Participants information[1] and Consent Form for participation in the clinical trial

"A training program for the development of social resources and their effects on the emotional, physical and social well-being of adults. "

(Full title of the study)

Dear participant, dear participants!

Medical University of Vienna studied extensively the possibilities to keep people healthy at the present time. To gain new insights it needs innovation, Know-how and cooperation. We therefore would like to invite to participate in the above mentioned scientific study.

Your participation in this study is voluntary. You can at any time without notice for any reason from the study. The refusal to respond or early withdrawal from this study have no adverse consequences for you.

Clinical trials are needed to win reliable new medical research findings. Indispensable for the conduct of a clinical trial is, however, that you agree to participate in this clinical trial writing. Please read the following text carefully:

Please sign the consent form on the last page of this document only

if you fully understand the nature and course of the study,
if you are willing to agree to the participation and
if you are on your rights as a participant in this study clear.

For this study, as well as for patient information and consent form a favorable opinion of the relevant ethics committee.

1. What is the purpose of the study?

The purpose of this study is to determine how a training program for social relationship, communication and personality development of the emotional, physical and social well-being affects adults. Likewise, it is examined whether an observed effect will last long term and how the training on the social environment of the participants of the training program affects.

These findings will advance our understanding of health and also captures both in future therapies, as in health promotion.

1 To improve readability in the text part of women on the simultaneous use and male persons terms are omitted. Meant and addressed are - if applicable - always both sexes.

2. How is the study carried out?

This study is being conducted at several locations and in several countries, and it will participate in a total of about 400 people in it. Your participation in this study is expected to take 1.5 years.

The 400 people participating are divided four equal groups:

A: Participants / In the training of the Institute Kutschera
B: trusted person of the participant / In A
C: Comparative person A (selected from B)
D: confidant of comparator C

You are in Group: A

As a member of the group A, you get these studies documents after registration at the Institute Kutschera the training program "Resonance Practitioner" sent in short-term requests you can this on the first day of the first module will be handed out. The documents include 4 questionnaires for the time point 1 and 4 subscriber information together with informed consent, 3 of which are located in the cover with the label "B". Among the later time points in the study you will then only each sent a questionnaire.
It is in this study is a PhD of the Center for Public Health at the Medical University of Vienna.
The questionnaires collect your current physical, social and emotional well-being.
Analysis of the questionnaires takes place at the Medical University of Vienna.

What should I do?

1. Documents in cover "A" fill out and return:

As a member of the group A we ask you if you agree to participate in the study by signing the consent form, fill out the questionnaire in the cover with the inscription "A" and returned in the prepaid envelope along with the signed consent form.

2. Place cover "B" to a person of trust:

The cover labeled "B" please pass it on to a person who is close to you is, which you have frequent contact and (if possible jointly cope with life mostly this is the male or female partner, possibly also a close friend or if they are over 18 years old girlfriend or their children). Spokespersons should (about 1.5 years) stay over the period of the study the same.

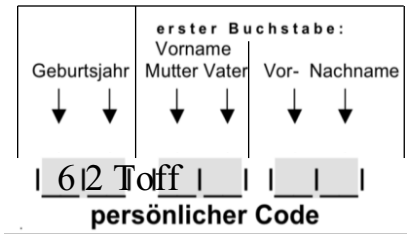
3. Write your personal code of your trusted person on your questionnaire:

On your questionnaire please provide, in addition to your personal code on the first page below the personal code of your spokesperson and information about your relationship with this person, so we can see the togetherness in the study, as this is important for the study result ,

This is determined from the last two digits of the year of birth of your trusted person, the first letter of the first name of the mother and the father of your trusted person, and the first initial and last name of your trusted person. This can be done together with your confidence, provided the latter agrees to participate in this study, by signing the consent form. personal for the determination of your code are used data on the same principle.

Here you will find a general example of how the personal code is created for you or your confidant.

Year of birth: 1962
First name of the mother: Tanja
First name of the father: Franz
own name: Anton tree



The following measures are carried out solely for reasons of study:

During this study, you are at the beginning (time 1) after one year (Time 2) and after 1.5 years (time 3) passed questionnaires and sent to you within 2 weeks of receipt already inscribed in the stamped envelopes filled back end.

Over a period of 1.5 years 3 Questionnaires must be completed in total. The Ausfülldauer each questionnaire will be between 50 and 60 minutes. Attendance over the entire study period and the correct, complete filling of the questionnaires is critical for the success of the study.

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

It is possible that you move through your participation in this questionnaire study no direct benefit to your health. However, they make a significant contribution in a scarcely studied area of research that could be in the future for many people benefit. This study is the first of its kind, which is why their special importance.

4. Are there any risks, discomfort and side effects?

By participating in this survey study is not risk, discomfort or side effect to go out for your health.

5. When will the study ended prematurely?

You can at any time without giving any reasons, revoke your willingness to participate and withdraw from the study without you thereby incurring any disadvantages. For ease of administration, we would ask you, if you possibly can, your leaving the study leader, Mr. DI Christoph Janka, promptly notify.

6. Data protection

As part of this clinical trial data is collected about you and being processed. It is basically to distinguish between

1) those personal data from which a person is directly identifiable (eg name, date of birth, address, social security number, screen shots ...)
2) pseudonymized personal data, which are data in which all the information that direct conclusions about the actual person allow either removed by a code (. e.g., a number) replaced or (for example in case of image recording) can be made unrecognizable.

However, despite compliance with those measures not be completely ruled out that it illegally will be a re-identification.

3) anonymous data in which a return can be ruled out on the concrete person.

Access to the data on which you are directly identifiable (see point 1), have the investigator and other employees of the Research Center, involved the medical in the clinical trial or your care. In addition, authorized and obliged to secrecy officer of the Medical University of Vienna and representatives of domestic and / or foreign health authorities and relevant competent ethics committees can take this data insight to the extent of the clinical trial is necessary or required for the verification of proper implementation. All persons who have access to this information, subject to the handling of the data to the applicable national data protection rules and / or the EU Data Protection Regulation (DSGVO).

The code that enables to allocate the pseudonymous data about you is stored only on your study center.

A transfer of data, especially to the sponsor and its contractors is only under a pseudonym or anonymously.
For any publications only the pseudonymous or anonymous data is used.
As part of this clinical trial no disclosure is provided of data to countries outside the EU (third countries).

Your consent is the legal basis for the processing of your personal data. You can always withdraw your consent to the collection and processing of data, without notice. After your withdrawal no more data is collected about you more. The data collected up to the cancellation can be further processed, however, in this clinical trial.

After DSGVO the rights of access, rectification, cancellation, restriction of processing, data portability and opposition you have to basically, as far as making the objectives of the clinical trial impossible or seriously affected and to the extent not contradict other legal regulations.

The expected duration of the clinical study is 3 years. The duration of the storage of your data on the end or termination of the clinical trial also is regulated by legislation.

If you have questions about how your data in this clinical trial, you should first contact your investigator. This can be your concern, if necessary, to the people who are responsible for data protection, forward.

Contact the Data Protection Officer of the institutions involved in this clinical trial:

DPO / r of the Medical University of Vienna: datenschutz@meduniwien.ac.at

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

7. Arise for participants costs? Is there any reimbursement or compensation?

Participation in this study is free of charge for you.

For participating in this study you will be reimbursed according to the following conditions: each participant who within 1.5 years, all three questionnaires

returned his person filled in the third questionnaire are vouchers worth a total of € 30, once after receipt - sent, which can be redeemed at well-known grocery stores. If you cancel their participation in the study early, you give us about it known. You will then aliquot vouchers - each filled out questionnaires each € 10, - sent -.
If you want to have not paid your participation in the study, you are welcome back again end at its discretion the vouchers.

8. Opportunity for discussion of other issues

For further questions related to this clinical trial, please ask your Study leader and the chairman of the study committee disposal. Also questions concerning your rights as a participant in this study, you will be answered.

Name the study leader: DI Christoph Janka

Can be contacted at: +4369917142413
n00027927@students.meduniwien.ac.at

Name of the Examiner: Assoc.-Prof. Priv-Doz. Dr. Thomas E. Dorner, MPH

Can be contacted at: thomas.dorner@meduniwien.ac.at

Consent form *(To be completed by the participant)*

I agree to participate in the clinical trial "A training program for the development of social resources and their impact on the emotional, physical and social well-being of adults.". I have been informed that I can refuse to participate without adverse consequences.

I'm in detail by means of this subscriber information and of course about the clinical Study, potential burdens and risks, as well as the nature, significance and implications of the clinical trial and been cleared up for me resulting requirements. I also have the text of this participant informed consent statement that a total of 6 pages includes read. I was answered by the investigator to understand and sufficiently encountered issues. I had plenty of time to decide. I currently have no further questions.
I'm going to the arrangements that are necessary to carry out the study, obey, however, I reserve the right to terminate my voluntary participation at any time without me arise from disadvantages.

I agree explicitly that my data collected in this clinical study as described in the "Privacy" section of this document can be used. In the event of missing or ambiguous filled data can I order data collection will be contacted by the investigator.

Two copies of this participant informed consent I received.
After consent I will send one copy of it signed back with the envelope sent along to the study leader.

....
(Date and signature of the participant)

....
(Date, name and signature of the responsible principal investigator)