evidence is also done through personal communication via experts in the field and industry

Section C: Building a High-Quality Search Strategy

- Develop a search: Based on the defined clinical question, break into concepts (PICO), find synonyms for terms
- Use Boolean logic: OR synonyms, AND concepts
- Use Controlled vocabulary when available: In PubMed, use MeSH and keywords found in citations to key article, MeSH databases
- Revise the search strategy
- Include tested study design filter if available
- Use PRESS tool to check search strategy

Documenting the Search and Conclusions

Download and store results in Endnote, ProCite, Reference Manager (same company), and RefWorks, QUOSA.

Use fields to store key information (e.g. how record is identified, reason for exclusion)

PRISMA is a standard transparent reporting of systematic review and meta-analysis. It is a tool that can be used to sort of get an overview of what is required to do a high quality rigorous review.



PRISMA 2009 Flow Diagram

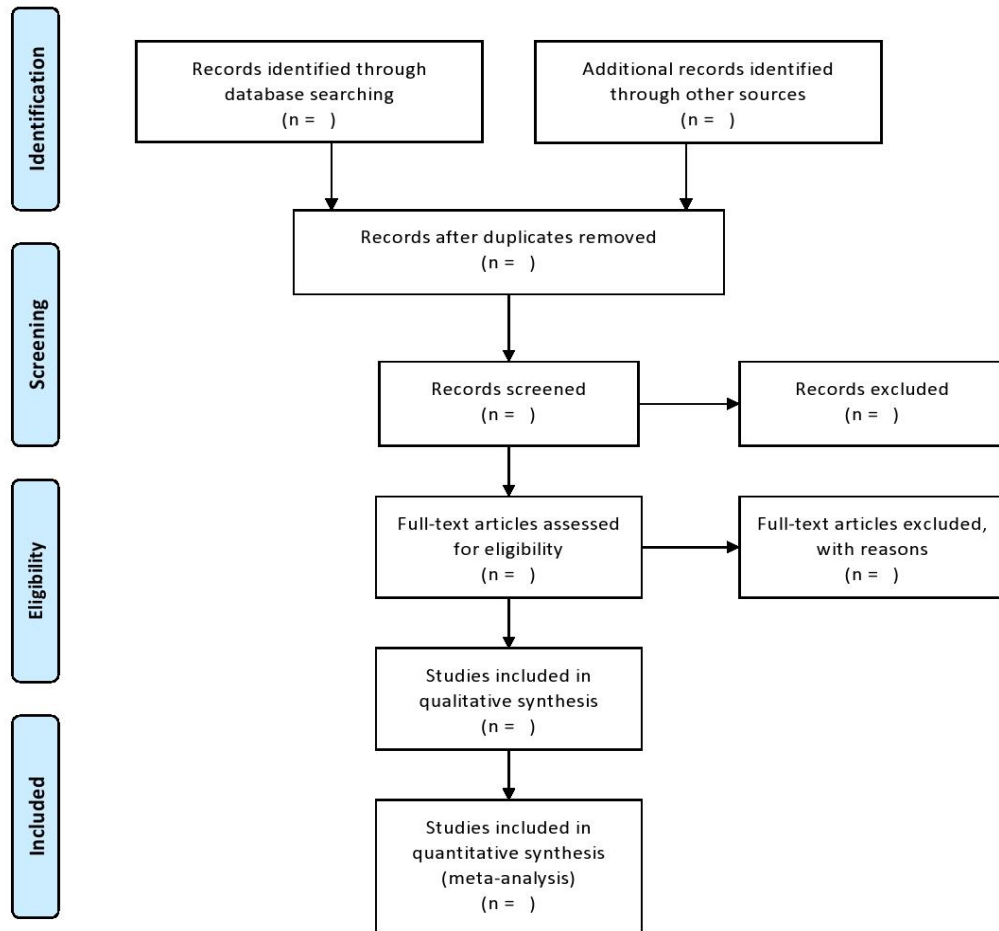


Figure 16: PRISMA Flow Diagram

MODULE 4 – ASSESSING THE RISK OF BIAS IN CLINICAL TRIALS

Section A: Why Bias in the Individual Study is Important to a Systematic Review and Meta-Analysis

Study Quality: “Quality refers to the methods used to conduct a study-the way the study was actually done.

Elements of study quality that can be assessed by reading study reports:

- Internal Validity (Minimization of bias)
- External Validity
- Relevance, Originality
- Ethics

Elements of study quality that cannot be assessed by reading study report:

- Protocol violations
- Quality of record keeping
- Quality of study procedures
- Degree to which the report actual study
- Falsification and fabrication

There are three main types of bias:

1. Selection bias
2. Information bias
3. Bias in the analysis

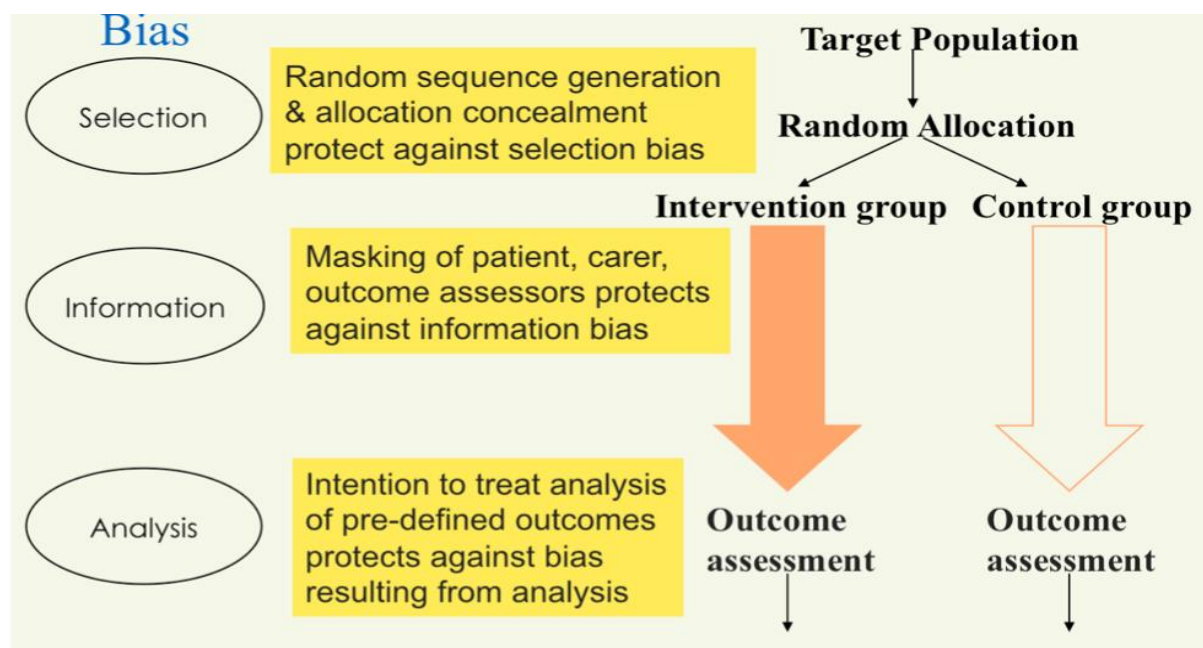


Figure 17: Types of bias

Section B: Selection Bias

Random Sequence Generation is a way patients are assigned to a particular intervention, it happens before the participants actually get the information of their allocation in the study. It determines a random order of assigning people into intervention and control groups. It accounts for known and unknown confounders. It prevents systematic differences between groups. It prevents selection bias.

Allocation Concealment is a complicated concept. It occurs at the start of the study during the allocation of participants. When a person is recruited to a study, no one is able to predict which group the person will be allocated to. Ensures strict implementation of the randomly generated sequence. It also prevents selection bias.

Section C: Information Bias

Masking of Participants and Personnel prevents information bias.

It assess carefully:

- Is it likely that masking was broken
- Avoid terms like “single masked” and “double masked.”
- Consider impact even if not feasible for this intervention

Section D: Bias in the Analysis

- Losses to follow-up
- Noncompliance
- Withdrawals
- Changes in the outcome measure (*post hoc* defined outcome)

Post Hoc Definition of outcomes: “Pre-specification of the primary and secondary outcomes protects against type 1 error.”

Primary outcome measure should be pre-specified in study protocol.

Section E: Displaying Study “Quality” in a Systematic Review

Quality scores are not used anymore. They are generic (common to all research studies) or particular (specific to the field). There is no gold standard for ‘true’ methodological quality of trial. Do not assign quality scores to individual studies.

It is related to internal validity. It has problems hence components is preferred.

MODULE 5 – MINIMIZING METABIAS

Section A: Standards for Systematic Review

The Institute of Medicine gathered together a group of experts in the field of medicine, public health, systematic reviews and other topics, and asked them to help develop a series of standards called the IOM Standards for Systematic Review.

Section B: Selection Bias

The most important selection bias is the Reporting bias. There are different types of reporting bias, one of the most important reporting bias is the “Publication bias – Unpublished studies tend to have different results than published studies.” “Selective outcome reporting is the results from a study that is published, out of which only some of the outcome is reported.” “Ascertainment bias is that studies that are easier to find may have different results from those that are harder to find.”

Another type of selection bias is Inclusion bias – If the author of the systematic review knows the results of many of the studies that are out there before the beginning the systematic review, and the author sets the eligibility criteria for that systematic review so the study is included or excluded specifically will affect the outcome of the systematic review and meta-analysis.

Section C: Information Bias

- Accuracy of quality assessment
- Accuracy of data abstraction
- Completeness of data abstraction

Section D: Bias in the Analysis

Statistical methods used influence overall estimates. Often, study heterogeneity is not explained.

Section E: Reporting Transparently

Reporting guidelines that help identify areas to consider for reducing bias:

- PRISMA: It is the reporting guideline for systematic reviews of clinical trials.
- MOOSE: It is old but still useful reporting guideline for observational studies.

MODULE 6 – QUALITATIVE SYNTHESIS AND INTERPRETING RESULTS

Section A: Qualitative Synthesis and Interpreting Results

“Meta-analysis was developed to replace the artistic narrative review with a scientific and systematic method. So far so good. Yet in fear of allowing bias to creep in, meta-analysis is typically mechanistic, driven more by concerns about reliability and replicability than about adding to understanding the phenomena of interest.”

Structure of systematic reviews:

1. Background and description of motivation for meta-analysis.
2. Methods:
 - Description of search strategy
 - Eligibility criteria
 - Description of data abstraction and management
 - Quality assessment
 - Statistical methods
3. Results:
 - Search yield
 - Qualitative synthesis
 - Quantitative synthesis (if warranted)
4. Discussion: Findings in context.

Section B: What is Qualitative Synthesis?

Qualitative Synthesis is defined as “an assessment of the body of evidence that goes beyond factual descriptions or tables. That, for example, simply detail how many studies were assessed, the reasons for excluding studies. The range of study sizes and treatments compared, or the quality of each study as measured by a risk of bias tool.”

The purpose of the qualitative synthesis is to develop and convey a deeper understanding of how an intervention might be working (or not), or whether a true association exists, for whom, and under what circumstances.

MODULE 7 – PLANNING THE META-ANALYSIS

Section A: Planning a Meta-analysis

Analytic framework, including the specification of comparisons, types of data, and summary measures, should address the study question. Meta-analysis is the statistical combination (variations on a weighted average) of the effect estimates from two or more separate studies.

Planning the analysis: Systematic reviews contain analyses of the primary studies (and primary studies include analyses of their participants.)

- Qualitative: Structured summary, description and discussion of the studies' characteristics that may affect the cumulative evidence.
- Quantitative: involves statistical analysis (meta-analysis)

Analysis Plan:

1. Obtain size of effect from similar studies estimating the same effect – Method: Standard pair-wise meta-analysis
2. Compare multiple intervention for the same condition – Method: Network meta-analysis.
3. Investigate the relationship between the size of an effect and characteristics of the studies – Method: meta-regression.

Section B: Introduction to Meta-analysis

The definition of **Meta-analysis** by Huque, in 1998 is “A statistical analysis which combines the results of several independent studies considered by the analyst to be ‘combinable’.”

Each study is summarized by an estimate of effect (the result). E.g. risk ratio

The overall measure of effect is a weighted average of the individual studies. Weighted averages reflect varying importance of trials.

Inverse Variance Weighted Average:

Combine estimates from individual studies as a weighted average:

$$\text{Weighted average} = \text{sum of (estimate x weight)}/\text{sum of weights} = \sum Y_i W_i / \sum W_i$$

$$\text{Variance (weighted average)} = 1/\text{sum of weights} = 1/\sum W_i$$

- Y_i – intervention effect estimated in the I th study
- W_i – weight given to the I th study and is usually chosen to be the inverse of the variance of the effect estimate.

Section C: Why do a Meta-analysis?

- Increase power and precision.
- Quantify effect sizes and their uncertainty.
- Assess homogeneity/heterogeneity of results.
- Answer questions not posed by the individual studies
- Settle controversies arising from conflicting studies..

Section D: Types of Data and Effect Measures

Effect is also called often as effect measures or measures of association.

In systematic reviews, there may be various types of ‘effect’

- Effect of health care interventions
- Association between an exposure and outcome
- Prevalence, or incidence

Types of Data:

1. Dichotomous data (dead or alive)
2. Continuous data (blood pressure)
3. Ordinal data (none/mild/moderate/severe)
4. Counts of infrequent event (number of strokes)
5. Time-to-event (survival times)

MODULE 8 – STATISTICAL METHODS FOR META-ANALYSIS

Section A: Fixed Effect Model

Performing a Fixed Effect Meta-analysis:

- Start with the observed effects and try to estimate the population effect through computing a weighted mean.

- Weight is assigned to each study in a fixed effect meta-analysis is

$$W_i = 1 / V_{YI} \text{ (} V_{YI} \text{ is the within study variance for study } i \text{.)}$$

- Weighted mean (M) is computed as

$$M = \sum Y_i W_i / \sum W_i$$

- Variance of the summary effect (V_M) is estimated as

$$V_M = 1 / \sum W_i$$

- Standard error of the summary effect (SE_M) is estimated as

$$SE_M = \sqrt{V_M}$$

- 95% lower and upper limits for the summary effect

$$LL_M = M - 1.96 \times SE_M$$

$$UL_M = M + 1.96 \times SE_M$$

- Z-value to test the null hypothesis that the common true effect θ is zero (zero effect in every study)

$$Z = M / SE_M$$

- Two-sided *p-value*

$$p = 2[1 - (\phi(|Z|))]$$

Section B: Random Effects Model

Performing a Random Effects Meta-analysis:

- Start with the observed effects and try to estimate the population effect through computing a weighted mean.

- Weight assigned to each study in a random effects meta-analysis is

$$W^*_i = 1 / V^*_{YI} \text{ (} V^*_{YI} \text{ is the within studies variance for study } i \text{. plus the estimate of between studies variance } T^2 \text{)}$$

$$V_{YI} = V^*_{YI} + T^2 \text{ (} T^2 \text{ is the between studies variance)}$$

$$T^2 = Q - df / C$$

- Weighted mean (M^*):

$$M = \sum Y_i W^*_i / \sum W^*_i$$

- Variance of the summary effect (V_{M^*}):

$$V_{M^*} = 1/\sum W_{i}^*$$

- Standard error of the summary effect (SE_{M^*})

$$SE_{M^*} = \sqrt{V_{M^*}}$$

MODULE 9 – WRAP UP

Topics Covered by course guides:

- “What is a systematic review and meta-analysis?”
- ”How to formulate a research question?”
- ”How to search for studies?”
- ”How to collect data?”
- ”How to assess the risk or bias of clinical trials?”
- ”How to synthesize the information and avoid bias in this process?”
- ”How to read the results of a meta-analysis?”

Learnings:

Systematic review uses pre-specified and rigorous methods to identify, appraise, and synthesize all evidence on a given topic. As a systematic reviewer, we should try to minimize bias and errors at each step of doing a systematic review. The most crucial step in doing a systematic review is to frame an answerable question.

METHODOLOGY

The course is a 6 week online course divided into 9 modules.

Week 1: The first week contains 1 introductory video and 3 readings. It contains the first module including 3 videos and 1 video from an expert from the field.

Week 2: This week contains the second module which has 6 videos and 1 video from an expert from the field. It also contains first peer graded assignment to be submitted by the learner. At the end of the module, there is a quiz containing 5 questions

Week 3: Third week requires the learner to complete 2 modules consisting of 5 videos and 1 quiz after each module of 5 questions.

Week 4: This week consists of 2 modules same as the previous week. Fifth module has 5 videos and a quiz of 5 questions. Sixth module has 3 videos and 1 video from an expert from the field and a quiz of 5 questions.

Week 5: Fifth week has 2 modules, Seventh module has 5 videos and a graded quiz of 5 questions whereas the eighth module has 3 videos and 1 video from an expert from the field with a quiz at the end of 5 questions.

Week 6: This is the final week consisting of 1 video and the second peer graded assignment. It also 1 video of closing remarks.

All the videos are concise and in lucid English language with subtitles to understand. The course is very insightful and also contains a discussion page for learners to discuss and ask doubts to the course guide. There are various appropriate pictures and tables used for better understanding.

KEY LEARNINGS

- Describe the steps in conducting a systematic review.
- Develop an answerable research question using the “Participants Interventions Comparisons Outcomes” (PICO) framework.
- The process used for collection and extraction of data from reports of clinical trials.
- Methods to critically assess the risk of bias of clinical trials.
- Explain and interpret the results of meta-analyses.

REFERENCE

1. <https://www.coursera.org/learn/systematic-review>
2. <http://prisma-statement.org>