The Impact of Social Media on Recruiting Patients For NASH Clinical Trials in Bangalore

By

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Candidate Declaration

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I certify that the dissertation titled: **The Impact of Social Media on Recruiting Patients For NASH Clinical Trials in Bangalore**

Submitted for the MSc degree in Pharmaceutical Business and Technology is a result of my own work and where references are made to the work of others, due acknowledgment is given.

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DEDICATION

I dedicate this dissertation to my **LORD JESUS**, my continuous strength and guidance throughout this academic journey. Thank you, LORD, for the grace and favour upon my life. Without you, I would not have made it this far. I dedicate this work to glorify your name.

Acknowledgments

I want to express my deepest gratitude to my mom, who is a strong pillar and constant support in this journey. Mom, you have always inspired me through your love, patience, strength, and sacrifices.

Secondly, I want to thank my brothers & family for their unwavering support in pursuing my Master's at Griffith College.

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List of Abbreviations

NAFLD- Nonalcoholic Fatty Liver Disease

MAFLD Metabolic Dysfunction-Associated Fatty Liver Disease

NASH- Nonalcoholic Steatohepatitis

WHO- World Health Organization

FDA- Food and Drug Administration

DCGI- Drugs Controller General of India

PNPLA3- Patatin-like phospholipase domain-containing protein 3

WHO- World Health Organization

CT- Clinical Trials

RA- Regulatory Authorities

EC- Ethics Committee

CRO- Clinical Research Organizations

IMP- Investigational Medicinal Product

IC- Informed Consent

CRC- Clinical Research Co-ordinators

SMART- Specific, Measurable, Attainable, Relevant, & Time-based.

PAG- Patient Advocacy Group

PRISM- Protocol for Increasing Accrual Using Social Media

DCT- Decentralized Clinical Trials

ICF- Informed Consent

EHR- Electronic Health Records

EMR- Electronic Medical Records

PAG: Patient Advisory Group

HCP- Healthcare Professional

CRP- Clinical Research Professional

EDC- Electronic Data Capture

EMA- European Medicines Agency

SMP- Site Monitoring Plan

IRB- Institutional Review Board

SPSS- Statistical Package for the Social Sciences

DF- Degree of Freedom

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Abstract

Fatty Liver Disease has become a public health concern among the people of Bangalore. The condition can occur with/without the consumption of alcohol and progress to NAFLD (Non-Alcoholic Fatty Liver Disease). The severe for NAFLD is NASH (Non-Alcoholic Steatohepatitis). When NASH is left untreated, it leads from fibrosis to cirrhosis. Currently, there are only 02 approved drugs, Saroglitazar, (approved by DCGI, India) and Rezdiffra (The FDA, USA). Many pharmaceutical companies are conducting clinical trials for NASH to bring novel therapies. However, patient recruitment has always been a challenge for NASH clinical trials.

The main objective is to investigate how social media platforms can be utilized to create awareness about NASH and Clinical trials. We want to understand what are the attitudes and preferences of people towards social media platforms, NASH & Clinicals. The research has utilized a mixed approach (Interviews/Surveys) to analyze the impact of social media platforms.

Social media are an unavoidable platform and primary source of information for more than 5 billion people across the globe. The research findings reveal that social media platforms are the primary source of health-related information. The top three platforms are YouTube, Instagram, and WhatsApp utilized by the people of Bangalore to understand complex health information and share the information on personal networks i,e friends & family. The people are aware of NASH, its risk factors, and Clinical trials however they lack detailed knowledge about the process. Though they are anxious about the fear of side effects but still are motivated to participate in clinical trials due to personal health benefits. Through a patient-centric approach, the CRPs suggested that transparent communication can be the key to addressing these fears and concerns.

This research has on focused on how social media platforms can be an effective method to educate the public to overcome the patient recruitment challenges for NASH Clinical trials.

Keywords: NASH, Clinical Trials, Patient Recruitment, Social Media Platforms, Participants, Clinical Research Professionals, Bangalore

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CHAPTER-01 INTRODUCTION

1.1 Overview of the Research

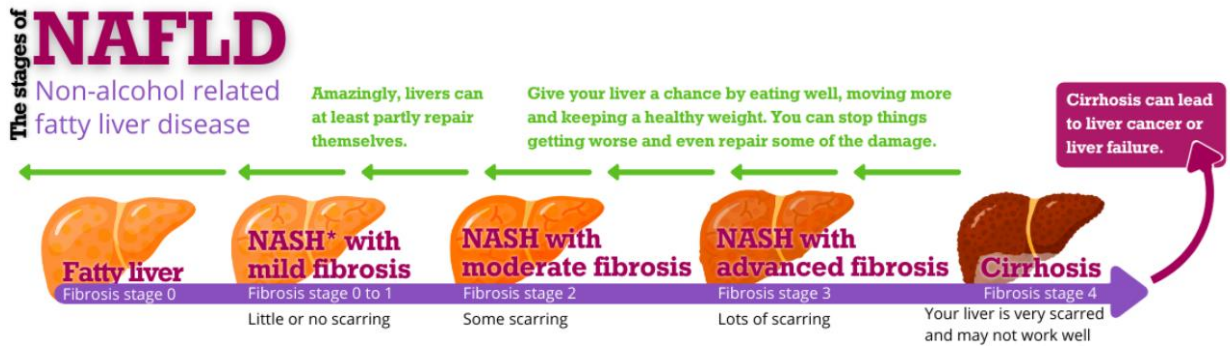
Our human body is made of different cells, tissues, and organs. Often, we consider the heart and lungs to be important vital organs because the heart continuously pumps blood, and the lungs help in the respiration process. Though the liver is the second largest solid organ in the body that performs different functions, we often overlook this organ (Stewart, 2023).

The liver has a dual function as an organ and a gland
1. Organ: It performs several functions such as detoxification, metabolism, storing vital vitamins and glycogen, and blood regulation.
2. Gland: It produces bile, which helps break down fat molecules. This prevents the accumulation of fat and improves the digestion process. & absorption of nutrients (Stewart, 2023).

When the fat molecules are not broken down, they start accumulating in the liver, which leads to a condition called fatty liver disease. The condition is often linked with obesity and metabolic diseases. As per WHO, obesity leads to health problems such as diabetes, liver disease, heart disease, and high blood pressure (World Health Organization: WHO, 2024).

Fatty liver disease is of two types:
• **Nonalcoholic Fatty Liver Disease (NAFLD)** is the most common form. It is associated with obesity and occurs in people who do not drink alcohol.
• **Alcoholic Liver Disease**: As the name suggests, it occurs in people who consume excess alcohol.

NAFLD is often asymptomatic (people can develop the disease without any symptoms) and progresses through four stages (Figure 1)
- Steatosis- Fat accumulation
- NASH- Inflammation
- NASH fibrosis- Tissue damage
- Cirrhosis- Permanent liver damage



[Figure 1 *Stages of NAFLD to NASH (MASLD, NAFLD, and fatty liver disease - British Liver Trust, 2024)]*

In Bangalore (India), fatty liver disease has become the most common disease because of the rise in obesity. Recent research in Bangalore (India) indicates that approximately 15-30% of people have been diagnosed with NASH. Currently, adopting a healthy lifestyle can be one of the ways to manage NASH, which includes regular exercise, having a healthy diet that helps to reduce fat, and replacing soft drinks with normal water.

Many global pharmaceutical companies are conducting clinical trials to understand the pathophysiology of NASH as the disease is underrecognized, underdiagnosed, and undertreated. One of the main challenges faced by the sponsors for clinical trials is patient recruitment.

Before the COVID-19 pandemic, patient recruitment was mainly through hospital advertisements and posters. However, post-pandemic, there has been a rise in health awareness among the public, and social media platforms have helped create awareness about the prevalent diseases. So, social media platforms have been playing a vital role in healthcare and search.

Therefore, this research aims to create awareness about the disease among the public and social media platforms like Instagram, Facebook, LinkedIn, and Twitter to overcome the recruitment challenges and understand public opinion about participation in Clinical Trials.

1.2 Research Purpose

NASH is a chronic fatty liver disease that affects more than 110 million people across the globe. The disease has increased in urban areas due to many lifestyle changes, lack of awareness, and limited diagnostic tools. Also, we have only 02 approved drugs to date. On the other hand, pharmaceutical companies are conducting several clinical trials to bring novel therapies to treat NASH. The major challenge faced by these companies is patient recruitment.

With the rise of social media platforms, there is an opportunity to identify effective platforms, content types, and engagement strategies that will help to overcome this challenge.
The primary purpose of this research is to investigate the effectiveness of social media strategies in recruiting patients for non-alcoholic steatohepatitis (NASH) clinical trials in India.

1.3 Research Hypothesis

The research hypothesis includes whether social media platforms can be the next game changer for patient recruitment in NASH Clinical Trials.

1.4 Research Aim and Objective

The secondary review analysis is through the existing literature review. Since NASH is an underdiagnosed silent disease, it becomes essential to create awareness among the public (Younossi et al., 2024). Patient recruitment has been a bottleneck for any clinical trial for

many pharmaceutical companies. When the patients are not recruited within the timelines, the clinical comes to a standstill, thereby delaying the development of novel treatments.

From the literature review, the authors have portrayed that social media platforms have impacted various therapeutic areas (Applequist et al., 2020). So, this research aims to study the impact of social media, and whether these platforms can help in patient recruitment for clinical trials.

The key objectives identified for this research are:

1. To create awareness and educate about Nonalcoholic steatohepatitis- Fatty Liver disease
2. To investigate public preferences and attitudes toward participation in clinical trials.
3. To identify the factors that influence public participation in clinical trials and overcome the challenges of using social media.
4. To examine social media platforms used by the public and identify the most effective time for advertisements to maximize participation in clinical trials.
5. To investigate and analyze the current patient recruitment methods in clinical trials in Bangalore.

1.5 Justification of the Research

Social media has always impacted society. Flatforms like Facebook, YouTube, WhatsApp, Twitter, and now Instagram have paved the way to reach larger groups of audiences. Recent developments show that social media can turn out to be a game changer in the clinical research field.

This research aims to add value to the existing knowledge of NASH clinical trials by investigating the role of social media in this process. These platforms help us to understand the opinions toward clinical trials. The selection of this topic has several reasons,

- Lifestyle Changes- Due to many lifestyle changes, there has been an increase in obesity and metabolic diseases, which are the primary causes of fatty liver disease.
- Awareness- The public is unaware that fatty liver disease (NASH) is associated with health conditions like diabetes, heart, and hypertension. So, it is essential to create awareness among the public.
- Social Media Platforms have always influenced society. So, we can utilize these platforms to create awareness about NASH and improve public participation in clinical trials.
- Patient Recruitment- One of the challenges faced by pharmaceutical companies is to meet the targeted patients to conduct clinical trials.
- Treatment- Currently, there is only 01 approved drug, Saroglitazar, given for Non-Cirrhotic NASH patients in India. However, the pathophysiology of NASH is not understood. Further research is essential to understand the disease NASH, and clinical trials are one step that helps in bringing innovative therapy to treat NASH.

1.6 Significance of NASH Research

The significance of this research is that it aims to understand public awareness about NASH & clinical trials, what is their attitude and preferences, factors that influence them to participate in clinical trials, and whether they use social media platforms.

- Fatty Liver Disease has become a public health concern, and it is essential to educate the public about the risks and complications of the disease. It will help the public to balance their lifestyle habits and understand the disease.
- Population: Since fatty liver is a silent disease, social media platforms can be utilized to create awareness and help reach a diverse population.
- Public Opinion: This research aims to investigate public attitudes toward clinical trials that will help identify factors influencing public participation.
- Interaction: Social media platforms provide space for interaction and help researchers and the public build relationships. Researchers can create engaging content and interact with users, which helps to increase awareness about clinical trials.
- Real-time Feedback: Researchers can utilize social media platforms to address any participant's concerns or questions, which will help to improve the recruitment process.
- Budget-Friendly: According to the literature review, traditional recruitment methods, such as advertisement and printed brochures, were expensive compared to social media platforms, which are budget-friendly. Using these platforms, pharmaceutical companies can reach the target population for clinical trials.
- The findings of this research will add value to the existing literature to overcome the challenge of patient recruitment in clinical trials, which is not only focused on NASH trials but can be applied to other therapeutic conditions.

1.7 Research Gaps

Potential gaps have been identified for every research study, and this research will aim to fill these gaps.

- Lack of Integration: In most cases, health systems are not integrated with social media platforms, a barrier to public participation.
- Social media is a valuable tool- There is limited research on how social media can be used as an effective platform to create awareness. However, its impact on recruiting targeted patients for clinical trials is limited.
- Cultural & Linguistic Barriers- Often, there are restrictions like culture and language barriers in clinical trials, because of which participation becomes a challenge.
- Public Preferences- There is a lack of research on understanding how the public engages with social media and their behaviours and preferences towards clinical trials.

1.8 Primary Research & Data Analysis

For this research, a mixed-methods approach was used as it combines qualitative and quantitative methods. The quantitative method will use surveys to gather data on public awareness and their preferences to participate in clinical trials. Subsequently, the qualitative method involves semi-structured interviews that will be conducted with clinical research professionals, healthcare providers, and the public to gain their perceptions and learn from their experiences.

After collecting the data, the findings will be analyzed using statistical methods and thematic analysis. The results will be transcribed and presented using data visualization techniques.

So, this research will aim to demonstrate the hypothetical statement, "Can social media platforms be the next game-changer for patient recruitment for NASH Clinical trials?". This research will help improve the patient recruitment process for clinical trials, which will lead to the development of effective treatment for NASH.

1.9 Research Structure

The dissertation is divided into 05 chapters. The first start chapter starts with the introduction. It provides an overview of this research, its purpose, hypothesis, aims, and objectives, justification of the research, highlights its significance, identifies gaps in existing research, and outlines the methods for primary data collection and analysis.

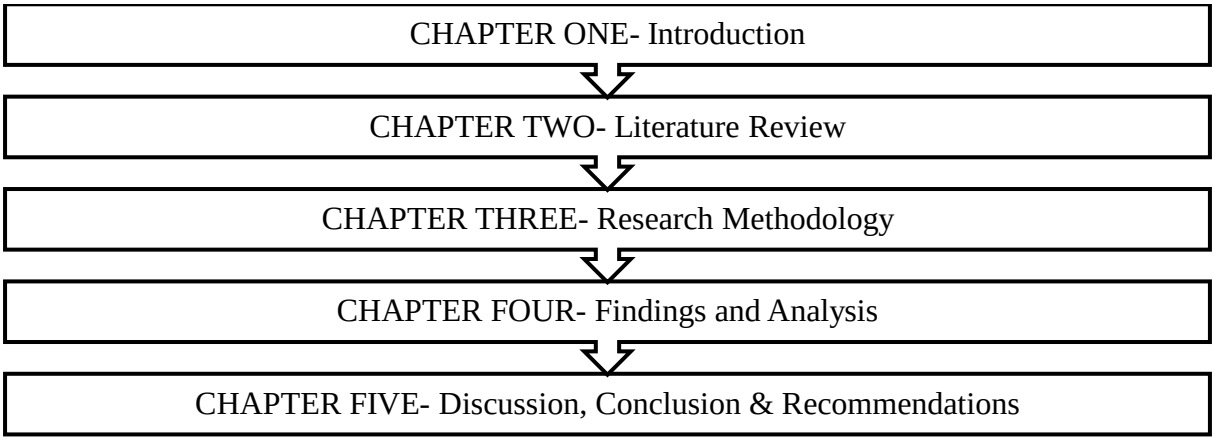
The second chapter of the dissertation will cover the literature review. The analysis is based on existing literature on Non-Alcoholic Steatohepatitis (NASH) disease, clinical trials, patient recruitment challenges, social media platforms, and the global landscape of NASH clinical trials, including those in India. The chapter has identified key themes and areas for further research and concludes with a conceptual framework and summary of the literature review findings.

The third chapter of the dissertation outlines the research methodology and design used to collect primary data. A mixed-methods approach combines qualitative and quantitative methods is used. The chapter details the research strategy, participant description, justification of the chosen methodology, data analysis and presentation procedures, ethical considerations, limitations, and conclusions.

The fourth chapter of the dissertation covers the findings and analysis. The chapter elaborates on the results of the primary data. There will be a discussion based on the answers received from the qualitative and quantitative survey and compared with secondary research. This comprehensive analysis provides valuable perspectives on the research questions and objectives.

The fifth chapter of the dissertation summarizes the main findings, discusses limitations, draws conclusions, and proposes recommendations for future research.

The dissertation is divided into five chapters and Figure 2 represents the structure of this research.



[Figure 2 *Creation of Research Structure by Researcher]*

CHAPTER-02 LITERATURE REVIEW

2.1 Fatty Liver Disease- An Introduction to Nonalcoholic Steatohepatitis (NASH)

The liver plays a dual role because of its function as an organ and gland. As an organ, it helps in metabolism and detoxification; as a gland, it produces bile juice to break the fat molecules and assist digestion. When the fat molecules accumulate in the liver, it leads to a condition called fatty liver disease.

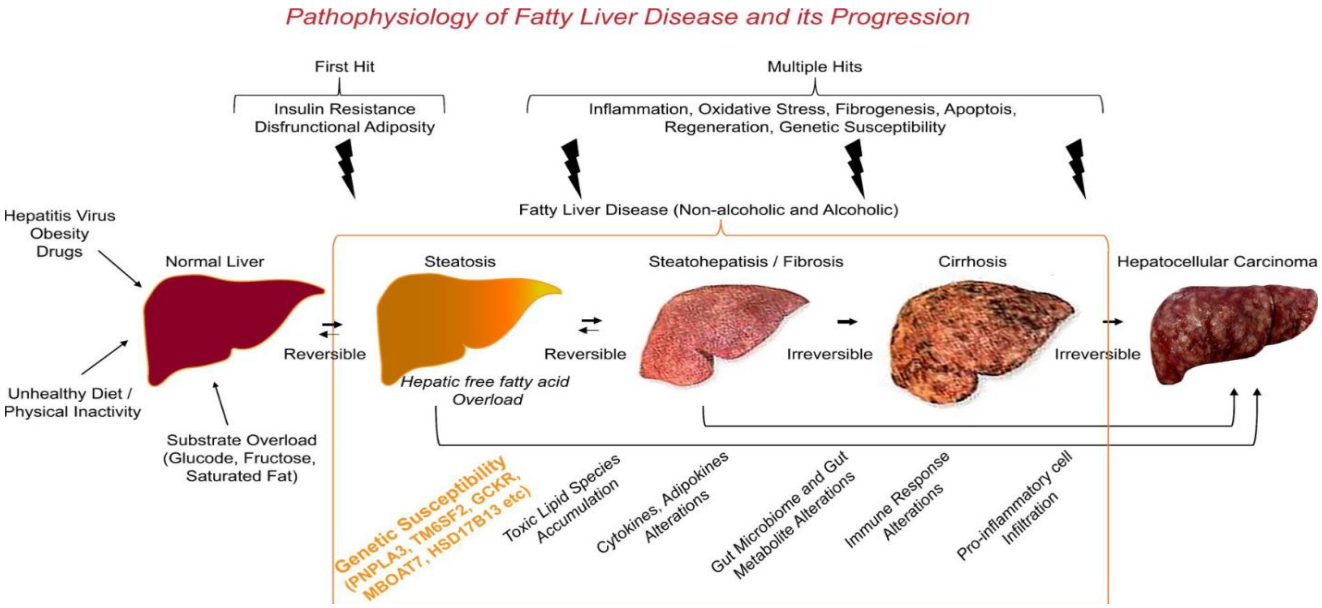
Fatty liver disease can occur in people who consume little or no alcohol as NAFLD (Nonalcoholic Fatty Liver Disease). NAFLD can further progress to a more severe form known as non-alcoholic steatohepatitis (NASH).

2.1.1 What is Nonalcoholic Steatohepatitis?

Nonalcoholic steatohepatitis is a severe form of NAFLD, and it is commonly called a silent disease. NASH is mainly associated with metabolic syndrome like obesity, type 2 diabetes, and risk of heart disease. Fatty Liver progresses into different stages:

- **Stage-01 Steatosis**: The accumulation of fat in the liver is called steatosis. Steatosis is detected when individuals take random tests like health check-ups.
- **Stage-02 NASH**: The most severe form of NAFLD is known as NASH [Nonalcoholic Steatohepatitis], where the liver undergoes inflammation.
- **Stage-03 NASH Fibrosis**: When liver inflammation continues, the liver tissues get damaged, yet the organ functions normally, which leads to the next stage, called NASH fibrosis.
- **Stage-04 Cirrhosis**: NASH fibrosis can further progress to a more severe stage where the liver gets permanently damaged which can lead to liver failure.

Currently, NASH has become the leading cause of chronic liver disease worldwide, and it's ~15 to 20% widespread across the Bangalore population.



[Figure 3 *Pathophysiology of Fatty Liver Disease & its Progression Stages, Mungamuri et al., 2023)]*

2.1.2 Who is affected by NASH?

Currently, there are more than 115 million people who are affected by NASH who have little or no alcohol. Many researchers are trying to find out the root cause of why some patients with NAFLD develop NASH while others do not develop this condition [Pfizer (2024)]. NASH is most commonly prevalent among people with the following risk factors

- Obesity: People with severe obesity (90%) or overweight (75%)
- Prediabetes/Type 2 Diabetes/Insulin Resistance: Approximately 30% to 60% of diabetic patients may develop NAFLD.
- Abnormal Cholesterol Levels It includes people with high cholesterol/ triglycerides in the blood.
- Age: NASH can impact any age group. It includes children because of the rise in obesity.
- Genetic Factors- There is ongoing research on whether genes can contribute to NASH. Scientists have identified *the PNPLA3* gene responsible for making adiponutrin (a protein found in liver cells) and believe that if there is any change to *the PNPLA3* gene Charlton (2024), it contributes to increasing fat production and decreases the breakdown of fat molecules in the liver.

Other risk factors are not common, but further research studies are ongoing

- Polycystic ovary syndrome (Hormonal Disorder caused by Ovaries)
- Menopause People at the post-menopausal stage are also at risk of NASH.
- Obstructive Sleep Apnea

2.1.3 What are the signs and symptoms of NASH?

Since NASH is a silent disease, there are few or no outward signs and symptoms. Some of the common symptoms are:

- People may experience some discomfort in the upper part of the belly.
- Fatigue

Some of the most common symptoms people experience with cirrhosis are

- Itching in the skin
- Swelling in the abdomen and legs
- Shortness of breath
- Jaundice (Symptoms like yellowing of the eyes and skin)
- Enlarged spleen
- Nausea
- Behavioural Changes- Confusion, Difficulty in speech
- Spider-like blood vessels below the surface of the skin

2.1.4 How can NASH be diagnosed?

Since NASH does not show any symptoms, healthcare professionals recommend that an individual to undergo specific tests to check the status of the liver. Some of them are:

- **Blood Tests** are suggested by healthcare professionals to check the health status of an individual. Blood test provides an overview of RBCs, WBCs & platelets and helps to detect various diseases.
- **Liver Function Test** helps to examine the liver enzymes and overall health status of the liver.

- **Hepatitis Test** is performed to diagnose if hepatitis viruses (Hepatitis- A, B & C) have caused the liver inflammation
- **Blood Glucose Test:** Fasting blood glucose helps to screen diabetic patients and assess glucose metabolism. For diabetic patients, Hemoglobin A1C tests check the average blood sugar levels in the previous months.
- **Lipid Profile** helps to check cholesterol levels and triglycerides as the individual can be at cardiovascular risk.
- **Imaging Procedures:** Following are the various imagining tests that are recommended to check the liver status

1. **Ultrasound**- If the initial stage of liver disease is suspected, the patient undergoes abdominal ultrasound.
2. **MRI (Magnetic Resonance Imaging)-** These tests are performed on early-stage liver diseases like fibrosis
3. **Elastography**- It is the latest imaging technique that is non-invasive and measures the stiffness of the organ. The commonly used elastographic techniques are transient (Detects scarring in the liver) and MRE (It combines sound waves+ ultrasound of magnet waves from MRI to produce a detailed image of the liver)
4. **Liver Biopsy** If other tests show signs of high damage to the liver, then the patient is recommended to undergo a Liver Biopsy. This procedure involves the removal of a small piece of tissue from the liver by inserting the needle through the abdominal wall. Though the procedure is uncomfortable, it is considered the best diagnosis for NASH. It details liver inflammation and shows how much the liver is damaged

2.1.5 How is NASH currently treated?

As obesity is on the rise and there is no standard treatment for NASH, it is always better to consult the doctor before starting any dietary supplements or herbal medicines as it may worsen the liver condition. Many healthcare providers recommend reducing weight through balanced diets, and regular exercise may help to reduce fat deposits and inflammation in the liver. Patients with NASH should strictly avoid alcohol as it enhances the conditions.

When NASH patients develop cirrhosis, healthcare providers recommend medications and minor procedures. If cirrhosis further damages the liver, then they are advised to undergo liver transplantation.

In India, Zydus Cadila (a global pharmaceutical company) conducted clinical trials to evaluate the safety and efficacy of Saroglitazar. The drug proved to show some improvements in liver enzymes and lipids in patients with NAFLD. Based on the clinical trial results, DCGI approved Saroglitazar for Non-Cirrhotic NASH.

In the USA, Madrigal is an ambitious biopharmaceutical company focused on bringing novel therapeutics for NASH. There is an ongoing clinical trial for Rezdiffra to examine the safety and efficacy of treating adults with NASH (Moderate to Advanced Liver Disease).

However, the FDA approved Rezdiffra based on the surrogate endpoint through an accelerated pathway in March 2024. Madrigal needs to provide the clinical study report after the clinical trial is completed in 54 months.

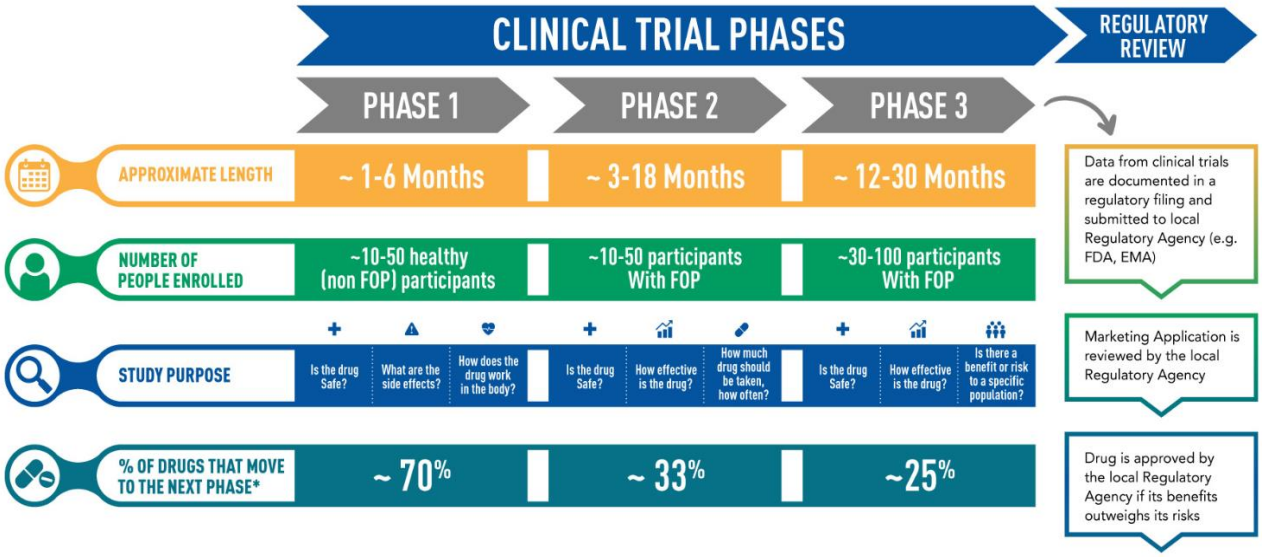
2.2 Introduction to Clinical Trials

Drug development is a long and complex process that takes more than a decade for a drug molecule to be approved by the regulatory authorities. Clinical trials (CT) are research studies in which new drug molecules are tested for safety and evaluated to check their effect on human health (WHO, 2020). During the trial, people will participate voluntarily to test the investigational medicinal product (IMP), vaccines, devices, and surgical procedures. Since it involves humans, the clinical trial protocols are planned, designed, completed, and approved by the regulatory authorities (RA) and the Ethics committee (EC) before initiation of the trial.

Before the clinical trial begins, researchers perform preclinical studies on animals in the labs. During this phase, the drug toxicity levels are tested before conducting trials on human beings. After the IMP is found to be safe from the preclinical studies, clinical trials are conducted on humans.

There are four phases in a clinical trial.

- **Phase I**: The studies are conducted on healthy participants to evaluate the safety efficacy and dosage levels of the IMP.
- **Phase II**: In this phase, after the IMP is confirmed to be safe it is tested on a larger group of people to check for adverse effects.
- **Phase III**: Clinical trials are conducted in different countries with a diverse population before the new treatment is approved.
- **Phase IV**: Following the IMP approval by the regulatory authorities, post-marketing studies help to monitor the side effects in a diverse group of patients.

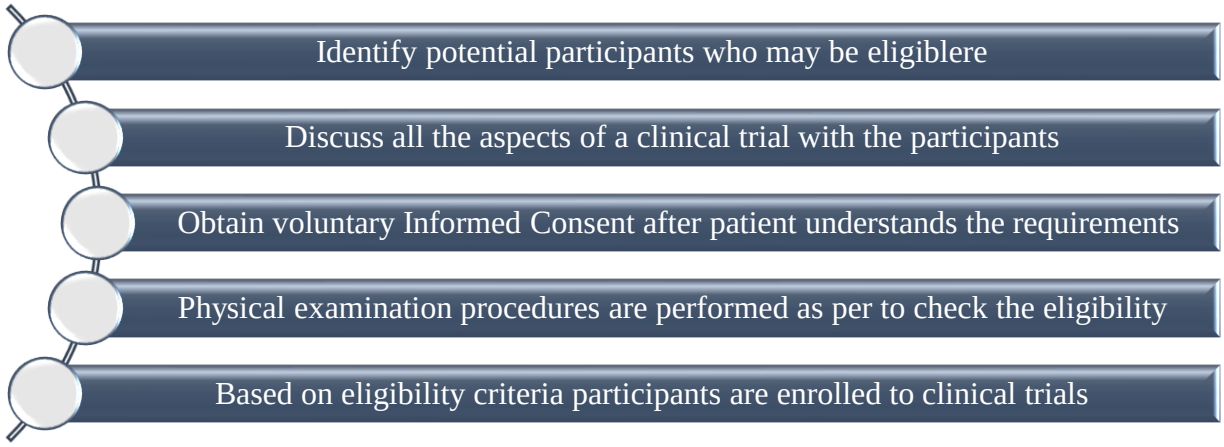


[Figure 4 *Clinical studies & Phases of Clinical trials, 2024*]

2.3 Process of Patient Recruitment in Clinical Trials

The clinical trials must be carried out with quality and integrity to ensure meaningful results are obtained after the trials are completed successfully (Wandile, 2023). The key elements that support a clinical trial are effective methods of recruiting patients and retaining sufficient

participants. For any clinical trial, participants are the core component, without which trials cannot be conducted. Clinical trial operations can begin once the recruitment strategy is approved, and clinical research coordinators can proceed to recruit the patients. The following steps are followed to recruit patients in a clinical trial:



[Figure 5 *(Chaudhari et al., 2020)- Patient Recruitment Steps*]

2.4 Patient Recruitment in Clinical Trials

According to research by Moseson, Kumar, and Juusola (2020), the patient recruitment process has always been challenging and time-consuming, and it is estimated to be about 25-30% for all clinical trials. Not all the participants are eligible only based on the inclusion and exclusion criteria of the protocol participants are screened & enrolled for a clinical trial. In 70% of the scenarios, the recruitment timelines are not met.

Before the pandemic, patient recruitment was through traditional methods such as advertisements, flyers, printed brochures, and healthcare providers. After the pandemic, virtual assistants such as mobile or online web applications have enabled a remote process to recruit, consent, and enroll patients. This process has helped to remove the barriers and maximize the number of participants by reaching a diverse population, which reduced recruitment time & cost.

In today's digital era, social media platforms have impacted society. Some clinical research organizations have started to use platforms such as Instagram, Facebook, Twitter, and LinkedIn. Though there are potential benefits, participants are concerned about their privacy & confidentiality, which is why hurdles always exist.

2.4.1 Traditional Versus Virtual Recruitment in Clinical Trials

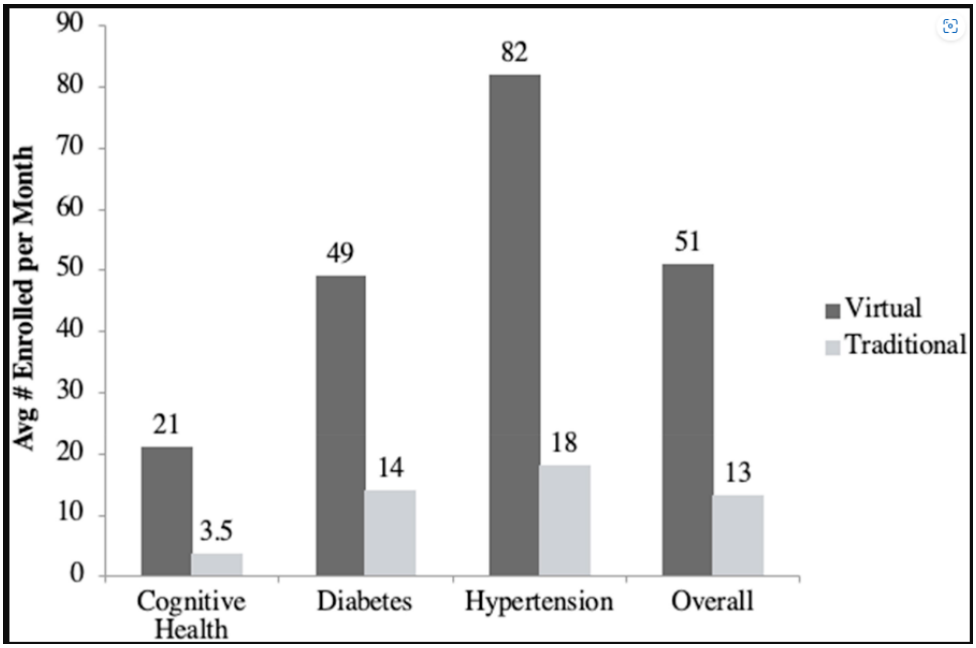
A comparative study was conducted by Moseson, Kumar, and Juusola (2020) to determine the appropriate method of patient recruitment traditional methods versus virtual methods. The virtual method involved recruitment through social media, mobile applications, and targeted advertisements, whereas the conventional method included advertisements and flyers. Using these two methods, a comparative study was conducted in the USA for different therapeutic areas such as hypertension, cognitive, and diabetes. Each therapeutic area had different comparators.

The hypertension studies were conducted over 12 weeks, the comparators included learning and telehealth interventions, dietary approaches, health games, and other digital programs aimed at reducing blood pressure.

On the other hand, in cognitive studies conducted for 12 months, the comparators included cognitive function in older patients, meditation, yoga, and music. Lastly, the diabetes studies were for 12 weeks and had comparators such as weight loss management, diabetes programs, diet, and exercise.

The comparative analysis was evaluated with parameters such as age, sex/race, recruitment method, time, and rate metrics. From the analysis, there were major differences between virtual assistance and traditional methods for various studies in patient recruitment.

- **Hypertension Studies**: There were ~80 participants recruited through virtual assistance, but it was to ~15-18 participants through the traditional method.
- **Cognitive Studies**: There were ~20 participants recruited in a month with virtual assistance, while only 04 recruited through the traditional method.
- **Diabetes Studies**: There were ~50 participants recruited in a month through virtual assistance, whereas it was ~10-14 through the traditional method.



[Figure 6 *(Moseson, Kumar, and Juusola, 2020) Comparison of Traditional Method vs Virtual Method of Patient Recruitmen*t]

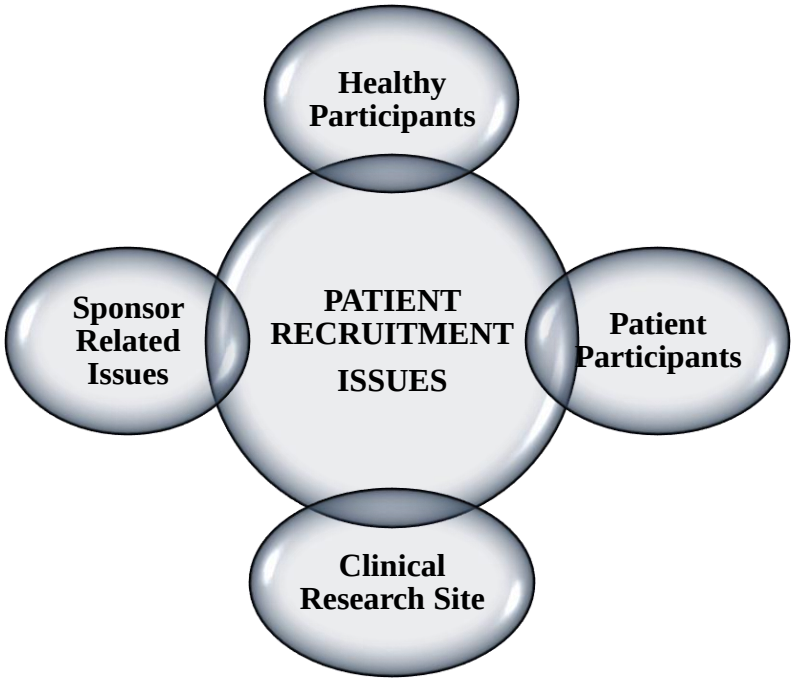
The findings from these studies showed that the virtual recruitment method recruited participants from diverse populations within a short time frame, while the traditional method was time-consuming and did not meet the recruitment timelines. Additionally, it was observed that female participation was high when compared to the opposite gender, so this was a limitation that needs to be addressed by the recruitment team.

The virtual method of recruitment was suitable for virtual clinical trials and was conducted by a digital company. This approach may not be appropriate for other therapeutic areas.

However, the virtual recruitment method showed that participants were enthusiastic to participate in clinical trials.

2.4.2 Patient Recruitment Challenges in Clinical Trials

Globally, patient recruitment is a well-recognized challenge for clinical trials. About ~50% of the clinical trials get terminated due to low enrollment [Wandile (2023)]. So, the study sponsors aim to meet the enrollment targets with the timelines as it is a sensitive and demanding task for the clinical research sites. According to Chaudhari et al. (2020), patient recruitment challenges can be classified into



[Figure 7 *(Chaudhari et al., 2020)- Challenges in Patient Recruitment*]

- **Challenges from Healthy Participants:**

1. Healthy participants (Male/Female) would be of active reproductive age, so they are advised to use contraceptives, which would be a challenge in the case of women. So, the women participants need permission from their spouses and family members to participate in the trial.
2. Some of the healthy participants take the advantage of receiving free health checkups and earn compensation for time and travel. Later when the screening results are received, they decide not to participate in the trial.
3. Some participants do not pay attention to the trial details or understand the risks of participation. Other participants with prior experience in clinical trials might have received high pay, so they attempted to negotiate the compensation and declined to participate.

- **Challenges faced by Patient participants:**

1. Based on their education, some participants need more time to understand and decide whether to participate/ not.
2. Participants are committed to their work schedule. It can be challenging for people to attend scheduled study visits due to their busy schedules at the workplace.

3. When participants live far from trial sites, it becomes challenging for people to travel frequently to the clinical trial sites.
4. Participants tend to decline to enroll and follow up in clinical trials during festive seasons slows the recruitment process.
5. Participants are concerned that they would receive a placebo instead of an actual treatment and the possibility of having side effects with IMPs.
6. Participants decide not to participate in Clinical trials when they come across discouragements from family and friends.

❖ **Challenges Faced by Sponsor**

1. The protocol's strict eligibility criteria mean that only half of the screened patients will be eligible for randomization, which affects the recruitment timelines. Ex: For males, the Hemoglobin range should be 13.5 to 18g/dL, when this criterion is not met they will be excluded from the trial
2. In multicentric clinical trials, sponsors often use central laboratories, so the laboratory reference ranges may differ from the normal ranges used by the research sites. It is a challenge as it may reduce the number of individuals participating in the trials.
3. When clinical trials are conducted, the sites which has highest patient recruitment then the sponsor decide to move investigational products from slow-recruiting sites to faster ones. Unfortunately, this can cause additional delays at the original site, even when there are potential participants.
4. If there is a delay in the disbursement of funds by the sponsor/CRO then the recruitment process can be impacted.

❖ **Challenges at Clinical Research Sites- Investigator**

1. Recruiting patients can be challenging when there are restricted budget, which limits the ability to target a larger population through advertisements.
2. The Clinical research coordinators (CRC) may face challenges in meeting the recruitment targets & timelines.
   Most people are unaware of or have misunderstandings about clinical trials.
3. The complexity of the clinical trial design can lead to slow recruitment.
4. Stringent protocols can increase the screen failure of patients which delay the recruitment process.

2.5 Introduction to Social Media

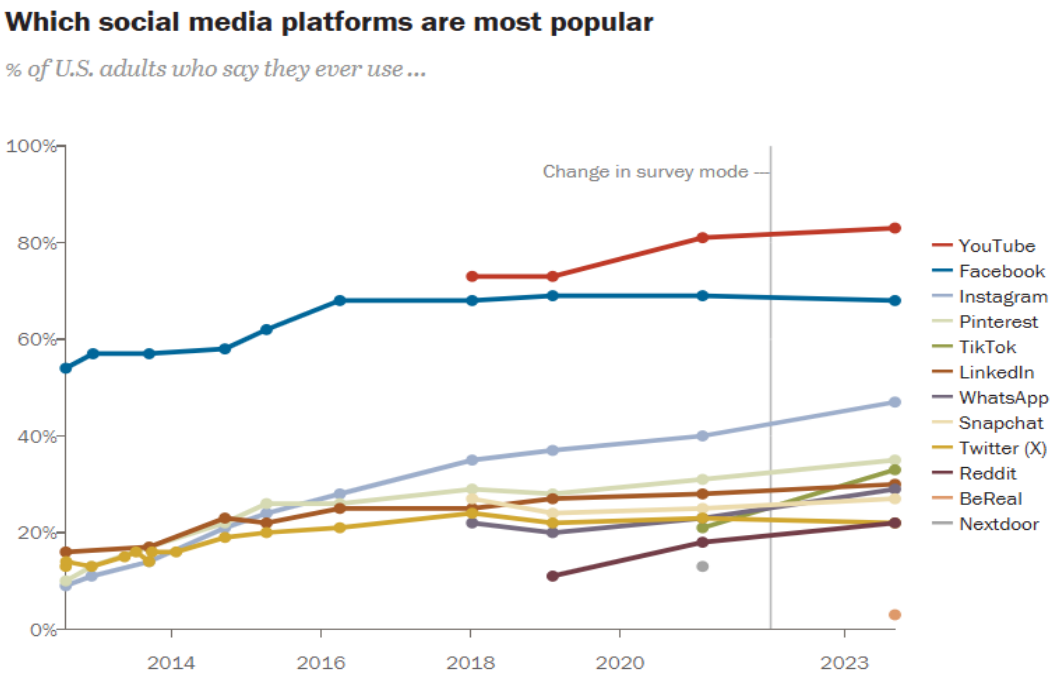
A social media platform is an online platform that allows users to create, share (thoughts, experiences, and ideas), and interact with content, information, and messages with other users through the Internet (Dwivedi *et al.*, 2021). The most popular social media platforms are

- Facebook
- Instagram
- YouTube
- LinkedIn
- Twitter
- TikTok
- WhatsApp

Each social media platform offers a range of features for its users. Some of the features seen in social media are

- ❖ Account: To start using social media platforms, the users should create a unique user ID & password to maintain confidentiality of the account.
- ❖ Engagement: Social media platforms allow users to share content such as images, videos, links, and other information. Social media platforms have features like message, share & comment can be used by users to share their opinions and engage with other users. Users can connect and like the personal pages of other users.
- ❖ Users can create groups and invite other users to join these groups who have similar interests in a particular area.
- ❖ Helps users to get the latest news or updates from other users.

Social media platforms have been impacting people around the globe. Communication was easy and also helped to reach a diverse population (Jeyaraman et al., 2023). Recently, the pandemic has influenced healthcare and research areas. In 2023, a survey was conducted by the Pew Research Centre for 04 Months to check the most social media platforms used by the public, and the results showed that Facebook and YouTube made a huge impact on the public.



[Figure 8 *(Author, 2024)- Pew Research Center- Survey for Social Media Platforms***]**

There are pros & cons to using social media platforms. Through social media method of communication has been made easier and connect with people around the world share information, and build personal and business bran

Social media platforms do have some disadvantages.

- Extensive use of social media can set unrealistic expectations which can impact personal relationships.
- Impact Relationships: Excessive use can lead to unrealistic expectations that impact the relationships.

- Privacy Concerns: Users must be careful about sharing personal information to avoid privacy breaches.
- Cyberbullying and harassment are also common issues on social media.
- Addition: Excessive use can lead to addiction, negatively impacting mental health. Moreover, the ease of sharing content can spread misinformation which impacts the harmony of the society.

Overall, social media platforms have digitally transformed communication, interaction, transaction, and information sharing by providing a convenient and accessible way to connect with others.

2.6 Bridging Clinical Research and Social Media

Since the pandemic, social media platforms have started to play a vital role in the healthcare sector. These platforms have made collaboration and communication easier for patients and healthcare providers. It helps to create awareness about health topics such as vaccinations and prevailing diseases and provides an update on the latest medical treatments.

A tutorial was discussed to bridge the gap between clinical research and social media platforms (Davidson, Mahendra, and Nicholson (2022). They explained it as a five-step process:

- **Understand the purpose & goals of the project** through SMART Criteria: Identify & understand the purpose of the project and use SMART criteria to achieve the goal of a project. It was an effective strategy to connect patients and healthcare organizations to communicate information about clinical research and collect feedback, which helped to make strategic changes.
- **Choose Right Social Media Platforms to Target Audience**: Identify the right target audience that includes patients, healthcare providers, and the public. To target the audience, choose the appropriate social media to achieve set goals.
- **Create Contents that Influence the Users**: Conduct prior research analysis of how current influencers create content, what models they use, and the innovative ideas implemented. Using this information, we can develop a brand for clinical trials that helps to reach a diverse audience.
- **Develop Unique Contents**: Based on different social media platforms, the contents can be created as text messages using hashtags, & links, videos, and temporary posts. As a best practice, it is essential to keep updated about strategic designs and accessibility.
- **Content Analysis**: After the content is created it must be accessible to share. We can use bibliometrics to track the responses, which can be used for promotion at the same perform analysis to check which is an effective method. Based on these, we can revise the contents to convey the message uniquely.

Using this modern approach, we can convey the information and bridge the gap between clinical research and social media platforms.

2.7 Social Media-Enabled Patient Recruitment for Clinical Trials

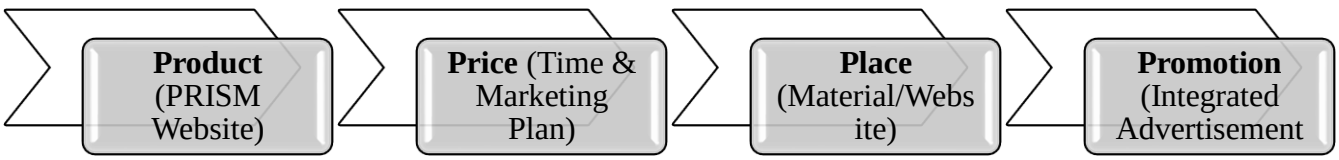
Researchers are exploring different patient recruitment strategies for clinical trials. Some of these ways are having open trials, telephone reminders, informative leaflets, and scarcity-based recruitment messages. The internet and social media are also being used because they are cost-effective and can help reach many people who might want to join. These online tools can help more people find out about and join medical research.

Applequist et al. (2020) conducted a study that focused on patient enrolment in rare disease clinical trials to compare the effective method- web-based direct-to-patient recruitment methods with traditional multicentre recruitment strategies. The participants were directed to the study website via the Patient Advocacy Group's (PAG) website and social media platforms (Facebook and Google+). The study discovered that traditional recruitment methods were more effective than online recruitment. However, online recruitment was hampered by a high dropout rate. Some challenges were encountered such as website design being incompatible with desktop, laptop, and mobile devices, the registration process being time-consuming due to repetitive steps, and the traditional informed consent form only added to the frustration, making it difficult for users to complete the registration.

In response to the challenges, an new integrated approach known as PRISM (Protocol for Increasing Accrual Using Social Media) was developed. PRISM was a well-organized and streamlined process that combines recruitment and referral tools with patient-focused content to improve the recruitment process [Applequist et al., 2020].

Through a qualitative approach, a professor conducted in-depth interviews with patients to collect feedback, which led to a change in the message approach. Using the feedback they updated the strategy. The new strategy included attractive infographics, photographed images, and educational posts about rare diseases, which made it easier for patients to share with others which increased engagement.

In the PRISM approach taglines were used such as "We can't achieve without you" and "Your participation will significantly benefit others who are suffering with rare diseases". The team also used the 4Ps of social marketing (Product, Price, Place, and Promotion) to influence behavior change. The PRISM website was created to be user-friendly, with clear and simple language explaining eligibility criteria, making it available to patients.



[Figure 9 *Applequist et al., 2020)- A Novel Approach to Conduct Clinical Trials]*

The PRISM strategy also included personalized communication for interested individuals who can receive information via text message, email, or phone call. Once eligibility was confirmed, the Google Maps feature assisted participants in locating the nearest clinical trial enrolment location.

Furthermore, PRISM was designed to be mobile-friendly, with visual icons to help patients read and understand the content on their mobile devices. Participants were paid according to policy. The site clinicians reviewed the enrolment metrics to evaluate the PRISM recruitment process, and patients provided feedback to share their experiences with the enrolment process in order to improve the tools [Applequist et al. (2020)].

Ortner et al. (2024) conducted similar research, comparing traditional patient recruitment methods, such as printing flyers and mailing invitations, with online patient recruitment via social media. It was discovered that traditional methods were time-consuming and costly, whereas online recruitment through social media was faster and cost-effective. The strategy used in this method was to direct users to the clinical trial recruitment page after clicking on the advertisement link, which provided enough information about the skin condition. The system allowed interested individuals to submit their contact information. Furthermore, patients who want to participate in clinical trials can upload photographs of their skin condition, and the clinic will contact them for further processing (Ortner et al., 2024). As a result, the online recruitment method for clinical trials outperformed the time-consuming traditional method. This method allowed healthcare professionals to evaluate more patients for the trials, reducing the time required by 10%.

The research (Baker, Mitchell, and Thomas, 2022) compared a social media-based recruitment strategy to traditional methods such as print advertisements and in-person recruitment (Ortner et al., 2024). It highlighted the importance of using social media and targeted platforms such as Facebook, Twitter, and Instagram to recruit patients for clinical trials involving skin conditions. Furthermore, when compared to other methods of recruitment, social media can be a low-cost option with a high enrolment rate.

The researchers (Baker, Mitchell, and Thomas, 2022) conducted a comparative analysis of paid and unpaid patient recruitment strategies through social media to determine the most effective approach for enhancing enrollment rates. The unpaid method did not incur charges and, reached out to a diverse population. At the same time, the paid method proved to be more cost-effective. It provided flexibility to target specific populations within a specified duration rather than utilizing recruitment agencies, which did not reach the appropriate patient groups for enrollment.

Though there are several advantages to using social media for patient recruitment, it also carries some limitations. Some of the drawbacks of the unpaid method were work intensive (Baker, Mitchell, and Thomas, 2022) as each social media platform was different and the information had to be customized as per specific requirements and posted regularly as per standard guidelines. For example, the Twitter platform has a character limit; on Reddit, the posts had to be frequently shared to ensure it's visible to the audience regularly.

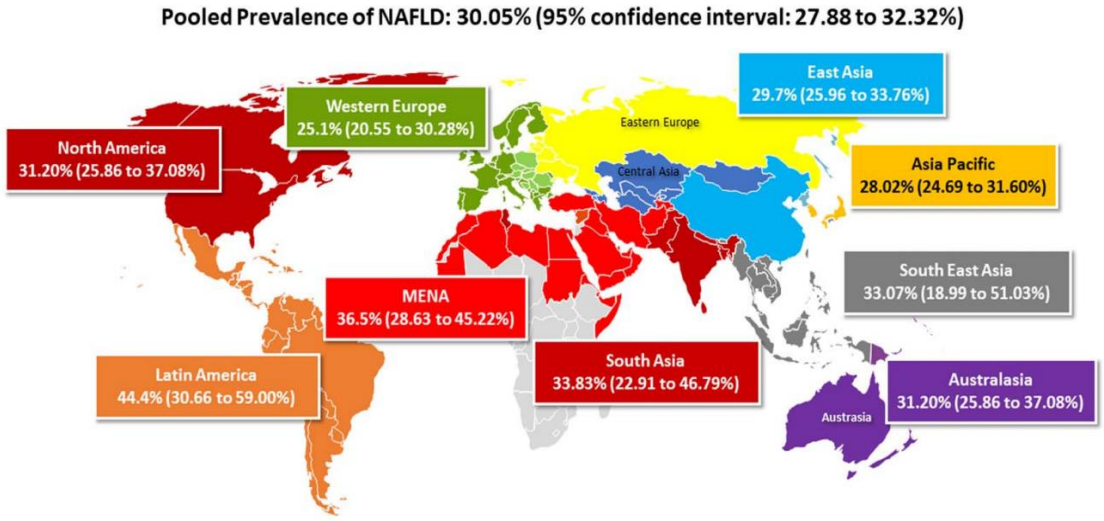
For the paid method, in the case of Facebook, standard guidelines had to be followed where the contents had to be reviewed and pre-approved before the posts were released on social media platforms. In case the contents are inappropriate, then contents lead to rejections later had to be altered and then resubmitted for review to post. For the unpaid methods, the metrics generation was challenging but, for the paid recruitment methods accurate reports were generated.

This limitation hampers the analysis and comparison of the effectiveness of the paid and unpaid methods for social media platforms. Another limitation discussed in the research was the cost of staffing and advertisement. Also, the unpaid method had different limitations such as the different timings of the year used by social media users. So, the patient enrollment rate was low during the festive season (Baker, Mitchell, and Thomas, 2022). It was observed that removing language as a barrier from the initial default settings would help recruit more patients (Ortner *et al.*, 2024).

Though there are several benefits of different platforms, the healthcare sector has yet to modify and implement standard ethical guidelines to gain more trust among the public and maximize the benefits.

2.8 Investigating the Landscape of Clinical Trials for Nonalcoholic Steatohepatitis (NASH) in India & Around the globe

Nonalcoholic Fatty Liver Disease (NAFLD) is the most common chronic liver disease, affecting 24 percent of the world's population. NASH (Nonalcoholic Steatohepatitis) which is projected to increase by approximately 20% by 2030. NAFLD is a major concern in India, particularly among the age groups 30 to 50 (Mireku and Mireku, 2023).



[Figure 10 *Zobair M. Younossi. et al. (2022)- Global Epidemiology of NAFLD & NASH***]**

NASH is an underdiagnosed disease due to its silent nature, making it critical to raise awareness among doctors and the general public. Currently, there are no standardized screening guidelines for NAFLD and NASH worldwide. Since the conditions are asymptomatic, Ultrasounds and routine blood tests are frequently used to diagnose. Despite normal liver enzyme levels, patients may still have fatty liver disease, emphasizing the importance of increased awareness and early detection.

There are currently only two approved medications in the world to treat NASH, leaving a significant unmet need. NASH is managed holistically, which includes addressing related metabolic disorders such as obesity, diabetes, and dyslipidemia. Alternative treatments, such as Ayurveda, herbal remedies, and yoga, are available in India and may provide some relief for patients suffering from NASH-related fatty liver disease.

In India (specifically, Lucknow), research is being conducted to prevent NASH from progressing to cirrhosis. This study is taking place at the Sanjay Gandhi Post Graduate Institute of Medical Sciences Department of Endocrinology (Mireku and Mireku, 2023).

When developing treatments for NASH, the pharmaceutical industry faces two challenges: patient recruitment and persuading patients to undergo invasive diagnostic biopsies even after they have been accepted into clinical trials.

The lack of effective treatments for NASH is a major impediment to patient recruitment, as biopsy results may not change disease management. In India and other countries, patient refusal is due to uncertainty. Furthermore, biopsies are prone to sampling errors (26%), as well as disagreements between local and central readers, which result in screen failures and decreased enrolment. Hepion Pharmaceuticals is developing non-invasive biomarkers to detect the early stages of nonalcoholic steatohepatitis.

Another challenge in treating NASH is genetic variation among patients, which means that one treatment may be effective for some but not for others. This "one size does not fit all" approach emphasizes the importance of personalized medicine approaches to address NASH patients' diverse genetic profiles and improve treatment outcomes.

The FDA recently approved Rezdiffra (Madrigal Pharmaceuticals) to treat NASH patients in the moderate to advanced stage, but the clinical trial (NCT03900429) is still ongoing. However, many pharmaceutical companies are racing to develop new drugs to treat NASH.

Currently, there are several clinical trials ongoing for NASH sponsored by pharmaceutical companies. To name a few:

1. Semaglutide [NCT04822181- Novo Nordisk] is an approved medication used in the treatment of type 2 diabetes in many countries. Additionally, an extended clinical trial is ongoing to check its effectiveness on NASH patients [Ucsd (2024)].
2. Saroglitazar Magnesium [NCT05011305- Zydus Therapeutics Inc], is used in the treatment of NASH, and there is an ongoing Phase II trial, which is expected to be completed by 2025 [Ucsd (2024)].
3. Emricasan (Caspase Inhibitor) [NCT03205345- Conatus Pharmaceuticals Inc] This is a multi-centric randomized clinical trial conducted in patients with NASH Cirrhosis.
4. Resmetriom [NCT03900429- Madrigal Pharmaceuticals, Inc]: This is a phase III trial conducted in the treatment of patients with NASH (Liver Fibrosis) [Harrison et al. (2024)].

2.9 Key Themes From as Secondary Research

Patient recruitment remains a challenge for clinical trial sponsors and research teams. Some of the major themes taken from the literature are:

- **NASH Prevalence and Burden**: NASH is underdiagnosed because of its asymptomatic and is estimated to rise by 20% by 2030.
- **Obstacles in NASH Clinical Trials**: Patient recruitment and influencing participants to undergo invasive diagnostic biopsies are the major challenges.

- **A Multi-Platform Social Media Strategy**: Twitter, Facebook, Instagram, and Reddit were more cost-effective and efficient. It also cut the time required to evaluate patients in clinical trials by 10%.
- **Social Media Strategies**: Create an effective social media strategy based on the SMART criteria to understand the clinical trial purpose and goals. This helps to identify the target audience and choose the best social media platforms to create and share content.
- **Methods of Patient Recruitment:** The research compared traditional methods (such as printing flyers and mailing invitations) to more efficient and cost-effective online social media platforms.
- **Challenges with Online Recruitment** (Applequist et al., 2020) The research identified several factors that contributed to low participant enrolment, including website design, a time-consuming registration process, and traditional informed consent forms.
- **Integrated approach** [Applequist et al. (2020)] An integrated approach was developed based on online recruitment challenges which were later combined into patient recruitment & referral, and a streamlined process was implemented to address challenges.
- **Marketing Principles in Social Media**: According to Applequist et al. (2020), the PRISM approach, which focuses on Product, Price, Place, and Promotion, promotes behavior change and participation.
- **Feedback Approach** [Applequist et al. (2020)]: Patients' feedback inspired a new approach with visually appealing infographics, relatable images, and educational posts to boost engagement.
- **Cost-Effectiveness:** Unpaid social media effectively reached a diverse patient base. Paid methods, on the other hand, proved to be less expensive and provided more targeting flexibility for clinical trial recruitment.
- **Drop-Off Rate:** Social media platforms can reduce drop-off rates and streamline recruitment for clinical trials.
- **Real-Time Capabilities:** Effective communication is crucial for any process. Social media allows for two-way communication, which aids in the immediate resolution of issues [Applequist et al., 2020].
- **Timeframes/Timelines**: The advertisements were customized to reach a diverse population within a particular timeframe. Social media can help to achieve the recruitment goal targets within the timelines (Reuter, 2020).

2.10 Areas for further research

Based on the literature review, the following areas require additional research.

- **Examine the prevalence and burden of NASH.**
- Identify factors contributing to the underdiagnosis of NASH.
- Effect of NASH on patients' quality of life.

- **Issues in NASH Clinical Trials**
  • Improve patient recruitment and motivation for NASH clinical trials.
  • Create non-invasive biomarkers for detecting early stages of NASH.

- **Social Media for Patient Education and Awareness.**
  • Use social media to create engaging content and educational materials to connect

with patients.
• Encourage participation in clinical research studies. Can social media technologies support decentralized clinical trials (DCT)?

❖ **Role of Healthcare Providers in Clinical Trials**
- To understand if healthcare providers promote and recommend their patients to participate in clinical trials.

❖ **Effective Recruitment Method**
- Identify factors that influence the public/patients to participate in clinical trials.

2.11 Conceptual Framework

Based on the literature review, the conceptual framework was created to investigate the following research objectives.

❖ **Awareness and Education about NASH (Nonalcoholic Steatohepatitis):** The objective is to create awareness among the public, about NASH risk factors, and the importance of early detection through social media platforms. P
❖ **Public Preferences & Attitudes towards Clinical Trials**: Qualitative & Quantitative (Interviews/surveys) will help to analyze and understand public perceptions and concerns towards clinical trials.
❖ **Factors that will influence public participation**: Surveys will help to investigate the influential factors for the public to participate in clinical trials and understand the different barriers that hinder them not to participating.
❖ **Social media platforms**: From the Surveys, we can identify what are the most common social media platforms used by the public in Bangalore. Analyze which is the appropriate platform in terms of flexibility, efficiency, and cost-effectiveness that will help to recruit participants for clinical trials.

The conceptual framework helped to identify the key variables that will help answer the below research questions.

1. NASH: How do we create awareness about NASH and educate the public about symptoms & early diagnoses?
- **Identified Variables**: Awareness & Education about NASH- This was measured through surveys.

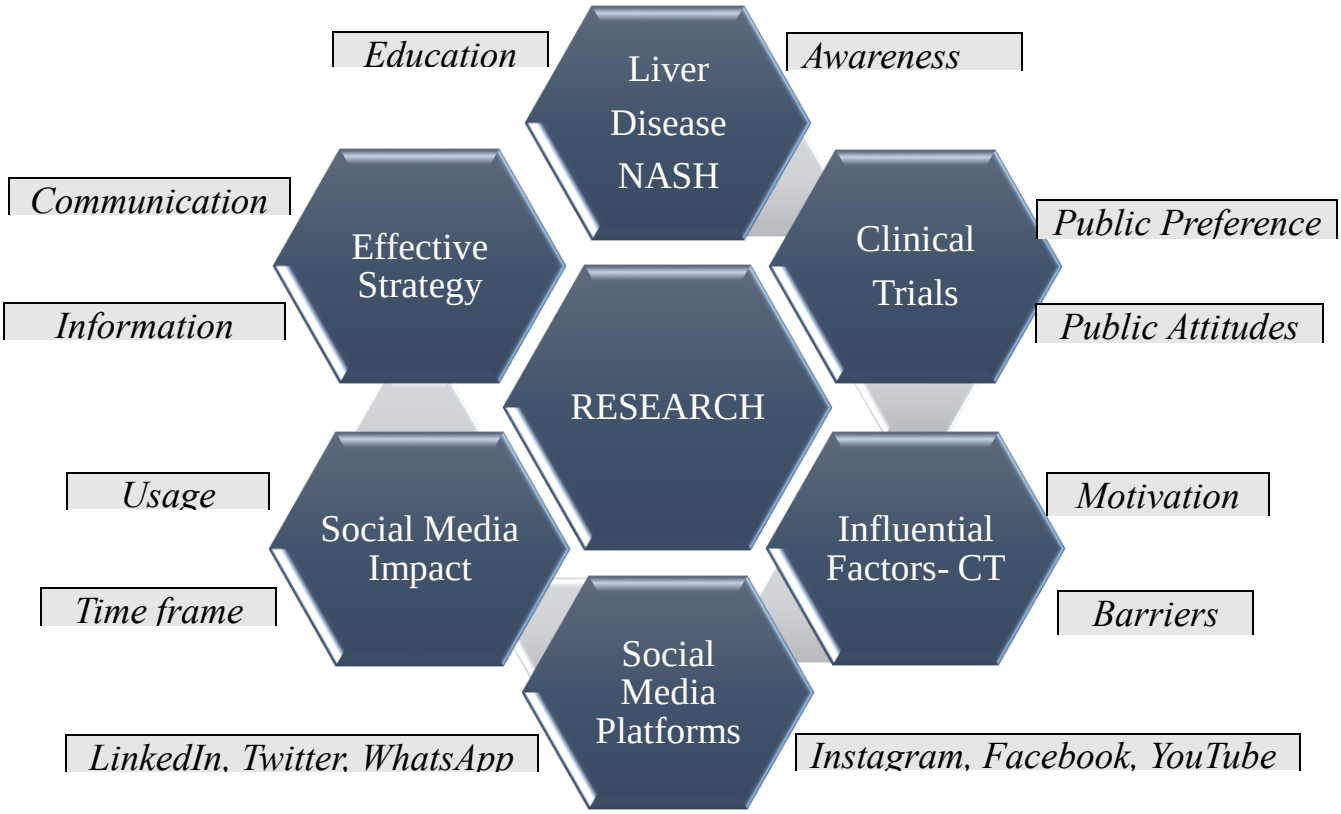
2. Clinical Trials: What is the public's awareness of their preferences and attitudes about clinical trials?
- **Identified Variables**: Public preferences (Mode of Communication for Clinical Trials) and attitudes (Trust, benefits & concerns)

3. Influential factors for Clinical Trials: What factors influence public participation & barriers that hinder them not to participate in clinical trials?
- **Identified Variables**: Motivation (Personal benefit) & Barriers (Fear & time constraints)

4. Social Media Platforms: Which social media platforms are used by the general public?
- **Identified Variables**: Instagram, Facebook, YouTube, LinkedIn, Twitter, & WhatsApp

5. Social Media Impact: How does social media impact society, and how frequently does the public use social media platforms?
- **Identified Variables**: Usage (Content engagement) & Timeframe (Evaluate the time)

6. Effective Strategy: What are the effective ways to recruit participants for clinical trials using social media platforms?
- **Identified Variables**: Communication & Information



[Figure 11 *Creation of Conceptual Framework by Researcher***]**

2.12 Conclusion

NASH is a severe form of NAFLD also known as silent liver disease that has affected 15-20% of the Bangalore population. Fat accumulation in the liver causes inflammation and fibrosis, which progresses to cirrhosis and, eventually, liver cancer.

There are currently two drugs approved for the treatment of liver diseases. The DCGI of India has approved Saroglitazar for the treatment of Non-Cirrhotic NASH patients, while the FDA of the United States has approved Rezdiffra for the treatment of moderate to severe liver

disease. In addition, pharmaceutical companies in India and many other countries are conducting clinical trials for NASH.

Patient recruitment for clinical trials has always been a difficult and time-consuming process, accounting for 25-30% of total clinical trials. Researchers conducted comparative studies to determine which method was more effective: traditional or virtual. Traditional methods such as advertisements and flyers may be less effective in today's digital age when compared with the Virtual method.

According to a Pew Research Centre survey, the most popular social media platforms are Facebook and YouTube. During the pandemic, social media has become increasingly important for spreading health-related information. Despite the numerous benefits provided by various platforms, the healthcare industry must continue to adapt and enforce ethical guidelines in order to build public trust.

In conclusion, NASH is a complex disease that requires a holistic approach to diagnosis and treatment. Pharmaceutical companies conduct clinical trials to develop novel treatments for NASH, but patient recruitment remains a significant challenge. The use of social media platforms has the potential to boost patient engagement and improve clinical trial efficiency. More research is required to develop effective NASH treatments and address the issues that patients face.

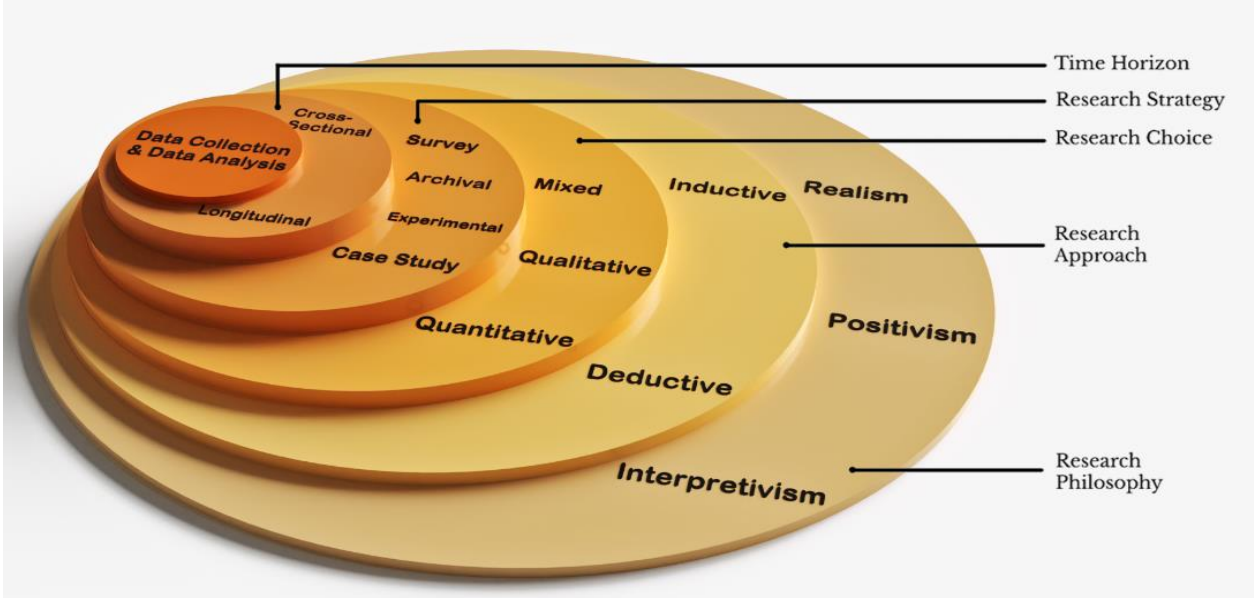
CHAPTER-03 RESEARCH METHODOLOGY

3.1 Introduction to Research Methodology

The research methods are an essential part of the study. It allows future researchers to review the data obtained in this study and identify new elements of the field that are yet to be studied. This research aims to investigate the influence of social media on raising awareness about Non-Alcoholic Steatohepatitis (NASH) and ask public opinion on clinical trials, while also examining which social media platforms are most effective for promoting clinical trials to overcome patient recruitment challenges.

3.2 Research Design- Onion Framework

The research onion framework organizes the research process into different layers.



[Figure 12 *Saunders et al. (2020) Research Onion Framework***]**

Research philosophy is the outermost layer of the framework. The research is suitable for the positivism and interpretivism philosophical approaches. Positivism is an objective reality observed and scientifically measured through quantitative methods. On the other hand, interpretivism focuses on subjective reality, where the qualitative method is used to understand the individual's experience and perspectives.

Research Approach is the second outer layer of the framework. The research approach combines deductive and inductive approaches. The deductive approach tests if social media strategies align with the present recruitment methods theories, while the inductive approach was used to draw understanding from the data.

Research Choice is the inner concrete layer of the framework. A mixed-method approach combines both qualitative and quantitative methods.

Research Strategy: The next inner layer of the framework is the research strategy which describes the methodology used to collect data for analysis. Surveys and interviews are the most commonly used research strategies.

Time Horizon: is the next inner layer of the framework. For this research, a cross-sectional was used to collect data from the general population over a shorter period.

Data Collection & Data Analysis: The most vital part of the research is the data collection and analysis layer. For the quantitative method, the data is collected through surveys and analyzed using statistical methods. In contrast, for the qualitative method, the interviews were conducted and analyzed through thematic analysis which adds value to the study and its final results.

The last stage of the research methodology will focus on the research sample size and target audience. Additionally, the research will justify the chosen research method and ethical implications, followed by a precise conclusion.

3.3 Research Sample Size

The sample size is calculated from the population size and confidence intervals of how accurately we can reflect the population (90%, 95%, & 99%). The margin of error indicates what error level can be accepted for the present research.

The SurveyMonkey platform provided an online sample size calculator. Using this portal the sample size was calculated as 190 based on Bangalore's population size (14008262) with a Confidence Level (90%) and Margin of Error (6%).

After the sample size was finalized, the surveys were distributed using various social media platforms, and the results derived from the findings can be generalized to draw a meaningful conclusion for further research.

3.4 Research Tool

To carry out this research, I identified Google Forms. This online platform was utilized to design the survey questionnaires and collect real-time responses from the participants. Another advantage of this platform was that the response was received, the data was arranged, and gave a quick overview of the data through visual presentation. The surveys were distributed through social media platforms such as WhatsApp, LinkedIn, and Instagram.

SurveyMonkey provides a unique feature build calculator that calculates the sample size based on the population size, confidence interval, and margin of error (%).

SPSS was used to perform the statistical analysis for the Quantitative research data.

3.5 Research Participants

For this research, the participants were chosen from clinical research professionals, healthcare providers, and the general public. Below is a brief description of the participants:

- Clinical Research Professionals: The participants come from various pharmaceutical companies working on clinical trials. These participants were approached through LinkedIn & some through WhatsApp through references. Some of the designations of the participants are clinical research coordinators (CRA), Clinical Project specialists,

and Clinical trial specialists who work on designing the clinical trials from the set-up phase till submission to regulatory authorities.

- Healthcare Providers: The participants included Ayurvedic healthcare providers and general physicians. The participants directly interacted with participants who were diagnosed with NASH. So, it was an added advantage to interview and draw potential insights and challenges patients go through.
- General Public: As the name suggests, the participants were the general public who voluntarily wanted to participate in the survey.

From these participants' potential opinions, feedback, motivations, barriers, and experiences were collected through surveys and interviews by maintaining confidentiality standards.

3.6 Effective- Survey Distribution and Schedule Interviews

The research survey links were distributed through LinkedIn, Instagram, and WhatsApp. These platforms are considered the most common networking sites which are not only cost-effective but also fast in sharing information. These platforms helped me to reach a wider group of professionals and the public.

WhatsApp was the first approach as it was convenient to share the survey links, where we got target responses from genuine people. On Instagram, the survey links were shared by other connections which helped to reach diverse populations and created visibility about NASH.

Professional networking sites like LinkedIn were the second approach for collecting potential responses from different clinical research backgrounds and helped to create awareness about NASH research. Through WhatsApp and LinkedIn, I got a few participants who were willing to share their expertise. So, interviews were scheduled at their convenience through Zoom meetings to share their opinions and experiences.

Based on the nature of the study these platforms were found to be a more appropriate method for distributing the surveys and scheduling interviews to achieve the research objectives. Another benefit is that timely responses helped to achieve the estimated sample size when compared to traditional methods where the questionnaire leaflet had to be provided to audiences. Furthermore, the platforms are user-friendly which allows people to respond on their own time and share the survey links with other connections.

3.7 Justification of Methodology- Research Onion Framework

The research methodologies used for this research are justified in detail.

3.7.1 Research Philosophy

The research topic focuses on social media impact and overcoming the recruitment challenges in NASH clinical trials. Based on the literature reviews, the theoretical & scientific methods provided valuable data. However, it did not share experimental insights from the research experts. So, this helped me to choose the best philosophy, positivism, and interpretivism approach to meet the research objectives.

The positivist approach is objective and states that knowledge is through observations and scientific measurements. The Quantitative method involves survey questionnaires that help to analyze the public attitudes toward clinical trials and their barriers to participation. This method will help to establish effective patient recruitment models using social media platforms and align with current trends so that we can shift from the traditional method to cost-effective methods (Alele and Malau-Aduli, 2023).

On the other hand, interpretivism is subjective based on an individual's experiences (Alele and Malau-Aduli, 2023). The qualitative approach helped to bring individual perceptions and personal experiences from professional backgrounds, such as healthcare providers and clinical research experts. The insights drawn from these experts can change the recruitment method, which may include being empathetic, creating content that can address specific concerns, and transparent communications that help to build trust that increases the willingness to participate in clinical trials.

In conclusion, positivism will help to quantify the metrics and standardize the recruitment process, whereas interpretivism helps to understand different individual experiences. Hence, combining these two approaches will help to recruit potential participants using social media platforms for NASH Clinical trials.

3.7.2 Research Approach

For this research, both deductive and inductive approaches were implemented. The deductive approach is a top-down approach that tests the hypotheses from the existing literature and then gathers knowledge. This systematic approach has been used in the quantitative method. It can be linked to the positivist paradigm as it helps collect, analyze, and interpret the data to draw scientific conclusions (Alele and Malau-Aduli, 2023).

The test hypothesis for this research is that the deductive approach will be suitable to test whether social media platforms create awareness about NASH and can influence participation in clinical trials. The quantitative method helped to test the hypothesis by distributing the surveys, and the data collected was collected. The results taken from these data can determine if social media platforms can be an effective recruitment tool for NASH Clinical Trials.

In contrast to this inductive approach is the bottom-up approach, which can be linked to the interpretivism paradigm. The qualitative method was appropriate and helped to identify patterns through observations and generate theories from the data collected. For this research, observations were made through social media engagements, and the interviews were conducted where individuals shared their experiences, & challenges encountered in patient recruitment for clinical trials. The data obtained through these interviews helped to identify patterns that helped to create new recruitment strategies to overcome current barriers faced by participants (Alele and Malau-Aduli, 2023).

In conclusion, the deductive approach focused on testing the research hypothesis from the existing literature/theories to determine how social media platforms can be effective in-patient recruitment. On the other hand, the inductive approach helped to draw insights from clinical research experts to develop new patient recruitment strategies.

3.7.3 Research Choice & Strategy

A research choice is a specific methodology chosen to carry out the research. The research methods include a quantitative method, a qualitative method, or a combination of both.

The quantitative method mainly focuses on numerical data and statistical analysis. This method tests the hypothetical data obtained through survey data and helps understand the relationship between various variables involved in the research. The survey strategy helped to understand the different social media platforms used by the public, awareness about NASH, and their attitude towards participating in clinical trials. The survey data helped to identify various patterns, and they were analyzed by using statistical software (Alele and Malau-Aduli, 2023).

In contrast, the qualitative method deals with non-numerical data. This method helps to understand an individual's perceptions about NASH clinical trials and challenges in recruitment through an interview strategy. The thematic analysis helped to identify descriptive narrations and themes (Alele and Malau-Aduli, 2023).

For this research, a mixed method was appropriate, as it integrates both quantitative and qualitative methods. This method has been used in various healthcare settings and the clinical research field. The strategy of using survey questionnaires and discussions through the interviews brings about multiple perspectives. The experimental data was analyzed through statistical software, and the thematic method helped to analyze the observations and individual perceptions.

To provide a brief rationale of why the mixed-method approach was used can be summarized into the following key points.

- **Expansion of the research**: It allows the researchers to explore the topic from different angles and paves the way for collecting in-depth details.
- **Holistic View**: The combination of qualitative and quantitative approaches provides a holistic view of the same/different opinions.
- **Develop New Methods**: From these research methods (interviews/surveys), we learn to create questions, and the ideas drawn from them can be tested later by using another type of research method.
- **Triangulation**: Using a mixed method approach interview or surveys, we can check and confirm it gives an accurate result.
- **New Insights**: Interviews & Surveys give different perspectives, opinions, or other viewpoints that help to understand the issue and draw new insights.

3.7.4 Research Time Horizon

The research time horizon is one of the inner layers of the research onion framework. The research is carried out based on two different time horizons, which can be longitudinal or cross-sectional.

The longitudinal time horizon requires a longer duration of time to explore complex data, which allows the researchers to observe the trends and changes and understand the

developments with time that can result in long-term impacts. However, the cross-sectional time horizon allows the researchers to collect the data within a short time frame.

In Clinical trials, patient recruitment is one of the challenges faced by every pharmaceutical company. Since this is academic research, it provides a timeframe from June 2024 to August 2024. So, a cross-sectional time horizon was chosen for this research to collect high-quality responses and feedback within the provided time frame. This method allowed us to address the research hypothesis by understanding the current trends of social media platforms and challenges in patient recruitment faced by the industries.

In conclusion, this research will add value from the results obtained to the field of clinical research for patient recruitment for NASH.

3.7.5 Research Data Collection

Data collection & analysis are the heart of the research and an important decision. Here, I have used qualitative (interview) and quantitative (survey) methods for data collection. Data Analysis is a process of analyzing & presenting the data which helps to derive meaningful insights for the research conducted (Soegaard, 2024).

The Qualitative Method includes data collection through interviews using the Zoom Meetings platform. The interviews helped to understand individuals' experiences and their expertise. The experts were from clinical research industries and healthcare providers who were approached through LinkedIn & WhatsApp and expressed their interest in participating. The participants were provided with a participant information leaflet (PIL) and an Informed Consent form (ICF).

The semi-structured interviews were chosen, and after the participants signed the informed consent. They were provided a pre-defined list of questions to explore different ideas, and interviews were scheduled based on the interviewee's convenience and availability. During the conversation in the interview, the flexibility of probing helped to gain more in-depth details from the interviewees to share their observations and experiences. The experts also provided innovative ideas to tackle the patient recruitment challenges & NASH (Alele and Malau-Aduli, 2023). The interviews were conducted from 22nd Jul to 02 Aug 2024, and the feedback received from the experts was recorded. The information was then transcribed, coded, and analyzed to meet the research questions and objectives.

The Quantitative Method includes data collection through surveys. In Clinical research, the survey method was more appropriate for the collection of opinions, beliefs, motivations, and barriers from the public. The questionnaires were designed in Google Forms, which included closed-ended questions, numerical rating scales, symbols, and adjective scales to make them more conversational and easier to respond to.

The platform provided the flexibility to collect the responses anonymously from the target population & cost-effectively analyze the data. Since quantitative data is numerically based the data was quantified & analyzed using statistical software such as t-test, chi-square, and SSPS software (Soegaard, 2024).

3.7.6 Research Data Analysis

The data analysis can be divided based on research methods.

- Thematic analysis: For the Qualitative method, the data analysis was through thematic analysis.
- Statistical Analysis: For the Quantitative method, the data analysis was done through statistical methods.

❖ **QUALITATIVE METHOD:** The data collected through interviews are analyzed into 04 parts

- Transcription
- Coding
- Themes Identification
- Final Analysis

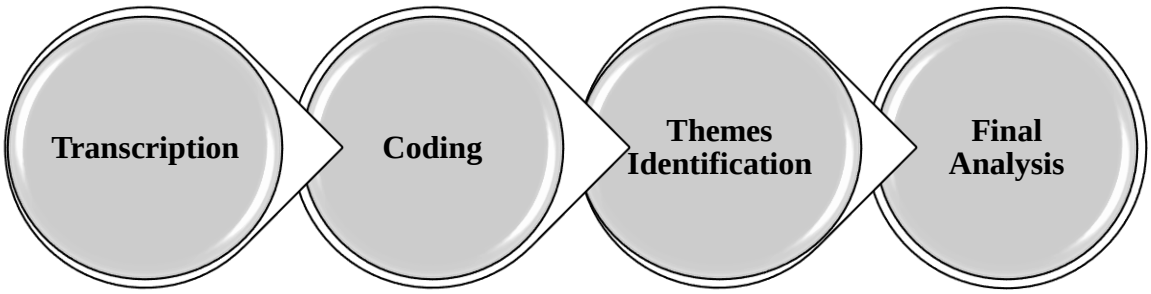
Transcription is the first step in the analysis. During the Zoom meeting, the captions option was turned so that it became easier to capture the phrases and themes. The captions generated were converted from a text document to a Word document. For each transcription, the interviewers were given “I" and the interviewee respondent R.

Coding is the next step in the analysis. Depending on the number of interviews taken to do the coding process, Microsoft Excel was chosen. The codes were assigned:

- Interviews: Each Interview taken was indicated and assigned a numerical number. Ex: CRP-01
- Question & Answers from Respondent: The interview question was indicated as IQ, and the Respondent as R. The answers from the respondents were transcribed to find the correlation between the responses.

Themes Identification is the last step in the analysis. The most important is to identify key themes from the information obtained from the interviewees. From the recordings, I have identified the most relevant information provided by the clinical research experts, which makes it easier to complete the work. Finally, the themes identified were assigned with reference numbers.

Final Analysis: From the interview, numerous themes were identified, but the relevant ones were grouped. These grouped themes were closely analyzed with the secondary data, which helped to answer research questions and objectives.



[Figure 13 *Alele and Malau-Aduli, 2023- Data Analysis for Qualitative Analysis***]**

QUANTITATIVE ANALYSIS: The survey questions can be divided into 04 parts for the analysis

- The **first part of the survey** is to ask the participants about the social media platforms:

- Do you use social media platforms?
- Which social media platforms do you use the most for health-related information?
- What time of the day do you usually browse social media for health information?
- How often do you use social media?
- How much time do you spend on social media daily during festive seasons?

With these questions, we can analyze how many participants use social media platforms, which platforms they use the most to read health information, and the frequency of using these platforms.

- The **second part of the survey** is to ask the participants about the advertisements and their engagement with social media platforms.

- How often do you notice advertisements on social media?
- What types of content do you find most engaging on social media
- How often do you engage with content shared by others on social media?
- Do you share health-related content on your social media?
- Who do you primarily share information with on social media?
- How often do you share information on social media?

With the above questions, we can analyze what kind of content helps people to understand health information and where & who they share the information.

- The **third part of the survey** focuses on asking about NASH awareness

Where do you usually get your health information from

- Have you heard of NASH fatty liver disease before seeing this post
- How would you rate your awareness of NASH
- What do you think could be the primary risk factors for developing NASH
- Which social media platform would you use to share information about NASH
- What type of information about NASH would you find most useful to share?
- How likely are you to recommend others to learn more about NASH

From the above questions, we can analyze if the participants have come across NASH, their perspectives, and whether they are willing to share the information with others about NASH.

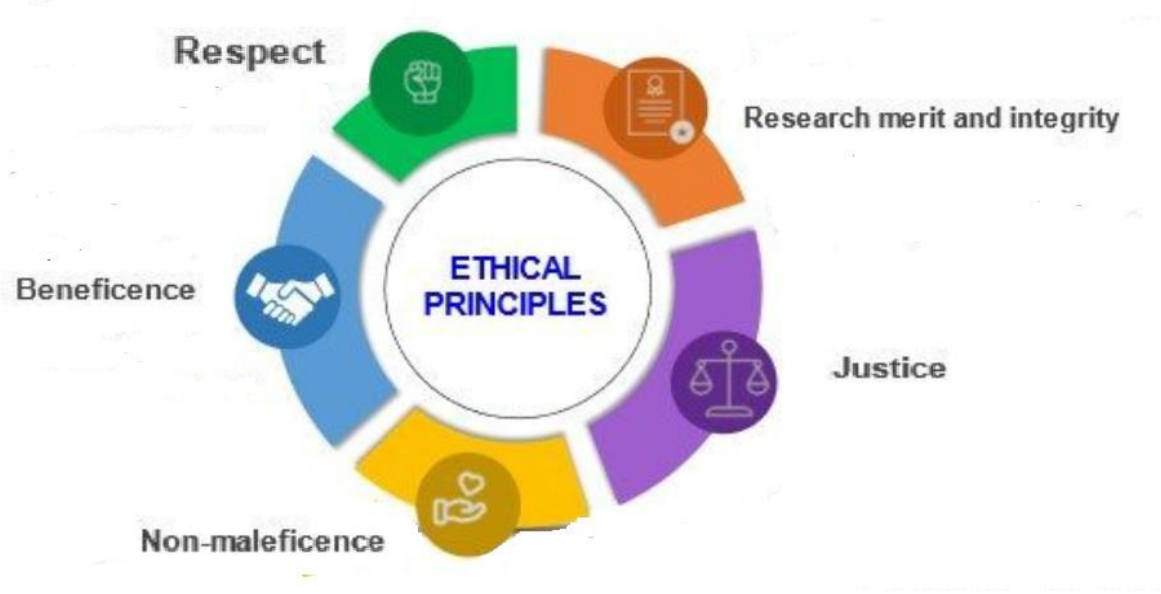
- The **last part of the survey** deals with NASH clinical trials.

- How familiar are you with clinical trials?
- What would motivate you to participate in a clinical trial?
- What concerns do you have about participating in clinical trials?
- What method of communication would be most effective in informing you about clinical trials?
- How likely are you to participate in a clinical trial if you receive the information through your preferred method of communication?
- What sources of information do you trust the most about clinical trials?
- How likely are you to share information about clinical trials for NASH with others?
- What motivates you to share clinical trial information for NASH

With these, we can analyze if the participants are aware of clinical trials, their concerns, their willingness to participate what is the mode of communication, and what sources they trust the most for clinical trials. Finally, what would motivate participants to share NASH Clinical trial information with others?

3.8 Ethical Principles & Considerations

Before any research is started, it is essential to submit the ethics document to ensure the researcher adheres to the ethical principles as it involves human interactions. For this research, interviews were conducted, and surveys were distributed after the ethics document received approval from the institution. The general ethical principles followed for this research are



[Figure 14 *Alele and Malau-Aduli, 2023), Principles of research ethics***]**

- **Respect for the Persons:** Participants had the right to make decisions based on their beliefs and values.
- **Beneficence**: This is to ensure the researcher promotes and protects the well-being of the participants.
- **Non-maleficence**: It is to ensure we avoid or minimize harm that is liable to affect the research participants.
- **Justice**: To ensure all the participants are treated fairly and minimize bias.
- **Research Merit & Integrity**: It's the researcher's responsibility to adhere to standards of integrity and ensure the research is conducted with quality & transparency.

To carry out this research the following ethical principles were considered.

Survey Participants: The survey's distribution message included a disclaimer message, Please note that your participation in this survey is completely anonymous, and we will not collect or retain any personally identifiable information. Furthermore, there was a brief description provided about the research topic to make the participants understand before they took the survey. The survey started with the first question "Do you voluntarily choose to participate in this research? so that they could proceed to complete the questionnaires.

Interview Participants: The participants were requested to share their email IDs. The participant's information leaflet provided a clear description of the research. The informed consent was also attached in case the participants were interested in participating they can sign the consent form and send it back to the researcher to share their opinions and experiences.

Storage of Interview Data: All the data collected through interviews are recorded and stored in a password-protected laptop and maintained as per confidentiality standards. The

interviewees were also informed that the data would be stored until the completion of research and a minimum of 02 years.

3.9 Conclusion

To conclude, this research methodology is based on the research onion framework helps to explore the impact of social media and patient recruitment challenges in NASH Clinical trials. The combination of positivism and interpretivism helps to study objective and subjective experiences. The mixed method combines qualitative & quantitative and provides an overview of recruitment challenges faced by clinical research experts and public awareness about NASH & clinical trials. Data collection is carried out through interviews and surveys whereas the data analysis is carried out through thematic and statistical methods. Finally, the ethical principles are considered to protect participants' privacy and promote transparency.

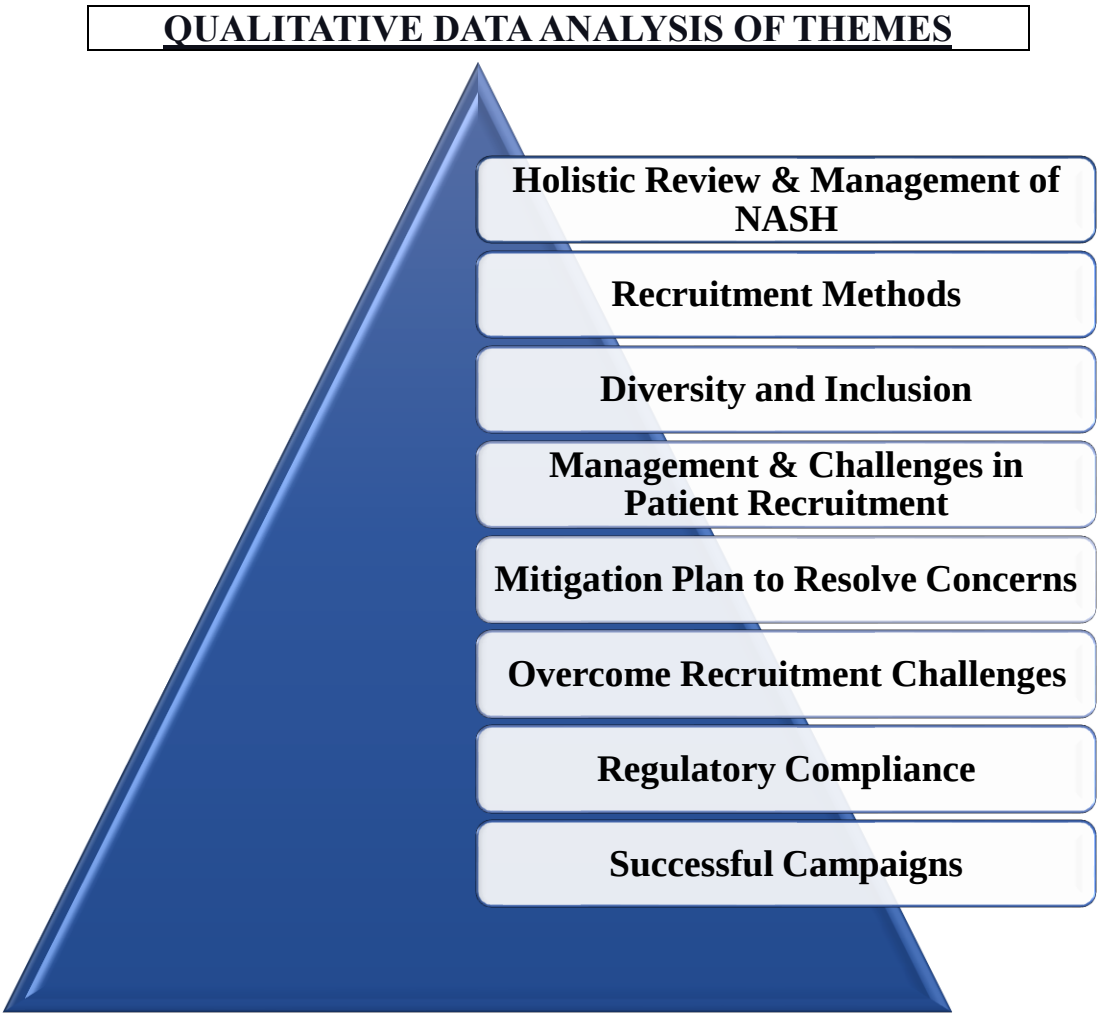
CHAPTER-04 FINDINGS AND ANALYSIS

The findings and analysis in this chapter are divided based on the Qualitative & Quantitative Approach.

4.1 Data Analysis for Qualitative Method

For the Qualitative Method, the interviews were conducted with healthcare professionals to draw insights about NASH, and patient recruitment challenges in clinical trials were discussed with Clinical Research Professionals.

From the interviews conducted, the key themes identified are



[Figure 15 *Thematic Analysis- Based on Qualitative Analysis By the Author***]**

4.1.1 Theme One: Holistic Review & Management of NASH

The HCP stated that NASH is a Fatty Liver Disease where fat accumulates in the liver Pfizer (2024). There are different stages in NASH:

- Grade-01 to Grade-02 Fatty Liver

- Fibrosis
- Liver Cirrhosis
- Liver Carcinoma

Symptoms: The symptoms observed in NASH patients are Yellow Eyes [*Inventiva Pharma* (2024)]

- Skin Jaundice
- Dark Yellowish Urine
- Swelling Tummy
- Blood Vomiting
- Black Stools
- Itchy Skins

Risk Factors: Some of the risk factors for NASH are

- Diabetes
- Obesity
- Hypertension
- Metabolic Syndrome
- Triglycerides
- Genetics
- Weight Loss
- Insulin Resistance
- Aging
- HDL Cholesterol

The HCP stated they advised the patient to undergo the following diagnosis to evaluate the condition of the liver:

- Advise patient for the following Scans
- Ultrasound Scan
- CT Scans
- Sonography to view the condition of the liver
- Blood Reports

Based on the reports, HCP advised the patient of the following lifestyle changes

- Having a balanced diet
- Increase Their Physical Activities- 45minutes of exercise
- Regular Health Check-Up & obtaining the opinion from a Liver specialist
- Healthy Weight Loss
- Lowering Triglycerides through diet & Medication
- Avoid Alcohol
- Diabetic Patients- Control Glucose levels

When asked how the HCP educates the patients about NASH, they communicate directly with the patients. Hence, they understand the Fatty Liver disease so that they follow a healthy diet and have regular exercise, which can reverse the condition of NASH.
One of the challenges encountered when educating the patients was the language so the HCP stated that the information about NASH was communicated in their native language.

The HCP stated they don't recommend the patients to clinical trials but they provide Homeopathic Medicines. There was a patient diagnosed with Grade 03 Fatty Disease, they were provided with Homeopathic Medicines for 1.5 months where the condition.

Discussion of Theme One: NASH is a health concern that is affecting millions of people around the world. As highlighted by the HCP the fatty liver can progress from steatosis to cirrhosis (Pfizer, 2024).

NASH is recognized as a silent disease. The common symptoms observed are jaundice, abdominal swelling, and other GI symptoms (Inventiva Pharma, 2024). Depending on the symptoms HCP recommends the patients undergo diagnosis as Ultrasound & CT scans which help to prevent the progression of the liver disease.

The risks identified for NASH are obesity, hypertension, diabetes, and other metabolic diseases (Pfizer, 2024). Considering the risks HCP advised the patients in their local languages which will help them to understand the disease to have regular exercise, a balanced diet, healthy weight loss, and control their glucose levels in the case of Diabetic patients. Though lifestyle changes are an option to reverse the condition, on the other hand, there are numerous clinical trials to bring novel therapies for NASH. Recently the FDA approved Rezdiffra (Madrigal, 2024) under the accelerated pathway to ensure the unmet needs of the society are met.

As the clinical trial continues to bring effective treatment it is essential to mitigate its impact on global health.

4.1.2 Theme Two: Recruitment Methods

One of the CRPs stated, "***Patient Recruitment: A bottleneck for every Clinical Trial" and "Strategy & Commitment To Achieve: Patient Recruitment Targets".***

Some of the sub-themes identified when asked what methods they implemented to recruit patients for clinical

- **Geographical Location**: Based on the locations, the CRP team collaborated with local physicians and established personalized engagements. This, was an effective strategy as the physicians had already established trust with the patients, was easy to refer potential candidates for clinical trials.
- **Patient Databases**: The second effective strategy was to utilize patient databases such as EHR (Electronic Health Records) and EMR (Electronic Medical Records). The potential candidates were identified using a keyword search and short-listed who might be eligible for clinical trials.
- **Secondary Databases**: The other databases used are Patient registries and ClinicalTrials.gov which helped to locate the patients who had similar medical conditions or who have expressed interest in participating in clinical trials.
- **Innovative Methods**: Social media platforms and online advertisements are effective strategies that make a difference in targeting specific demographic groups.

To further broaden the recruitment, they had partnerships to reach diverse populations

- **Vendor Systems**: Vendors are specialized in patient recruitment. Different vendor collaborations and strategies helped to identify potential participants.
- **Patient Advisory Group (PAG):** These groups help the sponsors design effective strategies to recruit patients and provide insights to overcome the recruitment challenges.
- **Community Campaign**: For campaigns, they used the traditional methods where they distributed flyers, and printed brochures that contained clinical trial information. Further, they translated the clinical trial information into local languages to be more inclusive and engage diverse communities. This process helped participants to understand about clinical trials and motivated them to participate in clinical trials.
- **Marketing Strategy**: The Ethics Committee ensures the advertising of clinical trial materials complies with the regulatory requirements so that the safety and rights of the patients are protected.

From the above, it was observed that clinical research professionals have different strategies to recruit patients for clinical trials.

Discussion of Theme Two: From the literature review [Moseson, Kumar, and Juusola (2020)] there was a comparative analysis done with traditional methods and virtual strategies. The finding revealed that virtual methods helped to create awareness and spread the clinical trial information at a faster rate and were more effective than conventional methods.

Further, there was a comparison made between, virtual methods [Moseson, Kumar, and Juusola (2020)] and the current methods adopted in the pharmaceutical industries by clinical research professionals.

Collaborating with healthcare professionals made referrals as an effective strategy for participants. On the other hand, patient databases like EHR & EMR helped to identify participants based on specific diseases. There were also community campaigns organized where flyers and advertisement materials were approved by the Ethics committee before they were distributed to the public.

The main advantage observed was that clinical trial information was translated into participants' local language which made it easier to understand the clinical information and to participate.

Furthermore, partnerships with different vendors and PAG provided insights into designing an effective patient recruitment strategy to reach diverse populations.

As technologies are improving, and novel diseases are evolving the strategies in the clinical research sector are taking the hybrid model, so social media platforms and online advertisements are effective methods when compared to other recruitment strategies.

4.1.3 Theme Three: Diversity and Inclusion

The three interview participants were asked whether they use social media platforms for patient recruitment and how they tend to recruit inclusive and diverse populations for clinical trials.

One of the CRPs stated, ***"Patient Recruitment- Yes, used Social Media Platforms as they are user-friendly when compared to other traditional methods such as distribution of flyers, emails, and telephone calls".***

The CRP stated that ***Instagram is a trending platform where the information shared is catchy and passed on the information to others. Some social media platforms are YouTube, WhatsApp, Twitter, Facebook, and Twitter.***

Another CRP stated that ***Social Media Platforms have become an increasingly important tool for recruiting patients.***

Comparing the literature review and discussions with Clinical Research professionals the following short themes were identified:

- **Diversity**: Social Media platforms are used as a recruitment tool to reach diverse populations and recruitment goals.
- **Target Right Participants**: These platforms have been an emerging trend that has enabled researchers to engage with the right participants.
- **Locations**: Irrespective of the geographical locations, social media has helped to reach diverse populations and different communities. The wide variety of content shared on these platforms helps to attract users.
- **Video content** made it easier for the participants to understand the clinical trial information. These platforms have been flexible and user-friendly which, helps to overcome the challenges in patient recruitment.
- **Virtual Engagements:** After, the covid times, virtual engagement has been more successful than in-person interactions; this is an advantage created by social media platforms to reach participants at their convenience and time frame. This is primarily for decentralized clinical trials.
- **Cost-Effective:** Social media platforms were found to be more user-friendly and cost-effective methods when compared to traditional methods.

In addition to social media platforms, there were other methods used by clinical research professionals

1. **Patient Registers & Community Groups**: The pharmaceutical companies partnered with these registries and groups to identify participants and reach diverse populations from different locations.
2. **Language Barriers**: This was a crucial step taken by the industries to translate the clinical trial information into their native language which made it easier to reach diverse populations. This allowed the individuals to participate in clinical trials.
3. **Training**: The CRP stated that the clinical patient recruitment team was trained to effectively communicate the information to the participants in their native language.

Discussion of Theme Three: From the literature review and the information gathered from the Clinical Research Professionals it has been observed that there is a specific emphasis on diversity to target the right participants from different geographical locations, and the existence of social media platforms such as Facebook, Instagram, YouTube, WhatsApp, and Twitter which are the emerging trends used by the pharmaceutical companies for patient recruitment.

The insights drawn from Ortner (et al., 2024) and CRP indicate that social media platforms are more flexible in breaking geographical barriers and accessing various communities to attract participants with engaging content that creates awareness about clinical trial information.

After the pandemic, there was a shift from traditional methods to virtual methods like social media platforms which became more effective and convenient to recruit participants for decentralized trials.

Social media has been a cost-effective method when compared to traditional methods [Baker, Mitchell, and Thomas (2022) and Ortner et al. (2024)] and also breaks the language barrier that helped to reach out to the minor communities.

Thus, we can conclude that social media platforms can be an effective strategy for patient recruitment for the present clinical trials.

4.1.4 Theme Four: Management & Challenges in Patient Recruitment

When asked how the CRPs manage patient recruitment, one of the CRPs stated that there are various EDC databases as tools to capture patient data and store and process the details. Since the clinical trials involve patients, it is essential to follow the regulatory guidelines based on the countries/regions and submit the regulatory documents. There are various tools and strategies to identify and engage potential patient participants some of the common ones are:

Tools- Identify Potential Participants	
Electronic Health Records	Electronic Medical records
Patient Registries	Patient Database with specific conditions- To identify potential participants
Tools- To manage & track diverse populations	
Social Media platforms	Data Collaboration Tools
Project Management Tools	Data Analytics Tools
Advantages of Strategic Tools	
Increases the efficiency	Improve the Accuracy
Enhance Potential Engagement	Better Tracking

[Figure 16 *Patient Recruitment Databases Based on Qualitative Data- By Author]*

When asked what the challenges encountered when recruiting the patients were, the CRP stated "Recruitment is a synonym for a challenge". The challenges encountered by the recruitment team are

1. **Commitment**: It is essential to select the right participants to meet the primary and secondary endpoints of the trials.
2. **Goals**: The patient recruitment method should be continuously monitored to achieve the recruitment goals committed to the project specifications.

3. **Survival of participants**: Patient recruitment ensures that participants are retained to complete the last visit of the clinical trials. It's their responsibility to monitor and provide supportive care during the trials.
4. **Drop-Out Rates**: During the trial, participants may encounter severe side effects due to the IMPs and personal circumstances that may lead to high drop-outs from clinical trials. So, it is essential to constantly communicate with the participants that helps to decrease the dropout rates.

The challenges encountered in understanding the participant's perspectives on clinical trials are

1. **Barriers**: Many participants are reluctant towards clinical trials due to mistrust or lack of awareness of the trial's purpose and benefits. Another challenge is to be lenient in eligibility criteria so that more diverse populations are included in clinical trials.
2. **Campaigns**: To create awareness about clinical trials it is essential to conduct educational campaigns where trial materials can be distributed to overcome the knowledge gaps.
3. **Phobias**: Fear is a common factor seen among the participants which includes personal expenses, travel constraints, hospitalization, and taking time out of work schedules. When these fear factors are addressed participants are willing to participate in clinical trials.

Finally, the challenge faced by the clinical sites are Operational Challenges. Clinical trials should be conducted as per the protocol, SOP, and guidelines that have been approved by the regulatory guidelines. Non-compliance with these guidelines will lead to failure in patient recruitment. So, it is necessary to provide regular training to ensure the personnel understand their roles and responsibilities to focus on a patient-centric approach.

Another CRP stated that we can overcome the challenges with the following solutions:

1. Clear Communication can help to bridge the knowledge gaps about clinical trials
2. Use simple materials to educate the patients
3. Simplify the eligibility criteria
4. Flexible schedules
5. Transport Assistance
6. Training for Clinical Staff
7. Streamline the Recruitment
8. Offer additional support to overcome the barriers

Discussion on Theme Four: Patient recruitment has always been a challenge for clinical trials (Wandile, 2023). From the literature review, it is observed that there are different challenges encountered by the sponsors, clinical sites, patient recruitment, and the participant's fear factors.

As the CRP stated participants face fear factors such as commitment to work schedules, travel constraints, placebo effect, fear of side effects, hospitalization, and other factors that discourage them from society. All these factors can lead to low recruitment, so patient recruitment needs to adhere to the regulatory-approved protocols, SOPs, and guidelines to overcome the challenges.

On the other hand, sponsors face there are challenges faced by clinical sites like budget constraints, which can limit reaching the diverse population, and sponsors' stringent eligibility criteria that can hinder the recruitment of potential participants.

To overcome these challenges patient recruitment needs to implement strategic solutions such as clear communication, simplifying the clinical trial educational material, and providing continuous support to the participants to complete all the scheduled visits and ultimately focusing on the staff training to engage with a diverse population to meet the recruitment goals which helps to bring novel therapies to the society.

4.1.5 Theme Five: Mitigation Plan to Resolve Concerns

The CRPs were asked how they resolved the concerns of the participants. One of the CRPs stated that every day is a new learning and an opportunity to resolve the issue uniquely.

The CRPs stated that ***the major concerns for the participants are safety & well-being, privacy protection, finance, logistic issues, and a patient-centric approach.***

- **Safety & Well-Being**: Many participants fear the side effects of the IMP and feel anxious about the trials. To mitigate this the clinical trial information & informed consent were simplified and translated into their local language so that the participants understand the risks and benefits of participation. This would allow the participants to make the right decision to participate or not in a clinical trial.
- **Privacy Protection**: Another concern of the participants is how their data is protected. The CRP stated that participants were explained the confidential guidelines on how their data is protected and stored as per the regulatory guidelines.
- **Finance**: Most of the participants are concerned about finance before they provide their consent to participate. The CRP shared that as per regulatory guidelines, the allocated compensation was transparently communicated to the participants, and clarified their concerns which led to positive participation in Clinical trials. Also, the team ensured they complied with regulations and did not encourage clinical trials as an earning platform.
- **Logistics**: The CRP stated that participants were also concerned about geographical location and traveling constraints which may affect their work schedule. To overcome these challenges, they ensured they went to the nearby local lab to provide their sample and later the samples were taken by the assigned vendor for further analysis.
- **Patient-Centric Approach** with Empathy & Compassion- Personalized attention to the participants-built trust and strong rapport to ensure they will be more comfortable participating in the clinical trial and retention becomes easier to reduce the dropout rates.

Addressing these concerns helped to create a positive environment for participants to know and participate in clinical trials.

Discussion of Theme Five: CRP plays an important role in addressing the concerns of the participants which included safety & well-being, privacy protection, finances, and logistical issues.

To mitigate these concerns the patient ensured the clinical trial information was simplified and translated to the native language based on the geographical location. Transparent

communication was the key to ensuring participants understood the risks & benefits of the clinical trials and how their personal data are protected as per regulatory guidelines. Based on the guidelines financial compensation was communicated and logistic concerns were resolved by having flexible schedules to reduce the travel burden.

Finally, being empathetic and paying personalized attention to the participants-built trust which created a positive environment for participants. Overall, the CRPs have contributed to have a positive impact on participants involved in clinical trials.

4.1.6 Theme Six: Overcome Recruitment Challenges

The CRPs were asked how they handle the situations when they don't meet the recruitment challenges.

One of the CRPs stated ***the recruitment challenge is complex & we ensure to always be on the wheels.***

Another CRP stated ***Social Media is a place to explore & enhance patient recruitment. Some of the complex challenges faced by the CRP's are***

1. **Recruitment** is a critical phase, and enrollment continues until it meets the requirements for a clinical trial. When sufficient participants are not met, then it hinders the statistical analysis and can impact the integrity of the clinical trials. The analysis shows a significant difference between the expected and the actual target of recruitment, indicating the patient recruitment strategy should align with the requirements of the clinical trials.
2. **Data-Driven Decision**: When the recruitment goals are not met, it is essential to perform the root cause analysis, which gives a detailed understanding to identify the issues. Based on the trend analysis, we can take proactive measures to adjust the recruitment strategies in making informed decisions.
3. **Timelines & Management:** There should be a strategic plan to track the recruitment progress, and a proactive approach to managing the participants. On the other hand, it enables team collaboration and effectively works as a team to address the obstacles & meet the recruitment timelines.
4. **Social Media Platforms:** As digital platforms are emerging for advertising and creating awareness, social media platforms are often overlooked. Using these platforms will help to reach a diverse population and will mark an innovative way to recruit participants for clinical trials.
5. **Flexibility in the Recruitment Criteria:** Stringent eligibility criteria can hinder potential participants so, it is essential to have flexible recruitment criteria that will enable to inclusion of a diverse population from different geographical locations, which can improve the recruitment strategies.
6. **Improvement**: Taking feedback from the team plays an important role in understanding the different barriers faced by the clinical sites and sponsors which helps to implement the corrective actions and continuously improve the process.
7. **Standardization**: It is always a best practice to establish a clear standard model that acts as a benchmark for all clinical sites to use these best practices to achieve recruitment targets.

Overall patient recruitment is a bottleneck for clinical which requires constant data analysis, proactive management & strategies to address the recruitment issues. As the digital platform progresses it is a good practice to embrace technology and use social media platforms to reach out to a diverse population which can create a positive impact and implement effective strategic methods for patient recruitment.

Discussion of Theme Six: Clinical Research Professionals face complex challenges to meet the recruitment goals. One of the CRPs shared a challenge where the drug had to be launched in a particular country. However, only 40% of recruitment was achieved, which led to a delay in the drug launch.

As per the CRPs, it is essential to perform the root cause analysis, and data analysis, and take feedback from the clinical site teams which are essential steps to improve the recruitment methods. Having effective timelines and management practices helps to track the progress & enables to building of a collaborative team to overcome the obstacles.

The digital trends cannot be overlooked as they can become the next game changer to reach diverse populations from different geographical locations which can be an efficient method to recruit participants.

Furthermore, the CRPs suggest practicing standard guidelines to overcome the barriers and continuously improve the recruitment process.

4.1.7 Theme Seven: Regulatory Compliance

Each country has its regulatory authorities and they ensure that the participants are protected (right, safety & well-being) when they participate in clinical trials. Examples of the regulatory authorities are

- The FDA (USA)
- Health Canada (Canada)
- EMA (Europe)

The CRPs were asked how they protect the participant's privacy details as per the regulatory guidelines. One of the CRP's stated ***Patient is always the priority when participants enter clinical trials and we adhere to regulatory guidelines to focus on patient safety and data protection.***

Some of the practices shared by the CRPs are

- **Documents**: For a clinical trial to be conducted the sponsors need to submit documents such as Protocol, Site monitoring plan (SMP), and Informed Consent to IRBs so that they deviate from the ethical guidelines, participants are protected and there are no unforeseen risks. The IBR continuously monitors whether the pharmaceutical industries are adhering to the regulatory protocols and also tracks the recruitment activities to ensure there is a transparent environment created for clinical trial participants.
- **Privacy Protection:** As per regulatory guidelines before the participant's details are recorded the informed consent is signed to adhere to the ethical guidelines, and comply with the regulations, also the participants are aware of how the data will be

collected, stored, and used for analysis as per the data governance practices. It is essential to monitor when using digital platforms such as social media platforms to protect the company's integrity and participant confidentiality.

- **Compliance Process**: Regulatory compliance is a commitment to ensure that clinical trials are conducted with integrity. There are dedicated regulatory compliance team to ensure the documents meet the regulatory standards before submission for approval. The CRPs stated that they continuously provide training to the staff to ensure the personnel understand their roles and responsibilities and follow best practices which ultimately focus on protecting patient safety.
- **Engagement**: Communication is the key that helps to engage the participants through the clinical trial process and this leads to retaining the participants and adhering to regulatory compliance. Another key is being empathetic and addressing the participant's concerns which builds trust and protects their identifiable data.
- **Audit Readiness**: It is essential to commit to ethical standards and meet the regulatory requirements that pave the way for a patient-centric approach in pharmaceutical companies.

Discussion of Theme Seven: Regulatory Compliance

The main focus in clinical trials is the participants and the regulatory authorities ensure that the participants are safe, data are secure and well-being are protected. Each country has its local regulatory authorities and IRB to track the clinical trial activities through the list of documents submitted by the sponsor companies. This helps the regulatory authorities to track the adherence to protocols and ethical standards.

Even before the participant's details are collected the CRPs ensure that they sign the informed consent form so that the participant is aware of the risks & benefits of the clinical trial and how the collected data will be stored and analyzed for regulatory submission. There are specific regulatory compliance teams who ensure CRPS are compliant with the regulatory guidelines and the team understands their roles and carries out responsibilities with due diligence.

The CRP team builds the participant's trust by giving one-to-one counsel and constantly supporting them to ensure they complete all the visits in clinical trials. So transparent communication played an important role in retaining the participants and reducing the dropout rates.

To conclude the CRPs, play a major role in ensuring participants are safe in clinical trials by adhering to all the regulatory guidelines and ethical standards which contributes to the overall conduct of clinical trials with integrity.

4.1.8 Theme Eight: Successful Campaigns

The CRPs were asked to share their experience handling successful campaigns and how they were managed.

CRP-01 experience: Before COVID-19, traditional methods such as flyers, pamphlets, and campaigns were implemented to attract potential participants. However, they came up with an effective strategy and designed a personalized approach that enabled the building of trust

through the effective communication skills of the CRP & helped to create awareness about clinical trials. Successful implementation of social media platforms was a cost-effective method that helped to reach a diverse population and through this, they were able to meet the recruitment targets, and the clinical trials were completed.

CRP-02 experience: Another CRP shared their experience of how they executed a successful campaign for rare diseases which is a challenge for patient recruitment. Some of the steps followed during this campaign are

1. Rare Disease is a challenge as there is a limited population affected by the disease. They created targeted ads on social media and also partnered with Patient Advisory Groups.
2. Simplified Questionnaires: The Questionnaires were designed to identify the right participants.
3. Visibility: To increase visibility posters and banners were installed in local healthcare hospitals which created awareness about clinical trials for rare diseases.
4. Trial Information: The educational material was translated into local languages which helped the clinical trial participants to understand the clinical trial information.
5. Social Media Platforms: Additionally using digital platforms such as social media helped to reach diverse groups and enroll potential participants.

Through this strategy, they gradually progressed every week and achieved the recruitment targets required to conduct trials for rare diseases. Additionally, they collected feedback from the participants which showed an 85% satisfaction rate indicating high response and awareness which helped to enroll the right participants.

CRP-03 experience: The CRP stated that "Marketing strategy through social media was a great success". They utilized social media platforms played a major role in patient recruitment and were successful in meeting the recruitment goals. Some tips shared by the CRP are

1. Targeted content to attract the participants
2. Streamlined the screening process
3. Interactive Videos- about Clinical Trials
4. Educational Materials: The trial information was translated and interpreted in the local language for a better understanding
5. Duration- 1.5 Months recruitment targets were met

Overall, the CRPs play a vital role in ensuring the participants are secure and at the same, they are compliant with the regulatory guidelines to recruit patients for clinical trials.

4.2 Data Analysis for Quantitative Method

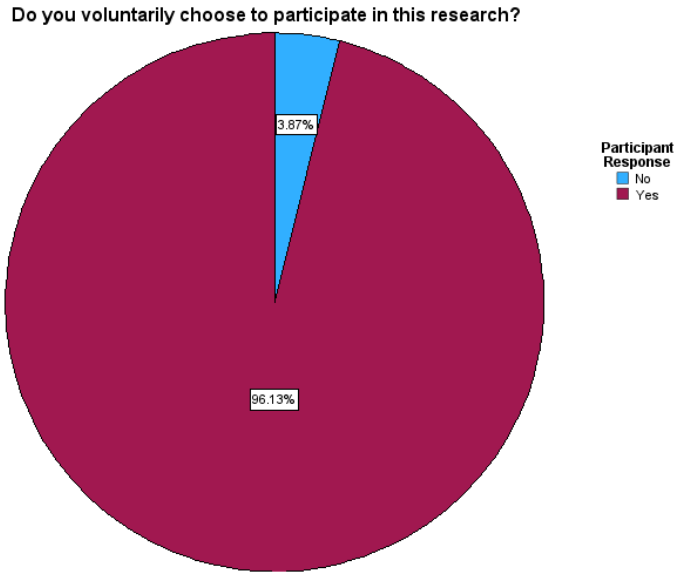
For the Quantitative Method, the surveys were conducted with the general public to draw insights about social media platforms used by the participants, their awareness of NASH, and perspective & attitudes about Clinical Trials.

QUANTITATIVE DATA ANALYSIS OF SURVEY RESULTS

Question 01 Do you voluntarily choose to participate in this research?

Do you choose to participate voluntarily?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	6	3.9	3.9	3.9
	Yes	149	96.1	96.1	100.0
	Total	155	100.0	100.0	



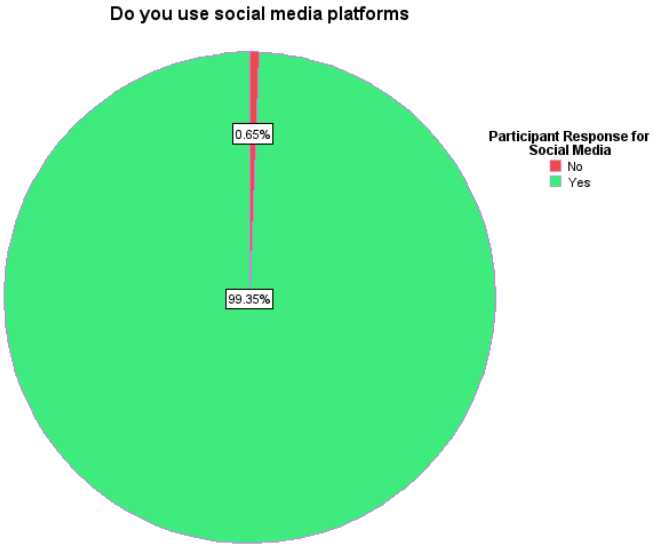
[Figure 17 *Survey 01- Survey Voluntary Participation]*

Question-01 Interpretation: There were a total of 155 people who participated in this research. A large number of participants (96.13%) chose to participate voluntarily which indicates their participation was of free will. On the other hand, there was a small fraction of participants (3.87%) who might felt compelled to participate or have misunderstood the question. So, from the response, it can be interpreted as there was a positive response from the general public.

Question 02 Do you use social media platforms (Facebook, Instagram, YouTube, LinkedIn)

Do you use social media platforms

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	1	.6	.6	.6
	Yes	154	99.4	99.4	100.0
	Total	155	100.0	100.0	



[Figure 18 *Survey 02- Use of Social Media]*

Question-02 Interpretation: Out of a total of 155 participants, 154 (99.4%) frequently use social media, which indicates that the participants have accepted these platforms that have a widespread effect on daily activities. On the other hand, only 01 (0.6%) of participants said they don't use social media. So, from the data obtained, we can interpret that social media platforms can used to study public preferences, attitudes, and trends towards NASH and Clinical Trials.

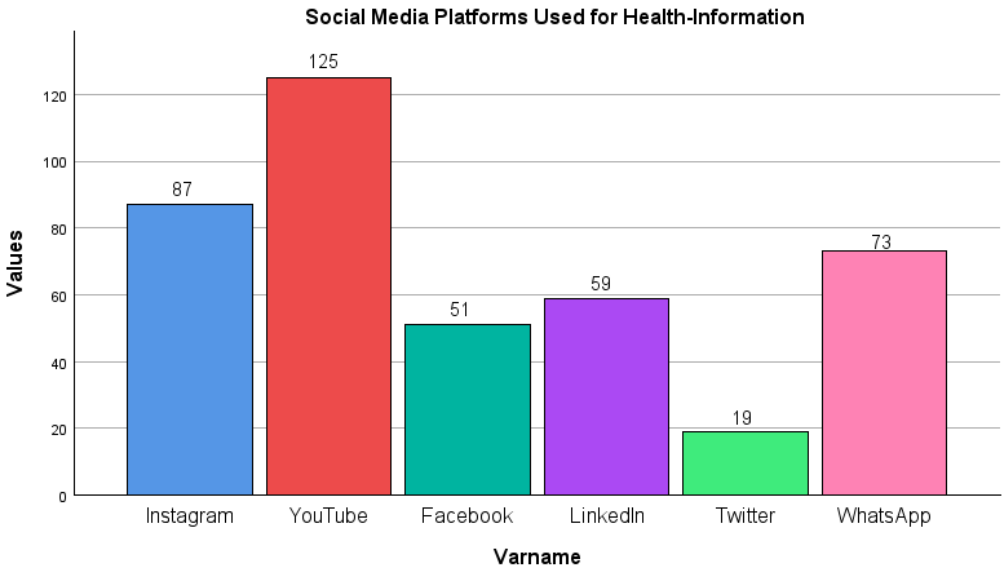
Question-03 Which social media platforms do you use the most for health-related information?

Question-03 Interpretation: Question-03 is a multiple-choice questionnaire where participants can select more than 01 response to see which is the most common platform used by the general public to know about health-related information. From the table, it is observed that the total percentage of participant responses (267.1%) exceeds 100%, which indicates that many participants use multiple social media platforms.

Social Media Platforms Used for Health-Information

		Responses		Percent of Cases
		N	Percent	
Social Media	Instagram	87	21.0%	56.1%
	YouTube	125	30.2%	80.6%
	Facebook	51	12.3%	32.9%
	LinkedIn	59	14.3%	38.1%
	Twitter	19	4.6%	12.3%
	WhatsApp	73	17.6%	47.1%
Total		414	100.0%	267.1%

In the SPSS software, multiple responses (Frequencies) analysis was used to analyze the data. From the above table, it is observed that YouTube (80.6%) is the most common platform used by participants, followed by Instagram (56.1%), WhatsApp (47.1%), whereas LinkedIn (38.1%), Facebook (32.9%), and Twitter (12.3%) have lower usage rates.



[Figure 19 *Survey 03- Social Media Platforms]*

From the figure, we wanted to check the most significant social media platforms "YouTube, Instagram & WhatsApp" so a chi-square test (Non-Parametric Analysis) was used to analyze the p-value.

Test Statistics

	YouTube	Instagram	WhatsApp
Chi-Square	58.226[a]	2.329[a]	.523[a]
df	1	1	1
Asymp. Sig.	<.001	.127	.470

a. 0 cells (0.0%) have expected frequencies less than 5. The minimum expected cell frequency is 77.5.

Based on the p-values for YouTube (<0.001), Instagram (0.127) & WhatsApp (0.470) indicate that YouTube is statistically significant and the most used social media platform for health-related information when compared to Instagram & WhatsApp.

Question 04 What time of the day do you usually browse social media for health information?

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
Morning	155	0	1	.13	.336
Afternoon	155	0	1	.10	.305
Evening	155	0	1	.33	.471
Night	155	0	1	.44	.498
Valid N (listwise)	155				

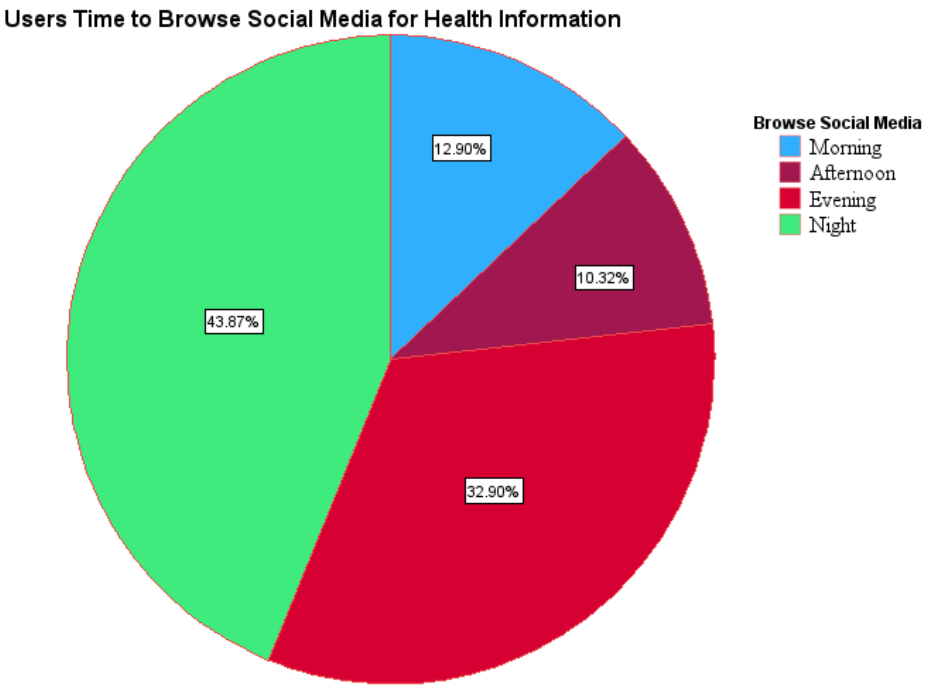
Question-04 Interpretation: Question-04 determines what time of the day the participants browse social media platforms for health information, whether it is morning, afternoon, evening & night.

Time Frequencies to Browse Social Media for Health-Information

		Responses		Percent of Cases
		N	Percent	
$Time[a]	Morning	20	12.9%	12.9%
	Afternoon	16	10.3%	10.3%
	Evening	51	32.9%	32.9%
	Night	68	43.9%	43.9%
Total		155	100.0%	100.0%

a. Dichotomy group tabulated at value 1.

From the above table, it is observed that most of the participants browse at night (43.9%) when compared to evening (32.9%), afternoon (10.3%), and morning (12.9%).



[Figure 20 *Survey 04- Social Media Platforms- User Times]*

From the figure, we interpret the data that Night is the most popular time followed by evening, afternoon, and morning. This trend can be due to many factors such as participants may have a busy schedule during the day, so evening & night can be the most convenient time to freely browse health information. On the other hand, morning and afternoon are considered fewer common times to browse health information.

Question 05 How often do you use social media?

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
Multiple times a day	155	0	1	.85	.363
Once a day	155	0	1	.10	.297
A few times a week	155	0	1	.03	.177
Rarely	155	0	1	.02	.138
Never	155	0	1	.01	.080
Valid N (listwise)	155				

Question-05 Interpretation: Question 05 determines how frequently the participants use social media, whether multiple times a day, once a day, a few times a week, rarely, or never.

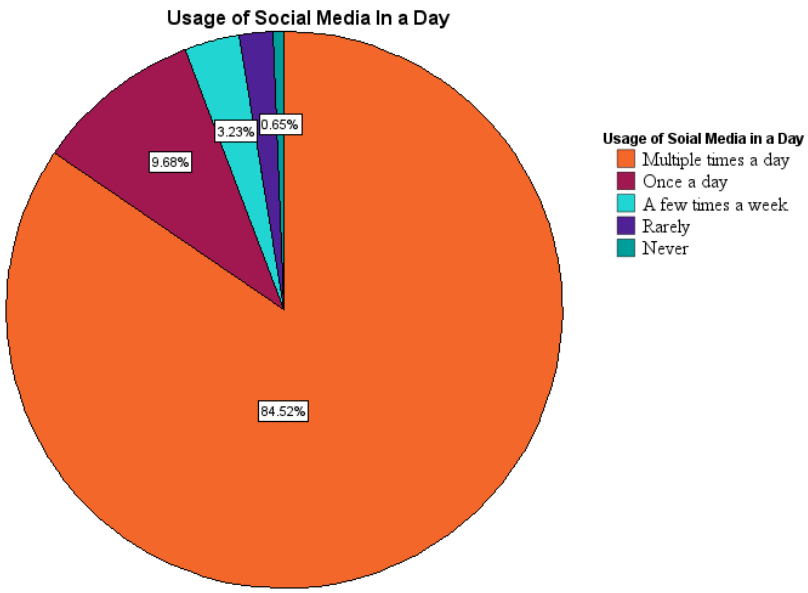
Usage of Social Media

		Responses N	Responses Percent	Percent of Cases
$Usage[a]	Multiple times a day	131	84.5%	84.5%
	Once a day	15	9.7%	9.7%
	A few times a week	5	3.2%	3.2%
	Rarely	3	1.9%	1.9%
	Never	1	0.6%	0.6%
Total		155	100.0%	100.0%

a. Dichotomy group tabulated at value 1.

The majority of the participants use social media multiple times a day (84.5%), which indicates they rely on these platforms to engage in various activities such as getting the latest news, sports, health, networking with people, education, learning, and marketing promotions. Earlier social media was known for connecting with friends & entertainment, but the trends indicate that social media platforms have become a part of everyone's lifestyle checking social media first thing in the morning and ending their day with it.

The other responses were once a day (9.68%) indicating that they use social media but in a controlled to stay updated with current affairs; a few times a week (3.23%), rarely (1.9%) & never (0.6%) indicates that the participants are selective to specific contents & engage less frequently or do not choose to engage in social media platforms.



[Figure 21 *Survey 05- Social Media Platforms- Usage]*

From the data analysis of social media usage patterns, there is a strong indication that the frequency of using these platforms multiple times a day serves as a primary source of communication and the participants engage in different contents. Overall, the data highlights a significant impact on modern lifestyles influencing how people connect and interact with each other around the globe.

Question 06 How much time do you spend on social media daily during festive seasons?

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
Less than 1 hour	155	0	1	.20	.401
1-2 hours	155	0	1	.38	.487
2-3 hours	155	0	1	.21	.411
More than 3 hours	155	0	1	.21	.406
Valid N (listwise)	155				

Question-06 Interpretation: Question 06 determines how frequently the participants use social media during the festive season.

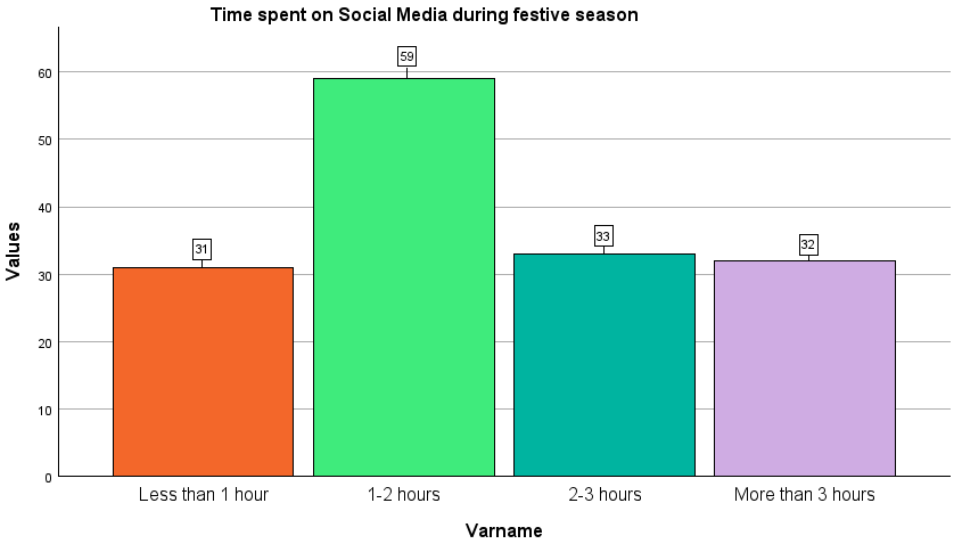
Time spent on Social Media during Festive Season

		Responses		Percent of Cases
		N	Percent	
$FestiveSeason[a]	Less than 1 hour	31	20.0%	20.0%
	1-2 hours	59	38.1%	38.1%
	2-3 hours	33	21.3%	21.3%
	More than 3 hours	32	20.6%	20.6%
Total		155	100.0%	100.0%

a. Dichotomy group tabulated at value 1.

From the statistics, we observe the amount of time spent during the festive season is 1-2 hours (38.1 %), which indicates that they moderately engage in social media platforms. Some participants have responded that they use less than 01 hours (20%) or more than 03 hours (20.6%), which indicates the diverse level of engagement. Some participants have limited usage, while others deeply immerse themselves in social media during festive seasons.

There is another group of participants who spend 2-3 hours (21.3%) on social media platforms which indicates extended engagement during festive seasons



[Figure 22 *Survey 06- Social Media Platforms- Usage During Festive Season]*

The data analysis shows that participants spend approximately 1-3 hours on social media platforms during the festive season. The other group of participants spent less than an hour; while the remaining participants spent more than 03 hours, which indicates that social media platforms play an important role during the festive season. These responses show how social media has impacted the participant's personal and cultural activities, even during festive times of the year.

Question 07 How often do you notice advertisements on social media?

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
Always	155	0	1	.40	.491
Often	155	0	1	.36	.482
Sometimes	155	0	1	.17	.381
Rarely	155	0	1	.04	.194
Never	155	0	1	.03	.159
Valid N (listwise)	155				

Question-07 Interpretation: Question 07 determines how often the participants notice advertisements on social media platforms whether it's always, often, sometimes, rarely, or never.

One group of participants noticed advertisements always (40%), which suggests that advertisements are unavoidable and contents do influence what they encounter on social media platforms.

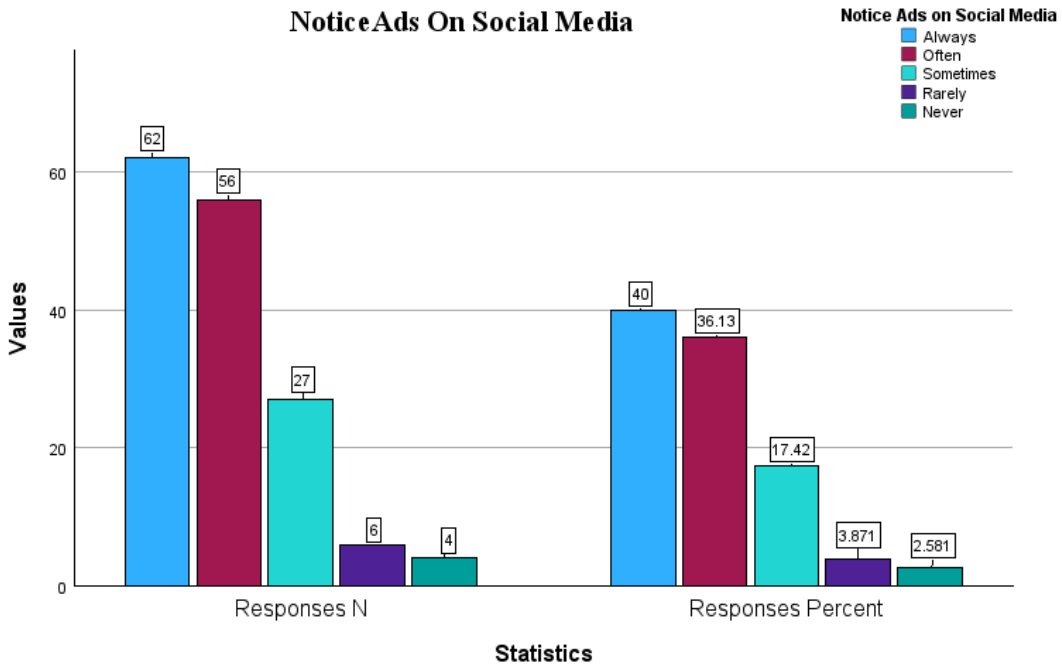
Another group said they (36.1%) encountered advertisements frequently which indicates that there is high exposure to advertisements which is part of the social media platforms experience.

Notice Advertisements on Social Media

		Responses		Percent of Cases
		N	Percent	
$NoticeAds[a]	Always	62	40.0%	40.0%
	Often	56	36.1%	36.1%
	Sometimes	27	17.4%	17.4%
	Rarely	6	3.9%	3.9%
	Never	4	2.6%	2.6%
Total		155	100.0%	100.0%

a. Dichotomy group tabulated at value 1.

Some participants noticed advertisements sometimes (17.4%) which indicates they ignore them or are not influenced by the social media content. The other two groups rarely (3.9%) & never (2.6%) indicate that they are not exposed to social media ads or they would have customized their content by using ad blockers.



[Figure 23 *Survey 07- Notice Ads on Social Media Platforms]*

An overall response (76%- Always & Often) indicates that advertisements are a highly visible component on social media and reach a diverse population. The participants may be influenced by the content posted on these platforms. The other part of the response (24%- Sometimes, Rarely & Never) indicates that though the advertisements are visible they are selective in engaging with social media contents which minimize exposure to these ads. From the data analysis, we can conclude that advertisements through social media platforms can reach a diverse population.

Question 08 What types of content do you find most engaging on social media?

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
Videos ads	155	0	1	.70	.458
Image ads	155	0	1	.45	.499
Blogs/ Articles	155	0	1	.43	.496
Podcasts	155	0	1	.35	.478
Webinars	155	0	1	.20	.401
Interactive Quizzes	155	0	1	.21	.411
Valid N (listwise)	155				

Question-08 Interpretation: Question 08 determines what type of content the participants find more engaging on social media platforms whether it's Video ads/ Image ads/ Blogs/ Articles/ Podcasts/ Webinars or Interactive Quizzes.

Type of Contents Engaging on social media

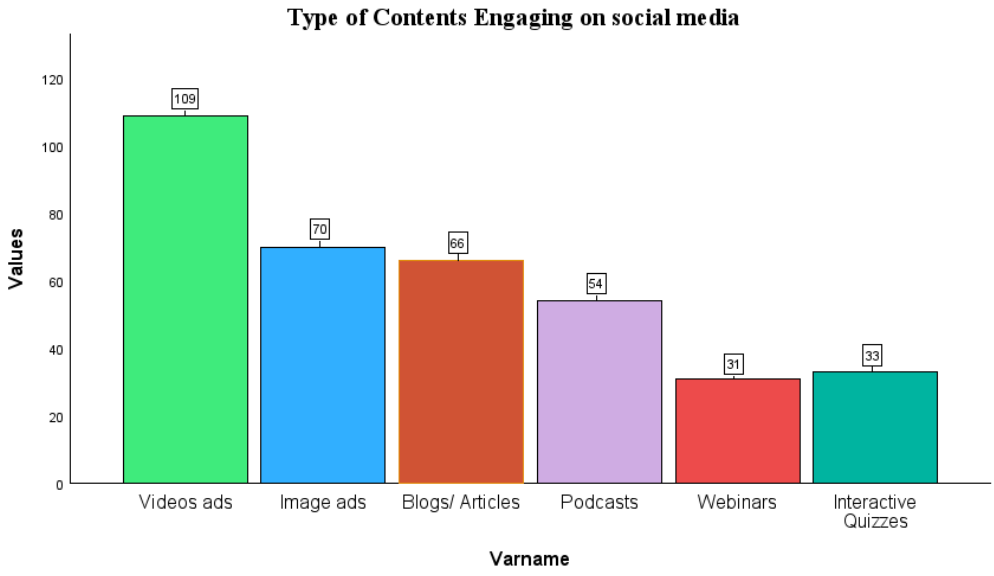
		Responses		Percent of Cases
		N	Percent	
$TypeofContents[a]	Videos ads	109	30.0%	70.3%
	Image ads	70	19.3%	45.2%
	Blogs/ Articles	66	18.2%	42.6%
	Podcasts	54	14.9%	34.8%
	Webinars	31	8.5%	20.0%
	Interactive Quizzes	33	9.1%	21.3%
Total		363	100.0%	234.2%

a. Dichotomy group tabulated at value 1.

From the survey results, 70% of the participants find video ads to be the most engaging content on social media platforms. This indicates that video content is a more effective method of capturing users' attention because visualization always conveys the message through a storytelling format. The second highest content was the Image ads (45%) which also play a significant role, unlike video ads. This was followed by Blogs/Articles (42.6%) indicating that written information on social media platforms still holds a considerable place and that most participants seek in-depth information.

Some participants feel podcasts (34.8%) have more engaging audio content due to convenience and enable users to capture information while they are engaged with multitasking. The other two responses were webinars (20%) & interactive quizzes (21.3%)

where participants still chose to be engaged with educational materials and interactive content.



[Figure 24 *Survey 08- Types of Contents on Social Media Platforms]*

From the data analysis we can interpret that video and image ads dominate through visual interactions and keep the users engaged on social media platforms. While the visualization captures users' attention still participants are engaged with blogs, podcasts & other formats which indicates that they absorb information through various contents based on their interests. Interactive quizzes & webinars still attract a smaller group of participants through educational content. This diversity of various contents can help to reach a diverse population based on user's preferences and interests through social media platforms.

Question 09 How often do you engage with content shared by others on social media?

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
Multiple times a day	155	0	1	.43	.496
Once a day	155	0	1	.19	.391
A few times a week	155	0	1	.17	.375
Once a week	155	0	1	.03	.159
A few times a month	155	0	1	.03	.159
Rarely	155	0	1	.17	.375
Valid N (listwise)	155				

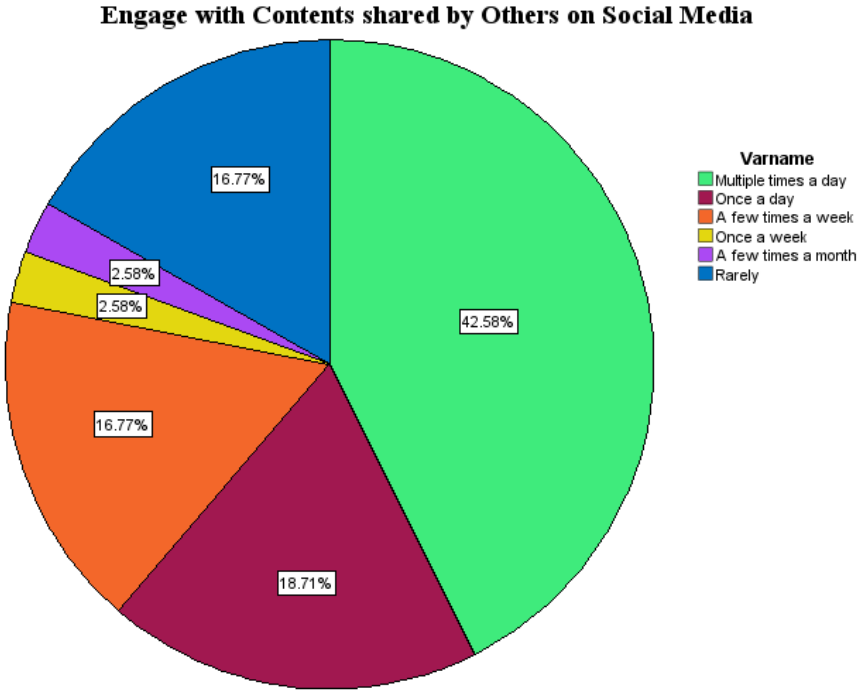
Question-09 Interpretation: Question 09 determines how frequently they engage with content shared on social media platforms.

Engage with Contents shared by Others on Social Media

		Responses		Percent of Cases
		N	Percent	
$EngageOtherContents[a]	Multiple times a day	66	42.6%	42.6%
	Once a day	29	18.7%	18.7%
	A few times a week	26	16.8%	16.8%
	Once a week	4	2.6%	2.6%
	A few times a month	4	2.6%	2.6%
	Rarely	26	16.8%	16.8%
Total		155	100.0%	100.0%

a. Dichotomy group tabulated at value 1.

Most participants engage multiple times a day (42.6%) with content shared on social media platforms, which suggests that users are highly active and regularly interact with different content shared by other users. The other participants responded they engaged with content once a day (18.7%) while others few times a week (16.8%), once a week & a few times a month (2.6%), and rarely (16.8%), which indicates that the users are less active and less interactive on social media platforms.



[Figure 25 *Survey 09- Engage Contents On Social Media]*

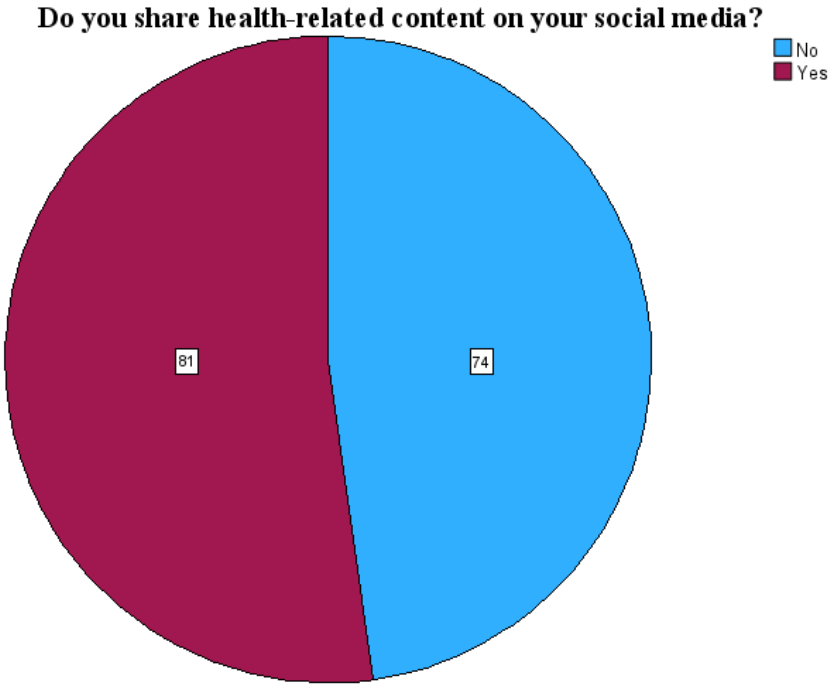
From the data analysis, users on social media platforms engage with various content shared by other users. Though there is significant engagement by users' multiple times a day & daily for different content. However, there is another group of participants who engage less frequently on social media platforms. By recognizing these patterns, we can customize the content strategically to study users' behaviours on social media platforms.

Question 10 Do you share health-related content on your social media?

Do you share health-related content on your social media?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	74	47.7	47.7	47.7
	Yes	81	52.3	52.3	100.0
	Total	155	100.0	100.0	

Question-10 Interpretation: Question 10 determines if participants share health-related content on social media platforms.



[Figure 26 *Survey 10- Share Contents On Social Media]*

From the survey results, 81 participants (52.3%) said they share the content on social media platforms & 74 participants (47.7%) don't share health-related content.

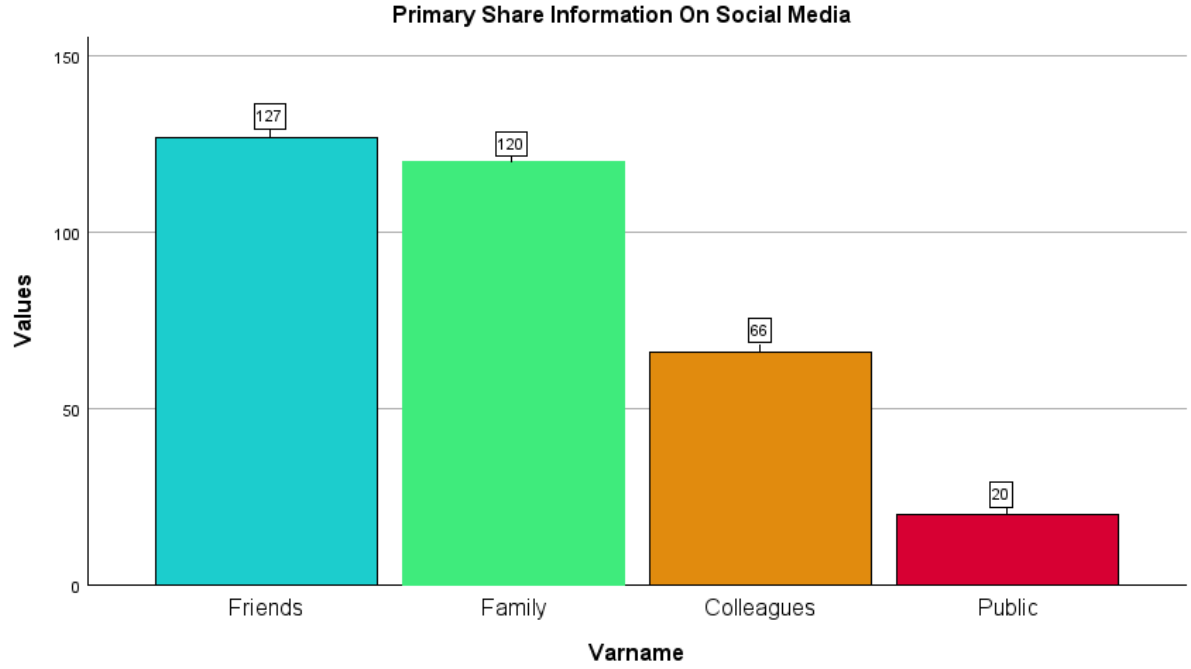
Question 11 Who do you primarily share information with on social media?

Primary Share Information On Social Media

		Responses		Percent of Cases
		N	Percent	
$Information[a]	Friends	127	38.1%	83.0%
	Family	120	36.0%	78.4%
	Colleagues	66	19.8%	43.1%
	Public	20	6.0%	13.1%
Total		333	100.0%	217.6%

a. Dichotomy group tabulated at value 1.

Question-11 Interpretation: Question 11 determines with whom participants share the information on social media platforms.



[Figure 27 *Survey 11- Primarily Share Information On Social Media]*

From the survey results, participants primarily share the information with friends (83%). The second highest response was from family (78.4%), followed by colleagues (43.1%) and the public (13.1%).

Overall participants mainly share the information with friends and family however, a smaller group share with colleagues and the public.

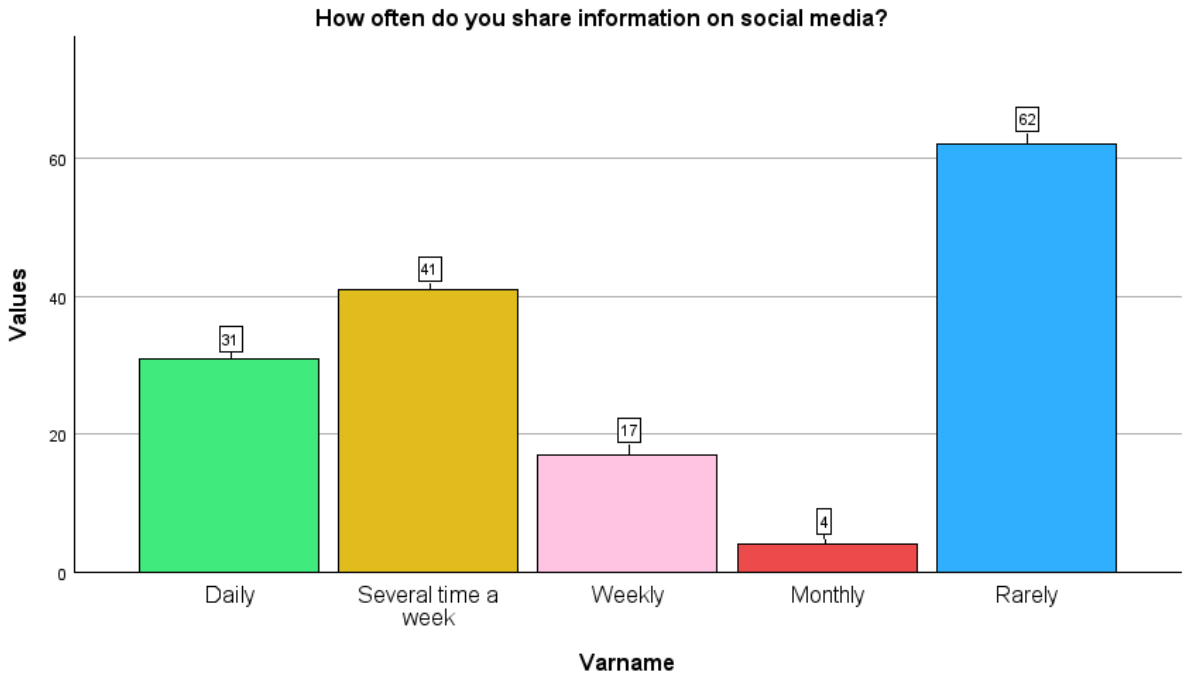
Question 12 How often do you share information on social media?

How often do you share information on social media?

		Responses		Percent of Cases
		N	Percent	
$Information[a]	Daily	31	20.0%	20.0%
	Severaltimeaweek	41	26.5%	26.5%
	Weekly	17	11.0%	11.0%
	Monthly	4	2.6%	2.6%
	Rarely	62	40.0%	40.0%
Total		155	100.0%	100.0%

a. Dichotomy group tabulated at value 1.

Question-12 Interpretation: Question 12 determines how frequently participants share information on social media platforms, whether Daily/ Several times a week/ Weekly/ Monthly or Rarely.



[Figure 28 *Survey 12- Frequency of Sharing on Social Media]*

From the data analysis we can observe that the most common frequency of sharing the information is rarely (40%) followed by several times a week (26.5%), which suggests that participants share the information infrequently. On the other hand, a smaller group of participants share information daily (20%), weekly (11%) & monthly (2%), which suggests that information is shared on an interval basis.

Question 13 Where do you usually get your health information from?

Where do you usually get your health information from

		Responses		Percent of Cases
		N	Percent	
$HM[a]	Social Media Platforms	100	32.9%	64.5%
	Health care providers	87	28.6%	56.1%
	Friends and family	84	27.6%	54.2%
	Advertisements	22	7.2%	14.2%
	Other specify	11	3.6%	7.1%
Total		304	100.0%	196.1%

a. Dichotomy group tabulated at value 1.

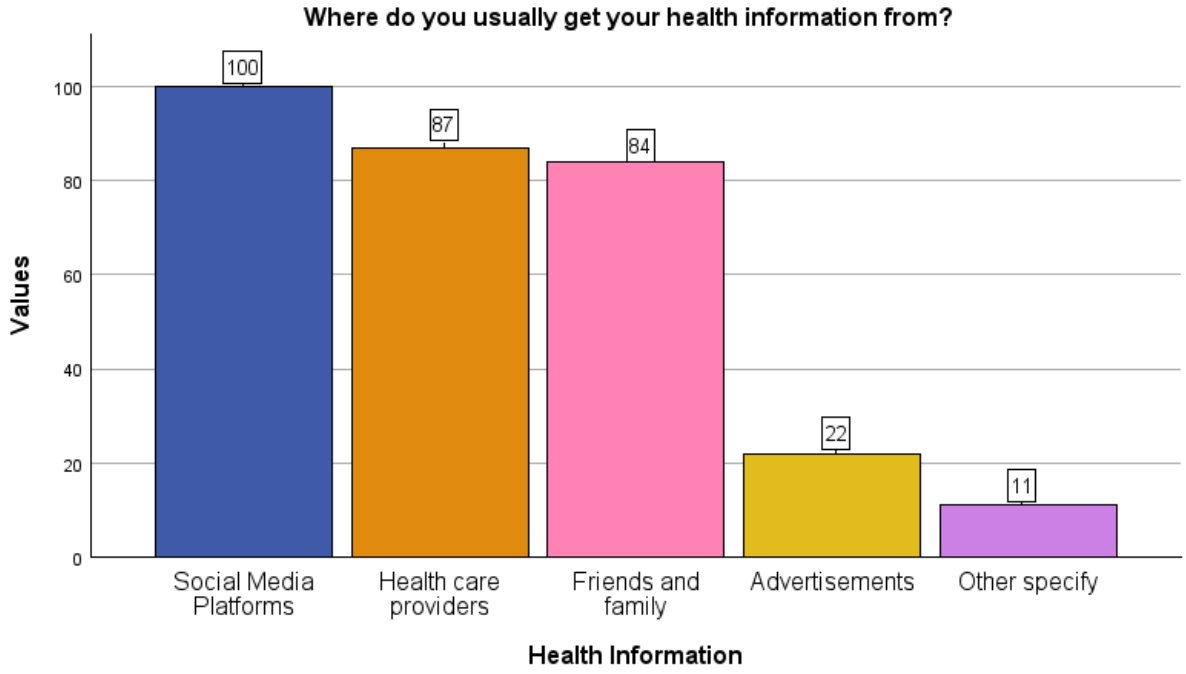
Question-13 Interpretation: Question 13 determines where the participants get the health information from Social Media Platforms/ Health Care Providers, Friends and Family, Advertisements, and Others (specified by respondents).

Most participants receive health information from social media platforms (32.9%) which suggests that they rely on YouTube, Instagram, Facebook, & WhatsApp. Since the participants are highly dependent on social media there is also a concern arises about the accuracy of the information shared.

The second-highest response was from healthcare providers (28.6%) which is a significant response as most participants believe in healthcare professional advice as the information provided is relevant and accurate.

The response for friends and family (27.6%) indicates that personal networks play an important role and one needs to validate the source of information received as social & trust factors play an important role. People trust the information that is shared from experienced sources.

There were minimal responses for Advertisements (7.2%) and Others (3.6%) which indicates that some participants are still dependent on Television ads, websites & health-related channels for health information.



[Figure 29 *Survey 13- Health Information]*

Overall, the data indicates that participants obtain health information from various sources which can be through digital or personal networks. The dominance of social media platforms highlights the importance of making a health-related decision. Though these platforms have impacted society still some participants approach healthcare professionals to seek health advice. Personal Networks play a vital role and the information can be trusted which is shared through friends & family. Advertisements & other sources may seek traditional methods to get health information.

Question 14 Have you heard of NASH [Nonalcoholic Steatohepatitis- Fatty Liver Disease] before

Have you heard of NASH

		Responses		Percent of Cases
		N	Percent	
$Familiar[a]	Veryfamiliar	26	16.8%	16.8%
	Somewhatfamiliar	39	25.2%	25.2%
	Heardofit	52	33.5%	33.5%
	Notfamiliaratall	38	24.5%	24.5%
Total		155	100.0%	100.0%

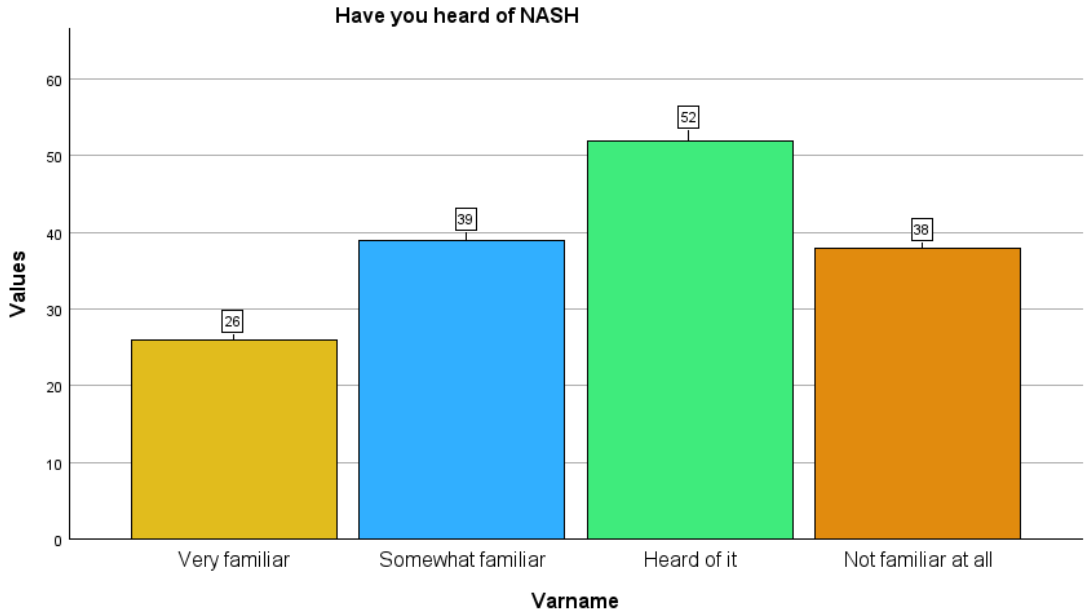
a. Dichotomy group tabulated at value 1.

Question-14 Interpretation: Question 14 determines the awareness of NASH among the participants, whether Very familiar/ Somewhat familiar/ Heard of it or Not familiar at all.

Many of the participants are very familiar (16.8%) with NASH, which indicates that they have a strong understanding of the disease, and the reasons can be due to personal or professional knowledge and maybe awareness about the condition.

The next group of participants is somewhat familiar (25.2%), with the condition. It indicates a moderate level of understanding about NASH; the participants may or may not fully understand the disease condition.

Most of the participants have heard of NASH (33.5%) which indicates they have a basic awareness of the condition and can also be a possibility well not understood by the participants. The last group of participants responded Not familiar at all (24.5%) which indicates that they don't have specific knowledge about the condition and a gap in public awareness.



[Figure 30 *Survey 14- Familiarity with NASH]*

Overall, from the data analysis, the combined responses (75%) indicate that participants have heard of NASH but a deep understanding is less common (16.8%- Very familiar). Even if there is awareness 25% of the participants are Not familiar with the condition. This suggests that awareness is essential to educate and provide more information about NASH. Social media platforms can be a way to increase awareness about NASH which could help in early detection of the disease and reduce the impact of its risks.

Question 15 How would you rate your awareness about NASH (Fatty Liver Disease)?

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
Excellent	155	0	1	.09	.288
Good	155	0	1	.27	.446
Average	155	0	1	.36	.482
Poor	155	0	1	.28	.449
VeryPoor	155	0	1	.10	.305
Valid N (listwise)	155				

Question-15 Interpretation: Question 15 determines how would participants rate the awareness of NASH, whether Excellent/ Good/ Average/ Poor/ Very Poor.

How would you rate your awareness about NASH

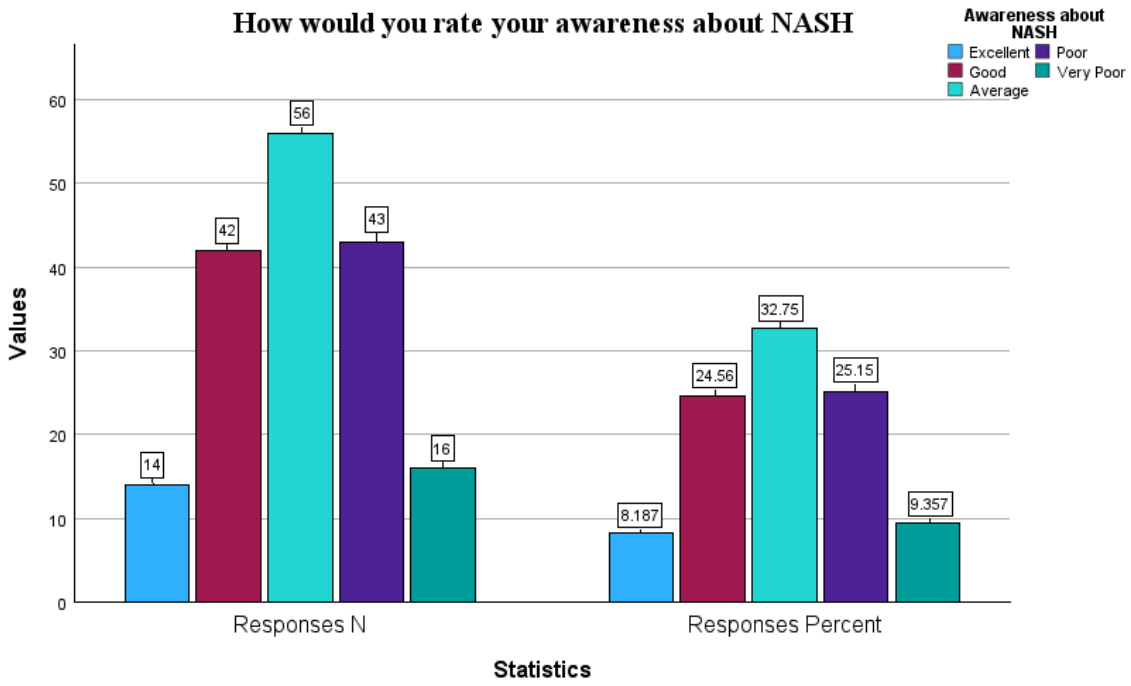
		Responses		Percent of Cases
		N	Percent	
$Awareness[a]	Excellent	14	8.2%	9.0%
	Good	42	24.6%	27.1%
	Average	56	32.7%	36.1%
	Poor	43	25.1%	27.7%
	VeryPoor	16	9.4%	10.3%
Total		171	100.0%	110.3%

a. Dichotomy group tabulated at value 1.

A minimal group of participants responded that they have an excellent (8.2%) awareness of NASH. This indicates that they are aware of the causes, symptoms, and treatments. Most of the participants have a good (24.6%) awareness of NASH which indicates they could have gained the knowledge through education/ personal or any other sources.

The majority of the participants rated Average (32.7%) awareness which indicates that have a basic understanding of NASH. Conversely minimal group of participants have minimal (poor- 25.1%) knowledge about NASH.

The last group of participants have very poor (9.4%) knowledge about NASH which indicates that they do not know the condition so it is essential to increase the awareness among the public.



[Figure 31 *Survey 15- Rate Awareness about NASH]*

From the data analysis, there is an average awareness of NASH among the participants which suggests improving the awareness and understanding of the condition. A combined response of Poor/ Very Poor (37%) NASH awareness indicates participants lack knowledge about the condition so this is an opportunity to awareness by educating the general public. Only a small group of participants have minimal awareness about NASH (Excellent/ Good). Overall, an awareness can improve early detection and management of NASH.

Question 16 What do you think could be the primary risk factors for developing NASH (Fatty Liver Disease)?

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
Obesity	155	0	1	.68	.469
Diabetes	155	0	1	.48	.501
HighCholesterol	155	0	1	.72	.452
PoorDiet	155	0	1	.59	.494
LackofExercise	155	0	1	.52	.501
Genetics	155	0	1	.26	.443
Valid N (listwise)	155				

Question-16 Interpretation: Question 16 determines what could be the primary risk factors that develop into NASH, whether Obesity/ Diabetes/ High Cholesterol/ Poor Diet/ Lack of Exercise or Genetics.

Primary risk factors for Developing NASH

		Responses		Percent of Cases
		N	Percent	
$RiskFactors[a]	Obesity	105	20.9%	67.7%
	Diabetes	74	14.7%	47.7%
	HighCholesterol	111	22.1%	71.6%
	PoorDiet	91	18.1%	58.7%
	LackofExercise	81	16.1%	52.3%
	Genetics	41	8.2%	26.5%
Total		503	100.0%	324.5%

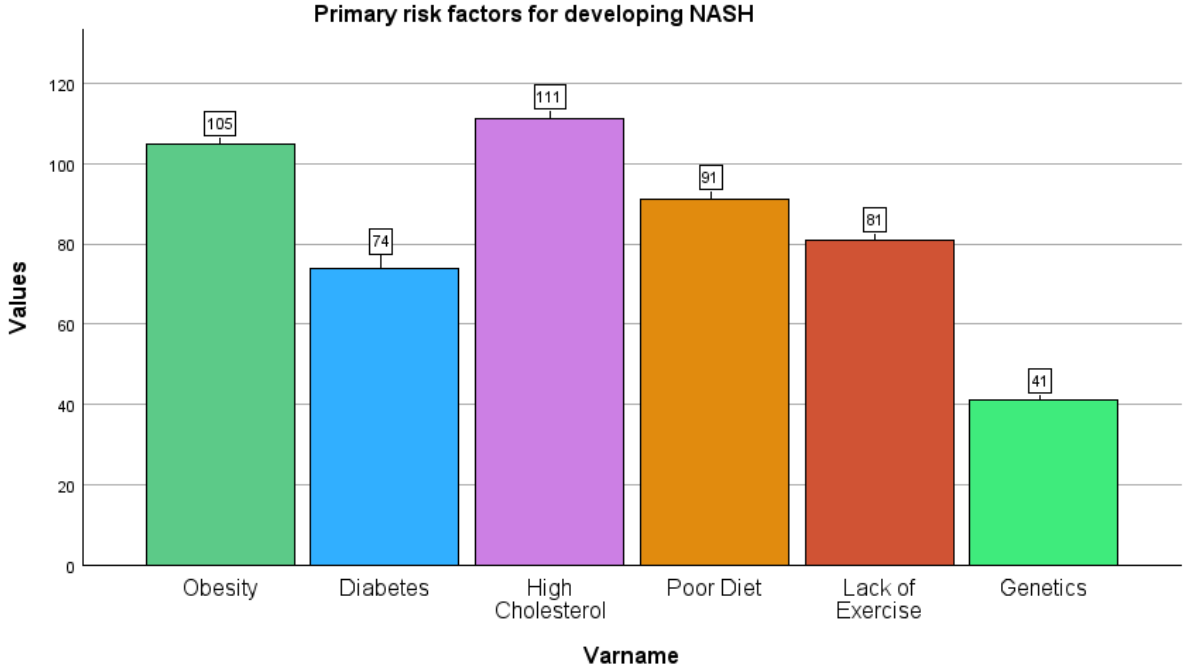
a. Dichotomy group tabulated at value 1.

The majority of the participants have identified High cholesterol (22.1%) as the primary risk factor, which suggests there is a strong awareness that high cholesterol levels can contribute to the development of NASH.

Another group of participants said Obesity (20.9%), which indicates that the general public is aware of the importance of maintaining a healthy weight to prevent NASH.

Some participants have identified poor diet (18.1%) as a key risk factor for NASH, which reflects that maintenance of unhealthy diets such as sugars, fats, and processed food can lead to the development of NASH. Lack of exercise (16.1%) can lead to NASH. Participants have an understanding that physical inactivity can contribute to NASH, which indicates the importance of maintaining a healthy lifestyle to prevent the condition.

Some participants believe that Diabetes (14.7%) can contribute to the condition. There is a strong correlation between NASH & type-2 diabetes, which indicates that participants understand that metabolic disorders can also lead to the development of NASH. A minimal group says that genetics (8.2%) can influence the condition when compared to other lifestyle changes.



[Figure 32 *Survey 16- Primary Risk Factors- NASH]*

From the data analysis, the major risk factors that contribute to NASH are high cholesterol, obesity, poor diet, and lack of exercise which suggests that lifestyle and metabolic disorders can lead to the development of NASH. Diabetes is another risk factor that can significantly contribute to the condition. Genetic is the least identified as the least risk factor which indicates that there is less awareness of the genetic component.

Overall, the data indicates that the participants understand that lifestyle changes and metabolic disorders can contribute to the development of NASH.

Question 17 Which social media platform would you use to share information about NASH?

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
Instagram	155	0	1	.55	.499
YouTube	155	0	1	.37	.485
Facebook	155	0	1	.34	.476
LinkedIn	155	0	1	.27	.446
WhatsApp	155	0	1	.61	.489
Twitter	155	0	1	.08	.278
Valid N (listwise)	155				

Question-17 Interpretation: Question 17 determines which platforms were used by the participants to share about NASH whether Instagram, YouTube, Facebook, LinkedIn, WhatsApp & Twitter.

Social Media Platforms Used to Share about NASH

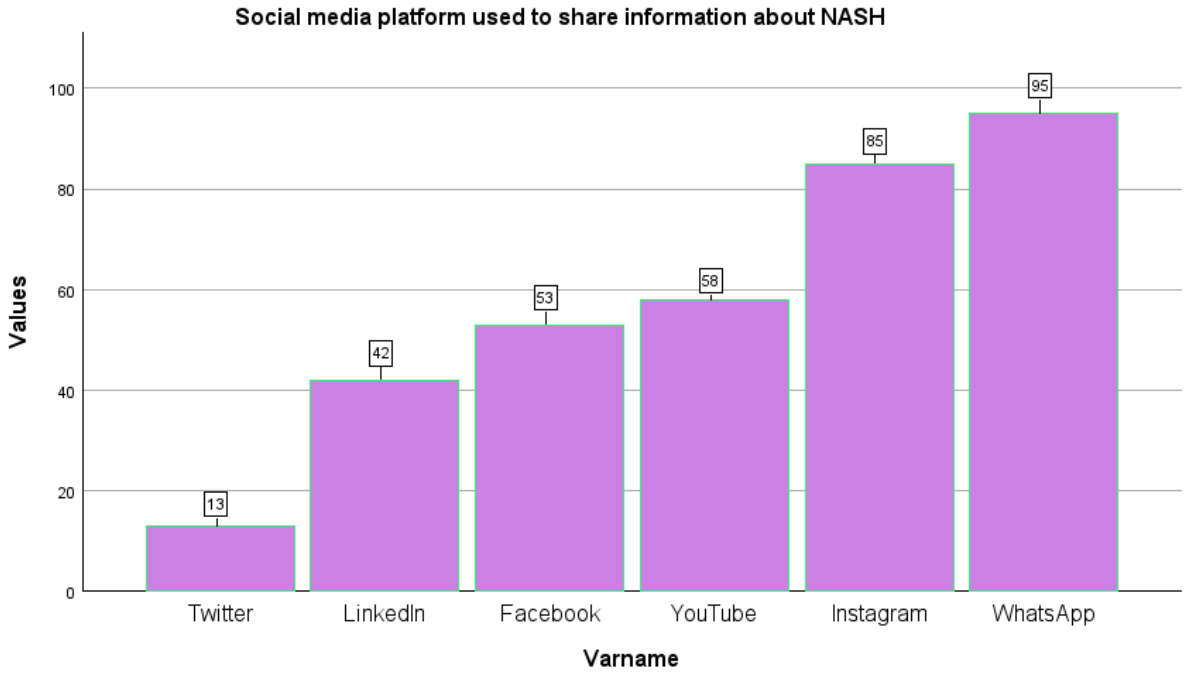
		Responses		Percent of Cases
		N	Percent	
$SM[a]	Twitter	13	3.8%	8.4%
	LinkedIn	42	12.1%	27.1%
	Facebook	53	15.3%	34.2%
	YouTube	58	16.8%	37.4%
	Instagram	85	24.6%	54.8%
	WhatsApp	95	27.5%	61.3%
Total		346	100.0%	223.2%

a. Dichotomy group tabulated at value 1.

The majority of the participants have chosen WhatsApp (27.5%) as the best social media platform to share information about NASH as it is the most common messaging app used for private & group communications.

The next popular platform is Instagram (24.6%) which is majorly used by the younger generation and captures users' attention due to visualization so it was another convenient platform to spread awareness about NASH.

Another group of participants chose YouTube (16.8%) because video ads are the easiest way to convey the message and make the general public understand about NASH. This was followed by Facebook (15.3%) which is a versatile platform to share videos/ articles/posts that can contribute to significant awareness about NASH. The last two platforms were LinkedIn (12.1%) a professional networking site & Twitter (3.8%) which are less suitable to spread awareness about NASH when compared to other platforms.



[Figure 33 *Survey 17- Share about NASH with Social Media Platforms]*

Overall, from the data it is observed that WhatsApp & Instagram are the top social media platforms where we can create awareness about NASH through customized visuals or direct messaging which is a convenient method to communicate the information. YouTube also plays an important role in educating the general public about the condition. The other platforms, Facebook, LinkedIn & Twitter have shown to have less impact as per the participant's response.

Question 18 What type of information about NASH would you find most useful to share?

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
SymptomsDiagnosis	155	0	1	.28	.452
TreatmentOptions	155	0	1	.10	.305
PreventionTips	155	0	1	.54	.500
Clinicaltrials	155	0	1	.04	.194
ResearchandStatistics	155	0	1	.03	.159
Other	155	0	1	.01	.113
Valid N (listwise)	155				

Question-18 Interpretation: Question 18 determines which information will be shared by the participants about NASH other users, whether Symptoms and Diagnosis/ Treatment Options/ Prevention Tips/ Patient Stories in clinical trials/ Research and Statistics or Others.

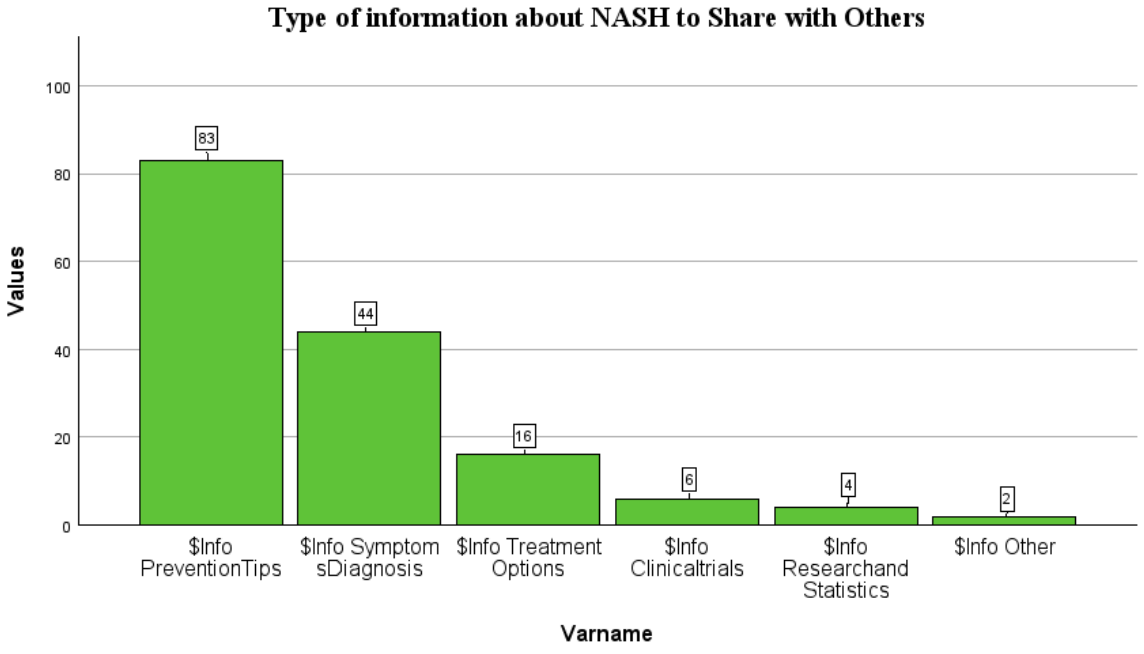
Type of Information About NASH

		Responses		Percent of Cases
		N	Percent	
$Info[a]	PreventionTips	83	53.5%	53.5%
	SymptomsDiagnosis	44	28.4%	28.4%
	TreatmentOptions	16	10.3%	10.3%
	Clinicaltrials	6	3.9%	3.9%
	ResearchandStatistics	4	2.6%	2.6%
	Other	2	1.3%	1.3%
Total		155	100.0%	100.0%

a. Dichotomy group tabulated at value 1.

The participants have chosen prevention tips (53.5%) to share about NASH, which indicates a strong desire for the population to know about the condition and suggest preventing the condition by adopting a healthy lifestyle. The next group of participants wanted to share about symptoms & diagnosis (28.4%) of NASH, which suggests they wanted others to learn the signs of the condition and how this can be diagnosed.

Some participants chose treatment options (10.3%) on how NASH can be managed or treated when the individual is affected by this condition. The next group of participants chose clinical trials (3.9%), possibly patients can treat themselves with the latest advancements, research & statistics (2.6%) is focused on the broader scientific group (Academic/ Clinical research), and other (1.3%) indicate a minimal group of participants focus on personal stories or other treatments.



[Figure 34 *Survey 18- Type of Information Shared with Others- NASH]*

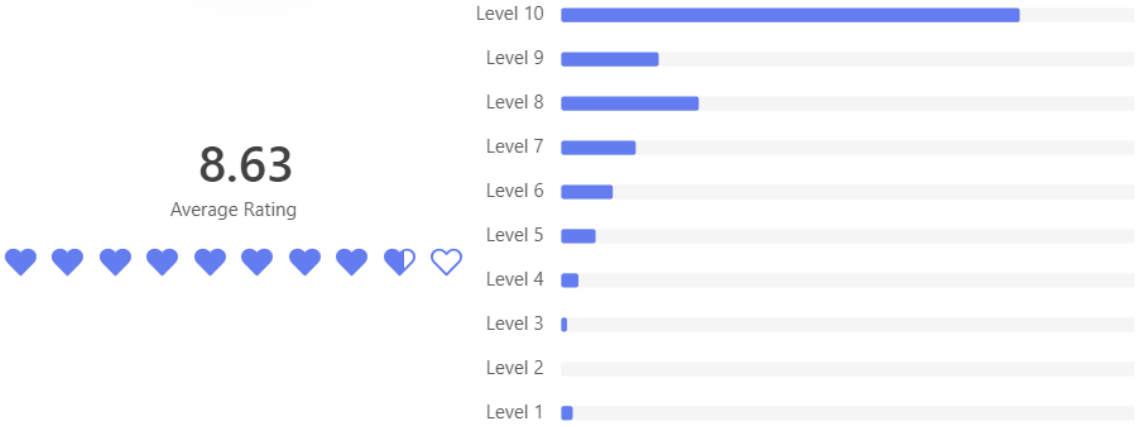
Overall, from the data, we observe there is a strong emphasis by the participants to ensure the population learns to prevent NASH by adopting a healthy lifestyle or getting awareness about the prevention tips. The other groups want the public to understand the signs and symptoms of the disease which helps in early detection. The last group of participants wants to educate the public about clinical research, treatment options, and other approaches for individuals who are affected by NASH. With the overwhelming response, I think social media platforms can be the best way to convey information about NASH.

Question 19 How likely are you to recommend others to learn more about NASH (Fatty Liver Disease)?

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
VAR00001	155	1	10	8.63	1.890
Valid N (listwise)	155				

Based on the response received the average rating scale for others to learn about NASH is 8.63 out of 10. This is the high rating which indicates that participants are likely to recommend others to learn about NASH.



[Figure 35 *Survey 19- Recommendations for Others to Learn about NASH]*

Question 20 How familiar are you with clinical trials

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
Veryfamiliar	155	0	1	.68	.469
Somewhatfamiliar	155	0	1	.20	.401
Notveryfamiliar	155	0	1	.23	.424
Notatallfamiliar	155	0	1	.12	.329
Valid N (listwise)	155				

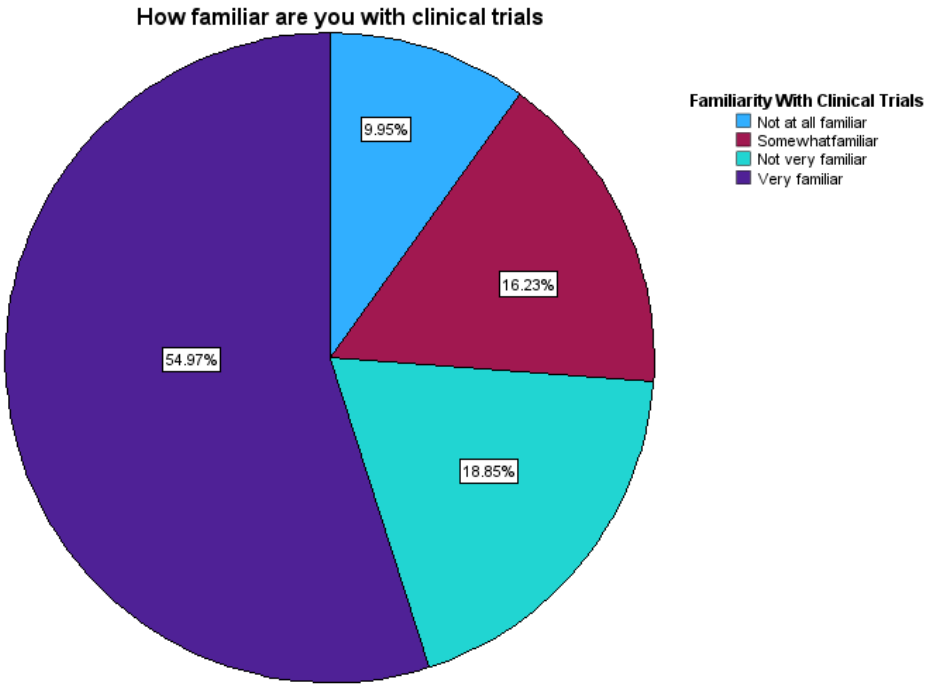
Question-20 Interpretation: Question 20 determines how well the participants are aware of Clinical Trials and whether Very familiar/ Somewhat familiar/ Not very familiar or Not at all familiar.

How familiar are you with clinical trials

		Responses		Percent of Cases
		N	Percent	
$Familiar[a]	Notatallfamiliar	19	9.9%	12.3%
	Somewhatfamiliar	31	16.2%	20.0%
	Notveryfamiliar	36	18.8%	23.2%
	Veryfamiliar	105	55.0%	67.7%
Total		191	100.0%	123.2%

a. Dichotomy group tabulated at value 1.

55% of the participants responded that they are very familiar with clinical trials which indicates that they understand the process, purpose, and significance of medical treatment. Another group of participants (18.8%) have a basic awareness of clinical trials but lack detailed knowledge of the process. The other group of participants is somewhat familiar (16.2%) which indicates that they have a moderate level of understanding and might not have a deep understanding of clinical trials. The last group of participants chosen was not at all familiar (9.9%) which indicates that they do not know clinical trials.



*[***Figure 36** *Survey 20- Familiarity With Clinical Trials]*

From the data analysis, we observe that familiarity with clinical trials can influence the participants for patient recruitment and participation in clinical trials. Since the majority of the participants are very familiar (54%) with clinical trials, this is a strong indication to educate the participants further about health-related topics. A significant portion (Somewhat

familiar/ Not very familiar) of people know about the trials however effectively communicating about the process will further enhance their understanding of the clinical trial process. The other group is not familiar at all with clinical trials so it is essential to address the knowledge gap social media platforms will help to create awareness about the process and reach out to diverse populations to influence them to participate in clinical trials.

Question 21 What would motivate you to participate in a clinical trial

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
Personalhealthbenefits	155	0	1	.70	.461
Financialcompensation	155	0	1	.28	.452
Accesstonewtreatments	155	0	1	.41	.494
healthcareproviders	155	0	1	.33	.471
medicalresearch	155	0	1	.51	.502
Valid N (listwise)	155				

Question-21 Interpretation: Question 21 determines what factors can influence the general public to participate in clinical trials.

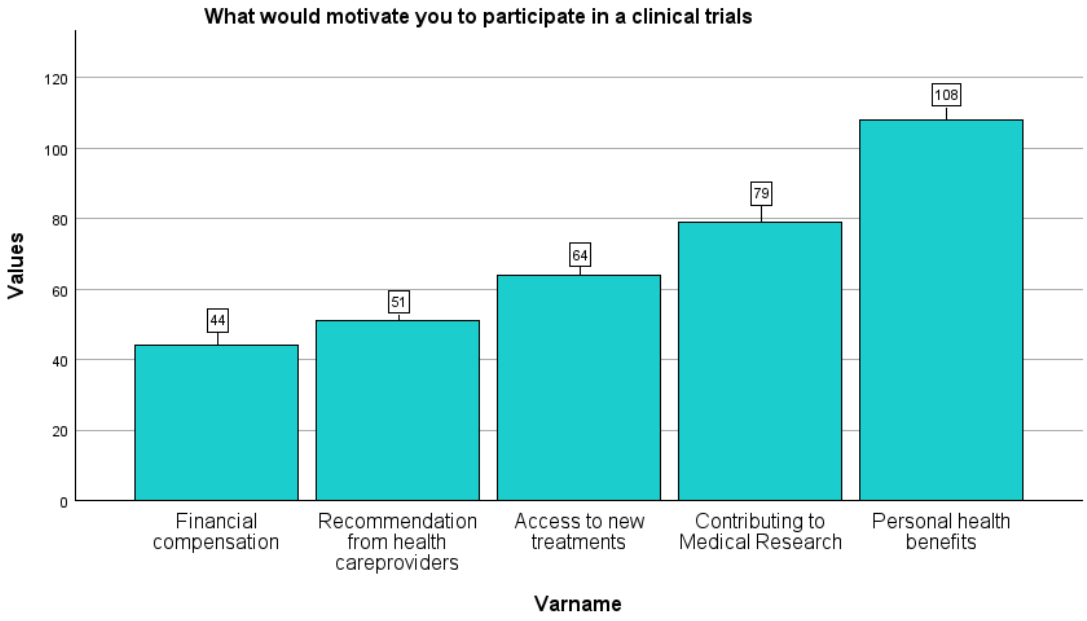
What would motivate you to participate in a clinical trial

		Responses		Percent of Cases
		N	Percent	
$Motivation[a]	Financialcompensation	44	12.7%	28.4%
	healthcareproviders	51	14.7%	32.9%
	Accesstonewtreatments	64	18.5%	41.3%
	medicalresearch	79	22.8%	51.0%
	Personalhealthbenefits	108	31.2%	69.7%
Total		346	100.0%	223.2%

a. Dichotomy group tabulated at value 1.

Most of the participants chose personal health benefits (31.2%) which indicates that people prioritize health above all factors and participation in clinical trials is an opportunity to improve their health. Another group of participants who had chosen to contribute to medical research (22.8%) shows that people have scientific knowledge about clinical trials and their participation can help bring new therapies that can have a positive impact on society. The next group had chosen access to new treatment (18.5%) which indicates they are motivated to experience the innovative IMP which can help to improve their health.

The other group mentioned recommendations from healthcare providers (14.7%) which shows the trust built by the healthcare providers and their advice would motivate them to take part in clinical trials. The last was financial compensation (12.7%) which had a minimal response which indicates finance can also play an important role however it is less prioritized when compared to other factors.



[Figure 37 *Survey 21- Motivation to Participate in Clinical Trials]*

Overall, from the data it is observed that people's strongest motivation was their health which can be improved by participating in clinical trials. This was followed by participants' desire to contribute to research, access new treatments, and trust in healthcare providers. Though financial compensation is a motivator there was a minimal response from the public. By taking these insights we can effectively strategize the patient recruitment plan.

Question 22 What concerns do you have about participating in clinical trials?

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
Lackofinformation	155	0	1	.51	.502
Fearofsideeffects	155	0	1	.72	.452
TimeTravelconstraints	155	0	1	.40	.491
Privacyconcerns	155	0	1	.36	.482
Mistrustinthemedicalcommunity	155	0	1	.30	.458
Valid N (listwise)	155				

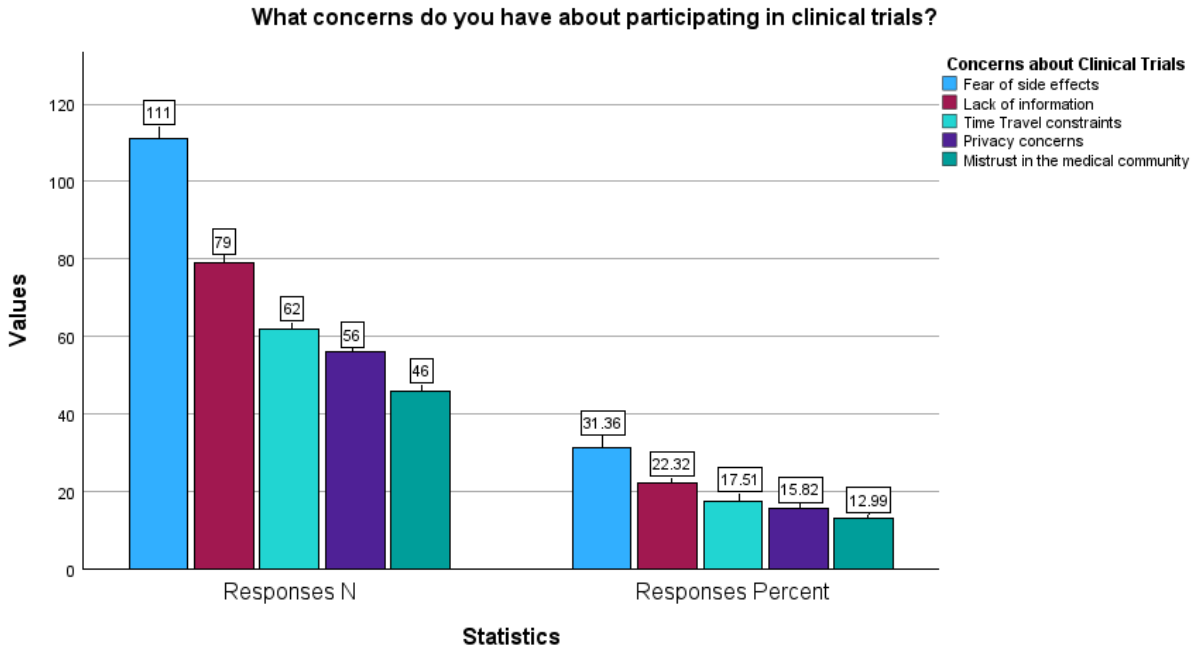
Question-22 Interpretation: Question 22 determines what concerns the participants encounter when they want to participate in clinical trials.

What concerns do you have about participating in clinical trials?

		Responses N	Responses Percent	Percent of Cases
$Concerns[a]	Fearofsideeffects	111	31.4%	71.6%
	Lackofinformation	79	22.3%	51.0%
	TimeTravelconstraints	62	17.5%	40.0%
	Privacyconcerns	56	15.8%	36.1%
	Mistrustinthemedicalcommunity	46	13.0%	29.7%
Total		354	100.0%	228.4%

a. Dichotomy group tabulated at value 1.

The most common worry about clinical trials among the participants was fear of side effects (31.4%), which indicates that adverse events can pose a major barrier to patient recruitment. Some participants acknowledge that there is a lack of information (22.3%) about clinical trials which indicates that the public does not have knowledge which can hinder their participation. Some participants might be committed to work schedules so time & travel (17.5%) can be a constraint. Another group of participants is anxious about personal & medical confidentiality information (15.8%). There was a minimal response to mistrust in the medical community (13%) as participants may have negative perceptions of medical institutions.



[Figure 38 *Survey 22- Concerns to Participate in Clinical Trials]*

Overall, from the data analysis, we observe fear of side effects is a major side effect which can be overcome by having transparent communication about the benefits and risks of a clinical trial. It is essential to educate the public by providing detailed information about trials, having flexible visit schedules, and explaining the confidentiality guidelines to address their concern. Mistrust is a challenge that can be overcome by having transparent communication, which can improve trust and the participation rate for clinical trials.

Question 23 What method of communication would be most effective in informing you about clinical trials?

Descriptive Statistics

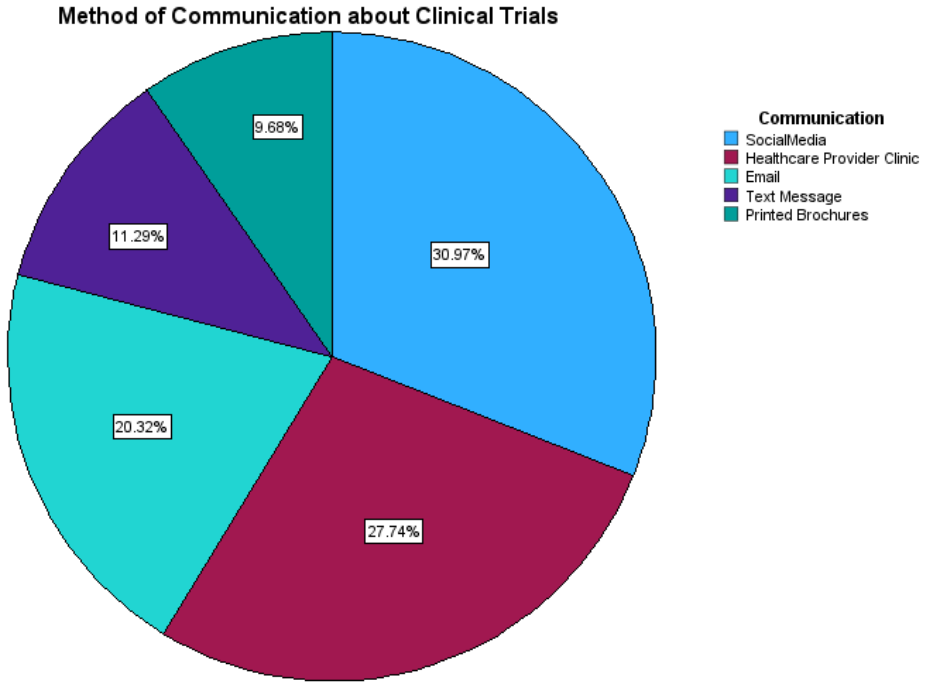
	N	Minimum	Maximum	Mean	Std. Deviation
SocialMedia	155	0	1	.62	.487
Email	155	0	1	.41	.493
HealthcareProviderClinic	155	0	1	.55	.499
PrintedBrochures	155	0	1	.19	.396
TextMessage	155	0	1	.23	.419
Valid N (listwise)	155				

Question-23 Interpretation: Question 23 determines which method of communication would be more suitable to inform about clinical trials to the participant.

Method of Communication about Clinical Trials

		Responses		Percent of Cases
		N	Percent	
$Method[a]	SocialMedia	96	31.0%	61.9%
	HealthcareProviderClinic	86	27.7%	55.5%
	Email	63	20.3%	40.6%
	TextMessage	35	11.3%	22.6%
	PrintedBrochures	30	9.7%	19.4%
Total		310	100.0%	200.0%

a. Dichotomy group tabulated at value 1.



[Figure 39 *Survey 23- Method of Communication- Clinical Trials]*

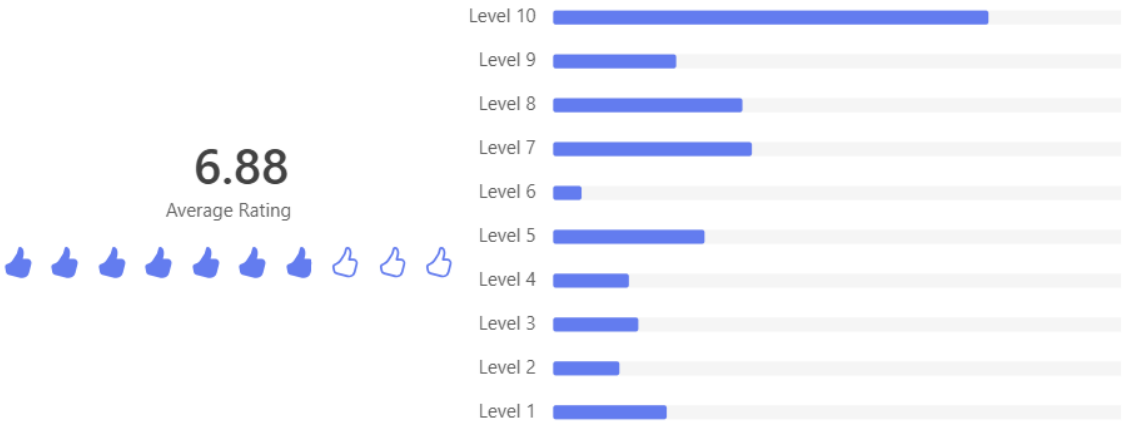
From the data analysis combined response suggests that most of the participants are interested in receiving information about clinical trials through social media platforms (31%), which is a cost-effective method, healthcare providers/clinics (27.7%) the source & information can be trusted, and email (20.3%) can help to provide detailed information about clinical trials. The other two responses were text messages (11.3%) can used as a reminder & printed brochures (9.7%) which is a traditional method that can still be implemented incise if they don't use digital platforms.

Question 24 How likely are you to participate in a clinical trial if you receive the information through your preferred method of communication

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
VAR00002	155	1	10	6.88	2.987
Valid N (listwise)	155				

Based on the response received, the average rating scale for people participating in clinical trials is 6.88 out of 10 which is a moderate willingness.



[Figure 40 *Survey 24- Participation in Clinical Trials]*

Question 25 What sources of information do you trust the most about clinical trials?

Descriptive Statistics

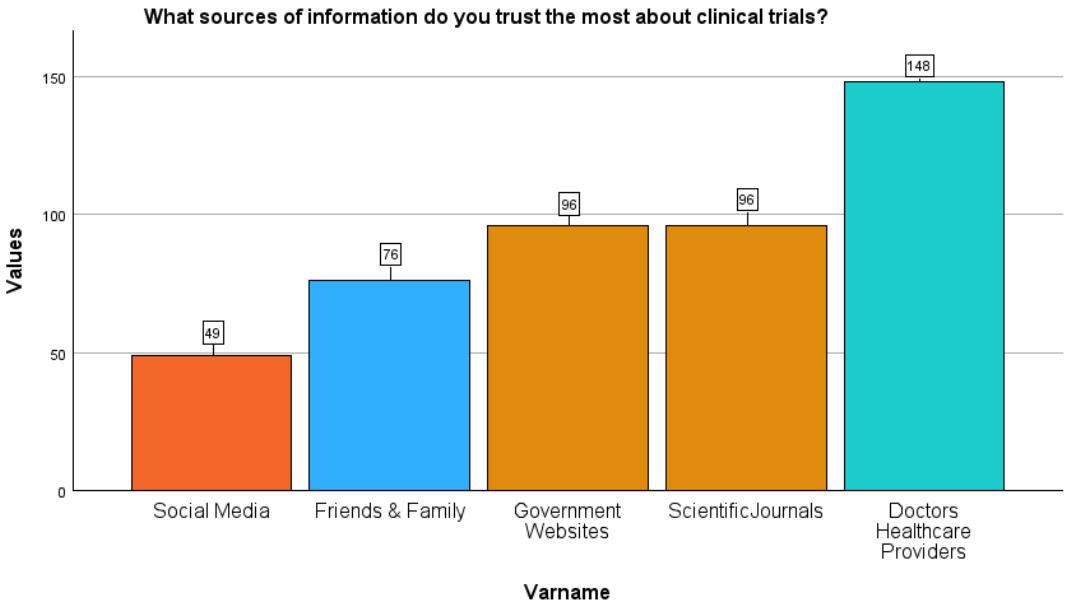
	N	Minimum	Maximum	Mean	Std. Deviation
DoctorsHealthcareProviders	155	0	1	.95	.208
SocialMedia	155	0	1	.32	.466
FriendsFamily	155	0	1	.49	.502
GovernmentWebsites	155	0	1	.62	.487
NewsMedia	155	0	0	.00	.000
ScientificJournals	155	0	1	.62	.487
Valid N (listwise)	155				

Question-25 Interpretation: Question 25 determines which source of information the participants trust the most when they hear about clinical trial information.

What sources of information do you trust the most about clinical trials?

		Responses		Percent of Cases
		N	Percent	
$Trust[a]	SocialMedia	49	10.5%	31.6%
	FriendsFamily	76	16.3%	49.0%
	GovernmentWebsites	96	20.6%	61.9%
	ScientificJournals	96	20.6%	61.9%
	DoctorsHealthcareProviders	148	31.8%	95.5%
Total		465	100.0%	300.0%

a. Dichotomy group tabulated at value 1.



[Figure 41 *Survey 25- Source of Information To Trust About Clinical Trials]*

From the data analysis, most of the participants chose Doctors/ Healthcare Providers (31.8%) which indicates they trust medical professionals and can influence them to participate. The second highest response (Government Websites & Scientific Journals 40%) shows the participants value the information and trust peer-reviewed sources for their health decisions. The next response was friends & family (16.3%), which indicates personal networks can also influence one's opinions for participation in clinical trials. There was a minimal response for social media (10.5%), showing it holds importance, however, it is the less trusted source compared to other sources. Hence, it is essential to create transparent communication while advertising on social media platforms.

Question 26 How likely are you to share information about clinical trials for NASH with others?

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
VAR00003	155	1	10	7.94	2.377
Valid N (listwise)	155				

Based on the response received the average rating scale for participants to share clinical trial information about NASH with others is 7.94 out of 10. This is a high rating scale which suggests that participants are likely to share this information with others.

[**Figure 42** *Survey 26- Share Information About NASH Clinical Trials with Others]*

Question 27 What motivates you to share clinical trial information for NASH

Question-27 Interpretation: Question 27 determines what motivates the participants to share clinical trial information about NASH with others.

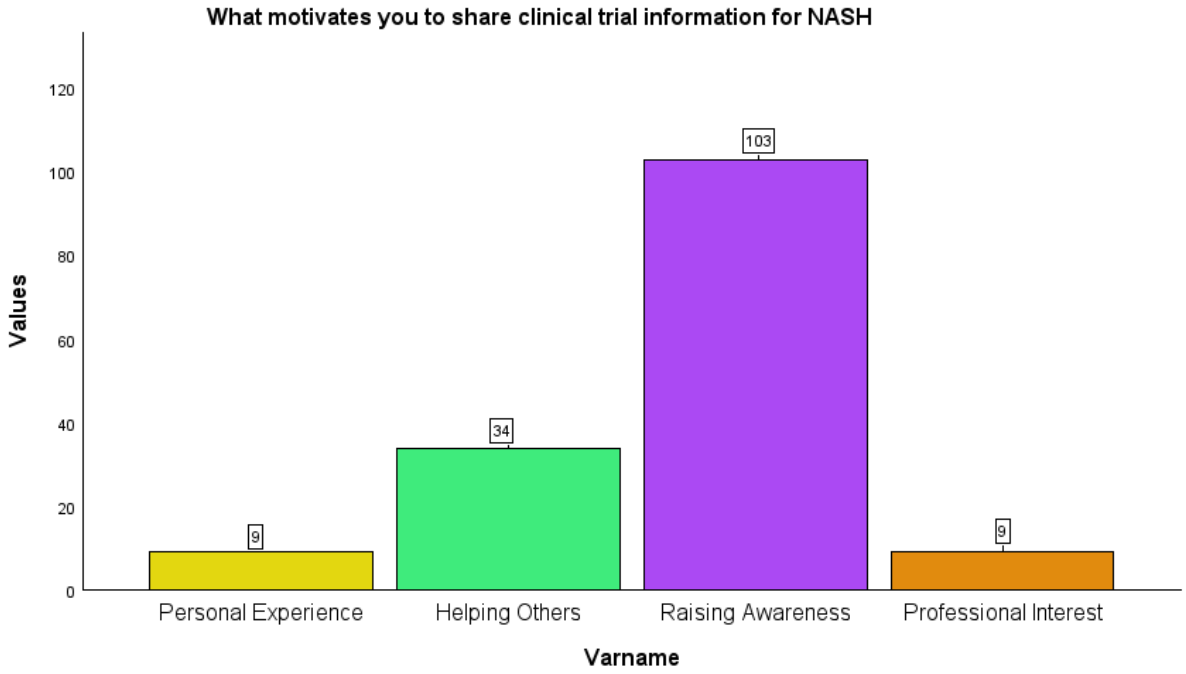
What motivates you to share clinical trial information for NASH

		Responses		Percent of Cases
		N	Percent	
$CTNASH[a]	Personal Experience	9	5.8%	5.8%
	Helping Others	34	21.9%	21.9%
	Raising Awareness	103	66.5%	66.5%
	Professional Interest	9	5.8%	5.8%
Total		155	100.0%	100.0%

a. Dichotomy group tabulated at value 1.

From the data analysis, the majority of the participants were motivated to raise awareness (66.5%) about clinical trial information about NASH which is a desire to make others

understand and have knowledge about the condition which may help in early detection and follow a healthy lifestyle. The next highest response was helping others (21.9%) which is a motivation to spread hope who might be affected by NASH. The last response had a similar response to personal experience (5.8%) and professional interest (5.8%) shared information based on their experiences.



*[**Figure 43** Survey 27- Motivation to Share about NASH Clinical Trials]*

Overall, we can conclude that the primary focus of this survey was to create awareness so the participants have different motivations to spread information about NASH to others and this is possible through effective communication and outreach to the population which have a positive impact on the society.

CHAPTER 05- DISCUSSION, CONTRIBUTION, LIMITATION, RECOMMENDATION & CONCLUSION

The main objective of this research was to create awareness about NASH using social media platforms to overcome patient recruitment challenges for clinical trials.

5.1 Discussion of the Research

5.1.1 Social Media Platforms

The findings from the survey and interviews reveal that social media platforms play a vital role and act as a key source of health information for the participants. The survey results demonstrated clearly that YouTube, Instagram, and WhatsApp are the common social media platforms used by the participants.

The data revealed that 80% of the participants use YouTube. This trend aligns with the literature review that video advertisements can engage users effectively, and even complex health information, when presented in a visual format, the general public can understand the details. Instagram and WhatsApp were the other two popular platforms that have kept the participants engaged multiple times a day. The other platforms Facebook, LinkedIn & Twitter did not make much impact as the participants had the least preference based on the contents.

Based on the time analysis, most participants used social media platforms predominantly during the night. Depending on the user's lifestyle patterns who multitask with various activities (work, home, life) allows them to use these platforms during the night and evening times. This is key information about the timing that can contribute to positive change in advertisements and creating awareness.

The participants majorly use these platforms multiple times a day & more than02 hours during festive seasons. According to the research findings, there is a strong preference for video & image advertisements which is an added advantage. Using these digital advantages pharmaceutical companies can easily educate the public by visualization and creating awareness for health information becomes easier and more convenient for the users.

Since the data is very evident people on social media for health information concerns raise how accurately the information is shared on these platforms. So pharmaceutical companies, healthcare providers, and social media platform CEOs collaborate to streamline the process and ensure integrity is maintained for health-related information.

The CRPs have emphasized the importance of adhering to regulatory guidelines and ethical principles play a vital role in ensuring participants' data & privacy are protected while using these digital platforms. For a patient-centric approach, transparent communication is the key which encourages people to participate.

Further CRPs have revealed a shift from the traditional method to social media platforms for patient recruitment in clinical trials which has led to successful campaigns. Integration of social media platforms in clinical trials is a key source of communication that has helped to resolve the fear factors, reach diverse populations, and share success stories of trial participants which has influenced other participants. Social media will be the next platform utilized to implement decentralized trials shortly.

5.1.2 Engagement in Social Media Platforms

The data collected from the survey highlights how social media platforms have integrated into a day-to-day lifestyle. It is the primary source to obtain any information be it health, news, sports, education, entertainment, and any other updates. Social media platforms have not only become a networking site to connect with other users around the globe but also the main source to receive health information. Covid-19 paved the way for virtual connection which made it easier for healthcare professionals and patients at their convenient place and time.

The findings highlight that participants validate the source and healthcare information internally & predominantly share externally with friends and family. It demonstrates that social media is making its way into personal networks through emotional ties which creates trust through online communication. In contrast, sharing with colleagues and the public had the least response may be due to less personal space/professionalism.

The frequency of sharing also depends on the types of content it was discovered from the findings that participants rarely shared information on social media platforms which raises a question of what would be the impact if health information were shared on these platforms. So, it is the responsibility of the companies to strategically design the content that helps the participants to engage in social media platforms.

Though there are recent advancements in technology still CRPs are challenged to meet the requirements for a clinical trial. A clinical trial is always focused on a patient-centric approach where trust and communication play an important role.

The CRPs stated they depend on social media platforms for patient recruitment to meet the target goals. They strategically planned to use social media to engage participants by having a real-time conversation which helped to break the barriers and educate the participants through transparent communication which enabled them to reach a diverse population and meet the recruitment goals which led to successful completion of clinical trials.

5.1.3 NASH Awareness

From the survey findings, it was observed that there was a general awareness about the participants among the public, which highlights both positive impact and knowledge gaps in understanding the disease condition.

75% of the participants had an awareness about NASH but lacked detailed information about the condition. In contrast, ~25% of the participants were not familiar with the condition which can pose a threat to public health if not addressed on time. These findings show the importance of educating people about NASH which will help in early detection and

prevention at the earlier stage. Using social media platforms can play a vital role in creating awareness about NASH and the possibility of managing it through a healthy lifestyle.

Since the participants have an awareness of NASH, they identified high cholesterol to be the primary risk factor followed by obesity. This is a positive sign that people understand the importance of maintaining a healthy lifestyle as poor diet and lack of exercise can also pose a threat to NASH. The other risk factors diabetes and genetics were thought of by the participants which highlights the need to further educate about the condition.

Platforms like YouTube capture the user's attention through visual ads and complex health information can be simplified through this strategy. On the other hand, WhatsApp's communication & Instagram's visual format were preferred platforms for sharing information about NASH which indicates an effective strategy to raise awareness about critical information.

Participants understand the importance of sharing information and for NASH they wanted others to know about the prevention measures. Additionally, the survey results indicate a desire to share with others to know about the symptoms & diagnosis which is crucial for managing the disease. Though there was minimal response to treatment options and clinical stories the focus was on lifestyle changes and preventive measures rather than treatment methods which was strongly highlighted by the participant's recommendation for others to learn about NASH.

5.1.4 People's Attitude, Preferences, Fear Factors, Influential Factors towards Clinical Trials

The research objective was to understand the importance of the public's attitudes and preferences about clinical trials. It also highlights participants' motivations, concerns, and methods of communication to know about these trials. These valuable insights were obtained through the quantitative data.

From the survey data, there was a strong (55%) indication that participants were familiar with clinical trials and understood the benefits and risks. However, the group fell into a category (45%) who were less familiar with clinical trials and lacked knowledge about the detailed approach. To address these gaps social media platforms should be strategically utilized to develop creative content which will help to reach a diverse population to know about clinical trials.

To understand the attitude of people toward clinical trials majority wanted to participate in clinical trials to improve their personal health which was there was their first & foremost priority. The second factor some wanted to contribute to the research indicates they had a deeper knowledge of clinical trials. Though financial compensation and flexibility in participation were necessary the top priority was personal health benefit.

When participants are interested in participating due to personal health benefits, I wanted to learn more about what factors hinder them from not to participating in clinical trials. The main factor identified was fear of side effects and lack of information about clinical trials. So, it was essential to address these concerns through transparent communication and discuss the

benefits and risks. So, it is essential to improve the public's understanding of the clinical trial process which will help to reduce the concerns and fear factors.

Once the participant's concerns have been addressed, we wanted to know which is the preferred method for communication. Most participants preferred to receive the information through social media platforms which notifies a cost-effective method to reach potential participants. This was followed by healthcare providers who would have established a strong connection with patients & built trust which is another channel to reach the right participants.

Additionally, we checked which source of information the participants trusted the most and it was evident from the data that the people are dependent on healthcare providers followed by peer-reviewed sources which can have a positive impact on an individual to participate in clinical trials. It further highlights there is a collaboration needed between pharmaceutical companies, and medical & research professionals to promote people's participation in clinical trials.

We also checked the likelihood of the participants to take part in clinical trials there was an average rating of 6.8 which shows a favourable attitude but yet there was a need to educate the people to create more awareness about clinical trials. In addition to the participation, we wanted to check if given an opportunity the participants share information about clinical trials and what motivates them to share this information with others a high score of 7.9 indicated that people recommend others to learn about NASH clinical trials and they strongly motivated to raise awareness about this condition. This supportive approach will influence others to participate in clinical research.

5.1.5 Patient Recruitment in Clinical Trials

For clinical trials, recruiting potential patients is always a challenge. The CRPs shared the challenges and an effective strategy that led to the successful completion of clinical trials.

Though there are several challenges CRPs have shifted from the traditional method of recruitment to adopting social media platforms. One of the effective methods was collaborating with local physicians where patient referral was easy. The HCPs would have already built trust and personal connection making it easier to recruit potential patients.

The CRPs also utilized different databases such as EMR & EHR to find the right participants for specific conditions such as rare diseases. Apart from this to reach diverse groups pharmaceutical companies have specialized vendors like PAG who design effective recruitment strategies to meet the recruitment goals for clinical trials. The CRPs have also conducted campaigns & reached out to community groups to educate the participants in their local language using the traditional methods.

With the advancement in technology, pharmaceutical companies have shifted from traditional methods to digital methods by adopting social media platforms like YouTube, Instagram, Facebook, and LinkedIn to reach out to a diverse group of participants.

To conclude the insights drawn from the literature review and experiences shared by the CRPs show a mix of both traditional and digital methods has been a strategic way to overcome the challenges of patient recruitment in clinical trials. Utilizing social media

platforms to reach a culturally diverse group and ensure meeting ethical standards and compliance with regulatory guidelines can be an efficient method of recruiting participants for clinical trials.

5.2 Contributions of the Research

The research has drawn new insights about NASH, social media platforms, and perspectives about clinical trials that will add value to the existing literature review.

1. **Social Media Platforms**: According to this research YouTube, Instagram, and WhatsApp were the top three social media platforms used for health-related information by people of Bangalore when compared to the literature, where Facebook and YouTube had a greater impact in the USA (Author, 2024).
2. **Time Analysis**: The research data identified that people use social media platforms multiple times a day during evening & night times. Additionally, during the festive season, people used these platforms for more than 2-3 hours compared to the literature, which found that the recruitment rate is low during the festive season (Baker, Mitchell, and Thomas, 2022).
3. **Preferences Towards Social Media Contents**: Most participants strongly preferred the visual approach, which is more engaging for understanding complex health information.
4. **Attitudes about Clinical Trials**: The research data revealed people are aware of clinical trials but lack a detailed understanding of the clinical trial processes.
5. **Fears & Motivations about CT:** The research revealed that people are anxious about the side effects and motivated to participate in clinical trials due to personal health benefits.
6. **Personal Networks:** The findings indicate that participants mainly share health-related information with personal networks such as friends & family rather than professional networks.
7. **Patient-Centric Approach:** The CRPs emphasized that transparent communication is the key to addressing the fears and concerns that influence participation in clinical trials.
8. **Decentralized Clinical Trials**: The Qualitative Findings revealed that social media platforms will become an innovative method to recruit patients for decentralized trials.
9. **Collaboration:** The research suggests that the collaboration of pharmaceutical companies, Healthcare & research professionals can use social media platforms to streamline the process of patients in clinical trials.

5.3 Research Limitations

Though there were contributions from this research there are limitations which are discussed below:

1. **Survey Sample**: The present survey sample does not fully represent the diversity of Bangalore which could lead to biased results. This limitation can impact the results when applied to a broader population.
2. **Target Participants**: Social media can reach a diverse population since this research did not collect sensitive information such as age and gender details, there is a limitation it may not effectively target the specific demographic i, e the older participants.

3. **Reporting Standards**: Social media are an effective platform however there are no standard & transparent guidelines for reporting the entire patient recruitment process and outcomes.
4. **Trends of Social Media**: As there is technological advancement the features in social media platforms can change with time which can impact the assessment of the public's attitude and preferences.
5. **Lack of Qualitative Interview**: There were minimal interviews taken with Healthcare Providers, there were insufficient insights was it limited to understanding how these professionals promote clinical trials and influence their patients to participate.

5.4 Future Recommendations

Some of the recommendations for further research are

1. **Sample Size & Diversity**: Future research is recommended to collect the demographic details and reach out to a more diverse population which will help to improve the findings and gain better insights from the general population.
2. **Collaboration**: Pharmaceutical companies and medical & research professionals need to collaborate to design an effective strategy to create awareness about clinical trials and use social media platforms to recruit potential participants which will help to reduce the mistrust about clinical trials.
3. **Resources & Training**: Social media is an emerging technology so pharmaceutical companies need to allocate appropriate budgets and train the right personnel to drive successful social media-based clinical trial recruitments.
4. **Regulatory & Ethical Guidelines**: It is recommended to implement standard regulatory & ethical guidelines while using social media platforms for patient recruitment. This will further help in the removal of misconceptions about clinical trials.
5. **Cost-Effectiveness**: Since social media platforms are a cost-effective method, it is suggested to compare the efficiency and expense of these platforms to the recruitment of potential participants for clinical trials.

5.5 Conclusion from the Research

This research aims to fulfill the objectives that social media platforms play a vital role in raising awareness about NASH and overcoming the patient recruitment challenges for clinical trials.

The findings through the mixed method approach (Qualitative & Quantitative Method) indicate that social media platforms have become a primary source for an individual to access health information through the top three platforms- YouTube, Instagram & WhatsApp which are considered the most preferred methods of communication.

Though there is a general awareness of NASH there is a need to educate the people and address the gaps to have a detailed understanding of the disease condition. The insights drawn from the research data describes the fear factors and mistrust about clinical trials which can be overcome by implementing social media platforms to create awareness and also having a transparent communication helps to build trust among the participants.

Integrating social media platforms is a modern method that aligns with the current lifestyle and thinking approach which is crucial to promote awareness about NASH and clinical trials.

Finally, to conclude collaboration of pharmaceutical companies, and medical and research professionals with the integration of social media platforms can bring in innovative methods of patient recruitment for clinical which ultimately contribute to improving society's quality of life.

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APPENDICES

Appendix- A- Informed Consent Form for Clinical Research and Healthcare Professionals

INFORMED CONSENT FORM

Researcher: Lavanya Kumari Perumal

Research Title: The Impact of Social Media on Recruiting Patients for NASH Clinical Trials in Bangalore.

Purpose of Research: The research aims to study social media impact to create awareness about Nonalcoholic Steatohepatitis (NASH- Fatty Liver Disease) and how to overcome the patient recruitment challenges for clinical trials in Bangalore.

- Do you choose to participate in this research? [Yes/No]
- I understand the title of this research, "The Impact of Social Media on Recruiting Patients for NASH Clinical Trials in Bangalore" [Yes/No]
- I understand the purpose of the research which is carried out by Lavanya Kumari Perumal in Griffith College, Dublin [Yes/No]
- I understand and confirm the requirements of this research [Yes/No]
- If the response is YES then please provide your consent for the following

Informed Consent	Yes/No
I understand and confirm that my participation is voluntary and withdraw at any point in time	
I understand that I will not benefit directly by participating in this research	
I understand and confirm that the interview will be conducted not more than 30 minutes	
I understand and confirm that the interview will be recorded and transcribed	
I understand the data collected will be used only for this research analysis	
I understand my identity will remain anonymous during the interview	
I agree to the use of anonymous quotes for this research	
I understand that the data will be stored for 02-04years as per confidentiality guidelines	
I have read & understood the above information and contact the researcher for any questions/information	

Researcher Supervisor Details

Name**:** Chiamaka Chiedozie

Contact mail: chiamaka.chiedozie@griffith.ie

Researcher Details

Name: Lavanya Kumari Perumal

Degree Programme: MSc Pharmaceutical Business and Technology [2024]

College Details: Griffith College, Dublin

Contact number: +353 894471681

Contact mail: lavanyakumari.perumal@student.griffith.ie

Signature of participant ----------

[Full Name – Printed] ----------

Date ----------

Signature of research participant ----------

Signature of researcher

I believe the participant is giving informed consent to participate in this study

Appendix- B- Participant Information Sheet for Clinical Research and Healthcare Professionals

Participant Information Sheet

Researcher: Lavanya Kumari Perumal

Research Title: The Impact of Social Media on Recruiting Patients for NASH Clinical Trials in Bangalore.

Dear Interviewee,

I invite you to participate in this research to study social media impact to create awareness about Nonalcoholic Steatohepatitis (NASH- Fatty Liver Disease) and how to overcome the patient recruitment challenges for clinical trials in Bangalore. This research is part of my Master's Dissertation in Pharmaceutical Business and Technology for Griffith College, Dublin.

Before I interview you need to understand what this research involves. It is voluntary and you can decide whether to participate or not in this research. If you choose to participate an information sheet will be provided and you can retain it. To confirm your participation an informed consent form will be signed by you. At any point, if you wish not to participate you can withdraw without any justification.

This research will provide an opportunity to interact with Clinical Research/Healthcare Professionals and the Public. It will help to understand the challenges involved in patient recruitment for clinical trials and how social media platforms can be utilized to create awareness about NASH (Fatty liver disease) and clinical trials. You have been chosen for this research as your experience will add value to this research and the interview will be arranged for approximately 30 minutes based on your availability. The interviews will be audio-recorded and transcribed for analysis.

The information collected during this research will be stored with all confidentiality guidelines. All the data will be protected and will not be identified during the research process. The data will be used for statistical analysis and stored securely on the researcher's password-protected laptop and USB. Only the researcher will have access to the data and the information collected will be stored for 02 years.

Please feel free to reach out to me at lavanyakumari.perumal@student.griffith.ie [Contact Details- +353 894471681].

Thank you.

Lavanya