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The Introduction of Health Apps and Wearables into the German Statutory Health Care System

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Foreword

Digital health devices such as health applications (apps) and wearables have evolved in recent years from leisure gadgets to serious monitoring and treatment tools, which is why these technologies enjoy ever-increasing attention from health care stakeholders and political decision makers. They are also becoming increasingly popular among the public [1]. Health apps and wearables can contribute more to the health care system than monitoring physical exercise, heart rate, or calories; they may support chronically ill patients with the management of their disease or stress related symptoms [2]. However, there is still little research on the effectiveness of health apps and wearables, and even fewer empirical studies on the implementation and integration of self-tracked health data into the health care sector [1]. Yet, to a certain extent, health apps and wearables might have significant potential to decrease ever-growing health care expenditures [3]. The sparse literature assigns an important role to the use of wearable technology and the integration of self-tracked health data. Hence, there might be promising advancements in terms of diagnosis, research, and development (R&D) [4]. Apps and wearables are considered beneficial in the field of preventive medicine because gamification and nudging of activity enhance personal motivation, compliance, and coordination [5, 6].

In 2019, Germany launched a pilot project and passed the Digital Care Act [7], which is one of the most progressive incentive systems for patient care digitization worldwide [8]. The Digital Care Act enables physicians to prescribe health apps for different digital devices, such as smartphones and wearables, and in the future for intelligent voice user interfaces. The health app-based treatment of patients is now funded by the sickness funds. A new fast-track certification process was implemented for the admission of digital health devices to the index of prescribable health apps, aiming to decrease market entry barriers and encourage innovation [9].

Yet, since the act is so unique, there may be some undiscussed aspects that could complement and therefore improve the act. Currently, there is no regulation or remuneration system for medical doctors who supervise the health app usage of their patients intended in the act. Furthermore, a digital dividend system for patients who share their self-tracked health data with health care agents for more efficient research is also not intended. Hence, the certification process for health apps and digital health devices has recently been regulated and facilitates the option of fast-track certification to enhance innovation and reduce the certification time and costs for health app providers. Uniquely, health apps can be preliminarily admitted to the official index, and for a period of 12 months after admission to the index, health app providers have to prove a positive care effect or impact for their health app [9]. This part of the regulation might be subject to additional potential risks and benefits.

The introduction of digital health applications into the German health care system might hold significant benefits, such as the improvement of treatment quality, the increase of efficiency, better patient education, and better self-management of diseases [5, 6]. Yet, many people have fundamental concerns about discrimination through a lack of data privacy or exclusions caused by socio-demographic factors [10-12].

Within the scope of my dissertation, I seek to outline the potential benefits and risks of statutory-financed health apps and wearables within the German health care system. This dissertation consists of three papers discussing health apps and wearables within the health care system. In the first paper, we identified key concepts for the inclusion of health apps and

wearables in the German statutory health care system. In the second paper, we analyzed the circumstances under which people would be willing to sell their self-tracked health data to different agents in the health care sector. Lastly, in the third paper, we compared a traditional treatment with an app treatment and thereby outlined a potential method to show the positive care effect of a health app treatment. Additionally, we polled different stakeholders from the German health care system to determine their opinions and general sentiments concerning health apps.

Research Projects

This dissertation consists of three research papers. Each approached the potential risks and benefits of health apps and wearables in the German statutory health care system from a different thematic and methodological perspective. The first paper was a scoping review and aimed to summarize the key literature concerning health apps and wearables and the option of incorporating them into standard medical care. The second paper was a specific form of discrete choice experiment, namely, separated adaptive dual response. The aim of this paper was to estimate the anticipated outcomes and monetary value of self-tracked health data for patients in Germany, and therefore add to the discussion about the feasibility of a digital dividend. The last paper described a multi-method approach, including an interview and a quantitative health app user data study. The aim of this study was to map the potential benefits of the Digital Care Act and to recommend supplementary elements to complete the act.

Paper I: Potential Benefits and Risks Resulting From the Introduction of Health Apps and Wearables Into the German Statutory Health Care System: Scoping Review[1]

Germany is the first country in the world which has introduced a digital care act as an incentive system to enhance the use of digital health devices, namely health apps and wearables, among its population. The act allows physicians to prescribe statutory-financed and previously certified health apps and wearables to patients. This initiative has the potential to improve treatment quality through better disease management and monitoring.

The aim of this paper was to outline the key concepts related to the potential risks and benefits discussed in the current literature on health apps and wearables. Furthermore, this study addressed the research question of which risks and benefits may result from the implementation of a digital care act in Germany.

We conducted the scoping study by searching the databases PubMed, Google Scholar, and JMIR using the keywords “health apps” and “wearables”. We discuss 55/136 identified articles published in English language in 2015 – March 2019 in this paper, using a qualitative thematic analysis approach.

Four key themes are identified within the articles: effectivity of health apps and wearables to improve health, users of health apps and wearables, the potential of brought along self-tracked data and concerns, and data privacy risks. Within these themes, three main stages of benefits for the German health care system are identified: usage of health apps and wearables, continuing to use health apps and wearables, and sharing brought along self-tracked data with different agents in the health care sector.

The Digital Care Act could lead to an improvement in treatment quality through better patient monitoring, disease management, personalized therapy, and better health education. However, physicians should play an active role in recommending and supervising health app use to reach digitally or health illiterate people. Age should not be an exclusion criterion. Yet, data privacy and security concerns are very widespread in Germany. Transparency about data processing should always be provided for the continuing success of the Digital Care Act in Germany [13].

[1]Heidel A, Hagist C. Potential Benefits and Risks Resulting From the Introduction of Health Apps and Wearables Into the German Statutory Health Care System: Scoping Review. JMIR Mhealth Uhealth. 2020 Sep 23;8(9), doi: 10.2196/16444 [13]

Paper II: Pricing through Health Apps Generated Data in Germany – Digital Dividend as a Game Changer: A Discrete Choice Experiment[2]

The objective of this paper was to study the circumstances under which German wearable and health app users would accept a digital dividend to share their self-tracked health data.

We used the discrete choice experiment alternative separated adaptive dual response to reduce extreme response behavior, which we expected considering the emotionally charged topic of health data sales, and to measure willingness to accept more accurately. Previous lab experimental settings led to unrealistic and high monetary demands. After the first online survey and two pre-studies, we validated four attributes for the final online study: monthly bonus payment, stakeholder, type of data, and data sales to third parties. We used a random utility framework to evaluate individual choice preferences. We randomly assigned respondents to one of two identical questionnaires with varying price ranges to test the expected prices of the main study for robustness.

During a period of three weeks, 842 respondents participated in the main survey, and 272 respondents participated in the second survey. The participants considered transparency about data processing and no further data sales to third parties very important for their decision to share data with different stakeholders, as well as adequate monetary compensation. Price expectations resulting from the experiment were quite high so that pharma and medical device companies would have to pay an average digital dividend of 237.30€/month for patient-generated health data of all types. Yet, we observed an anchor effect, which means that people were forming price expectations during the process and not ex ante. We observed a bimodal or a u-shaped distribution between extremely low-price expectations and extremely high price expectations, which again shows that personal data selling is a rather emotional decision. However, the results indicate that a digital dividend is a feasible economic incentive system. During the Covid-19 crisis, price expectations might have changed due to public sensitization to the need for big data research on patient-generated health data.

Health care companies might significantly benefit from the inclusion of big data analysis of patient-generated data into their research. The continuing success of data donation models is highly unlikely. The health care sector needs to engage in initiatives that address transparency and trust related to data processing. Adequate monetary compensation is an effective long-term measure to convince a diverse and large group of people to share high-quality continuous data for research purposes in Germany [14].

[2]Heidel A, Hagist C, Schlereth C. Pricing through Health Apps Generated Data in Germany - Digital Dividend as a Game Changer: Discrete Choice Experiment. PLOS ONE. 2021 JUL, doi: 10.1371/journal.pone.0254786 [14]

Paper III: The Digital Care Act – A Chance to Relieve the Dust from the German Health Care System: A Multi-Method Approach[3]

In 2019, Germany launched the Digital Care Act. The reform enables medical doctors to prescribe health apps and digital health devices as treatments to their patients. In December 2020, the first nine health apps were admitted to the index for digital health devices and are now available via medical prescription.

We aimed to determine to what extent the integration of health apps into the German statutory health care system could be considered beneficial and which aspects of the Digital Care Act could be complemented. We also shed light on the different inexplicit aspects of the reform.

First, we conducted a semi-structured interview study with 23 stakeholders in Germany and analyzed them thematically. Two researchers independently coded the transcripts using thematically relevant first- and second-order codes and found consensus about the final codes by merging the data. We used descriptive coding for the first-order codes and pattern coding for the second-order codes. Second, we carried out a quantitative study in cooperation with Kaia Health Software GmbH and analyzed anonymized data from 2208 users. We developed logistic regression models and multiple linear regression models using continuous self-assessment and login data. In the final step of the analysis, we compared the change in pain, which is to a large extent underestimated in our sample given the retrospective design of our study, and the costs of the Kaia treatment with traditional treatment.

We created 79 first-order codes and 9 second-order codes after the interview study. Most stakeholders thought that the additional option of prescribed health apps could improve the treatment quality of patients and enhance service portfolios. Prescribing health apps as treatments has various positive effects for patients, such as greater flexibility and a permanent reduction in waiting time for appointments. However, supervision and guidance through practitioners were highly recommended, as well as a specific remuneration system for their additional effort. If the act is to succeed, education and information activities on health apps for medical doctors need to be organized by statutory health insurance companies, app producers, and medical associations. Approximately 67% (1475/2208) of our Kaia user sample was able to keep their pain levels constant or improve their pain levels during the first quarter of the year. We observed that the frequency of exercising with Kaia had a positive effect on pain reduction. Age played just a minor role in pain improvement, but the older persons in our sample especially benefitted from the Kaia treatment.

Stakeholders within the German health care system have generally positive opinions about the Digital Care Act. App treatments with educational and monitoring capabilities can contribute to patient emancipation. However, the fast-track certification process involves several risks as well as opportunities for innovation. This unique certification process should encourage innovation within the German statutory health care system but could also attract free riders who could take advantage of the statutory reimbursement system. Our empirical study showed that user data have the potential to enable the examination and assessment of the cost effectiveness of health apps and may be used to compare them with traditional treatments. However, regulators should develop a clear health economic assessment framework so that cost-effectiveness studies can be implemented in a standardized way, comparing different apps and traditional treatments for the same purpose. We were able to show a positive care

[3]Heidel A, Hagist C, Spinler S, Schöneberger M. The Digital Care Act – A Chance to Relieve the Dust from the German Health Care System: A Multi-Method Approach. Unpublished Working Paper. 2020 Dec. [15]

effect for patients using the back-pain app Kaia. When the app-based treatment was compared with traditional treatment, our analysis showed that the app had the highest relative cost-effectiveness ratio [15].

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Scoping Review

Potential Benefits and Risks Resulting From the Introduction of Health Apps and Wearables Into the German Statutory Health Care System: Scoping Review[4]

Introduction

Health apps and wearables have experienced increasing popularity in recent years [1]. Health apps and wearables are able to contribute more to the health care system than monitoring physical exercise, heart rate, or calories; they may support chronically ill patients with the management of specific diseases such as Parkinson's disease, diabetes, tinnitus, or stress-related symptoms. Yet, Kotlikoff and Hagist [16] outlined already in 2009 that constantly increasing health care expenditure is one of the major social challenges for modern welfare states. Health apps and wearables might hold significant potential to decrease these costs. Apps and wearables are considered beneficial in the fields of preventive medicine and disease monitoring because the gamification of health enhances personal motivation and coordination. Germany has just launched one of the most progressive pilot projects in its health care history. The parliament passed the Digitale Versorgung Gesetz (DVG; digital care act) in 2019, which introduces the digitale Gesundheitsanwendungen (DIGA; digital health applications) into the German statutory health care system [7]. The DVG enables physicians to prescribe health apps for smartphones or wearables, which are covered for the insured by the sickness funds. This incentive system to introduce mobile health (mHealth) into the health care system is unique and exceptional worldwide [8]. The German Ministry of Health has shaped a completely new concept with the term DIGA. DIGA is a medical device within the scope of the European medical device regulation and classified as risk level I and not higher than a risk level IIa [9]. DIGA is a portable technology with the medical scope of monitoring, treatment, or reducing the effects of diseases [9]. Simple nutrition or menstrual cycle apps without any clear scope to improve the treatment effectivity of a medical condition are, for now, not considered as DIGAs.

Researchers in Germany are currently discussing the potential success of the act and the expected patient demand and acceptance. Experience with a regulation such as the DVG does not exist. According to a study by GfK, about 28% of Germans (25% female, 30% male) track at least one health parameter [17], and the average use from all 16 surveyed countries is 33%. Reasons to not track personal health data might be related to data security concerns, the accessibility of technology, or personal attitudes towards the recording of fitness parameters. We aimed to identify key concepts of the inclusion of health apps and wearables in the German statutory health care sector. We analyzed 55 of 136 identified articles to answer the research question: Which risks and benefits may result from the implementation of the digital care act in Germany?

Methods

According to Munn et al [18], we conducted a scoping study to identify key concepts of the inclusion of health apps and wearables into the German statutory health care sector. The study

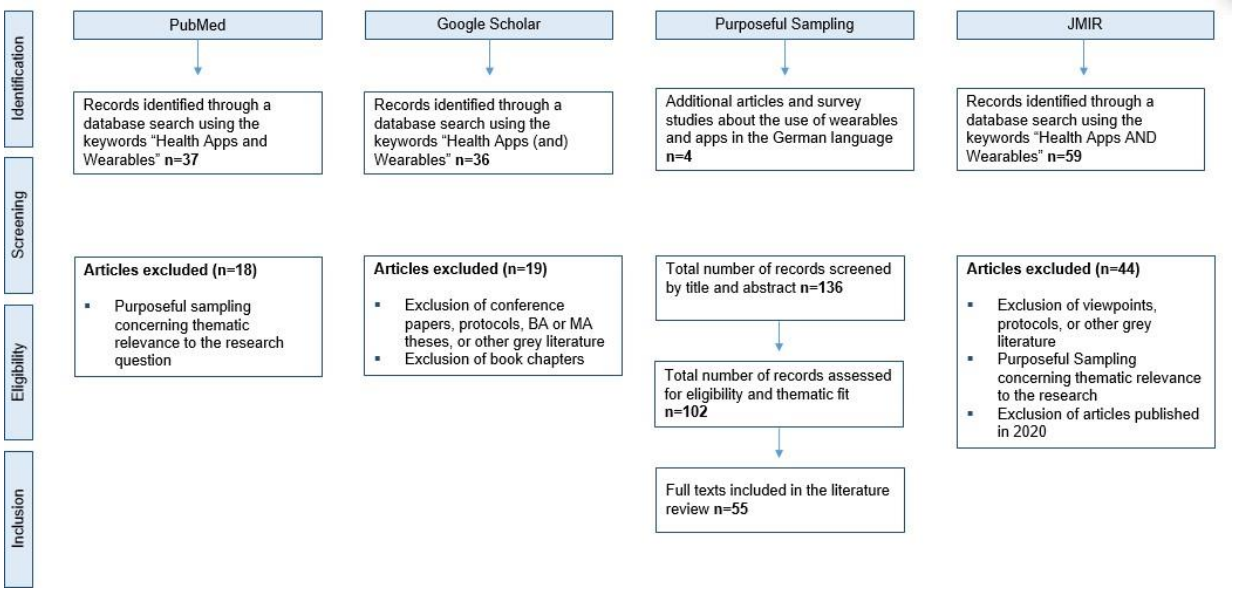
[4]Heidel A, Hagist C. Potential Benefits and Risks Resulting From the Introduction of Health Apps and Wearables Into the German Statutory Health Care System: Scoping Review. JMIR Mhealth Uhealth. 2020 Sep 23;8(9), doi: 10.2196/16444 [13]

aimed to draw a general picture about the risks and benefits of statutory financed mHealth solutions in Germany.

Scoping Method

We performed this study according to the guidelines of scoping studies by Colquhoun et al [19]. Colquhoun et al [19] advanced the 6 stages of scoping studies by Arksey and O'Melley [20]. They elaborated on different stages of research such as the identification of a research question and literature, study selection, charting data, summarizing, and consulting [20]. To ensure rigor and transparency, this literature review was guided by our research question [20]. We started the scoping study with a database search of PubMed using the keywords "health apps AND wearables" (Figure 1). The scoping of literature was limited to articles published in the English language from 2015 to March 2019 because literature on health apps and wearables, as well as the boom of using those technologies, experienced a steep increase in 2015 [21]. The search identified 37 potential items. A second search was conducted via Google Scholar by using the keywords "health apps (and) wearables," limiting the search again to literature published in the English language from 2015 to March 2019, and 36 items were identified. Then, another 2 articles in the German language and 2 survey studies in the German language were included in the study through purposeful sampling [22] because they were recommended. We conducted a third database search through JMIR using the search terms "health apps AND wearables" and identified 59 articles published from 2015 to March 2019 in English [Multimedia Appendix 1]. We conducted other trial searches using other keywords such as "mHealth," "fitness apps," "health apps," and "health data sharing" but the sampled literature had little fit with the research question. Hence, when searching only for the search term "health apps," JMIR returned 698 search results. However, we chose the search term "health apps AND wearables" for our study because this is the closest that the published literature gets in terms of the German DIGA concept [23].

Figure 1: *Scoping Process for Literature about Health Apps and Wearables*



Source: Own Depiction.

Identification of Relevant Articles

Conference papers, conference reports, protocols, viewpoints, letters, Bachelor and Master theses, or other grey literature were not included. First, we screened articles by title and

abstract. Literature relating to the themes of patient treatment with health apps or wearables, preventive care with apps or wearables, market studies about health app and wearable use, data privacy concerns, and patient use of health apps and wearables were included in this study. Hence, duplicates and ineligibility were further reasons for exclusion. Regarding the inclusion themes selected via purposeful sampling [22], 55 of 136 articles were included in this scoping study, and we analyzed the articles using a qualitative thematic analysis approach [Multimedia Appendix 1].

Results

Of the 55 studies, 22 studies were literature, website, or app reviews; 16 studies were qualitative studies; and 17 studies were survey, interview, or quantitative studies. Most survey studies were not representative. Overall, we concluded that there is a growing amount of health app and wearable literature, but there is still room for additional research because not every aspect of the introduction of mHealth solutions into the health care system is known yet. There are few long-term studies on the effectivity of the use of health apps and wearables as a form of patient treatment. We have no insights about the effects of DIGA prescription and usage over 5, 10, or 20 years. Most articles we reviewed originated in Western Europe, the United States, and Canada.

After article scoping and conceptualization of the main findings, 4 main themes emerged: users of health apps and wearables; effectivity of health apps and wearables to improve health; the potential of bring-your-own, self-tracked data; and concerns and data privacy risks.

Users of Health Apps and Wearables

A study by GfK reported that 33% of survey participants from 16 different countries used wearables or health apps to track their fitness or health on average [17]. The main reasons for people to use these devices is to improve their personal level of fitness or for self-motivation. In Germany, about 28% of people currently track their health - more men than women and rather younger than older people [17]. Another survey conducted by Statista [24] showed similar results. Users mainly focus on self-optimization. The youngest user group (18-29 years) has the largest proportion of app users [24].

Wiesner et al [25] conducted a field study and surveyed participants from a regional road race event about their use of wearables. They decided to survey sport-enthusiast runners because they anticipated that mainly young and active people use health apps and wearables. The study showed that 73% of the runner community used one or more wearables to track their activity [25]. Just 1% of the respondents used wearables sponsored by their health insurer [25]. The authors further asked about data privacy concerns of nonvoluntary data sharing, and 42% of the respondents “stated that they would not be concerned if data were shared in such a manner” [25]. This result might be significantly different when surveying a group of chronically ill or nonactive people. The results further show that the willingness to share data with different agents decreases for respondents in older age groups [25]. Most respondents of a US market study used health apps and wearables to monitor personal activity, nutrition, weight loss, or learn a new exercise [26]. Most of the surveyed users used their health or fitness apps at least once a day [26]. Just 20% of the respondents discovered an app through the recommendation of a physician [26]. Among the most frequent reasons for people to not use health apps and wearables were lack of interest, high prices, and lack of trust in data security [26].

Park et al [27] conducted a similar study in South Korea and achieved similar results. The main reasons to use health apps and wearables were concerns about personal health status, self-

optimization, innovative propensity, and trust in beneficial results. Surprisingly, the results indicated that the quality of the app has less influence on the decision whether to continue to use an app than social-cognitive factors [27]. Paré et al [28] also analyzed the motivation of people using health apps or wearables in Canada. They concluded that about 41% of the respondents used digital devices to self-track their health and physical activity (PA), which is significantly more than the German average. Furthermore, “a majority of digital self-trackers are young or mature adults (18-34 years), highly educated …, wealthy … and people who perceive themselves to be in good or very good health” [28]. Mosconi et al [29] and Ernsting et al [30] agreed with this statement and determined that young people in particular are interested in these technologies. Users feel generally more informed about their health when tracking different parameters, and 7 of 10 respondents improved or maintained their health condition by using an app or wearable [28]. Nevertheless, “one-third of consumer wearables end up in a drawer 6 months after purchase” [28]. This phenomenon occurs mainly with people with poor health or a chronic illness, indicating that this group loses interest in the technology when constantly reminded about a chronical condition or illness. Those people might feel pressured to be physically active [28].

Canhoto and Arp [31] agreed with Paré et al [28] by stating that many wearable and health app users stop using their devices after a while. Many insurance companies offer their members financial incentives and bonus programs to adopt a certain app or track specific health parameters [31]. The authors claimed that the inclusion of wearables and health apps in the health care system might have a significant positive influence on the treatment of chronic disease, like obesity or diabetes [31]. The widespread adoption and acceptance of these technologies are the key to their effectivity.

Christóvão [32] analyzed in his paper the influencing factors leading to app usage and the potential of health apps recommended and monitored by physicians. Perceived ease of use, perceived usefulness, peer influence, seniority, age, and gender were among the most important factors [32]. The author surveyed 199 fully qualified doctors and medical students to analyze the perceived usefulness of introducing health apps and wearables into patient care. Senior physicians and female physicians tended to use health apps less frequently if there was little peer influence, little perceived usefulness, and high complexity of usage [32]. Most of the respondents could imagine recommending health apps and wearables to patients. Collado-Borrell et al [33], Davis et al [34], and Lipschitz et al
[35] stated that many patients, nonetheless, already use health apps and wearables and are generally interested in the adaption of these technologies, independent of their age. However, Krebs and Duncan [26] rejected the view that all influencing factors are equally important. Wiesner et al [25] disagreed that gender significantly influences app usage, and Mackert et al [36] stated that health literacy plays an important role in the willingness to use these technologies.

Somers et al [37] conducted a contingent evaluation about the willingness-to-pay (WTP) for and willingness-to-accept (WTA) the use of health apps with different features. The results indicated that people value the promotion of wellbeing, social connectivity, and health care control [37]. Hence, Peng et al [38] identified the price of a wearable or health app as a significant influencing factor for the decision to adopt. The main reasons for people to abandon health apps or wearables after a certain period are, according to Peng et al [38], lack of time and effort and the lack of motivation and discipline. This means that apps or wearables alone cannot trigger a tremendous lifestyle change. The authors identified important reasons for people to use and continue to use health apps and wearables such as social competition,

intangible rewards, tangible rewards, hedonic factors, and internal dedication [38]. To set incentives for nonactive or chronically ill patients to adopt health apps or wearables, tangible rewards like bonus programs might be the most promising tool in the future because “money is one of the biggest motivators” [38]. Petersen et al [39] concluded that tracking health parameters and communication through internet platforms triggers more self-consciousness and leads to patient empowerment.

Effectivity of Health Apps and Wearables to Improve Health

A study from the German Ministry of Health [2] assigned health apps and wearables a significant role in the future and singled out the importance of incorporating self-tracked data into the physician’s daily routine and diagnostics. The stagnating telemedical development in Germany might be one of the major obstacles for the incorporation of DIGAs into the German health care system and needs further attention. However, Albrecht [2] argued that apps should be developed in cooperation with physicians, pharmaceutical companies, and health insurers to better meet the needs of the patients. The author claimed that the continuous use of health apps has a positive effect on personal health [2].

Mercer et al [40] conducted a participant’s study and provided wearables to 32 chronically ill participants (aged >50 years), which they evaluated according to questions derived from the technology acceptance model. They found out that older and chronically ill people perceive wearables as “useful and acceptable.” The use of wearables could enhance the level of PA because the devices create awareness of real motion [40]. Many older participants have not used a smartphone or tablet before and have strong concerns about their competencies. Yet, the technologies could remove barriers between physicians and patients [40]. Ehn et al [11] conducted a similar study. The authors concluded that the overall PA of the elderly increased during the study and that the wearables acted as a significant motivator [11]. However, they defined similar barriers for the use of wearables [11]. Schoeppe et al [5] reviewed 25 apps for children and adolescents and concluded that these apps have moderate quality overall. User engagement while using the app was not satisfactory, and the apps did not respond to individual needs. The authors ascribed to health apps for children and adolescents a high potential effectivity of sustainable behavioral change through gamification. They suggested, similar to Albrecht [2], cooperation of physicians, pharmaceutical companies, health insurers, and app developers [5]. Hartzler et al [41] and Hoffmann et al [42] also stressed the inclusion of gamification and interactive features as main factors for the success of health apps and wearables.

Firth and Torous [43] concluded their literature search by stating that there is still little empirical research available on the effectivity of health apps, specifically as a complementary treatment for schizophrenia: “People with schizophrenia are willing and able to use smartphones to monitor their symptoms, engage in self-directed therapeutic interventions, and increase their physical exercise.” Patients not officially diagnosed with schizophrenia or patients in acute stages report problems with app adherence [43]. Urrea et al [6] predicted that the use of health apps is an effective tool for the prevention of cardiovascular disease. Interventions via apps related to improvement and monitoring of smoking behavior, nutrition, and PA show positive results [6]. Hartmann et al [44], Christmann et al [45], and Ose et al [46] found significant potential of health apps and wearables for the treatment of depression. DIGAs might personalize care and reduce communication barriers with medical doctors. Gabriels and Moerenhout [47] and Martinez-Millana et al [48] concluded that the use of health apps and wearables help improve patients’ awareness and health education.

The Potential of Bring-Your-Own, Self-Tracked Data

Haghi et al [12] ascribed to bring-your-own, self-tracked data an important role because of the predictions and simulations that could be achieved using big data: “The Internet of Things is a new concept, providing the possibility of health care monitoring using wearable devices.” Health monitoring could be done to a large extent autonomously, using sensors like motion trackers, vital signs, and gas detectors [12]. Dimitrov [49] identified 4 main strategies: descriptive analysis, prescriptive analysis, predictive analysis, and simulations. The author predicted potential future savings in the health care sector because most patients could monitor their health by themselves and upload their data to a medical Internet of Things. Data analysis could be achieved using big data and digital health advisors, which could decrease the number of necessary annual visits to physicians [49]. Turankhia and Kaiser [50] agreed with Dimitrov [49] and identified the monitoring of patients at risk of atrial fibrillation with health apps and wearables as tools to increase the rate of early detection and therefore decrease physician visits. Heintzman [51] also argued that the management and monitoring of diabetes through apps could decrease costs for the health care system because the technologies offer individualized guidance. Henriksen et al [21] criticized that self-tracked data is, in most cases, uploaded to brand-specific repositories, which makes it difficult to share data with medical staff or compare data between different applications.

Vahabzadeh et al [52] identified mHealth primarily as a game changer in the treatment of depression and even as a measure of suicide prevention. The author stated that there is great potential to detect the risk of suicide early and to help individuals with specific apps tailored to their needs. However, medical doctors should not solely rely on these technologies for detection and treatment, given the tremendous pitfalls of a potential error [52]. Lüttke et al [53] agreed with the points made by Vahabzadeh et al [52]. They see great potential in the use of DIGAs as complementary to therapy.

Genes et al [4] researched the effectivity of asthma monitoring through health apps and concluded that there was improvement in asthma control and a decrease in necessary physician contact. More importantly, the use of the app helped to reduce barriers within patient-physician communication [4]. Yet, another study showed that the incorporation of bring-your-own, self-tracked data in preventive care programs might be very promising. The reason for the positive outlook is the advancement of patient education through data visualization and a better self-monitoring strategy [1]. However, the widespread adoption of these technologies and integration of the data in routine physician care are challenging [1]. Lobelo et al [1] recommended that health app developers, researchers, regulators, and medical staff conjointly develop solutions to ensure compliance, compatibility, and health data security. Brandt et al [3] conducted a study by interviewing general practitioners in Denmark, and a majority of the general practitioners already used health apps and are generally convinced about the effectiveness but do not “translate that into lifestyle change guidance for their patients.” The authors suggested that health apps and wearables have significant potential to improve diagnostics and are a complimentary treatment for patients.

Chung et al [54] found that patients get better insights about their specific condition and feel empowered and connected. Cresswell et al [55] ascribed the integration of bring-your-own, self-tracked data into the daily routine of physicians as an aspirational role in preventive care and diagnostics. Furthermore, Cresswell et al [55] agreed with Chung et al [54] that self-monitoring of vital parameters and data visualization empower and educate patients.

Knight and Bidargaddi [56] concluded that self-management of mental diseases through apps

leads to patient empowerment and the improvement of clinical care through better understanding. Ramkumar et al [57] agreed with this argument.

Concerns and Data Privacy Risks

Wichmann et al [58] criticized, despite all the potential benefits, the general academic enthusiasm about introducing DIGAs into the health care system, even though there is little empirical evidence about their long-term effectivity, or the usage over several years. Urban [59] conducted qualitative interviews to research the user perception of elderly people. The author claimed that health apps and wearables motivate elderly people to increase their activity, but they also cause them "to develop negative emotions that stand in a charged relationship to aging stereotypes." Elderly, who suffer from severe chronic conditions, feel discomfort integrating these technologies into their daily routine because the apps constantly remind them of their illness [59].

McCallum et al [60] agreed with Urban [59] and argued that the use of DIGAs are currently limited to mainly young and sportive people. To achieve widespread use, the usability and acceptability, especially of people with chronic conditions, need to be improved [60]. Data security issues are one of the main concerns for chronically ill people because they fear discrimination in different parts of their daily life [56]. Montgomery et al [61] supported this claim and demanded government regulation to enhance fairness and equity but also to protect personal data from the sale to third parties.

Groß and Schmidt [10] suggested that patients could be overstrained with the amount of data and sensors available. Hence, patients are not sufficiently trained to read and properly analyze health data and peak graphs. They are not able to assess the data and identify their relevance, which could lead to misinterpretation [10]. The authors also listed positive effects resulting from the use of health apps and wearables for patients like efficiency, control, goal orientation, and better organization [10]. Another major problem discussed in the paper is the concern about data security, the consequences of potential data theft, and data sales to third parties [10].

Hicks et al [62] and Huckvale et al [63] discussed in their studies privacy risks that could result from the use of fitness and health apps. Users of health and fitness apps rely on the ethical operation of app services and need to trust the apps they use [62,63]. However, app services, especially those offering free operation, mainly sell the collected data to third parties and hide these conditions in very long policy terms. The authors examined the privacy policies of 79 popular health apps and found that 89% of the apps communicate with online services and 90% also communicate with "one or more third-party services directly" [63]. The authors criticized that most health and fitness apps "rely mainly on self-declared compliance" [63]. Armstrong [64] came to the same conclusion with a similar study and suggested government regulation for health data processing. Tabi et al [65] and Jamaladin et al [66] also criticized the lack of clarity of conventional app stores and emphasized the need for professional health app stores and medical doctors' recommendation to their patients. Becker et al [67] agreed with Huckvale et al [63] and Armstrong [64] because most health apps are not certified as a medical device, which means that their data protection terms are, in most cases, not supervised by a government agency. However, certification processes take a long time and are expensive. Incentives for the certification of apps are currently missing. However, the German digital care act enables fast track certification for DIGAs, which allows for early market access and a 1-year test phase to prove a positive health care effect [7].

Discussion

During the analysis of 55 of the 136 papers, we found 4 main themes or concepts regarding the introduction of DIGAs in the health care system: users of health apps and wearables; effectivity of health apps and wearables; the potential of bring-your-own, self-tracked data; and concerns and data privacy risks. In terms of the introduction of the digital care act in Germany, health apps and wearables are supposed to have an overall positive effect for patients. The literature shows that patients with chronic conditions especially could benefit from the DVG through self-monitoring and health education but also through reduced communication barriers with their physicians [2, 11, 40, 43, 49].

However, there is still a lack of long-term empirical evidence about the effect of statutory financed DIGAs. Yet, it is not very clear how health app and wearable developers should prove a positive effect on medical care for patients after their 1-year test-phase. Long test phases and costly control group trials are not feasible for health apps and wearables [9]. Many authors criticize the pure amount of health apps and wearables available on the market and the difficulty for people to choose one specific to their needs. They argue that integrating health care staff into the process of app development and recommendation and supervision by physicians would increase the potential benefits of the technology [1, 21].

There are not just potential benefits but also severe direct and indirect privacy concerns and the fear of discrimination, for example, through the employer or health insurance company [68]. Users, especially in Germany, lack trust in many app providers concerning their data because of missing transparency. This is the reason why data privacy and data security are a major part of the DIGA certification process resulting from the digital care act. Hence, this is also why patient-tracked data is not automatically forwarded to the statutory sickness funds or the physicians. The patient should remain the owner of his data [9].

Transparency about data processing might be one of the major solutions to data privacy concerns. Users are generally more willing to share their data if application services are transparent about data processing than if it remains unclear or the user feels betrayed [69]. In European countries, personal data is understood to be personal property, and regulations such as the European General Data Protection Regulation (DSGVO) are set to protect this property [69].

In a second digitization phase, Germany could introduce another regulation that enables health care providers to offer patients a digital dividend to use their self-tracked data for research purposes. However, to price self-tracked health data might be very difficult because the users generally overestimate the price of their personal data: “By its nature, personal data is non-rival, cheap to produce, cheap to copy, and cheap to transmit” [69].

A recent study showed that many people in Germany are willing to share personal data in exchange for benefits or rewards: 12% agreed, 40% disagreed, and 48% did not want to answer the question [70]. Yet, 30 million German consumers use the Payback program initiated by the American Express Group, which involves selling consumer data for bonus points in certain stores [71]. Many people are not directly aware of the fact that they sell their data to Payback GmbH and the company sells the data to third parties [72]. When directly asked, people are often very sensitive to the commercial exploitation of personal data [73]. In the experiment by Cvrcek et al [73], the median bid accepted for location data was €43 (US $51.06). An experiment by Grossklags and Acquisti [74] showed that most participants are willing to sell their data but are not willing to pay for the protection. The average WTA for their data about individual quiz performance was US $7.06 and for their personal personal information was US

$31.80. The WTP to protect both types of data was US $0.80 [74]. The authors discovered that the type of personal data is individual and emotionally charged, influencing the WTP and WTA decision. When participants were asked about the number of their previous sexual partners, average WTA was US $2291.30, and WTP was US $12.10 [74]. Going a step further, when asked to auction their weight, age, and height, probands with a BMI below average demanded lower compensation to make their weight publicly available than probands with a BMI above average [75].

Hence, Von Wedel et al [76] showed that there is general interest in the inclusion of digital and mobile services in the German health care system. Yet, this gives a positive outlook for the success of the digital care act in Germany. According to the studies reviewed, we predict a high demand for DIGAs from young and healthy adults in the beginning. Yet, we believe that chronically ill and elderly patients benefit to a large extent from the regulation, which is why physicians and doctors should act as mediators and recommend, supervise, and accompany app use.

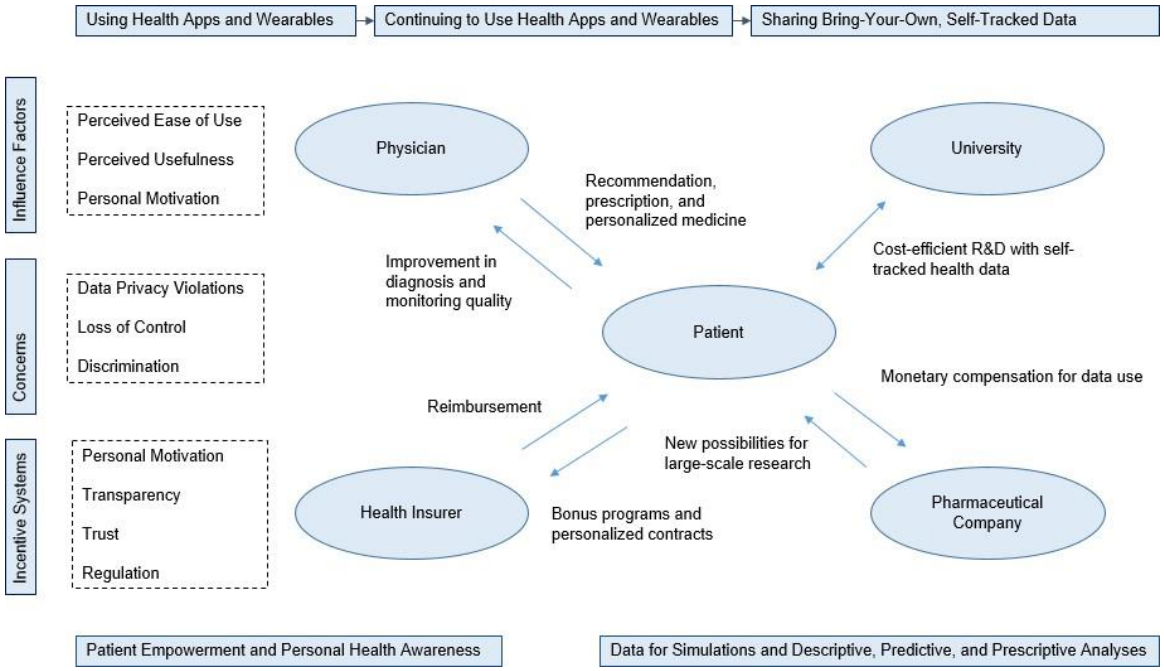
Three main stages of potential benefits for the German health care system were identified in the literature: usage of health apps and wearables [25, 28, 52], continuing usage of health apps and wearables [6, 59], and sharing self-tracked data with agents in the health care sector [4, 12]. Figure 2 shows the different stages mapped against the identified influence factors, concerns, and potential incentive systems.

The literature assigns each of the stages potential benefits when integrated into the health care system. The decision if individuals use health apps depends to a large extent on the perceived ease of use, perceived usefulness, trust, peer influence, personal health status, and technology literacy. Main concerns about the use of health apps and wearables discussed are data privacy violations or physical discomfort [26, 27]. Whether an individual decides to continue to use a health app or wearable depends on the usefulness of the app to achieve certain goals, personal discipline, motivation, and trust. The concerns about continuing to use an app or wearable seem to be almost identical to the ones about starting to use an app, but even more sensitive to personal discomfort and the individual distortions of chronic diseases [32, 38]. Presuming that the use of health apps and wearables has positive effects on the prevention of certain disease or aids treatments, the reasons why people stop using apps should be further studied, as well as potential incentive systems to assist people to continue to use these apps.

Some incentives named within the literature are bonus programs or physicians' recommendations. The last stage is the potential and willingness to bring along or share self-tracked data with different agents in the health care system. People seem to have very strong concerns about voluntarily sharing their self-tracked health data, which range from price discriminations to a lack of transparency and social embarrassment [37].

Referring to the research question of this paper, the digital care act and the introduction of statutory financed DIGAs could be considered societally beneficial. The widespread use of DIGAs allows patient empowerment, better monitoring of chronic diseases, and individualized advice. These benefits could not only reduce the number of mandatory visits to physicians and therefore the ever-growing expenses for the health care system but also lead to better resource allocation and improved treatment quality. Yet, Germany is the first country worldwide to introduce prescribed DIGAs. This is a significant chance to enhance digitization in the German health care sector and to build a foundation for a digital dividend to buy self-tracked patient data for research purposes. Yet, this experiment also bears risks when considering the volatile patient trust in data security.

Figure 2: *Stages From Use to Continuous Use to the Sharing of Self-Tracked Data*



Source: Own Depiction.

Limitations

This study might be affected by the limited amount of available research resulting from the search terms. This might give a unilateral perspective on the effectivity of health apps and wearables. Hence, we are always concerned about the selection bias of articles. However, the multidisciplinary perspective on the field of study, enhanced through articles from different schools of thought and different research disciplines, as well as the applied rigor of scoping studies, have contributed to eliminate the selection bias to a large extent. Further research should be conducted after the first DIGAs are certified and have entered the German health care market.

Conclusion

To conclude, 55 of the 136 articles were analyzed within this scoping study. First, 4 key themes were identified: users of health apps and wearables; effectivity of health apps and wearables to improve health; potential of bring-your-own, self-tracked data; and concerns and data privacy risks.

In December 2019, Germany passed the digital care act, which enables the statutory financed prescription of digital health devices by medical doctors. Based on this scoping study, we predict an overall beneficial effect for German patients, treatment quality, and general health literacy of the population. The main benefits are going to be visible in the fields of preventive care and patient monitoring and disease management. Three main stages of potential benefits for the health care system were identified: using health apps and wearables, continuing to use health apps and wearables, and sharing bring-your-own, self-tracked data with different agents in the health care sector.

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Discrete Choice Experiment

Pricing through Health Apps Generated Data – Digital Dividend as a Game Changer: A Discrete Choice Experiment[5]

Introduction

The COVID-19 crisis highlighted the importance of using the potential of patient generated health data (PGHD) not only to track personal encounters, but also for big data research and to understand various under-researched conditions that lead to acute or chronic diseases. For example, the Robert Koch Institute (RKI) has launched a COVID-19 data donation app in Germany [77]. Users may allow the app access to their wearables and donate any data recorded from health apps or tracking devices. The use of health apps and wearables enjoys ever-increasing popularity within society [1]. However, the willingness to donate self-tracked data might be of short duration, considering the special circumstances of the COVID-19 pandemic and the therefore current high level of trust the RKI holds within German society. A more sustainable and lasting solution to gain access to self-tracked data for research and development (R&D) purposes might be the payment of monetary compensation – a digital dividend.

The lack of transparency concerning data processing among some health app providers triggers trust issues and data privacy activism in most countries that are members of the Organization for Economic Co-operation and Development (OECD). Calls for compensation strategies such as a digital dividend are increasing steadily, as evidenced in German political debates about regulatory possibilities of such a dividend [78]. In most OECD countries, personal data is understood to be personal property. Regulations, such as the European General Data Protection Regulation (GDPR) and its translation into German national law, DSGVO, have evolved to protect the individual's data property, which means that a digital dividend becomes an ever more realistic future scenario.

Health data is understood to be among the most valuable personal data. The pharmaceutical industry in particular could experience significant benefits from engagement in big data research of realistic daily health data and increased efficiency over long and costly clinical trials as a result [79]. German government aims to become a data hub and buy large amounts of personal data as part of their digital strategy [80]. In December 2019, Germany passed the digital care act (Digitale Versorgung Gesetz, DVG), enabling physicians to prescribe health apps. Statutory health insurance companies will reimburse the costs for health apps to the individuals they insure, which is an internationally unique system of health app usage encouragement [7].

First, to research users' estimated willingness to accept a certain monetary compensation payment - a digital dividend - for sharing self-tracked health data and second, to determine the main factors for such a trade, we conducted a discrete choice experiment (DCE) in Germany. DCE is a choice-based survey method used to research people's preferences for different options in realistic choice scenarios, contrary to asking them directly about their preferences. We chose this method because people tend to have strong opinions about selling personalized

[5] Heidel A, Hagist C, Schlereth C. Pricing through Health Apps Generated Data in Germany - Digital Dividend as a Game Changer: Discrete Choice Experiment. PLOS ONE. 2021 JUL, doi: 10.1371/journal.pone.0254786 [14]

data when asked directly [78]. Previous experiments in lab settings led to demands for high monetary compensation for personal data [73, 75, 81]. We used a specific type of DCE, separated adaptive dual response (SADR), to get a more realistic picture of preferences. The experiment was launched before the outbreak of COVID-19 in Germany.

Therefore, we are going to answer the research question under which circumstances wearable and health app users would accept a digital dividend for their self-tracked health data. To answer the research question, we conducted two identical studies with different prices to test the general robustness of price estimates, as we expected people to overestimate the monetary value of their self-tracked data.

Background

Research about price expectations for self-tracked health data is still sparse. As the RKI COVID-19 data donation app was found to fight the severe social and physical effects of the pandemic, the data donation model enjoyed a significant trust advantage. Hence, there is already severe criticism of the RKI data donation model because the donated data is not pseudonymized directly. This leaves a security loophole and facilitates data misuse as well as identification of personalized fitness histories [82]. As soon as the RKI loses people's trust in its approach to data processing and the threat of the COVID-19 pandemic has eased, the donation model might become obsolete. Even though Skatova and Goulding argue that people donate their data mainly for altruistic reasons [83], the donation model does not reach a large-scale and diverse group of people [82], which would be needed for big data research with self-tracked data.

New technologies such as artificial intelligence and big data offer unprecedented possibilities for use of self-tracked health data in research and development (R&D), which would therefore decrease the costs and duration of expensive control group studies. This might be the next milestone in medical research. Self-tracked data is going to provide new insights using prescriptive, descriptive, predictive analysis and simulations [83-86], potentially improving treatment quality, preventive care, and diagnostics [85]. Hence, research about incentive systems to trigger a large and diverse group of users to share their data for R&D purposes is essential. Bataineh et al. criticized the market for personal data because it shows a significant imbalance [87]. App users are currently not compensated for the provision of their data, and the authors further criticized the lack of an adequate platform to monetize and trade self-tracked data [87]. The question about the compensation that people are willing to accept remains unsolved. This is despite the fact that there have already been some research attempts at answering this question, as described in the following section. However, an SADR study, i.e. a well-aligned, trade-off-based approach, has not yet been performed, even though the settings in this type of study allow for more realistic results.

Wathieu and Friedman analyzed the lack of confidence in online services and app providers and the general rejection of personal data trade [68]. Spiekermann et al. researched the conditions of the international market for personal data. They concluded that people tend to overestimate the monetary value of their data because they do not feel comfortable with the possibility of their data being linked back to them [69]. Many people have little knowledge about the market for personal data and barely know that the data of a single person is rather worthless. However, statistical clustering and digital phenotyping might help to find patterns or gain new insights about the occurrence of different chronic diseases [69]. Therefore, it might be difficult to find a realistic price for health data, depending on personal attitudes and

preferences. People often claim strong data privacy concerns, but over 30 million Germans use the payback system, a commercial bonus program offered by the American Express Group. This program enables the trade of consumer shopping information for bonus points. One bonus point equals one Euro Cent [71].

Cvrcek et al., Grossklags and Acquisti, and Hubermann et al. conducted experimental studies to estimate willingness to accept (WTA) and willingness to pay (WTP) for the disclosure of different personal information [73-75]. WTA demonstrates the minimum amount of money one has to offer an individual in order for them to give up a specific good or service. At the same time, WTP illustrates the maximum amount of money an individual would be willing to pay for a service or a good [88]. Many studies showed a significant disparity between WTA and WTP for the same good, which may relate to some form of loss aversion [88]. Aquisti et al. state that "what people say their data is worth depends critically on the context in which they are asked" [74]. This means that people's perception of their data's monetary value depends to a large extent on whether they are asked for their data to be protected or whether they are asked to sell their data.

Estimating WTA for PGHD seems difficult because personal price expectations are influenced by opinions, experience, settings, and attitudes. The amount may differ for each individual and depends on how emotionally charged the information is. For example, Cvrcek et al. discovered that participants would agree to publish their smartphone location points for 43.00€ [73]. Grossklags & Acquisti, on the other hand, conducted a quiz with participants and found that people would publish their quiz results on average for $7.06 USD and their personal information for $31.80 USD [74]. The WTP for protecting the same data was below one USD. When asked about number of sexual partners, the WTA averaged $2291.30 USD, and the WTP to protect the same data was $12.10 USD [74]. Such examples illustrate the significant gap between people's WTP and WTA for data privacy, which results from missing transparency about data processing and a lack of data privacy education. Many app providers offer their services free of charge for the user but sell user data to third parties or use advertisements on their platforms to finance their businesses. Users are often unconscious of these financing models. Furthermore, WTA depends to a large extent on the type of information provided. Hubermann et al. asked participants to auction information about their age, weight, and height for their study. They concluded that participants with a higher body mass index demanded higher prices for the information about their weight than people with a body mass index below average [75].

These experimental studies are groundbreaking in drawing a bigger picture about the practicability of a digital dividend. Participants were not asked to share their continuous real world health data in other experimental studies. In some studies, researchers were able to link the information back to the individuals [73-75, 88], whereas in reality, data should be stored and sold anonymized or at least pseudonymized. Making personalized data publicly available often leads to a feeling of embarrassment and, therefore, leads to people demanding higher prices for their information [89]. In most experiments [81, 75, 88], participants would agree to a one-time data trade for a single payment, whereas a continuous data exchange would be more feasible for large research projects; this is why a continuous digital dividend seems more realistic than a single reward for our study. The literature shows that transparency about data selling to third parties, as well as the nature of health data in particular, seem to be essential factors for the dividend demanded [78, 75, 68, 90]. Research about different incentive systems to trigger people to share their data with different R&D institutions is becoming increasingly important because large-scale self-tracked health data simulations could become a game

changer in the fight against the COVID-19 pandemic and beyond. This paper contributes to the current political and academic debate about a digital dividend for self-tracked health data, offering a different and more realistic methodological setting.

Data and Methods

To research the digital dividend demanded for self-tracked data, we conducted a DCE. Contingent valuation was no option for the purpose of our study because users had no price demand experience. Our study settings did not allow respondents to directly state their WTA but rather asked about their preferences for different real-world scenarios [91]. If asked directly, people with strong data privacy concerns and opinions tend to block any imagination about selling their self-tracked health data in surveys or interviews, leading to observations of extreme response behavior. Previous experiments in lab settings led to high demands for monetary compensation [81]. Another method might have been a quantitative data analysis with proxy values for data prices. Databases for digital data prices barely exist. Known models to estimate the price of personal data might include payback estimates [71]. However, these are not suitable to calculate the price of health data because health and health data are special goods. We expected that patient generated health data would be more valuable for the stakeholders than shopping data. In our online experimental survey, we showed respondents various offers for their self-tracked data. They had to decide which combination of circumstances they preferred and whether they accepted the offer. Based on these decisions, we estimated the extent to which each attribute level contributed to the observed decision [92].

Between May and October 2019, we conducted two pre-studies with 35 and 100 respondents prior to the final data acquisition, targeting primarily students from our University's network, who most likely used health apps or wearables to track health. Hence, we ran a power analysis using the results from the 100-respondent pre-test according to Bekker-Grob et al. [93]. The results showed that we needed a minimum of 192 respondents for each questionnaire when applying a significance level of $p \leq 0.05$. In December 2019, we conducted the main study over a period of three weeks with 842 respondents, and a second, identical study with 272 respondents which contained lower prices. We launched the second study with lower prices to test the price estimates of the main study for robustness. We carried out the two studies through a professional panel provider, Norstat GmbH, and targeted German speaking respondents aged 18 years to 99 years. By signing their terms and conditions, we committed ourselves to follow their code of ethics and the ESOMAR guidelines. In line with our power analysis, more than 192 respondents participated in either of the questionnaires.

Attributes and Attribute Levels

We conducted a scoping review, which can be found in a previous study [13], to decide on attributes and levels. Additionally, we used purposeful sampling for this study to identify the current state of experimental studies on the monetary value of health data [94]. To further validate the arising attributes and levels, we run an online survey about the importance of different attributes. Sixteen individuals participated in this survey; most of them were between 26 and 35 years old, users of health apps or wearables, and generally fit. Participants had to rank different attributes according to their perceived importance for the decision to sell their self-tracked health data. *Type of data storage* and *data sales to third* parties were the most important attributes for the decision to sell self-tracked data. The attribute *app provider* was not important to the respondents because the decision to trust an app provider had previously taken place when downloading or purchasing the app. Most participants claimed that the

specific *type of data* had a significant effect on the decision. We performed the first pre-study with 35 respondents and consequently eliminated the attribute *type of data storage* because respondents would solely focus on this attribute and ignore all others. Because of current public data protection initiatives, it is highly unlikely that stakeholders in the health care sector would be allowed to store personalized data. The second pre-study with 100 respondents led to the final validation of four attributes: monthly bonus payment (5€–75€ or 10€–31€), stakeholder (health insurer, pharmaceutical, and medical device company or universities), type of data (motion and cardio data, nutrition and lifestyle data or all data with health relevance) and data sales to third parties (raw data is going to be sold for profit, raw data is not going to be sold for profit or raw data is not going to be sold, statistically processed data is going to be sold). Table 1 shows the attributes and levels with which the respondents were confronted in the DCE survey [Multimedia Appendix 2].

Table 1: *Attributes and Levels*

Attributes	Levels							
Monthly Bonus Payment[6]	5€	15€	25€	35€	45€	55€	65€	75€
Monthly Bonus Payment[7]	10€	13€	16€	19€	22€	25€	28€	31€
Stakeholder	Health Insurer	Pharmaceutical and Medical Device Companies	Universities					
Type of Data	Motion and Cardio Data	Nutrition and Lifestyle Data	All Data with Health Relevance					
Data Sales to Third Parties	Yes, raw Data is going to be sold for Profit	No, raw Data is not going to be sold for Profit	Raw Data is not going to be sold, statistically processed Data is going to be sold					

Source: Own Depiction.

Experimental Design

The experimental design of the DCE simulates realistic decision scenarios, which illustrate the preferences of the respondents. Given that sharing health data is emotionally charged, we used the DCE alternative SADR to reduce extreme response behavior. The SADR method requires respondents to choose first among forced choice options and second among free choice options. Using the respondent's choice probability, which depends on the utility of the scenario selected and the other competing scenarios within the choice set, we estimated the minimum price at which respondents would sell their self-tracked data [95].

DCEs have been observed as being "popular preference elicitation methods, yet they can suffer from context effects, extreme response behavior, and problems with estimating consumers' willingness to pay" [96]. SADR outperforms traditional DCEs because the method first measures the attractiveness of all attributes and uses this information to adaptively identify

[6] Main Study
[7] Second Study

towards which offer a respondent becomes indifferent when accepting it [96]. Thus, SADR provides advantages in situations in which the threshold between accepting and not accepting an offer is heterogeneous across respondents. We conducted the study using the Dynamic Itelligent Survey Engine (DISE) online platform [97].

We first presented ten choice sets to the respondents, for which we forced them to decide between three different offers. We used a D-efficient linear probability model to estimate the main effects of attribute levels. The design D-efficiency is 97%. The reason why we chose to include an extraordinary amount of monthly bonus payment levels is because of price uncertainties. Estimating a realistic price for personal health data is difficult because there is no market price yet, so we chose eight levels for this attribute, given the unaffected design efficiency. We assumed a linear relationship for the price. The higher the offered price, the more likely data will be sold. The attributes are independent, and a level balance is given [98].

In the second part of the experiment, we adaptively generated six offers and asked respondents, whether they would accept or not. Schlereth and Skiera stated that the adaptive offer generation mechanism ensures that decisions are not biased through endogeneity [96, 99]. To avoid order effects, we randomized choice set order across respondents [100].

To test the robustness of the price estimates obtained from the main study, a second study was run in parallel with an alternative range of possible prices to account for the anchoring effect. Subjects were randomly assigned to either the main study or to the second study. Bevan & Pritchard described the phenomenon as follows: “Anchor effects are systematic changes in the judgement of series stimuli” [101]. This means that people who have no price expectations tend to take the given prices as an orientation point or an anchor. Hence, this means that the price expectations could be strongly correlated with the prices offered during the experiment.

Data

In December 2019, 842 respondents participated in the main study, and 272 respondents participated in the second study of our online experiment through the online panel Norstat GmbH. Norstat GmbH confirmed that our survey followed the ESOMAR international code on marketing, opinion, social research, and data analytics. All respondents’ data was stored pseudonymized on our university server in Germany. We requested no personal information from the respondents, and the answer to socio-demographic questions was voluntary and could be left out. Participation in the survey was also voluntary. Minors (<18 years old) did not participate. Respondents agreed to the terms and conditions before participation, first with Norstat GmbH and then when participating in our survey. We ensured the quality of answers by integrating an attention question, which resulted in the exclusion of respondents who did not attentively read the questionnaire. The attention question required that option B be chosen out of options A, B, C, and D. The main study contained a price range from 5€ to 75€ for certain circumstances to share self-tracked health data with different stakeholders. The sample reflected a heterogeneous group of German citizens [S5 Table].

Our sample consists of 47% (397/842) female respondents and therefore shows a gender balance. About 34% (298/842) of the respondents use health apps or wearables to track their health, and just about 4% (36/842) share their data with family, friends, physicians, or on social media platforms. Still, 73% (611/842) of the respondents would share their self-tracked data with physicians for better diagnostics and therapy. To ascertain the level of trust in different agents with their personal health data, respondents were instructed to distribute 100 points so that the agents trusted most would score the highest number of points. The results showed

that physicians scored on average 57.2 trust points, health insurance companies 15.5, universities 14.7, medical device companies 4.1, government institutions 3.5, pharmaceutical companies 3.3 and social media companies 1.7. This means that main research institutions in particular, like the pharmaceutical industry, government institutions, and medical device companies, score very low trust levels within German society.

Econometric Modeling

We estimated choice probabilities using methods similarly to those used by Schlereth et al. [100]. We ran a random utility framework to evaluate individual choice preferences [102]. Hence, we estimated a hierarchical Bayes multinomial logistic regression model using the software MATLAB [99]. Using an iterative process, the model evaluates the results on two levels; aggregate and specific behavior [99]. Significance levels and t-statistics are usually not assessed because through a large number of iterations, the ex post distribution is almost always significant [99]. The estimation assumes that a respondent h desires offer i, which maximizes his or her utility, given the utility function:

1.) $u_{h,i} = v_{h,i} + \varepsilon_{h,i}$ [100]

$u_{h,i}$ is the utility of a respondent to choose a digital dividend offer under specific circumstances for his or her self-tracked health data. $v_{h,i}$ is the deterministic part of the utility and contains all the observable information shown in the choice-sets, like all levels of the different attributes, while $\varepsilon_{h,i}$ is the error term and contains all unobserved information [100].

To determine the log-normal probability distribution of individuals selling their data under specific conditions to one stakeholder versus another, we use the following formula:

2.) $Pr_{h,a}(i) = Pr_{h,a}(i|1st\ choice) \cdot\ Pr_h(i|2nd\ choice)$

$$= \frac{\exp(v_{h,i'})}{\sum_{i' \in C_a} \exp(v_{h,0})} \cdot \frac{\exp(v_{h,i})}{\exp(v_{h,0}) + \exp(v_{h,i})}$$

$(h \in H, a \in A)$ [100]

$Pr_{h,a}(i)$ is the probability the participant h chooses the pricing plan i for each choice-set a [100]. H is the set of all respondents, A refers to all choice-sets in the experiment and C_a to the decision alternatives for prices shown in the first question of the choice-set [100]. Formula 2 illustrates a non-sequential model, hence we assume that two choices in a choice-set are independent by multiplying both corresponding probabilities [100, 103]. The multinomial logit model is conducted to resolve for the differences in consistency between the forced-preference question set and the free-acceptance question set [104], using the following formula:

3.) $L_h = \prod_{a \epsilon A} \prod_{i \epsilon C_a} \left(\frac{\exp(v_{h,i})}{\sum_{i^{\sim} \epsilon C_a} \exp(v_{h,i^{\sim}})} \right)^{d_{h,i,a}} \cdot \prod_{i' \epsilon C_{h'}} \left(\left(\frac{\exp(v_{h,i'})}{\exp(v_{h,0}) + \exp(v_{h,i'})} \right)^{d_{h,i'}} \cdot \left(\frac{\exp(v_{h,0})}{\exp(v_{h,0}) + \exp(v_{h,i'})} \right)^{1 - d_{h,i'}} \right)$

$(h \in H)$ [100]

L_h is the likelihood for predicting respondent h's observed choices [100]. The first part computes the probability that the respondent observes the decisions $d_{h,i,a}$. The second part estimates the probability of accepting ($d_{h,i'} = 1$) and not accepting ($d_{h,i'} = 0$) a concrete offer i from his or her set of individually seen offers $C_{h'}$ [100].

In a next step, we calculated the estimated $WTA_{h,i}$ of respondent h for offer i as a minimum marginal price people would accept to share their self-tracked health data, using the following formula:

4.) $WTA_{h,i} = \frac{X_i \cdot \beta_h}{\omega_h}$ [95]

In this formula, X_i is the design vector, β_h is the preference vector, and ω_h is the price parameter [95]. This way, we measured whenever a respondent became indifferent between accepting a monthly bonus payment offer or rejecting it, which implies that the utility of selling self-tracked data at a specific price, equal to his or her WTA, has the same price as the utility of not selling [95].

Results

Parameter Estimates

We estimated the parameters using a hierarchical Bayes multinomial logistic model, using the software MATLAB [100, 103]. The ß-parameter depicted in Table 2 measured the relative importance of a certain level of an attribute over another for each respondent's choice [95]. Through a careful selection of attributes and levels prior to the study, we offered as realistic scenarios as possible from which respondents could choose [105].

Table 2: *Parameter Estimates and Importance Weight of Attributes - Main Study*

Attribute	Level	ß-Parameter Average (Standard Deviation)	Importance Weight (Standard Error)
Constant Parameter		-2.45 (2.37)	
Monthly Bonus Payment	5 EUR - 75 EUR	0.09 (0.42)	20.70% (1%)
Stakeholder	Health Insurer	-0.06 (1.03)	23.82% (1%)
	Pharmaceutical and Medical Device Companies	-0.55 (0.73)	
	Universities	0.61 (0.76)	
Type of Data	Motion and Cardio Data	0.23 (0.45)	11.31% (0%)
	Nutrition and Lifestyle Data	0.12 (0.25)	
	All Data with Health Relevance	-0.35 (0.50)	
Data Sales to Third Parties	Yes, raw Data is going to be sold for Profit	-2.56 (1.91)	44.17% (1%)
	No, raw Data is not going to be sold for Profit	1.54 (1.14)	
	Raw Data is not going to be sold, statistically processed Data is going to be sold	1.03 (0.92)	

Source: Own Depiction

Data sales to third parties scored by far the highest importance weight (44.17%). If raw data is going to be sold to third parties, it is highly unlikely that individuals will choose to share their data with different agents. Hence, the sharing of personalized data is a value-laden topic. The results showed that people were sensitive to transparency about data processing and data security because they are afraid of discrimination. This supports the claims of Wathieu and Friedman that people are very concerned about indirect data security due to missing transparency during data processing [68]. The second most important attribute was the stakeholder. The pharmaceutical industry, medical device companies, and health insurers seem to suffer from large trust deficits. However, monthly bonus payments had an importance weight of 20.70%.

The results showed that a digital dividend could be an effective economic incentive system to motivate people to share their data for R&D purposes with different agents. The type of data was the least important attribute. People were less willing to share nutrition and lifestyle data than just motion and cardio data. We could not find any indicators that socio-demographic factors, such as age or gender [Multimedia Appendix 2], influenced the results in any particular way [106].

Willingness to Accept

Table 3 shows the estimated WTA participants demanded from different stakeholders if data was not sold to third parties and all their data with health relevance was shared in our experiment.

Table 3: *Willingness to Accept to share Self-Tracked Health Data – Main Study*

Stakeholder	Scenario	Mean Willingness to Accept (EUR/Month), Price Range 5€ -75€[8] (Standard Error)
Health Insurer	▪ All Data with Health Relevance ▪ Raw Data is not going to be sold for Profit	177.41 EUR (10.71 EUR)
Pharmaceutical and Medical Device Companies	▪ All Data with Health Relevance ▪ Raw Data is not going to be sold for Profit	237.80 EUR (14.36 EUR)
Universities	▪ All Data with Health Relevance ▪ Raw Data is not going to be sold for Profit	145.66 EUR (10.69 EUR)

Source: Own Depiction

The price expectations seem high but show that a digital dividend could be a working economic incentive system as many respondents were ready to share their data for a certain price. When considering a scenario in which all data is going to be shared and raw data is not further sold to third parties, universities would have to pay 145.66€/month to use the data. Health insurers would have incremental costs of 31.75€/month and pharmaceutical, and medical device companies would have incremental costs of 92.15€/month compared to universities. These price differences might be explained by a trust delta between the different stakeholders.

When plotting the estimated WTA of the scenario in which all data is shared and no data is sold to third parties with different stakeholders in histograms [Multimedia Appendix 2], we observed a bimodal or a u-shaped distribution between low price expectations (0€–5€) and high price expectations (>50€). When the scenario is offered by the health insurers, 28.62% (241/842) demanded 0€–5€ and 48.81% (411/842) demanded >50€. Similar distributions can be observed for the pharmaceutical and medical device companies as 38.95% (328/842) demanded 0€–5€, and 48.81% (344/842) demanded >50€, and the universities, as 45.97% (387/842) demanded 0€–5€ and 32.67% (275/842) demanded >50€. These differences between the two extreme poles of nearly donating self-tracked data and demanding high prices explain the high average estimated WTA and demonstrate that people have no consolidated price expectations or general knowledge about the monetary value of patient generated health data.

[8] Negative individual price calculations have been substituted with 0.00€ because negative prices appear within the calculations if the participants have a very strong feeling about data sharing. These prices are, however, unrealistic in a real-world scenario and distort the average price outcome.

A more realistic price scenario might be 15€–20€ per month, which was tested by Facebook in the "Atlas" experiment [107]. However, the project was criticized because teen users were asked to download a VPN, which tracked and stored personalized data from all other apps, including messaging and social media, on the device [107]. Facebook paid the participants $20/month USD.

In our study, considering a scenario if all data with health relevance was sold and no data sales to third parties took place for 20€/month; 54.91% of the participants would accept the offer from the university, 46.65% from the health insurer, and 38.87% would accept the offer from pharmaceutical or medical device companies. When offering 15€/month to share just cardio and fitness data and no data sales to third parties, 60.60% would accept the offer from the university, 52.45% from the health insurer, and 45.02% from the pharmaceutical or medical device company. We observed that people generally have high price expectation for their digital dividend because they overestimate the monetary value of their self-tracked data.

Pricing Robustness Test

To test the estimated WTA of the main study for robustness, we assigned respondents randomly to one of two identical questionnaires with varying price ranges to account for the anchoring effect. From among a total of 1,114 participants, 842 were directed to the main study with a price range of 5€–75€ and 272 were directed to the second survey with a reduced-price range of 10€ –31€ (Table 4).

Table 4: *Willingness to Accept to share Self-Tracked Health Data – Second Study*

Stakeholder	**Scenario**	**Mean Willingness to Accept (EUR/Month), Price Range 10€ - 31€[9] (Standard Error)**
Health Insurer	▪ All Data with Health Relevance ▪ Raw Data is not going to be sold for Profit	67.56 EUR (7.43 EUR)
Pharmaceutical and Medical Device Companies	▪ All Data with Health Relevance ▪ Raw Data is not going to be sold for Profit	93.35 EUR (9.04 EUR)
Universities	▪ All Data with Health Relevance ▪ Raw Data is not going to be sold for Profit	61.85 EUR (8.27 EUR)

Source: Own Depiction

Comparing the results of the main study with the second study, we observed an anchor effect as we got lower WTA estimates in the study with lower initial prices. The results of the second study showed that people did not have any experience with or expectation of the monetary value of their health data and yet overestimated their price. Furthermore, our output validated the argument that most stakeholders in the health care sector suffer from a lack of trust, which is why health insurers and pharmaceutical and medical device companies would need to pay higher prices for patient generated health data than universities.

In a scenario in which all data with health relevance was shared for 20€/month, and no data sales to third parties took place, 62.86% accepted the offer from the universities, 56.06% from

[9]Negative individual price calculations have been substituted with 0.00€ because negative prices appear within the calculations if the participants have a very strong feeling about data sharing. These prices are, however, unrealistic in a real-world scenario and distort the average price outcome.

the health insurers, and 45.51% from the pharmaceutical and medical device companies. When offering 15€/month for sharing just cardio and fitness data and no data sales to third parties took place; 63.94% accepted the offer from the universities, 57.65 % from the health insurers, and 47.28% from the pharmaceutical and medical device companies. These results were very similar to the ones from the first study and showed the general robustness of the data.

The robustness test showed that the design of the offer and the amount of the digital dividend demonstrated to participants had an observable effect on the respondents' price expectations. Even though the prices might be high, we observed that a monetary incentive could be an accepted instrument to continuously acquire a large and diverse amount of self-tracked health data.

Discussion

In this research, we complemented the current political discussion about a potential legal setting for digital dividends. The results of our analysis clearly showed that participants would share their health data for a digital dividend if no data sales to third parties occurred and stakeholders were transparent about data storage and processing. Hence, we derived from our results that German stakeholders in the health care sector in general and pharmaceutical companies in particular suffer from a significant lack of trust, which directly influences the price expectations for data. We agree with Spiekermann et al. and Wathieu and Friedman that people have difficulty estimating the monetary value of their data because they have little or no knowledge of its statistical use in R&D [68, 69]. However, we used a different experimental setting than previous studies have because we offered a monthly bonus payment to the participants for a continuous data exchange, rather than single payment for a one-time disclosure of personal data.

Our analysis also showed that socio-economic factors are either irrelevant to or play no role in whether a person would share his or her data with a health care stakeholder, if the stakeholder earns enough trust and is transparent about data use and processing. This conclusion might be especially interesting for the enhancement of pharmaceutical research because self-tracked data from a diverse group of people might complement or replace control group studies [108-110].

The robustness test showed an anchor effect for the prices [101], i.e. that people had no expectations or knowledge about the price of digital health data. Hence, this might be a chance to introduce a digital dividend because the market may set the price at first. The estimated WTA levels resulting from the study were higher than the attribute levels, which again signals the uncertainty about prices and the participants' diverging expectations. Future research should address the stakeholder side because we do not know if the participants' estimated WTA matches stakeholders' WTP. Hence, given the COVID-19 crisis and a conceivable resulting change of long-run preferences, a second study with lower prices should be repeated in the future. Price expectations might have changed because of the sensitization for the need to enhance and complement research with big data PGHD studies after the COVID-19 crisis.

Conclusion

In summary, stakeholders within the health care sector should engage in more transparency about data storage and data sales to third parties. Such an effort can encourage people to

share their self-tracked data with them for R&D. These companies seem to enjoy a low level of trust concerning the processing of personal data. People tend to overestimate the monetary value of their health data, which resulted in high prices demanded. Respondents were generally sensitive to further data sales to unknown third parties.

Nevertheless, the results showed that a digital dividend could be an accepted instrument to convince people to share their data for R&D purposes, having an importance weight of nearly 21%. The pharmaceutical industry in particular would benefit from the inclusion of big data PGHD research. There are high incremental costs for health insurance, pharmaceutical, and medical device companies in comparison to universities. Under certain conditions, 54.91% of the participants would sell their self-tracked data to universities, 46.65% to health insurers, and 38.87% to pharmaceutical or medical devices companies for 20€/month. When considering the scenario that all data is sold and raw data was not further sold to third parties, then universities would have to pay 145.66€/month to use the data. Health insurers would have incremental costs of 31.75€/month and pharmaceutical and medical device companies would have incremental costs of 92.15€/month compared to universities. For agents who would like to buy self-tracked data, it would be advisable to encourage more transparency and educational campaigns about their data processing and data security strategies to increase people's trust by dissolving the fear of personal discrimination.

A continuing success of the data donation model in Germany is questionable because people were triggered by the events of the COVID-19 crisis when engaging with the RKI data donation app. The discussions about the data security of the RKI data donation app already sparked fear about a lack of transparency and possible discrimination through data misuse. Transparency, trust, and monetary compensations are effective long-term measures to convince a diverse and large group of people to share their high-quality data. Hence, this is also an encouraging result as PGHD-research may help identify the reasons for chronic diseases or severe conditions. The public discussion about patient generated health data usage in R&D might also increase general health app usage and, therefore, health education through self-monitoring.

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Multi-Method Study

The Digital Care Act – A Chance to Relieve the Dust from the German Health Care System: A Multi-Method Approach[10]

Introduction

Germany is the first country worldwide to launch a digital care act (Digitale Versorgung Gesetz, DVG) in 2019, which enables medical doctors to prescribe health apps and wearables as treatments to their patients [7]. Therefore, health apps will become part of the German standard care basket paid by the statutory health insurance companies. Previously, health apps were offered on a voluntary and discretionary basis depending on the decisions of individual sickness funds (and private health insurance companies). The certification process for the health apps is an entirely new process and still leaves room for future research and discussion [9]. The Digital Care Act has the potential to decrease the costs associated with unnecessary doctor's visits, and substitute or complement other traditional treatments through new digital initiatives related to patient education and self-management. Yet, the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) has received 45 applications for admission to the index of digital health applications (Digitale Gesundheitsanwendungen, DIGA), which would sanction these apps as prescribable treatments [111]. In December 2020, the first nine health apps were admitted to the DIGA index, and they are now available via a doctor's prescription [112]. However, as the Digital Care Act is unique worldwide and new to the German health care system, some challenges might result. Furthermore, there are still some unsettled aspects of the act regarding the role of different stakeholders within the German health care sector. For this reason, we aimed to determine to what extent the integration of health apps into the German statutory health care system could be considered beneficial and which aspects of the reform act may need some adjustment. Therefore, we used a multi-method approach to shed light on different parts of the act. First, we directed an interview study with different health care stakeholders in Germany in the second quarter of 2019 to outline the general perception and expectations for the DVG. Secondly, in the first quarter of 2020, a quantitative study was conducted in cooperation with the health app provider Kaia Health Software GmbH. The study was applied to this case to illustrate how one could measure cost effectiveness using user data and determine whether an app treatment could be as effective as a traditional treatment. We expect that the acceptance of stakeholders and patients for app treatments has now changed to a large extent due to the experiences of the Covid-19 crisis, since location-independent, flexible, and at-home practicable solutions have gained importance.

Background

The process of prescribing health apps

The Digital Care Act regulates the prescription and certification of DIGAs and financial compensation through the statutory health insurance companies in Germany. The DVG is one of many initiatives by the German Federal Ministry of Health to modernize and digitize the German health care system. The aim of the act is to quickly introduce innovative digital

[10] Heidel A, Hagist C, Spinler S, Schöneberger M. The Digital Care Act – A Chance to Relieve the Dust from the German Health Care System: A Multi-Method Approach. Unpublished Working Paper. 2020 Dec. [15]

treatment solutions into the standard care portfolio and to give statutory health insurance companies the opportunity to encourage more efficiency and higher quality treatment [7]. The DVG enables statutory health-insured patients to claim digital solutions, if available, for disease management and treatment. Physicians, as the gatekeepers of the German health care system, are supposed to play a major role in the success of the DVG. According to the act, physicians are required to recommend and prescribe suitable health apps and supervise the app usage of the patients according to their individual disease progression [7]. Compensation for this supervision is not yet sufficiently regulated. Hence, the reform contains a subsection that states that practitioners' efforts shall be compensated, but a clear guideline, amount, or billing code is yet to be negotiated [7]. In May 2020, the board of the German Medical Association recommended compensation for practitioners providing advice and supervision, according to the billing code for practitioners (Gebührenordnungsposition, GOP) as number GOP 01470, which was introduced for the prescription of health apps [113]. This code reimburses the practitioner an amount of 2.00€ and may only be billed once per app [113]. Yet, there is a need to introduce a specific compensation system and establish individual billing codes for practitioners who continuously supervise app usage or even analyze self-tracked data for their patients. In Germany, most physicians in private practice are self-employed. Their motivation to enhance and recommend the use of health apps might also be debatable given the lack of financial incentives to do so. Furthermore, many private practitioners lack a range of digital solutions in their private practices [114]. Approximately only 56% to 58% of German private practitioners have already digitized processes, such as patient documentation, appointment planning, and waiting time management, for their practices [114]. Hence, just 37% of resident doctors are willing to standardize their patient documentation to accelerate the introduction of a digital patient file to encourage better patient data exchange between different specializations [114]. In Germany, there is an imbalance between demand and supply of physicians, partly explained by a general shortage of physicians, especially in rural areas, and partly explained by the unique statutory health care system and the apparent nearly unlimited and free doctor's treatment portfolio for statutory health-insured patients [115]. Many private practitioners, therefore, have little motivation to invest in the digitization of their processes and treatment of their patients.

Certification Process

The certification process for health apps and digital health devices was just recently specified within the digital device regulation (Digitale-Gesundheitsanwendungen-Verordnung, DiGAV) [116]. The BfArM published guidelines for health apps based on § 139e clause 8 (1) German social code (Sozialgesetzbuch, SGB V) [117]. The guidelines highlight that DIGAs need to be medical devices of the risk classes I or IIa, according to EU regulation 2017/745 [118]. The guidelines also explain the procedure for admission to the index of digital health devices. First, the app provider needs to apply to the BfArM to be admitted to the official index of reimbursable DIGAs. The BfArM then examines the app or the digital health device for safety, quality, data security, data privacy, and several functional requirements within a 3-month period after the application was submitted. Thereafter, the BfArM conducts a first assessment of the potential positive treatment effects of the app. If this evidence is not yet sufficiently demonstrated in studies and publications but all other requirements are fulfilled, the health app may still receive preliminary acceptance to the index according to § 139e SGB V [9]. During this time, the health app is in a 12-month test phase. The app can be prescribed through medical doctors during the test phase, and the health app provider may set the price for market entry. After 12 months, the health app provider needs to demonstrate sufficient proof of positive care effects. The

legislator uses the term positive care effect in the DVG and defines the concept as a medical beneficial outcome or patient-relevant procedural improvement in care [7]. In this paper, we have also referred to the concept of positive care effect to indicate the effectiveness of the app-based treatment. If sufficient proof of a positive care effect cannot be demonstrated, the app is removed from the index, and prescription is no longer possible. If the health app provider has demonstrated sufficient effectiveness, the price for usage of the app is negotiated with the national association of statutory health insurance funds [9]. This system of preliminary market access and reimbursement is supposed to facilitate innovation within the health care sector. After negotiating the final price, the app is permanently accepted to the DiGA index [9].

Materials and Methods

We used a multi-method approach to explore different aspects of the introduction of mHealth services in the German statutory health care sector. First, we conducted a semi-structured interview study with 23 stakeholders in Germany and thematically analyzed those [119]. Second, we carried out a quantitative study in cooperation with Kaia Health Software GmbH to demonstrate positive care effects and to compare the app-based treatment with the traditional treatment. We also seized the opportunity to determine whether retrospective user data are suitable for conducting a cost-effectiveness analysis.

Qualitative Study

First, we identified a focus group for the interview study. To analyze the general sentiments of the stakeholders within the German health care system about the Digital Care Act, we invited representatives of certification institutions, medical doctors, health app producers, medical chamber representatives, political actors, and statutory health insurance representatives to participate in our interview study. We contacted 65 stakeholders in Germany via purposeful sampling based on their profession and expertise between October 2019 and December 2019 [22]. Thereafter, 23/65 stakeholders responded to and participated in the study. Second, we created a suitable interview guide, discussed, and tested the questions in a real interview scenario with a previously selected stakeholder. All stakeholders agreed at the beginning of the interview to the collection of data and were informed that the pseudonymized transcripts of the interviews would be stored on our university server in Germany. No sensitive or personal data were collected. We conducted the interviews between October 2019 and January 2020 with a certification body representative (1/23), medical doctors (9/23), health app producers (2/23), medical chambers (4/23), political instances (5/23), and statutory health insurance representatives (2/23). Most interview partners were middle aged (Table 5) and almost equally distributed by gender (male (13/23) and female (10/23)).

Table 5: *Descriptive Statistics Qualitative Study*

Descriptive Statistics	**Distribution within Sample/Average**			
Medical Doctors	Female Male	4/9 (53%) 5/9 (47%)	Younger than 35 years old Between 35 and 50 years old Older than 50 years old	2/9 (22%) 4/9 (45%) 3/9 (33%)
Statutory Health Insurance Representatives	Female Male	1/2 (50%) 1/2 (50%)	Younger than 35 years old Between 35 and 50 years old Older than 50 years old	2/2 (100%) 0/2 (0%) 0/2 (0%)
App Certification Representative	Female Male	1/1 (100%) 0/1 (0%)	Younger than 35 years old Between 35 and 50 years old Older than 50 years old	1/1 (100%) 0/1 (0%) 0/1 (0%)
Medical Chamber Representatives	Female Male	0/4 (0%) 4/4 (100%)	Younger than 35 years old Between 35 and 50 years old	0/4 (0%) 3/4 (75%)

			Older than 50 years old	1/4 (25%)
Political Representatives	Female Male	2/5 (40%) 3/5 (60%)	Younger than 35 years old Between 35 and 50 years old Older than 50 years old	0/5 (0%) 3/5 (60%) 2/5 (40%)
Health App producers	Female Male	2/2 (100%) 0/2 (0%)	Younger than 35 years old Between 35 and 50 years old Older than 50 years old	1/2 (50%) 1/2 (50%) 0/2 (0%)

Source: Own calculation based on interview protocols

We used the software Atlas.ti to thematically analyze and cluster the transcripts. Two researchers, Heidel and Schöneberger, independently coded the transcripts using thematically relevant first- and second-order codes and found consensus about the final codes by merging the coding data and therefore consolidating the most important themes (final codes) through educated discussions [120]. The procedure to establish first-order codes consisted of highlighting the important parts of the transcripts and summarizing these through descriptive first-order codes [120–123]. In the second step, we comprised the descriptive first-order codes so that all duplicates could be removed without any loss of important information. In the final step, we used pattern coding to organize and cluster the second-order codes by the most relevant topics [120,124]. Within the first coding round, we identified 1048 first-order codes. After discussing their meaning, we merged these codes into 79 first-order codes. Finally, the first-order codes were clustered into nine second-order codes.

Quantitative Study

We conducted the quantitative study with anonymized user data from Kaia Health Software GmbH. The goal of the quantitative study was to provide evidence for the effectiveness of the Kaia health app treatment [125]. The app *Kaia Back Pain Relief* offers holistic back pain therapy, especially for chronically ill patients. The app includes components such as patient education, relaxation, and physical exercises. The type of exercise and the duration of each component are individually adjusted to the needs of the user by the application [126]. The exercises vary depending on a personal self-assessment of fitness, current back pain level, and previously completed exercises. Before the completion of a training session, users are asked to rate their current pain and sleep levels. We used these self-assessments of sleep and pain for our quantitative analysis. Kaia Health Software GmbH provided us with a convenient random sample of German users affiliated with a statutory health insurance company[11]. To be included within the sample, they must have at least logged on once during January 2020 and March 2020. Users who used the app as only a pain diary and did not complete any exercise, relaxation, or education activity were excluded from the sample. We included data from 2208 users in this study [127]. Kaia users agreed to the collection of data by signing the terms and conditions for usage of the app. We have stored the anonymized user data for our sample on our university server in Germany. The data did not contain any sensitive or personal information. We initially conducted a literature scoping study about differences in pain ex-post Kaia treatment and then illustrated the average pain level from our data sample over 30 treatment days in a quarter of a year. In Germany, physiotherapy can be prescribed to a statutory insured patient with a maximum number of five prescriptions for six physical therapy exercise sessions ranging from 15–20 minutes [128]. Kaia users exercise more frequently on average than traditional physical therapy patients, which is not just limited by frequency regulation but also by the budget available to the prescribing physician during a quarter year for statutory treatment prescriptions [128]. Since we analyzed retrospective data,

[11] In Germany, approximately 87.8% of the population were statutory health insured, 10.5% were privately insured, and 1.7% had another affiliation in 2019 [129]

we could not control for users who used Kaia and were simultaneously enrolled in physical therapy. Chronically ill patients may especially benefit from Kaia usage because exercise duration and exercise frequency may be selected by the patient without limits based on his or her needs. In our sample, most Kaia users were satisfied with the Kaia app, as indicated by the average net promoter score (8/10). Table 6 illustrates the data characteristics and shows that men and women are almost equally distributed within the sample. Our sample is, on average, middle aged (51 years old). Fifty-seven percent of these users suffer from chronic back pain and have a prior average Kaia usage pain level of 4/10 (10 = worst pain, 0 = no pain) and a prior average Kaia usage sleep quality of 6/10 (10 = best sleep, = 0 worst or no sleep) [**Fehler! Verweisquelle konnte nicht gefunden werden.**]. Finally, we conducted a cost-effectiveness analysis comparing the app treatment and traditional treatment, using known figures from the existing literature and the Kaia user data.

Table 6: *Descriptive Statistics Quantitative Study*

Descriptive Statistics	**Distribution within Sample/Average**	
Gender	Female Male	1161/2208 (53%) 1047/2208 (47%)
Average age		51 years (Min. age = 16, Max. age = 90)
Chronically ill patients	Pain duration more than 12 months prior to app usage	1266/2208 (57%)
Reasons for app usage	To reduce pain To strengthen back To learn to cope with pain To increase flexibility To increase spine stability To reduce stress	906/2208 (41%) 1066/2208 (48%) 467/2208 (21%) 838/2208 (37%) 844/2208 (38%) 523/2208 (23%)
Prior app usage fitness activities	Household tasks Everyday walking Easy sports Demanding sports	1622/2208 (73%) 1577/2208 (71%) 1572/2208 (71%) 610/2208 (28%)
Average pain level prior to app usage		4/10 (below medium)
Average sleep quality prior to app usage		6/10 (above medium)
Average net promoter score		8/10

Source: Own calculation based on data provided through Kaia Health Software GmbH.

We ran binominal logistic regression models to evaluate the impact of different variables on the change in pain level ≤ 0 using the logit:

5.) $L_i = \alpha_0 + \alpha_1 x_{1i} + \alpha_2 x_{2i} + \cdots + \alpha_{K-1} x_{K-1,i}$ [130].

The formula indicates that the variables $x_1 \ldots x_{K-1}$ impact the logarithmic chances of the dependent variables. The α-parameter shows the change of that logarithmic chance with a change in the respective independent variable [130]. We used the dependent variable pain relief yes or no. *Pain relief yes* indicates a decrease in pain level or remaining at the same pain level between the first and the last treatment day of our observational period. In our models we used the control variables gender, age, and chronical condition yes or no. *Chronic conditions yes* indicates a pain duration of 12 weeks or longer prior to app usage. Further, we used the independent variables number of treatment days, which is the number of individual Kaia trainings and usages during the first quarter of the year 2020 and the average durations

of the education, exercise, and relaxation elements completed in seconds. We conducted multiple linear regression models using OLS to understand the influence of different independent variables on the improvement of pain levels after Kaia treatment. According to Lai et al., the following formula was used:

6.) $Y_i = \beta_0 + \beta_1 X_{i1} + \beta_2 X_{i2} + \beta_{p-1} X_{i,p-1} + \varepsilon_i$ [131].

We used change in pain level as an independent variable, which is the difference between the individual pain level on treatment day one and on the last treatment day of the first quarter of the year. The change in pain level is supposed to indicate the success and effectiveness of the usage of the app. The control and independent variables remained the same as in the logistic regression models. As an explanatory variable, we further added the Kaia body group, which is an internal variable depicting the fitness and exercise difficulty of a user. We also added the independent variable training intensity, which is the difference in days between the first and the last treatment over the number of total treatments during the observational period. We used the statistical software R for the calculations [132].

Results

Qualitative Study

We observed a generally positive perception of the DVG and the option of prescribing health apps as a treatment in the future during the interview study [133-155]. However, most stakeholders would not want to overestimate the effect of health apps introduced as treatments in the German health care sector [140-146, 148, 151, 153, 154]. Medical doctors thought that prescribed health apps should be regarded as optional treatments and not as replacements or substitutions for traditional treatments [141–153]. After the coding process, we identified the following second-order codes or main topics addressed by the stakeholders:

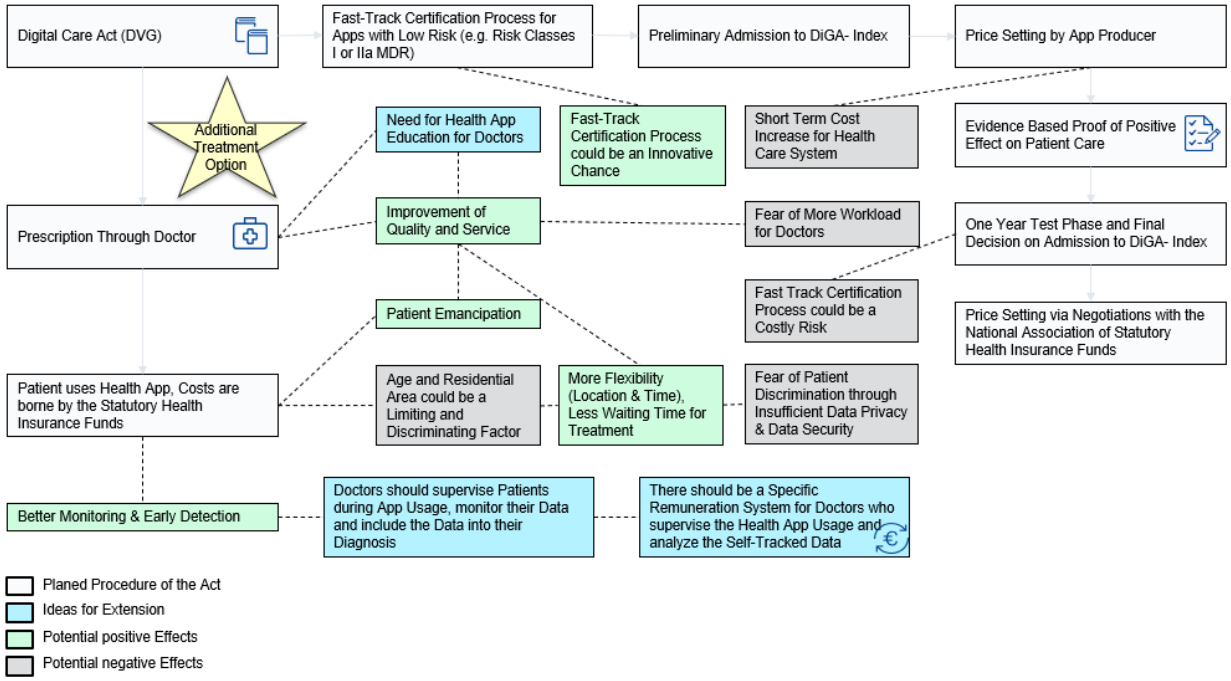
- Factor patient and potential care effects[12],
- Certification process[13],
- Chances for the health care system[14],
- Cost development[15],
- Factor doctor and potential effects on daily routine[16],
- Political incentive systems[17],
- Role of the statutory health insurer and reimbursement[18],
- Considerations for the app developers[19],
- Concerns about data use, data privacy, and data security[20].

The majority of stakeholders thought that the additional option of prescribing health apps could improve treatment quality for patients and enhance the service portfolio of resident doctors [133-152,155]. Most stakeholders argued that the use of health apps could lead to patient emancipation through better disease education and management [133, 134, 138, 139, 145, 151]. The use of health apps has various positive effects for patients, such as more flexibility in terms of location and time, as well as a permanent reduction in waiting time for appointments

[12] 12/79 first-order codes–200 quotes
[13] 9/79 first-order codes–112 quotes
[14] 7/79 first-order codes–93 quotes
[15] 7/79 first-order codes–61 quotes
[16] 14/79 first-order codes–293 quotes
[17] 8/79 first-order codes–78 quotes
[18] 7/79 first-order codes–58 quotes
[19] 5/79 first-order codes–28 quotes
[20] 10/79 first-order codes–108 quotes

[135, 140, 142, 143]. Many medical doctors would be delighted if health app usage would lead to less *unnecessary* doctor's visits and therefore again increase treatment time for patients with severe or complicated conditions [140, 141, 145–151, 153]. Furthermore, doctors would have the chance to detect chronic or severe conditions earlier through data insights, which they would not be able to obtain from traditional treatments or patient disease management systems [137, 139, 140, 143, 144, 155]. However, the fast-track certification might not only be a chance for improvement and innovation but also an opportunity to abuse the system by very high price settings and therefore create a short-term increase of costs within the German health care system [136–138, 141, 142, 144, 147, 149, 150, 152,154]. Some stakeholders recommended a pay-for-performance principle, which means that the final costs for the app should depend on the intensity of the real positive care effect verified during the one-year test phase [140, 142, 144, 146, 147, 151,155]. Medical doctors were especially concerned that patients might not use or might incorrectly use the app-based treatment [141, 148,149]. Therefore, app usage supervision and advice through medical doctors should be indispensable [135, 136, 140, 141, 148, 149, 151]. Yet, there is no sufficiently regulated incentive or remuneration system for physicians who would have an increased workload because of continuous app supervision. Stakeholders from all sectors of the health care system recommended the introduction of individual billing codes and an appealing remuneration system for physicians who supervise app treatments because they fear a blockage of the innovation [133, 134, 136, 138, 140, 141, 146-150, 152-155]. To prevent expensive app collection without usage from patients, some stakeholders suggested to monitor compliance and let patients pay for prescribed apps if they do not use them [133, 153, 155]. On the other hand, statutory financed health apps also foster the usage and perception of health apps in general within society. Technologies such as gamification and nudging may increase patient compliance and usage even further for specific treatments [133, 134]. Many stakeholders fear a lack of data security and data privacy for patients; medical doctors especially question the distribution of responsibility in cases of data theft and severe personal consequences for patients [140, 141, 146,148–150, 153,154]. Another concern was that many patients could be excluded from the app treatments because of demographic factors, such as age or local internet connection [135–142, 144,146–150,152–155]. Hence, there is an urgent need to educate doctors about health apps. Many doctors in private practice are quite old and do not have any incentive to additionally add research on health apps to their normal workloads [133–155]. All stakeholders recommended that statutory health insurance companies, health app producers, and medical chambers in particular should offer a wide portfolio of health app education initiatives to address the needs and interests of physicians with different specialties, ages, location characteristics, and different patient clientele [133–155]. Figure 3 presents the main findings and recommendations from the interview study.

Figure 3: *Benefits, Risks and Recommendations for the Digital Care Act*



Source: Own Illustration.

Quantitative Study

Approximately 57% (1266/2208) of the Kaia sample suffered from chronic back pain. Yet, we did not expect to observe a large-scale improvement in pain level because maintaining constant pain levels is already a significant achievement for patients with chronic conditions [156–158].

Estimating the average pain reduction from retrospective user data is indeed not trivial because many users tend to stop using a given health app if they no longer experience pain or significant improvements, which is why prospective clinical studies with ex-ante and ex-post questionnaire evaluations draw a more accurate picture of real pain reduction due to app treatment [159,160]. Therefore, prior to our estimation of pain level reduction in our sample, we conducted a scoping study using the PubMed.gov database with the search terms Kaia, app, and back pain. Currently, there are five published peer-reviewed research papers on pain level reduction due to the use of the Kaia health app. Table 7 illustrates the findings of the scoping study.

Table 7: *Scoping Review about Literature on Pain Level Reduction after Kaia Treatment*

Study	Objective	Method	Sample Size	Pain Level Reduction on the Scale 0-10 after 12 Weeks Kaia Treatment
Huber et al. (2017) [160]	To give an overview about the Kaia app to treat lower back pain	Retrospective data analysis at baseline, 4, 8 and 12 weeks after the app treatment	180 Kaia users	-1.05

Clement et al. (2018) [161]	To demonstrate the clinical outcomes due to an updated version of the app with new features	Retrospective data analysis at baseline, 12 and 24 weeks after the app treatment	998 Kaia users	-1.10
Toelle et al. (2019) [163]	To compare the effectiveness of the Kaia treatment with traditional physical therapy	Prospective clinical study at baseline, 6 and 12 weeks after the app treatment	48 patients treated with Kaia	-2.40
Priebe et al. (2020) [162]	To demonstrate the correlation between pain intensity and sleep quality while using a new Kaia app version	Retrospective data analysis at baseline, 4, 8 and 12 weeks after the app treatment	180 Kaia users	-1.04
Priebe et al. (2020) [159]	To compare the effectiveness of the Kaia treatment with traditional physical therapy	Prospective clinical study at baseline, 6 and 12 weeks after the app treatment	680 patients treated with Kaia	-1.85

Source: Own illustration based on literature referred to in the table

As expected prior to the scoping review, we observed underestimated pain reduction outcomes in the retrospective studies, ranging from -1.04 to -1.1 [160-162] compared to the ones from the prospective studies ranging from -1.85 to -2.4 [159, 163]. Although the retrospective studies observed decreasing pain levels for Kaia users, there was no specific questionnaire for these samples, which would allow for accurate categorization of patients according to their therapy experience. Hence, pain levels may be underestimated, as some Kaia users may have stopped using the app due to significant pain improvement, discontinuing their logging of their pain improvement in the application [159].

After calculating the average pain reduction and sleep quality improvement for our sample, we noted a similar (even greater) underestimation of pain level reduction from the Kaia treatment. The user data show just a short snapshot of Kaia user behavior and are therefore not appropriate to accurately predict pain reduction outcomes after a certain time period of using the app. However, the data are sufficient to illustrate the relationships between pain level improvement and certain factors. On average, Kaia users improved their pain level by -0.56 points and their sleep quality by 0.47 points within 30 Kaia sessions in our sample [127]. Yet, as already highlighted, these findings are not representative and do not consider any unobserved factors, such as pain progression during different seasonal changes in the year, or motion and nutrition beyond the Kaia treatment. The average change in pain level for the first 17 days showed a standard error of 0.02 to 0.05, and for the last 13 days it was in the range 0.05–0.09. The standard deviation was quite consistent and ranged from 2.11 to 2.18 between day 1 and day 30, which means that the self-assessed pain levels were very individual but also temporarily consistent and therefore no weakness. We observed similar results for average sleep quality. In the first 20 days, the standard error ranged between 0.01 and 0.05, and during the last 10 days, it ranged between 0.06 and 0.8. The standard deviation was quite constant during the 30 treatment days, ranging from 1.91 to 2.02 [Multimedia Appendix 3]. Yet, the results also showed that pain is difficult to generalize because people experience pain differently in different situations of their lives [164]. Our sample could be considered diverse, as it included people who exercise frequently and people who do not, chronically ill people, healthy people, and people with acute back pain, as well as younger and older people. Yet, we have no knowledge about patients who might use the Kaia app while simultaneously being enrolled in a traditional physical therapy program. Even though the data showed spreading losses, the data could provide valuable insights into the relationship between the improvement in pain level $x \leq 0$ and other variables. Therefore, we conducted a binominal logistic regression, as shown in Table 8.

Table 8: *Logistic Regression Model with the Dependent Variable Pain Relief*

Coefficients	Entire Sample	Chronic Pain Kaia Users	Non-Chronic Pain Kaia Users
Constant	5.220e-01 * (2.428e-01)	0.418 (0.317)	0.537 (0.358)
Gender/Female	7.025e-02 (9.367e-02)	0.140 (0.123)	-0.012 (0.145)
Age	7.151e-03 . (3.941e-03)	0.013 * (0.005)	-0.001 (0.006)
Chronical Condition/Yes	-8.399e-02 (9.496e-02)		
Number of Treatment Days	8.382e-03 ** (2.649e-03)	0.003 (0.004)	0.015 *** (0.004)
Average Education Duration	-3.832e-03 *** (4.557e-04)	-0.005 *** (0.001)	-0.006 *** (0.001)
Average Training Duration	-3.180e-05 (7.459e-05)	-0.000 (0.000)	0.000 (1.195)
Average Relaxing Duration	-4.350e-04 * (1.786e-04)	-0.001 * (0.000)	-0.001 (0.001)
Null deviance	2804.9 on 2198 degrees of freedom	1628.1 on 1255 degrees of freedom	1173.4 on 942 degrees of freedom
Residual deviance	2672.2 on 2191 degrees of freedom	1538.3 on 1249 degrees of freedom	1123.3 on 936 degrees of freedom
AIC	2688.2	1552.3	1137.3

Significance codes: 0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1 (Standard errors are reported in parentheses .*, **, *** indicates significance at the 90%, 95%, and 99% level)

Source: Own calculation based on data provided through Kaia Health Software GmbH.

The first model, based on the entire sample, illustrated a positive relationship between the number of treatment days and whether a user experienced a constant pain level or even a relief of pain. However, average education duration seemed to have a slight negative impact on pain relief. Another positive outcome is that increasing age seemed to have a limited effect and yet a slightly positive one on the chance of experiencing a reduction in pain or keeping pain levels constant by using the Kaia app. This shows that concerns about the exclusion of older patients if they have and use a smartphone with the app, seem unsubstantiated. All three models showed similar results, which is why the risk of multicollinearity between the variable chronic condition and the other independent and explanatory variables should be minimized. For the non-chronic sample, the results illustrated that the more that users exercise, the more likely it is that they will experience a decrease in pain level.

We developed multiple linear regression models to further estimate the relationship between the dependent variable, change in pain level after the Kaia treatment, and various independent variables, such as gender, age, chronic condition, and number of treatment days during the first quarter of 2020 [127].

Table 9: *Multiple Linear Regression Models with the Dependent Variable Change of Pain*

Coefficients	Model I	Model II	Model III
Constant	0.736 ** (0.238)	1.114 *** (0.252)	0.591 * (0.278)
Gender/Female	-0.009 (0.099)	-0.026 (0.100)	-0.054 (0.097)
Age	-0.006 (0.004)	-0.005 (0.004)	-0.004 (0.004)
Chronical Condition/Yes	0.300 ** (0.100)	0.290 ** (0.100)	0.223 * (0.098)
Number of Treatment Days	-0.010 *** (0.003)	-0.019 *** (0.002)	
Kaia Body Group		-0.001 *** (0.000)	-0.001 *** (0.000)
Intensity of Training			-0.001 *** (0.000)
Average Education Duration			0.005 *** (0.001)
Average Relaxing Duration			0.000 * (0.000)
R-squared	0.01249	0.02183	0.07275
Adjusted R-squared	0.01069	0.01958	0.06976
F-statistic	6.961 on 4 and 2202 DF	9.717 on 5 and 2177 DF	24.38 on 7 and 2175 DF
p-value	1.445e-05	3.417e-09	< 2.2e-16
AIC	10002.14	9873.285	9760.591

Significance codes: 0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1 (Standard errors are reported in parentheses .*, **, *** indicates significance at the 90%, 95%, and 99% level)

Source: Own calculation based on data provided through Kaia Health Software GmbH.

All models resulted in low β-values and high R-squared values, which is why none of the models was strong enough for specific predictions of the weight of the impact that an independent variable had, but they indicate their tendencies. Model I illustrated that the change in pain level and chronic condition/yes have a positive correlation. This means that many chronically ill people may experience high pain levels, which is quite common. Yet, we observed that the number of treatment days and the change in pain level have a negative correlation, which means that more exercise days lead to lower pain levels. We tested for multicollinearity by generating different models. No major changes in the variable parameters were observed.

Discussion

One of the major concerns identified during the interview study was that health apps might not provide the desired positive care effects and therefore could lead to an unnecessary short-term increase in costs for the German health care system. The results of the exemplary quantitative study showed a positive care effect if users regularly utilized the specific app at hand. However, compliance is not just an inhibitor for improvement in the digital sphere but

also in the analog treatment world. In particular, doctors expressed their concerns in the interview study that digital treatments could lead to a short-term cost increase because the app treatment requires self-motivation, which could lead to patients not using or not regularly using the app and, therefore, an absent positive care effect. Yet, many studies disagree with this standpoint because modern technologies, such as gamification and nudging, have shown a significant positive effect on patient compliance [165,166]. A major advantage of the app treatment versus the traditional treatment is that patients gain location and time flexibility. According to most stakeholders, this advancement could lead to an improvement in treatment quality and service due to an extension of health care portfolios. One of the most outstanding findings of the interview study was that all stakeholders agreed that there is a need to introduce an appealing financial incentive system to remunerate the increased workload that medical practitioners would have due to continuous app advice, supervision, and data analysis. All stakeholders demanded individual billing codes for practitioners to ensure the support and participation of these important gatekeepers.

We computed an exemplary cost-effectiveness ratio (CER) to compare the traditional treatment versus the app treatment in the case of chronic back pain using the argument:

7.) $CER = \frac{Total\ Cost}{Total\ Effectiveness}$ [167].

We referred to the reduction in pain levels to determine the total effectiveness. Wenig et al. researched the direct and indirect costs of back pain patients. They estimated that indirect costs, such as sick leaves or loss in productivity, alone result in average costs of approximately 709.50€/year per person [168], at expected pain level stagnation or a worsening pain level. In Germany, the maximum chargeable price for statutory physical therapy is legally regulated. Statutory health-insured patients may be prescribed a maximum of 5 prescriptions, including a maximum of 6 physical therapy sessions, which totals 30 sessions [128]. If patients need additional prescriptions, they need to take a mandatory treatment break of 12 weeks, and the reimbursement of further treatments has to be verified for each individual case by a physician [128]. Each session costs approximately 9.75€ for the statutory health insurance of the patient and an extra 10.00€ per prescription for the patient [128]. However, physiotherapy practices normally operate during regular business hours, which means that many employees need to attend physical therapy during their working hours. Therefore, we include two hours of lost productivity (travel time, waiting time, treatment time) using the 9.35€/hour German minimum wage in our calculations. This means that physiotherapy costs 903.50€ for our observation period (with a maximum of 30 training sessions). In a small study with mostly chronically ill back pain patients, Manion et al. discovered that physical therapy caused a pain relief of -1.1 pain points [169]. Hence, the CER for physiotherapy in our example is 821.36€/pain point reduction. Our Kaia app treatment sample included 57% chronically ill patients, which is why these cases are comparable. Unlimited Kaia app usage costs 99.00€/month [127]. Even though, we have shown higher Kaia usage pain improvement results in the literature ranging from -1.04 to -2.40 [159–163], for the sake of this study, we performed calculations using the underestimated pain improvement average of our sample. The app usage during our three-month observation period costs 297.00€ and the estimated average pain relief was -0.56 pain points, which resulted in a CER of 530.36€/pain point reduction [Multimedia Appendix 3]. Hence, the Kaia app treatment for back pain has at least a comparable (or even slightly better) outcome compared to traditional physical therapy. In the literature scoped, physical therapy was also outperformed by the Kaia treatment in terms of reduction in pain level [159–163].

The opportunities that app treatments offer through data generation and patient monitoring could improve research and diagnostics to a large extent because of their regular real-world and real behavioral documentation. The usage of retrospective user data for research purposes is another advantage of large-scale health app usage. We were able to conduct a cost-effectiveness analysis with continuous user data and demonstrated important influential factors for app usage outcomes. Yet, a major disadvantage of using continuous user data is that many external factors may not be controlled, such as whether users simultaneously participate in physical therapy. Further, using continuous user data might only result in a snapshot during continuous treatment and may not reveal final outcomes, which in turn could lead to the underestimation of results.

App treatments are not supposed to replace traditional treatments. Traditional treatments might still be better established, especially for acute conditions, for which the explanation and involvement of trained professionals are highly valued in society. However, app-based treatments offer many opportunities and additional benefits, which is why app-based treatments should be regarded as a valuable complement to medical care portfolios. Furthermore, physicians in Germany have a limited budget for statutory health-insured patients to prescribe physical therapy and might not even have the resources to prescribe every patient 30 sessions of physical therapy per quarter of a year [170]. Therefore, many patients need to wait for months to finally attend physical therapy. The app treatment in the case of chronic back pain might, therefore, be an effective and economical alternative for these patients. In the introduction phase of the act and to promote health app usage within society, DIGAs are supposed to be prescribed as extra-budgetary treatments [117], meaning that the prescription of traditional treatments versus the app treatments is not subject to direct monetary competition at this stage. However, once app treatments face the cost-containment measures of the sickness funds in the future and then need to compete with traditional treatments, their true effectiveness as well as acceptance among practitioners and patients will become apparent. The educational elements of the apps might additionally lead to more patient emancipation through a better understanding of personal conditions. Location and time flexibility are the biggest advantages of the new technologies, but they are also raise the most significant concerns for stakeholders because app usage requires personal initiative and self-motivation. Physicians should supervise and monitor patients' app usage to support the adequate use of the app as a treatment. This supervision might also help to prevent patients from collecting but not using reimbursable health apps and therefore exploiting the system. However, physicians should be properly remunerated for this service.

We conducted this study prior to the Covid-19 crisis. Hence, we now expect that the acceptance and valuation of the stakeholders with respect to health apps has increased due to their experiences during the lockdown in Germany introduced on March 25th, 2020. App treatments proved to be an important alternative when everyone was required to stay at home. Patients' demands for health apps may also have increased because many people tried to avoid unnecessary contact or were quarantined. Therefore, app-based treatments have shown great potential during these special times and for patients with special needs.

Limitations

This study was conducted prior to the Covid-19 crisis. We now expect higher acceptance and appreciation of app treatments and disease management after the experiences of lockdown and social distancing. We recommend a repetition of the study, especially of the interview study, after the crisis. We did not collect data for the self-assessment of physical therapy to

compare these with the results of our Kaia sample on our own. We recommend repeating the study by surveying physical therapy patients and Kaia app usage patients before and after treatment, thereby providing more reliable and better comparable results. Since we analyzed retrospective real-life user data in the study, we were not able to control for any users who were simultaneously enrolled in traditional physical therapy while they used the Kaia app. Studies that have solely evaluated the self-assessed pain levels of physical therapy patients are rare. The WHO international classification of functioning, disability, and health model is an established method to measure the effectiveness of physical therapy, which consists of an extensive patient self-assessment questionnaire and various professional physical tests [156, 157]. Data for the Kaia app have not yet been collected according to this model. However, we advise Kaia to extend the self-assessment questionnaire before the training and to launch further studies that include the functioning, disability, and health model to generate greater comparability with existing studies of traditional physical therapy. It would be very useful if all other back pain apps would introduce such a standardized assessment scheme to also establish better comparability between all back pain apps.

Conclusion

In conclusion, stakeholders within the German health care system had generally positive opinions about the Digital Care Act. The inclusion of health apps in the statutory health care system could improve the quality and service of treatment by expanding portfolios. Apps with education and monitoring options contribute to patient emancipation to a large extent. In general, the apps might lead to better monitoring through a higher frequency of data acquisition, which in turn could lead to the early detection of severe or chronic conditions. Location and time flexibility are one of the major advantages of the inclusion of health apps in the German health care system, as exemplified during the Covid-19 crisis. The fast-track certification process involves both opportunities and risks. This unique process encourages innovation within the statutory health care system but might also motivate free riders to abuse the system through very high app prices or insufficient evidence of effectiveness; however, technologies, such as nudging and gamification, also have the ability to improve patient compliance. Yet, the act is still incomplete because a remuneration system for app usage supervision through physicians is still absent. This is much requested by the stakeholders, considering the increase in workload. App education for physicians is also not yet organized, which should be one of the major priorities to ensure the success of the act. Many stakeholders were concerned that age might be a limiting factor for health app usage as a treatment. On the contrary, our quantitative study has shown that older patients also benefit from health apps. In our quantitative study, we were able to demonstrate a positive care effect for the use of the back-pain app Kaia, although the retrospective design of the study could lead to a significant underestimation of real pain level changes. Comparing the app treatment with the traditional treatment, we demonstrated a comparable CER for the app treatment, which means that Kaia is in no way inferior to the traditional treatment. We have also shown that a higher frequency of exercise leads to a greater chance of pain improvement, which is something the traditional treatment system cannot offer due to limited resources and regulations. Apps should therefore be considered a significant additional treatment option. Currently, health apps will not replace traditional treatments, but they offer new and complementary benefits, such as the enhancement of treatment possibilities, which should be recognized as a great opportunity for the German health care system.

Summary

In conclusion, each paper and methodological approach of this dissertation has contributed to highlighting the variety of potential risks and benefits associated with health apps and wearable devices that may occur when they are introduced through the Digital Care Act into the German statutory health care system. One of the major advantages for patients is that the act offers an opportunity for stakeholders to extend treatment portfolios, and hence deliver a better-quality health care service with time- and location-flexible alternative treatments. Yet, health apps might not be a panacea for all the problems that the German statutory health care system is facing, such as ever-increasing health care costs and the shortage of practitioners in rural areas. However, they might be a starting point for rejuvenating the system and paving the way forward with further innovative digital solutions to increase quality and efficiency.

We analyzed 55 academic articles as part of the scoping study of the first paper. We thereby identified four key themes related to health apps and wearables in the health care system: users of health apps and wearables, effectivity of health apps and wearables to improve health, the potential of bring-your-own, self-tracked data, and concerns and data privacy risks. Based on our scoping study, we predict that the Digital Care Act will have an overall beneficial effect on treatment quality and the general health literacy of patients. The main benefits will be noticeable in the fields of preventive care, patient monitoring, and disease management. However, as the use of health apps and wearables is a rather recent phenomenon, there is still little academic literature and few empirical studies available on the related long-term effects. In their articles, many authors highlighted that the main concerns are related to the data security of the apps and the potential risks of exclusion through age or other social-demographic factors [13].

Designed as an alternative to a discrete choice experiment, namely, a separated adaptive dual response approach, the second study has shown that the pharmaceutical industry and medical device companies especially need to engage in more data processing transparency to gain the trust of users and therefore encourage them to eventually share their self-tracked data with these companies. However, the participants of previous studies and our respondents tended to overestimate the monetary value of their health data, which made them very sensitive to the attribute further data sales to unknown third parties. This attribute is the least desired and yet can easily be excluded in real life through strict data processing rules and transparency. The results of our experiment have shown that a digital dividend is a feasible instrument to convince people to share their data for research purposes, with an importance weight of nearly 21%. Yet, the pharmaceutical industry might benefit to a large extent by including self-tracked health data as part of its research strategies because this real-life data might have the potential to decrease costs and efforts associated with time-consuming control group studies. Under specific conditions, 54.91% of participants would sell their data to universities, 46.65% would sell to health insurers, and 38.87% would sell their data to pharmaceutical or medical devices companies for 20€/month [14].

The multi-method approach of the third paper has shown that many stakeholders of the German health care system are generally open-minded and positively attuned toward health apps within the German statutory health care system and the reforms that the Digital Care Act brings. The results of the paper illustrate that health apps and wearable devices might improve

the quality and service of the treatment portfolios of German statutory health-insured patients. The educational and monitoring elements of health apps contribute to patient emancipation and could increase compliance through new technologies such as gamification and nudging. The fast-track certification process specifically introduced for health apps could foster innovation but might also motivate free riders to abuse the system. However, the act is still missing important aspects, such as a remuneration system for app usage supervision through physicians. Currently, there is no incentive system for physicians to engage in the prescription of and encouragement to use the apps. App education for physicians is also a very important missing element, as many physicians have no previous experience with or expertise related to health apps. Many stakeholders were concerned that age could be a limiting factor for app usage. However, in our quantitative study, we were able to show a contrary effect. In the quantitative section of the paper, we were also able to show that when the app treatment was compared with the traditional treatment, the app treatment seemed to be comparable to the traditional treatment. This means that app treatments should be regarded as a significant opportunity for the German statutory health care system [15].

References

1. Lobelo, Felipe, et al. The Wild Wild West: A Framework to Integrate MHealth Software Applications and Wearables to Support Physical Activity Assessment, Counseling and Interventions for Cardiovascular Disease Risk Reduction. Progress in Cardiovascular Diseases, vol. 58, no. 6, 2016, 584–594. doi: 10.1016/j.pcad.2016.02.007
2. Albrecht UV, editor. Opportunities and risks of health apps (CHARISMHA). Hanover, Germany: Peter L. Reichertz Institute for Medical Informatics at the TU Braunschweig and the Hannover Medical School; 2016:370.
3. Brandt, Carl Joakim, et al. General Practitioners' Perspective on EHealth and Lifestyle Change: Qualitative Interview Study. JMIR MHealth and UHealth, vol. 6, no. 4, 2018, 1–9. doi: 10.2196/mhealth.8988
4. Genes, Nicholas, et al. From Smartphone to EHR: a Case Report on Integrating Patient-Generated Health Data. Npj Digital Medicine, vol. 1, no. 1, 2018. doi: 10.1038/s41746-018-0030-8
5. Schoeppe, Stephanie, et al. Apps to Improve Diet, Physical Activity and Sedentary Behaviour in Children and Adolescents: a Review of Quality, Features and Behaviour Change Techniques. International Journal of Behavioral Nutrition and Physical Activity, vol. 14, no. 1, 2017, 1–10. doi: 10.1186/s12966-017-0538-3
6. Urrea, Bruno, et al. Mobile Health Initiatives to Improve Outcomes in Primary Prevention of Cardiovascular Disease. Current Treatment Options in Cardiovascular Medicine, vol. 17, no. 12, 2015, 1–12. doi: 10.1007/s11936-015-0417-7
7. Der Bundestag. Bundesgesetzblatt Teil I Nr. 49. Gesetz für eine bessere Versorgung durch Digitalisierung und Innovation (Digitale Versorgung Gesetz). 2019 Jul 22. URL: www.bgbl.de [accessed 2020-09-12]
8. Zeit Online. Jens Spahn: Krankenkassen Sollen Für Gesundheitsapps Zahlen. Die Zeit. 2019 May 15. URL: www.zeit.de/ digital [accessed 2020-09-12]
9. Bundesinstitut für Arzneimittel und Medizinprodukte. "Das Fast-Track-Verfahren Für Digitale Gesundheitsanwendungen (DiGA) Nach § 139e SGB V." Ein Leitfaden Für Hersteller, Leistungerbringer Und Anwender, 2020, pp. 1–136., www.bfarm.de/diga.
10. Groß D, Schmidt M. Ethical perspectives on E-health and health apps: Is all that is achievable desirable? Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz 2018 Mar 30;61(3):349-357. doi: 10.1007/s00103-018-2697-z
11. Ehn, Maria, et al. Activity Monitors as Support for Older Persons' Physical Activity in Daily Life: Qualitative Study of Users' Experience. JMIR MHealth UHealth, vol. 6, no. 2, 2018, 1–15. doi: 10.2196/mhealth.8345
12. Haghi, Mostafa, et al. Wearable Devices in Medical Internet of Things: Scientific Research and Commercially Available Devices. Healthcare Informatics Research, vol. 23, no. 1, 2017, 4–15. doi: 10.4258/hir.2017.23.1.4
13. Heidel A, Hagist C. Potential Benefits and Risks Resulting From the Introduction of Health Apps and Wearables Into the German Statutory Health Care System: Scoping Review. JMIR Mhealth Uhealth. 2020 Sep 23;8(9) doi: 10.2196/16444
14. Heidel A, Hagist C, Schlereth C. Pricing through Health Apps Generated Data in Germany – Digital Dividend as a Game Changer: A Discrete Choice Experiment. Unpublished Working Paper. 2020 Nov.
15. Heidel A, Hagist C, Schlereth C. Pricing through Health Apps Generated Data in Germany - Digital Dividend as a Game Changer: Discrete Choice Experiment. PLOS ONE. 2021 JUL, doi: 10.1371/journal.pone.0254786.
16. Kotlikoff L, Hagist C. Who's Going Broke? Comparing Growth in Healthcare Costs in Ten OECD Countries. NBER Working Paper No. w11833 2005 Dec;188(1), doi: 10.3386/w11833
17. GfK. Health and Fitness Tracking: Global GfK Survey. 2016 Sep. URL: https://cdn2.hubspot.net/hubfs/2405078/cms-pdfs/ fileadmin/user_upload/country_one_pager/nl/documents/global-gfk-survey_health-fitness-monitoring_2016.pdf [accessed 2020-09-12]
18. Munn Z, Peters MDJ, Stern C, Tufanaru C, McArthur A, Aromataris E. Systematic review or scoping review? Guidance for authors when choosing between a systematic or scoping review approach. BMC Med Res Methodol 2018 Nov 19;18(1):143 doi: 10.1186/s12874-018-0611-x
19. Colquhoun HL, Levac D, O'Brien KK, Straus S, Tricco AC, Perrier L, et al. Scoping reviews: time for clarity in definition, methods, and reporting. J Clin Epidemiol 2014 Dec;67(12):1291-1294. doi: 10.1016/j.jclinepi.2014.03.013
20. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. International Journal of Social Research Methodology 2005 Feb;8(1):19-32. doi: 10.1080/1364557032000119616

21. Henriksen A, Haugen Mikalsen M, Woldaregay AZ, Muzny M, Hartvigsen G, Hopstock LA, et al. Using Fitness Trackers and Smartwatches to Measure Physical Activity in Research: Analysis of Consumer Wrist-Worn Wearables. J Med Internet Res 2018 Mar 22;20(3):e110 doi: 10.2196/jmir.9157
22. Palinkas LA, Horwitz SM, Green CA, Wisdom JP, Duan N, Hoagwood K. Purposeful Sampling for Qualitative Data Collection and Analysis in Mixed Method Implementation Research. Adm Policy Ment Health 2015 Sep;42(5):533-544 doi: 10.1007/s10488-013-0528-y
23. Bundesministerium für Gesundheit. Verordnung über das Verfahren und die Anforderungen der Prüfung der Erstattungsfähigkeit digitaler Gesundheitsanwendungen in der gesetzlichen Krankenversicherung, 2020. Bundesgesetzblatt Teil I Nr. 18. 2020. URL: www.bgbl.de [accessed 2020-09-12]
24. Radtke R. Umfrage Zur Teilungsbereitschaft Von Gesundheitsdaten in Deutschland, 2016. Statista. 2018. URL: https://de. statista.com/statistik/daten/studie/712642/umfrage/umfrage-zur-teilungsbereitschaft-von-gesundheitsdaten-in-deutschland/ [accessed 2020-09-12]
25. Wiesner M, Zowalla R, Suleder J, Westers M, Pobiruchin M. Technology Adoption, Motivational Aspects, and Privacy Concerns of Wearables in the German Running Community: Field Study. JMIR Mhealth Uhealth 2018 Dec 14;6(12):e201 doi: 10.2196/mhealth.9623
26. Krebs P, Duncan DT. Health App Use Among US Mobile Phone Owners: A National Survey. JMIR Mhealth Uhealth 2015 Nov 04;3(4):e101 doi: 10.2196/mhealth.4924] [Medline: 26537656
27. Park M, Yoo H, Kim J, Lee J. Why do young people use fitness apps? Cognitive characteristics and app quality. Electron Commer Res 2018 Jan 29;18(4):755-761. doi: 10.1007/s10660-017-9282-7
28. Paré G, Leaver C, Bourget C. Diffusion of the Digital Health Self-Tracking Movement in Canada: Results of a National Survey. J Med Internet Res 2018 May 02;20(5):e177 doi: 10.2196/jmir.9388
29. Mosconi P, Radrezza S, Lettieri E, Santoro E. Use of Health Apps and Wearable Devices: Survey Among Italian Associations for Patient Advocacy. JMIR Mhealth Uhealth 2019 Jan 15;7(1):e10242 doi: 10.2196/10242
30. Ernsting C, Stühmann LM, Dombrowski SU, Voigt-Antons J, Kuhlmey A, Gellert P. Associations of Health App Use and Perceived Effectiveness in People With Cardiovascular Diseases and Diabetes: Population-Based Survey. JMIR Mhealth Uhealth 2019 Mar 28;7(3):e12179 doi: 10.2196/12179
31. Canhoto AI, Arp S. Exploring the factors that support adoption and sustained use of health and fitness wearables. Journal of Marketing Management 2016 Oct 26;33(1-2):32-60. doi: 10.1080/0267257X.2016.1234505
32. Veríssimo JMC. Usage intensity of mobile medical apps: A tale of two methods. Journal of Business Research 2018 Aug;89:442-447. doi: 10.1016/j.jbusres.2017.12.026
33. Collado-Borrell R, Escudero-Vilaplana V, Calles A, Garcia-Martin E, Marzal-Alfaro B, Gonzalez-Haba E, et al. Oncology Patient Interest in the Use of New Technologies to Manage Their Disease: Cross-Sectional Survey. J Med Internet Res 2018 Oct 23;20(10):e11006 doi: 10.2196/11006] [Medline: 30355554
34. Davis TL, DiClemente R, Prietula M. Taking mHealth Forward: Examining the Core Characteristics. JMIR Mhealth Uhealth 2016 Aug 10;4(3):e97 doi: 10.2196/mhealth.5659
35. Lipschitz J, Miller CJ, Hogan TP, Burdick KE, Lippin-Foster R, Simon SR, et al. Adoption of Mobile Apps for Depression and Anxiety: Cross-Sectional Survey Study on Patient Interest and Barriers to Engagement. JMIR Ment Health 2019 Jan 25;6(1):e11334 doi: 10.2196/11334
36. Mackert M, Mabry-Flynn A, Champlin S, Donovan EE, Pounders K. Health Literacy and Health Information Technology Adoption: The Potential for a New Digital Divide. J Med Internet Res 2016 Oct 04;18(10):e264 doi: 10.2196/jmir.6349
37. Somers C, Grieve E, Lennon M, Bouamrane M, Mair FS, McIntosh E. Valuing Mobile Health: An Open-Ended Contingent Valuation Survey of a National Digital Health Program. JMIR Mhealth Uhealth 2019 Jan 17;7(1):e3 doi: 10.2196/mhealth.9990
38. Peng W, Kanthawala S, Yuan S, Hussain SA. A qualitative study of user perceptions of mobile health apps. BMC Public Health 2016 Nov 14;16(1):1158 doi: 10.1186/s12889-016-3808-0
39. Petersen A, Schermuly AC, Anderson A. The shifting politics of patient activism: From bio-sociality to bio-digital citizenship. Health (London) 2019 Jul;23(4):478-494. doi: 10.1177/1363459318815944
40. Mercer K, Giangregorio L, Schneider E, Chilana P, Li M, Grindrod K. Acceptance of Commercially Available Wearable Activity Trackers Among Adults Aged Over 50 and With Chronic Illness: A Mixed-Methods Evaluation. JMIR Mhealth Uhealth 2016 Jan 27;4(1):e7 doi: 10.2196/mhealth.4225

41. Hartzler AL, BlueSpruce J, Catz SL, McClure JB. Prioritizing the mHealth Design Space: A Mixed-Methods Analysis of Smokers' Perspectives. JMIR Mhealth Uhealth 2016 Aug 05;4(3):e95 doi: 10.2196/mhealth.5742
42. Hoffmann A, Christmann CA, Bleser G. Gamification in Stress Management Apps: A Critical App Review. JMIR Serious Games 2017 Jun 07;5(2):e13 doi: 10.2196/games.7216
43. Firth J, Torous J. Smartphone Apps for Schizophrenia: A Systematic Review. JMIR Mhealth Uhealth 2015 Nov 06;3(4):e102 doi: 10.2196/mhealth.4930
44. Hartmann R, Sander C, Lorenz N, Böttger D, Hegerl U. Utilization of Patient-Generated Data Collected Through Mobile Devices: Insights From a Survey on Attitudes Toward Mobile Self-Monitoring and Self-Management Apps for Depression. JMIR Ment Health 2019 Apr 03;6(4):e11671 doi: 10.2196/11671
45. Christmann CA, Hoffmann A, Bleser G. Stress Management Apps With Regard to Emotion-Focused Coping and Behavior Change Techniques: A Content Analysis. JMIR Mhealth Uhealth 2017 Feb 23;5(2):e22 doi: 10.2196/mhealth.6471
46. Ose SO, Færevik H, Kaasbøll J, Lindgren M, Thaulow K, Antonsen S, et al. Exploring the Potential for Use of Virtual Reality Technology in the Treatment of Severe Mental Illness Among Adults in Mid-Norway: Collaborative Research Between Clinicians and Researchers. JMIR Form Res 2019 Jun 10;3(2):e13633 doi: 10.2196/13633
47. Gabriels K, Moerenhout T. Exploring Entertainment Medicine and Professionalization of Self-Care: Interview Study Among Doctors on the Potential Effects of Digital Self-Tracking. J Med Internet Res 2018 Jan 12;20(1):e10 doi: 10.2196/jmir.8040
48. Martinez-Millana A, Jarones E, Fernandez-Llatas C, Hartvigsen G, Traver V. App Features for Type 1 Diabetes Support and Patient Empowerment: Systematic Literature Review and Benchmark Comparison. JMIR Mhealth Uhealth 2018 Nov 21;6(11):e12237 doi: 10.2196/12237
49. Dimitrov DV. Medical Internet of Things and Big Data in Healthcare. Healthc Inform Res 2016 Jul;22(3):156-163 doi: 10.4258/hir.2016.22.3.156
50. Turakhia MP, Kaiser DW. Transforming the care of atrial fibrillation with mobile health. J Interv Card Electrophysiol 2016 Oct 15;47(1):45-50. doi: 10.1007/s10840-016-0136-3
51. Heintzman ND. A Digital Ecosystem of Diabetes Data and Technology: Services, Systems, and Tools Enabled by Wearables, Sensors, and Apps. J Diabetes Sci Technol 2015 Dec 20;10(1):35-41 doi: 10.1177/1932296815622453
52. Vahabzadeh A, Sahin N, Kalali A. Digital Suicide Prevention: Can Technology Become a Game-changer? Innov Clin Neurosci 2016;13(5-6):16-20 Medline: 27800282
53. Lüttke S, Hautzinger M, Fuhr K. [E-Health in diagnosis and therapy of mental disorders : Will therapists soon become superfluous?]. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz 2018 Mar 9;61(3):263-270. doi: 10.1007/s00103-017-2684-9
54. Chung AE, Sandler RS, Long MD, Ahrens S, Burris JL, Martin CF, et al. Harnessing person-generated health data to accelerate patient-centered outcomes research: the Crohn's and Colitis Foundation of America PCORnet Patient Powered Research Network (CCFA Partners). J Am Med Inform Assoc 2016 May 28;23(3):485-490 doi: 10.1093/jamia/ocv191
55. Cresswell KM, McKinstry B, Wolters M, Shah A, Sheikh A. Five key strategic priorities of integrating patient generated health data into United Kingdom electronic health records. J Innov Health Inform 2019 Jan 04;25(4):254-259 doi: 10.14236/jhi.v25i4.1068
56. Knight A, Bidargaddi N. Commonly available activity tracker apps and wearables as a mental health outcome indicator: A prospective observational cohort study among young adults with psychological distress. J Affect Disord 2018 Aug 15;236:31-36. doi: 10.1016/j.jad.2018.04.099
57. Ramkumar PN, Muschler GF, Spindler KP, Harris JD, McCulloch PC, Mont MA. Open mHealth Architecture: A Primer for Tomorrow's Orthopedic Surgeon and Introduction to Its Use in Lower Extremity Arthroplasty. J Arthroplasty 2017 Apr;32(4):1058-1062. doi: 10.1016/j.arth.2016.11.019
58. Wichmann F, Sill J, Hassenstein MJ, Zeeb H, Pischke CR. Apps zur Förderung von körperlicher Aktivität. Präv Gesundheitsf 2018 Oct 31;14(2):93-101. doi: 10.1007/s11553-018-0678-6
59. Urban M. 'This really takes it out of you!' The senses and emotions in digital health practices of the elderly. Digit Health 2017 Apr 12;3:2055207617701778 doi: 10.1177/2055207617701778
60. McCallum C, Rooksby J, Gray CM. Evaluating the Impact of Physical Activity Apps and Wearables: Interdisciplinary Review. JMIR Mhealth Uhealth 2018 Mar 23;6(3):e58 doi: 10.2196/mhealth.9054

61. Montgomery K, Chester J, Kopp K. Health Wearables: Ensuring Fairness, Preventing Discrimination, and Promoting Equity in an Emerging Internet-of-Things Environment. Journal of Information Policy 2018;8:34. doi: 10.5325/jinfopoli.8.2018.0034
62. Hicks JL, Althoff T, Sosic R, Kuhar P, Bostjancic B, King AC, et al. Best practices for analyzing large-scale health data from wearables and smartphone apps. NPJ Digit Med 2019 Jun 3;2(1):45 doi: 10.1038/s41746-019-0121-1
63. Huckvale K, Prieto JT, Tilney M, Benghozi P, Car J. Unaddressed privacy risks in accredited health and wellness apps: a cross-sectional systematic assessment. BMC Med 2015 Sep 25;13(1):214 doi: 10.1186/s12916-015-0444-y
64. Armstrong S. What happens to data gathered by health and wellness apps? BMJ 2016 Jun 23;353:i3406. doi: 10.1136/bmj.i3406
65. Tabi K, Randhawa AS, Choi F, Mithani Z, Albers F, Schnieder M, et al. Mobile Apps for Medication Management: Review and Analysis. JMIR Mhealth Uhealth 2019 Sep 11;7(9):e13608 doi: 10.2196/13608
66. Jamaladin H, van de Belt TH, Luijpers LC, de Graaff FR, Bredie SJ, Roeleveld N, et al. Mobile Apps for Blood Pressure Monitoring: Systematic Search in App Stores and Content Analysis. JMIR Mhealth Uhealth 2018 Nov 14;6(11):e187 doi: 10.2196/mhealth.9888
67. Becker S, Miron-Shatz T, Schumacher N, Krocza J, Diamantidis C, Albrecht U. mHealth 2.0: Experiences, Possibilities, and Perspectives. JMIR Mhealth Uhealth 2014 May 16;2(2):e24 doi: 10.2196/mhealth.3328
68. Wathieu L, Friedman AA. An Empirical Approach to Understanding Privacy Valuation. SSRN Journal 2007. doi: 10.2139/ssrn.982593
69. Spiekermann S, Acquisti A, Böhme R, Hui K. The challenges of personal data markets and privacy. Electron Markets 2015 Apr 29;25(2):161-167. doi: 10.1007/s12525-015-0191-0
70. GfK. Global GfK Survey: Willingness to Share Personal Data in Exchange for Benefits or Rewards. 2017. URL: https://cdn2.hubspot.net/hubfs/2405078/cms-pdfs/fileadmin/user_upload/country_one_pager/nl/images/ global-gfk_onderzoek_-_delen_van_persoonlijke_data.pdf [accessed 2020-09-12]
71. Payback G. Daten & Fakten. Payback GmbH. 2019. URL: https://www.payback.net/at/ueber-payback/daten-fakten/ [accessed 2020-09-12]
72. Biermann K. Payback zahlt nichts zurück. Die Zeit. 2019 Mar 10. URL: https://www.zeit.de/online/2008/30/payback [accessed 2020-09-12]
73. Cvrcek D, Kumpost M, Matyas V, Danezis G. A Study on the Value of Location Privacy. 2006 Oct Presented at: 5th ACM Workshop on Privacy in Electronic Society - WPES '06; 2006; Alexandria, VA. doi: 10.1145/1179601.1179621
74. Acquisti A, Grossklags J. Privacy Attitudes and Privacy Behavior: Losses, Gains, and Hyperbolic Discounting. Economics of Information Security 2007:165-178. doi: 10.1007/1-4020-8090-5_13
75. Huberman B, Adar E, Fine L. Valuating Privacy. IEEE Secur. Privacy Mag 2005 Sep;3(5):22-25. doi: 10.1109/msp.2005.137
76. von Wedel P, Hagist C, Saunders K. Erratum: Die Digitalisierung der Arzt-Patienten Beziehung in Deutschland: Ein Discrete Choice Experiment zur Analyse der Patientenpräferenzen bezüglich digitaler Gesundheitsleistungen. Gesundhökon Qual manag 2018 Feb 27;23(03):E1-E1. doi: 10.1055/a-0580-9556
77. Robert Koch-Institut. “Corona-Datenspende Blog.” RKI, Das Robert Koch-Institut Ist Ein Bundesinstitut Im Geschäftsbereich Des Bundesministeriums Für Gesundheit, May 2020, https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Corona-Datenspende.html ..
78. Wagner, Amina, et al. “Putting a Price Tag on Personal Information - A Literature Review.” Proceedings of the 51st Hawaii International Conference on System Sciences, 2018, doi:10.24251/hicss.2018.474.
79. Wasser, Thomas, et al. “Using ‘Big Data’ to Validate Claims Made in the Pharmaceutical Approval Process.” Journal of Medical Economics, vol. 18, no. 12, 2015, pp. 1013–1019., doi:10.3111/13696998.2015.1108919.
80. Die Bundesregierung. “Digitalisierung Gestalten Umsetzungsstrategie Der Bundesregierung.” Digitalisierung Gestalten Umsetzungsstrategie Der Bundesregierung, 2019, pp. 4–205, https://www.bundesregierung.de/resource/blob/992814/1605036/ad8d8a0079e287f694f04cbccd93f591/digitalisierung-gestalten-download-bpa-data.pdf .
81. Grossklags, Jens, and Alessandro Acquisti. “Privacy Attitudes and Privacy Behavior.” Economics of Information Security Advances in Information Security, 2007, pp. 1–22., doi:10.1007/1-4020-8090-5_13.
82. Petereit, Dieter. “CCC: Corona-Datenspende-App Des RKI Zeigt Sich Datenspendabel.” t3n Magazin, Yeebase Media GmbH, Apr. 2020, t3n.de/news/ccc-corona-datenspende-app-rki-1272328/.

83. Skatova, Anya, and James Goulding. “Psychology of Personal Data Donation.” PLOS ONE, vol. 14, no. 11, 2019, doi:10.1371/journal.pone.0224240.
84. Haghi, Mostafa, et al. “Wearable Devices in Medical Internet of Things: Scientific Research and Commercially Available Devices.” Healthcare Informatics Research, vol. 23, no. 1, 2017, pp. 4–15., doi:10.4258/hir.2017.23.1.4.
85. Dimitrov, Dimiter V. “Medical Internet of Things and Big Data in Healthcare.” Healthcare Informatics Research, vol. 22, no. 3, 2016, pp. 156–163., doi:10.4258/hir.2016.22.3.156.
86. Henriksen, André, et al. “Using Fitness Trackers and Smartwatches to Measure Physical Activity in Research: Analysis of Consumer Wrist-Worn Wearables.” Journal of Medical Internet Research, vol. 20, no. 3, 2018, pp. 1–19., doi:10.2196/jmir.9157.
87. Bataineh, Ahmed Saleh, et al. “Monetizing Personal Data: A Two-Sided Market Approach.” Procedia Computer Science, vol. 83, 2016, pp. 472–479., doi:10.1016/j.procs.2016.04.211.
88. Brown, Thomas C, and Robin Gregory. “Why the WTA–WTP Disparity Matters.” Ecological Economics, vol. 28, no. 3, 1999, pp. 323–335., doi:10.1016/s0921-8009(98)00050-0.
89. Acquisti, Alessandro, et al. “What Is Privacy Worth?” The Journal of Legal Studies, vol. 42, no. 2, 2013, pp. 249–274., doi:10.1086/671754.
90. Bansal, Gaurav, et al. “The Impact of Personal Dispositions on Information Sensitivity, Privacy Concern and Trust in Disclosing Health Information Online.” Decision Support Systems, vol. 49, no. 2, 2010, pp. 138–150., doi:10.1016/j.dss.2010.01.010.
91. Schlereth, Christian, et al. “Measuring Consumers' Preferences for Metered Pricing of Services.” Journal of Service Research, vol. 14, no. 4, 2011, pp. 443–459., doi:10.1177/1094670511418817.
92. Ryan, Mandy, et al. Using Discrete Choice Experiments to Value Health and Health Care. Springer, 2008, ISBN 978-1-4020-5753-3.
93. Bekker-Grob et al. “Sample Size Requirements for Discrete-Choice Experiments in Healthcare: a Practical Guide.” The patient, 2015, doi: 10.1007/s440271-015-0118-z.
94. Palinkas, Lawrence A., et al. “Purposeful Sampling for Qualitative Data Collection and Analysis in Mixed Method Implementation Research.” Administration and Policy in Mental Health and Mental Health Services Research, vol. 42, no. 5, 2013, pp. 533–544., doi:10.1007/s10488-013-0528-y.
95. Schlereth, Christian, et al. “Using Discrete Choice Experiments to Estimate Willingness-to-Pay Intervals.” Marketing Letters, vol. 23, no. 3, 2012, pp. 761–776., doi:10.1007/s11002-012-9177-2.
96. Schlereth, Christian, and Bernd Skiera. “Two New Features in Discrete Choice Experiments to Improve Willingness-to-Pay Estimation That Result in SDR and SADR: Separated (Adaptive) Dual Response.” Management Science, vol. 63, no. 3, 2017, pp. 829–842., doi:10.1287/mnsc.2015.2367.
97. Schlereth, Christian, and Bernd Skiera. “DISE: Dynamic Intelligent Survey Engine.” Quantitative Marketing and Marketing Management, 2012, pp. 225–243., doi:10.1007/978-3-8349-3722-3_11.
98. Street, Deborah J., et al. “Quick and Easy Choice Sets: Constructing Optimal and Nearly Optimal Stated Choice Experiments.” International Journal of Research in Marketing, vol. 22, no. 4, 2005, pp. 459–470., doi:10.1016/j.ijresmar.2005.09.003.
99. Süptitz, Joséphine, and Christian Schlereth. “Fracking: Messung Der Gesellschaftlichen Akzeptanz Und Der Wirkung Akzeptanzsteigernder Maßnahmen.” Schmalenbachs Zeitschrift Für Betriebswirtschaftliche Forschung, vol. 69, no. 4, 2017, pp. 405–439., doi:10.1007/s41471-017-0035-z.
100. Schlereth, Christian, et al. “Why Do Consumers Prefer Static Instead of Dynamic Pricing Plans? An Empirical Study for a Better Understanding of the Low Preferences for Time-Variant Pricing Plans.” European Journal of Operational Research, vol. 269, no. 3, 2018, pp. 1165–1179., doi:10.1016/j.ejor.2018.03.033.
101. Bevan, William, and Joan Faye Pritchard. “The Anchor Effect and the Problem of Relevance in the Judgment of Shape.” The Journal of General Psychology, vol. 69, no. 1, 1963, pp. 147–161., doi:10.1080/00221309.1963.9918440.
102. Thurstone, L. L. “A Law of Comparative Judgment.” Psychological Review, vol. 34, no. 4, 1927, pp. 273–286., doi:10.1037/h0070288.
103. Train, Kenneth. Discrete Choice Methods with Simulation. Cambridge University Press, 2009, ISBN 978-0521747387
104. Swait, Joffre, and Rick L. Andrews. “Enriching Scanner Panel Models with Choice Experiments.” Marketing Science, vol. 22, no. 4, 2003, pp. 442–460., doi:10.1287/mksc.22.4.442.24910.

105. Green, Paul E., and V. Srinivasan. “Conjoint Analysis in Consumer Research: Issues and Outlook.” Journal of Consumer Research, vol. 5, no. 2, 1978, p. 103., doi:10.1086/208721.
106. Field, Andy P., et al. Discovering Statistics Using R. Sage, 2012. ISBN 978-1-4462-0045-2.
107. Constine, Josh. “Facebook Pays Teens to Install VPN That Spies on Them.” TechCrunch.com, TechCrunch, 29 Jan. 2019, techcrunch.com/2019/01/29/facebook-project-atlas/.
108. Reuters. “Big Data: Die Pharmaunternehmen Buhlen Um Daten.” FAZ.NET, Frankfurter Allgemeine Zeitung, 2018, https://www.faz.net/aktuell/wirtschaft/die-grossen-pharmaunternehmen-buhlen-um-patientendaten-15480427.html.
109. Ferrero E, Brachat S, Jenkins JL, Marc P, Skewes-Cox P, et al. Ten simple rules to power drug discovery with data science. PLOS Computational Biology, vol. 16, no. 8, 2020, pp. 1-10., doi:https://doi.org/10.1371/journal.pcbi.1008126.
110. Madduri R, Chard K, D’Arcy M, Jung SC, Rodriguez A, Sulakhe D, et al. Reproducible big data science: A case study in continuous FAIRness. PLoS ONE, vol. 14, no. 4, 2019, pp. 1-22., doi:https://doi.org/10.1371/journal.pone.0213013.
111. Bundesinstitut für Arzneimittel und Medizinprodukte. “Digitale Gesundheitsanwendungen (DiGA).”Midizinprodukte, 2020, www.bfarm.de/DE/Medizinprodukte/DVG/_node.html.
112. Bundesinstitut für Medizinprodukte. “DIGA Verzeichnis.” DiGA, 2020, diga.bfarm.de/de/verzeichnis.
113. Kassenärztliche Bundesvereinigung. “Verordnung Von Gesundheits-Apps: Vergütung Geregelt.” Praxisnachrichten, Kassenärztliche Bundesvereinigung (KBV), Mar. 2021, www.kbv.de/html/1150_51239.php .
114. Kassenärztliche Bundesvereinigung. “Praxisbarometer Digitalisierung Stand und Perspektiven der Digitalisierung in der vertragsärztlichen und -psychotherapeutischen Versorgung.” IGES Institut GmbH, 2018, pp. 1–47.
115. Weber, Guido. “Die Patientenquittung – Ein Ungenutztes Marketing-Instrument in Der Gesetzlichen Krankenversicherung?” Gesundheits- Und Sozialpolitik, vol. 60, no. 1, ser. 2, 2006, pp. 30–37. 2, https://www.jstor.org/stable/26766634.
116. Bundesministerium Für Gesundheit, “Verordnung über das Verfahren und die Anforderungen der Prüfung der Erstattungsfähigkeit digitaler Gesundheitsanwendungen in der gesetzlichen Krankenversicherung.” Referentenentwurf, 2020.
117. Fünftes Buch Sozialgesetzbuch “Verzeichnis für digitale Gesundheitsanwendungen; Verordnungsermächtigung“ (SGB V), § 139e: 8(1).
118. EU Regulation 2017/745. “Medical Devices.” European Parliament and the Council.
119. Braun, V., & Clarke, V. Using thematic analysis in psychology. Qualitative Research in Psychology, 2(3), 2006.
120. Saldaña, J. “The Coding Manual for Qualitative Research.” Arizona State University: SAGE Publications Inc. 2013.
121. Vaismoradi, M., & Turunen, H. “Content analysis and thematic analysis: Implications for conducting a qualitative descriptive study.” Nursing & Health Sciences, 15(3), 2013, pp. 398-405.
122. Gehman, Joel, et al. “Finding Theory–Method Fit: A Comparison of Three Qualitative Approaches to Theory Building.” Journal of Management Inquiry, vol. 27, no. 3, 2017, pp. 284–300., doi:10.1177/1056492617706029.
123. Fereday, J., & Muir-Cochrane, E. “Demonstrating Rigor Using Thematic Analysis: A Hybrid Approach of Inductive and Deductive Coding and Theme Development.” International Journal of Qualitative Methods, 5(1), 2006. pp. 80-92.
124. Gioia, Dennis A., et al. “Seeking Qualitative Rigor in Inductive Research.” Organizational Research Methods, vol. 16, no. 1, 2012, pp. 15–31., doi:10.1177/1094428112452151.
125. Brodin, Håkan, and Stephen Hodge. “A Guide to Quantitative Methods in Health Impact Assessment .” Swedish National Institute of Public Health, 2008, pp. 1–30., doi:ISBN: 978-91-7257-598-1.
126. Kaia Health Software GmbH. “Kaia Health: Digitale Therapien Gegen Chronische Krankheiten.” Kaia Health EU, 2020, www.kaiahealth.com/de?utm_source=google.
127. Kaia Health Software GmbH. “User Data.” Company Internal Data, January – March 2020.
128. Heilmittelkatalog. “Zweiter Teil Zuordnung Der Heilmittel Zu Indikationen.” Zuordnung Der Heilmittel Zu Indikationen, § 92 6 (1) Number 2 SGB V, 2020, pp. 1–65.
129. Verband der Ersatzkassen e. V. “Daten Zum Gesundheitswesen: Versicherte.” Vdek.com/Presse, 2020, www.vdek.com/presse/daten/b_versicherte.html.
130. Kohler, Ulrich, and Frauke Kreuter. Datenanalyse Mit Stata Allgemeine Konzepte Der Datenanalyse Und Ihre Praktische Anwendung. De Gruyter Oldenbourg, 2017.
131. Lai, T.l, et al. “Strong Consistency of Least Squares Estimates in Multiple Regression II.” Journal of Multivariate Analysis, vol. 9, no. 3, 1979, pp. 343–361., doi:10.1016/0047-259x(79)90093-9.

132. Field, Andy P., et al. Discovering Statistics Using R. Sage, 2012. ISBN:978-1-4462-0045-2.
133. Heidel & Schöneberger. “Interview for Digitale Versorgung Gesetz Study: Health app producer 1.” 7 Nov. 2019.
134. Heidel & Schöneberger. “Interview for Digitale Versorgung Gesetz Study: Health app producer 2.” 19 Nov. 2019.
135. Heidel & Schöneberger. “Interview for Digitale Versorgung Gesetz Study: Political representative 1.” 28 Oct. 2019.
136. Heidel & Schöneberger. “Interview for Digitale Versorgung Gesetz Study: Political representative 2.” 8 Nov. 2019.
137. Heidel & Schöneberger. “Interview for Digitale Versorgung Gesetz Study: Political representative 3.” 4 Dec. 2019.
138. Heidel & Schöneberger. “Interview for Digitale Versorgung Gesetz Study: Political representative 4.” 12 Dec. 2019.
139. Heidel & Schöneberger. “Interview for Digitale Versorgung Gesetz Study: Political representative 5.” 7 Jan. 2020.
140. Heidel & Schöneberger. “Interview for Digitale Versorgung Gesetz Study: Medical chamber representative 1.” 1 Oct. 2019.
141. Heidel & Schöneberger. “Interview for Digitale Versorgung Gesetz Study: Medical chamber representative 2.” 31 Oct. 2019.
142. Heidel & Schöneberger. “Interview for Digitale Versorgung Gesetz Study: Medical chamber representative 3.” 6 Nov. 2019.
143. Heidel & Schöneberger. “Interview for Digitale Versorgung Gesetz Study: Medical chamber representative 4.” 11 Nov. 2019.
144. Heidel & Schöneberger. “Interview for Digitale Versorgung Gesetz Study: Representative health insurance company 1.” 14 Oct. 2019.
145. Heidel & Schöneberger. “Interview for Digitale Versorgung Gesetz Study: Representative health insurance company 2.” 30 Oct. 2019.
146. Heidel & Schöneberger. “Interview for Digitale Versorgung Gesetz Study: Physician 2.” 20 Nov. 2019.
147. Heidel & Schöneberger. “Interview for Digitale Versorgung Gesetz Study: Physician 3.” 22 Nov. 2019.
148. Heidel & Schöneberger. “Interview for Digitale Versorgung Gesetz Study: Physician 4.” 22 Nov. 2019.
149. Heidel & Schöneberger. “Interview for Digitale Versorgung Gesetz Study: Physician 5.” 26 Nov. 2019.
150. Heidel & Schöneberger. “Interview for Digitale Versorgung Gesetz Study: Physician 7.” 28 Nov. 2019.
151. Heidel & Schöneberger. “Interview for Digitale Versorgung Gesetz Study: Physician 8.” 28 Nov. 2019.
152. Heidel & Schöneberger. “Interview for Digitale Versorgung Gesetz Study: Physician 9.” 29 Nov. 2019.
153. Heidel & Schöneberger. “Interview for Digitale Versorgung Gesetz Study: Physician 1.” 7 Oct. 2019.
154. Heidel & Schöneberger. “Interview for Digitale Versorgung Gesetz Study: Physician 6.” 27 Nov. 2019.
155. Heidel & Schöneberger. “Interview for Digitale Versorgung Gesetz Study: Health app certification representative.” 1 Nov. 2019.
156. Rundell SD, et al. “Physical therapist management of acute and chronic low back pain using the World Health Organization's International Classification of Functioning, Disability and Health.” Physical Therapy, vol. 89, no. 1, 2009, pp. 82-90: doi: 10.2522/ptj.20080113.
157. Pfingsten, M., and P. Schöps. “Chronische Rückenschmerzen: Vom Symptom Zur Krankheit.” Zeitschrift Für Orthopädie Und Unfallchirurgie - Thieme, vol. 142, no. 2, 2004, pp. 146–152., doi:DOI: 10.1055/s-2004-822622.
158. Göbel, H. “Epidemiologie Und Kosten Chronischer Schmerzen Spezifische Und Unspezifische Rückenschmerzen.” Springer-Verlag, vol. 15, 2001, pp. 92–98.
159. Priebe, Janosch, et al. “Digital Treatment of Back Pain versus Standard of Care: The Cluster-Randomized Controlled Trial, Rise-UP.” Journal of Pain Research, vol. 13, 2020, pp. 1823–1838., doi:http://doi.org/10.2147/JPR.S260761.
160. Huber, Stephan, et al. “Treatment of Low Back Pain with a Digital Multidisciplinary Pain Treatment App: Short-Term Results.” Jmir Rehabilitation and Assistive Technologies, vol. 4, no. 2, 2017, pp. 1–9., doi:http://rehab.jmir.org/2017/2/e11/.
161. Clement, Innocent, et al. “Implementing Systematically Collected User Feedback to Increase User Retention in a Mobile App for Self-Management of Low Back Pain: Retrospective Cohort Study.” Jmir Mhealth and Uhealth, vol. 6, no. 6, 2018, pp. 1–12., doi:http://mhealth.jmir.org/2018/6/e10422/.
162. Priebe, Janosch, et al. “Less Pain, Better Sleep? The Effect of a Multidisciplinary Back Pain App on Sleep Quality in Individuals Suffering from Back Pain – a Secondary Analysis of App User Data.” Journal of Pain Research, vol. 13, 2020, pp. 1121–1128., doi:http://doi.org/10.2147/JPR.S232792.

163. Toelle, Thomas, et al. “App-Based Multidisciplinary Back Pain Treatment versus Combined Physiotherapy plus Online Education: a Randomized Controlled Trial.” Npj Digital Medicine, vol. 2, no. 34, 2019, pp. 1–9., doi:https://doi.org/10.1038/s41746-019-0109-x.
164. Cuenca-Martínez, Ferran, et al. “Effectiveness of Classic Physical Therapy Proposals for Chronic Non-Specific Low Back Pain: a Literature Review.” Physical Therapy Research, vol. 21, 2018, pp. 15–22., doi:doi: 10.1298/ptr.E9937.
165. Hoffmann, Alexandra, et al. Gamification in Stress Management Apps: A Critical App Review. JMIR Serious Games, vol. 5, no. 2, 2017. doi: 10.2196/games.7216
166. Schoeppe, Stephanie, et al. Apps to Improve Diet, Physical Activity and Sedentary Behaviour in Children and Adolescents: a Review of Quality, Features and Behaviour Change Techniques. International Journal of Behavioral Nutrition and Physical Activity, vol. 14, no. 1, 2017, 1–10. doi: 10.1186/s12966-017-0538-3
167. Zweifel, Peter, et al. Health Economics. Springer, 2009.
168. Wenig, Christina M., et al. “Costs of Back Pain in Germany.” European Journal of Pain, vol. 13, no. 3, 2009, pp. 280–286., doi:10.1016/j.ejpain.2008.04.005.
169. Mannion, A. F., et al. “Goal Attainment Scaling as a Measure of Treatment Success after Physiotherapy for Chronic Low Back Pain.” Rheumatology, vol. 49, no. 9, 2010, pp. 1734–1738., doi:10.1093/rheumatology/keq160.
170. Busse, R, and M Blümel. “Germany: Health System Review.” Health Systems in Transition, vol. 16, no. 2, 2014, pp. 1–296., ISSN: 1817-6127.

Multimedia Appendix 1[21]

Table 10: *Study Characteristics*

#	Study	Method	Data Source	Data Type	Sample Size	Sample Country
	PubMed Search: Health Apps and Wearables n= 37, Eligible n= 20					
1	Henriksen et al. (2018): "Using Fitness Trackers and Smartwatches to Measure Physical Activity in Research"	Literature Review	Six Databases (Queen's University Wearable Device Inventory, Gsm Arena, Wearables.com, SpecBucket, PrisGuide, the Vandrico Wearable Database)	Wearable Devices	423 wearables from 132 different brands	n.a.
2	Mercer et al (2016): "Acceptance of commercially available wearable activity trackers among adults aged over 50 and with chronic illness"	Qualitative Mixed Methods Approach,	Participants study testing four different health trackers	Health data from participants and user perception	30 chronically ill participants aged between 52 and 85 years	Canada
3	Firth & Torous (2015): "Smartphone Apps for Schizophrenia: A Systematic Review"	Literature Review	seven Databases (Ovid MEDLINE, the Cochrane Central Register of Controlled Trials, Health Technology Assessment Database, Allied and Complementary Medicine, Health and Psychosocial Instruments, PsycINFO, and Embase	Literature	226 Articles in total, 7 eligible articles, 5 studies for Apps AND Schizophrenia	n.a.
4	Dimitrov (2016): "Medical Internet of Things and Big Data in Healthcare"	Descriptive Qualitative Study	Selected Articles	Literature	27 Articles	n.a.
5	Haghi et al. (2017): "Wearable Devices in Medical Internet of Things: Scientific Research and Commercially Available Devices"	Literature Review	Selected Articles	Literature	51 Articles	n.a.
6	Vahabzadeh (2016): "Digital Suicide Prevention: Can Technology Become a Game-changer?"	Literature Review	Selected Articles	Literature	17 Articles	USA
7	Lobelo et al. (2016): "The wild wild west: A Framework to integrate mHealth software applications and wearables to support physical activity assessment, counseling and interventions for Cardiovascular Disease risk reduction"	Literature Review	MEDLINE, PubMed, Web of Science, World Wide Web	Literature	95 Articles	n.a.
8	Wiesner et al. (2018): "Technology Adaption, Motivational Aspects, and Privacy Concerns of Wearables in the German running community: Field Study"	Field Study, Survey	People at a regional road race event in 2017	Questionnaires	845 Surveys of runners	Germany
9	Urban (2017): "This really takes it out of you! The senses and emotions in	Qualitative Case Study	Elderly people	Semi-Structured Interviews	27 Middle-class elderly male and female people	Germany

[21]Heidel A, Hagist C. Potential Benefits and Risks Resulting From the Introduction of Health Apps and Wearables Into the German Statutory Health Care System: Scoping Review. JMIR Mhealth Uhealth. 2020 Sep 23;8(9), doi: 10.2196/16444 [13]

	digital health practices of the elderly"					
10	Ehn et al. (2018): "Activity Monitors as support for older persons' physical activity in daily life: Qualitative Study of Users' Experience"	Qualitative Study	Elderly people (median age: 83 years)	Interviews and User Diaries	8 Community-dwelling elderly people (median age: 83 years) testing two different wearable and tablet based Apps for 74 test days	Sweden
11	Brandt et al (2018): "General Practitioners' Perspective on eHealth and lifestyle change: qualitative interview study"	Qualitative Study	General practitioners from Southern Denmark (Purposeful sampled)	Semi-Structured Interviews	10 General practitioners (5 male, 5 female), engaged in electronic consultations	Denmark
12	McCallum et al. (2018): "Evaluating the Impact of Physical Activity Apps and Wearables: Interdisciplinary Review"	Literature Review	8 data bases (health and computing science)	Literature	111 Articles on physical activity and its measurement through Apps	n.a.
13	Cresswell et al. (2018): "Five key strategic priorities of integrating patient generated health data into United Kingdom electronic health records"	Qualitative Study	Literature from the American Medical Informatics Association	Literature	n.a.	North America, UK
14	Paré et al. (2018): "Diffusion of the Digital Health Self-Tracking Movement in Canada: Results of a National Survey"	National Survey	Canadian adults	Questionnaires	4109 Participants	Canada
15	Hicks et al. (2019) “Best practices for analyzing large-scale health data from wearables and smartphone apps”	Review and report about quantitative PGHD Studies	Articles which use large-scale PGHD data sets	Literature and Data such as Step count	75 Articles	n.a.
16	Lüttke et al. (2018): “E-Health in diagnosis and therapy of mental disorders. Will therapists soon become superfluous?”	Literature Review	Articles on mHealth solutions for mental disease	Literature	30 Articles	n.a.
17	Turankhia & Kaiser (2016): “Transforming the care of atrial fibrillation with mobile health”	Literature Review	Articles on mHealth tracking of AF patients	Literature	31 Articles	n.a.
18	Heintzman (2016). “A Digital Ecosystem of Diabetes Data and Technology: Services, Systems, and Tools Enabled by Wearables, Sensors, and Apps”	Literature Review	Articles on mHealth Solutions to monitor and manage Diabetes	Literature	97 Articles	n.a.
19	Knight & Bidargaddi (2018): ” Commonly available activity tracker apps and wearables as a mental health outcome indicator: A prospective observational cohort study among young adults with psychological distress”	Prospective Observational Cohort Trial Study	Mental Health Website ResearchOut.com	Self-reports on mental health and PGHD from other apps	120 male and female participants between 18-25 years old	Australia
20	Ramkumar et al. (2017): “Open mHealth Architecture: A Primer for Tomorrow’s Orthopedic Surgeon and Introduction to its use in Lower Extremity Arthroplasty”	Review	Articles about mHealth and surgery	Literature	38	n.a.
Google Scholar Search: "Health Apps (and) Wearables" n= 36 , Eligible n= 16, n= 4 Purposeful Sampled Articles in German						

21	Canhoto & Arp (2017): "Exploring the factors that support adoption and sustained use of health and fitness wearables"	Exploratory Qualitative Study	Literature on consumer technology adoption and Members of fitness centers	Literature and Interviews	20 participants in focus groups	Germany
22	Albrecht (2016): "Gesundheits-Apps und Prävention"	Literature Review	Pub Med. Scopus	Academic Articles	86 Articles	n.a.
23	Groß & Schmidt (2018): "Health und Gesundheitsapps aus medizinischer Sicht"	Normative Ethical Analysis	Selected Articles	Theoretical Literature	n.a.	n.a.
24	Genes et al. (2018): "From smartphone to EHR: a case report on integrating patient-generated health data"	Case Study	Asthma Patients	Self-tracked peak expiratory flow rate	4 voluntary patients with asthma	USA
25	GfK (2016): "Global GfK survey: Health and Fitness Tracking"	Survey Study	Consumers answering the online Survey	Questionnaire	More than 20 000 consumers aged 15 and older	16 Countries
26	Krebs & Duncan (2015): "Health App Use Among US Mobile Phone Owners: A National Survey"	National Survey	Cross-Sectional Survey	Questionnaire	1604 Mobile Phone Users	USA
27	Becker et al. (2014): "mHealth 2.0: Experiences, Possibilities, and Perspectives"	Qualitative Study	Various Databases	Literature	67 Articles	n.a.
28	Huckvale et al (2015): "Unaddressed privacy risks in accredited health and wellness apps: a cross-sectional systematic assessment"	Cross-Sectional Systematic Assessment of Data Privacy Practices	Health App	In-App Data Privacy Policy	79 Apps Certified as Clinically Safe	n.a.
29	Urrea et al. (2015): "Mobile Health Initiatives to improve outcomes in primary prevention of cardiovascular disease"	Qualitative Thematic Study	Selected Articles	Literature	50 Articles	n.a.
30	Statista (2018): "Mobile Health"	Survey Study	People living in Germany	Survey	5046 Participants within the age group 16-69 years old	Germany
31	Park et al. (2018): "Why do young people use fitness apps? Cognitive characteristics and App quality"	Interviews	College students	Self-report, Questionnaires	201 Participants from three different Universities using at least one fitness App	South Korea
32	Schoeppe et al. (2017): "Apps to improve diet, physical activity and sedentary behavior in children and adolescents: a review of quality, features and behavior change techniques"	Systematic Review of Health Apps for children	iTunes Store and Google Play Store	Health Apps rated at least with +4 based on 20 ratings, available in English, targeting children	25 Apps	Australia
33	Wichmann et al. (2018): "Apps for physical activity promotion. Attitudes, acceptance and utilization preferences among adults aged 50 years and above: results of focus group discussions"	Interview Study	Participants	Interviews and Discussions with Participants	15 People in three focus groups older than 50 years	Germany
34	Cristóvao Veríssimo (2018): "Usage intensity of mobile medical apps: A tale of two methods"	Mixed Methods Approach; Logistic Regression and fsQCA	Fully qualified doctors and medical Students engaged in a Medical Social Network	Survey	199 Respondents	USA

35	Peng et al. (2016): "A qualitative study of user perceptions of mobile health apps"	Thematic Inductive Analysis	Purposive sampled Smartphone Users	Five individual interviews	44 Participants	USA
36	Somers et al. (2019): "Valuing Mobile Health: An Open-Ended Contingent Valuation Survey of a National Digital Health Program"	Contingent Valuation Willingness to Pay Study	ResearchNow panel Members	National Survey	1679 Individuals and 305 Representatives of Dallas Intervention Communities	UK
37	Chung et al. (2016): "Harnessing person-generated health data to accelerate patient-centered outcomes research: the Crohn's and ColitisFoundation of America PCORnet Patient Powered Research Network"	Project Study to establish Patient centered Data Research	Clinical Data Research Network	Patient reports, outcomes and health behavior	14200 IBD (inflammatory bowel disease) Patients	USA
38	Petersen et al. (2019): "The shifting politics of patient activism: From bio-sociality to bio-digital citizenship"	Media Review	Scopus, Medline, Google, University Library	Media produced by patient activist 1980-today	76 Articles	n.a.
39	Armstrong (2016): "What happens to data gathered by health and wellness apps?"	Report	Articles on PGHD use	Literature	18 Articles	n.a.
40	Montgomery et al. (2018): "Health Wearables: Ensuring Fairness, Preventing Discrimination, and promoting Equity in an Emerging Internet-of-Things Environment"	Review	Articles on mHealth and Big Data	Literature	n.a.	n.a.
	JMIR Publications Search: "Health Apps AND Wearables" n= 59 , Eligible n= 15					
41	Hartmann et al. (2019): "Utilization of Patient-Generated Data Collected Through Mobile Devices: Insights From a Survey on Attitudes Toward Mobile Self-Monitoring and Self-Management Apps for Depression"	Online Survey	Online Panel Questback GmbH.	Questionnaires	825 Participants	Germany
42	Mosconi et al. (2019): "Use of Health Apps and Wearable Devices: Survey Among Italian Associations for Patient Advocacy"	Online Survey	Patients' Health Care Advocacy Associations	Questionnaires	227 completed Questionnaires	n.a.
43	Ernsting et al. (2019): "Associations of Health App Use and Perceived Effectiveness in People With Cardiovascular Diseases and Diabetes: Population-Based Survey"	Online Survey	Online Panel Gesellschaft für Innovative Marktforschung	Questionnaires	1500 Diabetes Patients	Germany
44	Gabriels & Moerenhout (2018): "Exploring Entertainment Medicine and Professionalization of Self-Care: Interview Study Among Doctors on the Potential Effects of Digital Self-Tracking"	Interview Study	Purposeful Sampling	Semistructured Interviews	12 General Practitioners and Cardiologists	Belgium
45	Tabi et al. (2019): "Mobile Apps for Medication Management: Review and Analysis"	Systematic App Search	iOS Apple App Store and Android Google Play Store	App Content	328 Apps	n.a.

46	Jamaladin et al. (2018): "Mobile Apps for Blood Pressure Monitoring: Systematic Search in App Stores and Content Analysis"	Systematic App Search	iOS Apple App Store and Android Google Play Store	Quality Scores	184 Apps	n.a.
47	Christmann et al. (2017): "Stress Management Apps With Regard to Emotion-Focused Coping and Behavior Change Techniques: A Content Analysis"	Content Analysis	Google Play Store	App Content	62 Free Apps	n.a.
48	Collado-Borrell et al. (2018): "Oncology Patient Interest in the Use of New Technologies to Manage Their Disease: Cross-Sectional Survey"	Cross-Sectional Survey	Hematology-Oncology Patients in a Day Hospital or the Pharmaceutical Care Consultancy	Questionnaires	611 Patients	Spain
49	Morrow Lipschitz et al. (2019): "Adoption of Mobile Apps for Depression and Anxiety: Cross-Sectional Survey Study on Patient Interest and Barriers to Engagement"	Cross-Sectional Survey Study	A single Veterans Health Administration	Questionnaires	149 Veterans	USA
50	Martinez-Millana et al. (2018): "App Features for Type 1 Diabetes Support and Patient Empowerment: Systematic Literature Review and Benchmark Comparison"	Systematic Literature Review and Benchmark Comparison	PubMed, Medline, Google Scholar, and Cochrane Trials	Literature	55 Articles	n.a.
51	Mackert et al. (2016): "Health Literacy and Health Information Technology Adoption: The Potential for a New Digital Divide"	Cross-Tabulation Analysis	Newest Vital Sign Measure of Health Literacy	Questionnaires	4974 Adults	USA
52	Hoffmann et al. (2017): "Gamification in Stress Management Apps: A Critical App Review	Review	Google Play Store	App Content	62 Stress Management Apps	n.a.
53	Hartzler et al. (2016): "Prioritizing the mHealth Design Space: A Mixed-Methods Analysis of Smokers' Perspectives"	Mixed-Methods Approach with Focus Groups and Surveys	Adults Interested in Quit Smoking	Questionnaires and Focus Group Session Brainstorming	40 Adults	USA
54	Davis et al. (2016) "Taking mHealth Forward: Examining the Core Characteristics"	Literature Review	n.a.	Literature	198 Sources	n.a.
55	Ose et al. (2019): "Exploring the Potential for Use of Virtual Reality Technology in the Treatment of Severe Mental Illness Among Adults in Mid-Norway: Collaborative Research Between Clinicians and Researchers"	Focus Group Interviews	Researchers, the Manager at a District Psychiatric Center, and the Manager of the Local Municipal Mental Health Service	Collaborative Research Team	n.a.	Norway

Source: Own Depiction.

Table 11: *Study Aims and Findings*

#	Study	Aim	Findings
	PubMed Search: Health Apps and Wearables n= 37, Eligible n= 20		
1	Henriksen et al. (2018): "Using Fitness Trackers and Smartwatches to Measure Physical Activity in Research"	▪ Analyzing change of consumer market for wearables ▪ Giving an overview of devices	▪ 11 most relevant brands for wearables are Apple, Fitbit, Garmin, Mio, Misfit, Polar, PulseOn, Samsung, TomTom, Withings and Xiaomi, ▪ Number of brands decreases over time ▪ Number of wearables on the market increases with additional sensors
2	Mercer et al (2016): "Acceptance of commercially available wearable activity trackers among adults aged over 50 and with chronic illness"	▪ Analyzing the perceived acceptability of wearables to increase personal fitness	▪ mHealth has a significant potential to help older patients to become more active ▪ Help to overcome barriers between patients and doctors
3	Firth & Torous (2015): "Smartphone Apps for Schizophrenia: A Systematic Review"	▪ Reviewing literature on apps for mental illnesses or schizophrenia	▪ People with schizophrenia are willing to record and engage with Apps to self-direct therapy ▪ There seems to be a potential benefit in the use of apps for psychotic illnesses
4	Dimitrov (2016): "Medical Internet of Things and Big Data in Healthcare"	▪ Examining the potential health data collected through apps and wearables	▪ Apps will improve the communication between doctors and their patients ▪ Storing the data collected by different sensors in a medical cloud and connecting the cloud to all relevant health institutions might have a significant cost reduction potential ▪ Digital health advisory will play an important role in the future
5	Haghi et al. (2017): "Wearable Devices in Medical Internet of Things: Scientific Research and Commercially Available Devices"	▪ Review about wearables, health apps and smart clothing in scientific papers and commercial websites	▪ Potential for the medical use of self-tracked health data might be significant ▪ Sensors in the area of semiconductor technology have improved to be more precise
6	Vahabzadeh (2016): "Digital Suicide Prevention: Can Technology Become a Game-changer?"	▪ Review the technical possibilities and feasibility to monitor and observe psychological health data in apps to predict the risk of suicide	▪ Significant potential in the supervision of self-tracked psychological data to prevent suicide risk ▪ Care should be taken because these technologies could be the source of error
7	Lobelo et al. (2016): "The wild wild west: A Framework to integrate mHealth software applications and wearables to support physical activity assessment, counseling and interventions for Cardiovascular Disease risk reduction"	▪ Review the utility of implementing health apps in the existing health care system ▪ Organizational framework to support the professional use of self-monitored data	▪ The use of mHealth to monitor and analysis health data seems promising in cardiovascular risk reduction ▪ These apps also help to motivate users to conduct a different life style ▪ The integration of self-monitored health data in the clinical care could be challenging
8	Wiesner et al. (2018): "Technology Adaption, Motivational Aspects, and Privacy Concerns of Wearables in the German running community: Field Study"	▪ Analyzing the motivation and data privacy concerns of healthy and active people who use wearables to track their fitness.	▪ 73% of running community uses fitness tracking to monitor their exercises ▪ 42 % of the participants are not concerned if their data would be shared with others ▪ 32 % would share their data with their physician.
9	Urban (2017): "This really takes it out of you! The senses and emotions in digital health practices of the elderly"	▪ Analyzing how well mHealth is suited for the use of elderly people ▪ What emotions does the use of mHealth trigger	▪ Elderly people develop negative emotions linked to aging stereotyped by using mHealth ▪ Using mHealth also motivated to engage in more physical activity.
10	Ehn et al. (2018): "Activity Monitors as support for older persons' physical activity in daily life: Qualitative Study of Users' Experience"	▪ Outlining the user experience of older people monitoring their health data with variables in daily life	▪ When monitoring health data with wearables, the physical activity of the probands increases ▪ Indicates a high potential to encourage more physical activity for older people ▪ Usability and reliability need to be improved to fit the consumer preferences of the group
11	Brandt et al (2018): "General Practitioners' Perspective on eHealth and lifestyle change: qualitative interview study"	▪ Outlining the practitioners' perspective on the use of self-tracked data for life style enhancement in Denmark	▪ General practitioners' use mHealth applications constantly for themselves but rarely for their patients ▪ The general practitioners assess the incorporation of self-tracked data in the eHealth system as beneficial
12	McCallum et al. (2018): "Evaluating the Impact of Physical Activity Apps and Wearables: Interdisciplinary Review"	▪ To assess the research designs and methods of literature on engagement, acceptability and effectiveness research of physical activity apps.	▪ Most articles on PA apps are randomized controlled trials ▪ A general evaluation guideline of health apps is urgently needed ▪ In most cases, an optimization based on the evaluation of the app does not take place

13	Cresswell et al. (2018): "Five key strategic priorities of integrating patient generated health data into United Kingdom electronic health records"	▪ Recommendation of five key strategies for the integration of self-monitored health data into the UK health system.	▪ Integration of self-monitored data into clinical applications is going to be a complex future process ▪ The study has identified technology, user, legal, and political related factors as main inhibitors for progress
14	Paré et al. (2018): "Diffusion of the Digital Health Self-Tracking Movement in Canada: Results of a National Survey"	▪ Analyzing the motivation of self-tracking and non-tracking ▪ Outlining possible barriers to the technology and benefits	▪ 66% of the participants use on a regular basis one or more applications to track their health ▪ There might be a high potential in home-monitoring health data of chronic ill patients with apps or wearables, increasing the patient empowerment.
15	Hicks et al. (2019) "Best practices for analyzing large-scale health data from wearables and smartphone apps"	▪ To create an manual on how to use large-scale PGHD sets to understand the relationship between health behavior and environmental, social or personal factors	▪ The challenge about producing large-scale PGHD research is that the data sets are most of the times 'messy', important data is often incomplete or shows selection bias ▪ The report give a manual on how to produce successful PGHD quantitative studies
16	Lüttke et al. (2018): "E-Health in diagnosis and therapy of mental disorders. Will therapists soon become superfluous?"	▪ To get an overview about the state of research on mental disease mHealth solutions, application possibilities, products and there effectivity in the fields of diagnostics and therapy.	▪ Using mHealth apps complementary to traditional methods to diagnose mental disease seems promising and effective ▪ There is great potential to reduce costs in the preventive care of mental disease and allocate personnel resources more effectively ▪ Screening and monitoring through Apps and wearables reduces barriers and could potentially improve the therapist-patient relationship
17	Turankhia & Kaiser (2016): "Transforming the care of atrial fibrillation with mobile health"	▪ To summarize the limitations and data gaps of monitoring and treating AF patients	▪ Especially wearables seem promising in the application of symptoms, heart rates and rhythms surveillance of AF or AF risk patients ▪ Reimbursement models should encourage AF patients to self-track and share their data ▪ These technologies have the potential to decrease the screening costs and enhance early detection of AF
18	Heintzman (2016). "A Digital Ecosystem of Diabetes Data and Technology: Services, Systems, and Tools Enabled by Wearables, Sensors, and Apps"	▪ To get an overview about the technological possibilities and effectivity of mHealth solution to accompany diabetes treatment	▪ PGHD in diabetes research has great potential to further research and understand glycemia in a realistic setting ▪ mHealth enables individualized guidance for patients and potentially decreases costs because of less professional surveillance and guidance
19	Knight & Bidargaddi (2018): "Commonly available activity tracker apps and wearables as a mental health outcome indicator: A prospective observational cohort study among young adults with psychological distress"	▪ To explore the potential of health apps and wearables as valid mental health assessment tool	▪ The collection of PGHD and the self-management of mental disease through apps might contribute to the patient empowerment ▪ The collection and processing of PGHD helps clinicians to improve clinical care through a better understanding of behavioral indicators
20	Ramkumar et al. (2017): "Open mHealth Architecture: A Primer for Tomorrow's Orthopedic Surgeon and Introduction to its use in Lower Extremity Arthroplasty"	▪ To get an general overview about the open mHealth architecture and its possibilities within orthopedic surgery	▪ Post-surgery interactive apps might help to manage pain and leads to patient empowerment ▪ Apps might lead to a more efficient allocation of resources
Google Scholar Search: "Health Apps (and) Wearables" n= 36, Eligible n= 16, n= 4 Purposeful Sampled Articles in German			
21	Canhoto & Arp (2017): "Exploring the factors that support adoption and sustained use of health and fitness wearables"	▪ To outline the key factors why people use mHealth applications and the key stakeholders interested in the health data	▪ The current German wearable user is in average young and sportive ▪ The users were especially interested in fitness apps or wearables, if they were designed to be goal oriented ▪ The visualization of the data and the possibility for data competition are significant variables
22	Albrecht (2016): "Gesundheits-Apps und Prävention"	▪ Reviewing the general conditions for using health apps in Germany	▪ Most Apps are clustered as Lifestyle apps ▪ There is little or no academic research on wearables ▪ The number of existing apps seems problematic because the software is in most cases not compatible and data is not interchangeable
23	Groß & Schmidt (2018): "Health und Gesundheitsapps aus medizinischer Sicht"	▪ Discussing the ethical assessment of health apps	▪ The philosophical evaluation models for health apps benefit the users and the doctors to categorize them and to understand their chances and risks
24	Genes et al. (2018): "From smartphone to EHR: a case report on integrating patient-generated health data"	▪ To evaluate the aspects of self-monitored data integration into the practitioners daily routine for disease management	▪ The potential of integrating and sharing self-monitored data with the physician is considered high for the patients ▪ There might be some pitfalls with the incorporation of the data in the daily routine of the physician.

25	GfK (2016): "Global GfK survey: Health and Fitness Tracking"	▪ Outlining the market for wearables and health tracking in a comparative setting	▪ 33% of the people in the 16 countries use health tracking ▪ The countries with most consumers using health tracking are China, Brazil and the USA ▪ Most people use health tracking to improve or maintain the personal status of physical fitness.
26	Krebs & Duncan (2015): "Health App Use Among US Mobile Phone Owners: A National Survey"	▪ To analyze the sociodemographic variables, motivation and history of health app und wearable users	▪ There is still a large proportion of citizens who do not use health apps or when using, already stopped using them ▪ Health apps should better consider consumer concerns and their usability needs
27	Becker et al. (2014): "mHealth 2.0: Experiences, Possibilities, and Perspectives"	▪ Analyzing the potential of health apps from a psychological, legal, clinical and technological perspective	▪ The potential of health apps is high ▪ Apps struggle with their "trustworthiness" ▪ Apps are in general underutilized ▪ When designing new Health apps, all stakeholders should be involved
28	Huckvale et al (2015): "Unaddressed privacy risks in accredited health and wellness apps: a cross-sectional systematic assessment"	▪ To outline the data protection gaps of certified "clinically safe" mHealth applications	▪ 89% of the Health apps uploaded information to online services ▪ 66% of the apps did not encrypt information when sending ▪ 92% did not encrypt information when stored locally ▪ There are significant gaps in the compliance with data protection principles, assuming that certification programs might not deliver the desired outcome
29	Urrea et al. (2015): "Mobile Health Initiatives to improve outcomes in primary prevention of cardiovascular disease"	▪ To outline the potential Health apps in preventive care for cardiovascular disease	▪ There are many health applications in this segment available ▪ Effectivity remains insufficiently studied ▪ Important to develop a guide for the evaluation of effectivity
30	Statista (2018): "Mobile Health"	▪ To describe characteristics of wearable users in Germany	▪ Wearable users are interested in the themes health, fitness and nutrition and want to use the apps for self-optimization ▪ the youngest group (18-29 years old) holds most health app users ▪ 55% would share their self-tracked health data in any case with their doctor, 15% with their health insurance and 7% would share with an internet company
31	Park et al. (2018): "Why do young people use fitness apps? Cognitive characteristics and App quality"	▪ To outline the motivation or reasons why people use health apps	▪ Young college students use health apps because of health concerns, innovation, expectation and self-efficiency
32	Schoeppe et al. (2017): "Apps to improve diet, physical activity and sedentary behavior in children and adolescents: a review of quality, features and behavior change techniques"	▪ To evaluate health apps available for children on a five point mobile rating scale	▪ Popular apps for children to improve physical activity, diet and sedentary behavior have a moderate quality ▪ It is important to promote the engagement of the user while using the app and they should respond better to the individual user's needs
33	Wichmann et al. (2018): "Apps for physical activity promotion. Attitudes, acceptance and utilization preferences among adults aged 50 years and above: results of focus group discussions"	▪ To gain insights into the motivation of health app use amongst a focus group aged 50 years and older	▪ Users of health apps rated the use of health Apps higher than the non-user focus group ▪ People had concerns about data safety and disliked apps, in which data had to be entered manually ▪ Simple apps with only a few features were liked more than apps with many features
34	Cristóvao Veríssimo (2018): "Usage intensity of mobile medical apps: A tale of two methods"	▪ Analyzing impact factors like peer influence, perceived usefulness and perceived usefulness of use	▪ High health app usage amongst the doctors and medical students depends on perceived usefulness and ease of use ▪ Apps, which are used to support the clinical practice attract an increasing number of doctors ▪ Senior doctors and young female doctors tend to use less health apps, if there is little peer influence, little perceived usefulness and little ease of use
35	Peng et al. (2016): "A qualitative study of user perceptions of mobile health apps"	▪ To outline the opportunities and challenges of health applications	▪ 57% of the participants used health apps before ▪ The main reasons for non-usage was lack of awareness, lack of app literacy, cost and the lack to need a health app ▪ The reasons for people to use health apps are motivation, dedication, social competition, entertainment and a reward system
36	Somers et al. (2019): "Valuing Mobile Health: An Open-Ended Contingent Valuation Survey of a National Digital Health Program"	▪ To evaluate the consumer perspective on potential benefits of mHealth	▪ Consumers appreciate health apps, which promote well-being, health care control and social connectivity ▪ Health apps should be tailored to the needs of the consumers and potential barriers should be better understood ▪ There is a positive correlation between willingness to pay of health apps and younger age and income

			▪ People who are in better health shape use mHealth more frequently
37	Chung et al. (2016): "Harnessing person-generated health data to accelerate patient-centered outcomes research: the Crohn's and ColitisFoundation of America PCORnet Patient Powered Research Network"	▪ To establish an online platform IBD patients to Upload PGHD and to enhance a patient centered research network	▪ The platform is popular amongst the IBD patients, about 14 200 patients registered online and chose which data they want to upload and how actively they want to participate in the formulation of research questions ▪ The platform as a network and data-base helps participants to gain insights about their condition and facilitates the monitoring and management of the disease
38	Petersen et al. (2019): "The shifting politics of patient activism: From bio-sociality to bio-digital citizenship"	▪ To analyze the shifting dynamics and media activity of HIV/AIDS and breast cancer groups	▪ Bio-based identity is an ever growing concept, enhanced through the internet and new communication and networking channels ▪ People gain more scientific and personal information such as reports based experiences through online health platforms ▪ Collected health data is seen as valuable in the future but there is a current asymmetry between those who collect and those who are selling the data
39	Armstrong (2016): "What happens to data gathered by health and wellness apps?"	▪ To report the processing of self-tracked health data	▪ Most apps or wearables offer little or no data protection for their consumers even though their use is encouraged by the NHS ▪ There is a current lack of data privacy education because many consumer agree to terms and conditions without reading them ▪ Many apps and wearables sell personal fitness data without even encrypting them ▪ There is a need for more government regulations about PGHD processing
40	Montgomery et al. (2018): "Health Wearables: Ensuring Fairness, Preventing Discrimination, and promoting Equity in an Emerging Internet-of-Things Environment"	▪ To outline data privacy concerns when using big data to analyze large-scale PGHD	▪ Government regulations are needed to enhance fairness and equity when for example health insurance companies use and analyze PGHD ▪ Further data privacy education is needed to encourage the companies to share their profit from data selling with the consumers ▪ Transparency about data processing is one of the most important points to gain the trust of the consumer
JMIR Publications Search: "Health Apps AND Wearables" n= 59 , Eligible n= 15			
41	Hartmann et al. (2019): "Utilization of Patient-Generated Data Collected Through Mobile Devices: Insights From a Survey on Attitudes Toward Mobile Self-Monitoring and Self-Management Apps for Depression"	▪ To understand the usage of self-monitoring via health apps and wearables of depression patients	▪ Apps may decrease treatment challenges for depression patients ▪ Sharing the self-tracked data with therapist might improve communication and increase adherence
42	Mosconi et al. (2019): "Use of Health Apps and Wearable Devices: Survey Among Italian Associations for Patient Advocacy"	▪ To research health care advocacy associations for patients about their opinion of health apps	▪ Many patients already use health apps ▪ Accessibility of apps should improve ▪ Many patients already appreciate use of apps
43	Ernsting et al. (2019): "Associations of Health App Use and Perceived Effectiveness in People With Cardiovascular Diseases and Diabetes: Population-Based Survey"	▪ To research perceived usefulness of health apps for managing diabetes and CVD	▪ Younger study participants rated health apps more effective than older people ▪ Health knowledge is an important factor as well as technology literacy ▪ Usability of apps should be increased
44	Gabriels & Moerenhout (2018): "Exploring Entertainment Medicine and Professionalization of Self-Care: Interview Study Among Doctors on the Potential Effects of Digital Self-Tracking"	▪ To understand doctors' opinion about patient self-tracking	▪ Opportunity for more personalized care ▪ Professionalization of self-care ▪ Patient empowerment ▪ But self-care also as hard work
45	Tabi et al. (2019): "Mobile Apps for Medication Management: Review and Analysis"	▪ To create an overview about medication plan apps	▪ There is a need for a professional health app platform ▪ Patient empowerment through health apps ▪ Too many apps on market ▪ Non-transparent apps, need to regulate standards
46	Jamaladin et al. (2018): "Mobile Apps for Blood Pressure Monitoring: Systematic Search in App Stores and Content Analysis"	▪ To evaluate blood pressure monitoring apps	▪ Quality of many apps poor ▪ Too many apps on market ▪ Few apps have a very good quality, these enhance patient self-management
47	Christmann et al. (2017): "Stress Management Apps With Regard to Emotion-Focused Coping and	▪ To give an overview about stress-management apps	▪ Apps include conventional methods of behavior change methods and new methods of emotion focused stress management ▪ Many apps combine different stress management strategies

	Behavior Change Techniques: A Content Analysis"		▪ Evidenced-based content missing in health app
48	Collado-Borrell et al. (2018): "Oncology Patient Interest in the Use of New Technologies to Manage Their Disease: Cross-Sectional Survey"	▪ To understand the patients' needs and willingness of disease self-management	▪ Patients very interested in apps for self-management ▪ Healthcare providers should play a more active role in the recommendation of a health app and supervision of its use
49	Morrow Lipschitz et al. (2019): "Adoption of Mobile Apps for Depression and Anxiety: Cross-Sectional Survey Study on Patient Interest and Barriers to Engagement"	▪ To evaluate the mental health app usage of patients	▪ Patients are generally interested in using these technologies but do not use them yet ▪ Privacy concerns are addressed ▪ Health care providers should supervise app usage
50	Martinez-Millana et al. (2018): "App Features for Type 1 Diabetes Support and Patient Empowerment: Systematic Literature Review and Benchmark Comparison"	▪ To evaluate features of diabetes apps	▪ Apps have potential to educate patients, track diabetes data and share the data with important health care stakeholder ▪ Many apps just enable data collection ▪ Apps should include more individualized self-management features
51	Mackert et al. (2016): "Health Literacy and Health Information Technology Adoption: The Potential for a New Digital Divide"	▪ To research the impact of health literacy on the use of health apps and wearables	▪ Health literacy is significantly associated with nutrition and fitness app usage ▪ People whore are more health literate find the use of health apps easier
52	Hoffmann et al. (2017): "Gamification in Stress Management Apps: A Critical App Review	▪ To give an overview about the use of gamification for stress management apps	▪ App users use little or no gamification in stress management apps ▪ Benefits of gamification should be more exploited in health apps to enhance adherence and behavior change
53	Hartzler et al. (2016): "Prioritizing the mHealth Design Space: A Mixed-Methods Analysis of Smokers' Perspectives"	▪ To give an overview about preferred features of quit smoking apps for smokers	▪ User preferences and best practice treatments should be included in the health app design ▪ People prefer rather personalized and interactive tools and features ▪ App should be designed more evidence based
54	Davis et al. (2016) "Taking mHealth Forward: Examining the Core Characteristics"	▪ To give an overview about all core characteristics of mobile health apps	▪ People are already using technologies and the adapt to the usage quite fast ▪ Connectivity is an important factor about the usage of health apps ▪ High potential for self-management ▪ Evidence based treatments should be included
55	Ose et al. (2019): "Exploring the Potential for Use of Virtual Reality Technology in the Treatment of Severe Mental Illness Among Adults in Mid-Norway: Collaborative Research Between Clinicians and Researchers"	▪ To research the potential of VR as complimentary mental illness treatment	▪ VR has great potential in the treatment of mentally ill patients ▪ Greatest potential lies in social skills and countering self-isolation ▪ Potential to educate family and friends of patient about the mental disease

1. The user group of health apps and wearables
2. Effectivity of health apps and wearables to improve health
3. The potential of brought along self-tracked data
4. Concerns and data privacy risks

Source: Own Depiction.

Multimedia Appendix 2[22]

Table 12: *Descriptive Statistics Discrete Choice Experiment*

Independent Variables		Distribution within Sample/Mean	German Average[23]
Gender	Female	53 %	51 %
	Male	47 %	49 %
	Divers	0.1 %	
Age	15-25 years	8 %	Less than 20 years: 18.4%
	26-35 years	12 %	20-40 years: 24.6%
	36-45 years	17 %	40-60 years: 28.8 %
	46-55 years	22 %	60-80 years: 21.7 %
	56-65 years	18 %	80 and older: 6.5%
	older than 65 years	23 %	
Monthly Household Net Income	N/A	11 %	
	Up to 500 EUR	3 %	Less than 1300 EUR: 16.3 %
	500 - 999 EUR	8 %	1300 EUR - 1700 EUR: 9.1 %
	1000 - 1999 EUR	25 %	1700 EUR - 2600 EUR: 20.6 %
	2000 - 2999 EUR	21 %	2600 EUR - 3600 EUR: 17.8 %
	3000 - 3999 EUR	18 %	3600 EUR - 5000 EUR: 17.5 %
	4000 - 4999 EUR	9 %	5000 EUR - 18000 EUR: 18.6 %
	more than 5000 EUR	5 %	
Education	No High School Diploma	0.4 %	4 %
	Hauptschule[24]	12 %	30.4%
	Mittlere Reife[25]	38 %	23.1%
	Fachhochschulreife[26]	9 %	Fachhochschul- oder
	Abitur[27]	18 %	Hochschulreife: 31.9 %
	University Degree (BA, MA or higher)	23 %	17.7 %

Source: Own Depiction.

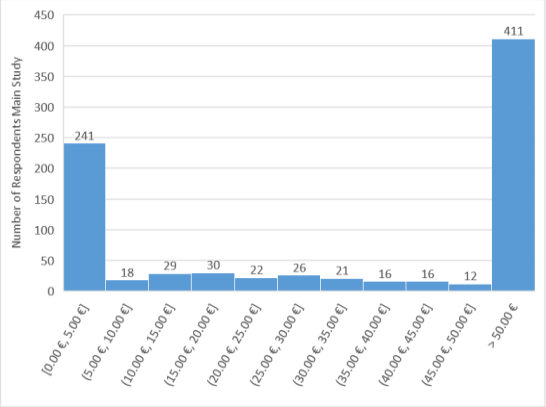
[22] Heidel A, Hagist C, Schlereth C. Pricing through Health Apps Generated Data in Germany - Digital Dividend as a Game Changer: Discrete Choice Experiment. PLOS ONE. 2021 JUL, doi: 10.1371/journal.pone.0254786 [14]
[23] "German Average" is based on data from destatis.de
[24] Lower Secondary Education
[25] High School Diploma (Secondary Education)
[26] Advanced Technical College Certificate (Upper Secondary Education)
[27] General Qualification for University Education

Table 13: *Multiple Linear Regression Models*

Coefficients	Dependent Variable: ß-parameter 'Data Sales to Third Parties'	Dependent Variable: ß-parameter 'Health Insurer'	Dependent Variable: Importance Weight 'Price'
Constant	0.005 **	0.509	0.0269 *
	(0.631)	(0.340)	(0.078)
Sex/Male	0.195	0.532	**0.005 ****
	(0.134)	(0.072)	**(0.017)**
Sex/Divers	**0.085 .**	0.101	0.466
	(1.906)	(1.028)	(0.236)
Age	**0.039 ***	0.943	0.293
	(0.045)	(0.024)	(0.006)
Health App & Wearable Usage/ No	0.308	**0.002 ****	**0.002 ****
	(0.147)	**(0.079)**	**(0.018)**
Fitness	**0.061 .**	0.181	0.519
	(0.040)	(0.022)	(0.005)
Health	0.170	0.903	0.376
	(0.041)	(0.022)	(0.005)
Monthly Household Net Income	0.691	**0.031 ***	0.625
	(0.037)	**(0.020)**	(0.005)
Education	**0.035 ***	0.195	0.895
	(0.048)	(0.026)	(0.006)
Perceived DSGVO Importance	**0.006 ****	0.100	0.108
	(0.046)	(0.025)	(0.006)
BMI	0.987	0.656	0.108
	(0.013)	(0.007)	(0.002)
Sharing of Fitness or Health Data/ No	0.231	0.578	0.697
	(0.333)	(0.180)	(0.041)
R-squared	0.036	0.031	0.039
Adjusted R-squared	0.023	0.019	0.026
F-statistic	2.806 on 11 and 830 DF	2.439 on 11 and 830 DF	3.061 on 11 and 830 DF

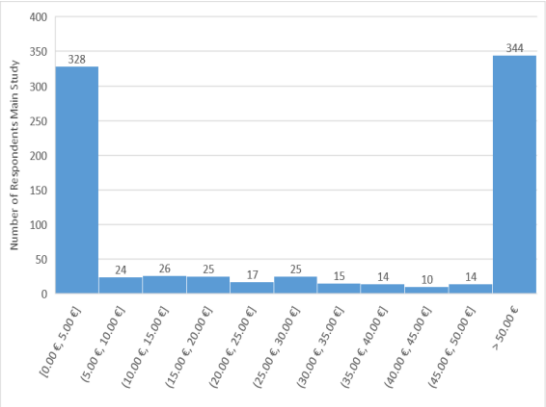
Source: Own Depiction.

Figure 4: *WTA from Health Insurers for All Data and no Data Sales to Third Parties*



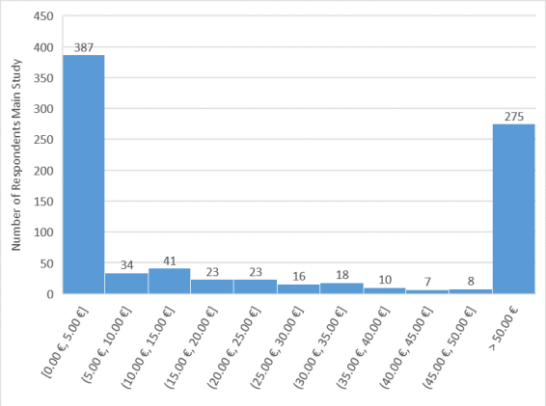
Source: Own Depiction.

Figure 5: *WTA from Pharmaceutical and Medical Device Companies for All Data and no Data Sales to Third Parties*



Source: Own Depiction.

Figure 6: *WTA from Universities for All Data and no Data Sales to Third Parties*



Source: Own Depiction.

Multimedia Appendix 3[28]

Table 14: *Average Pain Level over 30 Treatments*

Day	Pain Average	Standard Deviation	Standard Error
1	3.62961615	2.18168232	0.0208072
2	3.49154614	2.15007909	0.03068725
3	3.48580533	2.13756839	0.03638184
4	3.48900733	2.15696428	0.03936748
5	3.47106851	2.10821345	0.03972109
6	3.47774917	2.12681155	0.04078725
7	3.48112848	2.11644391	0.0413245
8	3.46341463	2.14893122	0.04262209
9	3.45654939	2.12321174	0.04282549
10	3.45654939	2.08972772	0.04302548
11	3.43944791	2.11719705	0.04467416
12	3.45056497	2.14783455	0.04660404
13	3.42107892	2.12338429	0.04745659
14	3.43827493	2.13900471	0.04966378
15	3.39895773	2.10667401	0.05069337
16	3.34482759	2.08342586	0.05169934
17	3.3819398	2.12099096	0.05485525
18	3.34985632	2.1007376	0.05630568
19	3.3409611	2.17209759	0.05998988
20	3.30800654	2.13043236	0.06089436
21	3.2489121	2.12107624	0.06257434
22	3.19907407	2.14320468	0.06521564
23	3.22709552	2.13406443	0.06662448
24	3.1486911	2.14829801	0.06951729
25	3.17346939	2.12184444	0.07144622
26	3.12439024	2.14701206	0.07497691
27	3.07942708	2.11228324	0.07622046
28	3.06406685	2.12084459	0.07914922
29	3.04504505	2.1355032	0.08274907
30	3.01935484	2.14339265	0.08608072

Source: Own calculation based on data provided through Kaia Health Software GmbH.

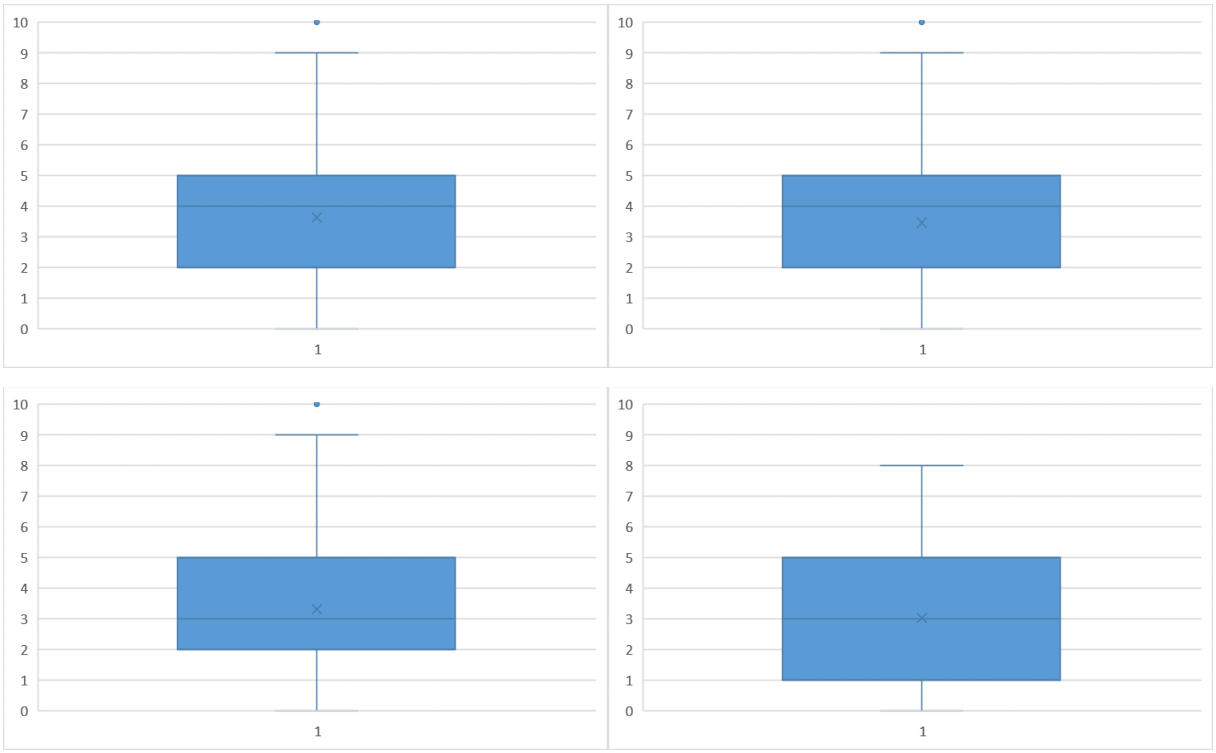
[28] Heidel A, Hagist C, Spinler S, Schöneberger M. The Digital Care Act – A Chance to Relieve the Dust from the German Health Care System: A Multi-Method Approach. Unpublished Working Paper. 2020 Dec. [15]

Table 15: *Average Sleep Quality over 30 Treatments*

Day	Sleep Average	Standard Deviation	Standard Error
1	6.36483536	2.02444906	0.01930763
2	6.4632308	2.02624453	0.0289198
3	6.4910197	1.98127438	0.03372168
l4	6.51598934	1.98660396	0.03625818
5	6.49627263	2.00001872	0.03768258
6	6.45531445	1.97392128	0.03785517
7	6.50057186	1.97135756	0.03849163
8	6.50039339	2.00839439	0.03983467
9	6.52861382	2.00044851	0.04034934
10	6.52861382	1.94973069	0.04014308
11	6.51246661	1.97638068	0.04170285
12	6.4952919	1.97308227	0.04281224
13	6.51148851	1.94890194	0.043557
14	6.51967655	1.97517383	0.04585993
15	6.57498552	1.95784653	0.0471121
16	6.61945813	1.91804113	0.04759539
17	6.56454849	1.99891555	0.05169801
18	6.58979885	1.97299802	0.0528819
19	6.60259344	2.00037233	0.0552471
20	6.63643791	1.92526238	0.05502996
21	6.71018277	1.92871454	0.05689943
22	6.66388889	2.00115622	0.06089324
23	6.63157895	2.00796872	0.06268783
24	6.73298429	1.98603906	0.06426671
25	6.74376417	1.92011005	0.06465347
26	6.79268293	1.95890506	0.06840793
27	6.88541667	1.91471236	0.06909123
28	6.8551532	1.93943727	0.07237916
29	6.85735736	1.98621147	0.07696413
30	6.86129032	1.98380803	0.07967165

Source: Own calculation based on data provided through Kaia Health Software GmbH.

Figure 8: *Boxplots Pain Level Day 1 – Day 10 – Day 20 – Day 30*



Source: Own calculation based on data provided through Kaia Health Software GmbH.

Table 16: *Calculations for the Cost-Effectiveness Ratios*

	Physical Therapy	**App Treatment**
Pain Level Relief	Average pain day 1: 4.7 points Average pain after 9 treatments: 3.6 Average pain relief: -1.1 points (treatment duration totaled 9 weeks) [169]	Average pain day 1: 3.63 points Average pain day 30: 3.02 points Average pain relief: -0.56 points [127]
Costs	Price per physical therapy = 9.75€ [128] Price per prescription = 10.00€ Minimum wage for 1 hour of productivity loss due to travel time to the treatment or time loss during the treatment (during normal working hours) = 9.35€ We calculated here with the maximum available number of physical therapy treatments for statutory health insured patients within a quarter of a year	Price for 1-month unlimited app usage = 99.00€ [126]
Calculations	$\text{CER Physical Therapy} = \frac{(9.75€ \times 30) + (10€ \times 5) + 2(9.35€ \times 30)}{-(-1.1)}$ $\text{CER Physicial Therapy} = 821.36\ €/\text{pain point reduction}$	$\text{CER App Treatment} = \frac{(99.00€ \times 3)}{-(-0.56)}$ $\text{CER App Treatment} = 530.36€/\text{pain point reduction}$

Source: Own calculations.