America's Clinical Research Hospital

Explore the NIH Clinical Center

Search the Studies - NIH Clinical Research Studies

Protocol Details

Chronic Fatigue Syndrome

This study is currently recruiting participants.

Summary | **Eligibility** | **Citations** | **Contacts**

Summary

Background:

Post-infectious chronic fatigue syndrome (PI-CFS) refers to long-lasting fatigue and inability to exercise that can occur after a person has an infection. It can also cause pain, sleep problems, depression, and anxiety. Researchers want to learn more about its causes.

Objective:

To learn more about PI-CFS.

Eligibility:

Adults ages 18 60 who have finished at least 7th grade and either:

have CFS that started after an infection

OR had Lyme disease, were treated, and don t have fatigue symptoms

OR have a functional movement disorder

OR are healthy volunteers

Design:

Participants will be initially screened in the outpatient clinic with:

Medical history

Physical exam

Intravenous (IV) line. A thin plastic tube is inserted into a vein.

Blood and urine collected

Questions about the participant s life and how they are feeling

Questions from a psychologist

Qualified participants will have:

Magnetic resonance imaging (MRI). Participants will lie in a machine that takes pictures of their brain. They may get a dye through their IV.

Grip strength tested

An activity monitor to wear and diary to keep track of daily activities and amount of fatigue

Saliva test

Tests of body functions such as sweating and breathing, being upright, blood pressure, and heart rate.

Collection of blood cells. Participants can choose to have the blood drawn through the IV or through a machine that filters blood cells and returns the liquid blood back into the participant s vein.

Number	16-N-0058
Sponsoring Institute	National Institute of Neurological Disorders and Stroke (NINDS)
Recruitment Detail	***Type:*** Participants currently recruited/enrolled ***Gender:*** Male & Female ***Min Age:*** 18 ***Max Age:*** 60
Referral Letter Required	No
Population Exclusion(s)	Non-English Speaking; Children
Special Instructions	Currently Not Provided
Keywords	Chronic Fatigue Syndrome; Lyme Disease; Healthy Volunteers; Movement Disorder
Recruitment Keyword(s)	None
Condition(s)	Chronic Fatigue Syndrome
Investigational Drug(s)	None
Investigational Device(s)	None
Intervention(s)	None
Supporting Site	National Institute of Neurological Disorders and Stroke

Medications will be reviewed during screening. Participants may be asked to taper off certain medicines.

After screening participants will return home. They will taper off medications and report any problems. They will also use the activity monitor and fatigue diary.

Participants will return for a 1-week inpatient hospital visit. During the visit, participants will perform a stationary bike exercise test twice. The purpose of the exercise test is to make participants tired. Tests will be performed before and after exercise testing. These include:

Questions about how participants are feeling

Samples of saliva, stool, and cheek skin

Thinking and memory tests

Heart monitoring

Measurements of your breath overnight

Transcranial magnetic stimulation. A brief electrical current to the scalp creates a magnetic pulse that affects brain activity.

Magnetic resonance imaging (MRI). Participants will lie in a machine that takes pictures of their brain. They will do thinking and exercise tasks during the MRI.

Lumbar puncture. Fluid will be removed by placement of a needle between the back bones.

They may also have, X-rays, and consultations.

--Back to Top--

Eligibility

INCLUSION CRITERIA:

Inclusion criteria for all participants:

-Adult participants aged 18-60 years at the time of enrollment.

-Self-reported completion of at least the 7th grade of school.

-Ability to speak, read, and understand English.

-Willing and able to complete all study procedures

-Participant has a primary care physician at the time of enrollment.

-Able to provide informed consent.

Additional inclusion criteria for participants with PI-CFS:

-A self-reported illness narrative of the development of persistent fatigue as the consequence of an acute infection. The persistent fatigue may have an acute onset or become progressively worse over 6 months.

-Documentation of fatigue starting after an infection by a physician in their medical records.

-Meet the 2005 Reeves standardized case definition of chronic fatigue syndrome. This includes:

--Having greater than or equal to 4 symptoms set forth in the 1994 Fukuda criteria.

--Severe fatigue as determined using the Multidimensional Fatigue Inventory (MFI): score of greater than or equal to 13 on the general fatigue subscale or greater than or equal to 10 on the reduced activity subscale.

--Functional impairment as determined using the Short-Form 36 (SF-36): score of greater than or equal to 70 physical function subscale, or greater than or equal to 50 on role physical subscale, or greater than or equal to 75 on social function subscale, or greater than or equal to 66 on emotional subscale.

--Symptom validity as determined using the Centers for Disease Control Symptom Inventory: score of greater than or equal to 25 on the Symptom Inventory Case Definition subscale.

-Fatigue onset greater than 6 months but less than 5 years prior to enrollment.

Additional inclusion criteria for healthy volunteer group:

None

Additional inclusion criteria for Documented Lyme Infection Asymptomatic group:

-Medical record documentation of fulfilling the probable or confirmed 2011 CDC Lyme Disease National Surveillance Case Definitions (http://wwwn.cdc.gov/nndss/conditions/lyme-disease/case-definition/2011/):

--Probable: A case of physician-diagnosed Lyme disease that meets laboratory criteria of evidence of infection (positive culture for B.burgdoferi, or two-tiered testing using criteria, or single-tier IgG immunoblot seropositivity using criteria, or CSF antibody positive for B.burgdoferi by Enzyme Immunoassay or Immunofluorescence Assay, when the titer is higher than it was in serum.

--Confirmed: A case of erythema migrans with a known exposure, or a case of erythema migrans with laboratory evidence of infection and without a known exposure, or a case with at least one late manifestation that has laboratory

evidence of infection.

-Have received accepted antibiotic treatment for Lyme Disease greater than or equal to 6 months prior to enrollment but less than 5 years prior to enrollment documented in their medical records.

Additional inclusion criteria for functional movement disorders group:

-A self-reported illness narrative of the development of persistent, paroxysmal, or episodic motor symptoms as the consequence of an acute event or exposure or occurring with an acute onset.

-Diagnosis of clinically definite FMD utilizing Fahn and Williams criteria.

--Documented psychogenic movement disorder: persistent relief by psychotherapy, suggestion or placebo, or observed without the movement disorder when unobserved.

--Clinically established psychogenic movement disorder: inconsistent over time or incongruent with a classical movement disorder, plus other false neurological signs, multiple somatizations, obvious psychiatric disturbances, distractibility, or deliberate slowness.

-The diagnosis of FMD must be made by a neurologist and documented in their medical records.

EXCLUSION CRITERIA:

Exclusion criteria for all participants:

-Active infection (e.g. influenza, urinary tract infection) by history, physical examination, or laboratory evaluations at the time of enrollment

-Current or past psychotic disorder including depression with psychosis, bipolar disorder, and schizophrenia

-Current DSM-5-defined major depression disorder, generalized anxiety disorder, post-traumatic stress disorder, panic disorder, or obsessive-compulsive disorder unless managed for more than six months with a stable treatment regimen

-Current or prior substance use disorder as diagnosed on the Structured Clinical Interview for DSM-5 (SCID-5) or positive urine toxicology results at enrollment

-Current suicidal ideation

-History of head injury with loss of consciousness, or history of head injury with amnesia lasting greater than a few seconds

-Current (within 1 week) use of prescription or over-the-counter medications, herbal supplements, or nutraceuticals that may influence brain excitability that the potential participant is either unwilling or clinically unable to safely wean off for the duration of the period of the inpatient admission. The possibility for a potential participant to be weaned off medication will be cooperatively determined by both the clinical investigative team and personal physicians. Examples of medications that influence brain excitability include tricyclic antidepressants, hypnotic, antiepileptic, antipsychotic medication, stimulants, antihistamines, muscle relaxants, dopaminergic medications, and sleep medications.

-Women who are pregnant, actively seeking to become pregnant, or have been pregnant in the year prior to study enrollment.

-Current or previous malignancy. Certain dermatologic malignancies (e.g. basal cell carcinoma) will be allowed.

-Current immunologic disorder (e.g. Type 1 diabetes, rheumatoid arthritis)

-Current or previous long term immune suppressive or immunomodulatory therapy. Systemic steroid use, even short-term, must not have been used within the month prior to enrollment

-Any medical condition (eg, congestive heart failure, coronary artery disease, chronic obstructive pulmonary disease, severe osteoarthritis, poorly controlled asthma) that would make the study procedures risky for the participant (e.g. exercise-induced angina and asthma) or that may confound the study results (e.g. untreated obstructive sleep apnea, severe osteoarthritis).

-Participation in a clinical protocol (e.g. anti-inflammatory drug intervention study) which includes an intervention that may affect the results of the current study.

-Inability to perform the bicycling exercise task.

-Not willing to allow for research samples to be shared with other researchers.

-Employees or staff at NIH that are directly supervised by the primary investigator or associate investigators.

Additional exclusion criteria for participants with CFS:

-Significant neurological disorder (e.g. neurodegenerative disorder, stroke, epilepsy).

-PI-CFS disease severity that makes it impossible for the volunteer to leave the home or requires inpatient treatment.

-Suspected, probable, or confirmed Lyme disease per 2011 CDC Lyme Disease National Surveillance Case Definitions.

-Underlying illness that may cause fatigue such as thyroid dysfunction, hepatitis, or other systemic diseases.

Additional exclusion criteria for healthy volunteer group:

-Clinical relevant fatigue as determined using the Multidimensional Fatigue Inventory (MFI): score of > 8 on the general fatigue subscale or > 6 on the reduced activity subscale.

-Significant neurological disorder (e.g. neurodegenerative disorder, stroke, epilepsy).

Additional exclusion criteria for Documented Lyme Infection Asymptomatic group:

-Clinical relevant fatigue as determined using the Multidimensional Fatigue Inventory (MFI): score of > 8 on the general fatigue subscale or > 6 on the reduced activity subscale.

-Significant neurological disorder (e.g. neurodegenerative disorder, stroke, epilepsy).

Symptoms or diagnosis of Post-Lyme Disease Syndrome

Additional exclusion criteria for functional movement disorders group:

-Clinical relevant fatigue as determined using the Multidimensional Fatigue Inventory (MFI): score of > 8 on the general fatigue subscale

-Significant neurological disorder (e.g. neurodegenerative disorder, stroke, epilepsy).

--Back to Top--

Citations:

Not Provided

--Back to Top--

Contacts:

Principal Investigator	Referral Contact	For more information:
Avindra Nath, M.D. National Institute of Neurological Disorders and Stroke (NINDS)	Brian T. Walitt, M.D. National Institute of Neurological Disorders and Stroke (NINDS) BG 10-CRC RM 2-1339 10 CENTER DR BETHESDA MD 20814 (301) 451-1683 brian.walitt@nih.gov	**Patient Recruitment and Public Liaison Office** Building 61 10 Cloister Court Bethesda, Maryland 20892-4754 **Toll Free:** 1-800-411-1222 **TTY:** 301-594-9774 (local),1-866-411-1010 (toll free) **Fax:** 301-480-9793 *prpl@mail.cc.nih.gov*

Clinical Trials Number:

NCT02669212

--Back to Top--