My7steps App Trial Study

Information for study participants and declaration of consent

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This study is planned and conducted by the ***International Psychosocial Organisation*** *(Ipso gGmbH)* and financed by *My7steps GmbH*. If you have any questions regarding the study, please contact us by mail or phone:

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Dear participant,

thank you for showing your interest in participating in our scientific study during a difficult time. We would like to introduce you to our medical product *My7steps App*, a digital application, and the associated study in more detail:

What is the background of this study?

Depressive disorders are amongst the most prevalent diseases across the globe, frequently resulting in severe consequences for both those affected and their environment. At the same time, the access to suitable therapeutic services often results in long waiting times. Over the last few years, internet-based interventions (IMIs) demonstrated their effectiveness in the treatment of mental health diseases and are perceived useful in reducing these waiting times. We want to further investigate this potential with your help.

What is My7steps App about?

The medical product *My7steps App* is an internet-based treatment to reduce mental health symptoms. In the *My7steps App*, psychotherapeutic principles are implemented in a digitalized way. The content of this app is divided into seven steps. In the course of the treatment you will receive information, you will be asked to classify or write down situations and you will be given tasks and exercises or explanations in the form of films and audio recordings. The *My7steps App* will adapt its subsequent content based on your individual answers.

How does the study work and how long does it take to participate?

As part of the study, we use standardized questionnaires to record your psychosocial health at the beginning and end of your participation. This is done in two phone calls, each lasting 30 to 45 minutes. Whether *My7steps App* is a suitable offer for you and whether you can take part in the study will be determined in an introductory video interview that takes place before you are included in the study and also lasts about 45 minutes. In total, three appointments are necessary for participation in the study, each lasting about 45 minutes and spread over 3.5 months of study time: two appointments at the beginning and one appointment at the end of the study.

Will there be different groups in the study?

Yes. The study participants will be allocated to two groups via randomization (comparable to the tossing of a coin): The "treatment group" will gain access to the *My7steps App* right away. The "control group" will be put on a waiting list for three months, before gaining access. Aside from this difference, both groups will receive the identical treatment. With this randomized allocation procedure, it is ensured that both groups are comparable. The likelihood of allocation to both groups is the same. At the end of the study, the control groups gains the same free-of-charge two-months access to the *My7steps App.*
The study will compare the treatment group and the control group. Unlike you, the interviewers do not know which group you have been allocated to. This procedure is called "blinding". Blind interviewers are crucial to guarantee unbiased test results. Therefore, we ask you to not inform your interviewers which group you have been allocated to!

What do I have to keep in mind?

At the end of the first telephone interview you will receive a short introduction to the *My7steps App*, while we prepare your registration. You will then receive an invitation email to independently complete your registration for the *My7steps App*. For this purpose, you need a device with internet access (e.g. Smartphone or computer) and in addition, internet access while using the program. We recommend the use of the *My7steps App* at regular intervals throughout the two months. Of course, you may also use alternative treatment options (e.g., psychotherapy, medication) while participating in the study. We only ask that you inform us about this upon request.

What is the personal gain when participating in this study?

As a study participant you will gain direct and free-of-charge access to the *My7steps App* upon activation. You can decide for yourself, when and how intensely you would like to use the program. There is a chance for you not to experience any change when participating. The results of the study, however, can have an impact in helping others in the future. The waiting control group receives free access to the *My7steps App* after the study.

Are there any risks associated with the study participation?

The *My7steps App* offers you a direct self-help option with no known risks. In isolated cases, it may happen that the user's psychological discomfort is not reduced or is reduced only slightly. This can cause a feeling of disappointment. As safety features, the app automatically responds to drastic deteriorations in self-assessment, the formulation of suicidal thoughts, or signs of contraindication. In these cases, the app prompts a psychologically trained staff member to review your case and contact you directly if there is a suspicion of a risk to your safety. This can be done through a text message, an email, or in urgent cases, a phone call. We strongly advise you to follow the recommendations and, if necessary, to seek further, direct and personal help on site. Help can be provided by a doctor, a psychological psychotherapist or an appropriate specialist. In case of acute emergencies, contact them immediately or dial the national emergency numbers of the fire department or police.

Are there costs and allowances attached to the participation in this study?

Participation in the study will not incur any additional costs for you or for the health insurance company. As compensation for your effort, you will receive €50 at the end of your participation.

Data protection and data processing

The protection of your personal data is very important to us. The data collected in this study include personally identifying information such as name, date of birth and sensitive personal health related information. These data will exclusively be assessed and processed for the purpose of this study. According to law regulations, we are obliged to give access to medical data to representatives of supervisory institutions and the responsible ethics committee in case of an inspection of our research project. In order to carry out your registration to the treatment, your contact data will be further processed by the manufacturer of *My7steps App.*
The following measures during storage and processing protect your personal data:

1. Access to *My7steps App* is password protected and communication is end-to-end encrypted. *My7steps App* complies with the German and European legal requirements for data protection.
2. The interviews conducted as part of the research project are not recorded and are conducted using the GDPR compliant provider *Senfcall* (for video consultations) or as telephone interviews.
3. The personal and clinical data collected as part of this research project are subject to the provisions of data protection law. They are recorded via a professional online survey and stored only in pseudonymized form[1] (i.e., encrypted). The data is archived under lock and key for a period of 15 years in accordance with legal regulations. During pseudonymization (encryption), your name and other identifying features are replaced by your access code to the *My7steps App* to make identification much more difficult. Access to this "key", which enables personal assignment of your data, is only granted to persons of the study team who have been expressly authorized and trained in psychotherapy. As soon as the purpose of the research permits, the key will be deleted and the collected data will thus be anonymized[2].
4. Anonymization is carried out as part of the statistical evaluation. The publication of the study results takes place exclusively in anonymized form.

Responsible for data processing are:

- Technical data *My7steps App*: Dr. Ralph Grobecker (Management, *My7steps GmbH*)
- Data backup in the study cloud: Maryam Gardisi (Management, *Ipso gGmbH*)
- Final dataset of the study: Dipl.-Psych. Pelle Bernhold (*Ipso gGmbH*)

Your rights as a study participant:

- You can decide at any time whether you wish to continue participating in the study. You have the right to revoke your consent at any time and without giving reasons, without any disadvantages arising from this.
- You have the right to request information about the personal data collected from you (along with delivery of a free copy), to have incorrect personal data concerning you corrected, and to request the deletion of personal data if they are no longer necessary for the purpose for which they were collected.
- The processing of personal data is only lawful with the consent of the study participants. In the event of revocation of the declaration of consent, further data collection will be terminated and access to the intervention will be deactivated. Collected data will be deleted, as long as further processing of the collected data is not supported by other lawful regulations. Assessed data will be deleted on participants' demand as long as the demand is in advance of study completion and anonymization, respectively. Deletion of already anonymized data is not possible. In exceptional cases, data collected up to the time of revocation may be further processed if this is necessary to fulfil a legal obligation.
- To exercise their data protection rights, study participants may contact the study director. In addition, they have the right to lodge a complaint with the data protection supervisory authority if they consider the data processing that has taken place to be unlawful:

Der Hamburgische Beauftragte für Datenschutz und Informationsfreiheit (Hamburg Commissioner for Data Protection and Freedom of Information)
Ludwig-Erhard-Str 22, 7. OG, 20459 Hamburg

Phone number: 040 428 54 - 4040
E-Mail: mailbox@datenschutz.hamburg.de
Online complaint form: https://datenschutz-hamburg.de/beschwerde/

DECLARATION OF CONSENT

[THIS DOCUMENT IS A VIEWING VERSION FOR YOU. THE CONSENT TAKES PLACE BY EMAIL]

1. Please save the attached PDF - this is your personal copy of the study information and consent form.
2. For consent, please reply directly to this email without removing the text we sent. This is the only way that your consent can be legally recognized.
3. Please copy the following bold and underlined text, and send it to us in the reply email. Please add the date and your full name below the text in your reply.

I hereby agree to participate in the research project described above.

I hereby consent to the processing of my personal data, in particular health data, as described.

All of my questions were adequately answered.

I was given copies of the study information and declaration of consent.

DATE_____FIRST NAME_____LAST NAME