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Zbukvic, I;Fisher, E;Stainton, A;Bryce, S;Kartal, D;Kunin, M;Nicholas, J;Hamilton, C;Smith, D;Murphy, M;Llerena, J;Unsworth, L;Cheng, N;Bowden, SC;Chakma, S;Clark, SR;Francey, S;Gao, C;Gee, D;Gelok, E;Harris, A;Hatfield, L;Hopkins, L;Morell, R;O'Halloran, C;Purdon, S;Schubert, KO;Scully, A;Tang, H;Thomas, A;Thompson, A;Uren, J;Wood, SJ;Zhao, W;Allott, K

Title:
Exploring the Implementation of Cognitive Screening in First-Episode Psychosis Settings: The CogScreen Implementation Study

Date:
2025-02

Citation:
Zbukvic, I., Fisher, E., Stainton, A., Bryce, S., Kartal, D., Kunin, M., Nicholas, J., Hamilton, C., Smith, D., Murphy, M., Llerena, J., Unsworth, L., Cheng, N., Bowden, S. C., Chakma, S., Clark, S. R., Francey, S., Gao, C., Gee, D. ,... Allott, K. (2025). Exploring the Implementation of Cognitive Screening in First-Episode Psychosis Settings: The CogScreen Implementation Study. Early Intervention in Psychiatry, 19 (2), https://doi.org/10.1111/eip.70004.

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Early Intervention in Psychiatry

WILEY

ORIGINAL ARTICLE OPEN ACCESS

Exploring the Implementation of Cognitive Screening in First-Episode Psychosis Settings: The CogScreen Implementation Study

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Received: 12 July 2024 | **Revised:** 5 December 2024 | **Accepted:** 12 January 2025

Funding: This work was supported by the Medical Research Future Fund (MRFF) as part of the MRFF Clinician Researchers: Applied Research in Health scheme (MRFAR000034) and The University of Melbourne Early Career Researcher Grant Scheme.

Keywords: CFIR | hybrid design | implementation | MoCA | SCIP | TFA | youth mental health

ABSTRACT

Aim: Accurate and appropriate cognitive screening can significantly enhance early psychosis care, yet no screening tools have been validated for the early psychosis population and little is known about current screening practices, experiences, or factors that may influence implementation. CogScreen is a hybrid type 1 study aiming to validate two promising screening tools with young people with first episode psychosis (primary aim) and to understand the context for implementing cognitive screening in early psychosis settings (secondary aim). This protocol outlines the implementation study, which aims to explore the current practices, acceptability, feasibility and determinants of cognitive screening in early psychosis settings from the perspective of key stakeholders.

Methods: Young people with first episode psychosis ($n = 350$), caregivers (minimum $n = 10$) and service providers (minimum $n = 12$) will be recruited from primary and specialist early psychosis services in Melbourne, Adelaide and Sydney, Australia. Two

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implementation science frameworks will inform data collection and analysis: the Theoretical Framework of Acceptability and the Consolidated Framework for Implementation Research. A mixed-methods design will be employed to collect and analyse data from questionnaires with young people, interviews with all stakeholder groups, and administrative processes. Quantitative data will be analysed using descriptive statistics. Qualitative data will be analysed through content analysis using deductive and inductive coding.

Results and Discussion: This protocol paper presents the rationale and methods for the CogScreen implementation study.

Conclusion: Together with accuracy findings, results from the implementation study will provide insights about the practices, experiences, enablers and barriers to cognitive screening in early psychosis services.

1 | Introduction

Cognitive impairments—including difficulties with memory, language, planning and problem solving—affect more than 80% of young people with early psychosis (Stainton et al. 2023) and are one of the strongest predictors of poor long-term functioning (Cowman et al. 2021; Santesteban-Echarri et al. 2017). Cognitive impairments often emerge before full-threshold psychotic symptoms and can reduce the effectiveness of psychological therapies for people with psychosis (Malla and Payne 2005). The first step to supporting cognition as part of treatment is accurate identification of cognitive strengths and challenges. While cognitive screening is recommended as part of best-practice care for people with psychosis, it is not routinely completed and no formal screening tools have been validated for young people with first episode psychosis (Bryce and Allott 2019; Galletly et al. 2016; Norman et al. 2017). Once cognitive strengths and challenges are identified, practitioners may adapt their usual approach to care with evidence-based interventions (Roebuck-Spencer et al. 2017) and needs-based modifications to their engagement with young people. While young people with mental health challenges, including first episode psychosis, have identified cognition as a priority for care, clinicians have reported low confidence in their ability to identify cognitive impairment in young people (Allott et al. 2019). A comprehensive understanding of the barriers and enablers to implementing cognitive screening as part of routine practice in early psychosis settings is key to designing effective strategies to improve service quality and outcomes. Though research is growing on the implementation of cognition-focused interventions, little is known about the implementation of cognitive screening tools in youth mental health settings (Bryce, Zbukvic et al. 2021; Zbukvic et al. 2023).

The CogScreen study is a hybrid type 1 design focused on cognitive screening for young people with first episode psychosis. Hybrid type 1 is one of three types of effectiveness-implementation studies, which has a primary aim of determining the effectiveness of a clinical intervention and a secondary aim to understand context for implementation. The primary aim of the CogScreen study is to determine the effectiveness of cognitive screening for identifying cognitive impairment in young people experiencing first episode psychosis. The protocol for the effectiveness study has been published separately (Stainton et al. 2024) and outlines the methodology for evaluating the diagnostic accuracy and test–retest reliability of two cognitive screening tools in a sample of 350 young people with first episode psychosis, relative to a neuropsychological assessment reference standard. In brief, young people will complete both the screening tools and a gold standard comprehensive assessment for cognitive challenges (Wechsler 2008). Individual results on the screening tools will be compared to results from the gold standard assessment to determine how accurately each screening tool can identify cognitive challenges. The two screening tools being assessed are the Screen for Cognitive Impairment in Psychiatry (SCIP) (Purdon and Psych 2005) and the Montreal Cognitive Assessment (MoCA) (Nasreddine et al. 2005), both of which have been validated in adults and show promise as reliable tests for cognitive impairment among young people with first episode psychosis (Bryce, Bowden et al. 2021; McIntyre et al. 2019; Pike, Poulsen, and Woo 2017; Yang et al. 2018). Neither, however, have been validated with young people experiencing psychosis and there is no known research on what might influence their implementation in youth mental health settings. The present protocol outlines the methodology to address the secondary aim of the CogScreen study, to explore the context for implementation of cognitive screening in early psychosis settings. This study aims to explore the experiences, acceptability, feasibility and determinants of cognitive screening in early psychosis settings from the perspective of young people with first episode psychosis, their caregivers and service providers.

2 | Methodology

2.1 | Frameworks

The present study is primarily informed by the Consolidated Framework for Implementation Research (CFIR; (Damschroder et al. 2022a, 2022b)). The CFIR offers a comprehensive, practical framework for exploring the barriers and enablers of implementation across various settings. The CFIR comprises five key domains associated with effective implementation: characteristics of individuals, intervention/innovations, inner (organisational) settings, outer (e.g., policy, funding) settings and the process of implementation (Damschroder et al. 2022b). The CFIR provides a robust theoretical underpinning and framework for designing data collection and analysis. The CFIR was selected as it allows for the assessment organisational-level context related to potential barriers and facilitators to successful implementation and has been broadly used in mental health settings (Kirk et al. 2016).

The theoretical framework of acceptability (TFA; (Sekhon, Cartwright, and Francis 2017)) will be used to explore the acceptability of cognitive screening practices and tools. Acceptability is increasingly emphasised as a key consideration in the design, evaluation and implementation of healthcare interventions (Sekhon, Cartwright, and Francis 2018).

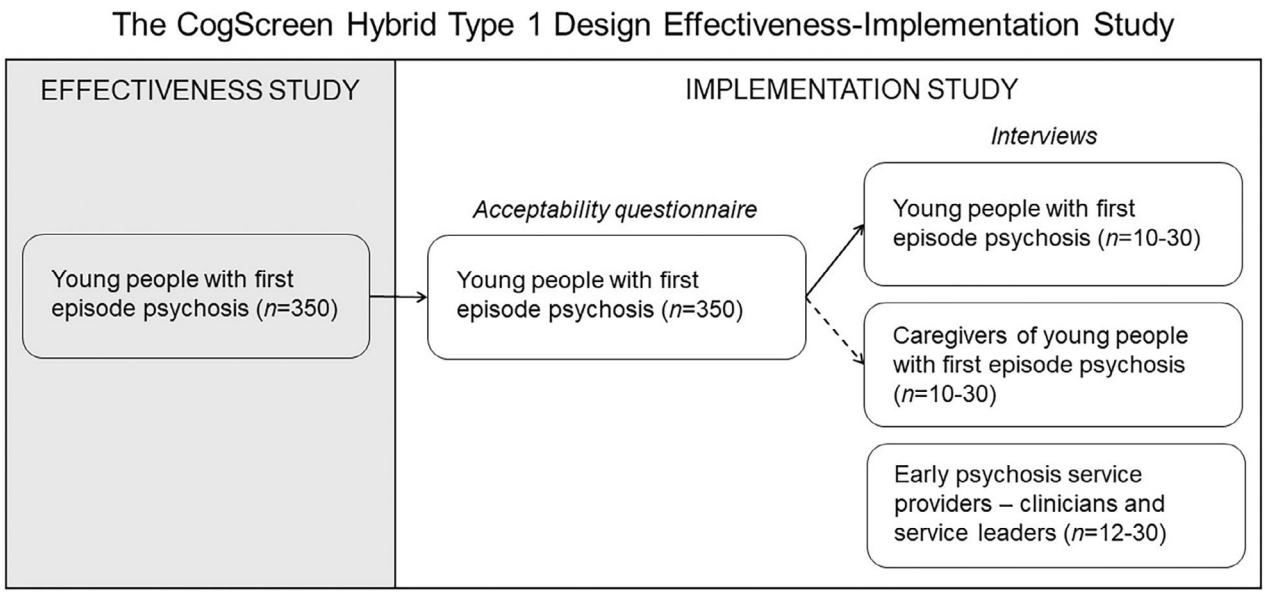

FIGURE 1 | Overview of participant groups in the CogScreen study. A subset of young people from the effectiveness study will be recruited to the implementation study (arrow). Caregivers of young people who take part in the effectiveness study will be recruited to the implementation study (broken line). Service providers including clinicians and leaders will be recruited from participating study sites.

TABLE 1 | Research questions and data sources.

	Data source/s			
Research question	**Young people**	**Caregivers**	**Providers**	**Process**
What are experiences of young people with first episode psychosis and caregivers in relation to cognitive difficulties in first episode psychosis, cognitive screening, and how cognitive difficulties have been addressed in early psychosis settings?	Interview	Interview		
What are the typical practices for cognitive screening and treatment in early psychosis settings?			Interview	
Is cognitive screening and the use of formal screening tools (SCIP/MoCA) acceptable from the perspective of young people with first episode psychosis, caregivers and providers?	Questionnaire interview	Interview	Interview	
Is cognitive screening and the use of formal screening tools (SCIP/MoCA) feasible from the perspective of providers?			Interview	
What are the anticipated barriers and enablers of cognitive screening using formal screening tools (SCIP/MoCA) in early psychosis settings?			Interview	Administrative data
What is involved in the process of cognitive screening using the SCIP/MoCA?				Administrative data
What are the recommendations for implementing and sustaining cognitive screening using the SCIP/MoCA in early psychosis services?	Interview	Interview	Interview	Administrative data

Acceptability can be measured prospectively and retrospectively, and is recognised in the CFIR as a potential predictor of implementation or adoption (Damschroder et al. 2022a). The TFA suggests that acceptability is a multi-faceted construct comprised of seven components: affective attitude, burden, ethicality, intervention coherence, opportunity costs, perceived effectiveness and self-efficacy. The TFA was selected as a comprehensive, evidence-informed framework for acceptability, which has been widely applied including in research with young people (Chen et al. 2022).

2.2 | Study Design

The present study comprises the implementation component of a hybrid type 1 study—the CogScreen study—being conducted over 3 years. An overview of the participant groups and flow for the CogScreen effectiveness (accuracy) study and the implementation study is provided in Figure 1.

A multilevel mixed methods design will be used for the implementation study, where data will be collected and analysed in parallel, with findings integrated to answer aspects of the same research questions (Schoonenboom and Johnson 2017). The CFIR and TFA frameworks have informed the design of qualitative and quantitative data collection tools and analysis plans. The implementation study design is cross-sectional, with relevant measures completed once by all participant groups. Process data will be collected continuously over the three-year study period as part of study management. Specific research questions and data sources for the implementation study are outlined in Table 1.

3 | Study Setting

Participants will be recruited through Australian specialist early psychosis treatment settings in Melbourne (Victoria), Sydney (New South Wales), and Adelaide (South Australia). All services offer specialist support for young people who are experiencing or at increased risk of experiencing psychosis, including counselling from mental health practitioners, for example, psychologists, services to family and other supporters, study and work support and medications. Some services are located within primary youth mental healthcare settings. All services are in urban areas in large capital cities (populations approximately 1.3–5.3 million).

3.1 | Participants

Participant groups include young people with first episode psychosis, their caregivers and early psychosis service providers (Figure 1).

3.1.1 | Young People With First Episode Psychosis

All young people who take part in the CogScreen primary accuracy study are eligible to take part in the implementation study. To enrol in the CogScreen study, young people must meet the following inclusion criteria:

- aged 12–25 years (inclusive);
- have a diagnosis of first episode psychosis;
- have the ability to provide informed consent;
- be receiving mental health treatment at one of the study sites;
- be clinically stable as determined by their treating team.

Young people are not eligible for the CogScreen study if they have received a comprehensive cognitive assessment within the past 12 months, however they may become eligible once 12 months have elapsed since this assessment. English fluency is not a requirement for participation. Interpreters will be made available for any young person who chooses to have English language support. There is no requirement related to length or stage of engagement with services to participate in the study.

Young people will be recruited to the primary CogScreen accuracy study based on random recruitment, in line with the STARD guidelines for classification accuracy studies (Cohen et al. 2016). If random recruitment is not possible at a recruitment site, consecutive recruitment will be considered as this will also result in a representative sample. All young people taking part in the study will provide written consent for themselves, with additional consent from a parent or legal guardian for those age 12–17 years.

All young people with first episode psychosis taking part in the primary effectiveness study ($n = 350$) will complete a brief acceptability questionnaire that contributes to the implementation study. This sample size was determined by a power analysis conducted for the primary effectiveness research question (Stainton et al. 2024). Young people who take part in the primary effectiveness study will be asked whether they are open to being contacted about participating in an interview. Purposive sampling will be used to engage a sample of young people with diverse experiences to take part in interviews, including young people accessing care across different participating sites, and who have different experiences of gender, culture, place of residence, education level and other individual and social factors that may influence their understanding of mental health and cognition, and engagement with mental health services. Separate consent will be obtained for interviews. Interviews will be conducted with minimum $n = 10$ young people, until data saturation is reached (i.e., when no new findings, concepts, or themes are evident in the data). This is based on established recommendations for reaching data saturation in theory-based studies, where interviews will be stopped after three consecutive interviews where no new findings emerge (Francis et al. 2010).

3.1.2 | Caregivers

Primary caregivers of young people with first episode psychosis taking part in the CogScreen study will be invited to take part in an interview, with permission from the young person engaged in early psychosis care. Primary caregivers may include parents, as well as guardians, partners, other family members, or carers

as defined by young people. All caregivers taking part in the study will provide written consent. Purposive sampling will be used to engage a sample of caregivers with diverse experiences, including those engaged with services across different participating sites, and who have different experiences of gender, culture, place of residence, education level and other individual and social factors that may influence caregiver role and engagement with mental health services. Interviews will be conducted with a minimum of $n = 10$ until data saturation is reached. Interviews will be stopped after three consecutive interviews where no new findings emerge (Francis et al. 2010). If preferred by participants, 3–6 focus groups will be conducted instead of interviews (Guest, Namey, and McKenna 2017; Hennink, Kaiser, and Weber 2019).

3.1.3 | Service Providers—Clinicians and Service Leaders

Clinicians/practitioners providing direct psychological support to young people attending participating early psychosis services, with a minimum Certificate IV training in mental health (or equivalent), will be invited to take part in an interview. These criteria were developed based on the qualifications of staff who are most likely to be responsible for administering cognitive screening tools in early psychosis settings. Leaders at early psychosis services participating in the CogScreen study who are responsible for managing the service (e.g., operation managers) will be invited to take part in an interview. All service providers taking part in the study will provide written consent. Interviews will be conducted with minimum $n = 12$ providers until data saturation is reached. This includes minimum $n = 6$ practitioners and $n = 6$ service leaders, at least one at each study site. Interviews will be stopped after three consecutive interviews where no new findings emerge (Francis et al. 2010).

3.2 | Data Collection and Analysis

3.2.1 | Demographics

Demographics of participating young people, caregivers and providers will be collected via survey or interview. For young people, demographic data will be collected via survey as part of the primary CogScreen effectiveness study and will also be used as part of the present implementation study.

3.2.2 | Acceptability Questionnaire

A short (eight item) questionnaire was developed to assess the acceptability of the SCIP and MoCA from the perspective of young people. The questionnaire is based on published questionnaire designed to address the seven components of the TFA (Sekhon, Cartwright, and Francis 2022). This questionnaire was modified in consultation with an advisory group comprising young people with lived experience of psychosis, as well as researchers and implementation practitioners with expertise in cognition, implementation science and early psychosis. All advisors had the opportunity to review the written questionnaire and then discuss items with the investigator responsible for overall design of the implementation study. The modified questionnaire developed for the present study comprises four-point Likert scales (e.g., "*doing the [SCIP/MoCA] fits with my values; 1 = strongly disagree, 2 = disagree, 3 = agree, 4 = strongly agree*.") and free text response questions for the young person to record any comments or feedback about their experience completing the cognitive screening tools. The questionnaire is completed immediately after *each* screening tool is completed by all young people participating in the CogScreen effectiveness study ($n = 350$). Following completion of the second screening tool, an additional forced response question asks for an indication of preference between the SCIP and the MoCA, and a final free response question invites any final feedback on both tools.

3.2.3 | Interviews

Interview guides based on the TFA and CFIR were developed for young people with first episode psychosis, caregivers, clinicians and service leaders. Interview guides were developed by the investigators with feedback from a panel of youth advisors with lived experience of psychosis.

For young people with first episode psychosis and caregivers, the interviews will discuss their experiences related to cognitive challenges and cognitive screening and treatment practices in early psychosis settings. Interviews will also explore the acceptability of cognitive screening and the SCIP/MoCA, as well as the anticipated barriers and enablers of and recommendations for cognitive screening in early psychosis settings. This includes questions about how they would like screening to be introduced and recommendations for how results are shared.

For providers, the interviews will focus on typical practices for cognitive screening and intervention, the feasibility and acceptability of cognitive screening and SCIP/MoCA tools, the anticipated barriers and enablers of, and recommendations for cognitive screening in early psychosis settings. Clinicians will have the opportunity to see the SCIP and MoCA as part of the interview procedure, to support reflections on the acceptability of the tools and anticipated barrier and enablers to implementation. Both clinicians and young people will be asked about when during treatment engagement should screening tools be completed.

3.2.4 | Process Data

3.2.4.1 | Site Characteristics. Site characteristic data will be gathered from each site during preparation for the study. This data will include information about the size of the service, local population characteristics, procedures and external policy context. An investigator will contact the site at least annually to ask about major changes to characteristics.

3.2.4.2 | Meeting Notes. Notes will be taken during all CogScreen team meetings, site meetings and site visits, to record relevant queries and strategies related to cognitive screening.

3.2.4.3 | Post-Screener Questionnaires. A brief, bespoke questionnaire was developed for research assistants to complete after administering the SCIP and the MoCA. This questionnaire records the duration and ease of administering and scoring each

screening tool, the time taken for the young person to complete the tool, any issues with fidelity of administration, as well as any adverse events or disruptions.

3.3 | Analysis

3.3.1 | Quantitative Data

Acceptability questionnaires will be analysed in line with published guidance from measure developers (Sekhon, Cartwright, and Francis 2022). Descriptive statistics will be used to characterise answers to each item (TFA construct) and generate an overall acceptability score for each questionnaire. A correlation matrix will be used to compare the relationships between overall scores and scores for each item on the scale for the SCIP and the MoCA. Overall acceptability and preference responses will be compared using t-tests.

Process data will be analysed using descriptive statistics, for example, time taken to complete SCIP/MoCA (mean, range), number of occurrences of adverse events or modifications during administration of cognitive tests.

3.3.2 | Qualitative Data

Free response text from acceptability questionnaires and data from interviews with young people and caregivers will be analysed using a form of directed content analysis using the TFA (Sekhon, Cartwright, and Francis 2017). Interviews with providers will be analysed using a form of directed content analysis using the CFIR (Damschroder et al. 2022b). Qualitative process data will be analysed through content analysis to understand the process of cognitive screening including any challenges to administration. To guide the analysis of qualitative data, codebooks will be developed including deductive constructs from frameworks as well as inductive codes relevant to the study research questions.

3.3.3 | Triangulation

Data from each participant group (young people, caregivers, providers) will be analysed separately. Quantitative and qualitative acceptability data from young people will be triangulated using an equal status concurrent design (i.e., QUANT + QUAL) (Schoonenboom and Johnson 2017), which allows for separate collection and analysis of quantitative and qualitative data, with integration during the interpretation phase (Schoonenboom and Johnson 2017). This approach provides a nuanced understanding of phenomena by comparing and corroborating findings from different methodological approaches (Schoonenboom and Johnson 2017).

4 | Discussion

The CogScreen hybrid type 1 study addresses a known gap between evidence and practice related to identifying cognitive challenges in young people with early psychosis (Stainton et al. 2024). Accurate, appropriate cognitive screening has the potential to significantly enhance early psychosis care, yet there are currently no tools available that have been validated with young people, creating a significant unmet clinical need. There is also very little known about current screening practices, experiences, or factors that may influence implementation in youth mental health settings including early psychosis settings. Combining data about the accuracy of two cognitive screening tools and implementation, the CogScreen study will address this gap and generate essential new knowledge to improve the quality of early psychosis care and support long-term functional and clinical outcomes.

The present study is the first-known implementation research to explore cognitive screening in early psychosis settings from the perspective of young people with first episode psychosis, their caregivers and service providers. While there is some research on the implementation of interventions targeting cognitive impairment in psychosis (Altman et al. 2024), most evidence relates to adult settings and may not apply to early psychosis settings that typically engage adolescents and young adults (Bryce, Zbukvic et al. 2021; Zbukvic et al. 2023). The present study will use a mixed methods design to collect data from young people, caregivers and providers, in addition to process data, to support a comprehensive understanding of cognitive screening practices and implementation considerations for early psychosis settings. Although the study is somewhat limited by a pragmatic design, whereby research assistants will administer the screening tools, the inclusion of clinicians in interviews will support the collection of important information about current practices and anticipated barriers and enablers to using the SCIP and MoCA as part of routine care.

With a strong methodological grounding in implementation science, the present study will contribute to understandings about the acceptability and determinants of cognitive screening and support the development of evidence-based strategies to support effective and sustainable implementation, for example, training, resources and tailored implementation action plans (Zbukvic et al. 2022; Zbukvic et al. 2022). The application of the TFA (Sekhon, Cartwright, and Francis 2018) and CFIR (Damschroder et al. 2022b) to guide data collection and analysis will support rigour and provide opportunities to engage in structured approaches to knowledge translation, dissemination, and implementation planning. This includes the future design of implementation strategies that aim to overcome barriers and leverage known enablers to embedding cognitive screening in early psychosis service settings. Together, findings will provide rich insights and contribute substantially to efforts to improve the provision of appropriate, timely, evidence-based care for people with early psychosis.

Acknowledgements

The investigator team would like to thank Professor Jill Francis for generously contributing her expertise towards the development of the acceptability questionnaire for this project. We also thank Associate Professor Magenta Simmons for providing independent support to our Youth Advisory Group. Open access publishing facilitated by The University of Melbourne, as part of the Wiley - The University of Melbourne agreement via the Council of Australian University Librarians.

Ethics Statement

The study was approved by the Melbourne Health Human Research Ethics Committee (HREC # 2022.275) and (HREC # 2022.086). The CogScreen project is registered on the Australian and New Zealand Clinical Trials Registry (ACTRN12623000236695).

Conflicts of Interest

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 collection tools including questionnaire and interview guides are available upon request from the corresponding author.

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