Gateway Neuroscience

October 29, 2024

PubChem Search: zelquistinel (NMDAR)

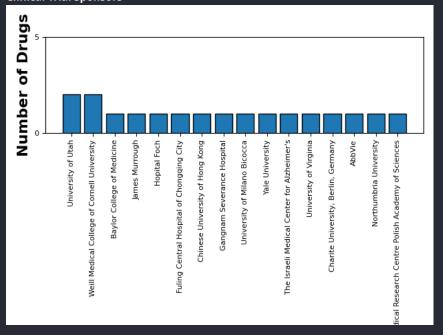
drug_name	active_ingredient	cid	sid	compound_synonyms	substance_synonyms	description	pubmed_ids	link
zelquistinel	NMDAR	132155398	[472419464, 387065541]	['Zelquistinel [WHO-DD]', 'CS-0116348', 'zelquistinel', 'Zelquistinel', 'NMDAR', 'terr-butyl (4S)-2- [(2S,3R)-1-amino-3-hydroxy-1-oxobutan-2-yl)-3-oxo-2,5-diazaspiro[3,4]octane-5-carboxylate', 'UNII-387WYR6N95', 'GATE251', 'G18567', 'HY-109164', 'DA-59265', 'MS-24891', '387WYR6N95', 'SCHEMBL19628505', '2151842-64-5', 'GATE-251', 'AGN241751', 'AGN-241751', 'CHEMBL5314944', 'Zelquistinel [INN]']	['Zelquistinel [WHO-DD]', 'GATE251', 'zelquistinel', 'NMDA RECEPTOR', 'GATE-251', 'Zelquistinel', '387WYR6N95', 'AGN241751', 'AGN-241751', '4R3XO922WS', '2151842-64- 5', 'NMDAR', 'Zelquistinel [INN]', 'N-methyl-D-aspartate receptor']			htt

NMDA

FDA Approvals

• No Approved Drugs Found

Clinical Trial Sponsors



Search Term	NCT Number	Study Title	Study URL	Acronym	Study Status	Brief Summary	Study Results	Conditions	Interventions	Sponsor	Collaborators	Phases	Enrollment	Funder Type	Stuc
						Moderate to severe									
						postoperative pain is									j
						relatively common after									i
						major abdominal surgery. It									
						is associated with less than									
						optimal surgical experience,									
						poor quality of recovery, and									
						the development of									

['example+9']	NCT06387303	Pain Control and Quality of Recovery After Intravenous Methadone Versus Intrathecal Morphine in Major Abdominal Surgery	http: nicalt rials.8 ov/st NCT0 6387 303	NOT_YET_RECRUITING	persistent postsurgical pain. Opioids remain a significant component of postoperative pain management. Side effects of opioids used for the treatment of postoperative pain include constipation, pruritus, nausea, and vomiting. Enhanced recovery after surgery (ERAS) protocols involve the utilization of multimodal analgesia. Analgesic techniques used include epidural analgesia, nerve blocks, and Intrathecal (IT) administration of morph ne. IT morphine reduces the postoperative opioid requirement for 18-24 hours after major abdominal surgery and reduces hospital length of stay (LOS) compared with epidural analgesia. A significant number of patients who receive IT morphine still experience moderate to severe postoperative p in. Additionally, many patients refuse the invasive procedure or cannot receive IT morphine due to procedure contraindications, thrombocytopenia, and/or coagulopathy.Intravenous (IV) methadone has a long analgesic half-life and has N- methyl-D-aspartate (NMDA) receptor antagonist and serotonin and norepinephrine reuptake inhibitor (SNRI) properties. It has previously been shown to reduce postoperative opioid requirements, postoperative nausea and vomiting (PONV), and postoperative spine, and cardiac surg ry. Similar findings have been shown in obstetric patients who underwent orthopedic, abdominal, complex spine, and cardiac surg ry. Similar findings have been shown in obsterir patients who underwent cesarean delivery under general anesthesia as well as patients who underwent gynecologic surgery. IV methadone has, however, never been compared with IT morphine as a postoperative analgesic. The hypothesis is that intravenous (IV) methadone is non-inferior to IT morphine is a postoperative and cardiac surg ry. Similar findings have been shown in obstetric patients who underwent gynecologic surgery. IV methadone has, however, never been compared with IT morphine as a postoperative and cardiac surg ry. Similar findings have been shown in obsterir patients who underwent gynecologic surgery. IV methadon	NO	Pain, Postoperative	DRUG: Methadone	DRUG: Morphine	University of Virginia	EARLY_PHASE1	218	отн
[ˈperampanelˈ]	NCT05786066	The Impact of AMPA Receptor Blockade on Ketamine's Anti- Suicidal Effects	http s://cli nicalt rials.g ov/st udy/ NCT0 5786 066	RECRUITING	quality of recovery after surgery. The purpose of this study is to test the hypothesis that the anti-depressant and anti- suicidal effects of the N- methyl-D-aspartate receptor (NMDAR) antagonist Ketamine is critically dependent on stimulation of Alpha-Amino-3-Hydroxy-5- Methyl-4-Isoxazole Propionic Acid receptors (AMPAR).	NO	Depressive Disorder	Major Depressive Disorder		Post Traumatic Stress Disorder	DRUG: Perampanel 6 MG	DRUG: Ketamine	DRU
					Major Depression is often resistant to treatment, and all of the currently marketed anti-depressants can cause significant side effects and may precipitate mania. The amount of this proposal is to perform a proof-of-concept RCT testing Palmitoylethanolamide (PEA)								

['3-alpha-hydroxy- 5-alpha-pregnan- 20-one', 'allopregnanolone', '3alpha-oh-dhp']	NCT06063369	PEA vs. Placebo for Major Depression	http s://cli nicalt nicals.8 NCTO 3609	PEA-01	RECRUITING	as a treatment for unipolar or bipolar depression, randomizing 100 patients to f-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-Q), 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, 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 MMDA-mediated excitatory neurotransmission. Showing that PEA-induced excitatory 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 for a role of inflammation in depression; PEA has potent immunorary effects by directly activating PPAR-q, which has a protective role against neuroinflammation by inhibition; the signaling mediated by toll-like receptor and anti-indirection and proved proved to citalopram, showing clinical improvements in patients ever randomized to receive 1200 mg/d of PEA or placebo added-on to citalopram, showin	NO		Major Depressive Disorder	DRUG: Palmitoylethanolamide	The Israeli Medical Center for Alzheimer's		PHASE2	100	ОТН
['uplizna']	NCT04372615	The ExTINGUISH Trial of Inebilizumab in NMDAR Encephalitis	http s://cli nicalt rials.g ov/st udy/ NCT0 4372 615	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. Determine the difference in	NO	Autoimmune Encephalitis	Encephalitis	DRUG: Inebilizumab	DRUG: Placebo	University of Utah		PHASE2	116

['uplizna']	NCT04372615	The EXTINGUISH Trial of Inebilizumab in NMDAR Encephalitis	http s://cli nicalt rials.g ov/st udy/ NCT0 4372 615	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
[ˈperampanelˈ]	NCT05756621	Dual Anti- glutamate Therapy in Super-refractory Status Epilepticus After Cardiac Arrest	http: nicalt rials,g ov/st: NCT0 5756 621	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 antiglutamatergic 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 particularly effective in the treatment of super-refractory SE with post-anoxic etiology. SE with post-anoxic etiology. 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 antiglutamatergic 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	Ospedaliera San Gerardo di	Azienda Ospedaliero- Universitaria di Modena	Aziei Ospi Univ Integ
['ono+2745',			http s://cli nicalt			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 (y-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', 'cns-7056']	NCT04968054	Comparison of IONM Between Remimazolam and Propofol	rials.g ov/st udy/ NCTO 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 periodo 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 anesthesia, we aim to investigate which intravenous anesthesia, we aim to investigate which intravenous anesthesia, we aim to investigate which intravenous proportate for intraoperative neurophysiological neurophysiological neurophysiological 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 s://cli rials.g ov/st udy: dy: 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]FPEB-PET) at rest and following a short pharmacological challenge with 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 for 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 [18FJPPEB-PET at rest and following short pharmacological challenges aimed at increasing glutamate and dopamine release.								
[cbd]	NCT04244058	Changes in Glutamatergic Neurotransmissior of Severe TBI Patients	http: s://cli nicalt nicalts: udy/ NCTO 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 primary controllers of the primary controllers of the primary controllers of 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 (3-118F)fluoro-542-pyridinylethynylibenzonitrile)-positron emission tomography (118F)FEB-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 depaminergic failure 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 depaminergic failure of the anterior forebrain mesocircuit.It. is unknown whether glutamatergic neurotransmission is affected across the population of subjects with poly and poly and presynaptic depaminergic failure of the anterior forebrain mesocircuit.	NO	Disorder of Consciousness	Traumatic Brain Injury	DRUG: Amantadine + L-DOPA	DRUG: NMDA blocker	Weill Medical College of Cornell University	EARLY_PHASE1 3	80

						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 [18FJFPEB-PET at rest and following short pharmacological challenges aimed at increasing glutamate and dopamine release.							
['cbd']	NCT03362879	Study Assessing Mono- and cOmbination Therapy With Levodopa-	http s://cli nicalt rials.g ov/st udy/ NCT0 3362 879	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 Press ReleaseDrug Trials	ccessdata.fda. gov/drugsatfd	ess-announcemen ts/fda-approves-fir st-oral-treatment-	https://www.ida.gov/drug s/drug-approvals-and-dat abases/drug-trials-snapsh ots-zurzuyae	71 IR71 IVAF	ZURZUVAE (ZURANOLONE)	['CAPSULE', 'ORAL']	https://\ essdata v/script: af/index ent=ove ocess&/ 217369
2019	4	Zulresso	hrevanolone	2019-03-19 00:00:00	To treat postpartum depression (PPD) in adult womenPress ReleaseDrug Trials Spanshot	cessdata.fda. gov/scripts/cd er/daf/index.c fm?event=ove	ess-announcemen ts/fda-approves-fir st-treatment-post-	https://www.fda.gov/drug s/drug-approvals-and-dat abases/drug-trials-snapsh	71 II DESSO	ZULRESSO (BREXANOLONE)	['SOLUTION',	https://i essdata v/script: af/index ent=ove ocess&/ 211371

Clinical Trial Sponsors

Novartis Pharmaceuticals Novartis Pharmaceuticals H. Lundbeck Als H. Lundbeck Als Massachusetts General Hospital Block Jacka Jac

Search Term	NCT Number	Study Title	Study URL	Acronym	Study Status		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', 'epidiolex', 'delta(1(2))-trans- cannabidiol', '(a+/-)-cannabidiol 'cbd', 'cannabidiol']	NCT0388336	Effects of Cannabidiol on Psychiatric Symptoms, Cognition, and O Cannabis Consumption in Cannabis Users With Recent- Onset Psychosis	https://clinicaltri als.gov/study/N CT03883360		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 Δ9-test and the control of	NO	Schizophrenia Spectrum Disorders	Cannabis Use	DRUG: Cannabidiol (CBD)	DRUG: Placebo	University of Maryland, Baltimore	Sh Hi
['baricitinib+(inctb028050)', 'ly+3009104', 'baricitinib+ (ly3009104, 'haricitinib+ (ly3009104, 'haricitinib+ (ly3009104), 'incb028050', 'baricitinib', 'incb028050', 'lncb028050+++,++++ly300910 'incb-028050', '17	a-propionate 'ly3009104', 'ly-3009104']	, NCT06381661	Adaptive Platform Trial for Personnalisation of Sepsis Treatment in Children and Adults: a Multi- national, Treatable Traits- guided, Adaptive, Bayesian Basket Trial	https://cli nicaltrial s.gov/stu dy/NCT0 6381661	PALETTE	NOT_YET_RECRUITING	PALETTE is a perpetual adaptive platform to efficiently study sepsis interventions within treatable traits' in allages patients enabling prompt evaluation of pandemic treatments. Treatable traits' in allages patients enabling prompt evaluation of pandemic treatments. Treatable traits, therapeutic targets didentified by phenotypes or endotypes (defined by phenotypes or endotypes (defined by phenotypes or endotypes (defined by phenotypes or endotypes or endotypes (defined by phenotypes or endotypes or endotyp	NO	Sepsis	DRUG: Tocilizumab	DRUG: Baricitinib	DRUG: Anakinra	Нуі

						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://clinicaltri als.gov/study/N CT06077526	NOT_YET_RECRUITING	Chronic Chronic Chronic Chronic 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 related to a primary diagnosis involving the musculoskeletal system, with an estimated 9.5 million visits [9]. Most ED related to a primary diagnosis involving the musculoskeletal system, with an estimated 9.5 million visits [9]. These ED related to a primary diagnosis involving the musculoskeletal system, with an estimated 9.5 million visits [9]. These to primary and preventative care, compounded by limited or no health insurance coverage [10]. Based on the Emergency Medical Treatment and Labor Att. EDs are required. Here we propuse a novel group assed intervention involving pain edustical activity options are required. Here we propuse a novel groups above intervention involving pain edustical activity options are required. Here we propuse a novel groups above in eventual to a community level hospital. The investigators will recruit 60 adults from a community hospital located in the Office of CMP on patients presenting to the ED of a community hespital located in the Shenandoah Valley region of Virginia; version of Virginia;	NO	Chronic Pain	BEHAVIORAL: P.E.A.K. RX	OTHER: Usual Care	Bridgewater	

					participants will be randomized to either Pain Education and Active Knowledge (PEAK.) 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.					
[pwv]	NCT04948489		https://clinicaltri als.gov/study/N CT04948489	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 (dinical questions and advance research on the best treatments).	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 students sevel 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://clinicaltri als.gov/study/N CT05712382	NOT_YET_RECRUITING	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 Striong identity and Coping Skills Program	https://clinicaltri als.gov/study/N CT05789446	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 wailist to receive services. The aims of this study are to: (1) confirm the efficacy of BaSICS by replicating previous findings, (2) Examine the changes 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		Chronic Stress	Anxiety	Depression	BEHAVIORAL: Building a Strong Identity and Coping Skills	Penn State University	

	i	,										
					for anxiety, depression, and							
					suicide scores,							
					changes in coping							
					mechanism, and HPA reactivity profiles							
					The goal of this clinical							$\overline{}$
					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							
		Confirmatory			randomly be enrolled							
		Efficacy of the	h		in either the					BEHAVIORAL:		
[ˈdaraˈ]	NCT05789446	Building a	https://clinicaltri als.gov/study/N	NOT_YET_RECRUITING	intervention (10) or	NO	Chronic Stress	Anxiety	Depression	Building a Strong	Penn State	
[uaia]	140103783440	Strong Identity	CT05789446		Participants enrolled in	140	CHI OHIC Stress	Allxiety	Depression	Identity and	University	
		and Coping Skills Program			the intervention group					Coping Skills		
		James Frogram			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							
					intervention groups to see if there is a							
					intervention groups to see if there is a difference in the reduction of markers							
					intervention groups to see if there is a difference in the reduction of markers for anxiety,							
					intervention groups to see if there is a difference in the reduction of markers for anxiety, depression, and							
					intervention groups to see if there is a difference in the reduction of markers for anxiety, depression, and suicide scores, changes in coping							
					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							
					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							
					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							
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					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 The goal of this clinical trial is to the efficacy of the Building a Strong Identity and							
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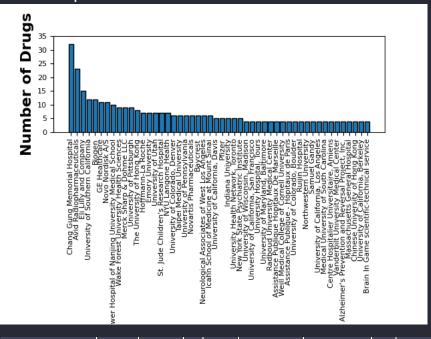
disorders and have direct effects on physiologic stress response systems (hypothalamic- pituitary-adrenal (HPA) axis), Researchers will compare the intervention and no intervention groups to		
See if there is a difference in the reduction of makers for animety, depression, and such several services of the services of	isch I Centrum Siteit van Medical Centrum Hedical Centrum Groningen	

		in their condition.Comparison Group:Researchers will compare participants receiving different types of BoNT-A products to see which one is more effective at reducing frown lines and maintaining these effects over time.The safety profiles of these products will also be compared to determine which has the fewest and least severe side effects.This study aims to fill important gaps in our understanding of Botulinum Neurotoxin Type A treatments, guiding more effective clinical decisions and improving patient outcomes.			
Olfactory and Olfactory and Olfactory and Functions in NCT06020937 Patients With Multiple Sclerosis: Case- control Study	https://clinicaltri als.gow/study/N CT06020937	The sensation of smell is influenced by the somatosensory and chemesthetic sensati-nors of the nose: for example, the cooling sensation of menthol or the prickle of carbon dioxide from carbonated drinks. These sensations are mediated in the nose by the trigeminal nerve and there is increasing evidence that trigeminal and olfactory functions are closely linked and potentially interdependent. In addition, trigeminal activation is crucial to the perception of nasal airflow. Some researchers speculate about the impact of trigeminal nerve on the entire olfactory sensation and about the presence of some specific "trigeminal RECRUITING cells" into the nose. Patients with Multiple sclerosis (MS) can suffer from quantitative olfactory disorders that generally are of light entity and do not interfere with daily life activities but it is important to underline that olfactory loss can be an onset sign of the MS. Considering the "trigeminal component" in the olfaction, because trigeminal nerve inflammation is quite common in MS patients due to central and peripheral inflammation, it could be possible that these patients suffer from changes in the quantitative, but more in the qualitative smell functions that are generally not identified because poorly investigated.	Multiple DIAGNOSTIC_TEST: Sclerosis TDI	DIAGNOSTIC_TEST: Cognitive Evaluation by Montreal Cogn Assessment	Anxiety and Visu

cognitive impairment

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	tor Positron Emission Tomography (PET) imaging of the brain to estimate β-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Altheimer Añs	https://wayba ck.archive-it.o rg//7993/2016 1022052138/ http://www.ac cessdata.fda. gov/scripts/cd er/drugsatfd a/index.cfm?f useaction=Se arch.SearchT erm=202008& SearchType=B asicSearch	nan	nan		AMYVID (FLORBETAPIR F- 18)	['SOLUTION', 'INTRAVENOUS']	https://s essdata w/scripts afont=ove ocess&/ 202008

Clinical Trial Sponsors



Search Term	NCT Number	Study Title	Study URL	Acronym	Study Status	Brief Summary	Study Results	Conditions	Interventions	Sponsor	Collaborators	Phases	Fnrollment	Funder Type	Study Type
						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									
			Π			results from "executive									
			Π			dyscontrol" or the									
						efficiency (or									
						inefficiency) with which									
						executive control									
						processes coordinate									
						other cognitive									
						processes/domains.									

The Targeted picket satisfy Study NCT05773430 NCT0577340 NCT0577	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 training, in our systematic review of 13 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 prepost experimental design of 120 adults with HAND including: 1) a Targeted Neurocognitive Training (ITM) group (n=60) to train each participant's two most impaired cognitive training improved performance in the targeted domains (e.g., attention & memory) assessed from a neurocognitive to training to determine feasibility and acceptability of the intervention. Exploratory Hypothesis: 1 Thruit improve cognitive domains (e.g., attention & memory) assessed from a neurocognitive domains (e.g., attention & memory) assessed from a neurocognitive domains (e.g., attention & memory) assessed from a neurocognitive domains (e.g., attention & memory) assessed from a neurocognitive domains (e.g., attention & memory) assessed from a neurocognitive domains (e.g., attention & memory) assessed from a neurocognitive domains (e.g., attention & memory) assessed from a neurocognitive domains (e.g., attention & memory) assessed from a neurocognitive domains (e.g., attention & memory) assessed from a neurocognitive domains (e.g., attention & memory) assessed from a neurocognitive domains (e.g., attention & memory) assessed from a neurocogniti	Cognitive Function Abnormal Training Older Adults Neurocognitive at Training 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.									
			_			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									
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						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									
			batter			training improved									
			<u>http</u> s://cli			performance in the targeted domain. In									
			nicalt			this feasibility study,									
		The Targeted	rials.g			we will assess 150				Cognitive			BEHAVIORAL:		
['efd']	NCT05773430	Neurocognitive	ov/st T	NT	SUSPENDED	PWH at baseline with	NO	HIV	Aging	Function	Cognitive	Older Adults		of Alabama	
['efd']	NCT05773430	maining (man)	ov/st udy/	NT	SUSPENDED	the expectation to	NO	HIV			Cognitive Training	Older Adults	Neurocognitive	at	
['efd']	NCT05773430	Neurocognitive Training (TNT) Study	ov/st T	NT	SUSPENDED		NO	HIV		Function		Older Adults	Neurocognitive		

	430	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 of determine feasibility of the intervention. Exploratory Aim 1 - Cognition: Compare adults who receive TNT to those 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 functioning in the targeted impaired cognitive functioning. Exploratory Hypothesis 2: TNT will reduce cognitive functioning, Exploratory Hypothesis 3: TNT will improve executive functioning, Exploratory Hypothesis 4: 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 training to target the				
		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.				
		Physical activity (PA) is essential for the prevention and treatment of chronic conditions. Despite its benefits, global physical inactivity is prevalent, contributing to chronic diseases and premature mortality. For patients with chronic kidney disease (CKD) and rheumatoid arthritis (RA), PA is particularly beneficial as it improves endothelial health, reduces cardiovascular risk, diminishes inflammation, and enhances quality of life. Given the chronic inflammation and immune system				

['pwv'] NCT0644036	htte sz//cii Physical nicals (ads.) dow./st. Actardiovascular ud/V. G440 369	PACaR NOT_YET_RECRUITING	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) Arthritis	Chronic Gidney Dysfunction Dysfunction	Arterial Exercise	OTHER: Phys Training group orier grou	ical of ity Franche-
			physical activity levels					

						cognitive function. Patient screening will begin with the identification of eligible patients in the Nephrology and Rheumatology departments. Day 0 will be the selection visit for participant information and consent. A week after Day 0, the inclusion visit and initial assessment (arterial stiffness, endotheilal function, disease impact, and blood markers for immunosenescence and inflammation, blood pressure, heart rate, PA level, quality of life, and cognitive functions) will be conducted for all patients. Next, only the patients in the experimental group will carry out a 47-minute cycling intermittent exercise session, perceived exertion assessment. They will redo the assessments after the assessments after the assessments after the assessments after the exercise. They will be another 16 sessions of supervised exercise by a health professional and a final session identical to the first for reassessment. Patients in the physical exercise program but will receive one call per week to discuss the physical exercise program but will receive one call per week to discuss the physical exercise program but will receive one call per week to discuss the physical exercise program but will receive one call per week to discuss the physical exercise program but their questions on the subject. The control group will continue								
['efd']	NCT06073717	Training Effects on Cognition in Breast Cancer Survivors: the BRAINonFIT	http: s://cli nicalt rials.g ov/st udv/ udv/ o6073 717	BRAINONFIT	RECRUITING	Ifestyle habits. The goal of this interventional study is to assess the effects of either physical exercise program or combined with cognitive training (dual motor and cognitive training program) on breast cancer survivors. The main questions it aims to answer are:* Analyze the effectiveness of a supervised dual-task training program or a physical exercise program on the executive functions of the participants.* Evaluate the impact of both interventions on physical function, physical function, physical function, and important biomarkers related to muscle-brain crosstalk, Participants will perform a 20-week supervised and controlled program, three times a week, along with weekly calorie and step challenges. Researchers will compare the dual-task training group, with the physical exercise group, and with a control group, which will perform the	NO	Breast Cancer Survivors		BEHAVIORAL: Exercise	BEHAVIORAL: Motor- cognitive Training	BEHAVIORAL: Health and Wellness	University of Seville	

					guideline recommendations of physical activity (non-supervised) to see how these intervention approaches can impact cognitive functions, physical functions, emotional aspects, and biomarkers related to muscle-brain crosstalk. Assessments will take place at three-time points: at baseline, after the intervention (20 weeks post-baseline) and after a 12-week follow-up period (32 weeks post-baseline).									
['5-isoleucine-angiotensin+ii', 'giapreza', '1-8-angiotensin+i', 'ile5-angiotensin+ii', 'isoleucine5- angiotensin+ii', 'angiotensin+ii', 'angiotensin+ii,'5-l-isoleucine-', 'ijpc-501', '5-l- isoleucineangiotensin+ii']	NCT05826912	Multi-Arm Multi-Stage Adaptive Platform Trial (APT) for the Acute Treatment of Traumatic Brain Injury	http s://cli nicalt rials.s uvdy. NCTO 5826 912	"BI-01 NOT_YET_RECRUITIN	The purpose of this study is to determine if experimental drug treatment improves recovery after TBI as compared to a control (placebo) group. Changes in recovery will be measured if throughout the study. The study drugs listed below are approved by the U.S. Food and Drug Administration (FDA) but are being used "off-label" in this study. This means that the drugs are not currently approved to treat TBI.	NO	Traumatic Brain Injury	DRUG: Atorvastatin Calcium	DRUG: Minocycline Hydrochloride	DRUG: Candesartan Cilexetil	DRUG: Placebo	University of California, San Francisco	United States Department of Defense	PHASE2
['baricitinib+(incb028050)', "ly+3009104', "Jak-iinhibitors:+baricitinib', "baricitinib+ (ly3009104,+incb028050)', "baricitinib', 'baricitinib+ (ly3009104)', incb028050', "incb028050++++++++Jy3009104', 'olumiant', 'incb+028050', 'incb- 028050', 'ly3009104', 'ly- 3009104']	NCT06439615	Baricitinib for the Lung Injury Following Spontaneous SAH	httip s://cli nicalt rials.g ov/st Buss udy/ NCT0 6439 615	S NOT_YET_RECRUITING	The present study is a randomized, parallel control, and double-blind trial designed to assess the efficacy of baricitinib in reducing the occurrence of pulmonary complications in patients with spontaneous subarachnoid hemorrhage (SAH). The research protocol incorporates an adaptive design, allowing for modifications to key elements such as the sample size enrolled during interim analysis.	NO	Spontaneous Subarachnoid Hemorrhage	Baricitinib 4	OTHER: Standard treatment	Tang-Du Hospital		PHASE2	100	OTHER
['Vis']	NCT05992831	Transcranial Magnetic Stimulation for MCI	http s://cli nicalt nials.8 pusy/ NCTO 5992 831	12 RECRUITING	The goal of this phase II study is to establish the dose-response curves of a safe and clinically feasible non-invasive brain stimulation technique (accelerated Transcranial Magnetic Stimulation (TMS)) to improve both depression and cognitive function in Mild Cognitive Impairment (MCI) patients with comorbid depression. It is known that TMS can effectively treat depression. Identifying the right dose of accelerated TMS in MCI patients is necessary prior to designing subsequent trials to determine efficacy. These results will inform future clinical trials of accelerated TMS for MCI, with the long-term goal of developing an efficacious treatment to prevent dementia. The goal of this phase II study is to establish the dose-response curves of a safe and	NO	Mild Cognitive Impairment	Depression	DEVICE: Accelerated iTBS	DEVICE: Sham Comparator	Medical University of South Carolina	National Institute on Aging (NIA)		60

[vis']	NCT05992831	Transcranial Magnetic Stimulation for MCI	http s://cli nicalt rials,8 u/dy/ NCT0 5992 831	PUSH2	RECRUITING	clinically feasible non- invasive brain stimulation technique (accelerated Transcranial Magnetic Stimulation (TMS)) to improve both depression and cognitive function in Mild Cognitive Impairment (MCI) patients with comorbid depression. It is known that TMS can effectively treat depression. Identifying the right dose of accelerated TMS in MCI patients with is necessary prior to designing subsequent trials to determine efficacy. These results will inform future clinical trials of accelerated TMS for MCI, with the long-term goal of developing an efficacious treatment to prevent dementia. The platform protocol	NO	Mild Cognitive Impairment	Depression	DEVICE: Accelerated ITBS	DEVICE: Sham Comparator	Medical University of South Carolina	National Institute on Aging (NIA)	NA	60
['c(pmp)']	NCT06404112	RECOVER- SLEEP: Platform Protocol, Appendix_B (CPSD)	http: s://cli nicals, 8 ros/st udy/. NCTO 112		RECRUITING	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-center, 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 addressed interventions. Specific sleep and circadian disorders addressed interventions. Specific sleep and circadian disorders addressed interventions for PASC-and 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 hythm disturbance).	NO	Long COVID	Long COVID- 19	Sleep Disturbance	DRUG: Melatonin	DRUG: Melantonin Placebo		Tailored	Duke University
						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									

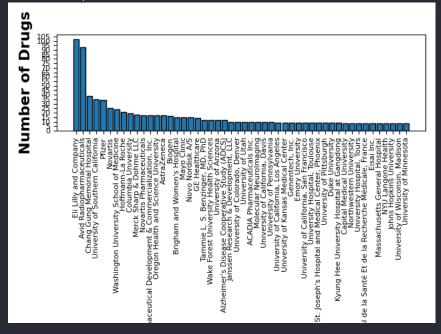
['sol	riamfetol']	NCT06404099	Platform	http: s://cli rials.s ov/st udy/ NCTO 6404 099	RECRUITING	interventions. For example, objectives, measures, and endpoints are generalized in the platform protocol, but intervention-specific features are detailed in separate appendices. This platform protocol is 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: Moddfinil Placebo	DRUG: Solriamfetol		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.a ccessdata.fda. gov/drugsatfd a_docs/label/ 2024/761248s 000lbl.pdf	nan	nan	KISUNLA	KISUNLA (DONANEMAB- AZBT)	['INJECTABLE', 'INJECTION']	https://\ essdata v/scripts af/index ent=ove ocess&/ 761248
2023	1	Leqembi	lecanemab-irmb	2023-01-06 00:00:00	To treat Alzheimer,Äôs diseasePress Release	https://www.a ccessdata.fda. gov/drugsatfd a_docs/label/ 2023/761269 Orig1s000lbl. pdf	https://www.fda.g ov/news-events/pr ess-announcemen ts/fda-grants-accel erated-approval-al zheimers-disease- treatment	nan	LEQEMBI	LEQEMBI (LECANEMAB- IRMB)	['INJECTABLE', 'INJECTION']	https://\ essdata v/scripts af/index ent=ove ocess&/ 761269
2021	26	Aduhelm	aducanumab-avwa	2021-06-07 00:00:00	To treat Alzheimer,Äôs diseasePress ReleaseDrug Trials Snapshots	http://www.ac cessdata.fda. gov/scripts/cd er/daf/index.c fm?event=ove rview.proces s&varApplNo =761178	https://www.fda.g ov/news-events/pr ess-announcemen	s/drug-approvals-and-dat	ADUHELM	ADUHELM (ADUCANUMAB-AVWA)	['INJECTABLE', 'INJECTION']	https://s essdata v/scripts af/index ent=ove ocess&/ 761178
2020	22	Tauvid	flortaucipir F18	2020-05-28 00:00:00	Diagnostic agent for patients with Alzheimer,Äôs diseasePress ReleaseDrug Trials Snapshot	http://www.ac cessdata.fda. gov/scripts/cd er/daf/index.c fm?event=ove rview.proces s&varApplNo =212123	https://www.fda.g ov/news-events/pr ess-announcemen ts/fda-approves-fir st-drug-image-tau- pathology-patient s-being-evaluated- alzheimers-diseas e	nan	TAUVID	TAUVID (FLORTAUCIPIR F-18)	['SOLUTION', 'INTRAVENOUS']	https://\ essdata v/scripts af/index ent=ove ocess&/ 212123
2013	20	Vizamyl	flutemetamol F 18 injection	2013-10-25 00:00:00	Afradioactive 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://wayba ck.archive-it.o rg//7993/2016 1022052135/ http://www.ac cessdata.fda. gow/scripts/cd er/drugsatfd a/index.cfm?f useaction=Se arch.SearchAc tion&searchT erm=203137& SearchType=B asicSearch	https://wayback.ar chive-it.org///799 3/2016102205213 5/http://www.fda. gov/NewsEvents/ Newsroom/PressA nnouncements/uc m372261.htm	nan	VIZAMYL	VIZAMYL (FLUTEMETAMOL F-18)	['INJECTABLE', 'INTRAVENOUS']	https://\ essdata v/script: af/index ent=ove ocess&/ 203137
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 Œs-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer Aôs Disease (AD) and other Causes of cognitive decline.	https://wayba ck.archive-it.o re//7993/2016 1022052138/ http://www.ac cessdata.fda. gov/scripts/cd er/drugsatfd afindes.cfm7/ useaction=5e arch.SearchAr tion&search1 erm=202008& SearchIype=B asicSearch	nan	nan	AMYVID	AMYVID (FLORBETAPIR F- 18)	['SOLUTION', 'INTRAVENOUS']	https://a essdata v/scripti af/index ent=ove ocess&/ 202008

Clinical Trial Sponsors



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 Dai
[a26]	NCT05006781	The Dose Finding Study of DAOIB Added to tDCS for AD	http. s://cli nicalt rials.g udy/ NS006 781		SUSPENDED	This is a 26-week randomized, double-blind, placebo-controlled trial. We will enroll patients with aMCl or mild AD. All patients with aMCl 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 functioning and quality of life in patients with aMCl or mild AD.	NO	Transcranial Direct Current Stimulation		DRUG: DAOIB	Chang Gung Memorial Hospital		PHASE2	140	OTHER	INTERVE
		The Dose Finding Study	http s://cli nicals,g			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 random via the treatment groups for 24 weeks; (1) Dose A group; (2)		Transcranial								

[a26]	NCT05006781	of DAOIB Added to tDCS for AD	ov/st udy/ NCT0 5006 781	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 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
[ˈə26ˈ]	NCT06413849	Telephone- coached "Graphic Narrative" Bibliotherapy for Dementia Caregivers	http s://cli nicalt rials.g ov/st udy/ NCTO 6413 849	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 Darkrapsy for Agitation in Dementia	http s://cli nicalt nov.st udy/ NCT0 952	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 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	NO	Agitation in Uncluding Alzheimer's Disease	OTHER: Virtual darkness	University of Bergen	NKS Olaviken Gerontopsychiatric Hospital	NA .	72	OTHER	INTERVENTIONAL	2024-08-(

						days of virtual darkness therapy, that is, exposure to light deprived of blue wavelengths from 19.00-08.00, provided in a secluded patient unit with circadian lightening. Primary outcome is 14 days change in agitation assessed with Cohen-Mansfield Agitation Inventory. Secondary outcomes are change in diurnal variation of motor activity assessed with a smartwatch, other BPSD, activities of daily living, quality of life, use of psychotropic drugs, use of restraints and coercion, length of hospital stay and resource utilization. The investigators will conduct focus group interviews with managers and staff in nursing homes to explore barriers, enablers and adaptions to support implementation of the new methods in municipal dementia care										
['vis']	NCT05992831	Transcranial Magnetic Stimulation for MCI	http s://cli nicalt rials.8 v.dy/. NCT0 5992 831	PUSH2	RECRUITING	The goal of this phase II study is to establish the dose-response curves of a safe and clinically feasible non-invasive brain stimulation technique (accelerated Transcranial Magnetic Stimulation (TMS)) to improve both depression and cognitive function in Mild Cognitive Impairment (MCI) patients with comorbid depression. It is known that TMS can effectively treat depression. Identifying the right dose of accelerated TMS in MCI patients is necessary prior to designing subsequent trials to determine efficacy. These results will inform future clinical trials of accelerated TMS for MCI, with the long-term goal of developing an efficacious treatment to prevent dementia. The platform	NO	Milid Cognitive Impairment	Depression	DEVICE: Accelerated iTBS	DEVICE: Sham Comparator	Medical University of South Carolina	National Institute on Aging (NIA)	NA .	60	OTHER
						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										

['solriamfetol']	NCT06404099	RECOVER- SLEEP: Platform Protocol, Appendix_A (Hypersomnia)	http: s://cli nicalt rials.8 ov/st udy/. NCT0 6404 099	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 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: Soiriamfetol	Duke University	
['c(pmp)']	NCT06404112	RECOVER- SLEEP: Platform Protocol, Appendix_B (CPSD)	http. s://cli nicati rials.8 udv/.0 NCT0 112	RECRUITING	The platform protocol is designed to be flexible so that it is suitable for a range of study settlings 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	Sieep Disturbance	DRUG: Melatonin	DRUG: Melantonin Placebo	Tailored lighting (TL)	Duke University	

['suv', 'florbetaben+ ((18)f)', 'florbetaben+f+18', 'florbetaben']	NCT06474013	A Clinical Trial to Evaluate the Initial Safety and Efficacy of Repetitive BBB (Blood Brain Barrier) Disruption Using High Intensity Focused Ultrasound 'ExAblate 4000 Type 2.1' in Patients With Alzheimer's Disease	nicalt rials.g ov/st udy/ NCT0 6474	NOT_YET_RECRUITING	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-(
['example+9']	NCT06042413	Prediction and Prevention of Postoperation Morbidity Morbidity	rials.g	NOT_YET_RECRUITING	health. This study will explore two main hypotheses: 1. Preoperative prehabilitation and proactive cognitive/behavioral interventions will effectively improve postoperative cognitive outcomes, morbidities, and mortality, and; 2. The proactive bundled interventions are superior to current standard of care in reducing postoperative cognitive outcomes, MACCE and mortality. Expected Outcome: Improved EHR algorithm will have higher predictive accuracy for MACCE and mortality while predicting postoperative cognitive outcomes.	NO	Alzheimer Disease	Alzheimer Disease Related Dementias	OTHER: Personalized CPC Prehabilitation	BEHAVIORAL: Cognitive Training	BEHAVIORAL: Meditation	BEHAVIORAL: Daily Exercise	BEHAVIORAL: Enhanced Social Support	OTHER: Proactive Bundle Interventions	PROCEDIC Pre-opers Standard
		Safety and Efficacy of Repetitive BBB	<u>http</u>		evaluate the initial safety and efficacy of opening the										

['suv', 'florbetaben+ ((18)f)', 'florbetaben+f+18' 'florbetaben']	NC106474013	Barrier) Disruption Using High Intensity Focused	s://cli nicalt rials.g ov/st udy/ NCTO 6474 013			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-(
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