

['3-alpha-hydroxy-5-alpha-pregnan-20-one', 'allopregnanolone', '3alpha-oh-dhp', '3alpha-oh-dhp']	NCT06063369	PEA vs. Placebo for Major Depression	https://clinicaltrials.gov/study/NCT06063369	PEA-01	RECRUITING	<p>as a treatment for unipolar or bipolar depression, randomizing 100 patients to 6-week treatment with PEA 1200 mg/d or matching placebo. There are several rationales for this study: (A) PEA acts at the peroxisome proliferator-activated receptor-alpha (PPAR-α), stimulating Allo biosynthesis. Allo is an endogenous, positive allosteric modulator of GABA-A receptors in glutamatergic neurons, including cortical and hippocampal pyramidal glutamatergic neurons and may be one of the endogenous regulators of depression and anxiety. (B) Sage Therapeutics has developed Allo which is FDA approved to treat post-partum depression, and is testing a molecular modification which can be administered orally for post-partum depression and unipolar depression, with mixed efficacy results. Pregnenolone, a precursor of neurosteroids, has also been reported to improve bipolar depression. Based on animal models, PEA increases Allo synthesis in areas of the brain thought to be involved in anxiety and depression. It may also favor the biosynthesis of sulfated forms of Allo and congeners that inhibit tonic rather than phasic NMDA-mediated excitatory neurotransmission. Showing that PEA-induced selective inhibition of tonic NMDA neurotransmission improves depression might enable development of steroid-based NMDA-inhibitor therapeutics. In addition, PEA-induced Allo upregulation potentiates GABA-A receptor-mediated inhibition. The NMDA and the GABAergic mechanisms may act in concert to improve behavioral outcomes. Since PEA increases Allo in the brain where it is endogenously formed, it might be more effective compared with exogenous administration, which is not site specific. There is evidence of a role of inflammation in depression; PEA has potent immunoregulatory and anti-inflammatory effects by directly activating PPAR-α, which has a protective role against neuroinflammation by inhibiting the signaling mediated by toll-like receptor 4. There is one published study which shows that PEA has an antidepressant effect in unipolar depression, 58 patients were randomized to receive 1200 mg/d of PEA or placebo added-on to citalopram, showing clinical improvements in patients receiving PEA.</p>	NO	Bipolar Depression	Major Depressive Disorder	DRUG: Palmitoylethanolamide	The Israeli Medical Center for Alzheimer's	PHASE2	100	OTH
['uplizna']	NCT04372615	The ExTINGUISH Trial of Inebilizumab in NMDAR Encephalitis	https://clinicaltrials.gov/study/NCT04372615	EXTINGUISH	RECRUITING	<p>Determine the difference in the modified Rankin score at 16 weeks in participants with anti-N-methyl-D-aspartate receptor (NMDAR) encephalitis treated with "first-line" immunomodulatory therapies provided as standard-of-care, and either inebilizumab (investigational agent) or placebo.</p>	NO	Autoimmune Encephalitis	Encephalitis	DRUG: Inebilizumab	DRUG: Placebo	University of Utah	PHASE2	116
						Determine the difference in								

[uplizna]	NCT04372615	The ExTINGUISH Trial of Inebilizumab in NMDAR Encephalitis	https://clinicaltrials.gov/study/NCT04372615	EXTINGUISH	RECRUITING	the modified Rankin score at 16 weeks in participants with anti-N-methyl-D-aspartate receptor (NMDAR) encephalitis treated with "first-line" immunomodulatory therapies provided as standard-of-care, and either inebilizumab (investigational agent) or placebo.	NO	Autoimmune Encephalitis	Encephalitis	DRUG: Inebilizumab	DRUG: Placebo	University of Utah		PHASE2	116
[perampanel]	NCT05756621	Dual Anti-glutamate Therapy in Super-refractory Status Epilepticus After Cardiac Arrest	https://clinicaltrials.gov/study/NCT05756621	SUPER-CAT	RECRUITING	Status epilepticus (SE) is found in 20-30% of patients in coma after cardiac arrest, is often refractory to medical therapy and is considered a negative prognostic factor. Intensity and duration of treatment of refractory and super-refractory post-anoxic SE pose the ethical dilemma between futility of treatments and, conversely, their premature suspension. A recent study by the Epilepsy Center of the San Gerardo Hospital has shown that patients with super-refractory post-anoxic SE and favorable prognostic indicators can achieve a good functional outcome in more than 40% of cases, if treated with intensive and protracted therapy. However, there is profound uncertainty about the best combination of antiseizure medications and anesthetics to use in this condition. A combined anti-glutamatergic therapy with ketamine (anti-NMDA receptor) and perampanel (anti-AMPA receptor), aimed at counteracting the excitotoxicity linked to global cerebral ischemia, could be particularly effective in the treatment of super-refractory SE with post-anoxic etiology. Preliminary results in the first 26 patients treated in the Coordinating Center of the project indicate that this therapy appears safe and highly effective (80% SE resolution, 40% good neurological outcome). The aim of the SUPER-CAT study is to investigate the efficacy and safety of combined therapy with ketamine and perampanel (dual anti-glutamatergic therapy) in patients with post-anoxic super-refractory status epilepticus, compared to other therapies, using a multi-centre, retrospective, cohort study design.	NO	Status Epilepticus	Cardiac Arrest	DRUG: Ketamine	DRUG: Any anti-epileptic and anesthetic therapy, excluding Ketamine and Perampanel	University of Milano Bicocca	Azienda Ospedaliera San Gerardo di Monza	Azienda Ospedaliero-Universitaria di Modena	Azienda Ospedaliero-Universitaria di Modena
[ono+2745',			https://clinicaltrials.gov/study/NCT05756621			Inhalation anesthetics significantly can delay latency and reduce amplitude of cortical MEPs and SSEPs signals compared to intravenous anesthetics by acting on not only GABA (γ-aminobutyric acid) receptors but also NMDA (N-methyl-D-aspartate) receptors, so total intravenous anesthesia (TIVA) have been more preferred for neurophysiological monitoring follow-up during surgery. However, just less than inhalation anesthetics, the decrease of amplitude and the delay of latency also occur according to the dose dependant of propofol. Moreover, it can cause various adverse effects such as delayed recovery after anesthesia or propofol infusion syndrome, consequently, combined methods with other agents or conversion to other relative anesthetics are being made.									

'remimazolam', 'cns+7056', 'cns-7056', 'ono2745', 'ono-2745', 'cns7056']	NCT04968054	Comparison of IONM Between Remimazolam and Propofol	trials,8 ow/st udy/ NCT0 4968 054		COMPLETED	Remimazolam is a ultra-short-acting benzodiazepine, and unlike conventional benzodiazepine drugs, it is rapidly metabolized in plasma and not accumulates in the body for long periods of infusion or even with high dose administration. Recently, there have been repored that continuous infusion of 0.5-1.5 mg/kg of remimazolam has little effect on the motor evoked potential (MEPs) of cervical spine surgery patients, but this is a case report without the control group; further prospective studies are definitely needed. Therefore, in the case of using propofol or remimazolam for total intravenous anesthesia, we aim to investigate which intravenous anesthetic is more appropriate for intraoperative neurophysiological monitoring by comparing the results of the somatosensory evoked potential (SSEPs) and MEPs according to these anesthetics.	NO	Ossification Posterior Longitudinal Ligament	Cervical Spondylotic Myelopathy	DRUG: Arm I (Propofol)	DRUG: Arm II (Remimazolam)	Gangnam Severance Hospital	NA	66
['cbd']	NCT04244058	Changes in Glutamatergic Neurotransmission of Severe TBI Patients	http://cli nicalt rials.g ov/st udy/ NCT0 4244 058		SUSPENDED	Studies in patients with disorders of consciousness (DOC) after severe brain injury implicate dysfunction of the anterior forebrain mesocircuit dysfunction a key underlying mechanism. The anterior forebrain metabolism in DOC is markedly downregulated across brain regions underpinning highly elaborated cognitive behaviors demonstrating a collapse of the level of synaptic background activity required for consistent goal-directed behavior and arousal regulation. Since dopamine levels are one of the primary controllers of the level of synaptic background activity within these forebrain structures and in regulating excitatory glutamatergic homeostasis, the investigators propose to investigate the specific contribution of presynaptic dopamine function in glutamatergic neurotransmission in posttraumatic DOC. The aim of the present study is to measure metabotropic glutamate receptors 5 occupancy in the main gutamatergic structures of the brain using (3-[18F]fluoro-5-(2-pyridinylethynyl)benzonitrile)-positron emission tomography ([18F]FPFB-PET) at rest and following a short pharmacological challenge with amantadine, an N-methyl-D-aspartate receptor (NMDA-R) antagonist, following L-DOPA, and amantadine + L-DOPA. Using this novel technique in DOC the investigators will characterize the relevance of a presynaptic deficiency to synthesize and/or release dopamine in the final regulation of excitatory interneurons of the anterior forebrain mesocircuit.It is unknown whether glutamatergic neurotransmission is affected across the population of subjects with DOC and, if this condition is secondary to a presynaptic dopaminergic	NO	Disorder of Consciousness	Traumatic Brain Injury	DRUG: Amantadine + L-DOPA	DRUG: NMDA blocker	Weill Medical College of Cornell University	EARLY_PHASE1	30

						failure of the anterior forebrain mesocircuit (i.e., down-regulation). Since the investigators previously identified the existence of a presynaptic dopaminergic deficit in these subjects due to a failure in the biosynthesis of dopamine, the investigators will evaluate if by providing the main biological substrate of the biosynthesis process (i.e., L-DOPA) the glutamatergic system regains homeostasis. The investigators therefore propose to investigate patients with posttraumatic DOC using [18F]FPEB-PET at rest and following short pharmacological challenges aimed at increasing glutamate and dopamine release.								
[cbd]	NCT04244058	Changes in Glutamatergic Neurotransmission of Severe TBI Patients	https://clinicaltrials.gov/study/NCT04244058	SUSPENDED	Studies in patients with disorders of consciousness (DOC) after severe brain injury implicate dysfunction of the anterior forebrain mesocircuit dysfunction a key underlying mechanism. The anterior forebrain metabolism in DOC is markedly downregulated across brain regions underpinning highly elaborated cognitive behaviors demonstrating a collapse of the level of synaptic background activity required for consistent goal-directed behavior and arousal regulation. Since dopamine levels are one of the primary controllers of the level of synaptic background activity within these forebrain structures and in regulating excitatory glutamatergic homeostasis, the investigators propose to investigate the specific contribution of presynaptic dopamine function in glutamatergic neurotransmission in posttraumatic DOC. The aim of the present study is to measure metabotropic glutamate receptors 5 occupancy in the main gutamatergic structures of the brain using (3-[18F]fluoro-5-(2-pyridinylethynyl)benzonitrile)-positron emission tomography ([18F]FPEB-PET) at rest and following a short pharmacological challenge with amantadine, an N-methyl-D-aspartate receptor (NMDA-R) antagonist, following L-DOPA, and amantadine + L-DOPA. Using this novel technique in DOC the investigators will characterize the relevance of a presynaptic deficiency to synthesize and/or release dopamine in the final regulation of excitatory interneurons of the anterior forebrain mesocircuit.It is unknown whether glutamatergic neurotransmission is affected across the population of subjects with DOC and, if this condition is secondary to a presynaptic dopaminergic failure of the anterior forebrain mesocircuit (i.e., down-regulation). Since the investigators previously identified the existence of a presynaptic dopaminergic deficit in these subjects due to a failure in the biosynthesis of dopamine, the investigators will evaluate	NO	Disorder of Consciousness	Traumatic Brain Injury	DRUG: Amantadine + L-DOPA	DRUG: NMDA blocker	Weill Medical College of Cornell University	EARLY_PHASE1	30	

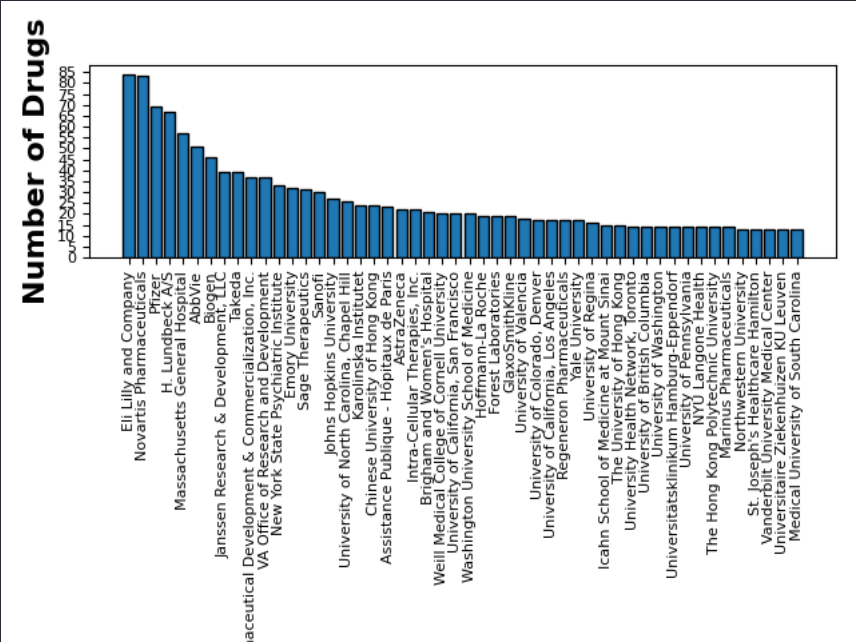
							If by providing the main biological substrate of the biosynthesis process (i.e., L-DOPA) the glutamatergic system regains homeostasis. The investigators therefore propose to investigate patients with posttraumatic DOC using [18F]FPET-PET at rest and following short pharmacological challenges aimed at increasing glutamate and dopamine release.									
['cbd']	NCT03362879	COMedication Study Assessing Mono- and cOMBination Therapy With Levodopa-carbidopa inteStinal Gel	http://clinicaltrials.gov/study/NCT03362879	COSMOS	COMPLETED		The purpose of this study is to evaluate treatment of advanced Parkinson's Disease (PD) patients on levodopa-carbidopa intestinal gel (LCIG) monotherapy in a routine clinical setting.	YES	Parkinson's Disease (PD)	AbbVie				412	INDUSTRY	OBS

depression

FDA Approvals

fda_year	fda_year_approval_count	fda_drug_name	fda_active_ingredient	fda_approval_date	fda_approved_use	fda_drug_link	fda_press_release	fda_drug_trials_snapshot	fda_2_drug_name	fda_2_active_ingredient	fda_2_dosage_form	fda_2_d
2023	30	Zurzuvae	zuranolone	2023-08-04 00:00:00	To treat postpartum depression-tPress ReleaseDrug Trials Snapshot	https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217369s000lbl.pdf	https://www.fda.gov/news-events/press-announcements/fda-approves-first-oral-treatment-postpartum-depression	https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots-zurzuvae	ZURZUVAE	ZURZUVAE (ZURANOLONE)	['CAPSULE', 'ORAL']	https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217369s000lbl.pdf
2019	4	Zulresso	brexanolone	2019-03-19 00:00:00	To treat postpartum depression (PPD) in adult womenPress ReleaseDrug Trials Snapshot	http://www.accessdata.fda.gov/scripts/cdr/daf/index.cfm?event=overview&process=varAppNo=211371	https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-postpartum-depression	https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots-zulresso	ZULRESSO	ZULRESSO (BREXANOLONE)	['SOLUTION', 'INTRAVENOUS']	https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/012509s000lbl.pdf

Clinical Trial Sponsors



Search Term	NCT Number	Study Title	Study URL	Acronym	Study Status	Brief Summary	Study Results	Conditions	Interventions	Sponsor	Collaborators	Phases	
						A large proportion of people with a schizophrenia-spectrum disorder, especially in the early stages of the disease, regularly consume cannabis. Cannabis							

['delta.1(2)-trans-cannabidiol', 'epidiolox', 'delta(1(2))-trans-cannabidiol', '(a+/-)-cannabidiol', 'cbd', 'cannabidiol']	NCT03883360	Effects of Cannabidiol on Psychiatric Symptoms, Cognition, and Cannabis Consumption in Cannabis Users With Recent-Onset Psychosis	https://clinicaltrials.gov/study/NCT03883360		WITHDRAWN	use is associated with poor prognostic outcome; however, there are no effective interventions targeted at reducing cannabis use or its deleterious effects in this population. The present trial is designed to test whether cannabidiol (CBD), a cannabinoid whose effects are in many ways antagonistic to those of Δ^9 -tetrahydrocannabinol (THC), can reduce psychiatric symptoms, cognitive deficits, and cannabis use in people with recent-onset psychosis who regularly consume cannabis.	NO	Schizophrenia Spectrum Disorders	Cannabis Use	DRUG: Cannabidiol (CBD)	DRUG: Placebo	University of Maryland, Baltimore	Sh Hi
['baricitinib+(incb028050)', 'ly+3009104', 'baricitinib+(ly3009104,+incb028050)', 'olumiant', 'baricitinib+(ly3009104)', 'incb028050', 'baricitinib', 'incb+028050', 'incb028050++++,++++ly3009104', 'incb-028050', '17	a-propionate', 'ly3009104', 'ly-3009104']	NCT06381661	Adaptive Platform Trial for Personalisation of Sepsis Treatment in Children and Adults: a Multi-national, Treatable Traits-guided, Adaptive, Bayesian Basket Trial	https://clinicaltrials.gov/study/NCT06381661	PALETTE	NOT_YET_RECRUITING	PALETTE is a perpetual adaptive platform to efficiently study sepsis interventions within 'treatable traits' in all-ages patients enabling prompt evaluation of pandemic treatments. Treatable traits, therapeutic targets identified by phenotypes or endotypes (defined by biological mechanism or by treatment response) through validated biomarkers (measurable characteristic reflecting normal or pathogenic processes, or treatment responses), may include multi-omics, cellular, immune, metabolic, endocrine features, or intelligent algorithms. PALETTE Bayesian adaptive design enables parallel investigations of multiple interventions for sepsis, and quick inclusion of pandemic pathogens. PALETTE's new conceptual model will respond to the challenges of standard approaches, i.e. series of sepsis trials,	NO	Sepsis	DRUG: Tocilizumab	DRUG: Baricitinib	DRUG: Anakinra	Hye

							each investigating one or two interventions, expensive, time consuming, and inappropriate in pandemic context.						
[example+9]	NCT06077526	Alleviating Burden of Chronic Musculoskeletal Pain in the Emergency Department	https://clinicaltrials.gov/study/NCT06077526		NOT_YET_RECRUITING	Chronic musculoskeletal pain (CMP) and lack of physical activity often co-exist, contributing to increased disability, non-communicable diseases (e.g., obesity, diabetes, hypertension), psychological comorbidity (e.g., anxiety and depression), and healthcare utilization and costs [1-6]. Many individuals with CMP seek assistance at emergency departments (ED). ED overuse has been an ongoing concern, with 1-in-5 Americans presenting to the ED at least once each year [7]. Of these visits, 24 million are for adults seeking help for chronic pain, with an additional 12 million due to exacerbations of an existing chronic pain condition [8]. In 2021, the fourth most common reason for seeking care in the ED related to a primary diagnosis involving the musculoskeletal system, with an estimated 9.5 million visits [9]. Most ED visits result in a 'treat and release' approach, potentially disrupting continuity of care and resulting in follow-up ED visits [10]. These ED visits for chronic pain are indicative of accessibility problems to community-based primary and preventative care, compounded by limited or no health insurance coverage [10]. Based on the Emergency Medical Treatment and Labor Act, EDs are required to stabilize all patients regardless of ability to pay [10]. To alleviate the burden of CMP on patients and EDs, improve access to quality healthcare, and mitigate initial and repeat ED visits, alternative options are required. Here we propose a novel group-based intervention involving pain education (PE) and physical activity (PA) implemented in CMP patients presenting to the ED of a community level hospital. The investigators will recruit 60 adults from a community hospital located in the Shenandoah Valley region of Virginia;	NO	Chronic Pain	BEHAVIORAL: P.E.A.K. Rx	OTHER: Usual Care	Bridgewater College		

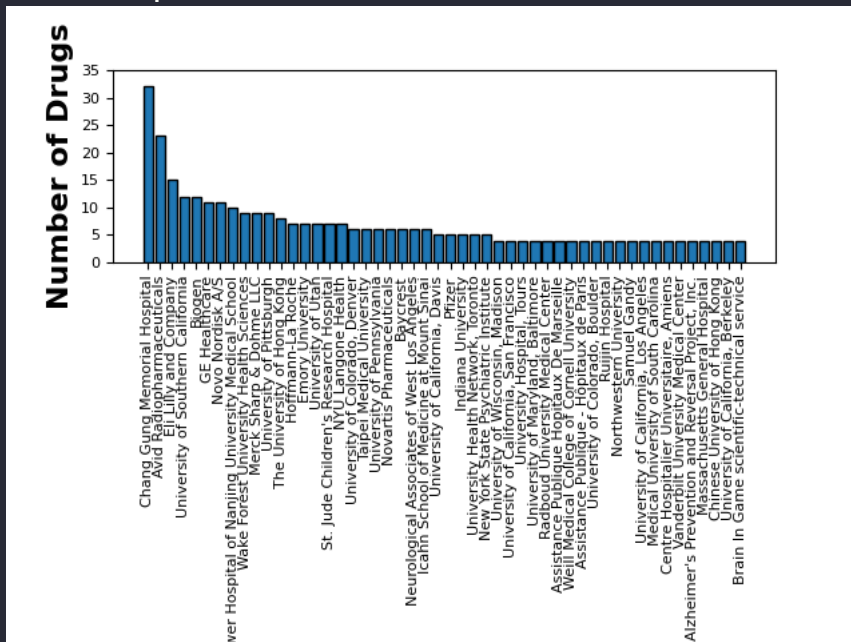
						participants will be randomized to either Pain Education and Active Knowledge (P.E.A.K.) Rx (24 sessions of group PE+ PA) or usual care. Research assessments are conducted with both groups at study entry (baseline), 8-weeks, 3-months, and 6-months.						
[pww]	NCT04948489	IUD and Norethindrone Acetate for Treatment of Endometriosis	https://clinicaltrials.gov/study/NCT04948489		NOT_YET_RECRUITING	Endometriosis is the most common reproductive disease afflicting young women, often leading to debilitating chronic pelvic pain and impaired quality of life. Safe, effective, and convenient long-term treatments are lacking for adolescents and young adults. The levonorgestrel-containing IUD (LNG-IUD) represents an attractive long-term drug delivery system for the treatment of endometriosis during adolescence and young adulthood. However, while the LNG-IUD has an acceptable safety profile, it is not associated with a favorable bleeding profile and may not fully suppress endometriosis pain when used as monotherapy. Investigators hypothesize that the addition of NETA will improve bleeding patterns, maximize pain control, and improve continuation rates of the IUD when the two medications are used in combination. This proposed prospective trial provides the ideal context in which to investigate these clinical questions and advance research on the best treatments for endometriosis.	NO	Endometriosis	DRUG: norethindrone acetate (NETA)	DRUG: Placebo	Boston Children's Hospital	
		Promoting				All students who enroll in the study will receive an efficacious counselor-delivered brief motivational intervention. The intervention is based in principles of motivational interviewing. Students complete a baseline assessment on their alcohol use and alcohol-related consequences. During the hour-long session, the counselor uses information from the baseline assessment to compare the student's level of alcohol consumption to that of peers at the same university, discuss choices that may lead to experiencing negative consequences, and provide opportunities for the student to set goals for risk reduction. This study will develop and pilot a maintenance						

[example+9]	NCT05712382	Maintenance of Change Following Brief Intervention for Alcohol Use	https://clinicaltrials.gov/study/NCT05712382		NOT_YET_RECRUITING	enhancement intervention. The intervention is expected to consist of four components, for example: (1) Student participants may learn to use techniques based in mindfulness to cope with negative emotions. (2) Student participants may identify barriers to reducing their alcohol use and identify protective strategies for navigating those barriers. (3) Student participants may be presented with narratives from other students who successfully resumed moderate drinking after a heavy drinking episode. Students may also be prompted to identify alcohol free activities that they enjoy and can engage in after experiencing a heavy drinking episode. (4) Parents may also receive a handbook encouraging communication with their student about alcohol use.	NO	Alcohol Drinking in College	BEHAVIORAL: Parent handbook	BEHAVIORAL: Coping with negative emotions	BEHAVIORAL: Problem-solving risky situations	BEHAVIORAL: Recovering from slips	Ma
[dara]	NCT05789446	Confirmatory Efficacy of the Building a Strong Identity and Coping Skills Program	https://clinicaltrials.gov/study/NCT05789446		NOT_YET_RECRUITING	The goal of this clinical trial is to the efficacy of the Building a Strong Identity and Coping Skills intervention within a sample of low-income and minoritized youth aged 11-14 who are seeking mental health treatment and have been placed on a waitlist to receive services.The aims of this study are to: (1) confirm the efficacy of BaSICS by replicating previous findings, (2) Examine the changes of coping mechanisms and symptom change over the course of the BaSICS intervention, and (3) test models of physiologic stress reactivity and regulation to capture biological "risk" and recalibration.Cohorts of 20 participants will randomly be enrolled in either the intervention (10) or control (10) groups. Participants enrolled in the intervention group will complete the BaSICS program and participants enrolled in the no intervention group will not be enrolled in the intervention program. The BaSICS program is designed to help treat anxiety, depression, and post-traumatic stress symptoms and disorders and have direct effects on physiologic stress response systems (hypothalamic-pituitary-adrenal (HPA) axis). Researchers will compare the intervention and no intervention groups to see if there is a difference in the reduction of markers	NO	Chronic Stress	Anxiety	Depression	BEHAVIORAL: Building a Strong Identity and Coping Skills	Penn State University	

						for anxiety, depression, and suicide scores, changes in coping mechanism, and HPA reactivity profiles							
[dara]	NCT05789446	Confirmatory Efficacy of the Building a Strong Identity and Coping Skills Program	https://clinicaltrials.gov/study/NCT05789446		NOT_YET_RECRUITING	<p>The goal of this clinical trial is to the efficacy of the Building a Strong Identity and Coping Skills intervention within a sample of low-income and minoritized youth aged 11-14 who are seeking mental health treatment and have been placed on a waitlist to receive services. The aims of this study are to: (1) confirm the efficacy of BaSICS by replicating previous findings, (2) Examine the changes of coping mechanisms and symptom change over the course of the BaSICS intervention, and (3) test models of physiologic stress reactivity and regulation to capture biological "risk" and recalibration. Cohorts of 20 participants will randomly be enrolled in either the intervention (10) or control (10) groups. Participants enrolled in the intervention group will complete the BaSICS program and participants enrolled in the no intervention group will not be enrolled in the intervention program. The BaSICS program is designed to help treat anxiety, depression, and post-traumatic stress symptoms and disorders and have direct effects on physiologic stress response systems (hypothalamic-pituitary-adrenal (HPA) axis). Researchers will compare the intervention and no intervention groups to see if there is a difference in the reduction of markers for anxiety, depression, and suicide scores, changes in coping mechanism, and HPA reactivity profiles</p>	NO	Chronic Stress	Anxiety	Depression	BEHAVIORAL: Building a Strong Identity and Coping Skills	Penn State University	
						<p>The goal of this clinical trial is to the efficacy of the Building a Strong Identity and Coping Skills intervention within a sample of low-income and minoritized youth aged 11-14 who are seeking mental health treatment and have been placed on a waitlist to receive services. The aims of this study are to: (1) confirm the efficacy of BaSICS by replicating previous findings, (2) Examine the changes of coping mechanisms and symptom change over the course of the BaSICS intervention, and (3) test models of physiologic stress reactivity and</p>							

['dara']	NCT05789446	Confirmatory Efficacy of the Building a Strong Identity and Coping Skills Program	https://clinicaltrials.gov/study/NCT05789446		NOT_YET_RECRUITING	regulation to capture biological "risk" and recalibration.Cohorts of 20 participants will randomly be enrolled in either the intervention (10) or control (10) groups. Participants enrolled in the intervention group will complete the BaSICS program and participants enrolled in the no intervention group will not be enrolled in the intervention program. The BaSICS program is designed to help treat anxiety, depression, and post-traumatic stress symptoms and disorders and have direct effects on physiologic stress response systems (hypothalamic-pituitary-adrenal (HPA) axis). Researchers will compare the intervention and no intervention groups to see if there is a difference in the reduction of markers for anxiety, depression, and suicide scores, changes in coping mechanism, and HPA reactivity profiles	NO	Chronic Stress	Anxiety	Depression	BEHAVIORAL: Building a Strong Identity and Coping Skills	Penn State University	
['daxxify', 'jeuveau']	NCT06448676	Head-to-Head Comparison of All Botulinum Neurotoxin Type A Products for Glabellar Rhytides	https://clinicaltrials.gov/study/NCT06448676		NOT_YET_RECRUITING	Study Type: This is a multicenter, triple-blind, randomized controlled trial.Purpose: The goal of this clinical trial is to compare the effectiveness and safety of all five commercially available Botulinum Neurotoxin Type A (BoNT-A) products for treating glabellar rhytides, commonly known as frown lines. This study is designed to provide comprehensive data on how these treatments compare in terms of improving frown lines and the duration of their effects.Main Questions the Study Aims to Answer:Which BoNT-A product provides the longest lasting effect on reducing glabellar rhytides? How do these products compare in terms of safety and the occurrence of side effects?Participant Tasks:Women aged 18 years or older with moderate to severe glabellar lines will participate.Participants will receive injections of a BoNT-A product into specific facial muscles.They will need to take weekly photographs using their smartphones to document changes in their frown lines.These photos will be securely sent to our research team for analysis. Participants will complete questionnaires at the start and end of the study to assess their satisfaction, quality of life, and any changes	NO	Wrinkle	DRUG: Botulinum toxin type A	Academisch Medisch Centrum - Universiteit van Amsterdam (AMC-UvA)	Universitair Medisch Centrum Groningen	PHASE4	

fda_year	fda_year_approval_count	fda_drug_name	fda_active_ingredient	fda_approval_date	fda_approved_use	fda_drug_link	fda_press_release	fda_drug_trials_snapshot	fda_2_drug_name	fda_2_active_ingredient	fda_2_dosage_form	fda_2_d
2012	9	Amyvid	Florbetapir F 18	2012-04-06 00:00:00	Used as a radioactive diagnostic agent for Positron Emission Tomography (PET) imaging of the brain to estimate (Es)-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer's Disease (AD) and other causes of cognitive decline.	https://wayback.archive-it.org/7993/20161022052138/http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchAction&searchTerm=202008&SearchType=BasicSearch	nan	nan	AMYVID	AMYVID (FLORBETAPIR F-18)	["SOLUTION", "INTRAVENOUS"]	https://accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=SearchAction&searchTerm=202008&SearchType=BasicSearch



[efd]	NCT05773430	The Targeted Neurocognitive Training (TNT) Study	https://clinicaltrials.gov/study/NCT05773430	TNT	SUSPENDED	<p>Based on the Executive Dyscontrol Hypothesis and underlying calculations of IIV, one way to improve cognition in PWH is through interventions that target improvements in their most severely impaired cognitive domains. We hypothesize such improvements, in turn, should reduce the strain placed on executive functioning resources, freeing up resources needed to compensate for impairments in any domain and, in turn, reducing IIV. Computerized cognitive training, widely used in the study team's prior work, is ideally suited to target impairments in select cognitive domains using computerized cognitive training. In our systematic review of 13 cognitive training studies in PWH, we found cognitive training improved performance in the targeted domain. In this feasibility study, we will assess 150 PWH at baseline with the expectation to recruit 120 PWH with HAND. Then we will use a two-group pre-post experimental design of 120 adults with HAND including: 1) a Targeted Neurocognitive Training (TNT) group (n=60) to train each participant's two most impaired cognitive domains (e.g., attention & memory) assessed from a neurocognitive battery at baseline, and 2) a no-contact control group (n=60). Aim 1 - Feasibility: To determine feasibility and acceptability of the intervention. Exploratory Aim 1 - Cognition: Compare adults who receive TNT to those who receive no training to determine whether they improve on the cognitive domains trained, show less cognitive IIV across domains and within a task, and demonstrate improved executive functioning. Exploratory Hypothesis 1: TNT will improve cognitive functioning in the targeted impaired cognitive domains. Exploratory Hypothesis 2: TNT will reduce cognitive IIV (both overall dispersion & inconsistency). Exploratory Hypothesis 3: TNT will improve executive functioning. Exploratory Hypothesis 4: TNT will improve global cognition and reduce HAND severity. Innovation 1 - This is the first study to use IIV to guide cognitive</p>	NO	HIV	Aging	Cognitive Function Abnormal	Cognitive Training	Older Adults	BEHAVIORAL: Targeted Neurocognitive Training	University of Alabama at Birmingham
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					training to target the most impaired cognitive domains to reduce cognitive IIV in HIV. Innovation 2 - This will be one of the first studies to prospectively include both types of cognitive IIV - dispersion and inconsistency - allowing us to examine the relationship between dispersion and inconsistency. Innovation 3 - The epicenter of HIV is in the Deep South where this study will occur.									
['efd']	NCT05773430	The Targeted Neurocognitive Training (TNT) Study	https://clinicaltrials.gov/study/NCT05773430	TNT	SUSPENDED	<p>People with HIV (PWH) often suffer from cognitive impairments known as HIV-Associated Neurocognitive Disorder (HAND). Cognitive impairments in PWH are not fully captured by traditional neurocognitive assessment; thus, we must examine cognitive performance both within a task (inconsistency) and across cognitive domains (dispersion), called Intra-Individual Variability (IIV). IIV predicts cognitive impairment/decline, altered brain morphology, and neuropathology in many clinical populations. Conceptually, IIV results from "executive dyscontrol" or the efficiency (or inefficiency) with which executive control processes coordinate other cognitive processes/domains. Based on the Executive Dyscontrol Hypothesis and underlying calculations of IIV, one way to improve cognition in PWH is through interventions that target improvements in their most severely impaired cognitive domains. We hypothesize such improvements, in turn, should reduce the strain placed on executive functioning resources, freeing up resources needed to compensate for impairments in any domain and, in turn, reducing IIV. Computerized cognitive training, widely used in the study team's prior work, is ideally suited to target impairments in select cognitive domains using computerized cognitive training. In our systematic review of 13 cognitive training studies in PWH, we found cognitive training improved performance in the targeted domain. In this feasibility study, we will assess 150 PWH at baseline with the expectation to recruit 120 PWH with HAND. Then we will</p>	NO	HIV	Aging	Cognitive Function Abnormal	Cognitive Training	Older Adults	BEHAVIORAL: Targeted Neurocognitive Training	University of Alabama at Birmingham

[pww']	NCT06440369	Physical Activity and Cardiovascular Risk	https://clinicaltrials.gov/study/NCT06440369	PACaR	NOT_YET_RECRUITING	<p>dysregulation in CKD and RA, PA may mitigate these effects and improve patient outcomes. The primary objective of this study is to evaluate the effects of a personalized aerobic exercise program on cardiovascular risk in patients with CKD or RA. The secondary objectives are to assess the effects on inflammation and immunosenescence; investigate the relationship between inflammation, immunosenescence, and various health outcomes; compare the impacts of chronic PA and PA guidance on cardiovascular risk, disease activity, lifestyle habits, cognitive functions, and quality of life. This study presents an interventional design. A total of 105 subjects are expected to participate in this study, including 45 CKD patients and 45 RA patients. Participants will be stratified by PA level and cardiovascular risk (SCORE 2 scale) and then randomized into three groups: Control Group: 15 CKD and 15 RA patients; Therapeutic Education Group: 15 CKD and 15 RA patients; and Experimental Group: 15 CKD and 15 RA patients. The inclusion criteria are: age > 50 years; diagnosed with CKD or RA; glomerular filtration rate between 45 and 29 ml/min/1.73 m² for CKD; DAS-28 score ≥ 2.6 for RA; medical clearance for PA; informed consent and affiliation with French social security. The exclusion criteria are: unstable corticosteroid therapy or >10 mg prednisone/day; uncontrolled hypertension; pregnancy; cognitive impairment preventing adherence to the program; inability to perform PA; legal incapacity or anticipated poor cooperation; lack of health insurance and participation in an incompatible study. The primary efficacy criterion of this study is changes in endothelial function (macrovascular arterial stiffness) and the secondary efficacy criteria are: endothelial function (microvascular hyperemia test); levels of inflammation and immunity (blood tests); physical activity levels and quality of life (questionnaires); disease-related functional impairment; disease activity and</p>	NO	Rheumatoid Arthritis	Chronic Kidney Diseases	Endothelial Dysfunction	Arterial Stiffness	Exercise	OTHER: Training group	OTHER: Physical activity orientation group	University of Franche-Comté
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['solriamfetol']	NCT06404099	RECOVER-SLEEP: Platform Protocol, Appendix_A (Hypersomnia)	https://clinicaltrials.gov/study/NCT06404099		RECRUITING	Interventions. For example, objectives, measures, and endpoints are generalized in the platform protocol, but intervention-specific features are detailed in separate appendices.This platform protocol is a prospective, multi-center, multi-arm, randomized controlled platform trial evaluating potential interventions for PASC-mediated sleep disturbances. The hypothesis is that symptoms of sleep and circadian disorders that emerge in patients with PASC can be improved by phenotype-targeted interventions. Specific sleep and circadian disorders addressed in this protocol include sleep-related daytime impairment (referred to as hypersomnia) and complex PASC-related sleep disturbance (reflecting symptoms of insomnia and sleep-wake rhythm disturbance).	NO	Long COVID	Long COVID-19	Hypersomnia	DRUG: Modafinil	DRUG: Modafinil Placebo	DRUG: Solriamfetol	DRUG: Solriamfetol Placebo	Duke University
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alzheimer

FDA Approvals

fda_year	fda_year_approval_count	fda_drug_name	fda_active_ingredient	fda_approval_date	fda_approved_use	fda_drug_link	fda_press_release	fda_drug_trials_snapshot	fda_2_drug_name	fda_2_active_ingredient	fda_2_dosage_form	fda_2_d
2024	22	Kisunla	donanemab-azbt	2024-07-02 00:00:00	To treat Alzheimer's disease	https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761248s000lbl.pdf	nan	nan	KISUNLA	KISUNLA (DONANEMAB-AZBT)	['INJECTABLE', 'INJECTION']	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cf/label/2024/761248s000lbl.pdf
2023	1	Leqembi	lecanemab-irmb	2023-01-06 00:00:00	To treat Alzheimer's diseasePress Release	https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761269Orig1s000lbl.pdf	https://www.fda.gov/news-events/press-announcements/ts/fda-grants-accelerated-approval-alzheimers-disease-treatment	nan	LEQEMBI	LEQEMBI (LECANEMAB-IRMB)	['INJECTABLE', 'INJECTION']	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cf/label/2023/761269Orig1s000lbl.pdf
2021	26	Aduhelm	aducanumab-awwa	2021-06-07 00:00:00	To treat Alzheimer's diseasePress ReleaseDrug Trials Snapshots	http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cf/label/2021/761178Orig1s000lbl.pdf	https://www.fda.gov/news-events/press-announcements/ts/fda-grants-accelerated-approval-alzheimers-drug	https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots/duhelm	ADUHELM	ADUHELM (ADUCANUMAB-AWWA)	['INJECTABLE', 'INJECTION']	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cf/label/2021/761178Orig1s000lbl.pdf
2020	22	Tauvid	flortaucipir F18	2020-05-28 00:00:00	Diagnostic agent for patients with Alzheimer's diseasePress ReleaseDrug Trials Snapshot	http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cf/label/2020/212123Orig1s000lbl.pdf	https://www.fda.gov/news-events/press-announcements/ts/drug-image-tau-pathology-patient-being-evaluated-alzheimers-disease	nan	TAUVID	TAUVID (FLORTAUCIPIR F-18)	['SOLUTION', 'INTRAVENOUS']	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cf/label/2020/212123Orig1s000lbl.pdf
2013	20	Vizamyl	flutemetamol F 18 injection	2013-10-25 00:00:00	A radioactive diagnostic drug for use with positron emission tomography (PET) imaging of the brain in adults being evaluated for Alzheimer's disease (AD) and dementia.Press Release	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cf/label/2013/205213Orig1s000lbl.pdf	https://www.fda.gov/news-events/press-announcements/ts/fda-grants-accelerated-approval-alzheimers-drug	nan	VIZAMYL	VIZAMYL (FLUTEMETAMOL F-18)	['INJECTABLE', 'INTRAVENOUS']	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cf/label/2013/205213Orig1s000lbl.pdf
2012	9	Amyvid	Florbetapir F 18	2012-04-06 00:00:00	Used as a radioactive diagnostic agent for Positron Emission Tomography (PET) imaging of the brain to estimate (C)-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer's Disease (AD) and other causes of cognitive decline.	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cf/label/2012/202008Orig1s000lbl.pdf	nan	nan	AMYVID	AMYVID (FLORBETAPIR F-18)	['SOLUTION', 'INTRAVENOUS']	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cf/label/2012/202008Orig1s000lbl.pdf

Number of Drugs

Entity	Number of Drugs
Eli Lilly and Company	102
Avid Radiopharmaceuticals	98
Chang Gung Memorial Hospital	88
University of Southern California	85
Pfizer	82
Novartis	78
Washington University, School of Medicine	75
Hoffmann-La Roche	72
Columbia University	68
Merck Sharp & Dohme LLC	65
Novartis Pharmaceuticals	62
Development & Commercialization, Inc.	60
Oregon Health and Science University	58
AstraZeneca	55
Brigham and Women's Hospital	52
Mayo Clinic	50
Novo Nordisk A/S	48
GE Healthcare	45
Tamming L. S. Benzinger	42
Wake Forest University Health Sciences	40
University of Arizona	38
Alzheimer's Disease Cooperative Study (ADCS)	35
Janssen Research & Development, LLC	32
University of Colorado	30
University of Michigan	28
ACADIA Pharmaceuticals Inc.	25
Molecular Neuroimaging	22
University of California, Davis	20
University of Pennsylvania	18
University of California, Los Angeles	15
University of Kansas Medical Center	12
Emory University	10
University of California, San Francisco	8
University Hospital, Toulouse	5
St. Joseph's Hospital and Medical Center, Phoenix	3
University of Pittsburgh	2
University of Illinois at Chicago	1
Kyung Hee University Hospital at Gangdong	1
Capital Medical University	1
Northwestern University	1
University Hospital, Tours	1
de la Santé Et de la Recherche Médicale, France	1
Esai Inc.	1
Massachusetts General Hospital	1
NYU Langone Health	1
Johns Hopkins University	1
University of Wisconsin, Madison	1
University of Minnesota	1

Search Term	NCT Number	Study Title	Study URL	Acronym	Study Status	Brief Summary	Study Results	Conditions	Interventions	Sponsor	Collaborators	Phases	Enrollment	Funder Type	Study Type	Start Date
[a26]	NCT05006781	The Dose Finding Study of DAOIB Added to tDCS for AD	https://clinicaltrials.gov/study/NCT05006781		SUSPENDED	This is a 26-week randomized, double-blind, placebo-controlled trial. We will enroll patients with aMCI or mild AD. All patients will receive 2 weeks of tDCS (5 sessions per week, 10 sessions in total) during the first 2 weeks of the study, and will also be allocated randomly to either of 4 treatment groups for 24 weeks: (1) Dose A group; (2) Dose B group; (3) Dose C group; (4) placebo group. We will assess the patients every 8 weeks during the treatment period (weeks 0, 10, 18, and 26). We hypothesize that augmentation with certain dose of DAOIB will yield better effect than tDCS alone in improving the cognitive function, global functioning and quality of life in patients with aMCI or mild AD.	NO	Transcranial Direct Current Stimulation	Dementia	DRUG: DAOIB	Chang Gung Memorial Hospital	PHASE2	140		OTHER	INTERVENTION
		The Dose Finding Study	https://clinicaltrials.gov/study/NCT05006781			This is a 26-week randomized, double-blind, placebo-controlled trial. We will enroll patients with aMCI or mild AD. All patients will receive 2 weeks of tDCS (5 sessions per week, 10 sessions in total) during the first 2 weeks of the study, and will also be allocated randomly to either of 4 treatment groups for 24 weeks: (1) Dose A group; (2)		Transcranial								

[a26]	NCT05006781	of DAOIB Added to tDCS for AD	pub/study/NCT05006781		SUSPENDED	Dose B group; (3) Dose C group; (4) placebo group. We will assess the patients every 8 weeks during the treatment period (weeks 0, 10, 18, and 26). We hypothesize that augmentation with certain dose of DAOIB will yield better effect than tDCS alone in improving the cognitive function, global functioning and quality of life in patients with aMCI or mild AD.	NO	Direct Current Stimulation	Dementia	DRUG: DAOIB	Chang Gung Memorial Hospital		PHASE2	140	OTHER	INTERVEN
[a26]	NCT06413849	Telephone-coached "Graphic Narrative" Bibliotherapy for Dementia Caregivers	http://clinicaltrials.gov/study/NCT06413849		NOT_YET_RECRUITING	This study aims to assess the efficacy of telephone-coached graphic narrative bibliotherapy in improving dementia caregiver depressive symptoms compared with the booklet group.	NO	Dementia Caregiver	Depressive Symptoms	Caregiving Appraisal	OTHER: Telephone coached graphic narrative bibliotherapy	OTHER: Control group	The Hong Kong Polytechnic University		NA	128
[example+9]	NCT06451952	Virtual Darkness Therapy for Agitation in Dementia	http://clinicaltrials.gov/study/NCT06451952	DARKDEM	NOT_YET_RECRUITING	Behavioral and psychological symptoms of dementia (BPSD) such as anxiety, depression, psychosis and agitation, are prevalent, often treatment resistant, resource demanding and significantly deteriorates cognition, independency, quality of life and mortality in people with dementia.The DARK.DEM trial aims at developing new diagnostics and treatment for BPSD in both specialized and municipal dementia care.The investigators will develop digital phenotyping by determining the convergent validity of data from a smartwatch against established psychometric scales for BPSD for patients admitted to NKS Olaviken gerontopsychiatric hospital.The investigators will conduct an open label single blinded randomized controlled trial to determine the effectiveness, feasibility and safety of virtual darkness as adjunctive treatment of agitation in patients with dementia admitted to the hospital. The investigators will randomize minimum 72 patients to treatment as usual (psychotropic drugs, psychological and environmental interventions) or 14	NO	Agitation in Dementia, including Alzheimer's Disease	OTHER: Virtual darkness	University of Bergen	NKS Olaviken Gerontopsychiatric Hospital	NA	72	OTHER	INTERVENTIONAL	2024-08-01

['solriamfetol']	NCT06404099	RECOVER-SLEEP: Platform Protocol, Appendix_A (Hypersomnia)	https://clinicaltrials.gov/study/NCT06404099		RECRUITING	allows comparative analysis across the interventions. For example, objectives, measures, and endpoints are generalized in the platform protocol, but intervention-specific features are detailed in separate appendices.This platform protocol is a prospective, multi-center, multi-arm, randomized controlled platform trial evaluating potential interventions for PASC-mediated sleep disturbances. The hypothesis is that symptoms of sleep and circadian disorders that emerge in patients with PASC can be improved by phenotype-targeted interventions. Specific sleep and circadian disorders addressed in this protocol include sleep-related daytime impairment (referred to as hypersomnia) and complex PASC-related sleep disturbance (reflecting symptoms of insomnia and sleep-wake rhythm disturbance).	NO	Long COVID	Long COVID-19	Hypersomnia	DRUG: Modafinil	DRUG: Modafinil Placebo	DRUG: Solriamfetol	DRUG: Solriamfetol Placebo	Duke University
['c(pmp)']	NCT06404112	RECOVER-SLEEP: Platform Protocol, Appendix_B (CPSD)	https://clinicaltrials.gov/study/NCT06404112		RECRUITING	The platform protocol is designed to be flexible so that it is suitable for a range of study settings and intervention types. Therefore, the platform protocol provides a general protocol structure that can be shared by multiple interventions and allows comparative analysis across the interventions. For example, objectives, measures, and endpoints are generalized in the platform protocol, but intervention-specific features are detailed in separate appendices.This platform protocol is a prospective, multi-center, multi-arm, randomized controlled platform trial evaluating potential interventions for PASC-mediated sleep disturbances. The hypothesis is that symptoms of sleep and circadian disorders that emerge in patients with PASC can be improved by phenotype-targeted interventions. Specific sleep and circadian disorders addressed in this protocol include sleep-related daytime impairment	NO	Long COVID	Long COVID-19	Sleep Disturbance	DRUG: Melatonin	DRUG: Melatonin Placebo	DEVICE: Tailored lighting (TL) Active	DEVICE: Tailored lighting (TL) Placebo	Duke University

[illegible]

['suv', 'florbetaben+ ((18)f', 'florbetaben+18', 'florbetaben']	NCT06474013	(Blood Brain Barrier) Disruption Using High Intensity Focused Ultrasound 'ExAblate 4000 Type 2.1' in Patients With Alzheimer's Disease	s//cli nicaltr ials.g ov/st udy/ NCT0 6474 013		NOT_YET_RECRUITING	blood brain barrier (BBB) in patients with Alzheimer's disease using the ExAblate 4000 Type 2.1, a MR guided high-intensity focused ultrasound surgical device that disrupts brain tissue.	NO	Alzheimer Disease	DEVICE: ExAblate 4000 Type 2.1	Korea University Anam Hospital		NA	15	OTHER	INTERVENTIONAL	2024-07-4
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