University of Nottingham
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Role profile

Job title	Clinical Trial Manager	Job family and level	Administrative, Professional and Managerial Level 4
School/ Department	School of Medicine/ Mental Health and Clinical Neurosciences	Location	University of Nottingham, Jubilee Campus

Purpose of role

You will work within the multi-disciplinary MindTech research team to manage research studies of digital technologies for mental health, including feasibility randomised controlled trials, cohort studies, process evaluations and other qualitative and quantitative research designs. A focus of the role will be managing the real-world evaluation of the ORBIT intervention as part of a new three-year NIHR i4i (Invention for Innovation) Product Development Award grant.

You will support study Principal Investigators with staffing (to include staff recruitment and induction), research governance and report writing. You will also manage research and administrative staff to ensure the smooth running of the studies. You will be responsible for overseeing and coordinating site monitoring visits, study set-up and close-down procedures, follow-up visits and research and regulatory approvals.

You will be involved with several studies and will be required to work as part of a team as well as independently managing trial documentation and centres and deliver the research goals. You will join an established team, led by Prof Chris Hollis, whose main areas of research interest are digital technology for mental health.

The School of Medicine recognises the importance of continuous professional development and therefore the importance of providing opportunities, structured support and encouragement to engage in professional development each year.

	Main responsibilities (Primary accountabilities and responsibilities expected to fulfil the role)	**% time per year**
1	**Project Management** • Assist with staff recruitment of personnel, training and support of the MindTech evaluation team • Set up, recruitment and close down of clinical studies • Initial protocol training of local and site staff with ongoing support • Monitoring the research progress to ensure compliance with and adherence to the project plan and to identify, evaluate and rectify problems • Reporting to the Principal Investigators and other staff as necessary regarding research and administrative issues relevant to participant recruitment	50%

	• Liaise with the research team including, Research Assistants, Research Nurses and Admin support to ensure all data is being collected and managed according to GCP guidelines. • Liaise with internal and external research and development teams, to ensure efficient set-up of study sites • Manage project progress and liaise with external collaborators, nationally and internationally (as appropriate). • Study finance and budget management. • Coordinate the preparation and publication of data, reports and information, ensuring that these meet legislative, contractual and ethical requirements • Create trial files, including trial master file and site files • Work with the study Principal Investigators to ensure that the trial is meeting its targets, is producing meaningful output and to predict and plan any changes that warrant requests to changes in protocol, funding or time • Ensure the inclusion of patient and public representatives at the appropriate levels and times	
2	**Trial and Research Governance:** • To write study protocols and contribute to other documents for submission for ethical and HRA/MHRA approval • To establish procedures to ensure adherence to trial protocols and administrative requirements • Liaise with the research team including the Research Assistants, Nurses and Admin support to ensure all data is being collected and managed according to GCP guidelines • Ensure timely recruitment of trial participants with secure randomisation processes and subsequent efficient and effective data management • Liaison with the Trials or Research Steering Committee and Data Monitoring and Ethics Committee with a particular view on compliance with Research Governance, Good Clinical Practice, Data Protection and Ethical Requirements • Maintain relationships and deal with queries from Governance bodies (Ethics, MHRA and the sponsor) in the set up and management of the research • Ensure compliance with GCP and MHRA guidelines • To act as a resource for trial participants and site investigators • To be responsible for remaining adequately informed of current clinical stroke trials, R&D activity and trial regulatory requirements • To be aware of specific stroke trial assessment training and complete as required • To identify personal and educational development needs associated with participation in current clinical trials and these are effectively communicated to the line manager	20%
3	**Support Study Principal Investigators:** • Day to day management of national research studies • Staff management, including recruitment of personnel, training and support	10%

	• Management of the MindTech trials team, particularly the administrative/follow-up teams • Regular reporting to senior management to ensure accountability • Absence and annual leave management to ensure adequate cover for the department • Maintain up to date information on research budget spend	
4	**Lead and manage the administrative/follow-up staff:** • Work to recruit and retain high quality research staff • Induction/training of new staff particularly follow-up staff • Provision of individual training and support • Conducting regular update meetings • Perform 6 monthly Appraisal Development Conversations (ADCs), highlighting issues and ensuring development of administrative staff	10%
5	**Trial promotion and management:** • Arrange and participate in research conferences • Promote, market and present current research • Arrange and participate in trial and research management meetings and teleconferences • Ensure resources are current and available	10%
6	**Other:** • Work flexibly to provide cover for members of the team during periods of absence • Any duties as required in accordance with the nature and grade of the post. • The School of Medicine recognises the importance of continuous professional development and therefore the importance of providing opportunities, structured support and encouragement to engage in professional development each year	N/A

Person specification

	Essential	**Desirable**
Skills	• IT skills, including Microsoft Word, Outlook and Office 365 • Excellent oral and written communication skills • Good presentation skills • Excellent interpersonal and organisation skills • Ability to work on own initiative and as part of a team • Financial awareness and budgetary experience	

	• Evidence of a high degree of personal initiative, responsibility and self-motivation, with a proactive approach to problem solving • Evidence of excellent organisational, planning and time management, including proven ability to manage a demanding workload involving multiple projects with accuracy and a high attention to detail despite competing priorities and challenging deadlines • Demonstrable experience of organising successful events and project delivery • Willingness to learn new skills and procedures • 'Can do' attitude • Excellent customer relations • High levels of resilience • Ability to deal with change • Flexible team player willing to do what it takes to get the job done; adaptable and enjoys a challenge	
Knowledge and experience	• Clinical research experience • Experience of staff supervision and management • Knowledge and experience of applying for NHS Ethical and Research & Development Approval. • Good Clinical Practice • Experience of writing research reports • Experience of trial set up, ongoing monitoring and closedown • Experience of working to tight deadlines • Management of budgets • Experience of establishing new and improving existing administrative systems and procedures and managing resources • Proven ability to communicate effectively with staff at all levels and to work collaboratively with academic and administrative colleagues	• Finance and budget management • Experience of mental health research • Substantial experience in a management role
Qualifications, certification and training (relevant to role)	• Degree (or equivalent) or substantial relevant work experience commensurate with the level of post	• Qualification in project management (e.g. PRINCE2) or substantial equivalent experience

		• Relevant postgraduate qualification, i.e., Masters or PhD in mental health or health research
Other	• Able and willing to travel nationally for trial promotion meetings, conferences and site monitoring • Willingness to adopt the vision and values of the School of Medicine	
Statutory, legal or special requirements	• Satisfactory Enhanced disclosure obtained from the Disclosure and Barring Service	

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Role profile

Expectations and behaviours

The University has developed a clear set of core expectations and behaviours that our people should be demonstrating in their work, and as ambassadors of the University's strategy, vision and values. The following are essential to the role:

Valuing people	Is always equitable and fair and works with integrity. Proactively looks for ways to develop the team and is comfortable providing clarity by explaining the rationale behind decisions.
Taking ownership	Is highly self-aware, looking for ways to improve, both taking on board and offering constructive feedback. Inspires others to take accountability for their own areas.
Forward thinking	Driven to question the status quo and explore new ideas, supporting the team to "lead the way" in terms of know-how and learning.
Professional pride	Sets the bar high with quality systems and control measures in place. Demands high standards of others identifying and addressing any gaps to enhance the overall performance.
Always inclusive	Ensures accessibility to the wider community, actively encouraging inclusion and seeking to involve others. Ensures others always consider the wider context when sharing information making full use of networks and connections.

Key relationships with others