Central Institute for Mental Health

J5 - D-68159 Mannheim,

MaKo Director of Studies: Prof. Dr. Ulrich Reininghaus; **Study telephone:** +49 6 21 17 03 - 1932**; Email:** mako-studie@zi-mannheim.de

Request to participate in medical research:

Mannheim Incidence and Cohort Study of Public Mental Health (MaKo)- Study Arm 2: Cohort Study

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Dear prospective study participant,

We are asking you here whether you would be willing to participate in our research project.

Your participation is voluntary. All data collected in this research project is subject to strict data protection regulations.

The research project is being carried out by the Central Institute of Mental Health (CIMH)/ Zentralinsititut für Seelische Gesundheit (ZI) under the direction of Prof. Dr. Reininghaus. If you are interested, we will be happy to inform you about the results of this research project.

We will explain the most important aspects to you and answer your questions in a meeting. Giving you an overview already, here are the most important matters. Further detailed information will then follow.

Why are we conducting this research project?

- With the second study arm of the Mannheim Incidence and Cohort Study, we want to investigate the development of the mental health of young people in the Rhine-Neckar region over the course of 12-24 months.

What do I have to do if I take part? - What will happen to me if I take part?

- Form of participation: If you decide to take part, you will have to complete questionnaires about your mental health, including in everyday life over the course of a week.
- Participation procedure: We ask you to take part in up to 5 appointments with subsequent documentation of your mood in everyday life. The appointments last between 2-5 hours. The mood documentation takes about 15 minutes per day over the course of a week.

What benefits and risks are associated with this?

Benefit

- There is no direct benefit for you if you take part in the study. However, you will help future patients.

Risk and exposure

- Participation costs time.

With your signature at the end of the document, you attest that you are participating voluntarily and that you have understood the contents of the entire document.

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Detailed information

1. Goal and selection

In this information document, we refer to our research objective as a *research project.* If you take part in this research project, you are a *participant*.
In this research project, we want to get to the bottom of the development of mental illness in people in two narrowly defined regions, namely Mannheim and the Rhine-Neckar region. We are asking you to participate in this research project because all persons aged 14 - 35 who are seeking treatment for mental distress or who are undergoing treatment for the first time due to various complaints in dealing with emotions (such as anxiety, depression or emotional instability) or due to unusual experiences (such as psychotic symptoms) can participate in this research project.
We are also looking for people between the ages of 14 and 35 who are healthy and have never been in treatment.

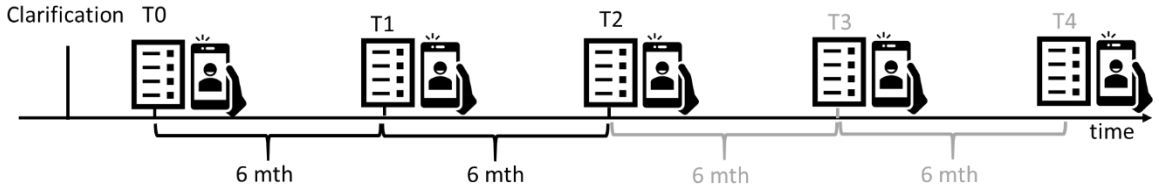
2. General information

As a basis for the planning of mental health care and the identification of new risk factors for mental health, it is necessary to investigate the development of mental health over time. At the Central Institute of Mental Health (CIMH),the **Mannheim Incidence and Cohort Study**
The mental health of young people from Mannheim and the Rhine-Neckar region will be examined over a period of 12 - 24 months. We are looking for a total of 340 participants. We would like to determine changes in mental health over time through multiple surveys. This will also enable us to identify risk and protective factors for mental health.

We carry out this research project in accordance with the regulations and laws. We also observe all internationally recognized guidelines. The responsible ethics committee has reviewed and evaluated the research project.

3. Procedure

In general, appointments can be made either at the CIMH or by video call with a secure and certified provider (e.g. RED Medical, Clickdoc, depending on availability). You decide how you would like to attend the appointment when you make it. You will need an internet-enabled device (smartphone, tablet, PC) with a microphone, loudspeakers, and camera as well as an internet browser for the video call. Please go to a quiet room for the duration of the call to ensure data security and a smooth process.
The illustration (see below) shows an overview of the dates.



<u>Informative discussion and examination of the inclusion criteria (duration: ca. 1-3 hours):</u>
First, we conduct a detailed consultation. We will then talk about your current and past mental health. We would like to make an audio recording of this conversation or interview if you agree to this (see declaration of consent at the end). The audio recording will be used to check whether the study staff agree on the conduct of the interview. The audio recording will be saved under your participant code (see point 9).
We may not be able to include you in the study if we determine that you do not meet the inclusion criteria.

Initial survey (T0, duration: ca. 1-2 hours):
Here we ask you to complete questionnaires. The questions relate to you personally, your background and your mental health and well-being. It takes about 2 hours to complete the questionnaires.

Documentation of mood in everyday life (duration: 15min per day on 6 days):
We then ask you to document your mood in everyday life over the course of one week using a smartphone app. This will give us a better picture of how your mood is progressing. The data will not be used for your treatment. The mood documentation is done with an app that you can install on your Android smartphone. If you do not have an Android smartphone, you can borrow a study smartphone from us. The app will remind you 8 times a day at random times (e.g. between 8 am and 10 pm) and ask you to enter short details (each lasting 2 minutes). At the end of the week, you can pause the app or return the study smartphone. You will then receive a short questionnaire for your feedback.

It is important that you refrain from answering the questions in potentially dangerous situations, especially in road traffic. Using the app as a cyclist, motorcyclist or even in a car while driving can be life-threatening under certain circumstances and constitutes an offense. In addition, the insurance cover explained under point 11 (see below) does not apply to persons who disregard required care in road traffic. The use of the study smartphone is only permitted for study purposes. If you have any problems with the study app or the study smartphone, please contact the study team (see header).

Follow-up survey (T1 to T4 if necessary, duration: ca. 2-3 hours each):
Every six months, we will invite you back for an appointment, which will be followed by a week with the study app. At the appointment, you will again complete questionnaires on your current mental health and we will conduct another interview (see above). The first follow-up survey is 6 months after your inclusion in the study (T1). The next follow-up survey is after one year (T2) and for some people a follow-up survey is also planned after one and a half years (T3) and two years (T4). Whether this applies to you depends on the date of your inclusion in the study.

We may have to exclude you from the research project prematurely or pause your participation in the study. This may happen if your symptoms worsen to such an extent that hospitalization is necessary.

4. Benefit

You will not personally benefit from participating. By documenting the mood in everyday life, positive effects on the mood have been proven. However, we cannot guarantee that this will be the case for you. The study primarily serves a scientific purpose. However, you are contributing to research into protective factors for mental illness, which will help to assess the need for care and treatment. The aim is to improve existing treatment and prevention measures.

5. Voluntariness and obligations

You are taking part voluntarily. If you do not want to take part in this research project or later withdraw your participation, you do not have to provide any reasons. Your treatment/support is guaranteed regardless of your decision.

If you take part in this research project, you will be asked to:

- to adhere to the specifications and requirements of the research project through the protocol;
- to inform the examiner / investigator about concurrent treatment and therapy by other physicians and about the intake of medication.

6. Risks and burdens

You are only exposed to minor risks through the research project. Whenever data is collected, stored, and transmitted via online portals, apps and/or mobile data collection, there is a data

protection risk for your personal data, e.g. due to unintentional interposition of third-party providers via malware or unsecured Internet access. In such a case, it is not possible to guarantee the protection of your personal data in accordance with the General Data Protection Regulation (DSGVO) despite our security precautions and the encryption of your data.

Burdens: Participation in the study requires your time (3 - 5 appointments with a total duration of 10-17 hours, mood documentation in everyday life takes approx. 15 min/day. The processing of numerous and time-consuming questionnaires, including questions about your own personality, can be stressful.

7. Alternatives

If you do not wish to participate in this research project but are open to the possibility of participating in other research projects, please speak to the study staff.

8. Results

There are

1. individual results of the research project that affect you directly,
2. objective final results of the entire research project.

Re 1: The investigator will inform you if there are any indications that you are so unwell that you or other people are in danger. You will be informed verbally and can then reconsider whether you wish to continue participating in the project. Re 2: The investigator can send you a summary of the overall study results at the end of the research project if you wish.

9. Confidentiality of data

9.1. Data processing and encryption

The legal basis for data processing is your voluntary consent (Art. 6 (1) (c) DSGVO).
In this research project
Prof. Dr. Ulrich Reininghaus,
Department of Public Mental Health,
Central Institute of Mental Health
J 5, 68159 Mannheim
Phone: 0621-1703 – 1931
Email: ulrich.reinighaus@zi-mannheim.de is responsible for the data processing.

For this research project, data about your person and health is collected and processed, partly in automated form. We collect information about your place of residence so that we can assign you to your district. The information about your street and house number are not stored, only the allocation to one of 38 districts in Mannheim.
This allocation is important for us, as we need to know for our research project how many people from which district are taking part and so that we can investigate whether there are differences between the districts. During data collection, your data will be stored under your individual study code (= pseudonymized). Your name is assigned to the study code on the so-called key list, which is kept locked away with the study leader. The key list always remains in the Department of Public Mental Health at the CIMH.
Only very few specialists will see your unencrypted data and only to fulfill tasks within the framework of the research project. These persons are subject to a duty of confidentiality. As a participant, you have the right to view and correct your data.

The research data is stored pseudonymously for 10 years. As a cohort of participants is created as part of the project and as this cohort is to be re-contacted years later, it is necessary for the data to be stored in pseudonymized form for as long as possible. Your consent to storage will therefore be obtained again after 10 years. If you wish, the research data can be anonymized. Anonymized research data will be deleted when this data is no longer required for its purpose.

9.2. Data protection

All data protection regulations are strictly adhered to. It is possible that your data may have to be transferred in encrypted form to countries outside the EU, for example for publication, and may be made available to other researchers. It is possible to pass on anonymous research data. You can also indicate on the consent form whether you agree to the transfer of study data in pseudonymized form.

9.3. Data protection for further use

Your data could be important for answering other questions at a later date and/or could later be sent to and used in another database in Germany or abroad for as yet undefined investigations (further use). This other database must adhere to the same standards as the database for this project.
For this further use, we ask you to sign another declaration of consent at the very end of this document. This second consent is independent of your participation in this project.

9.4. Data protection in Internet-based research

Any collection, storage, and transmission of data in the context of Internet-based research involves confidentiality risks (e.g. the possibility of identifying you). These risks cannot be completely ruled out and increase the more data can be linked together. The project management will take all measures to minimize these confidentiality risks for you.

For the video calls, the data is transmitted via the Internet using a so-called peer-to-peer (computer-to-computer) connection. Data processing contracts have been concluded with several video service providers with servers in Europe so that we can use the following software for video telephony, depending on availability:
- Clickdoc from the company La-Well Systems GmbH, Bünde
- Red Medical Systems GmbH, Munich

The video service provider guarantees that all content of the video appointment is encrypted end-to-end during the entire transmission process in accordance with the current state of the art and is neither viewed nor stored by the video service provider. All metadata will be deleted after 3 months at the latest. The video service provider is prohibited under criminal law from disclosing or making data accessible to unauthorized third parties.
The database in which, for example, your information from the questionnaires is stored is located on servers of the CIMH. Only authorized study staff have access to the data.

The study app was programmed by Movisens GmbH from Karlsruhe, Germany. Based on a data processing agreement, Movisens GmbH may process the data recorded by the app and store it in the data center of TelemaxX Telekommunikation GmbH in Karlsruhe, Germany, until the study director orders its deletion. Furthermore, a special rights system ensures that only the study staff involved, but not Movisens GmbH employees, can access the data stored by the app. The following security precautions have been taken in detail:
- 256-bit encrypted data transfer on all channels between app and server as well as between server and internet browser of the study staff.
- 256-bit encrypted data storage on the smartphone. Decryption only takes place on the server.
- The hosting provider (ProfitBricks), i.e. the company that stores the data, is responsible for data security, data protection and the secure server environment (in accordance with the European General Data Protection Regulation). The servers are operated by TelemaxX Telekommunikation GmbH in Karlsruhe, Germany and are ISO 27001 certified (ensuring reliability, confidentiality, integrity and authenticity).
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10. Withdrawal

You can withdraw your consent in writing or verbally at any time without giving reasons and without any disadvantage to you. If you withdraw your consent, no further data will be collected. However, the data processing that took place before you withdrew your consent remains lawful.

In the event of withdrawal, you can also request the deletion of your data.

After the evaluation, your data will be anonymized. The key assignment is destroyed so that nobody can find out afterwards that the data and samples originally came from you. This is primarily for data protection purposes.

If you have any concerns regarding data processing and compliance with data protection requirements, you can also contact the following data protection officers:

Data Protection Officer of the CIMH Mannheim
Dr. jur. Regina Mathes
Phone: +49 6 221 56 - 7036
E-mail*: datenschutzbeauftragter@zi-mannheim.de*

You have the right to lodge a complaint with any supervisory authority for data protection. You can find a list of the supervisory authorities in Germany at

https://www.bfdi.bund.de/DE/Infothek/Anschriften_Links/anschriften_links-node.html

11. Compensation

If you take part in this research project, you will receive the following compensation: The compensation depends on the number of appointments you have attended. After the interview, you will receive 20 euros, even if you cannot be included in the study. You will receive a further 20 euros for completing the questionnaires. You will also receive compensation for the mood documentation, depending on the number of entries. This means that you can receive between €20-60 per assessment time point. For the follow-up appointments after 18 and 24 months, you will receive an additional €20 each. This means that you can receive a compensation between €20 and €340 for your participation in the study. We will reimburse you for expenses such as travel costs incurred due to your participation. You or your health insurance company will not incur any costs as a result of your participation.

12. Liability

If you suffer any damage as a result of the research project, the Central Institute of Mental Health, which initiated the research project and is responsible for its implementation, is liable. The requirements and the procedure are regulated by law. The Central Institute of Mental Health has taken out liability insurance with BGV Badische Versicherungen under contract number V20/217 237/001 to cover liability in the event of damage. If you have suffered any damage, please contact the test management.

There is also a commuting accident insurance policy with BGV Badische Versicherungen under contract number V001271124. The insurance only covers accidents that affect the insured persons on direct journeys from their home to the examination/treatment center at the Central Institute of Mental Health in Mannheim and back. There is no insurance cover for journeys to other study centers. Insurance cover is only provided during the journeys. Insurance cover begins on the outward journey when leaving the home or on the return journey when leaving the examination/treatment center.
The insurance covers the journey to the examination/treatment center at the Central Institute of Mental Health in Mannheim for the purpose of starting the journey and ends with the arrival at the examination/treatment center at the Central Institute of Mental Health in Mannheim or with the return to the home. The insurance cover does not apply if the normal duration of the journey is extended or the journey itself is interrupted by purely private and personal measures (e.g. shopping, visits to restaurants for private purposes).

Furthermore, the loaned equipment is covered by insurance. If you notice any damage, please inform the director of studies.

Damage must be reported to the study director immediately.

13. Financing

The research project is fully paid for by the Central Institute of Mental Health (sponsor) and was funded by the German Research Foundation.

14. Contact persons

You can ask questions about participating in the project at any time.
Please also contact us if you have any uncertainties that arise during or after the research project under the following addresses.

Director of Studies:
Prof. Dr. Ulrich Reininghaus
Department of Public Mental Health
Central Institute of Mental Health
J 5, 68159 Mannheim
Phone: 0621-1703 - 1931
Email: ulrich.reininghaus@zi-mannheim.de

Trial management and study team:
Dr. Anita Schick
Department of Public Mental Health
Central Institute of Mental Health
J 5, 68159 Mannheim
Tel: +49 6 21 17 03 -1932
Email: mako-studie@zi-mannheim.de

15. Future research

In addition to participating in this study, your parents can consent to your pseudonymized data being used in future research projects. This will happen without you having to do anything else. The pseudonymized data would only be used for research that helps to find out more about health problems and how to treat them. If you do not agree to this further use of the data for future studies, you can still take part in this study. You can also withdraw your consent, which has no disadvantages for you. However, if data has already been included in published evaluations, it can no longer be withdrawn or erased.

Our research department is also constantly conducting new research and treatment studies. In the consent form, your parents can tick whether we may contact you for further studies. You are not agreeing to any further participation yet, but merely allowing the inquiry.

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MaKo Director of Studies: Prof. Dr. Ulrich Reininghaus; **Study telephone:** +49 6 21 17 03 - 1932**; Email:** mako-studie@zi-mannheim.de

Declaration of consent

As you are not yet of legal age, your parents' consent is required. Nevertheless, we would be pleased if you would also agree to participate in the study by signing it.

EK-II application number: (after submission)	**585-21**
Title of the Research project (scientific and lay language):	Mannheim Incidence and Cohort Study of Public Mental Health
Person responsible Institution (project management with address):	Central Institute of Mental Health, Department of Public Mental Health, J5, 68159 Mannheim
Place of implementation:	Central Institute of Mental Health, J5, 68159 Mannheim
Head of the research project at place of study: Surname and first name in block capitals:	Prof. Dr. Ulrich Reininghaus
Participant: Surname and first name in block capitals: Date of birth:	

I consent to the participation and processing of the above data.

□ **No** □ **Yes**

My parents have received a copy of the information leaflet and the declaration of consent. One copy remains at the test center.

Place, date	Signature of underage participant

Confirmation of the investigator: I hereby confirm that I have explained the nature, significance and scope of the research project to this participant. I confirm that I will fulfill all obligations in connection with this research project in accordance with applicable law. If, during this research project, I become aware of any aspects that could influence the participant's willingness to participate in the research project, I will inform him/her immediately.

Place, date	Surname and first name of the investigator in block capitals Signature of the investigator