
CLINICAL RESEARCH NURSE – TMS PRACTICE NURSE

JANUARY 2021



Location:	Orygen (Parkville) and Royal Melbourne Hospital (city campus)
Division:	Clinical Service Innovation / Research & Translation
Classification:	Nurses Award 2010 Registered Nurse Level 4
Employment type:	0.6 FTE Part time 12 months fixed term contract
Position reports to:	• Principal Investigator of the SKY-D trial and Project Manager SKY-D • Principle Investigator of TDAY and Clinical Specialist TMS

1. POSITION SUMMARY

The position is a dual role working as a Clinical Research Nurse and Transcranial Magnetic Stimulation (TMS) Practice Nurse based in the Orygen TMS Clinic (0.4 FTE) and as a Clinical Research Nurse on the Study of Ketamine for Youth Depression (SKY-D; 0.2 FTE).

This is an exciting opportunity for a nurse to work within a multidisciplinary team within the new TMS clinical service at Orygen, as well as on two clinical trials investigating novel treatments (TMS and low-dose ketamine) for young people with depression at Orygen.

The successful applicant will assist in the delivery of the two treatments, as well as contribute to the running of the associated clinical trials and administrative tasks. They will also be responsible for protecting the health, safety, and welfare of clinical patients and research participants, and will be required to liaise with doctors at Orygen, headspace and the community to ensure that optimal clinical care is provided for all young people under their care.

The Clinical Research Nurse/TMS Practice Nurse, under the guidance and supervision of experienced clinicians, project managers, and trial Principal Investigators (PI), will ensure that the integrity and quality of treatment protocols and clinical trials are maintained and conducted in accordance with federal, state and local regulations, HREC/RGO approvals, and Melbourne Health and Orygen policies and procedures, as well as ICH Good Clinical Practice (GCP) requirements.

1.1 Clinical Research Nurse/TMS Practice Nurse (0.4 FTE)

The Clinical Research Nurse/TMS Practice nurse will join the new TMS Clinic at Orygen. This role involves delivering TMS to young people with depression who are receiving clinical services from Orygen and/or participating in a clinical trial investigating the efficacy of TMS in young people with depression.

This position is primarily responsible for the administration of TMS treatments, the collection of information from clinical trial participants according to protocols, and associated administrative tasks.

1.2 Clinical Research Nurse on the SKY-D trial (0.2FTE)

The Clinical Research Nurse will join an innovative randomised controlled trial, the Study of Ketamine for Youth Depression (SKY-D), which aims to determine whether low-dose ketamine is an effective treatment for young people aged 16-25 years with moderate-to-severe depression.

This position is primarily responsible for the accurate completion of treatment visit procedures, including the administration of medication, phlebotomy, and the collection of information from study participants according to protocols.

2. POSITION CONTEXT

Orygen is the world's leading research and knowledge translation organisation focusing on mental ill-health in young people. Working side-by-side with young people, our partners and one another, we're redefining what's possible in global research, policy, education and clinical care. Find out more on our [website](#).

The Orygen Strategic Plan identifies developing, delivering and rolling-out best service models as a Strategic Priority, namely 'developing, implementing and evaluating an exemplar seamless integrated clinical service model for young people in the north and west region of Melbourne.'

The TMS research and clinical program is funded under an Innovation Grant from the Department of Health and Human Services.

SKY-D is an NHMRC-funded, investigator-initiated multi-site clinical trial that is sponsored by Orygen. The Melbourne Health site (incorporating activities at both Orygen and the Royal Melbourne Hospital city campus) is aiming to recruit 70 young people up to the end of 2022.

The Clinical Research Nurse will be working alongside a multidisciplinary team to deliver this innovative clinical trial, and will report to the Principal Investigator. When working directly in the clinic, the Clinical Research Nurse will report to and work alongside a psychiatric registrar or psychiatrist. Subject to direction, this position requires working with a degree of autonomy, and will be supported by a senior staff member at all times.

The SKY-D treatment visits are conducted at the Royal Melbourne Hospital Clinical Trials Centre, and research assessments are usually conducted either at Orygen in Parkville or at the Royal Melbourne Hospital.

3. ABOUT ORYGEN

VISION	Young people to enjoy optimal mental health as they grow into adulthood.
MISSION	Reduce the impact of mental ill-health on young people, their families and society.
VALUES	Respect, accountability, teamwork, excellence & innovation.
COMMITMENTS	Orygen has made a strategic commitment to partner with First Nations people of Australia, young people and their families, LGBTIQ+ people & culturally and linguistically diverse people.

4. KEY RESPONSIBILITIES/OUTCOMES

The Clinical Research Nurse/TMS Practice Nurse will:

4.1 TMS Clinic / Clinical Trial

- Work under the direction of the Head of Mood and Anxiety Research to promote, deliver and evaluate a TMS service/clinical trial.
- Facilitate the provision of information relating to TMS & the TMS Clinical Trial to individuals, families/carers and other organisations seeking guidance and support.
- Assist in all aspects of the preparation of patients for enrolling in a course of TMS & the TMS Clinical Trial including managing the intake of potential TMS patients / trial participants through screening and initial assessment.
- Provide TMS treatment to young people under the supervision of the treating psychiatrist and/or trial principle investigator according to each patient's/trial participant's treatment plan.
- Assist in the development of TMS treatment plans.
- Schedule appointments for psychiatric assessments and reviews, other pretreatment assessment appointments and all treatment appointments in accordance with TMS treatment plan.
- Facilitate trial data collection using validated psychometric tools.
- To remain up to date in developments relating to TMS in particular any safety issues.

4.2 Study of Ketamine for Youth Depression (SKY-D clinical trial)

- Work under the direction of the Principle Investigator and in collaboration with the study team to deliver the SKY-D protocol.
- Administer investigational medications and perform patient assessments during clinic visits.
- Perform medical tests and clinical assessments, including, but not limited to, vital signs, phlebotomy, and assessment of adverse and psychotomimetic effects.
- Provide patient education and medical information to study participants to ensure understanding of proper medication dosage and administration.
- Work in accordance with the study procedures manual, protocol and the Royal Melbourne Hospital Clinical Trials Centre Compendium.
- Remain up to date in developments relating to ketamine treatment, in particular any safety issues.

4.3 Other Responsibilities

- Liaise with referring clinicians, prospective patients and their families or carers as necessary, providing information and education as necessary.
- Determine the presence of side effects, and notify the Principle Investigator or study registrar of findings/issues.
- Ensure compliance with the study protocol by providing thorough review and documentation at each treatment visit.
- Review, assess and document medical history to determine compliance with protocol-defined eligibility requirements.
- Document medical data in patient chart to capture protocol requirements.
- Establish and maintain accurate and timely electronic medical record.
- Complete data entry as required.
- Be responsible for ensuring policy, practice and procedures aligned with national standards and GCP are in place for all staff within the clinic.
- Ensure that high quality standards are achieved by implementing and maintaining audit tools and records, that relevant equipment is maintained, and that supplies are ordered and stored appropriately.
- Register patients as required and establish and maintain accurate and timely electronic medical records.
- Maintain own ongoing professional development.
- Remain up to date in developments relating to ketamine treatment, in particular any safety issues.

- Undertake emergency procedure training at intervals required by Orygen and to report safety issues.
- Work within the bounds of relevant legislation/regulations (e.g., privacy, OH&S) and relevant professional codes of conduct.
- Other Orygen-related activities and responsibilities as directed by the Principal Investigator (or a nominee).

5. SELECTION CRITERIA

The following criteria must be met for consideration for this position:

5.1 Essential

- Registered Nurse, Division 1 (unrestricted) and registered with AHPRA.
- Experience in a practice nursing role and/or work in a community health setting, or as a clinical research nurse.
- Qualifications in medication administration.
- Demonstrated experience in clinical interviewing and ability to determine and plan for a young person's support needs, employing a shared-decision making approach.
- Demonstrated ability to work effectively in a multi-disciplinary team including research and administrative staff, and referring doctors and care teams, including capacity to work collaboratively with young people, parents, and carers.
- Demonstrated ability to make sound decisions in relation to conducting assessments and determining a young people's suitability for ongoing treatment and/or participation in a clinical trial.
- Well developed written and verbal communication skills.
- Ability to liaise and work with internal and external stakeholders including GP's, allied health, and other Orygen staff.
- Ability to set priorities, monitor work flows and develop best practice work standards.
- Competence regarding information technology, software packages and willingness to be trained and implement data collection and clinical record software.

5.2 Desirable

- Experience in delivering TMS services.
- Experience working in a clinical trial environment in accordance to GCP principles.
- Qualifications and experience in phlebotomy.
- Experience working with adolescents and young adults.
- Additional Qualifications in Mental Health Nursing, adolescent health, public health, community health, sexual and reproductive health or forensic health would be highly regarded (Post Graduate or Masters).
- Experience in administering clinical rating scales for depression.
- Training in Management of Clinical Aggression (MOCA) and Applied Suicide Intervention Skills Training (ASIST).

6. PROFESSIONAL AND ORGANISATIONAL KNOWLEDGE

The Clinical Research Nurse/TMS Practice Nurse will be expected to have:

- Capacity to work with a high degree of autonomy, subject to direction from senior staff.
- A sound ability to make decisions in relation to conducting assessments and determining a young people's suitability for ongoing TMS treatment. This will require proven skills in decision-making, problem-solving and risk management.
- A strong working knowledge of the common mental health, substance use and social problems faced by young people, and evidence-based treatments for major adolescent health issues.
- Knowledge and understanding of relevant legislation, government policies and strategic directions in relation to mental health and alcohol and other substances particularly as it relates to young people.
- A breadth of understanding of the different types of organisations involved in mental health and drug and alcohol service delivery to young people.

- Have knowledge of and work within the framework of early intervention, de-stigmatisation, diversity, inclusion, and non-discrimination.
- An understanding of and commitment to ethics and confidentiality issues, particularly in relation to the health and allied-health professions.
- Proficient computer skills with a demonstrated ability in word processing, PowerPoint and database programs, as required.

7. SPECIAL REQUIREMENTS

- Unrestricted right to live and work in Australia
- A current National Police Check will be required.
- Any offer of employment is conditional upon receipt and maintenance of a satisfactory Working with Children Check.
- GCP training is essential and is provided by Orygen.
- TMS treatment training is essential and is provided by Orygen.