伦理委员会批准函

Ethics Committee Approval Letter

审查编号 Approval No.：**SK2020-081**

项目名称 Study Title	分形音调疗法对耳鸣干预机制的临床研究		
试验产品名称 Study Product Name	NA	产品类别/规格 Product Category	NA
批准文号及发文单位(Approval No. and Issued By) NA		研究分期(Phase of Study) NA	
主要研究者(Principal Investigator) 吴帅		申办者(Sponsor) 复旦大学附属中山医院	
审查方式及日期 (Type & Date of Review)	□会议审查 (Meeting Review) ■快速审查(Expedited Review)2020 年 8 月 20 日		
会议地点 (Meeting Location)	NA		
会议出席情况 (Meeting Attendance)	NA		

下列研究相关文件已经批准

The following documents have been approved 吴

1. 研究方案；
2. 知情同意书：V1.0（草案），2020 年 8 月 10 日；
3. 主要研究者简历及研究人员名单；
4. 病例报告表：V1.0（草案），2020 年 8 月 2 日；
5. 耳背式助听器医疗器械注册证；
6. 助听器生产厂家资质

审查决定 Decision for this proposal and have been [√]:

[√] 同意 Approval

批准函有效期至： 2020 年 11 月 21 日

主任委员/副主任委员签名 Chair/Vice Chair Signature：

批准日期 Approval Date：2020 年 8 月 21 日

复旦大学附属中山医院伦理委员会(盖章)Stamp of ZSEC

联系方式：上海市徐汇区枫林路 180 号 邮编：200032 电话：021-31587871 传真：021-31587851

声明(Statement):
(请仔细阅读)

1. 复旦大学附属中山医院伦理委员会（以下简称本伦理委员会）的职责、人员组成、操作规范和记录遵循 ICH-GCP 及中华人民共和国国家药品监督管理局颁布的《药物临床试验质量管理规范》、《医疗器械临床试验质量管理规范》和《药物临床试验伦理审查工作指导原则》，并遵守中国相关法律和法规的规定。
2. **研究实施前提：**所有研究需经伦理委员会审查获得批准函后方可实施，实施过程应遵循伦理委员会批准的方案执行，应符合赫尔辛基宣言和 GCP 的基本原则。**特殊情况：**⑴属**《人类遗传资源采集、收集、买卖、出口、出境审批行政许可事项》**规定范畴的研究，获得中国人类遗传资源管理工作办公室批准/备案后，将批准/备案成功结果书面递交伦理委员会备案后方可实施。⑵属**《需进行临床试验审批的第三类医疗器械目录》**内医疗器械的临床试验，获得国家药品监督管理局备案成功结果书面提交伦理委员会备案后方可实施。⑶属**需在国家药品监督管理局备案/默示许可的项目**，获得备案成功结果/默示许可的结果及时提交伦理委员会备案后方可实施。
3. 研究过程中，对研究方案和知情同意书等相关文件所作的任何修订，均需得到本伦理委员会审查同意后方可实施。
4. 在复旦大学附属中山医院发生的严重不良事件或可疑且非预期严重不良反应等安全性信息需按伦理委员要求及时递交，伦理委员会有权对其评估做出新的决定。
5. 方案违背和偏离需及时报告本伦理委员会。
6. 需按照伦理初始审查伦理批准函的持续审查频率和首次批准时间提交持续审查申请，确保批准函到期前 1 个月递交持续审查申请，以获得伦理委员会的批准。(本伦理委员会有权根据实际开展情况改变持续审查频率)
7. 暂停/提前终止临床试验，需及时书面向本伦理委员会提出申请。
8. 研究结束时，需及时向本伦理委员会递交结题报告及相关附件。
9. 本批准函可能在其他参加单位伦理委员会备案，如对审查结果有不同意见，请及时与本伦理委员会联系。

联系方式：上海市徐汇区枫林路 180 号　　邮编：200032　　电话：021-31587871　　传真：021-31587851

Translated Version

Ethics Committee Approval Letter

Approval No.: **SK2020-081**

Study Title	Clinical Study on the Intervention Mechanism of Fractal Music Therapy on Tinnitus		
Study Product Name	NA	Product Category	NA
Approval No. and Issued By NA		Phase of study NA	
Principal Investigator Wu shuai		Sponsor Zhongshan Hospital Affiliated to Fudan University	
Type & Date of Review	☐ Meeting Review ■ Expedited Review 20 August 2020		
Meeting Location	NA		
Meeting Attendance	NA		

The following documents have been approved

1. Research proposal;
2. Informed consent form: V1.0(draft), August 10,2020;
3. Curriculum Vitae of major researchers and list of researchers;
4. Case report form: V1.0(draft), 2 August 2020;
5. Medical device registration certificate of ear back hearing aid;
6. Manufacturer qualification of hearing AIDS

Decision for this proposal and have been[√]:

[√]Approval

Validity of approval letter: January 21, 2020

Chair/Vice Chair Signature:

Approval Date:

Stamp of ZSEC

Statement

(Please read it carefully)

1. The responsibilities, personnel composition, operation specifications and records of the ethics committee of Zhongshan Hospital Affiliated to Fudan University(hereinafter referred to as the ethics committee) follow ICH-GCP. At the same time, it also abides by the "quality management standards for clinical trials of drugs", "quality management standards for clinical trials of medical devices" and "guiding principles for ethical review of clinical trials of drugs" issued by the State Drug Administration of the people's Republic of China. In addition, it complies with the provisions of relevant laws and regulations of China.

2. Research implementation premise: all research can be carried out only after being reviewed by the ethics committee and obtaining approval letter. The implementation process should follow the plan approved by the ethics committee and comply with the basic principles of Helsinki Declaration and GCP. Special circumstances: (1) within the scope of " Items of Administrative License for The Collection, Collection, Trading, Export and Exit of Human Genetic Resources", the study needs to be approved / filed by China human genetic resources management office, and the successful results of approval / filing shall be submitted to the Ethics Committee for filing before implementation. (2) Clinical trials of medical devices listed in the catalogue of category III medical devices subject to clinical trial approval can be implemented only after the successful results of the State Drug Administration are submitted to the Ethics Committee for filing. (3) It belongs to the project that needs to be filed / implied license in the State Drug Administration. It can be implemented only after the successful result of filing / implied license is obtained and submitted to the Ethics Committee for filing in time.3. In the process of research, any amendment to the research protocol, informed consent and other relevant documents must be reviewed and approved by the ethics committee before implementation.

4. Safety information such as serious adverse events or suspicious and unexpected serious adverse reactions occurred in Zhongshan Hospital Affiliated to Fudan University should be submitted in time according to the requirements of the ethics committee, and the ethics committee has the right to make new decisions on its evaluation.

5. Violation or deviation from the plan shall be reported to the ethics committee in a timely manner.

6. It is necessary to submit the application for continuous review according to the frequency and time of the first approval specified in the ethics approval letter, so as to ensure that the application for continuous review is submitted one month before the expiration of the approval letter, so as to obtain the approval of the ethics committee. (the ethics committee has the right to change the frequency of continuous review according to the actual situation).

7. The suspension/early termination of clinical trials shall be submitted to the ETHICS Committee in writing in time.

8. At the end of the study, the final report and relevant attachments should be submitted to the ethics committee in time.

9. This approval letter may be filed in the ethics committee of other participating units. If you have different opinions on the review results, please contact this ethics committee in time.

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