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EQUALITY, DIVERSITY AND INCLUSION

Count Me In: an inclusive approach towards patient recruitment for clinical research studies in the NHS

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ABSTRACT

Background Participation in clinical research is associated with better patient outcomes and higher staff retention and satisfaction rates. Nevertheless, patient recruitment to mental health studies is challenging due to a reliance on clinician or patient referrals (standard approach). To empower patients and make healthcare research more equitable, we explored a novel researcher-led approach, called 'Count Me In' (CMI).

Objective To evaluate a 12-month implementation of CMI in a routine clinical setting.

Methods CMI was launched in August 2021 in a mental health National Health Service (NHS) Trust in England. Patients (aged 18+) learnt about CMI at their initial clinical appointment. Unless they opted out, they became contactable for research (via research informatics searches).

Findings After 12 months, 368 patients opted out and 22 741 became contactable through CMI, including 2716 through the standard approach and 20 025 through electronic searches (637% increase). Of those identified via electronic searches, 738 were contacted about specific studies and 270 consented to participate. Five themes were identified based on patient and staff experiences of CMI: 'level of awareness and accessibility of CMI', 'perceptions of research and perceived engagement with CMI', 'inclusive research practice', 'engagement and incentives for research participation', and 'relationships between clinical and research settings'.

Conclusions CMI (vs standard) led to a larger and diverse patient cohort and was favoured by patients and staff. Yet a shift in the NHS research culture is needed to ensure that this diversity translates to actual research participation.

Clinical implications Through collaboration with other NHS Trusts and services, key funders (National Institute for Health and Care Research) and new national initiatives (Office for Life Sciences Mental Health Mission), CMI has the potential to address recruitment challenges through rapid patient recruitment into time-sensitive country-wide studies.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Despite the substantial benefits of clinical research to patients and staff, most clinical studies struggle to recruit patients, leading to slowing in the clinical research and innovation pipeline.

WHAT THIS STUDY ADDS

⇒ Count Me In offers a novel researcher-led recruitment approach, whereby everyone in contact with participating mental health services can hear about research relevant to their care, unless they choose not to.

⇒ Count Me In substantially increased the total number and diversity of patients contactable for research and was described as more inclusive, empowering (through increased autonomy) and efficient by patients and staff.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Ongoing improvements and an extension of Count Me In to other services and Trusts are needed to ensure a shift in the clinical research culture so that future clinical research can be representative of all patients.

⇒ Count Me In has the potential to offer a viable approach to address the recruitment challenges of all studies, from small-scale local to time-sensitive country-wide studies.

BACKGROUND

Research activity in clinical services can produce measurable benefits for patients and hospital staff.[1] Examples include reduced mortality rates for emergency admissions, patients being better informed about their diagnosis and treatment options, increased confidence in treating clinicians, improved patient experience, enhanced team-working, and better staff retention and recruitment rates.[1–3] Nonetheless, nearly 80% of clinical trials fail to reach their enrolment targets within agreed timelines,[4] with 19% terminated given unsuccessful participant enrolment.[5] This can lead to blockages and delays in the clinical research and innovation pipeline, and challenges in translating research into clinical practice.

The benefits of clinical research participation are recognised in the UK, with the Care Quality Commission (an independent national organisation to regulate health and social care in England) specifying research and innovation as a key priority in ensuring the provision of high-quality care.[6] Despite

being a strategic priority, patient recruitment to clinical research in the UK National Health Service (NHS) remains challenging.[7]

In a pilot study in 2018, we established whether the recruitment of patients to clinical research could be improved in a mental health NHS Trust by incorporating a clinician-led recruitment approach into routine clinical practice.[8] Clinical staff were asked to inform patients about research in general and to document their research preferences in the patient's electronic health record, thereby allowing research teams to recruit interested patients for specific, relevant studies when these become available. To be successful, this approach requires routine research conversations between clinicians and patients and diligent documentation of patient preferences. However, of 1779 patients, only 197 (11%) had their general research preferences discussed and documented by their clinician and only 143 (8%) wanted to hear more about available research opportunities. The low involvement of clinicians suggests that a clinician-led recruitment approach might not sufficiently address research recruitment challenges.[8] Additional challenges relating to this approach include clinicians acting as 'gatekeepers' to patient recruitment, competing clinical priorities and limited resources, clinician referrals being dependent on their level of research interest and engagement, and clinicians' perceptions of the benefits of research to their patients.[9–11] Hence, a sole reliance on direct referrals from clinicians may pose a major barrier to clinical research recruitment.[9] Moreover, clinician-led recruitment leads to less equitable access to research by failing to access participant groups that are representative of the general population, including often marginalised groups (eg, minority ethnic groups, older adults, and people with physical and mental health disabilities).[10] Overall, clinical staff and patients favour the concept of a researcher-led approach where all patients can be directly contacted by researchers unless they chose not to be.[10]

This study evaluates a novel approach towards research recruitment, called 'Count Me In' (CMI). In August 2021, CMI was launched in one NHS Trust in South England, aiming to improve recruitment rates and promote equitable access to research opportunities within participating services. CMI supplements standard recruitment (clinician referrals and self-referrals) with researcher-led recruitment, offering everyone in contact with participating adult mental health services the opportunity to hear about research relevant to their care, unless they choose not to. This paper presents the findings of a 12-month implementation study.

Objectives

- To describe research participation in the participating NHS Trust since August 2015.
- To describe any changes in research participation since the launch of CMI by:
  - Describing the number and characteristics of patients contactable for research via CMI, compared with the standard approach (clinician referrals and self-referrals).
  - Describing the number and characteristics of research studies that recruited patients for research through CMI.
- To describe patient and staff experiences of CMI.

METHODS

Study design and participants

The CMI implementation strategy was developed in consultation with the Trust Caldicott Guardian oversight and the Head of Information Governance to ensure correct data handling. Patient representatives were involved throughout the design and implementation as part of a strategic group.

All patients treated in the Trust's adult and older adult mental health services received information about the CMI process (online supplemental file 1). No restrictions were placed on patients' demographics or diagnostic criteria. Patients were excluded from the CMI cohort if they (a) actively expressed a wish not to hear about research opportunities in the Trust; (b) had registered for national data opt-out,[12] a national service that allows patients to opt out of their confidential patient information being used for purposes beyond their individual care and clinical audit; and (c) had been discharged from relevant services more than 5 years ago.

This evaluation consists of three parts, namely a quantitative analysis of research participation, a qualitative analysis of focus group findings and a brief descriptive survey.

Part 1: quantitative analysis

Historical records of research participation (from August 2015 to July 2022) were taken from the electronic research system 'Siteline'.[13] Siteline is routinely used by research teams across the NHS for participant recruitment and study management. All other statistics that refer to the implementation period were taken from the CMI Research Participation Form, which was added to the patients' electronic health records in August 2021 to document all research-related correspondence.

Data were treated descriptively and summarised by month and over the full 12-month implementation period using counts and frequencies. For figure 1 only, linear regression analysis was used to predict participant recruitment across time (predictor: time in years; outcome: total recruitment). Differences in proportions between the CMI cohort and study participants were tested for statistical significance using Fisher's exact test (function: prop.test() in R). Data were visualised using line graphs and bar charts in R V.3.6.2.[14] As CMI was implemented in the Trust's mental health services, we excluded studies without an explicit focus on mental health (eg, non-mental health COVID-19 studies).

Part 2: focus groups

Two focus groups were conducted to obtain feedback on the experiences of patients and staff members with CMI. Patients were eligible to participate if they had been under the care of a service in which CMI was implemented. They were recruited via online advertisements, shared via email by the Trust's research and development (R&D), experience and involvement, and volunteer team leads. Staff were eligible if they worked in a service in which CMI was implemented. They were recruited through online advertisements shared via email with all R&D staff members and published on the Trust's intranet. Interested patients and staff members contacted the research team and were sent a participant information sheet along with demographic and informed consent forms to complete. All participants provided informed consent prior to the focus groups commencing.

Both focus groups lasted approximately 60 minutes and were facilitated by two team members (CH and JL) on Microsoft Teams, using a semistructured topic guide (online supplemental file 2). Focus groups were audio-recorded via an encrypted recording device and automatically transcribed through Microsoft Teams. One patient was unable to attend the focus group and provided written feedback to topic guide questions. Patient focus group participants received £20 for their time.

Focus group transcripts were de-identified and compared with the audio recordings to check for accuracy. The de-identified

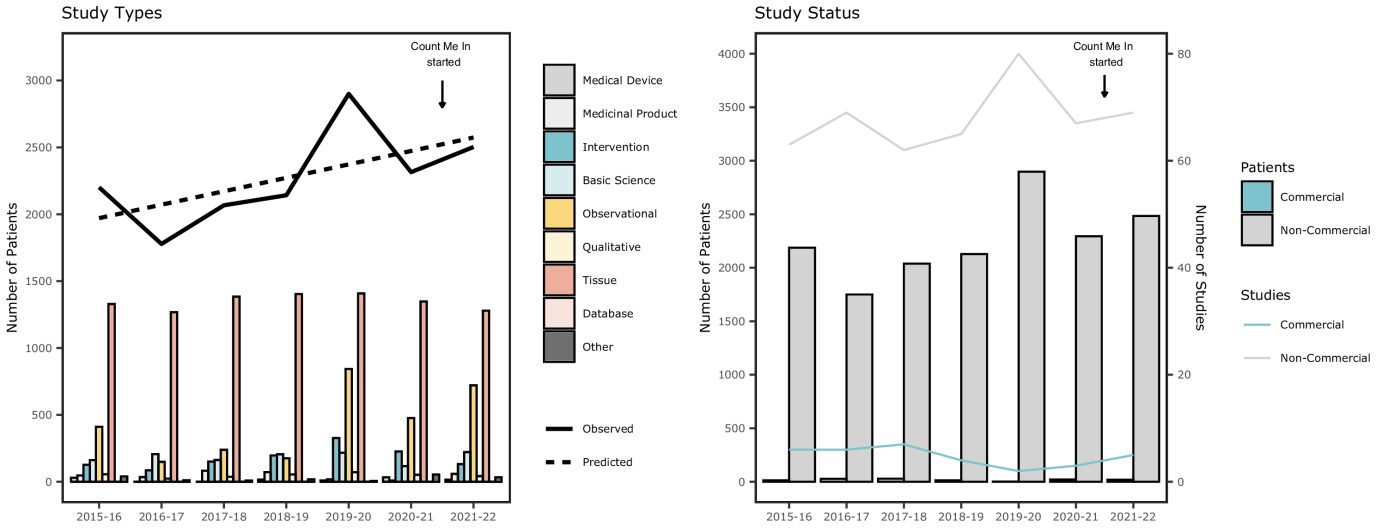

Figure 1 Patients recruited to clinical research studies over time by study type and status, based on Siteline historical data. The black line reveals the observed total across time, while the dashed line shows the predicted total across time. Study types: 'clinical investigation or other study of a medical device' (medical device), 'clinical trial of an investigational medicinal product' (medicinal product), 'other clinical trial to study a novel intervention or a randomised clinical trial to compare interventions in clinical practice' (intervention), 'basic science study involving procedures with human participants' (basic science), 'study administering questionnaires/interviews for quantitative analysis or using mixed quantitative/qualitative data' (observational), 'study involving qualitative methods only' (qualitative), 'study limited to working with human tissue samples (or other human biological samples) and data (specific project only)' (tissue), 'research database' (database), and 'other study' (other).

transcripts and email feedback were then coded using thematic analysis. A coding framework was established in Microsoft Excel, using the Framework approach, such that information relating to each category and code could be presented within and across focus groups.[15] Narrative summaries were collated and themes generated. Key quotes were selected to illustrate each theme. Two team members regularly discussed the data throughout the analysis process to ensure consistent interpretation of the themes generated.

Part 3: survey

Staff and patient surveys were created in Microsoft Forms to gather feedback on CMI. Both surveys were launched at the start of the implementation period, in August 2021, and remained open for 15 months. The surveys were distributed via a link posted on the Trust's website and shared in Trust newsletters and by researchers with interested patients and staff members. Consent was implied by completing the survey. Given a lack of responses received (staff: n=17; patient: n=4), findings are presented in online supplemental file 3.

FINDINGS

Figure 1 shows the enrolment of participants to clinical studies in the Trust's adult and older adult mental health services over a 7-year period. Overall, patient recruitment to clinical studies increased by 14% (from n=2201 in 2015–2016 to n=2503 in 2021–2022). The included studies were largely non-commercial (98.4%–99.9%) and studies focusing on 'human tissue samples and data' (49%–71%) or 'observational research' (eg, questionnaires or mixed quantitative and qualitative research; 8%–29%).

After a steady increase in patient recruitment between 2016 and 2020, patient recruitment declined in 2020–2021 during the COVID-19 pandemic. Since CMI was launched in August 2021, there was a small increase in the total number of recruiting studies (3% increase, from an average of n=72 in 2015–2021 to n=74 in 2021–2022) and patients recruited to these studies (12% increase, from an average of n=2234 in 2015–2021 to n=2503 in 2021–2022), compared with previous years. Yet the causal role of CMI in driving these increases beyond other secular trends remains unclear. Despite these small increases, patient recruitment to studies fell behind the predictions based on previous years.

During the same period, the number of patients contactable for research through CMI increased substantially (figure 2). Of 25 141 patients in the participating Trust's case load, 2032 (8%) opted out nationally and 368 (1%) opted out of CMI. Thus, 22 741 (91%) patients became contactable for research through CMI; 2716 (12%) were contactable through the standard approach (clinician referrals and self-referrals) and 20 025 (88%) through the research informatics searches. This was an increase of 637% compared with the standard approach (table 1). This increase in the total number of contactable patients translated to all patient characteristics, particularly patients aged 18–64 years, of 'Asian' or 'other' ethnic origin, female patients, and patients with a primary diagnosis of substance use, behavioural or personality disorders.

Of the 22 741 patients in the CMI cohort, 1298 (6%) were directly contacted about research in general and 738 (3%) were contacted about a specific study. Of these, 270 (37%) patients consented to participate in at least one study (figure 3). Compared with the overall CMI cohort, the study participants were more frequently aged 18–64 years (76% vs 69%; difference=7% (95% CI 2%, 13%), p=0.011) and 'white British or white other' (77% vs 56%; difference=21% (95% CI 16%, 27%), p<0.001), with a similar gender distribution (56% female and 43% male vs 60% female and 40% male; female: difference=−4% (95% CI −10%, 2%), p=0.288; male: difference=3% (95% CI −3%, 9%), p=0.332). The most common primary diagnoses of the study participants (vs CMI cohort) were mood disorders (27% vs 10%; difference=17% (95% CI 11%, 22%), p<0.001), psychotic disorders (26% vs 8%; difference=18% (95% CI 12%, 23%), p<0.001) and mental disorders due to known physiological conditions (17% vs 16%; difference=1% (95% CI −3%, 6%), p=0.565; online supplemental file 4).

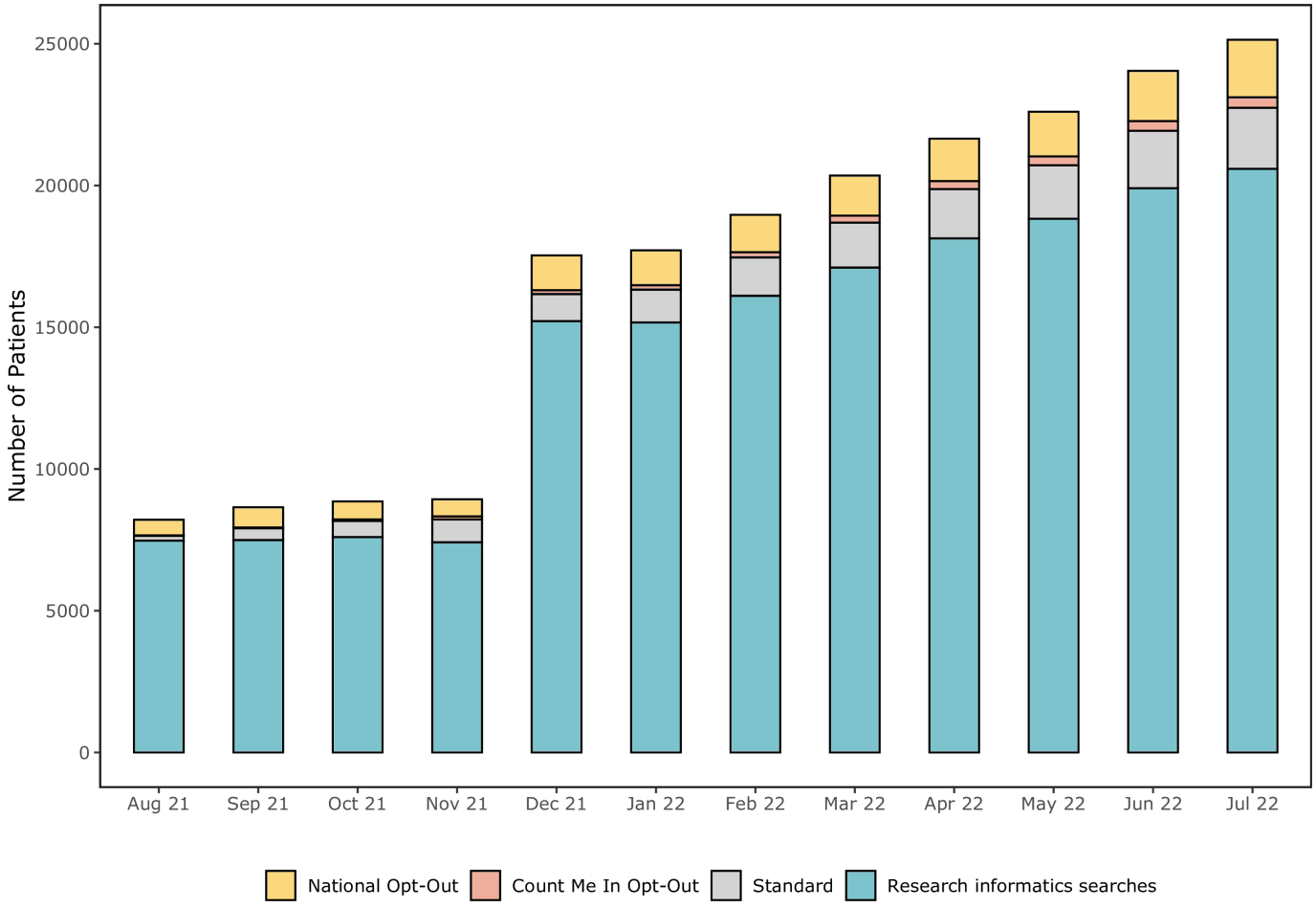

Figure 2 Accumulative number of patients in the Count Me In cohort over time. The sum of all parts reveals the accumulative number of patients in the participating Trust's case load by month. The sum of the bottom two parts reveals the total Count Me In cohort of patients contactable for research via the standard recruitment approach or through the research informatics searches.

Of all the participants recruited to studies within the implementation period, approximately 11%–14% (electronic health record form: n=270; Siteline: n=347) were recruited via research informatics searches and 86% (n=2156) were recruited via the standard approach (online supplemental file 5). Research informatics searches (vs standard) increased the recruitment of patients to commercial studies, focusing on medical devices or medicinal products, and non-commercial intervention studies (online supplemental file 6).

Experiences of CMI

Eleven participants contributed to the patient (n=4) and staff (n=7) focus groups (see online supplemental file 7). One additional patient provided written feedback on topic guide questions. Five themes were identified from the focus group discussions (for quotes, see online supplemental file 8).

Theme 1: 'level of awareness and accessibility of Count Me In'

There was a lack of awareness of CMI among patients and non-R&D staff members. Most patients perceived the Trust as research-active but did not know what research was taking place or that they were part of the CMI cohort. They could not recall receiving the CMI information letter. Staff and patient participants perceived the information around CMI as unclear and difficult to navigate. They requested more details about what 'opting out' meant and how to reverse an initial opt-out decision. Although CMI was perceived as a positive way to brand the opt-out initiative, participants stated that it could be more accessible and more widely promoted. Getting the right message across at the start and maintaining a personal approach were felt to be fundamental to any successful expansion of the initiative.

> Most of them have either missed it or can't remember receiving it, so half of the time they're not aware that they've been opted in. (Research staff member, R&D team)

Theme 2: 'perceptions of research and perceived engagement with Count Me In'

Patients and staff participants viewed research as important to improving care, if they were involved in setting research priorities and the findings were used to inform patient care. Some concerns were raised regarding societal reservations around clinical research, emphasising the need to clearly explain research opportunities to patients and to manage expectations if opportunities were not immediately available. Some R&D staff noted more patient engagement in research since CMI's launch, while others noted more patient uncertainty about why they had been contacted. Engagement with CMI appeared to vary across staff groups and clinical areas. Concerns were raised that clinicians may not feel the need to have research conversations with patients, viewing this task as being under the CMI remit. Some

Table 1 Patient characteristics by sampling approach

Patient characteristics	Sampling: patients contactable for research			
	Consent approaches			
	Standard consent (n=2716)	RI search (n=20 025)	% increase	Total CMI cohort (n=22 741)
Age, n (%)				
<18	151 (6)	0 (0)	0	151 (1)
18–64	1583 (58)	14 086 (70)	**790**	15 669 (69)
≥65	982 (36)	5939 (30)	505	6921 (30)
Gender, n (%)				
Female	1468 (54)	12 103 (60)	**724**	13 571 (60)
Male	1244 (46)	7905 (39)	535	9149 (40)
Indeterminate	4 (<1)	14 (<1)	250	18 (<1)
Unknown	0 (0)	2 (<1)	200	2 (<1)
Ethnicity, n (%)				
White	1963 (72)	10 784 (54)	449	12 747 (56)
Asian	71 (3)	554 (3)	**680**	625 (3)
Black	37 (1)	262 (1)	608	299 (1)
Mixed	81 (3)	351 (2)	333	432 (2)
Other	20 (1)	230 (1)	**1050**	250 (1)
Unknown	133 (5)	1275 (6)	**859**	1408 (6)
Null	411 (15)	6569 (33)	**1498**	6980 (31)
Primary diagnosis, n (%)				
Physiological	781 (29)	2842 (14)	264	3623 (16)
Substances	12 (<1)	198 (1)	**1550**	210 (1)
Psychotic	375 (14)	1548 (8)	313	1923 (8)
Mood	389 (14)	1931 (10)	396	2320 (10)
Stress	159 (6)	1099 (5)	591	1258 (6)
Behavioural	41 (2)	644 (3)	**1471**	685 (3)
Personality	61 (2)	711 (4)	**1066**	772 (3)
Intellectual	5 (<1)	20 (<1)	300	25 (<1)
Developmental	98 (4)	367 (2)	274	465 (2)
Childhood onset	82 (3)	276 (1)	237	358 (2)
Unspecified	5 (<1)	50 (<1)	900	55 (<1)
No diagnosis input	688 (25)	10 133 (51)	**1373**	10 821 (48)
Non-mental health diagnosis	20 (1)	200 (1)	900	220 (1)
Total cohort, n	2716	20 025	637	22 741

The CMI cohort includes patients identifiable both via the standard recruitment approach and the RI searches. The highest increases across categories are highlighted in bold. Gender: indeterminate: unable to be classified as either male or female; unknown: stated gender code was not recorded. Ethnicity: unknown: clinicians did not ask for the patient's ethnicity; null: left blank by the clinician.
CMI, Count Me In; RI, research informatics.

participants felt that extending CMI to other services could result in a heavier reliance on research departments.

> Clinicians could have backed off because they think their job is being done elsewhere centrally. (Clinical staff member, memory services)

Theme 3: 'inclusive research practice'

Staff and patient participants viewed CMI (vs standard) as a more inclusive recruitment approach, as more patients, across diverse demographic characteristics, become contactable for research. Screening lists on a larger cohort of contactable patients and less reliance on clinical referrals were felt to help with meeting recruitment targets, although direct referrals were still valued. Some concerns were raised among staff participants that recruitment was largely influenced by study characteristics (eg, sample size requirements and inclusion criteria). One patient participant felt that CMI enabled more patient autonomy over the research contact process, which could empower under-represented groups, including minority groups.

> It opens research up to people who might not have considered it otherwise. (Patient participant, 25–34 years of age, participating Trust service user)

Theme 4: 'engagement and incentives for research participation'

Participants noted 'fear of the unknown' and 'changing personal circumstances' as potential reasons for patients to decline research opportunities. Patients had varied preferences about research contact methods, but valued research conversations and autonomy to seek information about opportunities. Staff felt that CMI allowed for more open research conversations with patients, providing an opportunity to capture individual preferences and build better engagement. All participants stated a need for ongoing engagement with patients. This includes opportunities to be reapproached about CMI and updates on

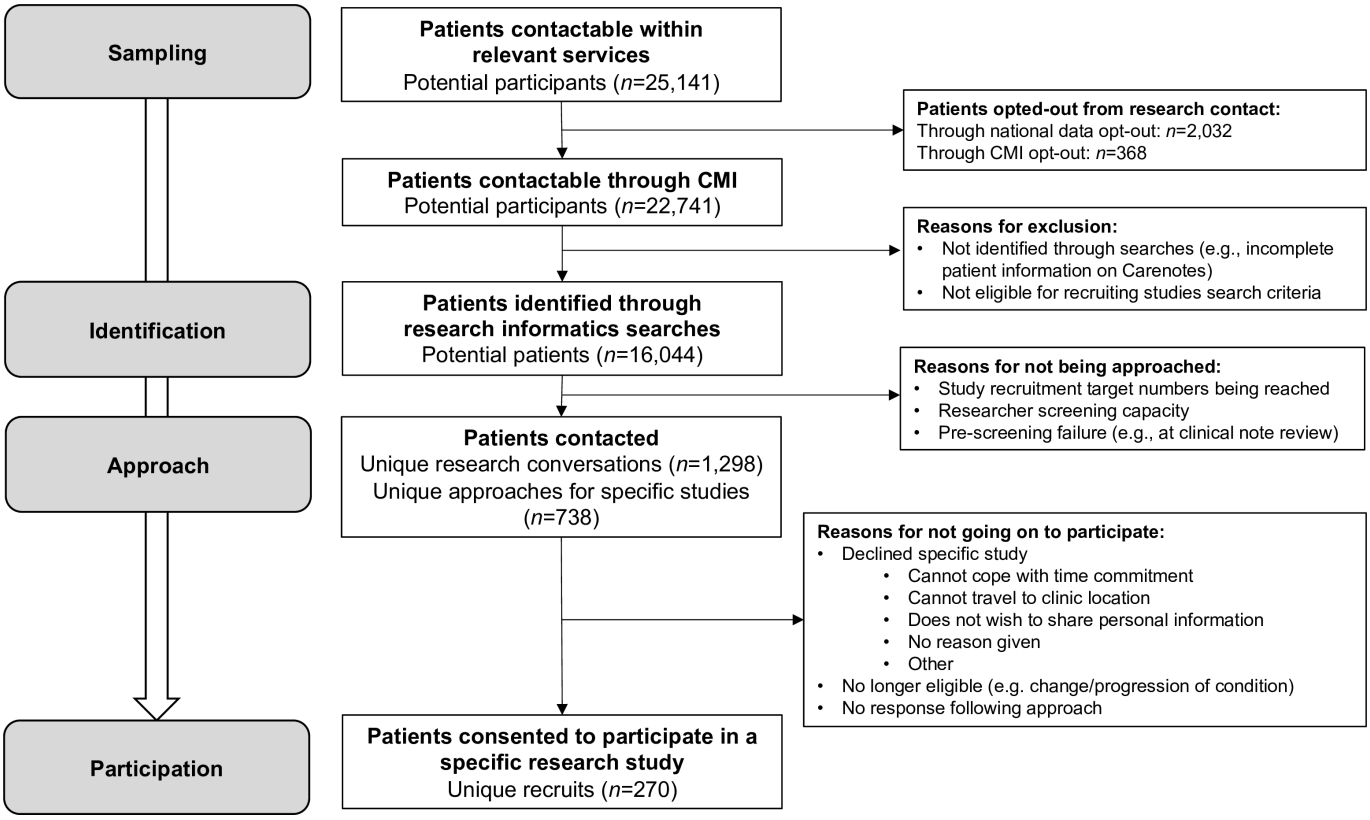

Figure 3 Flow diagram: participants recruited through CMI RI searches. CMI, Count Me In; RI, research informatics.

research opportunities and study findings in simple language so that patients could feel part of the research journey. Incentives for patients to participate in research included feeling valued, well informed, interested in the research and receiving feedback about their participation.

> I think it's important to people who are going to give up their time, their knowledge, their worries, that they are made to feel valued. (Patient participant, 65–74 years of age, participating Trust service user)

Theme 5: 'relationships between clinical and research settings'

Research was valued by staff and patients alike. CMI was described by all participants as a preferable approach for research contact, reducing reliance on clinician referrals and avoiding recruitment delays that arise from the perception that research is 'extra' to clinical duties and therefore dispensable when faced with time constraints. These competing demands for clinical staff were felt to be caused by increased service inefficiencies, an upsurge in remote patient contacts and changing service models. Staff participants emphasised ongoing communication and good working relationships between research teams and clinical services and felt that clinical services benefited from having research assistants embedded in their teams to facilitate this continuity.

> I think it's just because people are so kind of under-resourced and over-stretched that they just don't maybe do the things that are extra to what they have to do basically. (Clinical staff member, perinatal services)

DISCUSSION

This study presents a 12-month evaluation of CMI, a novel researcher-led recruitment approach aiming to improve recruitment rates and promote equitable access to clinical research opportunities within participating services. Compared with standard recruitment (clinician referrals or self-referrals), CMI substantially increased the number of patients contactable for clinical research, across key demographic characteristics. CMI was favoured by patients and staff and is described as more efficient, inclusive and empowering. However, the diversity in the CMI cohort did not translate to actual research participation as the CMI process was rarely used to recruit patients to open studies.

A recently published report, commissioned by the UK government and conducted by Lord O'Shaughnessy, has highlighted the persistent recruitment challenges in clinical trials, driven in part by the lack of research conversations between clinicians and patients, particularly from marginalised or disadvantaged backgrounds.[16] Here, we showed that, over the 12-month implementation period, CMI led to a substantial increase in the number of patients contactable for clinical studies. This finding aligns with previous research showing higher and quicker response rates where patients are recruited via an 'opt-out' (vs 'opt-in') method.[17] As CMI supplements the standard recruitment with research informatics searches that can be performed on the growing CMI cohort, it offers one way to meet recruitment targets and address common recruitment challenges.[4 7] By providing the foundation for a more inclusive research practice (eg, a diverse cohort), the CMI initiative has the potential to transform research practice, which aligns with the UK governmental levelling-up agenda and O'Shaughnessy's report.[18] The potential for CMI to promote inclusive research was recognised by focus group participants, who favoured CMI above the standard approach and aligns with previous research, showing that opt-out research approaches are generally preferred by patients.[10 17]

We saw an increase in research participation over a 7-year period, with a small dip in 2020–2021. Since the launch of CMI in 2021–2022, research participation again increased but did not recover, and the specific role of CMI beyond other secular background trends remains unclear. The temporary decline in research participation in 2020–2021 was probably explained by the impact of the COVID-19 pandemic on clinical research, as many studies in the UK[19] and beyond[20] were suspended to free up clinical staff and prioritise COVID-19 studies. While CMI research informatics searches were used to facilitate patient recruitment, especially to commercial studies, this only accounted for a small proportion of the observed increase in research participation since August 2021, suggesting that most patients were recruited via the standard approach. Indeed, focus groups revealed limited awareness and accessibility of CMI procedures among both patients and staff.

To ensure that the diversity in the CMI cohort translates to actual research participation, a shift in the research culture of NHS mental health services is needed, building on the pillars 'communication & training', 'partnership', and 'innovation'. 'Communication & training' refers to the investment of resources into staff training and patient information to increase awareness and accessibility of CMI processes. This may include accessible information on the benefits of research participation, what 'opting out' meant and how to reverse an initial opt-out decision, and clear communication to manage expectations if research opportunities are not readily available. This is important to ensure a long-term shift in research culture and adhere to good research governance standards.[21]

As the standard approach was valued as an adjunct to the CMI research informatics searches, 'partnership' refers to the engagement and empowerment of key stakeholders, including patients and clinicians, for NHS organisations to become truly research-active. This pillar builds on the James Lind Alliance, a non-profit initiative aimed to identify research priorities for researchers and research funders through the engagement of patients, carers and clinicians.[22] Given concerns regarding the lack of information to manage changing research preferences, this pillar also includes giving patients control to access and change their research preferences through an accessible patient portal linked to their electronic health record, as trialled in a previous USA-based study.[23]

Finally, patient recruitment was largely influenced by study characteristics. Therefore, 'innovation' refers to the need for future research to consider larger sample sizes, inclusivity and diversity of participants, and a broader range of study designs, including collaborations with industry, to maximise the benefits from CMI.

Limitations

This study has several limitations. The CMI initiative was evaluated after 12 months. However, a longer implementation period might be needed to promote a shift in research culture and ensure awareness of new procedures among all stakeholders. Indeed, following a period of study design and sponsorship review, it takes up to 2 months to receive ethical approvals for clinical studies,[24] meaning that studies that were designed to use CMI might have been in the process of receiving approvals when the evaluation was conducted. Similarly, the characteristics of patients recruited through CMI were largely determined by the eligibility criteria of the recruiting studies (eg, specific diagnostic or demographic groups and small sample sizes). This means that more time might have been needed, including the launch of new studies, to evaluate the full potential of CMI. Furthermore, patients and staff noted a lack of awareness and accessibility of information around CMI, leading to low recruitment rates. This underscores the need for ongoing staff training and clear communication for any future initiatives to be successful. Consistent with previous research,[10] patients and staff generally preferred the CMI process above the clinician-led recruitment approach. Nevertheless, the small number of survey and focus group participants might not be representative of all patients and staff members. A detailed exploration of potential signs of distress, dissatisfaction and complaints awaits further scrutiny. Given the lack of demographics and diagnostic input, the evaluation also highlighted the need for clinicians to complete patient characteristics on the electronic patient record fully to maximally benefit from CMI. Finally, we had to pull data from two systems to describe historical patient recruitment figures (Siteline) and CMI involvement (CareNotes Research Participation Form). Future initiatives should strive for a system that could integrate both CMI involvement and study management to avoid inconsistencies and streamline documentation.

CLINICAL IMPLICATIONS

We have shown that CMI can effectively be used to obtain a large cohort of diverse patients who are contactable for research and more representative of the general population, including minority ethnic groups, older adults, and people with physical and mental health disabilities. Compared with the standard approach (clinician referrals and self-referrals), CMI was favoured by patients and staff. However, a shift in the research culture of NHS mental health services, with dedicated resources, is needed to ensure that the diversity in the CMI cohort translates to actual research participation.

Through ongoing improvements and collaborations with international healthcare services, other NHS Trusts, key funders and national initiatives (eg, Office for Life Sciences Mental Health Mission, aimed at improving mental health research capacity in the UK and accelerate translation of discoveries into clinical practice[25]), CMI has not only the potential to address common recruitment challenges of small-scale local studies, but also to allow for rapid patient recruitment to time-sensitive country-wide studies, which can be crucial for future healthcare challenges.[16 26] The next stage of CMI should consider a cost-effectiveness analysis, process improvement and extension to other NHS Trusts (including community NHS Trusts for population-level translational research) to transform patient care and long-term clinical outcomes for the entire patient population.

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Contributors As the corresponding author, VH acted as the guarantor for this study and accepts full responsibility for the work, had access to the data, and controlled the decision to publish. All authors have made substantial contributions to the study conception and design, data acquisition, or analysis and interpretation of data. All authors have been involved in drafting the manuscript or revising it critically for important intellectual content and have given final approval of the manuscript submitted for publication. Each author accepts responsibility for the content of the manuscript and accountability for all aspects of the work.

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Competing interests AC has received research, educational and consultancy fees from INCiPiT (Italian Network for Paediatric Trials), CARIPLO Foundation, Lundbeck and Angelini Pharma.

Patient consent for publication Not required.

Ethics approval This study involves human participants, and the Trust's Caldicott Guardian advised on ethical and patient confidential issues. No formal ethical approvals were required as this project was considered a service evaluation. By obtaining the participants' informed consent prior to any research-related activities, researchers adhered to ethical standards and best research practices, as guided by local and national ethical committees and the Declaration of Helsinki 1975 principles (revision 2013). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article or uploaded as supplementary information. Syntax files related to this study are available on the Open Science Framework (project title: Count Me In: an inclusive approach towards patient recruitment for clinical research studies).

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