Consent form

Dear participants:

You will be invited to participant in a study directed by Prof. WANG Aimin and Prof. ZHAO Meng from the School of Nursing, Qingdao University and Qingdao caretaker otolaryngology head & neck surgery hospital. The researcher will make a fully explanation of the contents of the informed consent form to you, including the research purpose, process, benefits, possible risks, and the protection of your rights and interests during our study. Please make a careful decision whether to join in the study after reading this informed consent form. If you are participating in another study, please inform the researcher in advance.

Research purpose:

Currently, adenoid hypertrophy has a high prevalence, and the resulting adenoid hypertrophy is easily ignored. After adenoidectomy, it is difficult to solve the problem of facial muscle solidification and tension due to neuromuscular problems. At present, the conservative and effective method is to exercise muscle function in time. In previous studies, we have seen that the main reason why many people give up treatment is the lack of reasonable management and low compliance of parents. Therefore, this study aims to include parents and children in the study and carry out dyadic intervention. It is expected to improve parents' care ability and parental functioning, children's orofacial myofunction and compliance. Promoted in order to solve the problem of facial muscle tension by non-surgical means.

Research process:

This study is a randomized controlled trial in which you are randomly divided into a control group or an intervention group. If you are assigned to the control group, you will receive usual care; if you are assigned to the intervention group, you will receive the PCD-OMT program and usual care. The intervention will last for 12-week, followed by 12-week of follow-up.

Assessments will be conducted at baseline, post-intervention, and at 12-week follow-up, including demographic, feasibility, acceptability, orofacial myofunction, children's engagement, parental care abilities and parental functioning. No matter which group you are assigned to, it will not have a negative impact on your surgery and postoperative recovery.

Possible benefits of studying:

If you are assigned to an intervention group, you may master a better performance in care abilities and parental functioning. Your child(ren) may have a better performance in his/her orofacial myofunction. But it's also possible that you won't benefit from this research.

Risks and Discomforts of Research:

You will be asked about your experiences during the whole study, and answering these questions may cause you sadness or discomfort. At the same time, some issues may involve your personal privacy, and you may choose to terminate intervention at any time.

Other therapeutic interventions:

If you have a problem that the researchers cannot resolve, the researchers will provide you with resources or information to refer you to relevant health services.

Private issues:

If you decide to participate in this study, your personal information in this survey will be kept confidential. Your questionnaire will be identified by a study number rather than your name. Information that identities you will not be disclosed to members outside of the research team without your permission. The data will be kept and used by the researcher and members of the research team. This data cannot be used by others without the consent of the subject. When publishing research results, the identity of the subjects will be kept confidential and personal information and materials will never be disclosed.

Fees and Compensation:

There is no additional cost to participate in this study. If you are harmed because of participating in this study, such as damage related to this clinical study, you may receive free treatment and/or corresponding compensation.

Free exit:

During your participation in the study, please provide the truth about your situation and current mental state; inform the researcher of any discomfort you have experienced during this study; inform the researcher whether you have participated in other studies recently or are currently participating in other study. You can learn about the information and research progress related to this study at any time, and voluntarily decide whether to (continue) to participate or not (continue) to participate. If you participate in this study, no matter whether injury occurs or whether the injury is serious, you can choose to notify the researcher at any time to withdraw from the study. Your data will not be included in the research results, and any medical treatment and rights of you and your family will not be affected as a result. The researcher will also discontinue the study if you do not comply with the study plan or if continuing to participate in the study would cause serious harm to you.

Contact information:

If you have questions related to this study, or you have any discomfort or injury during the study, or you have questions about the rights of participants in this study, please contact your researcher: _____. Telephone: _____.

If you have any questions or concerns about your rights and health in participating in this study, you can contact the ethics committee of this study. Contact person: _____. Contact phone: _____.

Benefit sharing after the trial:

If the subject needs to know the relevant results of the study, the

researchers of this study can provide the subject's relevant personal information free of charge.

Consent form signature page

I have read this informed consent form.

I have the opportunity to ask questions and all were answered.

I understand that participation in this study is voluntary. I can choose not to participate in this study or withdraw after notifying the researcher at any time without being discriminated against or retaliated against, and any of my medical treatment and rights will not be affected as a result.

If I require additional treatment, or if I do not follow the study plan, or if I suffer a study-related injury, or for any other reason, the study researcher may terminate my continued participation in the study.

I will receive a signed copy of the Informed Consent form.

Name of the subject: _____

The subject's signature: _____

Date: _____

I have accurately informed the subject of this document and asked him/her to carefully read this informed consent form and answer the questions or questions raised carefully.

The subject's signature: _____

The subject's signature: _____

Date: _____

(Note: If the subject is illiterate, a witness signature is required. If the subject is incapacitated, an agent's signature is required.)