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ORIGINAL ARTICLE

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Validating cognitive screening in young people with first-episode psychosis: The *CogScreen* protocol

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Abstract

Aim: Cognitive impairments are a core feature of first-episode psychosis (FEP) and one of the strongest predictors of long-term psychosocial functioning. Cognition should be assessed and treated as part of routine clinical care for FEP. Cognitive screening offers the opportunity to rapidly identify and triage those in most need of cognitive support. However, there are currently no validated screening measures for young people with FEP. *CogScreen* is a hybrid effectiveness-implementation study which aims to evaluate the classification accuracy (relative to a neuropsychological assessment as a reference standard), test–retest reliability and acceptability of two cognitive screening tools in young people with FEP.

Methods: Participants will be 350 young people (aged 12–25) attending primary and specialist FEP treatment centres in three large metropolitan cities (Adelaide, Sydney, and Melbourne) in Australia. All participants will complete a cross-sectional assessment over two sessions including two cognitive screening tools (Screen for Cognitive Impairment in Psychiatry and Montreal Cognitive Assessment), a comprehensive neuropsychological assessment battery, psychiatric and neurodevelopmental assessments, and other supplementary clinical measures. To determine the test–retest reliability of the cognitive screening tools, a subset of 120 participants will repeat the screening measures two weeks later.

Results: The protocol, rationale, and hypotheses for *CogScreen* are presented.

Conclusions: *CogScreen* will provide empirical evidence for the validity and reliability of two cognitive screening tools when compared to a comprehensive neuropsychological assessment. The screening measures may later be incorporated into clinical practice to assist with rapid identification and treatment of cognitive deficits commonly experienced by young people with FEP.

KEYWORDS
adolescence, assessment, cognition, hybrid design, schizophrenia, STARD guidelines, youth mental health

1 | INTRODUCTION

The first episode of psychosis (FEP) disproportionately affects young people, with recent evidence suggesting that the onset of psychotic disorders peaks at 20.5 years of age (Solmi et al., 2022). FEP can significantly impact a person's everyday functioning, including the ability to obtain education or employment, form and maintain meaningful relationships, and live independently (Malla & Payne, 2005). Cognitive impairments, such as problems with processing speed, attention, and memory, are a core feature of FEP, affecting more than 75% of people with the illness (Stainton et al., 2023; Uren et al., 2017), and strongly predict poor long-term functioning (Cowman et al., 2021). Cognitive impairments often emerge before the onset of full-threshold positive symptoms, generally persist, or can become worse over time, and do not improve with antipsychotic medication (Catalan et al., 2021; Fett et al., 2020). Young people with mental health difficulties, including psychosis, have also reported that addressing cognition is a priority in their treatment (Bryce et al., 2023).

Early intervention guidelines for FEP identify comprehensive biopsychosocial assessments (which include assessing cognitive function) as an essential component of effective treatment (Early Psychosis Guidelines Writing Group and EPPIC National Support Program, 2016). However, cognitive assessments are not routinely conducted in youth mental health services and those that can offer them tend to have lengthy waitlists (Bryce & Allott, 2019). Of concern, an international Delphi study found that more than 90% of early psychosis experts regarded identification of cognitive deficits as a core competency for the early psychosis workforce (Osman et al., 2019). Clinicians working in youth mental health settings in Australia, however, have reported only moderate confidence in their ability to identify cognitive deficits (Allott et al., 2019). A valid cognitive screening tool would enable timely detection of cognitive impairments, encourage referrals for further assessment, and facilitate the treatment and management of cognitive issues even when comprehensive assessment is not possible (Bryce & Allott, 2019). Despite this, there is currently no validated screening tool for detecting impaired cognition in young people with FEP (Bryce et al., 2021).

In addition to the cognitive impairments which are commonly reported in FEP, clinicians have estimated that almost 30% of young people with early psychosis receiving treatment in primary care services in Australia present with a neurodevelopmental disorder, such as Autism Spectrum Disorder (ASD) or Attention-Deficit/Hyperactive Disorder (ADHD; Allott et al., 2019). However, these conditions may go undiagnosed in FEP services, where psychosis symptoms are the priority for treatment (Proffitt et al., 2018). Furthermore, characteristic impairments in cognitive functions seen in FEP, such as attention and executive functions, are also commonly observed in people with ASD and ADHD (Demetriou et al., 2018; Marije Boonstra et al., 2005). It is therefore important to understand how cognitive screening tools perform in young people with FEP when compared to a reference standard, and whether clinical or demographic factors, such as comorbid neurodevelopmental conditions, may influence their usefulness in this population and indicate when alternative cut-points are required.

Two screening tools which are commonly used with adults are the Screen for Cognitive Impairment in Psychiatry (SCIP; Purdon, 2005) and the Montreal Cognitive Assessment (MoCA; Nasreddine et al., 2005). The SCIP is the preferred screening tool in adults with psychiatric illness due to its focus on the most relevant cognitive domains and demonstrated utility and tolerability in adults with schizophrenia, bipolar disorder, depression, and ADHD (Knight & Baune, 2018; McIntyre et al., 2019). Furthermore, the SCIP has demonstrated good interrater and test–retest reliability, convergent validity, and sensitivity and specificity (Cuesta et al., 2011; Guilera et al., 2009; Rojo et al., 2010; Tourjman et al., 2019). In contrast, the MoCA is widely used in older adults with suspected cognitive impairment, a common precursor to dementia (Nasreddine et al., 2005). The MoCA has demonstrated acceptable validity in a sample of adults with schizophrenia (Yang et al., 2018) and good sensitivity and specificity in young people aged 15–29 years with congenital heart disease (Pike et al., 2017). A recent study comparing the reliability and validity of the SCIP and MoCA in a sample of adults with psychotic disorders (mean age ~ 43 years) found that the SCIP was more sensitive to detecting cognitive impairment than the MoCA (Murri et al., 2020). No previous study, to our knowledge, has examined the diagnostic accuracy (i.e., sensitivity and specificity) of any cognitive screening measure in young people with FEP (Bryce et al., 2021). As there is significant heterogeneity in the experience of cognitive impairment both between and within disorders affecting young people (Kavanaugh et al., 2020), and due to the unique trajectories of cognitive development in adolescence, it is important to examine whether the current screening tools used with adults are appropriate to use with this younger age group (Bryce et al., 2021).

The primary aim of the *CogScreen* study is to evaluate the diagnostic accuracy and test–retest reliability of two cognitive screening tools (the SCIP and MoCA) in young people with FEP, relative to a neuropsychological assessment reference standard. A secondary aim of *CogScreen* is to conduct a comprehensive implementation evaluation to explore the acceptability and feasibility of cognitive screening and identify the facilitators and barriers to implementing cognitive screening in FEP settings. The protocol of the implementation evaluation of this study will be reported elsewhere. It is hypothesised that both the SCIP and MoCA will accurately classify cognitive impairment in young people with FEP when compared to a neuropsychological assessment reference standard (i.e., strong criterion-related validity), and that both measures will show acceptable 2-week test–retest reliability. It also is hypothesised that the classification accuracy of the SCIP will be superior to the MoCA, given that the SCIP was specifically developed for individuals with psychiatric disorders.

2 | METHOD

2.1 | Ethics approval and trial registry

This study was approved by the Melbourne Health Human Research Ethics Committee (HREC/89942/MH-2022) and is registered on the Australian and New Zealand Clinical Trials Registry (ACTRN12623000236695).

2.2 | Study design

CogScreen will use classification accuracy methodology according to the 'Enhancing the QUAlity and Transparency Of health Research' standards for reporting diagnostic accuracy studies (STARD) guidelines (Cohen et al., 2016). The STARD criteria minimizes risk of biased findings, which can lead to inappropriate recommendations about cognitive screening, negatively affecting policy, clinical guidelines, and patient outcomes.

2.3 | Study setting

Participants will be recruited from Australian primary and specialist FEP early intervention treatment settings in Melbourne (Victoria), Sydney (New South Wales), and Adelaide (South Australia). An overview of the recruitment sites is provided in Table 1.

2.4 | Participants

Three hundred and fifty young people will be recruited into the study according to the following inclusion criteria: (1) aged 12–25 years (inclusive), (2) have a diagnosis of FEP, defined as having a diagnosable psychotic disorder which is currently being treated at an early intervention service, (3) able to provide informed consent, (4) are receiving mental health treatment at one of the recruitment sites, and (5) are clinically stable as determined by their treating team. To minimize potential practice effects, young people will be unable to participate if they have received a comprehensive cognitive assessment within the past 12 months. Young people can be reconsidered for the study if they remain eligible after the 12-month period has passed. Informed consent will be required from all participants, including from parents

TABLE 1 Overview of the recruitment sites.

Location	Recruitment site name
Melbourne, Victoria	Early Psychosis Prevention and Intervention Centre Alfred Headspace Early Psychosis Service
Adelaide, South Australia	Western Community Mental Health Eastern Community Mental Health Northern Community Mental Health North Eastern Community Mental Health headspace Early Psychosis (hEP) Service Adelaide
Sydney, New South Wales	Prevention Early Intervention & Recovery Service, Western Sydney Local Health District Bondi Early Psychosis Program, South-Eastern Sydney Local Health District headspace Early Psychosis (hEP) Service Parramatta headspace Early Psychosis (hEP) Service Mount Druitt

or legal guardians for people under 18 years of age. A subset of participants ($n = 120$) will be involved in the test–retest component of the study. Participants will be reimbursed for their time at a rate of $30 AUD per hour.

2.5 | Recruitment

Random recruitment will be employed to align with STARD guidelines for classification accuracy studies Clinical teams at the recruitment sites will generate a deidentified list of people being treated for FEP. The research team will then randomly select participants from this list using a random number generator. The research team will ask the clinical teams to consider whether the selected young person is eligible for the study and to seek permission from the young person for their contact details to be shared with the research team. If permission is granted, a member of the research team will speak to the young person, explain the study, review their eligibility, and invite them to consent. This is an iterative process which will be repeated with the clinical teams over the recruitment period. Alternative approaches (e.g., consecutive recruitment) may be considered, and documented accordingly, if random recruitment is not possible and would be a significant barrier to clinical site engagement and recruitment. A conservative consent rate of 30% into the study has been estimated based on previous research with FEP patients. The research team will carefully record participant flow into the study, including reasons for exclusion or declining participation.

2.6 | Measures

Participants will complete a standardized cross-sectional assessment comprising demographics (such as age, ethnicity, years of education, etc.), cognitive screening, a neuropsychological assessment battery, psychiatric and neurodevelopmental measures, and other supplementary clinical measures. The clinical measures will be used to characterize the clinical sample and to investigate the factors that influence cognitive screening performance in a real-world sample. An overview of the cognitive screening measures in comparison to the neuropsychological assessment is provided in Table 2 and the schedule of assessments for *CogScreen* is displayed in Figure 1. The assessments will be split over two days, ideally occurring within seven days of each other, to reduce participant burden. The assessments on each day will be completed by separate members of the research team to adhere to STARD guidelines (i.e., blinding of assessors so that the cognitive screening results are not known to the person conducting the neuropsychological assessment, and vice versa).

TABLE 2 The SCIP and MoCA compared to a gold-standard neuropsychological assessment.

SCIP	MoCA	Neuropsychological assessment
Comprised of five short tests measuring verbal learning and memory, working memory, verbal fluency, and psychomotor speed. A cut-off score of <70 (out of 100) is typically used to indicate cognitive impairment.	Comprised of 13 short tests measuring executive functions, visual–spatial skills, verbal memory, attention, working memory, language, and orientation. A cut-off score of <26 (out of 30) is typically used to indicate cognitive impairment.	Considered the gold-standard method for determining cognitive profile and diagnosing cognitive disorders across the lifespan.
The SCIP takes approximately 15 min to administer and can be administered by any health professional.	The MoCA takes approximately 10 min to administer and can be administered by any health professional.	These assessments take approximately 3–5 h to administer, and they can only be administered by neuropsychologists.
The SCIP is available in 16 languages and there are three equivalent versions.	The MoCA is available in 46 languages and there are three equivalent versions.	Neuropsychological assessments can be conducted in English, and an interpreter is needed for other languages.

The SCIP and MoCA will be completed using pen-and-paper and the order of administration of these measures will be counterbalanced. The tests included in the reference standard neuropsychological assessment battery were chosen to reflect the comprehensive cognitive assessment which would be completed by clinical neuropsychologists in their real-world clinical practice. The battery will be completed using Q-Interactive™ by Pearson (https://helloq.com.au), an iPad application that allows assessors to choose, administer and score clinical assessments in a secure way using two tablets connected by Bluetooth. The use of Q-Interactive is ideal as it aligns with contemporary clinical practice, is engaging and youth-friendly, and reduces administration and scoring errors.

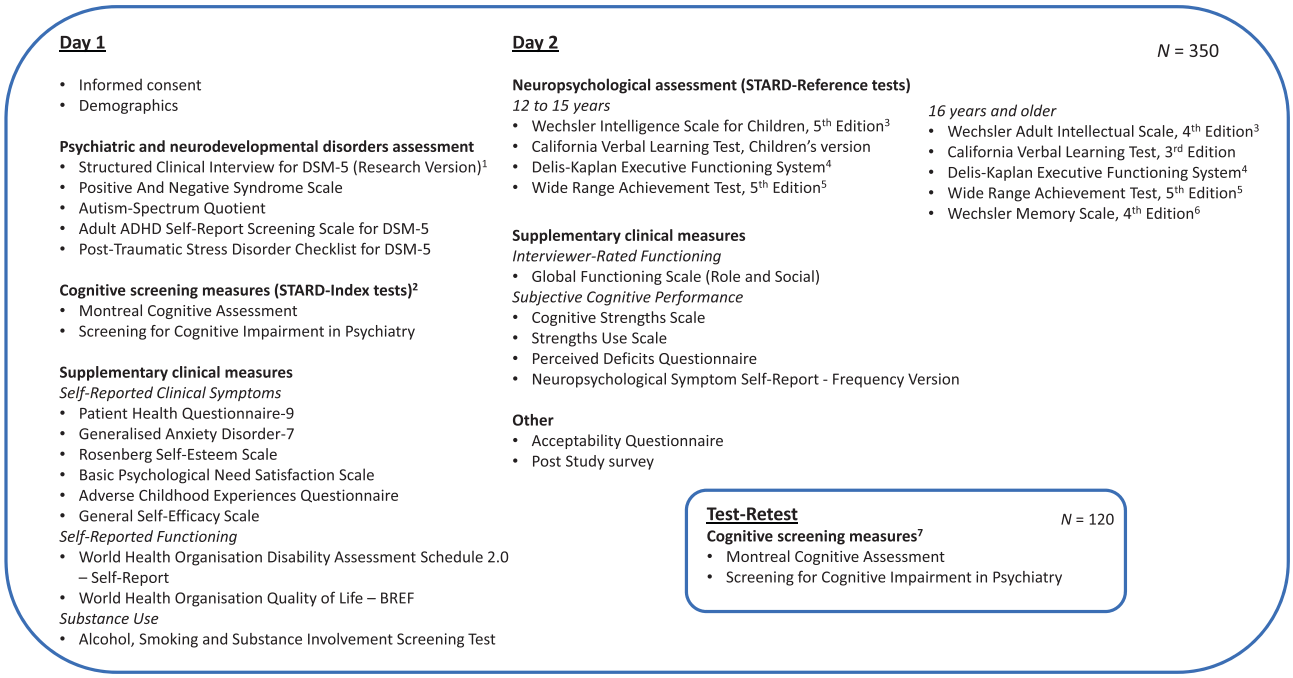

FIGURE 1 Schedule of assessments for *CogScreen*. Day 1 and 2 will be administered by different researchers in accordance with STARD guidelines. ADHD, attention deficit-hyperactivity disorder; DSM-V, diagnostic and statistical manual version 5; STARD, standards for reporting diagnostic accuracy studies. [1]Modules A to G. [2]Version 1 of each cognitive screening measure will be used, and order of administration will be counterbalanced. [3]Ten core subtests only. [4]Verbal Fluency subtest only. [5]Word Reading & Sentence Comprehension subtests only. [6]Logical Memory I & II subtests only. [7]Versions 1 and 2 of each cognitive screening measure will be used in a 1:1 ratio, and order of administration will be counterbalanced.

A subset of participants ($n = 120$) will complete the MoCA and SCIP again after two weeks to examine the test–retest reliability of these measures. All participants will be invited to participate in the test–retest component of the study until the required number of participants is obtained. For this retest visit, half of the participants ($n = 60$) will complete the original version of the screening measures, and the other half will complete the alternate version of the screening measures.

2.7 | Feedback

A standardized summary of neuropsychological assessment results will be made available to all participants. The results from the neuropsychological battery will be reviewed by clinical neuropsychologists on the research team and provided to the participant's clinician, who will share the results with the young person directly. This is to ensure that the information is shared appropriately and with support and so that the clinician can upload the information to the participant's medical record (if clinically appropriate). In cases where a concerning pattern of results are revealed on the assessment, such as possible intellectual developmental disorder or specific learning disorder affecting reading, there will be further consultation between the research and clinical teams in relation to the feedback of these results to the participant and options for further assessment and treatment.

2.8 | Youth advisory group

A youth advisory group (YAG), comprising seven young people with lived experience of psychosis from across Australia, including the cities where recruitment is occurring, was engaged before initiating the study. The YAG has provided consultation on study materials, procedures, and the feedback of neuropsychological assessment battery results to clinical teams. The study team will continue to consult the YAG for the duration of the study, and endeavour to communicate the outcomes of the study after its conclusion. The YAG ensures the study meets the needs of and protects the wellbeing of those with FEP and will also improve translation of findings. Some of the youth advisors are co-authors on this paper.

2.9 | Implementation evaluation

The comprehensive implementation evaluation will explore the acceptability and feasibility of cognitive screening and identify the facilitators and barriers to implementing cognitive screening in FEP settings. A subset of young people with FEP who completed the initial assessment will be invited to participate in an interview or focus group to share their experiences of cognitive screening. Separate interviews or focus groups will also be conducted with other stakeholders in FEP treatment settings, such as caregivers, clinicians, and service leaders as part of the implementation evaluation. The data

TABLE 3 Definitions of the classification accuracy indicators used in *CogScreen*.

Criteria	Description
Criterion validity	The screening measure performs well when compared to a comprehensive gold standard.
High sensitivity	The screening measure reliably identifies true cases of cognitive impairment (ideally >0.8).
High specificity	The screening measure reliably rules out false cases of cognitive impairment (ideally >0.8)
Likelihood ratios	Likelihood ratios are critically informative for interpreting screening findings for any individual patient of any age in clinical practice and minimizes overestimating test utility based on sensitivity and specificity alone.
Moderate-high positive likelihood ratio	The ratio of the proportion of participants with a positive test result and true cognitive impairment compared with the proportion of those with a positive test result and no cognitive impairment (ideally ≥5–10).
Low negative likelihood ratio	The ratio of the proportion of participants with a negative test result and true cognitive impairment compared with the proportion of those with a negative test result and no cognitive impairment (ideally <0.1).
Good retest reliability (i.e., Consistency)	The screening measure performs similarly across time, for example, on two separate occasions (ideally >0.8).

Note: Content adapted from Bowden (2017).

from this evaluation will inform the development of an implementation plan to support clinical practice change. The details of the implementation evaluation will be published elsewhere.

2.10 | Sample size calculation

The diagnostic accuracy study has been powered to achieve precision in the analyses, which considers the expected rate of clinically significant cognitive impairment (i.e., approximately 70–75%), sensitivity and specificity of ≥80%, and 95% confidence intervals (+/−5%). A sample of 350 is needed to achieve these parameters (Malhotra & Indrayan, 2010). For test–retest studies, stable, population representative estimates of correlation coefficients, which underly retest reliability estimates, require a sample of approximately 100 (Nunnally & Bernstein, 1994). A sample of 120 has been specified for the current study to allow for some data attrition.

2.11 | Statistical analysis

Several indicators of classification accuracy (criterion validity) will be calculated (e.g., sensitivity and specificity, and likelihood ratios [LR]) which are defined in Table 3. Clinical cognitive impairment will be defined as either: (1) ≥2 cognitive domain scores 1.5 SD below population mean on the reference test normative data, or (2) Full-Scale IQ <80 on the WISC-V/WAIS-IV (Wechsler, 2008). The study will first examine the performance of the typical cut-off scores of the SCIP (<70) and MoCA (<26; STARD Index measures) followed by exploration of the performance of other cut-scores using logistic regression and ROC analyses. LRs will be used to assist estimation of post-test probability across a relevant range of prevalence. Intra-class correlation coefficients for absolute agreement will be used for the retest reliability analysis (Bowden, 2017). To test the hypotheses that both cognitive screening tools will show accurate classification accuracy and retest reliability, a sensitivity and specificity of ≥80%, LR+ of ≥5, LR- of <0.1, and an intra-class correlation coefficient of 0.80 will be considered acceptable (Bowden, 2017). To test the hypothesis that the classification accuracy of the SCIP will be superior to the MoCA, their relative positive and negative LRs will be compared using the formula in Hayen et al. (2010). Alternative cut-offs for optimizing classification accuracy will be explored using logistic regression (Loring et al., 2009). All calculations will be overseen by the team statisticians.

3 | CONCLUSION

The results from the *CogScreen* classification accuracy study will provide empirical evidence for the validity and reliability of two cognitive screening tools (i.e., SCIP and MoCA) in a youth population when compared to a gold-standard neuropsychological assessment battery. The implementation evaluation component of this study will identify the facilitators and barriers to implementing cognitive screening in FEP settings. In combination, the results of the *CogScreen* study will address a critical unmet need in FEP treatment settings, inform clinical treatment guidelines in FEP, and provide a standard brief cognitive assessment that is easily translatable into real-world clinical practice.

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CONFLICT OF INTEREST STATEMENT

A/Professor Scott R. Clark received speaker/consultation fees from: Janssen-Cilag, Lundbeck, Otsuka and Servier and research funding from Janssen-Cilag, Lundbeck, Otsuka and Gilead. Professor Thompson has previously received speaker/consultation fees from: Otsuka, Eli Lilly, Sunovion and Servier and research funding from Janssen-Cilag and Pfizer. A/Professor Schubert has previously received speaker/consultation fees from: Janssen-Cilag, Lundbeck, Otsuka and research funding from Janssen-Cilag, Lundbeck, Otsuka and Gilead. Scot Purdon receives royalties from licensing the SCIP in Canada and Spain. Dr Harris has received consultancy fees from Janssen Australia, Lundbeck Australia and Seqirus. He has received payments for educational sessions run for Lundbeck Australia and Servier. He has developed educational material for Servier. He is the recipient of an investigator initiated grant from the Balnaves Foundation and Takeda Pharmaceutical Company. He is an investigator on an industry sponsored trial by Alto Neuroscience. He is the recipient of funding from the Australian Research Council, the Medical Research Futures Fund and the National Health and Medical Research Council. He has received philanthropic funding from The Balnaves Foundation. He is the chair of One Door Mental Health.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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