The Impact of Digital Therapeutics on the Pharmaceutical Industry in the Treatment of Mental Health Disorders

Carina Knop

Dissertation written under the supervision of professor Peter Rajsingh

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I Abstract

Digital alternatives to traditional treatment methods for mental health disorders are increasing. These digital therapeutics pose a threat to the traditional pharmaceutical company, having the ability to potentially replace some medications in the treatment. While the digital therapeutics sector is growing, the economic implications of the technology for pharmaceutical companies is rarely discussed in academic literature. This dissertation aims to close the knowledge gap by providing ex-ante predictions of the disruption potential of digital therapeutics in the treatment of mental health disorders.

A mixed research approach consisting of both expert interviews and a survey was used to collect market insights from both digital therapeutic and pharmaceutical industries. In combination with knowledge gathered from current literature, predictions about the disruption potential of digital therapeutics in the mental health care market were made. The findings indicated a high disruption potential for digital therapeutics within the mental health care market. A complete displacement of pharmaceuticals is unlikely. For future research, additional medical specialties or competitive capabilities of pharmaceutical companies can be examined as the market environment constantly changes.

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Keywords: Digital Therapeutics, Pharmaceutical Industry, Health Care, Disruptive Innovation, Mental Health Care, Technology Acceptance, Digitalization

II Abstrato

As alternativas digitais aos métodos tradicionais de tratamento das perturbações da saúde mental estão a aumentar. Estas terapêuticas digitais representam uma ameaça para a empresa farmacêutica tradicional, tendo a capacidade de potencialmente substituir alguns medicamentos no tratamento. Enquanto o sector da terapêutica digital está a crescer, o tema é raramente discutido na literatura académica sobre as implicações económicas da tecnologia para as empresas farmacêuticas. Esta dissertação visa colmatar a lacuna de conhecimentos, fornecendo previsões ex-ante do potencial de perturbação da terapêutica digital no tratamento de distúrbios da saúde mental.

Foi utilizada uma abordagem de investigação mista que consiste em entrevistas a peritos e num inquérito para recolher conhecimentos de mercado tanto da indústria terapêutica digital como da indústria farmacêutica. Em combinação com o conhecimento recolhido da literatura actual, foram feitas previsões sobre o potencial de perturbação da terapêutica digital no mercado dos cuidados de saúde mental. Os resultados indicaram um elevado potencial de perturbação da terapêutica digital no mercado dos cuidados de saúde mental. É improvável uma deslocação completa dos produtos farmacêuticos. Para investigações futuras, especialidades médicas adicionais ou capacidades competitivas das empresas farmacêuticas podem ser examinadas à medida que o ambiente do mercado muda constantemente.

Título: O impacto da terapêutica digital na indústria farmacêutica no tratamento dos distúrbios de saúde mental

Autor: Carina Knop

Palavras-chave: Terapêutica Digital, Indústria Farmacêutica, Cuidados de Saúde, Inovação Disruptiva, Cuidados de Saúde Mental, Aceitação de Tecnologia, Digitalização

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VI List of Abbreviations

Attitude	A
Behavioural Intention	BI
Center for Devices and Radiological Health	CDRH
Cognitive Behavioural Therapy	CBT
Digital Therapeutics	DTx
European Medicines Agency	EMA
Food and Drug Administration	FDA
Interview Partner	IP
Non-Alcoholic Fatty Liver Disease	NAFLD
Non-Alcoholic Steatohepatitis	NASH
Perceived Ease of Use	PEOU
Perceived Usefulness	PU
Post-Traumatic Stress Disorder	PTSD
Research and Development	R&D
Software as a Medical Device	SaMD
Subjective Norms	SN
Technology Acceptance Model	TAM
Theory of Reasoned Action	TRA
Unified Theory of Technology Acceptance and Use of Technology	UTAUT

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1 Introduction

Mental health disorders have been increasing in recent years, with disorders relating to anxiety and depression posing a public health concern globally (Harrison et al., 2011; Khademian et al., 2020; Patel & Butte, 2020; Polanczyk et al., 2015; World Health Organization, 2003, as cited in Khademian et al., 2020; World Health Organization, 2004, as cited in Khademian et al., 2020). However, the increasing need for treatment options cannot be met by the limited available mental health services. This leaves around 50-78 % of people dealing with mental health issues untreated in Europe and the United States of America alone (Jörg et al., 2016; Van Orden et al., 2015). This highlights the need for easily accessible alternative treatment options. Mental health treatments include psychotherapy and medications, either as stand-alone treatments or a combination of the two (Mayo Clinic, 2019).

However, a paradigm shift in the health care industry is challenging the traditional pharmaceutical business model, moving away from a one-size-fits-all model towards more personalized treatment solutions (Sverdlov et al., 2018). This shift fosters the development of innovative treatment options as viable alternatives to traditional medicine. One of the technologies threatening the pharmaceutical industry is software-based therapeutic interventions called digital therapeutics (DTx). DTx are evidence-based and can be used as monotherapy or in combination with traditional therapies to prevent, manage, and treat medical conditions (Digital Therapeutics Alliance, 2019).

1.1 Research Question and Hypotheses

As demand for treatment of mental health disorders is increasing globally, more and more alternative treatment options in the form of digital therapeutics are being developed. With an increasing number of digital therapeutic companies, the mental health care industry and its related business are changing. This dissertation aims to answer the following research question:

> Do digital therapeutics have the potential to disrupt the pharmaceutical industry in the treatment of mental health disorders?

Digital therapeutics may be considered as disruption using the theory of disruptive innovation developed by Christensen (1997). Based on this, three prepositions were developed:

P1: Digital therapeutics offer a new value proposition or target the price sensitive customer segment
P2: Digital therapeutics are underperforming the performance requirements of the mainstream market
P3: Digital therapeutics will be offered at a reduced price compared to medications

The unified theory of acceptance and use of technology (UTAUT) can be used to determine the current technology acceptance of digital therapeutics. Based on this, two hypotheses were developed:

H1: UTAUT is an adequate model to predict behavioural intent of using digital therapeutics
H2: Younger generations (Gen Z and Millennials) will have a higher technology acceptance of DTx

The market for digital therapeutics is still growing with approval processes not fully established. With the majority of DTx firms located in the United States of America, this thesis will mainly focus on this geography and market.

1.2 Structure

This dissertation is split into four sections to answer the research question. A literature review provides an overview of both the pharmaceutical and digital therapeutics industries as well as of predominant theories in disruptive innovation and technology acceptance. Subsequently, the research methodology, the data collection tools, and the applied data analysis methods are elaborated in the Methodology section. The Data Analysis chapter will provide the data gathered as well as an in-depth analysis thereof. Lastly, the Conclusion presents a summary of the most important conclusions as well as an outlook for the future of both industries.

2 Literature Review

2.1 Pharmaceutical Industry

The pharmaceutical industry has an iceberg structure with well-known research companies on the top and a multitude of generic, mostly unknown pharmaceutical companies at the bottom (Taylor, 2015). The well-known research pharmaceutical companies, often referred to as Big Pharma, consist of a few very large multinational corporations such as Eli Lily, Merck, Novartis, AstraZeneca, Pfizer, and Roche (Taylor, 2015). These research-based companies make up only a small fraction (<10 %) of the pharmaceutical industry as a whole; however, they account for around 40 % of the financing in the market (Noor & Kleinrock, 2013, as cited in Taylor, 2015). The generic companies are mainly unknown, even though they fulfil over 80 % of prescriptions in the US (Boehm et al., 2013, as cited in Taylor, 2015; Taylor, 2015). This market asymmetry is caused by the patent system. Research companies spend large sums on the development of new drugs and in return receive patents and market exclusivity for a finite number of years (Bunnage, 2011; DiMasi et al., 2003), whereas the generic companies produce the drug once the patent expires at a fraction of the cost (Taylor, 2015).

When talking about pharmaceuticals, there are different kinds of medicine that need to be distinguished. The most common types are prescription and over-the-counter, non-prescription drugs (Ellis, 2016). Here, we can differentiate between brand name and generic drugs. Brand name drugs are produced and marketed by Big Pharma, this means the company developed the active components in the drug and often holds a patent for the first years of commercialization (Ellis, 2016). In contrast, generic drugs are produced after the patent expires by companies that did not originally develop the drug and as such can offer it at lower price points than the name brand (Ellis, 2016; Taylor, 2015). Specialty drugs are often created for rare diseases in very limited supply as the demand is restricted due to the nature of diseases they are targeting (Ellis, 2016). Additionally, these drugs often require special handling and are sold at very high price points (Ellis, 2016). Personalized medicine uses genetics and genomics to develop medicine for different diseases by personalizing the treatment (Ellis, 2016). Here, the individual risk factors of the patient can be considered through the targeted therapy approach (Ellis, 2016). These personalised drugs only make up a fraction of the treatments offered; however, their usage is increasing (Ellis, 2016). Stakeholders hope that this targeted therapy allows for improved drug efficacy and gathering of more data on diseases (Ellis, 2016). Lastly, biotechnology, a subdivision of the

pharmaceutical industry, focusses on developing treatments that are often based on proteins (Ellis, 2016). These treatments tend to be expensive, and no generic alternatives are available in the market (Ellis, 2016).

2.1.1 Research-based and Generic Pharmaceutical Companies

Research-based pharmaceutical companies bring new drugs to market (Taylor, 2015). The business model of these research companies is quite different from business models found in other industries (Taylor, 2015). Research pharmaceutical companies operate in a high-risk business with an unusual value proposition (Taylor, 2015). These companies require large upfront investment since the research and development phases of new drugs can cost up to $2.5 billion (Ellis, 2016). Industry risk is highlighted by the fact that there is an actual success rate of drugs making it to market of less than one percent coupled with increasing regulatory requirements (Taylor, 2015). Once a drug is found to have efficacy during pre-clinical and clinical trials, the pharma company usually applies for a 20-year patent from the FDA to protect the intellectual property and retain market exclusivity for sales (Ellis, 2016). This is important for the manufacturer to be able to recoup development costs as well as offsetting failed attempts of other research areas (Ellis, 2016). Sales of patented drugs are the only time companies can profit off their investment (Ellis, 2016). Due to large R&D costs, the long-term nature of the drug development, as well as the high risk of failure, potential returns need to be considerable for drug development to be viable (Taylor, 2015).

Alternatively, generic pharmaceutical companies operate a low-cost, low-margin, and low-risk business model, producing drugs that contain the same active ingredients as brand name therapeutics whose patents have expired, with proven successful products (Taylor, 2015). Generic companies compete in a commodified market where differentiation is based on cost and profitability comes from market share (Taylor, 2015). The only R&D costs a generic pharmaceutical company might incur are process improvements to further reduce manufacturing costs (Taylor, 2015).

To be commercialized a drug needs to be approved by the regulator, typically the Food and Drug Administration (FDA) in the US or the European Medicines Agency (EMA) in the European Union (Taylor, 2015). In the US, manufacturers distribute medicines using wholesalers as middlemen who then sell the drugs to pharmacies or retailers (Ellis, 2016). The United States are the largest market for pharmaceutical companies with around 30-40 %

of global market share (Ellis, 2016). The importance of this market has led many pharmaceutical companies to have a US presence (Ellis, 2016) and consequently, almost half the drugs available on the market originate there (Daemmerich, 2011). Although, there have been advances in the US in biomedical research for many decades, research funding as well as clinical research has been decreasing (Ellis, 2016; Moses et al., 2015).

2.1.2 Threats to the Pharmaceuticals Business Model

Currently, the research segment of the pharmaceutical industry is facing several challenges. As mentioned above, due to the structure of the patent system, companies must recover development costs of both marketed and the failed drugs within a few of years of launch prior to patents expiring (Taylor, 2015). This short useful patent life causes research companies to spend large sums on marketing to increase customer awareness and sales (Taylor, 2015). Early patent filings also have risks as the concept and active ingredients become public knowledge, giving competitors access to the composition of the drug (Taylor, 2015). Longer development and trial periods due to increasing regulation are compounding risks (Taylor, 2015).

Another threat for traditional pharma is the inefficiency of the research and development of new drugs. Also, many research pharma companies rely on blockbuster drugs with yearly revenues of more than $1 billion, to finance future R&D efforts (Taylor, 2015). However, over the past several decades, it has become apparent that R&D is not as scalable as assumed and the development of a blockbuster drug cannot be assured simply by large R&D expenditures (Garnier, 2008; Munos, 2009; Taylor, 2015). Thus, maintaining current business of research pharmaceutical companies is a challenge.

Additionally, digital therapeutics are a threat as they are able to offer more scalable, less expensive alternatives to traditional drugs, whilst offering a higher level of personalization (Chung, 2019; Sverdlow et al., 2018; Yang et al., 2020). As pressures for more affordable, higher quality health care becomes stronger, pharmaceutical manufacturers will need to find new ways to protect their market share in a highly competitive market (Ellis, 2016).

2.1.3 Porter's 5 Forces Model

The Porter's 5 forces model (Porter, 1980) is arguably one of the most applied and widely known models to analyse the competitive environment within an industry. The model

evaluates the industry based on the threat of substitution, threat of new entrants, the buying power, and the supplier power which influence the rivalry in the market (Porter, 1980). The market forces in the pharmaceutical market result in a high rivalry and a highly competitive industry (Ellis, 2016). This rivalry is mainly caused by the high threat of substitution. As generic drugs largely displace brand drugs after their patent expires, substitution is a credible threat for research pharmaceutical companies (Taylor, 2015). Additionally, DTx could become substitutes as they can offer a more affordable alternative (Chung, 2019; Sverdlow et al., 2018; Yang et al., 2020). Figure 1 highlights all market forces.

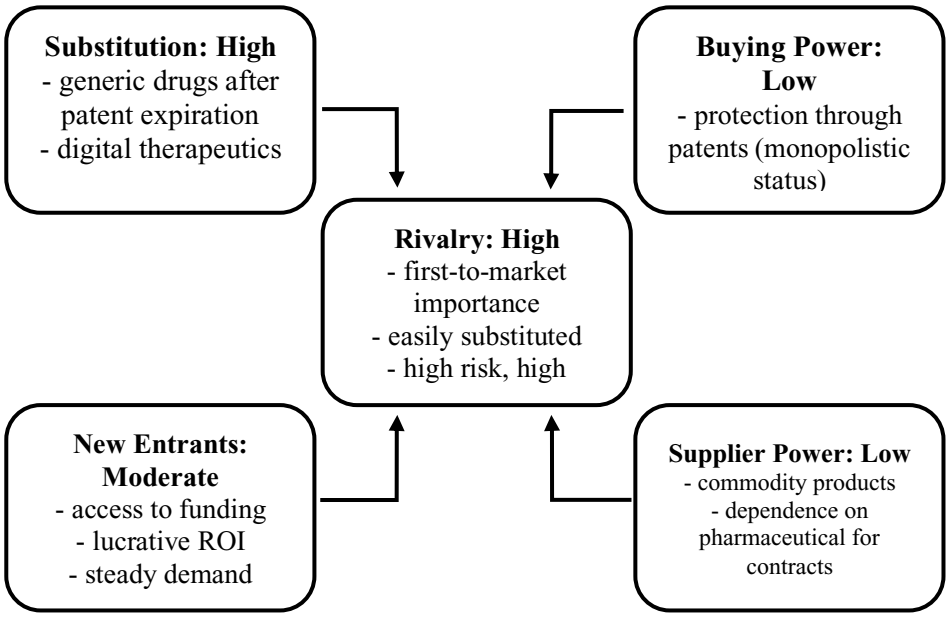

Figure 1: *Porter's Five Forces (Chung, 2019; Ellis, 2016; Porter, 1980; Taylor, 2015; Whiteside, 2022)*

2.2 Digital Therapeutics Industry

Digital therapeutics are evidence-based therapeutic interventions that deliver treatments through mobile phones and software infrastructures such as machine learning (DTx Alliance, 2019; Hong et al., 2021; Khirasaria et al., 2020; Meyer-Christian et al., 2021; Sverdlow et al., 2018). DTx can be used either as monotherapy replacing pharmacological treatments or in combination with other therapies (Digital Therapeutics Alliance, 2019; Hong et al., 2021; Khirasaria et al., 2020; Meyer-Christian et al., 2021; Sverdlow et al., 2018). Digital therapeutics can be divided into two subsets; non-prescription DTx, which are regulated but not cleared by the FDA, and prescription DTx, which are both cleared and regulated by the FDA (Hong et al., 2021) with classification dependent on medical function. DTx used to treat

diseases are classified as prescription DTx. Disease management as well as improving health with digital therapeutics can be classified as both prescription and non-prescription DTx depending on specific usages (Hong et al., 2021; Meyer-Christian et al., 2021). DTx exist for a variety of indications, mostly using cognitive behavioural therapy (CBT) for chronic conditions and previously unmet medical needs (Hong et al., 2021; Meyer-Christian et al., 2021).

2.2.1 Market Overview

In 2021, the size of the global market for digital therapeutics was $3.4 billion (Meyer-Christian et al., 2021) and this is expected to grow at a CAGR of 20.5% to 31.4%, possibly reaching $13.8 billion by 2027 (Allied Market Research, 2021a; Meyer-Christian et al., 2021). This growth is attributed to the increasing number of start-ups, most with clinical development programs to commercialise the technology (Chung, 2019). Most DTx compete in the B2B market through health plans and pharmaceutical companies (Hong et al., 2021). The largest market for DTx in 2019 was North America, accounting for around 70% of the market share, followed by Europe with around 30% (Gill et al., 2021). Due to the strong North American market share, the majority of the largest players in the DTx market are American (see Table 1 for an overview of some of the players and their therapeutic focus areas).

Company	Therapeutic Area	Location	Partnerships
Akili Interactive	Autism Spectrum Disorder Multiple Sclerosis Major Depressive Disorder Parkinson's Disease Anxiety Traumatic Brain Injury Sensory Processing Disorder	USA	Pfizer Shinogi
Click Therapeutics	Major Depressive Disorder Insomnia Acute Coronary Syndrome Schizophrenia Migraine Obesity	USA	Otsuka Boehringer Ingelheim
Pear Therapeutics	PTSD Schizophrenia Multiple Sclerosis Pain Migraine Epilepsy Oncology	USA	Novartis
Better Therapeutics	Diabetes Hypertension Hyperlipaemia NASH/ NAFLD	USA	
Happify Health	Multiple Sclerosis Migraine Depression Anxiety	USA	
Omada Health	Prediabetes Diabetes Hypertension Joint and Muscle Pain	USA	

Table 1*: DTx Companies and their Therapeutic Pipeline (Akili Interactive, 2022; Better Therapeutics, 2022; Click Therapeutics, 2022; Happify Health, 2022; Hong et al., 2021; Omada Health, 2022; Pear Therapeutics, 2022)*

Several factors are drivers of growth in the digital therapeutics industry. The increasing prevalence of major chronic diseases as well as mental health disorders has increased investment flow into the digital therapeutics industry (Hong et al., 2021; Meyer-Christian et al., 2021). Controlling health care spending and moving towards a more holistic, personalised model of medical treatment as well as a growing smart health care industry have further supported the development of the DTx market (Hong et al., 2021; Meyer-Christian et al., 2021). The digital therapeutics industry has also been attractive for venture capital and investors as the development costs are lower compared to pharmaceuticals, the technology is easy to distribute and easy to scale up in terms of application to similar medical disorders (Meyer-Christian et al., 2021). Venture capital funding in digital health innovators in the US

is steadily increasing, with total investments in the first half of 2021 already surmounting the total funding of 2020 (Meyer-Christian et al., 2021).

2.2.2 Regulatory Framework

In the United States, the Food and Drug Administration is responsible for clearing and regulating digital therapeutics (Hong et al., 2021). Specifically, DTx fall under the purview of the FDA's Center for Devices and Radiological Health (CDRH) as Software as a Medical Device (SaMD) is a subset of digital medicine (Hong et al., 2021; Sverdlow et al., 2018). In recent years, the FDA has taken several steps towards creating a clearer and faster path to approval, such as the 'Digital Health Innovation Action Plan', launching a digital health pre-certification programme or enacting the 21st Century Cures Act (CDRH, 2020; Hong et al., 2021; Khirasaria et al., 2020; Meyer-Christian et al., 2021).

Many stakeholders have called for a gold standard in digital therapeutics, highlighting the necessity for new therapeutic targets and regulatory oversight due to higher associated risks (Chung, 2019; Hong et al., 2021; Meyer-Christian et al., 2021).

2.2.3 Paradigm Shift in the Market

Several developments in recent years have fostered progress of digital therapeutics and opportunities for growth. The increasing use of mobile devices such as smartphones in day-to-day life has facilitated access to DTx and their treatments (Sverdlow et al., 2018). Technical improvements and innovations have also created better digital infrastructures around cloud-based technologies that DTx can utilise for their services (Sverdlow et al., 2018).

In the 21st century, the health care paradigm has shifted towards a higher level of personalization with tailored therapies for the curation or prevention of specific diseases instead of treating the symptoms (Sverdlow et al., 2018; Yang et al., 2020). This shift is mainly driven by technological and scientific improvements such as artificial intelligence (Meyer-Christian et al., 2021). DTx therapies are specifically optimized for such a paradigm shift towards personalized medical care, as their access to patient data and behaviour allow them to offer an individualized therapy (Chung, 2019; Sverdlow et al., 2018; Yang et al., 2020). The importance of digital technologies in health care was emphasized during the Covid-19 pandemic, as the internet and digital technologies provided continued access to

treatments (Awad et al., 2021; Gunasekeran et al., 2021; Kumar & Pumera, 2021). The switch to digital treatment during the pandemic has also highlighted other perks that digital therapeutics offer such as an increased access to treatment due to the high level of flexibility as well as a decrease in health care costs (Hong et al., 2021; Khirasaria et al., 2020; Steinhubl et al., 2015).

The transition of digital medicine, specifically ingestible sensor components, towards mainstream use in late 2017 (Chung, 2019; Sverdlow et al., 2018; Plowman et al., 2018) has paved the way for other digital health technologies. All digital medicine subsets, including digital therapeutics, benefit from digital medicine moving into the mainstream with technological treatments becoming more accepted and implemented.

2.3 Pharmaceutical Industry and Digital Therapeutics

Interactions between pharmaceutical and digital therapeutics companies along with research highlights several opportunities and threats for the pharmaceutical industry. Pharmaceutical companies can benefit from the significant amount of data collected by DTx as well as the technological innovation (Chung, 2019). Additionally, expanding their business to include digital therapeutics would allow pharmaceutical companies to create additional revenue streams whilst also targeting a broader customer segment. To enter the market a Big Pharma company can either buy an existing DTx start-up, establish their own DTx venture or cooperate with a DTx company in the development of a digital therapeutic for a specific indication. However, when investing into digital therapeutics, pharmaceutical companies run the risk of cannibalizing their own businesses.

Another important opportunity is data collected from digital therapeutics. Chung (2019) highlights the amount of information that can be acquired through data-driven interventions, benefiting development of additional treatments and further improvements of existing therapies. Damiati (2020) additionally underlines that data and technology, specifically artificial intelligence, which is often used in DTx, can be useful in drug development and to increase drug efficacy as well as the speed of innovation.

Furthermore, Awad et al. (2021) point out that digital therapeutics can complement the existing treatments through supporting the medical interventions, while highlighting the need

for a balance between digital tools and human intervention for optimal treatment. Contrarily, Chung (2019), Meyer-Christian et al. (2021), Sverdlow et al. (2018) as well as Yang et al. (2020) argue that digital therapeutics have the potential to replace the existing treatments of pharmacology in part or even completely. Digital therapeutics can offer a higher level of flexibility, increased privacy, consistent intervention quality as well as easier access to treatments than traditional pharmaceutic solutions (Chung, 2019; Sverdlow et al., 2018; Yang et al., 2020). Additionally, Chung (2019) highlights that digital therapeutics can be considered digital transformations of existing therapies and as such they can optimize upon the delivery and efficacy.

The paradigm shift towards a more personalized approach to medicine further fosters digital therapeutics as a treatment. The use of machine learning and artificial intelligence allows digital therapeutics to offer real-time, personalized treatments to patients (Awad et al., 2021; Sverdlow et al., 2018). This personalization poses a threat to traditional drug treatments catering to large customer groups, potentially significantly decreasing demand in the future (Yang et al., 2020). Digital therapeutics can provide novel treatments for previously untreated or undertreated indications, thus moving into potential growth markets for the pharmaceutical industry (Chung, 2019; Sverdlow et al., 2018).

Next to offering a potentially broader treatment catalogue, digital therapeutics can provide a cheaper and less invasive alternative to traditional medicine, which could result in a decrease of several billion dollars in health care expenditure (Khirasaria et al., 2020; Meyer-Christian et al., 2021; Sverdlow et al., 2018).

Overall, digital therapeutics are likely to change the pharmaceutical market, necessitating a modification of existing business models in the industry (Yang et al., 2020).

2.4 Disruption Theory

The theory of disruptive innovation was first formulated by Christensen (1997). His work built and expanded upon the theories of Schumpeter (1942), McKinsey & Foster (1986) and Moore (1991) (see Figure 2). Christensen (1997) theorizes that a potentially disruptive technological innovation often initially underperforms in terms of market performance and targets low-end niche segments. As such, incumbents are more focussed on the high-end,

high-revenue business. Over time, both the incumbent and the new entrant improve upon their products along mainstream performance measures. Continuous improvements of the innovative technology will allow the technology to appeal to mainstream market customers. Nevertheless, the new technology is still inferior to the incumbents' product as the incumbents are also continuing to improve their technology. However, incumbents run the risk of performance overshoots, exceeding performance demands of mainstream customers, by assuming that the product continuously needs to perform better. Market disruption occurs when new technology displaces the mainstream product, although underperforming on mainstream performance dimensions. (Christensen, 1997)

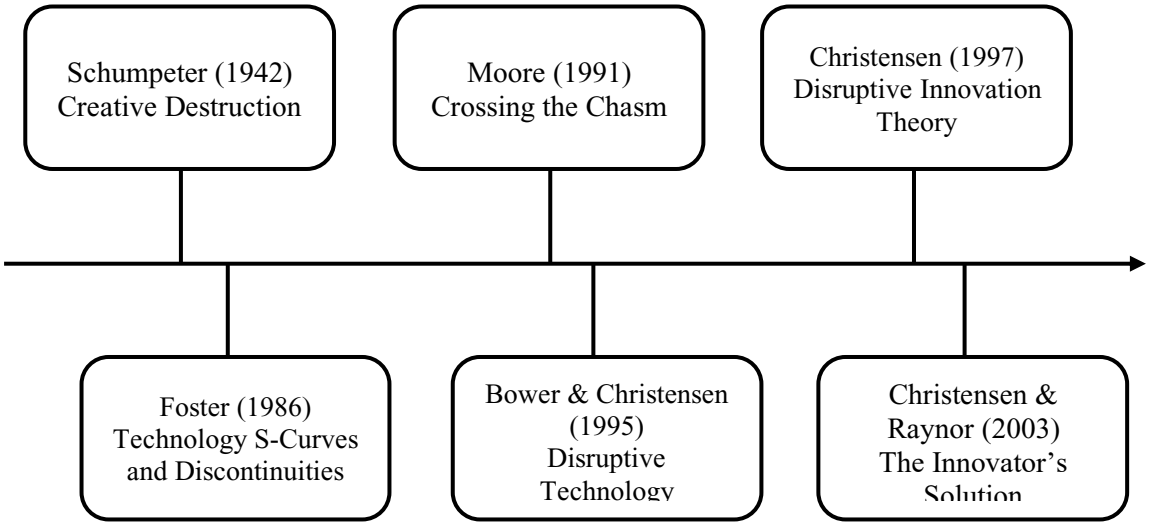

***Figure 2**: Timeline of Evolution of Disruptive Innovation Theory (Yu & Hang, 2010)*

2.4.1 Academic Discussion

The concept of disruptive innovation has been discussed and summarized by academics for many decades. However, all these different academic works have also caused some confusion and obscurity about the definition of the concept of disruption (Yu & Hang, 2010). Some of the main works discussing the scope of disruption include Adner (2002), Bower and Christensen (1995), Christensen and Raynor (2003), Clark (2003), Govindarajan and Kopalle (2006), Markides (1998 and 2005) as well as Paap and Katz (2004), to name a few. Additional works on the subject have shown that disruptive innovation can have a major impact on a market without completely replacing established technology, thus emphasising that disruption does not necessarily signify destruction (Schmidt & Druehl, 2008; Yu & Hang, 2010). Additionally, King and Tucci (2002) point out that not only can incumbents

withstand disruption, but they are in turn also able to become disruptors themselves given a company's transformational experience. Moreover, Markides (2005) highlighted that different innovations, such as business model innovation, are separate phenomena to for example technological innovation and as such concludes that different types of disruptive innovation should be considered as individual phenomena that have a distinctive effect on the market.

2.4.2 Expansion of the Theory

Based on the academic discourse around the topic of disruptive innovation, there has been both critique and expansion of the theory including by Govindarajan and Kopalle (2006), Schmidt and Druehl (2006) as well as Christensen and Raynor (2003) and Christensen et al. (2018). Christensen himself also has continuously improved upon his theory. He introduced the idea of two types of disruption, low-end and new-market disruptive innovation (Christensen & Raynor, 2003). With low-end disruptions, the targeted market segment produces the lowest profit and simultaneously the customers are the most over-served in the mainstream value network along mainstream value dimensions (Christensen & Raynor, 2003). New-market disruptions create an entirely new set of customer values and thus a separate market in which the new entrants must compete against non-consumption instead of incumbents (Christensen & Raynor, 2003).

Govindarajan and Kopalle (2006) introduced a new innovation measure that includes not only low-end but also high-end disruptions. This new measurement allows a broader view of disruptive innovation and expands upon Christensen's (1997) original theory of disruption in the low price and low performance spectrum of the market (Govindarajan & Kopalle, 2006). They determine that a disruptive innovation should meet four characteristics. Firstly, in terms of product attributes that are highly valued by the mainstream customer, the disruptive innovation should score lower than the established technology (Govindarajan & Kopalle, 2006). Secondly, the disruptive innovation should either target the more price sensitive segment of the mainstream market or create a new value proposition for a new customer segment (Govindarajan & Kopalle, 2006). Thirdly, the new technology should be sold at a lower price point than the mainstream product and lastly, it should enter the mainstream market from a niche (Govindarajan & Kopalle, 2006).

Schmidt and Druehl (2008) expanded the theory even further by differentiating between high-end and low-end disruption and breaking down low-end disruption further into three categories. To avoid ambiguities associated with the term disruption, they use encroachment to explain the process of a new product taking over a part of the sales volume in the market (Schmidt & Druehl, 2008). The first type of encroachment is high-end encroachment, in which the new product displaces the old product from the high-end of the market, it can be considered sustaining innovation (Schmidt & Druehl, 2008). The other three types of encroachment all move from the low end of the market upwards. Here, they differentiate between immediate low-end encroachment, fringe-market low-end encroachment and detached-market encroachment (Schmidt & Druehl, 2008). Immediate low-end encroachment means that the new product enters the existing market as a low-end disruptive innovation (Schmidt & Druehl, 2008). The fringe-market low-end encroachment indicates that the new technology has opened a new market in which the customer needs slightly differentiate from the low-end customer needs of the main market before the diffusion of the main market starts (Schmidt & Druehl, 2008). As detached-market low-end encroachment, Schmidt and Druehl (2008) identified the phenomenon in which the new technology opens a detached market where target customer needs are completely different from those in the main market before the encroachment starts. This extension aligns with disruption theory by Christiansen (1997) and its additions from Christensen et al. (2000, as cited in Schmidt & Druehl, 2008) further distinguishing different types of low-end disruption.

2.5 Technology Acceptance Theory

Research with the goal of explaining the acceptance and subsequent usage of new technologies has become more important in the past decades and can be considered one of the main research focuses within information systems (Rondan-Cataluña et al., 2015). Over the years, three main technology acceptance theories and models have been developed. The theory of reasoned action (TRA), the technology acceptance model (TAM) and the unified theory of acceptance and use of technology (UTAUT) can be considered some of the most popular (Rondan-Cataluña et al., 2015).

The theory of reasoned action, first introduced by Fishbein and Ajzen in 1975, studies the conscious behaviour of consumers. The authors hypothesise that specific behaviours of persons are predetermined based on their behavioural intension (BI), thus their intention to

execute said behaviour (Fishbein & Ajzen, 1975). A person's BI is additionally influenced by their attitude (A) and the subjective norms (SN) in relation to the action (see Figure 3) (Fishbein & Ajzen, 1975). TRA can be considered a general model, which means that it is not intended for a specific behaviour or technology allowing for an application of the model in many research areas (Fishbein & Ajzen, 1975).

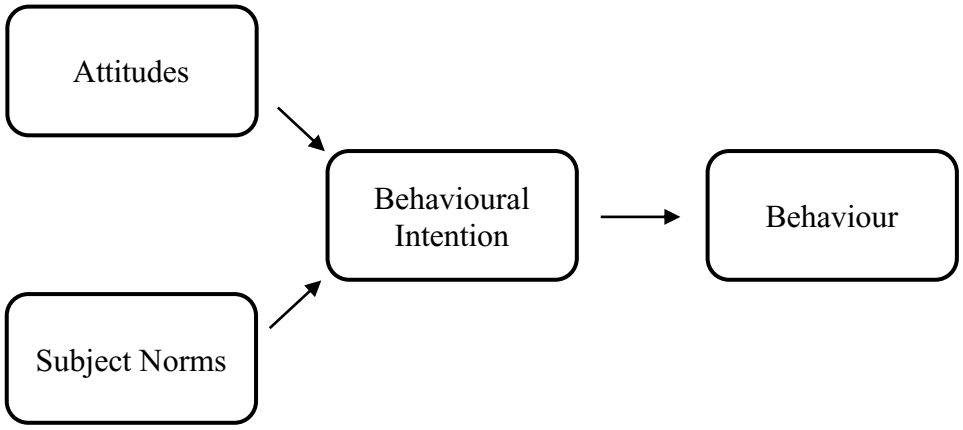

***Figure 3**:Theory of Reasoned Action (Fishbein & Ajzen, 1975)*

2.5.1 Technology Acceptance Model

The technology acceptance model (Davis, 1986) is derived from TRA and tailored to model the technology acceptance of information systems with the goal to provide a general explanation on the elements of computer acceptance. The model aims to identify variables that are determinants of computer acceptance (Davis, 1986). The two main influences on computer acceptance are perceived usefulness (PU) and perceived ease of use (PEOU). TAM has been established as a solid model to predict user acceptance. (Rondan-Cataluña et al., 2015)

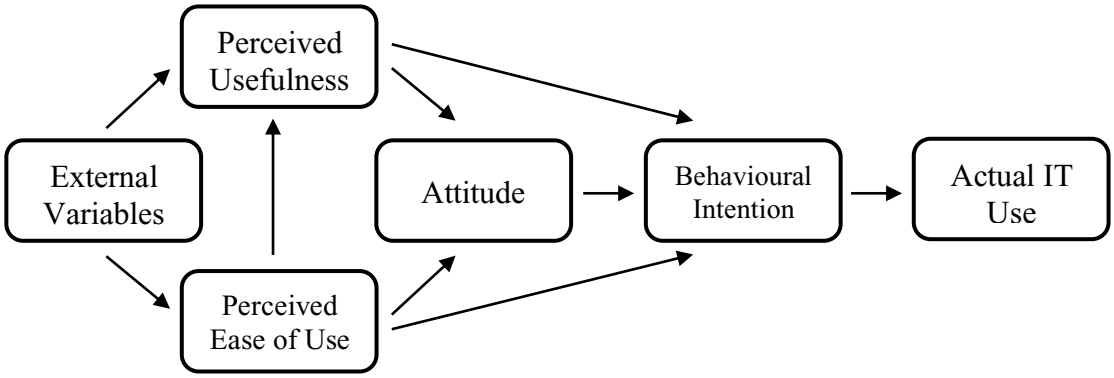

***Figure 4**: Technology Acceptance Model (Davis, 1986)*

Venkatesh and Davis (2000) expanded the original technology acceptance model, by including more precursors of PU. To improve upon the original model, TAM2 includes further theoretical constructs such as social influence process and cognitive instrumental processes (Venkatesh & Davis, 2000). Venkatesh and Bala (2008) further expanded the original technology acceptance model by adding the influences that precede PEOU, which were already determined by Venkatesh and Davis (1996) and Venkatesh (2000). In contrast to TAM2, which mainly focused on the influences on PU, TAM3 concentrates on PEOU. All versions of the model have been widely used for a multitude of technologies over the past decades (Rondan-Cataluña et al., 2015).

2.5.2 Unified Theory of Acceptance and Use of Technology

After a review and synthesis of the most popular models, Venkatesh et al. (2003) created the unified theory of acceptance and use of technology. The UTAUT incorporates elements of the most used models (eg. TAM, TRA) and its relevance is empirically validated (Venkatesh et al., 2003). UTAUT includes key moderating factors without losing the core structure (Rondan-Cataluña et al., 2015). The unified theory of acceptance and use of technology posits four influences on the acceptance and usage of new technology. Performance expectancy, effort expectancy, social influence as well as facilitating conditions have been found to have a direct influence on behavioural intention (Venkatesh et al., 2003). The theory has served as a model to study a multitude of technologies in both organizational and non-organizational settings (Rondan-Cataluña et al., 2015). As UTAUT reflects the internal view of the company, Venkatesh et al. (2012) expanded the model by adding three new determinants of BI: hedonic motivation, price value, and habit. The new model, UTAUT2, is aimed at consumer technologies (Rondan-Cataluña et al., 2015; Venkatesh et al., 2012).

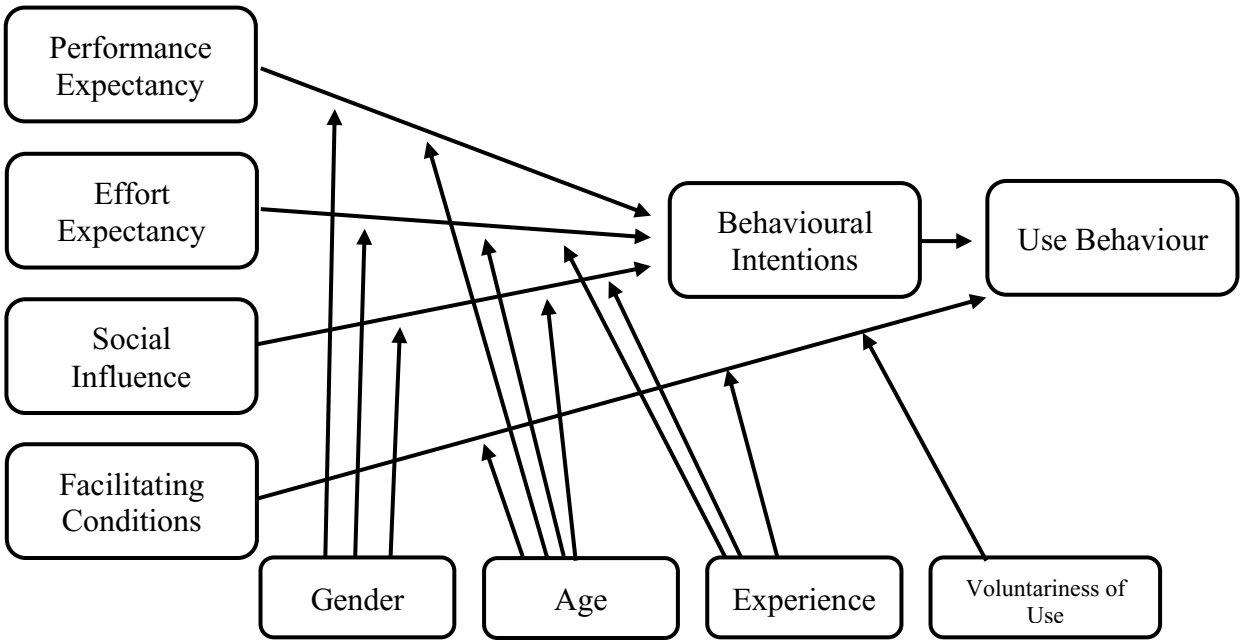

***Figure 5**: Unified Theory of Acceptance and Use of Technology (Venkatesh et al., 2003)*

3 Methodology

A mixed methods approach of non-standardized, semi-structured interviews in combination with a survey has been used in this dissertation. This methodology permits the collection of comprehensive data as well as a methodical study and comprehension of the complex relationship of digital therapeutics and the pharmaceutical industry. The approach has been confirmed by literature to be an appropriate method for a multi-facetted analysis (Molina-Azorin et al., 2017).

Secondary research has been conducted to establish a baseline knowledge of both industries as well as the relevant theoretical frameworks. Several databases have been consulted to collect current and historical journal articles which then have been processed and appropriately interpreted. The main search words used were ‘digital therapeutics’, ‘pharmaceuticals’, ‘digital health’, ‘disruption’, ‘innovation’ and several combinations thereof with the goal to determine the main stakeholders and processes together with the updated status of theoretical literature.

As part of the qualitative research, non-standardized, semi-structured interviews with experts in the field have been conducted. This approach endorsed an open dialogue between both parties to freely explore the topic whilst gathering specific data and insights. However, the interview quality suffers due to the subjective biases of the interviewees. Many insights on the interactions between pharmaceutical and digital therapeutics companies can be collected through this more flexible interview method, whilst maintaining a certain level of control and offering guidance to receive the desired information. (Walle, 2015)

In total 12 interviews were conducted lasting between 19:09 and 51:58 minutes. It is important to note that the interviewees voluntarily participated; however, wanted to stay anonymous. The collected data is subjective to the interviewee, their answers depict their personal opinions and are unrelated to their employers. The interview participants are all experts in the field of digital health, with a majority having a background in digital therapeutics (see Table 2). The interviews were systematically analysed using a coding tree that accentuated each participant’s opinions and underlined emerging trends of common viewpoints among several interviewees.

ID	Position	Company	Background
Interview Partner (IP) 1	Senior Director	Danforth Advisors	Extensive background in life sciences consulting and digital therapeutics
Interview Partner 2	Executive Director	Pear Therapeutics	Extensive experience in both pharmaceutical and DTx industry
Interview Partner 3	Manager	CVS Health	Experience in digital health and digital therapeutics
Interview Partner 4	C-Suite	Click Therapeutics	Extensive experience in innovative health care, neurobiology, and digital therapeutics
Interview Partner 5	Vice President	Click Therapeutics	Background in clinical operations and trial design
Interview Partner 6	Director	Click Therapeutics	Experience in cognitive neuroscience and digital therapeutics
Interview Partner 7	M.Sc. Public Health		Background in German public health policies and regulations and market access strategies
Interview Partner 8	Senior Leadership	Better Therapeutics	Digital Therapeutics, Quality Assurance in Life Sciences
Interview Partner 9	Ph.D. Candidate	British University	Research concerning human-algorithm interaction in health care
Interview Partner 10	Growth Project Strategist	Novartis Portugal	Background in Marketing and Pharmaceuticals
Interview Partner 11	Senior Leadership	Novartis	Extensive background in portfolio management with several pharmaceutical companies and pharmaceutical sciences
Interview Partner 12	Vice President	Digital Therapeutics Alliance	Extensive background in digital therapeutics and pharmaceuticals, trained pharmacist

***Table 2**: Interview Partners (own illustration)*

Quantitative research has been conducted in addition to the interviews to identify the technology acceptance of consumers for digital therapeutics. The survey was created based on the theoretical literature as well as the insights on digital therapeutics' challenges facing acceptance gathered during the expert interviews. The survey had 246 responses, of which 220 were completed, qualified answers. The study was actively collecting responses between the 29th of April and 17th of May 2022 in both English and German to gather a more diverse sample. The performance and effort expectancy as well as performance measurement preferences of consumers were determined to evaluate the behavioural intent of digital therapeutics usage. The collected data was statistically analysed using SPSS version 28.

4 Data Analysis

The findings from the mixed-methods research approach will be analysed and interpreted in this section of the thesis. Understanding the disruption potential of digital therapeutics requires a thorough insight into the market dynamics and impact on the pharmaceutical industry. Consequently, the external interviews were analysed and categorized by answers in the table below (Table 3).

4.1 Qualitative Analysis

The interviews provide insights into how digital therapeutics are perceived as a treatment method from the perspectives of several professionals in the industry. The interview partners have been asked one question about their background and 12 questions about the market (Appendix 1). The interviews have been conducted following a semi-structured approach. The order of questioning varied following the natural flow of the conversation. No sensible data was shared; therefore, answers were occasionally discussed in hypothetical scenarios. Most of the findings are summarized in the table below; however, additional insights, comments and explanations will be shared and discussed throughout the chapter. Based on the collected expertise in the interviews, the following prepositions are going to be examined:

P1: Digital therapeutics offer a new value proposition or target the price sensitive customer segment

P2: Digital therapeutics are underperforming the performance requirements of the mainstream market

P3: Digital therapeutics will be offered at a reduced price compared to medications

Category	Code	IP1	IP2	IP3	IP4	IP5	IP6	IP7	IP8	IP9	IP10	IP11	IP12
Efficacy	DTx need to have a better efficcacy than drugs											✓	
	DTx should have the same efficacy than drugs		✓	✓	✓	✓	✓		✓			✓	✓
	More research into efficacy needs to be done						✓						
Treatment	DTx as a monotherapy					✓	✓		✓			✓	✓
	DTx as co-therapy (part of a larger treatment plan)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	DTx as combination therapy (DTx & drug only approved in combination)		✓	✓			✓		✓	✓	✓	✓	
	DTx complement the drug treatment	✓			✓	✓	✓	✓		✓	✓	✓	✓
	DTx can substitute a drug		✓		✓						✓		
Performance Measures	Meeting industry gold standard		✓	✓	✓	✓					✓	✓	✓
	Adding new value propositions	✓	✓	✓	✓	✓	✓		✓	✓	✓		
	Failing to meet certain performance measures			✓		✓	✓		✓			✓	✓
	DTx offer a more favourable side effect profile	✓			✓		✓			✓		✓	
Pricing	DTx can be offered lower prices due to scaling and lower production costs		✓	✓	✓	✓	✓	✓	✓		✓	✓	✓
	The costs for the consumer are most likely very similar for both treatment options		✓	✓	✓			✓					
	DTx could be marketed similar to specialized drugs						✓						
Target Customer Groups	DTx target the same customer groups as pharmaceuticals		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	DTx target only the low-end of the pharmaceuticals market												
	DTx target only a niche segment of the pharmaceuticals market						✓						
	DTx can target additional/ new target groups			✓	✓	✓	✓		✓				
Market Division	DTx are a part of pharmaceuticals market		✓	✓	✓	✓	✓			✓	✓	✓	✓
	DTx are a niche in the pharmaceuticals market	✓	✓	✓	✓	✓	✓		✓	✓			
	DTx are expanding the pharmaceuticals market	✓					✓						
	DTx are a seperate market						✓	✓	✓				
Business Model Impact	DTx challenge the traditional pharmaceuticals business model				✓		✓		✓	✓	✓	✓	
	DTx pose no threat to the traditional pharmaceuticals business model	✓	✓	✓		✓		✓					✓
	Pharmaceutical companies could compete with own DTx capabilities			✓				✓	✓	✓	✓	✓	✓
	Pharmaceutical companies might have difficulty competing in DTx against specialized DTx comapnies			✓	✓		✓		✓		✓		
	DTx industry will likely adopt a similiar dynamic to pharmaceuticals					✓							
Future Direction	Collaboration between DTx and pharmaceutical companies	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓
	Competition between DTx and pharmaceutical companies			✓							✓	✓	✓
	Moving with current trends toward digitalization of treatments	✓	✓					✓			✓	✓	✓

Table 3: *Qualitative Content Analysis Results (own illustration)*

The interview partners have been divided into subgroups to evaluate the influence of the respective professional disciplines on the perception of the disruption potential of digital therapeutics. The first group of interviewees is currently employed at a digital therapeutics company, here IP2, IP4, IP5, IP6, IP8. Whilst they can provide the biggest insights into the mechanisms of digital therapeutics, they are likely to have a positive bias concerning digital therapeutics. The second group contains interview partners currently employed at a pharmaceutical company, IP10 and IP11. Here, a negative bias towards digital therapeutics is likely. The third group consists of IP1 and IP3, who are both currently employees of companies with a life sciences or health care focus. The fourth group can be described as regulatory, both partners have a background in the regulatory field (IP7 and IP12). Lastly, IP9 has a background in academia, researching the field of health care and the added benefit artificial intelligence can provide to the industry.

Group 1: Digital Therapeutics	IP2, IP4, IP5, IP6, IP8
Group 2: Pharmaceutical	IP10, IP11
Group 3: Life Science	IP1, IP3
Group 4: Regulatory	IP7, IP12
Group 5: Academia	IP9

Table 4: *Interview Partner Groups based on Professional Background (own illustration)*

4.1.1 Efficacy and Treatment

As mentioned during the literature review, prescription digital therapeutics need to proof their efficacy and safety during clinical trials to gain approval by the regulatory authorities. Thus, all digital therapeutics on the market should have an adequate level of efficacy. All interview partners highlighted, that the efficacy is dependent on each individual digital therapeutic and its mechanism of treatment.

Interview partners 2, 3, 4, 5, 6, 8, 11, and 12 mentioned that digital therapeutics should at least have the same or similar efficacy to traditional drugs to be competitive in the market. IP6 pointed out the necessity for more clinical validation of digital therapeutics, highlighting that specifically real-world evidence outside of clinical trials is needed. IP11 mentioned the criticality of reaching at least the same efficacy as drugs, stating that it would be more beneficial to have a higher efficacy to compete against established treatments in the market. Four interview partners, IP1, IP7, IP9, and IP10, did not feel comfortable positioning themselves with mention that efficacy is varying with each DTx. It is important to notice that all interview partners mentioned that the efficacy of a digital therapeutic, as with a medication, is dependent on the individual patient. Overall, based on the regulatory environment and the interviews, it is likely that DTx will fulfil the mainstream market performance requirements regarding efficacy.

In terms of treatment, 11 out of the 12 interviewees agreed that digital therapeutics can be used in co-therapy, using a DTx as part of a larger treatment plan. 9 partners viewed digital therapeutics as a complement to a traditional drug treatment, highlighting that it could improve the overall treatment for the patient. Interview partners 2, 3, 6, 8, 9, 10, and 11 mentioned that DTx could also be approved as part of a combination treatment in which the DTx had a significant effect on the adherence of the combined drug. Interestingly, none of the partners from group 4 saw this as a likely application. IP5, IP6, IP8, IP11 as well as IP12 mentioned that in certain cases DTx could be used as monotherapy. IP2, IP4, and IP10 stated that a digital therapeutic could substitute a drug during the treatment. Several interview partners (2, 4, 5, 6, 7, 8) highlighted that the replaceability of a drug by a digital therapeutic is highly dependent on the severity and stage of the disorder. All interview partners pointed out that the course of treatment should be aligned with industry best practice as well as being tailored to best serve the individual patient's needs. Thus, the replaceability of drugs is more

dependent on the individual patient than the product performance as each patient reacts differently to each treatment option.

4.1.2 Performance Measures and Pricing

Next to the efficacy of the treatment, there are other performance measures that are important to customers in the pharmaceutical market. Meeting the industry gold standard was mentioned 7 times when talking about the existing performance measures. These gold standards include the efficacy and safety of the treatment for the patient. In addition to meeting industry best practices, 9 interview partners mentioned that digital therapeutics can offer new value propositions compared to traditional drugs. Some of the new value propositions cited were the increased availability and easier access based on the treatment being a software. The more favourable side effect profile of digital therapeutics was the most cited value proposition. However, 6 partners (3, 5, 6, 8, 11, 12) stated that DTx are underperforming in other key performance measures such as treatment length and effort needed by the patient (taking a pill versus engaging with an app). IP9 added that from a physician's point of view the technology needs to be easily integrated in existing technological infrastructures. In case DTx are perceived to require more effort, there might be a reluctance to prescribe DTx.

Proposition 1, which assumes that digital therapeutics offer a new value proposition, cannot be rejected based on the insights gained from the interview. The majority of interview partners was in agreement that digital therapeutics offer a new value proposition compared to pharmaceuticals. The digital nature of the treatment allows DTx to compete with additional value propositions and offer new performances measures to the customers.

Additional assumptions about the market performance of DTx were made in P2. It was hypothesized that digital therapeutics are underperforming mainstream market performance measures. A small majority (6 out of 11 experts, one did not want to answer) stated that DTx are underperforming in certain performance measures in the market. Consequently, it can be said that P2 cannot be rejected.

Another key performance measure is the price of the treatment for the customer. 10 out of the 12 interviewees agreed that digital therapeutics can be offered at a lower price, mainly due to scaling and lower production costs. IP2, IP3, IP4, and IP7 added that the costs for insured

patients will likely be very similar for both the digital and the traditional treatment. IP6 pointed out that alternatively to competing with name brand drugs, DTx could also be marketed similar to a specialized drug. Both IP4 and IP12 highlighted the need for value-based pricing, evaluating the product on the value that is created through its usage.

The third proposition P3 assumed that digital therapeutics could be offered at a lower price than traditional pharmaceutical products. The large majority of interviewees was in agreement that digital therapeutics will most likely be offered at a lower price point than pharmaceuticals. Consequently, it is possible to say that P3 cannot be rejected.

4.1.3 Target Customer Groups

The target customers of digital therapeutics companies are the same groups of patients targeted by pharmaceutical companies. The majority of the interview partners agreed on this, citing that they all target patients with mental illnesses. IP1 chose not to position themselves. Additionally, it was mentioned that due to the prescriptive nature of both drugs and DTx, another major customer group are the payors and insurance companies. Several interview partners mentioned that the focus of prescriptive DTx is B2B, thus targeting other companies, in this case insurances. Five interview partners added that digital therapeutics can target more customer segments. Mentioned examples of such additional patient groups are people who experience adverse events with certain drugs or people that prefer not to take biological or chemical ingredients.

Subsequently, digital therapeutics will not only target the low-end of the customer segment. The second part of P1 needs to be rejected. However, this does not influence the disruptive potential of DTx.

4.1.4 Market Division

In terms of market division, most interviewees perceive digital therapeutics to be a part of the pharmaceutical market (IPs 2, 3, 4, 5, 6, 9, 10, 11, 12). IP5 explained their answer by outlining that both company groups target the same disease areas by providing treatments to mental health disorders. Eight of the interview partners (IPs 1, 2, 3, 4, 5, 6, 8, 9) described DTx as a niche of the larger pharmaceutical market, mainly based on the size of existing companies and investments made into research and development. In addition, IP1 and IP6 pointed out that DTx are expanding the market by adding new potential customers and

providing more treatment options. IP3 and IP6 compared the market between pharmaceuticals and DTx to a Venn diagram with a large overlap in market but still some separation. IP8 shared a similar view but described more separation between the two. IP7 and IP9 defined them as a separate market based on the mechanism of treatment. Therefore, digital therapeutics can be either seen as part of the large pharmaceutical market or a fringe market with a significant amount of overlap in regulatory frameworks, competition, and customers.

4.1.5 Business Model Impact

The impact on the pharmaceutical business model was the most divisive topic between interview partners. 50% of the interviewees perceive digital therapeutics capable of challenging the pharmaceutical business model and consequently have a lasting impact. Contrarily, the other 50% do not see DTx posing a threat to the traditional pharmaceutical model. It is interesting to note that whilst in all other group members are in agreement on the impact, the digital therapeutics group is split. IP2 and IP5 do not perceive DTx as a threat to the pharmaceutical model. In contrast, IP4, IP6, and IP8 propose that DTx can challenge the model. IP8 argues this position by pointing out that "medications treat symptoms, digital therapeutics treat the problem", indicating that DTx companies could reduce the potential patient pool for pharmaceutical companies. Remarkably, both members of the pharmaceutical group also perceive DTx as a threat to the traditional business model in the industry. This could indicate that the pharmaceutical industry has picked up on the developments and risk of disruption. IP3 argued that although DTx pose a threat to pharmaceutical companies, a significant replacement of drugs is highly unlikely as not everything can be treated using DTx.

Seven of the interview partners theorised that pharmaceutical companies would be able to compete with specialized digital therapeutics firms in the DTx space through the development of DTx capabilities. It was pointed out that such capabilities could be bought through M&A activities, developed in-house, or through the co-development of specific DTx with specialized firms. The last option is currently the most used one and was pointed out by several interview partners. However, IP8 pointed out that an in-house DTx unit would likely need to operate separately of the main business to accommodate the agile nature of a technology-based company. Five partners disagreed, stating the companies would have difficulty competing against specialized DTx companies, citing the hierarchical nature with

high levels of bureaucracy as a reason. IP6 additionally pointed out that Big Pharma might have difficulty acquiring the necessary talent, stating that they would compete with Amazon, Google, and other large technology companies for software engineers and other talent. The pharmaceutical companies' ability to mitigate the risk of disruption will be based on how well they are able to either build up capabilities to compete in DTx or the collaborative efforts between members of both industries.

4.1.6 Future Direction

The last area of interest was the future direction of the market and the future relationship between DTx and pharmaceuticals. Collaborative efforts and cooperation were mentioned 11 times. Interestingly, all members of groups 2 and 4 stated that there could be a competition between DTx and pharmaceuticals. Group 2 saw both as possible outcomes. IP11 clarified that if DTx threatens the core competencies of pharmaceutical companies by offering the same or better performance, then the market will be more competitive. Contrarily, IP12 stated that the aim should be healthy competition that ultimately benefits the patient by providing the best possible care. This point of view was supported by IP8 who highlighted the necessity of a patient-centric view in which the patient's well-being should be the main goal.

In addition, IP3, IP9, and IP11 pointed out that one challenge to digital therapeutics and their acceptance are the people. They highlighted that there needs to be a shift in the prescribers' perception of digital therapeutics to accommodate an implementation, pointing out the existing bias and comfort of prescribing what is known.

Consequently, the rivalry in the market will be dependent on several factors. The attitudes of companies on both sides and the perceived threat of the other will ultimately influence the market dynamics. The perceived threat of DTx will be connected to its ability to displace drugs in certain areas of the treatment as well as the extent to which DTx can replicate pharmaceutical's core competencies.

4.2 Quantitative Analysis

The survey aimed to determine the current technology acceptance of digital therapeutics, after it was highlighted as one of the key obstacles of digital therapeutics' implementation during the interviews. The study followed the design of the unified theory of acceptance and

use of technology by Davis (1986) with the goal of determining the current behavioural intention of using digital therapeutics to treat a mental health disorder. The objective of the survey is to answer the following hypotheses:

H1: UTAUT is an adequate model to predict behavioural intent of using digital therapeutics

H2: Younger generations (Gen Z and Millennials) will have a higher technology acceptance of DTx

4.2.1 Validity and Reliability

A total of 246 people participated in the study; however, only 220 answers were complete and qualified for the analysis. There was no limitation set on who could participate as the whole population qualifies for the usage of digital therapeutics. The survey answers were collected anonymously as mental health care is a personal topic and it was suspected that participants would answer more honestly under these conditions. The survey consisted of 19 questions that aimed at determining the performance expectancy, effort expectancy, and social influence of digital therapeutics. The main question types used in this survey were a mix of matrix and multiple choice questions. In addition, people were given a definition of digital therapeutics and a hypothetical scenario to assure that all people have the same basis when answering the questions.

Response bias is a considerable risk of survey design. To mitigate this, several questions with different wording were used to collect the same information. Additionally, to avoid central tendency, it was decided to use Likert scales ranging from one to four and one to five, depending on the category.

The participants were selected randomly to reduce sampling bias. The survey was distributed via a range of media platforms, such as WhatsApp, Facebook, Instagram, and LinkedIn as well as SurveyCircle. To increase the reach of the survey and to achieve more diversity in answers, the survey was distributed in both English and German. The study's questions can be found in Appendix 2 and 3. The findings of the study will be analysed in the following chapter.

4.2.2 Demographic Data

The demographic data of the survey are as follows. Out of the 246 people that started the survey, only 220 completed it. Out of these randomly selected participants, 58.9% were female. Around 53.2% were under the age of 30, with the majority of participants (60.3%) having a bachelor's degree or higher. 29.4% of the participants stated that they are students, 10.3% are working part time, 44.4% are full-time employees, 7% are unemployed, and 8.9% are retired.

4.2.3 Performance Expectancy

The performance expectancy was measured with a Likert scale question in the matrix format ranging from 'Not at all important' to 'Extremely important'. The given key performance indicators were based on the findings during the literature review and interviews. Efficacy, availability, price, treatment length, flexibility, accessibility, personalization, and side effects were rated by participants. The majority of participants (48.6%) consider efficacy very important when making a treatment decision. Availability was stated as moderately important by 43% and very important by 43.9% in the decision process. 35.5% of the participants perceived price as slightly important, followed by 32.2% moderately important and 18.7% important in treatment decisions. The length of the treatment was rated slightly important by 24.8%, moderately important by 37.4% and very important by 26.6%. Flexibility was very important for most of the participants (45.3%) when deciding on a treatment. The bulk of participants (45.3%) classified accessibility as very important. 32.7% of the participants indicated that personalisation is very important to them when making a treatment decision. Lastly, most of the participants (40.7%) stated that side effects are a very important factor when making a decision between treatment options. A more detailed breakdown of the distributions can be found in Table 5 below. In the performance measures that are most important to the patients (efficacy, flexibility, accessibility, and side effects) DTx are able to either meet or outperform the performance expectancy.

Performance Measure	Importance	Count	Percentage
Efficacy	Not at all important	3	1.4%
	Slightly important	6	2.8%
	Moderately important	31	14.5%
	Very important	104	48.6%
	Extremely important	70	32.7%
Availability	Not at all important	3	1.4%
	Slightly important	6	2.8%
	Moderately important	92	43.0%
	Very important	94	43.9%
	Extremely important	19	8.9%
Price	Not at all important	18	8.4%
	Slightly important	76	35.5%
	Moderately important	69	32.2%
	Very important	40	18.7%
	Extremely important	11	5.1%
Treatment Length	Not at all important	16	7.5%
	Slightly important	53	24.8%
	Moderately important	80	37.4%
	Very important	57	26.6%
	Extremely important	8	3.7%
Flexibility	Not at all important	5	2.3%
	Slightly important	19	8.9%
	Moderately important	74	34.6%
	Very important	97	45.3%
	Extremely important	19	8.9%
Accessibility	Not at all important	5	2.3%
	Slightly important	4	1.9%
	Moderately important	90	42.1%
	Very important	97	45.3%
	Extremely important	18	8.4%
Personalisation	Not at all important	4	1.9%
	Slightly important	38	17.8%
	Moderately important	57	26.6%
	Very important	70	32.7%
	Extremely important	45	21.0%
Side effects	Not at all important	2	0.9%
	Slightly important	20	9.3%
	Moderately important	44	20.6%
	Very important	87	40.7%
	Extremely important	61	28.5%

Table 5: *Performance Expectancy Distribution (SPSS output)*

4.2.4 Effort Expectancy

To measure the effort expectancy, the survey asked questions aiming at the effort to gain access to and learning the usage of digital therapeutics. The questions had a 4-step Likert scale format ranging from ‘Strongly agree’ to ‘strongly disagree’. Of the participants, 58.9% answered somewhat agree to finding it easy to gain access to a DTx while 28% chose somewhat disagree. The majority of the participants either somewhat or strongly agreed to

perceiving the usage of a DTx as easy to learn, 50.9% and 18.2% respectively. Thus, the effort expectancy of a digital therapeutics is perceived as rather low.

4.2.5 Social Influence

Social influence was measured based on two major influences in therapeutic decisions: friends and family, and the attending doctor. Again, a 4-step Likert scale was used to rate the influence level, ranging from 'A lot' to 'Not at all'. The attending physician was perceived to have a lot of influence by 50.9% of the participants, followed by a moderate influence (36.9%), a little influence (7.9%), and no influence at all (0.5%). Participants stating that a family member or a friend would have a moderate influence on the decision were 48.6%. These results were followed by 36% stating a high influence, 13.1% a little influence, and 2.3% no influence at all. These results highlight that generally the social perception of a treatment option can have a significant impact on the decision. Specifically, prescribers can influence a decision as patients generally trust their doctor's decisions. Physicians have also been identified as a key group to drive the acceptance of DTx during the interviews. This data additionally highlights the need for DTx to convince doctors of their advantages in order to become a viable alternative treatment option in the future.

4.2.6 Behavioural Intention

The behavioural intention, the intent of using a digital therapeutic, was tested by using a hypothetical scenario. The participants were asked to assume that both an available drug and an available digital therapeutic had a comparable efficacy and would yield similar results in treating their disease. Based on those assumptions they should state which treatment option they felt comfortable using. Answer possibilities were 'A medication', 'A digital therapeutic', 'Both', and 'Neither'. Most of the participants would feel comfortable using a digital therapeutic as a treatment option with 35% choosing only a DTx and 50% choosing both treatment options. Only a minority (12.6%) stated that they would only feel comfortable using a medication, and 2.3% did not feel comfortable with either option. See Figure 6 for a graphical representation of the results. These results display that there is a general intention of DTx usage in the surveyed population. Consequently, digital therapeutics could be expected to generate a comparably high level of technology acceptance.

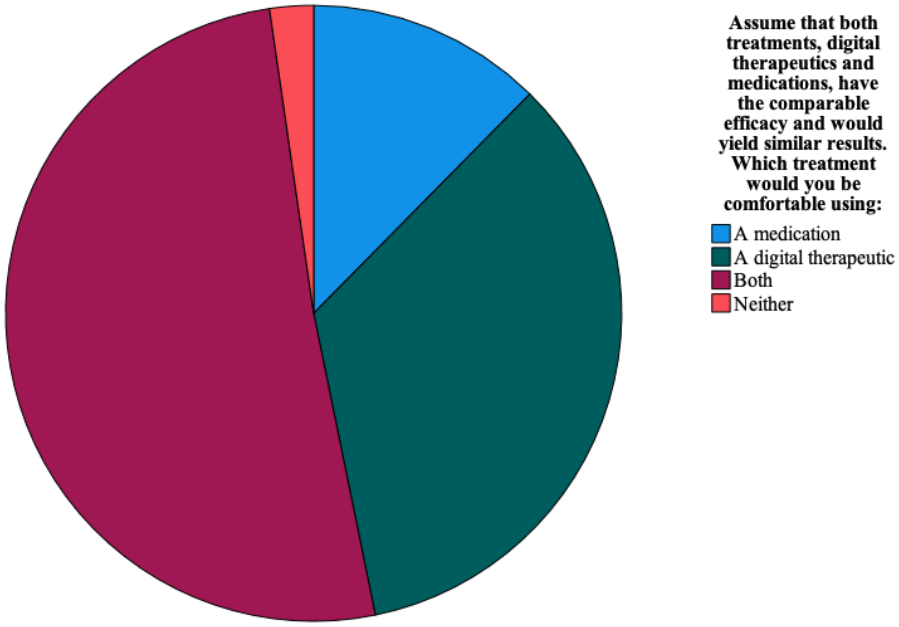

Figure 6: *Distribution of Behavioural Intention (SPSS output)*

4.2.7 Unified Theory of Acceptance and Use of Technology

As outlined in the literature review, the unified theory of acceptance and use of technology (Davis, 1986) has been established as a model to determine the technology acceptance of a new technology. The UTAUT model considers several moderating factors such as performance and effort expectancy, social influence as well as demographic determinants such as age, gender, and experience. In lieu of experience, this survey uses education and employment status.

First, a multinominal logistic regression analysis was used to determine whether UTAUT was an adequate model to determine the technology acceptance of DTx. The model fit test (see Figure 7) revealed a significance of <0.001, indicating that the null hypothesis can be rejected. Thus, UTAUT is a better fit than the baseline model of no independent variables to explain any variance in behavioural intention.

Model Fitting Information

Model	Model Fitting Criteria -2 Log Likelihood	Likelihood Ratio Tests Chi-Square	df	Sig.
Intercept Only	454.960			
Final	125.988	328.972	183	<.001

Figure 7: *Model Fit Test Results (SPSS output)*

Additionally, the goodness of fit test determined a significance of 1.000 for the UTAUT model (Figure 8). Thus, the null hypothesis can be accepted, the developed UTAUT model is a good fit to determine the technology acceptance.

Goodness-of-Fit			
	Chi-Square	df	Sig.
Pearson	129.104	450	1.000
Deviance	125.988	450	1.000

***Figure 8**: Goodness-of-Fit Test Results (SPSS output)*

Lastly, the pseudo R-squared values were evaluated to determine how much of the variance of BI can be explained by the model (Figure 9). The Cox and Snell value proposes that the model can explain 78.5% of the variance of BI whereas the Nagelkerke value suggests that 89.1% of the variance of BI can be explained by this version of the UTAUT model.

Pseudo R-Square	
Cox and Snell	.785
Nagelkerke	.891
McFadden	.723

***Figure 9**: Pseudo R-Squared Results (SPSS output)*

Based on the analysis, it is possible to determine that H1 (UTAUT is an adequate model to determine the technology acceptance of DTx) cannot be rejected. This means that UTAUT is a fitting model to explain almost all of the variance of the behavioural intention of using digital therapeutics.

The likelihood ratio test revealed that not all independent variables have a high significance in the model. All of the performance measures, except side effects, as well as age have a significant impact. However, the parameter estimates show that individually none of the variable parameter have a significance. Consequently, it was assumed that the variables are only significant in combination with each other. For the full results of the likelihood ratio test, please look at Appendix 4.

For the second hypothesis, it was assumed that younger generations, mainly Millennials and Gen Z, will have a higher BI than older generations. This assumes that those generations are

usually more comfortable using digital products, as they can be described as digital natives. Additionally, these generations were pointed out as possible early adopters of digital therapeutics during the interviews and consequently highlighted as a key target group.

The highest behavioural intention was observed in the age group of 58 to 75, with a total of 94.7% of people feeling comfortable either using a digital therapeutic or both a DTx and a medication. The second highest acceptance was recorded in the 31 to 40 age group with 88.9%, followed by the 18- to 24-year-olds with 88.2%, the 25- to 30-year-olds with 79.3% and 41- to 57-year-olds with 78.8%. Outliers were the under 18 and over 75 age groups with 100% and 75% acceptance respectively. These numbers are due to the low number of participants in these age groups. For a graphical representation on the data, please see Figure 10 and the results of the cross tables can be found in Appendix 5.

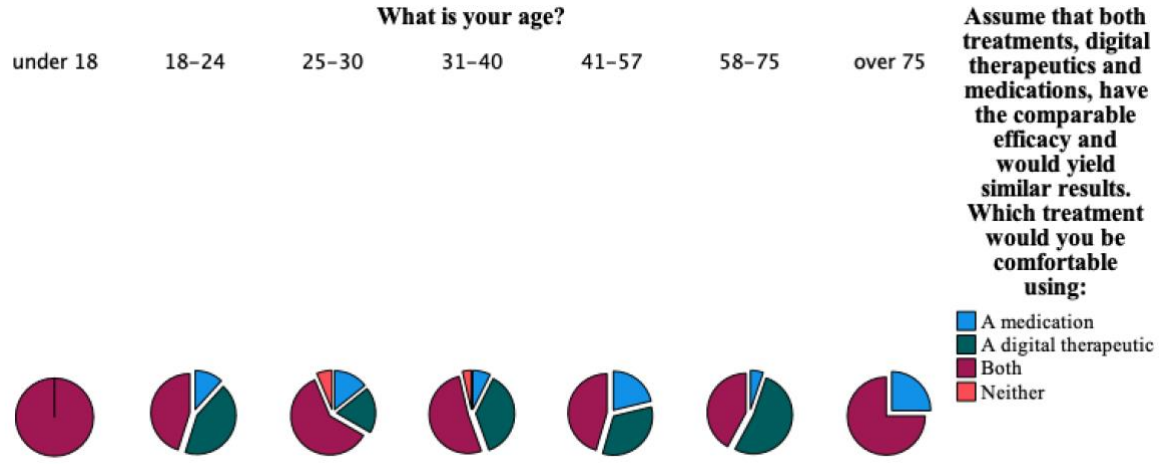

Figure 10: *Behavioural Intent Based on Age (SPSS output)*

The evenly distributed BI across all age groups does not indicate a higher technology acceptance for any age group. Additionally, a correlation analysis showed that there is no significant correlation between the two variables (Appendix 5). Thus, age has only a significance within the whole UTAUT model.

Based on the results of both the correlation and the cross-table analysis, H2 cannot be accepted. There seems to be no significant relationship between age and behavioural intention. This rejection of H2 indicates that the technology might be attractive across all age

groups. One of the reasons might be the value the technology provides by meeting the participants' performance expectancy indicated in the survey.

Overall, the data collected in the survey showed that the behavioural intention for digital therapeutics is high (85%). The high behavioural intention indicates a substantial technology acceptance of digital therapeutics within the surveyed population. A high technology acceptance rate will be a significant determinant of the disruptive potential of digital therapeutics. Without the acceptance of the mainstream market, a disruption is unlikely.

5 Conclusion

Mental health is becoming an increasing issue for global health care industries (Khademian et al., 2020). Consequently, significant research efforts are geared towards the treatment of mental health disorders. Next to the traditional medication and psychotherapy an increasing number of digital therapeutics companies are aiming to gain market approval for their software-based treatment options. The high risk, high reward business model of traditional research pharmaceutical companies is vulnerable to disruptive innovations.

The dissertation reviewed the relevant literature in disruptive innovation as well as technology acceptance theory. Additionally, overviews of the pharmaceutical and digital therapeutics industries were given. Key players and market developments were highlighted. The last section of the dissertation presents all significant results and offers an answer to the research question.

5.1 Research Question

The following research question will be answered now:

Do digital therapeutics have the potential to disrupt the pharmaceutical industry in the treatment of mental health disorders?

The pharmaceutical industry consists of a few large research companies and many rather unknown generic companies. The large research companies invest significant amounts in the development of new drugs in the hopes of generating a substantial return on investment. However, successful drug developments are rare and make the companies vulnerable to competition. In contrast, digital therapeutics can develop a new treatment option in a shorter amount of time and at significantly lower costs and consequently with lower risks associated.

Christensen (1997) as well as Govindarajan & Kopalle (2006) outline three key indicators of a disruptive innovation: lower prices, underperformance in mainstream market values, and a new value proposition or a targeting of the low-end market spectrum. Based on this theory, three prepositions have been made and subsequently analysed:

P1: Digital therapeutics offer a new value proposition or target the price sensitive customer segment
P2: Digital therapeutics are underperforming the performance requirements of the mainstream market
P3: Digital therapeutics will be offered at a reduced price compared to medications

A thorough analysis of qualitative data collected through literature reviews and expert interviews has shown that all three prepositions could not be rejected. Thus, digital therapeutics meet all indicators for and display a high potential to become a disruptive innovation.

DTx are able to provide a new value proposition to the customers. The digital nature of the treatment offers easy and fast access as well as constant availability. Through collected patient data, the technology can offer a high level of personalization, tailoring the treatment to the specific patient needs. Additionally, digital therapeutics can meet certain crucial market performance requirements such as efficacy and safety. Rigorous clinical trials, like those for drugs, ensure that not only does the treatment provide sufficient efficacy, but also the highest safety standards.

Although DTx can meet many of the market requirements and provide additional value propositions, not all mainstream market performance measures are met. In terms of treatment length, immediacy of efficacy, and patient effort, DTx are underperforming compared to medications. As the patient needs to interact with the software and spend a significant time per week on the exercises, it takes more effort and commitment from the patient than taking a daily medication. Additionally, in the case that an immediate relief of symptoms is needed, DTx will likely not be able to provide a solution. The technology is designed with a medium to long-term focus with positive effects being expected after two to three weeks.

Lastly, DTx can be offered at a lower price point due to the shorter and cheaper development times compared to drugs. Additionally, the technology can be easily scaled as there are no manufacturing or distribution logistics to consider, the patients only need access to the internet and likely an individualized access code.

However, digital therapeutics are still in the growth phase and disruption has not yet taken place. Several conditions will need to be met in order for a possible disruption. Firstly, regulatory frameworks for DTx need to be expanded to expedite the time to market. It was highlighted during the interviews that next to clinical trials, it is crucial for DTx to collect real-world evidence in addition to increase health care coverage of the technology. These factors will not only be helpful with the patients' technology acceptance, but specifically to convince the prescribing doctors of DTx. The need for a broad technology acceptance of health care professionals for the establishment of DTx in the market was highlighted several times during the interviews. Subsequently the unified theory of acceptance and use of technology (Davis, 1986) was used in combination with a survey to test the following two hypotheses:

H1: UTAUT is an adequate model to predict behavioural intent of using digital therapeutics
H2: Younger generations (Gen Z and Millennials) will have a higher technology acceptance of DTx

After a thorough quantitative analysis, H1 could not be rejected. UTAUT was proven significant and able to explain up to 89.1% of the variance of behavioural intention. The data collected from the survey showed a high acceptance of digital therapeutics with a total of 85% of all participants feeling comfortable using the technology for treating their mental health disorder. However, tests aimed at determining a relationship between the age of the participant and their BI did not hold. H2 could not be accepted indicating that digital therapeutics would not only be accepted by younger generations but also by older ones. This allows DTx to target the full market without being limited to certain age groups.

While digital therapeutics show a high disruption potential, its fulfilment will be dependent on the future market developments. Based on the insights collected during the interviews and the review of current literature, DTx could disrupt the pharmaceutical market in the treatment of mental health disorders as a fringe market encroachment (Schmidt & Druehl, 2008). However, it is unlikely that digital therapeutics would start the encroachment from the low end of the existing pharmaceutical market. If disruption takes place, it is likely that DTx will not fully replace pharmaceuticals but only displace medications on a small scale. Although digital therapeutics are well suited for the treatment of mental health disorders, the severity and stage of the disease will determine the likelihood of replacement. Based on the reviewed

literature, the shared knowledge during expert interviews, and the data collected during the survey, it is likely that the market will experience more collaboration with healthy competition between companies. Thus, it is probable that DTx will become an alternative treatment method that doctors can choose from when creating a treatment plan.

5.2 Limitations and Future Research

Limited data availability as well as a lack of reliable data are the main limitations of this dissertation. First, the qualitative data collected through the interviews is biased due to the display of personal opinions. Additionally, a majority of the interview partners either has a background in digital therapeutics or is working at a DTx company, which likely influences their personal views and opinions of success factors. By adding interview partners that have a variety of industry backgrounds without having a direct interest in the success of a digital therapeutic, the bias has been minimized; however not sufficiently. Moreover, the data obtained through the survey is not representative of the population, as the sample has mostly been filled out by younger people. There is also the possibility of a location bias as the majority of participants were in the US or Europe, here mainly Germany. Local health care systems and general cultural attitude towards mental health can have an influence on the answers. Thus, the reliability of the collected data cannot be guaranteed.

Second, the research focussed mainly on mental health care, for which digital therapeutics are well suited as a treatment option. It is uncertain whether the same conditions would hold for other indications and treatment areas in which DTx take on a more preventative or disease management capacity.

Lastly, the conclusions can only be drawn ex ante as a disruption has not yet taken place. There is no guarantee that a disruption will occur and predictions on future market developments are hypothetical and dependent on many external factors such as consumer acceptance and integration into payment plans. Whilst Govindarajan & Kopalle (2006) see a potential in predicting which firms are more likely to develop a disruptive innovation, the predictive ability of the theory is academically challenged (Danneels, 2004).

There are various expansions of this dissertation that can be taken into consideration in terms of future research. First, further research into a more specific indication within the mental

health disorder spectrum might provide more specific answers towards a possible market disruption. With a singular indication, as for example major depressive disorder (MDD), the treatment plan and medication are more regulated, and the point of drug displacement is more predictable.

Secondly, it could also be of interest to look at a specific medication to evaluate the individual displacement risk posed by digital therapeutics. This line of research is of special interest for pharmaceutical companies that want to evaluate the risk of disruption for a certain product to better predict their return on investment.

Another future research area can be the exploration of a digitalization of the pharmaceutical industry. As several of the interview partners highlighted, Big Pharma could enter the DTx market themselves by either acquiring an existing start-up or through in-house development of a digital treatment solution. Several challenges such as attracting the right talent, creating a business model which is more similar to that of a technology company or the risk of cannibalizing their own business would be interesting aspects to further look into. Pharmaceutical companies competing in DTx would require many internal changes in terms of business processes as well as the management of innovation.

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IX Appendix

Appendix 1: Interview Question Guide

Demographics

Introduction

a. Name:
b. Company:
c. Position:
d. Background:
e. Country:

Treatment/ Performance

1. How would you say pharmacology differs from DTx when treating mental health disorders for patients and health care professionals?
2. How would you describe the performance of DTx in contrast to pharmacology (drugs) when treating mental health disorders?
3. Do you see any difference between treating mental health disorders from treating other chronic diseases in terms of replaceability of traditional drugs and/or treatment through DTx? Why or why not?
4. How long does the treatment take on average if the DTx is used as monotherapy compared to traditional pharmacological monotherapy?

Market

1. How would you describe the performance measures in the market? Do you think DTx and pharmaceuticals compete on the same measures or different ones? Which?
2. How would you say pharmacology differs from DTx in terms of costs of development, costs for insurance and the patient?
3. How would you say DTx can impact the traditional pharmaceuticals business model? (e.g. revenue drivers…)
4. What would you say are the main customer target groups of DTx? Would you say they are targeting the same market segment that pharmaceuticals do or do they differ? (if yes, in what way?)
5. How would you describe DTx in relation to the pharmacology market? (e.g. broadening, change, separate)
6. How would you compare the speed of technological development/ innovation between DTx companies and pharmaceutical corporations?
7. How do you see DTx and Pharmacology interacting in the future?
8. In your professional opinion, do you see DTx as a threat to pharmacology as a treatment option? Why or why not?

Appendix 2: Survey - English

Intro

Dear participant,

Thank you very much for participating in this study! My name is Carina Knop and this study on the technology acceptance of digital therapeutics is an important contribution to the completion of my master thesis.

Your participation in this survey will be anonymous and voluntary, there will be no data collected that can identify the participant. Please answer as honestly as possible, there are no right or wrong answers. The survey should take you around 5 minutes to answer. If you have any questions about participation or my research, please contact me at: s-caknop@ucp.pt

By continuing to with this survey, you agree to voluntarily participate in this study.

Thank you for your support and participation!

Best, Carina

Demographics

Q1

What is your age?

- under 18
- 18 - 24
- 25 - 30
- 31 - 40
- 41 - 57
- 58 - 75
- over 75

Q2

What gender do you identify as?

- Male
- Female
- Non-binary / third gender
- Prefer not to say

Q3

What country do you live in?

Q4

What is the highest educational level you have finished?

- High School Diploma
- Appenticeship
- Bachelor degree
- Masters degree
- PhD

Q5

What is your employment status?

- Student
- Part Time
- Full Time
- Unemployed
- Retired

Performance Expectancy

Definition:

Please read the following definition carefully, as it is relevant for the following questions.

Digital therapeutics (DTx) deliver evidence-based, clinically validated therapeutic interventions that are driven by high quality software programs to prevent, manage, or treat a medical disorder or disease. They are used independently or in concert with medications, devices, or other therapies to optimize patient care and health outcomes.
(Digital Therapeutics Alliance, 2019)

For the following questions, please imagine that you have a diagnosed mental health disorder and you need a treatment. There are several options to choose from: medication, psychotherapy and a digital therapeutic.

Q6

What performance factors are important to you when making your treatment decision?

	Not at all important	Slightly important	Moderately important	Very important	Extremely important
Efficacy - Intervention shows an effect	○	○	○	○	○
Availability - Intervention is available any time	○	○	○	○	○
Price	○	○	○	○	○
Treatment Length - Time spent using the treatment	○	○	○	○	○
Flexibility - how flexible is the treatment, easy to integrate in lifestyle	○	○	○	○	○
Accessibility - Is it easy to gain access to the treatment	○	○	○	○	○
Personalisation - Are you able to personalise the treatment to fit your specific needs	○	○	○	○	○
Side Effects	○	○	○	○	○

Effort Expectancy

Q7

I use my smartphone for several hours a day.

- ○ Strongly agree
- ○ Somewhat agree
- ○ Somewhat disagree
- ○ Strongly disagree

Q8

Using digital therapeutics fits my lifestyle.

- ○ Strongly agree
- ○ Somewhat agree
- ○ Somewhat disagree
- ○ Strongly disagree

Q9

It is easy for me to gain access to digital therapeutics.

- ○ Strongly agree
- ○ Somewhat agree
- ○ Somewhat disagree
- ○ Strongly disagree

Q10

Learning to use a digital therapeutic would be easy.

- ○ Strongly agree
- ○ Somewhat agree
- ○ Somewhat disagree
- ○ Strongly disagree

Q11

It would be easier to take a pill every day.

- Strongly agree
- Somewhat agree
- Somewhat disagree
- Strongly disagree

Q12

When taking medications I worry about the side effects.

- Strongly agree
- Somewhat agree
- Somewhat disagree
- Strongly disagree

Q13

It would fit my lifestyle to work on my mental health for a few minutes every day on my phone.

- Strongly agree
- Somewhat agree
- Somewhat disagree
- Strongly disagree

Behavioural Intention

Q14

I perceive digital therapeutics are an effective treatment method.

- Strongly agree
- Somewhat agree
- Somewhat disagree
- Strongly disagree

Q15

I think digital therapeutics could have a positive effect over time.

- Strongly agree
- Somewhat agree
- Somewhat disagree
- Strongly disagree

Q16

I trust that a prescribed digital therapeutic will be effective in treating my condition.

- Strongly agree
- Somewhat agree
- Somewhat disagree
- Strongly disagree

Q17

Assume that both treatments, digital therapeutics and medications, have the comparable efficacy and would yield similar results.
Which treatment would you be comfortable using:

- A medication
- A digital therapeutic
- Both
- Neither

Social Influence

Q18

Your doctor is a strong supporter of digital therapeutics.
How much does this fact influence your decision?

- A lot
- A moderate amount
- A little
- Not at all

Q19

Several of my friends and family are convinced of digital therapeutics as a treatment method. This will influence my perception:

- A lot
- A moderate amount
- A little
- Not at all

Appendix 3: Survey - German

Intro

Lieber Teilnehmer,

vielen Dank, dass Sie sich dazu entschieden haben an meiner Studie teilzunehmen! Mein Name ist Carina Knop und diese Studie zur Technologie Akzeptanz von 'Digital Therapeutics' ist ein wichtiger Teil meiner Masterarbeit.

Die Teilnahme an dieser Studie erfolgt anonym und freiwillig, es werden keine persönlichen Daten erhoben. Bitte beantworten Sie die Fragen so ehrlich wie möglich, es gibt keine richtigen oder falschen Antworten. Die Umfrage sollte circa 5 Minuten dauern. Falls Sie Fragen zu dieser Umfrage oder meiner Arbeit haben, kontaktieren Sie mich bitte unter:
s-caknop@ucpt.pt

Durch Beantwortung der Fragen, stimmen Sie der freiwilligen Teilnahme an der Studie zu.

Vielen Dank für Ihre Unterstützung und Teilnahme!

Carina

Demographics

Q1

Wie alt sind Sie?

- Unter 18
- 18 - 24
- 25 - 30
- 31 - 40
- 41 - 57
- 58 - 75
- Über 75

Q2

Mit welchem Geschlecht identifizieren Sie sich?

- Männlich
- Weiblich
- Non--binär/ Divers
- Ich bevorzuge es nicht zu antworten

Q3

In welchem Land wohnen Sie?

Q4

Was ist Ihr höchster Bildungsabschluss?

- Schulabschluss
- Ausbildung
- Bachelor
- Master
- Doktor

Q5

Was ist Ihr momentanes Anstellungsverhältnis?

- Schüler/ Student
- Teilzeit
- Vollzeit
- Ohne Beschäftigungsverhältnis
- Rente

Performance Expectancy

Definition

Bitte lesen Sie die folgende Definition aufmerksam durch, sie ist relevant für die darauffolgenden Fragen.

Digital Therapeutics (DTx) liefert therapeutische Interventionen basierend auf klinischen Studien durch hochwertige Softwareprogramme (Apps) mit dem Ziel Krankheiten vorzubeugen, zu managen oder zu behandeln. Diese Methode kann als alleinstehende Behandlung oder in Kombination mit anderen Medikamenten, Geräten oder Therapien eingesetzt werden, um die Patientenversorgung und Behandlungsresultate zu optimieren.
(Digital Therapeutics Alliance, 2019)

Für die folgenden Fragen stellen Sie sich bitte vor, dass bei Ihnen eine psychische Krankheit diagnostiziert wurde, für welche Sie nun eine Behandlung benötigen. Sie haben mehrere Optionen aus denen Sie wählen können: Medikament, Psychotherapie und Digital Therapeutics.

Q6

Welche Leistungsfaktoren sind Ihnen wichtig, wenn sie eine Behandlungsentscheidung treffen?

	nicht wichtig	weniger wichtig	wichtig	sehr wichtig	extrem wichtig
Wirksamkeit - Die Intervention zeigt eine Wirkung	○	○	○	○	○
Verfügbarkeit - Die Intervention steht jeder Zeit zur Verfügung	○	○	○	○	○
Preis	○	○	○	○	○
Behandlungsdauer - Länge der Behandlung	○	○	○	○	○
Flexibilität - wie flexibel und leicht die Behandlung in den Alltag zu integrieren ist	○	○	○	○	○
Zugänglichkeit - ist es leicht die Behandlung zu erhalten	○	○	○	○	○
Personalisierung - kann die Behandlung an die persönlichen Bedürfnisse angepasst werden	○	○	○	○	○
Nebenwirkungen	○	○	○	○	○

Effort Expectancy

Q7

Ich benutze mein Smartphone für mehrere Stunden am Tag.

- ○ stimme zu
- ○ stimme eher zu
- ○ stimme eher nicht zu
- ○ stimme nicht zu

Q8

Digital Therapeutics passen zu meinem Lebensstil.

- ○ stimme zu
- ○ stimme eher zu
- ○ stimme eher nicht zu
- ○ stimme nicht zu

Q9

Es ist einfach für mich, Zugang zu Digital Therapeutics zu bekommen.

- ○ stimme zu
- ○ stimme eher zu
- ○ stimme eher nicht zu
- ○ stimme nicht zu

Q10

Der Umgang mit Digital Therapeutics ist einfach zu lernen.

- stimme zu
- stimme eher zu
- stimme eher nicht zu
- stimme nicht zu

Q11

Es ist einfacher eine Tablette jeden Tag zu nehmen.

- stimme zu
- stimme eher zu
- stimme eher nicht zu
- stimme nicht zu

Q12

Wenn ich Medikamente nehme, mache ich mir über die Nebenwirkungen Gedanken.

- stimme zu
- stimme eher zu
- stimme eher nicht zu
- stimme nicht zu

Q13

Es würde zu meinem Lebensstil passen, jeden Tag ein paar Minuten auf meinem Handy an meiner geistigen Gesundheit zu arbeiten.

- stimme zu
- stimme eher zu
- stimme eher nicht zu
- stimme nicht zu

Behavioural Intention

Q14

Ich nehme Digital Therapeutics als eine effektive Behandlungsmethode wahr.

- stimme zu
- stimme eher zu
- stimme eher nicht zu
- stimme nicht zu

Q15

Ich denke im Laufe der Zeit könnten Digital Therapeutics einen positiven Effekt haben.

- stimme zu
- stimme eher zu
- stimme eher nicht zu
- stimme nicht zu

Q16

Ich vertraue darauf, dass verordnete Digital Therapeutics bei der Behandlung meiner Erkrankung wirksam sind.

- stimme zu
- stimme eher zu
- stimme eher nicht zu
- stimme nicht zu

Q17

Gehen Sie davon aus, dass beide Behandlungen, Digital Therapeutics und ein Medikament, eine vergleichbare Wirksamkeit haben und ähnliche Ergebnisse liefern würden.
Mit welcher Behandlung würden Sie sich wohler fühlen?

- Medikament
- Digital Therapeutics
- beide
- keinem

Social Influence

Q18

Ihr Arzt*in ist ein großer Unterstützer von Digital Therapeutics.
Wie sehr beeinflusst diese Tatsache Ihre Entscheidung?

- sehr viel
- mäßig
- wenig
- gar nicht

Q19

Ein Freund*in oder Mitglied Ihrer Familie hat gute Erfahrungen mit Digital Therapeutics gemacht.
Wie sehr beeinflusst diese Tatsache Ihre Entscheidung?

- sehr viel
- mäßig
- wenig
- gar nicht

Appendix 4: Multinominal Logistic Regression Analysis SPSS Output

Model Fitting Information

Model	Model Fitting Criteria -2 Log Likelihood	Likelihood Ratio Tests Chi-Square	df	Sig.
Intercept Only	454.960			
Final	125.988	328.972	183	<.001

Goodness-of-Fit

	Chi-Square	df	Sig.
Pearson	129.104	450	1.000
Deviance	125.988	450	1.000

Pseudo R-Square

Cox and Snell	.785
Nagelkerke	.891
McFadden	.723

Likelihood Ratio Tests

Effect	Model Fitting Criteria -2 Log Likelihood of Reduced Model	Likelihood Ratio Tests Chi-Square	df	Sig.
Intercept	125.988[a]	.000	0	.
What performance factors are important to you when making your treatment decision? – Efficacy – Intervention shows an effect	120796.352[b]	120670.365	9	.000
What is your age?	341.435[b]	215.448	18	<.001
What gender do you identify as?	132.134[b]	6.146	6	.407
What is the highest educational level you have finished?	131.078[b]	5.090	12	.955
What is your employment status?	141.702[b]	15.715	12	.205
What performance factors are important to you when making your treatment decision? – Availability – Intervention is available any time	2053.306[b]	1927.319	9	.000
What performance factors are important to you when making your treatment decision? – Price	166.475[b]	40.487	12	<.001
What performance factors are important to you when making your treatment decision? – Treatment Length – Time spent using the treatment	178.104[b]	52.117	12	<.001
What performance factors are important to you when making your treatment decision? – Flexibility – how flexible is the treatment, easy to integrate in lifestyle	184.524[b]	58.536	12	<.001
What performance factors are important to you when making your treatment decision? – Accessibility – Is it easy to gain access to the treatment	136.920[b]	10.932	12	.535
What performance factors are important to you when making your treatment decision? – Personalisation – Are you able to personalise the treatment to fit your specific needs	199.487[b]	73.499	12	<.001
What performance factors are important to you when making your treatment decision? – Side Effects	133.111[b]	7.124	12	.849
It is easy for me to gain access to digital therapeutics.	193.683[b]	67.695	12	<.001
Learning to use a digital therapeutic would be easy.	141.060[b]	15.072	12	.238
Your doctor is a strong supporter of digital therapeutics. How much does this fact influence your decision	127.519[b]	1.531	9	.997
Several of my friends and family are convinced of digital therapeutics as a treatment method. This will influence my perception:	131.228[b]	5.240	9	.813

The chi-square statistic is the difference in -2 log-likelihoods between the final model and a reduced model. The reduced model is formed by omitting an effect from the final model. The null hypothesis is that all parameters of that effect are 0.

a. This reduced model is equivalent to the final model because omitting the effect does not increase the degrees of freedom.

b. Unexpected singularities in the Hessian matrix are encountered. This indicates that either some predictor variables should be excluded or some categories should be merged.

The file with the Parameter Estimates was unfortunately too long for this document due to the number of variables and combinations.

Appendix 5: Cross Table and Correlation

What is your age? * Assume that both treatments, digital therapeutics and medications, have the comparabl efficacy and would yield similar results. Which treatment would you be comfortable using: Crosstabulatio

			Assume that both treatments, digital therapeutics and medications, have the comparable efficacy and would yield similar results. Which treatment would you be comfortable using				
			A medication	A digital therapeutic	Both	Neither	Total
What is your age?	under 18	Count	0	0	2	0	2
		% within What is your age?	0.0%	0.0%	100.0%	0.0%	100.0%
		% within Assume that both treatments, digital therapeutics and medications, have the comparable efficacy and would yield similar results. Which treatment would you be comfortable using	0.0%	0.0%	1.8%	0.0%	0.9%
	18-24	Count	6	22	23	0	51
		% within What is your age?	11.8%	43.1%	45.1%	0.0%	100.0%
		% within Assume that both treatments, digital therapeutics and medications, have the comparable efficacy and would yield similar results. Which treatment would you be comfortable using	22.2%	29.3%	20.7%	0.0%	23.4%
	25-30	Count	9	12	38	4	63
		% within What is your age?	14.3%	19.0%	60.3%	6.3%	100.0%
		% within Assume that both treatments, digital therapeutics and medications, have the comparable efficacy and would yield similar results. Which treatment would you be comfortable using	33.3%	16.0%	34.2%	80.0%	28.9%
	31-40	Count	2	10	14	1	27
		% within What is your age?	7.4%	37.0%	51.9%	3.7%	100.0%
		% within Assume that both treatments, digital therapeutics and medications, have the comparable efficacy and would yield similar results. Which treatment would you be comfortable using	7.4%	13.3%	12.6%	20.0%	12.4%
	41-57	Count	7	11	15	0	33
		% within What is your age?	21.2%	33.3%	45.5%	0.0%	100.0%
		% within Assume that both treatments, digital therapeutics and medications, have the comparable efficacy and would yield similar results. Which treatment would you be comfortable using	25.9%	14.7%	13.5%	0.0%	15.1%
	58-75	Count	2	20	16	0	38
		% within What is your age?	5.3%	52.6%	42.1%	0.0%	100.0%
		% within Assume that both treatments, digital therapeutics and medications, have the comparable efficacy and would yield similar results. Which treatment would you be comfortable using	7.4%	26.7%	14.4%	0.0%	17.4%
	over 75	Count	1	0	3	0	4
		% within What is your age?	25.0%	0.0%	75.0%	0.0%	100.0%
		% within Assume that both treatments, digital therapeutics and medications, have the comparable efficacy and would yield similar results. Which treatment would you be comfortable using	3.7%	0.0%	2.7%	0.0%	1.8%
Total		Count	27	75	111	5	218
		% within What is your age?	12.4%	34.4%	50.9%	2.3%	100.0%
		% within Assume that both treatments, digital therapeutics and medications, have the comparable efficacy and would yield similar results. Which treatment would you be comfortable using	100.0%	100.0%	100.0%	100.0%	100.0%

Correlations

		What is your age?	Assume that both treatments, digital therapeutics and medications, have the comparable efficacy and would yield similar results. Which treatment would you be comfortable using
What is your age?	Pearson Correlation	1	-.056
	Sig. (2-tailed)		.413
	N	220	218
Assume that both treatments, digital therapeutics and medications, have the comparable efficacy and would yield similar results. Which treatment would you be comfortable using	Pearson Correlation	-.056	1
	Sig. (2-tailed)	.413	
	N	218	218