

## **Promoting COPD Wellness through Remote Monitoring and Health Coaching: A Randomized Study**

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## Abstract

**Rationale:** Quality of life (QoL) matters the most to patients with COPD and is associated with healthcare utilization and survival. Pulmonary Rehabilitation is the most effective intervention in improving QoL but has low uptake and adherence. Home-based programs are a proposed solution. However, there is a knowledge gap on effective and sustainable home-based programs impacting QoL in patients with COPD.

**Objectives:** To determine whether remote patient monitoring with health coaching improves the physical and emotional disease-specific quality of life measured by the Chronic Respiratory Questionnaire (CRQ).

**Methods:** This multicenter clinical trial enrolled 375 adult patients with COPD, randomized to a 12-week remote patient monitoring with health coaching (N=188) or wait-list usual care (n = 187). Primary outcomes include Physical and Emotional QoL measured by the Chronic Respiratory Questionnaire Summary scores(CRQ). Prespecified secondary outcomes included the CRQ domains -dyspnea, CRQ-fatigue, CRQ-emotions, CRQ-mastery, daily physical activity, self-management abilities, symptoms of depression/anxiety, ER/Hospital admissions, and sleep.

**Results:** Participants' age 69 $\pm$ 9 years; 59% women; FEV1 % 45 $\pm$ 19. At 12 weeks, there was a significant and clinically meaningful difference between the intervention vs. the control group in the physical and emotional CRQ summary scores: ((Change difference (95% CI) 0.54 points (0.36, 0.73) p<0.001, 0.51 (0.39, 0.69) p<0.001 respectively. In addition, all CRQ domains, Self-management, daily physical activity, Sleep, and Depression scores improved (p<0.01). CRQ changes were maintained at 24 weeks.

**Conclusions:** Remote monitoring with health coaching promotes COPD Wellness and behavior change given its effect on all aspects of QoL, self-management, daily physical activity, sleep, and depression scores. It represents an effective option for home-based rehabilitation.

Clinical trial registered with [clinicaltrials.gov](https://clinicaltrials.gov) (NCT03480386).

Health-related Quality of life is considered a critical patient-reported outcome in Chronic Obstructive Pulmonary Disease (COPD). It is not only what matters the most to the patient but is also associated with other meaningful outcomes, including hospitalizations and survival (1-3). Because of the increased recognition of patient symptoms and perceptions of health as a key component of the GOLD-COPD assessment and care (4), their role in precipitating healthcare events, and the impact on patients' lives, feasible and effective interventions that improve symptoms and consequently QoL in COPD are needed for comprehensive care of COPD.

Pulmonary Rehabilitation (PR) is the most effective non-pharmacological therapy to improve the quality of life for individuals with COPD. It is recommended by numerous management guidelines based on a strong body of evidence (5-7). Unfortunately, despite the proven benefits, PR programs have low participant uptake, insufficient attendance, and high drop-out rates. (8) Barriers to PR participation include transportation, access, symptom severity, acute exacerbations, lack of energy, and disruption of daily routines (7, 9). In addition, the COVID-19 pandemic dramatically reduced the average attendance of traditional center-based PR(10): new options are needed.

Recently, the American Thoracic Society (ATS) and the European Respiratory Society (ERS) recommended investigating alternative approaches to PR: Home-based Rehabilitation has been proposed as an option for delivering PR. (7) To date, two randomized controlled trials (RCTs) of unsupervised home-based PR in England and Australia have shown a non-inferior improvement in QoL when compared to conventional center-based PR in patients with stable moderate-to-severe COPD.(7, 11, 12)

Remote Patient Monitoring (RPM) of physiologic parameters has been proposed as another care option to improve QoL and health care utilization, but the results of three randomized studies have been disappointing. (13-16)

Health Coaching (HC) based on motivational interviewing has been reported to reduce COPD readmissions and facilitate successful home-based PR programs. (12, 17). We recently reported the results of a randomized study of RPM of lifestyle with HC that was feasible, exhibited high uptake and adherence, and was possibly effective for patients with COPD in the US.(18)

In the context of the knowledge gap on home-based programs for COPD to improve QoL and build on previous results and feedback from patients, we aimed to test the effect of a home-based program of RPM with HC on the physical and emotional quality of life in individuals with stable COPD. Secondarily we aimed to test the impact of RPM with HC on disease-specific measures of breathlessness, fatigue, emotions, mastery, health care utilization, daily physical activity, self-management, sleep, and symptoms of depression and anxiety.

## **Methods**

This study received Mayo Clinic IRB approval on January 11, 2018, #17-009449, was initially posted on [clinicaltrials.gov](https://clinicaltrials.gov) as NCT03480386 in March 2018, and the first patient was randomized in January 2019.

### **Study Design and Setting**

Multi-site randomized clinical trial with a wait-list control group. The study took place at Mayo Clinic, Rochester, MN, Mayo Clinic Jacksonville, FL, and Health Partners, Minneapolis-Saint Paul, MN.

### **Randomization**

Participants were randomized in a 1:1 ratio to either study group based on a pre-generated sequence of assignments through a computer-generated permuted block randomization with blocks of size four. Group 1 received the 12-week intervention, and Group 2 had a 12-week usual-care control period. We compassionately offered the intervention to the control group after completing the end-of-the control period measures. Due to the nature of the intervention, participants and clinicians were not blinded.

### **Inclusion criteria**

Participants with a clinical diagnosis of COPD (primary inclusion criteria) but confirmed by records, age 40 years or older, a history of a minimum of ten pack-years of smoking, and the ability to communicate in English.

### **Exclusion criteria**

High likelihood of being lost to follow-up: patients with active chemical dependency or inability to complete measures or follow commands due to neurologic or psychiatric impairment.

## Intervention

The 12-week program included weekly health coaching calls and a remote monitoring system (Figure 1) that had a computer tablet (figure 1-2), a Garmin Vivofit® activity monitor to use all the time during the 12-week intervention (no charging needed), and an oximeter (Nonin 3150® Saint Paul MN, USA) to use during the daily exercise routine of flexibility and balance loaded in the tablet (figure 2b).

The computer tablet provided had Wi-Fi (default) or cellular network capabilities (if Wi-Fi was not available) and captured daily steps (figure 2d) from the Garmin Vivofit®, the self-report of symptoms (fig.2c), and could send and receive messages to/from the coach (fig.2a). The data gathered on the tablet via Bluetooth (steps, compliance with daily exercises, messages, and symptoms) was transmitted to a server and, ultimately, to an online patient portal to monitor compliance with the rehabilitation routine and daily physical activity, Figure 3 a-d.

The weekly HC call aimed to be a behavior change intervention supported by the Motivational interviewing and Self efficacy theories (19, 20), including a reflection of daily steps (figure 2d), symptoms logged daily in the tablet (figure 2c), the compliance and feedback to the flexibility and balance video-guided exercises (figure 2d) and the setting of weekly goals.

Individuals were asked to complete three exercise practices daily, six days a week: two walks that lasted 6 minutes inside the home and an upper extremity simple yoga routine that lasted 12 minutes, guided by a recording from the computer tablet (figure 2b).

## **Health Coaches Training**

The training of the non-accredited health was based on Motivation Interviewing (MI) and mindfulness.

MI is an effective counseling technique that focuses on a collaborative, person-centered approach to elicit and strengthen motivation for change. The MI training of the health coaches consisted of reading the interactive book "Building Motivational Interviewing Skills: A Practitioner Workbook" by David Rosengren, the use of a commercially available virtual reality software for MI (Simmersion<sup>®</sup>), and role-playing. In addition, coaches attended weekly fidelity meetings where 10% of the coaching calls were randomized and rated by the team and the research psychologist for training purposes.

The mindfulness training included the practice of silence and deep listening as done in our previous work. Coaches were trained to choose a conversational mode that promoted empathy (as opposed to cheerleading) and to elicit aspects of the patient's life that provided meaning and purpose. The coaches did not have the responsibility of fixing problems but empowering patients for possibilities and trusting the coaching process that aims to create a receptive space for the patient.

The coaching group included two college graduates, a senior research coordinator with a master's degree in health administration, an international medical graduate, and a nurse.

## **Control Group**

Individuals in the control group had usual care and received an educational packet of 12 self-management themes for weekly self-study to match the intervention (12 encounters).



## Outcomes

The study's prespecified co-primary outcomes published on [clinicaltrials.gov](https://clinicaltrials.gov) (NCT03480386) were the changes in quality-of-life Physical and Emotional Summary scores of the **Chronic Respiratory Questionnaire (CRQ)** from baseline to 3 months as stated in the trial registration. Prespecified Secondary Outcomes included the Self-Management Ability Scale, Daily Physical Activity (Actigraph GT3X, Pensacola FL USA), Health Care Utilization, Patient Health Questionnaire PHQ-9, Generalized Anxiety Disorder 2-item, Social Support, and Sleep Quality (see online supplement for details).

This study used **two** activity monitors: The ActiGraph GTX3, which was worn on the wrist for one week all the time **before and after the 12-week intervention** (gold-standard measure of physical activity and sleep), and the Garmin Vivofit, which was used all the **time during the 12-week intervention** (no charging needed).

## Statistical Analysis

Changes from baseline to month three between arms were compared using two-sample, two-sided t-tests using an alpha of 2.5% for each primary endpoint. Each subject's changes were calculated as their month three value minus their baseline value. Linear regression models were used to model month three values after adjusting for age, FEV-1, baseline mMRC, and the baseline value of the endpoint.

Intent-to-treat analyses tested success rates between arms using Fisher's exact tests supplemented with logistic regression models that adjusted for differences in age, FEV-1,

baseline MMRC, and whether the subject was using medication for depression or anxiety. For the CRQ scales, success was defined as having an increase from a baseline of at least 0.5. If subjects had missing values for an endpoint, they were considered failures (not improved).

### Sample Size

Power calculations were based on two-sample, two-sided t-tests comparing the two groups at three months. A total sample of 196-300 complete participants had 80% power (N=196) or 90% power (N=300) to detect a difference of 0.5 (the minimal clinically important difference) (21) in the Chronic Respiratory Questionnaire (CRQ) Physical Summary Scale (Dyspnea-Fatigue) and Emotional Summary Scale (Emotions-Mastery). We used a standard deviation of 1.2 points based on our preliminary data and alpha of 0.025 (adjusted for two outcomes using a Bonferroni adjustment).

### Results

The CONSORT diagram in Figure 4 depicts participant recruitment, enrollment, withdrawals, and follow-up. **Accrual:** This study averaged an accrual rate of 11.4 subjects per month, and 60% of the accrual was during the COVID-19 pandemic (Figure e-1, online repository). Due to its home-based nature, the study accrued participants residing in 27 states of the USA (table e-1 online repository). The baseline characteristics of the participants were similar among the study groups. (Table 1). There was no difference in age, lung function (FEV1%), and respiratory

disability measured by the mMRC score between the group analyzed and the group that withdrew from the study from any cause.

Three hundred seventy-five patients were included in the final analysis. All 375 randomized subjects were included in the intent-to-treat analyses. The 23% overall withdrawal rate was similar in both arms. The missing data was very low at <10% in all the primary and secondary outcomes, with no differences between groups.

### **Primary Outcomes. Effect on CRQ Physical and Emotional Summary Scores. Table 2**

The intervention group showed a statistically and clinically significant difference in the two co-primary outcomes, the CRQ Physical and Emotional summary scores at 12 weeks (Table 2), between the intervention and control groups beyond the minimal clinically important difference for CRQ (0.5 points). There was also a significant difference in all the CRQ individual domains: Dyspnea, Fatigue, Emotions, and Mastery of dealing with COPD, all favoring the intervention group.

### **Linear Regression Models for Month 3 Values (table e-2)**

Linear regression models were used to model month three values after adjusting for age, FEV1, baseline MMRC, and the baseline value of the endpoint. The intervention was independently associated with improvements on all CRQ subscales, after adjusting for confounding factors. There were also significant independent associations between the intervention and several secondary outcomes: PHQ-9, mMRC, self-management (SMAS Total), Sleep (PSQI total), daily steps, total minutes in bed, and total sleep time.

The effect sizes for almost all the CRQ subscales are above the MCID of 0.5 points. The intervention was also associated with 670 more daily steps at month 3. (22).

### **The trajectory of improvement in the quality-of-life outcomes**

The significant changes from baseline in CRQ at week 12 were sustained until week 24 in the Physical and Emotional Summary scores (primary outcomes) Figure 5 as well as all the individual CRQ domains (Dyspnea, Fatigue, Emotions, and Mastery (figure e-2 online repository)). The control group did not improve in the initial 12 weeks (table 2) and then meaningfully improved after receiving the intervention (figure e-2 online repository).

### **Intent to Treat Analyses (table e-3):**

For intent-to-treat analyses, subjects with missing values were classified as not having improved. In ITT analyses, intervention subjects improved significantly more on the primary outcomes and all the CRQ individual domains. For example, 35% of intervention subjects improved by at least 0.5 points (MCID) on the CRQ Physical Subscale compared to only 12% of control subjects ( $p < 0.0001$ ), and 32% of intervention subjects improved by at least 0.5 points on the CRQ Emotional Summary score compared to 17% of control subjects ( $p < 0.0001$ ).

### **The number needed to treat (NNT)**

Based on the conservative ITT analysis, 4 and 6 patients are required to be treated to meaningfully improve 1 in the CRQ Physical Summary Score (Dyspnea-Fatigue) and the Emotional Summary Score (Emotion-Mastery).

**Secondary Outcomes: (Table 3)**

Participants in the intervention group demonstrated significantly greater improvements in each of the following outcomes between baseline and three months: the modified Medical Research Council dyspnea score (mMRC), the Self-management ability scale total score SMAS, total, the daily steps measured by Actigraph; the Pittsburgh sleep quality index total score; and the PHQ-9.

**Health Care Utilization from Baseline to Month 3**

Intervention subjects were less likely to have an ER visit during the 3-month intervention than the control group: 8.8% vs. 16.9%, respectively,  $p=0.052$ . There was no difference in hospitalizations (table e-5).

**Predictors of Response and Withdrawal (table e-4)**

Logistic models were used to find predictors of response and withdrawal. These models included arm, age, FEV-1, mMRC, BMI, and anxiety/depression medication use. Being on the intervention arm was the best predictor of response for almost all the study primary and secondary QoL endpoints. In addition, patients with *higher* baseline mMRC (worse) were more likely to respond to CRQ emotion domain. The only predictor of withdrawal in the study was whether the patient was taking depression or anxiety medications at baseline: Patients were about twice as likely to withdraw if they took anxiety/depression medications.

### **Health Coaching Calls and the Working alliance inventory (WAI)**

Subjects on the intervention arm had a median of 8 calls (out of 12 possible) with an average call length of 17 minutes. The WAI total score was 74.9 points, or 90% of the maximal score, indicating a high therapeutic alliance between the health coach and the patient. Compliance with the 6-times a week lower-extremity balance practice, upper-extremity flexibility practice, and reporting of symptoms and daily steps was 72%, 74%, and 76%, respectively.

### **Safety**

No adverse events were reported in the more than 6000 unsupervised balance and flexibility practices recorded.

### **Discussion**

We found that Remote Patient Monitoring (RPM) with Health Coaching (HC) produces a significant and clinically meaningful improvement in the disease-specific physical and emotional quality of life in moderate to severe COPD patients. This study is the first study of RPM in COPD that improves QoL: three previous RPM studies have been ineffective in improving quality of life or health care utilization(13-16, 23).

The difference between this RPM intervention and the ones tested in previous studies are two: First, the focus on monitoring lifestyle behaviors (daily steps and exercise practice) and symptoms instead of physiologic parameters. Second is the emphasis on patient engagement

and behavior change through weekly HC (previous studies have only on-demand contact with providers).

The linear models adjusting for age, FEV1, baseline mMRC, and the baseline value of the endpoint being modeled further confirmed the findings of the comparison between arms, showing the intervention as the sole predictor of the primary outcomes with estimates beyond the MCID and R Squares that are considered very high for social science models (Table e-2 online repository). After receiving the intervention, the significant improvement of the wait-control group further confirms the intervention's effectiveness (figures 5 and E2).

We found that unsupervised home rehabilitation with technology monitoring and HC resulted in improvement in daily physical activity measured by a validated activity monitor expressed in daily steps. This is the first randomized study of unsupervised home rehabilitation for COPD patients demonstrating clinically meaningful improvement in daily physical activity. Our results provide hope in the "how" of improving physical activity, a maker of overall wellness and better survival in COPD, which is still a challenge in the field(24-26).

The observed improvement in daily steps self-management abilities, depression, and sleep scores, in addition to the perceived improvement in dyspnea, fatigue, emotions, and mastery to live with COPD, plus the maintenance of the benefit after the intervention (figure 5), strongly suggest a behavior change in the patient. We confirmed our hypothesis that giving patients the option and the responsibility to set personal goals and make their plans will influence self-management, facilitate and stimulate behavioral change, and eventually lead to improved outcomes. Changing lifestyle through behavior change in a COPD home-based program is a novel aspect of this study.

We speculate that the HC based on Motivational Interviewing (MI) and mindfulness may have been key factors in behavior change. In addition, health Coaching has been demonstrated to be feasible and effective, with reported decreases in COPD readmissions and a sustainable improvement in quality of life and self-management (17, 27). We promoted mindfulness in the health coach by practicing silence and deep listening, and in the patient through the practice of awareness of the body and movement during the daily practices of slow walks and the standing or sitting simple yoga and also through heightened awareness of daily life events, including emotions.

This intervention did not have a predefined exercise prescription, as physical activity goals set with the coaches depended on the patient's motivations and mastery. Because of that, this intervention may not fulfill the complete criteria for the definition of conventional PR(6). However, we were guided by the World Health Organization (WHO) definition of Rehabilitation: "a set of interventions designed to optimize functioning and reduce disability in individuals with health conditions in interaction with their environment" (28). The improvement in all domains of quality of life, in the mMRC score, a measure of disability in COPD (29), depression scores, and self-management very likely accomplished the goal of Rehabilitation as defined by WHO. We aimed for a safe rehabilitation protocol at home and intentionally targeted a lifestyle change. Despite the differences, our findings align with the results of two other randomized studies (11, 12) on unsupervised home-based PR at improving quality of life.

We believe that a potential reduction in ER visits associated with the intervention deserves further exploration. We did reach a statistical improvement in daily physical activity measured by a validated activity monitor (table 3): this is a major accomplishment since



improving physical activity in COPD remains a challenge as no intervention to date has consistently improved this outcome. Interestingly we observed a pronounced decrease in physical activity over time in the control group. A decline in physical activity during a study period was similarly observed in our previous randomized study (18) and another group (21).

The implementation of remote Rehabilitation for COPD is an important challenge to conquer, even more now due to the need for remote programs in the context of the COVID-19.

**This intervention has a high likelihood of implementation:** Following the REAIMS framework(30), we believe that this intervention Reached the target population (figure 4), is Effective in improving QoL, and was the *only* significant factor associated with the completeness of the 12-week program after adjusting for age, FEV1%, and mMRC (table e-4 online repository). Furthermore, it is Acceptable: 72% of the participants were (electronically documented) with a 6-times a week exercise practice which is novel in the field. RPM with HC can be implemented in any PR center that contracts an RPM service and can use respiratory therapists or nurses as coaches. Regarding Maintenance and Sustainability: RPM with HC as tested is fully compliant with remote patient monitoring CPT codes (99453-4 and 99457-8) and "Remote Therapeutic Monitoring/Treatment Management "codes (98975, 98976, 98977, 98980, 98981) making this intervention sustainable.

The strengths of this study beyond its effectiveness results include its methodology, adequate sample size to test *a priori* hypothesis, the intention-to-treat analysis, the multicentered design, the theory-based intervention, the compliance with exercise, and the high study completion rate, and the data completeness. The conservative intention to treat analysis (Table e-3 online repository) confirmed the clinically meaningful benefit of the

intervention. It provided estimates of clinically meaningful improvement and a very low NNT for an intervention that seems feasible, effective, and sustainable. Only four patients need to be treated for one that has a clinically meaningful benefit in breathlessness -fatigue (most common symptoms in COPD) and six to improve the domain of emotion-mastery meaningfully. We found a range of improvement of QoL beyond the MCID after the intervention that ranged from 32-43%, which may seem low, but are comparable to the 44.5% of subjects that improved at least 4 points on the Saint George Respiratory Questionnaire Total at 12 weeks on the National Emphysema Treatment Trial (44.5%) after receiving state-of-the-art PR in the most reputable centers in the USA(31).

Our finding of improving emotional distress (depression) with this feasible intervention merits further exploration given the scarcity of treatments for COPD's prevalent depressive symptoms.

This study has several limitations: We cannot define the relative effectiveness of the various components of the intervention: RPM vs. HC. In addition, our recruitment was mainly in Caucasians, limiting the translation of the findings to other ethnic groups. However, the fact that we recruited 30% of patients that were of low income (<30K yearly in the household) fig 1, and rural participants, well-defined factors for poor adherence to interventions, is an asset to this study's generalizability (32). We Our results do not address the comparative effectiveness of the intervention beyond 12 weeks. Finally, we did not measure exercise capacity, an important outcome in PR, as all measures were done remotely (questionnaires and the ActiGraph were sent by mail).

In summary, this unsupervised form of home rehabilitation effectively improves what the patients most: *the quality of their life and perceived function as they live with COPD*. In addition, RPM with HC represents a sustainable alternative for individuals that cannot attend conventional PR or prefer a home intervention focused on lifestyle and behavior change. Health Coaching with lifestyle monitoring aimed to promote wellness, defined by the WHO as an active process of becoming aware of and making choices towards a fulfilling life and a state of balance and not merely the absence of disease (33).

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**Table 1:** Patient Demographics

	Control/Wait (N=187)	Intervention Now (N=188)
<b>Age Mean (SD*)</b>	68.676 (9.530)	69.335 (9.530)
<b>Female</b>	111 (59.4%)	101 (53.7%)

<b>BMI†</b> Mean (SD*)	29.129 (7.307)	28.561 (7.144)
<b>FEV1%‡</b> Mean (SD*)	45.274 (18.870)	44.103 (19.000)
<b>Taking Long-acting Bronchodilators</b>	144 (79.6%)	150 (81.1%)
<b>Taking inhaled corticosteroids</b>	165 (91.7%)	176 (95.1%)
<b>On long term antibiotics</b>	38 (20.9%)	49 (26.5%)
<b>On long term prednisone therapy</b>	34 (18.7%)	43 (23.2%)
<b>Taking Meds for Depression or anxiety</b>	75 (41.2%)	75 (40.5%)
<b>Ethnicity</b>		
Hispanic or Latino	1 (0.5%)	2 (1.1%)
Not Hispanic or Latino	181 (96.8%)	181 (96.3%)
Unknown/Not Reported	5 (2.7%)	5 (2.7%)
<b>White</b>	180 (96.3%)	177 (94.1%)
<b>High school or less</b>	67 (40.9%)	44 (25.7%)
<b>Married</b>	102 (60.4%)	102 (58.6%)
<b>Income &lt;=\$30,000</b>	55 (33.7%)	50 (30.1%)
<b>Current Smokers</b>	12 (7.3%)	15 (8.7%)
<b>Uses oxygen for sleep or activity</b>	53 (32.3%)	48 (28.1%)
<b>Living alone</b>	53 (32.5%)	54 (31.6%)

\*SD=Standard Deviation

†BMI=Body Mass Index

‡Volume of air the subject can exhale in one second divided by the expected 'normal' volume

**Table 2:** Primary Outcomes

<b>Intervention (N=187)</b>	<b>Usual Care (N=188)</b>
<b>Mean (SD) Score</b>	<b>Mean (SD) Score</b>

Measure	Baseline	At 3 months	Change in Score, Mean (95% CI)	Baseline	At 3 months	Change in Score, Mean (95% CI)	Difference, Mean Change (95% CI)	P Value
<b>Co-Primary Outcome</b>								
CRQ* Physical	3.8 (1.18)	4.35 (1.14)	0.37 (0.24, 0.51)	3.94 (1.13)	3.81 (1.2)	-0.17 (- 0.29, - 0.05)	0.54 (0.36, 0.73)	<0.001
CRQ* Emotional	4.48 (1.18)	5.02 (1.01)	0.43 (0.29, 0.57)	4.5 (1.19)	4.48 (1.21)	-0.08 (- 0.2, 0.05)	0.51 (0.31, 0.7)	<0.001
<b>Secondary Outcome</b>								
CRQ* Dyspnea	4.01 (1.42)	4.54 (1.41)	0.37 (0.21, 0.53)	4.21 (1.42)	4.01 (1.48)	-0.2 (- 0.34, - 0.05)	0.57 (0.35, 0.78)	<0.001
CRQ* Fatigue	3.57 (1.2)	4.13 (1.18)	0.39 (0.22, 0.55)	3.62 (1.18)	3.57 (1.2)	-0.13 (- 0.27, 0.01)	0.52 (0.3, 0.74)	<0.001
CRQ* Emotions	4.55 (1.17)	5.05 (1.01)	0.39 (0.24, 0.54)	4.57 (1.19)	4.55 (1.21)	-0.08 (- 0.21, 0.05)	0.47 (0.27, 0.66)	<0.001
CRQ* Mastery	4.35 (1.41)	4.96 (1.29)	0.5 (0.33, 0.67)	4.38 (1.4)	4.35 (1.41)	-0.07 (- 0.25, 0.11)	0.57 (0.32, 0.82)	<0.001

\*Chronic Respiratory Disease Questionnaire (Minimal Clinically Important Difference -MCID- =0.5 points )

Within-group change in the intervention group at 3 months. Difference between intervention and control groups at 3 months

**Table 3:** Other Secondary Outcomes

Measure	Intervention			Usual Care			Difference, Mean Change (95% CI)	P Value
	Mean (SD) Score			Mean (SD) Score				
	Baseline	At 3 months	Change in Score, Mean (95% CI)	Baseline	At 3 months	Change in Score, Mean (95% CI)		
MMRC*	2.74 (0.82)	2.49 (0.97)	-0.18 (-0.3, 0.07)	2.64 (0.86)	2.74 (0.8)	0.12 (0.01, 0.23)	-0.3 (-0.46, -0.14)	<0.001
SMAS-30†: Total Score	64.69 (12.87)	69.1 (12.22)	3.84 (2.44, 5.24)	64.19 (12.69)	65.2 (12.66)	0.54 (-0.62, 1.71)	3.3 (1.48, 5.11)	<0.001
PSQI‡ Total Score	9.39 (3.58)	8.48 (3.26)	-0.72 (-1.09, -0.34)	9.33 (3.52)	9.13 (3.61)	0.03 (-0.36, 0.42)	-0.75 (-1.28, -0.21)	0.0068
PHQ-9§ Score	6.11 (4.8)	4.48 (4.12)	-1.12 (-1.67, -0.58)	6.02 (5.44)	5.7 (5.02)	0.08 (-0.46, 0.62)	-1.2 (-1.97, -0.44)	0.0021
GAD2   Score	1.58 (1.75)	1.06 (1.38)	-0.42 (-0.68, -0.15)	1.48 (1.76)	1.2 (1.38)	-0.18 (-0.38, 0.03)	-0.24 (-0.57, 0.09)	0.1548
Mean Daily Steps**	7148.66 (3108.48)	7796.09 (3337.53)	478.63 (108.02, 849.25)	7117.01 (3212.03)	7047.49 (3248.72)	-146.53 (-458.5, 165.44)	625.16 (142.89, 1107.43)	0.0113
Mean Daily Light Physical Activity (min)**	493.35 (116.38)	516.75 (110.1)	17.51 (4.54, 30.49)	493.98 (101.73)	492.49 (115.33)	0.6 (-13.22, 14.42)	16.91 (-1.96, 35.78)	0.0788
Mean Daily Moderate Physical Activity (min)**	82.63 (61.7)	88.85 (62.06)	4.47 (-3.17, 12.11)	85.77 (71.26)	82.86 (71.5)	-4.82 (-11.66, 2.01)	9.29 (-0.91, 19.5)	0.0742
Total Sleep Time (min)**	386.16 (114.21)	400.06 (134.8)	10.57 (-15.57, 36.7)	410.73 (127.69)	397.56 (122.74)	-19.2 (-45.21, 6.81)	29.77 (-6.9, 66.43)	0.1125

\*Modified Medical Research Council Dyspnea Scale

†Self-Management Abilities Scale-30

‡Pittsburgh Sleep Quality Index

§Patient Health Questionnaire PHQ-9

|| Generalized Anxiety Disorder Two Item Questionnaire

\*\* Measured by Actigraph wGT3X-BT wore for 7 days continuously

Within-group change in the intervention group at 3 months. Difference between intervention and control groups at 3 months

## Figure Legends

**Figure 1:** Remote Monitoring with Health Coaching system

**Figure 2:** Figure 1 Footnote: a. Home screen depicting To Do List and Message Panel from the Health Coach, b. Flexibility and Balance Exercise Tab depicting the video library. Participants can choose to the Flexibility Practice seated or standing, c. Check-In tab. Participants are asked to answer 4 daily questions rating their overall well-being, breathing, level of energy and yesterday's progress to the step goal: d. The My Journey Tab documents the cumulative progress the participant has made in daily steps, minutes of daily practice and daily tracking of health-related questions.

**Figure 3:** The Overview Screen shows a high-level view of all active participants including data from activity monitor, compliance of practice, check-in questions and any messages. Under the Activity Monitor column, a red circle will display if the participant has waled fewer than 1,000 steps. The circle will be black if the participant walked more than 1,000 steps. In the Flexibility and Balance Column, the circle will be shaded in by the number of minutes of exercises completed. The bottom half of the circle depicts the Balance practice, the top half the Flexibility practice. The Check-In column depicts red circles if the participant answered 'Poor' in any category. The Trend Report displays the participant's progress over the 12-week intervention. The Weekly Report gives a daily recap of the participant's progress over the previous week. The Daily Report shows steps by the hour, how the participant answered the Check-In questions,

the time and length of the exercise, and the oxygen saturation at rest and during the exercise practice.

**Figure 4:** CONSORT diagram

**Figure 5:** Trajectory of Quality of life in the intervention and control groups



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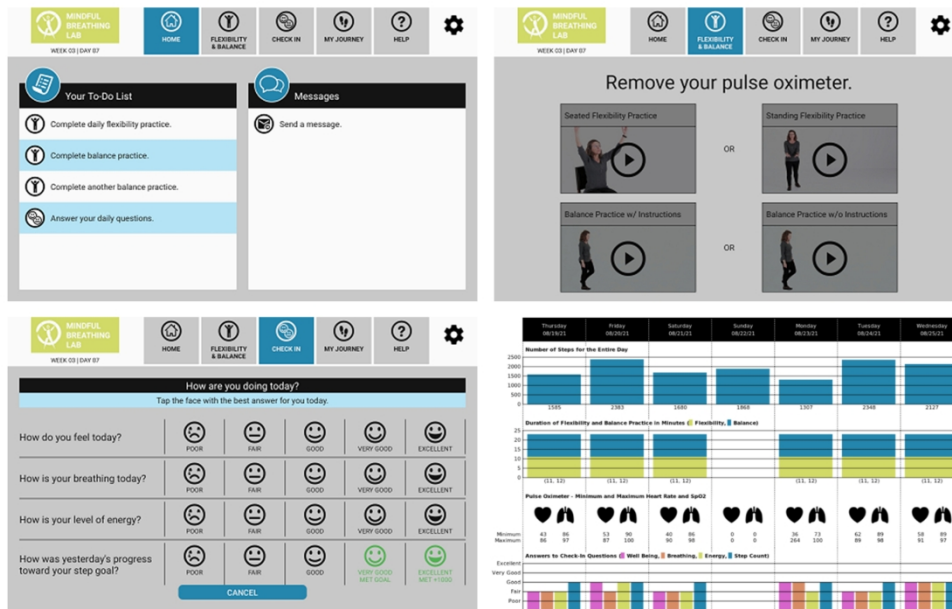
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Home Rehabilitation Program with Health Coaching overview

613x374mm (236 x 236 DPI)



Computer tablet screens

186x122mm (300 x 300 DPI)

### Overview Report

08/19/2021 - 08/25/2021

View for: Everyone

Note: Only showing patients with active remote monitoring.

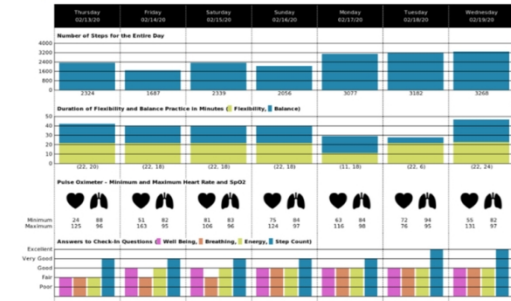
Subject ID	Activity Monitor	Flexibility & Balance	Check-In Questions	Messages	Reports
AZ test	○○○○○○○	○○○○○○○	○○○○○○○	📧	Weekly   Trend
HO5037	●●●●○○	○●○○○○○	○●○○○○○	📧	Weekly   Trend
HO5039	○○○○○○○	○○○○○○○	○○○○○○○	📧	Weekly   Trend
HO5040	●●●●●●	●●●●●●	○●○○○○○	📧	Weekly   Trend
HO5041	●●●●●●	●●○○○○○	●●○○○○○	📧	Weekly   Trend
HO5042	●●●●●●	●●●●●●	●●○○○○○	📧	Weekly   Trend
HO5043	●●●●●●	●●●●●●	●●○○○○○	📧	Weekly   Trend
HO5044	●●●●●●	○●●●●●	○●●●●●	📧	Weekly   Trend
HO5045	●●●●●●	○○○○○○○	○○○○○○○	📧	Weekly   Trend
HO5046	●●●●●●	●●○○○○○	●●○○○○○	📧	Weekly   Trend
HO5047	○○○○○○○	○●○○○○○	○○○○○○○	📧	Weekly   Trend
HO5048	○○○○○○○	○○○○○○○	●●○○○○○	📧	Weekly   Trend
HO5050	○○○○○○○	○○○○○○○	○○○○○○○	📧	Weekly   Trend
HO5051	●●●●●●	○○○○○○○	○○○○○○○	📧	Weekly   Trend
HP DEMO2	○○○○○○○	○○○○○○○	○○○○○○○	📧	Weekly   Trend
hp060	●●●●●●	●●○○○○○	●●○○○○○	📧	Weekly   Trend

### Weekly Report - rst076

02/18/2020 - 02/19/2020

Order Last 7 Days Home

Notes (None)



### Trend Report - rst076



### Daily Report - rst076

02/16/2020

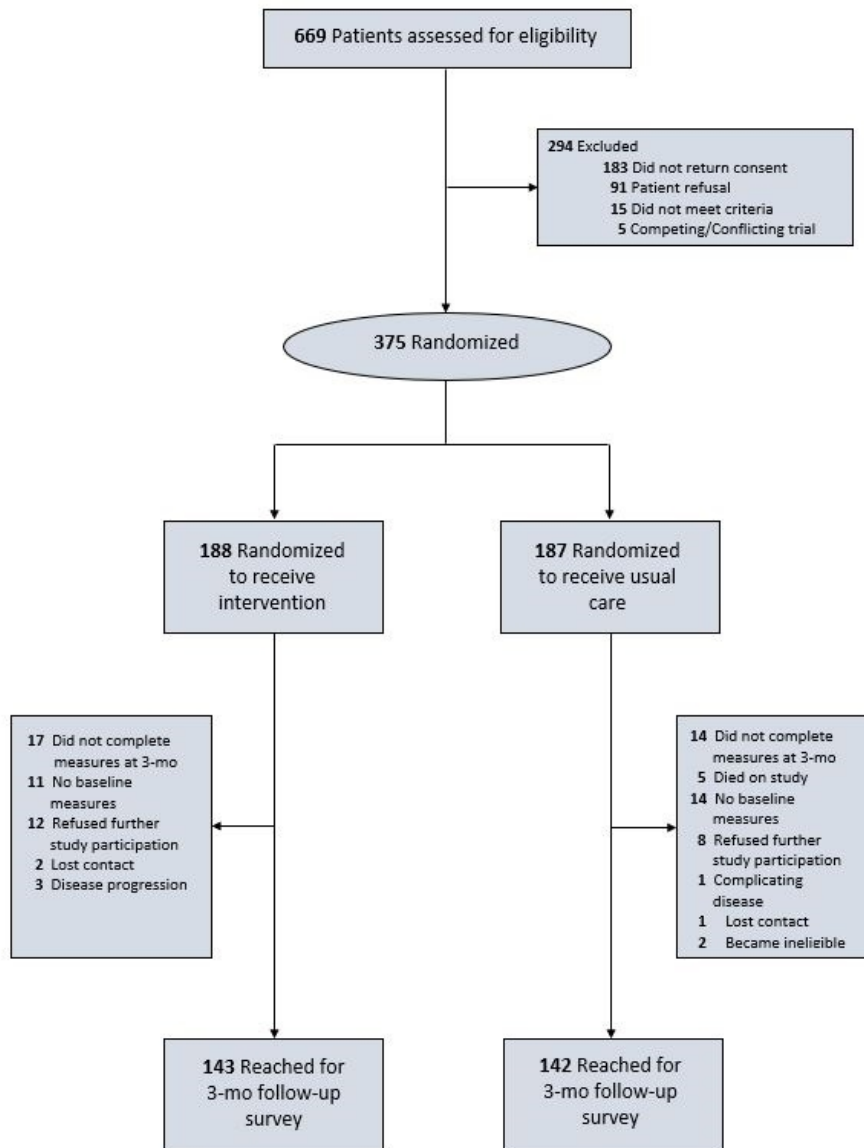
Order Today Home

Notes: All times in the time zone of the patient (Central Time)



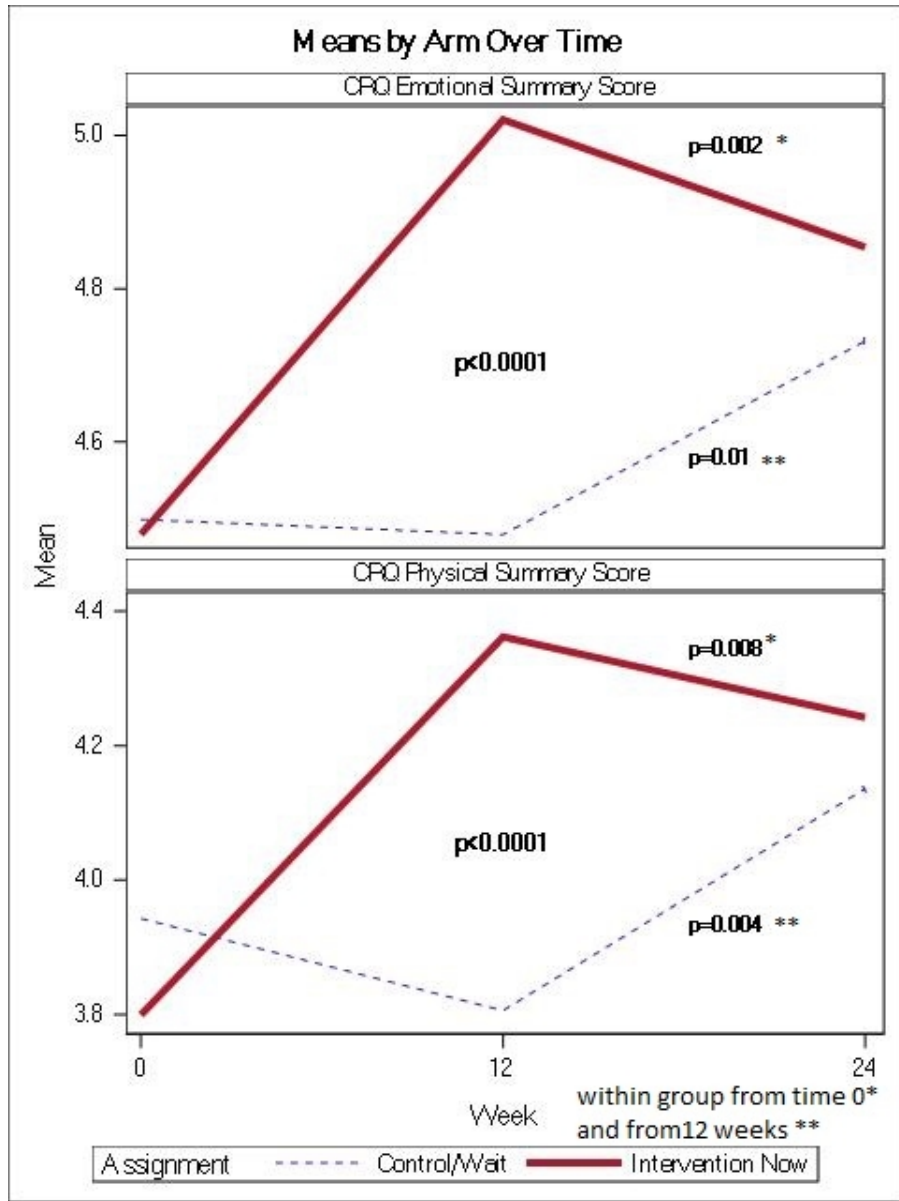
### Program Portal

125x122mm (300 x 300 DPI)



Consort Diagram

161x207mm (96 x 96 DPI)



Trajectory analysis of the main outcome

127x169mm (96 x 96 DPI)



## Online Material

### Promoting COPD Wellness through Remote Monitoring and Health Coaching: A Randomized Study

Roberto Benzo MD MS, Johanna Hoult MA, Charlene McEvoy MD, Matthew Clark Ph.D., Maria Benzo MD, Margaret Johnson MD, Paul Novotny MS.

	Control/Wait (N=187)	Intervention Now (N=188)
<b>Age</b>		
N	185	188
Mean (SD)	68.7 (9.5)	69.3 (9.5)
Median	68.0	69.0
Q1, Q3	63.0, 75.0	63.0, 77.0
Range	(45.0-92.0)	(37.0-91.0)
<b>Gender</b>		
Female	111 (59.4%)	101 (53.7%)
Male	76 (40.6%)	87 (46.3%)
<b>State</b>		
Missing	1	0
AL - Alabama	1 (0.5%)	0 (0.0%)
AZ - Arizona	1 (0.5%)	2 (1.1%)
AR - Arkansas	1 (0.5%)	1 (0.5%)
CO - Colorado	1 (0.5%)	2 (1.1%)
FL - Florida	15 (8.1%)	19 (10.1%)
GA - Georgia	1 (0.5%)	4 (2.1%)
IL - Illinois	3 (1.6%)	10 (5.3%)
IN - Indiana	2 (1.1%)	0 (0.0%)
IA - Iowa	16 (8.6%)	13 (6.9%)
KS - Kansas	1 (0.5%)	0 (0.0%)
KY - Kentucky	0 (0.0%)	1 (0.5%)
MD - Maryland	0 (0.0%)	1 (0.5%)
MI - Michigan	5 (2.7%)	3 (1.6%)
MN - Minnesota	105 (56.5%)	99 (52.7%)
MS - Mississippi	2 (1.1%)	0 (0.0%)
MO - Missouri	4 (2.2%)	0 (0.0%)
MT - Montana	0 (0.0%)	2 (1.1%)
NE - Nebraska	2 (1.1%)	1 (0.5%)
NY - New York	1 (0.5%)	1 (0.5%)
ND - North Dakota	1 (0.5%)	6 (3.2%)
SC - South Carolina	1 (0.5%)	0 (0.0%)

	Control/Wait (N=187)	Intervention Now (N=188)
SD - South Dakota	2 (1.1%)	5 (2.7%)
TN - Tennessee	0 (0.0%)	1 (0.5%)
TX - Texas	1 (0.5%)	0 (0.0%)
VA - Virginia	0 (0.0%)	1 (0.5%)
WI - Wisconsin	18 (9.7%)	16 (8.5%)
WY - Wyoming	1 (0.5%)	0 (0.0%)
Other	1 (0.5%)	0 (0.0%)

**MMRC: Baseline**

Missing	24	18
0	3 (1.8%)	4 (2.4%)
1	19 (11.7%)	12 (7.1%)
2	25 (15.3%)	24 (14.1%)
3	103 (63.2%)	114 (67.1%)
4	13 (8.0%)	16 (9.4%)

**FEV-1**

N	175	176
Mean (SD)	45.8 (19.7)	44.2 (19.4)
Median	43.0	43.0
Q1, Q3	30.0, 59.0	29.4, 57.1
Range	(13.0-102.0)	(1.8-101.0)

**GOLD Stage**

Missing	12	12
1	9 (5.1%)	8 (4.5%)
2	58 (33.1%)	56 (31.8%)
3	70 (40.0%)	67 (38.1%)
4	38 (21.7%)	45 (25.6%)

***Linear Regression Models (Table e-2)***

**Linear Regression Models for Month 3 Values:** Linear regression models were used to model month 3 values after adjusting for age, FEV1, baseline MMRC, and the baseline value of the endpoint being modeled. Adjusting for confounding factors, the intervention group had significant improvements on all CRQ subscales. There were also significant changes in several secondary outcomes PHQ-9, mMRC, self-management (SMAS Total), Sleep (PSQI total), daily Steps, mean minutes in light physical, and moderate activity.

The effect sizes for almost all of the CRQ subscales are above the clinically meaningful 0.5 sizes. The intervention was also associated with 670 more steps at month 3.

Endpoint	Arm Estimate	p-value	R-Square
CRQ Physical Summary Score	0.54	<.0001	0.62
CRQ Dyspnea Domain	0.57	<.0001	0.63
CRQ Fatigue Domain	0.52	<.0001	0.51
CRQ Emotional Domain	0.47	<.0001	0.54
CRQ Mastery Domain	0.54	<.0001	0.53
CRQ Emotional Summary Score	0.50	<.0001	0.57
MMRC	-0.28	0.0006	0.47
PHQ9 Score	-1.12	0.0021	0.60
SMAS Total	3.58	<.0001	0.66
GAD2	-0.18	0.1868	0.35
ISEL Appraisal	0.07	0.7639	0.48
ISEL Belonging	0.54	0.0070	0.63
ISEL Tangible	0.40	0.0743	0.46
ISEL Overall Support	0.92	0.0683	0.65
PSQI Total	-0.66	0.0122	0.63
Daily Steps #	670	0.0057	0.70
Sedentary time minutes #	-20	0.09	0.57
Light physical activity (1.5-3METs) in minutes #	18.74	0.056	0.55
Moderate physical activity (1.5-3METs) in minutes #	9.97	0.049	0.68

(# measured by Actigraph wtg3x)

**Intent to Treat Analyses:** For intent-to-treat analyses, subjects with missing values were classified as not having improved. In these ITT analyses, intervention subjects improved significantly more on all CRQ scales. In particular, 35% of intervention subjects improved by at least 0.5 on the CRQ Physical Subscale compared to only 12% of control subjects ( $p < 0.0001$ ).

Table e-3: Intent to Treat Analyses

	Control/Wait (N=187)	Intervention Now (N=188)	Total (N=375)	p value
<b>ITT: CRQ Physical Summary Score Improved <math>\geq 0.5</math></b>				<b>&lt;0.0001<sup>1</sup></b>
No	164 (87.7%)	122 (64.9%)	286 (76.3%)	
Yes	23 (12.3%)	66 (35.1%)	89 (23.7%)	
<b>ITT: CRQ Dyspnea Improved <math>\geq 0.5</math></b>				<b>0.0109<sup>1</sup></b>
No	153 (81.8%)	132 (70.2%)	285 (76.0%)	
Yes	34 (18.2%)	56 (29.8%)	90 (24.0%)	
<b>ITT: CRQ Fatigue Improved <math>\geq 0.5</math></b>				<b>&lt;0.0001<sup>1</sup></b>
No	154 (82.4%)	116 (61.7%)	270 (72.0%)	
Yes	33 (17.6%)	72 (38.3%)	105 (28.0%)	
<b>ITT: CRQ Emotion Improved by <math>\geq 0.5</math></b>				<b>0.0002<sup>1</sup></b>
No	157 (84.0%)	126 (67.0%)	283 (75.5%)	
Yes	30 (16.0%)	62 (33.0%)	92 (24.5%)	
<b>ITT: CRQ Emotional Summary Score Improved <math>\geq 0.5</math></b>				<b>0.0008<sup>1</sup></b>
No	155 (82.9%)	127 (67.6%)	282 (75.2%)	
Yes	32 (17.1%)	61 (32.4%)	93 (24.8%)	
<b>ITT: CRQ Mastery Improved <math>\geq 0.5</math></b>				<b>0.0008<sup>1</sup></b>
No	137 (73.3%)	106 (56.4%)	243 (64.8%)	
Yes	50 (26.7%)	82 (43.6%)	132 (35.2%)	
<b>ITT: Steps Improved <math>\geq 600</math></b>				0.0865 <sup>1</sup>
No	151 (80.7%)	137 (72.9%)	288 (76.8%)	
Yes	36 (19.3%)	51 (27.1%)	87 (23.2%)	

<sup>1</sup>Fisher Exact

Table e-3 a: Logistic models predicting clinically significant improvement at 3 months (per-protocol analysis)

	Control/Wait (N=187)	Intervention Now (N=188)	Total (N=375)	p-value
<b>Wk12: CRQ Physical Fct Improved <math>\geq 0.5</math></b>				<b>&lt;0.0001<sup>1</sup></b>
Missing	45	44	89	
No	119 (83.8%)	78 (54.2%)	197 (68.9%)	
Yes	23 (16.2%)	66 (45.8%)	89 (31.1%)	

**Table e-3 a: Logistic models predicting clinically significant improvement at 3 months (per-protocol analysis)**

	Control/Wait (N=187)	Intervention Now (N=188)	)	p-value
<b>Wk12:CRQ Emotional Subscale Improved <math>\geq 0.5</math></b>				<b>0.0003<sup>†</sup></b>
Missing	45	44	89	
No	110 (77.5%)	82 (56.9%)	192 (67.1%)	
Yes	32 (22.5%)	62 (43.1%)	94 (32.9%)	
<b>Wk12:Steps Improved <math>\geq 600</math></b>				<b>0.0189<sup>†</sup></b>
Missing	49	60	109	
No	102 (73.9%)	77 (60.2%)	179 (67.3%)	
Yes	36 (26.1%)	51 (39.8%)	87 (32.7%)	

### **Predictors of Response and Withdrawal (Table e-4)**

**Predictors of Response and Withdrawal:** Logistic models were used to find predictors of response and withdrawal. These models included arm, age, FEV-1, MMRC, BMI, and anxiety/depression medication use. Being on the intervention arm was the best predictor of response for almost all study endpoints. In addition, patients with higher baseline MMRC were more likely to respond to CRQ emotion.

The most meaningful predictor of withdrawal was whether or not the patient was taking depression or anxiety medications at baseline. Patients were about twice as likely to withdraw if they took anxiety/depression medications.

Endpoint	Arm p- value	Arm Odds	Other Significant Variables	Odds Ratio of Other Variable
ITT:CRQ Physical Summary Improved $\geq 0.5$	<.0001	3.86 (2.27,6.55)		
ITT:CRQ Dyspnea Improved $\geq 0.5$	0.0091	1.91 (1.18,3.10)		
ITT:CRQ Fatigue Improved $\geq 0.5$	<.0001	2.90 (1.80,4.67)		
ITT:CRQ Emotion Improved $\geq 0.5$	0.0004	2.49 (1.50,4.14)	MMRC	1.54 (1.10,2.16)
ITT:CRQ Emotional Summary Improved $\geq 0.5$	0.0007	2.33 (1.43,3.79)		
ITT:CRQ Mastery Improved $\geq 0.5$	0.0007	2.12 (1.37,3.27)		

Endpoint	Arm p-value	Arm Odds	Other Significant Variables	Odds Ratio of Other Variable
Withdrawal From the Study			FEV1%	1.02 (1.01,1.03)
			Depression or Anxiety Medication	2.01 (1.16,3.48)

Table e-5: Health Care Utilization

	Control/Wait (N=187)	Intervention Now (N=188)	Total (N=375)	p value
<b>Any ER Visits: at Month 3</b>				0.0521 <sup>1</sup>
Missing	45	41	86	
No	118 (83.1%)	134 (91.2%)	252 (87.2%)	
Yes	24 (16.9%)	13 (8.8%)	37 (12.8%)	
<b>Any Hospitalizations: at Month 3</b>				1.0000 <sup>1</sup>
Missing	45	41	86	
No	127 (89.4%)	132 (89.8%)	259 (89.6%)	
Yes	15 (10.6%)	15 (10.2%)	30 (10.4%)	

**Prespecified secondary measures Daily Physical Activity** was measured with the Actigraph GT3X (Actigraph, Pensacola FL USA), a validated tool to quantify physical activity(14). The Actigraph was worn for one week (15) 924-hours continuously on the wrist) to measure sedentary time, daily steps, and time in sedentary mode (<1.5 METs), mild physical activity (1.5-3 METs), moderate physical activity (3-6 METs), and also sleep efficiency variables. Self-management was measured with the **Self-Management Ability Scale -30**, which measures abilities, lifestyle, and function. The SMAS consists of 30 items graded on four- and five-point Likert scales, with a higher score indicating greater functional status. Scores on the subscales and the total score are transformed into a total composite score which ranges from 0 to 100 (16). Dyspnea was further quantified by the Medical Research Council Dyspnea score (mMRC) (17), a measure of disability in COPD. **Depression** was assessed with the Patient Health Questionnaire-9 item questionnaire, with a higher score indicating that depression may be present. **Finally, social support** was evaluated with the **Multidimensional Scale of Perceived Social Support (MSPSS)**, a 12-item scale designed to measure perceived social support from three sources: Family, Friends, and a Significant Other. - The score on the MSPSS ranges from 12-84, with a higher score indicating a greater amount of social support. The **Meaning in Life Questionnaire** is a ten-item questionnaire, with scores ranging from 10 to 70, that assess the participant's perception of purpose, meaning, and presence in life. A higher score indicates a perception of higher meaning and purpose. IN addition of

the activity monitor, sleep was measure with the Pittsburgh Sleep Quality Index (PSQI), a 9-item questionnaire assessing the quality and patterns of sleep. Scores range from 0-21; a total score < 5 is associated with good sleep quality and a score > 5 is associated with poor sleep quality. **Anxiety** was measured with the General Anxiety Disorder-2 item Questionnaire Score ranges from 0-6, with a higher score suggesting anxiety is present.

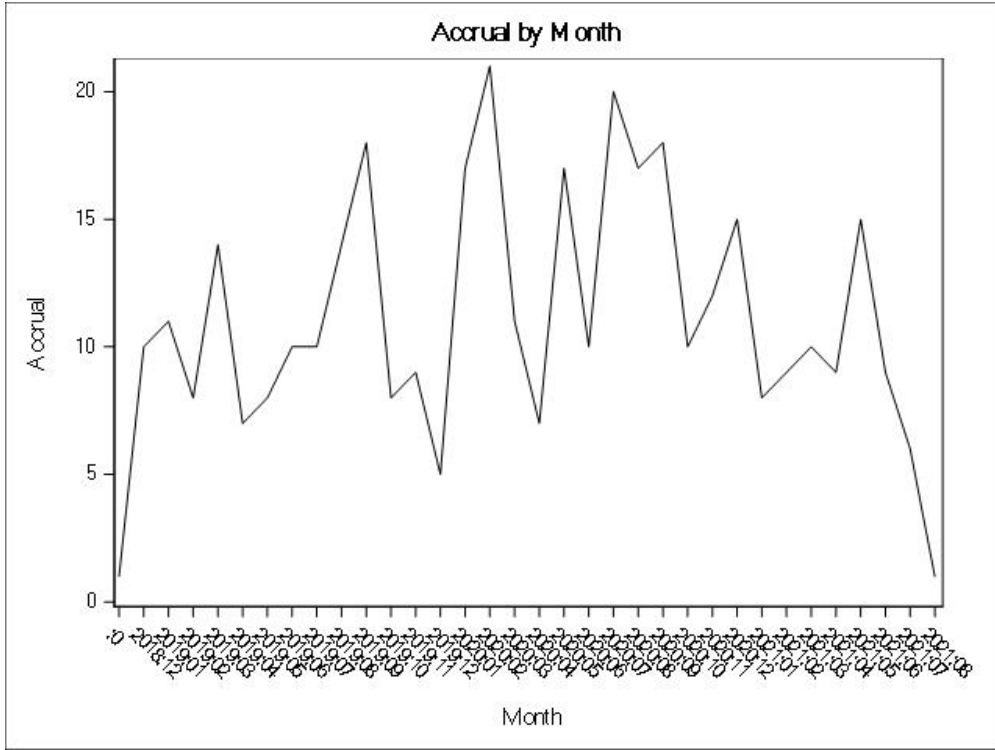
**Health Care utilization** (ED visits and Hospitalizations) was self-reported in the 3-month period and confirmed by reviewing patients' medical records.

**Working Alliance Inventory** short form (WAI) is a 12-item self-report questionnaire designed to assess the therapeutic alliance between the patient and the coach, with responses rated on a seven-point Likert scale, ranging from 1 (never) to 7 (always). The questionnaire was designed to cover three dimensions: (1) therapeutic goals, (2) tasks, and (3) bonds. The total score ranges from 12 to 84

### Figure Legends

**Figure e-1: Trajectory of accrual**

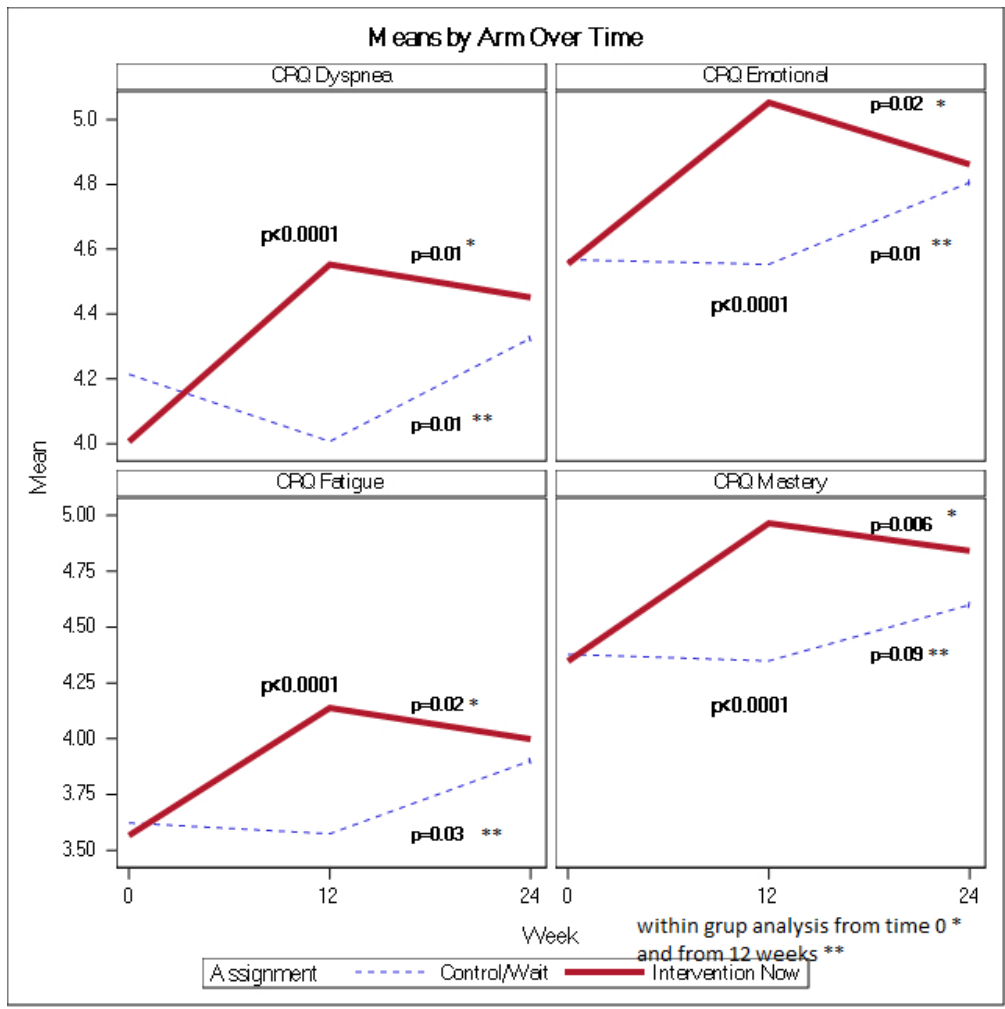
**Figure e-2: Trajectory of Individual CRQ Domains in the intervention and the Control Group**



Trajectory of accrual

169x127mm (96 x 96 DPI)





Trajectory analysis of CRQ domains

427x427mm (38 x 38 DPI)