STUDY INFORMATION SHEET AND CONSENT FORM FOR ADOLESCENTS AND CARETAKERS

Title of the study: Implementation of Interpersonal counselling for adolescents (IPC-A) in Finland

Invitation to participate in the study

We invite you to participate in this study, which examines whether depressed adolescents in upper comprehensive school benefit from interpersonal counselling. Your data will be used to determine how many adolescents need help with depression, how treatment is provided, and whether interpersonal counselling is effective and cost-effective compared to other treatment options.

This information sheet describes the study and your possible participation in the study. Please read this information leaflet carefully. If you have any questions, please contact the study personnel (contact information can be found at the end of this document). If you decide to participate in the study, it will be chiefly carried out by electronically answering questions on your phone or computer and the consent form will be signed at the same time. If the study is conducted as a paper survey, you will be asked to sign the consent form on the last page.

Each respondent will only see their own answers.

Voluntary nature of study
Participation in the study is voluntary.

You may refuse to participate in the study or withdraw the consent you have previously given at any point during the study without having to give any reason. If you wish to withdraw your consent to participation in the study, notify the study personnel. If you withdraw, your personal data collected up to that point may still be used as research material in this study if it is required for the implementation of the study and allowed by legislation.

Body conducting the study
This study will be carried out by the Finnish Institute for Health and Welfare (THL) and the University of Eastern Finland and the University of Helsinki as part of the IMAGINE consortium funded by the Strategic Research Council, which operates within the Academy of Finland. The IMAGINE research consortium studies the introduction of methods that support adolescents's mental health and the related monitoring instruments. Chief Physician Outi Linnaranta will be responsible for the project at THL, Professor Johanna Lammintakanen at the University of Eastern Finland, and Professors Erkki Heinonen and Jari J. Lahti at the University of Helsinki.

The data collected from adolescents, guardians and possibly the employee who helped the young person, and which this information sheet describes, will be reported in peer-reviewed international publications. The data in the study will be stored in THL's database, and the users will include THL, the University of Helsinki and the University of Eastern Finland as joint controllers. The controller's contact person for this study is Outi Linnaranta, (firstname.lastname@thl.fi), who, as the contact person for the joint register, will answer any questions concerning the processing of personal data.

Purpose of the study

The purpose of this study is to examine how adolescents in upper comprehensive school benefit from interpersonal counselling. We will examine how many adolescents would need and want treatment for depression and how the treatment is implemented. We will monitor the effectiveness and cost-effectiveness of interpersonal counselling compared to cases in which depression goes untreated or the young person receives some other treatment.

Persons who are pupils in upper comprehensive school will be invited to participate in this study. Data will be supplemented with surveys for one of young person's caretakers and where applicable, the employee who helped the young person.

We hope to involve as many adolescents as possible, including representatives of different minorities and adolescents with limited functionality. In this way, we will make an effort to determine whether the access to treatment is equal and whether IPC-A is suitable and available for all adolescents.

Research methods and procedures

Approximately 5,000-9,000 adolescents in Northern Finland, Eastern Finland, Inland Finland and Western Finland will take part in the study. Data collection will continue until the data includes approximately 400 adolescents who need or have received support for depression.

The **young person** will complete the first survey in the classroom. Completing the questionnaire will take no more than 30 minutes. If necessary, they will receive help from the teacher and research staff. All the adolescents participating in the study, as well as the guardians of persons under the age of 15, will be asked to give their written consent for participation in the study.

At the beginning of the study, the guardian will answer a survey on the young person's wellbeing. The guardian also gives consent for their own participation. Completing the questionnaire will take no more than 30 minutes.

All adolescents are monitored for the first six months regardless of whether they are depressed or not.

- During the monitoring, the young person responds to a short survey every two weeks to assess the young person's mood, possible need for support and the support received. Completing the questionnaire will take no more than 5 minutes.
- After three months and six months, the young person will be sent the same survey, which they answered at the beginning of the study. Completing the questionnaire will take no more than 20 minutes.
- At the six month point, we will also send a survey on the young person's wellbeing to the guardian. Completing the questionnaire will take no more than 20 minutes.

If a young person **experiences depression repeatedly** during the 6 months of monitoring, we will investigate the motivation for treatment and monitor the young person's condition more closely

- we will send the young person a survey in which we ask whether they are motivated to receive treatment.
- we will send the young person a survey on their condition and the treatment they have received one year after the start of the study.

If a young person **has received support or treatment for depression** during the 6-month monitoring period, we will determine what the treatment has included and whether the young person found it useful

- we will send the **young person** a survey on the benefits and adverse effects of the support or treatment received

- we will send a survey to the **employee** who helped the young person. It will contain information on the number and timing of visits.
- We may also ask the employee, guardian or young person for more detailed information about the treatment.

You can answer questions on your phone at a time that is best for you. We will not conduct blood tests or other examinations requiring visits.
We will collect information from various registers on

- whether the young person has needed specialised psychiatric care.
- what help and treatment the young person has needed otherwise. This will includes possible appointments with a physician or therapist, hospital treatment, reimbursement of medicines and child welfare services.

Register data will be collected from all participants spanning from 1 year before the start of the survey until 10 years after the beginning of the study.

Based on the monitoring, we will get an idea of how many people suffer from depression, how many people are treated and how the treatment is implemented. We will compare the prognosis of adolescents who have received interpersonal counselling to that of other adolescents. We will calculate the cost of interpersonal counselling, other treatment or leaving depression untreated.

If a young person has another situation requiring acute support other than depression or has already received treatment for depression or another mental illness during the past year, we can exclude the young person from monitoring.

Benefits of taking part in the study and potential risks and adverse effects
Participation in this study will not benefit you personally. The study will help research of the implementation of treatment for depression in Finland. With the help of the results, it will be possible to improve the equal implementation and effectiveness of care.

This study may involve deterioration of mood or increased anxiety when the subject is repeatedly asked about their symptoms. Serious adverse effects are unlikely.

Research costs and financial matters
No fee will be paid for participation in the study, and participation in the study is free of charge to you.
The project to which this study belongs has funding from Finland's Strategic Research Council and through the funding for the health and social services integration study provided to THL by the Ministry of Social Affairs and Health.

Processing of personal data and confidentiality of data
Your personal data will be processed for the scientific research described in this information sheet. The processing of personal data is based on section 21 a, subsection 4 of the Medical Research Act and on scientific research in the public interest under Article 6.1.e of the General Data Protection Regulation (personal data).

- public interest and public interest in the protection of public health (personal data Article 6.1.e, sensitive personal data Article 9.2.i)

During the study only your personal data needed for the express purpose of carrying out the study will be collected and processed. Personal data collected from you and research results will be processed confidentially as required by the legislation on the processing of personal data. Your identity will only be known to the researchers conducting the study, and they will all be subject to confidentiality. Your personal data will only be processed by the members of the research group who belong to the organisations of the National Institute for Health and Welfare, the University of Helsinki and the University of Eastern Finland while the study is underway. All personal data from which you can be directly identified (such as your name) will be deleted and replaced with a code number and stored separately from the encoded data and these will not be disclosed to persons outside the scope of the study.

You can be indirectly identified from the study, even if direct identification data, such as name, age or place of residence, are not utilised in the study and efforts are made to reduce the residual risk of identification.

The following information about you will be collected during the study from the following sources: the employee's notes on the number of visits, THL's registers and KELA registers.

Your personal data will not be transferred to parties outside the Finnish Institute for Health and Welfare, the University of Helsinki or the University of Eastern Finland, or to countries outside the EU and the European Economic Area (EEA).

The retention period of your data will be regulated by legislation and good scientific research practice. The data collection for the follow-up study will be completed by the end of 2024, 1-year monitoring by the end of 2025 and the 10-year register data by 2035. The data will be stored for 10 years from the time at which the last register data is collected, i.e. until the end of 2045.

Personal data and material will be stored on THL's secure web server. The data will be processed on computers that are password protected and whose password is known only to the researcher. A user ID, password and double verification using the Microsoft Authenticator application will be needed for logging into the computer. Personal data and research materials will be stored separate from one another, and the material will be processed in a format from which direct personal data has been deleted. Two persons have access to personal data: Outi Linnaranta (research data) and Marjut Grainger (data manager).

The publication of research results in scientific publications is a fundamental part of scientific research. You cannot be identified from the information published as the results will presented as a whole for the entire material. Several articles that will be based on the research results are to be published in peer-reviewed international journals. The study will be used for producing several theses, including three dissertations. In addition, we will ensure the use of the results when future decisions are made through Finnish publications and network cooperation.

Communication about research results
We will not inform the subjects of their personal research results before the one-year monitoring period ends. This is to ensure that we get a picture of the natural course of treatment. If, after this time, you then want to know about your results, you will be able to request them using the form available on our website. In this case, we will send the summary as a secure message.

The preliminary completion date of the first research results will be in autumn 2024, and the final results of this sub-study will be completed by 31 December 2035. We will provide up-to-date information on the results on our website and on social media.

Rights related to the processing of personal data
You have the right to see the personal data collected about you for this study and to obtain information on what your personal data has been used for, to whom it has been disclosed and for what purpose. You also have the right to request that the information be corrected or supplemented if you notice errors or deficiencies in it. You also have the right to request that the processing of your data be limited.

As the grounds for processing are public interest, you have the right to receive information on the processing of your personal data, unless otherwise provided in the Act, and you also have the right to access data, to rectify data, to restrict the processing of data and to object to the processing of data. You have the right not to be the subject of automated decision-making without a legitimate reason, which can be facilitated with legislation, which enforces appropriate procedures for protecting the rights and freedoms and justified interests of data subjects. In addition, you have an obligation to notify of any rectifications of personal data or restrictions to processing.

If you believe that the processing of your personal data is in breach of the EU General Data Protection Regulation (EU) 2016/679 or other applicable data protection legislation, you have the right to lodge a complaint with the supervisory authority. In Finland, the Data Protection Ombudsman acts as the supervisory authority.

Office of the Data Protection Ombudsman
Lintulahdenkuja 4, 00530 Helsinki, P.O. Box 800, 00531 Helsinki, Finland
Switchboard: +358 29 566 6700
Email: tietosuoja@om.fi

Additional information and contact details for researchers
If you have any questions about the study, please contact the following people:

Research data collected by:
Liminka and Oulu: Ulla Heikkilä, Research Assistant, +358 29 524 7801
Jyväskylä and Jämsä: Tiia-Reeta Kukko, Research Assistant, +358 29 524 7075
Hämeenlinna, Hattula and Forssa: Jasmin Kaljadin, Research Co-ordinator, +358 29 524 7780
All email addresses are in the format: firstname.lastname@thl.fi

Heads of research projects:
Outi Linnaranta
Chief Physician, THL
firstname.lastname@thl.fi
+358 29 524 7517 6

You can contact the Controller's data protection officer for any additional information on the processing of your personal data as part of the data collected in this study:
The Controller's contact person for this material: Outi Linnaranta, Chief Physician, THL
firstname.lastname@thl.fi +358 29 524 7517

THL's data protection officer
Jarkko Reittu Data Protection Officer, THL E-mail: tietosuoja@thl.fi +358 29 524 7474

Caretaker's consent for research concerning adolescents 14 years or younger

I, as a caretaker of a child below 15 years of age, have been asked for consent for participation of my child in the research project Implementation of adolescent interpersonal counseling in Finland.

I have read the above information and have received sufficient information about the purpose and implementation of the research project, the benefits and risks of the research project, data collection and processing, and my rights. I have had enough time to consider whether to participate in the examination. I have not been pressurised or persuaded to participate in the examination.

I understand that participation in this research project is voluntary. I am aware that my child and I have the right to refuse to participate in this research project, without explanation. We may withdraw our consent at any time without having to give a reason. Withdrawing my consent will not cause me or my child any negative consequences.

I have familiarised myself with the rights and restrictions of the data subject. With my signature, I confirm using my information in this research project described above. I give my voluntary consent for my child to serve as a research subject, and processing of personal data of my child belonging to special categories (data concerning health, racial or ethnic origin, and sexual orientation or activity).

☐ **yes.** With my signature, I confirm my voluntary consent for my child to serve as a research subject and give my permission to the above mentioned.

Provider of consent

Signature Place and date

_____ _____

Name clarification

_____

Email address of the consent giver _____

Mailing address _____

Recipient of consent

Signature Place and date

_____ _____

Name clarification

_____

Study participant information:

Name_____
Date of birth
_____

Name of the school and place
_____

Home address

_____

The original signed document remains in the archives of the responsible director of the research and a copy is given to the research subject. Consent is stored for as long as the material is in an identifiable form. If the material is anonymised or destroyed, consent no longer needs to be retained.

Implementation of adolescent interpersonal counseling (IPC-A) in Finland
Informed consent for research concerning adolescents 14 years or younger

I have been asked to consent for participation in the research project Implementation of adolescent interpersonal counseling in Finland.

I have read the above information. I have received enough information about the purpose and implementation of the research project, the benefits and risks of the research project, data collection and processing, and my rights. The content of the research project has been explained orally and I have received sufficient information concerning all my questions concerning the research. The research was explained by [NAME OF THE RESEARCHER].

I have had enough time to consider whether to participate in the research project. I have not been pressurised or persuaded to participate in the examination.

I understand that participation in this research project is voluntary. I am aware that I have the right to refuse to participate or cancel participation in this research project, without explanation, at any point. I may withdraw our consent at any time without having to give a reason. I decide to withdraw my consent, I will contact the research personnel.

Withdrawing my consent will not cause me any negative consequences. I am aware that if I withdraw my consent or my participation in the research is interrupted for any other reason, my data collected so far may still be processed for this research if required for the conduct of the research and permitted by law.

I have familiarized myself with the rights and restrictions of the data subject. By signing this, I confirm my participation in this study and voluntarily consent to be investigated and understand that my personal data concerning my health and other personal data will be processed as part of this research.

[ ] I would like to receive information about the completed study by email.

☐ **yes.** With my signature, I confirm my voluntary consent to serve as a research subject and give my permission to the above mentioned.

[Place] *__.__20__* ***[Place]*** *__.__20__*

I agree to participate in the study: Recipient of consent:

_____ _____
Research subject's signature Researcher's signature

_____ _____
Name clarification Name clarification

_____ _____
Research subject's email address Position/post

_____

Research subject's mail address _____

Recipient of consent

Signature Place and date

_____ _____

Name clarification

_____

[ ] The guardian of the young person has been informed of the study. The young person is under 15 years of age and his/her guardian has given his/her consent to participate in the research (to be filled in by the employee or researcher).

The original signed document remains in the archives of the responsible director of the research and a copy is given to the research subject. Consent is stored for as long as the material is in an identifiable form. If the material is anonymised or destroyed, consent no longer needs to be retained.

The information of the participant:

Name_____
_____

Date of birth
_____

Name of the school and place
_____

Home address

_____

Implementation of adolescent interpersonal counseling (IPC-A) in Finland

Informed consent, 15 to 18 years old

I have been asked to consent for participation in the research project Implementation of adolescent interpersonal counseling in Finland.

I have read the above information. I have received enough information about the purpose and implementation of the research project, the benefits and risks of the research project, data collection and processing, and my rights. The content of the research project has been explained orally and I have received sufficient information concerning all my questions concerning the research. The research was explained by [NAME OF THE RESEARCHER].

I have had enough time to consider whether to participate in the research project. I have not been pressurised or persuaded to participate in the study.

I understand that participation in this research project is voluntary. I am aware that I have the right to refuse to participate or cancel participation in this research project, without explanation, at any point. I may withdraw our consent at any time without having to give a reason. I decide to withdraw my consent, I will contact the research personnel.

Withdrawing my consent will not cause me any negative consequences. I am aware that if I withdraw my consent or my participation in the research is interrupted for any other reason, my data collected so far may still be processed for this research if required for the conduct of the research and permitted by law.

I have familiarised myself with the rights and restrictions of the data subject. By signing this, I confirm my participation in this study and voluntarily consent to be investigated and understand that my personal data concerning my health and other personal data will be processed as part of this research.

[ ] I would like to receive information about the completed study by email.

[*Place****]*** *__.__20__* ***[****Place****]*** *__.__20__*

I agree to participate in the study: Recipient of consent:

_____ _____

Research subject's signature Researcher’s signature

_____ _____

Name clarification Name clarification

_____ _____

Research subject's email address Position

Research subject's mail address _____

Recipient of consent

Signature Place and date

_____ _____

Name clarification

_____

The information of the participant:

Name_____

Date of birth

_____

Name of the school and place_____

Home address_____