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Interrupting chains of respiratory infections via remote patient monitoring in ambulatory care - a randomized controlled trial during the 2020/21 infection season

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ABSTRACT

Aim of the study: The aim of the study was to investigate patient satisfaction, saving of time and the possible reduction of visits to medical practices that use Remote Patient Monitoring (RPM) during treatment compared to usual care.
Methods: In a randomized controlled trial between October 2020 and May 2021, the participating medical practices were randomized into three groups (two different RPM systems, one control). Doctors were required to enroll patients ≥18 years with acute respiratory infection in possession of a web-enabled device, such as a laptop, tablet or computer. After a three-month study phase, doctors were asked to describe the treatment of their patients via online survey. Patients were also questioned. The analysis was carried out descriptively and through group comparisons.
Results: 51 practices with 121 patients were included. Overall, the results generally show a positive assessment of digital care on the patient side. As for the doctors, handling and integrating the systems into established practice routines seem to be a challenge. Further, the number of patient visits to the medical practice was not reduced by using the systems. Doctors did not save time, but the relationship to the patients was intensified.
Conclusion: While there was no indication for an increase in efficiency by using RPM systems, participating doctors indicated their potential for an enhanced interaction between doctor and patient. In particular, intensified interaction contact with patients with chronic diseases (e. g. COPD, long-COVID) could be of long-term interest and importance for doctors in ambulatory care.
Trial Registration: DRKS00023553.

1. Background

Coping with the COVID-19 pandemic reveals the importance of ambulatory care for patients with acute respiratory infections. In countries where ambulatory care could relieve and reduce the use of inpatient treatment, a more favorable course of the pandemic was initially observed. [1] Simultaneously, available intensive care resources were not overused. The ambulatory treatment of COVID-19 patients aims to monitor patients in their home environment. Unfortunately, telemedicine in ambulatory care is an emerging field of research and as such unable to provide best practise, although first trials with promising indications have been published. [2–6]

In addition to their primary function of assisting with an enhanced quality of care and reducing the risk of infection for patients and doctors, RPM systems can merge digitally recorded data in an anonymized or a pseudonymized way and thus provide real-time insight into the ambulatory care of patients with respiratory infections. Many providers have established themselves on the (German) market over the last years. However, the perception of users might differ from the provider's assessment of usability. Based on the current data, it is unknown if the systems provide reliable data for healthcare. Further, there are not enough research data proving that such systems can be used safely and quickly in the practices and if they might provide more favorable care effects, e.g. a lower hospital admission rate or a higher satisfaction among the practice team and the patient, remains inconclusive. Examining the suitability of RPM systems for the reduction of patients' visits to practices and treatment of patients with respiratory infections in their home environment is therefore necessary.

1.1. Aim of the study

The aim of this study was to examine satisfaction, saving of time and the potential reduction of patient visits to practices that use RPM systems compared to usual care.

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2. Methods

2.1. RPM systems

The two RPM systems used in this study are digital tools that support efficient and safer patient management. They were selected in a previous nationwide tender with some obligatory criteria for comparability, e. g. a patient and a doctor front-end to enter data, the option of entering at least the symptoms of a potential COVID-19 infection and the recording of typical symptoms of seasonal respiratory infectious diseases, as well as an easy and clear assignment of patients to a coordinating practice or to the doctor dashboard. An alert function for the doctor as soon as there are relevant changes in the dashboard and technical support at least during the opening hours of the practices were also required.

The RPM systems were used by doctors to monitor their patients' symptoms such as body temperature, heart rate or oxygen saturation. Corresponding measured metrics were entered manually by patients in the respective application e. g. on their mobile phone or tablet. Doctors could review and assess these measurements through their dashboard and were able to contact their patients in case of unusual or notable changes in parameters. Data records stored in the app gave healthcare practitioners an increased density of statistics within relevant parameters, leading to a more information and communication as a traditional in-person appointment in doctors' offices, or via phone call. Longtime recording of parameters was also visualized through the doctors' dashboard, giving healthcare practitioners a better understanding of the progression of their patients' condition over time. Using the RPM, patients could also see whether the information transmitted had been viewed by their respective physician, indicating them they were safely cared for.

The RPM tools therefore should not replace doctor-patient contacts in general but may be integrated as an additional component when treating patients with specific conditions.

Patients that used one of the two RPM systems initially received instructions at their doctor's office on how to register and how to access them on their devices. Treatment via RPM corresponded with the progress of a patient's infection, and subsisted upon their recovery. There were no additional interventions or instructions given by the doctor, except the task to constantly add information, e. g. symptoms, as requested by the app. By using the apps, patients were enabled to remain at home, leading to an interruption of chains of infection and reducing the transmission of contagious diseases. . After their infection, all patients were asked to fill out an online survey using a link e-mailed to them by their attending physician.

2.2. Study design and endpoints

This randomized controlled trial with three groups was carried out from October 2020 to May 2021. Both the doctors and their treated patients were included if they agreed to participate. The two intervention groups used one of the two RPM systems and the third group of doctors treated their patients in usual care without additional digital support. Doctors were required to include patients for a period of three months.

As for the doctors, we specified the following endpoints: effort in patient recruitment and ongoing management effort for monitoring (e.g. due to patient queries), time balance (savings vs. additional work), satisfaction and assessment of the quality of care (e.g. finding critical cases). Patients were asked to assess the quality of treatment received (e.g. reduced uncertainty, fears, expenditure of time) and their satisfaction.

2.3. Practices/doctors

After screening 84 practices/doctors in ambulatory care, 51 practices/doctors (general practitioners, internists, otorhinolaryngologists or pulmonologists treating patients with respiratory infections) were included in the study (Fig. 1). After enrollment, practices/doctors were either assigned to one of the two groups treating patients with a RPM system, or the control group using block randomization in the ratio of 1:1:1, based on randomization lists drawn up in advance.

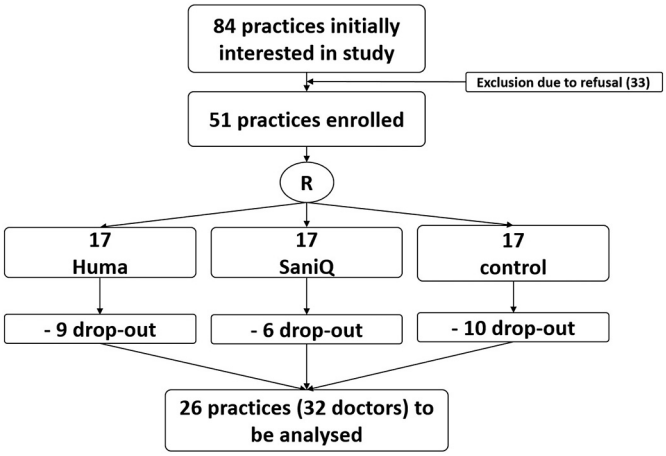

Fig. 1. CONSORT flow chart for the inclusion process of practices/doctors. Figure created by the authors.

2.4. Patients

Patients treated in the practices were eligible for inclusion if they were 18 years or older and had an acute respiratory infection (all respiratory infections were eligible, e.g. COVID-19, influenza, bacterial infections such as pneumonia as well as a cold). Patients without access to a web-enabled device (i.e. laptop, tablet or smartphone) were excluded. Insufficient skills of the German language in speech and writing also led to exclusion. Written consent was obtained from all patients prior to the trial. After screening 683 patients, 121 patients were enrolled in the same groups as their attending physicians (Fig. 2).

2.5. Control group

Patients in the control group did not receive any digital support during their treatment, but were also asked to fill in the online survey after recovery.

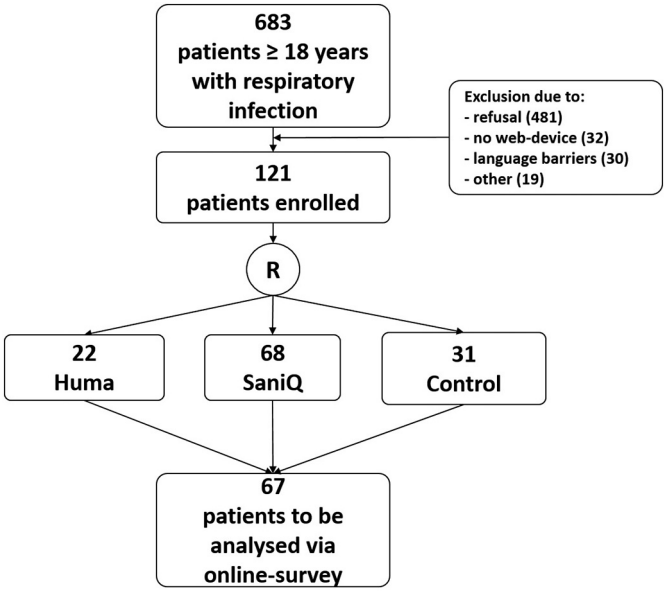

Fig. 2. CONSORT flow chart for the inclusion process of patients. Figure created by the authors.

2.6. Data collection via online survey

At the end of the study, all participating doctors were invited to take part in an online survey, which contained 43 questions (19 for the control group) about their patient characteristics and the endpoints mentioned above. The survey was accessible via a link sent by e-mail from the study site. Doctors were also required to forward the link for the patient survey to their enrolled patients by e-mail. The patient survey comprised of 45 questions (26 for the control group) on patient characteristics and the different endpoints. For many questions, both for doctors and patients, there were seven different possible answers ("totally agree", "mostly agree", "tend to agree", "tend to disagree", "mostly agree" and "strongly disagree" as well as the field "no answer"), using a Likert scale. Since the evaluation of these questions showed a differentiated response behavior, the first three possible answers for most questions were categorized as "yes" and the next three as "no" for better presentation; "no information" remained. In this publication, we publish a selection of the most important questions and answers concerning satisfaction and time savings.

2.7. Statistical analyzes

The statistical analyzes were mainly carried out descriptively. For the metric variables, we show mean values and standard deviation and for categorical variables, we demonstrate absolute values and percentages. Different tests for group comparisons were also carried out: analysis of covariance (ANCOVA) for metric variables, χ^2 tests for categorical ones). The evaluations were performed by using IBM SPSS Statistics 26 and Microsoft Excel 2016.

2.8. Ethics and study registration

Patients were required to sign an informed consent form in order to participate in the study. Patients were informed by their doctor in advance. The study was conducted in accordance with the ethical requirements of the current version of the Declaration of Helsinki. The study procedure and the associated documents were voted positively by the respective ethics committees. Further, the study was registered in the German Clinical Trials Register (DRKS00023553).

3. Results

3.1. Doctors' and patients' inclusion process and characteristics

Initially, 84 doctors were interested in participating in the study with their practices. After detailed information on the conditions of the study, 51 doctors/practices agreed to participate. They were randomized into the three groups, so that 17 practices could be assigned to each group. During the three-month intervention phase, 25 practices (49%) withdrew from the study within the first three weeks, so that the data from 26 practices (51%) with 32 participating doctors were available for analysis. This meant that 13 of them were assigned to RPM group 1, 12 in RPM group 2 and seven in the control group (Fig. 1). 23 (71.9%) doctors were male and the majority of the doctors (40.6%) was between 41 and 50 years old. Most doctors (46.9%) had little experience with clinical studies (1-5 so far) and 27 (84.4%) were practice owners (Table 1). During the three-month enrollment phase, a total of 683 patients were eligible to participate in the study. The majority (481 patients) refused to participate and 32 patients did not have the hardware needed to participate. 121 patients were enrolled, and 67 patients completed the online survey after their infection (22 from RPM group 1, 14 from RPM group 2 and 31 from the control group (Fig. 2)). Most of the patients were between 51 and 60 years old, and the majority was male (55.2%). Around two thirds (62.7%) had not used any health apps prior to taking part in this study and had no chronic disease (59.7%). About nine out of ten participating patients were non-smokers (85.1%) and most patients (53.7%) described the severity of their infection as medium (Table 2).

Table 1
Doctor characteristics ($n = 32$).

	Total cohort (n = 32) n (%)	RPM 1 ($n = 13$) n (%)	RPM 2 ($n = 12$) n (%)	Control ($n = 7$) n (%)	*p*-value
Doctors					
Age, years					n.a.
18–30	1 (3,1)	1 (7.7)	–	–	
31–40	3 (9.4)	2 (15.3)	1 (8.3)	–	
41–50	13 (40.6)	5 (38.5)	4 (33.4)	4 (57.1)	
51–60	13 (40.6)	4 (30.8)	6 (50.0)	3 (42.9)	
61–70	2 (6.3)	1 (7.7)	1 (8.3)	–	
Sex, male	23 (71.9)	11 (84.6)	7 (58.3)	5 (71.4)	n.a.
Practice owner	27 (84.4)	11 (84.6)	9 (75.0)	7 (100)	n.a.

Categorical variables are expressed as absolute and relative frequencies with n (%); n.a. = not available due to small number of cases; RPM = Remote Patient Monitoring. Table created by the authors.

3.2. Patient visits to the practices

The number of patient visits to the practice could not be reduced by using either RPM system: patients with a mild course of infection visited their practices 1.5 ± 0.8 times in RPM group 1 compared to 1.3 ± 0.7 times in RPM group 2 . Patients belonging to the control group visited with their doctor 2.3 ± 3.4 times, $p = 0.484$ (ANCOVA).

Patients with a severe course of infection 3.8 ± 1.2 compared to 3.8 ± 2.3 vs. 3.4 ± 1.1 visits, $p = 0.902$ (ANCOVA), respectively.

This is also confirmed by patients' answers regarding their number of visits to their practices: 1.7 ± 1.4 vs. 1.7 ± 1.2 vs. 1.6 ± 0.9 vs. 1.7 ± 1.8 visits, $p = 0.974$ (ANCOVA). Further, according to the statements of the doctors, the systems did not result in less phone calls from worried patients or less need for consultation.

3.3. Saving of time

The majority of doctors reported that instructing their patients regarding the use of the RPM systems took a lot of time. In addition, both patient care and practical procedures could not be made more efficient by using the RPM tool. Furthermore, the doctors mainly stated that the RPM systems did not save any time.

Table 2
Patient characteristics ($n = 67$).

	Total cohort (n = 67) n (%)	RPM 1 ($n = 22$) n (%)	RPM 2 ($n = 14$) n (%)	Control ($n = 31$) n (%)	*p*-value
Patients					
Age, years					n.a.
18–30	13 (19.4)	4 (18.2)	1 (7.1)	8 (25.8)	
31–40	11 (16.4)	3 (13.6)	3 (21.4)	5 (16.1)	
41–50	17 (25.4)	4 (18.2)	6 (42.9)	7 (22.6)	
51–60	20 (29.9)	8 (36.4)	3 (21.4)	9 (29.0)	
61–70	5 (7.5)	3 (13.6)	1 (7.1)	1 (3.2)	
71–80	1 (1.5)	–	–	1 (3.2)	
Sex, male	37 (55.2)	11 (50.0)	8 (57.1)	18 (58.1)	0.833
No chronic disease	40 (59.7)	10 (45.5)	10 (71.4)	20 (64.5)	0.228
Non-smoker	57 (85,1)	20 (90,9)	14 (100)	23 (74,2)	n.a.
Self-estimated severity of infection					n.a.
Mild	17 (25.4)	6 (27.3)	2 (14.3)	9 (29.0)	
Moderate	36 (53.7)	11 (50.0)	10 (71.4)	15 (48.4)	
Severe	9 (13.4)	4 (18.2)	–	5 (16.1)	
Don't know	5 (7.5)	1 (4.5)	2 (14.3)	2 (6.5)	

Categorical variables are expressed as absolute and relative frequencies with n (%); χ^2 tests were carried out to calculate group differences); n.a. = not available due to small number of cases; RPM = Remote Patient Monitoring. Table created by the authors.

3.4. Satisfaction

Both the groups with the RPM systems and the control group stated that they could adequately care for their patients and were satisfied with the care their patients received. The majority of the control group did not want an RPM system to assist with the care of patients.

Doctors belonging to RPM groups 1 and 2 felt that using RPM tools to assist with patient care was satisfactory, and that doctor-patient relationship was also improved. Overall, the majority of doctors was satisfied and said they would use the system again. This sentiment was mirrored by the majority of patients that stated they were overall satisfied, described their relationship with their doctor as improved and stated that they would use the respective system again.

4. Discussion

The RPM study investigated satisfaction, time savings and the possible reduction of patient visits to practices that use RPM systems during the treatment of patients with acute respiratory infections compared to usual care. In our study, we used an online survey to investigate the aforementioned endpoints. The survey consisted of many categories such as acceptance, usability and satisfaction, and contained several questions from the Telehealth Usability Questionnaire [7], which is based on the Technology Acceptance Model (TAM). The TAM including various modifications is one of the best-known and best-researched models to predict the acceptance of a technology by users. The TAM implies the assumption, confirmed by validation studies, that the technology acceptance of the target group and their intention to apply a new system is dependent of the subjectively perceived benefit and the ease of use of the system [8,9] Due to the limited length of the manuscript, we demonstrated the most important endpoints in this paper.

Although the effects of the COVID-19 pandemic have accelerated the development of telemedicine in general [10], the infection season 2020/21 represented a special challenge for general practitioners and specialists in ambulatory care. Overall, only a few doctors with their practices were willing to participate in the study, which is certainly also due to their extreme workload. Another reason could be that unclear remuneration or financing of telemedicine is perceived as a barrier [11] and could result in lack of interest in studies investigating telemedicine. Of the few doctors who agreed to participate, 25 practices (49%) dropped out during the course of the study, all within the first three weeks. It can be assumed that the start, combined with the installation of the systems and the associated training for the providers, but also the documentation effort associated with clinical studies and unavoidable for data protection and ethical reasons (patient information, declaration of consent and patient screening) led to the drop-outs. But also internal practice reasons, general time problems and technical difficulties were given by the doctors. Practices and doctors who had overcome this initial hurdle had no further difficulties in the course of the study.

According to statements by the participating doctors, fewer infection patients were treated in the practices than usual in the infection season examined, but the inclusion rate of the patients is still low at one fifth. There can various reasons for this, e. g. the special situation of the COVID-19 pandemic and the fact that infection patients with less severe courses may not see a need for digital care. Furthermore, patients with severe courses, may have missed ambulatory care or were no longer able to digitally document symptoms. It can be assumed that if patients with chronic diseases use these type of RPM systems, it could offer a bigger advantage due to the close relationship with the general practitioner or specialist.

The small number of cases both of the doctors ($n = 32$) and the patients ($n = 67$) as well as the different group sizes due to the drop-outs after the start of the study lead to a reduction in the statistical significance. Several tests for group comparisons could not be carried out. Trends observed in this study could turn out to be reliable effects with a larger sample size.

On the patient side, the results show a consistently positive assessment of digital care, even if differences in processing between the two groups that used an RPM system could be relevant in other contexts.

On the medical side, handling and integration of the systems into consisting practice processes in particular still seem to be a challenge. In general, technical maturity is seen as a promotional factor for telemedicine [11]. Furthermore, the use of the RPM systems did not result in a positive time balance in our study. Concerning the positive statements of the control group with regard to the quality and satisfaction of their treatment, the need for digital care options in ambulatory care should, if necessary, first be determined separately. Basically, there seems to be a great interest in digital patient care (see also [12]), but in detail there still a problem in the technical implementation. The systems should be able to be integrated into consisting processes as quickly and easily as possible and be able to be used with as little effort as possible by doctors in hectic everyday practice. Otherwise, the inhibition threshold for some doctors may be too high (see also the large number of doctors who dropped out at the beginning of the study).

5. Conclusion

Even if there were no indications for more efficiency by using the RPM systems, the doctors see great potential to intensify the interaction between doctor and patient. In particular, more intensive contact with patients with chronic diseases (COPD, long-COVID, etc.) could be of long-term interest and importance for doctors in ambulatory care.

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Contributor statement

SE, DS and SC planned and designed the study; SE wrote the manuscript and provided and cared for the study patients and collected data; ES served as statistic advisor; SC, ES and DS served as scientific advisors and interpreted the data; all authors critically reviewed the manuscript.

Declaration of Competing Interest

The authors declare no conflicts of interest.

References

[1] Karagiannidis C, Mostert C, Hentschker C, et al. Case characteristics, resource use, and outcomes of 10 021 patients with COVID-19 admitted to 920 German hospitals: an observational study. Lancet Respir Med. 2020;8:853–62. https://doi.org/10.1016/s2213-2600(20)30316-7.
[2] Annis T, Pleasants S, Hultman G, et al. Rapid implementation of a COVID-19 remote patient monitoring program. J Am Med Inform Assoc. 2020;27:1326–30. https://doi.org/10.1093/jamia/ocaa097.
[3] Provenzano DA, Sitzman BT, Florentino SA, et al. Clinical and economic strategies in outpatient medical care during the COVID-19 pandemic. Reg Anesth Pain Med. 2020;45:579–85. https://doi.org/10.1136/rapm-2020-101640.
[4] Gordon WJ, Henderson D, DeSharone A, et al. Remote patient monitoring program for hospital discharged COVID-19 patients. Appl Clin Inform. 2020;11:792–801.
[5] Wosik J, Fudim M, Cameron B, et al. Telehealth transformation: COVID-19 and the rise of virtual care. J Am Med Inform Assoc. 2020;27:957–62. https://doi.org/10.1093/jamia/ocaa067.
[6] Patel SY, Mehrotra A, Huskamp HA, et al. Trends in outpatient care delivery and telemedicine during the COVID-19 pandemic in the US. JAMA Intern Med. 2021;181:388–91. https://doi.org/10.1001/jamainternmed.2020.5928.
[7] Parmanto B, Lewis Jr AN, Graham KM, et al. Development of the telehealth usability questionnaire (TUQ). Int J Telerehabil. 2016;8:3–10. https://doi.org/10.5195/ijt.2016.6196.
[8] Harst L, Lantzsch H, Scheibe M. Theories predicting end-user acceptance of telemedicine use: systematic review. J Med Internet Res. 2019;21:e13117. https://doi.org/10.2196/13117.
[9] Davis FD. Perceived usefulness, perceived ease of use, and user acceptance of information technology. MIS Q. 1989;13:319–40. https://doi.org/10.2307/249008.

[10] Waschkau A, Steinhäuser J. Wandel des Bedarfs an Videosprechstunden in Zeiten einer Pandemie - eine qualitative Betrachtung. Z Allg Med. 2020;96(7):317–24. https://doi.org/10.3238/zfa.2020.0317-0324.
[11] Waschkau A, Zwierlein R, Steinhäuser J. Barrieren und fördernde Faktoren für telemedizinische Anwendungen in der hausärztlichen Praxis - Qualitative Ergebnisse einer Pilotstudie. Z Allg Med. 2019;95(10):405–12. https://doi.org/10.3238/zfa.2019.0405-0412.
[12] Krüger-Brand HE. Fernbehandlung: Weg frei für die Telemedizin. Dtsch Arztebl Int. 2018;115:965–8.