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Project audit state：The Task Is Successful.

*填写语言 Language	中文和英文-Chinese And English		
注册号信息 Registration Status	补注册Retrospective registration		
*注册题目	改善小儿雾化吸入治疗设备机械人护理的应用		
*Public title	Application of Improved Clean Care in Nebulization Inhalation Nursing in Pediatric Outpatient Clinics		
注册题目英文			
English Acronym			
*研究题目正式中文名称	改善小儿雾化吸入机械人护理的应用		
*Scientific title	Application of Improved Clean Care in Nebulization Inhalation Nursing in Pediatric Outpatient Clinics		
研究题目正式英文名称			
Scientific title acronym			
研究题目代号(项目缩写) Study subject ID			
临二项目登记号或其它机构的注册号			
The registration number of the Partner Registry or other registers			
*申请者姓名	高俊	*研究负责人	高俊
*Applicant	Jun Wu	*Study leader	Jun Wu
*申请者固定电话 Applicant's telephone	+86 130 2111 2628 请输入国际区号+86+area 区号不带0之间加空一个空格 Please enter the phone area code such as +86 xxx and add a space between the area code and the number	研究负责人电话 Study leader's telephone	+86 137 3813 8313 请输入国际区号+86+area 区号不带0之间加空一个空格 Please enter the phone area code such as +86 xxx and add a space between the area code and the number
	For public date: Please provide a work phone number		For public date: Please provide a work phone number
*申请者固定人传真号		研究负责人传真号	
*申请者固定人电子邮件 Applicant's E-mail	junwu0311@163.com	*研究负责人电子邮件 Study leader's E-mail	junwu0311@163.com
申请者网址(如果有的) Applicant's website(if exists)		研究负责人网址(如果有的) Study leader's website(if exists)	
*申请者联系人通讯地址	中国浙江省杭州市余杭区文一西路 1367 号	*研究负责人通讯地址	中国浙江省杭州市余杭区文一西路 1367 号
*Applicant's address	No. 1367, Wenyi West Road, Yuhang District, Hangzhou, Zhejiang Province, China	*Study leader's address	No. 1367, Wenyi West Road, Yuhang District, Hangzhou, Zhejiang Province, China
*申请者联系人邮政编码 Applicant's postcode		研究负责人邮政编码 Study leader's postcode	
*申请人所在单位	浙江大学医学院附属第一医院	*研究负责人所在单位	浙江大学医学院附属第一医院
*Affiliation of the Registrant	The First Affiliated Hospital, Zhejiang University School of Medicine	*Affiliation of the Leader	The First Affiliated Hospital, Zhejiang University School of Medicine
*是否经过伦理委员会批准 Approved by ethic committee	否 No	正在等待 Waiting	
*应提供伦理批件文件 Approved file of ethic committee	第大一院伦审2021研第(30)号-修-(2020CZ)FT Ethics	*应提交伦理批件的 Approved file of Ethical Committee	正在等待 Waiting 请填写研究组长的有伦理批件附置的非法人等（证券、营业、修正案、跟踪审查程序）
*伦理委员会的名称 Name of the ethics committee	浙江大学医学院附属第一医院IT伦理委员会		
	IT Ethics Committee of the First Affiliated Hospital, Zhejiang University School of Medicine		
*伦理委员会批准日期 Date of approval by ethic committee	2025-04-07		
*伦理委员会联系人	吕君娟		
*Contact Name of the ethics committee	Laiyin Lv		
*伦理委员会联系地址	中国浙江省杭州市余杭区文一西路 1367 号		
*Contact Address of the ethics committee	No. 1367, Wenyi West Road, Yuhang District, Hangzhou, Zhejiang Province, China		
*伦理委员会联系人电话 Contact phone of the ethics committee	+86 571 8723 3419 请输入国际区号+86+area 区号不带0之间加空一个空格 Please enter the phone area code such as +86 xxx and add a space between the area code and the number	伦理委员会联系人邮箱 Contact email of the ethics committee	
国家食品药品监督管理局批件号 Approved file	当年日期	日期格式(Approved file)	上传附件 Upload
国家食品药品监督管理局批件日期 Date of approved	当年日期	日期格式(Approved file)	上传附件 Upload
研究计划书 Study plan file	已上传附件 Attachment（说明不填写，不上传不产生审核流程 Upload the attachment if necessary, it will not be published） 上传与伦理审查时提交的最新版研究计划书		
知情同意书 Informed consent file	已上传附件 Attachment（说明不填写，不上传不产生审核流程 Upload the attachment if necessary, it will not be published） 上传与伦理审查时提交的最新版知情同意书，若无知情时填写，请上传时间相同或最新版知情同意书		
*研究实施负责机构(主要) Primary sponsor	浙江大学医学院附属第一医院		
	The First Affiliated Hospital, Zhejiang University School of Medicine		
*研究实施负责机构所在地区 Primary sponsor's address	中国浙江省杭州市余杭区文一西路 1367 号		
	No. 1367, Wenyi West Road, Yuhang District, Hangzhou, Zhejiang Province, China		
研究机构代码 Study code	*国家 Country: 中国	*标准国家 Country: 浙江	市(区县) City: 杭州
	每增加一条可一个单位(实时) Input only one institution	*具体地址 City: HangZhou	
	*单位 Institution: 浙江大学医学院附属第一医院	*具体地址 Address: 中国浙江省杭州市余杭区文一西路 1367 号	
	*机构名称英文 Institution: The First Affiliated Hospital, Zh	*具体地址 Address: No. 1367, Wenyi West Road, Yuhang District, Hangzhou, Zhejiang Province, China	
研究者所属单位 Sponsor's address	Input only one institution		
研究者所属单位 Sponsor's address	无		
	None		
*研究类别 Study type	呼吸道感染	研究类别代码 Study code	
*Target disease	Respiratory tract infections	Target disease code	
*研究阶段 Study type	干预性研究Interventional study	*研究设计 Study design	随机平行对照Parallel
*研究目的 Study phase	其它N/A		
*研究目的	1. 研究优质小流量氧流量对小儿雾化吸入护理中的操作可行性。 2. 评估优质小流量氧流量对小儿雾化吸入人教虎情绪的影响效果。 3. 分析优质小流量氧流量对小儿雾化吸入依从性的效果。		
*Objectives of Study	1.To explore the operational feasibility of modified clown therapy in nebulization inhalation nursing for pediatric outpatients. 2.To evaluate the effect of modified clown therapy on alleviating anxiety in children and their guardians. 3.To analyze the role of modified clown therapy in improving children's compliance with nebulization treatment.		
药物/器械/疗法干预措施			
Description for medicine or product of treatment in detail			
*纳入标准	1、年龄：2-7岁门诊哮喘患儿。 2、上下呼吸道感染。 3、神智清醒，具有一定的认知能力，且视觉、听觉正常。 4、意识可保更加行要化治疗。 5、同一个医师连续护理四次及疗程要求治疗		
Inclusion criteria	1.Age: Outpatient children aged 2-7 years. 2.Upper/lower respiratory tract infection. 3.Clear consciousness, with certain cognitive abilities, and normal vision and hearing. 4.First-time nebulization treatment (or first nebulization treatment in the past year). 5.Diagnosis and treatment provided by the same physician and nursing team throughout the entire process.		
*排除标准	1、认知障碍或意识障碍不清楚。 2、重心低上治疗用以前。 3、重度病状，合并呼吸衰竭者。 4、同时伴有心、肾等其它器官损害不全或其他疾病等。 5、排除健康或病毒所致（口腔溃疡、感染、上呼吸道、长期使用其它治疗药物的患者		
Exclusion criteria	1.Participants with cognitive impairment or congenital dyslexia. 2.Participants with allergies to drugs used in nebulization inhalation therapy. 3.Participants with severe pneumonia complicated by respiratory failure. 4.Participants with concurrent insufficiency of other organs (e.g., heart, liver, kidney) or other comorbid diseases. 5.Participants receiving long-term medications other than those for respiratory tract infection (e.g., oral antibiotics.		
*研究实施时间 Study execute time	2025-04-01 2025-06-30	*征募受试者时间段 Recruiting time	2025-04-14 2025-06-23 注意：如果是要求最大值，填写未来时间，如开始日期，结束时间，如果是要求最小值，则填写当前时间或最早之前日期时间表明招募时间未开始时间或时间
*研究组别 Interventions	*名称 Group: 干预组	*样本量 Sample size: 100	
	Group: Intervention Group		
	*干预措施 Intervention: 干预组护理人员在病房小病房执行，通过语音、面对小志联系了最多的表演动作，同时可根据情况对音量的情有性，并且选择互动方式，在要求治疗后，中，后期均分入小志的才干特。 每增加一条可一个单位(实时) Input only one Measure	干预措施代码 Intervention code: 每增加一条可一个代码Please input only one code	
	Nursing staff in the intervention group dress up as teddy bears. After training, medical clowns acquire basic performance skills and can flexibly choose interaction methods. Please input only one Measure		
*干预措施 Interventions	*名称 Group: 对照组	*样本量 Sample size: 100	
	Group: Control Group		
	*干预措施 Intervention: 对照组进行常规护理，参与护士根据要求过程中表几的情况是配合程度，对患儿进行语言和动作方面的安抚。 每增加一条可一个单位(实时) Input only one Measure	干预措施代码 Intervention code: 每增加一条可一个代码Please input only one code	
	Nursing staff in the control group provide routine care. Based on the children's anxiety levels and compliance during nebulization, the nurses offer verbal and physical comfort to		
*样本总量 Total sample size	200		
多中心研究参加单位所有全中心			
*研究参加单位 Countries of recruitment and research settings	*国家 Country: 中国	*标准国家 Country: 浙江	市(区县) City: 杭州
	每增加一条可一个单位(实时) Input only one institution	*具体地址 City: ZhaJiang	
	*单位(医院) Institution(hospital): 浙江大学医学院附属第一医院		*单位级别 Level of the institution: 三甲
	The First Affiliated Hospital, Zhejiang University School of Medicine		
	Input only one institution		*单位等级 Level of the institution: Tertiary A Tag: Tertiary, Tertiary A, Secondary, Secondary B, Primary, Community, Community A, Community B, Community C, N/A, no administrative level
*研究实施时间 Study execute time	2025-04-01 2025-06-30	*征募受试者时间段 Recruiting time	2025-04-14 2025-06-23 注意：如果是要求最大值，填写未来时间，如开始日期，结束时间，如果是要求最小值，则填写当前时间或最早之前日期时间表明招募时间未开始时间或时间
每项指标分别填写，如有三个指标则填写三次，请复制填写			
*指标中文名 Outcome Name	焦虑评分量表 每增加一条可一个指标	*指标类型 Type:	主要指标Primary indicator
	Difference in Anxiety Scores Input only one outcomes name	测量方法 Measure method:	
测量时机点 Measure time point of outcome			
*指标中文名 Outcome Name	雾化治疗配合度评分量表 每增加一条可一个指标	*指标类型 Type:	次要指标Secondary indic
	Difference in Nebulization Treatment Compliance Score Input only one outcomes name	测量方法 Measure method:	
测量时机点 Measure time point of outcome			
*指标中文名 Outcome Name	监护人焦虑评分量表 每增加一条可一个指标	*指标类型 Type:	次要指标Secondary indic
	Difference in Guardians' Anxiety Scores Input only one outcomes name	测量方法 Measure method:	
测量时机点 Measure time point of outcome			
*指标中文名 Outcome Name	护理满意度 每增加一条可一个指标	*指标类型 Type:	次要指标Secondary indic
	Nursing Satisfaction Input only one outcomes name	测量方法 Measure method:	
测量时机点 Measure time point of outcome			
填写样本类别即可，如不涉及可填"无"			
*样本中文名 Sample Name	无 每增加一条可一个，如"血液"，"唾液"等	组织 Tissue:	血液或其他组织或器官
	None Input only one such as "Blood", "Saliva" etc.		Specify tissue from which tissue or organ
*人体样本类别 Type of sample	其它Others	说明 Note:	说明保存容器或其他处理
			Specify expected time of preservation or other tips
征募研究对象类型 Recruiting status	儿童/Children	*年龄范围 Participant age	最小Min age: 2 3-years
性别 Gender	男性和女性	*年龄范围 Participant age	最大Max age: 7 3-years
*随机方法（请说明随机入组分组方法和盲法方法）	采用群组随机分组方式，以首次就诊时开同儿科门诊大夫（A 组长）作为分组依据，总研究员根据，收集手续研究的所有儿科门诊大夫信息，将其分为 A、B 两组，运用随机数字表，随机确定 A 组大夫对应的患儿进入小志疗法干预组，B 组大夫对应的患儿进入常规护理组，至之为止，总组数随分组的随机性。	盲法方法 Length of follow-up(include time period of outcome measure)	不 No/Open
	Cluster randomization was adopted, with grouping based on the different pediatric outpatient physicians (Physician A or Physician B) that children first consulted. Before the study initiation, information of all participating pediatric outpatient physicians was collected and these physicians were divided into Group A and Group B. Using a random number table, it was randomly determined that children under physicians in Group A would be assigned to the clown therapy intervention group and children under physicians in Group B to the routine care group, the		
研究实施是否需要知情同意 Sign the informed consent	否 No		
临床一般信息填写完整	无		
	None		
*Process of allocation concealment	不可分盲及盲底无Alone		
*盲法	无		
	None		
*Blinding	不可分盲及盲底无Alone		
随机编码管理的程序方法			
Rules of unsuer or sealing breaking			
统计方法名称			
Statistical method			
试验完成的统计分析集			
Calculated Results are the Study Completed			
上传说明或说明的统计分析集 Statistical analysis set and description of the test file upload	上传附件File upload		
是否公开或说明完成的统计分析集 Calculated Results are the Study Completed public	公开Public		
是否有一项以上的 Multi-center (site)	否 No		
*是否为多中心研究的统计分析集Is multicenter study	否 No		
大规模的数据管理工具的名称（如果有）Large-scale data management tool (if exists)	在文献库中，国家生物信息中心 https://ngdc.cncb.ac.cn/gsa		
*The way of sharing IPD (individual patient data) and protocol. If use web-based platform, please provide the URL	Within one year of publication, China Nation center for Bioinformation https://ngdc.cncb.ac.cn/gsa		
*数据采集和管理（简要说明）Data collection and Management (A standard data collection and management system include a CRF and an electronic data capture)	电子采集和管理		
	Electronic Data Capture		
数据可信性核查的具体内容 Data and Safety Monitoring	暂未确定Not yet		
研究计划书的研究数据收集表格（如果有）Study data collection form (if exists)			
Publication information of the protocol(research results) reprint(name of the journal, volume, issue, pages, time, in website)			
注册人 Name of Registrant	高俊(10235)		
注册时间 Date of Registration	2025-10-22 00:00:00		
项目状态 Date of Registration	注册中心		
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Tip: after you have completed the filling all the information in the registration form, you can select "Submit" button to apply for verification. Otherwise, select "Save" to save it and you can continue to work on filing.