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Review Article
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EMERGING TRENDS IN MICROBIOME BASED THERAPEUTICS

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ABSTRACT
The Human Microbiome has emerged as a critical determinant of health and disease, driving the development of microbiome-based therapeutics as a novel approach to precision medicine.. Emerging microbiome-based interventions include next-generation probiotics, prebiotics, synbiotics, postbiotics, live bio therapeutic products (LBPs), engineered microbial therapeutics, bacteriophage therapy, and fecal microbiota transplantation (FMT).These approaches have demonstrated promising therapeutic potential in gastrointestinal disorders, metabolic diseases, inflammatory and autoimmune conditions, neurological disorders, and cancer. Furthermore, artificial intelligence and machine learning are increasingly being integrated into microbiome research to identify microbial biomarkers, predict treatment responses, and support personalized therapeutic intervention

Keywords: *Human Microbiome, Microbiome-Based Therapeutics, Precision Medicine, Fecal Microbiota Transplantation (FMT), Live Biotherapeutic Products (LBPs), Artificial Intelligence (AI).*

INTRODUCTION
The Human Microbiome is the collection of trillions of microorganisms, including bacteria, fungi, viruses, and archaea, that inhabit different parts of the human body, particularly the gastrointestinal tract. These microorganisms play a vital role in maintaining health by supporting digestion, regulating metabolism, strengthening the immune system, and protecting against harmful pathogens. An imbalance in the microbiome, known as dysbiosis, has been associated with a wide range of diseases, including inflammatory bowel disease, obesity, diabetes, cancer, neurological disorders, and autoimmune conditions. Microbiome-based therapeutics is an emerging field of medicine that aims to prevent, manage, or treat diseases by modifying the composition or function of the human microbiomeRecent advances in genomics, metagenomics, artificial intelligence, and precision medicine have accelerated the development of innovative microbiome-based on intervention [1].

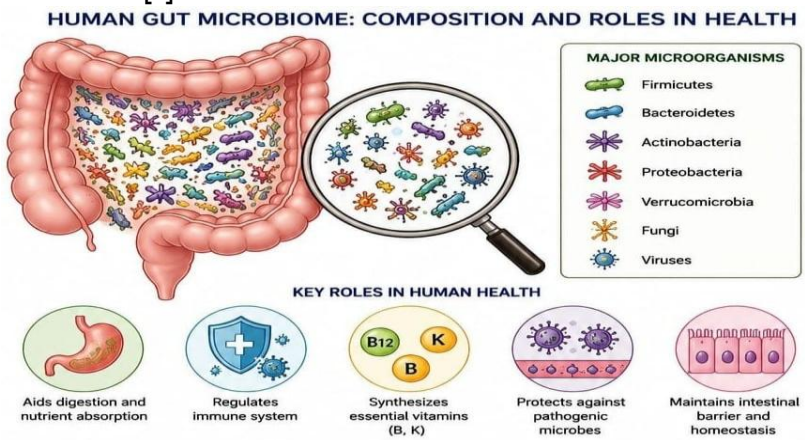

Figure 01: Human Gut Microbiome

The Human Microbiome refers to the collection of trillions of microorganisms, including bacteria, fungi, viruses, archaea, and protozoa, that naturally inhabit different parts of the human body. These microorganisms are present in the gastrointestinal tract, oral cavity, skin, respiratory tract, and urogenital tract, with the gut microbiome being the largest and most metabolically active microbial community. The microbiome functions as a dynamic ecosystem that interacts continuously with the host and contributes to maintaining physiological balance and overall health [2]. The

healthy gut microbiome performs several important physiological functions. It helps digest complex dietary carbohydrates that cannot be digested by human enzymes and converts them into short-chain fatty acids (SCFAs), which serve as an energy source for intestinal cells and possess anti-inflammatory properties. Beneficial microorganisms also synthesize essential vitamins such as vitamin K and several B-complex vitamins, regulate bile acid metabolism, maintain the integrity of the intestinal epithelial barrier, and prevent colonization by microorganism through competitive exclusion [3].

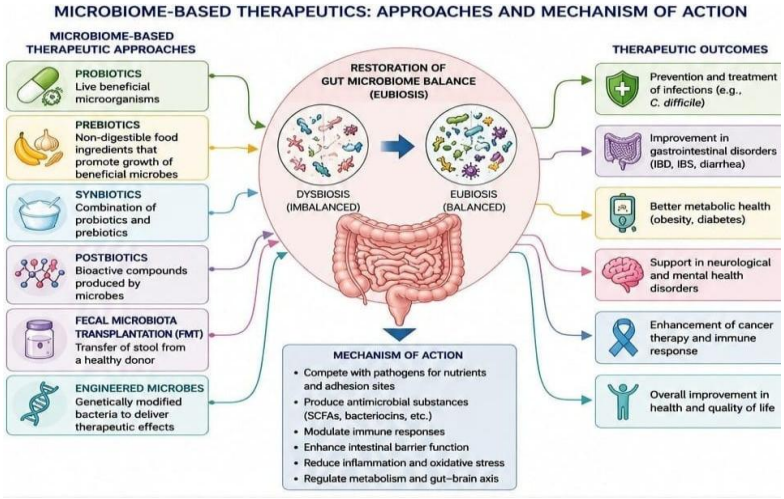

Figure 02: Microbiome Based Therapeutics

IMPORTANCE

Microbiome-based therapeutics have emerged as one of the most promising areas in modern medicine because they focus on restoring the balance of beneficial microorganisms rather than only treating disease symptoms. The human microbiome, particularly the gut microbiome, plays a vital role in digestion, metabolism, immune regulation, vitamin synthesis, and protection against harmful pathogens. Disruptions in the microbial community, known as dysbiosis, have been associated with a wide range of disorders, including inflammatory bowel disease obesity, diabetes, cardiovascular diseases, allergies, autoimmune disorders, neurological diseases, and certain cancers.. Microbiome therapeutics also contribute to combating antimicrobial resistance by reducing unnecessary antibiotic use promoting the restoration [4-5].

WIDE APPLICATIONS

Microbiome-based therapeutics have gained considerable attention because of their potential to treat a wide range of diseases by restoring the natural balance of microorganisms in the human body [6].

Gastrointestinal Disorders

The gut microbiome plays a central role in maintaining digestive health. Microbiome-based therapeutics have shown significant success in treating gastrointestinal diseases such as inflammatory bowel disease (IBD), irritable bowel syndrome (IBS), ulcerative colitis, Crohn's disease, and recurrent Clostridioides difficile infection. Probiotics, prebiotics, and fecal microbiota transplantation (FMT) help restore microbial diversity, reduce inflammation, improve intestinal barrier function, and promote healthy digestion [7].

Metabolic Disorders

Alterations in gut microbiota have been linked to obesity, type 2 diabetes mellitus, and metabolic syndrome. Beneficial microorganisms influence glucose metabolism, insulin sensitivity, fat storage, and energy balance. Modulation of the gut microbiome through dietary interventions, probiotics, and engineered microbes has shown promising results in improving metabolic health and reducing disease progression.

Cancer Therapy

The gut microbiome significantly influences the effectiveness of cancer immunotherapy and chemotherapy. Certain beneficial bacteria enhance immune responses against tumors and improve treatment outcomes. Researchers are investigating microbiome modulation to reduce treatment-related side effects and increase the efficacy of immune checkpoint inhibitors in various cancers, including colorectal cancer and melanoma.

Neurological Disorders

The gut–brain axis represents a bidirectional communication system between the gut microbiome and the central nervous system. Changes in gut microbial composition have been associated with neurological disorders such as Parkinson's disease, Alzheimer's disease, autism spectrum disorder, multiple sclerosis, anxiety, and depression. Microbiome-based therapies may improve neurological health by reducing neuroinflammation and regulating neurotransmitter production [8-9].

Autoimmune and Inflammatory Diseases

Microbiome imbalance contributes to abnormal immune activation in autoimmune diseases such as rheumatoid arthritis, systemic lupus erythematosus, psoriasis, and multiple sclerosis. Restoring microbial balance helps regulate immune responses, decrease chronic inflammation, and improve disease management [10].

Cardiovascular Diseases

Recent studies suggest that gut microorganisms influenrobiome-targeted therapies may reduce cardiovascular risk by improving lipid metabolism and decreasing harmful microbial metabolites associated with heart disease.

Skin Disorders

The skin microbiome also contributes to maintaining healthy skin. - Microbiome based therapies are being investigated for acne, eczema, atopic dermatitis, psoriasis, and wound healing. Beneficial microorganisms help maintain skin barrier integrity and suppress harmful pathogens.

Infectious Diseases

Microbiome modulation enhances resistance against pathogenic microorganisms by strengthening colonization resistance and improving immune function. Probiotics and bacteriophage therapies are being developed to prevent and manage antibiotic-resistant infections. continued advances in microbiome science are excepted to provider safer and more effcective and personalized therapeutics strategies for numerous chronic and infectious diseases [11].

DRAW BACKS

Although microbiome-based therapeutics have shown remarkable potential in preventing and treating various diseases, several scientific, clinical, and regulatory challenges still limit their widespread clinical application. Addressing these drawbacks is essential for the successful integration of microbiome-based therapies into routine healthcare.

Individual Variability

One of the major limitations is that the composition of the human microbiome differs significantly among individuals. Factors such as age, genetics, diet, lifestyle, geographical location, antibiotic use, and environmental exposure influence microbial diversity. As a result, the same microbiome-based therapy may produce different outcomes in different patients making personalized treatmemt strategies necessary.

Safety Concerns

Although probiotics and microbiome-based products are generally considered safe, certain patient populations, including immune compromised individuals, elderly patients, and critically ill patients, may be at increased risk of infection. In fecal microbiota transplantation (FMT), inadequate donor screening may lead to the transmission of pathogenic microorganisms or antibiotic-resistant bacteria.

Limited Long-Term Clinical Evidence

Most microbiome-based therapeutics is still under investigation, and long-term clinical data regarding their safety, efficacy, and durability remain limited. Large multicenter clinical trials are required before these therapies can be widely recommended for routine medical practice.

Regulatory challenges

Microbiome-based therapeutics involves living microorganisms, making their regulation more complex than conventional pharmaceutical products. Regulatory agencies continue to develop guidelines regarding manufacturing standards, product quality, donor screening, and clinical evaluation.

Manufacturing and Quality Control

Producing microbiome-based therapeutic products with consistent microbial composition, stability, viability, and potency remains technically challenging. Variations during production, storage, and transportation may affect therapeutic effectiveness.

High Cost

Advanced microbiome sequencing, metagenomic analysis, personalized microbial therapies, and fecal microbiota transplantation are relatively expensive procedures. High treatment costs may limit accessibility, particularly in developing countries [12].

ETHICAL AND SOCIAL ISSUES

The collection, storage, and transplantation of human micro biota raise ethical concerns regarding donor selection, informed consent, patient privacy, and long-term safety. Genetically engineered microorganisms also require careful ethical evaluation before clinical use.

Drug–Microbiome Interactions

Many commonly used medications, including antibiotics, proton pump inhibitors, and non-steroidal anti-inflammatory drugs, alter the gut microbiome composition. These interactions may reduce therapeutic effectiveness or produce unpredictable clinical responses.

Standardization Issues

Different laboratories often use different methods for microbiome sequencing, microbial analysis, and therapeutic formulation. Lack of standardized protocols makes comparison of research findings difficult and delays clinical translation [13].

MODELS

Experimental models are essential for understanding the role of the human microbiome in health and disease. These models help researchers investigate host–microbe interactions, evaluate the safety and efficacy of microbiome-based therapeutics, and develop new treatment strategies before clinical application.

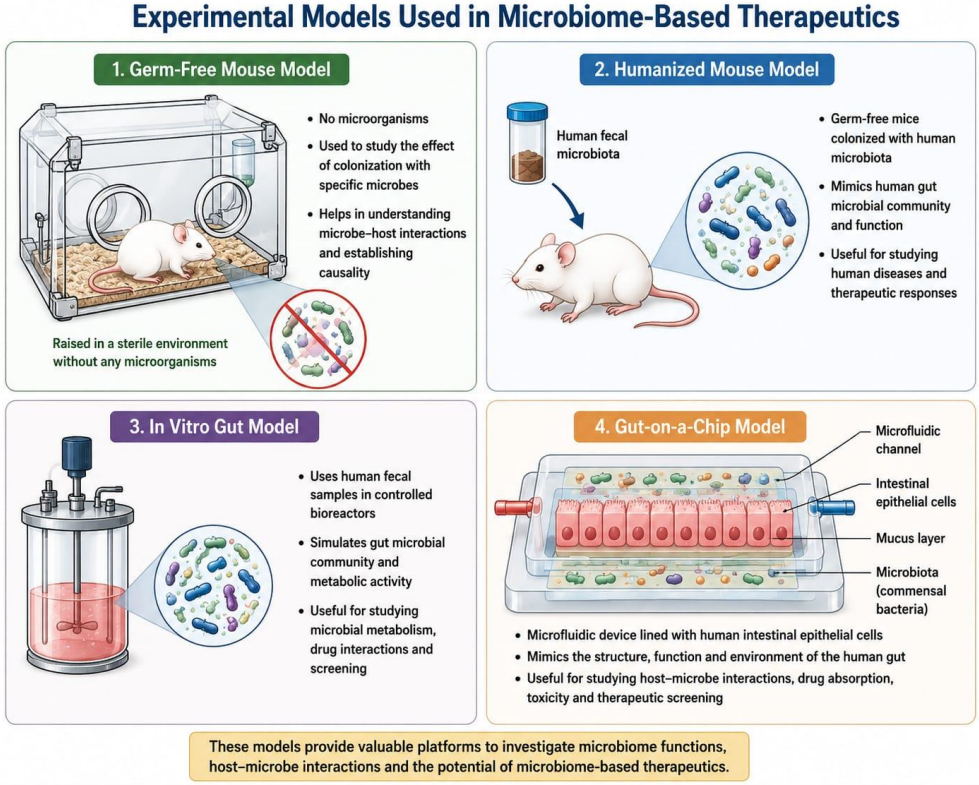

Figure 03: Experimental Models

Germ-Free Mouse Model

Germ-free mice are raised under completely sterile conditions without any microorganisms. These models are used to investigate the direct effects of specific microbes on host physiology, immune function, and disease progression [14].

Humanized Mouse Model

In this model, germ-free mice are colonized with human gut microbiota. It closely mimics the human intestinal microbial environment and is useful for studying human diseases and evaluating personalized microbiome-based therapies.

In Vitro Gut Model

This laboratory model simulates the human intestinal environment using cultured intestinal cells and beneficial microorganisms. It enables researchers to study microbial metabolism, drug–microbiome interactions, and therapeutic responses under controlled conditions.

Gut-on-a-Chip Model

Gut-on-a-chip is an advanced microfluidic platform that reproduces the structure and function of the human intestine. It allows researchers to investigate microbial interactions, intestinal barrier function, nutrient absorption, and drug responses more accurately than conventional laboratory model [15].

CONCLUSION

Microbiome-based therapeutics represent a transformative approach in modern precision medicine by targeting the human microbiome to prevent and treat a wide range of diseases. Advances in genomics, artificial intelligence, and microbial engineering continue to accelerate their clinical potential. Despite challenges related to safety, standardization, regulation, and long-term efficacy, ongoing research and innovative experimental models are expected to enable safer, more effective, and personalized microbiome-based therapies in the future.

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INFORM CONSENT AND ETHICAL STATEMENT
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