ISRCTN12094788 https://doi.org/10.1186/ISRCTN12094788

Testing an individualised digital decision assist system for the diagnosis and management of mental and behavior disorders in children and adolescents

Submission date
01/04/2020

Recruitment status
No longer recruiting

Registration date
08/04/2020

Overall study status
Completed

Last Edited
16/03/2022

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In Norway, 10-20% of the child and adolescent population have impairing mental health disorders. While many of these illnesses are single episodes that resolve, they can become chronic, or even lifelong conditions. Early evaluations, diagnosis, and treatment are critical to shortening single episodes of care, reducing possible comorbidity and long-term disability. Approximately 29% of child and adolescent mental diagnoses in Norway are Attention Deficit Hyperactivity Disorder (ADHD). It is a common disorder with high levels of comorbidity and nearly 2/3 of affected individuals have symptoms that persist into adulthood.

The Individualized Digital Decision Assist System (IDDEAS) is a new clinical decision support system (CDSS) for child and adolescent mental health services in Norway. CDSSs are technological advances that are designed to enhance clinical care –including evaluation, diagnosis, and treatment– by providing clinicians with step-by-step guidance, through a user-interface on their computer. The support provided by the system is based on standardized guidelines, big-data sets, and data from patient electronic health records. The IDDEAS system focuses on preventive care, early diagnostics and early intervention, as well as treatment and case management for ADHD in children and adolescents to start with. Later it will be expanded to other mental disorders. The system uses the latest clinical guidelines and Norwegian health datasets, along with data from the individual patient electronic health record, to present the clinician with evidence-based guidance in real-time. The project is developed from a service-user perspective to help develop a potential model for other future CDSS implementation and will serve as an important learning opportunity for the field and the healthcare system.

The study aims to improve the quality, competency and efficiency of child and adolescent mental health services by supporting diagnosis and treatment planning decision making with use of the IDDEAS clinical decision support system, during clinical care in real-time.

Who can participate?
Child and adolescent psychologists and psychiatrists working in CAMHS in 6 randomly selected child and adolescent mental health clinics located around Norway.

What does the study involve?
The study involves the design, modelling, development and mixed-method evaluation of IDDEAS. The participants will evaluate the system's usability, acceptability, validity and utility in a non-live and a live setting.

What are the possible benefits and risks of participating?
The main possible benefit of the study is the provision of decision support for clinicians in real-time during clinical sessions and improvement of clinical care. There are no major risks for clinicians taking part in the study. The main possible risk is the protection of data used in the system, which will be accounted for by following formal data protection procedures, including completion of a data privacy impact assessment (DPIA) to minimize these risks.

Where is the study run from?
NTNU - Regionalt kunnskapssenter for barn og unge - psykisk helse og barnevern (RKBU Midt-Norge) (Norway)

When is the study starting and how long is it expected to run for?
August 2020 to December 2023

Who is funding the study?
The Research Council of Norway (Norges forskningsråd)

Who is the main contact?
Prof. Norbert Skokauskas, norbert.skokauskas@ntnu.no

Contact information

Type(s)
Scientific

Contact name
Prof Norbert Skokauskas

Contact details
RKBU Midt-Norge
NTNU
Klostergata 46
Trondheim
Norway
7030
+47 73558973
norbert.skokauskas@ntnu.no

Additional identifiers

Protocol serial number

269117

Study information

Scientific Title
Individualised Digital DEcision Assist System (IDDEAS) for the diagnosis and management of mental and behavior disorders in children and adolescents

Acronym
IDDEAS

Study objectives
Providing clinicians with access to a real-time clinical decision support system will improve their clinical practices, including adherence to care guidelines, with respect to diagnosis and treatment of child and adolescent mental health disorders.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Regional Committees for Medical and Health Research Ethics, South East (REK, Sør-Øst) has assessed the IDDEAS application on the 9th of October 2019, concluding that “the project falls outside the scope of the Health Research Act, cf. section 2, and can therefore be implemented without approval of REK.” (+ 47 22 84 55 02; post@helseforskning.etikkom.no), ref: 2018/2186

Primary study design
Other

Study design
Mixed-methods study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Child and adolescent mental health health disorders

Interventions
The Individualized Digital Decision Assist System (IDDEAS) is a new clinical decision support system (CDSS) for child and adolescent mental health services in Norway. CDSSs are technological advances that are designed to enhance clinical care –including evaluation, diagnosis, and treatment– by providing clinicians with step-by-step guidance, through a user-interface on their computer. The support provided by the system is based on standardized guidelines, big-data sets, and data from patient electronic health records. The IDDEAS system focuses on preventive care, early diagnostics and early intervention, as well as treatment and case management for ADHD in children and adolescents to start with. Later it will be expanded to other mental disorders. The system uses the latest clinical guidelines and Norwegian health datasets, along with data from the individual patient electronic health record, to present the

clinician with evidence-based guidance in real-time. The project is developed from a service-user perspective to help develop a potential model for other future CDSS implementation and will serve as an important learning opportunity for the field and the healthcare system.

Child and adolescent psychologists and psychiatrists representing four randomly selected child and adolescent mental health clinics around Norway will participate. The participants will evaluate the system's usability, acceptability, validity and utility in a non-live and a live setting; in the non-live evaluation 10 fictional clinical case vignettes will be appraised and in the live evaluation 7 standard patient-encounter videos will be assessed with and without the use of the IDDEAS system.

Intervention Type
Other

Primary outcome(s)
Clinical Utility of the IDDEAS CDSS for diagnosis and treatment of child is measured by reviewing the participant's clinical diagnosis and treatment plan responses as a measure of sensitivity and specificity with the use of the CDSS compared to without the CDSS upon completion of the non-live evaluation and the live evaluation

Key secondary outcome(s)
1. Perceived clinical usability of the CDSS is measured using the system usability scale (SUS) directly following the evaluation (within 24 hours)
2. Perceived clinical relevance and validity of the system's user-interface content is measured using the content validity index (CVI) directly following the evaluation (within 24 hours)
3. Perceived appropriateness of the CDSS is measured using the User-Engagement Scale (UES) directly following the evaluation (within 24 hours)

Completion date
30/12/2023

Eligibility

Key inclusion criteria
Child and adolescent psychologists and psychiatrists working in CAMHS

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/08/2020

Date of final enrolment
01/08/2023

Locations

Countries of recruitment
Norway

Study participating centre
NTNU - Regionalt kunnskapssenter for barn og unge - psykisk helse og barnevern (RKBU Midt-Norge)
Klostergata 46
Trondheim
Norway
7030

Sponsor information

Organisation
Norges forskningsråd

ROR
https://ror.org/00epmv149

Funder(s)

Funder type
Research council

Funder Name
Norges forskningsråd (The Research Council of Norway)

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	17/09/2020	21/09/2020	Yes	No
Abstract results		01/10/2021	21/02/2022	No	No
Other publications	Article	15/12/2020	16/02/2022	Yes	No
Other publications	Editorial	01/05/2021	16/02/2022	Yes	No
Other publications	Review article	10/04/2017	16/02/2022	Yes	No
Other publications	Systematic review	01/11/2017	16/02/2022	Yes	No
Other publications	article in Dagens medisin	05/05/2021	21/02/2022	Yes	No
Other publications	patient awareness, attitudes, and opinions about EHR data storage and sharing	16/03/2022	16/03/2022	Yes	No