

Article

Child and Adolescent Capacity and Consent for Medical and Psychiatric Admissions and Health Decisions: A Research Project

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Abstract

Background: Competence (within the legal and bioethical framework in Spain, the term ‘competence’ is used as equivalent to healthcare decision-making capacity) in the field of child and adolescent psychiatry is a complex and evolving issue. Legal frameworks vary by country and legal tradition. Most concerns relate to treatment decisions within mental health, but in fact there is a wide range of decisions with a relevant impact on patients’ lives and quality of life over the long term. Forensic science must adapt its current practice to the worldwide challenge presented by this evidence. **Objectives:** This article will present a current research project about competence (healthcare decision-making capacity) in a sample of adolescent and child population in Spain. The final objective will be to validate the Spanish version of the MacCAT semi-structured interview consenting to psychiatric admission in adolescents in a mixed sample. We also examine some of the influences that must be taken into account in this research. **Methodology:** This is an instrumental and methodological study utilizing a sequential mixed-methods design (qualitative content validation followed by a quantitative psychometric evaluation). A process of adaptation of the Spanish MacCAT to consent to psychiatric admission in the adolescent population. A pilot study will initially be conducted to evaluate question comprehension and duration. Subsequently, a cross-sectional study will be carried out to assess inter-rater reliability, internal consistency, and validity. Evaluation will include clinical and neuropsychological assessment in five departments at two University Hospitals. **Expected results:** We will establish new evidence about the evaluation of competence in adolescent psychiatry; to date, no studies have been identified assessing the capacity to consent to psychiatric admission among Spanish-speaking adolescents, nor the factors potentially related to such competence. To our knowledge, the relationship between competence and illness awareness in the adolescent population remains unexplored in the literature, and its analysis constitutes one of the novel contributions of the present study. In addition, we will adapt and validate a well-known evaluation scale to the specific environments of our medical and psychiatric health departments. **Conclusions:** Objective evaluation of competence for medical interventions and treatments is a challenge in clinical and forensic examination. New evidence is necessary to operationalize classical evaluations in standardized ways, adapted to different countries, legal systems and forensic traditions.

Keywords: competence; healthcare capacity; adolescents; mature minor; MacCAT-T; validation



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1. Introduction

Competence (healthcare decision-making capacity) in the field of adolescent psychiatry is a complex and evolving issue. Legal frameworks vary by country and legal tradition. Most concerns relate to treatment decisions or admissions within mental health populations, but in fact there is a wide range of decisions with a relevant impact on the lives and quality of life of all types of patients over the long term. Old assumptions about competence and capacity must be revisited. Forensic science must adapt its current practice to the worldwide challenge presented by this evidence. It could decisively help promote children's and adolescents' rights, both internationally and locally [1].

A new United Nations declaration tackles collective responsibility towards future generations, crucially recognizing young people as active providers and contributors for their own health. In addition, WHO highlights six areas for immediate action to improve adolescent health and rights, including "Facilitate meaningful engagement of adolescents in decision-making and in the full cycle of programmes that affect them. Adolescents have agency and capabilities" [2].

1.1. Conceptual Framework: Definitions and Operationalization of Key Terms

Because the rationale, hypotheses, and interpretation of this study depend heavily on several related but non-equivalent constructs, we define and operationalize each of the key terms used throughout the manuscript before introducing the clinical and legal background.

Decision-making capacity refers to a clinical and functional construct: the presence of a specific set of psychological abilities—understanding relevant information, appreciating its significance for one's own situation, reasoning about treatment options, and expressing a choice—that enable a person to make a particular healthcare decision at a given moment [3]. Capacity is therefore decision-specific and time-specific: a person may have capacity for one decision but not another, and capacity for the same decision may fluctuate over time. Capacity is typically assessed by clinicians or, in research contexts such as this one, by trained evaluators using standardized instruments (e.g., the MacCAT, the CQ-ChP).

Competence, by contrast, is a legal construct: a formal determination, made by a court or, in clinical practice, attributed by a healthcare professional acting under a legal framework, that a person is entitled to exercise a given right (e.g., to consent to or refuse an intervention) [4,5]. In most jurisdictions, including Spain, competence is presumed once a person reaches the age of legal majority, and incompetence must be specifically established; for minors, the legal framework instead requires an individualized assessment of the minor's capacity in order to determine whether they may exercise that right directly or through a proxy. In Spanish law and bioethical practice specifically, and as used throughout this manuscript, the term "competence" is operationalized as equivalent to healthcare decision-making capacity in minors—that is, the clinical capacity construct described above is treated as the operational criterion for the legal determination of competence required under Spanish legislation [4,6–8]. This equivalence is a feature of the Spanish legal and bioethical framework rather than a universal terminological identity; in other jurisdictions and in part of the international literature, capacity and competence remain conceptually and procedurally distinct constructs (the former clinical, the latter judicial), and we make this distinction explicit here to avoid ambiguity when the terms are used interchangeably elsewhere in the text.

Maturity is a broader developmental construct, encompassing the cognitive, moral, and psychosocial development that underlies a minor's general capacity for autonomous functioning, independent of any specific decision [9]. Unlike capacity, maturity is not decision-specific; it reflects a more stable, slowly changing developmental status. In this study, maturity is operationalized through two complementary indicators: moral maturity,

assessed with the Maturtest (EVMM-17), and neuropsychological maturity, inferred from cognitive, linguistic, and reading-ability measures (Sections 6.2–6.4). Critically, maturity and decision-making capacity are treated in this study as related but empirically separable constructs (see Hypothesis 3.1.2): a minor may be judged broadly mature on developmental grounds yet lack the capacity for a specific healthcare decision, and conversely, capacity for a specific decision does not by itself establish general maturity.

Health literacy is a distinct construct referring to a person's ability to obtain, process, and understand basic health information needed to make appropriate health decisions in everyday life; it is related to, but not synonymous with, decision-making capacity, since a person may have adequate general health literacy yet lack capacity for a specific decision under acute clinical conditions (e.g., during a psychotic episode), or vice versa. Throughout this manuscript, "capacity or competence" (e.g., as used descriptively in the Introduction) refers jointly to the clinical and legal facets of the same underlying construct as operationalized for this Spanish-language study, rather than implying that the two terms are universally interchangeable in the broader literature.

1.2. Informed Consent Process

Informed consent is a process based on the recognition of the patient as a rational individual with the autonomy to make decisions regarding their own life and death. The requirement of capacity (the underlying clinical construct) or competence (its legal expression, as operationalized for this study in Section 1.1) is one of the key elements of this process. For consent to be valid, it must include at least three elements [10]:

- a. Information provided to the patient that is clear enough for them to accept or refuse treatment.
- b. Voluntariness, that is, giving consent freely, without coercion or external manipulation.
- c. Sufficient mental capacity to do so.

With the introduction of Informed Consent into clinical practice, the assessment of patients' decision-making capacity takes on crucial importance. Only if the patient is competent can they make autonomous decisions about their health.

In daily clinical practice with adolescent patients, it is necessary to assess competence using objective tools that include related factors (such as insight into the illness), especially when obtaining informed consent for invasive or high-risk procedures, psychiatric hospitalization, or participation in clinical trials, where the significance of the validity of such consent is much greater [11].

1.3. Competence: Capacity for Healthcare Decision-Making

Competence, or healthcare decision-making capacity, is defined by the presence of a certain number of abilities, primarily psychological (affective, cognitive, volitional), that enable a person to autonomously make a specific decision at a given moment [12–16].

The criteria for healthcare capacity primarily refer to patients' abilities to receive, understand, and rationally process information, make a decision, and communicate it appropriately. Some experts consider that, to have decision-making capacity in health matters, at least three aspects must be present simultaneously [3]:

- a. Understanding: The patient can comprehend relevant information about their illness, treatment options, and concepts of probability.
- b. Evaluation: Weighing the potential risks and benefits.
- c. Decision: To consent or refuse. A decision does not always have to be reasonable to be respected. However, if it does not seem reasonable and the matter being decided is serious, the patient's capacity must be assessed [3].

Current Spanish legislation implicitly establishes the healthcare professional's duty to assess the patient's capacity, but does not provide explicit guidance on the appropriate way to do so. In daily clinical practice, the assessment of competence is typically subjective, left to the discretion of the healthcare provider [4–9,17,18].

The problem is that there is no worldwide consensus on the definition of the skills to be assessed (criteria), when an adequate level is met (standards), or how they are measured (protocols), and there is no standardized procedure for assessing capacity objectively and appropriately. As a result, healthcare professionals lack clear guidelines on how to assess their patients' competence.

1.4. Assessment of Competence

The assessment of competence or healthcare decision-making capacity involves evaluating a certain number of psychological skills or abilities that the patient must possess to a sufficient degree [19–22].

Competence assessment should be a continuous process, integrated into the patient's clinical follow-up, rather than a one-time event. A single assessment should not be performed, as competence is a dynamic concept that can vary depending on the patient's psychological and physical circumstances, and significant fluctuations may occur over short periods of time. In fact, competence in children and adolescents is determined by a complex interplay of factors [23], including:

- The child's stage of development, particularly in terms of cognitive and rational abilities, but also emotional and moral development.
- Their social environment and prior experiences.
- The child's relationship with their family and with the healthcare professional.
- The information provided to the child about the treatment and their understanding of it.
- Their mental state at the time of decision-making [23].

The assessment of competence must always be conducted in relation to the healthcare decision at hand. For some authors [24], the consequences of a potential decision regarding the patient's own health or life are what define its complexity and, therefore, determine the degree of competence required to make it (the concept of a "sliding scale of capacity"). For other authors, the patient's competence must be determined before the decision is made, to avoid the paradox of considering the patient capable of accepting a treatment but incapable of refusing it [25].

The assessment made by the physician treating the patient in a specific situation is generally more valuable, especially if the physician knows the patient, than consulting a psychiatrist, except in cases of psychiatric disorders that raise doubts.

It is not necessary to systematically assess competence in individuals who show no signs of a disorder, but those with risk factors that could impair decision-making in that specific case should be evaluated. It is also advisable to assess patients who refuse a clearly beneficial treatment or hastily accept another that carries significant risks, and to re-evaluate those patients who experience a sudden change in their mental state.

1.5. Factors Related to Ability

Factors related to competence in adults include cognitive functions. Both the presence of cognitive impairment and a low level of education are factors that contribute to lower competence. Greater impairment of competence has been linked to poorer results on certain cognitive tests, such as the Mini-Mental State Examination or the WAIS (particularly the vocabulary subtest) [22,26].

Assessment of executive cognitive functions is a highly sensitive and specific measure for correctly classifying patients as competent or incompetent. Executive dysfunction is

also the primary predictor of the loss of capacity to consent to treatment in patients with Alzheimer's disease [27,28].

In the evaluations of ability, it would be advisable to include cognitive factors such as semantic knowledge, verbal recall, and simple reasoning skills in the assessment of competence, as a close relationship has been observed between these and the capacity to consent to medical interventions.

Functional status (for activities of daily living) has also been linked to decision-making ability. Several studies have observed a relationship between a lower level of competence and the deterioration of functional status in patients with severe and prolonged mental illness [10,29].

Psychopathological factors have also been linked to decision-making ability. The presence of psychotic symptoms is associated with refusal to consent to treatment, as several studies have shown.

In fact, one of the main problems interfering with the patient's ability to consent is a lack of insight. Unawareness of illness is one of the most important problems in severe psychiatric patients, especially in psychosis. Research on the lack of awareness of illness in psychosis has a long research history. A lack of insight has been related to a generally poorer prognosis of schizophrenia, predisposition to treatment non-adherence [30–32], higher relapse rates, increased number of involuntary hospital admissions, substance misuse, diminished psychosocial function and increased suicide risk [33–40].

Far fewer studies have been conducted on decision-making ability and the factors that influence it in adolescents. A direct relationship has been observed between a child's reading level and their decision-making ability [22].

In addition, adolescents have been found to have better cognitive ability to understand abstract concepts than adults, but a poorer understanding of the general determinants of hospitalization [41].

1.6. "Mature Minor" Concept

In adolescents, the concept of a "mature minor" is also a relevant legal designation for an adolescent under the age of majority who possesses sufficient capacity to participate in decision-making. Several countries have different regulations.

In Spain, the medical age of majority is defined under Basic Law 41/2002 on Patient Autonomy [42]. Patients aged 16 and older may give consent independently, without the need for consent from their parents or guardians, unless they are incapacitated or in exceptional cases (voluntary termination of pregnancy, clinical trials, assisted reproductive technologies, living donation, and advance directives).

Patients under 12 years of age must be heard and their opinion taken into account, but they will always require consent by proxy (given by their parents or guardians). For patients aged 12 to 16, consent will be given by proxy when they are not intellectually or emotionally capable of understanding the scope of the procedure.

Clinical situations, and critical (life-threatening) situations in particular, require specific forensic approaches.

Also in Spain, in case of life risk situations, "the physician, after assessing the child's maturity to understand the scope of the intervention and the existence or absence of serious risk, will request judicial authorization when they believe that the parents' decision is not in the best interests of the child's life or health. It has been argued that, even when the parents do not make the decision most favorable to life for justified reasons, the law requires the physician to inform the judge. This judicial intervention would not be necessary if the duty to decide in favor of life were understood in the sense, previously indicated, of a life lived in minimum conditions of dignity.... However, it is foreseeable that the healthcare

professional, to avoid subsequent liability claims, will consult the judicial authority when in doubt" [9].

In any case, the judge's decision must take into account the best interests of the child and will only be binding on the doctor when it denies the power to apply the treatment, since the authorization enables but does not oblige action, ultimately depending on the doctor's decision.

1.7. Assessment of Competence and Maturity

In summary, to assess a minor's competence, one must consider their cognitive capacity (understanding causes and consequences and making judgments), their emotional and psychological capacity (expressing and defending their ideas), and their decision-making ability (weighing risks and benefits and making choices).

Competence in children and adolescents is determined by a complex interaction of factors, such as the child's stage of development, particularly regarding cognitive and rational capacity; the social environment and prior experiences; the child's relationship with their family and with the healthcare professional; the information provided to them about the treatment and their understanding of it; and their mental state at the time of decision-making [43].

A better cognitive capacity to understand abstract concepts has been observed in adolescents (compared to adults), but with a poorer understanding of the general determinants of hospitalization [15,41].

This pattern is consistent with classic and recent findings on the development of treatment-related competence in minors [15,41], and with a 2025 systematic review identifying ten studies that assessed decisional capacity to consent to treatment in children and adolescents using the MacCAT-T and the CQ-ChP, among other instruments [44].

A direct relationship has been observed between the child's reading level and their decision-making capacity [22].

In Spain, there are no validated scales for assessing the capacity to consent to psychiatric admission in adolescent patients. Internationally, there is a scale (CQ-ChP) adapted for children and adolescents with psychiatric conditions. However, as far as we are aware, this scale has neither been adapted nor validated for use with Spanish-speaking adolescent populations [22,29].

In addition, in Spain, the Maturtest for assessing moral maturity in healthy adolescents was recently developed and validated in Catalonia and applied to a pediatric clinical population aged 12 to 16 years; however, it has not been used in psychiatric populations nor is it designed to assess the capacity to make healthcare decisions or to consent to psychiatric admission [45].

1.8. Shared Decisions

Over the past decades shared decision making has gained increased awareness by using a wide range of initiatives from passive information provision to more active initiatives seeking to support patients [46,47]. In partnership with their clinician, patients (and parents) will be encouraged to think about the available care options and the likely benefits and harms of each, to communicate their preferences, and help select the best course of action that fits these [48]. This collaborative approach has a positive influence on the development of patients' rights, and has specific barriers and potential benefits [49].

In an excellent review of decision-making in paediatrics, Bosch et al. (2025) [14] highlighted how the decision-making process becomes triadic because it includes the patient, the healthcare professional, and the parents as surrogates for a child's decision. They reviewed how "interventions to support decision-making in pediatrics mainly target

parents and that children and adolescents are often not involved in treatment or decision processes or that their wishes are not taken into account" [14].

In fact, forensic science must incorporate shared decision-making into its standards, because it fundamentally protects a patient's legal and ethical right to bodily autonomy and informed consent [50–52].

1.9. The MacCAT for Spanish Adolescent Population

The MacCAT was validated for the Spanish adult population at our own hospital [17], but, to our knowledge, it lacks validity in Spanish for our target population (adolescents with psychiatric conditions who must consent to their admission).

On the other hand, different previous publications included validation of the MacCAT for adolescent populations in different contexts and needs. In a previous population of 17 pediatric Dutch outpatients between 6 and 18 years at risk for an autosomal dominantly inherited cardiac disease, eligible for predictive genetic, Irma M. Hein and collaborators (2015) tested an adapted version of the MacCAT-T [53,54]. They found the MacCAT-T to be a feasible tool for judging competence in children and adolescents for involvement in the informed consent process.

In a sample of 12 German children (mean age, 9.87, range 7.7 to 12.2), Michael Koelch and collaborators (2010) studied competence through the MacCAT-CR and clinically assessed by trained clinicians [55]. They supported that the MacCAT-CR was practicable, and the time required was acceptable. Interrater reliability was excellent in children in their sample, but children performed less well than parents on this test. Whereas clinicians assessed all children as competent, lack of competence became apparent in the MacCAT-CR.

Finally, in another previous study in African populations [56], to assess the cognitive capacity of early ($n = 80$; 10–14 years), middle ($n = 20$; 15–17 years), and late adolescents ($n = 20$; 18–19 years) and their parents or guardians to provide informed consent, they used also the MacArthur Competence Assessment Tool for Clinical Research. Twenty transcripts were scored independently by two coders, and the intraclass correlation coefficient was 0.89. The results showed that early adolescents scored significantly lower ($p < 0.01$) than middle/late adolescent groups. The Authors also observed the paired dyad comparisons with their parents/guardians, observing no statistically significant difference in scores between parents/guardians and middle/late adolescents. This study supports "the practice of having middle and late adolescents provide independent informed consent for sexual and reproductive health studies." They also confirmed that "Early adolescents may benefit from supported decision-making approaches" [56].

In relationship with all these variables and dimensions, our project will establish new evidence about competence in adolescents, through the process of adaptation and validation of a well-known evaluation, the Spanish MacCAT version, to consent to psychiatric admission in the adolescent population, in the specific environments of our psychiatric health departments.

2. Purpose of the Study

The final aim of this study is to generate the scientific evidence required to develop a protocol for assessing competence in adolescents who must consent to admission to a mental health unit.

This need stems from the Spanish legal system's requirement to reform involuntary admission procedures in line with the United Nations Convention on the Rights of Persons with Disabilities (CRPD), with a view to strengthening the protection of fundamental rights and establishing specific safeguards for minors.

The study focuses primarily on adapting and validating the MacCAT semi-structured interview to assess the capacity to consent to admission—specifically, psychiatric admission—in adolescent patients. It also aims to validate a scale for assessing the capacity to consent to psychiatric admission (CQ-ChP) in Spanish.

We will establish new evidence about the evaluation of competence in adolescent psychiatry; to date, no studies have been identified assessing the capacity to consent to psychiatric admission among Spanish-speaking adolescents, nor the factors potentially related to such competence. To our knowledge, the relationship between competence and illness awareness in the adolescent population remains unexplored in the literature, and its analysis constitutes one of the novel contributions of the present study.

The scientific contribution of this project is fourfold rather than singular. First, it provides the first cultural and linguistic adaptation of the MacCAT-T to consent to mental health admission and the CQ-ChP for Spanish-speaking adolescents, addressing a specific gap in instrument availability for this population (Section 1.7). Second, it applies a validation approach that combines qualitative content validation with quantitative psychometric evaluation (reliability, internal consistency, and construct/criterion validity; Sections 4 and 8), rather than relying on translation alone. Third, the clinical population under study—adolescents undergoing acute psychiatric or paediatric admission—has not previously been examined with these instruments in the Spanish context, allowing the assessment of capacity under clinically realistic, high-stakes conditions. Fourth, and most distinctively, the study integrates psychometric validation with the analysis of developmental and clinical correlates of capacity (illness awareness, maturity, personality, parenting style; Sections 1.5–1.7 and Section 7.4), an integration that is, to our knowledge, absent from prior MacCAT-T and CQ-ChP validation studies in any language.

Therefore, it is necessary to evaluate factors that are hypothesized to be related to competence, based on previous literature studies conducted in adults and on various theories regarding neurocognitive and emotional maturation.

It is particularly relevant for this study to determine whether the adolescent's age affects their capacity, by analyzing the sample by age groups ranging from 12 to 17 years.

Sex-related differences in decision-making competence merit specific analysis in this study, as developmental neuroscience evidence suggests that boys and girls may differ not so much in overall cognitive ability as in the timing and tempo of neurocognitive maturation during childhood and adolescence [57,58].

It is also necessary to determine whether, in our setting—as described in the reviewed literature for adult patients—the competence of adolescent patients with psychiatric disorders is impaired due to their mental disorder, compared to adolescents with non-psychiatric medical conditions; it is necessary to determine whether competence is affected to a greater degree than might be apparent, and whether this impairment is related to factors such as illness awareness or the presence of psychotic or depressive symptoms, or to specific disorders (such as eating disorders—EDs or ADHD).

2.1. Research Questions

- Do questionnaires on healthcare decision-making capacity in adolescents classify the same patients as capable as the subjective assessments made by the therapist, the parents, and the patient themselves?
- Does age affect the ability to make healthcare decisions? Is health decision-making capacity lower in the 12–13 age group than in the 14–15 or 16–17 age groups?
- Is adolescent patients' illness awareness related to health decision-making capacity?
- Is health decision-making capacity related to reading level, intelligence, and vocabulary size, as in other studies?

- Is adolescents' health literacy related to other variables, such as parenting style or personality traits?
- Does psychiatric pathology in adolescents impair health literacy in the same way as medical pathology?
- Does psychiatric pathology interfere with adolescents' health literacy in the same way as it does in adults, according to previous studies?
- Is the presence of psychotic or depressive symptoms associated with lower competence in adolescent patients?
- Is health literacy compromised in patients with eating disorders? Is this related to a lack of illness awareness?
- Is health literacy compromised in patients with Attention-Deficit/Hyperactivity Disorder (ADHD)? Is this related to impulsivity?

2.2. Primary (General) Objectives of the Project

1. Adapt and validate the MacCAT in an adolescent population for assessing decision-making capacity to consent to admission—specifically, psychiatric admission.
2. Determine whether or not maturity and health-related decision-making capacity are equivalent in adolescents.
3. Determine whether there is a discrepancy in the assessment of medical decision-making capacity between objective evaluation (the MacCAT semi-structured interview and the CQ-ChP interviewer-administered questionnaire) and subjective impressions (from the clinician, parents, and the patient themselves).

2.3. Secondary (Specific) Objectives

1. To analyze whether age and sex affect adolescents' ability to make health-related decisions.
2. To analyze whether there are differences in the ability to make health-related decisions between adolescents with psychiatric conditions and those with medical conditions.
3. Identify variables related to decision-making capacity and determine their predictive value in different patient groups (psychiatric and pediatric).
4. Examine the relationship between illness awareness and decision-making capacity, particularly in certain psychiatric conditions (Conduct Disorder, Eating Disorder).

3. Hypotheses

3.1. Main Hypotheses

1. The MacCAT is valid for determining the capacity to make healthcare decisions regarding admission in the adolescent population, similar to adults.
2. Maturity (neuropsychological and moral) and competence are not equivalent in the adolescent population, in the same way that there are no equivalents in adults, in whom maturity is presumed and yet competence must still be assessed.
 - Immature adolescents are not competent (all adolescents considered immature will be deemed incompetent).
 - However, not all mature adolescents are competent (more than half of mature adolescents will not be deemed competent).
3. The objective assessment of competence, using questionnaires (CQ-ChP) and semi-structured interviews (MacCAT), differs significantly from the subjective assessment (clinical impression of the physician responsible for the adolescent, as established by Spanish legislation to assess the competence of minors).
 - The responsible physician's clinical impression underestimates adolescents' competence. The MacCAT identifies a greater number of competent adolescents than the clinician's subjective impression.

- Patients overestimate their healthcare capacity. The MacCAT identifies a smaller number of competent adolescents than their own self-assessment.

3.2. Secondary Hypotheses

1. Age influences competence. The younger the individual, the less likely they are to be deemed competent, based on both instrumental evaluation (CQ-ChP, MacCAT) and clinical impressions.
2. Having a psychiatric disorder during adolescence does NOT equate to a lack of competence.
 - Among adolescents with psychiatric disorders, there is a significant number of mature adolescents and adolescents with preserved legal capacity (less than half).
 - However, the number of competent adolescents is lower among those with a psychiatric disorder (less than half) than among those with a non-psychiatric disorder (more than half).
3. The most important variables directly related to health-related competence in adolescents (the higher the score on the variable, the higher the score on the MacCAT) are:
 - Intelligence quotient, vocabulary level.
 - Degree of functional autonomy.
 - Critical thinking ability.
 - Problem-solving and decision-making ability
 - Personality traits.
 - Parental parenting style (assertive and democratic).
4. Illness awareness is the main factor that determines the discrepancy between maturity (moral and psychological) and competence in adolescents.
 - The lower the level of illness awareness, the lower the health literacy (lower score on the MacCAT), regardless of maturity.
 - Adolescents with psychosis or anorexia nervosa have lower health literacy (lower scores on the MacCAT) than adolescents with ADHD or depression, in relation to a lower level of illness awareness.

4. Materials and Methods

4.1. Study Design

Sequential mixed-methods divided in two phases.

To avoid ambiguity regarding the scope of “validation” in this protocol, the two phases serve distinct and explicitly defined aims. Phase 1 (qualitative content validation) and the psychometric component of Phase 2 (Section 4.1.2, point 1) together constitute the validation study proper: their aim is to establish the content validity, cross-cultural equivalence, internal consistency (Cronbach’s alpha/McDonald’s omega), inter-rater and test–retest reliability, and construct/criterion validity (convergent and discriminant) of the Spanish adaptations of the MacCAT-T and CQ-ChP, following standard psychometric validation methodology [59,60].

The second component of Phase 2 (the prospective analytical cohort, Section 4.1.2, point 2) is explicitly exploratory and analytic rather than part of the core validation: once the instruments’ psychometric properties are established, this component investigates associations between the validated capacity scores and clinical/developmental variables (illness awareness, maturity, personality, parenting style), using the regression, moderation, and mediation analyses detailed in Section 7.

These two aims are conceptually and analytically distinct—establishing that an instrument measures capacity reliably and validly is a separate question from what capacity is associated with—and the sample size and power considerations in Section 7 are reported separately for each.

4.1.1. Study Phase 1: Qualitative Content Validation of the CQ-ChP and MacCAT Instruments

- Cross-translation of the CQ-ChP scale [22].
- Adaptation, by the Expert Committee, of the MacCAT [3,17] for use with the 12- to 17-year-old age group, taking into account that the scale is designed to identify “incompetent” adults and must identify “competent” adolescents.
- Audio recordings will be made of the interviews for the CQ-ChP and MacCAT instruments, to be scored by two observers—members of the expert committee—who have been previously trained in the content and evaluation of the scales.
- In this phase of scale validation, other questionnaires will also be administered: the Lleida Scale (to assess moral maturity), the SUMD (to assess illness awareness), the SCL-90-R (to rule out psychiatric disorders), the WISC-IV (estimated IQ subscales, to rule out intellectual disability), and subjective questionnaires.

Expert Consensus, Blinding, and Disagreement Resolution

Because no objective gold standard exists for adolescent decision-making capacity, expert clinical judgement functions as the principal comparator for criterion validity in this protocol, and its procedure is therefore specified in detail. The Expert Committee comprises at least two psychiatrists or clinical psychologists per case, with documented prior experience in capacity/consent assessment within the Spanish clinical and legal context, who were not involved in the patient’s direct clinical care. For each case, both experts independently score the audio-recorded MacCAT and CQ-ChP interviews and independently render a binary competence judgement (competent/incompetent) based on the recording alone; they are blinded to each other’s scores and judgements at the time of independent rating, and to the patient’s self-assessment and parental assessment (the “subjective assessment questionnaires,” Section 6.2), in order to avoid contaminating the instrumental and expert-judgement comparators that are subsequently contrasted with one another (Main hypotheses, Section 3.1). Experts are not blinded to the patient’s diagnosis or clinical history, as this information is part of the standard clinical judgement process being evaluated and cannot be meaningfully withheld without creating an artificial task.

Inter-rater agreement between the two experts is quantified using the weighted Kappa coefficient (Section 8). When the two experts disagree on the binary competence judgement, a third, senior member of the Expert Committee (not involved in the initial scoring) independently reviews the same recording and renders a third judgement; the final expert-consensus judgement for that case is then taken as the majority verdict among the three raters. Cases in which all three raters disagree (i.e., no majority is reached) are flagged and reported separately as indeterminate, rather than being forced into a binary classification, and the proportion of such indeterminate cases will be reported as an indicator of the practical reliability of expert judgement itself. We acknowledge, as discussed further in Section 11, that using expert consensus as the criterion standard means that criterion validity coefficients for the MacCAT and CQ-ChP are necessarily bounded by the reliability of expert judgement, and that any error or bias in expert judgement (including its well-documented subjectivity even among trained clinicians [25]) will be reflected in, and may attenuate, the estimated criterion validity of the instruments under evaluation.

4.1.2. Phase 2: Quantitative Psychometric Evaluation

Conducted in two stages:

- (1) Cross-sectional descriptive analysis: To define the baseline values of the variables of interest in the sample (cognitive ability, linguistic functions, reading ability, illness awareness, presence of depressive or psychotic symptoms, personality traits, problem-solving ability, critical thinking, and problem-solving skills, etc.).
- (2) Prospective analytical cohort study: To classify patients in the sample as “exposed” or “unexposed” to the various variables intended to be correlated, analyzing for each group whether or not they possess sufficient capacity to make healthcare decisions.

4.2. Setting and Procedures

Evaluation will include clinical and neuropsychological assessment in different departments at two University Hospitals of the Area: the Psychiatric and Pediatric Inpatient Units at Parc Taulí University Hospital (Sabadell, Barcelona, Spain), and the Day Hospital of Mutua de Terrassa University Hospital (Terrassa, Barcelona, Spain).

Patients and parents are required to sign a written informed consent form, and researchers will answer all questions and concerns raised by the participants. The study did not receive any financial support from public or private counterparts. The study is non-profit, and neither researchers nor participants received any financial compensation for their participation in the research.

All the interviews were recorded and anonymized, and identified by a number. Records will be evaluated by different researchers (at least two expert psychiatrists/psychologists with experience in capacity/consent assessment within the Spanish context) in order to ensure inter-observer agreement. A test–retest will be performed in a subset of the sample (approximately 20% of participants, clinically stable at both time points) with a 7-to-14-day interval between the two administrations. This interval follows the general psychometric recommendation that 2 to 14 days is an acceptable window for test–retest reliability assessment in clinical and patient-reported outcome instruments: a shorter interval risks inflating reliability through recall of specific items, while a longer interval risks genuine change in the underlying construct being mistaken for measurement error [61]. Because decision-making capacity, unlike a stable personality trait, can fluctuate with acute clinical status (e.g., resolving psychotic or depressive symptoms), only patients judged clinically stable by the treating team between the two assessments will be included in the test–retest analysis, and any change in clinical status during this interval will be recorded and reported as a potential source of measurement instability rather than unreliability.

This setting was selected in anticipation of a potentially greater impairment of capacity in more severely ill patients and those in a more acute stage of their condition. In this setting, it is more common to encounter situations where assessing capacity is particularly critical (more complex treatments, invasive procedures, hospitalization, etc.). It also allows for the assessment of understanding of the admission procedure and consent to it, which is particularly crucial in the psychiatric setting. It facilitates access to patients and the completion of the tests, causing them as little inconvenience as possible.

Given the full battery of instruments described in Section 6 and the clinical vulnerability of the target population (adolescents undergoing acute psychiatric or paediatric admission), data collection is organized across two sessions rather than a single visit, in order to limit cognitive load and fatigue. Session 1 (approximately 30 min, conducted within the first days of admission once the patient is judged by the clinical team to be in a condition suitable for evaluation) comprises: the sociodemographic questionnaire (5 min), the MacCAT semi-structured interview (10 min [62]), and the CQ-ChP interviewer-

administered questionnaire (10 min), administered in this order so that the more demanding, open-ended instrument (MacCAT) is completed before participant fatigue accumulates. Session 2 (approximately 45–60 min, scheduled within the following 2–3 days, clinical condition permitting) comprises the remaining self- and examiner-administered questionnaires (Maturtest, WISC-IV vocabulary/relevant subtests, PROLEC-SE-R, SCL-90-R, BFQ-NA, SPSI-A, SUMD, BIPQ, APQ, and the subjective assessment ratings; Section 6), grouped to alternate self-report and examiner-administered formats and to avoid placing two lengthy, effortful instruments consecutively. A short break (5–10 min) is scheduled at the mid-point of each session, and any session will be paused or rescheduled if the patient shows signs of fatigue, distress, or clinical instability, consistent with the ethical procedures described in Section 5. The full protocol is designed to be completed within a single hospital admission or day-hospital treatment episode, which in our setting typically allows for the 2–3 days needed to complete both sessions plus the test–retest assessment (Section 4.2) where applicable.

4.3. Target Population

The target population for this study consists of adolescents aged between 12 and 17 years inclusive (i.e., minors who have not yet reached the age of legal majority), who are admitted to a psychiatric inpatient unit or to a mental health day hospital, for psychiatric conditions.

The target population is intentionally restricted to a clinical sample (psychiatric and medical/paediatric admissions) rather than including a healthy, non-clinical comparison cohort in this phase. This decision was made for two reasons. First, the primary aim of this phase is to validate the Spanish adaptations of the MacCAT-T and CQ-ChP and to estimate the prevalence of impaired capacity specifically among adolescents for whom capacity assessment is clinically necessary (i.e., those facing an actual admission decision); a healthy-volunteer sample would not face this decision and would be expected to show ceiling effects on most capacity items, contributing little to the validation of discriminant or criterion validity. Second, recruiting and retaining a matched non-clinical cohort within the same protocol would substantially increase the complexity, cost, and duration of this already multi-instrument protocol (Section 6), creating a feasibility trade-off (see Sections 4.2 and 11). We acknowledge, as noted in Section 11, that the absence of a non-clinical comparison group limits our ability to establish normative (population) reference values for the Spanish MacCAT-T and CQ-ChP, and we treat the extension of this protocol to outpatient and non-clinical adolescent samples as a planned and necessary next phase rather than as an optional addition.

4.4. Exclusion Criteria

- Patients aged under 12 years, or aged 18 years and over (i.e., no longer minors).
- IQ < 70
- Inability to read.
- Not in a medical or psychiatric condition suitable for evaluation.
- Refusal to participate in the study (by the patient and/or their parents or guardians).

5. Ethical Considerations

The study has already been approved by the Ethical and Research Committee of the participating research centres and will be conducted according to local (Spanish) and international regulations, and the local and international rules governing the rights of children and adolescents in health research.

To ensure the ethical integrity of the entire project, participants will be asked to provide their express consent (by signing the informed consent form) to be included in the project.

Similarly, parental or guardian consent will be required for participation in the study. Only those patients who sign the informed consent form—along with at least one parent or guardian—will be included in the study.

They will be provided with a written information sheet and given 1–2 days to thoroughly read and understand the document and discuss the proposal among themselves before signing the consent form.

Express authorization will be requested to record the patient interviews on audio, as they must be evaluated by at least two experts unrelated to the interviewer, ensuring that these recordings will not be used for any other purpose and will not contain any personal patient data.

The audio format (rather than video) has been selected to ensure maximum patient confidentiality, given that the participants are minors.

6. Materials

6.1. Sociodemographic and Clinical Variables

Sociodemographic variables: Age, sex, educational level ((grade level and academic performance), parents' educational level, family socioeconomic status.

Clinical variables: Menarche, number of previous admissions, admission type (voluntary/involuntary), acceptance of admission, diagnosis, pharmacological treatment, medication adherence, family history of mental health disorders, family history of mental health admission.

6.2. Competence Assessment Instruments

For clarity and terminological consistency throughout this manuscript, the MacCAT is administered as a semi-structured interview: a trained examiner reads a standardized vignette and administers a fixed set of probe questions, but may use standardized follow-up prompts to clarify the patient's responses, and responses are scored by the examiner according to standardized anchors. The CQ-ChP is administered as an interviewer-administered (interviewer-rated) questionnaire: the examiner reads each item to the patient in a fixed order and records the patient's response, without open-ended probing. Both instruments are interviewer-administered rather than self-report, but they differ in structure (semi-structured vs. fully structured) and in the degree of clinical judgement required for scoring, which has implications for examiner training, standardization, and participant burden, as detailed below.

6.2.1. Modified Competency Questionnaire CQ-ChP

Billick et al. [22] modified the CQ (Competency Questionnaire) to suit children and adolescents with mental illness, resulting in the 17-item CQ-ChP. Through this test, they detected a significant association between competence and the vocabulary subtest of the intelligence test, as well as with reading level. It has been used in the English-speaking world and has not been validated in Spanish.

6.2.2. MacCAT

Grisso and Appelbaum developed the MacCAT-T (MacArthur Competence Assessment Tool for Treatment) [3]. This is one of the most specific protocols for assessing competence, in the opinion of experts. It has previously been used with adults with mental and medical conditions and is validated in Spanish [17]. It is not adapted for use with adolescents in Spain. For brevity, this instrument is referred to as "MacCAT" throughout the remainder of this manuscript.

6.3. Assessment of Maturity

The Maturtest (EVMM-17, Minor Maturity Assessment Scale), created by a team in Lleida (Spain) to assess the moral maturity of adolescents, based on Kohlberg's theory. It consists of 17 items, although a brief 9-item version is available. Validated in Spanish in the general adolescent population [45].

6.4. Neurocognitive Assessment

- WISC-IV (Wechsler Intelligence Scale for Children) [63]: Examiner-administered, lasting between 60 and 110 min. Ages 6 to 16. Assesses overall cognitive ability and four specific domains of intelligence, allowing for a more precise and in-depth analysis of cognitive processes. The structure of the WISC-IV consists of 15 tests (10 core and 5 optional) that yield a profile of scaled scores, a full-scale IQ, and 4 indices: Verbal Comprehension, Perceptual Reasoning, Working Memory, and Processing Speed.

- PROLEC-SE: Assessment of reading processes.

Created by J.L. Ramos and F. Cuetos [64]. Administered by a tester, in approximately 60 min. Ages 10 to 16 (5th grade to 8th grade). Assessment of reading ability and the cognitive processes involved in reading. The objective of PROLEC-SE is to assess not only overall reading ability but, above all, the cognitive processes involved and the strategies used. The battery consists of three blocks, corresponding to each of the main processes that make up the reading system: lexical, syntactic, and semantic.

6.5. Emotional State

- SCL-90-R: Symptom Checklist-90-R (90-item symptom test), Spanish version [65].

Developed by Leonard R. Derogatis for ages 13 and up. It is self-administered, and it takes 12 to 15 min. It is a symptom quantification tool that allows for the assessment of a wide range of psychological and psychopathological symptoms in both clinical and general populations. It assesses the presence of 90 symptoms and determines their intensity on a scale ranging from total absence (0) to maximum intensity (4). It is highly useful for conducting an initial assessment of patients as an objective method for symptom severity; it is also useful in clinical trials to help measure changes in symptoms such as depression and anxiety.

- The BFQ-NA (Big Five Questionnaire for Children and Adolescents), originally developed by Barbaranelli, Caprara, and Rabasca and adapted to the Spanish population by Del Barrio, Carrasco, and Holgado [66], assesses personality across the five dimensions of the Big Five model: Conscientiousness, Openness, Extraversion, Agreeableness, and Emotional Instability. The Spanish version comprises 65 self-report items rated on a five-point Likert scale and is suitable for children and adolescents aged 8 to 15–18 years, with good internal consistency and adequate factorial invariance across sex and age groups reported in Spanish validation studies [62,66].

6.6. Problem-Solving and Decision-Making Skills

- SPSI-A: Social Problem-Solving Inventory for Adolescents [67].

An English version for adolescents (ages 12 to 18) exists, although it has not been validated in Spanish. Developed by Frauenknecht and Black [67], it is a self-administered Likert-type inventory comprising three scales: Automatic Process, Problem Orientation (with Cognition, Emotion, and Behaviour subscales), and Problem-Solving Skills (with Problem Identification, Alternative Generation, Consequence Prediction, and Implementation/Evaluation/Reorganization subscales). Administration takes approximately 20 min. A Spanish-translated version has been used in a study at Complutense University of Madrid with adult patients, but has not undergone formal psychometric validation in Spanish.

6.7. Illness Awareness Questionnaires

- SUMD: Scale for assessing lack of awareness of mental disorder. Adapted by A. Ruiz, E. Pousa, R. Duño, J. Crossas, S. Cuppa, and G. García [68]. Used primarily in adults with psychotic disorders. The three general items will be included.

- BIPQ (Brief Illness Perception Questionnaire), developed by Broadbent et al. [69]: A 9-item, self-administered questionnaire taking approximately 2 min to complete. Eight items are rated on an 11-point scale (0–10) assessing cognitive representations of illness (consequences, timeline, personal control, treatment control, identity), emotional representations (concern, emotional response), and illness comprehensibility; a ninth, open-ended item asks respondents to list the three factors they believe caused their illness. Validated in Spanish for the adult population. It is used to assess illness awareness in medical conditions; it has not been used in psychiatric conditions.

6.8. Parenting Style Assessment Questionnaire

- APQ (Alabama Parenting Questionnaire) [59,70]: There is a version for parents and another for children. It is validated in Spanish and Catalan. It consists of 42 items, measures 5 parenting dimensions, and is self-administered. It is widely used in research involving children and adolescents.

6.9. Subjective Assessment Questionnaires

The patient, parents, and the attending physician will be asked whether they consider the patient to be generally mature, and mature/capable of making decisions regarding their health (accepting/refusing admission, treatment, and diagnostic tests).

These “subjective assessment questionnaires” are not standardized psychometric instruments but single-item, ad hoc dichotomous/ordinal ratings (mature/not mature; capable/not capable) elicited independently from three informants (patient, parent or guardian, and attending physician). They are distinct from the objective instrumental evaluation provided by the MacCAT and CQ-ChP, and are used specifically to operationalize the subjective comparator referred to throughout the Hypotheses and Objectives (Sections 2 and 3) and in the criterion-validity analyses (Section 8).

7. Sample Size

Since this is primarily a scale-validation study and the true values of the latent traits under study are not known a priori—and there is no objective gold standard against which to compare them—the sample size cannot be calculated using the standard procedures for hypothesis-driven studies (e.g., comparing two known proportions or means). Instead, the sample size has been justified in relation to the psychometric analyses planned (item-level stability, internal consistency, factor structure, and predictive/discriminant analyses), as detailed below.

7.1. Sample Size for Scale Validation (Subject-to-Item Ratio)

In scale-development and scale-validation studies, the required sample size is commonly estimated from the subject-to-item (or observation-to-variable) ratio rather than from a conventional hypothesis-testing power calculation, because the population parameters of the new instrument are unknown before data collection [60,71]. Recommendations for this ratio have varied widely across the psychometric literature, ranging from 3–6 to 20 observations per item, and a formal review found that the rationale for any single ratio is rarely justified empirically [71,72]. A commonly applied and frequently cited threshold is 10 to 15 observations per item, which has been shown in simulation studies of factor-analytic and item-calibration models to provide reasonably stable parameter estimates

for instruments of moderate length and communality [72,73]. Given the absence of a universally accepted standard, and consistent with the systematic review by Anthoine et al. [71] showing that roughly 90% of published validation studies use samples of 100 or more participants, we adopted the 10–15 observations-per-item ratio as a pragmatic, literature-supported benchmark for this study.

In addition, the sample sizes used in previous validation studies of the MacCAT-T and the CQ-ChP, performed in English-speaking or adult populations, were considered as an empirical reference.

For the 13 items of the MacCAT-T [17], applying the 10–15 observations-per-item rule yields a requirement of between 130 and 195 observations; for the 17 items of the CQ-ChP [22], between 170 and 255 observations would be required. Taking the more demanding instrument (CQ-ChP) and the lower bound of this range, together with the sample sizes reported in previous validation studies of the MacCAT-T in adults and of the CQ-ChP in English, a target sample size of 170 patients is proposed for Phase 1 (scale validation). This figure also exceeds the empirical median sample size ($n = 207$) reported across published validation studies of patient-reported outcome measures [71].

7.2. Sample Size for the Multivariate Logistic Regression Analysis

For Phase 2, a multivariate logistic regression model is planned to analyze the relationship between the binary outcome (competent/incompetent) and the candidate predictor variables (sociodemographic, cognitive, illness-awareness, and personality variables). The recommended minimum is 10 events per predictor variable (EPV) included in the model, based on simulation studies showing that lower EPV values are associated with biased regression coefficients, inflated Type I error, and unstable confidence intervals [74]. With a proposed sample of $n = 170$ and an anticipated model of up to 5–7 predictor variables (selected a priori from the literature reviewed in Sections 1.5–1.7), an EPV of 10 would require that the less frequent outcome category (e.g., “incompetent”) represent at least 29–41% of the sample (50–70 cases) for a 5-predictor model, or 41–59% (70–100 cases) for a 7-predictor model. Because this setting was deliberately selected to enrich the sample with patients undergoing acute psychiatric or pediatric admission—a population in which capacity impairment is expected to be more frequent than in unselected outpatients (see Section 4.2)—this proportion is considered plausible, although it will be monitored during recruitment. If the observed prevalence of incompetence is lower than anticipated, the number of predictors entered simultaneously into the multivariate model will be reduced (e.g., through a two-step selection strategy or stepwise entry guided by univariate association) to preserve an EPV of at least 10.

7.3. Power for Subgroup Comparisons

The protocol also includes comparisons of ability-scale scores between patient groups, age groups, and sociodemographic subgroups, using independent-samples tests (Student's *t*-test/Mann–Whitney U for two groups; ANOVA/Kruskal–Wallis for three or more groups). For a two-group comparison with a balanced allocation (e.g., $n = 85$ per group), the proposed total sample of 170 patients provides 80% power ($\alpha = 0.05$, two-tailed) to detect a between-group effect size of Cohen's $d \approx 0.44$ or larger; for an unbalanced split typical of an age-based subgroup comparison (e.g., 12–16 vs. 17 years, approximately 50 vs. 120 patients), the minimum detectable effect size at 80% power is $d \approx 0.48$. These values correspond to a small-to-medium effect by conventional benchmarks, indicating that the study is adequately powered to detect clinically meaningful differences of this magnitude, but is underpowered to reliably detect small effects ($d < 0.3$). For the correlational analyses (Spearman's coefficient) between the ability scales and continuous variables, a sample

of 170 provides approximately 75% power to detect a correlation of $r = 0.20$ and over 97% power for $r = 0.30$, but only about 50% power for a weak correlation of $r = 0.15$. These figures will be reported alongside effect sizes and confidence intervals when presenting subgroup and correlational analyses, so that null findings in smaller or more unbalanced subgroups (e.g., the 12–16-year-old subgroup referenced in Section 8) can be interpreted with appropriate caution regarding underpowering rather than as definitive evidence of no association.

7.4. Power for Effect-Size Estimation, Moderation, and Mediation Analyses

Several of the secondary objectives and hypotheses (Sections 2.3 and 3.2) imply not only direct group differences but also moderation (e.g., whether the association between illness awareness and decision-making capacity differs according to parenting style or personality traits) and mediation (e.g., whether illness awareness mediates the relationship between psychiatric pathology and decision-making capacity). All effect-size estimates reported throughout the study (Cohen's d for group comparisons, Spearman/Pearson's r for associations, odds ratios for the logistic regression model, and standardized path coefficients for moderation/mediation models) will be accompanied by 95% confidence intervals, in line with current recommendations to report effect sizes rather than relying on dichotomous significance testing alone [75].

Moderation will be tested by entering the product term of the predictor and the candidate moderator into the regression model, after centering both variables, and examining the increase in explained variance (ΔR^2) attributable to the interaction term [76]. Interaction (moderation) effects observed in non-experimental field studies are typically small, with a median effect size of $f^2 \approx 0.002$ – 0.01 and rarely exceeding $f^2 = 0.02$ – 0.03 [76,77]. With a sample of $n = 170$ and a model including up to three main-effect predictors plus one interaction term, statistical power to detect a small interaction effect ($f^2 = 0.02$) is approximately 44% at $\alpha = 0.05$, rising to approximately 82% for a small-to-moderate interaction ($f^2 = 0.05$) and exceeding 98% for a moderate interaction ($f^2 = 0.10$). Detecting a small interaction effect ($f^2 = 0.02$) with 80% power would require approximately 400 participants. The study is therefore adequately powered to detect moderation effects of small-to-moderate magnitude or larger, but, consistent with the broader literature on interaction effects in field research [77], may be underpowered to detect very small moderation effects; this limitation will be made explicit when interpreting non-significant interaction terms.

Mediation will be tested using the standard indirect-effect framework (path a: predictor $\rightarrow$ mediator; path b: mediator $\rightarrow$ outcome, controlling for the predictor) with bias-corrected bootstrap confidence intervals for the indirect effect ($a \times b$), which provide the highest power among the commonly used tests of mediation [78]. According to the empirically derived sample-size requirements of Fritz and MacKinnon [78] for 80% power using this method, the required sample ranges from $n = 462$ when both the a and b paths are small (standardized coefficient ≈ 0.14) to $n = 71$ when both paths are medium (≈ 0.39), and $n = 34$ when both paths are large (≈ 0.59). With the proposed sample of $n = 170$, the study is adequately powered ($>80\%$) to detect mediation effects in which both paths are at least medium in magnitude, or in which one path is small and the other is medium-to-large, but it is underpowered to detect mediation in which both the a and b paths are small. Given that most of the candidate mediators in this study (e.g., illness awareness, cognitive functioning) are expected, on the basis of the adult literature reviewed in Sections 1.5–1.7, to show at least moderate associations with both the predictor and the outcome, this sample size is considered acceptable for the planned exploratory mediation analyses; however, mediation findings will be interpreted as preliminary and will be reported together with bootstrap confidence intervals and effect sizes for the a and b paths, rather than as definitive confirmatory tests.

An estimated dropout/non-participation rate of 15% has been considered; recruitment will therefore target approximately 195–200 eligible patients to obtain a final analyzable sample of 170.

8. Data Analysis

A descriptive analysis of the variables will be conducted first, followed by application of the Kolmogorov–Smirnov normality test to determine whether the data follow a normal distribution. In cases of normal distribution, parametric tests will be applied; although these require stricter validity conditions, they offer greater power and reliability. For the remaining variables that do not follow a normal distribution, nonparametric tests will be applied; these do not require such validity conditions but are less powerful and more complex to calculate.

To assess the relationship between capacity and various variables, multivariate logistic regression, widely used in epidemiology—primarily in predictive studies—will be employed to analyze the relationships between a binary response (mature/immature, competent/incompetent) and various stimulus variables.

To assess the existence of significant differences between the scores on the ability scales by patient groups, sociodemographic variables, and psychometric variables, independent-samples tests will be used (Student's *t*-test or Mann–Whitney U test for two groups, and ANOVA or Kruskal–Wallis test for three or more groups, depending on the data distribution).

To determine the existence of an association between the different tests, a linear correlation analysis will be performed using Spearman's coefficient, and its level of significance will be calculated. The Mann–Whitney U test will be used to determine whether there are differences in the various scales between genders and age groups.

To assess the reliability of the scale, the statistical analysis will include an analysis of internal consistency, using Cronbach's alpha, for each item on each subscale and for the overall scale. To optimize the scoring system for the competency scales and determine the specific weight of each item, a specific extension of the Rasch measurement model, a parametric logistic model (OPLM), will be used.

The overall accuracy of the scores on the validated scales for classifying competence against the standard reference will be quantified using ROC curve analysis; the area under the ROC curve will serve as a validity coefficient, which should range from 50% (probable determination) to 100% (perfect determination).

To analyze the agreement or concordance among raters (inter-observer agreement), the Kappa coefficient will be calculated.

Additionally, an assessment of differences between observers will be conducted using independent samples *t*-tests (Student's *t*-test or Mann–Whitney U test for two groups, and ANOVA or Kruskal–Wallis test for three or more groups, depending on the data distribution).

To quantify reproducibility, intraclass correlation coefficients can be used for the overall scores on the scales. To quantify the inter-rater reproducibility of the scale items, the weighted Kappa coefficient will be calculated. Given our special interest in the 12- to 16-year-old age group, the ICC and Kappa values calculated separately for this age group will be compared.

The optimal cutoff point for the adapted scale and the sensitivity and specificity rates will be determined using the Youden method, with the cutoff point corresponding to the one with the lowest rates of false positives and false negatives.

The same method can be used to determine the validity of age (or age range) as a predictor of the ability to provide informed consent. The required level of significance will be $p < 0.05$.

9. Applicability and Practical Utility

This study represents a qualitative advance in key aspects of the medico-legal approach to minors, while also advancing our understanding of adolescents' capacity and maturity in our context.

The assessment of capacity—an ethically and legally required process—is of great relevance to clinical practice, especially among children and adolescents.

It is essential in cases of doubt, particularly if there is a disagreement between the parents and the patient, or in the selection of patients for clinical trials.

It is crucial to have a validated tool for the objective assessment of capacity.

On a practical level, its use is proposed to determine whether an adolescent patient is capable and mature enough to provide valid consent in situations where conflicts frequently arise, such as:

- Psychiatric admission, determining whether it must be done with a court order (if the patient is deemed incapable).
- Invasive or high-risk diagnostic procedures (such as endoscopy).
- Treatments with significant side effects (such as cancer treatments).
- Chronic treatments (e.g., insulin therapy), where, if the patient is considered “immature or incapable,” the treatment may be administered involuntarily with parental consent.
- Surgical procedures.
- Clinical trials.

Its use is also proposed in all cases where there is a conflict between the opinions of the physician, the parents, and the patient, as well as in cases where the patient refuses a treatment or procedure with high benefit and low risk or accepts one with high risk and low benefit.

Outside the medical field, it might be useful to adapt this approach to assess minors' decision-making capacity, such as in parental custody proceedings, where adolescents aged 12 and older must be heard and their opinions taken into account, depending on their capacity and maturity.

10. Implications

Developing a protocol for the systematic assessment of maturity and health capacity, which also incorporates directly related factors (such as illness awareness), represents a step forward in an assessment that has thus far been subjective, despite its enormous significance, allowing for a comprehensive and objective standardization of assessment among professionals.

Having a validated objective scale to assess adolescents' healthcare competence is crucial from both ethical and clinical perspectives, enabling those considered mature and capable to actively make decisions regarding their health.

In the field of mental health, it would also support the possibility of voluntary psychiatric admissions for adolescents deemed mature and capable—as is done in other specialties—and limit involuntary admissions to those who are immature or mature but incapable, thereby safeguarding the rights of minors.

11. Study Limitations

There is no “gold standard” test for capacity in adolescents; therefore, it must be determined based on the opinion of a panel of experts, which remains subjective despite their prior education and training.

For proper validation of a capacity scale, it is recommended that it be applied not only in hospital settings but also in outpatient settings, as well as in healthy subjects; this should be carried out in an expansion of the current project.

Various studies suggest that children between the ages of 7 and 12 also have the capacity to make decisions [15,22,26], so the application should be expanded to this age group in the future.

Furthermore, by including only patients who sign the informed consent form (themselves and their parents or guardians), a bias may arise by excluding those with potentially greater impairment of their capacity; however, this is unavoidable in order to ensure the ethical integrity of the study.

12. Conclusions

New objective, systematic evaluations of competence and capacity in forensic examination are needed. Capacity/competence for authorization of medical interventions and treatments is a challenge in daily clinical and forensic practice.

New evidence is necessary to operationalize classical evaluations in a standardized way, adapted to different countries, legal systems and forensic traditions. Our project will establish new evidence about capacity in child and adolescent psychiatry. In addition, we will adapt and validate a well-known evaluation scale to the specific environments of our medical and psychiatric health departments. It will be useful, both for forensic specialists and for clinicians, in making difficult decisions about capacity and consent in daily practice.

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