Doctoral Thesis

The Performance of Health Care Services Amid the COVID-19 Pandemic and the Digital Health Transformation

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A Health Economic Analysis

Submitted to

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To

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Preliminary Notes

The German healthcare system is undergoing a profound transformation. On the one hand, the daily provision of healthcare services is being affected by a multitude of challenges, ranging from demographic change to shortages of medical staff and soaring healthcare expenditures. At the same time, new digital technologies are disrupting traditional clinical pathways and medical procedures.

Adding to the complexity, a unique challenge was posed by the COVID-19 pandemic, which is still impacting the healthcare system today following the unprecedented emergence of the crisis in 2020. Apart from the direct health risks it posed to individuals, the pandemic led to indirect effects such as contact restrictions, lockdowns, reallocation of scarce resources, and hesitancy among patients to seek medical care due to uncertainties. As a result, healthcare delivery experienced substantial disruption, likely leading to divergent medical outcomes in the long term.

Amidst these challenges, in contrast, the COVID-19 pandemic also acted as a catalyst for the adoption of digital applications in healthcare. While such applications existed prior to the pandemic, their integration into healthcare was limited due to various uncertainties. However, the pandemic necessitated rapid utilization of digital solutions like telemedicine in the form of video consultations to avoid the risk of infection.

Addressing these issues requires rigorous empirical research and health economic analyses to quantify the pandemic's negative impact on the healthcare system and to mitigate adverse trends in medical care access and inequalities among patient groups.

Moreover, digital applications in the healthcare system demand comprehensive evaluations based on real-world clinical data to make informed decisions about their long-term benefits and risks for different stakeholders. For instance, the extended use of telemedicine must be justified by evidence of providing similar or greater benefits to patients, physicians, hospitals, and the environment.

This health economic doctoral thesis aims to employ a selected set of empirical methods to both investigate the current challenges in the German healthcare system in the context of the COVID-19 pandemic and to evaluate the use of digital health applications to sustainably improve the medical care for patients. To achieve these objectives, the dissertation comprises the following five published scientific papers, each contributing valuable insights to the field of health economic research. The initial two papers address challenges posed to the German healthcare system by the COVID-19 pandemic, while the subsequent three papers focus on the digitization of healthcare.

The first paper, *COVID-19 pandemic and waiting times in outpatient specialist care in Germany: an empirical analysis,* examines potential effects of the COVID-19 pandemic on waiting times for outpatient specialist care in Germany. Based on an experiment in which 908 outpatient specialist practices in Germany were called before and during the COVID-19 pandemic, the offer of an appointment and the waiting time for the appointment are used as key health economic predictors of healthcare access. Different insurance statuses and regions with varying levels of healthcare supply are examined to additionally uncover inequalities among different patient groups. Data from 589 collected appointments from surgeons and orthopedists, gynecologists, dermatologists, otorhinolaryngologists, and ophthalmologists are analyzed using a linear mixed effect model. The study shows two main counteracting effects during the pandemic. First, the average waiting time for appointments decreased. This reduction in waiting time is attributed to patient uncertainty about potential infection risks, which may have freed up capacities in physicians' practices. Second, the probability of patients not receiving an appointment at all significantly increased during the pandemic, suggesting that the exceptional situation caused by the COVID-19 pandemic may have led to uncertainty among physicians, resulting in a decrease of appointment allocations. Furthermore, inequalities in healthcare access regarding patients' insurance status and the regional level of supply persisted during the pandemic showing that policymakers and healthcare providers should focus on maintaining access to regular care during COVID-19, especially for vulnerable patient groups, to avoid adverse long-term health outcomes.

The second publication, *COVID-19 related decline in cancer screenings most pronounced for elderly patients and women in Germany: a claims data analysis,* compares the utilization of cancer screenings before and during the COVID-19 pandemic. The study analyzes claims data from all legally regulated preventive health services spanning from 2017 to 2020 for a cohort of 15,833,662 patients covered by Germany's largest statutory health insurance fund to identify vulnerable patient groups and to provide insights that can optimize the allocation of healthcare resources and prevent long-term deteriorations in health outcomes. By analyzing 42,046,078 screenings, the study reveals varying levels of utilization for individual cancer screenings, but an overall significant decrease of 21.46% during the pandemic. The most substantial decline is observed among the elderly and women, highlighting their increased vulnerability. Furthermore, the study finds no evidence of catch-up effects for total screenings throughout the year 2020. The implications of reduced cancer screenings are concerning, as delayed or missed early detection can lead to escalated treatment costs, diminished quality of life, and higher mortality rates. It is crucial for policymakers and healthcare providers to take these findings

into account and target resources strategically to reduce the burden on health outcomes and public health in the long term.

The third paper, titled *Assessing telemedicine efficiency in follow-up care with video consultations for patients in orthopedic and trauma surgery in Germany: randomized controlled trial*, constitutes the first part of a prospective randomized controlled trial (RCT) investigating the use of telemedicine in orthopedic and trauma surgery follow-up care designed and conducted by the author of the doctoral thesis. The RCT was performed in the Department of Trauma, Hand and Reconstructive Surgery of the University Hospital Giessen, with registration ID DRKS00023445 of the German Clinical Trials Register. A total of 60 patients with various shoulder and knee conditions were enrolled in the study and were assigned to either the intervention group, receiving a video consultation, or the control group, attending an in-person consultation in the clinic. The primary objective is to assess the efficiency of telemedicine by evaluating patient and physician satisfaction with digitized follow-up care and the overall quality of care provided. Data from 52 patients (after eight withdrawals) show that patients express slightly higher satisfaction with video consultations compared to in-clinic-consultations, although this difference is not statistically significant. After excluding video consultations affected by technical problems, no significant difference can be found in physician satisfaction between groups. The analysis further highlights the potential of telemedicine for a broader range of patients, and individuals with prior telemedicine experience demonstrate a higher willingness to adopt telemedicine for follow-up care.

In the fourth paper, *Economic and environmental impact of digital health app video consultations in follow-up care for patients in orthopedic and trauma surgery in Germany: randomized controlled trial*, the data of the above-mentioned RCT are considered from an economic perspective, accounting for environmental effects. The economic analysis includes travel and time costs as well as production losses, while the environmental effects assessed consider greenhouse gas emissions, carbon monoxide, volatile hydrocarbons, nitrogen oxides, and particulates, leading to the calculation of environmental costs. To account for potential uncertainties, the analyses are completed with various sensitivity analyses. Replacing an in-clinic appointment with a video consultation can yield mean cost savings of €76.52 per patient by reducing travel costs, time costs, and production losses. Telemedicine also has a positive environmental impact, saving approximately 11.248 kg of greenhouse gases, 0.070 kg of carbon monoxide, 0.011 kg of volatile hydrocarbons, 0.028 kg of nitrogen oxides, and 0.0004 kg of particulates per patient. This leads to environmental cost savings ranging from €3.73 to €9.53 per patient.

The fifth paper, *Digitization of follow-up care in orthopedic and trauma surgery with video consultations: health economic evaluation study from a health provider's perspective*, provides the third and final part of the conducted RCT in the form of a health economic analysis from the healthcare provider's perspective. It assesses the suitability of video consultations in follow-up care and evaluates their financial implications, aiming to provide essential data for stakeholders to make informed decisions regarding the digitization of ambulatory care. The economic analysis considers treatment time, personnel costs, capacity for additional treatable patients, and determines the break-even point for video consultations, taking into account different scenarios in the form of a sensitivity analysis. The findings show that telemedicine reduces personnel costs by 25% attributed to time efficiencies and allows the healthcare provider to accommodate additional patients. In addition, the analysis indicates a break-even point of 23 video consultations per month (ranging from 12 to 38) to achieve cost neutrality.

The comprehensive evaluation of the utilization of telemedicine in the follow-up care of orthopedic and trauma surgery patients from multiple perspectives by means of an RCT demonstrates that video consultations can be efficiently applied to a wide range of patients and provide benefits to multiple stakeholders such as cost savings, productivity gains, and environmental improvements without compromising quality of care and satisfaction. Based on this exploration of clinical data, decision makers can be holistically supported in utilizing digital health, not only during the COVID-19 pandemic, but also beyond.

In total, the five publications of this doctoral thesis analyze various health economic aspects of two acute and major disruptive influences on the German healthcare system. Combined, these analyses hold profound scientific relevance as they provide valuable insights for healthcare providers, policy makers, and researchers on the provision of demand-driven, high-quality, and equitable healthcare based on empirical methods and real-world data.

1 COVID-19 Pandemic and Waiting Times in Outpatient Specialist Care in Germany: An Empirical Analysis

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COVID-19 pandemic and waiting times in outpatient specialist care in Germany: an empirical analysis

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Abstract

Background: International healthcare systems face the challenge that waiting times may create barriers to accessing medical care, and that those barriers are unequally distributed between different patient groups. The disruption of healthcare systems caused by the COVID-19 pandemic could exacerbate this already strained demand situation. Using the German healthcare system as an example, this study aims to analyze potential effects of the COVID-19 pandemic on waiting times for outpatient specialist care and to evaluate differences between individual patient groups based on their respective insurance status and the level of supply.

Methods: We conducted an experiment in which we requested appointments by telephone for different insurance statuses in regions with varying levels of supply from 908 outpatient specialist practices in Germany before and during the COVID-19 pandemic. Data from 589 collected appointments were analyzed using a linear mixed effect model.

Results: The data analysis revealed two main counteracting effects. First, the average waiting time has decreased for both patients with statutory (mandatory public health insurance) and private health insurance. Inequalities in access to healthcare, however, remained and were based on patients' insurance status and the regional level of supply. Second, the probability of not receiving an appointment at all significantly increased during the pandemic.

Conclusions: Patient uncertainty due to the fear of a potential COVID-19 infection may have freed up capacities in physicians' practices, resulting in a reduction of waiting times. At the same time, the exceptional situation caused by the pandemic may have led to uncertainty among physicians, who might thus have allocated appointments less frequently. To avoid worse health outcomes in the long term due to a lack of physician visits, policymakers and healthcare providers should focus more on regular care in the current COVID-19 pandemic.

Keywords: COVID-19, Corona, Waiting time, Outpatient, Specialist, Health service, Healthcare access, Inequalities

Background

Waiting times are serious challenges for international healthcare systems. Since they affect patients' access to medical care, international institutions such as the Organisation for Economic Co-operation and Development (OECD) are addressing this issue [1].

Waiting times can negatively affect perceived satisfaction on the demand side by delaying treatments for patients, thus extending their state of suffering and leading to uncertainty [2, 3]. In addition to declining patient satisfaction, however, the potential risk that waiting times lead to inferior health outcomes is a cause for concern. Study results show an association between increased waiting times and poorer health outcomes for some conditions such as psychosis, increased hospitalizations for ambulatory care sensitive conditions, and higher mortality [4–6].

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Unequal access to care for specific groups is an additional challenge in many healthcare systems. International studies have analyzed this problem using various approaches. It has been shown that patient characteristics such as income, education and socioeconomic status can have a significant effect on the extent of waiting times and access to healthcare, resulting in inequalities. These effects are apparent in both inpatient [2, 7–10] and outpatient care [11, 12].

In addition to these factors, the insurance status of patients can also lead to unequal access to healthcare [13]. Although the distribution of waiting times is a significant component of everyday care for patients, empirical evaluations of the impact of insurance statuses on waiting times are limited in current research [14]. Few studies have so far addressed this issue in depth.

Germany, with its two-tier insurance system, provides a suitable framework for analyses of differences between insurance statuses [15, 16]. Health insurance is mandatory in Germany and people are either covered by statutory health insurance (SHI) or by private health insurance (PHI). In 2021, around 89% of patients are covered by SHI, whereas 11% of the population are insured by PHI [17]. German SHI is a public scheme that is mandatory for the majority of the population. Only a minority of the population is exempt from SHI and can voluntarily take out PHI. SHI premiums are based on the income of the insured, whereas PHI premiums are risk-based [18]. Any unequal treatment of these two insurance groups may largely be due to the fact that physicians can charge medical interventions for PHI patients both more frequently and at higher rates [19]. The resulting financial incentive for physicians to treat PHI patients preferentially [15] has been evaluated in a small number of studies for both inpatient and outpatient settings in Germany. These studies show that PHI patients receive earlier access to care than SHI patients due to faster appointment scheduling [14, 15, 19, 20]. Schwierz et al. also found that hospitals that discriminate based on patients' insurance status show better financial results [20].

Three studies analyzed experimental data of German outpatient specialist care: Lungen et al. (2008) [21], Heinrich et al. (2018) [22] and Werbeck et al. (2020) [23]. Using an experimental design in which outpatient specialists were called and asked for an appointment, these studies examined determinants of waiting times with a special focus on patients' insurance status. All three studies conclude that PHI patients receive preferential treatment regarding waiting times.

All of these observations show that difficulties arise both from waiting times themselves and from differences in waiting times between individual patient groups. As a result, international healthcare systems are trying to counter the effects resulting from a form of rationing [10] and discrimination [11] through policy interventions [1], highlighting the fact that the organization of medical supply is critical.

The global COVID-19 outbreak, which was declared a pandemic by the World Health Organization (WHO) in March 2020 [24], could exacerbate this condition. COVID-19 is disrupting healthcare systems and medical care worldwide. This could have a major impact on previously existing structures and processes on the demand and supply side of healthcare [25]. Waiting times could be one of the variables that are strongly affected by the current pandemic.

Although research on COVID-19 is strong in a variety of fields, and there is heightened awareness of the need not to neglect patients without COVID-19 [26–28], there are currently no analyses of changes in waiting times in the context of the pandemic. This is what the present analysis focuses on. We seek to analyze the potential effect of the COVID-19 pandemic on outpatient specialist care in terms of waiting time and to evaluate differences for patient groups with different insurance statuses, using the German healthcare system as an example. In addition, our study contributes to the existing literature by explicitly including the level of supply in Germany and examining it for potential inequalities. It is evident that there are structural differences and barriers to accessing healthcare in Germany. According to the German Social Law, the goal of healthcare should be to ensure that patients are treated according to their needs and in a uniform manner. Favoring a particular patient group or accepting structural differences in care is inconsistent with this guiding principle [19, 29]. In this sense, it is essential to consider the impact of the COVID-19 pandemic on an already strained demand situation.

Methods

Data collection

The present study was originally designed to analyze waiting times for outpatient specialist care for different patient groups based on their respective insurance status and the level of supply. However, due to the unexpected occurrence of the COVID-19 pandemic, the study objective was adapted. We therefore conducted an experiment in which we called outpatient specialist practices and asked for an appointment in order to evaluate waiting times and the impact of the COVID-19 pandemic. Data collection design is similar to that used by Lungen et al. [21], Heinrich et al. [22] and Werbeck et al. [23].

In line with the original study design, the analysis focused on general outpatient specialist care that was not directly involved in the treatment of COVID-19. Physicians of highly specialized medical fields were excluded. Surgeons and orthopedists, gynecologists, dermatologists,

otorhinolaryngologists as well as ophthalmologists were contacted because they represented the most frequently practicing specialists.

Regionally, the federal state of Bavaria was examined, as the difference between over- and underserved areas was particularly pronounced there. Using data from the Bavarian Association of Statutory Health Insurance Physicians (BASHIP), the regions most affected by over- and undersupply were identified. With the help of the physician and psychotherapist search of BASHIP, the specialists of the medical specializations described above were selected in the respective regions. The first data collection took place in April 2019 and the second one in April 2020. In both years every practice was contacted by employees of the institute: once as a patient with SHI coverage and once as a patient with PHI coverage. The insurance status was randomized. The aim was to analyze potential differences in waiting times based on patients' insurance status.

On the basis of a given protocol, the practices were called and asked for the next possible appointment regardless of a specific physician. The reasons given for the examination were an eye examination, back pain, a gynecological examination, a hearing test and screening for skin cancer. These are, among others, the most common reasons for treatments by the respective specialists. All queries avoided giving the impression of an emergency. Each appointment was rejected at the end of the call to ensure that resources were protected. The time between the call and the first possible appointment was recorded. This number of days was adjusted for weekends and public holidays. Thus, the waiting time considered represents the number of weekdays. If no appointment was assigned, it was noted with a reason. Missing data for practices that were newly opened or closed in 2020 were also noted. Due to the repeated measurements and partially missing data, the observation represents an unbalanced panel.

Statistical methods

In a first step, results are presented as mean, standard deviation and median. Univariate statistics are considered to measure the influence of the COVID-19 pandemic on waiting times. The measurements (longitudinal data) are correlated because they were obtained from the same practices. Since waiting times are not normally distributed and observations are dependent, the non-parametric Wilcoxon signed-rank test was used to compare the parameters between 2019 and 2020. Pearson's Chi-squared test was applied to examine differences in the likelihood of receiving an appointment between insurance statuses. Because of multiple testing, the significance levels were adjusted by a Bonferroni-Holm correction.

Furthermore, in the context of the subsequent multivariate analysis, a linear mixed effect model (LMEM) was applied. LMEMs contain fixed effects that allow a systematic time trend component in the average response to be modelled to assess systematic differences between parameters with respect to the time trend. In addition, they take into account the correlation structure within practices and the random variation in time between practices on the basis of random effects.

Using the maximum-likelihood estimation procedure, a large number of differently constructed models were computed and compared based on the Akaike information criterion (AIC). The purpose was to find the best possible model for the data collected.

The computation of the intraclass correlation coefficient (ICC) with a random intercept only model revealed evidence of substantial clustering, where 42.4% of the variation in waiting times resulted from differences between practices. The variation in the random intercept was statistically significant. We included random intercepts for the practices as well as random slopes for the effect of year for the practices. Missing values were considered to be missing at random (MAR) because they do not depend on the waiting time itself.

Because of the non-normal distribution, the dependent variable waiting time was logarithmized. A simple and an extended model were used to analyze the data. The following equation reflects the simple model:

$$\ln(WT)_{ij} = (ß_0 + u_{0j}) + (ß_1 + u_{1j})*YEAR_{ij} + ß_2*SPEC_{ij} + ß_3*INS_{ij} + ß_4*SUP_{ij} + \varepsilon_{ij}.$$

As fixed effects, we entered year, medical specialization, insurance status and level of supply.

Year is coded as a dummy variable for 2019 and 2020. The categorial variable medical specializations contains surgeons and orthopedists, gynecologists, dermatologists, otorhinolaryngologists and the reference group ophthalmologists. The remaining two fixed effects are also coded as dummies. PHI and SHI determine the insurance status, and the level of supply consists of oversupply and undersupply.

$$\ln(WT)_{ij} = (ß_0 + u_{0j}) + (ß_1 + u_{1j})*YEAR_{ij} + ß_2*SPEC_{ij} + ß_3*INS_{ij} + ß_4*SUP_{ij} + ß_5*WEEKD_{ij} + ß_6*DAYT_{ij} + ß_7*(YEAR_{ij}*SPEC_{ij}) + \varepsilon_{ij}.$$

The extended model includes all effects of the simple model, despite a control for the fixed effects weekday of call categorized for the workdays Monday to Friday, with Friday as reference category and the dummy variable daytime of call comprising morning and afternoon. Additionally, an interaction effect between year and medical specialization was added. Visual inspection of residual plots for both models did not reveal any obvious deviations from linearity, homoscedasticity or normality.

Results

There were $n = 213$ practices in 2019 and $n = 241$ practices in 2020 that were contacted twice. The number of practices changed because some practices were closed and others were reopened. Thus, a total of 908 observations were collected, which resulted in 598 appointments. The inclusion rate (percentage of appointments received from practices contacted) was 63.38% for SHI in 2019, 72.30% for PHI in 2019, 57.26% for SHI in 2020, and 67.22% for PHI in 2020, with an overall inclusion rate of 64.87%.

The following reasons resulted in no appointment being set up. In 27.3% of the cases, the practice did not treat the inquired indication; 18.41% of practices were newly opened or closed within both years; 13.30% did not accept new patients; in 13.30% of cases the practices could not be reached by telephone; 13.30% of appointments were declined due to the COVID-19 pandemic; 11.25% of practices were on vacation or temporarily closed; finally, 3.07% of requests were denied because a referral was required or the practice could be visited without an appointment.

Table 1 shows the mean, standard deviation and median as well as the comparison of the parameters between 2019 and 2020 with help of the Wilcoxon signed-rank test. There are strong deviations between the mean and the median within the groups as well as considerable differences in the mean waiting time between the individual groups.

The differences between the mean and median and the large standard deviation can be explained by strong outliers in the data set. For instance, the maximum waiting time is 162 days for SHI 2019, 120 days for PHI 2019, 259 days for SHI 2020, and 122 for PHI 2020. The graphical illustration of the waiting times showed that the data are not normally distributed; they are right skewed as well as leptokurtic.

The overview reveals that the longest mean waiting time, at 26.13 days, was faced by SHI patients in 2019. PHI patients had to wait approximately nine days less, resulting in a mean of 17.37 days. For both insurance statuses, the waiting times decreased in 2020 by an overall average of almost 8 days or exactly 35.2% with 17.09 days for SHI patients and 11.09 days for PHI patients.

The Wilcoxon signed-rank test reveals significant differences in the comparison of the groups. The waiting time for SHI patients is significantly lower in 2020 than in 2019 ($z = -4.33$, $p = <.001$, $n = 102$, $r = .43$). The same applies for PHI patients ($z = -4.01$, $p = <.001$, $n = 124$, $r = .36$). Simultaneously, the findings of the observation support the already existing literature [21–23]. Both in 2019 ($z = -5.78$, $p = <.001$, $n = 132$, $r = .50$) and in 2020 ($z = -4.04$, $p = <.001$, $n = 129$, $r = .36$) SHI patients had to face significantly longer waiting times than PHI patients. According to Cohen's effect size, 2019 shows a strong effect. However, it can also be seen that the overall difference in waiting time between SHI and PHI patients became significantly smaller in 2020 with a mean of 10.40 to 5.76 days ($z = -2.20$, $p = .028$, $n = 96$, $r = .22$). The change between the two years is also reflected in the level of supply. The average value between SHI and PHI patients was considered for under- and oversupplied

Table.1 Test statistic – Wilcoxon signed-rank test

Variables	n	Mean	SD	Median	Variables	n	Mean	SD	Median	z	p	r
Waiting time 19 SHI	135	26.13	29.55	15	Waiting time 20 SHI	138	17.09	30.48	5	−4.33	< .001	.43
Waiting time 19 PHI	154	17.37	20.25	12	Waiting time 20 PHI	162	11.09	18.83	4	−4.01	< .001	.36
Waiting time 19 SHI	135	26.13	29.55	15	Waiting time 19 PHI	154	17.37	20.25	12	−5.78	< .001	.50
Waiting time 20 SHI	138	17.09	30.48	5	Waiting time 20 PHI	162	11.09	18.83	4	−4.04	< .001	.36
Difference 19	132	10.40	23.75	2	Difference 20	129	5.76	22.14	1	−2.20	.028	.22
Waiting time undersupply 19	43	24.78	21.31	17	Waiting time undersupply 20	41	18.57	29.55	6.5	−2.94	.003	.54
Waiting time oversupply 19	89	18.52	21.67	10.5	Waiting time oversupply 20	88	8.93	10.33	4	−3.75	< .001	.46
Waiting time Surgeons & Orthopedists 19	38	10.79	9.30	7	Waiting time Surgeons & Orthopedists 20	40	4.34	4.98	3	−4.71	< .001	.86
Waiting time Gynecologists 19	39	23.59	28.53	15	Waiting time Gynecologists 20	38	20.30	18.34	15.25	−.97	.330	.19
Waiting time Dermatologists 19	14	34.40	17.45	31	Waiting time Dermatologists 20	8	12.75	9.27	12.25	−2.02	.043	.90
Waiting time Otorhinolaryngologists 19	23	18.63	20.35	9	Waiting time Otorhinolaryngologists 20	26	3.88	2.85	3.25	−3.96	< .001	.87
Waiting time Ophthalmologists 19	18	26.31	20.30	21.75	Waiting time Ophthalmologists 20	17	23.50	38.45	12.5	−1.78	.075	.49

regions. The waiting times decreased from 24.78 in 2019 to 18.57 days in 2020 ($z = -2.94$, $p = .003$, $n = 30$, $r = .54$) in regions with undersupply and from 18.52 to 8.93 days ($z = -3.75$, $p = <.001$, $n = 66$, $r = .46$) in regions with oversupply. In this context, it is noticeable that patients in underserved regions face higher waiting times than those in overserved regions. Considerable differences are also apparent when considering the medical specializations. The average waiting time for SHI and PHI patients decreased for all specializations. While the results for gynecologists and ophthalmologists are not statistically different from zero, the mean waiting times for surgeons and orthopedists decreased significantly by 6.45 days ($z = -4.71$, $p = <.001$, $n = 30$, $r = .86$), for dermatologists by 21.65 days ($z = -2.02$, $p = .043$, $n = 5$, $r = .90$) and for otorhinolaryngologists by 14.75 days ($z = -3.96$, $p = <.001$, $n = 21$, $r = .87$) in 2020. This represents strong effects according to Cohen's d. Thus, it appears that waiting times decreased for all parameters due to the COVID-19 pandemic.

It should be noted, however, that the result for dermatologists and the difference between the insurance statuses 2019 and 2020 are no longer statistically different from zero after a Bonferroni-Holm correction.

In addition to considering the waiting times within the groups, the probability of receiving an appointment at all was also analyzed using Pearson's chi-square. To avoid bias, only two reasons that practices offered for not making assignments were considered here: not accepting new patients and not assigning appointments due to the COVID-19 pandemic. The results can be found in Table 2.

The analysis shows that the probability of receiving an appointment decreased significantly in 2020 (80.9%) compared to 2019 (89.8%) ($\chi^2(1) = 10.68$, $p = .001$, $n = 693$, $V = .124$). The lower likelihood of receiving an appointment due to the COVID-19 pandemic is also reflected in the segmentation between the insurance statuses. SHI patients received significantly fewer appointments when comparing 2019 (84.4%) to 2020 (74.6%). ($\chi^2(1) = 4.97$, $p = .026$, $n = 345$, $V = .120$). Also, PHI patients received appointments less frequently between 2019 (95.1%) and 2020 (87.1%) ($\chi^2(1) = 6.58$, $p = .010$, $n = 348$, $V = .137$). At the same time, unequal access to healthcare is also evident in the likelihood of receiving an appointment. Thus, SHI patients (79.1%) were significantly less likely to receive an appointment than PHI patients (90.08%) in both years ($\chi^2(1) = 18.51$, $p < .001$, $n = 693$, $V = .163$). This is also reflected in the analysis of the two years. PHI patients were more likely to receive appointments both in 2019 (95.1%) and in 2020 (87.1%) than SHI patients (2019: 84.4%, 2020: 74.6%) (2019: ($\chi^2(1) = 10.00$, $p = .002$, $n = 322$, $V = .176$); 2020: ($\chi^2(1) = 9.37$, $p = .002$, $n = 371$, $V = .159$)).

The decreased likelihood of receiving an appointment in 2020 is also evident in underserved regions with 11.5% fewer appointments ($\chi^2(1) = 5.10$, $p = .024$, $n = 238$, $V = .146$) and in overserved regions with 7.5% fewer appointments ($\chi^2(1) = 5.64$, $p = .018$, $n = 455$, $V = .111$).

The probabilities decreased in all medical specializations, but the change was only significant for gynecologists, who went from 86.3% in 2019 to 73.6% in 2020 ($\chi^2(1) = 5.50$, $p = .019$, $n = 227$, $V = .156$), and for dermatologists, who went from 96.8% to 69.4% ($\chi^2(1) = 8.46$, $p = .004$, $n = 67$, $V = .355$). Again, the effects for SHI appointments 2019 compared to 2020, for undersupply and oversupply, and for gynecologists do not hold up to a Bonferroni-Holm correction.

Throughout this analysis, no expected cell frequencies were below five, except for surgeons and orthopedists on

Table.2 Test statistic – Pearson's chi-square

Variables	Probability	Variables	Probability	χ^2	df	p	n	V
Appointment 19	89.8%	Appointment 20	80.9%	10.68	1	.001	693	.124
Appointment SHI 19	84.4%	Appointment SHI 20	74.6%	4.97	1	.026	345	.120
Appointment PHI 19	95.1%	Appointment PHI 20	87.1%	6.58	1	.010	348	.137
Appointment SHI both years	79.1%	Appointment PHI both years	90.8%	18.51	1	< .001	693	.163
Appointment SHI 19	84.4%	Appointment PHI 19	95.1%	10.00	1	.002	322	.176
Appointment SHI 20	74.6%	Appointment PHI 20	87.1%	9.37	1	.002	371	.159
Undersupply 19	87.3%	Undersupply 20	75.8%	5.10	1	.024	238	.146
Oversupply 19	91.0%	Oversupply 20	83.5%	5.64	1	.018	455	.111
Surgeons & Orthopedists 19	96.3%	Surgeons & Orthopedists 20	95.6%	.05	1	.820	170	.017
Gynecologists 19	86.3%	Gynecologists 20	73.6%	5.50	1	.019	227	.156
Dermatologists 19	96.8%	Dermatologists 20	69.4%	8.46	1	.004	67	.355
Otorhinolaryngologists 19	100%	Otorhinolaryngologists 20	98.2%	.86	1	.353	102	.092
Ophthalmologists 19	75.8%	Ophthalmologists 20	66.2%	1.43	1	.231	127	.106

the one hand and otorhinolaryngologists on the other. For these two comparisons, Fisher's exact test was applied, but without showing effects statistically different from zero.

The comparison of the overall effects for the simple and extended model can be seen in Table 3.

The results of the LMEMs for both models are presented in Table 4. Compared to the simple model with an AIC of 1578, the extended model exhibits an AIC of 1551 and can thus display the data more appropriately. Nevertheless, the comparison of the simple with the extended model was applied to examine the robustness of the results. The comparison reveals that, despite controlling for weekday and time of call as well as including an interaction term in the extended model, the main effects are almost the same in both models. Thus, it can be assumed that both models can robustly represent the effects.

For the simple model, the overall effect of all independent variables on the logarithmized dependent variable waiting time are statistically significant at the 5% significance level. However, when considering the different medical specializations, it is found that only the effects of surgeons and orthopedists as well as otorhinolaryngologists are statistically significant compared with the reference group of ophthalmologists. Compared with ophthalmologists, patients in surgeons' and orthopedists' practices have to face 70.03% (exact computation: $100(e^{(-1.205)}-1)$) less waiting time (p = <.001, b = – 1.205, SE = .173). For otorhinolaryngologists, the waiting time is 62.47% less than for ophthalmologists (p = <.001, b = –.980, SE = .194). The comparison with gynecologists and dermatologists is not statistically different from zero. Considering the year, it appears that COVID-19 reduced waiting time by 7.97 days or 52.43% for patients in 2020 compared to 2019 (p = <.001, b = –.743, SE = .078). The insurance status also plays an important role in this model, showing that PHI patients have a 35.27% reduction in waiting time (4.60 days) compared with SHI patients (p = <.001, b = –.435 SE = .063). In addition, the simple model reveals that patients in overserved regions receive appointments 31.48% or 3.98 days faster than in underserved regions (p = .001, b = –.378, SE = .116).

The directions of the effects all remain the same in the extended model and, moreover, all significant results persist. Again, the overall effects are significant at the 5% level, regardless of the extension of the model.

The fixed effects insurance status and level of supply remain unchanged in the extended model. Hence, PHI patients also receive appointments significantly faster in this design. SHI patients have an increased waiting time by 4.73 days or 35.08% (p = <.001, b = –.432 SE = .060). In addition, appointments are scheduled 30.72% faster in overserved than in underserved regions (4.01 days) (p = .002, b = –.367, SE = .116).

The fixed effects weekday and daytime of call show overall significant effects. Considering the individual effects, however, it is evident that they are partly not statistically different from zero. Simultaneously, the other results of the model remain stable. This demonstrates that controlling for weekday and daytime does not reduce the influence of the other effects.

Nevertheless, the extension of the model reveals that the effect of year on waiting time is influenced by the different medical specializations. The cross-level interaction shows that the effect of year varies depending on the individual medical specializations. Although the general effect of the year remained nearly stable, with the inclusion of the interaction effect patients received appointments on average 55.60% or 9.05 days faster in 2020 compared to 2019 (p = <.001, b = –.812, SE = .079).

With regard to the medical specializations, the comparison between ophthalmologists and three different groups (i.e. surgeons and orthopedists, gynecologists, and otorhinolaryngologists) is statistically significant in this model. On average, patients receive appointments 66.11% faster for surgeons and orthopedists (p = <.001, b = – 1.082, SE = .190), 32.50% faster for gynecologists (p = .034, b = –.393 SE = .185), and 48.98% faster for

Table.3 LMEM - Comparison of the Overall Effects of the Models

	Simple Model				Extended Model			
Source	**N df**	**D df**	**F**	***p*-Value**	**N df**	**D df**	**F**	**p-Value**
Intercept	1	190.69	1383.61	< .001	1	234.22	1224.95	< .001
Medical specialization	4	191.71	21.86	< .001	4	186.62	23.89	< .001
Year	1	199.45	90.49	< .001	1	169.79	105.12	< .001
Insurance status	1	175.54	48.41	< .001	1	167.14	51.30	< .001
Level of supply	1	193.56	10.55	.001	1	183.87	9.97	.002
Weekday					4	385.56	3.57	.007
Daytime					1	320.15	4.76	.030
Medical specialization * Year					4	166.44	9.24	< .001

Table.4 LMEM - Comparison of the Models

	Simple Model			Extended Model		
Parameters	**Estimate**	**SE**	**p-Value**	**Estimate**	**SE**	**p-Value**
Intercept	3.597	.166	< .001	3.394	.188	< .001
Surgeons & Orthopedists	−1.205	.173	< .001	−1.082	.190	< .001
Gynecologists	−.217	.167	.195	−.393	.185	.034
Dermatologists	.046	.219	.834	.211	.240	.382
Otorhinolaryngologists	−.980	.194	< .001	−.673	.212	.002
Year 2020	−.743	.078	< .001	−.750	.180	< .001
PHI	−.435	.063	< .001	−.432	.060	< .001
Oversupply	−.378	.116	.001	−.367	.116	.002
Friday				−.140	.132	.290
Thursday				.078	.086	.363
Wednesday				.305	.113	.008
Tuesday				.258	.111	.020
Afternoon				.168	.077	.030
Year 2020* Surgeons & Orthopedists				−.238	.225	.292
Year 2020* Gynecologists				.619	.227	.007
Year 2020* Dermatologists				−.105	.301	.728
Year 2020* Otorhinolaryngologist				−.584	.250	.021

otorhinolaryngologists (p = .002, b = −.673, SE = .212) compared with ophthalmologists. At the same time, the significant interaction effects for gynecologists and otorhinolaryngologists over time have to be considered. These indicate that waiting times developed differently for the individual specializations. The significant interaction effect for gynecologists shows that this specialization developed differently over time compared to ophthalmologists (p = .007, b = .619, SE = .227). On average, patients thus receive appointments at gynecologists more quickly than at ophthalmologists in both years. Yet, compared to ophthalmologists in 2020, the waiting time remains almost stable for gynecologists. The significant negative interaction effect for otorhinolaryngologists (p = .021, b = −.584, SE = .250) reveals that in 2020 the waiting times for otorhinolaryngologist appointments decreased more strongly than those for ophthalmologist appointments.

Discussion

The main purpose of this study was to examine whether the COVID-19 pandemic caused changes in waiting times for outpatient specialist care in Germany. The analysis of the experimental data revealed two major findings. First, in line with the results from the univariate analysis, the multivariate analysis was able to expose, among other effects, that waiting times decreased significantly between 2019 and 2020. Second, however, it was also found that the probability of receiving an appointment at all significantly decreased at the same time. These counteracting effects could be caused by both sides of the physician-patient relation.

On the one hand, it appears desirable that waiting times have decreased in 2020 compared to 2019. On the other hand, the question is what reasons led to this change. These reasons cannot be clearly determined by the analysis.

International studies show a reduction in medical conditions unrelated to COVID-19 in hospitals and emergency departments (ED), for example (acute) myocardial infarction or strokes [30–32]. This can be explained by the fact that overall hospital and ED visits decreased, especially early in the pandemic, leading to an increase in mortality as urgent cases could not be treated in time. The studies conclude that patients no longer visit medical facilities, or visit them too late, because they fear an infection with SARS-CoV-2, resulting in a healthcare access barrier [33–36]. This picture not only emerges for acute cases. There is evidence that patients also used preventive and elective care less [37].

We assume that these results can be applied to our analysis, and that this could be a reason why waiting times were shorter overall in 2020 than in 2019. Patients do not keep their appointments or do not request

appointments due to the risk of infection with SARS-CoV-2. Supporting evidence might also be provided by the varying effects of the different medical specializations on waiting time. Compared with the previous year, the waiting times for otorhinolaryngologists decreased the most. In sum, it seems plausible that patients' higher reluctance to schedule appointments caused the physicians to record an increase in free capacities and to be able to schedule appointments more quickly.

Following this reasoning, it could be assumed that the free capacities are directly linked to a faster allocation of appointments. However, the data analysis shows contradictory results, and patients were even less likely to receive an appointment. This means that even if there is demand, it is served less frequently despite higher free capacities. Hence, the reduced probability of receiving an appointment contradicts the faster allocation of appointments. At the time of data collection, the National Association of Statutory Health Insurance Physicians (NASHIP) had not issued any specific instructions regarding the allocation of appointments (status: April 04, 2020) [38]. Thus, the reduction in supply cannot be attributed to policy interventions. We therefore suggest that reduced supply may also be associated with uncertainty, this time on the provider side. Given that physicians did not receive specific policy instructions and were affected by a completely new situation, non-urgent appointments might have been scheduled less frequently.

Overall, the two main effects suggest that uncertainties due to COVID-19 may have arisen on both the supply and the demand side: Patients go to see physicians less often, and physicians make appointments less frequently. This, however, can cause severe problems when non-urgent cases are left untreated and develop into serious health conditions. The potential risk of focusing only on COVID-19 patients and forgetting about non-COVID-19 patients, such as patients with chronic conditions, has already been pointed out in the literature [26–28, 39]. In the long term, this problem could lead to increased morbidity or mortality in addition to that associated with COVID-19 [27]. This conclusion was also reached in a WHO interim report from 2020, which, in addition to the risk of morbidity and mortality, also indicated that reasons for health service disruption could be attributed to both providers and patients [25].

However, further research is needed to examine the causes of the change in waiting times.

Beside that, the economic consequences of untreated (chronic) diseases must be taken into account. In Germany, an outpatient causes mean costs of €475 per year, whereas an inpatient causes mean costs of €4239 [40]. Therefore, cases that are not treated in outpatient care and result in hospitalizations can have a high financial impact, which is compounded by severe disease progression and mortality.

However, beyond the two main effects studied, our analysis was able to obtain other results that correspond to the findings in existing literature. We evaluated a mean waiting time for SHI of 26.13 and for PHI of 17.37 in 2019, and of 17.09 for SHI and 11.09 for PHI in 2020. The waiting times found by Lungen et al. [21], Heinrich et al. [22], and Werbeck et al. [23] are quite similar. Compared to their studies, our experimental design differs in that we selected practices in over- and underserved regions, called the same practices, contacted all practices as both SHI and PHI patients, and collected our data in the same time period in 2019 and 2020, respectively, to avoid seasonal influences. Nevertheless, in line with their findings, we have also identified unequal access to healthcare, depending on patients' insurance status. PHI patients receive an appointment significantly faster and more frequently than SHI patients. This effect was also found in studies of inpatient care as well as in studies without an experimental design [14, 15, 19, 20]. Despite the exceptional situation caused by COVID-19, the preferential treatment of PHI patients has not changed. Thus, unequal access to healthcare persists.

In contrast to other studies, we included the level of supply in our analysis to examine whether there are other disparities beside patients' insurance status. In this context, we found that patients receive appointments more quickly in overserved regions than in underserved ones. Waiting times decreased in both levels of supply between 2019 and 2020. Nevertheless, the difference between the regions remained stable. This shows that, in addition to insurance status, the regions' level of supply can also constitute a healthcare access barrier. Although we controlled for the weekday and daytime of call in the extended model of the multivariate analysis, all of these results were robust and significant.

Our study has some limitations. One limitation is that only one call was made per insurance status in each year, and that this single call for SHI and PHI patients may not be representative of ordinary practice organization.

Another limitation arises from the fact that the analysis cannot determine a direct effect of COVID-19 on waiting times. To address this issue, consideration was given to the inclusion of COVID-19 incidence in the multivariate analysis. Unfortunately, incidence values are not available in the administrative districts of the practices for the days of calls. Therefore, the overall incidence for the federal state of Bavaria was included on the days of calls. However, the effect of this variable was not statistically different from zero in either model examined. Furthermore, the previously significant effect of year was also no longer statistically different from zero after COVID-19 incidence had been included, and both

AIC values worsened. The subsequent examination of the VIF value provided strong evidence of multicollinearity. Therefore, COVID-19 incidence was removed from the models. However, the year dummy can simultaneously be considered a dummy variable for COVID-19.

In addition, a reform was introduced in Germany on May 11, 2019 to ensure that patients receive appointments more quickly (Appointment Service and Supply Act (TSVG)) [41]. Thus, a mixed effect could be present. Given that the reform was introduced with the goal of SHI patients receiving an appointment as quickly as PHI patients [41], however, the study results demonstrate that an unequal distribution still remains. Nevertheless, it can be assumed that the enormous magnitude of the COVID-19 pandemic had a strong impact on the practices. Moreover, our analysis represents only a snapshot at the beginning of the first strong outbreak of COVID-19 in Germany and the results may not be generalizable. Waiting times and the likelihood of receiving an appointment can constantly change during the course of the COVID-19 pandemic. Yet despite this, and in light of the possibility of vaccination, our implications remain. We are still in a state of emergency, and it is not yet foreseeable when medical care will be able to return to a regular schedule. Furthermore, such drastic events as the COVID-19 pandemic can occur again, and both physicians and patients should be suitably prepared for these circumstances. The results show that even in exceptional situations such as a pandemic, regular care should not be disregarded and constant care should be maintained for patients. Sufficient resources must be available for physicians to provide medical care alongside pandemic care. At the same time, patients must be supported in seeking medical care as needed. Only through continuous care can inferior health outcomes be avoided. There is now the chance to learn from such observations for the future, to be able to mitigate medical as well as economic risks in the best possible way.

Conclusions

The statistical analysis of the data collected in our experiment has practical relevance, as it shows that, in addition to the health risk emerging from the COVID-19 pandemic, regular patient care is also impaired due to the current situation. Although the waiting times for most medical specializations have decreased, the likelihood of receiving an appointment at all has also decreased. Patient uncertainty due to the fear of a potential infection with SARS-CoV-2 could be the cause of free capacities in practices. If appointments are not kept, there is a long-term risk of worsening health status and thus health outcomes. Beside medical risks, this could also have health economic consequences. Although policy decisions are currently concerned with the COVID-19 pandemic, regular care must not be ignored. It has to be ensured that physicians can treat patients safely in their practices. In addition, encouraging patients to continue to seek medical care and arrange appointments should be of interest to public health. To this end, it is particularly important to moderate patients' fears and uncertainties. This should be ensured by both policymakers and by the healthcare providers themselves. Only if the supply and demand side manage to normalize care, can long-term negative consequences be avoided.

Abbreviations

AIC: Akaike information criterion; BASHIP: Bavarian Association of Statutory Health Insurance Physicians; COVID-19: Coronavirus disease 2019; ED: Emergency departments; LMEM: Linear mixed effect model; MAR: Missing at random; NASHIP: National Association of Statutory Health Insurance Physicians; OECD: Organisation for Economic Co-operation and Development; PHI: Private health insurance; SARS-CoV-2: Severe acute respiratory syndrome coronavirus 2; SHI: Statutory health insurance; TSVG: Appointment Service and Supply Act; WHO: World Health Organization

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Authors' contributions

JM and CG designed the study. JM collected the data, conducted the analysis, interpreted the data and drafted the manuscript. CG provided guidance on interpretation of the data und gave critical feedback on the manuscript. All authors contributed to the critical revision of the manuscript and approved the final version to be published.

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Availability of data and materials

The datasets used and analyzed in this study are available from the corresponding author on reasonable request.

Declarations

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Not applicable.

Consent for publication

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Competing interests

The authors declare that they have no competing interests.

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Publisher's Note

2 COVID-19 Related Decline in Cancer Screenings Most Pronounced for Elderly Patients and Women in Germany: A Claims Data Analysis

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RESEARCH

COVID-19 related decline in cancer screenings most pronounced for elderly patients and women in Germany: a claims data analysis

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Abstract

Purpose This study aimed to analyze the utilization of cancer screenings in Germany before and during the COVID-19 pandemic in 2020. The objective of the analysis was to identify the population at particular risk and to derive recommendations for the future use of resources to prevent long-term deteriorations in health outcomes.

Methods The analysis was conducted based on claims data of all preventive health services for 15,833,662 patients from the largest statutory health insurance fund in Germany. Utilization of general female cancer screening, general male cancer screening, general health checkup, colorectal cancer screening stool test, colorectal cancer screening consultation, colonoscopy, skin cancer screening, and mammography screening was compared before (2017–2019) and during (2020) the pandemic.

Results Data of a total of 42,046,078 observed screenings showed that the utilization of the individual screenings developed differently, but that the overall utilization decreased significantly by 21.46% during the COVID-19 pandemic ($p < 0.001$). At the same time, no catch-up effects were detected for total screenings throughout the entire year 2020. The highest decline in screenings was found for the elderly ($p < 0.001$) and women ($p < 0.001$).

Conclusion Because the elderly are at higher risk for cancer, the omission of early detection might lead to higher treatment costs, reduced quality of life, and higher mortality. In addition, women's medical care in particular has been negatively affected, for example, by the interruption of mammography screenings and the lack of catch-up effects. Therefore, resources must be targeted to reduce burdens on health outcomes and public health in the long term.

Keywords Claims data analysis · COVID-19 · Cancer screening · Gender inequalities · Age inequalities · Public health

Background

Noncommunicable diseases such as cancer and cardiovascular diseases have a negative impact on public health by causing approximately 71% of deaths worldwide each year. Moreover, they are associated with reduced quality of life and lower life expectancy, as well as economic burdens in the form of rising treatment costs and declining productivity (Dzau et al. 2017; World Economic Forum 2017; World Health Organization 2021). Preventive health services are an important component of public health as early detection and treatment of noncommunicable diseases such as cancer and their precursors can reduce incidence, disease severity, and mortality (World Health Organization. Regional Office for Europe 2020). As a result, countries around the world, including Germany, offer screening programs that are legally regulated. For example, since 2008, a skin cancer screening program has been offered free of charge for patients with statutory health insurance (SHI) in Germany. The program's effects were desirable from a public health perspective: since its introduction, an increased incidence of skin cancer has been observed, but the cases detected were mainly in earlier stages of the disease (Girbig et al. 2021). Especially in malignant melanoma, early diagnosis and treatment are crucial as it has a direct impact on the survival rates (Girbig et al. 2021; McBain et al. 2021). Early diagnosis also plays an important role in successful treatment for other types of cancer, underlining the relevance of preventive health

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services for health-care systems (World Health Organization. Regional Office for Europe 2010).

The screening program in Germany comprises a total of ten different services and primarily focuses on the early detection of cancer. Only the screening for colorectal cancer, cervical cancer, and breast cancer is organized and eligible patients are invited based on a register, while other screenings can be utilized opportunistically. Screening utilization varies in Germany with respect to the individual examinations, sex, and age. For example, more than 50% of women younger than 70 years make use of female cancer screening every 3 years. Male cancer screening, on the other hand, is only used by up to 35% in at least 5 out of 10 years. In total, participation rates were relatively constant before the COVID-19 pandemic (Tillmanns et al. 2021).

With the spread of the COVID-19 pandemic since March 2020 (World Health Organization. Regional Office for Europe 2022), however, international health-care systems have been disrupted (World Health Organization 2020). In addition to the direct medical impact from infections and associated mortality, the pandemic has led to widespread limitations in medical services (Wang et al. 2020). For example, a change in the utilization of outpatient services such as for cancer screenings was observed internationally (Chen et al. 2021; Damerow et al. 2020; Doubova et al. 2021). The postponed or canceled screenings, however, could be linked to the risk of delayed diagnosis and, thus, more severe disease progressions and the duration of suspended screenings and potential catch-up effects will have a strong impact on long-term death rates (Alkatout et al. 2021; Blumen et al. 2016; Burger et al. 2021; Duffy et al. 2022; Kregting et al. 2021; Maringe et al. 2020; Yong et al. 2021).

Compared to international findings, scientific publications on the utilization of preventive health services during the pandemic based on German data are limited (Alkatout et al. 2021; Mayo et al. 2021). However, to contain the impact of postponed and canceled screenings in Germany and to best prevent poorer health outcomes, increased mortality and rising health-care expenditures, a targeted use of limited health-care resources is essential in the long term. Prioritization of particularly vulnerable patient groups is only possible if differences in utilization are known, which can only be derived from examining trends across all preventive health services offered in a country and goes beyond simply analyzing individual screenings.

This explorative study attempts to fill the existing research gap by analyzing the utilization of all preventive health services and cancer screenings legally regulated for German patients using claims data from 15,833,662 patients in the SHI before and during the COVID-19 pandemic to identify the population at particular risk and to derive recommendations for the best possible use of resources in future preventive health programs. In addition, the change in outpatient reimbursement of screenings before and during COVID-19 will be compared in the form of a health economic analysis as part of this study.

Methods

Study design and data source

The retrospective claims data analysis was based on national claims data from adult persons who were insured at the Allgemeine Ortskrankenkasse (AOK) in Germany between 2017 and 2020. AOK consists of 11 regional health-care funds and together they represent the largest SHI fund in Germany. With 27 million insured persons, around one-third of the entire German population is covered by AOK (AOK-Bundesverband 2022; Schulz et al. 2020).

The data analyzed in the study were provided by the AOK Research Institute (WIdO) and served the primary purpose of the reimbursement of services between providers and payers. WIdO processed the requested data on the basis of a predefined study protocol and made them available for the purpose of the study. The study protocol was prepared in accordance with the guideline for Good Practice of Secondary Data Analysis (GPS) (Swart et al. 2015). In addition, the Consensus German Reporting Standard for Secondary Data Analyses, Version 2 (STROSA 2) was used as a guidance for the reporting of the study, as it was developed especially for the particular requirements of German claims data analyses (Swart et al. 2016).

The anonymized data set contained the claims data of the fee schedule items (GOP) for all preventive health services legally regulated for adult persons with SHI coverage in Germany. These included GOP 01730, 01760, and 01761 for general female cancer screening, 01731 for general male cancer screening, 01732 for general health checkup, 01734 and 01738 for colorectal cancer screening stool test, 01740 for colorectal cancer screening consultation, 01741 for colonoscopy, 01745 and 01746 for skin cancer screening, and 01750 for mammography. Beyond these GOPs, the data set included claims data for regionally agreed services for the listed screenings. Only claims data for early detection of abdominal aortic aneurysms were omitted because a complete data set for this preventive health service was not available for the observation period of the study. The term "screening" will be used synonymously for all preventive health services considered in the study.

The data set comprised the aggregated number of claims data on a monthly basis from January 2017 to December 2020, specified by the age and sex of patients eligible for the respective examinations. Age categories were formed on the age calculated at the end of December 2020. Only the claims data of AOK were used, and no further data linkage

was performed. Table 1 provides an overview of the data obtained.

Sample and population

The study included all AOK insured persons who were 25 years and older, eligible for the individual screenings based on their age and sex, insured in all quarters from 2017 to 2020, and who did not die in the fourth quarter of 2020. Patients that were participating in a primary physician model were excluded from the data set for data protection reasons. An a priori sample size calculation was not performed due to the explorative study design.

Legal basis and data protection

Claims data are transferred to the AOK according to § 295 of the German Social Code, Book V. The transfer of social data such as claims data for the purpose of research is regulated in § 67b and § 75 of the Social Code, Book X. As the data holder, the WIdO has consented to the provision of the data for the exclusive purpose of this study, taking into account data protection measures. Because the data set submitted by the WIdO only contained the aggregated number of screenings, the anonymized data did not allow any conclusions about individual persons. For this reason, no informed consent was required from the individuals included in the data set. Furthermore, according to the GPS guideline, the consultation of an ethics committee is not required for analyses of claims data (Swart et al. 2015).

Data processing, statistical analyses, and health economic analysis

During data preparation, the age categories 25–39 years, 40–59 years, 60–79 years, and > 80 years from a study by Kremer and Thurner (2020) were used to further summarize the age of the patients (Kremer and Thurner 2020). In addition, to compare utilization of screenings before COVID-19 and during COVID-19, the number of claimed screenings in the years 2017, 2018, and 2019 were averaged. This approach was intended to compensate for potential bias in previous years and to provide an approximation of the actual effects of the pandemic. Thus, the average utilization values from 2017 to 2019 were set as the time before COVID-19. Although the COVID-19 pandemic was declared as such not before March 2020, the first cases were reported in January 2020, which is why the values from 2020 were declared as the time during COVID-19 in the context of this study for the simplicity of the calculation.

The arithmetic mean and standard deviation (SD) of the change in monthly screening utilization before and during the COVID-19 pandemic were calculated using the observations from each GOP differentiated by sex and age category. Due to the sex- and age-based eligibility of the screenings, the total number of data points for the calculation of the mean and SD of each screening was 37 per month. Concerning the evaluation of differences in the utilization of screenings between women and men, only screenings that were available to both sexes were considered, resulting in a calculation of the mean and SD from a total of 14 data points per month per sex. Statistical analysis included the conduction of the binomial test to examine whether utilization changed significantly during the COVID-19 pandemic compared with the time before COVID-19. For this purpose, the respective proportion of utilized screenings during COVID-19 was compared with the proportion of utilized screenings before COVID-19 based on the number of insured persons that did not change during the observation period. This analysis comprised the individual GOPs, sex, and age of the patients. In addition, the independence of screening utilization before and during COVID-19 over the time course was tested using Pearson's Chi-square test. This analysis was furthermore extended by distinguishing between sex and age categories. Effect sizes were calculated using Cramer's V. The p value was set a priori at 0.05 to test two-sided significance. The Bonferroni–Holm correction was applied due to the multiple testing. Because of the small p values, even after adjustment

Table 1 Overview of the screenings and eligible patients considered

GOP	Type of examination	Sex	Age[a]
01730, 01760, 01761	General female cancer screening	Female	≥ 25 years
01731	General male cancer screening	Male	≥ 50 years
01732	General health checkup	Female and Male	≥ 40 years
01734, 01738	Colorectal cancer screening stool test	Female and Male	≥ 55 years
01740	Colorectal cancer screening consultation	Female and Male	≥ 55 years
01741	Colonoscopy	Female and Male	≥ 60 years
01745, 01746	Skin cancer screening	Female and Male	≥ 40 years
01750	Mammography screening	Female	≥ 55–69 years

[a]The age groups were raised by 5 years compared to the actual eligibility for the respective preventive health services, as the age of the patients was calculated at the end of 2020

based on the number of tests performed in the respective tables, the original p values did not change and thus the Bonferroni–Holm correction had no effect on the reported results.

To be able to depict the change in preventive health services financially, the study compared outpatient reimbursement before and during COVID-19. For this purpose, the German uniform value scale (EBM) for outpatient billing of services provided by the SHI was considered. The calculation of the compensation for the respective GOPs studied was based on the four quarters of the years 2017–2020. Changes in the reimbursement of GOPs within the quarters considered were taken into account. Time before COVID-19 represented the average costs of the years 2017, 2018, and 2019. The calculation included the multiplication of the reimbursement of the individual GOPs with the number of screenings performed, which were provided by the WIdO. If simultaneous billing of several GOPs was not possible, the mean value of the reimbursement was used for the calculation (this was the case for GOPs 01760 and 01761 as well as 01745 and 01746).

Results

Total utilization

In total, data from 15,833,662 AOK insured individuals in the following age categories were included: (1) 25–39 years: 1,908,846 (female), 2,013,686 (male); (2) 40–59 years: 2,731,103 (female), 2,832,784 (male); (3) 60–79 years: 2,371,561 (female), 2,113,089 (male); (4) ≥ 80 years: 1,229,909 (female), 632,684 (male).

These patients attended 11,225,261 screenings in 2017, 11,353,234 screenings in 2018, and 10,743,594 screenings in 2019. This resulted in an average of 11,107,363 attended screenings before COVID-19 (averages for the years 2017–2019). During COVID-19 (in the year 2020), the number of screenings decreased significantly by 21.46% to 8,723,989 ($p = < 0.001$), as shown in Table 2 with the binomial test. Among individual screenings, the largest decrease in utilization was observed for the general health checkup with 45.35% less examinations ($p = < 0.001$). With 5.99% less examinations, the smallest decrease was seen in general male cancer screening ($p = < 0.001$). A significant decrease in utilization was also evident for the remaining GOPs. The colorectal cancer screening consultation, however, was the only exception with a significant increase of 8.92% during COVID-19 ($p = < 0.001$). Figure 3 in Appendix provides a graphical illustration of the change in utilization of the individual screenings.

Figure 1 shows the mean percentage change in monthly utilization of all screenings during COVID-19 compared to the utilization before COVID-19 which is indicated by the horizontal line at 0. It was found that the monthly utilization throughout 2020 was below the average utilization before COVID-19. Screening uptake was already lower in January and February 2020 (January: mean = − 18.69%, SD = 34.94%; February: mean = − 20.67%, SD = 33.29%). This decline worsened in March (mean = − 38.73%, SD = 27.60%) and reached its low point in April with a mean of 52.34% (SD = 23.28%) fewer screenings. After utilization had approached to the previous years' levels in July (mean = − 6.88%, SD = 20.92%), another decline occurred in August (mean = − 21.37%, SD = 19.99%). Following a slight recovery in the fall, utilization dropped again in the winter, culminating in a mean percentage change of − 13.60% (SD = 19.63%) in December 2020. Both the mean percentage utilization and its SD for the months March, April, May, and August 2020 were lower than previous years' values, indicating a sharp decline in the utilization of all screenings in these months. For the remaining months, the mean of the total screenings was also below the previous years' values, but the large SDs that exceeded the horizontal line at 0 showed that individual screenings varied in these months, with some screenings meeting or even exceeding previous years' levels. Overall, the mean number of screenings during 2020 did not reach the previous years' average in any month. As the mean screening utilization did not exceed the mean screening utilization from previous years to compensate for missed screenings, no catch-up effects could be detected.

This trend is also evident in Table 3, in which monthly utilization of screenings before and during COVID-19 was further examined using the Chi-square test. The analysis showed that total screening utilization was significantly related to the respective time period ($\chi^2(1) = 164{,}057$, $p = < 0.001$, $V = 0.091$). In addition to the analysis of the total screenings, claims data for individual GOPs were examined on a monthly basis. A significant association in the time course of utilization was also detected for each individual screening at the $p < 0.001$ significance level. The largest effect size was found to be $V = 0.221$ for mammography screening, followed by $V = 0.124$ for the general health checkup. Effect sizes of the other screenings were lower.

The monthly change in the individual GOPs revealed a decline in utilization in most cases when comparing the before COVID-19 and during COVID-19 time horizon. The largest drop was seen in April 2020 for mammography screenings with a 98.71% decrease compared to before COVID-19. The general health checkup, with an average of 70.03% fewer utilizations in April 2020, was also affected greatly compared to the previous years' levels. The percentage change in utilization, however, differed between screenings. While some screenings were performed less frequently, other screenings were requested more frequently in the same month than before COVID-19. For example, more colorectal

Table 2 Investigation of the change in utilization during compared to before COVID-19

GOP	Utilization	*z*-value	*q*	*p*
Total screenings		– 1313.88	0.298	< 0.001
Before COVID-19	11,107,363			
During COVID-19	8,723,989			
Change (%)	– 21.46%			
General female cancer screening		– 212.84	0.779	< 0.001
Before COVID-19	3,492,421			
During COVID-19	3,147,838			
Change (%)	– 9.87%			
General male cancer screening		– 64.56	0.935	< 0.001
Before COVID-19	1,027,356			
During COVID-19	965,852			
Change (%)	– 5.99%			
General health checkup		– 842.22	0.822	< 0.001
Before COVID-19	2,811,569			
During COVID-19	1,536,466			
Change (%)	– 45.35%			
Colorectal cancer screening stool test		– 257.44	0.963	< 0.001
Before COVID-19	583,324			
During COVID-19	392,478			
Change (%)	– 32.72%			
Colorectal cancer screening consultation		80.12	0.96	< 0.001
Before COVID-19	638,853			
During COVID-19	695,823			
Change (%)	8.92%			
Colonoscopy		– 43.64	0.995	< 0.001
Before COVID-19	85,341			
During COVID-19	66,919			
Change (%)	– 21.59%			
Skin cancer screening		– 375.68	0.878	< 0.001
Before COVID-19	1,931,488			
During COVID-19	1,442,453			
Change (%)	– 25.32%			
Mammography screening		– 86.23	0.966	< 0.001
Before COVID-19	537,010			
During COVID-19	476,160			
Change (%)	– 11.33%			

cancer screening consultations were utilized each month starting in June than in the same period before COVID-19. Comparing all GOPs, demand for colorectal cancer screening consultations increased the most, whereas demand for general health checkups decreased the most.

Differences in utilization with regard to sex and age

Beyond the consideration of the general utilization of screenings, differences due to patients' sex and age were analyzed in more detail. Over the course of COVID-19, utilization of total screenings available to women decreased significantly by 20.56% from 7,450,140 before COVID-19 to 5,918,073 ($p = < 0.001$) and for men by 23.28% from 3,657,223 to 2,805,916 ($p = < 0.001$). In the age group 25–39 years, the utilization of total screenings decreased by 4.56% ($p = < 0.001$), in the age group 40–59 years by 18.65% ($p = < 0.001$), in the age group 60–79 years by 23.75% ($p = < 0.001$), and for patients aged 80 years or older by 37.02% ($p = < 0.001$). These results can be found in Table 4.

The mean percentage change in the monthly utilization of screenings before and during COVID-19 was differentiated between women and men in Fig. 2. Only GOPs that could be claimed for both sexes were considered. The mean utilization of screenings has declined to a greater extent for females

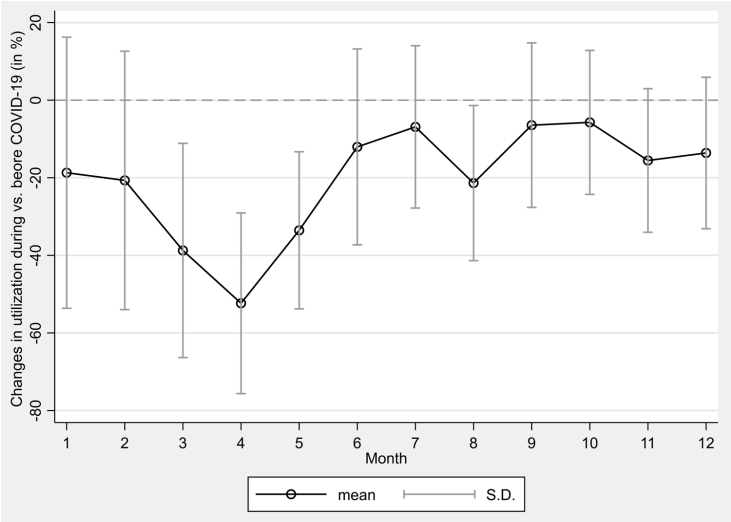

Fig. 1 Percentage change in monthly utilization of screenings before and during COVID-19

than for males in each month when compared to the average utilization before COVID-19. The strongest difference between the sexes was observed in April. While the mean decrease in utilization for males was 54.48% (SD = 24.34%), females utilized on average 60.92% fewer screenings (SD = 20.07%) in April compared with the previous years' average. However, for the months July and October through December, the overlapping SD suggests that in relation to the time period before COVID-19, the difference in screening utilization between sexes became smaller. The smallest difference in the mean percentage change to the time period before COVID-19 was observed in October (female: mean = − 13.37%, SD = 18.96%; male: mean = − 12.63%, SD = 20.17%).

Furthermore, in Table 5 sex differences are examined in more detail for the entire year 2020 compared with the before COVID-19 period for screenings that were available to both women and men. The decrease in total utilization of screenings was significantly more pronounced for women than for men during COVID-19. The largest difference between sexes was found for colonoscopy with a drop of 23.32% for women and 19.64% for men ($\chi^2(1)=21$, $p = < 0.001$, $V = 0.012$). The largest decrease in examinations offered for both sexes was observed for the general health checkup with a decrease of 46.47% for women and 43.93% for men ($\chi^2(1) = 531$, $p = < 0.001$, $V = 0.011$). Colorectal cancer screening consultation increased for women and men during COVID-19 compared to before COVID-19. While women used these examinations on average 7.51% more often, the demand increased by an average of 10.72% for men compared to previous years ($\chi^2(1) = 71$, $p = < 0.001$, $V = 0.007$).

Detailed tables of monthly screening utilization by women and men before and during COVID-19 are provided in Appendix 2 and 3.

Differences in the change of utilization could also be observed with regard to the age of the patients, as presented in Table 6. The change in utilization of total screenings was significantly related to patient age ($\chi^2(2) = 14{,}559$, $p = < 0.001$, $V = 0.038$). The higher the age of the patients, the lower was the utilization of total screenings. While there were 27.11% fewer screenings in total recorded in the 40–59 years age category, the decline was 31.84% in the 60–79 years age category, and reached a maximum of 42.49% fewer screenings in the > 80 years age category. In addition, a significant decrease in utilization with increasing age was observed for all examinations, for which both women and men were eligible. Only the colorectal cancer screening stool test had a greater decrease in utilization among those aged 55–59 years (− 36.96%) than among those aged 60–79 years (− 28.18%). Nevertheless, the greatest decline was again found among those > 80 years of age (− 41.66%) ($\chi^2(2) = 1558$, $p = < 0.001$, $V = 0.040$). For colorectal cancer screening consultations, an increase in utilization during COVID-19 of 36.73% was observed among patients in the age category 55–59 years compared with before COVID-19. For patients aged 60–79 years, utilization changed by − 0.41% and patients > 80 years had a decrease in utilization of 9.02% ($\chi^2(2) = 8354$, $p = < 0.001$, $V = 0.079$). Another greater difference was found for colonoscopy, which showed

Table 3 Time course and screening utilization before and during COVID-19

GOP	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	χ^2	*df*	*p*	*V*
Total screenings													164,057	11	< 0.001	0.091
Before COVID-19	1,215,844	1,087,095	1,125,801	942,706	1,021,052	895,074	858,610	781,113	864,040	798,702	930,417	586,910				
During COVID-19	988,555	862,381	689,788	449,273	678,610	787,345	799,532	614,217	808,407	752,995	785,821	507,065				
Change (%)	− 18.69%	− 20.67%	− 38.73%	− 52.34%	− 33.54%	− 12.04%	− 6.88%	− 21.37%	− 6.44%	− 5.72%	− 15.54%	− 13.60%				
General female cancer screening													38,226	11	< 0.001	0.076
Before COVID-19	368,213	321,953	345,948	300,294	326,851	287,816	269,587	241,576	272,378	258,782	305,337	193,687				
During COVID-19	350,615	298,934	257,862	177,870	261,730	290,600	276,434	212,374	288,067	263,247	288,355	181,750				
Change (%)	− 4.78%	− 7.15%	− 25.46%	− 40.77%	− 19.92%	+ 0.97%	+ 2.54%	− 12.09%	+ 5.76%	+ 1.73%	− 5.56%	− 6.16%				
General male cancer screening													10,208	11	< 0.001	0.072
Before COVID-19	115,109	100,819	104,417	86,940	90,377	78,537	73,672	68,792	75,677	76,624	94,064	62,328				
During COVID-19	115,458	99,903	81,800	55,984	76,537	83,474	80,437	64,102	83,665	79,455	87,148	57,889				
Change (%)	+ 0.30%	− 0.91%	− 21.66%	− 35.61%	− 15.31%	+ 6.29%	+ 9.18%	− 6.82%	+ 10.56%	+ 3.69%	− 7.35%	− 7.12%				
General health checkup													66,487	11	< 0.001	0.124
Before COVID-19	343,938	307,421	307,212	249,182	265,781	226,001	211,844	191,465	210,096	174,823	201,171	122,634				
During COVID-19	180,476	156,609	113,783	74,671	115,925	136,182	147,658	107,864	142,885	137,240	136,029	87,144				
Change (%)	− 47.53%	− 49.06%	− 62.96%	− 70.03%	− 56.38%	− 39.74%	− 30.30%	− 43.66%	− 31.99%	− 21.50%	− 32.38%	− 28.94%				
Colorectal cancer screening stool test													7613	11	< 0.001	0.088
Before COVID-19	63,503	62,237	66,886	39,554	47,195	43,163	43,644	38,762	45,425	43,557	52,241	37,158				
During COVID-19	41,272	41,261	32,711	17,387	29,073	33,332	37,684	25,835	36,548	35,114	35,955	26,306				
Change (%)	− 35.01%	− 33.70%	− 51.09%	− 56.04%	− 38.40%	− 22.78%	− 13.66%	− 33.35%	− 19.54%	− 19.38%	− 31.17%	− 29.21%				
Colorectal cancer screening consultation													6157	11	< 0.001	0.068
Before COVID-19	58,057	52,418	54,666	51,021	57,347	50,669	54,647	50,475	54,568	54,145	60,908	39,931				
During COVID-19	75,668	66,136	53,371	39,914	54,228	61,141	65,178	51,389	64,980	60,491	61,753	41,574				
Change (%)	+ 30.33%	+ 26.17%	− 2.37%	− 21.77%	− 5.44%	+ 20.67%	+ 19.27%	+ 1.81%	+ 19.08%	+ 11.72%	+ 1.39%	+ 4.11%				
Colonoscopy													731	11	< 0.001	0.069
Before COVID-19	8054	7345	7976	6971	7561	7041	7013	6711	6964	6652	7634	5419				
During COVID-19	7061	6340	5665	3694	5000	5787	6154	5040	6391	5636	5855	4296				
Change (%)	− 12.33%	− 13.68%	− 28.97%	− 47.01%	− 33.87%	− 17.81%	− 12.25%	− 24.90%	− 8.23%	− 15.27%	− 23.30%	− 20.72%				
Skin cancer screening													24,560	11	< 0.001	0.085
Before COVID-19	208,776	186,521	187,778	166,746	179,647	158,256	158,148	141,581	151,952	136,006	155,578	100,501				
During COVID-19	167,006	143,761	110,183	79,212	113,330	127,998	139,076	104,758	132,869	122,525	121,265	80,470				

Table 3 (continued)

GOP	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	χ^2	*df*	*p*	*V*
Change (%)	− 20.01%	− 22.93%	− 41.32%	− 52.50%	− 36.92%	− 19.12%	− 12.06%	− 26.01%	− 12.56%	− 9.91%	− 22.06%	− 19.93%				
Mammography screening													49,629	11	< 0.001	0.221
Before COVID-19	50,194	48,381	50,918	41,998	46,292	43,590	40,055	41,751	46,981	48,113	53,484	25,253				
During COVID-19	50,999	49,437	34,413	541	22,787	48,831	46,911	42,855	53,002	49,287	49,461	27,636				
Change (%)	+ 1.60%	+ 2.18%	− 32.41%	− 98.71%	− 50.78%	+ 12.02%	+ 17.12%	+ 2.64%	+ 12.82%	+ 2.44%	− 7.52%	+ 9.44%				

Table 4 Investigation of the change in utilization of all screenings before and during COVID-19 with regard to sex and age

Patient group	Utilization	*z*-value	*q*	*p*
Total screenings female		− 775.13	0.529	< 0.001
Before COVID-19	7,450,140			
During COVID-19	5,918,073			
Change (%)	− 20.56%			
Total screenings male		− 507.82	0.769	< 0.001
Before COVID-19	3,657,223			
During COVID-19	2,805,916			
Change (%)	− 23.28%			
Total screenings 25–39 years		− 56.91	0.927	< 0.001
Before COVID-19	1,149,367			
During COVID-19	1,096,952			
Change (%)	− 4.56%			
Total screenings 40–59 years		− 443.48	0.737	< 0.001
Before COVID-19	4,163,724			
During COVID-19	3,387,341			
Change (%)	− 18.65%			
Total screenings 60–79 years		− 590.80	0.719	< 0.001
Before COVID-19	4,449,227			
During COVID-19	3,392,557			
Change (%)	− 23.75%			
Total screenings > 80 years		− 449.42	0.915	< 0.001
Before COVID-19	1,345,045			
During COVID-19	847,139			
Change (%)	− 37.02%			

a 17.87% reduction in the number of cases in the 60–79 years age category and a 54.32% reduction in the > 80 years age category ($\chi^2(1) = 890$, $p = < 0.001$, $V = 0.076$). The utilization by age groups can be found in Appendix 4 for women, and in Appendix 5 for men.

Health economic analysis

The results of the health economic analysis revealed notable variations in the reimbursement of preventive health services for SHI patients before and during COVID-19. The calculation in Table 7 shows that before COVID-19 a yearly mean of €274,937,166 was reimbursed for screenings and checkups. During COVID-19, reimbursement decreased to €219,378,343, resulting in a reduction of €55,558,823. The smallest decrease was noted in general male cancer screenings at €432,939, whereas the largest decrease was present in the general health checkups at €36,973,751. The only screening that was billed more often during COVID-19 was the colorectal cancer screening consultation with a change of €1,570,553.

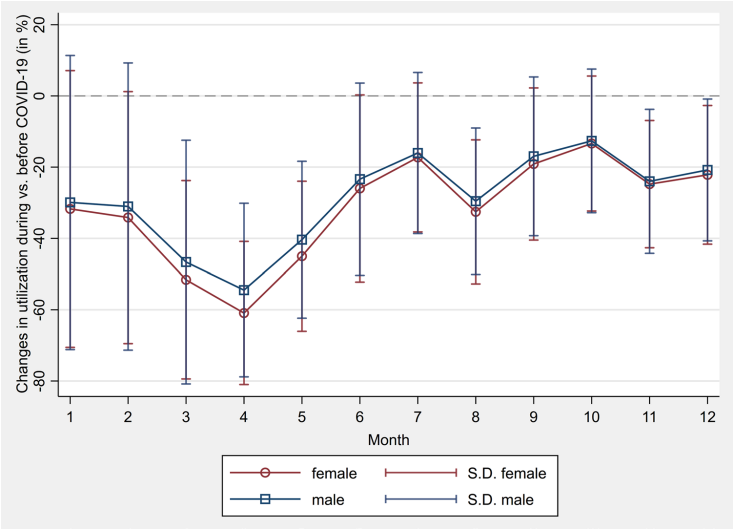

Fig. 2 Percentage change in monthly utilization of screenings before and during COVID-19 comparing women and men

Table 5 Comparison of utilization between sex before and during COVID-19 for screenings available to both women and men

GOP	Female	Male	χ^2	*df*	*p*	*V*
Total screenings			1088	1	< 0.001	0.010
Before COVID-19	3,420,708	2,629,867				
During COVID-19	2,294,075	1,840,064				
Change (%)	– 32.94%	– 30.03%				
General health checkup			531	1	< 0.001	0.011
Before COVID-19	1,574,858	1,236,711				
During COVID-19	842,988	693,478				
Change (%)	– 46.47%	– 43.93%				
Colorectal cancer screening stool test			168	1	< 0.001	0.013
Before COVID-19	364,352	218,973				
During COVID-19	240,043	152,435				
Change (%)	– 34.12%	– 30.39%				
Colorectal cancer screening consultation			71	1	< 0.001	0.007
Before COVID-19	358,816	280,037				
During COVID-19	385,754	310,069				
Change (%)	+ 7.51%	+ 10.72%				
Colonoscopy			21	1	< 0.001	0.012
Before COVID-19	45,048	40,293				
During COVID-19	34,541	32,378				
Change (%)	– 23.32%	– 19.64%				
Skin cancer screening			317	1	< 0.001	0.010
Before COVID-19	1,077,634	853,853				
During COVID-19	790,749	651,704				
Change (%)	– 26.62%	– 23.67%				

Table 6 Comparison of utilization between age before and during COVID-19

GOP	40–59 years	60–79 years	> 80 years	χ^2	*df*	*p*	*V*
Total screenings				14,559	2	< 0.001	0.038
Before COVID-19	2,367,027	2,727,664	955,885				
During COVID-19	1,725,231	1,859,157	549,751				
Change (%)	– 27.11%	– 31.84%	– 42.49%				
General health checkup				12,244	2	< 0.001	0.053
Before COVID-19	1,205,688	1,149,165	456,716				
During COVID-19	735,828	596,004	204,634				
Change (%)	– 38.97%	– 48.14%	– 55.19%				
Colorectal cancer screening stool test[a]				1558	2	< 0.001	0.040
Before COVID-19	156,597	332,382	94,345				
During COVID-19	98,721	238,720	55,037				
Change (%)	– 36.96%	– 28.18%	– 41.66%				
Colorectal cancer screening consultation[a]				8354	2	< 0.001	0.079
Before COVID-19	181,986	363,951	92,916				
During COVID-19	248,832	362,455	84,536				
Change (%)	+ 36.73%	– 0.41%	– 9.02%				
Colonoscopy				890	1	< 0.001	0.076
Before COVID-19		76,645	8696				
During COVID-19		62,947	3972				
Change (%)		– 17.87%	– 54.32%				
Skin cancer screening				2334	2	< 0.001	0.026
Before COVID-19	822,756	805,520	303,212				
During COVID-19	641,850	599,031	201,572				
Change (%)	– 21.99%	– 25.63%	– 33.52%				

[a]Data from patients ≥ 55 years

Table 7 Change in outpatient reimbursement for screenings before and during COVID-19

GOP	Reimbursement before COVID-19	Reimbursement during COVID-19	Change
Total screenings	€274,937,166	€219,378,343	€– 55,558,823
General female cancer screening	€67,057,068	€59,944,056	€– 7,113,012
General male cancer screening	€15,680,030	€15,247,091	€– 432,939
General health checkup	€91,712,390	€54,738,639	€– 36,973,751
Colorectal cancer screening stool test	€4,252,667	€3,234,019	€– 1,018,648
Colorectal cancer screening consultation	€7,279,721	€8,850,274	€1,570,553
Colonoscopy	€17,697,434	€13,365,208	€– 4,332,226
Skin cancer screening	€39,550,547	€34,805,686	€– 4,744,860
Mammography screening	€31,707,309	€29,193,370	€– 2,513,940

Discussion

Key findings

The aim of this claims data analysis was to investigate the utilization of all preventive health services and cancer screenings offered to SHI patients in Germany before and during the COVID-19 pandemic. The study revealed two major findings. First, the utilization of total screenings decreased during the COVID-19 pandemic, but trends in utilization varied with respect to individual screenings. Second, screening utilization has developed differently among patient groups.

Change in screening utilization

The analysis showed that the number of total screenings decreased significantly in Germany by around 21.46% in 2020 compared to before COVID-19 ($p < 0.001$). In addition, the 4-year observation period revealed a decrease

of total screenings throughout the course of 2020, with the largest declines being temporally related to the lockdowns introduced in Germany. In addition to the largest change in perceived screenings in April 2020 (− 52.34%), a decrease of about 24% was also noted in ambulatory care utilization for that month, as shown by Bayindir and Schreyögg (2022) (Bayindir and Schreyögg 2022). While ambulatory care utilization returned to prior-year levels during the year (Bayindir and Schreyögg 2022), no catch-up effects were detected in our study throughout the entire year.

The decline in utilization of cancer screenings shown in our study is consistent with international findings (Doubova et al. 2021; Lantinga et al. 2021; Mantellini et al. 2020; Song et al. 2021). For example, a systematic review by Alkatout et al. (2021) and a meta-analysis by Mayo et al. (2021) reported a substantial decline in screenings worldwide (Alkatout et al. 2021; Mayo et al. 2021). Compared to the existing literature, however, our study goes beyond examining only individual screenings by providing evidence on the development of screening utilization based on the analysis of the entire prevention program in Germany and differentiates between individual patient groups.

In addition, the change in utilization before and during COVID-19 developed differently for the individual preventive health services. The highest decrease was found in general health checkup with 45.35%, followed by declines in colorectal cancer screening stool test with 32.72%, skin cancer screening with 25.32%, and colonoscopy with 21.59%. Changes were less marked in the sex-specific screenings: mammography screening, general female cancer screening, and general male cancer screening with − 11.33%, − 9.87%, and − 5.99% respectively. In contrast, colorectal cancer screening consultation, the only screening that does not involve a physical examination, increased by 8.92% in 2020. Consultation numbers as of June 2020 even surpassed the number of consultations for this screening compared to the same time period before COVID-19.

The overall negative development of patient numbers during the pandemic, both internationally and in Germany, as well as the different directions and magnitudes of changes in the utilization of the individual cancer screenings could have various causes: (1) A decrease in patient demand, which most likely is linked to the fear of an infection with SARS-CoV-2 (Hajek et al. 2021; Lazzerini et al. 2020). For example, a survey from the USA found that approximately 40.9% of respondents postponed or even avoided physician visits until June 2020 because they were concerned about COVID-19 (Czeisler et al. 2020). (2) A decrease in supply due to the suspension of services and programs, such as the interruption of breast cancer screening programs for different time periods in countries like Australia, the Netherlands, and the UK (Figueroa et al. 2021). Mammography screenings were also suspended in Germany at the beginning of the pandemic (Ärztezeitung 2020), which is reflected in our data set with a decrease of 98.71% in April 2020. At the same time, there is evidence that the likelihood of receiving appointments in outpatient practices in Germany decreased at the onset of the pandemic (Muschol and Gissel 2021), which may also have contributed to the change in case numbers for preventive health services. (3) The different multiyear eligibility of each screening may have had an influence on utilization. For example, patients are only eligible for the general health checkup every three years, which could lead to the effect that this checkup might be more likely to be postponed by patients or physicians. (4) The respective medical procedure may have had an impact on utilization. Procedures such as skin cancer screenings or colonoscopies with pronounced physical contact and a presumably more time-consuming treatment have decreased, whereas colorectal cancer screening consultations that do not require intense physical contact have increased. In addition, the ability to perform these screenings with the help of video consultations might have also led to an increase in this type of screenings. (5) High utilization of screenings prior to the pandemic could be an indicator of the perceived relevance of the respective screenings, which persisted during the pandemic. In particular, general cancer screening for women, mammography screening, and general cancer screening for men were utilized comparatively frequently by eligible patients in 2019 with 46%, 25%, and 23%, respectively (Tillmanns et al. 2021).

Decline for women and the elderly

In addition to the general change in the utilization of individual screenings in Germany, our study also found that the utilization of screenings developed differently with regard to patient-specific characteristics such as sex and age. For screenings that can be claimed for both sexes, a significantly stronger decrease was observed for women than for men (32.94% vs. 30.03%). Structural changes in the population that occurred during the COVID-19 pandemic may have influenced utilization. For example, during the COVID-19 pandemic, the gender care gap was reflected in women having to perform more unpaid care work. This shift of time resources could have influenced women's use of medical care (Pacheco et al. 2021; Power 2020).

Patients' age also had a significant impact on screening utilization. The older the patients, the greater the decrease in utilization of screenings. While total screenings in 2020 decreased by 27.11% for those aged 40–59 years, the decrease was greatest among patients aged 80 years and older, at 42.49%. The decline in utilization might be related to the fact that older individuals are at increased risk for a severe COVID-19 progression and have an increased risk of mortality (Romero Starke et al. 2021). In addition, the elderly are often affected by health-care inequalities as they face access barriers to health-care systems and suffer from delays in medical care (Jang and Kim 2020; Saif-Ur-Rahman et al. 2021). The assumption that this effect may be exacerbated during the pandemic can be supported by our findings and leads to concerns that the health status of the elderly may deteriorate (Jang and Kim 2020).

Impact on policy and practice

Our results show that in an international comparison, a large number of state regulated preventive health services and screenings have not been performed in Germany either. The concern that cancer and other noncommunicable diseases, especially in early stages, are detected later also applies to Germany due to this trend. This circumstance could lead to a more severe disease progression and worse health outcomes for patients causing higher morbidity and mortality. This concern is supported for Germany by two studies from Jacob et al. (2021, 2022), which found that the number of cancer diagnoses decreased significantly in German practices during the COVID-19 pandemic (Jacob et al. 2021, 2022). For example, in April 2020, there were 32.0% fewer new cancer diagnoses in gynecology practices and 44.4% fewer in dermatology practices (Jacob et al. 2021).

Economic effects

Finally, our health economic analysis revealed that the change in utilization of preventive health services during COVID-19 also led to variations in outpatient reimbursement. Our calculation showed that approximately €55,558,823 were billed less during COVID-19. A WIdO report by Tillmanns et al. (2021) presented the 2019 and 2020 spending for preventive health services. These calculations showed a difference of around €49 million. Although the WIdO calculation considered more chargeable services and only took the years 2019 and 2020 into account, it resulted in similar overall differences, supporting our findings (Tillmanns et al. 2021). In the long term, however, these saved costs will most likely be offset by the costs arising from an increased burden and duration of diseases due to delayed or omitted early detection. First evidence of cancer treatment in Germany suggests considerable decreases in cancer diagnoses and cases such as skin cancer as well as gynecologic and breast cancer during the pandemic (Jacob et al. 2021, 2022; Kaltofen et al. 2022; Kleemann et al. 2022). The total amount of the additional costs caused by this development, however, will only be quantifiable in the future.

Practical implications

Our results show that individual screenings and patient groups underwent different shifts during the COVID-19 pandemic and that the utilization was particularly impaired among women and elderly patients. To be able to maintain public health in the long term and to be able to mitigate an increase in health-care spending, there are some practical implications in order to allocate limited medical resources in the best possible way. In the future, greater utilization of screenings should be promoted, and appropriate interventions have to be implemented by policymakers and health-care providers to support catch-up effects. Patients should be encouraged to continue using preventive health services and the safety of screenings should also be highlighted in the event of future unforeseeable developments.

Screenings that have seen the greatest decline in 2020, such as the general health checkup, colorectal cancer stool test, skin cancer screening, and colonoscopy, should be promoted the most. Furthermore, education on the utilization of cancer screening has to be tailored to individual groups of the population. In particular, access barriers for women and older patients need to be lowered and available resources should be targeted to these vulnerable groups. The use of digital applications could be promoted in the form of apps or telemedicine when suited for the respective examinations. During the COVID-19 pandemic, the use of telemedicine has increased in many areas, such as outpatient care in general medical practices or follow-up care of surgery patients, often providing satisfactory results (Knörr et al. 2022; Muschol et al. 2022). Some cancer screenings have also been supported by telehealth services (Price et al. 2022). One area that is particularly suitable for the use of telemedicine is dermatology (Trettel et al. 2018). For the screening of skin cancer, the use of artificial intelligence can also be beneficial (Sangers et al. 2021). Our study has shown that the COVID-19 related decrease in cancer screening utilization was strongly pronounced among older patients, i.e. they

could be the population that benefits the most from digital health alternatives to conventional in-person screenings. When using digital health applications, it should therefore be ensured that older patients face no access barriers and that the applications are adapted to the needs and abilities of older people.

Finally, it is essential to continue monitoring the development of the utilization of screenings in the future, to timely recognize potential shifts in utilization for different patient groups, and to aim for timely reallocation of resources.

Limitations

This study has four main limitations. First, due to data protection, access to patient data is highly regulated for research in Germany. For this reason, the study was based on an aggregated data set and an analysis of individual factors was not possible. For example, no conclusions could be drawn about the socioeconomic status of patients, although this may have had an impact on the utilization of screenings and should therefore be investigated further in future studies. In addition, besides the COVID-19 pandemic, other factors could have had an impact on the utilization of screenings in 2020, which could not be determined within the scope of the study due to the data basis. However, we consider the strong influence of the COVID-19 pandemic to be the primary driver for the development of screening utilization. Second, because of the data structure, the annual number of eligible patients for the respective screenings could not be detected. In addition, it could be the case that individual patients changed age groups during the observation period. Because of the rather large data set, however, this should not have resulted in any major bias. Third, the retrospective study design only allowed for an analysis of the past screening utilization, which is why it was not possible to make statements about future developments in screenings and prognoses about the effect of omitted screenings on future development of cancer diagnoses and disease severity within the scope of the study. Finally, the data set included a vast number of the insured population in Germany. Nevertheless, not the entire population was represented within the data set and insurance-specific patient characteristics may differ from other insured patients, especially in private health insurances.

Conclusion

This was the first study that examined changes in the utilization of all preventive health services and cancer screenings available to SHI patients in Germany during the COVID-19 pandemic. Based on the analysis of claims data from the largest German statutory health insurance fund, it was found that the utilization of the individual screenings developed differently during the COVID-19 pandemic with an overall decline in utilization and no catch-up effects throughout 2020. This negative trend is also reflected in the international context. The patient groups of women and the elderly were particularly affected by the decline in cancer screenings. The postponement or omission of early detection of noncommunicable diseases is associated with the fear of worse health outcomes in the form of more severe disease progressions and increased mortality in the long term. At the same time, this could lead to increased health-care expenditures and a loss of productivity for the German economy. To counteract the negative trend, there is an urgent need for catch-up effects, especially for screenings, which have experienced a particularly severe reduction of utilization. To this end, resources should be targeted to encourage patients to make greater use of preventive health services and to support physicians in offering these services. To assist the delivery of screening in the future, the adoption of digital applications such as telemedicine, apps, or artificial intelligence should be expanded, as their increasing use since the onset of the pandemic has demonstrated their potential in this medical area. Only through focused collaboration between policymakers and health-care providers can the serious burdens that occurred during the COVID-19 pandemic and that extend beyond the direct impact of the pandemic be mitigated in the long term.

Appendix 1

See Fig. 3.

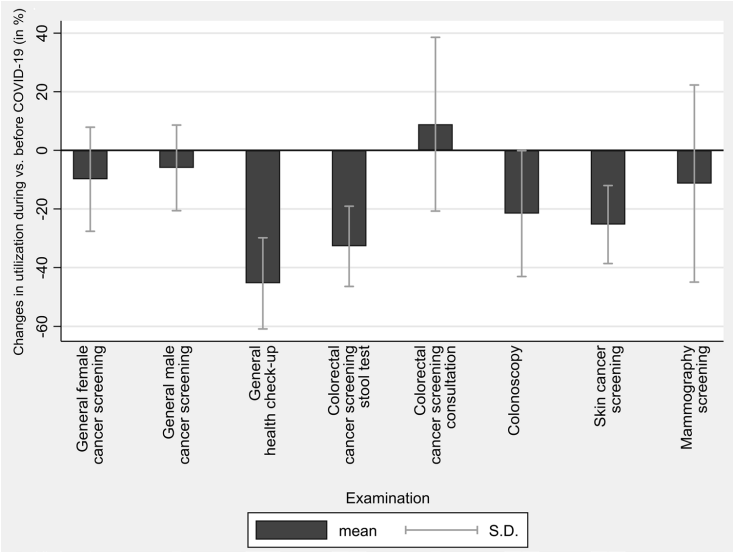

Fig. 3 Percentage change per individual screening during COVID-19 compared to before COVID-19

Appendix 2: Comparison of monthly utilization by women before and during COVID-19

GOP	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	χ^2	*df*	*p*	*V*
Total													122,645	11	< 0.001	0.096
Before COVID-19	790,066	712,846	750,674	635,019	695,108	610,747	581,983	527,185	587,664	543,332	628,677	386,838				
During COVID-19	655,347	573,918	463,527	292,812	461,588	546,188	548,664	419,702	558,080	517,363	540,812	340,072				
Change (%)	− 17.05%	− 19.49%	− 38.25%	− 53.89%	− 33.59%	− 10.57%	− 5.73%	− 20.39%	− 5.03%	− 4.78%	− 13.98%	− 12.09%				
General female cancer screening													38,226	11	< 0.001	0.076
Before COVID-19	368,213	321,953	345,948	300,294	326,851	287,816	269,587	241,576	272,378	258,782	305,337	193,687				
During COVID-19	350,615	298,934	257,862	177,870	261,730	290,600	276,434	212,374	288,067	263,247	288,355	181,750				
Change (%)	− 4.78%	− 7.15%	− 25.46%	− 40.77%	− 19.92%	+ 0.97%	+ 2.54%	− 12.09%	+ 5.76%	+ 1.73%	− 5.56%	− 6.16%				
General health checkup													42,127	11	< 0.001	0.132
Before COVID-19	186,685	170,274	172,293	142,020	152,815	128,925	120,522	107,949	118,418	98,171	111,638	65,150				
During COVID-19	95,634	84,365	60,939	39,575	63,992	76,705	83,967	59,792	79,887	76,999	75,057	46,076				
Change (%)	− 48.77%	− 50.45%	− 64.63%	− 72.13%	− 58.12%	− 40.50%	− 30.33%	− 44.61%	− 32.54%	− 21.57%	− 32.77%	− 29.28%				
Colorectal cancer screening stool test													5040	11	< 0.001	0.091
Before COVID-19	37,329	37,579	42,066	24,287	29,920	27,799	27,473	24,169	29,322	27,332	32,955	24,122				

GOP	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	χ^2	*df*	*p*	*V*
During COVID-19	24,082	24,717	20,090	9941	17,572	20,672	23,014	15,416	22,952	21,960	22,794	16,833				
Change (%)	− 35.49%	− 34.23%	− 52.24%	− 59.07%	− 41.27%	− 25.64%	− 16.23%	− 36.21%	− 21.72%	− 19.65%	− 30.83%	− 30.22%				
Colorectal cancer screening consultation													4080	11	< 0.001	0.074
Before COVID-19	31,564	28,790	30,730	28,659	32,615	28,848	30,967	28,313	31,129	30,752	34,520	21,929				
During COVID-19	41,342	35,951	28,610	21,203	30,433	34,622	36,783	28,431	36,625	34,327	34,787	22,640				
Change (%)	+ 30.98%	+ 24.87%	− 6.90%	− 26.02%	− 6.69%	+ 20.02%	+ 18.78%	+ 0.42%	+ 17.66%	+ 11.62%	+ 0.77%	+ 3.24%				
Colonoscopy													493	11	< 0.001	0.079
Before COVID-19	4196	3770	4163	3670	3979	3775	3716	3561	3707	3568	4115	2827				
During COVID-19	3644	3298	2834	1791	2505	2996	3202	2592	3407	2957	3113	2202				
Change (%)	− 13.16%	− 12.52%	− 31.93%	− 51.20%	− 37.04%	− 20.64%	− 13.83%	− 27.21%	− 8.10%	− 17.12%	− 24.35%	− 22.11%				
Skin cancer screening													16,132	11	< 0.001	0.093
Before COVID-19	111,886	102,099	104,556	94,092	102,637	89,993	89,663	79,867	85,730	76,615	86,628	53,870				
During COVID-19	89,031	77,216	58,779	41,891	62,569	71,762	78,353	58,242	74,140	68,586	67,245	42,935				
Change (%)	− 20.43%	− 24.37%	− 43.78%	− 55.48%	− 39.04%	− 20.26%	− 12.61%	− 27.08%	− 13.52%	− 10.48%	− 22.37%	− 20.30%				
Mammography screening													49,629	11	< 0.001	0.221
Before COVID-19	50,194	48,381	50,918	41,998	46,292	43,590	40,055	41,751	46,981	48,113	53,484	25,253				
During COVID-19	50,999	49,437	34,413	541	22,787	48,831	46,911	42,855	53,002	49,287	49,461	27,636				
Change (%)	+ 1.60%	+ 2.18%	− 32.41%	− 98.71%	− 50.78%	+ 12.02%	+ 17.12%	+ 2.64%	+ 12.82%	+ 2.44%	− 7.52%	+ 9.44%				

Appendix 3: Comparison of monthly utilization by men before and during COVID-19

GOP	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	χ^2	*df*	*p*	*V*
Total													42,598	11	< 0.001	0.081
Before COVID-19	425,778	374,249	375,127	307,686	325,943	284,328	276,626	253,928	276,376	255,370	301,741	200,072				
During COVID-19	333,208	288,463	226,261	156,461	217,022	241,157	250,868	194,515	250,327	235,632	245,009	166,993				
Change (%)	− 21.74%	− 22.92%	− 39.68%	− 49.15%	− 33.42%	− 15.18%	− 9.31%	− 23.40%	− 9.43%	− 7.73%	− 18.80%	− 16.53%				
General male cancer screening													10,208	11	< 0.001	0.072
Before COVID-19	115,109	100,819	104,417	86,940	90,377	78,537	73,672	68,792	75,677	76,624	94,064	62,328				
During COVID-19	115,458	99,903	81,800	55,984	76,537	83,474	80,437	64,102	83,665	79,455	87,148	57,889				
Change (%)	+ 0.30%	− 0.91%	− 21.66%	− 35.61%	− 15.31%	+ 6.29%	+ 9.18%	− 6.82%	+ 10.55%	+ 3.70%	− 7.35%	− 7.12%				
General health checkup													24,768	11	< 0.001	0.113
Before COVID-19	157,253	137,147	134,919	107,163	112,966	97,077	91,322	83,517	91,678	76,652	89,533	57,483				
During COVID-19	84,842	72,244	52,844	35,096	51,933	59,477	63,691	48,072	62,998	60,241	60,972	41,068				
Change (%)	− 46.05%	− 47.32%	− 60.83%	− 67.25%	− 54.03%	− 38.73%	− 30.26%	− 42.44%	− 31.28%	− 21.41%	− 31.90%	− 28.56%				
Colorectal cancer screening stool test													2737	11	< 0.001	0.086
Before COVID-19	26,174	24,658	24,820	15,267	17,275	15,364	16,171	14,593	16,103	16,226	19,286	13,036				
During COVID-19	17,190	16,544	12,621	7446	11,501	12,660	14,670	10,419	13,596	13,154	13,161	9473				
Change (%)	− 34.32%	− 32.91%	− 49.15%	− 51.23%	− 33.42%	− 17.60%	− 9.28%	− 28.60%	− 15.57%	− 18.93%	− 31.76%	− 27.33%				

GOP	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	χ^2	*df*	*p*	*V*
Colorectal cancer screening consultation													2191	11	< 0.001	0.061
Before COVID-19	26,494	23,628	23,936	22,363	24,732	21,821	23,679	22,162	23,439	23,392	26,388	18,002				
During COVID-19	34,326	30,185	24,761	18,711	23,795	26,519	28,395	22,958	28,355	26,164	26,966	18,934				
Change (%)	+ 29.56%	+ 27.75%	+ 3.45%	− 16.33%	− 3.79%	+ 21.53%	+ 19.91%	+ 3.59%	+ 20.97%	+ 11.85%	+ 2.19%	+ 5.18%				
Colonoscopy													260	11	< 0.001	0.060
Before COVID-19	3857	3575	3813	3301	3583	3266	3297	3150	3257	3084	3519	2592				
During COVID-19	3417	3042	2831	1903	2495	2791	2952	2448	2984	2679	2742	2094				
Change (%)	− 11.42%	− 14.91%	− 25.75%	− 42.34%	− 30.36%	− 14.54%	− 10.47%	− 22.29%	− 8.38%	− 13.14%	− 22.08%	− 19.20%				
Skin cancer screening													8711	11	< 0.001	0.076
Before COVID-19	96,891	84,422	83,222	72,654	77,010	68,263	68,485	61,714	66,222	59,391	68,950	46,631				
During COVID-19	77,975	66,545	51,404	37,321	50,761	56,236	60,723	46,516	58,729	53,939	54,020	37,535				
Change (%)	-19.52%	-21.18%	-38.23%	-48.63%	-34.09%	-17.62%	-11.33%	-24.63%	-11.31%	-9.18%	-21.65%	-19.51%				

Appendix 4: Comparison of female utilization between age categories before and during COVID-19

GOP	25–39 years	40–59 years	60–79 years	> 80 years	χ^2	*df*	*p*	*V*
Total screenings					49,935	3	< 0.001	0.061
Before COVID-19	1,149,367	2,864,384	2,658,900	777,489				
During COVID-19	1,096,952	2,356,907	2,007,544	456,670				
Change (%)	– 4.56%	– 17.72%	– 24.50%	– 41.26%				
General female cancer screening					8808	3	< 0.001	0.036
Before COVID-19	1,149,367	1,350,438	814,114	178,503				
During COVID-19	1,096,952	1,231,165	699,064	120,657				
Change (%)	– 4.56%	– 8.83%	– 14.13%	– 32.41%				
General health checkup					6270	2	< 0.001	0.051
Before COVID-19		646,276	630,480	298,102				
During COVID-19		385,588	324,562	132,838				
Change (%)		– 40.34%	– 48.52%	– 55.44%				
Colorectal cancer screening stool test[a]					1465	2	< 0.001	0.049
Before COVID-19		110,355	198,460	55,537				
During COVID-19		65,387	142,682	31,974				
Change (%)		– 40.75%	– 28.11%	– 42.43%				
Colorectal cancer screening consultation[a]					4001	2	< 0.001	0.073
Before COVID-19		111,979	192,864	53,973				
During COVID-19		146,618	190,884	48,252				
Change (%)		+ 30.93%	– 1.03%	– 10.60%				
Colonoscopy					505	1	< 0.001	0.080
Before COVID-19			40,341	4707				
During COVID-19			32,481	2060				
Change (%)			– 19.48%	– 56.24%				
Skin cancer screening					1629	2	< 0.001	0.030
Before COVID-19		450,060	440,908	186,667				
During COVID-19		347,037	322,823	120,889				
Change (%)		– 22.89%	– 26.78%	– 35.24%				
Mammography screening[a]					302	1	< 0.001	0.017
Before COVID-19		195,276	341,734					
During COVID-19		181,112	295,048					

GOP	25–39 years	40–59 years	60–79 years	> 80 years	χ^2	*df*	*p*	*V*
Change (%)		– 7.25%	– 13.66%					

[a]Data from patients ≥ 55 years

Appendix 5: Comparison of male utilization between age categories before and during COVID-19

GOP	40–59 years	60–79 years	> 80 years	χ^2	*df*	*p*	*V*
Total screenings				3435	2	< 0.001	0.023
Before COVID-19	1,299,341	1,790,327	567,556				
During COVID-19	1,030,434	1,385,013	390,469				
Change (%)	– 20.70%	– 22.64%	– 31.20%				
General male cancer screening[a]				1710	2	< 0.001	0.029
Before COVID-19	250,983	565,715	210,657				
During COVID-19	249,833	539,288	176,731				
Change (%)	– 0.46%	– 4.67%	– 16.10%				
General health checkup				5745	2	< 0.001	0.055
Before COVID-19	559,412	518,685	158,614				
During COVID-19	350,240	271,442	71,796				
Change (%)	– 37.39%	– 47.67%	– 54.74%				
Colorectal cancer screening stool test[b]				436	2	< 0.001	0.034
Before COVID-19	46,243	133,922	38,808				
During COVID-19	33,334	96,038	23,063				
Change (%)	– 27.92%	– 28.29%	– 40.57%				
Colorectal cancer screening consultation[b]				4601	2	< 0.001	0.088
Before COVID-19	70,007	171,087	38,943				
During COVID-19	102,214	171,571	36,284				
Change (%)	+ 46.01%	+ 0.28%	– 6.83%				
Colonoscopy				384	1	< 0.001	0.073
Before COVID-19		36,305	3989				
During COVID-19		30,466	1912				
Change (%)		– 16.08%	– 52.06%				
Skin cancer screening				674	2	< 0.001	0.021
Before COVID-19	372,696	364,613	116,545				

GOP	40–59 years	60–79 years	> 80 years	χ^2	*df*	*p*	*V*
During COVID-19	294,813	276,208	80,683				
Change (%)	− 20.90%	− 24.25%	− 30.77%				

[a]Data from patients ≥ 50 years
[b]Data from patients ≥ 55 years

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Declarations

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3 Assessing Telemedicine Efficiency in Follow-Up Care With Video Consultations for Patients in Orthopedic and Trauma Surgery in Germany: Randomized Controlled Trial

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Original Paper

Assessing Telemedicine Efficiency in Follow-up Care With Video Consultations for Patients in Orthopedic and Trauma Surgery in Germany: Randomized Controlled Trial

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Abstract

Background: Telemedicine can help mitigate important health care challenges, such as demographic changes and the current COVID-19 pandemic, in high-income countries such as Germany. It gives physicians and patients the opportunity to interact via video consultations, regardless of their location, thus offering cost and time savings for both sides.

Objective: We aimed to investigate whether telemedicine can be implemented efficiently in the follow-up care for patients in orthopedic and trauma surgery, with respect to patient satisfaction, physician satisfaction, and quality of care.

Methods: We conducted a prospective randomized controlled trial in a German university hospital and enrolled 60 patients with different knee and shoulder conditions. For follow-up appointments, patients received either an in-person consultation in the clinic (control group) or a video consultation with their physician (telemedicine group). Patients' and physicians' subsequent evaluations of these follow-up appointments were collected and assessed using separate questionnaires.

Results: On the basis of data from 52 consultations after 8 withdrawals, it was found that patients were slightly more satisfied with video consultations (mean 1.58, SD 0.643) than with in-clinic consultations (mean 1.64, SD 0.569), although the difference was not statistically significant (*P*=.69). After excluding video consultations marred by technical problems, no significant difference was found in physician satisfaction between the groups (mean 1.47, SD 0.516 vs mean 1.32, SD 0.557; *P*=.31). Further analysis indicated that telemedicine can be applied to broader groups of patients and that patients who have prior experience with telemedicine are more willing to use telemedicine for follow-up care.

Conclusions: Telemedicine can be an alternative and efficient form of follow-up care for patients in orthopedic and trauma surgery in Germany, and it has no significant disadvantages compared with in-person consultations in the clinic.

Trial Registration: German Clinical Trials Register DRKS00023445; https://www.drks.de/drks_web/navigate.do?navigationId=trial.HTML&TRIAL_ID=DRKS00023445

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KEYWORDS

telemedicine; video consultations; follow-up; efficiency; orthopedic; trauma surgery; mobile phone

Introduction

Background

International health care systems are facing several major challenges. Some of these challenges are structural and have evolved over the years, while others have occurred as sudden shocks. Demographic change and a shortage of health care professionals are among the increasingly important structural challenges and have been impacting patient care for years. On the one hand, the rising number of older and multimorbid patients is leading to a demographic change, which is associated with a higher demand for health care services. On the other hand, there is a growing shortage of specialists to meet this demand efficiently. Simultaneously, an asymmetrical distribution of medical service providers leads to deficits in health care. Particularly in rural regions, patients have to travel longer distances, and thus incur higher costs. In the long term, this could lead to limited access to health care for a subset of patients [1-3].

Beyond these structural challenges, health care systems have recently had to cope with the sudden COVID-19 pandemic [4], starting with its global outbreak in March 2020 [5]. The pandemic has placed several important restrictions on the delivery of medical care; for example, social distancing has become necessary to avoid infections [6,7]. Hospitals, which are at a particular risk of causing a pandemic outbreak owing to their high number of interactions and patients, have introduced protective measures [8,9]. Some patients avoid medical appointments for fear of infection [10,11], and hospitals have been postponing nonurgent treatments and interventions to save resources [6,7,12]. The lack of physician-patient interactions and avoidance of treatments could lead to worsening health outcomes in the future [13].

Both structural challenges and the pandemic shock will likely have a long-term impact on the health care system and delivery of care. As a result, existing structures will need to be reconsidered [2,3,14].

One important tool for overcoming these challenges and guaranteeing effective health care in the medium to long term could be the use of telemedicine. Telemedicine offers the ability to provide medical care through real-time video consultations, without the need for personal contact and regardless of location. This could free up clinical resources, improve access to care, and increase safety for patients and medical staff [3,15-18].

Telemedicine is already being applied successfully in various medical fields [19,20], but its use has so far been less common in orthopedic and trauma surgery owing to the specialty's heavy reliance on palpation and dynamic testing and telemedicine's inherent constraints [7]. In addition, regardless of medical specialty, there were barriers that still negatively impacted readiness for adoption despite the benefits of telemedicine. These barriers included, for example, resistance to change, lack of technical literacy, or uncertainties about costs and reimbursement [21,22]. However, since the outbreak of the COVID-19 pandemic, the need for telemedicine has increased considerably in the field of orthopedic and trauma surgery, among other medical areas [7,16,18]. More specifically, telemedicine can support outpatient care in hospitals, such as follow-up examinations to prior interventions [23]. While vital for successful treatment [24], these follow-up examinations entail a travel burden for patients who are often immobile or in pain due to their condition. Therefore, telemedicine could offer a suitable alternative [25].

In 2019, German hospitals admitted a total of 854,410 patients in orthopedic surgery and 759,356 patients in trauma surgery, making the combination of orthopedic and trauma surgery one of the largest areas of care in Germany [26]. Increasing the use of telemedicine to relieve clinics and patients of unnecessary burdens in this broad field could provide significant benefits. Although these benefits can be determined only by clinical evaluation, randomized controlled trials (RCTs) examining telemedicine in orthopedic and trauma surgery are rare, with few exceptions.

In an RCT, Buvik et al [23,27,28] compared standard consultations in an orthopedic outpatient clinic of a hospital with video consultations assisted by a trained nurse at a regional medical center in Norway. It was shown that telemedicine is a safe alternative, that its use can be cost-effective, and that there are no significant differences in patient satisfaction and health status between the treatment group and the control group [23,27,28].

Sathiyakumar et al [29] also found no significant differences in patient satisfaction between telemedicine and in-person follow-up for patients with closed orthopedic trauma injuries in a level 1 trauma center in the United States. In this RCT, telemedicine was associated with time and travel savings for patients [29].

The use of telemedicine for a postoperative follow-up of arthroscopic rotator cuff repair surgery was investigated by Kane et al [30] in the United States. Their RCT concluded that telemedicine can be used safely and effectively for this condition, that patient satisfaction was similar, and that time savings were achieved for both patients and physicians [30].

Objectives

However, prior research has left several questions unaddressed, which are considered based on our research design. One of them is whether the use of telemedicine is efficient not only for a restricted number of individual diseases but also for a wider range of medical conditions. Another important question is with regard to the practicality of telemedicine without the need to involve additional staff to assist patients during video consultations [23,27,28]. Furthermore, it is questionable whether international study results can be transferred to the German health care system, especially because studies show that German patients are skeptical about the use of telemedicine [31].

The aim of our RCT was to investigate whether telemedicine can be used efficiently in follow-up care for patients in orthopedic and trauma surgery in Germany. To answer this question, the RCT compared an in-person consultation in a German university hospital (level 1 trauma center) with the use of telemedicine, namely a video consultation between the physician and patient. All consultations were for the follow-up

care of patients with knee and shoulder conditions who displayed a variety of conditions, had previously been treated in the clinic, and were eligible to participate in the study. For their video consultation, patients did not have to travel to the clinic but could have their follow-up appointment on the web, regardless of their location. For this study, the aspects of patient satisfaction, physician satisfaction, and quality of care were considered as the most important factors to quantify the output of telemedicine. Therefore, they were included in the evaluation of telemedicine under the overarching term "efficiency." It is hoped that studying telemedicine in broad-based use for follow-up care and analyzing its effects comprehensively will contribute to informing health care providers' decision-making in future.

Methods

Study Design

This study was conducted as an open, prospective, interventional, 1:1 randomized controlled monocenter trial at a German university hospital (University Hospital Giessen, Department of Trauma, Hand and Reconstructive Surgery). The randomized and controlled design is based on the CONSORT (Consolidated Standards of Reporting Trials) [32]. The effects of telemedicine on follow-up care were examined with the parallel implementation of an intervention group, which received follow-up care through a real-time video consultation, and a control group, which received a standard follow-up consultation in the clinic.

Ethics Approval

The local ethics committee of the University of Giessen reviewed and approved this study (AZ 73/20). The study was registered in the German Clinical Trials Register (ID: DRKS00023445).

Definition and Characteristics of the Trial Population

The trial population consisted of knee and shoulder patients who have already been treated in the department. The patients' medical conditions varied, and Multimedia Appendix 1 lists their ICD-10 codes. Their medical conditions included, for example, fractures of the patella and femur, impingement syndrome of the shoulder, and orthopedic joint implants.

To adequately guarantee the safety of patient care, recruitment for the RCT observed the following inclusion criteria in addition to the ICD-10 codes: (1) patients need the ability to consent, as well as the mental and physical ability to participate in the telemedical consultation. (2) As part of the consultation, patients' conditions should require no more than a visual examination and a conversation without the need to be touched or moved by the treating physician or other physical interactions. For legal reasons, (3) a previous outpatient or inpatient stay at the clinic is required, and (4) patients must be ≥18 years. To be able to use telemedicine, it is assumed that (5) patients own a computer, laptop, tablet, or smartphone, including a microphone and camera, and (6) they have a stable internet connection. Finally, (7) patients have to speak German to understand the declaration of consent.

The concern with patient safety is also reflected in the exclusion criteria. Thus, patients with (1) neurological diseases that do not allow the use of computer systems and (2) patients with a diagnosis of dementia, blindness, or deafness were excluded. In addition, patients were excluded if they (3) have a need for in-person presence and on-site diagnostics or treatments (eg, medical imaging, laboratory, stitches, or drainage) or (4) have to be touched or moved by the treating physician. This ensured that patients who required personal contact with a physician were not at risk. Finally, (5) a lack of willingness to participate in the study or (6) the failure to consent were further added to the exclusion criteria.

Recruitment and Randomization of Study Participants

After the initial screening for inclusion and exclusion criteria, patients were asked either at the clinic or by telephone if they would like to participate in the study during their next follow-up appointment. To be able to participate, the patients had to provide informed consent after receiving written and oral information. Consent could be withdrawn at any time, without providing reasons.

We followed a 2-armed parallel group design, and patients enrolled in the study were randomly assigned in a 1:1 ratio to either the intervention arm (telemedicine follow-up) or the control arm (in-person follow-up consultation in the clinic). To ensure better balance between the arms while minimizing predictability, block randomization with randomly selected block sizes of 4, 6, and 8 was applied [32]. One member of the study staff organized the allocation of the blocks, while a different member performed the randomization of the patients. For this purpose, sealed envelopes were used. Given that the intervention was a video consultation, blinding of the physicians or patients was not possible. At the end of the recruitment process, depending on the treatment arm, the patients received an appointment either in the clinic or for a video consultation. Patients in the intervention group also received written instructions on how to be prepared for the video consultation to minimize potential technical difficulties.

Procedures

Intervention Arm

Study participants who were assigned to the intervention arm received a one-time telemedical follow-up via a real-time videoconference instead of a standard consultation in the department. The one-time appointment was intended to avoid bias through learning effects. The web-based video consultation used the web-based software CLICKDOC of the German telemedicine provider CGM Mobile Services GmbH. This software is certified for and widely used in the German health care system. On the day of their appointment, the patients received log-in details for the video consultation from their physicians via SMS text message or email. No additional registration was required for the video consultation. At the arranged time, both the attending physician and the patient logged in to the software program, and the video consultation was conducted. Patients were able to use a computer, laptop, tablet, or smartphone to join the video consultation. If technical problems were noted, patients were contacted by phone and

scheduled for a clinic visit, as needed. Immediately after the video consultation, the patients received log-in details via email and were asked to evaluate the consultation via web-based questionnaires.

Control Arm

Study participants, who were assigned to the control group, attended a standard follow-up consultation at the university hospital. This follow-up was conducted by the same physicians who also treated the intervention arm. Immediately after the consultation, patients in the control arm were asked to fill out the questionnaires at the clinic.

Outcome and Data Collection

To answer the research questions and analyze the outcome parameters, that is, patient satisfaction, physician satisfaction, and quality of care, different questionnaires were completed by patients and physicians.

The primary outcome patient satisfaction was measured using the German questionnaire Zufriedenheit in der ambulanten Versorgung–Qualität aus Patientenperspektive of the National Association of Statutory Health Insurance Physicians in Germany [33,34]. This validated questionnaire is an appropriate way of investigating patient satisfaction in the German outpatient sector. To adequately reflect the specific conditions of this study, individual items of the questionnaire were modified and some were added. This included excluding questions that were not relevant to the purpose of our study. The additional questions addressed whether patients experienced the treatment they wanted, how much time the physician had provided, how comfortable patients felt with the treatment, whether they were agitated, and how punctual the treatment appointment was. In addition, patients were asked to rate their overall satisfaction with their respective follow-up appointment using German school grades, where grade 1 represents "very good" and grade 6 represents "inadequate." The other questions were answered using a 4-point Likert scale, where higher scores represented higher satisfaction. Finally, the patients were asked which option they would choose for their next follow-up appointment.

Physician satisfaction, as one of the secondary outcome parameters, was assessed by questionnaires that the physicians answered following each patient consultation. The questionnaires were self-designed and differed slightly depending on the study arm. In both groups, the physicians were asked whether all medical questions could be clarified, which option the physicians would choose for the next follow-up appointment, and how satisfied they were with the consultation. Satisfaction was also surveyed using school grades in this case. The questionnaire in the intervention group was supplemented with the questions of whether a technical irregularity occurred during the treatment and whether the consultation had to be terminated due to this malfunction.

To evaluate the quality of care as a secondary outcome, patients received the German version of the "EQ-5D-5L" questionnaire from the EuroQol Group during enrollment [35]. Patients were asked to rate their current health-related quality of life between 0 and 100 on a visual analog scale (VAS). After 3 months, the questionnaire was completed again to measure the impact of the interventions on health-related quality of life.

Sample Size

We performed a priori power analysis using the software G*Power 3.1.9.6 (Heinrich Heine University) which calculates the sample size based on the power, significance level, and effect size [36]. To determine the effect size, we used the study by Sharareh and Schwarzkopf [25] as a baseline, which conducted a group comparison of patient satisfaction with telemedicine. As the resulting effect size represented a very strong effect that we did not expect in our study, we used half of the effect size (1.095) to perform the sample size calculation. This resulted in approximately 19 study participants for each group to achieve a power of 90% in a 2-sided *t* test for independent samples with a global significance level of 5%. The sample size was increased by 10% for both groups to accommodate potential dropouts or withdrawals and by another 10% to counteract a potentially skewed distribution of patient satisfaction. This resulted in a case number of 23 patients per randomization arm. To consider the possible loss of power when using nonparametric methods, the sample size was increased to 30 patients per arm, resulting in a total of 60 enrollments.

Statistical Analysis

The statistical evaluation of the study included descriptive statistics of the demographic characteristics and parameters collected in the questionnaires. Continuous and ordinal data were reported as mean values, SDs, and medians. Categorical data were presented as absolute and relative frequencies. Differences between the 2 study arms were analyzed using the Mann-Whitney *U* test or Fisher exact test, and effect sizes were reported by Pearson correlation coefficient (*r*) or Cramer V. These nonparametric tests were used because most of the data were not normally distributed, assumptions were not met, or the underlying scale was ordinal. For patient and physician satisfaction, a subgroup analysis based on medical indications was performed. In addition, the Wilcoxon signed-rank test was used to evaluate the longitudinal data of the EQ-5D-5L VAS. Owing to incomplete questionnaires, the reported group size (n) was different for each test. The data were analyzed based on intention-to-treat. The *P* value was set a priori at .05 to test 2-sided significance. The Bonferroni-Holm correction was applied but did not affect the reported results.

To examine the suitability of telemedicine for follow-up appointments in detail and to investigate the type of patients who would use telemedicine, a binary logistic regression was performed. The variable "Which option would you choose for your next appointment?" from one of the patient questionnaires was used as the dependent variable, with the dichotomous outcome "telemedical follow-up" or "standard consultation." The independent variables added to the model were the categorical parameters "group" with the outcome telemedicine group or control group; "indication" in the form of knee or shoulder; "sex" as male or female; "age" divided into the categories 18 to 40 years, 41 to 60 years, and >60 years; and finally, prior experience with video calls. This exploratory model sought to investigate the factors that influence the decision to use telemedicine when offering video consultations in clinical

practice. Bootstrap validation was performed to confirm the validity of the results. A receiver operating characteristic curve was used to assess the accuracy of the model.

Results

Overview

The patients were recruited and attended their follow-up appointments between September 2020 and April 2021. The last questionnaires for the second data collection of the EQ-5D-5L were sent in July 2021. For organizational reasons, the number of eligible patients could not be recorded until 2 months after the start of recruitment, resulting in a total of 102 eligible patients.

In total, 60 patients agreed to participate in the study and were randomized; 30 patients were allocated to the intervention arm and 30 patients, to the control arm. After randomization, 8 patients withdrew from the study. None of these patients were excluded by the physicians. Thus, 26 patients in the intervention arm and 26 patients in the control arm could be analyzed. Figure 1 shows the CONSORT flow diagram outlining the process of patient recruitment and data analysis. In total, 100% (26/26) of patients in the intervention arm and 90% (26/29) of patients in the control arm completed the questionnaires after the follow-up appointment. With regard to the physician questionnaires, 100% (26/26) in the telemedicine group and 96% (25/26) in the control group were completed. In the intervention group, 100% (26/26) of the EQ-5D-5L questionnaires were returned at baseline, and 69% (18/26) were returned after 3 months; in the control group, 88% (23/26) of the questionnaires were returned at baseline, and 58% (15/26) were returned after 3 months.

Demographic characteristics of patients, such as sex, age, medical indication, distance from clinic, and health status showed no significant differences between the 2 groups (Table 1).

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) flow diagram.

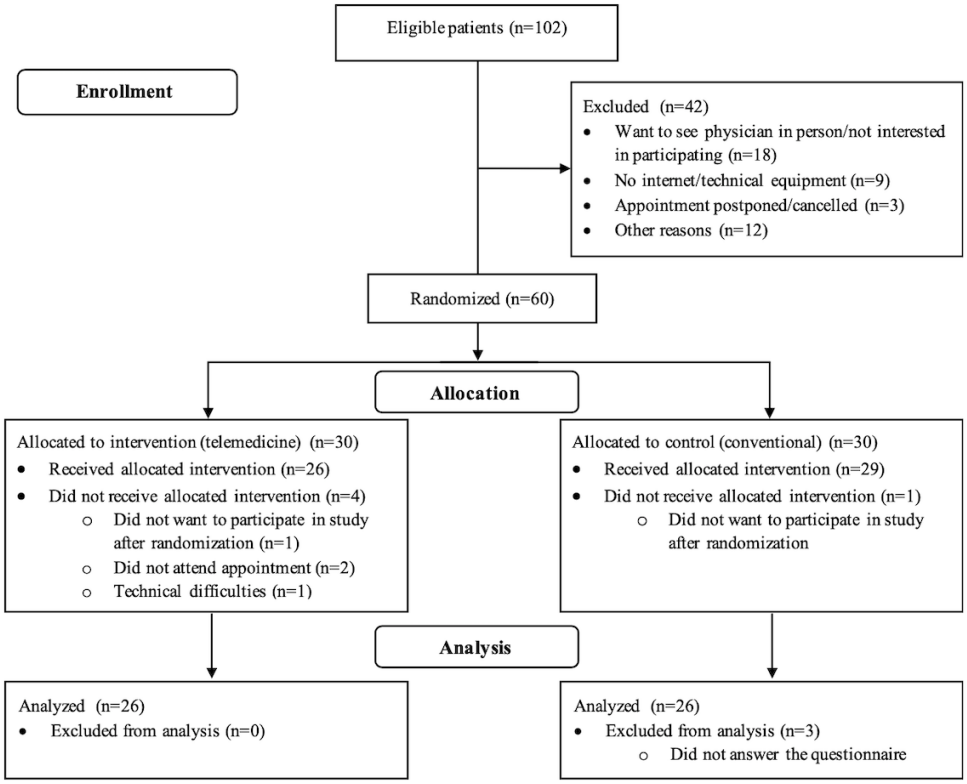


Table 1. Demographic characteristics of patients.

	Telemedicine group (n=26)	Control group (n=26)	*P* value
Sex, n (%)			.99[a]
Female	11 (42)	10 (39)	
Male	15 (58)	16 (61)	
Age (years), n (%)			.36[a]
18-40	7 (27)	5 (19)	
41-60	17 (65)	15 (58)	
>61	2 (8)	6 (23)	
Medical indication, n (%)			.99[a]
Knee	10 (39)	9 (35)	
Shoulder	16 (61)	17 (65)	
Distance from clinic (km), mean (SD)	37.00 (32.06)	31.58 (22.62)	.65[b]
Self-assessed health status, mean (SD)	2.88 (1.033)	2.91 (0.848)	.96[b]

[a]Fisher exact test.

[b]Mann-Whitney *U* test.

Patient Satisfaction

To measure perceived patient satisfaction, patients in both groups were asked to rate their satisfaction with their respective follow-up appointment using German school grades.

Although group comparison showed that patients were slightly more satisfied with telemedicine follow-up (mean 1.58, SD 0.643) than with in-person follow-up in the clinic (mean 1.64, SD 0.569), the difference was not statistically significant (*P*=.69; Table 2). This result was not affected by a subgroup analysis of the 2 medical indications, namely knee or shoulder. Analysis of the other aspects of the adapted Zufriedenheit in der ambulanten Versorgung–Qualität aus Patientenperspektive questionnaire, such as organization, information, interaction, and participation, showed no significant differences between the groups, with a few exceptions. The waiting time (*P*<.001), atmosphere (*P*<.001), and punctuality of the appointment (*P*=.002) were more satisfying for patients in the telemedicine group than in the control group, with medium to strong effects (*r*=0.440 to *r*=0.760). Box and whisker plots of all distributions can be found in Multimedia Appendix 2.

A strong effect was also evident in the preference for the next follow-up appointment between the groups, which was analyzed with Fisher exact test (*V*=0.542). While patients in the control group preferred to visit the clinic again (16/25, 64%), almost all patients in the telemedicine group (23/26, 88%) chose telemedicine for their next follow-up appointment (*P*<.001). However, a clear majority (32/51, 63%) of all patients chose a video consultation for their next appointment, whereas only 37% (19/51) chose a standard consultation.

Table 2. Patient satisfaction.

	Telemedicine group			Control group			*P* value[a]	Pearson correlation coefficient (*r*)
	Value, n	Value, mean (SD)	Value, median	Value, n	Value, mean (SD)	Value, median		
Overall patient satisfaction	26	1.58[b] (0.643)	1.5	25	1.64[b] (0.569)	2.00	.69	0.071
Satisfaction knee patients	10	1.80[b] (0.632)	2.00	9	1.89[b] (0.601)	2.00	.95	0.077
Satisfaction shoulder patients	16	1.44[b] (0.629)	1.00	16	1.50[b] (0.516)	1.5	.72	0.092
How satisfied are you with the waiting time?	26	2.88[c] (0.326)	3.00	25	2.12[c] (0.881)	2.00	<.001	0.546
How satisfied are you with the atmosphere?	26	2.85[c] (0.368)	3.00	25	2.08[c] (0.277)	2.00	<.001	0.760
How punctual was your appointment?	26	2.35[c] (0.689)	2.00	25	1.60[c] (0.913)	2.00	.002	0.440

[a]Mann-Whitney *U* test.

[b]German school grades; 1=very good to 6=inadequate.

[c]4-point Likert scale; higher scores=higher satisfaction.

Physician Satisfaction

Physicians in the control group were significantly more satisfied with the follow-up appointments (mean 1.32, SD 0.557) than those in the telemedicine group (mean 2.42, SD 1.419; *P*=.001; *r*=0.466), as shown in Table 3. The subgroup analysis showed that this difference was also significant for the treatment of shoulder patients (*P*=.006) but not for knee patients (*P*=.08). However, a further group comparison, in which video consultations with technical irregularities were removed, revealed no significant group differences in physician satisfaction (mean 1.47, SD 0.516 and mean 1.32, SD 0.557; *P*=.31). In addition, there were no significant differences in their ability to address all relevant medical questions (telemedicine group: 25/26, 96%; control group: 25/25, 100%; *P*=.99; *V*=0.139).

Table 3. Physician satisfaction.

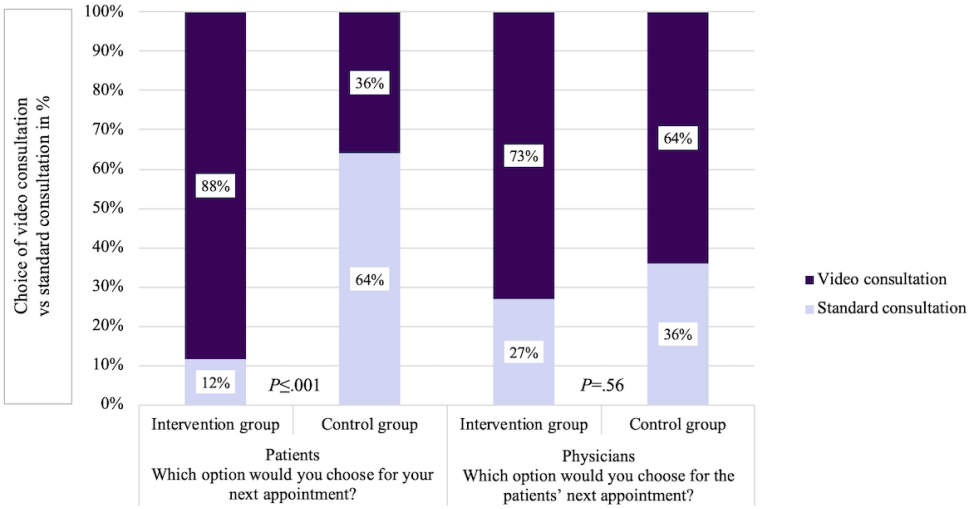
	Telemedicine group			Control group			*P* value[a]	Pearson correlation coefficient (*r*)
	Value, n	Value, mean (SD)	Value, median	Value, n	Value, mean (SD)	Value, median		
Overall physician satisfaction	26	2.42[b] (1.419)	2.00	25	1.32[b] (0.557)	1.00	.001	0.466
Satisfaction knee patients	10	2.30[b] (1.829)	1.50	10	1.10[b] (0.316)	1.00	.08	0.449
Satisfaction shoulder patients	16	2.50[b] (1.155)	2.00	15	1.47[b] (0.640)	1.00	.006	0.492
Physician satisfaction without technical irregularities	15	1.47[b] (0.516)	1.00	25	1.32[b] (0.557)	1.00	.31	0.167

[a]Mann-Whitney *U* test.

[b]German school grades; 1=very good to 6=inadequate.

For the next follow-up appointment, physicians recommended a telemedical consultation for most patients, regardless of the study arm (19/26, 73% of the telemedicine group; 16/25, 64% of the control group; *P*=.56; *V*=0.098). Overall, physicians recommended telemedicine to 69% (35/51) of patients for further follow-up. A comparison of the patients and physicians and their respective choices for the next follow-up appointment is shown in Figure 2.

Figure 2. Patient and physician choice of next follow-up appointment.



Quality of Care

Quality of care was assessed by surveying patients' perceived health-related quality of life before and after the follow-up visit, using the EQ-5D-5L VAS. As shown in Table 4, the differences in quality of life between the groups were not significant, neither at baseline (P=.24) nor after treatment (P=.69). The difference in quality of life before and after the follow-up appointment was also not statistically significant between the intervention and control arms (P=.19). In this case, the group size changed because only complete data sets could be considered for analysis. In both groups, it was shown with the Wilcoxon signed-rank test that the perceived average quality of life increased after treatment, although not significantly, (telemedicine group: mean 69.77, SD 20.551 to mean 70.44, SD 19.509; P=.93; r=0.027; control group: mean 66.30, SD 18.292 to mean 69.33, SD 15.216; P=.11; r=0.440).

Table 4. Quality of care.

	Telemedicine group			Control group			P value[a]	Pearson correlation coefficient (r)
	Value, n	Value, mean (SD)	Value, median	Value, n	Value, mean (SD)	Value, median		
EQ-5D-5L VAS[b] baseline	26	69.77[c] (20.551)	79.00	23	66.30[c] (18.292)	75.00	.24	0.169
EQ-5D-5L VAS 3 months	18	70.44[c] (19.509)	72.5	15	69.33[c] (15.216)	75.00	.69	0.073
Δ EQ-5D-5L VAS	18	0.833[c] (16.468)	0.00	14	6.43[c] (13.921)	6.00	.19	0.237

[a]Mann-Whitney U test.

[b]VAS: visual analog scale.

[c]Scale from 0 to 100.

Binary Logistic Regression

Binary logistic regression was used to examine the types of patients who would use telemedicine for their follow-up appointment. For this purpose, the potential influence of different variables on patients' preference for their next follow-up appointment was analyzed (Table 5). The model was statistically significant (χ^2_6=22.3; P=.001; Nagelkerke R^2=48.4%). It was found that medical indication, sex, nor age had a significant influence on the choice of telemedicine. However, previous experience with video calls before the study (P=.03) and the respective study arm in which the patients were treated (P=.001) contributed significantly to predicting the choice of telemedicine.

Table 5. Binary logistic regression.

Variables	Coefficient (β; SE)	*P* value	Odds ratio (95% CI)
Study arm	2.760 (0.836)	.001	15.793 (3.066-81.351)
Indication	.004 (0.810)	.99	1.004 (0.205-4.913)
Sex	–0.686 (0.868)	.43	0.504 (0.092-2.761)
Previous experience with video calls	1.726 (0.802)	.03	5.620 (1.168-27.038)
Age (years)			
18-40	–0.388 (1.280)	.76	0.678 (0.055-8.333)
41-60	.587 (1.044)	.57	1.799 (0.232-13.919)
>61 (reference)	_[a]	.59	—
Constant	–1.436 (1.031)	.16	0.238[b]

[a]Reference category.

[b]95% CI value is not applicable.

Patients were 15.8 times more likely to consider telemedicine as a treatment option for further follow-up care if they had already experienced telemedicine than if they had previously been in the control group. Prior experience with general videoconferencing increased the likelihood of participating in telemedicine by 5.6-fold compared with no experience. As a measure of accuracy, the area below the receiver operating characteristic curve was 0.86 ($P<.001$), which indicated that the model has an appropriate fit to predict whether a patient will choose telemedicine for the next follow-up appointment.

Discussion

Principal Findings

This study aimed to investigate whether telemedicine can be used efficiently for outpatient orthopedic and trauma surgery follow-up care in Germany in a university hospital from the perspective of patients, physicians, and the quality of care. Our data analysis showed that the use of telemedicine had no significant drawbacks compared with traditional clinical consultations in almost all aspects studied. Patients were even slightly more satisfied with telemedicine, regardless of their medical condition, although the difference was not statistically significant. In addition to overall satisfaction, the authors analyzed specific indicators of satisfaction. Aspects such as waiting time, atmosphere, and punctuality can be significantly improved by using telemedicine. Advantages for patients might arise from the fact that they can interact with their physicians in a familiar environment and do not have to be present in the hospital. The atmosphere, which is the sentiment that patients experience during medical consultations, is perceived to be more pleasant at home than at the hospital. In addition, the waiting time and punctuality of consultations could be evaluated more positively, as patients could use the time at home and are not limited to waiting in the clinic waiting room. In addition, being able to consult a physician from the comfort of home without having to travel and without experiencing long waiting times is a benefit that could have a positive impact on patients' well-being. The results in the RCTs by Buvik et al [28], Sathiyakumar et al [29], and Kane et al [30] are similar to our findings regarding patient satisfaction. However, these RCTs differ from our study design, as they focus mainly on using telemedicine for individual medical conditions or in a specific setting, such as an outpatient clinic with staff support [28-30].

Although the group comparison showed that physicians were less satisfied with telemedicine than with standard consultations, this lower satisfaction can probably be attributed to technical irregularities. When they were excluded from the analysis, there was no significant difference in satisfaction between the 2 groups for physicians as well. The comparison also showed that technical difficulties have a stronger influence on physician satisfaction than on patient satisfaction. This could be related to the fact that physicians must follow a fixed schedule, which is sensitive to disruptions. The fact that patients are more satisfied with telemedicine than physicians was also identified in the study by Buvik et al [28]. Nevertheless, the high number of video consultations with technical irregularities (11/26, 42%) could have a negative impact on satisfaction with telemedicine over time, and we could not determine whether the irregularities were system related or because of human error. This challenge could be mitigated by the fact that ongoing technological improvements could help make telemedical consultations both easier and more reliable.

Patients' health-related quality of life did not differ significantly between groups. This might indicate that the application of telemedicine is suitable for the patient group studied and does not have a negative impact on the quality of care. However, it must be noted that telemedicine is suitable only for patients who are already in an advanced stage of the treatment process and who do not currently require follow-up care in the clinic. Therefore, the disease pattern and condition of each patient were reviewed by the physicians before their participation in the study. Generally, the change in quality of life will be less pronounced at this later stage of the treatment process.

All patients in the telemedicine group of this study experienced only 1 telemedical consultation. However, even with this minimal gain in experience, it can be seen that these patients would more frequently opt for telemedicine than those in the control group. Results of other RCTs showed the same conclusion [28-30,37]. Kane et al [30] argued that this could

be associated with the fact that people prefer the known rather than the unknown. Thus, familiarity could influence the choice of the type of consultation. However, in addition to this effect, we assume that there is an initial barrier for patients to use telemedicine, for example, technical hurdles. This barrier is overcome for the vast majority of patients once they have participated in their first video consultation. Thereafter, patients were more willing to use telemedicine again, indicating that they considered it an appropriate treatment option. Therefore, it is important to introduce eligible patients to the use of telemedicine and to support them in case of potential uncertainty. At the same time, the learning effect could also increase long-term satisfaction with telemedicine as patients become more confident in using the digital application and learn how to avoid sources of error. Therefore, satisfaction may be even higher among patients who use telemedicine more often. In contrast, physicians recommend telemedicine for most patients, regardless of the study arm. This may be because they prioritize medical value over patients' prior experiences with this consultation format. The fact that physicians recommend telemedicine despite their initially lower level of satisfaction with it is a further indication of the appropriateness of telemedicine.

Unlike other studies, we also investigated for which patients telemedicine is best suited, as the sensible choice of a promising target group is crucial for the success of telemedicine applications in practice. We were able to show that telemedicine need not be restricted to a specific group of patients but can be provided broadly. Telemedicine was positively evaluated by both knee and shoulder patients with varying ICD-10 codes. Furthermore, binary logistic regression revealed that demographic characteristics had no significant influence on the choice of telemedicine; only prior experience was decisive. This is particularly relevant for clinical practice, as in the long run only the broad-based use of telemedicine for a heterogeneous group of patients is likely to be efficient. When treating single conditions or a small subset of patients, important economies of scale might not be achieved. However, it should be noted that the patients in our trial were comparatively young. Thus, we cannot reject with certainty that a particularly older age might reduce patients' willingness to participate in telemedicine. However, with the rapid progress of digitalization and its use, this would become less relevant in the future [38].

Nevertheless, the expanded adoption of telemedicine is accompanied by barriers for certain patient groups. In some cases, the use of digital technologies is restricted to older adults, socially deprived people who lack financial means, people without internet access (eg, in rural areas), or members of ethnic minorities [39]. To prevent potential disadvantages and exclusion of these patient groups, policy makers need to consider the following aspects: national internet access infrastructure, access to digital equipment, availability of digital applications in the required languages, deployment of health workers to support patients during video consultations, access to trainings on how to use telemedicine, and the introduction of programs that support digital health literacy [40].

Limitations

Our study had some limitations. First, we based our sample size calculation on a study by Sharareh and Schwarzkopf [25], which measured a large difference in satisfaction between groups. As a result, our recruited sample size consisted of only 60 patients, which corresponds to a larger expansion of the original sample size calculated. On the basis of our data, we could not detect such a large difference between the groups. Thus, the restricted sample size may have influenced the statistical power of the tests. For example, the results of the binary logistic regression could become more robust with a larger sample size. Furthermore, because of the small sample size, we had to validate the binary logistic regression by bootstrapping and could not split the data set to perform a separate evaluation and validation. Nevertheless, our sample size was comparable with that of other studies, such as that of Kane et al [30].

Another limitation concerns the questionnaires used. International studies have shown that the number of validated questionnaires in this context is limited [23]. This problem is particularly acute in German studies. Therefore, we had to adapt validated questionnaires and partly create them.

The use of pen-and-paper questionnaires, on the one hand, and web-based questionnaires, on the other hand, could also have led to discrepancies. In particular, all questions had to be completed in the web-based questionnaires, but this was not true for the pen-and-paper questionnaires completed in the clinic. However, for organizational reasons, no uniform implementation was possible. This problem also arose for comparable studies. On the other hand, studies have shown that patients usually provide similar health-related answers regardless of survey formats [41-43].

When evaluating the results, it should be noted that all patients recruited from the intervention and control groups consented to participate in telemedicine. Thus, there was an initial interest in telemedicine among participants. This might have led to a self-selection bias in favor of higher satisfaction with telemedicine from the start because patients who were more comfortable with digitalization were more likely to participate in the study [22]. Although all patients consented to undergo a video consultation, it was found that patients in the intervention group were more likely to choose a video consultation for their next follow-up appointment than those in the control group, further supporting the effect of comfortability. Although this self-selection bias is evident for all telemedicine evaluations with a similar study design, it leads to the limitation that the data do not show results for the general population but only show results for patients with a baseline interest in telemedicine [22]. Short of forcing patients to participate in telemedicine, a procedure that appears both unethical in principle and unfeasible in clinical practice, there is no acceptable way of addressing this limitation. In 2018, the percentage of German patients who found video consultations helpful in orthopedic and trauma surgery was 30.5% [31]. However, the higher willingness to participate in our study might suggest that this number will increase in the long term, making our results more generalizable.

Finally, we considered only 1 follow-up consultation in our study design to avoid bias owing to potential learning effects.

Thus, no conclusions regarding long-term satisfaction with telemedicine can be made in the context of our study. We suggest that future studies analyze long-term satisfaction with telemedicine in orthopedic and trauma surgery follow-up care. In this context, it should also be investigated how challenges in standard clinic appointments, such as undetected diseases or complications, develop in the context of performing video consultations, particularly in larger patient populations. Future studies concerning the acceptance of telemedicine in Germany and the possible reasons for its rejection would also be of interest. Finally, the causes of technical irregularities should be analyzed in detail to improve the long-term provision of telemedicine.

Practical Implications

In summary, our results suggest that the effective implementation of telemedical follow-up care ideally meets several conditions. First, the appropriateness of telemedicine should be individually assessed for each patient. In our study, age and sex did not significantly influence telemedicine choice. Nevertheless, physicians should consider whether the patient's condition and circumstances allow for a video consultation. Before implementing a video consultation in a clinic, criteria should be established to assist with patient selection. These criteria could be based on the inclusion and exclusion criteria of our study, complemented by clinic-dependent characteristics. In addition, suitable patients should be supported to overcome initial uncertainties.

Second, before each consultation, each patient should be assessed individually to determine whether a video consultation is sufficient or whether the patient should attend the clinic. Although physicians in our study would recommend a video consultation as the next appointment for most patients (73% in the intervention group and 64% in the control group), clinical consultations might still be necessary. Moreover, if any medical issues cannot be clarified in a video consultation or if problems occur, additional in-clinic treatment should always be possible, as was the case in this study. To be able to ensure patient safety in the long term, the monitoring, documentation, and control of adverse events is another indispensable factor in this context as well.

Our data refer to patients in orthopedic and trauma surgery. Nevertheless, our results and considerations for practical implications could be transferred to outpatient follow-up examinations in other specialties, such as general and visceral surgeries, if conversations and visual examinations are sufficient for the intended treatment. Therefore, our study could be used as a basis for decision-making regarding the use of telemedicine in different medical fields, supplemented by specialty-specific determinants.

Conclusions

Compared with international findings, this study highlights that telemedicine is an efficient option for patients in Germany with a broad range of indications in orthopedic and trauma surgery, especially for follow-up appointments. Most patients in the telemedicine group preferred their next follow-up appointment to be a video consultation rather than a standard in-clinic consultation. All patients in this study participated in telemedicine without any prior test run or support from staff, which corresponds to real-life conditions encountered in everyday clinical practice. Clearly, some consultations will always have to occur in hospitals, but telemedicine can be applied efficiently to a wide range of diagnoses and a wide range of patients, thus reducing the burden on patients, physicians, and clinical resources. The COVID-19 pandemic has acted as a catalyst for the widespread uptake of telemedicine. On the one hand, this provided a safe alternative to prevent infections. On the other hand, it demonstrated the benefits of telemedicine. This is why video consultations should find their way into health care beyond the COVID-19 pandemic as a supplement to clinical care.

Acknowledgments

The authors wish to thank Dr med Alexander Eicher for his support in organizing the study. This research did not receive any funding from an external body.

Conflicts of Interest

None declared.

Multimedia Appendix 1

International Classification of Diseases-10 codes of health conditions studied.
[DOCX File , 14 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Box and whisker plots.
[DOCX File , 14988 KB-Multimedia Appendix 2]

Multimedia Appendix 3

CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 322 KB-Multimedia Appendix 3]

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Abbreviations

CONSORT: Consolidated Standards of Reporting Trials
RCT: randomized controlled trial
VAS: visual analog scale

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Multimedia Appendix 1

Table S1: International Classification of Disease-10 codes of health conditions studied	
Shoulder: M75.1, M75.6, M75.0, Z96.60, M75.4, M19.91, S43.1, S42.20, S42.00, M75.2, M75.3, S43.0	**Knee:** S83.53, S83.54, S83.2, S83.0, M22.0, M23.32, M23.35, M17.1, M17.5, M21.16, M21.06, S83.3, S83.44, S83.43, S82.18, S82.0, S72.3, S72.43, M25.56, M76.5, S83.6, S76.1, S86.8

Multimedia Appendix 2: Box and whisker plots

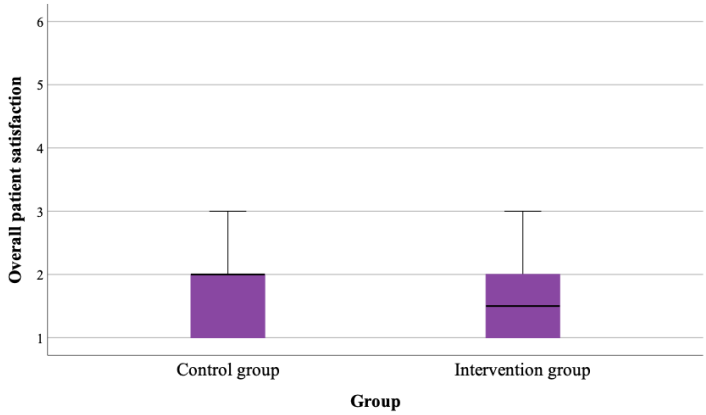

Figure S1: Box and whisker plot patient satisfaction

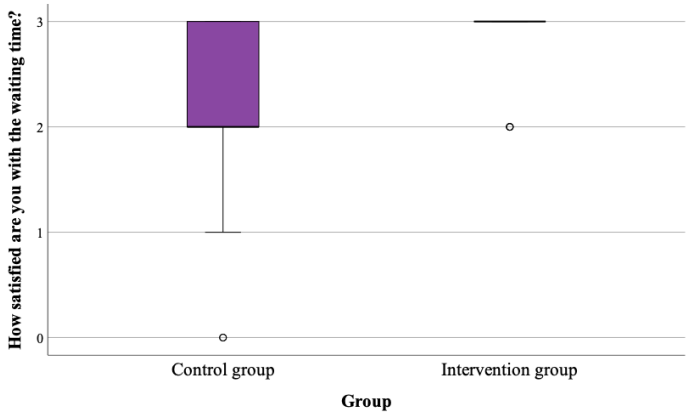

Figure S2: Box and whisker plot waiting time

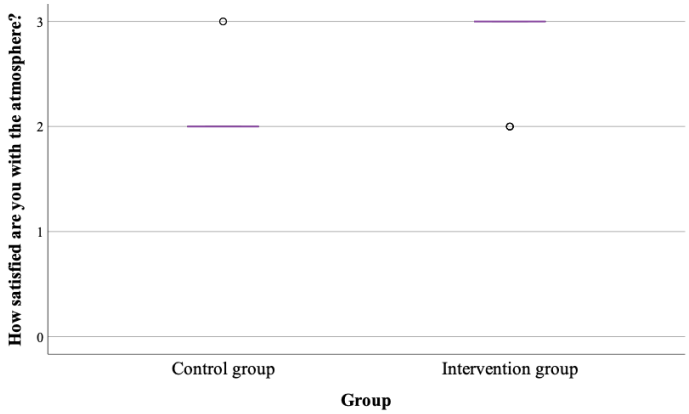

Figure S3: Box and whisker plot atmosphere

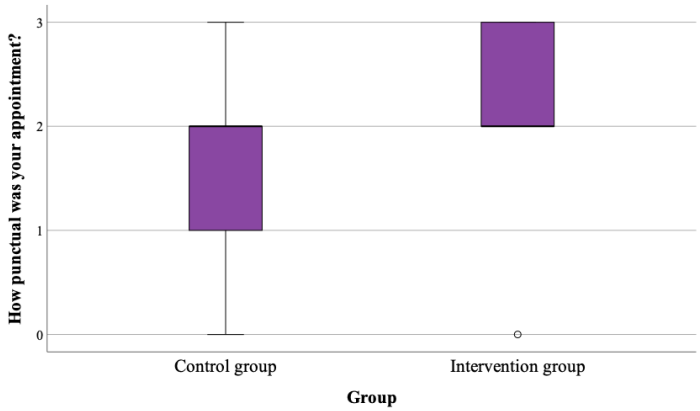

Figure S4: Box and whisker plot punctuality

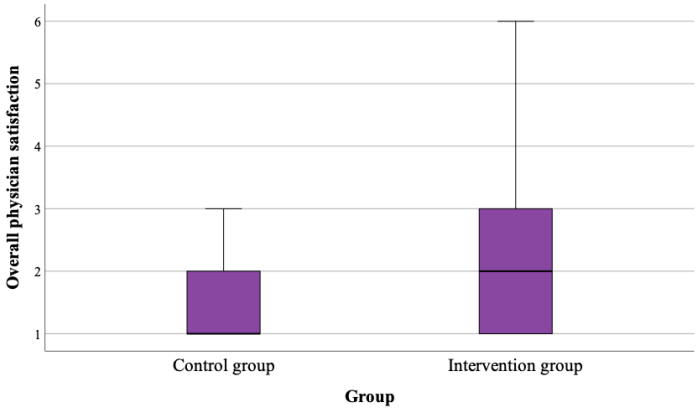

Figure S5: Box and whisker plot physician satisfaction

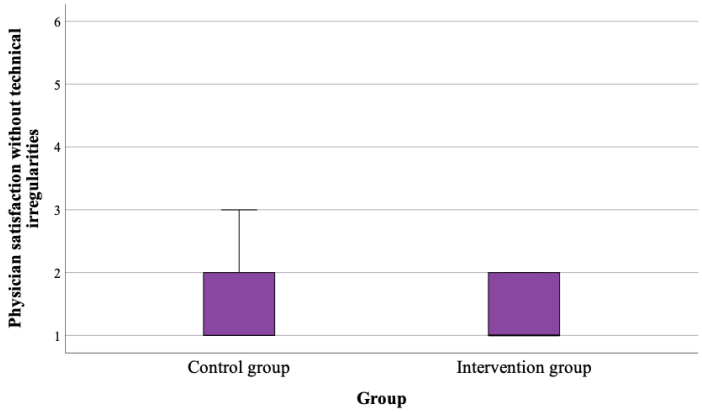

Figure S6: Box and whisker plot physician satisfaction without technical irregularities

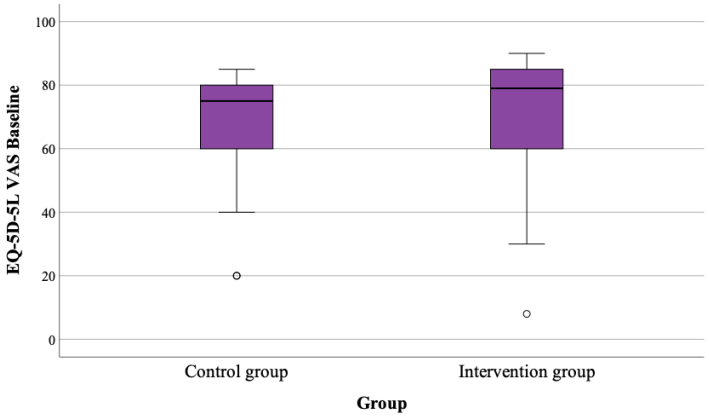

Figure S7: Box and whisker plot EQ-5D-5L VAS baseline

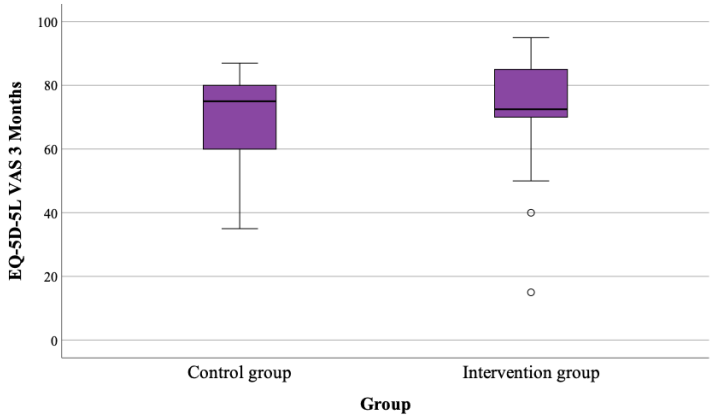

Figure S8: Box and whisker plot EQ-5D-5L VAS 3 months

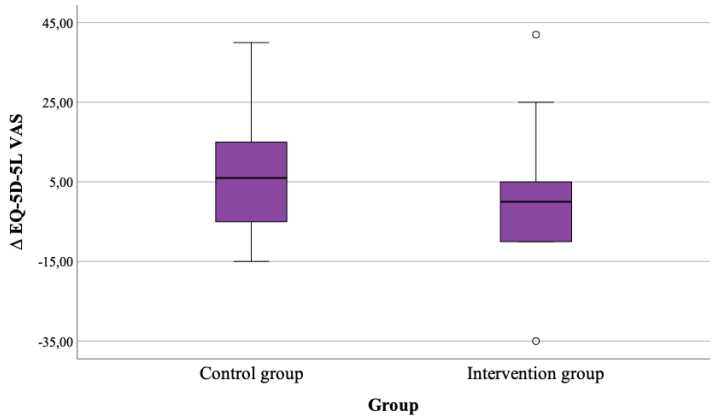

Figure S9: Box and whisker plot Δ EQ-5D-5L VAS

Multimedia Appendix 3: CONSORT-eHEALTH checklist (V 1.6.1)

CONSORT-EHEALTH (V 1.6.1) - Submission/Publication Form

The CONSORT-EHEALTH checklist is intended for authors of randomized trials evaluating web-based and Internet-based applications/interventions, including mobile interventions, electronic games (incl multiplayer games), social media, certain telehealth applications, and other interactive and/or networked electronic applications. Some of the items (e.g. all subitems under item 5 - description of the intervention) may also be applicable for other study designs.

The goal of the CONSORT EHEALTH checklist and guideline is to be
a) a guide for reporting for authors of RCTs,
b) to form a basis for appraisal of an ehealth trial (in terms of validity)

CONSORT-EHEALTH items/subitems are MANDATORY reporting items for studies published in the Journal of Medical Internet Research and other journals / scientific societies endorsing the checklist.

Items numbered 1., 2., 3., 4a., 4b etc are original CONSORT or CONSORT-NPT (non-pharmacologic treatment) items.
Items with Roman numerals (i., ii, iii, iv etc.) are CONSORT-EHEALTH extensions/clarifications.

As the CONSORT-EHEALTH checklist is still considered in a formative stage, we would ask that you also RATE ON A SCALE OF 1-5 how important/useful you feel each item is FOR THE PURPOSE OF THE CHECKLIST and reporting guideline (optional).

Mandatory reporting items are marked with a red *.
In the textboxes, either copy & paste the relevant sections from your manuscript into this form - please include any quotes from your manuscript in QUOTATION MARKS,
or answer directly by providing additional information not in the manuscript, or elaborating on why the item was not relevant for this study.

YOUR ANSWERS WILL BE PUBLISHED AS A SUPPLEMENTARY FILE TO YOUR PUBLICATION IN JMIR AND ARE CONSIDERED PART OF YOUR PUBLICATION (IF ACCEPTED).
Please fill in these questions diligently. Information will not be copyedited, so please use proper spelling and grammar, use correct capitalization, and avoid abbreviations.

DO NOT FORGET TO SAVE AS PDF _AND_ CLICK THE SUBMIT BUTTON SO YOUR ANSWERS ARE IN OUR DATABASE !!!

Citation Suggestion (if you append the pdf as Appendix we suggest to cite this paper in the caption):
Eysenbach G, CONSORT-EHEALTH Group
CONSORT-EHEALTH: Improving and Standardizing Evaluation Reports of Web-based and

Mobile Health Interventions
J Med Internet Res 2011;13(4):e126
URL: http://www.jmir.org/2011/4/e126/
doi: 10.2196/jmir.1923
PMID: 22209829

* Required

Your name *
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Title of your manuscript *
Provide the (draft) title of your manuscript.

Assessing Telemedicine Efficiency in German Follow-up Care With Video Consultations for Patients in Orthopedic and Trauma Surgery: A Randomized Controlled Trial

Name of your App/Software/Intervention *

If there is a short and a long/alternate name, write the short name first and add the long name in brackets.

CLICKDOC

Evaluated Version (if any)

e.g. "V1", "Release 2017-03-01", "Version 2.0.27913"

Your answer

Language(s) *

What language is the intervention/app in? If multiple languages are available, separate by comma (e.g. "English, French")

German

URL of your Intervention Website or App

e.g. a direct link to the mobile app on app in appstore (itunes, Google Play), or URL of the website. If the intervention is a DVD or hardware, you can also link to an Amazon page.

https://clickdoc.elvi.de/#/login

URL of an image/screenshot (optional)

Your answer

Accessibility *

Can an enduser access the intervention presently?

- ○ access is free and open
- ○ access only for special usergroups, not open
- ◉ access is open to everyone, but requires payment/subscription/in-app purchases
- ○ app/intervention no longer accessible
- ○ Other:

Primary Medical Indication/Disease/Condition *

e.g. "Stress", "Diabetes", or define the target group in brackets after the condition, e.g. "Autism (Parents of children with)", "Alzheimers (Informal Caregivers of)"

Orthopedic and trauma surgery follow-up

Primary Outcomes measured in trial *

comma-separated list of primary outcomes reported in the trial

Patient satisfaction

Secondary/other outcomes

Are there any other outcomes the intervention is expected to affect?

Physician satisfaction, Quality of care

Recommended "Dose" *

What do the instructions for users say on how often the app should be used?

- ○ Approximately Daily
- ○ Approximately Weekly
- ○ Approximately Monthly
- ○ Approximately Yearly
- ○ "as needed"
- ◉ Other: No App, One-time video consultation

Approx. Percentage of Users (starters) still using the app as recommended after 3 months *

- ◉ unknown / not evaluated
- ○ 0-10%
- ○ 11-20%
- ○ 21-30%
- ○ 31-40%
- ○ 41-50%
- ○ 51-60%
- ○ 61-70%
- ○ 71%-80%
- ○ 81-90%
- ○ 91-100%
- ○ Other:

Overall, was the app/intervention effective? *

- ○ yes: all primary outcomes were significantly better in intervention group vs control
- ○ partly: SOME primary outcomes were significantly better in intervention group vs control
- ◉ no statistically significant difference between control and intervention
- ○ potentially harmful: control was significantly better than intervention in one or more outcomes
- ○ inconclusive: more research is needed
- ○ Other:

Article Preparation Status/Stage *

At which stage in your article preparation are you currently (at the time you fill in this form)

- ○ not submitted yet - in early draft status
- ◉ not submitted yet - in late draft status, just before submission
- ○ submitted to a journal but not reviewed yet
- ○ submitted to a journal and after receiving initial reviewer comments
- ○ submitted to a journal and accepted, but not published yet
- ○ published
- ○ Other:

Journal *

If you already know where you will submit this paper (or if it is already submitted), please provide the journal name (if it is not JMIR, provide the journal name under "other")

- ○ not submitted yet / unclear where I will submit this
- ◉ Journal of Medical Internet Research (JMIR)
- ○ JMIR mHealth and UHealth
- ○ JMIR Serious Games
- ○ JMIR Mental Health
- ○ JMIR Public Health
- ○ JMIR Formative Research
- ○ Other JMIR sister journal
- ○ Other:

Is this a full powered effectiveness trial or a pilot/feasibility trial? *

- ○ Pilot/feasibility
- ◉ Fully powered

Manuscript tracking number *

If this is a JMIR submission, please provide the manuscript tracking number under "other" (The ms tracking number can be found in the submission acknowledgement email, or when you login as author in JMIR. If the paper is already published in JMIR, then the ms tracking number is the four-digit number at the end of the DOI, to be found at the bottom of each published article in JMIR)

- ◉ no ms number (yet) / not (yet) submitted to / published in JMIR
- ○ Other:

TITLE AND ABSTRACT

1a) TITLE: Identification as a randomized trial in the title

1a) Does your paper address CONSORT item 1a? *

I.e does the title contain the phrase "Randomized Controlled Trial"? (if not, explain the reason under "other")

- ◉ yes
- ○ Other:

1a-i) Identify the mode of delivery in the title

Identify the mode of delivery. Preferably use "web-based" and/or "mobile" and/or "electronic game" in the title. Avoid ambiguous terms like "online", "virtual", "interactive". Use "Internet-based" only if Intervention includes non-web-based Internet components (e.g. email), use "computer-based" or "electronic" only if offline products are used. Use "virtual" only in the context of "virtual reality" (3-D worlds). Use "online" only in the context of "online support groups". Complement or substitute product names with broader terms for the class of products (such as "mobile" or "smart phone" instead of "iphone"), especially if the application runs on different platforms.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 1a-i? *

Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Follow-up Care With Video Consultations"

1a-ii) Non-web-based components or important co-interventions in title

Mention non-web-based components or important co-interventions in title, if any (e.g., "with telephone support").

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 1a-ii?

Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

1a-iii) Primary condition or target group in the title

Mention primary condition or target group in the title, if any (e.g., "for children with Type I Diabetes") Example: A Web-based and Mobile Intervention with Telephone Support for Children with Type I Diabetes: Randomized Controlled Trial

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 1a-iii? *

Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Assessing Telemedicine Efficiency in German Follow-up Care With Video Consultations for Patients in Orthopedic and Trauma Surgery: A Randomized Controlled Trial"

1b) ABSTRACT: Structured summary of trial design, methods, results, and conclusions

NPT extension: Description of experimental treatment, comparator, care providers, centers, and blinding status.

1b-i) Key features/functionalities/components of the intervention and comparator in the METHODS section of the ABSTRACT

Mention key features/functionalities/components of the intervention and comparator in the abstract. If possible, also mention theories and principles used for designing the site. Keep in mind the needs of systematic reviewers and indexers by including important synonyms. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 1b-i? *

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"For their follow-up appointments, patients received either an in-person consultation in the clinic (control group) or a video consultation with their physician (telemedicine group)."

1b-ii) Level of human involvement in the METHODS section of the ABSTRACT

Clarify the level of human involvement in the abstract, e.g., use phrases like "fully automated" vs. "therapist/nurse/care provider/physician-assisted" (mention number and expertise of providers involved, if any). (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 1b-ii?

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"For their follow-up appointments, patients received either an in-person consultation in the clinic (control group) or a video consultation with their physician (telemedicine group)."

1b-iii) Open vs. closed, web-based (self-assessment) vs. face-to-face assessments in the METHODS section of the ABSTRACT

Mention how participants were recruited (online vs. offline), e.g., from an open access website or from a clinic or a closed online user group (closed usergroup trial), and clarify if this was a purely web-based trial, or there were face-to-face components (as part of the intervention or for assessment). Clearly say if outcomes were self-assessed through questionnaires (as common in web-based trials). Note: In traditional offline trials, an open trial (open-label trial) is a type of clinical trial in which both the researchers and participants know which treatment is being administered. To avoid confusion, use "blinded" or "unblinded" to indicated the level of blinding instead of "open", as "open" in web-based trials usually refers to "open access" (i.e. participants can self-enrol). (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 1b-iii?

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"A prospective randomized controlled trial conducted in a German university hospital enrolled 60 patients with different knee and shoulder conditions. For their follow-up appointments, patients received either an in-person consultation in the clinic (control group) or a video consultation with their physician (telemedicine group). Patients' and physicians' subsequent evaluations of these follow-up appointments were collected and assessed using separate questionnaires."

1b-iv) RESULTS section in abstract must contain use data

Report number of participants enrolled/assessed in each group, the use/uptake of the intervention (e.g., attrition/adherence metrics, use over time, number of logins etc.), in addition to primary/secondary outcomes. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 1b-iv?

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Based on data from 52 consultations after 8 withdrawals, it was found that patients were slightly more satisfied with video consultations (mean 1.58) than with in-clinic ones (mean 1.64), although the difference was not statistically significant (P=.690). After excluding video consultations marred by technical problems, no significant difference was found in physician satisfaction between the groups (mean 1.47 vs 1.32, P=.310). Further analysis indicated that telemedicine can be applied to broader groups of patients, and that patients who have prior experience with telemedicine are more willing to use it for follow-up care."

1b-v) CONCLUSIONS/DISCUSSION in abstract for negative trials

Conclusions/Discussions in abstract for negative trials: Discuss the primary outcome - if the trial is negative (primary outcome not changed), and the intervention was not used, discuss whether negative results are attributable to lack of uptake and discuss reasons. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 1b-v?

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Telemedicine can be an alternative and efficient form of follow-up care in orthopedic and trauma surgery in Germany, and it has no significant disadvantages compared with in-person consultations in the clinic."

INTRODUCTION

2a) In INTRODUCTION: Scientific background and explanation of rationale

2a-i) Problem and the type of system/solution

Describe the problem and the type of system/solution that is object of the study: intended as stand-alone intervention vs. incorporated in broader health care program? Intended for a particular patient population? Goals of the intervention, e.g., being more cost-effective to other interventions, replace or complement other solutions? (Note: Details about the intervention are provided in "Methods" under 5)

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 2a-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The aim of our randomized controlled trial is to investigate whether telemedicine can be used efficiently in follow-up care for orthopedic and trauma surgery patients in Germany. To answer this question, the RCT compares an in-personal consultation in a German university hospital (Level 1 trauma center) with the use of telemedicine, namely a video consultation between physician and patient. All consultations were for follow-up care of knee and shoulder patients who displayed a variety of conditions, had previously been treated in the clinic, and were eligible to participate in the study. For their video consultation, patients did not have to travel to the clinic, but could have their follow-up appointment online regardless of their location. The subsequent evaluation of telemedicine and its efficiency focuses on patient satisfaction, physician satisfaction, and quality of care. It is hoped that studying telemedicine in broad-based use for follow-up care and analyzing its effects comprehensively will contribute to informing healthcare providers' decision-making in future."

2a-ii) Scientific background, rationale: What is known about the (type of) system

Scientific background, rationale: What is known about the (type of) system that is the object of the study (be sure to discuss the use of similar systems for other conditions/diagnoses, if appropiate), motivation for the study, i.e. what are the reasons for and what is the context for this specific study, from which stakeholder viewpoint is the study performed, potential impact of findings [2]. Briefly justify the choice of the comparator.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 2a-ii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"One important tool for overcoming these challenges and guaranteeing effective healthcare in the medium to long term could be the use of telemedicine. Telemedicine offers the ability to provide medical care through real-time video consultations, without the need for personal contact and regardless of location. This could free up clinical resources, improve access to care, and increase safety for patients and medical staff. Telemedicine is already being applied successfully in various medical fields, but its use has so far been less common in orthopedic and trauma surgery. Since the outbreak of the COVID-19 pandemic, however, the need for telemedicine has risen considerably in these fields as well."
"Prior research, however, has so far left several questions unaddressed. One of them is whether the use of telemedicine is efficient not only for a restricted number of individual diseases, but also for a wider range of medical conditions. Another important question concerns the viability of deploying telemedicine under realistic conditions and cost constraints in clinical practice: It is not clear whether telemedicine remains viable for a wider range of medical conditions when offered without incurring the additional cost of human resources required to support patients in video consultations, as in an outpatient clinic. Furthermore, it is questionable whether international study results can be transferred to the German healthcare system, especially since studies show that German patients are skeptical regarding the use of telemedicine."

2b) In INTRODUCTION: Specific objectives or hypotheses

Does your paper address CONSORT subitem 2b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The aim of our randomized controlled trial is to investigate whether telemedicine can be used efficiently in follow-up care for orthopedic and trauma surgery patients in Germany."

METHODS

3a) Description of trial design (such as parallel, factorial) including allocation ratio

Does your paper address CONSORT subitem 3a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The study was conducted as an open, prospective, interventional, 1:1 randomized, and controlled monocenter trial at a German university hospital (University Hospital Giessen, Department of Trauma, Hand- and Reconstructive Surgery). The randomized and controlled design is based on the Consolidated Standards of Reporting Trials (CONSORT). With the parallel implementation of an intervention group, which received follow-up care through a real-time video consultation, and a control group, which received a standard follow-up consultation in the clinic, the effects of telemedicine on follow-up care were examined"

3b) Important changes to methods after trial commencement (such as eligibility criteria), with reasons

Does your paper address CONSORT subitem 3b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable for our study.

3b-i) Bug fixes, Downtimes, Content Changes

Bug fixes, Downtimes, Content Changes: ehealth systems are often dynamic systems. A description of changes to methods therefore also includes important changes made on the intervention or comparator during the trial (e.g., major bug fixes or changes in the functionality or content) (5-iii) and other "unexpected events" that may have influenced study design such as staff changes, system failures/downtimes, etc. [2].

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 3b-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Technical irregularities in 42% of the video consultations conducted involving image problems, sound problems, and internet problems.

4a) Eligibility criteria for participants

Does your paper address CONSORT subitem 4a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Inclusion criteria: "(1) Patients need the ability to consent, as well as the mental and physical ability to participate in the telemedical consultation. (2) Patients' conditions require no more than a visual examination. For legal reasons, (3) a previous outpatient or inpatient stay at the clinic is required, and (4) patients have to be 18 years or older. To be able to use telemedicine, it is assumed that (5) patients own a computer, laptop, tablet or smartphone, including a microphone and camera, and (6) they have a stable internet connection. Finally, (7) patients have to speak German in order to understand the declaration of consent." As well as specified ICD-10 codes.
"Exclusion criteria: "Patients with (1) neurological diseases that do not allow the use of computer systems, and (2) patients with a diagnosis of dementia, blindness or deafness are excluded. Also, patients are excluded if they (3) have a need for in-person presence and on-site diagnostics or treatments (eg, medical imaging, laboratory, stitches, drainage) or (4) have to be touched or moved by the treating physician. This ensures that patients who require personal contact with a physician are not put at risk. Finally, (5) a lack of willingness to participate in the study or (6) the failure to consent are further exclusion criteria."

4a-i) Computer / Internet literacy

Computer / Internet literacy is often an implicit "de facto" eligibility criterion - this should be explicitly clarified.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 4a-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"To be able to use telemedicine, it is assumed that (5) patients own a computer, laptop, tablet or smartphone, including a microphone and camera, and (6) they have a stable internet connection."
"Patients with (1) neurological diseases that do not allow the use of computer systems, and (2) patients with a diagnosis of dementia, blindness or deafness are excluded."

4a-ii) Open vs. closed, web-based vs. face-to-face assessments:

Open vs. closed, web-based vs. face-to-face assessments: Mention how participants were recruited (online vs. offline), e.g., from an open access website or from a clinic, and clarify if this was a purely web-based trial, or there were face-to-face components (as part of the intervention or for assessment), i.e., to what degree got the study team to know the participant. In online-only trials, clarify if participants were quasi-anonymous and whether having multiple identities was possible or whether technical or logistical measures (e.g., cookies, email confirmation, phone calls) were used to detect/prevent these.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 4a-ii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"After initial screening for inclusion and exclusion criteria, patients were asked either at the clinic or by telephone if they would like to participate in the study during their next follow-up appointment."

4a-iii) Information giving during recruitment

Information given during recruitment. Specify how participants were briefed for recruitment and in the informed consent procedures (e.g., publish the informed consent documentation as appendix, see also item X26), as this information may have an effect on user self-selection, user expectation and may also bias results.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 4a-iii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"To be able to participate, patients had to provide informed consent after receiving written as well as oral information. Consent could be withdrawn at any time without providing reasons."

4b) Settings and locations where the data were collected

Does your paper address CONSORT subitem 4b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"At the end of the recruitment process, depending on the treatment arm, the patients received an appointment either in the clinic or for a video consultation."

4b-i) Report if outcomes were (self-)assessed through online questionnaires

Clearly report if outcomes were (self-)assessed through online questionnaires (as common in web-based trials) or otherwise.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 4b-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Intervention group: "Immediately after the video consultation, patients received login details via email and were asked to evaluate the consultation via online questionnaires."
Control group: "Directly after the consultation, patients of the control arm were asked to fill out the questionnaires at the clinic."

4b-ii) Report how institutional affiliations are displayed

Report how institutional affiliations are displayed to potential participants [on ehealth media], as affiliations with prestigious hospitals or universities may affect volunteer rates, use, and reactions with regards to an intervention.(Not a required item – describe only if this may bias results)

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 4b-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable for our study.

5) The interventions for each group with sufficient details to allow replication, including how and when they were actually administered

5-i) Mention names, credential, affiliations of the developers, sponsors, and owners

Mention names, credential, affiliations of the developers, sponsors, and owners [6] (if authors/evaluators are owners or developer of the software, this needs to be declared in a "Conflict of interest" section or mentioned elsewhere in the manuscript).

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 5-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable for our study.

5-ii) Describe the history/development process

Describe the history/development process of the application and previous formative evaluations (e.g., focus groups, usability testing), as these will have an impact on adoption/use rates and help with interpreting results.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 5-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable for our study.

5-iii) Revisions and updating

Revisions and updating. Clearly mention the date and/or version number of the application/intervention (and comparator, if applicable) evaluated, or describe whether the intervention underwent major changes during the evaluation process, or whether the development and/or content was "frozen" during the trial. Describe dynamic components such as news feeds or changing content which may have an impact on the replicability of the intervention (for unexpected events see item 3b).

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 5-iii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable for our study.

5-iv) Quality assurance methods

Provide information on quality assurance methods to ensure accuracy and quality of information provided [1], if applicable.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 5-iv?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable for our study.

5-v) Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used

Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used. Replicability (i.e., other researchers should in principle be able to replicate the study) is a hallmark of scientific reporting.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 5-v?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable for our study.

5-vi) Digital preservation

Digital preservation: Provide the URL of the application, but as the intervention is likely to change or disappear over the course of the years; also make sure the intervention is archived (Internet Archive, webcitation.org, and/or publishing the source code or screenshots/videos alongside the article). As pages behind login screens cannot be archived, consider creating demo pages which are accessible without login.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 5-vi?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable for our study.

5-vii) Access

Access: Describe how participants accessed the application, in what setting/context, if they had to pay (or were paid) or not, whether they had to be a member of specific group. If known, describe how participants obtained "access to the platform and Internet" [1]. To ensure access for editors/reviewers/readers, consider to provide a "backdoor" login account or demo mode for reviewers/readers to explore the application (also important for archiving purposes, see vi).

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 5-vii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"On the day of their appointment, patients received login details for the video consultation from their physicians via text message or email. No additional registration was required for the video consultation. At the arranged time, both the attending physician and the patient logged in to the software program and the video consultation was conducted."

5-viii) Mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework

Describe mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework [6] used to design them (instructional strategy [1], behaviour change techniques, persuasive features, etc., see e.g., [7, 8] for terminology). This includes an in-depth description of the content (including where it is coming from and who developed it) [1]," whether [and how] it is tailored to individual circumstances and allows users to track their progress and receive feedback" [6]. This also includes a description of communication delivery channels and – if computer-mediated communication is a component – whether communication was synchronous or asynchronous [6]. It also includes information on presentation strategies [1], including page design principles, average amount of text on pages, presence of hyperlinks to other resources, etc. [1].

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 5-viii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The online video consultation used the web-based software CLICKDOC of the German telemedicine provider CGM Mobile Services GmbH. This software is certified for and widely used in the German healthcare system. On the day of their appointment, patients received login details for the video consultation from their physicians via text message or email. No additional registration was required for the video consultation. At the arranged time, both the attending physician and the patient logged in to the software program and the video consultation was conducted. Patients were able to use a computer, laptop, tablet or smartphone to join the video consultation."

5-ix) Describe use parameters

Describe use parameters (e.g., intended "doses" and optimal timing for use). Clarify what instructions or recommendations were given to the user, e.g., regarding timing, frequency, heaviness of use, if any, or was the intervention used ad libitum.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 5-ix?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Study participants who were assigned to the intervention arm received a one-time telemedical follow-up via a real-time videoconference instead of a standard consultation in the department."

5-x) Clarify the level of human involvement

Clarify the level of human involvement (care providers or health professionals, also technical assistance) in the e-intervention or as co-intervention (detail number and expertise of professionals involved, if any, as well as "type of assistance offered, the timing and frequency of the support, how it is initiated, and the medium by which the assistance is delivered". It may be necessary to distinguish between the level of human involvement required for the trial, and the level of human involvement required for a routine application outside of a RCT setting (discuss under item 21 – generalizability).

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 5-x?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Intervention group: "At the arranged time, both the attending physician and the patient logged in to the software program and the video consultation was conducted."
Control group: "Study participants, who were assigned to the control group attended a standard follow-up consultation at the university hospital. This follow-up was conducted by the same physicians, who also treated the intervention arm."

5-xi) Report any prompts/reminders used

Report any prompts/reminders used: Clarify if there were prompts (letters, emails, phone calls, SMS) to use the application, what triggered them, frequency etc. It may be necessary to distinguish between the level of prompts/reminders required for the trial, and the level of prompts/reminders for a routine application outside of a RCT setting (discuss under item 21 – generalizability).

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 5-xi? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"On the day of their appointment, patients received login details for the video consultation from their physicians via text message or email."

5-xii) Describe any co-interventions (incl. training/support)

Describe any co-interventions (incl. training/support): Clearly state any interventions that are provided in addition to the targeted eHealth intervention, as ehealth intervention may not be designed as stand-alone intervention. This includes training sessions and support [1]. It may be necessary to distinguish between the level of training required for the trial, and the level of training for a routine application outside of a RCT setting (discuss under item 21 – generalizability.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 5-xii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Patients in the intervention group also received written instructions on how to perform the video consultation to minimize potential technical difficulties."

6a) Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed

Does your paper address CONSORT subitem 6a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The primary outcome patient satisfaction was measured using the ZAP questionnaire of the National Association of Statutory Health Insurance Physicians (NASHIP) in Germany."
"Immediately after the video consultation, patients received login details via email and were asked to evaluate the consultation via online questionnaires."
"Physician satisfaction as one of the secondary outcome parameters was assessed by questionnaires that the physicians answered following each patient consultation. The questionnaires were self-designed and differed slightly depending on the study arm."
"To be able to evaluate quality of care as a further secondary outcome, patients received the German version of the "EQ-5D-5L" questionnaire from the EuroQol Group during enrollment."
"After 3 months, the questionnaire was completed again to measure the impact of the interventions on health-related quality of life."

6a-i) Online questionnaires: describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed

If outcomes were obtained through online questionnaires, describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed [9].

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 6a-i?

Copy and paste relevant sections from manuscript text

Not applicable for our study.

6a-ii) Describe whether and how "use" (including intensity of use/dosage) was defined/measured/monitored

Describe whether and how "use" (including intensity of use/dosage) was defined/measured/monitored (logins, logfile analysis, etc.). Use/adoption metrics are important process outcomes that should be reported in any ehealth trial.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 6a-ii?

Copy and paste relevant sections from manuscript text

Not applicable for our study.

6a-iii) Describe whether, how, and when qualitative feedback from participants was obtained

Describe whether, how, and when qualitative feedback from participants was obtained (e.g., through emails, feedback forms, interviews, focus groups).

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 6a-iii?

Copy and paste relevant sections from manuscript text

Not applicable for our study.

6b) Any changes to trial outcomes after the trial commenced, with reasons

Does your paper address CONSORT subitem 6b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Any changes to trial outcomes after the trial commenced, with reasons

7a) How sample size was determined

NPT: When applicable, details of whether and how the clustering by care provides or centers was addressed

7a-i) Describe whether and how expected attrition was taken into account when calculating the sample size

Describe whether and how expected attrition was taken into account when calculating the sample size.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 7a-i?

Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"A group comparison of patient satisfaction with telemedicine in a study by Sharareh & Schwarzkopf (2014) served as the basis for our sample size calculation. This resulted in approximately 17 study participants for each group to achieve a power of 90% in a 2-sided t-test for independent samples with a global significance level of 5%. The sample size was increased by 10% for both groups to accommodate potential dropouts or withdrawals, and by another 10% to counteract a potentially skewed distribution of patient satisfaction. This resulted in a case number of 21 patients per randomization arm. To take into account the possible loss of power when using non-parametric methods, the sample size was finally increased to 30 patients per arm and thus to a total of 60 enrollments."

7b) When applicable, explanation of any interim analyses and stopping guidelines

Does your paper address CONSORT subitem 7b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Termination criteria were established for the individual study participants. (1) The occurrence of disease symptoms that required the physical presence of the patient in the clinic. (2) Occurrence of technical problems that could not be solved in the short term. (3) Voluntary termination of the study at any time by the study participant, without giving reasons and without any disadvantage for the further treatment.
These criteria as well as unexcused absences from the consultation resulted in the recording of the study participants as dropouts/withdrawals. Patients were then treated regularly and independently of the study in the clinic.

8a) Method used to generate the random allocation sequence

NPT: When applicable, how care providers were allocated to each trial group

Does your paper address CONSORT subitem 8a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Following a 2-armed parallel group design, patients enrolled in the study were randomly assigned at a 1:1 ratio to either the intervention arm (telemedicine follow-up) or the control arm (in-person follow-up consultation in the clinic)."

8b) Type of randomisation; details of any restriction (such as blocking and block size)

Does your paper address CONSORT subitem 8b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"To ensure better balance between the arms while minimizing predictability, block randomization with randomly selected block sizes of 4, 6, and 8 was applied. One member of the study staff organized the allocation of the blocks, while a different member performed the randomization of the patients."

9) Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned

Does your paper address CONSORT subitem 9? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"For this purpose, sealed envelopes were used."

10) Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions

Does your paper address CONSORT subitem 10? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"One member of the study staff organized the allocation of the blocks, while a different member performed the randomization of the patients."

11a) If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how

NPT: Whether or not administering co-interventions were blinded to group assignment

11a-i) Specify who was blinded, and who wasn't

Specify who was blinded, and who wasn't. Usually, in web-based trials it is not possible to blind the participants [1, 3] (this should be clearly acknowledged), but it may be possible to blind outcome assessors, those doing data analysis or those administering co-interventions (if any).

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 11a-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Given that the intervention was a video consultation, blinding of physicians or patients was not possible."

11a-ii) Discuss e.g., whether participants knew which intervention was the “intervention of interest” and which one was the “comparator”

Informed consent procedures (4a-ii) can create biases and certain expectations - discuss e.g., whether participants knew which intervention was the “intervention of interest” and which one was the “comparator”.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 11a-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Due to the study design, patients knew whether they were in the intervention group or control group.

11b) If relevant, description of the similarity of interventions

(this item is usually not relevant for ehealth trials as it refers to similarity of a placebo or sham intervention to a active medication/intervention)

Does your paper address CONSORT subitem 11b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable for our study.

12a) Statistical methods used to compare groups for primary and secondary outcomes

NPT: When applicable, details of whether and how the clustering by care providers or centers was addressed

Does your paper address CONSORT subitem 12a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Differences between the two study arms were analyzed using the Mann-Whitney U test or Fisher exact test, and effect sizes were reported by Pearson's correlation coefficient (r) or Cramer's V."
"In addition, the Wilcoxon signed-rank test was applied to evaluate the longitudinal data of the EQ-5D-5L VAS."

12a-i) Imputation techniques to deal with attrition / missing values

Imputation techniques to deal with attrition / missing values: Not all participants will use the intervention/comparator as intended and attrition is typically high in ehealth trials. Specify how participants who did not use the application or dropped out from the trial were treated in the statistical analysis (a complete case analysis is strongly discouraged, and simple imputation techniques such as LOCF may also be problematic [4]).

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 12a-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Data were analyzed based on intention-to-treat."

12b) Methods for additional analyses, such as subgroup analyses and adjusted analyses

Does your paper address CONSORT subitem 12b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"For patient and physician satisfaction, a subgroup analysis based on medical indication was performed."
"To examine the suitability of telemedicine for follow-up appointments in more detail, and to investigate for which patients telemedicine is most appropriate, a binary logistic regression was performed."

X26) REB/IRB Approval and Ethical Considerations [recommended as subheading under "Methods"] (not a CONSORT item)

X26-i) Comment on ethics committee approval

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem X26-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The local ethics committee of the University of Giessen reviewed and permitted the study. In addition, the study was registered at the German Clinical Trials Register (ID:DRKS00023445)."

x26-ii) Outline informed consent procedures

Outline informed consent procedures e.g., if consent was obtained offline or online (how? Checkbox, etc.?), and what information was provided (see 4a-ii). See [6] for some items to be included in informed consent documents.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem X26-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"To be able to participate, patients had to provide informed consent after receiving written as well as oral information. Consent could be withdrawn at any time without providing reasons."

X26-iii) Safety and security procedures

Safety and security procedures, incl. privacy considerations, and any steps taken to reduce the likelihood or detection of harm (e.g., education and training, availability of a hotline)

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem X26-iii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"If technical problems were noted, patients were contacted by phone and scheduled for a clinic visit as needed."

RESULTS

13a) For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome

NPT: The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider in each center

Does your paper address CONSORT subitem 13a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"A total of 60 patients agreed to participate in the study and were randomized. 30 patients were allocated to the intervention arm and 30 patients to the control arm. After randomization, 8 patients withdrew from the study. None of these patients were excluded by the physicians. Thus, 26 patients in the intervention arm and 26 patients in the control arm could be analyzed."

13b) For each group, losses and exclusions after randomisation, together with reasons

Does your paper address CONSORT subitem 13b? (NOTE: Preferably, this is shown in a CONSORT flow diagram) *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Can be found in the CONSORT flow diagram.

13b-i) Attrition diagram

Strongly recommended: An attrition diagram (e.g., proportion of participants still logging in or using the intervention/comparator in each group plotted over time, similar to a survival curve) or other figures or tables demonstrating usage/dose/engagement.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 13b-i?

Copy and paste relevant sections from the manuscript or cite the figure number if applicable (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable for our study.

14a) Dates defining the periods of recruitment and follow-up

Does your paper address CONSORT subitem 14a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Patients were recruited and attended their follow-up appointments between September 2020 and April 2021. The last questionnaires for the second data collection of the EQ-5D-5L were sent out in July 2021."

14a-i) Indicate if critical “secular events” fell into the study period

Indicate if critical “secular events” fell into the study period, e.g., significant changes in Internet resources available or “changes in computer hardware or Internet delivery resources”

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 14a-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

While study period: COVID-19 pandemic.

14b) Why the trial ended or was stopped (early)

Does your paper address CONSORT subitem 14b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable for our study.

15) A table showing baseline demographic and clinical characteristics for each group

NPT: When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group

Does your paper address CONSORT subitem 15? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Can be found in Table 1: Demographic characteristics of patients.

15-i) Report demographics associated with digital divide issues

In ehealth trials it is particularly important to report demographics associated with digital divide issues, such as age, education, gender, social-economic status, computer/Internet/ehealth literacy of the participants, if known.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 15-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Can be found in Table 1: Demographic characteristics of patients.

16) For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups

16-i) Report multiple “denominators” and provide definitions

Report multiple “denominators” and provide definitions: Report N’s (and effect sizes) “across a range of study participation [and use] thresholds” [1], e.g., N exposed, N consented, N used more than x times, N used more than y weeks, N participants “used” the intervention/comparator at specific pre-defined time points of interest (in absolute and relative numbers per group). Always clearly define “use” of the intervention.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 16-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"In total, 100% of patients in the intervention arm and 90% (26/29) of patients in the control arm completed the questionnaires after the follow-up appointment. Of the physician questionnaires, 100% in the telemedicine group and 96% (25/26) in the control group were completed. In the intervention group, 100% of the EQ-5D-5L questionnaires were returned at baseline and 69% (18/26) after 3 months; in the control group, 88% (23/26) of the questionnaires were returned at baseline and 58% (15/26) after 3 months."

16-ii) Primary analysis should be intent-to-treat

Primary analysis should be intent-to-treat, secondary analyses could include comparing only “users”, with the appropriate caveats that this is no longer a randomized sample (see 18-i).

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 16-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Data were analyzed based on intention-to-treat."

17a) For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)

Does your paper address CONSORT subitem 17a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Although group comparison showed that patients were slightly more satisfied with telemedicine follow-up (mean 1.58) than with in-person follow-up in the clinic (mean 1.64), the difference was not statistically significant (P=.690) (Table 2)."
"The waiting time (P<.001), atmosphere (P<.001), and punctuality of the appointment (P=.002) were more satisfying for patients in the telemedicine group than in the control group, with medium to strong effects (r=.440 to r=.760)."
"A strong effect was also evident in the preference for the next follow-up appointment between the groups (V=.542). Whereas patients in the control group would prefer to visit the clinic again (64.0%), almost all patients in the telemedicine group (88.5%) would choose telemedicine for their next follow-up appointment (P<.001)."
"Physicians in the control group were significantly more satisfied with follow-up appointments (mean 1.32) than those in the telemedicine group (mean 2.42) (P=.001, r=.466), as shown in Table 3."
"However, a further group comparison, in which video consultations with technical irregularities were removed, revealed no significant group differences in physician satisfaction (mean 1.47 & 1.32, P=.310). In addition, there were no significant differences in the ability to address all relevant medical questions. For the next follow-up appointment, physicians would recommend a telemedical consultation for most patients regardless of the study arm (73.1% telemedicine group; 64.0% control group; P=.555)."
"As shown in Table 4, differences in quality of life between the groups were not significant, neither at baseline (P=.242) nor after treatment (P=.686). The difference in quality of life before and after the follow-up appointment also did not meet statistical significance between the intervention and the control arm (P=.187). In this case, the group size has changed, because only complete data sets could be considered for analysis. In both groups, the perceived average quality of life increased after treatment, although not significantly (telemedicine group: mean 69.77 to 70.44, P=.934; control group: mean 66.30 to 69.33, P=.108)."

17a-i) Presentation of process outcomes such as metrics of use and intensity of use

In addition to primary/secondary (clinical) outcomes, the presentation of process outcomes such as metrics of use and intensity of use (dose, exposure) and their operational definitions is critical. This does not only refer to metrics of attrition (13-b) (often a binary variable), but also to more continuous exposure metrics such as "average session length". These must be accompanied by a technical description how a metric like a "session" is defined (e.g., timeout after idle time) [1] (report under item 6a).

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 17a-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable for our study.

17b) For binary outcomes, presentation of both absolute and relative effect sizes is recommended

Does your paper address CONSORT subitem 17b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Can be found in the Tables.

18) Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory

Does your paper address CONSORT subitem 18? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Although group comparison showed that patients were slightly more satisfied with telemedicine follow-up (mean 1.58) than with in-person follow-up in the clinic (mean 1.64), the difference was not statistically significant (P=.690) (Table 2). This result was not affected by a subgroup analysis of the 2 medical indications, namely knee or shoulder."
"Subgroup analysis showed that this difference was also significant for the treatment of shoulder patients (P=.006), but not for knee patients (P=.076). However, a further group comparison, in which video consultations with technical irregularities were removed, revealed no significant group differences in physician satisfaction (mean 1.47 & 1.32, P=.310)."
"Binary logistic regression was used to examine for which patients telemedicine follow-up is appropriate. For this purpose, the potential influence of different variables on patients' preference for their next follow-up appointment was analyzed (Table 5). The model was statistically significant $\chi2(6) = 22.334$, P=.001, Nagelkerke`s R2 = 48.4%. It was found that neither medical indication, gender nor age had a significant influence on the choice of telemedicine. However, previous experience with video calls before the study (P=.031) and the respective study arm in which the patients were treated (P=.001) contributed significantly to predicting the choice of telemedicine."

18-i) Subgroup analysis of comparing only users

A subgroup analysis of comparing only users is not uncommon in ehealth trials, but if done, it must be stressed that this is a self-selected sample and no longer an unbiased sample from a randomized trial (see 16-ii).

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 18-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable for our study.

19) All important harms or unintended effects in each group

(for specific guidance see CONSORT for harms)

Does your paper address CONSORT subitem 19? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"High number of video consultations with technical irregularities (42%, 11/26)"

19-i) Include privacy breaches, technical problems

Include privacy breaches, technical problems. This does not only include physical "harm" to participants, but also incidents such as perceived or real privacy breaches [1], technical problems, and other unexpected/unintended incidents. "Unintended effects" also includes unintended positive effects [2].

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 19-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"High number of video consultations with technical irregularities (42%, 11/26)"

19-ii) Include qualitative feedback from participants or observations from staff/researchers

Include qualitative feedback from participants or observations from staff/researchers, if available, on strengths and shortcomings of the application, especially if they point to unintended/unexpected effects or uses. This includes (if available) reasons for why people did or did not use the application as intended by the developers.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 19-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable for our study.

DISCUSSION

22) Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence

NPT: In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group

22-i) Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use)

Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use).

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 22-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The aim of this study was to investigate whether telemedicine can be used efficiently for outpatient orthopedic and trauma surgery follow-up care in Germany at an university hospital from the perspective of patients, physicians, and the quality of care. Our data analysis shows that the use of telemedicine has no significant drawbacks compared with traditional clinical consultations in almost all aspects studied. Patients were even slightly more satisfied with telemedicine regardless of their medical condition, although the difference was not statistically significant. In addition to overall satisfaction, the authors also analyzed more specific indicators of satisfaction. Aspects such as waiting time, atmosphere and punctuality could be improved by using telemedicine."

22-ii) Highlight unanswered new questions, suggest future research

Highlight unanswered new questions, suggest future research.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 22-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable for our study.

20) Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses

20-i) Typical limitations in ehealth trials

Typical limitations in ehealth trials: Participants in ehealth trials are rarely blinded. Ehealth trials often look at a multiplicity of outcomes, increasing risk for a Type I error. Discuss biases due to non-use of the intervention/usability issues, biases through informed consent procedures, unexpected events.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 20-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The use of pen-and-paper questionnaires on the one hand and online questionnaires on the other could also have led to discrepancies. In particular, all questions had to be completed in the online questionnaires, but the same was not true for pen-and-paper questionnaires completed in the clinic. For organizational reasons, however, no uniform implementation was possible. This problem also arose for comparable studies. On the other hand, studies show that patients usually provide similar health-related answers regardless of survey formats.
Finally, when evaluating the results, it should be noted that all recruited patients consented to participating in telemedicine. This might have led to a bias in favor of higher satisfaction with telemedicine from the start, which explains why our data do not show results for the population. Short of forcing patients to participate in telemedicine, a procedure which appears both unethical in principle and unfeasible in clinical practice, there is no acceptable way of addressing this limitation."

21) Generalisability (external validity, applicability) of the trial findings

NPT: External validity of the trial findings according to the intervention, comparators, patients, and care providers or centers involved in the trial

21-i) Generalizability to other populations

Generalizability to other populations: In particular, discuss generalizability to a general Internet population, outside of a RCT setting, and general patient population, including applicability of the study results for other organizations

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 21-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"In sum, our results suggest that the effective implementation of telemedical follow-up care ideally meets several conditions. First, the appropriateness of telemedicine should be assessed for each patient individually, and suitable patients should be supported in overcoming any initial uncertainties. Second, if any medical issues cannot be clarified in a video consultation, or if problems occur, additional in-clinic treatment should always be possible, as was the case in the present study. Third, technical irregularities should be monitored over the long term, as telemedicine is beneficial only if the physicians using it are satisfied with its workability."

21-ii) Discuss if there were elements in the RCT that would be different in a routine application setting

Discuss if there were elements in the RCT that would be different in a routine application setting (e.g., prompts/reminders, more human involvement, training sessions or other co-interventions) and what impact the omission of these elements could have on use, adoption, or outcomes if the intervention is applied outside of a RCT setting.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 21-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable for our study.

OTHER INFORMATION

23) Registration number and name of trial registry

Does your paper address CONSORT subitem 23? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"German Register for Clinical Trials, ID: DRKS00023445"

24) Where the full trial protocol can be accessed, if available

Does your paper address CONSORT subitem 24? *

Cite a Multimedia Appendix, other reference, or copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The full trial protocol can be requested from the corresponding author.

25) Sources of funding and other support (such as supply of drugs), role of funders

Does your paper address CONSORT subitem 25? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The research did not receive funding from an external body.

X27) Conflicts of Interest (not a CONSORT item)

X27-i) State the relation of the study team towards the system being evaluated

In addition to the usual declaration of interests (financial or otherwise), also state the relation of the study team towards the system being evaluated, i.e., state if the authors/evaluators are distinct from or identical with the developers/sponsors of the intervention.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem X27-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Conflicts of Interest: None declared.

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- ○ yes, major changes
- ○ yes, minor changes
- ◉ no

What were the most important changes you made as a result of using this checklist?

Not applicable for our study.

How much time did you spend on going through the checklist INCLUDING making changes in your manuscript *

I spent two hours to complete the checklist.

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- ○ no
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- ◉ no
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Any other comments or questions on CONSORT EHEALTH

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4 Economic and Environmental Impact of Digital Health App Video Consultations in Follow-Up Care for Patients in Orthopedic and Trauma Surgery in Germany: Randomized Controlled Trial

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7.4

Original Paper

Economic and Environmental Impact of Digital Health App Video Consultations in Follow-up Care for Patients in Orthopedic and Trauma Surgery in Germany: Randomized Controlled Trial

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Abstract

Background: Following the Riyadh Declaration, digital health technologies were prioritized in many countries to address the challenges of the COVID-19 pandemic. Digital health apps for telemedicine and video consultations help reduce potential disease spread in routine health care, including follow-up care in orthopedic and trauma surgery. In addition to the satisfaction, efficiency, and safety of telemedicine, its economic and environmental effects are highly relevant to decision makers, particularly for the goal of reaching carbon neutrality of health care systems.

Objective: This study aims to provide the first comprehensive health economic and environmental analysis of video consultations in follow-up care after knee and shoulder interventions in an orthopedic and trauma surgery department of a German university hospital. The analysis is conducted from a societal perspective. We analyze both economic and environmental impacts of video consultations, taking into account the goal of carbon neutrality for the German health care system by 2030.

Methods: We conducted a prospective randomized controlled trial comparing follow-up care with digital health app video consultations (intervention group) to conventional face-to-face consultations in the clinic (control group). Economic impact included the analysis of travel and time costs and production losses. Examination of the environmental impact comprised the emissions of greenhouse gases, carbon monoxide, volatile hydrocarbons, nitrogen oxides, and particulates, and the calculation of environmental costs. Sensitivity analysis included calculations with a higher cost per ton of carbon dioxide equivalent, which gives equal weight to the welfare of present and future generations.

Results: Data from 52 patients indicated that, from the patients' point of view, telemedicine helped reduce travel costs, time costs, and production losses, resulting in mean cost savings of €76.52 per video consultation. In addition, emissions of 11.248 kg of greenhouse gases, 0.070 kg of carbon monoxide, 0.011 kg of volatile hydrocarbons, 0.028 kg of nitrogen oxides, and 0.0004 kg of particulates could be saved per patient through avoided travel. This resulted in savings of environmental costs between €3.73 and €9.53 per patient.

Conclusions: We presented the first comprehensive analysis of economic and environmental effects of telemedicine in the follow-up care of patients in orthopedic and trauma surgery in Germany. Video consultations were found to reduce the environmental footprint of follow-up care; saved travel costs, travel time, and time costs for patients; and helped to lower production losses. Our findings can support the decision-making on the use of digital health during and beyond the COVID-19 pandemic, providing

decision makers with data for both economic and environmental effects. Thanks to the pragmatic design of our study, our findings can be applied to a wide range of clinical contexts and potential digital health applications that substitute outpatient hospital visits with video consultations.

Trial Registration: German Clinical Trials Register DRKS00023445; https://tinyurl.com/4pcvhz4n

(J Med Internet Res 2022;24(11):e42839) doi: 10.2196/42839

KEYWORDS

carbon neutrality; digital health; environmental impact; health economics; net-zero; orthopedic; sustainability; telemedicine; trauma surgery; video consultations

Introduction

Medical care does not always require patients' attendance in the hospital [1], mainly because digital health affords physicians and patients the opportunity to have synchronous video consultations online [2]. When used for outpatient follow-up care in orthopedic and trauma surgery, for example, video consultations can relieve patients of any restrictions on their mobility or of the need to travel long distances [3-5]. Patient satisfaction, physician satisfaction, and clinical outcomes often show comparable results between telemedicine and conventional face-to-face (F2F) examinations in the hospital, demonstrating that video consultations can be a safe and efficient alternative for patient care in orthopedic and trauma surgery [6-13].

After the outbreak of the COVID-19 pandemic, the role of digital health has been highlighted by the Riyadh Declaration [14]. Following the global pandemic response, there has been an increasing interest in telemedicine in clinical practice to reduce potential disease spread as well as in science, which is reflected in a growing number of literature reviews [2,15-20]. The number of clinical trials, however, remains limited. In particular, there are only a few health economic analyses of the use of telemedicine in orthopedic and trauma surgery follow-up care [15,21].

In addition to patient satisfaction and quality of care, the societal perspective needs to consider both economic and environmental effects in order to support stakeholders in deciding whether to implement telemedicine in orthopedic and trauma surgery. Following the United Nations Sustainable Development Goals, the 125th German Medical Assembly declared in 2021 that the German health care system should become carbon-neutral by 2030 [22]. One way of meeting this requirement might be the implementation of video consultations to supplement or substitute clinic consultations. Whether this is possible, however, must first be determined by investigations. A positive environmental impact of telemedicine has already been demonstrated in certain cases: for example, in the reduction of carbon monoxide, carbon dioxide, and nitric oxides [23-25]. However, analyses of the environmental impact of video consultations in the field of orthopedic and trauma surgery are limited, and no studies based on German data exist to date.

The aim of this study is to provide the first health economic analysis comparing telemedicine in the follow-up of patients in orthopedic and trauma surgery with knee and shoulder disorders with conventional F2F examinations in the clinic in Germany. The analysis focuses on the societal perspective, considering, on the one hand, the patients' point of view in terms of potential time and cost savings and, on the other hand, the environmental impact regarding potential savings of emissions and environmental costs.

Methods

Study Design

The data used for the health economic analysis were obtained by a prospective randomized controlled trial (RCT) conducted at a single German university hospital—University Hospital Giessen, Department of Trauma, Hand and Reconstructive Surgery, Level-1 trauma center—between September 2020 and April 2021. The RCT was reported according to the Consolidated Standards of Reporting Trials (CONSORT) [26]. Patients in orthopedic and trauma surgery were randomly assigned 1 to 1 to an intervention group or a control group for a single follow-up appointment. The intervention group did not attend a standard outpatient follow-up appointment in the clinic but had a real-time online video consultation with the treating physician instead. The control group, on the other hand, was treated conventionally and received a F2F examination in the clinic. In both the intervention group and the control group, the examinations were performed by the same physicians. The study population had already received conservative or surgical treatment for various knee and shoulder conditions in the clinic.

Ethical Considerations

Patients who were eligible for the study based on the inclusion and exclusion criteria in Textbox 1 were asked either at the clinic or by telephone if they wished to participate in the RCT. After a detailed verbal explanation of the study, including the conduct of a health economic analysis as part of the study, all study participants provided written informed consent. To protect the privacy of participating patients, pseudonymization of the study data took place. Study participants were not compensated for their participation. The local ethics committee of the University of Giessen approved the RCT (AZ 73/20), and the study was registered in the German Clinical Trials Register (DRKS00023445).

Textbox 1. Inclusion and exclusion criteria of the randomized controlled trial.

Inclusion criteria:

- 18 years or older
- Previous outpatient or inpatient stay at the clinic, with an operation or conservative therapy
- Need of a follow-up that does not require more than a visual examination
- Ownership of a computer, laptop, tablet, or smartphone with microphone and camera
- Stable internet connection
- Mental and physical ability to consent and to participate
- Sufficient knowledge of German in order to understand the declaration of consent
- Shoulder International Classification of Diseases, Tenth Revision (ICD-10) codes: M75.1, M75.6, M75.0, Z96.60, M75.4, M19.91, S43.1, S42.20, S42.00, M75.2, M75.3, and S43.0
- Knee ICD-10 codes: S83.53, S83.54, S83.2, S83.0, M22.0, M23.32, M23.35, M17.1, M17.5, M21.16, M21.06, S83.3, S83.44, S83.43, S82.18, S82.0, S72.3, S72.43, M25.56, M76.5, S83.6, S76.1, and S86.8

Exclusion criteria:

- Neurological diseases that preclude the use of digital devices
- Diagnosis of dementia, blindness, or deafness
- Need for presence in the clinic and on-site treatment and diagnostics (ie, imaging, laboratory, stitches, and drainage)
- Appointments where the patient has to be touched and moved by the treating physicians
- Lack of willingness to participate
- Failure to consent

Sample Size and Randomization

The sample size calculation of the underlying RCT was based on an a priori power analysis. As a conservative estimate, we used half of the effect size of 2.19 that was observed for the findings of patient satisfaction with telemedicine in a study by Sharareh and Schwarzkopf [8]. The effect size of 1.095 yielded 19 patients per study arm for a power of 90% in a 2-sided *t* test with a 5% significance level. To increase statistical power and to compensate for potential withdrawals and dropouts, missing responses, and a skewed distribution of results, the number of participants was expanded to 30 patients for each group. In total, 60 eligible patients were recruited for the study.

Using block randomization with randomly varying block sizes (ie, 4, 6, and 8), 30 patients were assigned to a follow-up with telemedicine (intervention group), and 30 patients were assigned to a conventional F2F follow-up in the clinic (control group). The parallel-design randomization and assignment process was performed independently of the treating physicians by study staff using sealed envelopes.

Course of the Study

The video consultations in the intervention group were browser based for physicians and multiplatform for patients, including a digital health app or browser-based software from a German telemedicine provider. The software complies with the legal requirements in Germany and is recognized by the National Association of Statutory Health Insurance Physicians. The university hospital paid a monthly fee for each physician to use the software. Video consultation procedures were deliberately kept as simple and as functional as possible to ensure that they would be viable in regular clinical practice: all video consultations were performed directly between the physicians in the clinic and the patients, regardless of their location. No other medical providers, such as local caregivers or others, were involved. Patients received written instructions on how to conduct the video consultation, and no additional clinical staff were required to assist the patients. This pragmatic study design appeared to be the most promising one for a health economic evaluation seeking to produce valid, generalizable results [27]. Patients in the intervention group did not have to bear any additional costs or out-of-pocket payments for using telemedicine, as the digital health app or browser-based software was free for them to use. They were only required to have a smartphone, tablet, laptop, or computer with a microphone and camera, and an adequate internet connection. The examination itself was paid for by their respective health insurance. Patients in the control group did not have to pay any additional costs either; their costs for an in-clinic follow-up appointment (eg, travel costs) were the same as those they would have paid outside of study participation.

After the follow-up appointments, patients in both the intervention and control groups completed questionnaires. These questionnaires included questions about the distance between the patients' homes and the clinic, the amount of time spent for the appointment (eg, travel and waiting time), and the potential need to be absent from work to attend the appointment. Further information on the study can be found in a previous publication by Muschol et al [13].

Statistical Analysis and Health Economic Evaluation

The RCT data are presented as mean and SD, median and IQR, or percentage. To compare the intervention and control groups, the Mann-Whitney *U* test was used for continuous variables and the Fisher exact test was used for categorical ones. Statistical significance was assumed at $P \leq .05$.

The health economic analysis was based on data collected from the questionnaires and other official, external data. The study design was guided by recommendations for health economic analyses in the context of eHealth interventions, and the study examined non–health care costs associated with the use of telemedicine from a societal perspective [27,28]. The analysis proceeded in two steps. In the first step, economic effects of the societal perspective were examined from the patients' point of view. This involved, firstly, calculating and comparing three types of non–health care costs associated with medical appointments:

1. Travel costs were calculated following recommendations for empirical standard costs for health economic evaluations in Germany [29].
2. Time costs were assessed by assigning monetary values to patients' travel time, waiting time, and total time spent on appointments based on Verbooy et al's [30] valuation approach to unpaid work and leisure time.
3. Production losses due to patients' absence from work while attending their appointments were computed using Germany's average gross hourly wage in 2021 and average working hours for all German full-time and part-time employees in 2019 [31,32].

When tallying total costs from a societal perspective, it was felt to be appropriate to differentiate between patients who were employed and patients who were not employed, given that production losses are only relevant for patients who are employed.

In the second step, the effects of the societal perspective were evaluated in the form of the environmental impact of telemedicine. The analysis of the environmental impact was conducted using data from the German Federal Environment Agency. It comprised three different aspects. First, the environmental impact in terms of greenhouse gases, carbon monoxide, volatile hydrocarbons, nitrogen oxides, and particulates was calculated by multiplying the average emissions per passenger-kilometer (pkm) by the kilometers patients traveled by car to and from the clinic. This calculation was based on an average car occupancy of 1.4 passengers, as the average emissions are specified by the Federal Environment Agency on the basis of this value [33]. A separate calculation of emissions from public transportation was not performed within the study because only 1 patient in the control group and 1 patient in the telemedicine group used or would have used public transportation. Second, the average environmental costs incurred per pkm by the patients' trips per car were calculated. For this purpose, the cost rate of the Federal Environment Agency of €195 per ton of carbon dioxide equivalent was applied (a currency exchange rate of €1=US $0.97 is applicable) [34,35]. This value is based on a higher weighting of the welfare of current versus future generations [35].

In a third step, the potential savings in emissions and environmental costs were estimated in a model calculation if 8 patients per week would conduct a video consultation instead of a clinic consultation, as was the case in our study [33-35].

Sensitivity Analysis

Finally, a sensitivity analysis was performed to evaluate the robustness of the findings. For the patients' point of view in the societal perspective, this analysis studied the effect of differentiating between full-time and part-time employment when calculating production losses [32]. For the environmental impact of the societal perspective, the sensitivity analysis considered the following:

1. A cost rate from the Federal Environment Agency for the calculation of the environmental costs of €680 per ton of carbon dioxide equivalent, which gives equal weight to the welfare of present and future generations [34,35].
2. A total of 16 patients with a video consultation per week for the analysis of potential savings in emissions and environmental costs [33-35].

For the calculation of the environmental costs, both €195 and €680 per ton of carbon dioxide equivalent were considered [34,35]. As the Federal Environment Agency reports both cost rates, the aim of the sensitivity analysis was to show how the equal weighting of the welfare of present and future generations (€680) compared to the higher weighting of the welfare of present versus future generations (€195) affects the environmental costs.

Results

General Findings

Of the 60 patients recruited—intervention group (n=30) and control group (n=30)—4 patients in each of the groups withdrew from the study. Thus, data from a total of 52 patients could be considered for the health economic evaluation, with several variables displaying a lower n value due to missing items on some patient questionnaires. The progress of the recruited patients through the trial is shown in a CONSORT flow diagram in Multimedia Appendix 1.

Demographic patient characteristics are shown in Table 1. No significant differences were observed between the telemedicine group and the control group.

Regarding the variables used for calculating costs, however, the differences between the groups were partially significant, as shown in Table 2. Treatment duration in the intervention group, at 8.23 minutes on average, was significantly shorter than that in the control group, at 10.92 minutes on average ($P=.02$). The average waiting time in the online waiting room for the telemedicine software was also significantly shorter than that experienced in the clinic (6.73 minutes vs 36.88 minutes, respectively; $P<.001$). The largest intergroup difference, however, was observed in total patient time spent per follow-up appointment. An appointment in the telemedicine group took an average of 21.92 minutes out of the patients' days, whereas an appointment in the control group required patients to spend 154.80 minutes on average ($P<.001$). There was no significant

difference between the potential travel distance and travel time the telemedicine group would have faced if required to travel to an in-clinic appointment and the actual travel distance and travel time faced by the control group. The groups also did not differ significantly in patients' absence from work due to their appointments. Nevertheless, of the employed patients, only 5% (1/20) were absent from work so they could attend the appointment in the telemedicine group, compared with 16% (3/19) in the control group, as shown with the Fisher exact test (P=.34). In the telemedicine group, 1 patient had to visit the clinic again for further treatment. As this would also have been required after an F2F consultation and, therefore, occurred independently of the video consultation, this additional visit was not included in the cost calculation.

Table 1. Demographic characteristics of patients.

Characteristics	Telemedicine group (n=26), n (%)	Control group (n=26), n (%)	P value[a]
Medical indication			.99
Knee	10 (38)	9 (35)	
Shoulder	16 (62)	17 (65)	
Age (years)			.36
18-40	7 (27)	5 (19)	
41-60	17 (65)	15 (58)	
>60	2 (8)	6 (23)	
Female	11 (42)	10 (38)	.99
Employed	20 (77)	19 (76)[b]	.99

[a]P values were based on the Fisher exact test.

[b]Percentage of n=25 due to missing item on questionnaire.

Table 2. Variables included for cost calculation.

Variables	Telemedicine group (n=26)			Control group (n=26)			P value[a]
	Participants, n (%)	Mean (SD)	Median (IQR)	Participants, n (%)	Mean (SD)	Median (IQR)	
Treatment duration (minutes)	26 (100)	8.23 (4.45)	6.00 (5-10)	25 (96)	10.92 (5.58)	10.00 (8-14.5)	.02
Travel distance (kilometers)	26 (100)	37.00 (32.06)	30.00 (10-46.25)	25 (96)	31.58 (22.62)	28.00 (15.5-45)	.65
Actual and potential travel time (minutes)	26 (100)	38.46 (21.72)	40.00 (18.75-46.25)	25 (96)	34.80 (20.89)	30.00 (20-40)	.42
Waiting time (minutes)	26 (100)	6.73 (6.84)	5.00 (1.75-10)	24 (92)	36.88 (27.54)	30.00 (15-48.75)	<.001
Total time spent on appointment (minutes)	26 (100)	21.92 (10.40)	22.50 (13.75-30)	25 (96)	154.80 (79.75)	150.00 (105-197.5)	<.001

[a]P values were based on the Mann-Whitney U test.

Patients' Perspectives

The cost calculation from the patients' point of view in the societal perspective showed that patients in the control group had to pay an average of €18.95 in travel costs, based on a cost of €0.30 for each kilometer travelled to and from the clinic, as shown in Table 3. There were no travel costs for patients in the telemedicine group because they did not have to attend the clinic. If they had had an in-clinic follow-up, however, their average travel costs would have been €22.20.

The time costs resulting from follow-up appointments in both groups were estimated at €16.00 per hour to account for both unpaid work time and leisure time that patients lost. The average cost of patients' travel time was €18.56 in the control group. Again, patients in the telemedicine group faced no travel time costs due to the trip they avoided. Yet, the potential cost of their travel time would have been €20.51. The increased waiting time in the clinic was reflected in time costs of €9.83 in the control group, compared with €1.79 in the intervention group.

The difference in time costs between the groups became even more pronounced when the total time patients spent on their follow-up appointments was valued. Whereas patients with a telemedical appointment had average total time costs of €5.85, those with an in-clinic appointment had total time costs of €41.28. In other words, a telemedical rather than an in-clinic

follow-up appointment would have saved patients €35.43 in average time costs.

Finally, the production loss due to patients' absence from work while they were attending their appointments was calculated. This was based on an average hourly wage of €29.48 in Germany and an overall average of 6.96 working hours per day per full-time or part-time German employee. With 1 patient absent in the telemedicine group and 3 patients absent in the control group, total production losses were €205.18 and €615.54, respectively. With 20 employed patients in the telemedicine group and 19 employed patients in the control group, the costs due to lost production averaged €10.26 for a telemedical follow-up and €32.40 for an in-clinic one.

Taking employment status into account, the total costs of a follow-up appointment were €16.11 for an employed patient in the telemedicine group and €92.63 for an employed patient in the control group. For an unemployed patient, the total costs decreased to €5.85 in the telemedicine group and to €60.23 in the control group due to the irrelevant production loss. Multimedia Appendix 2 presents the cost calculations in detail.

Table 3. Cost calculation from the patients' perspective.

Costs	Telemedicine group	Control group	Difference
Travel costs (€[a]), mean (SD)	0 (0)	18.95 (13.57)	18.95
Travel time costs (€), mean (SD)	0 (0)	18.56 (11.14)	18.56
Waiting time costs (€), mean (SD)	1.79 (1.82)	9.83 (7.34)	8.04
Total time costs (€), mean (SD)	5.85 (2.77)	41.28 (21.27)	35.43
Production loss (€)	205.18	615.54	410.36

[a]A currency exchange rate of €1=US $0.97 is applicable.

Environmental Impact

To calculate the emissions saved in the telemedicine group due to the avoided trips to and from the clinic, 152 g/pkm for greenhouse gases, 0.94 g/pkm for carbon monoxide, 0.15 g/pkm for volatile hydrocarbons, 0.38 g/pkm for nitrogen oxides, and 0.006 g/pkm for particulates were applied based on an average car occupancy of 1.4 passengers. This led to the result that around 11.248 kg of greenhouse gases, 0.070 kg of carbon monoxide, 0.011 kg of volatile hydrocarbons, 0.028 kg of nitrogen oxides, and 0.0004 kg of particulates were saved per patient with the help of video consultations. Table 4 also shows the total emissions saved for the 26 patients in the telemedicine group. For example, as a result of the video consultations, emissions of 292.448 kg of greenhouse gases could be avoided in our study. The calculation of environmental costs saved in the telemedicine group is based on environmental costs of €0.05045 per pkm. This value represents the average environmental costs of gasoline and diesel powered cars. The use of telemedicine saved approximately €3.73 in environmental costs per patient, resulting in a total of €97.07 for all patients in our study. Finally, the potential savings can also be seen in the model calculation for 1 year if 8 patients per week had a video consultation instead of a clinic consultation, as was the case in our study. For this calculation, the average distance between the home of the patients in the telemedicine group and control group and the clinic was used. With a total of 384 patients who would not have to travel to the clinic each year due to video consultations, a total of 4009.88 kg of greenhouse gases, 24.80 kg of carbon monoxide, 3.96 kg of volatile hydrocarbons, 10.02 kg of nitrogen oxides, and 0.16 kg of particulates could be avoided. In addition, at €195 per ton of carbon dioxide equivalent, €1330.91 in environmental costs could be saved.

Table 4. Saved emissions and environmental costs in the telemedicine group.

Emissions and costs	Per patient	Total
Greenhouse gases (kg)	11.248	292.448
Carbon monoxide (kg)	0.070	1.809
Volatile hydrocarbons (kg)	0.011	0.289
Nitrogen oxides (kg)	0.028	0.731
Particulates (kg)	0.0004	0.012
Environmental costs (€[a])	3.73	97.07

[a]A currency exchange rate of €1=US $0.97 is applicable.

Sensitivity Analysis

In the subsequent sensitivity analysis, several adjustments were made. First, the cost calculation from the patients' point of view was modified to test the effect of alternative assumptions on the valuation of production losses. Assuming that all patients who were absent from work were employed full time (ie, 8.2 hours per day), the societal cost of lost production would have increased to €241.74 (mean €12.09, SD 54.05) in the telemedicine group and to €725.21 (mean €38.17, SD 90.56)

in the control group. In contrast, assuming only part-time employment of 3.9 hours per day for all patients who were absent from work, the costs of lost production would have decreased to €114.97 (mean €5.75, SD 25.71) in the telemedicine group and to €344.92 (mean €18.15, SD 43.07) in the control group. These assumptions would have changed the total costs for employed patients to €17.94 for full-time employees and €11.60 for part-time employees in the telemedicine group, as well as to €98.40 for full-time employees and €78.38 for part-time employees in the control group.

Second, the calculation of environmental costs was adjusted to the cost rate of €680 per ton of carbon dioxide equivalent, which increased the average environmental costs of gasoline and diesel cars to €0.12885 per pkm. Due to this adjustment, the environmental costs saved in the telemedicine group would have been €9.53 per patient and €247.91 in total.

In addition, if a total of 16 patients per week had a video consultation instead of a clinic consultation, approximate emissions of 8019.76 kg of greenhouse gases, 49.60 kg of carbon monoxide, 7.91 kg of volatile hydrocarbons, 20.05 kg of nitrogen oxides, and 0.32 kg of particulates could be saved. Environmental costs could furthermore be reduced by €2661.82, at €195 per ton of carbon dioxide equivalent, or by €6798.33, at €680 per ton of carbon dioxide equivalent.

Discussion

Principal Findings

This analysis of the economics of using telemedicine in follow-up care for patients in orthopedic and trauma surgery in a German university hospital showed that implementing video consultations enabled time and cost savings for patients, savings in environmental costs, and reductions in emissions.

Implications for Patients

Seen from the patients' point of view in the societal perspective of the health economic analysis, the use of telemedicine was not associated with additional costs (eg, out-of-pocket payments) for the patients in our study. On the contrary, compared with the control group, telemedical appointments resulted in cost savings due to the avoidance of travel and the reduction in time costs.

Previous economic evaluations by Buvik et al [36] and Ohinmaa et al [37] also showed that telemedicine saved travel time and travel distance—and, thus, travel costs—in sparsely populated Scandinavian countries even though patients had to travel to a local caregiver for their appointment [36,37]. Similarly, RCTs by Sathiyakumar et al [9] and Kane et al [12] found savings in travel distances and time spent as well, but these studies did not feature economic analyses [9,12]. Reducing travel burdens is an important societal benefit of telemedicine, as it can ensure better access to medical care. In particular, patients in rural regions and hospitals that seek to offer their medical services beyond their own region stand to benefit. At the same time, however, all patients must still be able to reach their local clinic when video consultations are not sufficient.

Since our trial ended in 2021, our analysis did not consider the energy pricing dynamics following the 2022 European energy crisis. Actual savings in travel costs could be far higher in future digital health deployments.

In addition, the results of the analysis showed that the average costs of lost production were lower for a video consultation compared to a clinical consultation, indicating that telemedicine may have a positive impact in this regard as well. The potential of telemedicine to reduce lost work time—and, thus, production losses—reported here is consistent with the findings of other RCTs [9,12,36,37].

From a societal point of view, the use of telemedicine saved average total costs for employed patients of €76.52 per follow-up appointment, ranging from €66.78 to €80.46 in the sensitivity analysis. Most likely, the real savings would be even higher, as patients often wish or require an accompanying person for a clinic consultation, and the cost and time savings of companions were not considered in the study. The finding that video consultations save overall costs compared with conventional F2F examinations in follow-up care is also confirmed by Buvik et al's [36] analysis. It should be noted, however, that in our calculation patient time lost due to a follow-up appointment was assigned a monetary value independently of any production losses, because including such time costs is strongly recommended in health economic methodology [28,30].

Implications for the Environment

In addition, from the environmental point of view in the societal perspective, our analysis showed that for each patient who received a video consultation instead of a clinic consultation, emissions of 11.248 kg of greenhouse gases, 0.070 kg of carbon monoxide, 0.011 kg of volatile hydrocarbons, 0.028 kg of nitrogen oxides, and 0.0004 kg of particulates could be saved due to avoiding traveling by car. International studies have also demonstrated the reduction of emissions through the use of telemedicine, although the level of individual emissions differs in the respective studies [38,39]. For example, in a study by Udayaraj et al [23], telemedicine led to a reduction of 3527 miles and saved 1035 kg of carbon dioxide for kidney transplant patients in the United Kingdom. A retrospective analysis of patients in vascular surgery in the United States by Paquette and Lin [24] found a reduction of 1632 kg of carbon dioxide; 42,867 g of carbon monoxide; and 3160 g of nitric oxides by performing a total of 146 telemedicine encounters. In addition, based on Spanish data, a study by Vidal-Alaball et al [25] showed an average reduction of 3248.3 g of carbon dioxide, 4.05 g of carbon monoxide, and 4.86 g of nitric oxides per patient in a telemedicine program that included different specialties.

In our study, up to 8 patients could be treated weekly via telemedicine, which can lead to an annual improvement in the environmental footprint for a single German university orthopedic and trauma surgery department alone. Although the performance of telemedicine is not suitable for all patients in orthopedic and trauma surgery, the reduction in emissions could be improved by increasing the number of patients treated by video consultations each week. If the number of patients were

expanded to the 1903 hospitals in Germany and included specialties suitable for telemedicine, such as general and visceral surgeries or dermatology, the call of the 125th German Medical Assembly in 2021 for a net-zero German health care system could be substantially supported [22].

In addition to the emission savings themselves, our study also showed that the introduction of telemedicine can also contribute to a reduction in environmental costs from the societal perspective.

Implications for Practice

This health economic analysis provides clinical evidence that can improve stakeholders' decision-making on implementing telemedicine both in and beyond the current COVID-19 pandemic. It was shown that the use of telemedicine in the follow-up care of orthopedic and trauma surgery benefits both patients and the environment from an economic perspective. Given the pragmatic design of this study, it can be expected that its main findings can be applied by decision makers in other clinical contexts as well.

When deciding whether to implement telemedicine, however, health care providers should consider other aspects besides the economic and environmental benefits. First, the quality of care provided by telemedicine must be ensured. Patient and physician satisfaction, efficiency, and the safety of the video consultations in terms of the same clinical outcomes achieved in F2F consultations play an important role. Various studies show that these goals can be achieved by introducing telemedicine in orthopedic and trauma surgery [6-12]. In addition, we have extensively analyzed patient and physician satisfaction, as well as quality of care for the study cohort in a previous publication [13]. Second, the costs of the technological infrastructure for telemedicine (eg, for electricity, internet connection, and hardware, such as computers and laptops with cameras and microphones) have to be considered. This infrastructure, however, is expected to be part of the standard equipment in most hospitals, as was the case in our study.

Limitations

This study also has some limitations that should be noted. First, although the results were primarily based on actual data collected in the course of an RCT, some assumptions had to be made to be able to calculate costs. Travel costs saved, for example, were calculated based on the assumption that patients have their video consultations at home. In fact, they could have them anywhere, meaning that patients' actual travel costs from that place to the hospital may well be higher or lower. The distance from home and the time spent on the appointments (eg, travel and waiting times) were furthermore queried via a questionnaire, and the actual distances and times could potentially differ slightly from the information provided by the patients. In addition, the original calculation of production loss lacked information on whether patients were employed full time or part time. For this reason, a sensitivity analysis sought to identify possible deviations and to evaluate the robustness of the findings.

Furthermore, given that data on time costs for German patients were missing in the literature, Verbooy et al's [30] valuation approach was used, which was based on Dutch data. However, assuming that the Dutch population is reasonably similar to the German one, this minor inconsistency appears unlikely to have distorted overall results.

Finally, one of the inclusion criteria of the study was patients' ownership of a technical device (smartphone, computer, etc) that allowed them to make video calls. This requirement could lead to socioeconomic inequalities being exacerbated, because only patients with adequate financial means might be able to benefit from cost savings due to telemedicine [40]. This inequity could not be avoided within the study, but it is an important issue with practical relevance and should be taken into account by policy makers.

Conclusions

The use of telemedicine was found to reduce the environmental footprint and to save travel costs, travel time, and time costs for patients, and it helped to lower production losses from a societal perspective compared to F2F consultations in Germany. Thus, telemedicine helps to reduce costs in multiple dimensions. These results were demonstrated in the first health economic analysis of the use of telemedicine in follow-up care for patients with knee and shoulder disorders in orthopedic and trauma surgery, based on data from Germany. Simultaneously, this study provided economic and environmental evidence supporting stakeholders, such as hospitals, patients, and policy makers, who may consider extending the use of telemedicine in and beyond the COVID-19 pandemic. In addition, these findings might be relevant beyond the medical specialty of orthopedic and trauma surgery; they could be applied to other clinical contexts and to a wide range of potential digital health applications that substitute outpatient hospital visits with video consultations.

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Data Availability

The data sets generated and analyzed during this study are available from the corresponding author upon reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Consolidated Standards of Reporting Trials (CONSORT) flow diagram.
[DOCX File , 87 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Detailed presentation of cost calculations.
[DOCX File , 30 KB-Multimedia Appendix 2]

Multimedia Appendix 3

CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 345 KB-Multimedia Appendix 3]

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Abbreviations

CONSORT: Consolidated Standards of Reporting Trials
F2F: face-to-face
pkm: passenger-kilometer
RCT: randomized controlled trial

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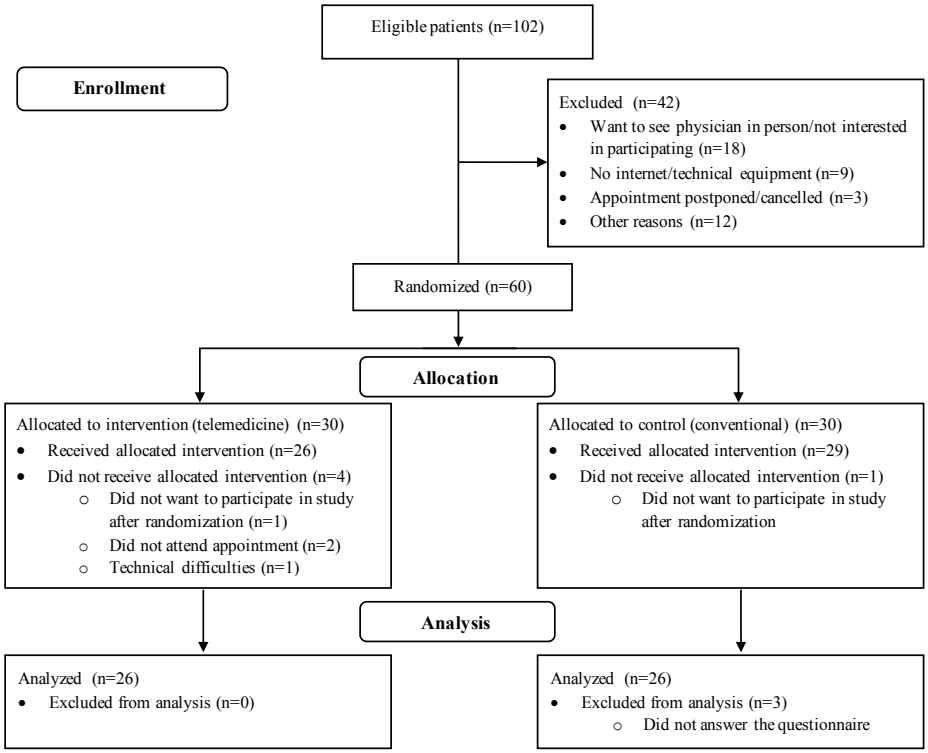
Multimedia Appendix 1:

CONSORT (Consolidated Standards of Reporting Trials) flow diagram



Multimedia Appendix 2: Detailed presentation of cost calculations

Table S1: Detailed presentation of cost calculation from the patients' point of view

	Telemedicine group		**Control group**	
	Calculation	(Mean) Costs	Calculation	(Mean) Costs
Average travel costs	0 (Potential: 37.00 km x 2 x 0.3)	€0 (Potential: €22.20)	31.58 km x 2 x 0.3	€18.95
Average travel time costs	0 (Potential: 38.46 minutes x 2 x (€16/60 minutes))	0 (Potential: €20.51)	34.8 minutes x 2 x (€16/60 minutes)	€18.56
Average waiting time costs	6.73 minutes x (€16/60 minutes)	€1.79	36.88 minutes x (€16/60 minutes)	€9.83
Average total time costs	21.92 minutes x (€16/60 minutes)	€5.85	154.8 minutes x (€16/60 minutes)	€41.28
Production loss	((34.8 hours/5 days) x €29.48 x 1 patient)/20 patients	Total: €205.18 Mean: €10.26	((34.8 hours/5 days) x €29.48 x 3 patient)/19 patients	Total: €615.54 Mean: €32.40
Total costs	Patients in employment: Travel costs + Total time costs + Production loss Patients not in employment: Travel costs + Total time costs	Patients in employment: €16.11 Patients not in employment: €5.85	Patients in employment: Travel costs + Total time costs + Production loss Patients not in employment: Travel costs + Total time costs	Patients in employment: €92.63 Patients not in employment: €60.23

Table S2: Detailed presentation of cost calculation of the environmental impact

	Per patient		**In total**	
	Calculation	Emissions/costs	Calculation	Emissions/costs
Greenhouse gases	(37.0 km x 2 x 152 g/pkm)/ 1000	11.248 kg	((37.0 km x 2 x 152 g/pkm)/ 1000) x 26	292.448 kg
Carbon monoxide	(37.0 km x 2 x 0.94 g/pkm)/ 1000	0.070 kg	((37.0 km x 2 x 0.94 g/pkm)/ 1000) x 26	1.809 kg
Volatile hydrocarbons	(37.0 km x 2 x 0.15 g/pkm)/ 1000	0.011 kg	((37.0 km x 2 x 0.15 g/pkm)/ 1000) x 26	0.289 kg
Nitrogen oxides	(37.0 km x 2 x 0.38 g/pkm)/ 1000	0.028 kg	((37.0 km x 2 x 0.38 g/pkm)/ 1000) x 26	0.731 kg
Particulates	(37.0 km x 2 x 0.006 g/pkm)/ 1000	0.0004 kg	((37.0 km x 2 x 0.006 g/pkm)/ 1000) x 26	0.012 kg
Environmental costs per €195 per ton of carbon dioxide equivalent	37.0 km x 2 x €0.05045/pkm	€3.73	(37.0 km x 2 x €0.05045/pkm) x 26	€97.07
Environmental costs per €680 per ton of carbon dioxide equivalent	37.0 km x 2 x €0.12885/pkm	€9.53	(37.0 km x 2 x €0.12885/pkm) x 26	€247.91

Multimedia Appendix 3: CONSORT-eHEALTH checklist (V 1.6.1)

CONSORT-EHEALTH (V 1.6.1) - Submission/Publication Form

The CONSORT-EHEALTH checklist is intended for authors of randomized trials evaluating web-based and Internet-based applications/interventions, including mobile interventions, electronic games (incl multiplayer games), social media, certain telehealth applications, and other interactive and/or networked electronic applications. Some of the items (e.g. all subitems under item 5 - description of the intervention) may also be applicable for other study designs.

The goal of the CONSORT EHEALTH checklist and guideline is to be
a) a guide for reporting for authors of RCTs,
b) to form a basis for appraisal of an ehealth trial (in terms of validity)

CONSORT-EHEALTH items/subitems are MANDATORY reporting items for studies published in the Journal of Medical Internet Research and other journals / scientific societies endorsing the checklist.

Items numbered 1., 2., 3., 4a., 4b etc are original CONSORT or CONSORT-NPT (non-pharmacologic treatment) items.
Items with Roman numerals (i., ii, iii, iv etc.) are CONSORT-EHEALTH extensions/clarifications.

As the CONSORT-EHEALTH checklist is still considered in a formative stage, we would ask that you also RATE ON A SCALE OF 1-5 how important/useful you feel each item is FOR THE PURPOSE OF THE CHECKLIST and reporting guideline (optional).

Mandatory reporting items are marked with a red *.
In the textboxes, either copy & paste the relevant sections from your manuscript into this form - please include any quotes from your manuscript in QUOTATION MARKS,
or answer directly by providing additional information not in the manuscript, or elaborating on why the item was not relevant for this study.

YOUR ANSWERS WILL BE PUBLISHED AS A SUPPLEMENTARY FILE TO YOUR PUBLICATION IN JMIR AND ARE CONSIDERED PART OF YOUR PUBLICATION (IF ACCEPTED).
Please fill in these questions diligently. Information will not be copyedited, so please use proper spelling and grammar, use correct capitalization, and avoid abbreviations.

DO NOT FORGET TO SAVE AS PDF _AND_ CLICK THE SUBMIT BUTTON SO YOUR ANSWERS ARE IN OUR DATABASE !!!

Citation Suggestion (if you append the pdf as Appendix we suggest to cite this paper in the caption):
Eysenbach G, CONSORT-EHEALTH Group

CONSORT-EHEALTH: Improving and Standardizing Evaluation Reports of Web-based and Mobile Health Interventions
J Med Internet Res 2011;13(4):e126
URL: http://www.jmir.org/2011/4/e126/
doi: 10.2196/jmir.1923
PMID: 22209829

* Required

Your name *
First Last

Jennifer Muschol

Primary Affiliation (short), City, Country *
University of Toronto, Toronto, Canada

Justus Liebig University Giessen, Giessen, Ger

Your e-mail address *
abc@gmail.com

Jennifer.Muschol@wirtschaft.uni-giessen.de

Title of your manuscript *
Provide the (draft) title of your manuscript.

Economic and Environmental Impact of Digital Health App Video Consultations in Follow-up Care for Patients in Orthopedic and Trauma Surgery in Germany: Randomized Controlled Trial

Name of your App/Software/Intervention *

If there is a short and a long/alternate name, write the short name first and add the long name in brackets.

CLICKDOC

Evaluated Version (if any)

e.g. "V1", "Release 2017-03-01", "Version 2.0.27913"

Your answer

Language(s) *

What language is the intervention/app in? If multiple languages are available, separate by comma (e.g. "English, French")

German

URL of your Intervention Website or App

e.g. a direct link to the mobile app on app in appstore (itunes, Google Play), or URL of the website. If the intervention is a DVD or hardware, you can also link to an Amazon page.

https://clickdoc.elvi.de/#/login

URL of an image/screenshot (optional)

Your answer

Accessibility *

Can an enduser access the intervention presently?

- ○ access is free and open
- ○ access only for special usergroups, not open
- ◉ access is open to everyone, but requires payment/subscription/in-app purchases
- ○ app/intervention no longer accessible
- ○ Other:

Primary Medical Indication/Disease/Condition *

e.g. "Stress", "Diabetes", or define the target group in brackets after the condition, e.g. "Autism (Parents of children with)", "Alzheimers (Informal Caregivers of)"

Orthopedic and trauma surgery follow-up

Primary Outcomes measured in trial *

comma-separated list of primary outcomes reported in the trial

Patient satisfaction (reported in another paper

Secondary/other outcomes

Are there any other outcomes the intervention is expected to affect?

Economic impact, Environmental impact

Recommended "Dose" *

What do the instructions for users say on how often the app should be used?

- ○ Approximately Daily
- ○ Approximately Weekly
- ○ Approximately Monthly
- ○ Approximately Yearly
- ○ "as needed"
- ◉ Other: One-time video consultation

Approx. Percentage of Users (starters) still using the app as recommended after 3 months *

- ◉ unknown / not evaluated
- ○ 0-10%
- ○ 11-20%
- ○ 21-30%
- ○ 31-40%
- ○ 41-50%
- ○ 51-60%
- ○ 61-70%
- ○ 71%-80%
- ○ 81-90%
- ○ 91-100%
- ○ Other:

Overall, was the app/intervention effective? *

- ○ yes: all primary outcomes were significantly better in intervention group vs control
- ○ partly: SOME primary outcomes were significantly better in intervention group vs control
- ○ no statistically significant difference between control and intervention
- ○ potentially harmful: control was significantly better than intervention in one or more outcomes
- ○ inconclusive: more research is needed
- ◉ Other: Better health economic outcome for intervention group, but no statisti

Article Preparation Status/Stage *

At which stage in your article preparation are you currently (at the time you fill in this form)

- ○ not submitted yet - in early draft status
- ○ not submitted yet - in late draft status, just before submission
- ○ submitted to a journal but not reviewed yet
- ○ submitted to a journal and after receiving initial reviewer comments
- ◉ submitted to a journal and accepted, but not published yet
- ○ published
- ○ Other:

Journal *

If you already know where you will submit this paper (or if it is already submitted), please provide the journal name (if it is not JMIR, provide the journal name under "other")

- ○ not submitted yet / unclear where I will submit this
- ◉ Journal of Medical Internet Research (JMIR)
- ○ JMIR mHealth and UHealth
- ○ JMIR Serious Games
- ○ JMIR Mental Health
- ○ JMIR Public Health
- ○ JMIR Formative Research
- ○ Other JMIR sister journal
- ○ Other:

Is this a full powered effectiveness trial or a pilot/feasibility trial? *

- ○ Pilot/feasibility
- ◉ Fully powered

Manuscript tracking number *

If this is a JMIR submission, please provide the manuscript tracking number under "other" (The ms tracking number can be found in the submission acknowledgement email, or when you login as author in JMIR. If the paper is already published in JMIR, then the ms tracking number is the four-digit number at the end of the DOI, to be found at the bottom of each published article in JMIR)

- ○ no ms number (yet) / not (yet) submitted to / published in JMIR
- ◉ Other: ms#42839

TITLE AND ABSTRACT

1a) TITLE: Identification as a randomized trial in the title

1a) Does your paper address CONSORT item 1a? *

I.e does the title contain the phrase "Randomized Controlled Trial"? (if not, explain the reason under "other")

- ◉ yes
- ○ Other:

1a-i) Identify the mode of delivery in the title

Identify the mode of delivery. Preferably use “web-based” and/or “mobile” and/or “electronic game” in the title. Avoid ambiguous terms like “online”, “virtual”, “interactive”. Use “Internet-based” only if Intervention includes non-web-based Internet components (e.g. email), use “computer-based” or “electronic” only if offline products are used. Use “virtual” only in the context of “virtual reality” (3-D worlds). Use “online” only in the context of “online support groups”. Complement or substitute product names with broader terms for the class of products (such as “mobile” or “smart phone” instead of “iphone”), especially if the application runs on different platforms.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 1a-i? *

Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Digital Health App Video Consultations in Follow-up Care"

1a-ii) Non-web-based components or important co-interventions in title

Mention non-web-based components or important co-interventions in title, if any (e.g., "with telephone support").

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 1a-ii?

Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

1a-iii) Primary condition or target group in the title

Mention primary condition or target group in the title, if any (e.g., "for children with Type I Diabetes") Example: A Web-based and Mobile Intervention with Telephone Support for Children with Type I Diabetes: Randomized Controlled Trial

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 1a-iii? *

Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Patients in Orthopedic and Trauma Surgery in Germany"

1b) ABSTRACT: Structured summary of trial design, methods, results, and conclusions

NPT extension: Description of experimental treatment, comparator, care providers, centers, and blinding status.

1b-i) Key features/functionalities/components of the intervention and comparator in the METHODS section of the ABSTRACT

Mention key features/functionalities/components of the intervention and comparator in the abstract. If possible, also mention theories and principles used for designing the site. Keep in mind the needs of systematic reviewers and indexers by including important synonyms. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 1b-i? *

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"We conducted a prospective randomized controlled trial in a German university hospital comparing follow-up care with digital health app video consultations (intervention group) to conventional face-to-face consultations in the clinic (control group)."

1b-ii) Level of human involvement in the METHODS section of the ABSTRACT

Clarify the level of human involvement in the abstract, e.g., use phrases like “fully automated” vs. “therapist/nurse/care provider/physician-assisted” (mention number and expertise of providers involved, if any). (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 1b-ii?

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

1b-iii) Open vs. closed, web-based (self-assessment) vs. face-to-face assessments in the METHODS section of the ABSTRACT

Mention how participants were recruited (online vs. offline), e.g., from an open access website or from a clinic or a closed online user group (closed usergroup trial), and clarify if this was a purely web-based trial, or there were face-to-face components (as part of the intervention or for assessment). Clearly say if outcomes were self-assessed through questionnaires (as common in web-based trials). Note: In traditional offline trials, an open trial (open-label trial) is a type of clinical trial in which both the researchers and participants know which treatment is being administered. To avoid confusion, use “blinded” or “unblinded” to indicated the level of blinding instead of “open”, as “open” in web-based trials usually refers to “open access” (i.e. participants can self-enrol). (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 1b-iii?

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

1b-iv) RESULTS section in abstract must contain use data

Report number of participants enrolled/assessed in each group, the use/uptake of the intervention (e.g., attrition/adherence metrics, use over time, number of logins etc.), in addition to primary/secondary outcomes. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 1b-iv?

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

1b-v) CONCLUSIONS/DISCUSSION in abstract for negative trials

Conclusions/Discussions in abstract for negative trials: Discuss the primary outcome - if the trial is negative (primary outcome not changed), and the intervention was not used, discuss whether negative results are attributable to lack of uptake and discuss reasons. (Note: Only report in the abstract what the main paper is reporting. If this information is missing from the main body of text, consider adding it)

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 1b-v?

Copy and paste relevant sections from the manuscript abstract (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

INTRODUCTION

2a) In INTRODUCTION: Scientific background and explanation of rationale

2a-i) Problem and the type of system/solution

Describe the problem and the type of system/solution that is object of the study: intended as stand-alone intervention vs. incorporated in broader health care program? Intended for a particular patient population? Goals of the intervention, e.g., being more cost-effective to other interventions, replace or complement other solutions? (Note: Details about the intervention are provided in "Methods" under 5)

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 2a-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Following the global pandemic response, there has been an increasing interest in telemedicine in clinical practice to reduce the potential disease spread, but also in science, which is reflected in a growing number of literature reviews [2,15–20]. The number of clinical trials, however, remains limited. In particular, there are only few health economic analyses of the use of telemedicine in orthopedic and trauma surgery follow-up care [15,21]. In addition to patient satisfaction and quality of care, the societal perspective needs to consider both economic and environmental effects in order to support stakeholders in deciding whether to implement telemedicine in orthopedic and trauma surgery."

2a-ii) Scientific background, rationale: What is known about the (type of) system

Scientific background, rationale: What is known about the (type of) system that is the object of the study (be sure to discuss the use of similar systems for other conditions/diagnoses, if appropiate), motivation for the study, i.e. what are the reasons for and what is the context for this specific study, from which stakeholder viewpoint is the study performed, potential impact of findings [2]. Briefly justify the choice of the comparator.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 2a-ii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"When used for outpatient follow-up care in orthopedic and trauma surgery, for example, video consultations can relieve patients of any restrictions on their mobility or of the need to travel long distances [3–5]. Patient satisfaction, physician satisfaction, and clinical outcomes often show comparable results between telemedicine and conventional face to face (F2F) examinations in the hospital, demonstrating that video consultations can be a safe and efficient alternative for patient care in orthopedic and trauma surgery [6–13]."

2b) In INTRODUCTION: Specific objectives or hypotheses

Does your paper address CONSORT subitem 2b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The aim of this study is to provide the first health economic analysis comparing telemedicine in the follow-up of orthopedic and trauma surgery patients with knee and shoulder disorders with conventional F2F examinations in the clinic for Germany. The analysis focuses on the societal perspective, considering on the one hand the patients' point of view in terms of potential time and cost savings and on the other hand the environmental impact regarding potential savings of emissions and environmental costs."

METHODS

3a) Description of trial design (such as parallel, factorial) including allocation ratio

Does your paper address CONSORT subitem 3a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The data used for the health economic analysis were obtained by a prospective RCT conducted at a single German university hospital (University Hospital Giessen, Department of Trauma, Hand and Reconstructive Surgery, Level 1 trauma center) between September 2020 and April 2021. The RCT is reported according to the Consolidated Standards of Reporting Trials (CONSORT)[26]. Orthopedic and trauma surgery patients were randomly assigned 1:1 to an intervention group or a control group for a single follow-up appointment."

3b) Important changes to methods after trial commencement (such as eligibility criteria), with reasons

Does your paper address CONSORT subitem 3b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable for our study.

3b-i) Bug fixes, Downtimes, Content Changes

Bug fixes, Downtimes, Content Changes: ehealth systems are often dynamic systems. A description of changes to methods therefore also includes important changes made on the intervention or comparator during the trial (e.g., major bug fixes or changes in the functionality or content) (5-iii) and other “unexpected events” that may have influenced study design such as staff changes, system failures/downtimes, etc. [2].

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 3b-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

4a) Eligibility criteria for participants

Does your paper address CONSORT subitem 4a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Inclusion criteria
18 years or older
Previous outpatient or inpatient stay at the clinic (with an operation or conservative therapy)
Need of a follow-up that does not require more than a visual examination
Ownership of a computer, laptop, tablet, or smartphone with microphone and camera
Stable internet connection
Mental and physical ability to consent and to participate
Sufficient knowledge of German in order to understand the declaration of consent
Shoulder ICD-10 codes:
M75.1, M75.6, M75.0, Z96.60, M75.4, M19.91, S43.1, S42.20, S42.00, M75.2, M75.3, S43.0
Knee ICD-10 codes:
S83.53, S83.54, S83.2, S83.0, M22.0, M23.32, M23.35, M17.1, M17.5, M21.16, M21.06, S83.3, S83.44, S83.43, S82.18, S82.0, S72.3, S72.43, M25.56, M76.5, S83.6, S76.1, S86.8"

"Exclusion criteria
Neurological diseases that preclude the use of digital devices
Diagnosis of dementia, blindness or deafness
Need for presence in the clinic and on-site treatment and diagnostic (imaging, laboratory, stitches, drainage)
Appointments where the patient has to be touched and/or moved by the treating physicians
Lack of willingness to participate
Failure to consent"

4a-i) Computer / Internet literacy

Computer / Internet literacy is often an implicit “de facto” eligibility criterion - this should be explicitly clarified.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 4a-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

4a-ii) Open vs. closed, web-based vs. face-to-face assessments:

Open vs. closed, web-based vs. face-to-face assessments: Mention how participants were recruited (online vs. offline), e.g., from an open access website or from a clinic, and clarify if this was a purely web-based trial, or there were face-to-face components (as part of the intervention or for assessment), i.e., to what degree got the study team to know the participant. In online-only trials, clarify if participants were quasi-anonymous and whether having multiple identities was possible or whether technical or logistical measures (e.g., cookies, email confirmation, phone calls) were used to detect/prevent these.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 4a-ii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Patients who were eligible for the study based on the inclusion and exclusion criteria in Table 1 were asked either at the clinic or by telephone if they wished to participate in the RCT."

4a-iii) Information giving during recruitment

Information given during recruitment. Specify how participants were briefed for recruitment and in the informed consent procedures (e.g., publish the informed consent documentation as appendix, see also item X26), as this information may have an effect on user self-selection, user expectation and may also bias results.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 4a-iii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

4b) Settings and locations where the data were collected

Does your paper address CONSORT subitem 4b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The intervention group did not attend a standard outpatient follow-up appointment in the clinic, but had a real-time online video consultation with the treating physician instead. The control group, on the other hand, was treated conventionally and received a F2F examination in the clinic."

4b-i) Report if outcomes were (self-)assessed through online questionnaires

Clearly report if outcomes were (self-)assessed through online questionnaires (as common in web-based trials) or otherwise.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 4b-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"After the follow-up appointments, patients completed questionnaires in both the intervention and control group."
Intervention group received online questionnaires.
Control group completed the questionnaires in the clinic.

4b-ii) Report how institutional affiliations are displayed

Report how institutional affiliations are displayed to potential participants [on ehealth media], as affiliations with prestigious hospitals or universities may affect volunteer rates, use, and reactions with regards to an intervention.(Not a required item – describe only if this may bias results)

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 4b-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

5) The interventions for each group with sufficient details to allow replication, including how and when they were actually administered

5-i) Mention names, credential, affiliations of the developers, sponsors, and owners

Mention names, credential, affiliations of the developers, sponsors, and owners [6] (if authors/evaluators are owners or developer of the software, this needs to be declared in a “Conflict of interest” section or mentioned elsewhere in the manuscript).

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 5-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

5-ii) Describe the history/development process

Describe the history/development process of the application and previous formative evaluations (e.g., focus groups, usability testing), as these will have an impact on adoption/use rates and help with interpreting results.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 5-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

5-iii) Revisions and updating

Revisions and updating. Clearly mention the date and/or version number of the application/intervention (and comparator, if applicable) evaluated, or describe whether the intervention underwent major changes during the evaluation process, or whether the development and/or content was “frozen” during the trial. Describe dynamic components such as news feeds or changing content which may have an impact on the replicability of the intervention (for unexpected events see item 3b).

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 5-iii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

5-iv) Quality assurance methods

Provide information on quality assurance methods to ensure accuracy and quality of information provided [1], if applicable.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 5-iv?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

5-v) Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used

Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used. Replicability (i.e., other researchers should in principle be able to replicate the study) is a hallmark of scientific reporting.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 5-v?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

5-vi) Digital preservation

Digital preservation: Provide the URL of the application, but as the intervention is likely to change or disappear over the course of the years; also make sure the intervention is archived (Internet Archive, webcitation.org, and/or publishing the source code or screenshots/videos alongside the article). As pages behind login screens cannot be archived, consider creating demo pages which are accessible without login.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 5-vi?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

5-vii) Access

Access: Describe how participants accessed the application, in what setting/context, if they had to pay (or were paid) or not, whether they had to be a member of specific group. If known, describe how participants obtained “access to the platform and Internet” [1]. To ensure access for editors/reviewers/readers, consider to provide a “backdoor” login account or demo mode for reviewers/readers to explore the application (also important for archiving purposes, see vi).

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 5-vii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

On the day of their appointment, the patients received log-in details for the video consultation from their physicians via SMS text message or email. No additional registration was required for the video consultation. At the arranged time, both the attending physician and the patient logged in to the software program, and the video consultation was conducted.

5-viii) Mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework

Describe mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework [6] used to design them (instructional strategy [1], behaviour change techniques, persuasive features, etc., see e.g., [7, 8] for terminology). This includes an in-depth description of the content (including where it is coming from and who developed it) [1]," whether [and how] it is tailored to individual circumstances and allows users to track their progress and receive feedback" [6]. This also includes a description of communication delivery channels and – if computer-mediated communication is a component – whether communication was synchronous or asynchronous [6]. It also includes information on presentation strategies [1], including page design principles, average amount of text on pages, presence of hyperlinks to other resources, etc. [1].

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 5-viii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The video consultations in the intervention group were browser-based for physicians and multi-platform for patients including a digital health app or a browser-based software from a German telemedicine provider. The software complies with the legal requirements in Germany and is recognized by the National Association of Statutory Health Insurance Physicians. The university hospital paid a monthly fee for each physician to use the software. Video consultation procedures were deliberately kept as simple and functional as possible to ensure that they would be viable in regular clinical practice: All video consultations were performed directly between the physicians in the clinic and the patients, regardless of their location. No other medical providers, such as local caregivers or others, were involved. Patients received written instructions on how to conduct the video consultation, and no additional clinical staff were required to assist the patients."

5-ix) Describe use parameters

Describe use parameters (e.g., intended "doses" and optimal timing for use). Clarify what instructions or recommendations were given to the user, e.g., regarding timing, frequency, heaviness of use, if any, or was the intervention used ad libitum.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 5-ix?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

5-x) Clarify the level of human involvement

Clarify the level of human involvement (care providers or health professionals, also technical assistance) in the e-intervention or as co-intervention (detail number and expertise of professionals involved, if any, as well as "type of assistance offered, the timing and frequency of the support, how it is initiated, and the medium by which the assistance is delivered". It may be necessary to distinguish between the level of human involvement required for the trial, and the level of human involvement required for a routine application outside of a RCT setting (discuss under item 21 – generalizability).

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 5-x?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

5-xi) Report any prompts/reminders used

Report any prompts/reminders used: Clarify if there were prompts (letters, emails, phone calls, SMS) to use the application, what triggered them, frequency etc. It may be necessary to distinguish between the level of prompts/reminders required for the trial, and the level of prompts/reminders for a routine application outside of a RCT setting (discuss under item 21 – generalizability).

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 5-xi? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

On the day of their appointment, patients received login details for the video consultation from their physicians via text message or email.

5-xii) Describe any co-interventions (incl. training/support)

Describe any co-interventions (incl. training/support): Clearly state any interventions that are provided in addition to the targeted eHealth intervention, as ehealth intervention may not be designed as stand-alone intervention. This includes training sessions and support [1]. It may be necessary to distinguish between the level of training required for the trial, and the level of training for a routine application outside of a RCT setting (discuss under item 21 – generalizability.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 5-xii? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"All video consultations were performed directly between the physicians in the clinic and the patients, regardless of their location. No other medical providers, such as local caregivers or others, were involved. Patients received written instructions on how to conduct the video consultation, and no additional clinical staff were required to assist the patients."

6a) Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed

Does your paper address CONSORT subitem 6a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"After the follow-up appointments, patients completed questionnaires in both the intervention and control group. These questionnaires included questions about the distance between the patients' homes and the clinic, the amount of time spent for the appointment (eg, travel and waiting time), and the potential need to be absent from work to attend the appointment."
"The health economic analysis was based on data collected in the questionnaires and other official, external data. Study design was guided by recommendations for health economic analyses in the context of eHealth interventions, and the study examined non-healthcare costs associated with the use of telemedicine from a societal perspective [27,28]. The analysis proceeded in two steps. In a first step, economic effects of the societal perspective were examined from the patients' point of view. This involved, firstly, calculating and comparing three types of non-healthcare costs associated with medical appointments: (1) Travel costs were calculated following recommendations for empirical standard costs for health economic evaluations in Germany [29]. (2) Time costs were assessed by assigning monetary values to patients' travel time, waiting time, and total time spent on appointments based on Verbooy et al's [30] valuation approach to unpaid work and leisure time. (3) Production losses due to patients' absence from work while attending their appointments were computed using Germany's average gross hourly wage in 2021 and average working hours for all German full-time and part-time employees in 2019 [31,32]. (...) In a second step, the effects of the societal perspective were evaluated in the form of the environmental impact of telemedicine. The analysis of the environmental impact was conducted using data from the German Federal Environment Agency. It comprised three different aspects. First, the environmental impact in terms of greenhouse gases, carbon monoxides, volatile hydrocarbons, nitrogen oxides, and particulates was calculated (...). Second, the average environmental costs incurred per Pkm by the patients' trips per car were calculated. (...)."

6a-i) Online questionnaires: describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed

If outcomes were obtained through online questionnaires, describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed [9].

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 6a-i?

Copy and paste relevant sections from manuscript text

Your answer

6a-ii) Describe whether and how "use" (including intensity of use/dosage) was defined/measured/monitored

Describe whether and how "use" (including intensity of use/dosage) was defined/measured/monitored (logins, logfile analysis, etc.). Use/adoption metrics are important process outcomes that should be reported in any ehealth trial.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 6a-ii?

Copy and paste relevant sections from manuscript text

Your answer

6a-iii) Describe whether, how, and when qualitative feedback from participants was obtained

Describe whether, how, and when qualitative feedback from participants was obtained (e.g., through emails, feedback forms, interviews, focus groups).

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 6a-iii?

Copy and paste relevant sections from manuscript text

Your answer

6b) Any changes to trial outcomes after the trial commenced, with reasons

Does your paper address CONSORT subitem 6b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable for the study.

7a) How sample size was determined

NPT: When applicable, details of whether and how the clustering by care provides or centers was addressed

7a-i) Describe whether and how expected attrition was taken into account when calculating the sample size

Describe whether and how expected attrition was taken into account when calculating the sample size.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 7a-i?

Copy and paste relevant sections from manuscript title (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

7b) When applicable, explanation of any interim analyses and stopping guidelines

Does your paper address CONSORT subitem 7b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Termination criteria were established for the individual study participants. (1) The occurrence of disease symptoms that required the physical presence of the patient in the clinic. (2) Occurrence of technical problems that could not be solved in the short term. (3) Voluntary termination of the study at any time by the study participant, without giving reasons and without any disadvantage for the further treatment.
These criteria as well as unexcused absences from the consultation resulted in the recording of the study participants as dropouts/withdrawals. Patients were then treated regularly and independently of the study in the clinic.

8a) Method used to generate the random allocation sequence
NPT: When applicable, how care providers were allocated to each trial group

Does your paper address CONSORT subitem 8a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Orthopedic and trauma surgery patients were randomly assigned 1:1 to an intervention group or a control group for a single follow-up appointment."

8b) Type of randomisation; details of any restriction (such as blocking and block size)

Does your paper address CONSORT subitem 8b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Using block randomization with randomly varying block sizes (4, 6, and 8), 30 patients were assigned to a follow-up with telemedicine (intervention group) and 30 patients to a conventional F2F follow-up in the clinic (control group)."

9) Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned

Does your paper address CONSORT subitem 9? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The parallel-design randomization and assignment process was performed independently of the treating physicians by study staff using sealed envelopes."

10) Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions

Does your paper address CONSORT subitem 10? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The parallel-design randomization and assignment process was performed independently of the treating physicians by study staff using sealed envelopes."

11a) If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how
NPT: Whether or not administering co-interventions were blinded to group assignment

11a-i) Specify who was blinded, and who wasn't

Specify who was blinded, and who wasn't. Usually, in web-based trials it is not possible to blind the participants [1, 3] (this should be clearly acknowledged), but it may be possible to blind outcome assessors, those doing data analysis or those administering co-interventions (if any).

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 11a-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Blinding of physicians or patients was not possible.

11a-ii) Discuss e.g., whether participants knew which intervention was the "intervention of interest" and which one was the "comparator"

Informed consent procedures (4a-ii) can create biases and certain expectations - discuss e.g., whether participants knew which intervention was the "intervention of interest" and which one was the "comparator".

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 11a-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

11b) If relevant, description of the similarity of interventions

(this item is usually not relevant for ehealth trials as it refers to similarity of a placebo or sham intervention to a active medication/intervention)

Does your paper address CONSORT subitem 11b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable for the study.

12a) Statistical methods used to compare groups for primary and secondary outcomes

NPT: When applicable, details of whether and how the clustering by care providers or centers was addressed

Does your paper address CONSORT subitem 12a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The RCT data are presented as mean, median, standard deviation, or percentage. To compare the intervention and control groups, the Mann-Whitney U test was used for continuous variables and the Fisher exact test for categorical ones. Statistical significance was assumed at P=<.05."

12a-i) Imputation techniques to deal with attrition / missing values

Imputation techniques to deal with attrition / missing values: Not all participants will use the intervention/comparator as intended and attrition is typically high in ehealth trials. Specify how participants who did not use the application or dropped out from the trial were treated in the statistical analysis (a complete case analysis is strongly discouraged, and simple imputation techniques such as LOCF may also be problematic [4]).

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 12a-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Data were analyzed based on intention-to-treat.

12b) Methods for additional analyses, such as subgroup analyses and adjusted analyses

Does your paper address CONSORT subitem 12b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Finally, a sensitivity analysis was performed to evaluate the robustness of the findings. For the patients' point of view in the societal perspective, this analysis studied the effect of differentiating between full-time and part-time employment when calculating production losses [32]. For the environmental impact of the societal perspective, the sensitivity analysis considered (1) a cost rate of the Federal Environment Agency for the calculation of the environmental costs of €680 per ton of carbon dioxide equivalent which gives equal weight to the welfare of present and future generations [34,35], and (2) 16 patients with a video consultation per week for the analysis of potential savings in emissions and environmental costs [33–35]. For the calculation of the environmental costs, both €195 and €680 per ton of carbon dioxide equivalent were considered [34,35]. "

X26) REB/IRB Approval and Ethical Considerations [recommended as subheading under "Methods"] (not a CONSORT item)

X26-i) Comment on ethics committee approval

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem X26-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

x26-ii) Outline informed consent procedures

Outline informed consent procedures e.g., if consent was obtained offline or online (how? Checkbox, etc.?), and what information was provided (see 4a-ii). See [6] for some items to be included in informed consent documents.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem X26-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

X26-iii) Safety and security procedures

Safety and security procedures, incl. privacy considerations, and any steps taken to reduce the likelihood or detection of harm (e.g., education and training, availability of a hotline)

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem X26-iii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

RESULTS

13a) For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome

NPT: The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider in each center

Does your paper address CONSORT subitem 13a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Of the 60 patients recruited (intervention group n = 30, control group n = 30), 4 patients in each of the groups withdrew from the study. Thus, data from a total of 52 patients could be considered for the health economic evaluation."

13b) For each group, losses and exclusions after randomisation, together with reasons

Does your paper address CONSORT subitem 13b? (NOTE: Preferably, this is shown in a CONSORT flow diagram) *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Can be found in the CONSORT flow diagram in Appendix 1.

13b-i) Attrition diagram

Strongly recommended: An attrition diagram (e.g., proportion of participants still logging in or using the intervention/comparator in each group plotted over time, similar to a survival curve) or other figures or tables demonstrating usage/dose/engagement.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 13b-i?

Copy and paste relevant sections from the manuscript or cite the figure number if applicable (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

14a) Dates defining the periods of recruitment and follow-up

Does your paper address CONSORT subitem 14a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"The data used for the health economic analysis were obtained by a prospective RCT conducted at a single German university hospital (...) between September 2020 and April 2021."

14a-i) Indicate if critical “secular events” fell into the study period

Indicate if critical “secular events” fell into the study period, e.g., significant changes in Internet resources available or “changes in computer hardware or Internet delivery resources”

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 14a-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

14b) Why the trial ended or was stopped (early)

Does your paper address CONSORT subitem 14b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable for the study.

15) A table showing baseline demographic and clinical characteristics for each group

NPT: When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group

Does your paper address CONSORT subitem 15? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Can be found in Table 2 "Demographic characteristics of patients".

15-i) Report demographics associated with digital divide issues

In ehealth trials it is particularly important to report demographics associated with digital divide issues, such as age, education, gender, social-economic status, computer/Internet/ehealth literacy of the participants, if known.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 15-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Can be found in Table 2 "Demographic characteristics of patients".

16) For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups

16-i) Report multiple “denominators” and provide definitions

Report multiple “denominators” and provide definitions: Report N’s (and effect sizes) “across a range of study participation [and use] thresholds” [1], e.g., N exposed, N consented, N used more than x times, N used more than y weeks, N participants “used” the intervention/comparator at specific pre-defined time points of interest (in absolute and relative numbers per group). Always clearly define “use” of the intervention.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 16-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Can be found in "General Findings". Focus of the paper was the health economic analysis.

16-ii) Primary analysis should be intent-to-treat

Primary analysis should be intent-to-treat, secondary analyses could include comparing only “users”, with the appropriate caveats that this is no longer a randomized sample (see 18-i).

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 16-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

17a) For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)

Does your paper address CONSORT subitem 17a? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Can be found in "General Findings". Focus of the paper was the health economic analysis.

17a-i) Presentation of process outcomes such as metrics of use and intensity of use

In addition to primary/secondary (clinical) outcomes, the presentation of process outcomes such as metrics of use and intensity of use (dose, exposure) and their operational definitions is critical. This does not only refer to metrics of attrition (13-b) (often a binary variable), but also to more continuous exposure metrics such as “average session length”. These must be accompanied by a technical description how a metric like a “session” is defined (e.g., timeout after idle time) [1] (report under item 6a).

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 17a-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

17b) For binary outcomes, presentation of both absolute and relative effect sizes is recommended

Does your paper address CONSORT subitem 17b? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Focus of the paper was the health economic analysis.

18) Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory

Does your paper address CONSORT subitem 18? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"In the subsequent sensitivity analysis, several adjustments were made. First, the cost calculation from the patients' point of view was modified to test the effect of alternative assumptions on the valuation of production losses. Assuming that all patients who were absent from work were in full-time employment (8.2 hours per day), the societal cost of lost production would have increased to €241.74 (mean €12.09)in the telemedicine group and to €725.21 (mean €38.17) in the control group. In contrast, assuming only part-time employment of 3.9 hours per day for all patients absent from work, the costs of lost production would have decreased to €114.97 (mean €5.75) in the telemedicine group and to €344.92 (mean €18.15) in the control group. These assumptions would have changed total costs for patients in employment to €17.94 for full-time employees and €11.60 for part-time employees in the telemedicine group as well as to €98.40 (full-time) and €78.38 (part-time) in the control group.
Second, the calculation of environmental costs was adjusted to the cost rate of €680 per ton of carbon dioxide equivalent, which increased the average environmental costs of gasoline and diesel cars to €0.12885 per Pkm. Due to this adjustment, the environmental costs in the telemedicine group would have been €9.53 per patient and in total €247.78. In addition, if a total of 16 patients per week had a video consultation instead of a clinic consultation, approximately the emission of 8019.76 kg of greenhouse gases, 49.60 kg of carbon monoxides, 7.91 kg of volatile hydrocarbons, 20.05 kg of nitrogen oxides, and 0.32 kg of particulates could be saved. Environmental costs could furthermore be reduced by €2,661.82 (at €195 per ton of carbon dioxide equivalent) or by €6,798.33 (at €680 per ton of carbon dioxide equivalent)."

18-i) Subgroup analysis of comparing only users

A subgroup analysis of comparing only users is not uncommon in ehealth trials, but if done, it must be stressed that this is a self-selected sample and no longer an unbiased sample from a randomized trial (see 16-iii).

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 18-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

19) All important harms or unintended effects in each group
(for specific guidance see CONSORT for harms)

Does your paper address CONSORT subitem 19? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Not applicable for the study.

19-i) Include privacy breaches, technical problems

Include privacy breaches, technical problems. This does not only include physical "harm" to participants, but also incidents such as perceived or real privacy breaches [1], technical problems, and other unexpected/unintended incidents. "Unintended effects" also includes unintended positive effects [2].

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 19-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

19-ii) Include qualitative feedback from participants or observations from staff/researchers

Include qualitative feedback from participants or observations from staff/researchers, if available, on strengths and shortcomings of the application, especially if they point to unintended/unexpected effects or uses. This includes (if available) reasons for why people did or did not use the application as intended by the developers.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 19-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

DISCUSSION

22) Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence

NPT: In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group

22-i) Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use)

Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use).

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 22-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"This analysis of the economics of using telemedicine in follow-up care for orthopedic and trauma surgery patients in a German university hospital showed that implementing video consultations enabled time and cost savings for patients, savings in environmental costs, and reductions in emissions."

22-ii) Highlight unanswered new questions, suggest future research

Highlight unanswered new questions, suggest future research.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 22-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

20) Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses

20-i) Typical limitations in ehealth trials

Typical limitations in ehealth trials: Participants in ehealth trials are rarely blinded. Ehealth trials often look at a multiplicity of outcomes, increasing risk for a Type I error. Discuss biases due to non-use of the intervention/usability issues, biases through informed consent procedures, unexpected events.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 20-i? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

"Finally, one of the inclusion criteria of the study was patients' ownership of a technical device (smartphone, computer, etc) that allowed them to make video calls. This requirement could lead to socioeconomic inequalities being exacerbated, because only patients with adequate financial means might be able to benefit from cost savings due to telemedicine [40]. This inequity could not be avoided within the study, but it is an important issue with practical relevance and should be taken into account by policymakers."

21) Generalisability (external validity, applicability) of the trial findings

NPT: External validity of the trial findings according to the intervention, comparators, patients, and care providers or centers involved in the trial

21-i) Generalizability to other populations

Generalizability to other populations: In particular, discuss generalizability to a general Internet population, outside of a RCT setting, and general patient population, including applicability of the study results for other organizations

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 21-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

21-ii) Discuss if there were elements in the RCT that would be different in a routine application setting

Discuss if there were elements in the RCT that would be different in a routine application setting (e.g., prompts/reminders, more human involvement, training sessions or other co-interventions) and what impact the omission of these elements could have on use, adoption, or outcomes if the intervention is applied outside of a RCT setting.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem 21-ii?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

OTHER INFORMATION

23) Registration number and name of trial registry

Does your paper address CONSORT subitem 23? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

German Clinical Trials Register DRKS00023445;
https://www.drks.de/drks_web/navigate.do?
navigationId=trial.HTML&TRIAL_ID=DRKS00023445

24) Where the full trial protocol can be accessed, if available

Does your paper address CONSORT subitem 24? *

Cite a Multimedia Appendix, other reference, or copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The full trial protocol can be requested from the corresponding author.

25) Sources of funding and other support (such as supply of drugs), role of funders

Does your paper address CONSORT subitem 25? *

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

The research did not receive funding from an external body.

X27) Conflicts of Interest (not a CONSORT item)

X27-i) State the relation of the study team towards the system being evaluated

In addition to the usual declaration of interests (financial or otherwise), also state the relation of the study team towards the system being evaluated, i.e., state if the authors/evaluators are distinct from or identical with the developers/sponsors of the intervention.

	1	2	3	4	5	
subitem not at all important	○	○	○	○	○	essential

Does your paper address subitem X27-i?

Copy and paste relevant sections from the manuscript (include quotes in quotation marks "like this" to indicate direct quotes from your manuscript), or elaborate on this item by providing additional information not in the ms, or briefly explain why the item is not applicable/relevant for your study

Your answer

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- ◉ no

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Your answer

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- ○ yes
- ◉ no
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This would involve for example becoming involved in participating in a workshop and writing an "Explanation and Elaboration" document

- ○ yes
- ○ no
- ○ Other:

Any other comments or questions on CONSORT EHEALTH

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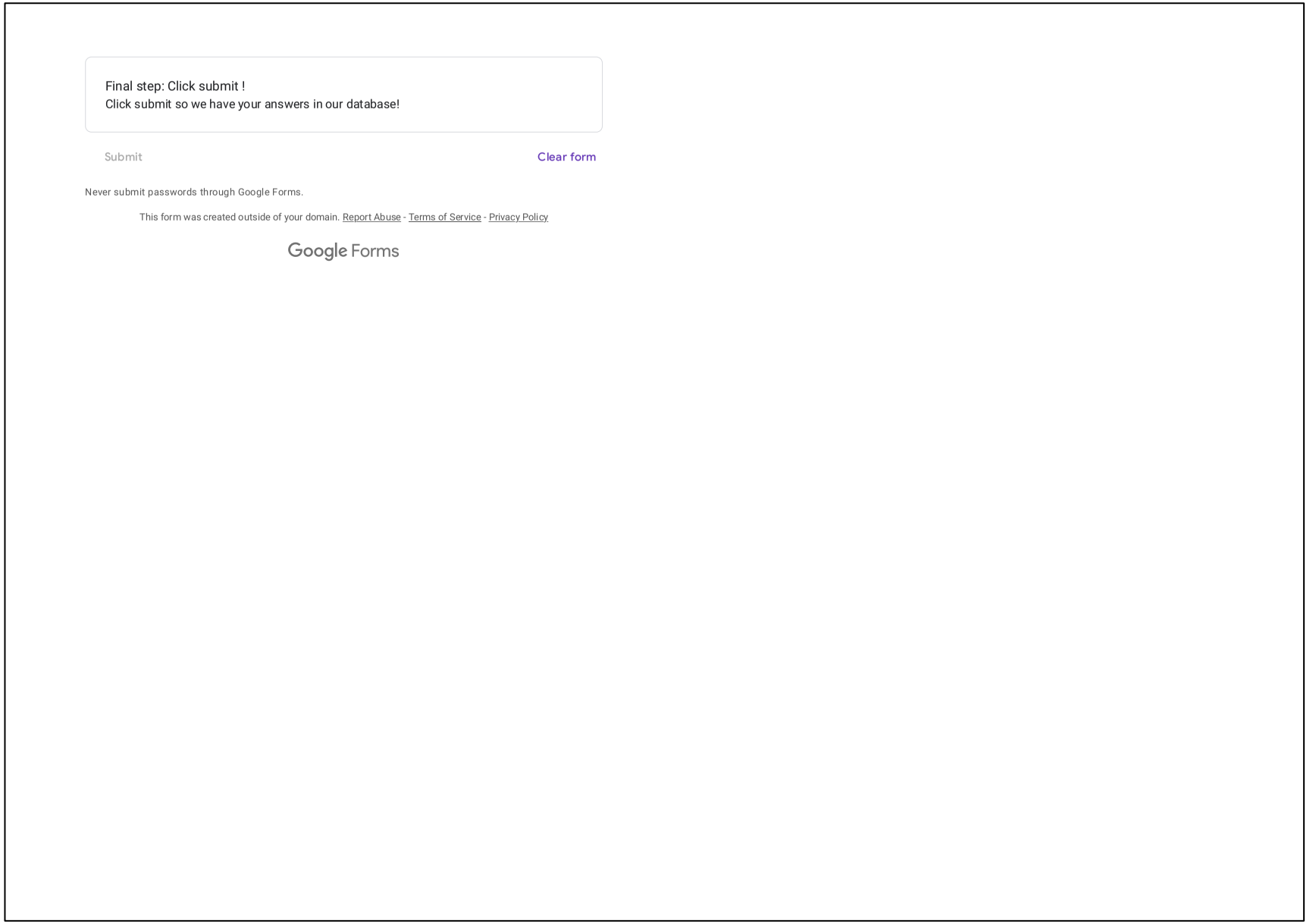
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5 Digitization of Follow-Up Care in Orthopedic and Trauma Surgery With Video Consultations: Health Economic Evaluation Study From a Health Provider's Perspective

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Original Paper

Digitization of Follow-Up Care in Orthopedic and Trauma Surgery With Video Consultations: Health Economic Evaluation Study From a Health Provider's Perspective

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Abstract

Background: Recommendations for health care digitization as issued with the Riyadh Declaration led to an uptake in telemedicine to cope with the COVID-19 pandemic. Evaluations based on clinical data are needed to support stakeholders' decision-making on the long-term implementation of digital health.

Objective: This health economic evaluation aims to provide the first German analysis of the suitability of video consultations in the follow-up care of patients in orthopedic and trauma surgery, investigate the financial impact on hospital operations and personnel costs, and provide a basis for decisions on digitizing outpatient care.

Methods: We conducted a randomized controlled trial that evaluated video consultations versus face-to-face consultations in the follow-up care of patients in orthopedic and trauma surgery at a German university hospital. We recruited 60 patients who had previously been treated conservatively or surgically for various knee or shoulder injuries. A digital health app and a browser-based software were used to conduct video consultations. The suitability of telemedicine was assessed using the Telemedicine Satisfaction Questionnaire and the EQ-5D-5L questionnaire. Economic analyses included average time spent by physician per consultation, associated personnel costs and capacities for additional treatable patients, and the break-even point for video consultation software fees.

Results: After 4 withdrawals in each arm, data from a total of 52 patients (telemedicine group: n=26; control group: n=26) were used for our analyses. In the telemedicine group, 77% (20/26) of all patients agreed that telemedicine provided for their health care needs, and 69% (18/26) found telemedicine an acceptable way to receive health care services. In addition, no significant difference was found in the change of patient utility between groups after 3 months (mean 0.02, SD 0.06 vs mean 0.07, SD 0.17; *P*=.35). Treatment duration was significantly shorter in the intervention group (mean 8.23, SD 4.45 minutes vs mean 10.92, SD 5.58 minutes; *P*=.02). The use of telemedicine saved 25% (€2.14 [US $2.35]/€8.67 [US $9.53]) in personnel costs and increased the number of treatable patients by 172 annually, assuming 2 hours of video consultations per week. Sensitivity analysis for scaling up video consultations to 10% of the hospital's outpatient cases resulted in personnel cost savings of €73,056 (US $ 80,275.39) for a senior physician. A total of 23 video consultations per month were required to recoup the software fees of telemedicine through reduced personnel costs (break-even point ranging from 12-38 in the sensitivity analysis).

Conclusions: Our study supports stakeholders' decision-making on the long-term implementation of digital health by demonstrating that video consultations in the follow-up care of patients in orthopedic and trauma surgery result in cost savings and productivity gains for clinics with no negative impact on patient utility.

Trial Registration: German Clinical Trials Register DRKS00023445; https://drks.de/search/en/trial/DRKS00023445

(J Med Internet Res 2023;25:e46714) doi: 10.2196/46714

KEYWORDS

digital health; economic evaluation; health economics; orthopedic; personnel costs; productivity gains; telemedicine; trauma surgery; utility; video consultations

Introduction

The adoption of digital technologies has progressed only gradually in health care systems, and uncertainty, especially with respect to the suitability and financial effects, has often acted as a drag on the broader use of digital health applications such as telemedicine [1-6]. The COVID-19 pandemic, however, has been transformative. Recommendations for health care digitization as issued with the Riyadh Declaration led to a strong increase in the use of telemedicine in medical specialties, including orthopedic and trauma surgery. The pandemic has boosted both demand for and supply of video consultations [1,3-5,7,8]. Under new pandemic rules, such as contact restrictions to contain infections, previous concerns about telemedicine have faded into the background, and the use of telemedicine appears likely to continue beyond the pandemic [1,7,9].

To support stakeholders' decision-making on the long-term use of telemedicine in orthopedic and trauma surgery, analyses from a health provider's perspective based on clinical data are required. Critical insights concerning the suitability of video consultations for patient care and the financial effects associated with telemedicine can be obtained by performing health economic evaluations.

This health economic evaluation aims to provide the first German analysis of the suitability of video consultations in the follow-up care of patients in orthopedic and trauma surgery, to investigate the associated financial and personnel impact, and to provide a basis for future decision-making on implementing telemedicine from a health provider's perspective based on data from a randomized controlled trial (RCT). All economic analyses will be conducted from a health provider's perspective, that is, from the perspective of the economic entity providing the health service. In this analysis, the economic entity providing follow-up care is a German university hospital. University hospitals provide the highest level of care in the German health care system and serve as important pioneers for establishing new standards of care.

Germany is the largest European health care market, with health expenditures of €457 billion (US $502.34 billion) in 2021 [10]. Despite its economic size, progress in health care digitization has been slow, with only 23% of adults having received a video consultation during the COVID-19 pandemic compared to a 45% average among Organization for Economic Cooperation and Development (OECD) countries [11]. Economic data from the health provider's perspective showing the economic viability of telehealth remains a critical requirement for further diffusion of video consultations and other digital health care technologies.

Health economic evaluations of medical services and procedures, including telemedicine, are helpful at 2 distinct levels. First, on the macro level, health expenditures constitute a sizable part of spending for national economies. Data from the OECD show that OECD countries' health care spending averaged about 8.8% of their gross domestic product before the COVID-19 pandemic in 2019. Individual countries, such as the United States at 16.8% and Germany at 11.7%, spent a significantly higher share on health [11]. It is estimated that during the COVID-19 pandemic, however, average health care spending as a share of the gross domestic product has already increased to 9.7% for 2020, and current forecasts indicate that the COVID-19 pandemic might further increase health expenditures in the long term [11,12]. Consequently, procedures and technologies that reduce costs and thus relieve the burden on health care systems are urgently needed. Only health economic evaluations can determine whether or not telemedicine holds this potential. Second, on the micro level, it is essential for various stakeholders, including hospitals and physicians, to know whether new procedures and technologies cause additional costs or promise to reduce costs while maintaining, or perhaps even increasing, patient utility. Only if new procedures are not inferior to conventional ones can their long-term implementation be recommended. Health economic evaluations thus serve to support stakeholders' decision-making [13-15]. Apart from 2 Scandinavian studies, however, health economic evaluations that provide results from a health provider's perspective in orthopedic and trauma surgery based on data from an RCT are limited [16,17].

In this analysis, we go beyond the health economic analysis of the RCT's implemented scenario of 2 hours of video consultations per week. We extend our analysis with extensive calculations for scaling up video consultations in specific hospital departments as well as the entire hospital, analyzing the health economic effects of video consultations for 1%-10% of all patients who receive outpatient care at the hospital.

Methods

Study Design

We conducted an RCT to examine the use of telemedicine in the follow-up care of patients in orthopedic and trauma surgery at the University Hospital of Giessen, Germany, between September 2020 and April 2021. Our study design had 3 main goals: evaluation of patient and physician satisfaction, evaluation

of economic and environmental impact from a societal perspective, and a health economic analysis of digitization from the hospital's perspective. The first 2 evaluations have been previously published with a detailed description of our study design [18,19].

A total of 60 patients previously treated surgically or conservatively in the clinic for various shoulder and knee conditions were recruited for the RCT in the clinic or by telephone and were randomized in a 1:1 ratio. To participate in the study, patients had to be eligible to undergo a video consultation for their follow-up appointment. Patients in the intervention group (n=30) received a 1-time follow-up appointment through an online video consultation with their attending physician. The video consultation could be conducted by patients using a digital health app or a browser-based software. If a video consultation was not possible or if further diagnostics such as imaging were needed, patients could receive a face-to-face (F2F) appointment at any time. Patients in the control group (n=30) attended their follow-up appointment conventionally in the clinic.

In the Department of Trauma, Hand, and Reconstructive Surgery at the University Hospital of Giessen, a 1-hour time frame for video consultations was set up 2 days a week during regular clinic consultation hours as part of the RCT. Up to 8 telemedicine appointments were scheduled per week. Patients in both study arms were seen by the same senior physicians. These senior physicians used a laptop equipped with a camera and microphone to conduct the video consultations with a browser-based software. Although the technical equipment was already available in the clinic, additional costs in the form of monthly license fees for the use of the software occurred for the hospital during the study. Due to the simple design of the software, however, no training of the respective physicians and thus no training costs were required.

Ethical Considerations

A detailed study protocol for the planned RCT was submitted and approved by the local ethics committee of the University of Giessen before the start of the study (AZ 73/20). Furthermore, the RCT was registered with the German Clinical Trials Register (DRKS00023445). Patients received comprehensive information about the study before participation and had to provide informed consent. No compensation was provided for participation in the study.

Analysis of Telemedicine Suitability and its Economic Effects

The consideration of the health provider's perspective comprised a bilateral analysis. In the first step, it was investigated whether telemedicine is suitable for hospitals in the follow-up care of patients in orthopedic and trauma surgery. As suggested by current literature, the investigation of video consultations' suitability focused on the effectiveness of physician-patient communication and service provided in the form of a technology evaluation [4]. For this purpose, patients in the intervention group completed the Telemedicine Satisfaction Questionnaire (TSQ) by Yip et al [20], as this questionnaire evaluates the ability of telemedicine to meet the health care needs of patients [20]. Given that the TSQ was published in English, the questionnaire was translated into German with the help of the translation, review, adjunction, pretest, and documentation procedure, as recommended by the Leibniz Institute for the Social Sciences in Germany, during the preparation of the study [21]. The investigation of suitability furthermore included that patients in both groups completed the EQ-5D-5L questionnaire from the EuroQol Group, both at the time of recruitment and 3 months after recruitment, to assess differences in utility in terms of health-related quality of life between both groups [22]. The results of the first and second data collection of the EQ-5D-5L questionnaire were evaluated using the German EQ-5D-5L value set. The resulting utility values serve as a preference-based, health-related measure of quality of life and can range from –0.661 to 1. In this case, a utility value of 1 represents the best possible health status [23]. To avoid potential bias, utility was calculated only for patients who had completed both EQ-5D-5L questionnaires.

The descriptive analysis of the questionnaires included the presentation of the mean, SD, median, and relative frequencies. In addition, the Mann-Whitney *U* test was conducted to detect potential differences in the outcome of the EQ-5D-5L questionnaire between both groups.

In a second step, the economic effects of the use of video consultations were evaluated. These economic calculations comprised 4 different aspects with various sensitivity analyses and were guided by recommendations for health economic analyses in the context of eHealth interventions [24]. First, the time physicians spent on the respective consultations was compared between telemedicine and F2F consultations with the Mann-Whitney *U* test. The respective time difference was used to calculate personnel costs for both examination forms. As no additional support by nurses or other medical staff was required to perform the video consultations, the calculation of personnel costs focused exclusively on physicians' salaries. More specifically, the hourly cost of a senior physician from the collective wage agreement for university hospitals was included in the calculation [25]. The use of publicly available data should ensure greater transparency and better transferability of the results. To increase this transparency and transferability, the personnel costs of deputy chief physicians, specialists, and assistant physicians were further considered in the cost calculation in the form of a sensitivity analysis. Second, model calculations were performed to consider the impact of expanding the number of video consultations on personnel cost savings. An expansion of video consultations was considered for different salaries and for both the respective department and the entire university hospital, with around 342,000 patients receiving outpatient care per year. Third, based on the time differences, the number of treatable patients was calculated and compared between telemedicine and F2F consultations. The number of additional treatable patients was further calculated by varying the weekly number of F2F consultations substituted by video consultations. Lastly, the break-even point of telemedicine was calculated by including personnel costs and software fees. For this purpose, the official monthly fee for unlimited use of the telemedicine software per physician was assessed [26]. Hospitals' preexisting and readily available resources, including

technical equipment (laptops with audio and video capabilities), an internet connection, and clinical premises, were not included in the cost calculation. Different assumptions were also made for the calculation of the break-even point in order to provide better transferability of the data. A sensitivity analysis included a lower software fee for a package that allows a maximum of 20 telemedical consultations per month and the salary of a deputy chief physician, a specialist, and an assistant physician rather than that of a senior physician [25,26].

Results

General Findings

The health economic evaluation was based on data from 26 patients in the intervention group and 26 patients in the control group after the withdrawal of 4 study participants in both treatment groups. In the telemedicine group, 42% (11/26) of participants were female, and 58% (15/26) were male. In addition, 27% (7/26) of participants in the telemedicine group were between 18 and 40 years of age, 65% (17/26) were between 41 and 60 years of age, and 8% (2/26) were aged 61 years or older. The reason for a follow-up appointment was a knee disorder in 38% (10/26) of cases and a shoulder disorder in 62% (16/26) of cases in the telemedicine group. In the control group, 38% (10/26) of patients were female, 62% (16/26) were male, 19% (5/26) were between 18 and 40 years of age, 58% (15/26) were between 41 and 60 years of age, and 23% (6/26) were aged 61 years or older. The medical indication of a knee disorder was given to 35% (9/26) of patients in the control group, and 65% (17/26) had a follow-up appointment due to a shoulder disorder. There were no significant differences between patient characteristics in both groups.

Suitability of Telemedicine

The evaluation of the TSQ focused on the questions that evaluated physician-patient communication and the service provided and showed whether telemedicine is appropriate for use in clinical practice. These results are presented in Table 1.

On a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree), the mean score for whether patients could easily talk to their health care provider was 4.73 (SD 0.60). The questions of whether patients could clearly hear their health care provider, whether the health care provider was able to understand the patients' health care conditions, and whether patients could see their health care provider as if they were meeting in person were evaluated with mean scores of 4.46 (SD 0.95), 4.19 (SD 0.75), and 4.04 (SD 0.92), respectively. In addition, patients were asked to rate whether they received adequate attention through video consultations (mean 4.19, SD 0.80), whether telemedicine provided for their health care needs (mean 3.92, SD 0.63), whether they found telemedicine an acceptable way to receive health care services (mean 3.92, SD 0.74), and whether they were overall satisfied with the quality of service being provided through telemedicine (mean 4.54, SD 0.76). The distribution of the questions can be found in Figures 1 and 2.

The comparison of utility associated with health-related quality of life, as assessed by the German EQ-5D-5L value set, revealed no significant differences between both groups, either at baseline or after 3 months, as shown in Table 2.

Table 1. Suitability of telemedicine.

Telemedicine group (n=26)	Mean[a] (SD)	Median[a] (IQR)
I can easily talk to my health care provider	4.73 (0.60)	5.00 (5-5)
I can hear my health care provider clearly	4.46 (0.95)	5.00 (4-5)
My health care provider is able to understand my health care condition	4.19 (0.75)	4.00 (4-5)
I can see my health care provider as if we met in person	4.04 (0.92)	4.00 (4-5)
I do receive adequate attention	4.19 (0.80)	4.00 (3.75-5)
Telemedicine provides for my health care need	3.92 (0.63)	4.00 (3.75-4)
I find telemedicine an acceptable way to receive health care services	3.92 (0.74)	4.00 (3-4.25)
Overall, I am satisfied with the quality of service being provided through telemedicine	4.54 (0.76)	5.00 (4-5)

[a]5-point Likert scale; from 1=strongly disagree to 5=strongly agree.

Figure 1. Distribution of the Telemedicine Satisfaction Questionnaire responses regarding physician-patient communication (n=26).

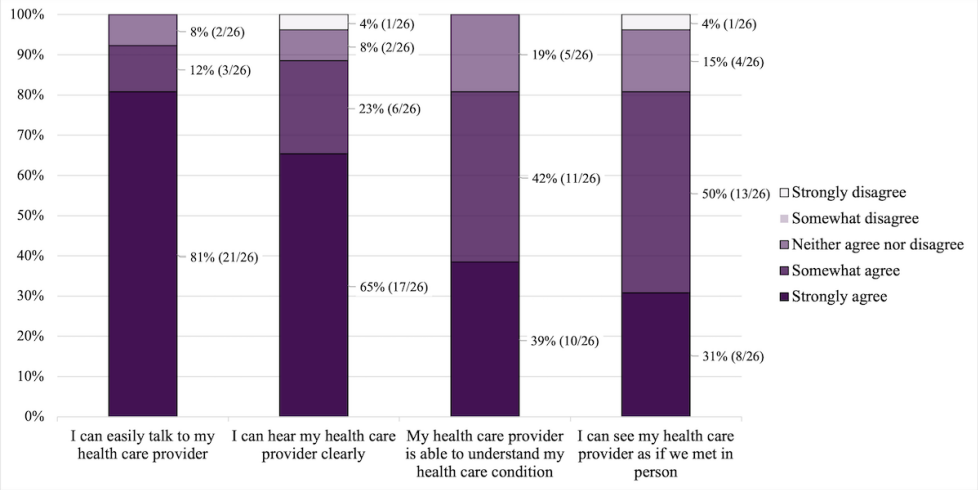

Figure 2. Distribution of the Telemedicine Satisfaction Questionnaire responses regarding service provided (n=26).

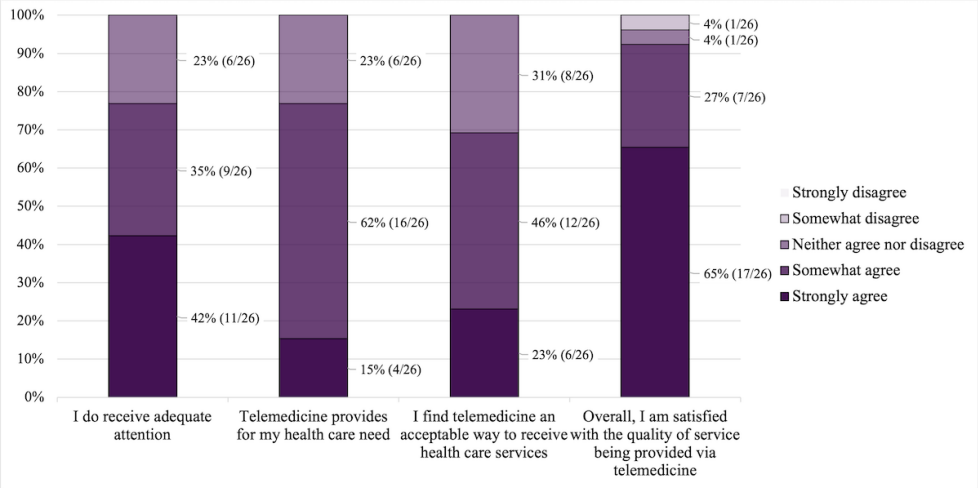

Table 2. Comparison of utility values between groups.

Variables	Telemedicine group (n=26)			Control group (n=26)			*P* value[a]
	Participants, n (%)	Mean (SD)	Median (IQR)	Participants, n (%)	Mean (SD)	Median (IQR)	
Utility value at baseline	16 (62)	0.80 (0.19)	0.88 (0.77-0.91)	14 (54)	0.74 (0.27)	0.85 (0.70-0.89)	.36
Utility value after 3 months	16 (62)	0.82 (0.19)	0.89 (0.81-0.91)	14 (54)	0.81 (0.23)	0.87 (0.79-0.92)	.94
Δ utility value	16 (62)	0.02 (0.06)	0.00 (0.00-0.04)	14 (54)	0.07 (0.17)	0.03 (0.01-0.08)	.35

[a]*P* values were based on the Mann-Whitney *U* test.

The mean utility values at baseline were 0.80 in the telemedicine group and 0.74 in the control group (*P*=.36). After 3 months, the utility values increased to 0.81 for the telemedicine group and 0.82 for the control group (*P*=.94). Although this utility increase in the control group, at 0.07, was stronger than that in

the telemedicine group, at 0.02, the difference in change between the groups was not statistically significant (P=.35).

Economic Effects

The economic effects of video consultations for the follow-up care of patients in orthopedic and trauma surgery from the health provider's perspective comprised several calculations. First, the treatment duration that was used for the health economic calculations showed a significant difference between both groups. In the intervention group, the treatment duration, at an average of 8.23 (SD 4.45; median 6.00, IQR 5-10) minutes, was significantly shorter than that in the control group (average 10.92, SD 5.58 minutes; median 10.00, IQR 8.0-14.5 minutes; P=.02). Based on the salary of a senior physician, a video consultation resulted in average personnel costs of €6.54 (US $7.19) and an F2F consultation in personnel costs of €8.67 (US $9.53). The time saving of 2.69 minutes between both groups corresponded to a saving of €2.14 (US $2.35) in personnel costs for each telemedicine appointment, compared with an in-clinic one; that is, with the help of telemedicine, 25% (€2.14 [US $2.35]/€8.67 [US $9.53]) of personnel costs could be saved. Table 3 shows the personnel costs for different physician salaries in the context of the sensitivity analysis. Savings in personnel costs ranged from €1.29 (US $1.42) to €2.51 (US $2.76) per video consultation.

Second, when treating 8 patients through telemedicine in 2 consultation hours per week, as was the case in this study, this would result in savings of €820.28 (US $901.67) per year in personnel costs for senior physicians. The sensitivity analysis showed that the savings ranged from €496.18 (US $545.41) to €964.92 (US $1060.66) per year for the different salaries, as can be seen in Table 4.

If video consultations were expanded to all 6 specialty consultation hours of the department with 24 patients per week, the annual savings in personnel costs would be €2460.84 (US $2705.00) for a senior physician, ranging from €1488.55 (US $1636.24) to €2894.76 (US $3181.98).

In addition, if telemedicine were expanded to more departments and about 1% (n=3420) of the 342,000 patients who receive outpatient care at the university hospital were treated by video consultations per year, €7305.62 (US $8030.48) of personnel costs could be saved for senior physicians (ranging from €4419.14 [US $4857.61] to €8593.81 [US $ 9446.49] in the sensitivity analysis). At 5% (17,100/342,000) and 10% (34,200/342,000) of all outpatient cases, respectively, the personnel costs saved would increase to €36,528.09 [US $40,152.41] and €73,056.18 [US $80,304.81] for senior physicians, ranging from €22,095.72 [US $24,288.06] to €85,938.09 [US $94,464.87].

Third, with an average treatment duration of 8.23 minutes per patient in the intervention group, around 7.29 patients per hour could be treated on average through a video consultation. The average treatment duration of 10.92 minutes for patients in the control group leads to an average of 5.49 treatable patients based on F2F consultations. If 2 hours of F2F consultations per week were substituted by video consultations, 172.41 additional patients could be treated annually, as shown in Table 5.

If 5 hours were substituted, the number of additionally treatable patients could increase to 431.01, and if 10 hours were substituted, the number could increase to 862.03 additional patients per year.

Lastly, the monthly fee for unlimited use of the telemedicine software was €49.00 (US $53.86) per physician. This resulted in a break-even point of 22.94, meaning that the costs of telemedicine would be recouped through savings in personnel costs after 23 telemedicine consultations per month and physician. A lower software fee of €29 (US $31.88) would lower the break-even point to 13.58 telemedical consultations per month and physician. In this case, however, the health provider's profit margin would be capped because the lower software fee entails an upper limit of 20 telemedical consultations per month. Table 6 shows that the break-even point ranged from 11.54 to 37.92 for the different software fees and salaries. Multimedia Appendix 1 presents a detailed presentation of model calculations.

Table 3. Analysis of personnel costs. A currency exchange rate of €1=US $1.10 is applicable.

Personnel costs	Video consultation (€)	F2F[a] consultation (€)	Difference (€)
Senior physician	6.54	8.67	2.14
Deputy chief physician	7.69	10.20	2.51
Specialist	5.22	6.92	1.71
Assistant physician	3.95	5.25	1.29

[a]F2F: face-to-face.

Table 4. Analysis of the substitution of face-to-face (F2F) consultations with video consultations. A currency exchange rate of €1=US $1.10 is applicable.

Substituted F2F consultations	Saved personnel costs (€)
2 consultation hours per week	
Senior physician	820.28
Deputy chief physician	964.92
Specialist	654.88
Assistant physician	496.18
6 consultation hours per week	
Senior physician	2460.84
Deputy chief physician	2894.76
Specialist	1964.65
Assistant physician	1488.55
1% (3420/342,000) of patients who receive outpatient care at the clinic	
Senior physician	7305.62
Deputy chief physician	8593.81
Specialist	5832.56
Assistant physician	4419.14
5% (17,100/342,000) of patients who receive outpatient care at the clinic	
Senior physician	36,528.09
Deputy chief physician	42,969.04
Specialist	29,162.82
Assistant physician	22,095.72
10% (34,200/342,000) of patients who receive outpatient care at the clinic	
Senior physician	73,056.18
Deputy chief physician	85,938.09
Specialist	58,325.64
Assistant physician	44,191.44

Table 5. Analysis of additional patients treatable when substituting face-to-face (F2F) consultations with video consultations.

Substituted F2F consultations	Additional patients treatable, n
2 hours of video consultations per week	172.41
5 hours of video consultations per week	431.01
10 hours of video consultations per week	862.03

Table 6. Analysis of the break-even point (number of telemedicine consultations per month and physician). A currency exchange rate of €1=US $1.10 is applicable.

Type of physician and amount of software fee	Break-even point
Senior physician (€49)	22.94
Senior physician (€29)	13.58
Deputy chief physician (€49)	19.50
Deputy chief physician (€29)	11.54
Specialist (€49)	28.73
Specialist (€29)	17.00
Assistant physician (€49)	37.92
Assistant physician (€29)	22.44

Discussion

Principal Results

This health economic analysis from a health provider's perspective showed important insights for stakeholder decision-making on the long-term use of telemedicine in the follow-up care of patients in orthopedic and trauma surgery by examining both the suitability of video consultations and the associated financial and personnel effects.

The results of the TSQ indicated that the majority of patients positively evaluated the physician-patient communication and service provided through video consultations. These results are similar to findings in other surgical specialties [27,28].

Although video consultations were 25% (2.69/10.92 minutes) shorter than F2F consultations, there was no significant difference in patient utility regarding health-related quality of life between the telemedicine group and the control group. In a former study, we already compared the EQ-visual analog scale between the intervention and the control group [18]. In this study, we furthermore considered the responses of the EQ-5D descriptive system and evaluated them using the German value set in order to analyze whether significant differences between the groups occurred. The comparison shows that no significant differences were found between video consultations and F2F consultations, neither for the visual analog scale nor for the descriptive system based on the German value set. Thus, it could be argued that telemedicine can save costs while maintaining patient utility—a finding supported by Buvik et al [29], who were also unable to show relevant differences in EQ-5D-assessed patient utility between telemedical and F2F follow-ups [29]. At the same time, it is important to monitor the use and implementation of telemedicine so as to ensure that patient utility is not negatively affected by shortening treatment duration in the long run. Nonetheless, the fact that a video consultation is less time-consuming for physicians than a clinical consultation is also confirmed in an RCT of telemedicine in the follow-up of arthroscopic rotator cuff surgery conducted by Kane et al [30], who also did not find any negative patient outcomes associated with the performance of video consultations [30].

From the health provider's perspective, these results suggest that video consultations might be suitable for use in orthopedic and trauma surgery. The potential of video consultations is further underlined by previous studies that found comparable results to F2F consultations in terms of physician and patient satisfaction, efficiency, quality of care, and benefits from a societal perspective [16,18,19,29-32].

The economic impact of using telemedicine can be differentiated for clinics both as providers of medical services and as employers. As providers of medical services, clinics benefit from productivity gains due to a reduced consultation time, which on the one hand could lead to lower personnel costs and thus relieve the burden on the health care system, and on the other hand could result in an increased capacity of a clinic and thus improve patient care through shorter waiting times and mitigate the shortage of physicians in the health care system [33,34]. In addition, the implementation of telemedicine could result in a competitive advantage for clinics, as communication with patients is simplified and, as a result, a service beyond the local environment could be offered [35]. As telemedicine is associated with cost and time savings for patients as well, the offering of video consultations could furthermore help to recruit new patients [16,17,19,30]. The implementation of video consultations could also create the possibility of a home office for physicians. The resulting benefit of the clinic as an employer could be a competitive advantage in personnel recruitment as well as an increase in the satisfaction of the permanent personnel, as studies indicate an improved work-life balance associated with working from home [36,37]. Alternative working arrangements are especially attractive for all physicians taking care of a family. In its 2018 policy tag on work-life balance, the World Medical Association argued for the promotion of inclusiveness through gender equality. In particular, the World Medical Association encouraged more efforts to explore telecommunication opportunities to allow for more flexibility in balancing the work-life demands of physicians [38].

A holistic view of the economic effects of telemedicine, however, must consider not only the cost savings but also the additional costs incurred by the clinic as a result of the technology.

A minimum of 23 video consultations per physician per month was required to recoup the costs of investing in telemedicine software through a reduction in personnel costs resulting from time savings. In the sensitivity analysis, the break-even point ranged from 11.54 to 37.92 video consultations. A lower

software fee, however, effectively capped the number of video consultations at 20 per month. Whether this is a viable option for decision makers in practice depends on their individual objectives. Competing providers of telemedicine software in Germany may well offer lower fees that would help lower the break-even point. A given hospital's possibility of negotiating individual terms of use and fee structures with telemedicine providers might be another important aspect to take into account when implementing telemedicine. Finally, physicians' incomes are rising continuously. The calculations of personnel costs were based on the cost rates in effect at the time the study was conducted. In 2023, salaries will increase by up to 5.13%. The savings of higher personnel costs through telemedicine will then be accompanied by a lower break-even point. The break-even points calculated in earlier contributions by Buvik et al [16] (183 telemedicine consultations per year from the health provider perspective and 151 from the societal perspective) and Ohinmaa et al [17] (80 consultations from the societal perspective) cannot be directly compared with the break-even point arrived at in our analysis. Their studies (1) focused on telemedicine provided with the help of a local caregiver rather than independently of location, and (2) featured other aspects in their cost calculations [16,17].

This health economic evaluation provides clinical evidence on the apparent ability of telemedicine to provide similar patient utility at lower cost and can therefore improve stakeholders' decisions on implementing telemedicine in the follow-up care of patients in orthopedic and trauma surgery both in and beyond the current COVID-19 pandemic [39]. The potential transferability of these findings to other medical specialties due to the practical study design has high practical relevance, particularly in light of rising health care expenditures and ongoing shortages of physicians [12,33].

Limitations

There are 3 main limitations. On the one hand, the treatment duration was not measured precisely but was collected from the physicians by means of a questionnaire. However, individual deviations should compensate for each other in total. Furthermore, the technical equipment, the internet connection, and the clinical premises were not considered in the overall cost analysis, as these were already available and did not cause any additional costs for the clinic. In the case of a transfer to other clinics, these costs should be examined in advance. Another limitation arises from the response rates to the 2 data collections of the EQ-5D-5L questionnaire: only patients who had completed both questionnaires were included in the calculation to avoid potential bias. As a result, the group sizes considered were limited.

Conclusions

The first health economic evaluation based on data from a German RCT demonstrated that the use of telemedicine might be suitable for the follow-up care of patients in orthopedic and trauma surgery regarding the physician-patient communication and service provided and that video consultations are less time-consuming for physicians compared with conventional F2F consultations, resulting in personnel cost savings and productivity gains for clinics without any negative impact on patient utility. These findings were collected from the health provider's perspective and can thus provide targeted support to stakeholders in decision-making on the long-term use of telemedicine. Results might differ for other specialties of surgery and for different implementations of digital health, such as remote monitoring. However, our results could be helpful in estimating the effects before the implementation of digital processes in other specialties.

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Data Availability

The data sets generated and analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Detailed presentation of cost calculations.
[DOCX File , 21 KB-Multimedia Appendix 1]

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Abbreviations

F2F: face-to-face
OECD: Organization for Economic Cooperation and Development
RCT: randomized controlled trial
TSQ: Telemedicine Satisfaction Questionnaire

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Multimedia Appendix 1: Detailed presentation of cost calculations

	Senior physician	Deputy chief physician	Specialist	Assistant physician
Personnel costs per video consultation	€8,004.59 / 168 hours / 60 minutes x 8.23 minutes = €6.54	€9,416.03 / 168 hours / 60 minutes x 8.23 minutes = €7.69	€6,390.60 / 168 hours / 60 minutes x 8.23 minutes = €5.22	€4,841.95/ 168 hours / 60 minutes x 8.23 minutes = €3.95
Personnel costs per F2F consultation	€8,004.59 / 168 hours / 60 minutes x 10.92 minutes = €8.67	€9,416.03 / 168 hours / 60 minutes x 10.92 minutes = €10.20	€6,390.60 / 168 hours / 60 minutes x 10.92 minutes = €6.92	€4,841.95/ 168 hours / 60 minutes x 10.92 minutes = €5.25
Substitution of two consultation-hours (8 patients) per week with video consultations	384 patients x (€8,004.59 / 168 hours / 60 minutes x 10.92 minutes) - 384 patients x (€8,004.59 / 168 hours / 60 minutes x 8.23 minutes) = €820.28	384 patients x (€9,416.03 / 168 hours / 60 minutes x 10.92 minutes) - 384 patients x (€9,416.03 / 168 hours / 60 minutes x 8.23 minutes) = €964.92	384 patients x (€6,390.60 / 168 hours / 60 minutes x 10.92 minutes) - 384 patients x (€6,390.60 / 168 hours / 60 minutes x 8.23 minutes) = €654.88	384 patients x (€4,841.95 / 168 hours / 60 minutes x 10.92 minutes) - 384 patients x (€4,841.95/ 168 hours / 60 minutes x 8.23 minutes) = €496.18
Substitution of six consultation-hours (24 patients) per week with video consultations	1,152 patients x (€8,004.59 / 168 hours / 60 minutes x 10.92 minutes) - 1,152 patients x (€8,004.59 / 168 hours / 60 minutes x 8.23 minutes) = €2,460.84	1,152 patients x (€9,416.03 / 168 hours / 60 minutes x 10.92 minutes) - 1,152 patients x (€9,416.03 / 168 hours / 60 minutes x 8.23 minutes) = €2,894.76	1,152 patients x (€6,390.60 / 168 hours / 60 minutes x 10.92 minutes) - 1,152 patients x (€6,390.60 / 168 hours / 60 minutes x 8.23 minutes) = €1,964.65	1,152 patients x (€4,841.95 / 168 hours / 60 minutes x 10.92 minutes) - 1,152 patients x (€4,841.95/ 168 hours / 60 minutes x 8.23 minutes) = €1,488.55
1% of ambulatory patients in the clinic treated via video consultations	342,000 patients x 0.01 x (€8,004.59 / 168 hours / 60 minutes x 10.92 minutes) - 342,000 patients x 0.01 x (€8,004.59 / 168 hours / 60 minutes x 8.23 minutes) = €7,305.62	342,000 patients x 0.01 x (€9,416.03 / 168 hours / 60 minutes x 10.92 minutes) - 342,000 patients x 0.01 x (€9,416.03 / 168 hours / 60 minutes x 8.23 minutes) = €8,593.81	342,000 patients x 0.01 x (€6,390.60 / 168 hours / 60 minutes x 10.92 minutes) - 342,000 patients x 0.01 x (€6,390.60 / 168 hours / 60 minutes x 8.23 minutes) = €5,832.56	342,000 patients x 0.01 x (€4,841.95 / 168 hours / 60 minutes x 10.92 minutes) - 342,000 patients x 0.01 x (€4,841.95/ 168 hours / 60 minutes x 8.23 minutes) = €4,419.14
5% of ambulatory patients in the clinic treated via video consultations	342,000 patients x 0.05 x (€8,004.59 / 168 hours / 60 minutes x 10.92 minutes) - 342,000 patients x 0.05 x (€8,004.59 / 168 hours / 60 minutes x 8.23 minutes) = €36,528.09	342,000 patients x 0.05 x (€9,416.03 / 168 hours / 60 minutes x 10.92 minutes) - 342,000 patients x 0.05 x (€9,416.03 / 168 hours / 60 minutes x 8.23 minutes) = €42,969.04	342,000 patients x 0.05 x (€6,390.60 / 168 hours / 60 minutes x 10.92 minutes) - 342,000 patients x 0.05 x (€6,390.60 / 168 hours / 60 minutes x 8.23 minutes) = €29,162.82	342,000 patients x 0.05 x (€4,841.95 / 168 hours / 60 minutes x 10.92 minutes) - 342,000 patients x 0.05 x (€4,841.95/ 168 hours / 60 minutes x 8.23 minutes) = €22,095.72
10% of ambulatory patients in the clinic treated via video consultations	342,000 patients x 0.1 x (€8,004.59 / 168 hours / 60 minutes x 10.92 minutes) - 342,000 patients x 0.1 x (€8,004.59 / 168 hours / 60 minutes x 8.23 minutes) = €73,056.18	342,000 patients x 0.1 x (€9,416.03 / 168 hours / 60 minutes x 10.92 minutes) - 342,000 patients x 0.1 x (€9,416.03 / 168 hours / 60 minutes x 8.23 minutes) = €85,938.09	342,000 patients x 0.1 x (€6,390.60 / 168 hours / 60 minutes x 10.92 minutes) - 342,000 patients x 0.1 x (€6,390.60 / 168 hours / 60 minutes x 8.23 minutes) = €58,325.64	342,000 patients x 0.1 x (€4,841.95 / 168 hours / 60 minutes x 10.92 minutes) - 342,000 patients x 0.1 x (€4,841.95/ 168 hours / 60 minutes x 8.23 minutes) = €44,191.44
Break-even point €49.00 software fee	€49 / (10.92 minutes x (€8,004.59 / 168 hours / 60 minutes) - (8.23 minutes x (€8,004.59 / 168 hours / 60 minutes))) = 22.94	€49 / (10.92 minutes x (€9,416.02 / 168 hours / 60 minutes) - (8.23 minutes x (€9,416.03 / 168 hours / 60 minutes))) = 19.50	€49 / (10.92 minutes x (€6,390.60 / 168 hours / 60 minutes) - (8.23 minutes x (€6,390.60 / 168 hours / 60 minutes))) = 28.73	€49 / (10.92 minutes x (€4,841.95 / 168 hours / 60 minutes) - (8.23 minutes x (€4,841.95 / 168 hours / 60 minutes))) = 37.92
Break-even point €29.00 software fee	€29 / (10.92 minutes x (€8,004.59 / 168 hours / 60 minutes) - (8.23 minutes x (€8,004.59 / 168 hours / 60 minutes))) = 13.58	€29 / (10.92 minutes x (€9,416.02 / 168 hours / 60 minutes) - (8.23 minutes x (€9,416.03 / 168 hours / 60 minutes))) = 11.54	€29 / (10.92 minutes x (€6,390.60 / 168 hours / 60 minutes) - (8.23 minutes x (€6,390.60 / 168 hours / 60 minutes))) = 17.00	€29 / (10.92 minutes x (€4,841.95 / 168 hours / 60 minutes) - (8.23 minutes x (€4,841.95 / 168 hours / 60 minutes))) = 22.44

Treatable patients	Video consultation: 60 minutes / 8.23 minutes = 7.29 patients per hour F2F consultation: 60 minutes / 10.92 minutes = 5.49 patients per hour 2 hours of video consultations per week: 96 hours x (60 minutes / 8.23 minutes) - 96 hours x (60 minutes / 10.92 minutes) = 172.41 patients 5 hours of video consultations per week: 240 hours x (60 minutes / 8.23 minutes) - 240 hours x (60 minutes / 10.92 minutes) = 431.01 patients 10 hours of video consultations per week: 480 hours x (60 minutes / 8.23 minutes) - 480 hours x (60 minutes / 10.92 minutes) = 862.03 patients

6 Conclusion

In conclusion, this health economic doctoral thesis sheds light on the performance of healthcare services in Germany during a profound transformative process triggered by the COVID-19 pandemic, which both caused a global health crisis but also acted as a catalyst for the widespread adoption of digital health solutions. The emergence of the COVID-19 pandemic exposed vulnerabilities in the German healthcare system, leading to shifts in healthcare delivery, accessibility, and utilization.

The initial two papers of the dissertation reveal divergent trends in waiting times for outpatient specialist care and a substantial decline of cancer screening utilization in Germany, emphasizing disparities among various patient groups, while particularly highlighting the vulnerability of certain patient populations. These findings underscore the urgent need for targeted resource allocations to address challenges in healthcare delivery during and beyond the COVID-19 pandemic to prevent adverse health outcomes and public health deteriorations in the long-term.

The subsequent three papers focus on the role of digital health applications, particularly telemedicine, in addressing these challenges and optimizing healthcare delivery. Based on an RCT and comprehensive health economic analyses, these publications examine the suitability and advantages of video consultations in the outpatient follow-up care of patients in orthopedic and trauma surgery. These multifaceted investigations provide stakeholders with valuable insights into potential cost savings, productivity gains, and environmental benefits, reinforcing the argument for its adoption and integration into healthcare services beyond the pandemic.

By exploring these diverse topics, the doctoral thesis aims to significantly enhance the comprehension of health economics' relevance and implications in the context of unprecedented and transformative global events, such as the COVID-19 pandemic, along with the potential of digitization in shaping the future of healthcare services. The dissertation contributes profoundly to the health economic discourse by examining both the disruption caused by the pandemic and the opportunities presented by digital health applications. Through comprehensive analyses of real-world data and evidence-based findings acquired through a variety of empirical methods, the publications presented in this dissertation provide a holistic approach to support healthcare providers, policymakers, and researchers in their decision-making, thus contributing to the development of a more efficient, accessible, and sustainable healthcare system in the modern era.

Affidavit

I hereby declare that I completed the papers submitted and listed hereafter independently and with only those forms of support mentioned in the relevant paper or in the following supplementary list. When working with the authors listed, I contributed no less than a proportionate share of the work. In the analyses that I have conducted and to which I refer in the papers, I have followed the principles of good academic practice, as stated in the Statute of Justus Liebig University Giessen for Ensuring Good Scientific Practice.

Jennifer Muschol, M.Sc.
Gießen, January 05, 2024

Submitted Papers

Muschol, J., & Gissel, C. (2021). COVID-19 pandemic and waiting times in outpatient specialist care in Germany: an empirical analysis. *BMC Health Services Research*, *21*(1), 1076. https://doi.org/10.1186/s12913-021-07094-9

Muschol, J., Strauss, C., & Gissel, C. (2023). COVID-19 related decline in cancer screenings most pronounced for elderly patients and women in Germany: a claims data analysis. *Journal of Cancer Research and Clinical Oncology*, *149*(8), 5345–5367. https://doi.org/10.1007/s00432-022-04433-z

Muschol, J., Heinrich, M., Heiss, C., Knapp, G., Repp, H., Schneider, H., Thormann, U., Uhlar, J., Unzeitig, K., & Gissel, C. (2022). Assessing Telemedicine Efficiency in Follow-up Care With Video Consultations for Patients in Orthopedic and Trauma Surgery in Germany: Randomized Controlled Trial. *Journal of Medical Internet Research*, *24*(7), e36996. https://doi.org/10.2196/36996

Muschol, J., Heinrich, M., Heiss, C., Hernandez, A. M., Knapp, G., Repp, H., Schneider, H., Thormann, U., Uhlar, J., Unzeitig, K., & Gissel, C. (2022). Economic and Environmental Impact of Digital Health App Video Consultations in Follow-up Care for Patients in Orthopedic and Trauma Surgery in Germany: Randomized Controlled Trial. *Journal of Medical Internet Research*, *24*(11), e42839. https://doi.org/10.2196/42839

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