Protocol Informed Consent (online)

TITLE: **The Mere-measurement effect in patient-reported outcomes: A randomized control trial with speech pathology patients**

STUDY INITIATOR: Institute for Outcomes Research, MUW

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Participant information[1] and declaration of consent for participation in the study

The Mere-measurement effect in patient-reported outcomes: A randomized control trial with speech disorder patients

Dear participant!

We invite you to participate in the above-mentioned study.

Your participation in this study is voluntary. You can withdraw from the study at any time without giving reasons. Refusal to participate or premature withdrawal from this study has no negative consequences for you.

Studies are necessary in order to obtain reliable new medical research results. However, an essential prerequisite for conducting a study is that you give your consent to participate in this study.

Please read the following text carefully.

Please agree to the declaration of consent only

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

The responsible ethics committee issued a favourable opinion on this study, as well as on the participant information and consent form.

1 What is the purpose of the study?

The so-called "mere-measurement effect", also known as the question-behaviour effect or assessment reactivity effect, describes an effect on people's attitudes and actions that is

[1] For the sake of readability, the use of both male and female personal terms has been omitted in the text. Where applicable, both genders are always meant and addressed.

triggered purely by how, for example, a question is asked (formulated positively or negatively).

This "mere-measurement effect" can be observed in many different areas. For example, people who are asked to express their views and thoughts on a healthier lifestyle, such as exercising more or eating more healthily, may subsequently be more motivated to actually exercise more or eat more healthily after the survey (written or verbal). This change in behaviour results purely from exposure to the survey/measurement and is presumably explained by an increased awareness of the topic surveyed.

So far, however, the "effect of mere measurement" has hardly or not at all been investigated in questionnaires (patient reported outcomes = PROs). PROs are any kind of feedback from a patient on his/her state of health. This study will focus on common PROs of speech disorders. A speech disorder is a condition in which a person has problems creating or forming the speech sounds needed to communicate with others.

Specifically, we want to know:

Do positively worded questions in questionnaires have a different effect on you, e.g. reading a positive text, compared to negatively worded questions?

Does the frequency of completing questionnaires change this effect?

2 How does the trial work?

This study is being conducted by the Medical University of Vienna, Institute for Outcomes Research. A total of 167 patients with a diagnosed speech disorder and 33 healthy individuals are included in this study. These people were recruited via "Probando" (www.probando.io).

People are randomised into one of 6 groups. The term randomized refers to the process of assigning participants to groups by chance, or without reason. All groups are asked to read and digitally record a standardised text at the beginning and end of the study. The standardised text describes a beautiful landscape in nature. Reading the text aloud takes about 45 seconds. We use SoSci Survey(www.soscisurvey.de) to send the questionnaire to you and to record the text being read aloud. SoSci Survey is a web-based application for creating online questionnaires. SoSci Survey is based in Munich (Germany) and therefore fulfils all European data protection requirements.

In addition, we ask 4 of these 6 groups to complete a standardised questionnaire (PROM) on a weekly basis, which is often used in practice to assess the severity of speech disorder. Depending on the group, this questionnaire varies (questionnaires with more positive and/or more negative wording) and the frequency of completion (2 to 4 times at one-week intervals). Completing the questionnaire takes an average of 15 minutes. In the two control groups – the groups which will not complete the experimental questionnaires (positive or negative) – the subjects will only provide demographic information and participate in the read aloud exercise.

3 What are the benefits of participating in the study?

It is possible that you will not derive any direct health benefits from your participation in this study. However, by participating in this study, you will help us to better understand how the different wording of PROs/questionnaires affect people with speech disorders. This may also directly benefit people with speech disorders in future research, when developing new questionnaires.

4 Are there risks, complaints and side effects?

As you only have to complete questionnaires or read a text for this study, you are not exposed to any risk or possible side effects by participating in this study. The only risk you are exposed to in our study is the disclosure of your data. In order to protect your data, only codes (so-called pseudonyms) are used in the questionnaire. Furthermore, your data will only be stored on the server of SoSci Survey (Germany) and the Medical University of Vienna (Austria). Both institutions must comply with the data protection regulations of the European Union.

5. What if you withdraw from the study prior to completion?

You can revoke your willingness to participate at any time without giving reasons and withdraw from the study without incurring any disadvantages.

6. Data protection

Data about you will be collected and processed as part of this study. A basic distinction must be made between

1) personal data by which a person can be directly identified (e.g. name, date of birth, address, national insurance number, photographs, etc.),
2) pseudonymised personal data, i.e. data in which all information that allows direct conclusions to be drawn about the specific person is either removed, replaced by a code (e.g. a number) or (e.g. in the case of image recordings) made unrecognisable. However, despite compliance with these measures, the possibility of unauthorised re-identification cannot be completely ruled out.
3) anonymised data that cannot be traced back to a specific person.

Access to the data by which you can be directly identified (see point 1) is granted to the investigator and other investigators of the study who are involved in the study. In addition, authorised representatives of the sponsor (Medical University of Vienna, Spitalgasse 23, 1090 Vienna) who are obliged to maintain confidentiality, as well as representatives of domestic and/or foreign health authorities and the relevant ethics committees may inspect this data, insofar as this is necessary or prescribed for the verification of the proper conduct of the study. All persons who have access to this data are subject to the applicable national data protection regulations and/or the EU General Data Protection Regulation (GDPR) when handling the data.

The code that makes it possible to assign the pseudonymised data to your person is only stored at your study centre.

The data will only be passed on in pseudonymised or anonymised form.

Only pseudonymised or anonymised data will be used for any publications.

Within the scope of this study, no transfer of data to countries outside the EU (third country) is planned.

Your consent forms the legal basis for the processing of your personal data. You can withdraw your consent to the collection and processing of your data at any time without giving reasons. No further data about you will be collected after you withdraw your consent. However, the data collected before you withdraw your consent may continue to be processed in the context of this study.

According to the GDPR, you are generally entitled to the rights of access, rectification, erasure, restriction of processing, data portability and objection, provided that this does not render impossible or seriously impair the objectives of the study and provided that this does not conflict with other statutory provisions.

The expected duration of the study is 15 months. The duration of the storage of your data beyond the end or cancellation of the study is regulated by law.

If you have any questions about the handling of your data in this study, please contact your investigator first. If necessary, they can forward your request to the persons responsible for data protection.

Contact details of the data protection officers of the institutions involved in this study:

Data Protection Officer of MedUni Vienna: datenschutz@meduniwien.ac.at

You have the right to lodge a complaint with the Austrian Data Protection Authority about the handling of your data (www.dsb.gv.at; e-mail: dsb@dsb.gv.at).

7 Are there any costs for the participants? Is there a reimbursement of costs or remuneration?

Your participation in this study will not incur any additional costs for you.

To compensate you for your time, you will receive 50 euros after completing the study.

8. Possibility to discuss further questions

Your investigator and his staff will be happy to answer any further questions you may have in connection with this study. They will also be happy to answer any questions concerning your rights as a participant in this study.

Name of contact person: **Dr Preston Long MA MSc**

Available at: preston.long@meduniwien.ac.at or +43 1 40400 16373

9. Declaration of Consent

I agree to participate in the study "The mere measurement effect of patient self-assessments: A randomised controlled trial with speech-language pathology patients". I am aware that I can refuse to participate without any adverse consequences.

I am also aware that I can contact Dr. Preston Long at any time if I have further questions. I have understood the clinical trial, possible burdens and risks, as well as the nature, importance and scope of the clinical trial and the requirements it imposes on me. I have also read the text of this information and consent form, which comprises a total of 5 pages. I can ask Dr. Preston Long any questions I may have at any time. I have had sufficient time to make up my mind. I have no further questions at this time.

I will comply with the instructions necessary for the conduct of the study, but I reserve the right to terminate my voluntary participation at any time without incurring any disadvantages.

I expressly agree that my data collected as part of this study may be processed as described in the "Data protection" section of this document.