工作记忆训练对精神分裂症患者执行功能效果的再思考：一项机器学习研究

下载XML文档

注册号: Registration number:	ChiCTR2500109018
最近更新日期: Date of Last Refreshed on:	2025-09-10
注册时间: Date of Registration:	2025-09-10
注册号状态:	补注册
Registration Status:	Retrospective registration
注册题目:	工作记忆训练对精神分裂症患者执行功能效果的再思考：一项机器学习研究
Public title:	Rethinking the Effects of Working Memory Training on Executive Functions in Schizophrenia: A Machine Learning Approach
注册题目简写:	
English Acronym:	
研究课题的正式科学名称:	工作记忆训练对精神分裂症患者执行功能效果的再思考：一项机器学习研究
Scientific title:	Rethinking the Effects of Working Memory Training on Executive Functions in Schizophrenia: A Machine Learning Approach
研究课题代号(代码): Study subject ID:	
在二级注册机构或其它机构的注册号: The registration number of the Partner Registry or other register:	

申请注册联系人:	张统一	研究负责人:	赵鑫
Applicant:	Tongyi Zhang	Study leader:	Xin Zhao
申请注册联系人电话: Applicant telephone:	+86 136 2619 0241	研究负责人电话: Study leader's telephone:	+86 139 1942 5826
申请注册联系人传真 : Applicant Fax:		研究负责人传真: Study leader's fax:	
申请注册联系人电子邮件: Applicant E-mail:	psyzhaoxin@nwnu.edu.cn	研究负责人电子邮件: Study leader's E-mail:	psyzhaoxin@nwnu.edu.cn
申请单位网址(自愿提供): Applicant website(voluntary supply):	https://www.nwnu.edu.cn/	研究负责人网址(自愿提供): Study leader's website(voluntary supply):	https://www.nwnu.edu.cn/
申请注册联系人通讯地址:	中国甘肃省兰州市安宁东路967号	研究负责人通讯地址:	中国甘肃省兰州市安宁东路967号
Applicant address:	No.967, Anning East Road, Lanzhou City, Gansu Province, China	Study leader's address:	No.967, Anning East Road, Lanzhou City, Gansu Province, China
申请注册联系人邮政编码: Applicant postcode:	730070	研究负责人邮政编码: Study leader's postcode:	730070
申请人所在单位:	西北师范大学		
Applicant's institution:	Northwest Normal University		
研究负责人所在单位:	西北师范大学		
Affiliation of the Leader:	Northwest Normal University		

是否获伦理委员会批准:	是		
Approved by ethic committee:	Yes		
伦理委员会批件文号: Approved No. of ethic committee:	伦研批第(NWNU202405)号	伦理委员会批件附件: Approved file of Ethical Committee:	查看附件View

批准本研究的伦理委员会名称：	西北师范大学心理学院伦理委员会
Name of the ethic committee：	Northwest Normal University School of Psychology Ethics Committee
伦理委员会批准日期： Date of approved by ethic committee：	2024-04-27
伦理委员会联系人：	周爱保
Contact Name of the ethic committee：	Aibao Zhou
伦理委员会联系地址：	中国甘肃省兰州市安宁东路967号
Contact Address of the ethic committee：	No.967, Anning East Road, Lanzhou City, Gansu Province, China
伦理委员会联系人电话： Contact phone of the ethic committee：	+86 931 797 5316
伦理委员会联系人邮箱： Contact email of the ethic committee：	psychology@nwnu.edu.cn

研究实施负责（组长）单位：	西北师范大学
Primary sponsor：	Northwest Normal University
研究实施负责（组长）单位地址：	中国甘肃省兰州市安宁东路967号
Primary sponsor's address：	No.967, Anning East Road, Lanzhou City, Gansu Province, China

试验主办单位(项目批准或申办者)： Secondary sponsor：	国家：	中国	省(直辖市)：	甘肃	市(区县)：	兰州
	Country：	China	Province：	GanSu	City：	Lanzhou
	单位(医院)：	兰州市第三人民医院	具体地址：	甘肃省兰州市七里河区建兰新村130号		
	Institution hospital：	The Third People's Hospital of Lanzhou	Address：	No.130, Jianlan Xincun, Qilihe District, Lanzhou City, Gansu Province, China		

经费或物资来源：	国家自然科学基金
Source(s) of funding：	National Natural Science Foundation of China
研究疾病：	精神分裂症
Target disease：	Schizophrenia
研究疾病代码：	F20.9
Target disease code：	F20.9
研究类型：	干预性研究
Study type：	Interventional study
研究所处阶段：	其它
Study phase：	N/A
研究设计：	随机平行对照
Study design：	Parallel
研究目的：	本研究旨在评估自适应工作记忆训练对精神分裂症患者执行功能的改善效果，并使用机器学习方法量化患者执行功能谱沿精神病-健康连续体的变化。主要目的包括：(1)评估自适应N-back工作记忆训练相比于非自适应训练和常规治疗在改善精神分裂症患者执行功能方面的疗效；(2)使用支持向量机分类器量化干预后患者执行功能谱向健康对照组谱系的转移程度；(3)通过整合因果推断与机器学习方法，识别预测治疗反应的基线因素，为精准精神医学和个体化认知干预提供科学依据。
Objectives of Study：	This study aims to evaluate the efficacy of adaptive working memory training on executive functions in patients with schizophrenia and quantify changes in executive function profiles along the psychosis-health continuum using machine learning approaches. The primary objectives include: (1) to assess the effectiveness of adaptive N-back working memory training compared to non-adaptive training and treatment-as-usual in improving executive functions in schizophrenia patients; (2) to quantify the degree to which patients' executive function profiles shift toward those of healthy controls following intervention using support vector machine classifiers; (3) to identify baseline predictors of treatment response by integrating causal inference with machine learning methods, thereby providing scientific evidence for precision psychiatry and individualized cognitive interventions.
药物成份或治疗方案详述：	
Description for medicine or protocol of treatment in detail：	
纳入标准：	(1) 年龄在 18–65 岁之间； (2) 由两名住院精神科医师根据《国际疾病分类》第十版（ICD-10）标准（F20.9）诊断为精神分裂症，并经《精神障碍诊断与统计手册》结构化临床访谈（SCID）进一步确认； (3) 临床病情稳定，定义为在连续 6 周内使用同一类抗精神病药物维持治疗，总 PANSS（阳性与阴性症状量表）评分变化小于 20%； (4) 具有充分的认知和交流能力，能够完成实验任务，并自愿签署知情同意书。
Inclusion criteria	(1) Age between 18 and 65 years; (2) Diagnosis of schizophrenia established by two resident psychiatrists according to the International Classification of Diseases, 10th Revision (ICD-10) criteria (F20.9), and further confirmed with the Structured Clinical Interview for DSM (SCID); (3) Clinically stable, defined as receiving the same type of antipsychotic medication at a maintenance dose for at least six consecutive weeks, with less than a 20% change in total Positive and Negative Syndrome Scale (PANSS) score; (4) Sufficient cognitive and communicative ability to complete experimental tasks and voluntarily provide written informed consent.
排除标准：	(1) 存在严重躯体疾病，如严重心血管或脑血管疾病、癫痫、恶性肿瘤等； (2) 矫正视力低于 0.8； (3) 长期使用影响认知功能的药物（如苯二氮卓类、抗组胺药、抗胆碱药、镇静剂）或有酒精滥用史； (4) 抗精神病药物剂量超过奥氮平当量 35 mg/日； (5) 出现明显的锥体外系副作用或其他可能影响行为任务执行的严重不良反应； (6) 有器质性脑损伤史，如外伤性脑损伤或脑血管疾病； (7) 入组前 6 个月内存在物质滥用； (8) 入组前 3 个月内参与过其他临床研究。

Exclusion criteria:	(1) Presence of severe physical illnesses, such as major cardiovascular or cerebrovascular diseases, epilepsy, or malignant tumors; (2) Corrected visual acuity below 0.8; (3) Long-term use of medications known to impair cognitive function (e.g., benzodiazepines, antihistamines, anticholinergics, sedatives) or a history of alcohol abuse; (4) Antipsychotic medication dosage exceeding the olanzapine-equivalent of 35 mg/day; (5) Prominent extrapyramidal symptoms or other severe adverse drug reactions that may interfere with the performance of behavioral tasks; (6) History of organic brain injury, such as traumatic brain injury or cerebrovascular disease; (7) Substance abuse within six months prior to enrollment; (8) Participation in other clinical studies within three months prior to enrollment.

研究实施时间: Study execute time:	从 From 2024-05-01至 To 2024-10-15	征募观察对象时间: Recruiting time:	从 From 2024-05-05 至 To 2024-07-31

干预措施:
Interventions:

组别:	自适应N-back工作记忆训练组	样本量:	48
Group:	Adaptive N-back Working Memory Training Group	Sample size:	
干预措施:	自适应N-back工作记忆训练	干预措施代码:	ANWMT
Intervention:	Adaptive N-back Working Memory Training	Intervention code:	
组别:	非自适应1-back对照组	样本量:	48
Group:	Non-adaptive 1-back Control Group	Sample size:	
干预措施:	非自适应1-back训练	干预措施代码:	N1BT
Intervention:	Non-adaptive 1-back Training	Intervention code:	
组别:	常规治疗组	样本量:	48
Group:	Treatment-as-Usual Group	Sample size:	
干预措施:	常规治疗	干预措施代码:	TAU
Intervention:	Treatment as Usual	Intervention code:	

研究实施地点:
Countries of recruitment and research settings:

国家:	中国	省(直辖市):	甘肃	市(区县):	兰州
Country:	China	Province:	Gansu	City:	Lanzhou
单位(医院):	兰州市第三人民医院	单位级别:	三甲		
Institution hospital:	The Third People's Hospital of Lanzhou	Level of the institution:	Tertiary A		

测量指标:
Outcomes:

指标中文名:	执行功能综合评估	指标类型:	主要指标
Outcome:	Executive Function Composite Assessment	Type:	Primary indicator
测量时间点:	基线和干预后	测量方法:	基于E-Prime 3.0软件平台的计算机化执行功能测试，包括工作记忆更新任务、数字广度倒背任务、Stroop任务、Go/No-Go任务、数字转换任务的综合评估
Measure time point of outcome:	Baseline and post-intervention	Measure method:	Computerized executive function assessment based on E-Prime 3.0 software platform, including running-memory updating task, digit span backward task, Stroop task, Go/No-Go task, and number-switching task
指标中文名:	PANSS临床量表	指标类型:	主要指标
Outcome:	PANSS Clinical Scale	Type:	Primary indicator
测量时间点:	基线和干预后	测量方法:	基于精神科医师访谈的阳性和阴性症状量表评估
Measure time point of outcome:	Baseline and post-intervention	Measure method:	Assessment based on psychiatrist interviews using Positive and Negative Syndrome Scale

采集人体标本:
Collecting sample(s) from participants:

标本中文名:	无	组织:	
Sample Name:	none	Tissue:	
人体标本去向	使用后销毁	说明	
Fate of sample:	Destruction after use	Note:	

征募研究对象情况: Recruiting status:	结束 /Completed	年龄范围: Participant age:	最小 Min age 18 岁 years 最大 Max age 65 岁 years
性别:	男女均可	Gender:	Both
随机方法（请说明由何人用什么方法产生随机序列）:	由研究统计学家使用计算机生成的随机数字表产生随机序列，按1:1:1比例将144名参与者随机分配到三个组别		

Randomization Procedure (please state who generates the random number sequence and by what method)：	Random sequence generated by study statistician using computer-generated random number table, with 144 participants randomly allocated to three groups in a 1:1:1 ratio
是否公开试验完成后的统计结果：Calculated Results after the Study Completed public access：	公开/Public
盲法：	单盲研究，参与者对分组情况保持盲态；数据分析人员知晓分组情况，但不参与临床评估或干预。
Blinding：	This was a single-blind study: participants were blinded to group allocation, while data analysts were aware of group assignment but did not participate in clinical assessments or intervention procedures.
试验完成后的统计结果（上传文件）：	点击下载
Calculated Results after the Study Completed(upload file)：	download
是否共享原始数据：IPD sharing	是Yes
共享原始数据的方式（说明：请填入公开原始数据日期和方式，如采用网络平台，需填该网络平台名称和网址）：	研究数据将在相关论文正式发表后开放共享。研究者可通过电子邮件联系通讯作者（psyzhaoxin@nwnu.edu.cn）申请获取。
The way of sharing IPD”(include metadata and protocol, If use web-based public database, please provide the url)：	The research data will be made openly available upon the formal publication of the related paper. Researchers may request access by contacting the corresponding author via email (psyzhaoxin@nwnu.edu.cn).
数据采集和管理（说明：数据采集和管理由两部分组成，一为病例记录表(Case Record Form, CRF)，二为电子采集和管理系统(Electronic Data Capture, EDC)，如ResMan即为一种基于互联网的EDC：	使用标准化病例记录表(CRF)收集数据，采用SPSS和Python进行电子数据管理和分析。所有数据均进行双人录入验证以确保准确性
Data collection and Management (A standard data collection and management system include a CRF and an electronic data capture：	Data collected using standardized Case Record Forms (CRF) with electronic data management and analysis conducted using SPSS and Python. All data underwent double entry verification to ensure accuracy
数据与安全监察委员会：Data and Safety Monitoring Committee：	无/No

返回列表