

Information for participants and declaration of consent to participate in the study:

Causal prediction model for non-invasive brain stimulation during second language learning

Dear prospective participant,

We would like to invite you to participate in the study mentioned above. (*Optional:* We will provide more information in a detailed conversation.)

Your participation in this study is voluntary. You can refuse to participate at any time, without having to give a reason, or also withdraw your agreement to participate once the study has already started. There will be no negative consequences for you if you refuse to participate or if you withdraw from this study early.

This kind of study is necessary to gain new, reliable *academic* research results. However, your written consent to participate in the study is an indispensable prerequisite for us to conduct this study. Please take time to read the following information carefully (*optional:* in addition to the explanatory talk), and do not hesitate to ask questions.

Please only sign the declaration of consent

- if you have fully understood the type and procedure of the study,
- if you are willing to give your consent to participate, and
- if you are aware of your rights as a participant in this study.

1. What is the purpose of this study?

Language learning performance has been shown to be mainly modulated by the neuronal activity of some specific brain areas, e.g., Broca's area. In this study, to investigate how to actively induce changes of brain states related to language learning, we will apply one type of non-invasive brain stimulation (NIBS) technique, i.e., transcranial alternating current stimulation (tACS), to you. That means very weak alternating currents (~1mA) will be applied over your scalp with the aim to stimulate neuronal activity, which has been proved to be a very safe technique (refer to section 4). Meanwhile, simultaneous brain activity will be recorded via electroencephalography (EEG) and used to find the most representative brain state in order to analyze the causal role played by NIBS in the change of brain state. Our ultimate goal is to develop a personalized NIBS treatment for post-stroke aphasia patients.

2. What is the procedure of the study?

Our study will be held in the EEG lab of the Research Group Neuroinformatics,

and it will include at least 10 participants.

You will participate in the study for one to ten recording sessions allocated on different days (separated by at least two days and no more than two weeks), and each session lasts 3-4 hours. At the beginning of each session, the EEG and NIBS equipment will be prepared, and a conductive gel will be applied on the scalp. After a 5 min recording of resting state, i.e., keeping relaxed, we will start with a calibration block during which you will be asked to read out the prepared materials as well as answer questions such that we can evaluate your initial language performance. Subsequently, we need to emphasize that we will only choose NIBS parameters whose safety has already been validated and verified in previous studies, e.g., 4Hz-, 10Hz- and 40Hz-tACS, etc. Next, we will apply these carefully selected interventions, i.e., NIBS, in randomized order to you and in the meantime, you will need to answer questions based on either heard audio files or watched videos which are related to language learning, e.g., vocabularies, grammar, dialogue, etc., for 1-3 blocks (20 minutes each, and depending on your fatigue).

After the stimulation block(s), you will be asked to do another calibration block in order to evaluate your language performance after stimulation and 5 minutes resting state will be recorded at last. The brain activity will be recorded by electroencephalography (EEG) during the whole session.

You should be currently learning a non-native language (e.g., non-German native speakers learning German). Since this study aims at healthy subjects, we will require you having no speaking related deficits and being able to speak your native language fluently. You will be remunerated hourly for your participation (see 9.).

3. What are the benefits of participating in the study?

In the initial stage of the study, it is unlikely that you gain any long-term (e.g., health-related) benefits from participating in this study. We do, however, hope that in a later stage, our methods will be able to assist you in improving your language learning capability during the study.

4. What are the possible risks of taking part this study? Could participants experience any discomfort or other side effects?

Recording brain activity with EEG is passive and considered to be fully safe. The conductive gel applied to the skin under the electrodes may cause skin irritation or redness, though these side effects subside after a few hours or days. To minimize the risk of irritations, the gel will be applied with an individual, disposable syringes. Right after the end of the study, you will be given the chance to shower, and we will provide clean towels and shampoo.

Regarding transcranial alternating stimulation (tACS), it is considered to be a safe NIBS technique without the adverse events after stimulation present in other NIBS techniques. You may feel skin sensation, i.e., tickling or warmth on the skin, under the stimulation electrodes, most often at the beginning of sham and real stimulation. In addition, dizziness is also reported with low-frequency tACS (4Hz) when the electrodes are placed over the parietal cortex. Moreover, phosphenes have been reported in short period tACS studies (8-

second stimulation) that used bipolar electrodes with one of the two electrodes placed close to the forehead or occipital cortex. Importantly, we need to emphasize that these feelings typically disappear quickly and to the best of our knowledge, there are no reports of these adverse effects in tACS when all of the electrodes are placed over the temporal cortex, which is known to be related to the speech generation and audio perception. Nevertheless, gamma tACS (40Hz) has been reported as differentially modulating learning performance in the phonetic categorization task of young and older adults. However, to date, all reported adverse events of tACS have been transient rather than persistent. No serious adverse effects have been reported in either healthy subjects or patients.

Please inform the researcher if you feel uncomfortable or if you wish to terminate the stimulation. To smoothly apply the stimulation, the sinusoidal signal of the tACS will be ramped up for the first 1.5 s and ramped down during the last 1.5s.

This study only includes healthy, adult, English speaking participants capable to consent. You must have normal or corrected to normal vision and be currently learning German as a non-native language. The study may be extended to include other non-native language learners, e.g., English, Chinese, French, etc. Furthermore, none of the following circumstances should apply to you:

- Hearing impairment
- Speech impairment
- Cardiac implants
- Metallic implant in the head
- Seizure disorder
- Medication-resistant epilepsy in immediate relative
- Neuroactive or psychoactive medication
- History of fainting spells
- Pregnancy
- Implanted pumps, stimulators, or shunts
- Ongoing rehabilitation of speech generation or auditory perception
- Psychiatric or neurological disease
- Substance abuse
- Attention-deficit hyperactivity disorder
- Medication affecting the central nervous system
- Migraines
- Chronic skin disorder
- Failure to give written consent

If any of the above circumstances apply to you, please let the study leader know now.

5. Does participating in the study have any other effects on participants' lifestyle? What are the obligations resulting from participating?

The study contains two types of sessions: recording via EEG and stimulation. Both of them are conducted in a purely non-invasive and very safe way. Therefore, both sessions will not have any effect on the your lifestyle. We do, however, have the obligations for you that before any session of the study, you shall not drink any alcohol or take any mind-altering substances (drugs),

starting from the evening on the day before the recording session.

6. What should participants do if they experience symptoms of complaints, unwanted side effects and/or injuries?

If you experience any discomfort or side effects during the study, please immediately inform the person administering the study.

In the case that you do experience any side effects after the study, please inform the study coordinator (see 10.) immediately.

7. In what cases is it necessary that participants withdraw from the study early?

You can withdraw your consent to participate in the study at any time, without having to give a reason and without any disadvantage to you.

The study coordinator may decide to terminate your participation in the study. Possible reasons for this might be:

- a) You do not meet the requirements of the study.
- b) The study coordinator has the impression that further participation in the study is not in your best interest.

8. How will the data collected in this study be used?

Two types of data will be recorded in this study: EEG and voice recording. All of the data collected in this study will be used for scientific research within the Research Group Neuroinformatics and scientific publications as well as presentations. Only the staff working on the study (see 10.) have access to the data and are obliged to maintain secrecy.

Both the EEG and voice data will be first pseudonymized through the allocation of an ID number, under which the data will be saved. This way, those who do not have the “key” will not be able to deduce any information about your person. You will never be mentioned by name, without exception. Even in possible publications of the data collected in the course of this study, your name will not be mentioned, and it will not be possible to draw any conclusions about you.

We need to emphasize that your audio recordings represent an integral part of the studied data, which is why any modifications made to disguise your voice would likely skew scientific conclusions drawn from this study. We thus will not make any such modifications. Moreover, you will only speak out the answer for the heard question, which is either repeating the pronunciation of a word or filling the missing part within a sentence purely based on grammar such that we will not record any of your own opinions or other personal information.

If you wish to delete or receive a copy of the data collected from your participation in this study, you may contact the study leader (see 10.). Deletion or receiving a copy of your data is possible until one month after the end of your participation, which is when the link between your personal data

and your ID number will be destroyed, and the data is permanently anonymized.

9. Will there be any costs for the participants? Will they receive reimbursement or remuneration?

You will not incur any costs from participating in this study. For your participation in this study, you will receive a fixed amount of 12€ per hour. Moreover, preparation (approx. 40 min.) and time for showering after the recording session (30 min.) will be included in the calculation of total time spent.

10. Possibility to discuss further questions

If you have any further questions (now or at a later time) about the study or your rights as a participant, the study coordinator will be happy to answer them.

Name(s) of the contact person(s):

Study coordinator	Name: Jiachen Xu E-mail: jiachen.xu@univie.ac.at Phone: +43-1-4277-79621
Principal investigator	Name: Moritz Grosse-Wentrup E-mail: moritz.grosse-wentrup@univie.ac.at Phone: +43-1-4277-79610
Other relevant persons:	Name: Anja Meunier E-mail: anja.meunier@univie.ac.at Phone: +43-1-4277-79621

11. Declaration of consent

Name of the participant in block letters:

Date of birth:

I agree to participate in the study *Causal prediction model for non-invasive brain stimulation during second language learning*.

Jiachen Xu provided me with clear and detailed information about the objectives, significance and scope of the study, as well as about the requirements resulting from my participation in the study. In addition, I have read this information text for participants and the declaration of consent, especially section 4 (regarding risks, discomforts or side effects). The study coordinator answered all my questions sufficiently and in a comprehensible manner. I had enough time to decide whether I would like to participate in this study. At the moment, I have no further questions.

I will follow the instructions that are necessary for conducting this study. However, I reserve the right to end my voluntary participation at any time, without this being to my disadvantage. If I want to withdraw from the study, I can do so at any time by contacting "*Name of contact person*", either in writing or verbally.

At the same time, I agree that my data collected in this study are recorded and analysed.

I agree that my data are permanently saved electronically in anonymised form. The data are saved in a form that is only accessible to the project management and are secured according to current standards.

If I want my data to be deleted at a later time, I can arrange for it by contacting Jiachen Xu (Email: jiachen.xu@univie.ac.at, Phone: +43 1-4277-79621) either in writing or via telephone, and without having to give a reason.

I have read and understood the information for participants. In the explanatory meeting, I had the opportunity to ask all the questions I was interested in. My questions were answered fully and in a comprehensible manner.

I have received a copy of this information for participants and declaration of consent. The original remains with the study coordinator.

(Date and signature of the participant)

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(If applicable: Date and signature of a parent)

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(Date, name and signature of the study coordinator)

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