



**PSICONEXIA PREDICT.
Development and validation of a digital
instrument for assessing psychopathological risk
in the adult population.**

Abstract

The extremely high burden of patients with mental health problems, the high economic costs associated with these problems and the limited time available for assessing them correctly are some of the current challenges that every health system must deal with. In addition, the consequences of the global coronavirus pandemic SARS-CoV2 (COVID-19) are having a major impact on mental health. This research study aims to provide responses to the previous challenges by developing and validating a new digital instrument for assessing psychopathological risk, Psiconexia Predict. This tool will improve the limitations of the paper-based assessment tests that are commonly used in clinical practice. Specifically, we will carry out multicenter research to validate Psiconexia Predict with adults. The digital platform is currently being developed. This platform will make it possible to add and modify the content of Psiconexia Predict (currently in paper format) without investing a lot of time, resources or effort. In conclusion, it is essential to develop a more efficient psychological evaluation tool that can help those mental health units or clinics with a high number of patients. For example, the instrument could considerably reduce the time and resources required for traditional evaluation. Furthermore, this evaluation must be equally large, reliable, and valid to correctly detect mental health problems and classify their level of psychopathological risk. That is, it is necessary to achieve a balance between brevity, ease of administration, maximum rigor, and a broad range of applications. We believe that new technologies can be very helpful in achieving this goal.

Why is it important to conduct this research? Mental health, the next invisible wave

According to a recent United Nations report, mental health problems are considered one of the greatest challenges our society must face in the coming years, especially after the unpredictable psychological consequences of the global pandemic produced by the SARS-COV2 coronavirus (COVID-19). The same report highlights that in Europe 38.2% of its 514 million inhabitants (approximately 164.8 million people) suffer from some type of mental disorder. Finally, in Spain according to the Spanish National Health Survey 2017, one in ten citizens aged 15 years or more, has been diagnosed with a mental disorder, and between 4% and 6% of children and adolescents have been diagnosed with a serious mental disorder. The high prevalence of mental health problems has led to unsustainable economic costs for health systems. Previous studies in the European Union have estimated that direct and indirect costs related to mental disorders are nearly 798 billion euros per year. The current situation, which is already quite worrying, may worsen significantly in the coming decades. In 2010, the World Health Organization (WHO) warned that Western economies cannot sustain this economic burden and that by 2030, these expenditures could increase by 2.4 times, with mental health-related economic losses of up to \$6 trillion worldwide.

In addition, numerous studies have raised serious concerns about the need to improve and maximize detection rates of mental health problems. This is particularly true in clinical settings that have a high number of patients (i.e., primary care) and that often lack materials, resources, and available time to accurately assess and detect these problems.

Finally, the global pandemic caused by COVID-19 is increasing the prevalence of the mental health disorders described above. Specifically, the WHO and the Lancet's Commission on Global Health agree that many people who previously had little experience with anxiety and distress may be experiencing an increase in the frequency and intensity of these symptoms. And those who previously had a mental health problem may experience a worsening of their condition and a greater impact on different areas of their lives. Therefore, an immediate priority is to collect high-quality data on the effects of the COVID-19 pandemic on the mental health of the entire population and vulnerable groups. In addition, since most patients with mental disorders are initially treated in primary care services, and considering the serious problems in detecting mental disorders in this area, **it is necessary to develop more cost-effective methodologies for the early detection and treatment of mental disorders.**

What will this project address? Psiconexia Predict, connecting mental health to the digital revolution

The current research proposal aims to provide an innovative and effective response to the challenges discussed above by developing and validating a digital tool for the early detection of the risk of suffering a wide variety of mental health problems in both children/adolescents and adults. We have called this instrument Psiconexia Predict. Psiconexia Predict has a system that classifies psychopathological risks and determines whether people are at **low, medium or high** risk of suffering from a certain mental health disorder. This computerized classification system can be very helpful in monitoring the mental health of the general population and the most vulnerable groups. In addition, it could provide immediate, up-to-date, high-quality clinical information that can be particularly useful for assisting professionals who attend health care facilities that have a high number of patients (e.g., in primary care). Most importantly, it can be used to boost preventive interventions aimed at helping those individuals who, despite not meeting all the requirements for being diagnosed with a mental health disorder, present certain psychopathological symptoms that could worsen considerably in the medium or long term.

The **main aim** of the project is to carry out a multicenter research study to validate the Psiconexia Predict tool. Although the digital instrument has an adult and child-adolescent version, the current proposal focuses exclusively on validating the adult version. As a **main**

hypothesis, it is expected that Psiconexia Predict will be a reliable and valid digital instrument for detecting and classifying psychopathological risk in adult populations. In other words, it is expected to show psychometric measures of sensitivity, specificity and positive and negative predictive values that are as good as the "gold standard" test and the diagnostic interview for the evaluation of mental health in adults (MINI, Mini International Neuropsychiatric Interview).

The current research proposal could have several clinical implications in the field of mental health. On one hand, it is expected that the digital format of Psiconexia Predict will lead to a significant reduction in administration time as it gathers a large amount of data in a simple and flexible way, and the results are available immediately. Therefore, it will make it possible to overcome one of the main limitations of mental health diagnostic interviews (the long time the assessment takes), and accelerate the entire evaluation process, making it much more efficient. This assessment tool will also make it possible to increase the early detection rates of a wide variety of psychological disorders or mental health problems. Psiconexia Predict has several assessment modules, which include mood disorders, anxiety disorders, addictions, post-traumatic stress disorder, obsessive-compulsive disorder, neurodevelopmental disorders, and eating disorders, among others. **Early detection of mental health problems is essential for their correct therapeutic treatment and for a better long-term prognosis.** Thus, new technologies offer us a unique opportunity, through computers, mobile devices, and other devices, to make mental health assessment much more accessible to the entire population. This can be particularly useful for appropriately addressing the growing mental health demand due to the COVID-19 pandemic. Finally, another of the main advantages of using the Psiconexia digital platform is that it will allow the assessment instrument to be modified in a smooth and simple way. Therefore, the instrument can be easily adapted to future changes that may be necessary during the research (for example, after the first pilot study), and/or in future stages after its validation.

How will this project be conducted? An empirically-based methodology

Based on the statistical analyses described below, it is necessary to have a sample of a minimum of 134 healthy adults and 134 adults at high risk of suffering from a mental disorder to evaluate the performance of Psiconexia Predict and compare it to the MINI interview. Women and men between 18 and 70 years old (a similar age range as in previous studies), who present any sort of mental health-related problem affecting their daily life, will be recruited in adult mental health centers (CSMA). Participants in the control group will be recruited in different university campuses and through the related social networks and media.

The necessary authorization will be obtained from the ethical committee of the university and the hospitals or clinical centers that participate in the study. In addition, participants will be provided with information about the benefits and possible adverse effects of the study, and all participants will be asked to sign written informed consent and data use agreement forms to be accepted into the study.

The confidentiality of the data will also be respected. To this end, participants will be deidentified with a numerical code, so that their anonymity will always be guaranteed. All documents containing personal data, including the patient file generated in the digital platform, will be encrypted (e.g., using BCrypt encrypt software) and only authorized research personnel will have access to the participants' identification data. Specifically, all data will be kept in our digital cross-platform database, based on MongoDB technology, which will be protected by a login and a password. Finally, all researchers and therapists collaborating in the study will sign a confidentiality document.

This research will follow the **Findable, Accessible, Interoperable and Reusable (FAIR)** principles, and will use quantitative and qualitative data based on the outcomes of Psiconexia Predict and MINI. Specifically, the pre-analysis data will be delivered and stored in comma-separated-values

(CSV), and Excel format. The following statistical analyses will be conducted either with SPSS or with the R software. Specifically, sensitivity, specificity, and positive and negative predictive values will be calculated. In addition, Cohen's Kappa analyses will be conducted to assess the degree of agreement between Psiconexia Predict and MINI in each of their modules. Finally, logistic regression analyses will be carried out to evaluate, in more detail, the relationship between the degrees of severity (low, medium and high risk) found by Psiconexia Predict and the presence or absence of the disorders evaluated by MINI. The operator-receptor curve, specifically the area under a curve, will also be assessed to study the efficiency of the test; that is, its ability to differentiate people who have a disorder (true positives) from those who are considered to have a disorder erroneously (false positives).

A long-term data sharing and preservation plan will be used to store and make the data publicly accessible beyond the life of the project. The data will be deposited in an institutional Digital Repository, a digital resource containing open-access digital versions of publications and data related to research activities of our host organization. Finally, in terms of the expected timeline, data sharing procedures will start after the planned publications are completed.

Will this project be feasible? A SWOT feasibility analysis

Based on eight general focus areas usually addressed by feasibility studies, including areas such as acceptability, demands, implementation, practicality, adaptation, integration, expansion, and limited-efficacy testing, the following SWOT analysis and detailed risk mitigation measures are proposed:

STRENGTHS	WEAKNESSES
High acceptability, particularly among young people. Very practical tool in those settings with low resources and time available. Wide variety of assessment modules (SSSS). Implementation. Currently an alpha version of the digital platform is being developed.	Limited-efficacy testing. No previous validation study of the paper-based version (e.g., validity content). Some mental health disorders not included (e.g., psychotic disorders, psychosomatic or dissociative disorders, etc.). Only compared with the MINI diagnostic interview, and not with other scales or screening tests.
OPPORTUNITIES	RISKS
High demand for assessing mental health issues due to COVID-19 consequences. Easy adaptation. Changing program contents or procedures to be appropriate in a new situation. Expansion potential of the current tool with different populations (children and teens) and/ or in different settings.	Lower acceptability among older patients and/or the possible reluctance of clinical professionals to use P-Predict (e.g., due to the digital format). Integration of the digital software into an existing clinical infrastructure. Risks during the implementation. Highly-sensitive clinical data and risk of breach of confidentiality.
WEAKNESSES AND RISKS MITIGATION STRATEGIES	
Limited-efficacy testing: Previous evaluation of the validity of the content of the instrument by mental health professionals and experts. Some mental health disorders not included: In future studies, P-Predict's modules will be individually compared with other scales/screening tests. Only compared with the MINI: An extended version with more psychopathological modules will be created. Acceptability risk (elderly patients and professionals): During the development of the digital tool, a pilot study will be conducted to improve the usability and overall user experience of the tool. And an intense free training will be provided to clinical professionals to resolve any doubts about how to use P-Predict. Integration and Implementation: Strong cybersecurity data measures (e.g., deidentification by a numerical code, files encrypted, login and password protected files, etc).	