NIHR/OLS Mental Health Mission

Capacity Development Workstream

Scoping report on barriers and enablers within the mental health research in the UK

Contents

Executive summary

This report details a scoping exercise conducted from September to December 2023 to inform the Capacity Development workstream of the NIHR/OLS Mental Health Mission (MHM) about barriers to and enablers of mental health research in the UK. Findings are expected to guide the Capacity Development Workstream strategic decisions within the remit of the MHM. The work involved review of relevant literature, policies, central NIHR portfolio national database, and consulting 30 stakeholders, including research delivery managers, academic training leads, business developers, NIHR portfolio analysts, and mental health principal investigators and clinical academics. Interviewed stakeholders represented MHM workstreams, four Mental Health NHS Trusts, two Universities, and Clinical Research Network (CRN) National Coordinating Centre and regional CRNs from Greater Manchester and North West Coast. A charity representative, Mental Health Translational Research Collaboration (MH-TRC) industry facing partner, and Mental Health Incubator were also consulted in preparation of this report. Scoping report V1.0, dated 14-02-2024, was shared with the MHM central team and MH-TRC leads across the country for their feedback. Received comments and suggestions were addressed in this report (V2.0, dated 09-07-2024).

The principal barriers identified included a lack of mental health researchers, limited research training and funding opportunities for researchers, competing demands between service delivery and research opportunities, lack of collaborations between mental health researchers and industry and low number of commercial clinical trials in the UK. There were also significant geographical inequalities in the volume of mental health research and general perception of research not seen as being an integral part of routine clinical care.

Despite the barriers, a number of opportunities were identified such as schemes to support future mental health researchers, including training, mentoring, shadowing and placement opportunities; support for Mental Health Trusts to build their research capacity and capability; promoting collaborations between stakeholders, including researchers and pharmaceutical companies/health technology businesses; schemes to integrate research into clinical training and practice, and use of innovative research designs to maximise research outcomes with minimal strain on healthcare services. Close collaboration with partner organisations, such as the NIHR Incubator for Mental Health Research and Royal College of Psychiatrists, can improve the dissemination of capacity building initiatives, and training and development opportunities.

Abbreviations

ARC	Applied Research Collaboration
CIMD	Clinical investigation of a medical device
CRF	Clinical Research Facility
CRN	Clinical Research Network
CTMIP	Investigational medicinal product
ICA	Integrated Clinical and Practitioner Academic
HCP	Healthcare professional responsible for care
MH-TRC	Mental Health Translational Research Collaboration
MHM	Mental Health Mission
MHMTC	Mental Health Mission Midlands Translational Centre
NIHR	National Institute for Health and Care Research
OLS	Office for Life Science
OOPR	Out of Programme for Research
PAs	Blocks of time, usually equivalent to four hours, in which contractual duties are performed
R&D	Research and development
SME	Small and medium-sized enterprises

Introduction

Currently, only around one in three people with a mental health needs access mental health services, and an estimated 1.2 million people are on the waiting list for community mental health services in the UK (1). According to GP survey data over 12% of adult population with long -term conditions across England report having mental health difficulties (2) with the highest reported prevalence in North East and North Cumbria, South Yorkshire, Cheshire and Merseyside (3). Even though the mental health workforce has grown by over 20% in the last five years, the demand for mental health services is much higher than service provision (1). Staff shortages remain a major obstacle to further improvement and expansion of mental health care. Also, limited translation of research driven innovations into routine clinical care adds towards the burden on the mental healthcare system. Whilst some other therapeutic areas benefit from significant research involvement and scientific breakthroughs (4, 5), people diagnosed with mental health conditions in the UK are often prescribed medications licenced decades ago with a wide range of side effects (6, 7). The number of clinical trials in mental health is significantly lower compared to some other therapeutics areas, such as cancer, haematology or neuromuscular disorders (8). The aim of this review is to explore the mental health research landscape, identify barriers and opportunities and propose potential solutions to facilitate mental health research in the UK.

Methods

This work has been conducted within the remit of the NIHR/OLS Mental Health Mission (9) Capacity Development workstream. The overall aim was to identify barriers to and opportunities for mental health research in the UK, which would subsequently inform strategic capacity development decisions.

The following strategies and resources were reviewed:
- The UK Mental Health Mission (MHM MASTER 081122)
- World Health Organisation database on mental health clinical trials 1999-2022
- Chief Nursing Officer for England's strategic plan for research 2021 (10)
- NIHR Open Data Platform database on mental health clinical trials 2008-2022 (11)
- Allied Health Professions' Research and Innovation Strategy for England 2022 (12)
- MH-TRC priorities
- Freedom of Information Request Reference FOI-1460408 2023
- Scoping exercise to identify critical areas for NMAHP academic clinical career development 2023 (13)

In addition, 30 stakeholders were consulted in preparation of this report. They were research delivery managers, academic training leads, business developers, NIHR portfolio analysts, and mental health investigators and researchers. Interviewed stakeholders represented:
- Mental Health NHS Trusts
  - Greater Manchester Mental Health NHS Foundation Trust
  - Pennine Care NHS Foundation Trust
  - Lancashire & South Cumbria NHS Foundation Trust
  - Sussex Partnership NHS Foundation Trust
- Universities
  - University of Manchester
  - Anglia Ruskin University
- Clinical Research Networks (CRN)
  - National Coordinating Centre

- - - o   Regional CRNs
- - - - ▪   Greater Manchester CRN
- - - - ▪   North West Coast CRN
- MH-TRC industry facing partner
- NIHR Incubator for Mental Health Research
- UK-wide network of MH-TRCs, whose feedback on Scoping Report V1.0, dated 14-02-2024, was addressed in this report (V2.0, dated 09-07-2024).

Results

Barriers

Lack of mental health researchers	The lack of mental health researchers was reported at every level - both at the senior investigator level but also lack of researchers for research service delivery.
	NIHR CRN Mental health research delivery managers reported lack of mental health principal investigators to lead on both academic and commercial research studies. Mental health researchers and NIHR CRN business development team reported that commercial Sponsors often require Principal Investigators to be NHS consultants with research experience. Due to a low number and limited capacity of such investigators, delivery of these studies is deemed unfeasible.
	There is a lack of research active senior clinicians to promote early proactive engagement with medical trainees. The Medical Schools Council and Mental Health Trusts report reduced number of clinical academic posts over the last decade with a large proportion of clinical academics currently approaching retirement (14).
	NIHR CRN business development team and Trusts report lack of raters, who administer a scale (i.e. an instrument used to measure severity of signs and symptoms of disease or document diagnosis for purposes of clinical research; outcome measure) to research participants, which has been identified as a bottle neck in some mental health studies. Whilst a dementia rater toolkit is available to support dementia research pipeline, there are currently no national plans to offer mental health rater training.
Limited research training and funding opportunities	The NIHR CRNs have gradually reduced the funding opportunities for research PAs for Principal Investigators within the NHS. Research active NHS organisations no longer receive NIHR research capability funding for NIHR Senior Investigators (15). The NIHR have not provided specific reasons for reduced Research PAs (Principal Investigators) funding but explained that funding allocations and policies were affected by changing government priorities, budget constraints, and changes in research strategy.
	Research active mental health professionals, including nurses, report difficulties securing funding, such as pre-doctoral clinical and practitioner

academic fellowship (16). In addition, following successful funding application, they face significant challenges getting released from their clinical duties and securing research protected time. One of the research nurses reported leaving their clinical post and getting a new job in a research active NHS Trust with an expectation that in the event of a successful NIHR Internship application they would get support to pursue with research training. Laboured and challenging progression up the clinical academic career pathway discourages many healthcare professionals from pursuing such career. More challenges and opportunities specific to nursing, midwifery and allied health profession (NMAHP) academic clinical career development can be found in Oxford Health NIHR Biomedical Research Centre Scoping exercise (13).

Even though medics have a well-defined Integrated Academic Training pathway (17), doctoral and post-doctoral opportunities for mental health clinicians are limited. It is also worth noting that medically qualified trainees who successfully apply for research fellow positions are required to get 'Out of Programme for Research (OOPR)' for the School of Psychiatry for the duration of research post. As time spent in research outside of and ACF or ACL does not count towards psychiatry training, it discourages many trainees from applying for such positions and makes research posts challenging to appoint. Successful appointees usually stay in a research post for no more than a year before coming back to their training, which negatively affects the sustainability of research fellow posts.

Low number of commercial clinical trials in the UK	The NIHR reports that only 6.3% of mental health studies on the CRN portfolio are commercial (11). The NIHR Industry team highlighted numerous challenges in setting up and opening mental health commercial studies, including (a) too restrictive eligibility criteria, (b) long list of exclusion criteria, which limits the number of eligible patients, (c) significant delays in site set up processes due to high workload of the clinical and R&D personnel, (d) delays in recruitment due to lengthy capacity and capability approvals, (e) limited staff resources leading to patients going into standard care pathways and not being recruited to studies, and (f) clinicians not keen to involve patients in clinical trials. Consulted mental health researchers in the NHS organisations reported a lack of capacity to deliver commercial studies, especially those of high intensity. They also highlighted that some of the commercial clinical trials are not well embedded into clinical practice and sometimes require installing separate research clinics. NIHR CRN research delivery managers reported that mental health Trusts with capacity and capability to deliver commercial clinical trials were not always being identified and selected as research sites at a study set-up stage in the UK. They sometimes need to actively seek to be included as a study site after becoming aware of already ongoing study.
Lack of collaborations between mental	The NIHR business development team reported that the expert guidance services available for industry planning commercial research in the UK

health researchers and industry	are underutilised. The NIHR early feedback service (18) and specialty leads are often not being consulted before setting clinical trials up in the UK. This lack of engagement diminishes study feasibility for a number of reasons, including: (a) study design might be poorly compatible with patient pathways in the UK; (b) restrictive requirements for study staff, such as Principal Investigators or raters, who administer scale for research participants; (c) patient eligibility requirements too restrictive, which affects recruitment and retention. Business engagement team at the University of Manchester report very limited engagement between mental health researchers and pharma and health technology businesses. The main barriers identified by the University Manchester Innovation team were slow contracting processes and complex intellectual property negotiations when facilitating collaborations between researchers and industry.
Slow contracting and governance processes	Contracting delays is a barrier not only for collaboration with industry but also has a major effect on multi-centre academic studies. Consulted clinical academics provided multiple examples of significant delays in setting up mental health research studies due to slow contracting and governance processes. It is at least partly due to the risk averse culture of University/NHS Trusts contracts offices, where risks of proceeding with research are being assessed, while risks associated with delaying research studies are being rarely taken into consideration.
Competing demands between service delivery and research opportunities	Even though the NIHR CRNs offer various local and national research support programmes (Appendix 1 and 2), CRN training leads report lack of engagement in training pathways from mental health NHS Foundation Trusts. Research delivery training programmes are rarely attended by mental health doctors, nurses, midwives, or allied healthcare professionals. Research leads within mental health NHS Foundation Trusts notice that one of the main reasons why mental health professionals do not engage with research training pathways is the shortage of clinical staff. With stretched mental health clinical services there is very limited capacity, managers are often not able to support their staff seeking research training opportunities. Additional strain onto clinicians might be due to the pandemic-driven decline of CRN integration within clinical teams. Some researchers report that prior to the pandemic, physical presence of CRN staff in clinics facilitated patient recruitment, especially in severe mental illness research. Pandemic triggered set-up of remote working introduced additional challenges, where patient recruitment is being managed by CRN staff in a remote setting less effectively, or recruitment responsibilities are taken on by already busy clinicians.
Geographical inequalities and cultural perceptions	Royal College of Psychiatrists estimate that only around 0.4% of mental health patients take part in clinical research in the UK. Research is not being seen as an integral part of clinical care by mental health patients

and healthcare professionals. NHS Trust R&D leads report that this is a particularly big issue in the UK regions outside the south of England and that areas of the upmost mental healthcare need are not being adequately represented in research. The NIHR reports that over 93% of mental health research takes place in England, with Northern Ireland, Wales and Scotland jointly representing only 6% of mental health research in the UK.

NHS Trusts R&D leads also report challenges due to perception of research amongst non-research active nurses and allied healthcare professionals. Research is not being seen as part of their professional role until senior level. Even though the NHS England has launched a strategic plan for research nursing (10), aiming to promote nurses' involvement in research and develop future nurse leaders of research, it is not entirely clear to what extent this national strategy is being implemented in practice. The NHS England-funded national survey for chief nurses investigates how organisations have responded to the national strategy and if they are building their own nursing research capacity. Nurse research and education team, who have been involved in the survey, report lack of engagement and challenges in getting response form mental health NHS Trusts and private organisations.

NIHR CRNs research delivery managers, clinical academics, and NHS Trusts research and innovation teams also report that some clinicians act as gatekeepers and are not always willing to include their patients in clinical research. If a patient is well, then their healthcare professional responsible for care (HCP) tend not to risk compromising patient's wellbeing by participating in a study. If a patient is unwell, then HCPs tend to doubt their ability to participate in a study and/or to provide a valid consent. Some HCPs also have strong opinions as to what treatments their patients should be receiving and, hence, are preventing them from getting randomised for clinical trials. Some clinicians also believe that commercial research aims to licence a drug without necessarily benefiting a patient group or NHS service.

Enablers

Support for mental health researchers

There are new opportunities to help develop Principal Investigators, such as NIHR Associate Principal Investigator Scheme, aimed at any healthcare professional to increase their involvement in research (19). Within the remit of Mental Health Mission, the Mental Health Mission Midlands Translational Centre (MHMTC) are also piloting local Principal Investigator Training events in 2024 and, if proved successful, similar events could be rolled out across the country.

Other training opportunities involve the NIHR Integrated Clinical and Practitioner Academic (ICA) Programme, which allow fully funded clinical research, research training and professional development, while maintaining clinical practice and salary. Worth noting that these awards are competitive and from total of 1566 applications, only 695 have been

successful for ICA personal awards (Freedom of Information Request Reference FOI-1460408). More research training, mentoring, and shadowing opportunities are encouraged.

Support trusts in building their research capacity and capability	New opportunities at organisational level include the NIHR Mental Health Research Group Awards, aiming to build research capacity in research inactive mental health organisations under guidance from research-established centres for mentoring and knowledge exchange (20). This has a scope for tackling geographical inequality and increase research activities in areas of high mental health burden in the UK. Mental health Trusts are working towards increasing their activity in both academic and commercial research, which is outlined in their research strategies (21, 22). NHS Trusts that are involved in delivering commercial clinical research are encouraged to establish income distribution model to incentivise research teams and grow research capacity (23). As part of this model, income generated from commercial research could fund additional research or research related activities, including secured research time for investigators. That might be particularly important in the current research landscape considering that the NIHR has significantly reduced research PAs funding. Trusts R&D leads highlight that funding of research PAs would free up clinicians' time for research delivery and new grant applications, which would contribute to sustainable research capacity development model.
Promote collaborations between stakeholders	The MHM has set up an Industry Working Group (IWG) who have established the UK MHM Industry Founding Members Programme with pharmaceutical companies to invite and facilitate commercial mental health research in the UK. The IWG also works closely with MHM workstreams and demonstrator sites to develop Industry Relevant Capabilities Compendium to help initiate new collaborations with both pharmaceutical and medical technology companies for interventional commercial clinical trials. The CRN Business development team highlights the scope for improvement in communication between industry and the NIHR structures. Better visibility and understanding of the NIHR infrastructure would help industry engage better in research support services, such as the NIHR early feedback service available to industry planning to perform commercial research in the UK (18). As part of this service, specialty leads provide early protocol review and protocol development feedback to enhance feasibility and aid study delivery in the UK. It is worth noting that the NIHR can also help industry to identify interested sites with capacity and capability, which include hospitals, community health centres and GP practices across the UK (24). Networking events involving mental health researchers and Small and medium-sized enterprises (SMEs) might be an efficient way to promote engagement and collaborations. The University of Manchester Research

Development and Innovation team suggests that successful collaboration case studies and newsletters signposting to industry collaboration opportunities have a potential to promote such initiatives.

Integrate research into clinical training and practice	NHS Trusts Research and Innovation leads suggest that having research included in healthcare professionals' job descriptions at a junior level would raise research awareness and help research to be seen as an integral part of healthcare roles. It would help to promote a shift in current perception that research is not part of their role at least until senior level. MHM Capacity Development workstream and Royal College of Psychiatrists are working together to pilot research delivery and training posts for junior doctors approved as part of their psychiatry training. That has a potential for sustainable capacity development boost as research delivery positions, such as research fellows, would no longer require medics to take time out of training to fulfil research posts. With research posts counting towards psychiatry training, they would become easier to recruit and maintain. Other initiatives include integrating research placements into medical core training, such as six months rotation on CRFs for medical trainees. That would rapidly increase research capability and help raise future research leaders. The Mental Health Research Incubator team suggests that research capacity could be built by getting various third sector (charity) organisations more involved in research. Special interest research groups, which bring together people with relevant lived experience, researchers and practitioners, could provide a valuable guidance in embedding community organisations in research.
Promote use of innovative research designs to maximise research outcomes with minimal strain on healthcare services	Mental health researchers and Trusts R&D Leads report that a more patient-centric approach and decentralised clinical trials with reduced number of hospital visits, might help with patient recruitment, retention, study feasibility and geographical diversity of research participants. At least one of the Trusts are currently bidding to host a mobile research unit through their clinical research network. Training and development of academic expertise in decentralised clinical trials methodologies are needed to support such initiatives. Mental Health Mission industry facing partners highlight that the use of digital healthcare technologies, smartphones and wearables, has the scope of significantly reducing the mental health burden without any additional strain on the healthcare system. These digital tools allow collection of longitudinal personalised data, enhance self-awareness of patients own health and well-being. The implementation of digital healthcare technologies use in mental health research would require support from active neutral engagements, i.e., regular patient interaction with individuals who have knowledge in smartphones and wearables, and strengths in active listening with some health-related

background. Such setting would not put additional strain on clinical research staff and is likely to be cost effective. There is also an unmet need for studies on cost-effectiveness of smartphones and wearables use in healthcare.

Collaborate with the National Dementia and Addiction Missions	MHM and the Dame Barbara Windsor Dementia and OLS Addiction Missions are facing some overlapping capacity building challenges. MHM Capacity Development workstream will work together with the other Missions to optimise the use of resources and increase impact of capacity and capability building initiatives. One initiative could be learning from the Dementia Rater training programme that has been successfully implemented, in consultation with industry, coordinating centres and CRNs, to support the dementia research pipeline. It has a potential to increase study feasibility and speed up study set-up as trained raters can be identified at a research site selection stage. Having trained raters in rural communities with less research active hospitals also can also help diversify participant population taking part in research. The Dementia rater training programme development leads report interest from mental health researchers and CRN training teams in setting up similar rater training programme for mental health research. Such initiative has not yet been established due to lack of resources.
Improve patients and public involvement, enhance research visibility and raise awareness	Clinical academics report that research clinics are very helpful in linking researchers with potential study participants. Such clinics use targeted social media to raise research awareness, and advertise studies and research registries amongst members of the public. Increased awareness allows identification of study participants outside secondary care and facilitate self-referral. Research clinics also present a great training and development opportunity for psychiatry trainees and other mental healthcare professionals allowing them to get involved in clinical research. Research clinics not only utilise their existing skills but also help them perceive research as an integral part their clinical roles. It can also help study participants see that not only their anonymised research data can help others, but they also can get useful clinical assessments done as a result of their involvement in research. Signposting and promoting research opportunities for patients and public, as well as raising awareness of training and development resources for healthcare professionals will be pivotal for efficient future research capacity growth. The MHM Capacity Development workstream closely collaborates with partner organisations, such as the NIHR Incubator for Mental Health Research and Royal College of Psychiatrists, for visibility and accessibility of capacity and capability building initiatives and training and development resources.

Conclusion

Mental health research capacity development relies on supporting future researchers and promoting collaboration with industry. Supported research training programmes and dedicated clinical academic roles has the potential to successfully bridge the gap between clinical care and research and provide additional opportunities for clinical staff to become engaged in a research active career (25).

Guided by scoping report findings and research capacity development needs by MHM demonstrator sites and other workstreams, MHM Capacity Development Workstream has already launched capacity and capability building initiatives, including Foundation Year 2 Mental Health Research Taster Days Awards (26), allowing junior doctors to get involved in mental health research in leading academic centres in the UK; and the Mental Health Mission Research Posts Awards 2024, allowing researchers apply for research posts funding to aid delivery of MHM objectives.

More training, development and networking initiatives are due to be launched in collaboration with MHM workstreams and demonstrator sites, as well as external partners. The MHM Capacity Development workstream strategic decisions are guided and progress is monitored by a dedicated Oversight Committee.

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Appendix 1.

National Research Development Programmes (Research Delivery Specific)

Programme Title	Provider/Status	Professional Group
Associate Principal Investigator Scheme	Fully operational across all speciality groups	Any healthcare professionals
Principal Investigator Pipeline Programme	NIHR Nursing and Midwifery Office	Research Nurses and Midwives
Clinician Researcher Credentials Framework	NIHR / Academy of Medical Royal Colleges	Experienced health and care practitioners from all professional backgrounds

Appendix 2**.**

NIHR CRN Greater Manchester and North West Coast Local Researcher Development Programmes

Programme Title	Provider/Status	Professional Group
Early Career Researcher Development Programme	NIHR CRN GM & NWC	Nurse, Midwife or Allied Health Professional
Research Scholars Programme	NIHR CRN GM & NWC	New Consultants or General Practitioners within the last 5 years of taking up their post Nurses (usually Band 7 or above) Allied Health Professionals (usually Band 7 or above)
Advanced Research Scholars Programme	NIHR CRN GM & NWC	Experienced Principal Investigators or co-investigators on NIHR grant award/s