



A Study of Virtual Reality as a Mental Health Tool and its impact and potential in the Healthcare Sector

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Abstract

Title: A Study of Virtual Reality as a Mental Health Tool and its impact and potential in the Healthcare Sector

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The recent global attention to the importance of mental health has created a growing demand for effective and accessible treatments. Innovation and technology have advanced to meet this demand, consequently disrupting the healthcare sector. Virtual Reality (VR), a technology that integrates users with an immersive computer-generated space, has been developed as a sophisticated treatment tool for various mental health disorders, such as anxiety, depression, and dementia. Start-ups noticed this opportunity and quickly adapted the technology from the experimental stages to a marketable product. The objective of this study was to analyze the impact of the emerging market for VR mental health treatment on the healthcare sector in Europe, and to explore the potential future impact and evolution.

This study was conducted via qualitative research consisting of two approaches: desk research and semi-structured interviews (SSIs) with founders and employees of Europe's leading start-ups in this market. This investigation combined a sector analysis and interviews to create three case vignettes. This case-based research approach was developed to incorporate the sector's context, general and theoretical concepts, and the reality experienced by current market players.

The hardware segment of the VR market is dominated by the world's leading technology companies, such as Google, Facebook and Sony, while the software segment is composed of highly competitive starts-ups. Specifically in the VR mental healthcare sector in Europe, the B2B market and delivery of SaaS is controlled by start-ups. In conclusion, while the market is still in early stages of development, it already demonstrates high growth potential.

Keywords:

healthcare, virtual reality, mental health, digital health market, innovation, technology, mHealth

Resumo

Título: Um estudo da realidade virtual como uma ferramenta da saúde mental e o seu impacto e pontência no setor da saúde

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Os crescentes problemas de saúde mental estão a criar uma procura crescente por tratamentos que sejam acessíveis e eficazes. Aiovação e tecnologia têm sido mobilizadas para atender a esta procura. A realidade virtual, uma tecnologia que coloca os utentes num espaço imersivo gerado por um computador, parece ser uma ferramenta sofisticada no tratamento de alguns distúrbios mentais, como a ansiedade, depressão e alguns sintomas de demência. As start-ups identificaram essa oportunidade no mercado e rapidamente adaptaram esta tecnologia a produtos comerciais. O objetivo deste estudo é analisar o impacto do mercado emergente da RV na saúde mental, no sector da saúde na Europa e avaliar o seu potencial impacto futuro e evolução.

Este estudo foi conduzido através de uma investigação de base qualitativa (com recurso a desk research e entrevistas semiestruturadas com fundadores e funcionários de start-ups líderes no mercado). Esta investigação, resultou na criação de três casos-exemplo o que permite incorporar: o contexto de setor, os conceitos gerais e teóricos bem como a realidade vivida pelosatores neste mercado.

O segmento do hardware do mercado da RV é dominado pelas maiores empresas tecnológicas, como Google, Facebook e Sony, enquanto o segmento do software é constituído por start-ups altamente competitivas e especializadas. O mercado da RV para saúde mental na Europa, é um mercado B2B que fornece SaaS e está controlado por start-ups. Em conclusão, apesar deste mercado estar ainda nas fases iniciais do seu desenvolvimento, demonstrou já ter grandes possibilidades de crescer.

Palavras-Chave:

Cuidados de saúde; Realidade virtual; Saúde mental; Mercado da saúde digital; Inovação; Tecnologia; mHealth

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List of Abbreviations:

- AD Alzheimer’s Disease
- ADHD Attention Deficit Hyperactivity Disorder
- CBT Cognitive Behaviour Therapy
- EU European Union
- GDP Gross Domestic Product
- GSR Galvanic Skin Response
- MCI Mild Cognitive Impairment
- MD Medical Device
- MDR (Medical Device Regulation)
- OCD Obsessive Compulsive Disorder
- QMS Quality Management System standard

SaaMD Software as a Medical Device

SaaS Software as a Subscription

TA Thematic Analysis

UN United Nations

VC Venture Capital

VR Virtual Reality

VRAR Virtual Reality and Augmented Reality

VRET Virtual Reality Exposure Therapy

WHO World Health Organization

1 - Introduction

The Healthcare industry is a large economic sector of heterogeneous activities with several involved sectors, thereby making one of the most complex areas of financial and infrastructural investment. (Petrova-Gotova et al., 2016) Its success depends on many factors: the model of health system and a country's macro and micro-economic characteristics, among others (Handler et al., 2001). To lessen the disparities through European Union countries, the European Structural and Investment Funds (ESIF) invested approximately nine billion euros in respective European healthcare systems from 2014 to 2020 (European Commission, 2020b). Irrespective of the healthcare model, in member countries of the EU, health is typically a significant part of public budgets. In 2018, public expenditure accounted for almost 75% of healthcare budget (*Health at a Glance: Europe 2020*, 2020).

Today's healthcare organizations are based on values and principles established in the early 20th Century. (Appelbaum & Wohl, 2000). There are global changes which drive transformation and organizations should use them to its advantage, since the rate of change in healthcare is accelerating (Al-Abri, 2007). Entering the 21st century, governments and medicinal drug companies are still the primary investors, but technological companies are becoming increasingly larger investors, due to the expectations and innovation around digital health (Kapoor et al., 2020).

Digital technology is significantly changing the ways in which people experience healthcare and contesting what healthcare entails (Hein et al., 2020). These technologies have presented a disruption and significant impact on the healthcare market because it revealed potential for more technological investments and advancements. As a result, the healthcare industry can now present a newly competitive business sector since it is the subject of higher performance expectations from consumers and strong competitive pressure facing providers (Goddard, 2015).

1.1 Problem definition

In the 21st century, the percentage of the population suffering from mental health issues is growing significantly (WHO European Framework for Action on Mental Health, 2021). This has been theorized to be attributed to several social and cultural change, which could have contributed to a rise in diagnosed mental health issues (Bor et al., 2014).

“The Society of Performance” is a phenomenon which is now a prevalent paradigm of modern social societies, introduced as the result of the introduction of neoliberalism and its core concept of “competition as main criteria of subjective value”(Gancitano & Colamedici, 2018). This alludes that the definition of a person’s value should be based on his performance and accomplishments, encouraging efforts and commitments. However, it has become inevitable that people perceive more anxiety and stress about their own performance. One contributing factor is theorized to be the increasing rate of usage of social media (Holmgren & Coyne, 2017). They represent the stage of our performances, and in fact, most social media users admit feeling *social media fatigue* and the coined term of *Fear of Missing Out (FOMO)*. (Dhir et al., 2018) The term refers to the feeling missing something that is happening in our absence or in a situation we are not included in. It might lead to an excessive use of social media, which had been demonstrated as correlated to the rise of anxiety and depression. (Hilal Bashir & Shabir Ahmad Bhat, 2017)

Mental health issues were already increasing in the last 20 years (Twenge et al., 2019). In 2020, the Covid-19 pandemic has exacerbated the scenario. The World Health Organization (WHO) is concerned about the potential long-term consequences of Covid-19, on both mental and physical health (Mental Health and COVID-19 - WHO, 2022). The applied measures of social distancing and the fear for personal health, or to lose friends and relatives, have affected our everyday life, and have led to an increase in diagnosed mental health cases including generalized anxiety disorder, obsessive-compulsive disorders, depression (Kumar & Nayar, 2020). This growing prevalence has necessitated the use of innovative intervention to meet the growing demand for mental healthcare (Hirschtritt & Insel, 2018). The advanced and sophisticated technology of VR was shown to be a powerful tool in managing mental health issues, such anxiety, depression, phobias and so on (Skurla et al., 2021). Recent studies into the use of virtual reality in psychosis, autism spectrum disorder and Attention Deficit Hyperactivity Disorder (ADHD) are promising (Emmelkamp & Meyerbröker, 2021).

The COVID-19 pandemic identified systematic problems in current healthcare systems and pushed these systems to their limits (European Commission, 2020). The challenges facing EU healthcare institutions created the need to implement digital healthcare and remote intervention for both mental and physical health. New technologies offer more accessible healthcare, and these innovations may be able to change the present market in unforeseen ways (Kapoor et al., 2020). The use of advanced technologies can offer alternative options to increase wellbeing, in easier and more comfortable ways. Non-face-to-face healthcare induces

a shift from existing hospital-centered to consumer-centered healthcare, offering freedom of time and space to consumers (Han & Lee, 2021a).

One of these technologies is virtual reality, an operational computer-generated system, in three-dimensional space, in which users are seemingly integrated (Gebara et al., 2016). The principal virtue of virtual reality is the ability to give users the sense of being somewhere else. If in addition, the user interacts with something in the real world, then it is called Augmented Reality (Stevens, 2014). Virtual reality's most popular manifestations are in entertainment, but it also offers benefits in medical settings. The latest applications of virtual reality integrated into healthcare include robotic surgery, psychological therapies, pain management, and physical therapy (Sharma & Kshetri, 2020; Valmaggia et al., 2016). This technology has the potential to revolutionize the healthcare industry because of its disrupting nature, making treatment more accessible and affordable, as patient may be able to access VR treatments in their own homes.

Start-ups are taking the opportunity offered by VRAR to apply it in different areas in healthcare. In Europe this market is growing quickly (Virtual Reality in Healthcare, Fortune Business Insights, 2020). Start-ups had the ability to move from experimental setting and academic contexts to markable solutions. For this purpose, Regulatory sandboxes are a key element for start-ups in the Fin-Tech industry (Cornelli et al., 2020) A regulatory sandbox is a framework that allows innovations-testing in a controlled environment under the regulator's supervision (Thomas, 2018).

1.2 The aim of this industry review

The aim of this study is to capture the features and characterize an emerging market: the market for VR application for mental health in Europe. The aim of the author is to conduct an industry analysis and create an overview of the digital health market, focusing on the approaches and main focuses of VR applied to mental health treatments.

Through the selected methodology, the author will address the main questions of:

- How is the market of Virtual Reality applied in healthcare? And, in particular, mental health treatments?
- How will this market evolve?

1.3 Structure

The first chapter of this paper provides an analysis of the context of this research. By introducing some key information of the digital health market, chapter one has the aim to explore the general topic of innovation adoption and digital transformation in healthcare. Chapter two introduces the main topics of Mental Health and Virtual Reality to explore the role of start-ups in this scenario, setting some background knowledge necessary to a better comprehension of the following chapters. Chapter three analyses the methodology used in the process of informational acquisition and analysis of the relevant market. Chapter four presents a case vignettes analysis of selected European Start-ups present in the sector and how they are contributing in the role of pioneers in this market. Chapter five provides the author's findings and answers as relevant to the defined research questions, analyzing the relevant market of Virtual Reality in Healthcare, while providing insight to the foreseeable the future of this market. The analysis includes potentially influential and factors to the future state of the healthcare environment, in terms of technological innovations and impacts. Chapter six contains the discussion around the treated topics. It primarily analyzes and uses the previous results to discuss them. Chapter seven elaborated upon the potential limitations of this current work and some suggestions for future work and provides suggestions for future research. The last chapter provides conclusion of this study and consequently provide some recommendations for start-ups.

2 - Background

2.1 Healthcare market and Innovation

The meeting of a population's health needs is the primary goal of every healthcare system. (Surampalli et al., 2020). The use of the System of Health Accounts allows the comparison between national health expenditures, which is an element that gained considerable importance (World Health Organization, 2011). For this reason, in 2008 the WHO established the Commission on Social Determinants of Health to address the factors leading to disparities in access to healthcare resources and in healthcare spending (World Health Organization, 2008). In 2019, healthcare spending accounted on average for 10% of the EU's GDP. The exact percentage varies among EU Member States ranging from 7% of GDP in the Eastern Europe to 11% of GDP in the Northern Europe (Health at a Glance: Europe, 2020). The European Commission adopted a Strategic Plan for the period 2020-2024, to increase the effectiveness of government spending, provide expertise on healthcare systems and encourage innovation and the adoption of modern technologies (European Commission, 2020c).

2.1.1 Digital Health

Digital health is defined as the field of study concerned with the application of advanced digital technologies to improve physical well-being (Mesko, 2020). It includes a wider spectrum of technologies, such as Internet of Things, Artificial intelligence, big data and robotics (Vial, 2019). The strengthening of healthcare systems through the application of digital health technologies is a fundamental topic nowadays such that the WHO, as a normative institution, has provided global strategy guidelines (*Global Strategy on Digital Health 2020-2025*, 2021). These guidelines have the purpose of providing structure and orientation to public policy makers in Member States for their respective healthcare industry systems, populations, and relevant stakeholders. It will lead to concrete actions and results within 2025.

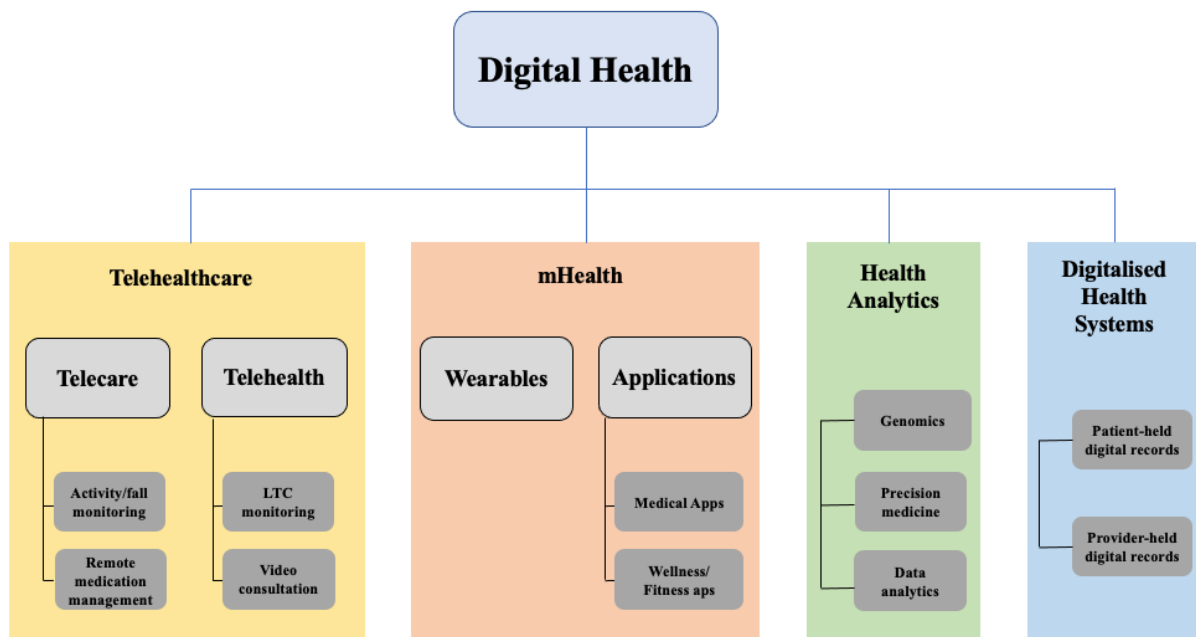
Deloitte, a global consulting firm, classified the digital health industry into four sectors (*Global Market Report*, 2020):

- *Tele-healthcare* is the sector of non-face-to-face medical services. It is based on the exchange of clinical data between patients and doctors in order to provide medical remote services.

- “**mHealth**” is the sector of wearable devices and related applications (apps) as software-based solution.
- “*Health Analytics*” is the sector that respond to the need to manage large data sets for health purposes.
- “*Digitalized health systems*” is the sector of personal health information.

Figure 1 Classificazione of the Digital Health Market

Source: Global Market Report, 2020



The size of the Digital Health Market was estimated to be over USD 106 billion in 2019 by a record published by the Global Market Insights. The publication also predicts that this industry will grow at 28,5% Compound Annual Growth Rate (CAGR) through 2026. The Korea International Trade Association also estimated the Global Digital Healthcare Market size forecast by sector, and predicted that one of these four sectors, the mHealth, will potentially present a 38,3% Annual Average Growth rate (Han & Lee, 2021b).

Although the EU only accounts for 30% of the mHealth Market, the European segment is the one that is growing faster, with a CAGR of 61,1% in the past years. (*Market Study on Telemedicine*, 2018) Furthermore, according to a Statista Report on worldwide investments in mHealth companies, the preferred sectors of investments are mainly Telehealth, Personal Health and Fitness, followed by the sector of Mental Health (*MHealth Statista Report*, 2020).

2.1.2 Digital transformation of the healthcare industry

Digital transformation was defined by (Vial, 2019) as “a process that aims to improve an entity by triggering significant changes to its properties through combinations of information, computing, communication, and connectivity technologies”. While digital transformation of healthcare is initially disruptive, it has proven potential to enhance health outcomes. These disruptions trigger strategic responses and alter the present healthcare organizations’ value creation paths, which leads to structural changes and more functionally optimized outcomes such as greater access and more personalized care. Digital transformation in the healthcare industry leads to the shift from the traditional industry into new market segments in terms of value propositions. These new markets are mainly focused on disease prevention, disease prediction and self-care (Hermes et al., 2020).

Disease prevention aims to increase lifestyle quality through improving diet, mental health, and cognitive functions. Individuals have control over these matters, they have the choice to avoid certain behaviors, such as use of tobacco and regular consumption of sugary foods (Breslow, 1999).

The market of disease prediction uses the advantages of the new digital technologies, such as big data, machine learning and artificial intelligence, to predict diseases before they become detrimental and provide treatments. The digitalization of health care records and its explicit international interoperability represent a significant passage towards innovation. The most reliable technology that can ensure the secure sharing of clinical data is blockchain technology (Namasudra et al., 2022.). Blockchain technology is expected to have many potential benefits, and a significant impact overall on the medical industry. However, blockchain data management solutions will require some degree of cultural change, as human factors remain one of the stable limitations of transforming healthcare innovations.

Self-care is defined as a “naturalistic decision-making process addressing both the prevention and management of chronic illness, with core elements of self-care maintenance, self-care monitoring, and self-care management” (Riegel et al., 2017). Essentially, digital transformations lead to a shift in the attitude towards healthcare, from a reactive healthcare to a proactive one. It has another important consequence: digital transformation influences the whole ecosystem, moving from linear value chains into digital-mediated two-sided markets (Constantinides et al., 2018). Disruptive changes will alter the basis of competition, creating new opportunities to redefine business models and enter new markets. Healthcare companies

will have to make strategic decisions and create transformational business models to survive in the market, prompting further innovation, which will in turn provide better care to consumers.

2.1.3 Adoption of Innovation in Healthcare

As the COVID-19 pandemic has accelerated the process of adopting technological innovations, discussions about digital healthcare have once again emerged. The pandemic demonstrated the demand for telemedicine, which was selected as the most necessary non-face-to-face technology after COVID-19. However, even before the pandemic, the digital healthcare industry was expected to grow.

Healthcare organizations are, by definition, complex systems. Health systems are defined as complex because of their unpredictability and nonlinear interactions of its components (Martínez-García & Hernández-Lemus, 2013), this in turn increases the difficulty of introducing innovation as well as makes uncertainty unattractive for innovators and investors. In contrast to healthcare organizations, the structures, procedures, and processes associated with innovation in other industries, such as tech-companies and consumer goods firms (Terzi, 2014), are significantly more favorable for adopting innovations (Anshari & Almunawar, 2021). In fact, only a few health care organizations outside academic centers have relevant budgets to spend on R&D, compared to Corporate R&D. One of the main reasons for this slow adoption is that healthcare organizations are deeply subject to the influence of larger systems: such societal, industrial, and political systems (Plsek & Plsek, 2003). Especially political systems serve as regulators for certain technological adoptions, legislation and political pressure are relevant external forces in innovative improvements in healthcare (Herzlinger, 2006). Control the behavior of a complex system through regulations is not the optimal solution in healthcare. The case of the redesign of the Australian healthcare demonstrates that the creation of more regulations may cause health systems to worsen (Lipsitz et al., 2012).

After the difficulty of the processes of generating, testing, and implementing an innovation in the healthcare market, there is also another factor that limits the capability of healthcare organizations to improve: *resistance to change* (Landaeta et al., 2008).

2.2 Mental health and Virtual Reality

2.2.1 Historic perspective

In China in 1100 a.C., mental illness was defined as the imbalance between Yin and Yang, based on the concept of Taoism. Thousands of years later, Hippocrates developed his humoral pathological theory, in which he defined the healthy normal condition of a man as: “*the balance between the body fluids and external environment*” (Fea, 2019). This thesis written in 2022, will use the following comprehensive definition of mental health, laying on the **same** fundamental concept of *balance* as its predecessors:

“Mental health is a dynamic state of internal equilibrium which enables individuals to use their abilities in harmony with universal values of society” (Galderisi et al., 2015).

2.2.2 Current definition

The author has decided to define Mental Health in the broad term given by the WHO, including in the mental disorders category all the disorders that influence thinking, perceptions, emotions, behavior, and relationships, as anxiety, stress, depression, bipolar disorder, psychoses, dementia, autism and so forth (WHO, 2022).

2.2.3 Stress, anxiety, and depression

Overall, the most common mental health issues are stress and anxiety (American Psychological Association, 2019). Regarding the former, the American Psychological Association (APA) publishes an annual report titled the “Stress in America Survey”. The report of 2019 highlights an average stress level of 4,9, on a scale of 1 to 10, where 3,8 is considered a healthy stress level. The population segments that were determined by this survey to be the most stressed are *Generation Z* and *Millennials*, which means the individuals born in or after 1981 (Schweitzer et al., 2010). These generations *present* a significantly higher average stress level, respectively 5,4 and 5,8 (American Psychological Association, 2019).

The report of 2021, compared to the report of 2019, was able to illustrate the differences in mental health between the pre-pandemic and post-pandemic world. In the 2021 report, *Generation Z* and *Millennials* were still determined to be the generation most affected by mental health problems. In fact, their average stress level increased by 0,1 from the 2019 report. Nearly 75% of the total survey respondents stated that they were experiencing behavior changes due to stress, and were experiencing symptoms such as feelings of anxiety,

decision-making fatigue, changes in sleeping habits and chronic feelings of being overwhelmed. Comparing the reported sources of stress between 2019 and 2021 reports, the categories which had the highest increase were: *the economy* with a +13%, *personal safety* with a +9% and *housing costs* for a +6% (American Psychological Association, 2021).

Related to stress, one of the most common and increasingly prevalent mental health conditions that population have reported experiencing is *burnout*, defined as the psychological consequence of a high amount of chronic fatigue from excessive work demands (Koutsimani et al., 2019). Returning to the presence of the highly competitive Society of Performance, in which people feel pressured to maximize their productive output, the chronic pressure of this demand can may not be sustainable with mental health, causing an increase in mental health issues such as anxiety and depression. Anxiety and Depression both come from the perception of threats but in two different ways. Anxiety is predictive of threats, it is future-oriented, while depression is focused on the present condition or connected to the past (Dobson, 1985). They may also occur simultaneously and require specific treatments to manage symptoms. The treatments for many mental health issues may include psychological therapies, such as cognitive behavior therapy and dialectical behavior therapy, as well as pharmacological treatments.

In the case of anxiety, one digital treatment that received considerable attention is Virtual Reality Exposure Therapy (VRET). It consists in evoking the object or the situation of the patient's fear in a virtual environment, working as an exposure-based treatment. It is a successful method in treating anxiety disorders and it is a particular form of cognitive behavior therapy (CBT) (Oprış et al., 2012, Anderson et al., 2013).

In the case of depression, VR therapy can also be used as a powerful treatment tool, used instead to aid in the reinforcement of self-directed compassion in individuals high in self-criticism, which is one of the major factors in depressive disorders (Falconer et al., 2016).

There are also some tools that have potential treatment effects for both anxiety and depression, such as meditation and mindfulness. These treatments are techniques that have existed for centuries as practices in Eastern cultures, as part of Buddhist and Hindu practices, both arriving to Western mainstream culture in the 2000's. Since then, they have gained popularity. Even if these two terms are often misunderstood, meditation is a wide concept and mindfulness is part of this umbrella (Behan, 2020). Mindfulness relies on the concept of being aware and focused on the present moment. Meditation is originally a spiritual contemplation

technique, but nowadays it is widely used as a therapeutic practice based on mental training on concentration (D. J. Lee et al., 2018).

2.2.4 Distraction and pain management

One of the best ways to alleviate pain is to introduce a distraction and VR can be a great tool for distracting patients from their pain (Hoffman, 2004). For example, patients with severe burn injuries report that their pain drops dramatically when they engage in virtual-reality programs while doctors and nurses treat their wounds. Pain has a significant psychological component, the patient's thoughts at the moment of the experience of pain, is a significant psychological component in their perception of the pain. The reduction of the amount of pain felt is correlated to the interpretation of the amount of pain-related brain activity, namely *pain signals*. When human attention is engaged in the virtual world, less attention is left for processing pain signals.

“External objects provide an attachment point for the mind. A sufficiently involving object that demands skillful engagement can pull us out of ourselves to join the world beyond our heads.”(Crawford, 2015)

VR treatments can have different levels of immersion leading to three different kinds of treatments: immersive, semi-immersive or full immersive. This particularity allows treatments to be personalized, as needed, which leads to higher engagement rates. The reason is that immersive VR stimulates selective attention, so the individual feels completely distracted from everything that is external. For these reasons, immersive VR is the most used type of treatment.

2.2.5 Fighting fears

The commonly prescribed therapeutic treatment to psychologically treat phobias is Exposure Therapy (Garcia-Palacios et al., 2001): gradually introducing the patient to elements of the object or situation of fear until the patient is accustomed and the trigger no longer elicit a phobic response. The reasoning behind this technique is that, through the exposure of the patient to the object or situation of his fear, the patient will elaborate and rationalize the fear and become more comfortable with it. This strategy has demonstrated that it is indeed effective in changing the way the patient perceives the object of their fear. The physical

implementation of this strategy in actual practice can be extremely intense for patients, as phobias can elicit extreme panic responses, even in controlled environment (Garcia-Palacios et al., 2007). Moreover, exposure therapy can have logistical complications and financial costs to create the experience, and it is also difficult to predict what will happen in the environment. In a real scenario, there are uncontrollable variables that may interfere with the exposure experience (Gutiérrez Maldonado, 2002). The implementation of VR Exposure Therapy can thereby provide various benefits: the intensity of the experience can be more closely controlled by the executing practitioner, the experience can be safer in a controlled setting, and the cost of setting up the experience may be reduced. This allowed VR to provide a more comfortable and safe treatment option to overcome mental health issues.

2.2.6. Dementia

Another global public health problem is the rising number of people affected from neurodegenerative diseases. Neurodegenerative diseases compromise memory, language, and behaviors. Dementia is a major neuro-cognitive disorder that severely interfere with everyday life and autonomy. It is the loss of cognitive functioning, affecting memory, language, thinking and social abilities. It is important to emphasize that it is not a specific disease; Dementia is a broad term that it used to represents a group of diseases and illnesses. Alzheimer's Disease is a one of the most frequent type of dementia.

It is predicted that the number of patients affected with dementia will increase up to 150 million people worldwide by 2050. This is also congruent with present financial trends; the cost of dementia increased by 35% between 2010 and 2015 (WHO, 2012). The further significance of dementia is that it does not only affect the single individual experiencing the condition. Since dementia presents a cognitive disorder with varying levels of symptoms, from memory loss to hallucinations, individuals may be incapable of maintaining their previous level of independence and may even be a threat to themselves or others. In some circumstances, they may require full time care or supervision. This can affect families which now need to care for the individual and manage the symptoms (World Alzheimer Report: Journey through the Diagnosis of Dementia, 2021).

Dementia is one of the mental health issues most affected from stigma and lack of awareness. It is estimated that globally 75% of people who suffer from it are not diagnosed. Moreover, the global pandemic of COVID-19 further reduced the access to healthcare services for people with dementia, by necessitating social distancing which limits caretaker abilities and introducing further unfamiliarity, which can trigger more severe symptoms of dementia.

Dementia can be considered one of the most significant mental health challenges in 21st century, mainly because the pharmacological approach has not been able to demonstrate an effective symptom management or treatment solution. The unsuccessful attempts of pharmacological treatments have highlighted the need for preventive interventions and holistic interventions, including environmental, lifestyle and behavioral changes. Among the recognized non-pharmacological approaches are exercise, cognitive training, and recently virtual reality. Despite the effectiveness, the latter is still undertreated. Physical exercise is a widely medically recognized factor which contributed to the overall health of the body and mind, but it carries an increased risk of injury in aging and senior populations, which are notable those at an increase to developing dementia (Htut et al., 2018). Technology-based treatments are an innovative option which has the potential to reduce this problem. VR may be able to provide stimulating exercise experiences in a more controlled environment, which may lead to a lower risk of injury while exercising. Furthermore, VR has been demonstrated to be a powerful tool in reducing cognitive decline and improving memory functions.

The most common type of VR therapy used for Dementia treatment is Reminiscence therapy. VR has high potential and effectiveness in reminiscence therapies because of the immersive image-based technology. Reminiscence therapy for dementia patients may trigger memories and past events and it can be used to start conversations with the patient. The VR experience is then usually assisted by a specialist who has the role of providing support to the patient, before, during and after the virtual experience. When the patient wears the VR headset and sees familiar locations or activities, the identification of these elements is meant to trigger good memories and provoke into the patient emotions of joy, satisfaction, and enjoyment. The engagement is usually measured using questionnaires and semi-structured interviews conducted by the staff. It has been shown that the patient is usually more talkative and expressive of positive emotions, which causes an improved social-emotional behavior and facilitated verbal interaction. This process gives adequate qualitative data to evaluate the treatment process and patient's condition. However, in some sessions, bad memories or

trauma are triggered in the patient, which may result in a state of confusion for the patient at the end of the session.

2.3 Start-ups

Start-ups, amongst other features, can be characterized by having limited financial resources, disruptive ideas and little experience with financial markets and laws (R. J. Mann & Sager, 2007). Despite the strong ambition and visions of many start-ups, 9 out of 10 start-ups fail (Patel, 2019). This is typically due to a lack of experience in a key component of business management or a lack of funds. Start-ups are usually founded around a core innovative concept or technology. Innovation can have many different forms, as a product or service, new organizational structure, or new processes technology and so on. (Baregheh et al., 2009). A successful start-up is usually a start-up whose innovation goes beyond their product/service, providing added value by reinventing the fundamentals of a business.(Lindgardt et al., 2009) However, it is not innovation alone that determines the success of a start-up; if the business is not appropriately managed or sponsored, the start-up may still fail to provide the disruption that would lead to marketable success.

For these reasons, a useful condition for start-ups are *regulatory sandboxes*. This discussion started in the fintech worlds. A regulatory sandbox is a support system for technological innovation. It is a controlled environment where it is possible to test a technological innovation with the aim of verifying the impact on the market (Goo & Heo, 2020) and what are the supervision issues (Goo & Heo, 2020) by creating a “protected space where some bureaucratic and regulatory aspects are temporarily facilitated”. There is a two-ways benefit, both for the tech companies and for the governing authorities. The need for a regulatory sandbox derives from the pivotal position that regulation has on fintech companies, which is similar to digital health companies. In these ways, companies can understand the weight of these regulations on their business idea, and then make a more informed analysis as to if they own a profitable project or not. Nonetheless, the need also comes from the authorities’ side: the aim of these regulations is to protect consumers and the market from unfortunate events such as the 2008 financial crisis. Many countries introduced regulatory sandboxes, including Italy and the Netherlands, in order to support innovations and attract investments. Fin-techs entering a sandbox usually see a relevant increase of around 15% in fundings compared to companies that did not enter. Furthermore, they benefit from reduced regulatory costs, so the

sandbox is also a helpful tool to overcome both regulatory and financial barriers (Cornelli et al., 2020).

In the digital health market and in general in the health sector, innovations suffer from a problem defined as *pilotitis*, which refers to the frustration at “demonstrating successful outcomes from narrowly focused interventions targeting relatively small populations” (Huang et al., 2017). Regulatory sandboxes can be a valid help to solve this problem, as the adoption in India in 2019 demonstrated (Bhatia et al., 2020). A closer successful case is the regulatory sandbox established from the European Institute of Innovation and Technology (Leckenby et al., 2021).

In addition to the help provided from regulatory sandboxes, another relevant element in the start-ups development is Venture Capital (VC). VC investors are more interested in the early stages of entrepreneurship (Andrusiv et al., 2020) and are particularly fascinated in the sector of start-ups with a social purpose involved in innovation. Start-ups commonly require considerable financial investment before they are able to be profitable. Therefore, funding plays a major role, both from private and public institutions. However, fundings that comes from public institutions usually does not represent a higher quote than 5%. The average start-up in this sub-sector is young, innovative, with less than 5 years in the business and with no more than 10/20 employees. For five consecutive years, this sector received increasing investments and it is estimated that 2022 will not be different (The BioRegion Report, 2021).

3 Methodology

The objective of this research paper is to capture the features and thereby characterize a new emerging market: the VR market in Europe and its applications in mental health treatments. The author decided to conduct the study using qualitative research, due to the nature of the topic. The research questions are:

- How is the market of Virtual Reality applied in healthcare and, in particular, in mental health treatments?
- How will this market evolve?

The selected methodology consists in two main approaches:

- **Desk research** uses secondary information obtained in various studies from other authors. It represents an efficient way to conduct research, since identifying what is already known cut cost and time spent (Stewart & Kamins, 1992).
- **Series of semi-structured interviews (SSIs)** to start-up funders or employees in relevant positions in some leading European start-ups in this industry.

3.1 Desk research

Desk research is a type of secondary research, meaning that the author used pre-existing data from previous research (Heaton, 2008). It is a common method to investigate additional research questions or to verify previous findings. In this case, the reason for this research approach is to elaborate and analyze more on the topic. Desk research are usually conducted through:

- **Formal data sharing.** These sources include industry studies, books, journals, and scientific media. This is a powerful and reliable mode of analysis since these data and informational sources must respect ethical and legal requirements to be published.
- **Informal data sharing** with relevant actors in the interested ecosystem.

3.2 Semi-structured interviews (SSIs)

Semi-Structured Interviews (SSI) are a strategic data collection method to gain knowledge about the study phenomenon. It is a common method in qualitative research due to its

versatile and flexible nature, so the interviewer is able to collect information about the desired topic while also having the potential to improvise based on the responses that are received. The goal is to obtain spontaneous but in-depth answers that can generate discussion. For this reason, questions must be open-ended (McIntosh & Morse, 2015). These interviews were conducted one-on-one and on average each interview lasted between 40 to 60 minutes. All the interviews were conducted in English and based on the interview guide prepared previously. They were conducted remotely, and the researcher informed the interviewees that neither their name nor of the company of employment would be included in the research. The reason for this choice is related to confidentiality and was permitted so the interviewee could be more relaxed and comfortable with expressing their thoughts and opinions (Woods & McNamara, 1980).

3.2.1 Preparing the Interview-guide

To conduct a semi-structured interview, it is necessary that the interviewer possesses preliminary knowledge on the research topic. This knowledge is used to identify gaps in the areas of existing literature, and areas of potential further investigation, which the questions for the interview will address. The questions are prepared beforehand, at the moment of the interview guide development, which is a process of four main phases (Kallio et al., 2016):

1) Identifying the prerequisites: The first phase consists of the evaluation of the appropriateness of the method for the given research questions.

2) Identifying the main areas: The second phase is the identification of the main areas of the selected topic, based on previous knowledge. The suggested method is to create a list of the keywords of the topic to outline the broad relevant categories of interest. Furthermore, boundaries need to be set on the research chosen topic, so that the scope of the project can be tightly circumscribed.

3) Formulation of the question stems: At this stage, the interview guide is created. The questions can be on:

- Main themes, covering the main areas of the topic. These answers can emerge by starting a question with the 5 W's: What, Who, Where, When and Why (Chenail, 2011). These questions have the ice-breaking role and should come progressively and logically.

- Follow-up questions, usually asked after a general question, with the aim to elicit further information from the interviewee to increase the depth of the provided answer, further elaborate or explain the interviewee's reasoning or thought, or to prompt more detailed responses.

4) Pilot test: This is the final phase, and it is based on the testing of the questionnaire by internal and external testing to ensure its quality (P. Mann, 1985). Then, the process continues through the exposure of the interview guide to mock interviews, which would simulate the SSI process. This test may provide crucial information about the implementation, effectiveness, intelligibility, and relevance of the designed guide, and allow the interviewer to reflect, analyze, and consequently make any necessary adjustments to the guide.

The final interview guide can be found in Appendix I.

3.2.2 Population identification

The identification of the population of the study is a fundamental step. The author conducted the research to identify which European start-ups could be suitable for the purpose of this study. Samples in qualitative research are commonly smaller than samples of quantitative research. (Crouch & McKenzie, 2006) The reason is intrinsic to the nature of the study, a desired focus on the depth of few, specific cases. Moreover, the number of conducted interviews do not interfere with the quality of the study due to the concept of saturation. Depending the specific research case, saturation is the point where all relevant data is gathered, and no new ideas appear emerge; further interviews would not provide any undiscovered insights or information. Consequently, probing and prompting during interviews are identified as fundamental techniques to assure adequate quality and depth of the study and to determine if the saturation point is reached with the selected sample size (Weller et al., 2018). For the study, the author identified three leading start-ups operating in the specific and relevant market of study; these will be further referred as: Start-up A, Start-up B and Start-up C. Start-up A is a small start-up and it was possible to connect directly with the founder. The situation of Start-up B and C is different, since they are bigger organizations. Relevant figures were chosen as interview subjects, in the case of Start-up B it was the Chief Scientific Officer and in the case of Start-up C it was the Sales Director.

3.3 Methodology to analyze the results

3.3.1 Sector analysis

In this study, the author's objective was to conduct a thorough industry analysis by implementing a structured business research methodology to study the VR market in healthcare. This investigation utilized a sector analysis: “an industry analysis focused on a segment of industries of a particular type, in a given economy, by considering common opportunities, challenges, and main goals,” (Aithal, 2017). A desk analysis was conducted to obtain an in-depth overview of the market and its current structure, and semi-structured interviews were an additional tool to expand the depth of the analysis, including an exploration of the market’s intricacies, such as relationships with other sectors, internal dynamics, and future potential. The direct result of the semi-structured interviews is a group of three case vignettes. Case vignettes are an appreciable tool in an industry analysis. A Case Vignette is a broadly used method in qualitative studies related to healthcare. It is one of the main variants of the case study method (Kathiresan & Patro, 2013). Case vignettes describe hypothetical situations that are representative of main trends (Gourlay et al., 2014). In this thesis, the case vignettes are not hypothetical, they are based on real data obtained from research but as this was preliminary and very superficial, the choice of labeling them as case vignettes rather than case-studies was preferred. Qualitative case-based research gives a significant contribution to the contextualization of general and theoretical concepts (Doz, 2011). There are recent examples of studies using case vignettes in an industry analysis on public services (Rice, 2017) and on the Oil & Gas industry (Heim et al., 2019). Each case vignettes represents a start-up. The method used to describe these start-ups is Gartner’s framework from 1985. This framework focuses on the main four aspects that describe a start-up: individual characteristics, entrepreneurial behaviors, strategy, and environment (Gartner, 1985).

The author also chose to develop this industry analysis using the five competitive forces framework, a well-recognized business framework developed by Michael Porter in 1979 (Dobbs, 2014). The framework is based on the postulate that there are key factors in an industry which can provide an understanding of where the potential and power lie in the sector, which can provide useful insights for potential entrants and current competitors in the markets when developing their business strategies. The underlying premise is that a firm’s profitability and strategic positioning are affected by the industry structure. The main characteristics of the industry analyzed in this framework are the bargaining power of

suppliers and buyers; the threat of new entrants and the threat of substitute products/services (Porter, 1979). In 2008, Porter updated this model to extend the framework, emphasizing the capacity of its application for practical business guidance, and further reaffirming the capacity of the model to aid in strategy development (Ural, 2014). Presently, this framework is a standard tool in industry analysis (Dobbs, 2014). This model was chosen by the researcher for its capacity to describe the industry of VR in healthcare at the present moment, as well as to provide insight for potential expansion and change (Bruijl, 2018).

3.3.2 Thematic analysis

All the interviews were transcribed on paper and consequently analyzed through thematic analysis. Thematic analysis (TA) is a recognized method in qualitative research, originally developed for psychology research by Braun and Clarke. The aim of this analysis is for the researcher to become familiar with the data and leading to a better understanding of the context (Castleberry & Nolen, 2018). As previously established, the researcher is already familiar with the topic and existing themes and literature, so to develop the interview guide and to understand the responses provoked by the interviewees and to form coherent and logical follow-up questions. This knowledge is critical to the achievement of good quality semi-structured interviews and consequently, a good quality thematic analysis. This analysis relies on the researcher's judgements, choices and interpretations. Therefore, following a step-by-step guide is a useful tool for the researcher to limit the subjectiveness of their methodology and consequent analysis. Thematic analysis has four main steps:

- 1) Dissecting the data and creating significant categories. The result is the identification of the main "codes" and patterns through the collected data.
- 2) Reassembling the codes within themes. These themes are then organized in thematic hierarchies that provide a broad landscape of the data.
- 3) Interpretation by the researcher. This is the most critical step of the process. The researcher must make analytical conclusions from the data.
- 4) Conclusion. This is the last step of the process, and it is now to reply to respond to the research questions through the conclusions of the study.

The results of the thematic analysis will be summarized in Appendix II.

4 – Results

4.1 Case Vignettes

This chapter will provide the analysis of three case vignettes referring to three leading European Start-ups in this relevant market from which the interviewees were able to represent. The author chose to not disclose the name or specific details of these companies, for the reader to not be influenced by previous own insights or preconceived perceptions. The aim of this chapter is to take a deeper, investigative approach into the target market. These companies have many characteristics in common but also many differences, these aspects will be better examined subsequently. The main characteristics of these three case vignettes are summarized in Table 1.

4.1.1. Case A

Start-up A is an Eastern Europe company, founded right before the COVID-19 pandemic. The idea came from the principle of Intergenerational solidarity. The founders realized there was a need in the healthcare market that was not being addressed in a particular demographic: the aging population. The current generation of elderly people have spent their lives in a completely different way than the previous generations. Elderly people of this era experienced a freedom that other previous generations might not have experienced. In fact, traveling as a leisure activity become a real phenomenon while these people were young. As people physically age, travel becomes more difficult due to various physical stressors, making it less accessible to senior citizens. Start-up A focused on the potential to provide elderly people the experience and sensation of traveling through VR, enabling abandoned or bedridden seniors to travel via virtual reality. The current target group of Start-up A is elderly people, primarily populations in nursing homes. However, their product has potential for usage for other target populations, such as people who may have physical disabilities or limited mobility. They primarily targeted residents of nursing homes for the ease of their testing process, but they are planning to eventually expand to the B2C market and hospitals.

The aim is to give the client the perceptions and sensation of travelling that would be experienced in the outside world, which is helpful for maintaining physical and mental well-being. They want to improve health and social care through new technologies in the long run.

These experiences usually last 10 minutes each and have been demonstrated to have powerful impact on the patient. After the experience, seniors suddenly start having clearer memories and becoming more talkative. For this reason, the session finishes with a talk between the patient and a specialist. The overall experience has been shown to have positive effects on their mental health and mood, especially for patients affected with depression. The feedback so far has been extremely positive, seniors are excited about these VR experiences, with enthusiastic reactions. There are several studies that have shown that these experiences can activate the brain more effectively than television or other kind of media. In addition, these experiences can also improve cognitive abilities and help slow the onset of dementia, which could provide a lasting benefit to the patient, as well as an enriching experience.

Start-up A is delivering a SaaS (Software as a Service), through a monthly subscription. They outsourced the production of the VR Headsets, so they can put all their efforts into providing content. They are not dependent on complex technologies, and their software does not require the usage of smartphones or computers. In addition, the VR headset have been specifically adapted so that seniors can also wear prescription glasses under them, increasing the accessibility of the service. It is possible to have city tours, walks in the nature and many other types of VR experiences. Their content is presently completely produced in Europe due to the travel restriction of the pandemic, but they are planning to create new international experiences. To create such immersive experiences, there is an extensive planning process behind the creation of each content experience. The first phase consists off the script's creation, created taking into account the preferences and need of their target population: senior citizens. Then, the content creators travel with all the necessary film and recording equipment, and work for several hours collecting film on location. The quality of the film used has to be particularly high in order to guarantee the immersive and realistic feeling of the virtual trip.

The original business model was to offer the project for retirement homes as part of a subscription. However, since the pandemic significantly weakened nursing homes financially, they decided to offer a pilot version completely free of charge. Due to the pandemic, they took all the necessary measures to protect employees and the operations of the entire company. As a result, start-up A well managed the covid-19 crise, and the company is currently growing.

4.1.2 Case B

Start-up B is a company from western Europe company, formed with a pioneering mission to “*free the potential of the brain*”. Their focus is on the power of the human brain to “disconnect” through the mechanism of medical hypnosis. There are several potential medical applications for this technology, such as the reduction of the sensation of pain, the reduction of stress and anxiety, and promotion of the relaxation of the nervous system (Ledford et al., 2021).

For the purpose of pain management, VR has the potential to be applied in lieu of sedatives or anesthetics for medical procedures. It is named hypno-analgesia and it may be used as a supplementary form of anesthesia. While some patients have adverse reactions or negative side effects when treated with anesthesia, so this new technology would provide an alternative or supplemental treatment technique in the healthcare field. Hypno-analgesia can also be used for post-operative pain management, either to replace or limit the usage of opioids, anti-inflammatories, or chemical sedatives. Moreover, a secondary effect is the reduction of the anxiety and stress that patients experience during their medical procedures. The VR is able to redirect their focus and attention from the medical procedure to a more relaxing and positive experience. The business’s target group is hospitals and clinics that are willing to use non-pharmacological solutions to relieve pain, stress, and anxiety in their patients.

This technology has the potential for use with several medical procedures, and the techniques have all been clinically validated. The basis of VR and hypnosis as a pain management technique was based on 13 published scientific papers which demonstrated that hypnosis through VR was able to provide a reduction of anxiety in patients of up to 90% during surgeries and medical procedures and was able to reduce the usage of almost 50% of opioid painkiller consumption post-procedure.

This innovative technology quickly garnered attention from venture capitalist funds, and the business has recently received several million euros in a series A funding round. Start-up B provides a Software as a Medical Device (SaaSMD) and does not produce their own hardware in-house, as most of their competitors.

4.1.3. Case C

Start-up C is a southern Europe company, providing an innovative service and specifically catering to mental health professionals, thereby currently operating only in the B2B sphere. The service aims to provide more personalized treatment and comprehensive care: via the platform, the clinicians have the ability to plan and take control of the sessions even when working remotely. Therapists must complete a training on how to properly use the platform and implement appropriate follow-up practices. They have access to considerable material as tutorials, manuals, online courses, and case studies. The platform is currently used by more than 2000 professionals worldwide.

The aim of this company is to give easy access to mental health intervention and to perform powerful treatments through the VR technology, in person and remotely. Their immersive experiences are proven to give impressive benefits for anxiety and eating disorders, depression, attention problems and so forth. These experiences are used in CBT, exposure therapy and other type of treatment.

As start-up A and start-up B, start-up C outsourced the production of the headset. However, they are closely working in collaboration with their manufacturer, so that they technically participate on the creation of the headset. In addition, start-up C also measure the sweat gland activity through a galvanic skin response (GSR) which is also not produced in-house. The GSR gives relevant information on the patient' intensity of the emotional state. This gives to the therapist the possibility to take control in every moment and to understand the most relevant stimuli. The virtual experiences are built on impressive and powerful paradigms of psychology, that are medically validated. Their platform is the most comprehensive in the market with more than 140 VR environments in multiple languages that can be used by clinicians to help them treat a variety of conditions. The platform also provides many services such as improved end-of-session reports, educational content, and new avatars for a more personalized experience. The session can start with the VR experience and continue with a conversation with the therapist, or differently, some therapists prefer to assist the VR experiences by removing the audio and following the session being the guide voice. This is a possibility that some patients prefer because they feel more comfortable with their own therapist's voice.

These VR experiences are mainly focused on anxiety disorders. In fact, more than 40% of the experiences are dedicated to anxiety and phobias like flying, driving, animals and so on. Then

they have virtual experiences for OCD, addictive disorders, eating disorders and ADHD and so forth. An interesting feature of Start-up C is that they have VR experiences for Mindfulness and Relaxation, and they are currently planning to integrate more and more experiences in the Meditation category. Start-up C have other two future plans, that are VR experiences dedicated to Pain Management and to Depression.

The key of their success in healthcare is to provide solutions patient-centered. They are continuously investing in the advanced research that characterizes them. For this reason, they are collaborating with renowned private and public institutions and recently received more than 10 million in fundings. Furthermore, Start-up C highly benefited from the current market situation. The increased demand for mental health services and the need for effective remote tools in treating mental health, represent a combination of factors responsible for the result of 2021: Start-up C more than doubled its footprint and for 2022, it is expected an even higher growth.

4.2 – Market Research

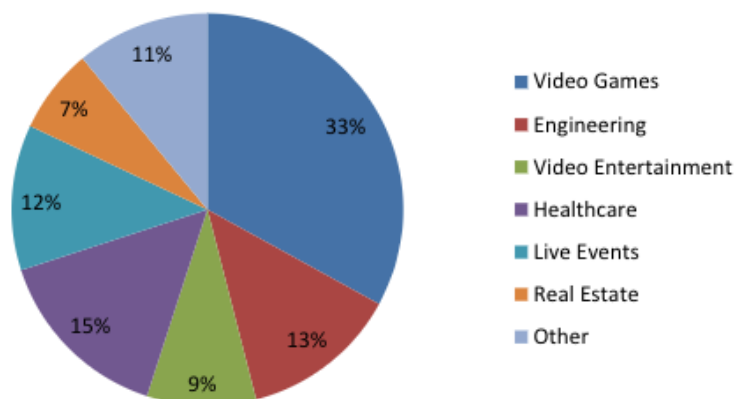
The expansion of VR is still in its early stages. Overall, the Global Virtual Reality market grew by 35% in 2020 and it is expected to reach an increase of 198,9% within 2025 (MarketLine Industry Profile Global Virtual Reality, 2021). The market has three main segments (*State of the Market & Trends to Watch OVERVIEW Catalyst, 2018*) :

- *The hardware segment* accounts for more than 60% of the market, indicating that the hardware is still the main focus at this stage.
- *The software segment* accounts for around 30% of the market and it is dominated by small companies and start-ups.
- *Content*, which accounts for around 22% of the global market revenues.

VR technology have many different applications. Companies have the potential to focus on entertainment, gaming, travel, or medical applications. Videogaming is still the biggest vertical segment in this market. The VR gaming industry is forecast to grow to 2,4 U.S. dollars by 2024 (Clement, 2022).

Figure 2 VRAR Revenue by vertical segment, 2025

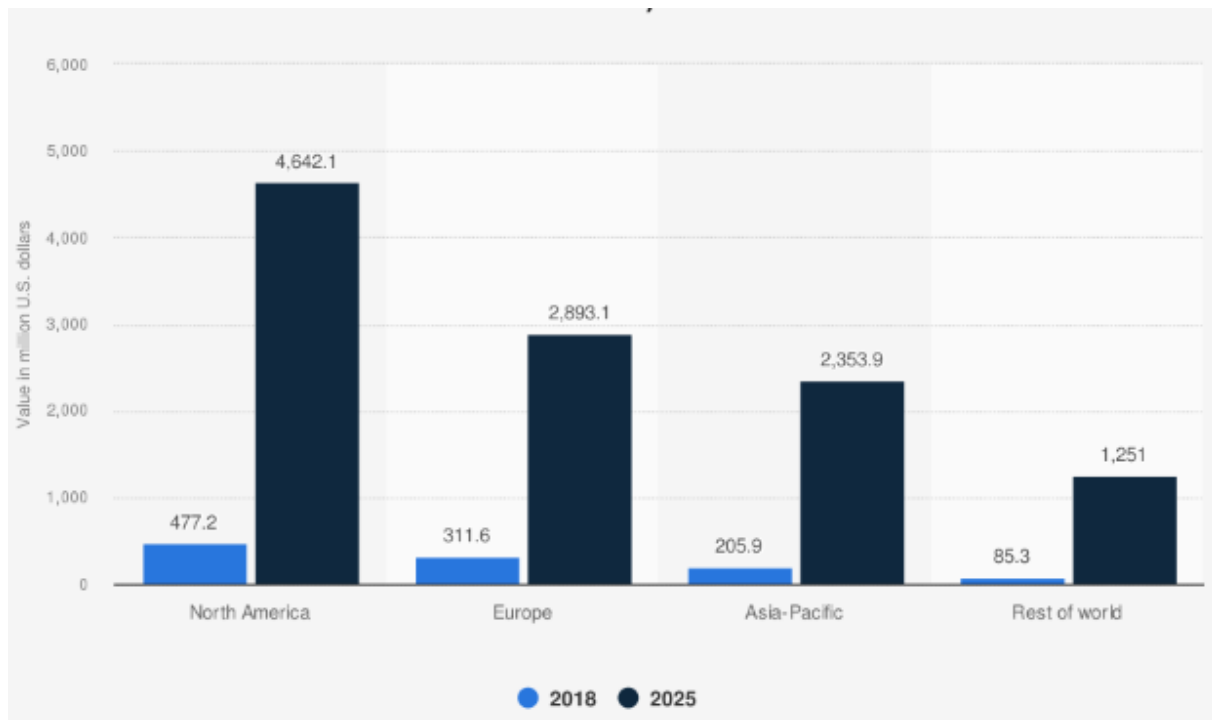
Source:Catalyst Market Report, 2018



The graph below illustrates predictions about the future growth of the industry: The expected growth by region (in Million U.S. dollars). Regarding the geographical segmentation, the market will grow in each region, the biggest growth will be in North America (*State of the Market & Trends to Watch OVERVIEW Catalyst, 2018*).

Figure 3 Global Healthcare AR and VR market in 2018 and 2025, by region

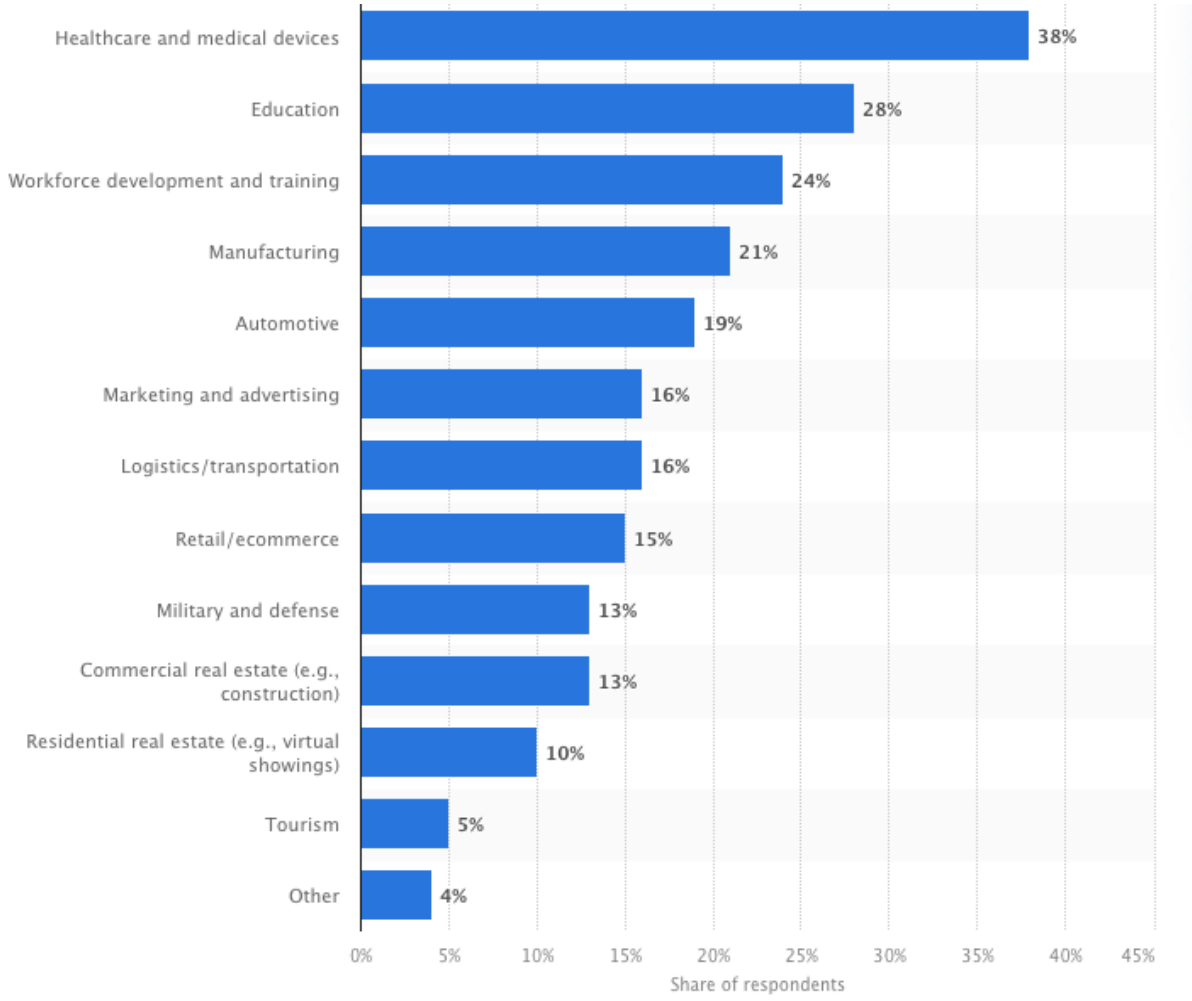
Source: Catalyst Market Report, 2018



The Virtual Reality Market in Healthcare is expected to register a CAGR of 33.18% from 2019 to 2026 (Manjrekar & Sumant, 2020). VR has the potential to revolutionize the healthcare industry in the coming years. While there are many different industries that will be affected by this innovation, healthcare seems to be one that who will witness the most disruption due to the rapid growth of innovation and the high importance and financial potential of the sector. The expected growth depends on the numerous applications that VR has in healthcare: it helps in medical training, in performing surgeries, it is a powerful diagnostic tool, and it has a relevant impact in some medical treatments for mental and physical health issues (Perkins, 2020).

Figure 4 Sectors expected to witness the most disruption from VR Technologies

Source: Augmented and VR survey Report, 2020



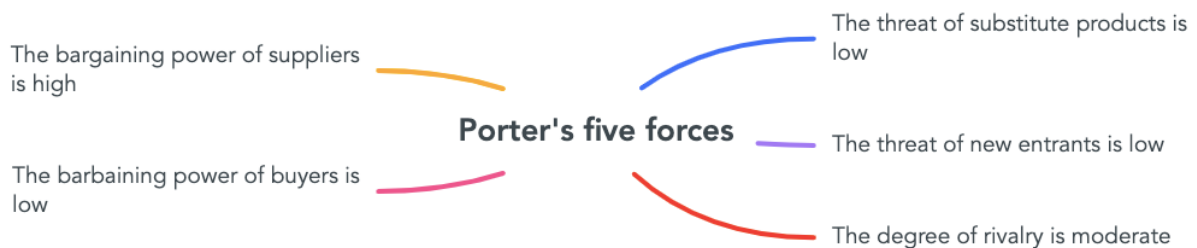
5 – Discussion

Through the selected methodology, the author will address the two research questions.

5.1. The Market of Virtual Reality applied in healthcare

To sum up the main key points of this industry analysis, according to the Porter's Framework:

Figure 5 Porter's five Forces Model



The degree of rivalry is moderate due to the balance of these segments: Hardware, software, and content. The hardware segment presents a strong degree of rivalry between IT leading companies as Sony, Facebook, and Apple. The software segment has a low degree of rivalry because of the spread of start-ups in the market, like the content segment. For these reasons, these three forces together are balanced, and the market shows a moderate degree of rivalry.

The threat of new entrants is low because there are many vertical segments. New entrants must try to infiltrate the market by focusing on a specific niche or segment of the software market, which presents less potential for demand than if the entrant were to instead compete on the development of new headset. Breakthroughs in display technologies over the next few years have the potential to lower the cost of the headsets, but until now the home-private market does not possess much feasible potential for expansion due to high associated cost.

The threat of substitute product/service is low, since the market is still in its embryonic stage of the industry life-cycle model (Peltoniemi, 2011). In fact, it is characterized by high prices and low volumes, but with a high expected growth. Moreover, the threat of substitute product/service is low because of the potential for diversification of VR applications through various vertical segments.

The bargaining power of supplier is high since most of the companies in this market have not integrated vertically all the processes and need suppliers. In the most common case of a software producer company, as the ones previously analyzed, they need a supplier for the VR headsets and those suppliers have a high bargaining power, since they can raise their prices or reduce the availability of their products.

The bargaining power of buyers is low because the market is relatively new and there are not many alternatives. When there are a significant number of companies delivering the same product/services, consumers have more options and consequently more bargaining power, however this is the opposite case.

An essential aspect of this market is the high interoperability between the hardware and the software segment (Adenuga et al., 2015). This is the demonstration that the market is well balanced by different actors and different segments. They harmoniously work together to create products that operate in conjunction. This strong industry value chain integration may need specific interoperability standards for VR in healthcare.

5.2. VR in mental health treatments

The analysis conducted in this research showed that, in Europe, there is a prevalence of start-ups in this industry, which shares some similarities. First of all, they are all European Start-ups, but from three different zones of Europe, according to the UN European Geoscheme (*United Nation GeoScheme for Europe*, 1999): Start-up A in eastern Europe, Start-up B in western Europe and Start-up C in southern Europe.

Start-up A and Start-up B deliver their products in many countries of the continental European area, and they are all expanding with an incredible speed. Start-up C was founded in the southern European zone, but it expanded incredibly and has now its headquarters in the US. The expansion in the U.S. was a powerful strategic decision (*State of Mental Health in America*, 2022) because:

- Almost the 20% of the adult population in the U.S. is experiencing a mental illness,
- One half of them report an unmet need for treatment

- The U.S. market is more willing to accept and adopt technological innovation. This is demonstrated from the R&D expenditure of the U.S. compared to the European Countries.(*OECD Main Science and Technology Indicators, 2022*)

These companies are considered start-ups with a social mission, and they are all focused on mental health, but in some different legal ways. The product of Start-up A is now on the market as an entertainment product, so it is not sponsored as a medical device. They are not interested in starting the procedure to be defined as a medical device for the moment.

Regardless of the demonstrated benefits on mental health, the experiences are now only advised to people in a good mental condition. Start-up B's product is classified as a medical device (Class I) and it is also certified by ISO 13485, which ensures high quality and safety levels. Start-up C uses an interesting expedient. They do not have any legal certifications as a medical device and for this reason their product is advised with the sentence: "*a tool for mental health.*" It must be considered a tool in therapy and not the main treatment.

The start-ups analyzed are all operating in the B2B market and are not producing the hardware in-house. Start-up A and Start-up C are defined as SaaS and Start-up B as SaaSMD. For this reason, the chosen start-ups are an accurate representation of the market trend, focused on software and not on the hardware side of this market. Regarding their approach with the regulation, all of them expressed a concern. They all stated the difficulty of being capable to follow the current regulation and the new EU MDR complexity is even higher than it previously was. Being certified as a MD has many pros but it is a process worth to go through **at the right timing of a company's lifetime**. The current state of the market is full of start-ups at the early stages of their activity, which explain the reduced number of start-ups providing "medical devices".

Start-up A is focused on nursing homes, targeting elderly people, and proposing a product meant to entertain them. Start-up B has a specific target group: hospitals and clinics. Start-up C perfectly represent the relevant market discussed and analyzed in this dissertation because they are focused on two key elements:

- Virtual Reality as the main technology used and,
- Mental Health issues

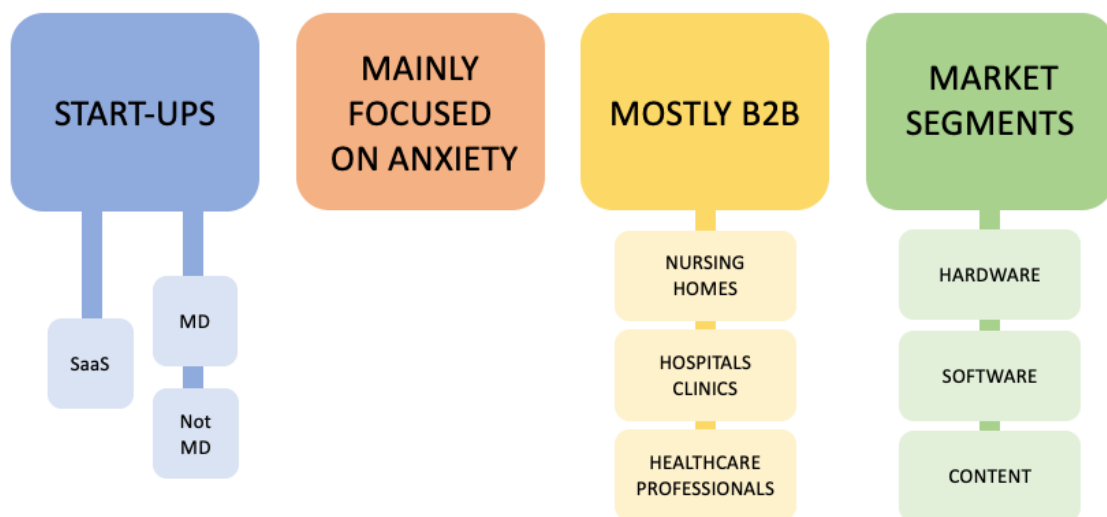
Table 1 Common aspects and differences

	Start-up A	Start-up B	Start-up C
Main mental health issue treated	Dementia and Depression	Pain Management Anxiety and Stress	Anxiety, Phobias, ADHD, Eating Disorders, Addictive disorders
Geographic zone	Western Europe	Eastern Europe	Southern Europe
Expansion	Many EU countries	Many EU countries	EU countries and U.S.
Legal Definitions	Entertainment product	Medical device (Class I)	A tool in psychologic therapy
Market	B2B	B2B	B2B
Software producer	SaaS	SaaSMD	SaaS
Hardware	Outsourced	Outsourced	Outsourced
Target Group	Nursing homes	Hospitals and clinics	Therapists and Psychologists

To sum up, Figure 6 shows the main characteristics of this market.

Figure 6 Main characteristics of the market

European VR Market in Mental Health



5.3 Growth drivers

There are many factors to consider when evaluating the future of the VR market. First, the rising interest in this market is attracting always more investors. Regarding hardware providers, there is a strong pressure on component vendors to lower costs. The pressure flow then to businesses and public services **to increase operational efficiency and digitalize**

services. As the VR headsets become more affordable, the market will unquestionably have a major increase of the B2C sector.

Situations, as a global pandemic, can create the right environment for innovations. Innovators in complex systems must take advantage of emergencies to offer potential solutions for concrete and new problems (Dougherty, 2017). The typical rationality of conventional strategies is not profitable in emergence circumstances, as it usually is. For this reason, covid-19 represented a growth driver. People lived a completely different life in the past two years: remote jobs, remote school, remote exams, and tests. Everything it was part of our everyday life, when possible, translocated on remote mode. Therefore, the restrictions incentivized the technology adoption and the need of remote interventions and at the same time VR is becoming a more conventional and affordable technology. For example, the need for remote medical treatments and the demand for online and interactive learning sessions increased drastically. Medical students faced challenges for practical sessions, as no available technology could offer face-to-face or clinical condition such as education. On the other hand, in a situation of economic deceleration, other kind of investments were privileged as a result of a more cautious approach, in terms of capital investments.

Covid-19 had a huge impact on the mental health market. It had a positive influence in **pulling down stigmas around mental health.** The market will increase because:

- From the patient side, it is unfortunately increasing the demand for mental health services,
- From the clinician side, they need better tools, both in-person and remotely.

Metaverse is a word coined by Neal Stephenson in 1992. In his sci-fi novel named Snow Crash, he defined the metaverse as a VR-based world, where it is possible to experience a new digital universe through a personal avatar. (Lee et al., 2021) Recently, Facebook did a major re-branding into the name Meta, because Mark Zuckerberg decided to bet everything on the concept of Metaverse. In his opinion this is going to be the next evolution of social connection. His aim is to create an immersive virtual environment where people can do any kind of activity. Before the official re-branding he was quietly buying up the metaverse through many investments and acquisitions on companies related to the VR technologies. In the post Covid-19 world where spending everyday hours doing remote work and school is considered “normal”, the idea of Metaverse perfectly suits the world nowadays. It might be the next technology shock that our society will have to face, in which Virtual Reality will

become as usual as holding a Smartphone in our hands. When the metaverse will be a regular part of our life, the prices of VR headsets will probably decrease, and people will have to own one of it to take part on it.

It is not a surprise that the 2017 Global Grand Challenges Summit (GGCS), identified VR as one of 14 Grand Challenges awaiting solutions in the 21st Century. (U.S. National Academy of Engineering, 2017) The advancement of some emerging technologies like AI, big data, VR and 5G is taking the world closer to the metaverse.

Maybe we are a step closer to Douglas Engelbart's dream. Engelbart was an engineer and a researcher, known for being the creator of the first mouse in world. This is ironical because he had much more merits that simply that. Two decades before the personal computer, at a time where Steve Jobs and Bill gates were only teenagers, Engelbart had an intuition that, some decades later, drove the tech-revolution. It is defined the Engelbart's dream, and it is based on the idea that digital technology can help make this world a better place. He was convinced that through digital technology, people were able to "*augment their collective human capabilities*", meaning that to get advantages of a shared intellectual space, to solve any kind of complex problem. (Engelbart, 1962)

Over the years, the demand for a higher speed internet connection and a smoother communication increased incredibly. The reasons why the fifth generations of mobile networks (5G) seem a necessary technology in 2022 is that it can ensure faster and wider connection, larger range of user connected and higher data rates. (Gao & Li, 2022)

On the other side, there are only a few elements that might be considered growth inhibitors of this market. New industries are usually affected by some common issues. Prices must be captivating to overcome the natural hesitancy to adopt radically new devices.

5.4 Regulation

The use of normative strategies should be discouraged. As previously stated, healthcare is a complex system and "as more regulations are created to control the behavior of a complex system, the more the system may deviate from a desired outcome" (Lipsitz et al., 2012).

There is an exception, the Medical Device Regulation (MDR). It is a regulation that ensures high standard of safety and quality for all the medical devices that are produced or supplied in member states on EU (*Regulation (EU) 2017/754*, 2017). The MDR is also applicable to medical

devices that do not have medical purposes, but are related to human body, such as contact lenses. The transitional period was supposed to end in 2020, however because of the global pandemic the end was postponed to May 2021. Contrary to directives, regulations do not need national implementation measures, therefore it is immediately binding. The aims of this regulation are: to improve safety and performance of European Medical Devices, strengthen post-market Surveillance and settle differences in the European countries (Kaule et al., 2020).

Quality Management System standard (QMS) are a significant tool to comply with the stringent and demanding requirements of MDR. The accreditation of a QMS helps in facilitate trade, manage risks, enter new markets, and increase trust in the product. Figure 7 shows some of the applicable harmonized standards for medical devices; some are specifically for the company, some for the product, and some for the software (Beckers et al., 2021).

Source:(Beckers et al., 2021)

Figure 7 List of Quality Management Standards for medical devices.

Company	EN ISO 13485: Applicable for designers and manufacturers of MD
	EN ISO 27001: Applicable for MD manufacturers
Product	EN ISO 14971: Risk management to MD
	EN 1041 Information requirements to supply by manufacturers
Software	IEC 82304-1: Requirements for health software products
	EN 62304: Software life cycle requirements for MD

5.5 The future of this market

The analysis of the market combined with an analysis of the aspects and elements that may influence this market in the long run, give as a result a prospect of how this market is possible to evolve.

1)**High expected growth**, according to the previously identified growth drivers.

2)When the market will overcome this initial stage and will assess, the companies that are already on the market **may desire to change**, meaning that:

- The competition will be higher and companies may decide to go for **strategic choices and structural changes**, such as internationalization and verticalization.

Verticalization may disrupt the current balance between the segments inside this market.

- Companies may choose to expand to the **B2C market**.
- Company will **expand the set of mental health treatments provided** through their service or product, since they already expect and plan to do.

3)As the competition becomes more intense, the **need of companies to be in compliance** with the current regulation will significantly increase. Overall, this is a good aspect for the final consumer and also for the quality of the market. However, companies need to be prepared on the current regulation and also need to individuate the proper moment to start the process for the MDR.

6 – Limitation and further research

A key limitation of this research paper is that the **sample** of interviewed start-ups was only composed of six companies in the chosen sector. However, this sample may still be able to provide insight and effectively represent the chosen market, since they provide a geographic scope across Europe, provide insight in the B2B sector of the market across both medical devices and mental health tools. Despite the scope of the research subjects, it is still possible that a larger sample may have led to different observations and conclusions. **However**, the sample provide insights from start-ups from not only three different countries, but from three different zones of Europe, according to the UN European Geoscheme. Further research would be considered necessary to confirm the result of the current study.

Regarding the methodology, the author chose to select relevant research papers and systematic reviews without defining any timeframe, in order to be able to elaborate on previous trends and older theories as well as more contemporary theories and frameworks. The desk research may suffer from the **lack of a consistent number of prior research studies**, since the nature and the innovation of the topic. **To mitigate** the lack of available data, the conduction of the semi-structured interviews was effective and productive in providing depth to the information obtained, while also addressing the core research questions of the study.

A limit of qualitative research, especially of interviews, is that the author's interpretation of the finding is significantly **subjective**. The author adopted **thematic analysis precisely to reduce any possible subjective bias**. Future researchers should revise the specific method for gathering data, in order to overcome possible bias.

Further research should investigate the medium and long-term effects of these interventions on mental health and the mental health industry. Moreover, further research should be conducted to investigate the differences between the effects of the treatment on different types of mental health issues. Since the topic is still very young and presents multiple potential directions of growth and disruption, further research is strongly advised for a comprehensive overview.

The research period for writing this paper officially ended in May 2022, further on updates will be required to catch up with the evolution of this growing market.

7 – Conclusion and recommendation

The findings reveal that VR is a great tool for issues connected with mental health. According to the reviewed studies, the VR experiences reported a high level of engagement and immersion. It is a good starting point for the implementation of VR technology in the medical sector, with a large potential for a widespread implementation. Furthermore, VR treatments also have the possibility to generate positive effects that are not specifically targeted by the mental treatment issued, such as

- General enjoyment of the participant,
- Relaxation of the participant through optimal, engaging, and pleasant virtual environments with often natural stimuli (Riches et al., 2021).
- The ability to offer new or otherwise potentially physically inaccessible opportunities or experiences to the patient, such as traveling internationally, visiting a museum, or mountain-climbing.
- Some virtual experiences can also provide stimuli to trigger physical activity, which can have many positive effects for the patient, not only as a result of the physical activity itself, but also due to the correlated improvements in cognitive functions.

The negative aspects are related to the need of supervision and active work by specialists, in selected situations. Another negative aspect is related to the negative social implications of VR as a technology. There is the risk that the technology may provoke addictive behaviors or an increase in social withdrawal. There are also other concerns connected to VR, such as the potential to experience side effect during or after the virtual experience. Patients may suffer from dizziness, nausea and headaches, hallucinations, or balance problems (Tyrrell et al., 2018). Another concern is associated with the wearability of the VR headset, as patients might feel discomfort and agitation. However, the reviewed studies are mainly conducted on small samples, vary on outcome measures, and present a considerable variation in the duration of the studies.

The purpose of this research paper was to study an innovative and thrilling market. The author wanted to analyze the driving forces of this market and understand what are the factors that will bring change. As we have already discussed, many are the forces that have the power to shake this market, fortunately mainly for the good. As far as we can see nowadays, the market of virtual reality will undoubtedly increase and its application in mental health are already

unbelievable. The beauty of this market and of the start-ups that are part of it, is inside their social purpose. Chase innovation for the good of humanity is something that goes beyond entrepreneurship and profitability.

The case vignettes showed a clear trend of start-ups in this market. They are all software producers and B2B, all with a specific target group defined. The tendency is correct and coherent with their growth plans. Based on the findings of this research, the author proposes a set of recommendations for the start-ups operating in this market.

7.1 Recommendation for start-ups

VR is an advanced and disruptive technology and start-ups have to take advantage of it. We are still in an early phase of adoption, so it is the perfect timing to exploit this market opportunity. The author's recommendations to start-up can be summarized in:

Target your audience: define specifically who is your target group and work consistently in that direction. New entrants should focus on a specific niche in the market, to get advantage of one characteristic of this market: the significant number of vertical segments.

Invest in marketing: The use of this innovative technology in mental health is still unpopular and unknown. People may not know the product and might not know its effectiveness on mental health. Moreover, many of these companies are defined as social enterprises, so the marketing expenditure is not only to reach new consumers but also to spread awareness on the topic.

Price: Considering the current state of the economy, people is not willing to spend a considerable amount of money for innovations. Start-ups should consider the idea of offering free trials or sales on special periods throughout the year, as for example, the World Mental Health Day on October 10th.

CE Mark: The process to obtain a CE mark can be difficult and complicated, but it is undoubtedly worth it. Affix the CE mark on the product in sale demonstrate compliance with the essential requirements of the EU legislation in force and it is necessary to launch and marketing a product into the European Economic Area (EEA) as a medical device.

Provide safety: As in all the health-related matters, safety is an important part. People is scared on the consequences and side-effects of health-products. Invest on QMS and get accredited as they demonstrate safety and ensure the professionalism of the company.

Arrive first: Timing is a relevant matter in health-related matters. Consumers tend to trust the first comer when the first experience is good. The fear to try new health-related product is usually high and people tend to be risk adverse on this.

Consumer preferences: In designing new VR experiences, start-up and companies should consider the importance of consumer consultation. Evaluating properly what is the taste of the chosen target group represents a key decision.

Attract investors: It is strongly advised to take part of industry fairs to spread awareness. Moreover, being in a novel market usually represents an advantage for investor because of diversification reasons. Proof of the potential of a new market is demonstrable through analytical business plans and marketing plans, financial projections, and demonstrations of targets interest. It is also crucial to be able to demonstrate transparency and professionalism.

7.2 Recommendation for healthcare professionals

Healthcare professionals have a major role in this market, in establishing its primary acceptance in the mental health market. In the first place they are the ones dealing with this advanced new technology, since the market is almost exclusively B2B. Healthcare professional need to learn how to work and deal with the treatments provided through VR, as indicated in Case C of the case vignettes presented in this thesis.

The author's recommendations to this category are the following:

- **Try to overcome the resistance to change in the first place.** Keep in mind that offering better interventions and more effective treatments is the ultimate goal in healthcare.
- **Study the benefits** that this new technology is able to provide for mental health issues, in order to be fully aware of the how to provide this service to patients.
- **Be able to explain this innovation to the patients.** Convince patients, especially the older ones, to rely on a new technology may not be easy. For this reason, healthcare professionals represent a fundamental category in the implementation of innovations in healthcare.
- **Spread awareness** on the benefits that VR can provide for the treatment of mental health issues.

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Appendixes

Appendix I – Interview Guide

Focus Area:	Questions:
Warming up	Q1: What do you think are the pros of using VR in health treatments?
	Q2: What do you think are the cons of using VR in health treatments?
General questions regarding the Start-up	Q3: Does the company produce in-house experiments on functionality?
	Q4: What is the target group of your company? Is it B2B or B2C?
	Q5: Are you producing both the software and the hardware?
	Q6: Is the product you are selling, considered a Medical Device or does it have any certification?
Exploration of present aspects	Q7: Have COVID-19 had any influence on your company?
	Q8: What are the main difficulties in pursuing innovation in this market?
	Q9: Would you say that EU support technological innovation in healthcare? How?
Exploration of future aspects	Q10: What do you think are the growth drivers of this industry?
	Q11: What do you think are the growth inhibitors of this industry?
	Q12: What do you think will be the future scenario of this industry? What might be in your opinion the future developments?
Fundings	Q13: What is the procedure to get grants and fundings?
	Q14: How easy is to get access to EU fundings?

Appendix II: Thematic Analysis

Themes	Codes	Excerpt from Interview Transcript
VR in Health-Care	Positive Aspects	“VR has shown to be a valuable resource for many treatments that consists in immersive stimulus.”
	Negative Aspects	“Some patients might suffer from nausea or dizziness; it is a situation we have to take into account.”
	Experiments	“We have conducted some pilot programs, completely free of charge, and they demonstrated to be a powerful resource for us to gather data on our product.”
Relevant Market	Target Group	“We decided to target elderly people, because they are the population group we were thinking when creating our product. However, we are aware that our product may be extended to other target groups, and we will expand when the circumstances will allow it.”
	Production	“We outsourced the manufacturing of the VR headset for the easiness of the whole process.”
	COVID-19	“The pandemic represented a challenge for us since we had launched our product just some months before. We are proud of how well we handled the situation though.”
Adopting innovation in healthcare	Difficulties	“Healthcare is a very delicate market; people do not tend to trust innovative health-products.”
	Legal definition	“We do not have any CE mark or health-certifications, so we cannot sponsor our product mentioning health benefits, even if clearly there are.” “The process to get certified as a medical device is not easy, but it is worth in the end.”
	EU Support	“EU represents a supportive force for us. The extend of its help depends on which country you are operating. Some countries are more open to innovation than others and it is the case of Germany.”

The future of this industry	Growth drivers	“We expect this market to grow considerably, because we believe in the power of virtual reality, as a technology.”
	Growth inhibitors	“A disadvantage of this business is the cost of the VR headset, which raises the cost of our product significantly.”
	Future developments	“The popularization of the Metaverse will have a huge impact on our market, which will probably give us one good reason to move on to the B2C market”