Telemedical management of symptomatic COVID-19 outpatients

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Shareable abstract (@ERSpublications)
COVID-SMART is the first randomised, clinical trial systematically assessing the use and benefit of telemedicine during the COVID-19 pandemic https://bit.ly/3UflKsH

Cite this article as: von Falkenhausen AS, Geipel S, Gail A, *et al*. Telemedical management of symptomatic COVID-19 outpatients. *ERJ Open Res* 2024; 10: 00277-2024 [DOI: 10.1183/23120541.00277-2024].

Received: 23 March 2024
Accepted: 16 April 2024

Abstract

Background COVID-19 remains a challenge to individual health and healthcare resources worldwide. Telemedical surveillance might minimise hospitalisation and direct patient–physician contacts. Yet, randomised clinical trials evaluating telemedical management of COVID-19 patients are lacking.

Methods COVID-SMART is a randomised, open-label, controlled clinical trial investigating whether telemedicine reduces the primary end-point of hospitalisation or any unscheduled utilisation of an emergency medical service within 30 days of follow-up. Key secondary end-points included mortality and primary end-point components. We enrolled acutely infected SARS-CoV-2 patients suitable for outpatient care. All presented with ⩾1 risk factor for an adverse COVID-19 course. Patients were randomised 1:1 into a control group receiving standard of care and an intervention group receiving smartphone-based assessment of oxygen saturation, heart rate and electrocardiogram, and telemedical counselling *via* a 24/7 emergency hotline.

Results Of 607 enrolled patients (mean±SD age 46.7±13.5 years), 304 were randomised into the intervention and 303 into the control group. The primary end-point occurred in 6.9% (n=21) of the intervention and in 9.6% (n=29) of the control group (hazard ratio (HR) 0.72, 95% confidence interval (CI) 0.41–1.26; p=0.24). No deaths occurred during follow-up. Fewer intervention group participants utilised outpatient-based emergency medical services (HR 0.43, 95% CI 0.20–0.90; p=0.03).

Conclusions COVID-SMART is the first randomised clinical trial assessing the benefit of telemedicine in an acute respiratory infectious disease. Whereas telemedical management did not reduce the primary end-point of hospitalisation, fewer intervention group patients used outpatient-based emergency services, suggesting a potential benefit for less-acutely infected individuals.

Introduction

Despite vaccination, healthcare systems worldwide remain exposed to high COVID-19 incidence rates, in particular following loosened general measures against viral spread [1]. Individuals are at continuous risk of infection due to generally high infection rates, mutating COVID-19 subtypes [2], and an attenuated protection by remote vaccinations [3, 4]. Season changes will likely further spike infection rates around the world. At the same time, the resumption of non-COVID care limits resources in hospitals that were allocated to COVID-19 patients during the earlier phases of the pandemic. Therefore, hospital resources for COVID-19 patients should be reserved primarily for those at high risk of an adverse disease course, based on infection-related symptoms and comorbidities [5]. Yet, the most relevant comorbidities are common and include arterial hypertension, obesity, diabetes mellitus and active smoking, rendering prioritisation a major challenge [6–8].

Telemedicine is a promising resource-sparing strategy that may help to improve monitoring of COVID-19 patients while reducing the need for in-person contacts both in outpatient and inpatient settings. Yet, little evidence is available to support the advantage of telemedical over standard management in COVID-19 patients. A small single-arm observational study in Germany indicated that a device-based telemedicine concept appears possible [9]. Another observational study in a large but geographically circumscribed health management organisation reported a reduction of 1.8 deaths per 1000 patients at 30 days with monitoring, while in-person contacts were increased [10]. In a subsequent randomised clinical trial, the same group reported that home pulse oximetry information on top of a text-message-based telemedicine concept did not improve survival [11]. So far, a randomised clinical trial demonstrating the benefit of telemedicine in COVID-19 patients has not been reported.

Here we report the results of the COVID-SMART trial, a single centre, open-label randomised clinical trial testing the hypothesis that a smartwatch-based telemedicine concept including pulse oximetry information and electrocardiogram (ECG) recordings can improve the outcome of symptomatic COVID-19 outpatients affected by clinical risk factors for an adverse course of disease.

Methods

Study design and trial oversight

COVID-SMART is an investigator-initiated, prospective, randomised, open-label, controlled, parallel group, single centre clinical trial. The trial was conducted by researchers of the University Hospital, LMU Munich, Germany. Information about the trial was conferred to potential participants by the Munich health authorities when mandating domestic isolation following a PCR-confirmed SARS-CoV-2 infection. Potential participants were further informed about the trial through flyers at SARS-CoV-2 test centres, podcasts, press releases and social media outlets. Individuals interested in participation could then contact the study team by phone, e-mail or through a contact form on the study website available for the duration of the trial at www.covid-smart.de. All contacts were subsequently screened for inclusion and exclusion criteria and eventually enrolled in the trial. No unsolicited contact was initiated by the study team.

The study was approved by the responsible ethics committee (EK 20-448) and by the data protection officer (accession number 1595) at LMU Munich. The COVID-SMART study has been registered with clinicaltrials.gov (NCT04471636). All patients provided written informed consent to study participation and to the data protection concept.

Inclusion and exclusion criteria

Patients eligible for participation in COVID-SMART were $\geqslant$18 years of age and acquired a PCR-confirmed SARS-CoV-2 infection within the preceding 7 days. All participants needed to present with symptomatic COVID-19 and had to be affected by at least one of the following risk factors for an adverse clinical course: treated or untreated arterial hypertension; active smoking of at least five cigarettes per day; body mass index $\geqslant 30\ kg \cdot m^{-2}$; atrial fibrillation; diabetes mellitus; systolic or diastolic heart failure; coronary artery disease status post percutaneous coronary intervention or coronary artery bypass graft surgery. Patients were suitable for outpatient care at the time of enrolment. Participants had to have an up-to-date smartphone with sufficient internet connectivity at the location of their domestic isolation and had to be able to handle the provided smartwatch after instructions.

We excluded patients not consenting to study participation or the data protection concept and those not fulfilling inclusion criteria. We further excluded individuals residing >50 km outside the region of Munich, individuals who participated in another clinical trial or those who required hospitalisation at the time of enrolment. Only one participant per household was allowed and study participation was not allowed a second time in case of symptomatic re-infection.

Randomisation and study procedures

Enrolled and consented patients were randomised in a 1:1 fashion into an intervention and a control group. Randomisation was computer-based using the WolframAlpha randomisation function in simple blocks of 50 participants (Wolfram Research, Wolfram Alpha LLC, USA). No stratification of confounding factors was performed.

Both the intervention and the control groups had unrestricted access to all resources of the German healthcare system at their own discretion. The intervention group additionally received a smartwatch and 24/7 access to a telemedicine team of physicians. We used the smartwatch "Scanwatch" (Withings, Issy-les-Moulineaux, France), capable of on-demand pulse oximetry measurements and single-lead ECG recordings. The telemedicine centre was accessible by phone throughout the study duration in case of pathological

measurements or any kind of symptomatic or non-symptomatic inquiries about active COVID-19. All physicians were trained and experienced in the care and counselling of COVID-19 patients and had remote access to the patient-specific, objective oxygen saturation measured by pulse oximetry (S_{pO_2}) and ECG measurements of the smartwatch through the pseudonymised Withings web-based frontend (Withings, Issy-les-Moulineaux, France).

Upon study enrolment, patients were visited during their domestic isolation by a member of the study team for consent, to record demographic and anthropometric characteristics, COVID-19 related information, vaccination status, past medical history, medication use and quality of life information using the EQ-5D instrument. In the intervention group, patients also received technical instructions on the installation and use of the smartwatch as well as access to information of the telemedicine centre. Patients had access to their individual measurements and were instructed to contact the 24/7 emergency hotline in case of heart rate >100 beats·min^{-1}, S_{pO_2} <95% or any ECG alerts. The study team did not proactively contact the patient. All study data were transferred for storage into a SQL database using an Apache webserver with a PHP framework, operated as a virtual server within the patient data infrastructure of the LMU University Hospital.

Follow-up

All patients were followed for 30 days from enrolment. Follow-up was performed by phone using a standardised questionnaire to record the occurrence of end-points during the study period and obtain information on the current health status and quality of life. End-points were considered when they occurred between PCR confirmation of the SARS-CoV-2 infection until 30 days after randomisation.

End-point definitions

The primary end-point was a composite of any hospitalisation or any unscheduled utilisation of a hospital-based or outpatient-based emergency medical service during follow-up. Secondary end-points were the components of the primary end-point, specifically any hospitalisation, any unscheduled utilisation of a hospital-based or any unscheduled utilisation of an outpatient-based emergency medical service during follow-up. Thereby, hospital-based emergency care involved presentation of the patient to the emergency department of a hospital for acute medical care (= utilisation of hospital-based emergency medical service). For outpatient-based medical care, patients had the option to call an emergency ambulance for acute transportation to an emergency department (= utilisation of emergency medical rescue/ambulance). For less acute medical conditions, patients had the option to present to an outpatient medical on-call practice or to request an on-call physician to visit them at home (= utilisation of outpatient on-call physician). Further secondary end-points were encounters with the primary care physicians, as well as all-cause mortality and COVID-19-related mortality. To obtain qualitative patient-reported outcome measures, we used questionnaires to ask patients in the intervention and control groups about their subjective perception of telemedical care in the setting of acute COVID-19.

Sample size considerations and statistical analysis

We calculated an occurrence of the primary end-point in 20% of our control group. We anticipated an occurrence of the primary end-point in 10% of our intervention group. To reach a power ($1 - \beta$) of 90% at a two-sided alpha error rate of 5%, we required 532 patients (266 patients per group). To account for possible dropouts, we planned to enrol 300 patients per group.

Discrete data are presented as absolute and relative frequencies. Continuous variables are presented as mean±SD or medians and interquartile range as appropriate. For the analyses of the primary and secondary end-points, we fitted Cox proportional hazards models assessing the time to end-point occurrence. Deviations from the proportional hazard's assumption were assessed using the Schoenfeld method. For end-point visualisation, we plotted Kaplan–Meier curves and assessed differences between groups using log-rank tests. Subgroup analyses were visualised by Forest plots. We performed all analyses using R (version 3.6.1; The R Foundation for Statistical Computing, Vienna, Austria) embedded in R-Studio (version 1.2.1335; Integrated Development for R, RStudio, Boston, MA, USA). Two-sided p-values <0.05 were considered significant.

Role of the funding source

The funder and sponsor had no role in the study design, data collection, data analysis, data interpretation, writing of the report or decision to submit for publication.

Results

Between October 2020 and May 2022 we enrolled 607 patients with an acute, symptomatic, PCR-confirmed SARS-CoV-2 infection and at least one pre-specified risk factor for an adverse course of

disease. Of these patients, 304 were randomised into the intervention group and 303 were randomised into the control group. Seven patients in the intervention group and five patients in the control group were lost to follow-up. The study flow is visualised in figure 1.

The mean age of study patients was 46.7±13.5 years and 54.9% (n=333) were men. As defined by the inclusion criteria, all participants presented with risk factors for an adverse course of COVID-19. In particular, the mean body mass index was 28.3±6.1 $kg \cdot m^{-2}$, 47.3% (n=287) had arterial hypertension, 29.3% (n=178) were active smokers and 11.7% (n=71) had diabetes mellitus. Baseline characteristics were well balanced between the randomisation groups (table 1). In accordance with the comorbidity profile, the use of prescription drugs was common, predominantly including antithrombotic therapy, ACE inhibitors or angiotensin receptor blockers, β blockers, diuretics and statins. The most reported COVID-19 associated symptoms were coughing, nasal drip, fever, fatigue and loss of smell. At least one vaccination against COVID-19 had been received by 77.9% of participants.

Primary and secondary end-points

The primary end-point, a composite of any hospitalisation or any unscheduled utilisation of a hospital-based or outpatient-based emergency medical service during follow-up, occurred in 21 (6.9%) patients of the intervention group and in 29 (9.6%) patients in the control group (hazard ratio (HR) 0.72; 95% CI 0.41–1.26; p=0.24) (table 2). The temporal occurrence of the primary end-point is visualised by a Kaplan-Meier plot in figure 2a.

Components of the primary end-point and other secondary end-points are reported in table 2. Any hospitalisation occurred in 2.6% in the intervention and 3.0% in the control group (HR 0.90; 95% CI 0.35–2.32; p=0.82). The utilisation of a hospital-based emergency medical service did not differ between the intervention and control groups. An outpatient-based emergency medical service was used more frequently in the control group (HR 0.43; 95% CI 0.20–0.90; p=0.03; figure 2b). More than one-third of patients in either group consulted their primary care physicians. No death occurred during follow-up.

In subgroup analyses, we assessed the occurrence of the primary end-point stratified by age, sex, diabetes, obesity, vaccination status and active smoking predisposing to an adverse outcome of COVID-19. None of the subgroups revealed a differential treatment benefit compared to our primary analysis (figure 3).

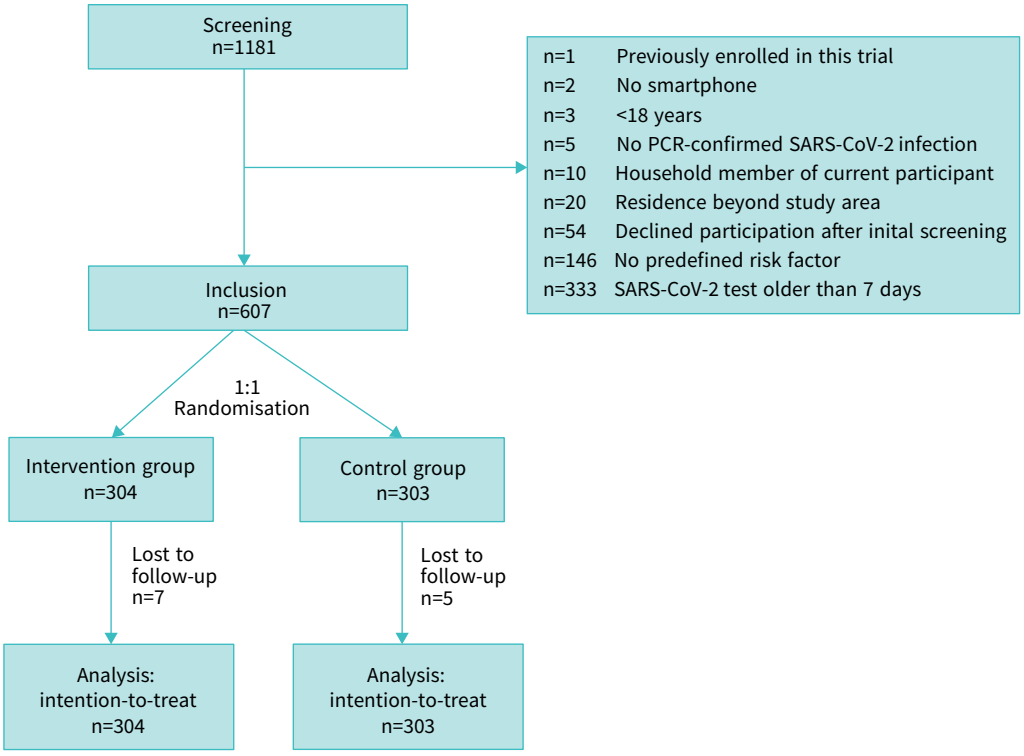

FIGURE 1 Study flow for the intention-to-treat analysis. Patients lost to follow-up were censored.

TABLE 1 Baseline characteristics

	Intervention group[#]	Control group[¶]	p-value
Demographics			
Age years, mean±SD	46.6±12.7	46.8±14.2	0.808
Male sex, n (%)	155 (51.0)	178 (58.7)	0.061
BMI kg·m^{-2}, mean±SD	28.3±6.1	28.4±6.1	0.831
Comorbidity profile, n (%)			
Arterial hypertension	142 (46.7)	145 (47.9)	0.871
Hypercholesterolaemia	72 (23.7)	61 (20.1)	0.281
Diabetes mellitus	27 (8.9)	44 (14.5)	0.043
Active smoking	85 (28.0)	93 (30.7)	0.533
Chronic kidney disease	8 (2.6)	6 (2.0)	0.358
Coronary artery disease	18 (5.9)	18 (5.9)	1.00
Myocardial infarction	6 (2.0)	11 (3.6)	0.234
Heart failure	10 (3.3)	7 (2.3)	0.285
Atrial fibrillation	12 (3.9)	18 (5.9)	0.349
Stroke	7 (2.3)	6 (2.0)	0.504
History of cancer	23 (7.6)	22 (7.3)	0.878
COPD	3 (1.0)	4 (1.3)	1.00
Asthma	50 (16.4)	36 (11.9)	0.104
Liver disease	15 (4.9)	28 (9.2)	0.052
Vaccination status, n (%)			
At least one SARS-CoV-2 vaccination	242 (79.6)	231 (76.2)	0.634

BMI: body mass index. [#]: n=304; [¶]: n=303.

The provision of a 24/7 telemedicine service to the intervention group was utilised by 23.7% of all patients during the study period. Based on the visual analogue scale as part of the EQ-5D instrument for the assessment of quality of life, the median change was +10 points (interquartile range 0–20 points) in the intervention group *versus* ±0 points (interquartile range −10–20 points) in the control group (p=0.88). Two-thirds of patients in the intervention group stated that telemedicine improved their care during COVID-19, and 74.0% stated that telemedicine reduced fear during COVID-19. Over 90% of intervention group patients would like to benefit from telemedicine care again, whereas 43.6% of the control group indicated that they would have preferred access to telemedicine support.

Discussion

In our randomised clinical trial, we allocated symptomatic non-hospitalised COVID-19 patients at risk for an adverse course of disease to either receive standard management or a smartwatch-based telemedicine

TABLE 2 Primary and secondary end-points during follow-up

	Intervention group, n (%)[#]	Control group, n (%)[¶]	HR (95% CI)	p-value
Primary end-point				
Hospitalisation or unscheduled utilisation of hospital- or outpatient-based emergency medical service	21 (6.9)	29 (9.6)	0.72 (0.41–1.26)	0.24
Secondary end-points				
Hospitalisation	8 (2.6)	9 (3.0)	0.90 (0.35–2.32)	0.82
Hospitalisation due to COVID-19	2 (0.7)	4 (1.3)	0.50 (0.09–2.74)	0.43
Hospitalisation for other reasons	7 (2.3)	5 (1.7)	1.42 (0.45–4.47)	0.55
Utilisation of hospital-based emergency medical service	10 (3.3)	8 (2.6)	1.26 (0.50–3.19)	0.63
Utilisation of outpatient-based emergency medical service	10 (3.3)	23 (7.6)	0.43 (0.20–0.90)	0.03
Utilisation of emergency medical rescue/ambulance	5 (1.6)	5 (1.7)	1.01 (0.29–3.48)	0.99
Utilisation of outpatient on-call physician	7 (2.3)	20 (6.6)	0.34 (0.15–0.81)	0.02
Consultation of primary care physician	109 (35.9)	114 (37.6)	0.92 (0.71–1.20)	0.56
Death during follow-up	0 (0)	0 (0)	n.a.	n.a.

Primary and secondary end-points reported as absolute and relative frequencies of occurrence during 30 days of follow-up. Subgroups may show a higher sum of event rates than their parent category due to the occurrence of an event in more than one subgroup. HR: hazard ratio; n.a.: not applicable. [#]: n=304; [¶]: n=303.

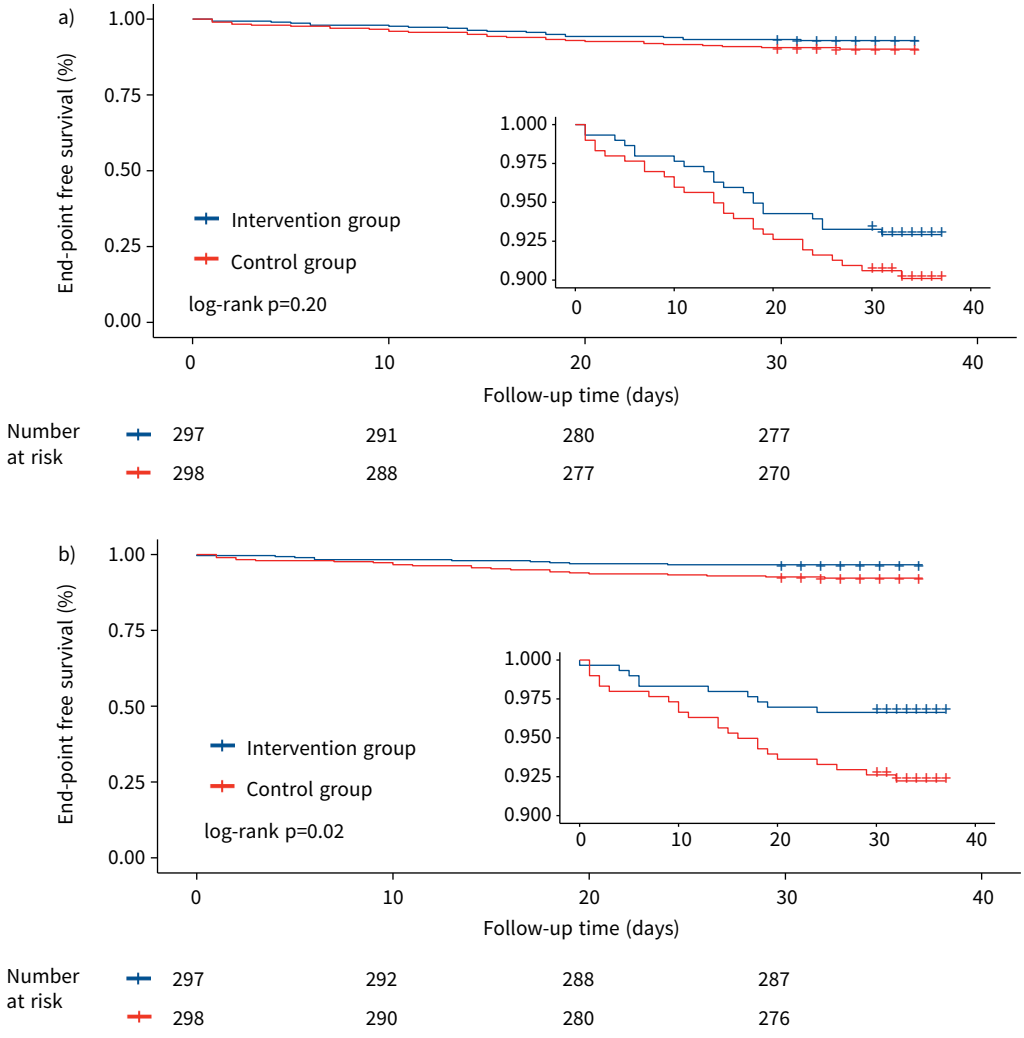

FIGURE 2 Kaplan–Meier plots show the end-point free survival for a) the primary end-point composed of hospitalisation or any unscheduled utilisation of hospital- or outpatient-based emergency medical services and b) the secondary end-point of utilisation of outpatient-based emergency medical services.

care. Regarding the primary end-point of hospitalisation or unscheduled utilisation of outpatient emergency medical service, we found no difference between treatment arms. Yet, we observed that patients receiving telemedicine care less frequently utilised an outpatient-based emergency medical service.

In the beginning of the SARS-CoV-2 pandemic, the prospect of COVID-19 disease was a threat to individual health, particularly in high-risk patients for an adverse course [12, 13]. With the advent of vaccines [14–16] and therapeutic options [17], combined with less virulent SARS-CoV-2 variants [18, 19], the threat to individual health faded. Yet, the increasing number of infected patients increased pressure on the capacity of healthcare systems worldwide [20]. Today, many patients seek medical attention for non-COVID-19-related health issues while being actively infected with SARS-CoV-2. Throughout all phases of the pandemic, and to the present day, the provision of care to COVID-19 patients constitutes a burden to healthcare systems and their providers, and in fact high-risk patients such as those who are immunocompromised remain especially vulnerable to active COVID-19. For all others, care for vaccinated COVID-19 patients mostly shifted from inpatient and intensive to outpatient care as the number of hospitalisations decreased [21].

Telemedicine care combining access to experienced physicians with the availability of objective disease-relevant parameters like oxygen saturation or an ECG promised to alleviate the pressure on healthcare providers and resources. Based on initial data from the Robert Koch Institute in May 2020, we

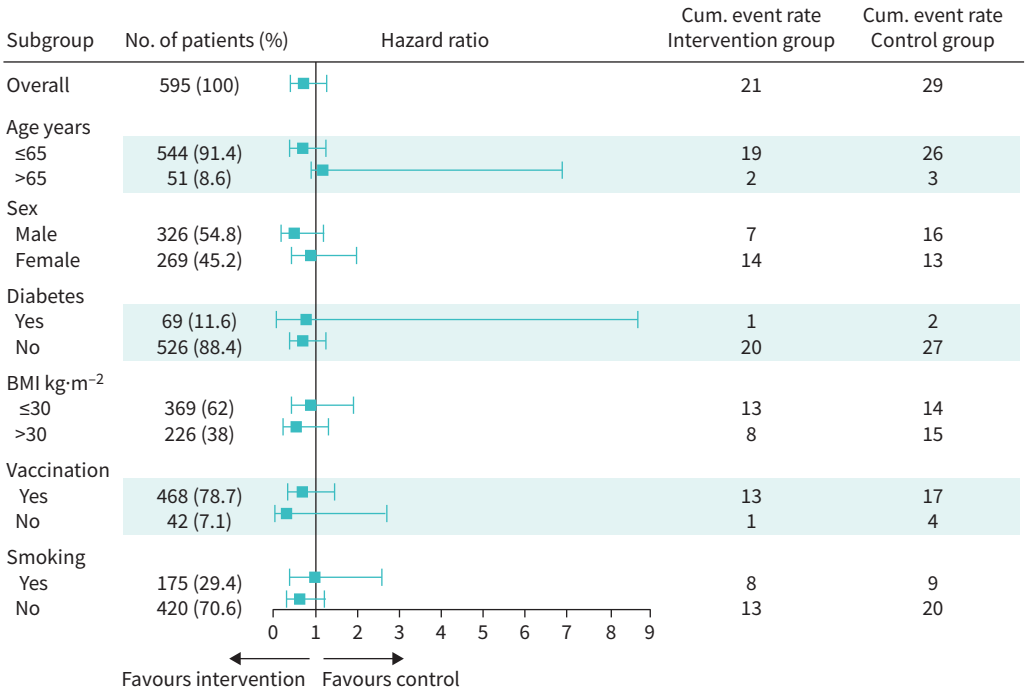

FIGURE 3 Visualisation of subgroup analyses for the primary end-point. BMI: body mass index; Cum.: cumulative.

anticipated a 20% incidence rate of the primary end-point in our target population at risk for severe COVID-19. We further anticipated that telemedicine care could reduce this rate to 10%. However, with the described attenuated pandemic kinetics, and despite recruitment of all planned participants, we only observed a 9.6% incidence of our primary end-point in our control group. As a point estimate, we found a 28% relative reduction of the primary end-point in our intervention group, but this difference did not reach statistical significance.

Considering the increasing importance of outpatient-based COVID-19 care, we observed that our telemedicine concept reduced the unscheduled utilisation of outpatient-based emergency medical care by 56%. This effect was driven by patients seeking the attention of outpatient on-call physicians, whereas the utilisation of emergency ambulances providing immediate transport to an emergency room was comparable across treatment groups. This indicates that the telemedicine concept of COVID-SMART might be most suited to coordinate care and reduce in-person medical contacts of infectious individuals in a subacute, less symptomatic context.

Facing the risk of infection transmission, the need to reduce in-person contacts in the COVID-19 pandemic has been recognised early on. Telemedicine care thereby promised a good balance between maintaining a high standard of care and a reduction of contacts. It remains an important question whether the concept of telemedicine would withstand scientific evaluation. Telemedicine for COVID-19 care has been examined previously; recent reviews report various attempts to use smartwatches and wearables, mostly for symptom monitoring and contact tracing [22]. Only few studies have demonstrated that telemedicine in COVID-19 is practicable also for continuous monitoring of objective health measures like heart rate and oxygen saturation. A study by Wurzer *et al*. [9] showed that provision of an in-ear device for such 24/7 surveillance transmitted to a telemedicine team of physicians is feasible. Yet, randomised controlled trials demonstrating the benefit of telemedicine in COVID-19 are sparse. One of the few existing randomised controlled studies investigated the addition of oxygen saturation measurements to a text message-based telemedicine concept [11]. As a result, the authors found that such an addition provided no significant benefit. Importantly, the reported telemedicine concept itself had only been evaluated based on a retrospective, observational analysis [10, 23]. Hence, our COVID-SMART study may be the first randomised clinical trial evaluating the benefit of telemedicine care to COVID-19 patients. This is emphasised particularly as we investigated the clinically relevant composite primary end-point of hospitalisation or any unscheduled utilisation of a hospital-based or outpatient-based emergency medical

service. Against the expectations raised that telemedicine may improve the level of medical care while reducing personal contacts, the primary result of our study was negative.

A number of factors may have contributed to the neutral findings and the dynamic of the pandemic may have played the most important role. At the beginning of the pandemic, the menace of SARS-CoV-2 was highest, resulting in the most threatening burden on healthcare systems and the strictest restriction measures [24]. Yet, during this phase, the absolute numbers of COVID-19 patients in ambulatory care were low [25], limiting a speedy study enrolment. In contrast, as the pandemic evolved with more virulent SARS-CoV-2 variants, higher absolute numbers of infected individuals were registered [26]. However, the more benign course of COVID-19 combined with increasing vaccination rates led to a reduced threat to personal health and fading associated fear, both negatively impacting the willingness to participate in our study as well as the occurrence of our primary end-point.

Patients recruited into our study were affected by a high risk of an adverse course of COVID-19 as defined by the inclusion criteria. One might speculate that such an at-risk cohort is more ready to seek emergency medical attention despite the provision of telemedicine care due to the severity of symptoms. This is further reflected by the neutral findings of our secondary end-point of utilisation of an emergency medical rescue and ambulance service. Against this background it is interesting to note that we did observe a difference in our secondary end-point of utilisation of an outpatient-based emergency medical service for less acute circumstances. Although this finding may serve only as hypothesis-generating, one might postulate that telemedicine care may be of highest usefulness in less symptomatic patients. However, facing the negative result of our study and considering the high effort for the provision of 24/7 on-call physicians, a systematic, clinical implementation of our concept to date seems inappropriate.

Interestingly, the rate of contacts with the participants' primary care physicians during the study period did not reach statistical significance but numerically more control group patients contacted their primary care physician. Furthermore, we noted a high acceptance of our innovative telemedical concept with 90% of patients in the intervention group stating that they would use telemedical care in the light of active COVID-19 again. This finding is well in line with previous analyses that showed a sufficient patient satisfaction with telehealth providers during the COVID-19 pandemic [27].

A few limitations need to be considered when interpreting our data. First, we enrolled voluntary participants in domestic isolation. Given German data protection regulations, unlike in previous studies [11], no direct contact *via* the healthcare provider was possible. Instead, intense communication efforts were required to inform our target population about our study. This rendered it possible for all SARS-CoV-2 infected at-risk individuals in our catchment area to participate irrespective of their insurance status or healthcare provider. Yet, it may have introduced some degree of selection bias favouring more health-literate individuals. The requirement of a personal smartphone may have further accentuated selection bias. We aimed to reduce such bias by using a smartwatch compatible with any current smartphone and common operating system. We also acknowledge that our study was conducted open-label at a single centre in Germany only, which may limit the transferability to other, possibly less developed healthcare systems. Furthermore, our results may not be fully transferable to other risk groups for COVID-19, such as immunocompromised patients.

In conclusion, we conducted one of the first and largest prospective randomised clinical trials investigating the benefit of an innovative smartphone-based telemedicine care concept in COVID-19 patients at risk for an adverse course of disease. Despite such an at-risk cohort, our telemedicine care concept provided no significant benefit to our patients regarding our primary end-point. Interestingly, non-acute outpatient-based emergency medical contacts were reduced in the intervention group. Future studies may need to target the benefit of telemedicine in lower risk or less severely affected individuals.

Acknowledgements: The use of the EQ-5D-questionnaire has been approved under tracking number 36922. We thank all participants who voluntarily contributed to our cohort. We further thank the health authority of the Bavarian state capital Munich (Gesundheitsreferat der Landeshauptstadt München) for the continuous support throughout the conduct of our study.

Data availability: Data will be shared by the corresponding author upon request.

Provenance: Submitted article, peer reviewed.

Ethics statement: The study was approved by the responsible ethics committee (EK 20-448) and by the data protection officer (accession number 1595) at LMU Munich.

This study is registered at www.clinicaltrials.gov with identifier number NCT04471636.

Author contributions: A.S. von Falkenhausen: data curation, formal analysis, investigation, project administration, visualisation and writing (original draft); S. Geipel and A. Gail: investigation; C. Scherer: investigation, formal analysis and software; S. Stockhausen, L.E. Sams, F. Becker, P.M. Doldi and E. Lemmermöhle: investigation; M. Schleef, M. Becker, P. de Villèle and M. Lauterbach: investigation and resources; S. Massberg: conceptualisation, funding acquisition and supervision; S. Kääb: conceptualisation, data curation, formal analysis, funding acquisition and supervision; M.F. Sinner: conceptualisation, data curation, formal analysis, funding acquisition, project administration, supervision, validation, visualization and writing (original draft).

Conflict of interest: A.S. von Falkenhausen declares to be granted support from the German Research Foundation. C. Scherer reports speaker honoraria from AstraZeneca outside the submitted work. P. de Villèle reports being an employee of Withings, the manufacturer of Scanwatch, the smart watch that was used in this trial. M.F. Sinner declares being granted support from the German Centre for Cardiovascular Research and with travel support from Biotronik. All other authors declare no potential conflict of interest.

Support statement: This study was supported by the German Centre for Cardiovascular Research (DZHK) through a grant to M.F. Sinner (81X1600211). A.S. von Falkenhausen was supported by the German Research Foundation (413635475) through the clinician scientist program in vascular medicine (PRIME). Funding information for this article has been deposited with the Crossref Funder Registry.

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