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What is the impact of research champions on integrating research in mental health clinical practice? A quasiexperimental study in South London, UK

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ABSTRACT

Objectives Key challenges for mental health healthcare professionals to implement research alongside clinical activity have been highlighted, such as insufficient time to apply research skills and lack of support and resources. We examined the impact of employing dedicated staff to promote research in community mental health clinical settings.

Design Quasiexperiment before and after study.

Setting South London and Maudsley National Health Service Foundation Trust.

Participants 4455 patients receiving care from 15 community mental health teams between 1 December 2013 and 31 December 2014.

Outcome measures The proportion of patients approached for research participation in clinical services where research champions were present (intervention group), and where research champions were not present (comparison group).

Results Patients in the intervention group were nearly six times more likely to be approached for research participation (Adj. OR=5.98; 95% CI 4.96 to 7.22).

Conclusions Investing in staff that promote and drive research in clinical services increases opportunities for patients to hear about and engage in clinical research studies. However, investment needs to move beyond employing short-term staff.

Strengths and limitations of this study

- The quasiexperimental design enables us to evaluate the relationship between a service-level intervention and opportunities for patients to hear about and engage in clinical research studies.
- Our study may have been affected by selection bias due to the lack of randomisation.
- We only considered the impact of the intervention up to 6 months, therefore we did not account for trends over a longer period of time that may influence the effect of the intervention.

INTRODUCTION

In the UK, the National Health Service (NHS) constitution promises to make research accessible to all persons using its services.[1] Yet, there are discrepancies in the level of investment and engagement in research across healthcare providers and patients.[2] Recruitment into mental health research is reported to be more challenging compared with physical health studies.[3 4] However, the challenge is not solely related to the actual recruitment of participants as emerging evidence suggest that patients are willing to participate in research when they are reassured that their personal information will be kept confidential,[5] or they simply take part for altruistic reasons.[6]

A good part of the challenge rests on the practical difficulties of getting researchers to meet potential participants. Researchers have to broker meetings with busy clinicians who are relied on to remember the details of several projects and explain these to their patients. In addition, the modern dispersed mental health service may mean the researcher juggles visits across multiple community clinic sites. The upshot is persistent, if understandable, failures to recruit to target and on time.[7 8]

In an attempt to improve existing processes, the South London and Maudsley NHS Trust (SLaM) introduced a system whereby clinical staff are expected to ask all their patients whether they might be interested in approaches from researchers for studies that could be relevant for their condition (Consent for Contact (C4C)), and responses ('yes' or 'no') are recorded in electronic health records (EHRs). These responses form a searchable register through which an investigator can identify potential participants who have given this broad consent to be contacted.

The register and C4C system has been described in detail elsewhere.[5 9 10] Ultimately, of course, the requirement on clinicians to take and record consent on patients' EHRs does nothing to address many of the underlying issues including how to balance this activity against the demands of clinical responsibility,[11] insufficient time to apply research skill,[12 13] lack of sufficient information to discuss research studies with patients,[14 15] lack of support from managers[16] and not being recognised as a partner or not having a voice in the research process.[17]

In this paper, we addressed the question of whether a short-term investment in dedicated teams and staff can have a sustained benefit over and above the impact of implementing research as part of clinical activity through the C4C programme. We assessed the usefulness of employing research champions (RCs) (ie, staff with both clinical and research responsibility). A team-level intervention in clinical services that focus on psychotic disorders (often regarded as particularly challenging for research recruitment) could help to tackle some of these fundamental issues as reflected in C4C sign up, that is 'yes' or 'no' responses.

METHODS

Study design and participants

We employed a before-and-after quasiexperiment design. The study was conducted in four South London boroughs (Lambeth, Southwark, Croydon and Lewisham) within community mental health teams serving approximately 4800 people with stable, chronic psychotic disorders at SLaM between December 2013 and December 2014.

SLaM is the largest mental health provider in the UK serving urban and suburban population in South London and specialist services elsewhere in the UK.[18 19] Clinical services for psychosis serve on average 7000+ patients per year and are structured around four service lines based on different stages of illness from the first episode through continuing care.[19] At the time of the study, there were 15 case-management community mental health teams providing continuing care for people with stable, chronic psychotic disorder in the Trust.

In this study and as demonstrated by Callard and colleagues,[9] individuals were recruited to a research register so that researchers can invite them to research studies.

Procedure and team allocation

Recruitment as usual

The procedures for implementing the C4C model are provided in a previous paper.[9] In brief, C4C was set up as part of clinical activities whereby healthcare professionals routinely ask their patients whether they might be interested in being contacted about relevant research opportunities. To support the implementation, a dedicated team of clinicians and project workers referred to as 'C4C implementation team' coordinated C4C activities across SLaM. All teams across the Trust have attended an ongoing promotional campaign that raises awareness of C4C among service users and staff, including posters with information about how interested patients might get involved in research and C4C. A short film that describes the concept and process of C4C tailored to staff and patients is also widely available via the Trust intranet page and public-facing internet. The C4C implementation team also holds an annual 1 day event on 20 May to acknowledge and celebrate the International Clinical Trials Day (National Institute for Health Research 2014). C4C stalls are held across the main hospital sites of SLaM on the day. The aims of the day are to raise awareness of the importance and benefit of research, showcase some of the research studies currently running within the organisation and invite service users to sign up for C4C. Clinicians are required to ask a proportion of patients on their caseload per month, which is regularly reviewed and discussed in team meetings. Patients' agreement (or refusal) to join the C4C register is primarily sought by their clinicians as part of routine clinical contacts. Patients' responses are recorded electronically in their EHRs.

For the present study, community teams providing services to people suffering from psychotic disorders were invited to apply for additional funding in order to employ RCs to work in each borough.

Of the four boroughs, clinical services in two boroughs (Southwark and Lewisham) took up the opportunity to employ RCs in addition to C4C recruitment as usual and are referred to here as the intervention group. The remaining two boroughs had C4C recruitment as usual only and are referred to as comparison group.

Intervention

The intervention involved RCs working within clinical services specifically to discuss research participation with patients and record those who are interested (and consented) or refused onto the EHR. There were 10 clinical teams in the intervention group. The RCs' role was advertised internally across the intervention teams as a secondment opportunity. In identifying the RCs, a number of key essential requirements were assessed including: clinical qualification, for example, nursing, social work or occupational therapy; extensive clinical experience; broad knowledge of mental disorders and treatment models; and excellent communications, computer and organisational skills. These qualities were assessed in an interview. Two nurses were employed as RCs; they were allocated to spend 2 weeks in each intervention team at 37.5 hours per week. An average unit, costs of £35 per hour for the year 2013/2014, was used to estimate the cost per RC[20] during the intervention period; therefore, a total of £26 250 was invested in both RCs. RCs attended 1 day training on how to engage patients in C4C before undertaking the task of recruiting and signing up patients. They also had training in research governance particularly regarding informed consent and assessment of mental capacity to provide consent. RCs were supervised by the

clinical team leaders and C4C project manager during their allocation to each intervention team.

The role of RCs involved actively having conversations about research and explaining research participation (C4C) to patients and recording their response ('yes' or 'no') in the EHRs. RCs also encouraged other healthcare professionals in each team to discuss research participation with patients, for example, when they visited patients at home. Consent or refusal was recorded in patients' EHRs by RCs and other clinicians in the teams. In addition, RCs played the role of 'go-to-person' within the teams, such that team members could direct questions or issues about research participation to them. Placement of RCs in the intervention teams took place between 1 March and 30 June 2014.

Source of data

Data were drawn from the Maudsley Biomedical Research Centre (BRC) Clinical Records Interactive Search tool (CRIS).[18] Briefly, CRIS provides a daily updated, anonymised copy of the Trust's electronic clinical record. The C4C model is embedded as a clinical activity, and so consent or refusal to join the C4C register is recorded on these electronic case records and thus searchable through CRIS.

Data collection and analysis

Inclusion criteria

Patients were included if they were active in and receiving care from participating community mental health teams at specific time points (T) as follows:

- T1=3 months before intervention (1 December 2013)
- T2=Start of intervention (1 March 2014)
- T3=End of intervention (30 June 2014)
- T4=3 months postintervention (30 September 2014)
- T5=6 months postintervention (31 December 2014)

Outcome measures

The primary outcome measure was the proportion of patients recorded as having been approached for research participation at each time point. This measure was chosen as the primary outcome as it characterises the success and uptake of C4C, and it is a robust assessment of impact of the intervention. Furthermore, a number of previous studies have also used the proportion of C4C approaches as primary outcome measure.[15 21] From CRIS, we identified and extracted information for teams included in the study as independent variables and the proportion of patients on the team caseload who were asked about C4C as binary outcome variable. Sociodemographic information (gender and age) were collected at patient level as covariates for logistic regression analysis.

Data were analysed using STATA V.12.[22] χ^2 tests were used to compare proportion of C4C approaches in intervention and comparison groups by time-point. Binary logistic regression models were applied to assess associations between patients approached for C4C and study arm (comparison vs intervention group) with and without adjusting for demographic factors. Since our primary sampling unit was the participating teams, the *cluster (team)* option was specified for the logistic regression models in STATA. This provides robust estimates of standard errors, and the approach is recommended when data is drawn from units within a population.[23]

RESULTS

C4C approaches

In total, 15 community mental health teams participated in the study (10 in intervention (n=2684); 5 in comparison (n=1771) group). A total of 4455 patients were receiving care across the teams during the study period. Mean age was 45.7 (SD=11.9) years. There were 1871 women (756 in comparison group and 1115 in intervention group) and 2584 men (1014 in comparison group and 1570 in intervention group). There were no differences in the number of asked C4C, by gender (men 31.3%; women 31.7%, X^2=0.05, df=1, p=0.82) or by age (mean 46.6; 95% CI=45.90 to 47.43, p=0.24). Thirty-nine patients were discharged from the intervention group between T1 and T2. There were no recorded patient discharges in the comparison group during the study period.

Table 1 Associations between proportions of patients asked C4C and study group

	Control		Intervention		ORs with 95% CIs			
Time points	Number of patients on caseload	Percentage asked C4C (%)	Number of patients on caseload	Percentage asked C4C (%)	Unadjusted OR	95% CI	Adj. OR *(adjusted for age and gender)*	95% CI
T1	300	2.7	394	5.1	1.95	0.63 to 10.31	1.71	0.45 to 10.26
T2	301	5.3	355	6.8	1.29	0.28 to 5.86	1.32	0.32 to 5.39
T3	341	15.2	585	40.3	3.75	2.65 to 5.32*	3.78	2.63 to 5.45*
T4	392	11.7	657	44.4	6.01	4.97 to 7.28 *	5.98	4.96 to 7.22*
T5	437	13.3	693	39.3	4.22	3.01 to 5.90 *	4.13	2.94 to 5.79*

*p<0.001.
C4C, Consent for Contact.

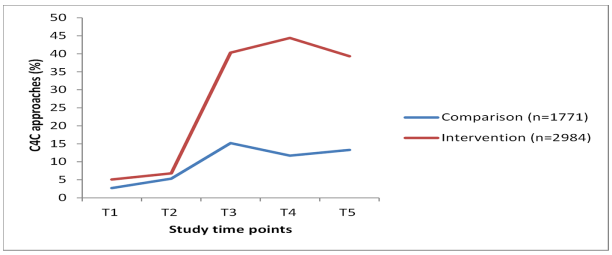

Figure 1 Comparison between control and intervention group for the proportion of patients asked C4C. C4C, Consent for Contact.

Table 1 shows the breakdown of patients active to teams in the intervention and comparison groups who were recorded as having been approached for C4C by study time-point along with 95% CIs. There were no significant differences between intervention and comparison groups before intervention (T1) and at start of intervention (T2), although the intervention group were slightly ahead in approaching patients for C4C. While recruitment rose across both groups, at T3, it was greatest in the intervention group as patients were nearly four times more likely to be asked C4C (adj. OR=3.78; 95% CI 2.63 to 5.45, p<0.001). The evidence was stronger and sustained 3 months later at T4 when patients were six times more likely to be asked (adj. OR=5.98; 95% CI 1.96 to 7.22, p<0.001). The association of increased likelihood of being asked C4C remained robust in the intervention group at 6 month postintervention (adj. OR=4.13, 95% CI 2.93 to 5.79, p<0.001) at T5. Figure 1 displays a graphical illustration of the difference between comparison and intervention groups across the study time points.

DISCUSSION

Main findings

The RC intervention had a positive and sustained impact on the proportion of patients asked about C4C compared with recruitment as usual.

During the 3 months before the intervention, the lack for difference between our two groups suggests that there were no substantial differences in the C4C activity prior to the recruitment of research champions. Similarly, we did not observe any differences among patients who were approached for C4C in the intervention or control groups by gender or age. Another study also found no gender differences.[21]

Evidence of change was demonstrated immediately after the intervention and sustained up to 6 months later. This reflects that given the space, time and resources, research and clinical responsibilities can be aligned.[6 17 24]

The observed growth in the comparison group overtime supports previous findings that suggest C4C is an acceptable infrastructure for research recruitment.[5 9] However, the slight drop (4%) in proportion of patients approached in the intervention group at 6 months may hint at washout effect of end of RCs' placement. This may reinforce the previously reported insufficient resources and support to devote time to research.[13 16] The evidence from the present study suggests that implementation of research as part of clinical activity requires strategies beyond raising awareness.

Strengths and limitations

A number of research studies have investigated factors associated with participating in C4C.[10 25] However, this is the first study to report on relationship between service-level intervention and being approached for C4C. One of the strengths therefore is that we were able to extract data on 4455 patients at team and individual levels to investigate impact of service-related intervention in facilitating research recruitment. Furthermore, the availability of data on number of patients approached for C4C at different time points increased our ability to detect the full impact of the intervention. Although we did not carry out a cost–benefit analysis, using a nationally published unit cost[20] of community-based mental health nurse provides a financial implication of the investment in our intervention group, which is a useful resource for investment especially in a time of cost saving. In addition, our finding of increased proportion of patients approached for C4C in the intervention group is consistent with previous studies.[21 26]

A key limitation of this study is the lack of randomisation that may have led to the introduction of bias. The most obvious is the possibility that the teams who took up the opportunity of additional funding were also those most interested in helping research. We have assumed that all persons receiving care within the participating teams would be asked about participating in research; our study may still suffer selection bias as it is likely that clinicians may have approached higher functioning patients[21] who may be more likely to attend appointments at clinics and therefore have more opportunity to see the RCs. Another limitation is that we only considered assessment of the intervention up to 6 months; therefore, we have not accounted for trends over a longer period of time that may influence the effect of the intervention.

CONCLUSION

This study highlights some key issues in integrating research as part of clinical activity across mental health services with implication for future development. Our results suggest that investing in clinicians that promote research in clinical services increases opportunities for patients to hear about and engage in clinical research studies and may be an important early step in getting systems such as C4C implemented. However, investment needs to move beyond employing short-term staff.

Contributors All authors conceived the study; SO analysed data and drafted the manuscript with guidance and input throughout from TKJC, DR and TW. All authors offered comments on revisions.

Competing interests None declared.

Ethics approval The SLaM BRC Centre Clinical Register Interactive Search System (CRIS) was approved as an anonymised dataset for secondary analysis by the

Oxfordshire Research Ethics Committee (reference 08/H0606/71) for mental health research.[18] A local permission was obtained from a service user-led oversight committee (reference CRIS- 920) that provides governance for and monitor all projects conducted using the SLaM CRIS. The SLaM C4C model was reviewed and approved by the National Information Governance Board for Health and Social Care (NIGB, now known as Confidential Advisory Group) and Ethics and Confidential committee (reference ECC 2–08/2010).

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Data sharing statement No additional data are available.

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