SKKIPPI-Study
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Information for participants

SKKIPPI –
A study of psychosocial distress among parents and their children during their first year of life[1]

What is the aim of this study?

The aim of the study is to identify psychosocial stress and burdens among parents after child birth in order to prevent such stress and burden in the future and provide help early on for affected people. In addition we hope that the results of the study will contribute to improving care for parents in the future.

Why was I selected?

Your child was randomly selected from the registration office in your region (Berlin, Leipzig or Flensburg). The data was legally submitted to us by the registers office[2] according to § 34 of the German registration law (Meldegesetz).

How will I benefit from participating in this study?

If you feel stressed or overburdened we will share information on care opportunities in your area. If you do not feel stressed or overburdened you will not likely directly benefit from participating in this study. However, you will act as a comparison group to improve the care of parents and children with psychosocial distress.

What does the process of participating in this study look like?

We would ask you to participate in an online survey lasting about 10-15 mins (participation via smartphone is possible). If necessary the survey can be filled out on paper as well. We will ask you questions about pregnancy and birth, possible psychosocial stress and the health of your child. Based on your answers if we notice that you may suffer from psychosocial distress, we would like to follow up with one or two interviews on the phone. Maybe we will invite you to participate in another interview.

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[1] Title of the study: Prevalence of and risk fractors for psychosocial stress among parents of infants: the prospective cohort study of the SKKIPPI Project

[2] The registration office is not associated with the content of the study and has no influence over the amount of written reminders you may receive

Does the participation cost anything?

No. Participation in this study is free.

Do I have to participate in this study?

No. Participation in this study is voluntary. You can withdraw your consent and end your participation in the study at any point without having to state reasons and without any disadvantages.

Are there any risks for me?

You may find some of the questions very personal, but we still hope that you will be able to answer all of them. If your psychosocial stress is so pronounced, that you require further help, we would refer you accordingly.

How will data and privacy protection be ensured?

In this study we place high value on data protection. Any person with access to your data is lawfully bound to comply with data protection standards. The study complies with the German Federal Data Protection Act an all other applicable data protection regulations (e.g. the European General Data Protection Regulation EU-GDPR). For more information on data protection please visit www.skkippi.de.

Your personally-identifiable data (name, address, phone number, e-mail address, etc) will be stored for a maximum of 10 years and will then be deleted. It is strictly protected from unauthorised access. The storage of data is important for saving your verification of consent, for any queries and for further contact. Your data will only be used by us and not be passed on for other purposes.[3] Your data from the survey and interview will only be stored with a participants number (this is called pseudomization). The data that can identify your person (e.g. name) will be stored separately from your answers from the survey.

Who will use my data and for what?

Your data will be scientifically analysed in a pseudonymized manner, meaning your person will not be identifiable. Any research results will be published in an anonymous manner, meaning nothing can be traced back to your person.

Who is responsible for this study?

The Institute for Social Medicine, Epidemiology and Health Economics at Charité Berlin.
The responsible study lead is Prof. Thomas Keil. The study is publicly financed by the Innovationsfond of the German Gemeinsamer Bundesausschuss (Federel Joint Committee).

We hope we were able to answer all of your questions. Please take your time to decide if you would like to participate.
If you have further questions you are welcome to contact our administrative office:

SKKIPPI Administrative Office
Institute for Social Medicine, Epidemiology und Health Economics– Charité Universitätsmedizin Berlin
Tel. 030-450529147
E-Mail: skkippi@charite.de
www.skkippi.de

For questions regarding data protection please contact:

Stabsstelle Datenschutz (Data Protection Unit) – Charité Universitätsmedizin Berlin

Charitéplatz 1, 10117 Berlin, Tel. 030-450580016, E-Mail: datenschutz@charite.de

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[3] An order data processor (K+L DruckenPlus GmbH) was merely commissioned once to print and send this letter.

Institute for Social Medicine, Epidemiology and Health Economics

Additional information about the General Data Protection Regulation (GDPR)

SKKIPPI - A study of psychosocial distress among parents and their children during their first year of life [1]

Dear participant,

in the context of your invitation to participate in the above-mentioned study we have already informed you in the participants information and the consent form about data protection and the handling of your personal data. Due to the new EU General Data Protection Regulation (GDPR) that came into force on 25/05/2018 we would like to further inform you about these additional rights in more detail.

- Right of access, Art. 15 GDPR
You have the right to obtain information about your personal data that are being stored.

- Right to rectification, Art. 16 GDPR
If you find that your personal data that are being processed are false, you can demand rectification. Taking into account the purpose of data processing, incomplete data must be completed.

- Right to erasure, Art. 17 GDPR
You have the right to demand deletion of your data, if there are certain reasons for deletion. This is especially the case if the data is no longer needed for the purpose for which it was originally collected or processed.

- Right to restriction of processing, Art. 18 GDPR
You have the right to restrict the processing of your data. This means, that your data will not be deleted but marked to restrict further processing or use.

- Right to object, Art. 21 GDPR
You have the fundamental right to object even legitimate data processing, carried out for the public benefit, by public authorities or based on the legitimate interest of an institution.

- Right to data portability, Art. 20 GDPR
If data processing is carried out by automated means based on your consent or a contract, you have the right to demand the provision of your data in a structured, common and machine-readable format.

Complaint to the regulatory authority due to data protection violation

Asides from your option to take legal action, you have the right to issue a complaint to a regulatory body, if you consider the processing of your data inappropriate with regards to data protection.

Berlin Commissioner for Data Protection and Freedom of Information (Berliner Beauftragte für Datenschutz und Informationsfreiheit)
Friedrichstraße 219, 10969 Berlin
E-Mail: mailbox@datenschutz-berlin.de, Tel.: +49 30 13889-0

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[1] Title of the study: Prevalence of and risk fractors for psychosocial stress among parents of infants: the prospective cohort study of the SKKIPPI Project