

SUMMARY OF PROMIS WAVE 2 PROTOCOLS

Chronic Obstructive Pulmonary Disease (COPD) Protocol Summary Information

Organization's Unique Protocol ID: 07-02

Brief Title: Validation of PROMIS Banks with COPD Exacerbations

Official Title: Validation of PROMIS Banks with COPD Exacerbations

Study Type: Observational

Human Subjects Review: Submitted, approved

Board approval number: 08-0138

Board Name: University of North Carolina Institutional Review Board

Board Affiliation: University of North Carolina

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Oversight Authorities: United States: Institutional Review Board

Sponsor: National Institutes of Health

Collaborators: University of Pittsburgh, Duke University, NorthShore University Health System

Brief Summary: This is a prospective, longitudinal study of adult patients with Chronic Obstructive Pulmonary Disease (COPD), patients who will be enrolled when their COPD is considered clinically stable or during an acute exacerbation. This design will allow both within-person and between person comparisons by exacerbation experience. Comprehensive clinical and patient-reported assessments will be performed at baseline and at 3 months (end of study). Subsets of items will be administered by interactive voice response (IVR) over the course of the study to measure changes in key symptoms over the course of recovery from an exacerbation. A subset of patients will be interviewed at the end of the study to assess content validity of PROMIS items in this patient population.

With such a study design, we will be able to evaluate the validity of the PROMIS items in this patient population under

acute and stable conditions and evaluate responsiveness of several PROMIS item banks under conditions of known change in an underlying chronic disease. We will also evaluate stability of sub-domains that are not hypothesized to change with COPD exacerbations.

Objectives

To assess the reliability and content and construct validity (including responsiveness to change) of PROMIS instruments in patients with COPD during stable state and during acute exacerbations of COPD. Specifically, we have the following aims:

1. To evaluate the reliability (internal consistency, test-retest reliability) of the PROMIS Computer Adaptive Tests (CATs) / short forms.
2. To compare CAT / short form scores in the PROMIS domains with clinical assessments of COPD patients when the patient is initially considered stable. Clinical assessments will include COPD GOLD Stage, forced expiratory volume during the first second (FEV1), and 6-minute walk distance.
3. To evaluate changes in CAT/short form scores in the PROMIS domains from the nadir with an exacerbation compared to within person stable disease state.
4. To compare responsiveness to change of the PROMIS CAT/short form scores with the comparable subscale scores from the St. Georges Respiratory Questionnaire (SGRQ) and to estimate minimally important differences (MID) for the domains of the PROMIS CAT/shortforms.
5. To compare results from 7 day recall period obtained from PROMIS CAT/shortform scores to the results obtained from the EXACT-PRO (daily diary approach with 1 day recall period) administered during the first 7 days of the study.
6. To perform a qualitative review for content validity of the PROMIS items.
7. To explore the impact of literacy on computer based testing as measured by missing data, rate, variance and differences in mean PROMIS CAT/short form scores.

We hypothesize the following with respect to the above objectives:

1. The PROMIS CATs and short forms will be internally consistent and have good test-retest reliability.
2. There will be significant correlations between PROMIS scores and clinical assessment in both groups.
3. There will be significant improvement (positive slope)

in the PROMIS measures in COPD patients during recovery from exacerbation to a stable period.

4. PROMIS items will have comparable responsiveness to the SGRQ and that there will be significant improvement in PROMIS measures following the exacerbation.
5. Patients will have similar results on the 7 day recall PROMIS items compared to EXACT-PRO items.
6. Qualitative data from cognitive interviews of patients with COPD will provide evidence in support of content validity of PROMIS items

Overall Recruitment Status:	Recruiting
Study Start Date:	July 1, 2008
Study Completion Date:	June 30, 2009
Study Design: (Observational Study Model)	Cohort
Time Perspective:	Prospective
Enrollment:	Target: 180
Number of Groups/Cohorts:	2
Primary and Secondary Outcome Measures	Changes in scores on PROMIS measures
Primary Outcome Measure:	Change in scores on PROMIS measures from baseline to 3 months. Comparing patients starting in stable state to patients having an exacerbation.
Group/Cohort Label:	Stable, Exacerbation
Group/Cohort Description:	Stable: Patients who are stable have not had a COPD exacerbation in the past 2 months Exacerbation: Patients with an exacerbation have been diagnosed and started on treatment for an exacerbation within the past 3 days.
Intervention Type:	None
Conditions or Focus of Study:	COPD
Study Population Description:	People presenting to primary care or specialty clinics with COPD either with exacerbation or not. People admitted to the hospital with a COPD exacerbation.
Sampling Method:	Non-probability sample

Eligibility Criteria:**Inclusion:**

- Gender: Male or Female (We will attempt to enroll approximately 50% men/women)
- Age: ≥ 40 years
- Diagnosis: An established clinical history of COPD in accordance with the GOLD definition (Chronic obstructive pulmonary disease (COPD) is a preventable and treatable disease with some significant extrapulmonary effects that may contribute to the severity in individual patients. Its pulmonary component is characterized by airflow limitation that is not fully reversible. The airflow limitation is usually progressive and associated with an abnormal inflammatory response of the lung to noxious particles or gases.)
- A history of smoking (at least 10 pack/year history)
- Access to and able to communicate on a touch tone telephone
- Read and speak English
- Able to see and interact with a computer screen, mouse and keyboard
- Informed Consent: A signed and dated written informed consent prior to study participation
- For those enrolled into the exacerbation group, patients must have been diagnosed with an exacerbation within 3 days of the day of enrollment.
- For those enrolled in the stable state group, the patient will be considered stable if he or she has been exacerbation-free for a minimum of 2 months prior to enrollment.

Exclusion:

- A subject will not be eligible for inclusion in this study if in the investigator's opinion the patient has any concurrent medical or psychiatric condition that may preclude participation in this study or completion of self-administered questionnaires (e.g., moderate to severe dementia and/or severe, uncontrolled schizophrenia, or other condition that would render them unable to complete a questionnaire).
- History of asthma without co-existent COPD as the primary diagnosis.
- Patients experiencing a current heart failure exacerbation. A diagnosis of heart failure is not in itself an exclusion criterion.

Gender:

Both

Age Limits:

Minimum age: 40 years
Maximum age: N/A

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