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Assessing the effectiveness of a screening interview for identifying observable cues of mental health disorders using artificial intelligence and in various modes of interaction

Submission date
14/03/2025

Recruitment status
No longer recruiting

Registration date
16/04/2025

Overall study status
Completed

Last Edited
07/05/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Accurate and effective initial psychiatric assessments are crucial for determining appropriate (therapeutic) interventions for pediatric populations. The objective of this study is to enhance the diagnostic process by verifying that the pre-clinical interviews capture essential, actionable data in a manner that respects the cognitive and emotional capacities of young patients. This research aims to validate the relevance, content, and clinical utility of a pre-clinical interview questionnaire within pediatric psychiatric practice. The first part of the study focuses on ensuring that the language and content of the questionnaire are age-appropriate and effectively tailored to the developmental stages of child and adolescent patients. The second part of the study evaluates the feasibility and autonomy of pediatric subjects in completing the interview independently, potentially in a home setting. The study employs three distinct methods of administering the pre-clinical interview:
1. Self-administration using a chatbot
2. Human administration and
3. Robot-assisted administration

Who can participate?
Children and teenagers aged 10-19 years who are patients at the pediatric psychiatry unit of the University Medical Center Maribor can take part. Participants must be able to understand and answer questions, speak the local language fluently, and have permission from their parents or guardians. Young people with severe intellectual disabilities, uncorrected vision or hearing problems, or serious medical conditions that might affect their participation will not be included.

What does the study involve?
Participants will be randomly assigned to one of three interview methods:
- Completing the interview alone using a tablet with a chatbot or a paper questionnaire
- Having the interview conducted by a pediatric psychiatrist
- Having the interview guided by a friendly humanoid robot called Frida

All participants will answer the same set of questions. The sessions will be video-recorded to capture both what participants say and their body language. After the interview, participants will share their thoughts about the experience.

What are the possible benefits and risks of participating?
Benefits include contributing to improvements in mental health assessment for young people, gaining self-awareness about mental health, and experiencing innovative technology. Possible risks include feeling uncomfortable discussing personal topics and concerns about privacy, though strict confidentiality measures are in place. Emotional support will be available during all interviews.

Where is the study run from?
The study takes place at the University Medical Center Maribor's pediatric psychiatry unit in Slovenia.

When is the study starting and how long is it expected to run for?
July 2024 to May 2025

Who is funding the study?
This research is funded by the European Commission's Horizon Europe research and innovation programme, project SMILE (Supporting Mental Health in Young People: Integrated Methodology for cLinical dEcisions and evidence-based interventions) , GA. 101080923 , and project CERTAIN (Certification for Ethical and Regulatory Transparency in Artificial Intelligence), GA. 101189650.

Who is the main contact?
The study is led by Dr Izidor Mlakar (scientific supervisor) from the University of Maribor and Dr Hojka Gregorič Kumperščak (clinical supervisor) from the University Medical Center Maribor.

Contact information

Type(s)
Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Pediatric RObot-aided versus Moderator-led Interview Screening (PROMIS): Comparative effectiveness of three pre-clinical assessment modalities for identifying observable mental health cues in children and adolescents ages 10-19

Acronym
PROMIS

Study objectives
H1 - The pre-clinical interview questionnaire will be validated as age-appropriate and relevant, contributing significantly to the assessment of child and adolescent psychiatric conditions.
H2 - The value of the pre-clinical interview questionnaire, as determined by its ability to enhance clinical understanding and decision-making in child and adolescent psychiatry, will not differ significantly across the three interview modalities (technology alone, human interaction, and robot-assisted).
H3 - Children and adolescents will demonstrate a high level of feasibility and willingness to complete the pre-clinical interview independently, with significant variations observable between the three arms.
H4 - Children and adolescents will report higher preferences and comfort levels with interactive and engaging interview methods such as those involving socially assistive robots or user-friendly chatbot interfaces.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 04/07/2024, Medical Ethics Commission (University Medical Center Maribor) (Ljubljanska ulica 5, Maribor, 2000, Slovenia; +386 2 321 2489; eticna.komisija@ukc-mb.si), ref: UKC-MB-KME-32/24

Study design
Prospective controlled mixed-methods study randomized with three arms

Primary study design
Interventional

Study type(s)
Diagnostic, Screening

Health condition(s) or problem(s) studied
Assessment of pre-clinical psychiatric interview methodologies for pre-screening of mental health disorders in children and adolescents aged 10-19 years

Interventions
This interventional study employs a prospective, controlled, mixed-methods design with three randomized arms to evaluate different approaches to pre-clinical psychiatric interviews for children and adolescents (ages 10-19). Participants (n=90) are randomly allocated to one of three intervention arms (30 per arm):
1. Self-Administration (Chatbot): Participants complete the interview independently using either a tablet with a chatbot application or paper questionnaire in a distraction-minimized environment without real-time human interaction.
2. Human Administration: A pediatric psychiatrist conducts the interview in a standard clinical setting following traditional psychiatric assessment approaches.
3. Robot-Assisted Administration: The socially assistive humanoid robot "Frida" (model Pepper, programmed with speech recognition and synthesis capabilities in Slovenian) facilitates the interview process with remote operator monitoring.

All intervention arms use identical pre-clinical interview questionnaires. Sessions are video-recorded to capture both verbal responses and non-verbal cues. Following the intervention, participants evaluate their experience using standardized assessment tools. The sample size (90 participants) was calculated to detect a medium effect size (d=0.5) with an alpha of 0.05 and power of 0.80

Randomization:
We prepared a list of 90 unique identifiers, pre-allocated equally with 30 identifiers per treatment arm, and used Excel's RAND() function to generate a random sequence. The identifiers were then sorted based on these random numbers to create the final allocation order. Participants were sequentially assigned the next available identifier from this randomized sequence upon enrollment, ensuring balanced distribution across the three treatment arms while maintaining allocation concealment.

Intervention Type
Other

Primary outcome(s)

1. The relevance, the content (also consider language is age-appropriate), and the value of the pre-clinical interview questionnaire for child and adolescent psychiatric practice. Measured using a custom questionnaire for experts to evaluate the value of a screening interview, focusing on information relevance, clinical utility, and integration with other assessments. The questionnaire will assess how the interview contributes to understanding children's and adolescents' mental health, treatment planning, and overall clinical evaluation. The questionnaire is applied once and after reviewing each diary recording
2. Feasibility and willingness of children and adolescents to carry out and complete the interview independently. Measured using custom participant questionnaire (2 items) and BFI-2-XS and ITAS, before the experiment

Key secondary outcome(s))
1. Compare the effectiveness and responses when the interview is moderated by different methods: a chatbot as a moderator, a human moderator, and a socially assistive humanoid robot as moderator measured using BIDR-16 immediately after the experiment
2. Evaluate the user experience (UX) of children and adolescents under the different moderators using a combination of G-MISS and custom participant questionnaire (1 item) with the screening interview immediately after the experiment

Completion date
31/05/2025

Eligibility

Key inclusion criteria
1. Included in Child and Adolescent Psychiatric treatment: patients of the Unit for pediatric and adolescent psychiatry of the University Medical Centre Maribor (inpatient or outpatient)
2. Age Range: 10 - 19 years old at the time of consent.
3. Cognitive Ability: Participants must have the cognitive capacity to understand and respond to the questions posed in the interviews. This can be preliminarily assessed through a short standardized cognitive screening appropriate for the age group.
4. Language Proficiency: Participants must be fluent in the language in which the interviews are conducted to ensure accurate understanding and response to the questions.
5. Consent: Participants must be able to provide written informed consent or assent, and legal guardians must provide written informed consent for participation in the study for those younger than 15.
6. Availability: Participants must be available for the duration required to complete all study components, including any follow-up evaluations or debriefings.

Participant type(s)
Patient, Health professional

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
10 years

Upper age limit
19 years

Sex
All

Total final enrolment
108

Key exclusion criteria
1. Intellectual disability: Children and adolescents with mild to severe intellectual disabilities that may interfere with their ability to understand or engage with the interview process as designed.
2. Urgent Psychiatric Conditions: Children and adolescents experiencing life-threatening conditions or other conditions requiring immediate psychiatric treatment; e.g. agitation, aggression, acute psychosis
3. Sensory Impairments: Children with uncorrected hearing or visual impairments that would prevent interaction with the chatbot, human interviewer, or robot, unless reasonable accommodations can ensure effective participation.
4. Medical Conditions: Severe medical conditions or instability that could interfere with the participant's ability to attend sessions or respond reliably, such as uncontrolled epilepsy or significant physical illnesses requiring intensive care.

Date of first enrolment
31/01/2025

Date of final enrolment
30/04/2025

Locations

Countries of recruitment
Slovenia

Study participating centre
University Medical Centre Maribor, Unit for pediatric and adolescent psychiatry
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Sponsor information

Organisation
University Clinical Centre Maribor

ROR
https://ror.org/02rjj7s91

Funder(s)

Funder type
Government

Funder Name
HORIZON EUROPE Framework Programme

Alternative Name(s)
Horizon Europe, Horizon Europe Programme, Framework Programme, Horizon Europe, EU Framework Programme, Horizon

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request (Dr Izidor Mlakar, izidor.mlakar@um.si).
Some of the datasets generated and/or analysed during the current study will also be published as a supplement to the results publication.

IPD sharing plan summary
Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes