What do physicians think about the use of telemedicine to recruit and assess participants in mHealth clinical studies as a consequence of the COVID-19 pandemic?

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Abstract

Background: The COVID-19 pandemic created a golden opportunity for digital health. Nevertheless, studies to validate mHealth solutions are still missing. To expedite those studies while ensuring patient safety, the use of telemedicine technologies for patient recruitment and assessment could be a suitable alternative to traditional study designs with face-to-face visits.

Objective: To evaluate physician's opinion and availability to participate in mHealth clinical studies with patient recruitment and assessment via telemedicine and to identify characteristics associated with the openness to participate.

Methods: Cross-sectional, observational, anonymous web survey-based study including 237 physicians (general practitioners (GP), allergists, pulmonologists, and pediatricians from Portugal and Spain) that collaborated with an asthma mHealth project (INSPIRERS). The web-survey was made available between May 28th and June 11th and included questions about physicians' and clinical practice characteristics, and physician's availability and perceived difficulties to recruit and assess patients using telemedicine technologies.

Results: The response rate was 51% (n=120). Most (74%) physicians were available to participate in mHealth clinical studies with patient recruitment and assessment via telemedicine, but 62% anticipated lower recruiting capacity and 40% an increased difficulty in obtaining quality data. Eight percent considered these studies viable but would be unavailable to participate and 18% believed that they would be unviable. Physicians with ?40 years old, from secondary care specialties (vs GP) and that used apps in personal life or in clinical practice were more likely to be available to participate (odds ratio with 95% confidence interval: 4.25[1.26-14.28], 10.66[2.80-40.51], 4.58[1.57-13.40], and 7.37[1.76-30.86], respectively).

Conclusions: Three-quarters of physicians were available to participate in mHealth clinical studies with patient recruitment and assessment through telemedicine. Age group, medical specialty, and app use were associated with the openness to participate.

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Keywords:

clinical studies, COVID-19, data collection, digital technologies, mHealth, patient recruitment, research methods, telemedicine

Introduction

The COVID-19 pandemic led to striking changes in healthcare delivery[1] and clinical research[2, 3]. The need to minimize social interactions and to use quarantine to prevent infection dissemination created a golden opportunity to expedite the implementation and dissemination of telehealth technologies, including telemedicine appointments. In the USA, between March 2nd and April 14th 2020, the number of telemedicine visits increased up to 4345%[1]; steep increases were also observed in European countries.[4]

In clinical research, patient recruitment and assessment are traditionally based on one or more in-person visits. Studies that rely on face-to-face contacts cannot just be transformed into digital formats without adjusting several methodological and ethical aspects.[5] This poses a major challenge in the context of a pandemic, such as COVID-19. In fact, COVID-19 led to a tremendous disruption of clinical research with up to 80% of non-COVID-19 trials being stopped or interrupted[6]. Patient enrolment and recruitment were identified as the most impacted study activities.[7] As a mitigation strategy, European[8] and USA[9] regulatory entities recommended that, whenever feasible, virtual patient visits should be considered, but suggested that starting new studies or recruiting new patients should be critically assessed under the premise that patient safety always prevails. Nevertheless, studies on mHealth technologies to validate remote monitoring solutions that can be used to follow-up patients during a pandemic were considered necessary.[10, 11] To meet the need for further studies while ensuring patient safety, designing study protocols based exclusively on virtual visits and data collection, whenever feasible, could be a suitable alternative. However, the acceptability of virtual studies to assess mHealth technologies was not previously described.

This study aimed to evaluate physician's opinion and availability to participate in mHealth clinical studies with patient recruitment and assessment via telemedicine and to identify characteristics associated with the openness to participate.

Methods

This was a cross-sectional, observational, anonymous web survey-based study including all the 237 physicians (general practitioners (GP), allergists, pulmonologists, and pediatricians from Portugal and Spain) that cooperated with the INSPIRERS project. INSPIRERS is an asthma mHealth project aiming to develop and evaluate a mHealth app to measure and improve medication adherence in adolescents and adults with persistent asthma.[12] The web-survey, implemented in the Google™ Forms platform, was sent by email and made available between May 28th and June 11th, at the end of

the first COVID-19 wave in Portugal. The survey included questions about general physicians' characteristics, clinical practice before COVID-19 pandemic and at the date of the survey completion, and physician's availability and perceived difficulties to recruit patients for mHealth clinical studies using telemedicine technologies (with a checklist of anticipated difficulties and free text). A description of the statistical analyses performed is presented as supplementary material (Supplementary Methods).

Results

One hundred and twenty physicians (51% response rate) participated, 64% female with a mean(SD) age of 41(12) years old (Supplementary Table 1). At the time the questionnaire was answered, two-thirds of the physicians had presential appointments, more than 90% had telephone appointments, and only 14% had video appointments. In a typical week during the first wave of the COVID-19 pandemic, most patients were consulted by telephone (median[P25-P75] of 71%[56-100]) and only 17%[7-38] had a video appointment (Supplementary Table 2). The participants reported to do telephone or video appointments preferentially (37%) or exclusively (51%) at the healthcare institution.

Most (74%) physicians considered viable and were available to participate in mHealth studies with patient recruitment and assessment via telemedicine. However, 62% anticipated lower recruiting capacity and 40% an increased difficulty in obtaining quality data (Figure 1). Eighteen percent considered these studies unviable and 8% considered them viable but they would be unavailable to participate. The most frequently perceived barrier was the lack of patient availability (52%), but the absence of adequate equipment and difficulties related to obtaining informed consent through digital technologies were also reported (Figure 1). In a multivariable logistic regression model, physicians with 40 years old or younger and those from a secondary care specialty (vs GP) were significantly more likely to be available to participate (odds ratio, OR, with 95% confidence interval [95%CI]: 4.25[1.26-14.28] and 10.66[2.80-40.51], respectively). The use of apps in personal life or in clinical practice was also associated with a higher odds of being available (OR[95%CI]: 4.58[1.57-13.40] and 7.37[1.76-30.86], respectively; Table 1).

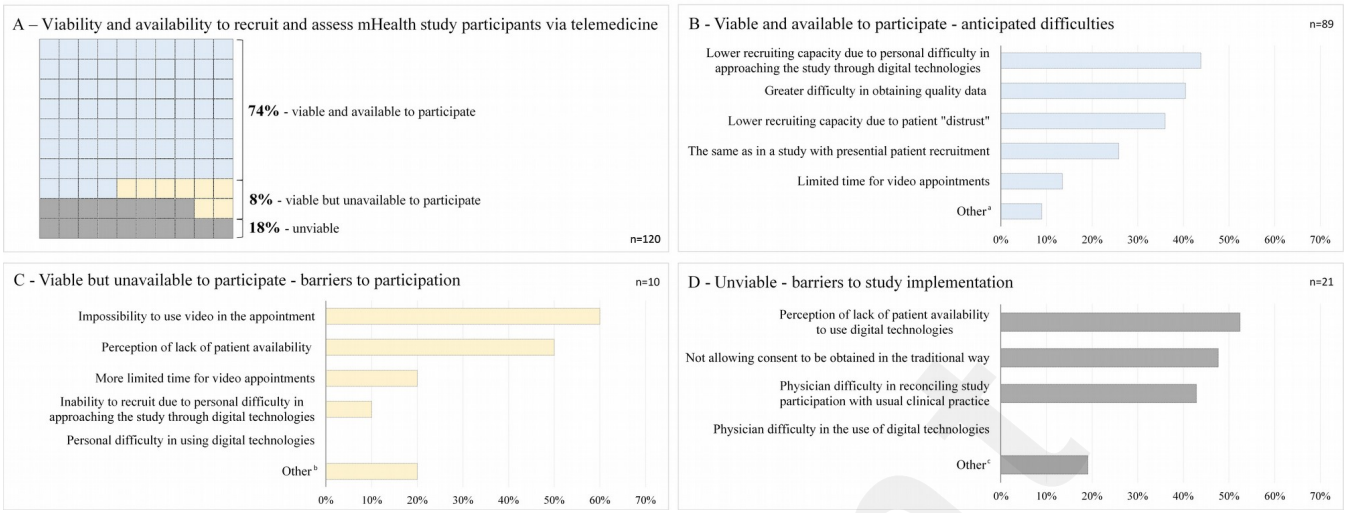

Figure 1: Physician's perceived viability and self-reported availability to recruit and assess patients via telemedicine in the context of mHealth clinical studies (panel A). Panels B, C and D present, respectively, the difficulties anticipated by physicians available to participate in these studies, the reasons for considering them viable but being unavailable to participate and the reasons for considering them unviable.

[a] increased difficulty in data collection (n=2), lack of adequate equipment to perform video appointments (n=1), perceived patient difficulty in the use of digital technologies (n=1) or study understanding (n=1), lower access to patients with stable disease (n=1) and increased difficulty in convincing patients to participate (n=1) and in supporting study procedures during the visit (n=1).
[b] lack of practice performing video appointments (n=1) and due to department changes related to the COVID-19 pandemic (n=1).
[c] lack of adequate equipment to perform video appointments (n=2), personal difficulty presenting the study through digital technologies (n=1) and impossibility to do physical examination (n=1).

Table 1: Unadjusted and adjusted odds ratio (OR) with 95% confidence intervals (95%CI) for being available to participate in mHealth clinical studies with patient recruitment and assessment using telemedicine technologies.

	Unadjusted[a]			Adjusted[b]		
	OR	**[95%CI]**	***P* value**	**OR**	**[95%CI]**	***P* value**
Physician's personal characteristics						
Sex, female (vs male)	1.62	[0.70-3.73]	0.256	NI		
Age, years	0.98	[0.95-1.02]	0.288	NI		
Age group, ≤40 years (vs >40 years)	1.59	[0.70-3.63]	0.270	4.25	[1.26-14.28]	0.019
Specialist (vs resident)	0.99	[0.41-2.36]	0.973	NI		
Years of clinical practice	0.99	[0.96-1.03]	0.575	NI		
Setting, private (vs public)	1.33	[0.14-12.43]	0.801	NI		
Secondary care (vs General Practice)	2.94	[1.26-6.89]	0.013	10.66	[2.80-40.51]	0.001
Medical specialty				NI		
General Practice	Ref.		0.043			
Allergy and Immunology	2.61	[0.97-7.00]	0.058			
Other specialties	3.53	[1.07-11.65]	0.038			
Country and region				NI		
North (Portugal)	Ref.		0.178			
Center (Portugal)	0.99	[0.37-2.64]	0.986			
Other Portuguese regions and Spain	3.38	[0.89-12.90]	0.075			
Current clinical practice						
Total number of patients per week	1.00	[0.99-1.02]	0.607	NI		
Having presential appointments	1.57	[0.68-3.65]	0.291	NI		
Average duration[c]	1.00	[0.92-1.09]	0.995	NI		
Average number of patients/week	1.00	[0.97-1.03]	0.951	NI		
Average proportion of patients[d]	1.00	[0.98-1.01]	0.575	NI		
Having telephone appointments	4.25	[0.89-20.17]	0.069	NI		
Average duration[c]	1.03	[0.95-1.10]	0.498	NI		
Average number of patients/week	0.99	[0.98-1.01]	0.335	NI		
Average proportion of patients[d]	1.00	[0.99-1.02]	0.977	NI		
Having video appointments	6.58	[0.83-51.82]	0.074	NI		
Average duration[c]	34.41	[0.00-.]	0.996	NI		
Average number of patients/week	1.02	[0.89-1.16]	0.801	NI		
Average proportion of patients[d]	1.04	[0.97-1.12]	0.223	NI		
Type of appointments (summary)[e]						
Only telephone appointments	Ref.		0.135	Ref.		0.280
Presential +/- telephone appointments	1.54	[0.63-3.73]	0.345	1.26	[0.44-3.55]	0.669
Video +/- presential +/- telephone	8.35	[0.99-	0.052	6.66	[0.65-	0.111

appointments		70.77]			68.43]	
Patterns of physician app use / recommendation						
App use in personal life	2.67	[1.13-6.30]	0.025	4.58	[1.57-13.40]	0.005
App use in clinical practice	2.95	[0.97-8.98]	0.056	7.37	[1.76-30.86]	0.006
App recommendation to patients	2.87	[1.24-6.64]	0.014	NI		

[a] A p-value ≤0.30 in the unadjusted analysis was used to select variables to be tested in the multivariable regression.
[b] Model characteristics and fitting: 79.8% overall percentage of correct prediction; Nagelkerke R square of 0.348; Hosmer and Lemeshow p-value of 0.329
[c] Considering subsequent appointments
[d] Considering a typical week
[e] 35(29%) had only telephone appointments; 67(56%) had presential+/-telephone; n=17(14%) had video+/-presential+/-telephone
NI, not included. Ref., reference category

Discussion

To our knowledge, this is the first study showing that up to three-quarters of physicians with at least one previous participation in clinical research involving face-to-face visits are available to participate in mHealth clinical studies with patient recruitment and assessment via telemedicine technologies. In a challenging period when clinical research has been disrupted, finding solutions to resume suspended studies or to kick-off new investigations is of utmost importance. Digital technologies might be game-changer in this context.[2, 3] In clinical trials there was a 6 fold-increase in the use of remote patient interactions (57% vs 9% pre-COVID-19) and this change to virtual care is expected to persist after the COVID-19 pandemic.[13] Telemedicine clinical visits, remote patient monitoring, online patient recruitment and eConsent were the interventions that clinical trial investigators selected as the most interesting and that they believed would bring more value to research.[13] In fact, in a survey of 25 organizations with ongoing clinical trials in the USA, telemedicine was the most frequently adopted technology during the COVID-19 pandemic and eConsent was perceived as one of the simplest innovations to implement, despite only less than half of the organizations were already using it.[14] Although most of the published data reports to clinical trials, real-life observational studies, predictably, face similar challenges. In a mHealth clinical study with virtual patient recruitment and assessment, at least eConsent and telemedicine visits would be needed, and the recent experience demonstrated that it can be achieved in weeks instead of months or years, as previously thought.[13] Nevertheless, in our sample, the lack of adequate equipment to perform video appointments and difficulties related to obtaining informed consent during telemedicine visits were amongst the most reported barriers to study implementation and participation, and were underlying the perception of lack of study viability and the unavailability to participate. Even in those physicians that reported being available to participate, some concerns regarding patient recruitment and data quality were raised. In fact, these digital approaches still require rigorous

validation and standardization before they can substitute the existing methods.[13] Moreover, our findings suggests that additional training, especially targeting remote data collection methods and communication skills through telemedicine, might be needed even for physicians with previous research experience.

In this study, physicians that were available to participate in mHealth clinical studies with patient recruitment and assessment via telemedicine were more likely to be ≤40 years old, from secondary care specialties, and to use apps either in personal life or in clinical practice. Knowledge of the factors that are associated with a higher openness to participate in these studies might support a more efficient site and investigator selection for clinical research. A previous study reported that younger healthcare workers (vs those with >50 years old) use digital technology more frequently, are more confident and present less anxiety using it, and are more prone to perceive it as useful and to have positive attitudes towards technology.[15] The increased availability shown by younger doctors might be related to a higher digital literacy in this age group. Nevertheless, in the multivariable model, the significant association with the age group was present even after adjusting for app use, suggesting that additional aspects might be underlying this relationship. However, we did not collect data to fully assess digital literacy and we cannot exclude it as the major reason for the association with age.

Secondary care physicians have traditionally been more involved in clinical research than GP specialists. A 2018 report from the National Institute for Health Research, in England, found that, out of the 7840 general practices in England, only 32% were active in research, in contrast with 99% of hospital trusts.[16] In our study, all physicians participated in at least one previous clinical study, but we did not assess the overall research experience, which might have influenced their availability. Moreover, most GP physicians were having telephone appointments and only 7% had video appointments. The lack of experience with video appointments may also play a role.

As only physicians collaborating with the INSPIRERS project were invited to participate in this study, most working in Portugal, these results cannot be directly generalized to physicians with different backgrounds. Moreover, this study only explored physician’s opinion. It is also important to explore the patient’s perspective regarding participation in virtual studies to assess mHealth technologies and to evaluate its relationship with digital literacy. In fact, to be successful, all stakeholders in clinical research should be open to and find virtual mHealth studies acceptable.

Most physicians were available to participate in mHealth clinical studies with patient recruitment and assessment via telemedicine, despite identifying some barriers. Age group, medical specialty, and app use were associated with the openness to participate in virtual mHealth studies.

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Conflict of Interests

None to declare.

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Supplementary Files

Figures

Multimedia Appendixes

Supplementary methods.
URL: http://asset.jmir.pub/assets/43d03141c0537e07c80c72ba2bbded2f.docx

Supplementary Table 1.
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