The NIH
Exercise Therapy for Advanced Lung Disease Trials:

Response and Adaptation to Aerobic Exercise in Patients with Interstitial Lung Disease
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National Institutes of Health Clinical Center
Department of Rehabilitation Medicine
We have no disclosures to report.

Objectives:

- Provide an overview of the NIH Clinical Center and opportunities for patients
- How individuals can participate in clinical trials
- Provide background and study information on our randomized controlled trial (RCT) for ILD aerobic exercise therapy:
  - What patients in the study experience
    - Testing
    - Exercise
    - Education
  - Study findings of two representative subjects
  - Care beyond the study and the transition to community PR
National Institutes of Health
Clinical Center

Bethesda, Maryland
NIH Clinical Center

- America's Research Hospital
- Located on the NIH campus in Bethesda, MD
- Bench–to-Bedside Research

- The Clinical Center marked its 60th anniversary in July 2013 and dedicated its new hospital, the Mark O. Hatfield Clinical Research Center, in 2004.

- More than 500,000 research participants since the hospital opened in 1953.
NIH Clinical Center Facts

**Medical milestones** –

- Development of chemotherapy for cancer
- First use of an immunotoxin to treat a malignancy (hairy cell leukemia)
- Identification of the genes that cause kidney cancer, leading to the development of six new, targeted treatments for advanced kidney cancer
- Demonstration that lithium helps depression
- First gene therapy
- First treatment of AIDS (with AZT)
- Development AIDS/HIV and hepatitis testing
NIH Clinical Center Facts

• Currently about 1600 clinical research studies in progress
  • 50% are studies of natural history of disease, especially rare diseases
  • 50% are clinical trials, often first in human testing of new drugs and therapies.
NIH Clinical Center Facts

- More than 10,400 new patients in 2016
- More than 5,200 inpatient admissions in 2016
- More than 100,100 outpatient visits in 2016
- An average hospital stay of 8.7 days
- Some 1,200 credentialed physicians, dentists, and PhD researchers
- Some 620 nurses
- 450 allied health-care professionals, such as pharmacists, dietitians, medical technologists, imaging technologists, therapists, medical records and medical supply staff
- More than 1,600 laboratories conducting basic and clinical research
NIH Clinical Center Facts

• Areas of clinical study include:
  - Aging, alcohol abuse and alcoholism, allergy, arthritis and musculoskeletal and skin disease, cancer, child health, chronic pain, deafness and other communication disorders, dental and orofacial disorders, diabetes, digestive and kidney diseases, eye disorders, heart, lung, and blood diseases, infectious diseases, medical genetics, mental health, stroke

• 27 Institutes and Centers, including:
  - National Cancer Institute
  - National Institute of Allergy and Infectious Diseases
  - Clinical Center
Clinical Research – The Big Picture

- **ClinicalTrials.gov**
  - Find studies conducted in all 50 states and in 197 countries.
  - Find information pertaining to studies on:
    - Disease or condition
    - Intervention (medical product, behavior, or procedure being studied)
    - Title, description, and design of the study
    - Requirements for participation (eligibility criteria)
    - Locations where the study is being conducted
    - Contact information for the study locations
    - Links to relevant information on other health Web sites:
      - National Library of Medicine’s MedlinePlus® for patient health information
      - PubMed for citations and abstracts of scholarly articles
Clinical Center
Department of Rehabilitation Medicine

- Clinical Care – PT/OT/ST
- Clinical Research
  - Effects of Exercise in Patients with:
    - Traumatic Brain Injury
    - Systemic Lupus Erythematosus (SLE)
    - Chronic Fatigue
    - Prostate Cancer
    - Pulmonary Hypertension
    - Interstitial Lung Disease
ILD - Principal Investigators

Leighton Chan, MD, MPH
Chief, Rehabilitation Medicine Department

Randall Keyser, PhD
Associate Professor
George Mason University
College of Health and Humans Services, Department of Rehabilitation Science

Steven Nathan, MD, FCCP
Director, INOVA Advanced Lung Disease Program
Background

- Based on study of 13 Patients with ILD and no PH enrolled as controls in another trial (2009)
- Showed improvements in 6MWD and HRQOL after aerobic exercise training.

*Cardiorespiratory Function Before and After Aerobic Exercise Training in Patients with Interstitial Lung Disease*


Changes in fatigability following intense aerobic exercise training in patients with interstitial lung disease.


# Pilot Study – Subgroup of 13 ILD Patients w/o PH

## Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, mean (SD), years</strong></td>
<td>57.0 (9.1)</td>
</tr>
<tr>
<td><strong>Female, n (%)</strong></td>
<td>9 (69)</td>
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<tr>
<td><strong>Race/ethnicity, No. (%)</strong></td>
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<tr>
<td>White</td>
<td>11 (85)</td>
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<tr>
<td>African American</td>
<td>2 (15)</td>
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<tr>
<td><strong>BMI, mean (SD), kg/m²</strong></td>
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<td><strong>Supplemental O₂ Use, No. (%)</strong></td>
<td>5 (38)</td>
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<td><strong>Diagnosis</strong></td>
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<td>Nonspecific interstitial pneumonitis (NSIP)</td>
<td>6 (46)</td>
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<td>Idiopathic pulmonary fibrosis (IPF)</td>
<td>3 (23)</td>
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<tr>
<td>Scleroderma</td>
<td>2 (15)</td>
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<tr>
<td>Desquamative interstitial pneumonia</td>
<td>1 (8)</td>
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<tr>
<td>Sjögren's syndrome</td>
<td>1 (8)</td>
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<tr>
<td><strong>NYHA/WHO Functional Classification, No. (%)</strong></td>
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<tr>
<td>Class II</td>
<td>6 (46)</td>
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<td>Class III</td>
<td>7 (54)</td>
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<td><strong>Pulmonary Function Test, mean (SD)</strong></td>
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<tr>
<td>FVC, % predicted</td>
<td>52.9 (18.0)</td>
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<td>FEV1, % predicted</td>
<td>57.0 (20.3)</td>
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<tr>
<td>FEV1/FVC, % predicted</td>
<td>83.4 (3.6)</td>
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</table>
Pilot Study Design: ILD w/o PH

Following screening & enrollment

Pre-Intervention Testing

PFT, 6MWT
Self-Report Questionnaires
Cardiopulmonary exercise test on treadmill

Exercise & Education

Post-intervention Testing

10 Weeks
Untrained (white bars) and trained (black bars) patients with ILD

After training:
- CPET time to fatigue was $163 \pm 130$ sec longer ($p = 0.001$)
- Time to anaerobic threshold was $145 \pm 15$ sec longer ($p < 0.001$)
- Peak work rate was $43 \pm 37$ watts higher ($p = 0.002$)
- 6MWD was $52 \pm 48$ meters farther ($p = 0.001$)

Error bars equal one standard deviation unit
Muscle oxygenation measured non-invasively with NIRS
Untrained (white bars) and trained (black bars) patients with ILD
Bars represent concentration changes for oxygenated, deoxygenated, total and difference in hemoglobin/myoglobin.
[deoxygenated-Hb/Mb] (p = 0.037) and [difference-Hb/Mb] (p = 0.027) were significantly greater in the trained versus the untrained state.
Error bars represent one standard deviation unit.
Pilot ILD Results: Self-report Questionnaire

SF-36 Scores

- Physical Functioning
- Role Physical
- Bodily Pain
- General Health
- Vitality
- Social Functioning
- Role Emotional
- Mental Health

FSS Total Score: *P=.002

- Physical Functioning: *P=.002
- Role Physical: *P=.001
- Bodily Pain: *P=.295
- General Health: P=.111
- Vitality: *P=.027
- Social Functioning: *P=.017
- Role Emotional: P=.116
- Mental Health: P=.299
Pilot ILD Results: Performance Measures

- **6MWT Distance (meters)**: Pre: 420 ± 20 meters, Post: 472 ± 25 meters
  - *P = .002
  - 52 meters improvement
  - 12.4% change

- **Treadmill Time (min)**: Pre: 15 ± 2 minutes, Post: 17 ± 3 minutes
  - *P < .001
  - 2.7 minutes longer
  - 22.6% change

- **Time at anaerobic threshold (min)**: Pre: 6 ± 1 minutes, Post: 8 ± 2 minutes
  - *P = .003
  - 2.3 minutes longer
  - 46.5% change
New ILD Study - 2014

- Prospective cohort study, RCT with crossover design
- Primary Objective
  - To determine the efficacy, safety and tolerability of aerobic exercise for patients who have interstitial lung disease (ILD) uncomplicated by pulmonary hypertension to determine appropriate pulmonary rehabilitation exercise guidelines.
- 5-year randomized controlled trial
- 60 ILD patients without PH
- Randomized to an intervention consisting of
  - Aerobic exercise training plus patient education (AET+) OR
  - Control condition that includes patient education only (CON)
ILD Study Design

Following screening & enrollment

Pre-Intervention Testing
- PFT, Echo, 6MWT
- Self-Report Questionnaires
- Cardiopulmonary exercise test on treadmill

Randomized

10 Weeks
- Exercise & Education (EXE)
- Education Only (CON)

Post-intervention Testing
Research Aims

• Determine the influence of AET+ on physical work capacity (PWC) in patients with ILD:
  • 6MWT distance, Peak work rate (PWR) on treadmill CPET, Perceived fatigability
• Characterize the CR adaptation to AET in patients with ILD
  • Time to AT and muscle oxygenation
• Determine the influence of AET on patient-reported measures
  • Fatigue, Physical Activity, HRQOL
• 1-Year Follow up
  • Hospitalizations, acceptance for transplant, mortality
Participant Profile

- 60 ILD patients living in the greater Washington metropolitan area referred for pulmonary rehabilitation:
  - INOVA Advanced Lung Disease Program
  - Local Pulmonary Rehabilitation Programs and pulmonary practices
  - Clinical Trials.gov / Self-referral / Research Match
  - Clinical Center Facebook & Twitter.
Inclusion Criteria

- Ages 21 - 80 years
- Dx of Interstitial Lung Disease
  - Idiopathic Pulmonary Fibrosis (UIP)
  - Non-Specific Interstitial Pneumonia (NSIP)
  - Sarcoidosis
  - Other forms of interstitial lung disease
- No syncope or significant chest pain for at least one month
- WHO functional Class II and III
  - Class I if 6MWT < 400 meters
  - Class IV if 6MWT > 50 meters
- No prior pulmonary rehabilitation received within the last six months and not currently in a maintenance program
- Sedentary - <30 min exercise on 3 or more days/week in the last 6 months
- Echocardiogram showing absence of pulmonary hypertension
Exclusion Criteria

- Resting O2 saturation ≥ 90% on O2
- Unable to complete a treadmill cardiopulmonary exercise test (CPET)
- Diagnosis of ischemic heart disease
- Left ventricular dysfunction with EF < 50% or cardiomyopathy
- Acute cor pulmonale
- Significant hepatic or renal dysfunction
- Metastatic cancer with a life expectancy of less than one year
- Disabling stroke

- Active substance abuse
- Severe psychiatric disease
- Patients on antiretroviral therapy
- Uncontrolled diabetes mellitus with a history of DKA
- Mitochondrial disease
- Pregnancy
- Ongoing tobacco use
- Acceptance onto a lung transplant waiting list
- Participation in active ILD drug trials
- General medical complications that pose a risk to exercise testing or training as determined by the PI (such as severe peripheral vascular disease, etc.)
Recruitment and Enrollment

- Pre-enrollment
  - Patient contacted by phone
  - Study information / Inclusion/Exclusion Criteria
  - Record release
    - H/P, PFT, 6MWT, echo/cath reports, chest CT, biopsy, recent office notes

- Scheduled for:
  - H/P, labwork, EKG, echo, PFT
  - 6MWT, CPET
Benefits of Participating in Pulmonary Rehab Research at the NIH Clinical Center

- Benefit to science
- Cost of all study-related diagnostics and treatment
  - e.g. Equivalent of Phase 2 PR
- Consultations to other departments
  - PT (orthotics, edema management)
  - Diabetes
  - Cardiology
- Remuneration - $300 per testing visit
- Local transportation, if needed
- Clinical coordination with community physicians and PR facilities.
Study Design

Inclusion

Baseline Tests

Block Randomization

Exercise + Education

Patient education and aerobic exercise training (AET+)

Repeat Tests

AET+ Finished

Patient education only and no aerobic exercise training (CON)

Repeat Tests

Control group (CON) crosses over to exercise training

Patients originally assigned to the control group finished

1. Echocardiogram
2. Pulmonary Function Test
3. Health Related Quality of Life Questionnaires
   - SGRQ
   - FSS
   - HAP
   - SF36V2
   - POMS
   - K-BILD
4. Six Minute Walk Test
5. Arterial Occlusion Muscle Oxygenation Capacity Test
6. tCPET
   - Pulmonary Gas Exchange Analysis
   - Heart Rate Measurement
   - Near Infrared Spectroscopy
   - Bioelectrical Impedance Plethysmography

*Pregnancy test for applicable patients
Testing

- PFT, Echo, bloodwork
- 6 MWT on 80m “track”
- NIRS
- ZCG (Cardiac Impedance)
- Treadmill CPET
6MWT

- 80 m “track” around NIH Clinical Center atrium
- ATS Guidelines
- Portable O2 tank, staff manages
- Wireless pulse oximeter, HR, RPD, RPE
- Fatigability scale before and after
Near-infrared Spectroscopy - NIRS

- Non-invasive measurements using a light signal
- Similar to pulse oximetry
- Signal comes from hemoglobin
- Shows balance between oxygen delivery and utilization
- Occlusion testing to determine nadir
- Rebound effect due to reactive hyperemia
ZCG - Impedance Cardiography

- Number and position depend on the measurement device
- Blood is a good conductor
- More blood (increased volume) --> decreased impedance (Z)
- Signal represents the changes of the thoracic impedance due to variations in the blood flow.
Treadmill Testing

- Peak HR, VO$_2$
- VE/VO$_2$, VE/VCO$_2$
- Anaerobic Threshold
- SpO2
- RPE/RPD
Hyperoxic Testing

- Hyperoxic testing
- FiO2 of 40%
- Douglas bag
- If patient is prescribed oxygen for activity
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<th>Minute</th>
<th>Speed</th>
<th>Grade</th>
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# Quality of Life Questionnaires

<table>
<thead>
<tr>
<th>Survey</th>
<th>Assesses</th>
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<tbody>
<tr>
<td>St. George’s Respiratory Questionnaire I (SGRQ-I), (IPF version)</td>
<td>Disability, disease level, symptom level</td>
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<tr>
<td>Fatigue Severity Scale (FSS)</td>
<td>Clinical improvement</td>
</tr>
<tr>
<td></td>
<td>Easy to use and score</td>
</tr>
<tr>
<td>Human Activity Profile (HAP)</td>
<td>Physical activity levels</td>
</tr>
<tr>
<td>Short-Form 36 - Version 2 (SF36v2)</td>
<td>HRQOL in 8 domains, not specific to lung disease</td>
</tr>
<tr>
<td>Profile of Mood States (POMS)</td>
<td>6 dimensions of mood (tension/anxiety, depression/dejection, anger/hostility, vigor/activity, fatigue/inertia, confusion/bewilderment)</td>
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<tr>
<td>King’s Brief ILD Health Status Questionnaire (K-BILD)</td>
<td>3 Domains (Breathlessness/Activity, Chest symptoms, Psychological)</td>
</tr>
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</table>
Control Arm

- Education provided in 9 modules
  - Orientation, Anatomy/Physiology, Breathing Retraining
  - Lung Disease
  - Medications
  - Oxygen & Sleep
  - Pulmonary Diagnostics
  - Emotional & Social Wellbeing, Panic Control
  - Nutrition, Fall Prevention
  - Preventing Infection, Airway Clearance
  - Advance Care Planning, Energy Conservation
  - Exercise, Disease Management, Community Resources

- Crossover to Exercise Arm
Exercise Arm

- 10-week treadmill walking program
- Concurrently scheduled education sessions weekly.
- 30-45 minutes per session, 3 times a week
- Subjects train in a prescribed target heart rate zone
  - 70 – 80% heart rate reserve equivalent to a “vigorous” intensity workout
- Minimum attendance of 24 sessions (80%) required
Training

- 10 weeks of treadmill training (3x/week)
- Training initiated at 30 min, increased 1 minute per session until 45 min reached
- Timer starts when heartrate reaches target zone
- THR zone 70-80% of heart rate reserve (HRR)
- No telemetry unless ectopy seen on CPET or patient is symptomatic
- If desaturation occurs below 80% exercise is stopped until sats are above 90%
- Amount of $O_2$ used is consistent on pre-post CPETs but ad lib during training to maintain sats
## Exercise Data to Date

<table>
<thead>
<tr>
<th>Subject</th>
<th>% in THR zone</th>
<th>% HRR</th>
<th>Highest O2 Use (L/min)</th>
<th>Avg SpO2</th>
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<td>4.2 / 2.5</td>
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**Pre-Post Study Comparison**

65 y.o. male, severe ILD, HSP, 91 kg,
Tested on FiO2 40%

<table>
<thead>
<tr>
<th></th>
<th>Pre-Study</th>
<th>Post-Study</th>
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<tbody>
<tr>
<td>6 MWT Distance</td>
<td>431 m</td>
<td>523 m</td>
</tr>
<tr>
<td>Peak HR 6MWT</td>
<td>120</td>
<td>130</td>
</tr>
<tr>
<td>Peak HR CPET</td>
<td>139</td>
<td>140</td>
</tr>
<tr>
<td>CPET Time to Fatigue</td>
<td>11:22 (5.3 METs)</td>
<td>14:00 (6.4 METs)</td>
</tr>
<tr>
<td>Stage Completed (Speed/Grade)</td>
<td>Stage 5 (2.0 mph x 7.5%)</td>
<td>Stage 7 (3.0 mph x 7.5%)</td>
</tr>
<tr>
<td>Training Heartrate Zone 70-80% HRR</td>
<td>118 – 125 bpm</td>
<td></td>
</tr>
<tr>
<td>Training Speed/Grade</td>
<td>2.4 mph x 2.0%</td>
<td>2.3 x 5.0%</td>
</tr>
<tr>
<td>Training METs</td>
<td>3.7 METs</td>
<td>4.6 METs</td>
</tr>
</tbody>
</table>
## Pre-Post Study Comparison
69 y.o. male, mild ILD, HSP, 99 kg
Tested on Room Air

<table>
<thead>
<tr>
<th></th>
<th>Pre-Study</th>
<th>Post-Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 MWT Distance</td>
<td>575 m</td>
<td>688 m</td>
</tr>
<tr>
<td>Peak HR 6MWT</td>
<td>131</td>
<td>147</td>
</tr>
<tr>
<td>Peak HR CPET</td>
<td>167</td>
<td>169</td>
</tr>
<tr>
<td>CPET Time to Fatigue</td>
<td>16:30 (8.9 METs)</td>
<td>18:42 (10.0 METs)</td>
</tr>
<tr>
<td>Stage Completed (Speed/Grade)</td>
<td>Stage 8 (3.0 mph x 10.0%)</td>
<td>Stage 9 (3.0 mph x 12.5%)</td>
</tr>
<tr>
<td>Training Heart rate Zone 70-80% HRR</td>
<td>140 – 150 bpm</td>
<td>140 – 150 bpm</td>
</tr>
<tr>
<td>Training Speed/Grade</td>
<td>3.0 mph x 4.5%</td>
<td>3.0 x 6.0%</td>
</tr>
<tr>
<td>Training METS</td>
<td>5.4 METs</td>
<td>6.1 METs</td>
</tr>
</tbody>
</table>
After the Study

- Monthly phone calls for follow-up
  - Are they still exercising, how much, how often?
  - Any hospitalizations?
  - Listed for transplant?
- Difficulties with transition to PR
  - Need for oxygen during exercise
  - No Medicare B for Phase 2
  - No convenient program, traffic, distance
  - Getting records sent & referrals signed
- Care Coordination
  - Local pulmonologist must supervise Phase 2/3 PR
  - May also have MD at Advanced Lung Disease Clinic (INOVA, Hopkins, Umd.)
Transition Planning

- Of 14 who have completed so far:
  - Phase 2 Pulmonary Rehab (6)
    - INOVA (1), Holy Cross (1), Shady Grove (2), Frederick (1), Out-of-state (1)
  - Maintenance PR (3)
    - Shady Grove (3)
  - Opted out of PR program (5)
    - Home exercise (3) - Home treadmill, mall walking, senior programs
    - Fell off the wagon (2) - Travel for work, finances, insurance
- Of (4) Phase 2 completers –
  - Exercising at home or in community without O₂ (2)
  - Transitioned to maintenance program with O₂ (1)
  - Stopped exercise (1) – Being evaluated for transplant
Observations About Exercise

- Able to tolerate more than what you’d expect
- $O_2$ ad lib
- Positive feelings about what exercise has done for them
  - More energy, feel better, more confident
- Good adherence with exercise post study
- Oxygen needs make continued exercise problematic
Questions?