

Career Development Series 2022

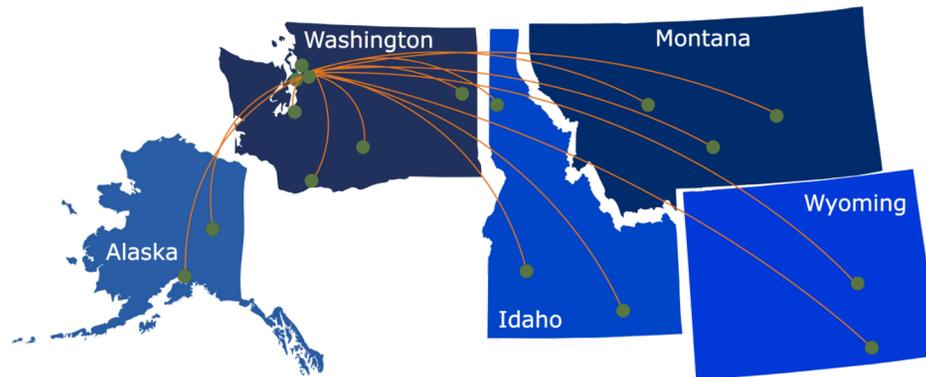
Increasing Discoverability and Transparency: ClinicalTrials.gov and Your Professional Profile

Presentation will begin at 12:00 PM (PT)



ITHS

Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.



What We Offer:

- 1 Research Support Services:** Members gain access to the different research services, resources, and tools offered by ITHS, including the ITHS Research Navigator.
- 2 Community Engagement:** Members can connect with regional and community based practice networks
- 3 Education & Training:** Members can access a variety of workforce development and mentoring programs and apply for formal training programs.
- 4 Funding:** Members can apply for local and national pilot grants and other funding opportunities. ITHS also offers letters of support for grant submissions.

Contact ITHS

Director of Research Development



- Project Consultation
- Strategic Direction
- Resources and Networking

Melissa D. Vaught, Ph.D.
ithsnav@uw.edu
206.616.3875

Scientific Success Committee

- Clinical Trials Consulting
- Guidance on Study Design, Approach and Implementation
- Feedback on Design and Feasibility

[https://www.iths.org/investigators/
services/clinical-trials-consulting/](https://www.iths.org/investigators/services/clinical-trials-consulting/)

Feedback

At the end of the seminar, a link to the feedback survey will be sent to the email address you used to register.

Career Development Series 2022

Increasing Discoverability and Transparency: ClinicalTrials.gov and Your Professional Profile

Presented by:

Leslie Gascon, MBA, MS(LIS), AHIP
UW Health Sciences Library



Lynly Beard, MLIS
UW Health Sciences Library



ITHS

Institute of **Translational** Health Sciences

ACCELERATING RESEARCH. IMPROVING HEALTH.

Learning Objectives

At the end of the session, attendees will be able to:

- 1** Describe the role of ClinicalTrials.gov in increasing the transparency of clinical research
- 2** Describe the legal, NIH, and publisher requirements for submitting data
- 3** Know where and how to build an ORCID profile
- 4** Know how to create a profile in Google Scholar, and how to claim it in Web of Science, Semantic Scholar and Dimensions

Why is a Librarian Talking About This?

- We provide support throughout the research lifecycle.
- We help people find, use, manage, & share information.
- ClinicalTrials.gov is hosted by the National Library of Medicine.



Image credit: Brian Dewey

ClinicalTrials.gov

Database Contents

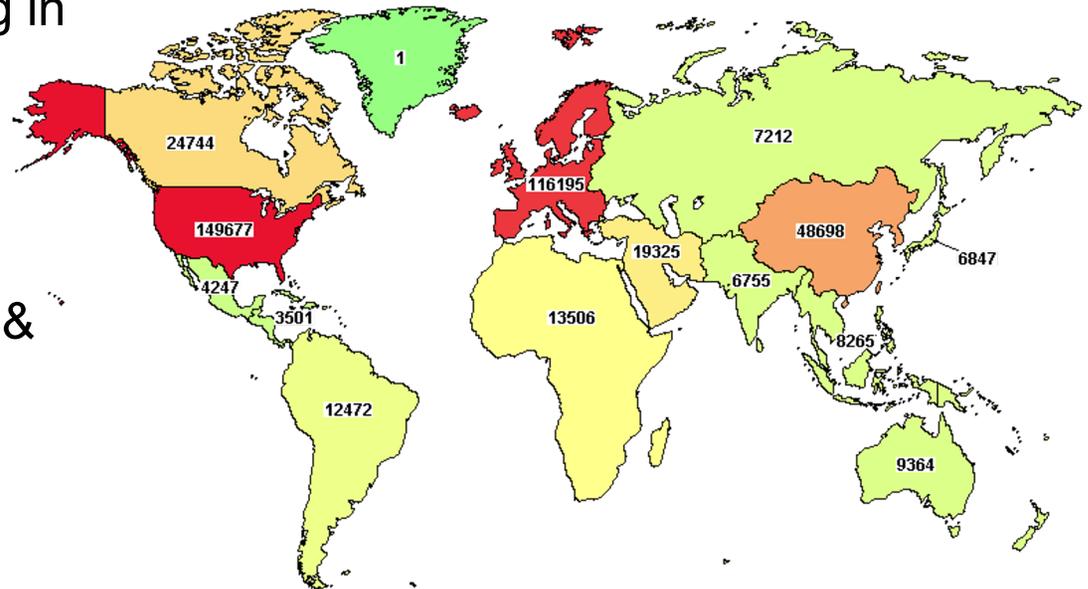
- Clinical trial registry (starting in 2000)
- Trial results (starting in 2008)

Data Submitters

- Trial sponsors, both private & public

Audiences

- Patients & families
- Researchers & clinicians
- Study record managers



[All Studies on ClinicalTrials.gov](https://clinicaltrials.gov) as of February 8, 2022

Contents of ClinicalTrials.gov

- ClinicalTrials.gov now
 - <https://clinicaltrials.gov/>
- Beta Clinical Trials.gov
 - <https://beta.clinicaltrials.gov/>

Search Results for:

Viewing 1-10 out of 403,640 studies

10 studies per page

Download

NEW

COMPLETED

Which is Better Piezosurgery or LLLT in Accelerating Orthodontic Tooth Movement

CONDITIONS

Class II Malocclusion

LOCATIONS

Damascus, Syrian Arab Republic

NEW

NOT YET RECRUITING

Human Umbilical Cord-derived Mesenchymal Stem Cells for Decompensated Cirrhosis (MSC-DLC-1)

CONDITIONS

Decompensated Cirrhosis

LOCATIONS

Beijing, China

NEW

NOT YET RECRUITING

Vonoprazan Efficacy to Prevent Post Variceal Band Ligation Ulcer

CONDITIONS

Trial Details

- Study design
- Outcome measures
- Inclusion & exclusion criteria
- Status and relevant dates



Thrive, a Computerized Cognitive Behavior Therapy Program to Treat Depression Among Rural Montanans

ClinicalTrials.gov Identifier: NCT03244878

Study Design Go to

Study Type: Interventional (Clinical Trial)
Actual Enrollment: 464 participants
Allocation: Randomized
Intervention Model: Parallel Assignment
Intervention Model Description: Participants are randomized to either the wait-list controlled group or intervention group. Intervention period is 8 weeks. Data collection occurs at baseline, 4 weeks, and 8 weeks, with longer-term follow-up assessments.
Masking: None (Open Label)
Primary Purpose: Treatment
Official Title: Randomized Controlled Trial of a Culturally-adapted Version of Thrive, a Computerized Cognitive Behavior Therapy (cCBT) Program to Treat Depressive Symptoms, Syndromes, and Disorders Among Rural Montanans

Actual Study Start Date: May 1, 2017
Actual Primary Completion Date: January 31, 2018
Actual Study Completion Date: January 31, 2018

Resource links provided by the National Library of Medicine

[MedlinePlus Genetics](#) related topics: [Depression](#)
Drug Information available for: [Nicotine tartrate](#) [Nicotine polacrilex](#)
[U.S. FDA Resources](#)

Study Overview

[Contacts and Locations](#)

[Participation Criteria](#)

[Study Plan](#)

[Sponsor and Collaborators](#)

[More Information](#)

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Study Overview

Brief Summary:

This study evaluates a culturally-modified version of Thrive, a computerized Cognitive Behavior Therapy program to treat depressive symptoms, syndromes, and disorders among rural Montanans. Study participants will be randomized to either a wait-list treatment as usual or the Thrive program.

[Show more](#)

Detailed Description:

Montana ranks high among states on mental health disorder prevalence and low on access to mental health care. It has the highest suicide rate in the nation. Of Montana's 56 counties, 10 are classified as rural and 45 as frontier, accentuating distance challenges in accessing care. New

[Show more](#)

OFFICIAL TITLE

Randomized Controlled Trial of a Culturally-adapted Version of Thrive, a Computerized ... [Show more](#)

CONDITIONS	TYPE OF STUDY	ENROLLMENT (ACTUAL)
Depressive Symptoms	Interventional	464
INTERVENTION / TREATMENT	PHASE	OTHER STUDY ID NUMBERS
Behavioral: Thrive	Not Applicable	MS033017-FC
STUDY START (ACTUAL)	PRIMARY COMPLETION (ACTUAL)	STUDY COMPLETION (ACTUAL)
May 1, 2017	January 31, 2018	January 31, 2018

Benefits to the Public

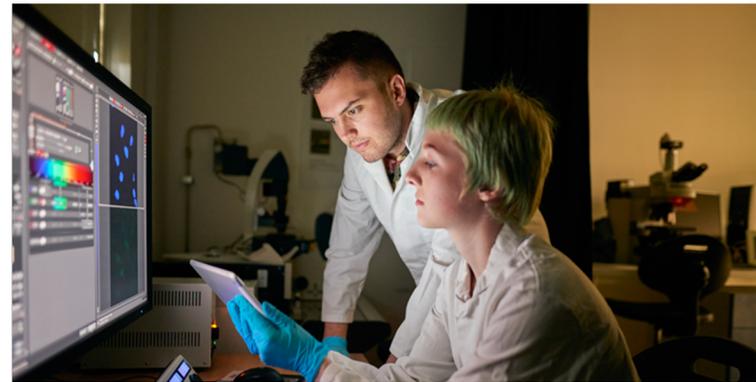
- Meet **ethical obligation to human subjects**, i.e., that results will be used to help others/inform science.
- Enhance **patient access** to enrollment in clinical trials.
- Increased **transparency** of clinical research being conducted by pharmaceutical companies and with federal funding.
- May contribute to increased **public trust** in clinical research.



Image credit: U.S. Air Force
photo/ Airman 1st Class Kyle
Johnson

Benefits to the Clinical Research Process

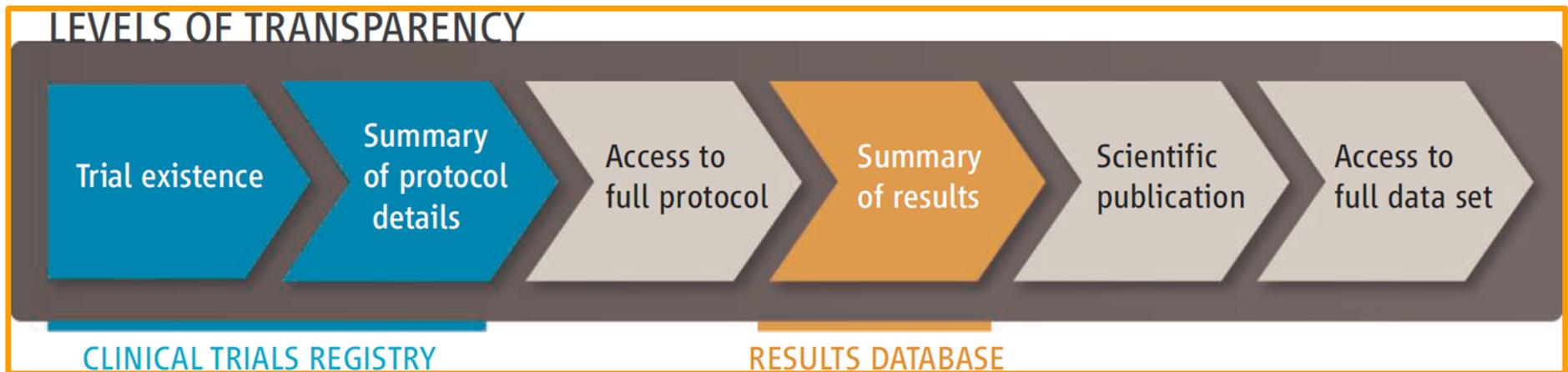
- Inform future research and research funding decisions.
- Mitigate information bias (e.g., non-publication).
- Evaluate research integrity (e.g., adherence to protocol).
- Prevent duplication of trials of unsafe or ineffective interventions.
- Provide access to data to support evidence-based medicine.



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CC BY-NC-ND

Levels of Transparency

“Transparency exists along a continuum from documentation that a trial exists to full disclosure of the results data set at the end of the trial.”



Illustrating the Benefits of a Trial Registry and Results Database



Photo by bongkarn thanyakij from Pexels

Diana's imaginary clinical trial:

JAVA

Java's Association with Virus Anxiety

How does drinking coffee affect anxiety in telecommuting workers during the COVID-19 pandemic?

What Do You Think?

Assuming this is a well-designed, IRB-Approved, NIH-funded trial...

How does registration of this trial benefit other clinical researchers?

How does registration of this trial benefit the public?

If this trial doesn't demonstrate a clear association between coffee drinking and anxiety during a pandemic, what is the benefit of reporting the results in ClinicalTrials.gov?

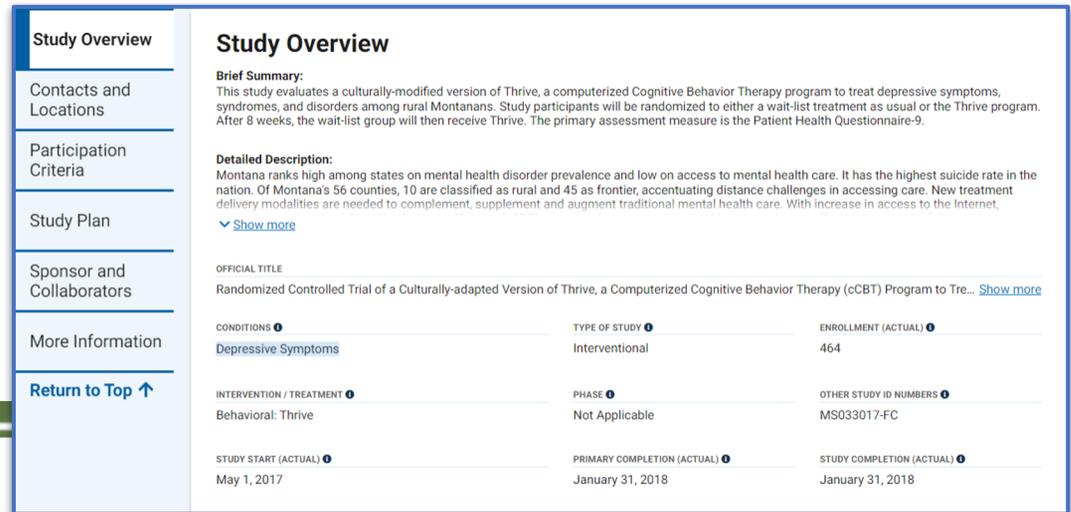
JAVA: How does drinking coffee affect anxiety among telecommuting workers during the COVID-19 pandemic?



Information Should Be Complete & Discoverable

To fulfill its purpose, the information in ClinicalTrials.gov should be complete and discoverable.

- Consider the **users** of the information.
- Record formats & terminology need to be **standardized**.
- Data needs to be **high quality**.



The screenshot shows a study overview page with a sidebar menu and a main content area. The sidebar menu includes: Study Overview (selected), Contacts and Locations, Participation Criteria, Study Plan, Sponsor and Collaborators, and More Information. Below the menu is a 'Return to Top' link with an upward arrow.

Study Overview

Brief Summary:
This study evaluates a culturally-modified version of Thrive, a computerized Cognitive Behavior Therapy program to treat depressive symptoms, syndromes, and disorders among rural Montanans. Study participants will be randomized to either a wait-list treatment as usual or the Thrive program. After 8 weeks, the wait-list group will then receive Thrive. The primary assessment measure is the Patient Health Questionnaire-9.

Detailed Description:
Montana ranks high among states on mental health disorder prevalence and low on access to mental health care. It has the highest suicide rate in the nation. Of Montana's 56 counties, 10 are classified as rural and 45 as frontier, accentuating distance challenges in accessing care. New treatment delivery modalities are needed to complement, supplement and augment traditional mental health care. With increase in access to the Internet,
[Show more](#)

OFFICIAL TITLE
Randomized Controlled Trial of a Culturally-adapted Version of Thrive, a Computerized Cognitive Behavior Therapy (cCBT) Program to Tre... [Show more](#)

CONDITIONS	TYPE OF STUDY	ENROLLMENT (ACTUAL)
Depressive Symptoms	Interventional	464
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Who Requires Trial Registration?



- ICMJE policy applies to many scientific journals, such as American Journal of Nursing, Pediatrics, & Transplantation



- Trial registration is a condition of consideration for publication.
- FDAAA 801 and 42 CFR Part 11 “The Final Rule” require that Applicable Clinical Trial data be submitted no later than 21 days after enrollment of 1st participant.
- Results must be reported no later than 1 year after primary completion date.



- Trial registration and results reporting are requirements for NIH-funded trials, whether or not they are FDA regulated.



- Organizations such as the Gates Foundation, Wellcome Trust, & PATH require trial registration & results reporting.



- Trials submitting claims to the Centers for Medicare & Medicaid Services must include the NCT number from ClinicalTrials.gov.

ICMJE = International Committee of Medical Journal Editors

FDAAA 801 = Section 801 of the Food and Drug Administration Amendments Act of 2007

Global Perspective

Joint Statement on Public Disclosure of Results from Clinical Trials (2017)

“In addition to the ethical imperative, poor allocation of resources for product development and financing of available interventions, and suboptimal regulatory and public health recommendations may occur where decisions are based on only a subset of all completed clinical trials.”

<https://www.who.int/news/item/18-05-2017-joint-statement-on-registration>

Are 100% of Applicable Clinical Trials Registered?



“Missed Deadlines” Reporting Trial Results

Missed deadlines

Among more than 4700 clinical trials examined by *Science*, less than 45% had their results reported early or on time to ClinicalTrials.gov.



(GRAPHIC) N. DESAI/*SCIENCE*; (DATA) CLINICALTRIALS.GOV, VIA TRIALSTRACKER

“Science analyzed ClinicalTrials.gov records of all clinical trials with results legally required to be reported between 18 January 2018 and 25 September 2019.”

Piller, Charles.
FDA and NIH let clinical trial sponsors keep results secret and break the law.
Science Jan 2020

doi:10.1126/science.aba8123

Expanded FDA Regulation and New NIH Policy

Significant Changes in Trial Registration as of 2017

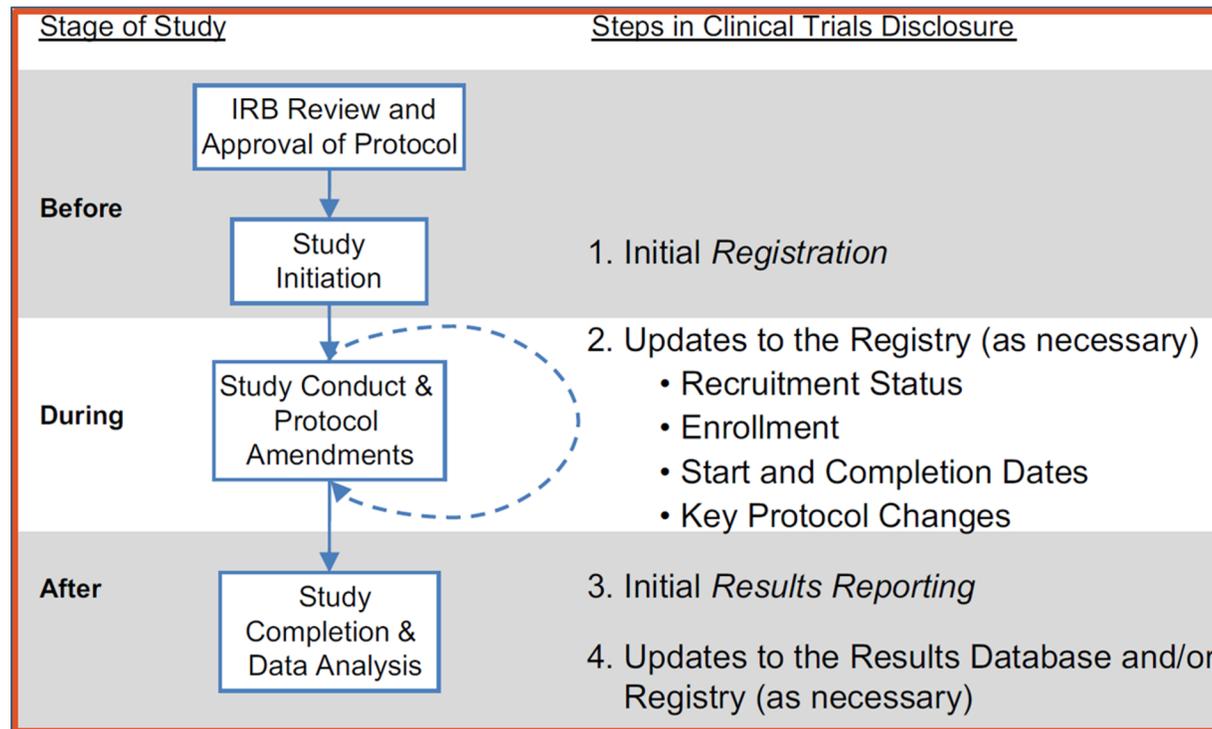
A summary table describes the changes. Three especially noteworthy changes (highlighted by the UW Human Subjects Division) are:

1. All clinical trials funded in whole, or in part, by NIH must be registered, regardless of study phase or type of intervention.
2. Study consent forms must contain a sentence about the trial registration, using the words provided by the FDA and NIH.
3. Penalties for non-compliance may include:
 - Identifying the clinical trial record as non-compliant in ClinicalTrials.gov
 - Suspension or termination of grant or contract funding, if required registration and reporting cannot be verified
 - Consideration of the non-compliance in future funding decisions
 - Civil monetary penalties to the "responsible party" (PI) of up to \$10,000/day

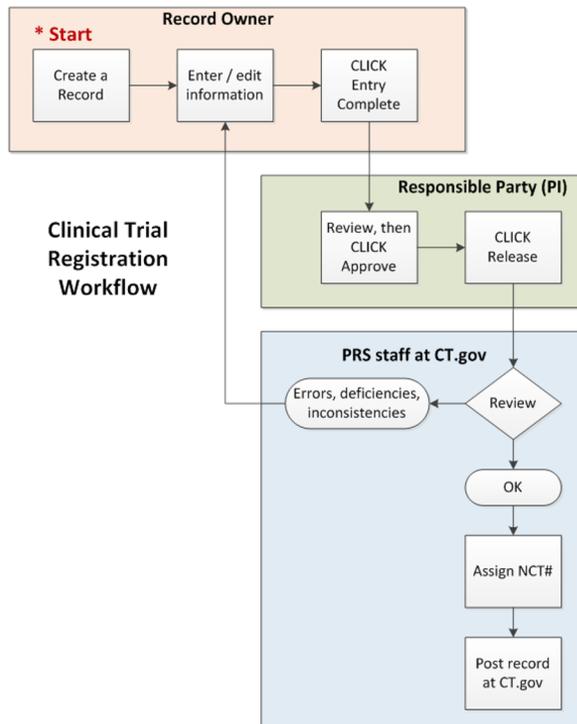
Roles & Legal Responsibilities at UW

Who	What	Why
Lead PI	<ul style="list-style-type: none"> • Register the trial • Update the record • Report the results • Consent statement 	42 CFR 11 NIH Policy
Site PI	Consent statement	42 CFR 11 NIH Policy
IRB	Consent form has the statement	21 CFR 50.25(c) 21 CFR 56.111(a)(4,5)
UW 	<ul style="list-style-type: none"> • Institutional contact for ClinicalTrials.gov • Help with researcher account 	ClinicalTrials.gov requirement

When Do Registration & Results Reporting Occur?



Clinical Trial Registration Workflow



Record Owner

Responsible Party
(Principal
Investigator)

Protocol Registration
& Results System
(PRS) Staff at
ClinicalTrials.gov

Help Is Available

- Help from your institution's human subjects department.
- Tools to help you determine if your study is considered a clinical trial under the NIH's revised definition.
- Possible to upload study data to ClinicalTrials.gov from within the NIH's eRA Human Subjects System
- ClinicalTrials.gov user support materials.
 - "How to" information
 - Policies of VA, National Cancer Institute, PCORI, etc.



Submitting High Quality Information: Specificity and Consistency

- Required Data Elements
- Internal Consistency
- Appropriate Level of Specificity
- Standardized Terminology When Appropriate

ClinicalTrials.gov Results Data Element Definitions for
Interventional and Observational Studies:

prsinfo.clinicaltrials.gov/results_definitions.html

Study Overview

Contacts and Locations

Participation Criteria

Study Plan

Sponsor and Collaborators

More Information

[Return to Top ↑](#)

How is the study designed?

DESIGN DETAILS

Primary Purpose: Treatment
Allocation: Randomized
Interventional Model: Parallel Assignment
Interventional Model Description: Participants are randomized to either the wait-list controlled group or intervention group. Intervention period is 8 weeks. Data collection occurs at baseline, 4 weeks, and 8 weeks, with longer-term follow-up assessments.
Masking: None (Open Label)

NUMBER OF ARMS 2

ARMS AND INTERVENTIONS

Participant Group/Arm	Intervention/Treatment
Experimental: Intervention - Thrive program Participants will receive access to the Thrive program for 8 weeks	Behavioral: Intervention type: Thrive A interactive computerized program using structured content of cognitive behavior therapy
No Intervention: Wait-list Control Participants will have no access to the Thrive program for 8 weeks upon enrollment. They will receive a link to the NIMH website to read about information on depression.	

What is the study measuring?

PRIMARY OUTCOME MEASURES

Outcome Measure	Measure Description	Time Frame
Patient Health Questionnaire-9	Clinical measure of depressive symptom severity. Self-reported with a score range from 0 to 3 (not at all to nearly every day)	2 weeks

SECONDARY OUTCOME MEASURES

Outcome Measure	Measure Description	Time Frame
Generalized Anxiety Disorder-7	Self-reported measure of anxiety symptoms with a scale from 0 to 3 (not at all to nearly every day)	2 weeks
Work and Social Adjustment Scale	Self-reported measure of a chronic condition's impact on daily work and social life with a scale of 0 to 8 (none to very severe)	1 year
Connor-Davidson Resilience Scale	Self-reported assessment of personal resilience with a scale of 0 to 3 (not true at all to often true)	1 month

ClinicalTrials.gov Protocol Registration Quality Control Review Criteria Examples

- Refer to interventions by the **same name** throughout the study record.
- If more than one name is used for the same drug (e.g., a generic name and a brand name), clearly indicate in the study record that the drugs are the same.
- In the Arm Description or Group/Cohort Description include details about the intervention strategies administered (e.g., dosage, dosage form, frequency of administration, duration of administration) or groups evaluated.
- Use, if available, appropriate descriptors from NLM's Medical Subject Headings (MeSH) thesaurus.

Quality Control Review Criteria for Registration and Results

JAVA: Java's Association with Virus Anxiety

Population: regular coffee drinkers who are working from home during the COVID-19 pandemic.

Study Design: 360 people, randomized to pre-pandemic level of coffee consumption or increased coffee consumption.

Protocol: Participants drink either their pre-pandemic amount of coffee consumption or consume an additional cup of coffee each day for 60 days.

Outcomes: Anxiety measured with the Generalized Anxiety Disorder (GAD-2) screening measure



Photo by bongkam thanyakij from Pexels

Some Required Data Elements for Trial Registration

Brief Summary; Condition or Disease; Outcome Measure Title; and Time Frame Fields Are Highlighted

Study Description Go to

Brief Summary:
This prospective, randomized, double-blind study will enroll nonsmoking female subjects undergoing laparoscopic bariatric surgery under general anesthesia. The hypothesis of this study is that female nonsmokers who receive nicotine via nasal spray immediately before waking up from anesthesia will need less pain medications 24 hours after the surgery compared to the subjects who receive placebo spray.

Condition or disease	Intervention/treatment	Phase
Pain, Postoperative	Drug: Nasal Nicotine Spray Drug: Nasal Normal Saline Spray	Phase 4

Primary Outcome Measures :

1. Postoperative Opioid Use During the Postanesthesia Care Unit (PACU) Stay, and the First 24 Hours Postoperatively [Time Frame: During PACU stay (approximately 94 minutes after operation), 24 hours after operation]

Opioid use was calculated in intravenous morphine equivalents (iv MEQ) according to the Mayo Clinic Pharmacy opioid conversion calculator based on the recommendations from the American Pain Society. Specifically, the following conversion was used: 10 mg iv fentanyl=1.5 mg iv hydromorphone=20mg oral oxycodone=30mg oral hydrocodone.

More Suitable Documentation: A or B?

Data Element: Primary Disease or Condition Being Studied in the Trial

A	B
Worrying	Anxiety [a Medical Subject Heading]

Test Searches

🔍 Keywords (Optional)

worrying

📍 Location (Optional)

📏 Distance (Optional)

- Select -

Narrow your search

[Clear all filters](#)

Search Results for:

worrying (includes synonymous conditions like Worry, Worries, and [7 related terms](#))

Viewing 1-10 out of 1,694 studies

10 studies per page

worrying (includes synonymous conditions like Worry, Worries, Worried, Did you worry, Have Worried, Worry Frequency, Frequency of Worrying, Had Worrying, Worry About What Will Happen)

anxiety

- Select -

Narrow your search

[Clear all filters](#)

Search Results for:

anxiety (includes synonymous conditions like Anxiety Disorders, Anxiety Disorder, and [17 related terms](#))

Viewing 1-10 out of 23,291 studies

10 studies per page

anxiety (includes synonymous conditions like Anxiety Disorders, Anxiety Disorder, anxiety symptoms, Anxiety Scale, anxious, anxiety symptom, symptoms anxiety, anxieties, Angst, Feeling anxious, Anxiousness, Feel anxious, Anxious behavior, Anxiety Visual Analogue Scale, Unspecified anxiety disorder, Visual Analogue Anxiety Scale, Anxiety NOS, Anxiety reaction, Reaction anxiety)

More Suitable Documentation: A or B?

Data Element: Study Description: Brief Summary

Objective: study the association between the amount of coffee consumption and level of anxiety

Data Element: Arm Title (Used for Interventional Studies)

A	B
Experimental Arm 1: Pre-pandemic amount of coffee daily	Experimental Arm 1: Pre-pandemic amount of caffeine daily

More Suitable Documentation: A or B?

Data Element: Outcome Measure Title

A	B
Anxiety	Mean change from baseline in scores on the Generalized Anxiety Disorder (GAD-2) screening measure

More Suitable Documentation: A or B?

Data Element: Outcome Measure: Time Frame

A	B
Daily through study completion	Daily for 60 days

Improved Access to Trial Details for Researchers & Clinicians

Randomized Controlled Trial > Pediatrics. 2019 Nov;144(5):e20190802.
doi: 10.1542/peds.2019-0802. Epub 2019 Oct 9.

Previsit Screening for Parental Vaccine Hesitancy: A Cluster Randomized Trial

Douglas J Opel^{1,2}, Nora Henrikson³, Katherine Lepere⁴, Rene Hawkes³, Chuan Zhou^{4,2}, John Dunn³, James A Taylor²

Affiliations + expand

PMID: 31597690 PMCID: PMC6855815 DOI: 10.1542/peds.2019-0802

[Free PMC article](#)

Abstract

Objective: To evaluate the effect of vaccine hesitancy screening on childhood vaccine uptake.

Methods: We conducted a cluster randomized controlled trial in pediatric primary care clinics in Washington state. Vaccine-hesitant parents (VHPs) with a healthy newborn receiving health

Associated data

> ClinicalTrials.gov/NCT02708745



Related information

[MedGen](#)

Grant support

R21 HD083770/HD/NICHD NIH HHS/United States

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ACTIONS

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NEXT RESULT
2 of 2

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EN

Data for Large-Scale Analysis

Table. Sex Bias in Clinical Studies Determined From Published Articles and Clinical Trial Records^a

Disease Category	Global Female Prevalence Fraction	Measurement Unit	Published Articles			AACT Records		
			Studies or Participants, No.	Female Participant Fraction	Sex Bias (95% CI)	Studies or Participants, No.	Female Participant Fraction	Sex Bias (95% CI)
Cardiovascular	0.51	Studies	14 371	0.37	-0.14 (-0.14 to -0.13) ^b	2164	0.41	-0.10 (-0.11 to -0.09) ^b
		Participants	540 050 700	0.49	-0.02 (-0.06 to -0.01)	2 229 071	0.39	-0.12 (-0.15 to -0.08) ^b
Diabetes	0.48	Studies	3727	0.45	-0.03 (-0.03 to -0.02) ^b	1420	0.46	-0.03 (-0.03 to -0.02) ^b
		Participants	38 420 434	0.48	0.00 (-0.05 to 0.04)	4 823 058	0.47	-0.01 (-0.08 to 0.02)
Digestive	0.60	Studies	1282	0.49	-0.11 (-0.12 to -0.10) ^b	348	0.54	-0.06 (-0.08 to -0.04) ^b
		Participants	8 519 928	0.51	-0.09 (-0.13 to -0.07) ^b	147 821	0.56	-0.03 (-0.06 to -0.01)
Hepatitis A, B, C, and E	0.44	Studies	1131	0.34	-0.09 (-0.10 to -0.09) ^b	632	0.37	-0.06 (-0.07 to -0.05) ^b
		Participants	1 833 724	0.37	-0.06 (-0.17 to 0.06)	243 846	0.39	-0.05 (-0.07 to -0.03) ^b
HIV/AIDS	0.50	Studies	1741	0.33	-0.17 (-0.18 to -0.16) ^b	387	0.27	-0.23 (-0.25 to -0.21) ^b
		Participants	30 459 386	0.53	0.02 (-0.09 to 0.06)	155 531	0.35	-0.15 (-0.20 to -0.11) ^b
Kidney, chronic	0.57	Studies	2554	0.40	-0.17 (-0.17 to -0.16) ^b	476	0.42	-0.15 (-0.16 to -0.13) ^b
		Participants	18 747 970	0.44	-0.13 (-0.18 to -0.09) ^b	201 763	0.42	-0.15 (-0.17 to -0.12) ^b
Mental	0.48	Studies	3635	0.47	-0.01 (-0.02 to 0.00) ^b	1650	0.44	-0.04 (-0.05 to -0.03) ^b
		Participants	58 097 584	0.48	-0.01 (-0.19 to 0.07)	463 645	0.49	0.00 (-0.01 to 0.02)
Musculoskeletal	0.56	Studies	2418	0.66	0.10 (0.09 to 0.11) ^b	983	0.70	0.14 (0.13 to 0.15) ^b
		Participants	5 898 338	0.60	0.03 (0.00 to 0.08)	438 112	0.65	0.09 (-0.05 to 0.18)
Neoplasms	0.51	Studies	11 121	0.40	-0.11 (-0.11 to -0.11) ^b	3179	0.41	-0.10 (-0.11 to -0.10) ^b
		Participants	54 377 430	0.49	-0.03 (-0.04 to -0.01) ^b	2 946 236	0.50	-0.02 (-0.09 to 0.03)
Neurological	0.59	Studies	3431	0.50	-0.09 (-0.10 to -0.09) ^b	1338	0.52	-0.07 (-0.08 to -0.06) ^b
		Participants	10 576 242	0.53	-0.06 (-0.09 to -0.03) ^b	497 964	0.65	0.06 (-0.01 to 0.12)
Respiratory, chronic	0.48	Studies	2800	0.43	-0.04 (-0.05 to -0.04) ^b	1161	0.44	-0.03 (-0.04 to -0.02) ^b
		Participants	116 410 829	0.48	0.00 (-0.05 to 0.02)	1 231 162	0.47	-0.01 (-0.04 to 0.01)
Total ^c	0.54	Studies	48 211	0.42	-0.12 (-0.12 to -0.11) ^b	13 738	0.45	-0.09 (-0.09 to -0.08) ^b
		Participants	883 392 565	0.49	-0.05 (-0.06 to -0.03) ^b	13 378 210	0.48	-0.06 (-0.09 to -0.03) ^b

Improved Access to Information for Patients & Families

Narrow your search

[Clear all filters](#)

Study Status

Looking for participants

Not yet recruiting (1)

Recruiting (9)

No longer looking for participants

Active, not recruiting (3)

Completed (89)

Terminated (5)

Other

Enrolling by invitation (0)

Suspended (0)

Withdrawn (2)

Unknown (1)

Expanded Access

Eligibility Criteria

Sex

All (10)

Female (10)

Male (10)

Age

Child (birth - 17) (10)

Adult (18 - 64) (6)

Older adult (65+) (3)

Search for ADHD

Filtered for Not yet recruiting, Recruiting, Enrolling by invitation, Child (birth - 17)

adhd (includes synonymous conditions like Attention deficit, hyperactivity disorder, Attention-deficit hyperactivity disorder, Attention Deficit Disorder, Attention Deficit Disorder with Hyperactivity, Attention Deficit Hyperactivity Disorders, Attention Deficit Disorders with Hyperactivity, disorder hyperactivity, Attention deficits)

Study Status

Looking for participants

Not yet recruiting (1)

Recruiting (9)

No longer looking for participants

Active, not recruiting (3)

Completed (89)

Terminated (5)

Other

Enrolling by invitation (0)

Suspended (0)

Withdrawn (2)

Unknown (1)

Expanded Access

Eligibility Criteria

Sex

All (10)

Female (10)

Viewing 1-10 out of 10 studies

10 studies per page

Download

RECRUITING

Treating Parents With **ADHD** and Their Young Children Via Telehealth: A Hybrid Type I Effectiveness-Implementation Trial

CONDITIONS

ADHD Parenting

LOCATIONS

Seattle, Washington, United States

[Show all locations \(2\)](#)

RECRUITING

Lifestyle Enhancement for **ADHD** Program 2

CONDITIONS

Attention Deficit Hyperactivity Disorder

LOCATIONS

Seattle, Washington, United States

RECRUITING

Carboxylesterase 1 Genetic Variation and Methylphenidate in **ADHD**

CONDITIONS

Attention Deficit Hyperactivity Disorder **ADHD**

Give feedback

Classic website



“Access to more information about clinical trials is good for patients, the public and science. The final rule and NIH policy...will help maximize the value of clinical trials...and help us honor our commitments to trial participants, who do so much to help society advance knowledge and improve health.”

~NIH Director Francis Collins

<https://www.nih.gov/news-events/news-releases/hhs-takes-steps-provide-more-information-about-clinical-trials-public>

Resources and Further Reading

- [PRS User's Guide](#): Instructions for using the Protocols Registration & Results System (PRS) to submit clinical study information to ClinicalTrials.gov
- [Quality Control Review Criteria for Registration and Results](#). ClinicalTrials.gov.
- [Frequently Asked Questions on ClinicalTrials.gov & FDAAA](#). National Institutes of Health.
- [FDAAA 801 and the Final Rule](#). Summary of Food and Drug Administration (FDA) requirements relating to ClinicalTrials.gov
- [Summary Table of HHS/NIH Initiatives to Enhance Availability of Clinical Trial Information](#). National Institutes of Health.
- [NIH Definition of Clinical Trial Case Studies](#).
- [Steps to Compliance for NIH Awardees](#).
- [Clinical Trial Registration Policy](#). International Committee of Medical Journal Editors
- ClinicalTrials.gov staff email: register@clinicaltrials.gov

Resources and Further Reading, cont.

- University of Washington Human Subjects Division: [Clinical Trials Registration and Reporting](#)
- Fred Hutch Clinical Research Support: [CTRP & ClinicalTrials.gov](#)
- Seattle Children's Clinical Research Support Office: [Registration of Clinical Research Trials on ClinicalTrials.gov](#)
- Friedman, L., Furberg, Curt, DeMets, David L., Reboussin, David, & Granger, Christopher B. (2015). Fundamentals of clinical trials (Fifth ed.). New York: Springer. Chapter 20 "Reporting and Interpreting of Results." [*ebook version available to UW affiliates*]
- Piller C. (2020). [FDA and NIH let clinical trial sponsors keep results secret and break the law](#). *Science*. doi:10.1126/science.aba8123
- [FDAAA Trials Tracker](#). Evidence Based Medicine DataLab, University of Oxford.

Acknowledgements

- Diana Louden, MLS, Life Sciences Librarian, UW Libraries
- Kristina Elliott, MLS, Web Content and Outreach Coordinator, ClinicalTrials.gov
- Elaina Vitale, MLIS, formerly Academic Coordinator at the National Network of Libraries of Medicine, Middle Atlantic Region
- Emily Patridge, MLS, Assistant Director of Clinical Research & Data Services, University of Washington Health Sciences Library
- University of Washington Human Subjects Division Staff

Questions

Leslie Gascon, MBA, MS(LIS), AHIP

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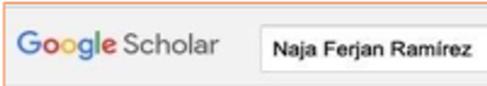
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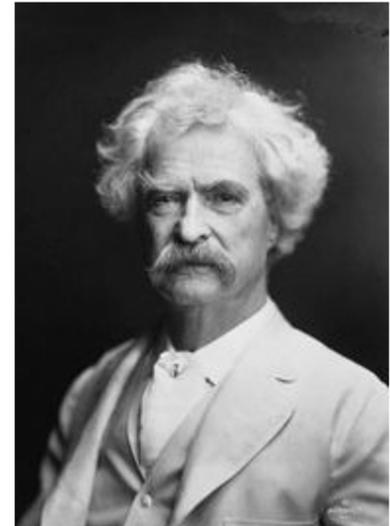
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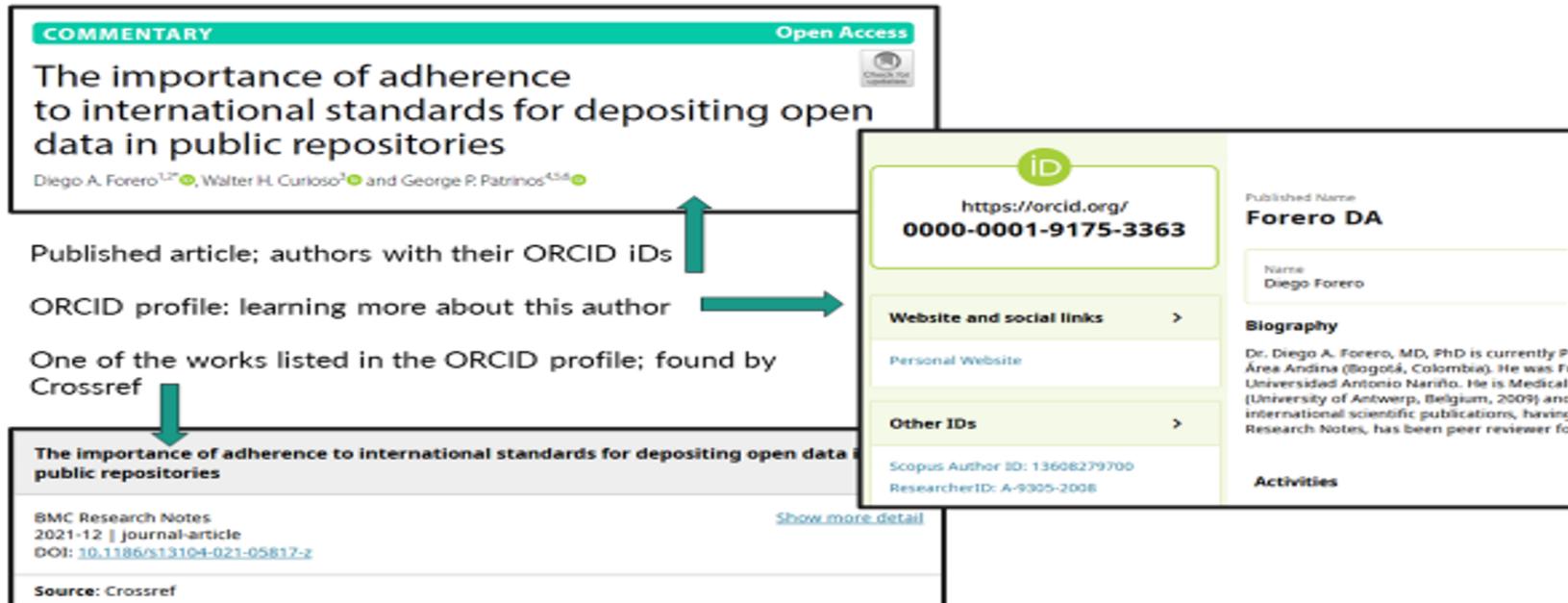
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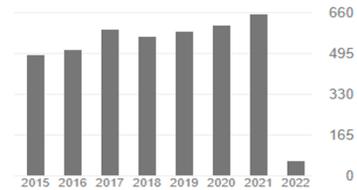
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The association between self-reported racial discrimination and 12-month DSM-IV mental disorders among Asian Americans nationwide GC Gee, M Spencer, J Chen, T Yip, DT Takeuchi Social science & medicine 64 (10), 1984-1996	525	2007
A nationwide study of discrimination and chronic health conditions among Asian Americans GC Gee, MS Spencer, J Chen, D Takeuchi American journal of public health 97 (7), 1275-1282	516	2007
The relationship between knowledge of recent HbA1c values and diabetes care understanding and self-management M Heisler, JD Piette, M Spencer, E Kieffer, S Vijan Diabetes care 28 (4), 816-822	457	2005
An examination of the African American experience of everyday discrimination and symptoms of psychological distress KH Banks, LP Kohn-Wood, M Spencer Community mental health journal 42 (6), 555-570	423	2006
Race, stress, and physical health: the role of group identity. DR Williams, MS Spencer, JS Jackson Oxford University Press	348	1999
Effectiveness of a community health worker intervention among African American and Latino adults with type 2 diabetes: a randomized controlled trial MS Spencer, AM Rosland, EC Kieffer, BR Sinco, M Valerio, G Palmisano, ... American journal of public health 101 (12), 2253-2260	338	2011
Racial and Ethnic Approaches to Community Health (REACH) Detroit partnership: improving diabetes-related outcomes among African American and Latino adults IT...	275	2005

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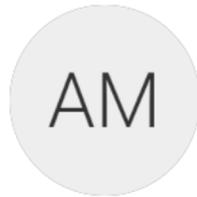
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Organizations

2008-2022 University of Washington
2020-2021 Medical College of Wisconsin
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Awards

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634
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124,511
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Sch Social Work
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2018-2020

Years

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Nghiem, Paul T (Nghiem, Paul T.) ✓

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2019, JAIDS Journal of
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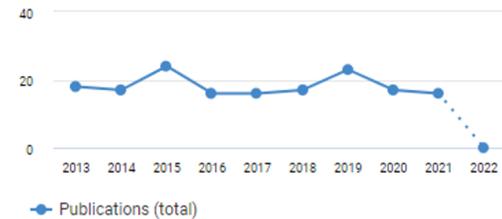
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2020, New England Journal of Medicine - Article

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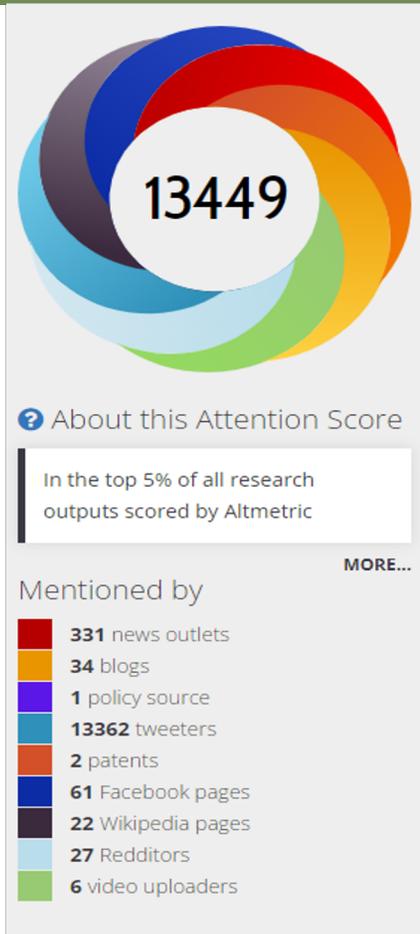
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2008, The Journal of Infectious Diseases - Article

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Authors David Beran, Irl B. Hirsch, John S. Yudkin

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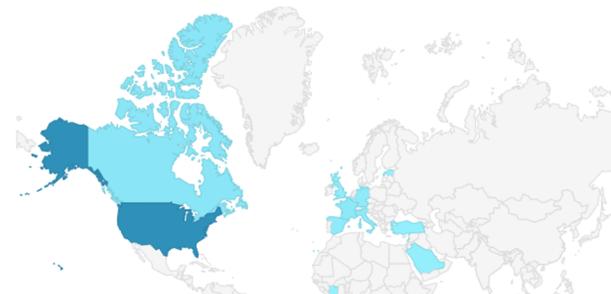
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Title	PD-1 Blockade with Pembrolizumab in Advanced Merkel-Cell Carcinoma
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Pubmed ID	27093365 ↗
Authors	Paul T. Nghiem, Shailender Bhatia, Evan J. Lipson, Ragini R. Kudchadkar, Natalie J. Miller... [show]
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Irl B. Hirsch

2 Publications

Management of diabetes and hyperglycemia in hospitals.

[S. Clement](#), [S. Braithwaite](#), +4 authors [I. Hirsch](#) · Medicine · Diabetes care · 1 February 2004

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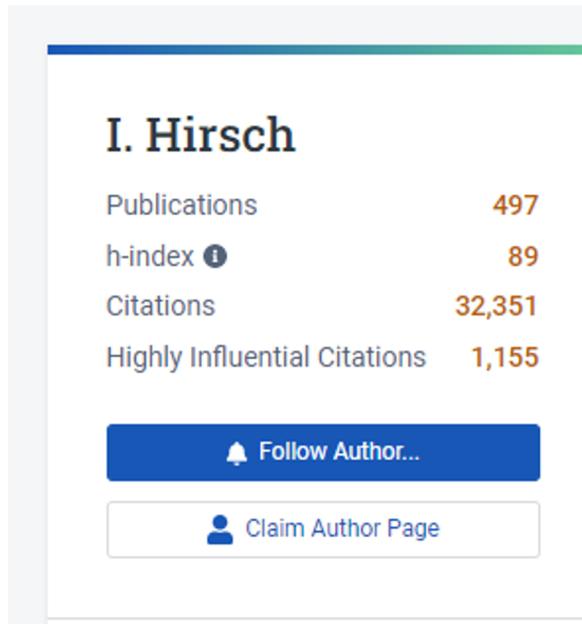
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<input type="checkbox"/> 1	Hirsch, Irl B.	253	69	University of Washington, Medicine	Seattle	United States
	View last title ▼					
<input type="checkbox"/> 2	Hirsch, Irl B.	151	40	University of Washington School of Medicine	Seattle	United States
	View last title ▼					

CORRECTIONS

All of these databases have places to ask for corrections or for help.

Please claim your profile! Make yourself findable.

It used to be “Who you knew”. Now it’s “Who Knows You”.

Put it on your calendar!!



Plan one hour a
month to update
your CV and your
ORCID!



Research Impact is a story you
create - not something that
simply happens to you!



Please contact me for assistance!

Lynly Beard

lynly@uw.edu

<https://calendly.com/lynly> for zoom appointments

Thank You!

Open for Questions

ITHS

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Feedback Survey

A link to the feedback survey has been sent to the email address you used to register.

Please get out your device, find that email, and spend a few moments completing that survey before you leave today.

Tip: If on a mobile device, shift view to landscape view (sideways) for better user experience.