- **Official title:** Feasibility of Accessible Video Mental Healthcare Triage and Assessment - A Clinical Pilot Study
- **NCT number**
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Informed consent form

Information about research and quality assurance regarding internet treatment

In this document, you will receive information about what it means to participate in the ongoing research project:
Evaluation of the pilot project "Psychiatry Direct" - Development and implementation of digital triage between specialist psychiatry and primary care for patients in southwestern SLSO.

What is the project and why do you want me to participate?
The purpose of the research project is to evaluate the digital service you will now use, Psychiatry Direct in the app Always Open. We want to examine patients' experiences and satisfaction as well as wait times and the type of care that patients later receive. The research sponsor for this project is Region Stockholm, and the research is conducted in collaboration with Karolinska Institute (KI). We are inviting all users of Psychiatry Direct to participate, and if you choose to participate, this can help ensure and develop the quality of care. The project aims to determine whether this is a way that simplifies access for individuals seeking help for mental health issues.

How does the study work?
Psychiatry Direct is currently being introduced as a pilot project in regular care. To evaluate this, the research study uses only care data that would have been collected anyway: brief surveys you are asked to answer before and after your digital meeting in Psychiatry Direct, and information about your care visits. As a participant in the research project, there are no additional questions or data collection.

Possible consequences and risks of participating in the study
By participating, you give us the opportunity to evaluate the benefits of Psychiatry Direct and provide input for improving the design of the service. Data management will be done in a pseudonymized form, and data will be reported at the group level so that no individual individuals can be identified.

What happens to my data?
The research project will collect information about you. Data will be retrieved from Region Stockholm's journal system, the app Always Open in which Psychiatry Direct is conducted, and the survey system Webropol. The information is requested from Region Stockholm according to existing routines and is stored on secure systems. A code list will be established in which your data will be assigned a study ID (pseudonymization). The data is stored according to KI's guidelines for research documentation. Data will be processed for research purposes according to the EU General Data Protection Regulation (GDPR) based on the legal grounds of performing a task of public interest. Your responses and results will be processed so that unauthorized persons cannot access them. The responsible party for your personal data is Region Stockholm (the research sponsor). According to the EU General Data Protection Regulation, you have the right to access the data about you that is processed in the study free of charge and, if necessary, have any errors corrected. You may also request that data about you collected in the research project be deleted and that the processing of

your personal data be restricted. If you wish to access the data, please contact Lina Martinsson (lina.martinsson@ki.se, 08-123 389 88). The data protection officer can be reached at gdpr.slso@regionstockholm.se. If you are dissatisfied with how your personal data is processed, you have the right to lodge a complaint with the Swedish Authority for Privacy Protection (IMY), which is the supervisory authority (08-657 61 00, imy@imy.se).

How will I receive information about the results of the study?
The results will be compiled at the group level and published in a scientific journal.

Insurance and compensation
Any adverse effects resulting from the treatment are covered by standard patient and drug insurance.

What do I do if I do not want to participate in the study?
If you do not want to participate in the study or have questions about your participation or anything else related to the study, please contact us as below or raise it during the digital meeting you will have in Psychiatry Direct.

Participation is voluntary
Your participation is voluntary, and you can choose to withdraw from participation at any time. If you wish to withdraw from participation, you do not have to state why, and it will not affect your future care or treatment. Since the measurements and data involved are included in regular care and in quality work within the relevant healthcare units, they will still be collected but not used for research purposes. If you would like to withdraw your participation in the research, you can contact us at 08-123 389 88.

Responsible researcher for the study:
Lina Martinsson, MD, Region Stockholm, lina.martinsson@regionstockholm.se, 08-123 389 88
