Feasibility of mHealth Devices in Monitoring of Heart Rate, Physical Activity and Respiratory Function in Smokers with and without Respiratory Symptoms and COPD

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Abstract: ***Background*:** Chronic obstructive pulmonary disease (COPD) is a global public health problem, and continuous monitoring is essential for both its management as well as the management of other chronic diseases. Telemonitoring using mobile health (mHealth) devices has the potential to promote self-management, improve control, increase quality of life, and prevent hospital admissions. ***Objective*:** This proof-of-concept study aims to assess feasibility, accuracy, and reproducibility of biosensing (mHealth) devices in monitoring of heart rate, physical activity and respiratory function in smokers with and without respiratory symptoms and COPD. ***Methods***: A total of 3 cohorts, with 9 participants in each, used mHealth devices for 90 days while undergoing the current standard of care. These groups were: 9 "non-COPD," otherwise healthy, smokers; 9 "grey zone" smokers (forced expiratory volume in 1 second/ forced vital capacity ≥0.70 after bronchodilator treatment; COPD Assessment Test ≥10); and 9 smokers diagnosed with Stage 1-3 COPD. Two mHealth devices were utilized in the study: (1) the AnaMed Original Equipment Manufacturer device (OEM) that measures distance, energy expenditure, heart rate, and heart rate variability by using photoplethysmographic method and displays the results on a watchface, smartphone or a tablet, and (2) the Air Next mobile spirometry portable device that performs spirometric measurements (FEV1, FVC and FEV1/FVC ratio) by a turbine mechanism and displays the results on a smartphone or a tablet. The mHealth devices were compared against industry standards. Recruitment, retention and adherence rates were 35%, 100%, and 63% respectively. Additionally, a questionnaire was administered to assess the participants' perceptions of the mHealth technologies used. ***Results:*** The AnaMed device was demonstrated as precise in measuring heart rate, and less so when measuring number of steps and meters. It is unreliable in measuring SpO2. It is easy to use, requires no significant technical support. The Air-Next Spirometer is a simple and very precise instrument for detecting obstructive airway diseases which was confirmed when compared to the industry standard. It is easy to use, which could make it especially useful for non-specialized care and in-home setting and other areas. ***Conclusion***: We demonstrated that both devices, AnaMed and AirNext can provide precise measurements or heart rate and spirometric data, and it is feasible to incorporate them into a routine clinical practice for remote monitoring of chronic conditions such as COPD. However, such task would require some efforts to take care of technical and logistical issues, i.e. sending reminders, synching devices with smartphones, communication efforts.

Keywords: COPD, feasibility study, mobile health apps, mHealth, smokers.

1. INTRODUCTION

Telemonitoring is a promising alternative or adjunct to the provision of traditional health care services in COPD [1]. Although some studies have shown that telemonitoring may improve some clinical outcomes and reduce health care costs [2, 3], the effects of telehealth interventions on emergency department attendance, hospital admissions, duration of admissions, health-related quality of life, costs, and mortality remain less certain [4 - 8]. Telemedicine became especially important during the COVID-19 pandemic [9].

In a study of telemedicine in the home setting using multiple activity sensor monitoring equipment in COPD patients, the augmentation of traditional telemedicine methods with motion sensing, spirometry, and symptom diaries appeared feasible [10]. In a literature review (141 randomized trials; n=37,695) of studies of eHealth practices, such as telemetry, telephone calls, or home visits by nurse specialists, most studies were relatively short term (<6 months) and did not yield strong evidence for telemedicine use in the management of chronic diseases [11]. However, the comparison of outcomes in studies using telehealth applications is difficult due to advances in monitoring and communications technology and heterogeneity in the type of monitoring, the disease entity and severity, and the variations in the process of care brought about by the telemedicine intervention [11].

Although peak flow monitoring has been used for at-home detection of asthma exacerbations, and studies in the past have monitored vital signs and symptoms in patients with COPD [12], few studies have attempted to deploy spirometry for home monitoring of COPD [13]. With technical advances, spirometry is increasingly being used to track the progress of COPD over time and to identify acute exacerbations [14 - 18].

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While the number of COPD mHealth devices is rapidly increasing, most have not been validated as clinically effective tools for the management of the disease. In addition to empowering patients and facilitating disease self-management, mHealth offers promising aid to COPD researchers to help them personalize treatments based on patient-specific profiles and integrates symptom occurrence and medication usage with environmental and genomic data. An integrated and targeted practice-managed approach that uses mHealth technologies in primary care settings will be most effective for the early identification, monitoring, and management of chronic diseases, particularly COPD and cardio-metabolic syndrome (i.e, combined diabetes mellitus, systemic arterial hypertension, central obesity, and hyperlipidemia). Health information technologies are revolutionizing health care by assisting patients in self-monitoring and decision-making, driving a shift toward a care model increasingly centered on personal use of digital and web-based tools [19-21]. Because there is a dearth of evidence that direct-to-consumer mHealth tools are effective or that they provide accurate disease recommendations, they are not yet widely used in clinical practice. Nonetheless, the preponderance of mHealth is gradually increasing in health care, industry, and as a subject of research [22].

This study aims to investigate the feasibility and utility of using mHealth devices to improve the treatment, assessment, compliance, and outcomes of smokers with and without respiratory symptoms/COPD. It namely means to assess the feasibility of mHealth devices in current smokers with and without respiratory symptoms or COPD by monitoring physical activity, vital signs, and respiratory function, and aims to assess the validity of mHealth devices in detecting vitality parameters as compared to industry standards.

2. MATERIALS AND METHODS

Study Design

The design of the study was described in detail in the study protocol published earlier [22].

This is a proof-of-concept, open-label, three-arm, observational, single-center feasibility study. The participants were 27 men and women age 40 – 59 smokers 10 pack-year cigarettes. They were divided in three cohorts used the mHealth devices for 90 days while undergoing the current standard of care based on their smoking disease state or lack of disease state. The groups were made up of three cohorts:

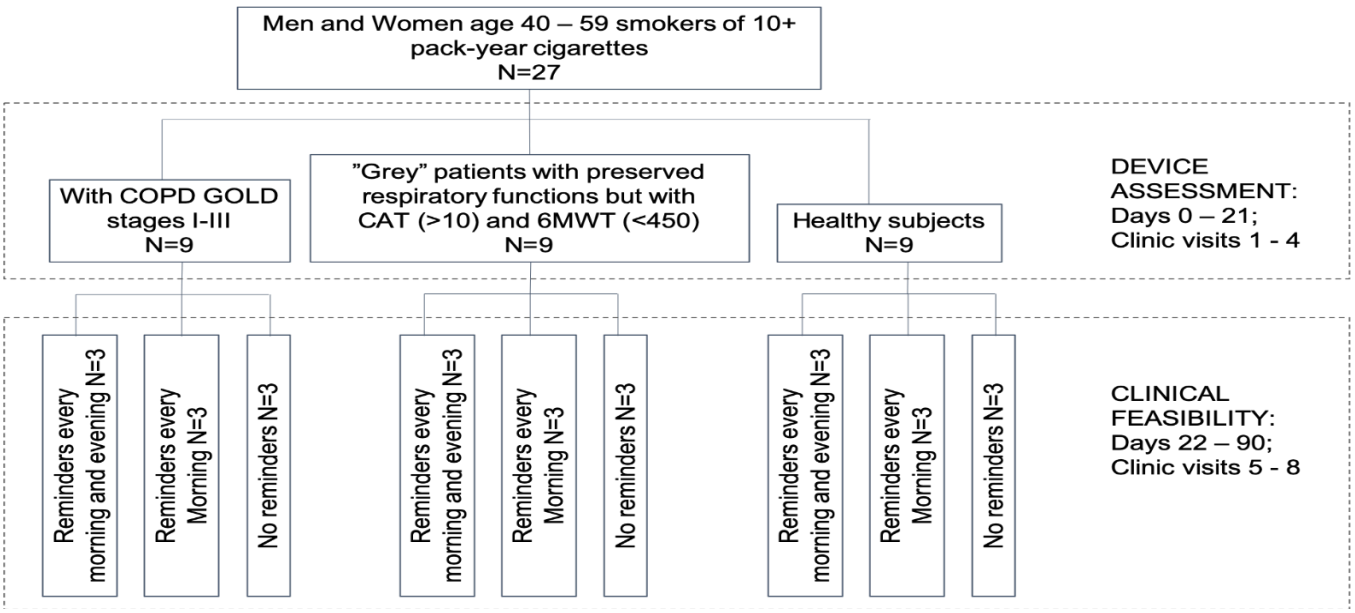
Asymptomatic current smokers: no symptoms (CAT<10, 6MWT≥450 meters) and preserved pulmonary function based on spirometry (FEV_1/FVC of at least 0.70 after bronchodilation treatment and FVC ≥80% of the expected value) and respiratory symptoms (CAT ≥10); OR

“Grey zone” current smokers: initially preserved pulmonary function based on spirometry, but with clinical symptoms based on CAT (>10) and 6MWT (<450); OR

Current smokers with a confirmed diagnosis of COPD (Global Initiative for Chronic Obstructive Lung Disease [GOLD] stage I-III).

The study design is illustrated by flowchart presented in Figure 1.

Figure 1: Flow chart illustrating study procedures.



In each group, nine participants were randomly assigned to three types of reminders: three participants were reminded every morning by text message or phone call and contacted every evening by phone or chat services (eg, Skype, WhatsApp, Viber, texting) to share their experiences and feedback on mHealth device usage; three participants received only morning reminders; and three participants received neither morning reminders nor evening communication/feedback.

Study Devices and Assessments

Two mHealth devices were utilized in the study: the AnaMed OEM bracelet (measures step counts, energy expenditure, heart rate, and heart rate variability) and the Air Next mobile spirometry device (Nuvoair AB, Stockholm, Sweden) (measures FEV_1, FVC, and forced expiratory flow).

The mHealth devices were compared to the industry standards presented in Table 1. Additionally, a questionnaire was administered to assess the participants' perceptions of the mHealth technologies used.

Table 1: Assessments of mHealth Devices versus Standard of Care.

Objectives	Technology Evaluated	Industry Standards	Outcome Measures/ Data Collection Instrument
Spirometry	Air Next mobile spirometer (FEV_1, FVC)	BTL-08 SPIRO before (without) and post-bronchodilator use	FEV_1, FVC (Air Next)FEV_1, FVC (BTL-08 SPIRO)
Physical activity/ Exercise capacity	AnaMed OEM device software-derived endpoints (step counts, distance)	6-Minute Walk test	Step counts (total number of steps taken during a 6MWT): software-derived from Garmin Vívofit 4 and AnaMed OEM device; Distance walked (total meters achieved during a 6MWT): software-derived from Garmin Vívofit 3 and AnaMed OEM device
Blood oxygenation saturation	AnaMed OEM device software-derived endpoint SpO2	Vive DMD 1003 pulse oxymeter	SpO2 (AnaMed OEM device; Vive DMD 1003 pulse-oximeter)
Heart rate	AnaMed OEM device software-derived endpoint heart rate	Manually counting heart rate during rest after and 6-minute-walk test	Heart rate (AnaMed OEM device) Heart rate (manually counted/determined during a period of rest and 6-minute-walk test)

At the Kazakhstan Academy of Preventive Medicine COPD Center, standard spirometry data are collected by using the BTL-08 SPIRO (BTL Industries Limited, United Kingdom) spirometry system. The spirometer used in this study is tested and continuously standardized with a 3-liter syringe. Quality assessments were performed throughout the study.

The Vive Precision DMD 1003 pulse oximeter was used to get peripheral capillary oxygen saturation (SpO2) and pulse readings at the Kazakhstan Academy of Preventive Medicine COPD center and was used for comparison to the results produced by the AnaMed OEM device.

Outcome Measure

Safety and tolerability were evaluated through adverse events (AEs), lung function tests, vital signs, and supportive care medications. Primary measures were defined as rates of recruitment, retention, and adherence as well as safety of the intervention that are common for feasibility studies [23]. Recruitment is defined as the number of potential participants screened for study eligibility versus the number of people who enrolled in the study. Retention is defined as the proportion of participants enrolled who completed the intervention and all study measures. Adherence to the study protocol is determined as the proportion of participants enrolled who had all their mHealth parameters registered every day.

Study Procedures

The study lasted 90 days and had two stages. Schedule of visits and study activities presented in Table 2. The first stage included the initial period of using the mHealth devices (Days 1-21) to evaluate the validity of collecting vitality parameters (eg, heart rate, blood oxygenation, steps/motion) on mHealth devices. The main period of use for the mHealth devices (Days 22-90) was the second stage, which aimed to evaluate the feasibility of participants using these devices.

Standard spirometry was performed to diagnose and monitor COPD. Providing of mHealth devices involved the provision of the AnaMed OEM device, the Air Next mobile spirometer, and instructions/review of how to use these tools (print and verbal instructions). For the assessment of the AnaMed OEM device, the participants' SpO2 was measured at each visit using industry-standard pulse oximetry devices, and for the assessment of the Air Next spirometer, participants hosted the mobile spirometer at home for once daily measurements. Measurements were validated at Study Center visits using an industry-standard device before and after the use of a bronchodilator.

Participant Recruitment and Registration

We employed various nonprobability sampling techniques, including quota and snowball sampling methods, to recruit study participants. The Kazakhstan Academy of Preventive Medicine research team registered patients for each mHealth device. Installation and user guides for each technology used included labeled photographs and written instructions used by all teams and patients during setup. All equipment has been tested before deployment. Training was provided on setup, installation, and use as well as individual checklists, decision trees, and troubleshooting information. The break for charging is at a standard time (20:00) across arms. In addition to direct phone communication, WhatsApp, texting, and other types of messaging systems were used for sharing daily experiences each evening to assist with assessing the level of comfort and address issues with wearing the AnaMed OEM device and using the Air Next mobile spirometer.

Table 2: Schedule of Visits and Study Activities.

		Device Assessment Period			Clinical Feasibility Study			
	Screening	Baseline Visit	Interim Visit	Final Visit	Interim Visits		Final Visit	
Visit	1	2	3	4	5	6	7	8
Days	1	7	14	21	28	35	56	90
Informed consent process	X							
Study eligibility and smoking status	X							
Review medical history (incl. physical and BMI measurement)	X	X	X	X	X	X	X	X
COPD assessment test	X							
Spirometry*	X	X	X	X	X	X	X	X
6-minute walk test	X	X	X	X	X	X	X	X
Carbon Monoxide breath level	X	X	X	X	X	X	X	X
Provide the study requirements handout	X							
Dichotomous questionnaire for visit readiness	X							
Provide mHealth devices**	X							
Assessment of AnaMed OEM device+		Continuous monitoring						
Assessment of Air Next mobile spirometer against standard++		Continuous monitoring						

Data Collection, ClouDoc Clinical Research Platform.

Participants synchronized their wearable device (AnaMed OEM device) and the Air Next mobile spirometry device by signing into their account. Data are stored in a local health information platform called ClouDoc. It is a client-driven software platform that provides high quality, objective patient measures, along with comprehensive data management, analytics, and logistics support.

ClouDoc combines medical data capture and management expertise with the power and flexibility of a cloud-based system. It gives the ability to monitor patients remotely and in near real-time with the following characteristics:

Instant visibility of patient data, including adverse events data cases, site metrics, and study-wide progress provide greater trial oversight.

Scheduled home-based data uploads via mobile device or PC allow to remotely monitor patient compliance and behavior between site visits.

Create and export custom reports such as Health Passport and GCP-compliant ambulatory reports containing different configurations of site and/or patient data for archiving and analysis outside of ClouDoc.

Spirometry

The Air Next mobile spirometer was used by patients to assess respiratory function. To use it, patients must hold their hands on tubular grips or use wrist clamps. Subsequent respiratory efforts allow the determination of inspiratory capacity and FEV_1. Participants were categorized for analysis using the GOLD staging system according to their spirometry, which was performed before and after two inhalations of salbutamol (0.1 μg per inhalation). Among the criteria needed to make a diagnosis of COPD are deficits in the rate at which one can forcefully exhale. Most experts consider a low ratio (<0.70) of the FEV_1 to the FVC after bronchodilator use to be a key diagnostic criterion. Bronchodilator responsiveness was considered positive if the participant has a ≥12% change in FEV_1 or FVC above prebronchodilator measurements.

Six-Minute Walk Test

This test measures the distance that a patient can quickly walk on a flat, hard surface in 6 minutes [24]. The KAPM clinic utilizes a 100-ft hallway to perform the 6MWT.

Physical Activity

Study participants measured their pedometer-determined physical activity using the AnaMed OEM wearable devices. While performing the six-minute walk test, participants simultaneously used the AnaMed OEM and Garmin Vivo (Garmin Ltd, Olathe, Kansas, United States) devices to compare step counts from both devices.

Chronic Obstructive Pulmonary Disease Assessment Test

The CAT was used as an add-on test with existing assessments in COPD (eg, with FEV_1). It is a simple and reliable measure of health status in COPD as it assists patients and their physicians in quantifying the impact of COPD on the patient's health. The CAT is a validated, short (8-item) questionnaire to be completed by patients [25].

User Experience Questionnaire

Questionnaires were administered to assess participant's mHealth device use experience. One questionnaire was administered for each device. The questions addressed comfort levels and ease of daily vital measurements. The interviews were conducted by clinical investigators not involved with the quantitative monitoring or analysis to reduce the possibility of bias.

Data Management

All study data were stored in the information technology Unit of the Kazakhstan Academy of Preventive Medicine. Verification of eligibility was completed via a web questionnaire after participants signed the consent form, and participants were tracked for the completion of all the study data.

All electronic files were encoded using a 128-bit advanced encryption standard and are password protected on a computer with both hardware and software firewalls. The locator form and any documents with identifying information are kept in a separate folder and kept locked in filing cabinets.

Statistical Analysis

For this proof-of-concept phase, access to device-derived data is enabled via a cloud-to-cloud solution. Statistical comparisons were made between the mobile biosensing device–derived data and the data derived from the standard diagnostic equipment and methods. Agreement analysis was performed for both binary and quantitative measures. For binary variables, percent of agreement (overall, positive, and negative agreement) as well as Kappa coefficient, *P* value, and 95% confidence interval will

be calculated. For two quantitative measures of a parameter, we used the Bland-Altman method (Bland-Altman plot and limits of agreement). The Bland-Altman plot analysis allowed us to evaluate a bias between the mean differences and to estimate an agreement interval, within which 95% of the differences between two quantitative methods of measurement are included. Correlation analysis also ran to calculate Pearson's correlation coefficient and the 95% confidence interval.

The agreement analysis was done for baseline, 7-day, 14-day, 21-day, 28-day, 56-day, and 90-day visits separately and for the data pooled from all measurements. Within-Subject study design was accounted for to assess accuracy and precision for a single mobile device. All statistical analyses were done for all participants and by study group. Additionally, we compared trends of binary and quantitative outcomes from three study groups wearing mobile devices.

The analysis was performed using R Statistical Software (R Foundation for Statistical Computing, Vienna, Austria).

Ethics Approval

The Ethics Committee of the Academy of Preventive Medicine approved this study on June 3, 2019. The study has been registered at ClinicalTrials.gov (NCT04081961).

3. RESULTS

The rate of recruitment was 35%. From 77 potential participants screened for study eligibility, 27 were enrolled in the study. After 90 days of observation, none of the participants dropped out from the study, so the retention rate was 100%. Adherence to the study protocol, i.e. the proportion of participants enrolled from whom all mHealth parameters registered every day, was 63% (17/27).

Data on blood oxygenation (SpO2) and heartbeat collected by AnaMed OEM device and Vive DMD 1003 pulse oximeter before and after 6MWTt presented in table 3. Correltion between the heartbeat data collected by Anamed OEM Device vs Vive DMD 1003 Pulse oximeter is illustrated in figure 2.

The Anamed OEM device was demonstrated as precise in measuring heart rate: Pearson's correlation between Anamed OEM and standard Pulse oximeter before and after 6MWT was 0,97 and 0,92, respectively. The AnaMed OEM device was unreliable in measuring SpO2 Person correlation between AnaMed OEM and standard Pulse oximeter before and after 6MWT was 0,50 and 0,42, respectively.

Data on spirometric parameters collected by AirNext Mobile Spirometer and BTL-08 SPIRO standard spirometer before and after bronchodilation presented in table 3. Correlation between Forced Expiratory Volume in 1 second (FEV1) and Forced Vital Capacity (FVC) collected by AirNext Mobile Spirometer and BTL-08 SPIRO Standard spirometer presented in figure 3.

The AirNext mobile spirometer was demonstrated as precise in measuring FEV1 and FVC: Pearson's correlation of FEV1 between the AirNext mobile spirometer and BTL-08 SPIRO standard spirometer before and after bronchodilation was 0,97 and 0,95, respectively. Pearson's correlation of FVC between the AirNext and BTL-08 SPIRO Standard spirometer before and after bronchodilation was 0,95 and 0,92, respectively.

Data on spirometric parameters collected in three cohort groups (COPD patients, "Grey" patients and healthy participants) without bronchodilation are presented in figures 4 – 6. There are similarities in patterns of dynamics in spirometric parameters (FEV1, FVC and FEV1/FVC) collected by AirNext mobile spirometer and BTL-08 SPIRO standard spirometer among those three cohorts.

Table 3: SpO2 and Heartbeat data collected by AnaMed OEM device and Vive DMD 1003 pulse oximeter.

	AnaMed, mean	Pulsoximeter Vive DMD 1003, mean	Mean of difference	SD of difference	Pearson's Correlation
SpO2 before 6MWT	96,53	95,15	1,38	1,67	0,50
SpO2 after 6MWT	96,77	95,78	0,99	1,70	0,43
Heartbeat per minute before 6MWT	74,91	74,74	0,17	2,12	0,97
Heartbeat per minute after 6MWT	84,82	84,90	-0,08	3,65	0,92

Figure 2: Heartbeat per minute: Anamed OEM device vs Vive DMD 1003 pulse oximeter.

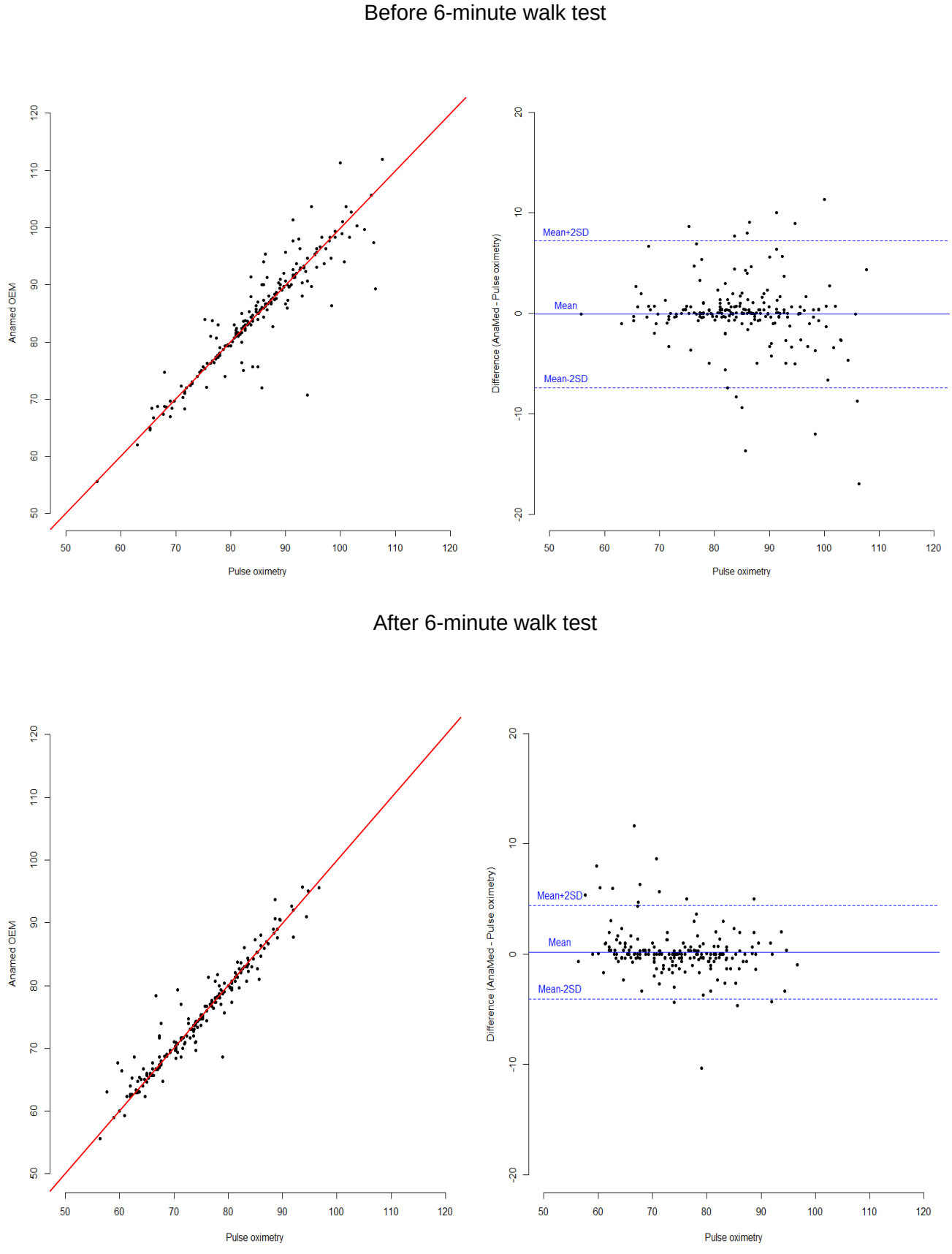


Figure 3: Spirometry data: AirNext Mobile Spirometer vs BTL-08 SPIRO (without bronchodilation).

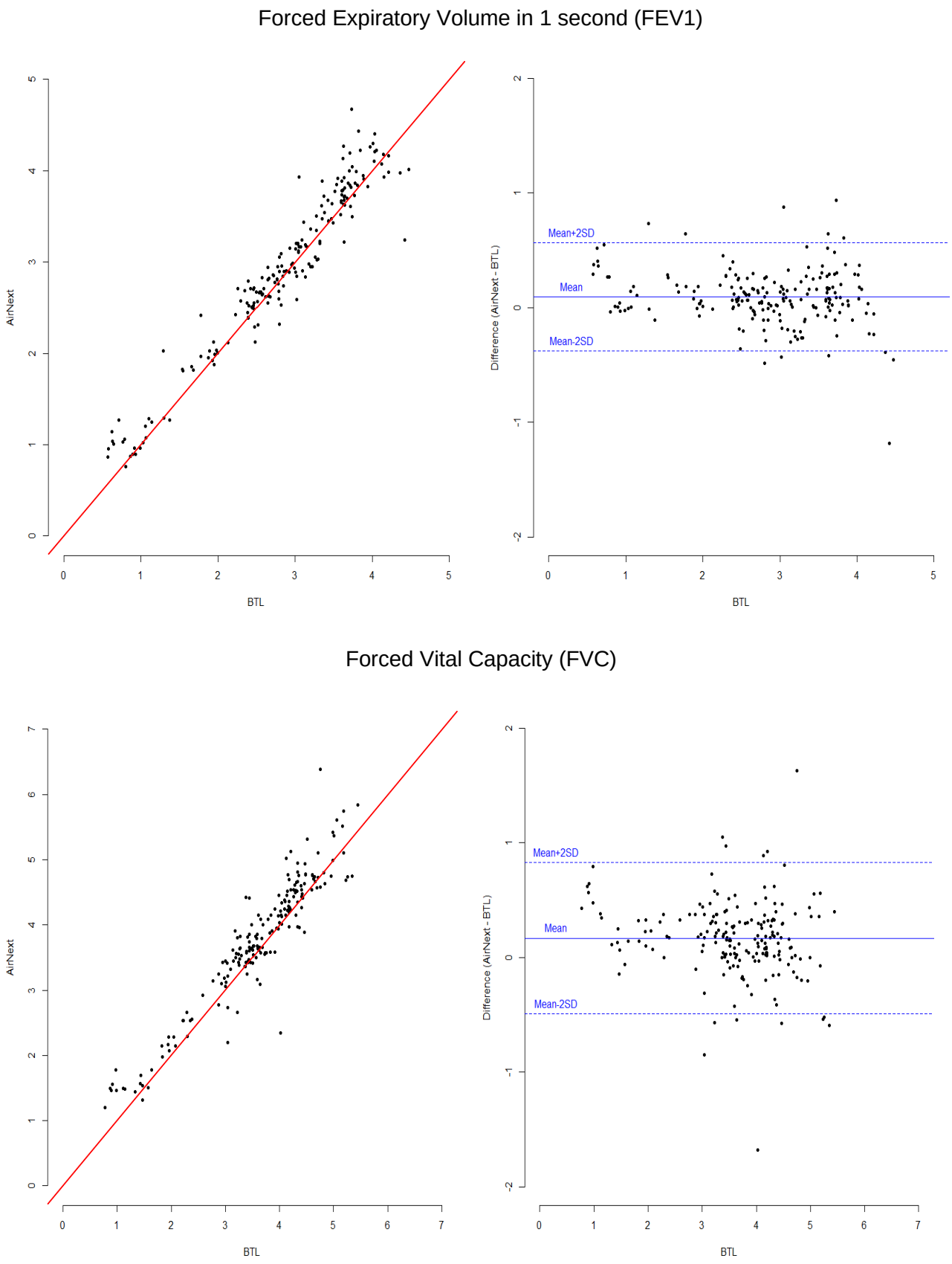


Figure 4: Forced expiratory volume in 1 second before bronchodilation when measured by AirNext mobile spirometer and BTL-08 SPIRO standard spirometer.

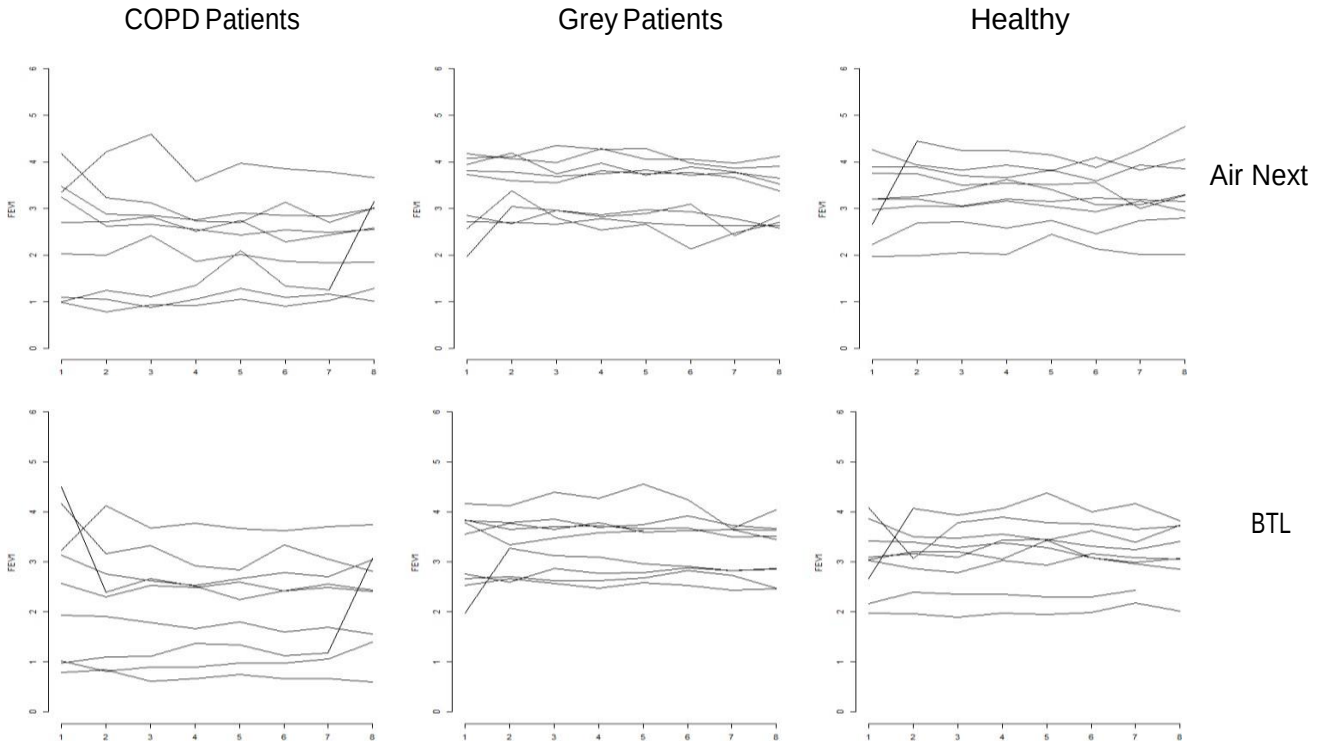


Figure 5: Forced Vital Capacity before bronchodilation when measured by AirNext mobile spirometer and BTL-08 SPIRO standard spirometer.

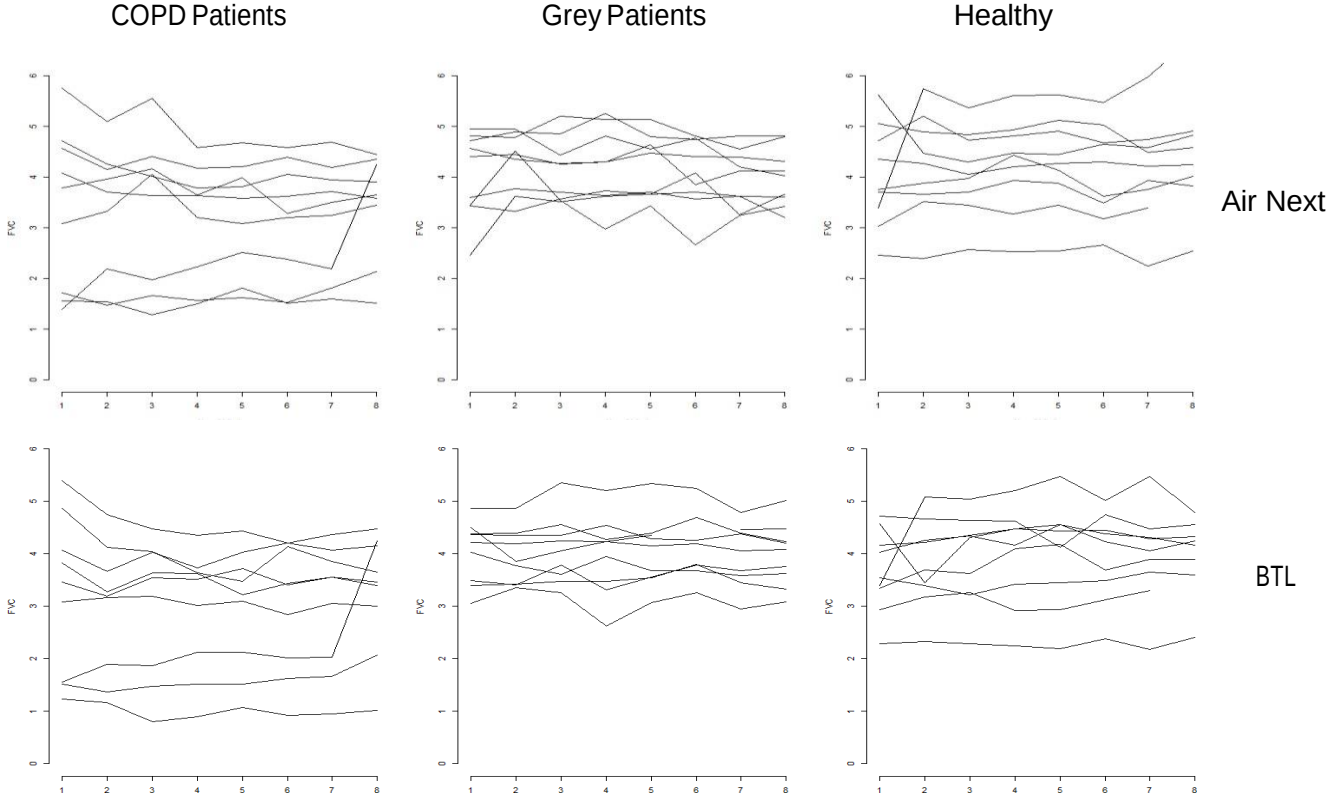


Figure 6: FEV1/FVC ratio before bronchodilation when measured by AirNext mobile spirometer and BTL-08 SPIRO standard spirometer.

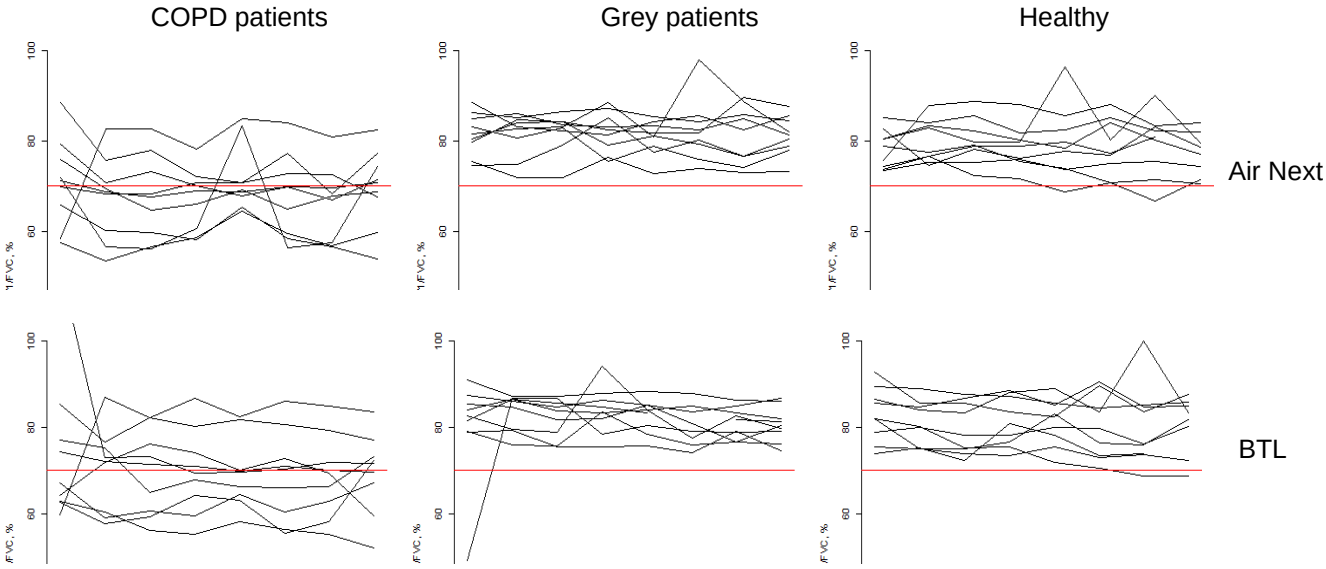


Table 4: Spirometric parameters collected AirNext mobile spirometer and BTL-08 SPIRO standard spirometer.

	AirNext Mobile Spirometer mean	BTL Standard spirometer mean	Mean of difference	SD of difference	Pearson's Correlation
Forced expiratory volume in 1 second before bronchodilation	2,92	2,83	0,09	0,24	0,97
Forced expiratory volume in 1 second after bronchodilation	3,00	2,95	0,05	0,29	0,95
Forced vital capacity before bronchodilation	3,77	3,60	0,17	0,33	0,95
Forced vital capacity after bronchodilation	3,81	3,68	0,13	0,40	0,92

Table 5 presents the participants answers to the questionnaire were administered to assess participant's experience with AnaMed OEM device. As seen, vast majority of the participants felt comfortable with using equipment to complete daily assignments (94 percent); satisfied with learning how to use the equipment to complete daily assignments (94 percent); satisfied with overall easiness to complete daily assignments (84 percent); noticed no skin irritation, squeezing, etc. (95 percent); satisfied with convenience in size, images (94 percent); had no problem with charging the device (88 percent); satisfied with user experience (85 percent); had no problems with syncing the device with smartphone (82 percent); satisfied with user instructions (90 percent); satisfied with technical assistance by the staff of the Academy of Preventive Medicine (93 percent); satisfied with how messages and reminders sent (88 percent).

Table 6 presents the participants answers to the questionnaire was administered to assess participant's experience with AirNext mobile spirometer. As seen, vast majority of the participants felt comfortable with using equipment to complete daily assignments (94 percent); satisfied with learning how to use the equipment to complete daily assignments (91 percent); satisfied with overall easiness to complete daily assignments (86 percent); satisfied with user instructions (94 percent); satisfied with technical assistance by the staff of the Academy of Preventive Medicine (96 percent); satisfied with research personnel available for troubleshooting and replacement of equipment. (88 percent). The only issue was with syncing the device with smartphone: 16 percent of participants reported that they neutral or strongly disagree that there was no problem with syncing the device with smartphone.

Table 5: Responses to the User Satisfaction Questionnaire: AnaMed OEM.

QUESTIONS ASKED	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
I feel comfortable using the equipment provided to complete my daily assessments.	0.00%	0.00%	2.50%	3.70%	93.80%
It was easy to learn how to use the equipment provided to complete my daily assessments.	0.00%	0.00%	0.00%	6.20%	93.80%
Overall, I am satisfied with how easy it is to complete my daily assessments.	1.20%	0.00%	2.50%	12.30%	84.00%
Wearing the device does not cause skin irritation, squeezing, or other inconvenience	0.00%	0.00%	0.00%	4.90%	95.10%
The dial is convenient in size; images are easily distinguishable, understandable	0.00%	0.00%	0.00%	6.20%	93.80%
It is not a problem for me how often the device is charged/ charging the device is not a problem	2.50%	0.00%	0.00%	9.90%	87.70%
The mobile application is user-friendly; the information is highly accessible, understandable and useful.	4.90%	0.00%	0.00%	9.90%	85.20%
I have no problem syncing my device with a smartphone	1.20%	0.00%	0.00%	17.30%	81.50%
Instructions (such as online help, on-screen messages, and other documentation) provided with the equipment are clear.	0.00%	0.00%	1.20%	8.60%	90.10%
When problems arise that require the assistance of KAPM technical support, someone is available to assist and is helpful in troubleshooting equipment.	3.70%	0.00%	0.00%	3.70%	92.60%
When problems arise, research and/or home health personnel are available to assist with troubleshooting, replacement of equipment.	2.50%	0.00%	0.00%	9.90%	87.70%
I am quite satisfied with how messages and reminders are sent.	1.20%	0.00%	9.90%	16.00%	72.80%

Table 6: Responses to the User Satisfaction Questionnaire: AirNext Mobile Spirometer.

QUESTIONS ASKED	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
I feel comfortable using the equipment provided to complete my daily assessments.	1.20%	0.00%	1.20%	3.70%	93.80%
It was easy to learn how to use the equipment provided to complete my daily assessments.	0.00%	0.00%	1.20%	7.40%	91.40%
Overall, I am satisfied with how easy it is to complete my daily assessments.	3.70%	0.00%	1.20%	8.60%	86.40%
I have no problem syncing my device with a smartphone	1.20%	0.00%	14.80%	25.90%	58.00%
Instructions (such as online help, on-screen messages, and other documentation) provided with the equipment are clear.	1.20%	0.00%	0.00%	4.90%	93.80%
When problems arise that require the assistance of KAPM technical support, someone is available to assist and is helpful in troubleshooting equipment.	0.00%	0.00%	0.00%	3.70%	96.30%
When problems arise, research and/or home health personnel are available to assist with troubleshooting, replacement of equipment.	0.00%	0.00%	0.00%	12.30%	87.70%

4. DISCUSSION

This study is the first step in a series of studies aiming to investigate the effect of using mHealth devices to improve the treatment, assessment, compliance, and outcomes of smokers with and without respiratory symptoms of Chronic Obstructive Pulmonary Disease (COPD).

COPD accounted for 3.2 million deaths globally in 2015 [26] and is the fourth leading cause of death both worldwide and in Kazakhstan [27]. COPD is a heterogeneous condition, with a variety of disease-related phenotypes [28, 29], and its main risk factor is cigarette smoking [30]. The chronic airflow limitation that characterizes COPD is caused by obstructive bronchiolitis and parenchymal destruction (emphysema). Pulmonary emphysema is a form of COPD; however, pulmonary emphysema without airway obstruction is common in smokers [31, 32]. Smokers with symptoms suggestive of COPD who do not qualify for a diagnosis of COPD based on spirometry are referred to as “grey zone” COPD patients. They have preserved pulmonary function (forced expired volume in 1 second/forced vital capacity [FEV_1/FVC] of at least 0.70 after bronchodilator and FVC ≥80% of the expected value) and respiratory symptoms (COPD assessment test [CAT] ≥10).

Continuous monitoring is vital for the management of COPD. Implementing telemedicine and mobile health (mHealth) innovations has allowed clinicians to intervene in COPD earlier and prevent complications. However, there remain challenges in the form of alarm frequency and response, both of which need to be implemented into the existing workflow [33]. Data flow and workflow processes need to be designed with precision at the outset if telemedicine is to be applied in clinical practice. Telemonitoring using mHealth devices has the potential to promote self-management, improve control, increase quality of life, and prevent hospital admissions [34 - 37]. Technological advances in mHealth home telemonitoring (electronic health [eHealth]) programs and systems can affect care for patients with COPD [11, 38 - 41]. mHealth devices are an emerging opportunity in clinical studies, and their utility (ie, sensitivity, accuracy, and reproducibility) has previously been assessed for telemonitoring for COPD [38].

This feasibility and proof-of-concept study aimed to assess utility (sensitivity, accuracy, and reproducibility) of biosensing (mHealth) devices in monitoring of heart rate, physical activity and respiratory function in smokers with and without respiratory symptoms and COPD.

In this study we assessed the utility (accuracy and precision) of using mHealth devices in detecting vitality parameters in current smokers with and without respiratory symptoms/COPD (e.g., heart rate, blood oxygenation, steps/motion, blood pressure).

We studied the AnaMed OEM bracelet that measures heart rate, blood oxygenation (SpO2), number of steps and meters by using photoplethysmographic method and displays the results on a watchface, smartphone or a tablet.

The AnaMed device was demonstrated as precise in measuring heart rate, and less so when measuring number of steps and meters. It is unreliable in measuring SpO2.

We also determined that the AnaMed OEM bracelet is easy to use and requires no significant technical support.

We also examined Air-Next mobile spirometer, which is a portable device that performs spirometric measurements (FEV1, FVC and FEV1/FVC) ratio by a turbine mechanism and displays the results on a

smartphone or a tablet.

Our study demonstrated that the Air-Next mobile spirometer is a simple and very precise instrument for detecting obstructive airway diseases which was confirmed when compared with the industry standard. It is easy to use, which could make it especially useful for non-specialized care and in-home setting and other areas

5. CONCLUSION

Many studies have shown that mHealth tools are effective or that they provide accurate disease recommendations.

We demonstrated that both devices, AnaMed OEM and AirNext mobile spirometer can provide precise measurements or heart rate and spirometric data, and it is feasible to incorporate them into a routine clinical practice for remote monitoring of patients with COPD and other chronic conditions.

6. LIMITATIONS

This study is a small-scale, exploratory, pilot study which is looking to answer questions about whether a larger trial is feasible or not and seeks to get estimates of parameters required for the calculation of the sample size of the main study. The results of this study cannot be used to estimate the effect size of using mHealth devices because the sample size is too small.

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ABBREVIATIONS

6MWT	six-minute walk test
CAT	Chronic Obstructive Pulmonary Disease Assessment Test
COPD	chronic obstructive pulmonary disease
FEV_1	forced expiratory volume in 1 second
FVC	forced vital capacity
GOLD	Global Imitative for Chronic Obstructive Lung Disease
mHealth	mobile health
OEM	original equipment manufacturer
SpO2	peripheral capillary oxygen saturation

FOOTNOTES

Authors' Contributions: The study was designed by AS, BZ, and AS drafted the manuscript. All authors critically revised the manuscript and then read and approved the final manuscript.

Conflicts of Interest: None declared.

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