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 for your child's participation in medical research:

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

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Dear parents or legal guardians,

We ask you here whether you agree that your child may participate in our research project. Your child's 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 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 that your child may participate, he or she must complete questionnaires on his or her mental health, including in everyday life over the course of one week.
- Participation procedure: We ask your child to take part in up to 5 appointments with subsequent mood documentation 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

- Your child will not benefit directly from taking part in the study. However, it will help future patients.

Risk and exposure

- Participation costs time.

By signing at the end of the document, you attest that your child is participating voluntarily and that you and your child have understood the contents of the entire document.

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 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 received treatment. Your child may therefore be suitable for participation in the study.

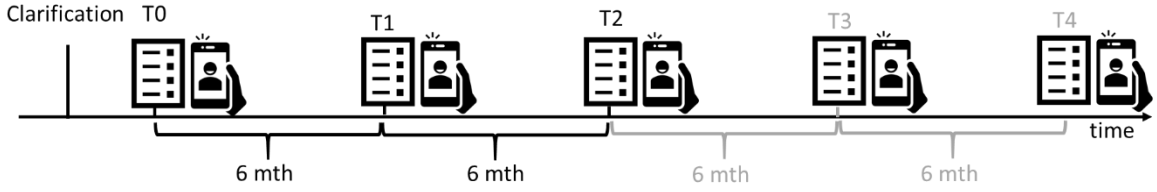
2. General information

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 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 and your child decide how you would like to attend the appointment when you make the appointment. An internet-enabled device (smartphone, tablet, PC) with microphone, loudspeakers, and camera as well as an internet browser is required 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 will conduct a detailed information session with you and your child. We will then talk to your child about their current and past mental health. We would like to make an audio recording of this conversation or interview if you and your child 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 your child in the study if we determine that he or she does not meet the inclusion criteria.

Initial survey (T0, duration: ca. 1-2 hours):

Here we ask your child to complete questionnaires. The questions relate to your child's personality, background, mental health and well-being.

Documentation of mood in everyday life (duration: 15min per day on 6 days):
We then ask your child to document their mood in everyday life over the course of one week using a smartphone app. This helps us to get a better picture of how your child's 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 your child does not have an Android smartphone, they can borrow a study smartphone from us. The app reminds your child 8 times a day at random times (e.g. between 8 am and 10 pm) and asks them to enter short details (each lasting 2 minutes). At the end of the week, you can pause the app or return the study smartphone. Your child will then receive a short questionnaire for their 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 your child has any problems with the study app or the study smartphone, they should 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 your child to another appointment, which will be followed by a week with the study app. At the appointment, your child will again complete questionnaires on their current mental health, and we will conduct another interview (see above). The first follow-up survey is 6 months after study inclusion (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 your child depends on the date of study inclusion.

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

4. Benefit
You and your child will not personally benefit from participating. Documenting the mood in everyday life has proven positive effects on mood. However, we cannot guarantee that this will be the case for your child. The study primarily serves a scientific purpose. However, your child is 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
Your child is taking part in the study voluntarily. If your child no longer wishes to take part or if you later wish to withdraw your consent to participate, you do not have to provide reasons for this. The treatment/care of your child is guaranteed regardless of your decision.

If your child takes part in this research project, he or she 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 exposes your child to only 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 child's 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 your child does not wish to participate in this research project, but is open to the possibility of participating in other research projects, you can talk to the study staff.

8. Results

There are

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

Re 1: The investigator will initiate the necessary measures and assistance if there are any indications that your child is a danger to themselves or others. You can reconsider whether your child may continue to participate in the project.
Re 2: The investigator can provide your child and you with 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 on your child's person and health is collected and processed, partly in automated form. We collect information about your child's place of residence so that we can assign it to a district in the small-scale segmentation of the city of Mannheim. The information on the street and house number is not stored, only the allocation. This data is required to be able to report results with a spatial reference and to be able to investigate geographical differences. During data collection, your child's data will be stored under an individual study code (= pseudonymized). Your child's name is assigned to the study code on the so-called key list, which is kept locked away with the study director. Persons who do not have access to this key list cannot draw any conclusions about the identity of your child. The key list always remains in the Public Mental Health Department at the CIMH. Only very few professionals will see your child's unencrypted data, and only to fulfill tasks within the framework of the research project. These persons are bound to confidentiality. As a participant, your child has the right to view and correct his/her data.

9.2. Data protection

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 recontacted years later, it is necessary for the data to be stored in pseudonymized form for as long as possible. After 10 years, your consent to storage will therefore be obtained again. 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.

9.3. Data protection

All data protection regulations are strictly adhered to. It is possible that your child's 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.

9.4. Data protection for further use

Your child's 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.

9.5. 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 your child). 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 is 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, the information provided by your child in the questionnaires is stored is located on the servers of the ZI. 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 and your child 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 child's data.

After evaluation, the data is anonymized. The key assignment is destroyed so that nobody can find out afterwards that the data originally came from your child. 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 your child takes part in this research project, you or your child will receive the following compensation. The compensation depends on the number of appointments your child has attended. After the interview, your child will receive 20 euros, even if your child cannot be included in the study. They will receive a further 20 euros for completing the questionnaires. They will also receive compensation for the mood documentation, depending on the number of entries. This means that your child can receive between €20-60 per assessment time point. For the follow-up appointments after 18 and 24 months, they will also receive an additional €20 each. This means that your child can receive an allowance of between €20 and €340 for their entire participation in the study. We will reimburse your child for expenses such as travel costs incurred due to participation. There are no costs for you or your child or their health insurance company due to participation.

12. Liability

If your child suffers harm 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 your child has 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 and your child 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 child's pseudonymized data being used in future research projects. The use of data for future research questions will not cause any additional work for your child. You are free to consent to the use of your pseudonymized data for future research. The 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 not to participate, your child 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 that your child can be contacted for further studies. You are not agreeing to any further participation, 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:	

- Me and my child 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.
- My child is taking part in this research project voluntarily and accepts the content of the written information provided on the above-mentioned research project. We have had sufficient time to make a decision.
- Our 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 child's unencrypted data for testing and control purposes, but under strict confidentiality.
- I am aware that my child's 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. Me and my child can withdraw from participation at any time and without giving reasons. The further treatment of my child is guaranteed regardless of participation in the research project. The data and samples collected up to that point will still be used for the evaluation of the research project.
- I agree that my child's family doctor may be informed about my child's 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 interests of my child's health, the trial management may terminate or pause my child's participation at any time.
- I agree that my child's data may continue to be used in anonymized form if I withdraw my consent.

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Optional consent:

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

  □ **No** □ **Yes**

- I consent to my child's study data being used in pseudonymized form for future research

  □ **No** □ **Yes**

- I agree that me and my child 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 with my child. I am aware that me and my child 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 child's 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 results at the end of the research project:

  □ **No** □ **Yes**

I consent to my child's participation and the 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 the 1st legal guardian of the participant

Place, date	Signature of the 2nd legal guardian of the participant

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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

Confirmation of the investigator: I hereby confirm that I have explained the nature, significance and scope of the research project to the parents of 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 take part in the research project, I will inform him/her immediately.

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