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Introduction

This task will provide a detailed market analysis per use case, which will assist the DAIsy project to position itself within the relevant markets. Please note the AI landscape is changing rapidly, and changes in 2024 might still require report extensions or adaptations in 2025.

Netherlands Use Case 1: Major Depressive Disorder (MDD)

Introduction

Recent studies suggest a concerning trend of increasing MDD cases in the coming decade. Factors such as heightened stress levels, lifestyle changes, and the lingering impact of global events may contribute to a rise in the prevalence of MDD. Additionally, improved awareness and reduced stigma surrounding mental health issues could lead to more individuals seeking diagnosis and treatment. The evolving societal landscape and ongoing efforts to destigmatize mental health concerns highlight the importance of proactive measures in addressing the anticipated growth. This underscores the need for continued research, accessible mental health services, and market initiatives to mitigate the impact of this concerning trend.

Market Characterization (Key Trends, Stakeholders)

The market for MDD involves a range of treatments, including pharmaceuticals and therapies. Key trends include a growing emphasis on personalized care, the integration of technology, and the rise of digital- telemedicine. Medical centers such as the Amsterdam University Medical Centers (AUMC) play a crucial role as stakeholders, providing diagnostic services, treatment facilities, and contributing to research and innovation in the evolving landscape of MDD care. The market is dynamic, with ongoing efforts to enhance diagnostic precision and treatment effectiveness amid challenges such as stigma and treatment-resistant depression.

Market Size

Globally, an estimated 280 million adults suffer from depression, with more women than men affected by the disorder [1]. A surge of 25% is estimated to stem from the COVID pandemic and related lockdown measures [2]. The Depressive Disorders market worldwide is projected to grow by 0.92% (2024-2028) resulting in a market volume of €20.67bn in 2028 [3]. By 2030, MDD is projected be the leading cause of burden of disease [4].

Competitive Products & Services

The market of MDD is rapidly changing. We predict a rise in competitive services in the landscape, as the use of multimodal AI products for MDD is still in the early stages of market development.

Legal Aspects

Regulations need to be met involving data privacy and ethical use of AI before implementation into the market can be granted. This is especially true in the medical field as there are strict data and technology regulation measurements in place. Some legal aspects related to the implementation of AI in the context of MDD:

- **Regulatory Compliance:** Compliance with regulations governing data privacy, such as the General Data Protection Regulation (GDPR) in the European Union, is paramount. Any AI-driven solutions must adhere to strict protocols for the collection, storage, and processing of patient data to safeguard confidentiality and privacy.
- **Ethical Use of AI:** Ensuring the ethical use of AI in MDD treatment involves addressing concerns such as transparency, accountability, and fairness. Transparency entails disclosing how AI algorithms operate and make decisions to patients and healthcare providers. Accountability involves clearly defining roles and responsibilities in the development, deployment, and maintenance of AI systems. Fairness requires mitigating biases that may inadvertently affect certain demographic groups disproportionately.
- **Medical Device Regulation:** Depending on the classification of our AI-based tool used for MDD treatment, they may be subject to medical device regulations. Compliance with standards such as ISO 13485 for quality management systems and ISO 14971 for risk management is necessary to ensure the safety and effectiveness of these devices.
- **Clinical Validation:** Before AI-driven solutions for MDD can be deployed in clinical settings, they must undergo rigorous validation to demonstrate their safety, efficacy, and reliability. Clinical trials and real-world evidence generation are essential steps in this validation process, requiring adherence to regulatory requirements for conducting clinical research.
- **Liability and Accountability:** Clarifying liability and accountability in cases of adverse outcomes related to AI-driven MDD interventions is crucial. Assigning responsibility between developers, healthcare providers, and regulatory authorities requires clear legal frameworks that account for the unique challenges posed by AI technologies.
- **Continued Monitoring and Compliance:** Post-market surveillance and ongoing monitoring of AI-based MDD interventions are necessary to ensure continued compliance with regulations and standards. This includes monitoring for adverse events, updating algorithms based on new evidence, and maintaining transparency with stakeholders regarding any changes or updates to the technology.

Assessing Risks and Contingency Plans

The heterogeneity of MDD, including treatment-resistant forms, complicates the development of effective interventions. Additionally, individual variations in symptoms and responses to treatment contribute to the challenge of providing personalized and targeted therapies. Continuous investment in research to better understand the underlying mechanisms of MDD, identify novel therapeutic targets, and develop innovative treatment modalities. Embracing a personalized medicine approach by tailoring treatments based on individual patient characteristics, genetics, and biomarkers to improve efficacy and reduce side effects will be the key to avoiding risks.

Netherlands Use Case 2: Eating Disorder (ED)

Introduction

Eating Disorders are difficult to treat, similarly as MDD. There is only approximately 50% of patients who recover after treatment and even after successful treatment, relapse is high. The social costs of ED are large. Data from the UK show that almost half of ED patients will wait longer than a year before seeking help. This is of particular concern as late intervention appears to be the single most important predictor of relapse. Those who sought early help showed a relapse rate of 33%, compared to an average level of 63% from all those who sought

later help [8]. Time to diagnosis commonly takes another year, and time to treatment an additional 6 months. Although addressing waiting times is important, early detection and intervention needs to be a priority as well. Early detection and treatment is estimated to lead to 30% less relapse, and the cycle of symptom emergence to recovery and possible relapse takes 6 years. With increased amounts of collected ED patient data, and new AI methods, there is a large market opportunity for introducing valuable solutions in improving the outcome of this vulnerable patient group.

Market Characterization (Key Trends, Stakeholders)

The global eating disorder market is expected to witness market growth at a rate of 5.8% in the forecast period of 2022 to 2029 [7]. Data Bridge Market Research report on eating disorder market provides analysis and insights regarding the various factors expected to be prevalent throughout the forecast period while providing their impacts on the market's growth. The rise in healthcare sector globally is escalating the growth of eating disorder market.

Eating disorder refers to a complex mental health condition that usually requires psychiatric and medical assistance. A common misconception exists regarding eating habits such as overeating eating is healthy lifestyle choice. The disorder might develop with obsession with food, body weight and size that leads to some serious health problems including diabetes, cardiovascular diseases, anxiety, and depression, among others.

The rise in the prevalence of binge eating disorder across the globe acts as one of the major factors driving the growth of eating disorder market. The increase in the incidences of obesity among population and rise in occurrence of eating disorder especially among women accelerate the market growth. The rise in Research and Development in pharmaceutical companies for enhancing the treatment and surge in government initiatives to increase the awareness further influence the market. Additionally, surge in healthcare expenditure, development in technology, supportive government legislation and rise in social media influence positively affect the eating disorder market. Furthermore, research on new indications extend profitable opportunities to the market players in the forecast period of 2022 to 2029 [5].

On the other hand, concerns regarding side-effects of the treatment and stigma associated with the eating disorder are expected to obstruct the market growth. The lack of awareness regarding the disorder is projected to challenge the eating disorder market in the forecast period of 2022-2029.

Market Size

Next to the healthcare market, the apps built for eating disorders can be applied as well as in health and well-being market. There is a growing inclination towards healthy lifestyle, which has boosted demand for fitness apps with nutrition and diet functionality. Based on Data Bridge market research global diet and nutrition apps market is expected to grow with a CAGR 17.61% in the forecast period of 2022 to 2030 [6]. The exponential growth of the market is driven also by the increased percentage of the obese population. For example, the US has large obese population, which is almost the 40% in 2019, while in Europe this is 23%. The obesity epidemic is not restricted to them only, resulting in increased demand for fitness and weight loss controlling app with food intake tracking.

Competitive Products & Services

The downloads of fitness and health apps increased globally by 46.0% in 2020 according the World Economic Forum. There key players on the market include: Adidas, Appster, FitnessKeeper, Fitbit, Inc., Azumio, Inc., MyFitnessPal Inc., Noom, Nike, etc. For instance, MyFitnessPal offers personalized diet and activity tracking to its users, generating a revenue of $6.7M in June 2020. Health and fitness apps show the highest retention rates across all categories with 96.0% of users using only one of these apps.

Legal Aspects

Assessing Risks and Contingency Plans

Turkish Use Case 1: Major Depressive Disorders (melancholia, catatonic, seasonal and psychotic depression)

Introduction

This project aims to develop an artificial intelligence ecosystem that continuously monitors patients with Major Depressive Disorder (MDD) by tracking their vital parameters using wearable sensor technology and analyzing audio and visual recordings obtained through a mobile application, from hospitalization to post-discharge. This project aims to offer a new solution in the field of mental health, aiming to assist in more effectively managing patients' health conditions and improving the treatment process. With the goal of addressing the increasing mental health needs and providing better healthcare services using artificial intelligence technologies in this field to enhance patients' quality of life, this project seeks to demonstrate the potential of clinical applications and AI-supported solutions in the healthcare sector. The integration of wearable medical devices into the healthcare sector, particularly for monitoring and treating Major Depressive Disorders (MDD), is at the forefront of NP Brain Hospital's innovative project. This report delves into the market analysis of wearable medical devices, emphasizing their pivotal role in enhancing patient care and the treatment process within the framework of the hospital's project.

Market Characterization (Key Trends, Stakeholders)

The use of wearable sensors in clinical applications has become a significant trend in the healthcare sector. This trend enables real-time monitoring of patient vital signs, providing healthcare professionals with better and faster intervention capabilities. In this context, the integration of wearable sensor technology with a mobile application developed for monitoring vital parameters of patients with major depressive disorder allows doctors to continuously monitor patients health status and enables intervention when necessary.

Among the stakeholders are professionals in the healthcare sector (doctors, nurses, psychologists), patients and their families, healthcare technology companies, academic institutions, and government agencies. These stakeholders play critical roles in the development, implementation, and acceptance of wearable sensor technology.

Market Size

In recent years, wearable health technology has gained significant popularity, driven by rapid advancements in biosensor technology, battery sizes, and overall performance. This convergence of technology and healthcare is expected to propel the global wearable medical devices market to a value of USD 41.75 billion by 2024, with projections soaring to USD 86.20 billion by 2029, indicating a robust CAGR (Compound Annual Growth Rate) of 15.60% during the forecast period [9]. With their ability to monitor patients and measure various health parameters seamlessly, wearable medical technologies offer a proactive approach to wellness, ensuring users stay informed and engaged in managing their health effectively. The global wearable medical devices market is on an upward trajectory, expected to reach $77.3 billion by 2025, propelled by their increasing adoption for health and fitness, healthcare, and industrial monitoring due to the aging global population [13]. Wearable technologies, especially in healthcare, promise non-invasive, continuous monitoring, offering significant potential for personalized medicine and improved care quality [12].

North America leads the market, supported by comprehensive reimbursement policies and advanced healthcare technologies. The Asia Pacific region is expected to witness the highest growth rate, driven by increasing healthcare expenditures and a growing geriatric population [10].

Competitive Products & Services

Legal Aspects

The vital data collected and processed from wearable sensors are subject to significant legal regulations under Turkey's Personal Data Protection Law (KVKK). Within this framework, ensuring data privacy and security, obtaining valid permissions for data collection and usage, defining data processing purposes and limitations, managing data storage processes, and safeguarding the rights of data subjects are crucial considerations. The processing and storage of vital data collected through wearable sensors must fully comply with the requirements of the KVKK, representing a legal obligation for healthcare service providers and application developers, and is critical for protecting the rights and privacy of data subjects.

Diagnostic and patient monitoring devices dominate the market, driven by the rising prevalence of chronic diseases and the demand for continuous health monitoring. The United States holds a significant market share, attributed to the high incidence of cardiovascular and lifestyle-related diseases and the robust presence of major players like Garmin Ltd and Fitbit Inc. [14].

Assessing Risks and Contingency Plans

Despite the market's potential, wearable medical devices face challenges such as high costs, limited reimbursement policies, and regulatory hurdles. However, companies are engaging with regulatory bodies to secure product approvals, demonstrating a commitment to compliance and market trust [11].

Turkish use case 2: Distinguishing Bipolar and Unipolar Depressive Disorder

Introduction

By DAIsy project; it is expected to prove the added value of AI in every stage of the mental health treatment process chain. The artificial intelligence-supported solution will increase its power in the health sector, especially in the diagnosis and treatment of MDD and bipolar disorder diseases targeted by Türkiye use case 2.

Market Characterization (Key Trends, Stakeholders)

Depression is different from usual mood fluctuations and short-lived emotional responses to challenges in everyday life. During a depressive episode, the person experiences depressed mood (feeling sad, irritable, empty) or a loss of pleasure or interest in activities, for most of the day, nearly every day, for at least two weeks.

Comprehensive Mental Health Action Plan 2013-2030 builds upon its predecessor and sets out clear actions for Member States, the WHO Secretariat and international, regional and national partners to promote mental health and well-being for all, to prevent mental health conditions for those at-risk and to achieve universal coverage for mental health services.

In 2019, 40 million people experienced bipolar disorder [15]. People with bipolar disorder experience alternating depressive episodes with periods of manic symptoms. The bipolar disorders treatment market is anticipated to reach 5212.49 Million € by 2030 at 3.40% CAGR during the forecast period 2022-2030 consisting North America, Europe, Asia-Pacific, and Rest of the World (RoW).

Market Size

According to 2023 report "Health and Pharmaceutical Sectoral Overview" published by KPMG Türkiye, the healthcare and pharmaceutical sector continues to grow globally with the development of digital technologies. Global healthcare spending is expected to reach €10.5 trillion in 2025 and the pharmaceutical market is expected to reach €1.4 trillion. In addition to the growth of the market, the digital health and pharmaceutical era also has the potential to revolutionize healthcare services. Digitalization in the sector; wearable technologies and big data, offers benefits such as faster and more accurate diagnoses, personalized treatments, and improved patient quality of life.

Turkey's government has released the country's National Artificial Intelligence Strategy for 2021-2025. The Turkish government had announced an ambitious policy blueprint aimed at making the country's AI sector account for at least 5% of GDP by 2025. The government has announced several other initiatives to promote the use of AI in healthcare, including the "Digital Health Transformation Program," which aims to provide residents across the nation with electronic health records, telemedicine services, and AI-powered health applications.

Competitive Products & Services

In Türkiye, there is no available AI based completely integrated solution targeting the project aims related with diagnosis and treatment of MDD and bipolar disorder diseases focusing on distinguishing bipolar and unipolar depressive disorder.

Legal Aspects

Regulations which involves data privacy and ethical use of AI for healthcare need to be met before giving the product of this project to market. Regulations for Turkey's Personal Data Protection Law (KVKK) is important to protect the rights of the participants. For securing the confidentiality of participant data and maintaining full compliance with KVKK regulations, approval need to be taken from the ethics committee. This not only underscores the commitment to ethical practices but also serves as a proactive step in aligning with legal requirements, fostering trust among stakeholders, and promoting responsible and secure use of AI in healthcare.

Assessing Risks and Contingency Plans

When implementing Generative AI applications for Major Depressive Disorder (MDD), notable risks encompass ethical considerations, potential inaccuracies in clinical assessments, reliance on data quality, safety concerns for patients, and issues related to interpretability. To mitigate these risks, contingency plans emphasize regular audits and updates, adopting a human-in-the-loop approach, providing transparent documentation, implementing robust security measures, obtaining patient consent and facilitating education, incorporating diverse stakeholder input, establishing fallback mechanisms, adhering to regulatory requirements, ensuring continuous monitoring, and incorporating feedback loops. These measures are designed to enhance accuracy, safeguard patient privacy, improve interpretability, and maintain ethical standards throughout the development of the AI model in the healthcare domain.

German use case 1: Multimodal neurofeedback

Introduction

The emerging mega trend of mental health requires new tools to improve therapeutic care while lowering costs so that more people can be helped.

Available tools for this market have achieved practicality and evidence-based acceptance, so that multimodal neurofeedback, through which the client's brain learns to improve its self-regulation makes it suitable as part of basic therapy for a wide range of disorders incl. depression, as it can modulate brain activity and improve mood and cognition.

Providing an open-source toolbox will be flexible and adaptable to different depression profiles and therapeutic goals and gain market acceptance much quicker than with non-disclosed technology.

The proposed multimodal neurofeedback system will have a positive business impact by offering a cutting-edge solution for mental health care, addressing unmet clinical needs, and reaching a large and growing market of potential customers.

Market Characterization (Key Trends, Stakeholders)

Mental health is an emerging global megatrend that will require more and more effective tools to reduce costs and help patients. Patients are now more educated and are looking for methods to avoid taking medication with severe side effects. In addition to patients as stakeholders, it is also important to consider the pharmaceutical industry, which currently derives the greatest economic benefit from this clinical area.

The acceptance of technologies in this market has also been increasing for years. Neurofeedback is already well known in many countries and clinicians and therapists are beginning to actively enquire about it. Some clinics are already budgeting money for technical solutions in the field of mental health, making them important stakeholders in this area alongside government and church humanitarian agencies.

Classic neurofeedback methods, which are mostly based on operant conditioning, have become indispensable. However, the potential of more advanced tools that also take into account the combination of different neurofeedback technologies (multimodal approach of this project) or the use of artificial intelligence has now also been recognised by the various players in the mental health market.

Market Size

In industrialized countries, the percentage of people suffering from mental illness who receive treatment varies significantly. Stigma, lack of awareness, and barriers to seeking help often prevent individuals from accessing appropriate care. But efforts to improve mental health literacy, reduce stigma, and enhance access to treatment are ongoing. As a result, more and more patients who need help are actively seeking it.

Apart from pharmaceuticals, there is currently little technical support for treatments in the area of mental disorders. For this reason, the market size is difficult to estimate, as technological solutions are confronted with the argument that they are unnecessary.

Depending on the country, we currently assume that neurofeedback systems are available in the range of 0.25% to 4.6%, meaning that a large market share still appears to be untapped. In Europe alone, we estimate that there are at least 156,000 potential customers for a multimodal neurofeedback system, depending on the country and the acceptance of the therapy method (e.g. 55,000 practices and clinics in Germany, only 22,400 in France). Assuming a sales price of approx. 12,000 euros, this results in a market potential of 1.9 billion euros in Europe in the first step. Additional to this potential, there is the possibility of generating recurring sales by offering associated SaaS.

Competitive Products & Services

There are currently no known products that combine EEG and fNIRS neurofeedback that match our multimodal approach from the project. For this reason, only separate solutions for EEG neurofeedback and fNIRS neurofeedback can be considered as competitive products.

In addition to BEE Medic, large parts of the global EEG neurofeedback market are shared by the following competitors: NeuroCare (Germany) with products for SCP neurofeedback, MindMedia (Netherlands) and Thought Technology (CDN) with products for classical bio- and neurofeedback approaches (e.g. frequency band training). In the USA in particular, the company Brain Master is attempting to occupy a large part of the market for classic neurofeedback and SCP training.

For fNIRS neurofeedback only Turbosatori from NIRx seems to be commercially available as a medical product. Measured in terms of economic indicators, the company behind it cannot yet have a large market share.

Legal Aspects

Neurofeedback is not yet regulated in most countries. Individual countries have already recognised the potential and developed their own reimbursement figures for treatment with neurofeedback (e.g. Croatia), while in other countries neurofeedback is viewed very critically and may only be used by doctors, for example (e.g. Turkey).

As it is used for therapeutic purposes, it is subject to basic requirements for medical devices such as the European Medical Device Regulation 2017/745. In the USA, the FDA considers neurofeedback systems to be 510(k) exempt in its Code of Federal Regulations 21 CFR Rule 882.5050, which allows for easy placing on the market. There are exceptions for wired systems.

The only known specialised application standard is 2010-2012- IEEE Recommended Practice for Neurofeedback Systems, which also only covers EEG neurofeedback systems.

In principle, there is nothing to impede the placing on the market of the multimodal neurofeedback system if it is carefully developed into a medical device following the project.

Assessing Risks and Contingency Plans

From a technological perspective, new providers on the market with pioneering new technologies could pose a risk for subsequent commercialization (as in any industry). Currently, providers for the homecare market appear, as this would seem much larger at first glance. So far, however, no home-use systems have been identified by the consortium that even come close to the effectiveness of classic EEG neurofeedback in a clinical setting. Regular monitoring of the market is the most important measure here.

Wishful thinking and science fiction may lead to solutions that are fundamentally flawed. Marketing channels may be overloaded with marketing of flawed solutions. This may sustainably harm the reputation. For this reason, regular provision of generally accessible information - also for patients - is an essential risk minimisation measure.

German use case 2: Virtual therapy assistance

Introduction

The project proposes a virtual therapy assistant that can supplement other treatments for depression in adults. The assistant monitors and displays behavioural and contextual data, such as social interactions, and uses questionnaires to help patients self-evaluate their mood and triggers. The assistant also offers psychoeducation based on the data, to help patients learn and apply coping skills in different situations. The assistant aims to provide practical and immediate support, as well as to enable more personalized therapy by understanding each patient's profile.

Market Characterization (Key Trends, Stakeholders)

Depressive disorders affect millions of people around the world and are often treated with psychological interventions. However, some trends and stakeholders are changing the landscape of depression care in the market.

Some of these trends are:

- Personalized care, which tailors the treatment to the individual needs and preferences of each patient
- The integration of technology, which enables remote access to mental health services and tools, such as digital-telemedicine
- Full treatment approaches, which combine medication, therapy, and lifestyle changes, to provide a holistic solution for depression

Some of the stakeholders involved in the market are:

- Pharmaceutical companies, which develop and market antidepressant drugs and other medications for depression
- Healthcare providers, which offer diagnosis, counseling, and treatment for depression
- Government agencies, which regulate, fund, and promote mental health initiatives and policies

The corona lockdown has also had a negative impact on the mental health of many people, worsening their depression symptoms and limiting their access to care. This poses a challenge for the market, but also an opportunity to innovate and improve the quality and availability of depression care.

Market Size

The depressive disorders market in Germany is expected to record sales of around EUR 0.80 billion in 2023. Sales are expected to grow at a compound annual growth rate (CAGR 2023-2028) of 0.98%, resulting in a forecast market volume of €0.84 billion in 2028. In a global comparison, the largest share of sales is expected in the USA (€ 5,217.00 million in 2023). Converted to the size of the population, this market will generate sales of around € 231.60 per capita in 2023 [16-17].

Competitive Products & Services

There are several depression apps available for therapeutic support that either complement or prepare for formal therapy. Well-known apps such as Novego, MindDoc, Selfapy and deprexis24 are not only recognized by health insurance companies but have also proven their effectiveness in scientific studies. These platforms provide a curriculum based on static learning content that users can engage with over several weeks. The apps also contain interactive components and sometimes offer direct therapy contact to increase user motivation. In addition to the systems mentioned above, the project aims to integrate highly individual therapy content. This personalized content is generated by advanced AI algorithms that consider various elements from the user's context. These elements include environmental conditions, weather, app usage history, and data from wearables. To the consortium's knowledge, there is currently no other commercially available solution that offers such a comprehensive, personalized and multimodal therapy experience.

Legal Aspects

Virtual therapy assistance software, which provides mental health services or support through a digital platform, raises several legal aspects that need to be considered by providers. Here are some key legal considerations:

1. Licensing and Credentials: Therapists using the software must be properly licensed in the jurisdiction where they practice and where the patient is located. Software providers should have mechanisms to verify the credentials of healthcare professionals using their platform.

2. Confidentiality and Privacy: Compliance with laws GDPR in Europe, or other local data protection regulations is essential to protect patient information. The software must ensure secure communication and storage of patient records.

3. Informed Consent: Clear and comprehensive informed consent must be obtained from patients for receiving virtual therapy, including explanations of how the technology works, potential risks, confidentiality measures, and any data handling practices.

4. Liability and Malpractice: Providers need to ensure that their malpractice insurance covers teletherapy services. Additionally, terms of service for the software should clearly delineate liability in case of technical issues or therapeutic misadventures.

5. Cross-Border Issues: When virtual therapy involves crossing state or national boundaries, it can complicate regulatory compliance due to differing laws on telehealth across jurisdictions.

6. Accessibility: Virtual therapy software must adhere to regulations ensuring accessibility to individuals with disabilities.

7. Emergency Protocols: There should be clear protocols for handling emergencies when immediate intervention is required but may be complicated by the virtual nature of the service.

8. Record Keeping: Accurate and secure record-keeping is crucial for continuity of care as well as for legal protection.

9. Ethical Considerations: Providers should maintain ethical standards as per guidelines from professional bodies regarding dual relationships, confidentiality, and professional conduct over teletherapy platforms.

10. Technology Standards and Reliability: Ensuring that the software meets high standards for reliability and uptime is important to avoid interruptions in care that could result in harm to patients.

Assessing Risks and Contingency Plans

Assessing the risks of virtual mental therapy software involves a comprehensive analysis to identify potential issues that may affect its efficiency, security, and effectiveness. Here's a framework for risk assessment and the development of contingency plans:

1. Data Security and Privacy Risks: - Assess vulnerabilities to data breaches or unauthorized access. - Ensure compliance with GDPR for protecting patient information.

- Contingency Plan: Implement strong encryption, regular security audits, and immediate breach notification protocols.

2. Software Reliability Risks: - Evaluate the risk of software outages or malfunctions. - Regularly update and test software to reduce bugs or failures.

- Contingency Plan: Develop redundancy systems and quick recovery methods for software crashes.

3. Clinical Efficacy Risks: - Validate the therapeutic approaches used in the software against empirical evidence. - Monitor effectiveness through user feedback and clinical outcomes.

- Contingency Plan: Establish a protocol for regular review and updates of therapeutic content.

4. User Engagement Risks: - Understand barriers to user engagement such as usability issues or lack of personalization. - Use design thinking to create an intuitive user interface and experience.

- Contingency Plan: Create channels for user feedback and incorporate adaptive learning algorithms.

5. Compliance with Legal and Ethical Standards: - Stay up-to-date with laws regarding teletherapy practices across different regions. - Develop clear terms of service, informed consent processes, and ethical guidelines.

- Contingency Plan: Set up legal support to address any compliance issues proactively.

6. Interruption of Service Risks: - Plan for scenarios like internet outages, server problems, or natural disasters affecting service availability. - Implement cloud-based solutions with high uptime guarantees and distributed architecture if possible.

- Contingency Plan: Have backup communication channels (e.g., phone lines) in place.

7. Risk of Misdiagnosis or Therapeutic Missteps: - Train AI algorithms with diverse datasets to minimize biases and inaccuracies. - Pair virtual therapy with human oversight where necessary.

- Contingency Plan: Establish clear guidelines for referral to human therapists or emergency services when needed.

8. Market Acceptance Risks: - Research market readiness for virtual mental therapy tools among both therapists and patients. - Develop marketing strategies that effectively communicate benefits and ease concerns about virtual therapy.

- Contingency Plan: Adjust marketing strategies based on consumer feedback and uptake rates.

Portuguese use case: Major Depressive Disorder

Introduction

The Portuguese Use Case main goal is to develop an AI-driven mental health solution for MDD patients to manage and improve their health condition, by identifying, acquiring, and integrating heterogeneous data sources and combine AI algorithms and decision support systems for enhanced insights and ensure data privacy and security while using AI.

The continuous collection of data enables the implementation of targeted interventions, ranging from personalized therapy regimens to real-time support mechanisms. Moreover, the seamless integration of AI into everyday life through mobile apps and wearables ensures that individuals have access to support and resources whenever needed, fostering a culture of proactive mental health management.

Market Characterization (Key Trends, Stakeholders)

In Portugal, the understanding of Depressive Disorders in the market is growing due to significant key trends and diverse stakeholders. People are leaning more towards full treatment approaches, combining medication, therapy, and lifestyle changes, emphasizing a growing preference for comprehensive solutions among consumers.

Stakeholders in the Portuguese market, including pharmaceutical companies, healthcare providers, and government agencies, are actively engaged in addressing the challenges presented by the high prevalence of mental health disorders. Moreover, the steady growth trajectory projected for the market underscores Portugal's significant contribution to the global landscape of Depressive Disorders.

Market Size

In Portugal, the market for Depressive Disorders is robust, with revenue reaching US$158.70 million in 2024, representing a steady growth rate of 3.2%. Projections show a consistent upward trend, with an expected annual growth rate from 2024 to 2028 of 1.55%, reaching a market volume of US$168.80 million by 2028 [18]. These figures highlight Portugal's significant contribution to the global Depressive Disorders market. Despite potential challenges, such as access to mental healthcare services and societal stigmas, Portugal's commitment to mental health initiatives highlights a positive view for market expansion. Investments in research, treatment facilities, and public awareness campaigns are pivotal in sustaining this growth trajectory, ensuring better outcomes for individuals grappling with MDD across Portugal. The steady growth in the Depressive Disorders market, combined with its commitment to mental health initiatives, suggests a promising future with potential for further expansion.

Competitive Products & Services

In Portugal, there is no available Al based completely integrated in a single solution targeting the Portuguese use case goals, which are related with diagnosis and treatment of MDD. There is however a wide range of applications currently being used for the management of depression and anxiety related aspects for patients with Depressive Disorders (among which are included MDD Patients). In this scope, it highlighted some of the most popular mHealth apps available in the market.

Happify offers evidence-based activities targeting mindfulness, gratitude, and positive thinking, potentially benefiting individuals with Major Depressive Disorder (MDD). It provides personalized tracks and daily exercises, serving as a complement to therapy. While simple, tasks are backed by research, enhancing mental health. The user-friendly interface makes it accessible to a wide range of users.

MoodGym is a web-based program rooted in Cognitive Behavioral Therapy (CBT) principles, offering modules on feelings, thoughts, coping techniques, stress management, and relationships. Despite challenges like high non-adherence rates, its evidence-based approach makes it suitable for individuals with MDD, although its interface may be outdated.

'This Way Up' provides courses focused on stress, worry, sadness, and shyness through CBT techniques. It offers weekly lessons with homework assignments, tailored for teenagers and adults. While lacking in feedback and interaction, its efficacy depends on user engagement, making it more suitable for stress and worry than specifically diagnosed MDD.

Woebot, a mobile app, delivers CBT techniques through interactive text-based conversations, primarily for young adults experiencing stress. While effective for mild stress, its suitability for MDD is uncertain due to limitations in responding to complex situations and lack of empirical support. Additional professional support may be more beneficial for MDD patients.

Legal Aspects

The development of the Portuguese Use Case should be done in accordance with all Portuguese and European directives, including GDPR. Validation studies will comply Helsinki's declaration, written explicit informed consents will be obtained before any data collection / processing. The storage of health personal data will be managed in way to guarantee privacy and protection for all data cycle. Reliable technological standards will be used in order to establish secure acquisition, communication, processing, storage and destruction of data. Tecnology will be tested to ensure correct functioning.

Assessing Risks and Contingency Plans

The Portuguese Use Case will process personal health data, with inherent risk of data security and privacy. Recommended standards and practices to reduce these risks will be applied, including authentication good practises and encryption of data. Vulnerabilities to data breaches or no authorized access will be scanned and solved. An auditing system will be in force and continuous monitoring of accesses will be implemented to detected as early as possible any breach. Immediate breach protocols for notification will be implemented.

Malfunction software risk will be reduced by adequate reliability testing and accessed by monitoring fails. A regular review and update system will be implemented to mitigate problems.

The AI-driven mental health solution for MDD will be integrated in the daily-life of persons with MDD implementing targeted interventions, that should affect positively their mental health. Clinical validation of the interventions needs to be provided. The risk of an effect different from expected exists and needs to be considered. Effectiveness needs to be monitored using user feedback and outcomes.

As in any digital health solution, the lack of user engagement and abandonment is a relevant risk. The development of the solution for the Portuguese use case will include final users' input, to achieve better fitting with users' needs. Features allowing personalization will be included and users feedback incorporated for continuous improvement.

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