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 Sir or Madam,

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)/ Zentralinstitut 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 carrying out 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 on 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

- You will not benefit directly from participating in the study. However, you will help future patients.

Risk and exposure

- Participation costs time.

By signing at the end of the document, you confirm 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 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 anyone between the ages of 14 and 35 who is seeking treatment for psychological distress or who is undergoing treatment for the first time for various complaints related to dealing with emotions (such as anxiety, depression or emotional instability) or for unusual experiences (such as psychotic symptoms) can take part 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

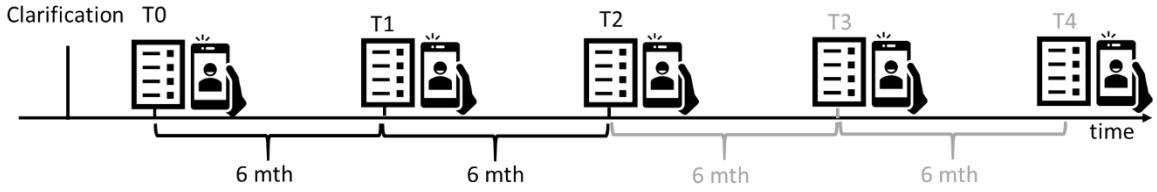
As a basis for the planning of mental health care and the identification of new risk factors for mental health, it is necessary to investigate the development of mental health over time. The **Mannheim Incidence and Cohort Study at** the Central Institute of Mental Health (CIMH) will therefore examine the mental health of young people from Mannheim and the Rhine-Neckar region over a period of 12 - 24 months. We are looking for a total of 480 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.



Informative discussion and examination of the inclusion criteria (duration: ca. 1-3 hours):

First, we conduct a detailed consultation. We then talk about your current and past mental health. From this conversation or interview we would like to make an audio recording 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, 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. Mood documentation is carried out using an app that you can install on your Android smartphone. If you do not have an Android smartphone, you can borrow a study smartphone form 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 queries in potentially dangerous situations, especially in road traffic. Operating the app as the driver of a motor vehicle 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 some people are also scheduled for a follow-up survey 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, it contributes to research into protective factors for mental illness, which helps to assess the need for care and treatment. The aim is to improve existing treatment and prevention measures.

5. Voluntariness and obligations

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

If you participate in this research project, you will be asked 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

The research project only exposes you to minor risks. 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, a guarantee for the protection of your personal data in accordance with the General Data Protection Regulation (DSGVO) is not possible 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 during the course of the project if there are any indications of acute danger to yourself or others. 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 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 data processing.

For this research project, your personal and health data is collected and processed, partly in automated form. We collect information about your place of residence so that we can assign you to a district in the small-scale segmentation of the city of Mannheim. The information on your street and house number is not stored, only the allocation to a neighborhood of 38 districts in Mannheim. This data is required to be able to report results with a spatial reference and to be able to examine geographical differences. 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 by the study director. Persons who do not have access to this key list cannot draw any conclusions about your person. The key list always remains in the Department of Public Mental Health at the ZI.
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 your 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 comply with 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 end-to-end encrypted 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).

10. Withdrawal

You can withdraw your consent at any time in written form or verbally without giving reasons and without any disadvantage to you. If you withdraw your consent, no further data will be collected. However, the data processing carried out up to the point of withdrawal remains lawful.

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

After evaluation, your data is anonymized. The key assignment is destroyed so that nobody can find out afterwards that the data 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 CIMHI Mannheim
Matthias Gerberding 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 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 immediately to the study director.

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, we would like to know whether you agree to your pseudonymized data being used in future research projects. The use of data for future research questions will not cause you any additional work. You are free to consent to the use of your pseudonymized data for future research. Your pseudonymized data may only be used for scientific health-related research to find new ways of understanding, detection, treatment, prevention or cure health problems. If you decide against this, you can still take part in this study. Even if you initially give your consent, you can withdraw it at any time without giving reasons. However, data that has already been included in published analyses cannot be withdrawn or erased.

Our research department is also constantly conducting new research and intervention studies. In the consent form, you can indicate whether you agree to be contacted for further studies. You are not agreeing to any further participation yet, but merely authorizing the inquiry.

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Declaration of consent

Written declaration of consent to participate in a research project
Please read this form carefully. Please ask if there is anything you do not understand or would like to know. Your written consent is required for participation.

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 have been informed verbally and in writing by the undersigned investigator about the purpose, the course of the research project, about possible advantages and disadvantages as well as about possible risks.
- I am taking part in this research project voluntarily and accept the content of the written information provided for the above-mentioned research project. I have had sufficient time to make my decision.
- My questions in connection with participation in this research project have been answered. I will keep the written information and receive a copy of my written declaration of consent.
- I agree that the responsible experts of the project management and the ethics committee responsible for this research project may inspect my unencrypted data for testing and control purposes, but under strict confidentiality.
- I am aware that my health-related and personal data can only be passed on in encrypted form for research purposes for this research project (including abroad). The sponsor guarantees that data protection in accordance with EU standards will be observed. If it is not possible to guarantee data protection according to EU standards an explicit reference is made to this and the different level of data protection abroad and the measures taken to protect the rights of the participants will be explained. I can withdraw from participation at any time and without giving reasons. My further treatment is guaranteed regardless of my participation in the research project. The data collected up to that point will still be used for the evaluation of the research project.
- I agree that my general practitioner may be informed about my participation in the research project.
- I have been informed that the Central Institute of Mental Health has taken out insurance to cover damages resulting from the research project.
- I am aware that I must comply with the obligations set out in the information leaflet. In the interest of my health, the test management may exclude me at any time.
- I agree that my data may continue to be used in anonymized form if I withdraw my consent.

Optional consent:

- I agree that I may be contacted by members of the research department for information about future studies:

  □ **No** □ **Yes**

- I consent to my study data being used in pseudonymized form for future research:

  □ **No** □ **Yes**

- I agree that I may be contacted again at a later date so that further information can be collected:

  □ **No** □ **Yes**

- I consent to audio recording of mental health interviews. I am aware that I can withdraw this consent at any time:

  □ **No** □ **Yes**

- I release _____ (treating doctors/ therapists) from the confidentiality obligation and related data protection duties with respect to the study staff. I declare that the study staff may inspect my patient file with the persons named above. Conversely, I release the study staff from their confidentiality obligation towards the above named doctors/therapists.

  □ **No** □ **Yes**

- I would like to receive a summary of the overall study results at the end of the research project:

  □ **No** □ **Yes**

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

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

Place, date	Signature of participant

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

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, in the course of the 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.