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Challenges and solutions to participation in mental health clinical trials: Count Me In 2.0

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ABSTRACT

Mental health clinical trials in the UK face significant recruitment barriers, with mental health studies comprising just 3.3% of approved interventional medicinal product trials. Challenges include the limited numbers of trials and clinician gatekeeping—where clinicians decide whether or not to inform patients about research opportunities, limiting patient awareness and recruitment. The 'Count Me In' (CMI) approach, an opt-out recruitment model launched in Oxford in 2021 and then in Liverpool City Region in 2024, aimed to address these issues by directly contacting patients to discuss research opportunities, empower them in the shared decision process and embed participation in research into real-world clinical care. In this paper, we discuss the need for advancing beyond the original CMI model, including the requirement for enhanced data capture, mechanism for patient outreach that prioritises inclusive practices for improving participation and ensuring diverse, representative trial populations.

INTRODUCTION

There has been ongoing interest in revitalising the UK's clinical trial ecosystem driven by the Association of the British Pharmaceutical Industry,[1] the O'Shaughnessy review[2] and embedded in the National Health Service's (NHS) new 10-year strategic plan. Importantly, when patients are involved in clinical research, they experience better outcomes.[3]

In this perspective paper, we focus on mental health trials. We first summarise how this speciality fares in trial activity and argue there are challenges which require special attention to reverse the trend of worsening clinical trial activity in mental healthcare institutions; namely:

- Macro-factors: the paucity of clinical trials in mental health compared with other disease areas.
- Institutional factors: the inertia in NHS mental healthcare institutions.
- Factors arising from the 'patient by institution' interaction: the widespread culture where patients are unaware of research opportunity and institutions have a lower appetite or maturity for research.

We then outline a sociotechnical framework developed explicitly for increasing participation in mental health research—Count Me In (CMI)—that has been implemented in two NHS organisations in the UK (Oxford and Liverpool City Region) in 2021 and 2024, respectively. We conclude by surfacing specific challenges learnt during CMI's implementation and describing a new 'CMI 2.0' that advances on the original framework.

THERE ARE NOT MANY TRIALS (ANYWAY) …

The UK ranks seventh in the world for overall number of clinical trials.[4] A detailed analysis of interventional medicinal product (IMP) trials submitted to the UK Medicines and Healthcare products Regulatory Agency between 2019 and 2023 showed that mental illness accounted for only 3.3% of over 4000 approved trials.

This positions mental health clinical trials at ninth place, accounting for just under 30% of the total approvals,[5] with cancer studies ranked first.[5] These data inform us that, at least for IMPs, there are few opportunities for people with mental illness to participate in clinical trials.

RECRUITMENT IS CHALLENGING … AND WE ARE STARTING TO DISENTANGLE THE REASONS

Recruitment difficulties are a well-recognised barrier in mental health research. A recent Wellcome-commissioned report examining digital tools for improving participation in trials concluded that academic trials recruit less than industry-sponsored trials and between 35% and 69% of trials fail to meet a threshold of 95% of the target sample size.[6] The report identified 18 challenges that rehearse previously published work[7 8] and include:

- Lack of opportunity—with participation rarely being actively presented as part of routine care.
- Patients' prior negative experiences with the mental healthcare system and healthcare professionals.
- Clinicians are being too busy, unaware of trials hosted at their organisation or 'gatekeeping' often by making assumptions about patients' suitability or preferences.
- Trial design, including stringent eligibility criteria, is poorly adapted to the needs and characteristics of people with mental illness in the real world.

For the perspective of patients' willingness to participate in clinical trials, their primary concerns revolve around issues of invisibility and limited awareness. These factors continue to be the most significant obstacles that prevent patients from engaging in clinical trials.[7 9] To address these issues, the first step is to establish direct contact with

patients and provide them with the opportunity to discuss their participation in research and why such participation is necessary.

NAVIGATING AROUND BARRIERS …

The CMI system[10] was designed and piloted for 12 months in 2021 at Oxford Health NHS Foundation Trust (OHFT). Patients (aged 18+) learnt about CMI at their initial clinical appointment and, unless they opted out, they became contactable by approved OHFT researchers, to hear about research studies that may be of interest to them. This mechanism (which patients may explicitly opt out from) means that the initial opportunity to hear more about research is no longer dependent on many of the identified barriers above, as all patients are given the opportunity to make the decision for themselves about whether or not to hear more.

The CMI pilot illustrated the potential of the model to improve recruitment in mental health trials and to support NHS trusts to build larger and more diverse patient cohorts for research. The study identified themes that remain challenging.[10]

- Inclusive research practices, culture and relationships between clinical and research settings.
- Understanding patients' awareness and engagement with CMI and research activity more generally.
- How to improve the use of mental healthcare electronic health records (EHRs) to streamline identifying cohorts of eligible patients. In the Oxford pilot study, around 48% of patients where CMI would enable contact about research opportunity lacked primary diagnostic information, and 31% had no recorded ethnicity.

Count Me In 2.0

Aligning what we have learnt from the current implementation of CMI, we propose ways to approach outstanding issues to improve recruitment in clinical trials in mental health—organised around inclusivity and culture, data capture/reuse and fidelity and patient-facing knowledge mobilisation on research. As in the original CMI, we endorse a sociotechnical approach.

INCLUSIVITY, CULTURE AND RELATIONSHIPS

Under-representation in mental health trials is not well-researched. A review of published mental health trial results in the USA found that, at most, only half of the participants' ethnicities were reported, and fewer than one-third included data on socioeconomic status.[11] A study of 1683 trials found that race and ethnicity were rarely reported and minorities were under-represented in mental health drug trials,[12] reinforcing evidence that marginalised and disadvantaged people are less able to access or engage with research.[2]

The routine collection of data relevant to under-represented communities, a problem in secondary mental health care,[13] can be partially addressed through proactive and inclusive strategies such as CMI to address these disparities by embedding research offers into routine care pathways, ensuring that all patients are systematically considered for participation unless they opt out.

DATA CAPTURE AND REUSE FOR IDENTIFYING PARTICIPANTS

Our experience, in secondary specialist mental healthcare, when estimating feasibility and then identifying the *actual* patients to be approached via CMI suggested a clear need for higher fidelity data that is amenable to flexibly query to obtain high-quality cohorts. Of note, data quality was an issue in mental health participant recruitment from primary care[14] and, as described above, with high levels of absent primary diagnosis, many participants will be overlooked for even the most superficial and cursory automated searches for eligibility. The O'Shaughnessy review[2] similarly notes underuse of data assets in the UK to improve trial delivery. There is a clear need to develop more sophisticated technologies that are privacy-preserving and enable semi-automated parsing of EHRs[15] to help locate patients who meet eligibility—particularly as in the authors' experience, clinical trials increasingly make reference to phenotypic descriptions for eligibility such as depression with anhedonia, treatment refractoriness alongside detailed and specific exclusion criteria. Similarly, incorporating measurement-based care into routine clinical practice and services, such as baseline and regular follow-up patient-reported and clinician-reported outcome measures (PROMs and CROMs), would also facilitate identifying eligible participants and monitoring outcomes. For example, some trials require that patients meet a maximum or minimum threshold on some PROM/CROM, and currently, routinely collected data does not include relevant disorder-specific or phenotype-specific measurements because they are perhaps perceived as being of value only to research. Beyond increasing the fidelity of routinely collected data for research, measurement-based care improves patient outcomes.[16]

ENHANCING PATIENT AWARENESS AND RECRUITMENT IN MENTAL HEALTH RESEARCH

The findings from the Wellcome report are recapitulated in our experience implementing CMI in an additional, second UK mental health provider. We consulted over 300 stakeholders and our engagement workshops revealed overwhelming positive acceptance and support for the CMI system,[9] highlighting its potential to improve research inclusivity across diverse and underserved groups. Our findings also identified crucial concerns regarding communication preferences and accessibility, the desire for additional support and family involvement, ethical considerations around informed consent and data quality and specific hesitations from minoritised ethnic and vulnerable groups, all of which underpins the critical need for building trust and fostering coproduction in the CMI system's implementation.

Transparent and timely communication is therefore essential. A major barrier is the lack of awareness among both patients and healthcare professionals, identified by the Institute of Medicine as a primary factor in recruitment difficulties.[17] This is particularly evident in mental health contexts, where trial awareness is notably low.[18] Studies in NHS hospitals show that research information is rarely made available at the point of care, creating a significant gap between research opportunities and potential participants.[19] To address this, tailored outreach strategies are needed. Community engagement activities, such as hosting local events, distributing information at community centres and churches, and featuring on local radio programmes can help demystify research and foster public trust.[20] Educational efforts targeting patients and their families are also vital; improving knowledge of mental health conditions and research processes reduces stigma and enhances willingness to participate.[17] Involving family members in recruitment is particularly effective, as their support often influences decisions to consent.[20]

Building partnerships with patient organisations and support groups can further improve recruitment by facilitating the two-way exchange of trial-related information.[21 22] Institutional strategies such as creating online clinical trial portals and maintaining research registers linked to EHRs have proven successful in improving recruitment efficiency.[23 24] Additional recommendations include launching public awareness campaigns such as

the UK's 'I Am Research' initiative,[25] enabling both professional and self-referral pathways,[26] and embedding patient and public involvement in research, which is associated with improved recruitment outcomes and participant confidence.[27]

From our experience, early engagement with the research and development department drafting a standard operating procedure, clarifying governance requirements and providing evidence of patient benefits can help overcome initial hurdles. Collaborating with clinical staff, local charity or community organisations and city council to align research with service priorities. Our experience of implementing CMI[9] further demonstrates the value of a bottom-up approach to research engagement and highlights a core issue in mental health research: poor, incomplete data and under-representation, driven by limited outreach and systemic disengagement. Many service users and staff lack the language, confidence or belief that research is 'for them', highlighting the need for proactive, inclusive and sustained engagement strategies when rolling out CMI 2.0.

To improve recruitment and close these gaps, we recommend:

1. Community-led outreach to co-design messaging and build trust.
2. Culturally relevant education that addresses misconceptions and language barriers.
3. Opt-out recruitment systems that widen inclusion ethically. CMI is a sociotechnical framework for implementing an 'opt-out' system that removes gatekeeping, is compatible with clinical governance, reduces friction in engaging patients to participate in studies and can contribute to reducing inequities seen in health research.
4. Partnerships with local groups to normalise research participation.
5. Technology-assisted trial participant identification to enable local clinical information (eg, EHR) systems to be mined for suitable, eligible patients. We propose that this foundation can be supplemented with data mining technology such as natural language processing/understanding (NLP/U)—including using a patient-centred approach[28] to enable rapid and accurate identification of potentially eligible participants. However, different parts of a healthcare system will have different informatics capabilities (ie, some may not have facility for implementing NLP/U technologies) and different population disease burden that could lead to selection bias (eg, a well-funded metropolitan teaching hospital will have more research, more informatics capability to support that research but may also have very different disease prevalence than a more economically deprived, local general hospital). This may motivate implementing the technology for trial cohorting using a regional hub-and-spoke model where the NLP/U technology resides in a hub where it can be supported and ingests data from important 'spokes' to maintain equity and reduce selection bias.

In conclusion, there is an increasing support for the use of opt-out recruitment models. Traditional opt-in methods rely on clinical staff passing on information about relevant research to patients and often then patients initiating contact with researchers. This approach limits recruitment due to the number of barriers it presents for both patients and clinicians. In contrast, opt-out models, such as CMI, enable researchers to approach patients to share information about research options, unless they explicitly 'opt-out'. Evidence shows that this approach significantly improves recruitment and increases the inclusion of participants with mental health conditions, especially for people from minoritised ethnic communities who face significant challenges and disparities in seeking and engaging in mental health services.[29] It also reduces selective recruitment by minimising clinician gatekeeping. While concerns about autonomy remain, transparent opt-out systems with clear refusal mechanisms can ethically balance inclusivity and informed choice. The next step is to design and carry out a randomised trial to properly evaluate the CMI approach across multiple NHS Trusts in the UK.

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