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TITLE: Molecular Studies to Identify Mechanisms That Underlie Symptom Improvement in Microbiota Transfer Therapy Patients

PRINCIPAL INVESTIGATOR: Stephen J Walker

CONTRACTING ORGANIZATION: Wake Forest University Health Sciences, Winston Salem, NC

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Stephen Walker

E-Mail: swalker@wakehealth.edu

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Wake Forest University Health Sciences
Medical Center Blvd
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13. SUPPLEMENTARY NOTES

14. ABSTRACT

The purpose of this study is to perform molecular analysis (transcriptomic and metabolomic assays) on samples (whole blood, serum, and stool) derived from 84 adults with autism spectrum disorder (ASD) undergoing microbiota transfer therapy (MTT), and 84 adult controls, from an on-going CDMRP-funded clinical trial (James Adams, PI; Arizona State University) to identify mechanisms that underlie symptom improvement following MTT. Due to the onset of the coronavirus pandemic, recruitment at the ASU site has been severely curtailed since March 2020, and so sample collection and transfer to me has been limited to a portion of the initial 35 ASD sample sets, and 11 control sample sets. Because these samples need to be assayed in batches, although we have begun sample processing, we have not yet begun the molecular assays. We will get the assays underway in the Winter of this year (2023) and have requested, and been granted, a no-cost extension to complete the work in 2024.

15. SUBJECT TERMS

Autism spectrum disorder, gastrointestinal, microbiota transfer therapy, transcriptomics, microbiome, metabolomics

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
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1. INTRODUCTION

The purpose of this study is to perform molecular analysis (transcriptomic and metabolomic assays) on samples (whole blood, serum, and stool) derived from 84 adults with autism spectrum disorder (ASD) undergoing microbiota transfer therapy (MTT), and 84 adults without ASD (controls), from an on-going CDMRP-funded clinical trial (James Adams, PI; Arizona State University) to identify mechanisms that underlie symptom improvement following MTT. In the subjects with ASD that receive MTT, whole blood, serum, and stool are collected at three time points: (1) baseline, (2) after 8 weeks, and (3) after 16 weeks, and assayed for gene expression and metabolite changes that occur over time. Profiles derived from whole blood, serum, and stool samples from individuals without ASD and who do not undergo MTT serve as 'normal' baseline transcriptomic and metabolomic profiles.

2. KEYWORDS

Autism spectrum disorder, gastrointestinal, microbiota transfer therapy, transcriptomics, microbiome, metabolomics

3. ACCOMPLISHEMENTS

- **What were the major goals of this project?**
  There are 7 tasks detailed on the SOW associated with this project. Task 1 requires procurement of the appropriate IRB and HRPO approvals. Tasks 2 and 3 describe sample processing, Tasks 4 and 5 describe acquisition of the molecular (transcriptomic and metabolomic) datasets; Task 6 describes metabolomic data analysis and visualization; Task 7 describes integrated omics data analysis.

- **What was accomplished under these goals?**
  To date, only Task 1: "Secure IRB and HPRO approvals to receive and use the specimens (human anatomical substances - HAS)" has been completed. As of November 2023, the sample sets (stool, plasma, and Paxgene whole blood) from 93 individuals (52 individuals receiving MTT and 41 NT controls) have been received in the PI's laboratory. Samples processing (total RNA from Paxgene blood; Task 2) has begun and molecular assays and data analyses described in Tasks 2-7 will get underway in December 2023.

- **What opportunities for training and professional development has the project provided?**
  Nothing to report.

- **How were the results disseminated to communities of interest?**
  Nothing to report.

- **What do you plan to do during the next reporting period to accomplish the goals?**
  Throughout the course of the next reporting period, we expect to process and assay the study samples. Throughout the period we will be processing the samples on hand and,

as sufficient numbers of samples have been prepared and qc'd for batch assay, we will initiate the molecular data generation and analyses.

4. IMPACT

- **What was the impact on the development of the principal discipline(s) of the project?**
  Nothing to report.

- **What was the impact on other disciplines?**
  Nothing to report.

- **What was the impact on technology transfer?**
  Nothing to report.

- **What was the impact on society beyond science and technology?**
  Nothing to report.

5. CHANGES/PROBLEMS

- **Changes in approach and reasons for change**
  Nothing to report.

- **Actual or anticipated problems or delays and actions or plans to resolve them**
  This project is entirely dependent on getting study samples (whole blood, serum, and stool) from Dr. Adams' clinical trial and therefore the delays Dr. Adams has experienced since March 2020 in being able to enroll and follow-up with participants in his study have impacted our ability to begin sample processing and data generation. Now that all the relevant restrictions are lifted, we anticipate that we can bring this project fully back online and finish processing and assaying samples throughout the next reporting period (May 2023 through May 2024). We have asked for and received a second one year no-cost extension to allow for completion of the Tasks outlined in the SOW.

- **Changes that had a significant impact on expenditures**
  The inability to perform the lab work outlined in Tasks 2-7 over this last two years has resulted in a significant reduction in expenditures during this reporting period. We anticipate that we will get back on track with expenditures in the next reporting period.

- **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**
  Nothing to report.

6. PRODUCTS

- **Publications, conference papers, and presentations**
  Nothing to report.

- **Website(s) or other internet site(s)**
  Nothing to report.

- **Technologies or techniques**
  Nothing to report.

- **Inventions, patent applications, and/or licenses**
  Nothing to report.

- **Other products**
  Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

- **What individuals have worked on this project?**
  - **Name:** Stephen Walker
  - **Project Role:** PI
  - **Researcher ID:** 0000-0002-0732-2366
  - **Nearest person month worked:** 2.6
  - **Contribution to project:** Dr. Walker is responsible for project oversight and management.
  - **Funding Support:** this award

  - **Name:** Trang Simon
  - **Project Role:** Technician IV
  - **Researcher ID:** n/a
  - **Nearest person month worked:** 2.4
  - **Contribution to project:** Ms. Simon is responsible for RNA isolation and QC for RNA-Seq experiments.
  - **Funding Support:** this award

  - **Name:** Nicole Roberts
  - **Project Role:** Technician II
  - **Researcher ID:** n/a
  - **Nearest person month worked:** 5.0
  - **Contribution to project:** Ms. Roberts is responsible for sample handling/processing.
  - **Funding Support:** this award

  - **Name:** Yosauri Fernandez-Figuereo
  - **Project Role:** Graduate Student
  - **Researcher ID:** n/a
  - **Nearest person month worked:** 1.5
  - **Contribution to project:** Ms. Fernandez-Figuereo is responsible for sample handling/processing.

- **Funding Support:** this award

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**
  Yes (please see Other Support Document in Appendices).

- **What other organizations were involved as partners?**
  - **Organization Name:** Arizona State University
  - **Location of Organization:** Tempe Arizona
  - **Partner's contribution to the project:** Dr. James Adams provides samples (whole blood, serum, and stool) from participants in his CDMRP-funded clinical trial for this project.

8. SPECIAL REPORTING REQUIREMENTS

Nothing to report.

9. APPENDICES

Other Support Document.

Research Support – Stephen Walker

Previous

Title: Evaluation of Hydrodistention Response as a Clinical Sub-Phenotype in IC/BPS
Time Commitment: 4.8 calendar months (25% effort)
Role: Principal Investigator
Supporting Agency: NIH NIDDK/MAPP
Performance Period: 07/01/2015 – 06/30/2019
Level of Funding:
Goals: The goals of this proposal are to correlate findings based on current interview scores and clinical measures with molecular information, i.e., gene expression profiles from bladder biopsy tissue, to determine which clinical information is most useful (i.e., sensitive, and specific for IC) diagnostically. The second primary objective is to collect and evaluate quantitative data on how well patients respond to bladder hydrodistention therapy so that, by using this information, a clinician can make an informed decision about who would likely benefit from this therapy and for how long the benefit would likely last.
Overlap: None

Title: Biomarkers for Molecular-Based Decision-Making in Diagnosis and Treatment of Interstitial Cystitis
Time Commitment: 4.2 calendar months (35% effort)
Role: Principal Investigator
Performance Period: 08/01/2015 – 07/31/2018
Level of Funding:
Supporting Agency: NIH R21 DK106554-01
Goals: The goals of this proposal, designed to develop such a tool, are twofold: (1) to correlate anesthetized bladder capacity of IC patients, specifically patients with low (<400 mL) capacity, with gene expression profiles from bladder biopsy tissue, to identify and confirm the underlying pathophysiology and also to identify a clinically useful biomarker and, (2) to determine, from gene expression profiling of peripheral blood from the same IC patients, if there is a sensitive and specific biomarker for IC in blood that can be used to facilitate diagnosis and rational treatment.
Overlap: None

Title: Effects of Microgravity on the Risks of Space Radiation-Induced Leukemogenesis
Time Commitment: 0.72 calendar months (6% effort)
Role: Co-Investigator
Supporting Agency: NASA NNX17AE49G
Name, address of funding agency's procuring Contracting/Grants Officer: Benjamin Benvenutti; benjamin.s.benvenutti@nasa.gov; Space Life and Physical Sciences Research and Applications Division 300 E ST SW, Washington, D.C. 20546-0001
Performance Period: 02/01/2017 – 07/2019
Level of Funding:
Goals: To investigate this possibility by testing the effects (alone/in combination) of μG and IR/radiomimetics on the ability of primary human HSC to generate normal numbers of functional immune cells of each lineage, focusing on the formation of DC subsets and appropriate expression of TLR family members
List of Specific Aims:
1. Measure levels of spontaneous and low dose IR/radiomimetic-induced DNA damage and DNA damage response (DDR) kinetics in human HSC exposed to μG.
2. Perform transcriptomic analyses to define HSC signaling pathways significantly affected by μG and IR/radiomimetics alone and in combination.
3. Test the ability of HSC to differentiate into functional immune cells in μG, and express appropriate TLRs.

4. Test the ability of generated NK cells to recognize and lyse leukemic cell lines.
Overlap: None
Title: Autism GI Research
Role: Principal Investigator
Supporting Agency: BHARE Foundation
Performance Period: unrestricted
Level of Funding:
Goals: The goal of this project is to evaluate the metabolomics signature in biospecimens from autism spectrum disorder children who have gastrointestinal inflammation.
Overlap: None

Title: Pilot Studies for the Further Molecular Characterization of Gastrointestinal Co-Morbidity in Autism Spectrum Disorder:
Time Commitment: 7.2 calendar months (15% effort)
Role: Principal Investigator
Supporting Agency: Anonymous Sponsor
Performance Period: 05/11/2015 – 05/11/2017
Level of Funding:
Goals: Previously demonstrated an ASD-associated ileocolitis that significantly overlaps with, yet is distinct from, classic IBD (e.g., Crohn's disease and ulcerative colitis); validate previous findings and extend them to identify biomarkers in peripheral blood that are shared with those markers obtained from diseased intestinal tissue.
Overlap: None

Title: Novel Microfluidic Biomarker Detection Platforms to Monitor In Vivo Effects of SPE and GCR Radiation, using Mice with Human Hematopoietic Systems
Time Commitment: 0.96 calendar months (8% effort)
Role: Co-Investigator
Supporting Agency: s/Baylor – NASA Translational Research Institute
Name, address of funding agency's procuring Contracting/Grants Officer: Virginia E. Wotring, Ph.D., Texas Medical Center Innovation Institute, 2450 Holcombe Blvd, Suite X, Houston TX, 77021, Email: virginia.wotring@bcm.edu
Performance Period: 11/01/2017 – 10/31/2021
Level of Funding:
Goals: Our goal is to identify early and persistent biomarkers of response that may identify susceptibility pathways, genes, and regulatory elements associated with onset and progression of human hematological disease (focusing on leukemia) following exposure to mission-relevant doses of space radiation.
Overlap: None

Title: Development of Blood-Based Biomarker for Gastrointestinal Inflammation in GI-Symptomatic Children with ASD
Time Commitment: 0.24 calendar months (2% effort)
Role: Principal Investigator
Supporting Agency: Anonymous
Name, address of funding agency's procuring Contracting/Grants Officer: Not available
Performance Period: 08/21/2018 – 08/20/2021
Level of Funding:
Goals: Refine the putative peripheral blood-base expression signature for ASD through the addition of data from 2 sets of control samples
Overlap: None

Title: ASD-GI Treatment
Time Commitment: 0.12 calendar months (1% effort) (no salary support requested)
Role: Co-Investigator
Supporting Agency: The Brain Foundation
Name, address of funding agency's procuring Contracting/Grants Officer: Pramilla Srinivasan, Pleasanton, CA, 94588.
Performance Period: 03/01/2019 – 02/28/2022
Level of Funding:
Goals: The goal of this study is to develop a standard-of-care for children with autism spectrum disorder and co-occurring chronic gastrointestinal symptoms. In this study we will quantify, over one year, GI symptom improvement and behavioral/cognitive changes in 25 ASD children receiving treatment for gastrointestinal symptoms. Patients will be monitored by three validated ASD questionnaires (Vineland Checklist, SARS-2, and ABC Checklist) and two new (not yet validated) GI questionnaires developed by the PI specifically for children with ASD: (1) Gastrointestinal Symptom Scale (GiSS) ASD Bowel Movement Chart and, (2) GiSS-ASD Externalizing GI Behaviors Log.
Overlap: None

Current

Title: 1R01HL135853-01A1 Prenatal Cell and Gene Therapy for Hemophilia A
Time Commitment: 0.36 calendar months (3% effort)
Role: Co-Investigator
Supporting Agency: NIH/NHLBI
Name, address of funding agency's procuring Contracting/Grants Officer: Ryan Lombardi; **Performance Period**: 07/14/2017 – 06/30/2023
Level of Funding:
Goals: To prove the safety and efficacy of using cells as a FVIII delivery platform and demonstrate the ability of IUTx to cure or improve HA phenotype and defeat the immune-related hurdles that currently hinder clinical HA treatment.
List of Specific Aims:
1. Determine the ideal cell source to obtain the highest long-term engraftment levels and the in vivo distribution patterns that maximize release of FVIII into the circulation.
2. Use HA sheep to demonstrate that an IUTx approach using the optimal cell source and FVIII transgene construct, can be curative, or at least permanently convert severe HA to a mild phenotype.
3. Test whether receiving IUTx precludes inhibitor induction following postnatal FVIII infusion and/or induces tolerance that persists even after postnatal challenge with FVIII in adjuvant.
Overlap: None

Title: 1R01DK124599-01 Molecular Characterization of a Large Cross-Sectional and Longitudinal Collection of Patients to Investigate Disease Progression in IC/BPS
Time Commitment: 2.28calendar months (19% effort)
Role: Principal Investigator
Supporting Agency: NIH/NIDDK
Name, address of funding agency's procuring Contracting/Grants Officer: Charlette Kenley, **Performance Period**: 05/01/2020 – 04/30/2024
Level of Funding:
Goals: Objectives for this proposal are to use a sophisticated molecular profiling approach, in a broadly heterogeneous group of IC/BPS patients, to: (1) identify patient subgroups that share a similar disease etiology

and are therefore likely to respond, as a group, to therapy that targets the underlying mechanism and, (2) identify gene expression modules that are predictive of disease progression in IC/BPS.
Overlap: None

Title: W81XWH2010275 - Molecular Studies to Identify Mechanisms that Underlie Symptom Improvement in Microbiota Transfer Therapy Patients
Time Commitment: 2.46 calendar months (20.5% effort)
Role: Principal Investigator
Supporting Agency: USAMRAA
Name, address of funding agency's procuring Contracting/Grants Officer: Ebony S. Simmons **Performance Period**: 05/01/2020 – 04/30/2024
Level of Funding:
Goals: Specific Aim #1: Evaluation of gene expression changes that occur following full spectrum microbiota (FSB) treatment in individuals with ASD and chronic gastrointestinal symptoms. Specific Aim #2: Evaluation of metabolite changes that occur following FSB treatment in individuals with ASD and chronic gastrointestinal symptoms. Specific Aim #3: Using a combined molecular profile (gene and metabolite expression) to derive mechanistic insight regarding symptom improvement following FSB treatment in individuals with ASD and chronic gastrointestinal symptoms.
Overlap: None

Title: Lung Organ Tissue Equivalent Platform for Modeling Chlorine Gas Toxicology and Medical Countermeasure Efficacy
Time Commitment: 0.60 calendar months (5% effort)
Role: Co-Investigator
Supporting Agency: DHHS 75A50119C00058 ASPR-BARDA Office of Assistant Secretary for Preparedness and Response (ASPR)/Biomedical Advanced Research and Development Authority (BARDA)
Name, address of funding agency's procuring Contracting/Grants Officer: Ethan Mueller, US Dept. of Health & Human Services, Office of Assistant Secretary for Preparedness and Response, O'Neill House Office Bldg., Room Number: 21C08, Washington, DC 20515,
Performance Period: 09/26/2019 – 06/30/2024
Level of Funding:
Goals: The overarching goals of the proposed program include validation of the OTE platform for modeling chlorine-mediated pulmonary toxicity, delineating the biochemical toxicity pathways associated with varying levels of chlorine exposure, and screening of compounds, either new or repurposed, as potential countermeasures to pulmonary chlorine injury. Accomplishing these goals would be a significant step towards demonstrating the potential of the OTE platform for the rapid characterization of unknown pulmonary toxins and informing the targeted screening of potential countermeasures.
Overlap: None

Title: Double-Blind, Placebo Controlled Study to Establish the Safety and Efficacy of Super-Concentrated, Freeze-Dried Aloe Vera in the Management of the Symptoms of Interstitial Cystitis
Time Commitment: 0.12 calendar months (1% effort)
Role: Principal Investigator
Supporting Agency: Desert Harvest, Inc.
Name, address of funding agency's procuring Contracting/Grants Officer: Not available
Performance Period: 01/01/2021 – 12/31/2031
Level of Funding:
Goals: The primary objective of this clinical trial is to monitor the safety and efficacy of Desert Harvest's super-concentrated, freeze-dried aloe vera in the management of the symptoms of interstitial cystitis. The symptoms

that will be monitored will include urinary frequency, nocturia, dysuria, urinary urgency, and suprapubic pain. Response to therapy will be monitored through questionnaires including the Quality-of-Life Assessment, IC Symptom/Problem Index, MOS Sexual Functioning Guide, University of Wisconsin Symptom Survey, Health Status Questionnaire, Genitourinary Pain Index, and 24-Hour Voiding Diaries.
Overlap: None

Title: W81XWH2110294 A Rapid and Simple Blood Test to Identify Gastrointestinal Inflammation in Children with ASD
Time Commitment: 1.80 calendar months (15% effort)
Role: Principal Investigator
Supporting Agency: Department of Defense
Name, address of funding agency's procuring Contracting/Grants Officer: Asha Phillips
asha.k.phillips.civ@mail.mil
Performance Period: 05/01/2021 – 04/30/2024
Level of Funding:
Goals: Characterize the gene expression profile of the ASDEC phenotype, including: (a) identification of a gene expression based molecular signature in peripheral blood, (b) validation of the blood-based biomarker that is sensitive and specific and can be useful as a minimally-invasive tool for guiding diagnosis and treatment of gastrointestinal inflammation in children with ASD and (c) testing the utility of the biomarker in pre- and post-treatment blood samples from a series of ASDEC patients.
Overlap: None

Title: RPP: #22-01 Using Organ Tissue Equivalents & AI for Predictive Pathologies & Treatment
Time Commitment: 1.20 calendar months (10% effort)
Role: Co-Investigator
Supporting Agency: ATI/MCDC/DTRA
Name, address of funding agency's procuring Contracting/Grants Officer: Not available
Performance Period: 4/01/2022-05/31/2027
Level of Funding:
Goals: The overall objective of this project is to combine the science of machine learning (ML) with the science of 3D organ and tissue culture
Overlap: None

Title: R01DK12833 - Investigation of Non-Invasive Pulsed Electromagnetic Field (PEMF) Therapy for Female Patients with Interstitial Cystitis / Bladder Pain Syndrome (IC/BPS)
Time Commitment: 2.16 calendar months (18% effort)
Role: Principal Investigator
Supporting Agency: National Institute of Health
Name, address of funding agency's procuring Contracting/Grants Officer: Charlene Kenley NIDDK, kenleyc@extra.niddk.nih.gov,
Performance Period: 04/01/2022 – 03/31/2025
Level of Funding:
Goals: Interstitial cystitis/bladder pain syndrome (IC/BPS) represents a potentially life-long chronic pain disorder that is challenging to diagnose, difficult to treat, and often results in a severely diminished quality-of-life. In this pilot and feasibility clinical trial, we will evaluate the safety and efficacy of a non-invasive therapeutic strategy, pulsed electromagnetic field therapy (PEMF), for pain management in IC/BPS patient subgroups. The goal is to provide preliminary data that will lead to large, hypothesis-driven, multi-center clinical trials.
Overlap: None

Title: Exploring the proposed anti-inflammatory mechanism of action of pulsed electromagnetic field therapy using urothelial cells from patients with interstitial cystitis/bladder pain syndrome)
Time Commitment: 0.12 calendar months (1% effort)
Role: Principal Investigator
Supporting Agency: International Urogynecological Association
Name, address of funding agency's procuring Contracting/Grants Officer: Not available
Performance Period: 08/01/2022 – 07/31/2023
Level of Funding:
Goals: Interstitial cystitis/bladder pain syndrome (IC/BPS) represents a potentially life-long chronic pain disorder that is challenging to diagnose, difficult to treat, and often results in a severely diminished quality-of-life. In this pilot and feasibility clinical trial, we will evaluate the safety and efficacy of a non-invasive therapeutic strategy, pulsed electromagnetic field therapy (PEMF), for pain management in IC/BPS patient subgroups. The goal is to provide preliminary data that will lead to large, hypothesis-driven, multi-center clinical trials.
Overlap: None

Title: Assessment of Urinary Polymerase Chain Reaction (PCR) and Next Generation Sequencing (NGS) Technology in the Evaluation and Management of Females with Chronic Bladder Pain and Cystitis-Like Symptoms. Protocol 20211649
Time Commitment: 0.06 (.05% effort)
Role: Principal Investigator
Supporting Agency: MicroGenDx
Name, address of funding agency's procuring Contracting/Grants Officer: Not available
Performance Period: 10/27/2021 – 10/31/2026
Level of Funding:
Goals: To perform a prospective clinical evaluation of the risks and benefits of PCR/NGS technology in the practical clinical evaluation and management of patients with bladder pain syndrome (BPS) and chronic cystitis-like symptoms (CCS) pursuant to the protocol.
Overlap: None

Title: Using urine derived progenitor stem cells to model bladder urothelium dysfunction in interstitial cystitis/bladder pain syndrome.
Time Commitment: 0.12 (1% effort)
Role: Principal Investigator
Supporting Agency: Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction Foundation (SUFUR).
Name, address of funding agency's procuring Contracting/Grants Officer: Not available
Performance Period: 12/30/2022 – 12/30/2024
Level of Funding:
Goals: Having a relevant and practical disease model that could be used to test urothelial barrier function would enable a multitude of important research applications, e.g., to better understand disease etiology, patient stratification, and disease progression – all supporting the overall objective to develop new and effective therapeutics to treat this highly heterogeneous and complex disorder.
Overlap: None

Pending

Title: P20 RFA-DK-22-027 Investigation of Fibrosis as an Etiologic Factor for Disease Progression in Interstitial Cystitis / Bladder Pain Syndrome (IC/BPS)
Time Commitment: 2.40 calendar months (20% effort)
Role: Co-Investigator

Supporting Agency: NIH
Name, address of funding agency's procuring Contracting/Grants Officer: Not available
Performance Period: 12/01/2023 – 11/30/2026
Level of Funding:
Goals: Establish a secure, encrypted, HIPAA compliant, cloud-based registry for VCA-NET accessible to
Overlap: None

Overlap: As additional awards are received commitment will be adjusted appropriately and in accordance with sponsor approval.