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Investing in clinical staff to embed research in mental health clinical services: a quasi-experimental study.

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Title:

Investing in clinical staff to embed research in mental health clinical services: a quasi-experimental study.

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Key words: recruitment, mental health, consent, psychosis, research participation.

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: Quasi-experiment before and after study.

Setting: South London and Maudsley NHS Foundation Trust (SLaM).

Participants: 4,455 patients receiving care from fifteen community mental health teams between 1st December 2013 and 31st December 2014.

Outcome measures: the proportion of patients approached for research participation in clinical services where research champions were present (intervention group) and comparison group where there were no research champions present.

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 – 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. Ensuring that research roles and responsibility are embedded in the job descriptions of all clinical staff of mental health service providers would be crucial in realising the goal of making research an everyday business.

Strengths and limitations of this study

- Describes how research activity can be embedded as part of routine clinical care.
- Highlights the importance of investing in clinical staff to promote and drive research in clinical settings.
- Quasi-experimental study evaluates the relationship between service-level intervention and opportunities for patients to hear about and engage in clinical research studies.
- Lack of randomisation may have led to the introduction of bias.

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 with the understanding that they have autonomy over their participation [5] and are reassured of confidentiality of their personal information [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 upon 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 juggle visits across multiple community clinic sites. The upshot is persistent, if understandable failures to recruit to target and on time [7].

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 are recorded in electronic health records. 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, 8, 9]. Ultimately, of course, the requirement to take and record consent on patients electronic health records does nothing to address many of the underlying issues including how to balance this activity against the demands of clinical responsibility [10], insufficient time to

apply research skill [11, 12], lack of sufficient information [13, 14], lack of support from managers [15] and not being recognised as a partner or not having a voice in the research process [16] .

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 (i.e. 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.

Methods

Study design and participants

We employed a before and after quasi-experiment 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 [17, 18]. 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 [18]. 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 [8], individuals were not recruited to research studies but to a research register so that researchers can approach and 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 [8]. To support the implementation, a dedicated team of clinicians and project workers referred to as 'C4C implementation team' coordinated C4C activities. 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 which 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 one-day event on 20th May to acknowledge and celebrate the International Clinical Trials Day (National Institute of 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. 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 research champions to work in each borough.

Of the four boroughs, clinical services in two (Southwark and Lewisham) took up the opportunity to employ research champions in addition to C4Crecruitment as usual and are referred to here as the intervention group. The remaining two boroughs had recruitment as usual only and are referred to as comparison group.

Intervention

The intervention involved research champions (RCs) working within clinical services specifically to discuss research participation with patients and record those who are interested (and consented) or refused onto the electronic health records. In identifying research champions a number of key essential requirements were assessed including: clinical qualification e.g. nursing, social work or occupational therapy; extensive clinical experience; broad knowledge of mental disorders and treatment models; excellent communications, computer and organisational skills. These qualities were assessed in an interview. The role involved RCs actively having conversations about research and explaining research participation (C4C) to patients and recording their response ('yes' or 'no') on the electronic health records. Two nurses were employed as RCs; they worked full time hours (37.5hrs per week) in each team of the intervention boroughs for two weeks. An average unit cost in 2013/14 of £35 per hour per RC was used [19] during the intervention period, therefore a total of £26,250 was invested in both RCs. RCs attended one 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 encouraged other healthcare professionals in each team to discuss research participation with patients, for example, when they visited patients at home. Subsequently, RCs provided administrative support to record patients' response onto the electronic health record. In addition RCs played the role of 'go-to- person' within the team, such that team members could direct questions or issues about research participation to them. Placement of RCs in clinical teams took place between 1st March and 30th June 2014.

Source of data

Data were drawn from the Maudsley Biomedical Research Centre (BRC) Clinical Records Interactive Search tool (CRIS) (Stewart et al., 2009). 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 follow:

T1 = 3 month before intervention (1st Dec 2013)

T2 = Start of intervention (1 March 2014)

T3 = End of intervention (30 June 2014)

T4 = 3 months post intervention (30 Sep 2014)

T5 = 6 months post intervention (31 Dec 2014)

Outcome measures

The primary outcome measure was the proportion of patients recorded as having been approached for research participation by 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. 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. Socio-demographic information (gender and age) were collected at patient level as covariates for logistic regression analysis.

Data were analysed using STATA version 12 [20]. Chi-squared 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 association between patients approached for C4C and study arm (comparison vs. intervention group) with and without adjusting for demographic factors. Since our primary sampling unit is the participating boroughs, the *cluster (borough)* 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[21]

Ethical 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 [17]. A local permission was obtained from a service user-led oversight committee (reference CRIS- 920) which 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).

Results

Consent for contact approaches

In total, fifteen community mental health teams participated in the study (10 in intervention (n=2684); 5 in comparison (n=1771) group). A total of 4,455 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 and 1115 in intervention group) and 2584 men (1014 in comparison; 1570 in

intervention group). Thirty-nine patients were discharged from the intervention group between T1 and T2.

Table 1 shows the breakdown of patients active to teams in the intervention and comparison groups who are recorded as having been approached for C4C by study time-point along with 95% confidence intervals (CI). 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 – 5.45, p<0.001). The evidence was stronger and sustained three months later at T4 when patients were six times more likely to be asked (adj. OR= adj. OR= 5.98; 95% CI= 1.96 – 7.22, p<0.001). The association of increased likelihood of being asked C4C remained robust in the intervention group at six month post intervention (adj. OR=4.13, 95% CI =2.93 – 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.

Table 1 here:

Figure 1 here:

Discussion

Main findings

The research champion intervention had a positive and sustained impact on the proportion of patients asked about consent for contact compared to recruitment as usual.

During the three month before the intervention, the lack for difference between our two groups may reflect the previously reported challenges for clinicians to engage in research such as extra burden and interruption to clinical workflow [22].

Evidence of change was demonstrated immediately after the intervention and sustained up to six months later. This reflects that given the space, time and resources, research and clinical responsibilities can be aligned [16, 22].

The observed growth in the comparison group overtime supports previous findings that suggest C4C is an acceptable infrastructure for research recruitment [8, 9]. However, the slight drop (4%) in proportion of patients approached in the intervention group at six month may hint at washout effect of end of research champions placements and may reinforce the previously reported insufficient resources and support to devote time to research [12, 15]. The evidence from the present study suggests that implementation of research as part of clinical activity require strategies beyond raising awareness, but research champion roles need to be maintained and sustained overtime.

Strengths/ Limitation

A number of research studies have investigated factors associated with participating in consent for contact [5, 6]. 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 4,455 patients at team and individual level to investigate impact of service related intervention in facilitating research recruitment. Further, 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 [19] 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.

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 who may be more likely to attend appointments at clinics and therefore have more opportunity to see the research champions. Another limitation is that we only considered assessment of the intervention up to six months, therefore we have not accounted for trends over longer 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. Ensuring that research roles and responsibility are embedded in the core job descriptions of all clinical staff of mental health service providers would be crucial in realising the goal of making research an everyday business.

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AUTHOR CONTRIBUTIONS

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

COMPETING INTERESTS

None declared

DATA SHARING

No additional data are available.

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Tables and figure

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

Time points	Control		Intervention		Odds ratios with 95% confidence intervals			
	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 – 10.31	1.71	0.45 – 10.26
T2	301	5.3	355	6.8	1.29	0.28 – 5.86	1.32	0.32 – 5.39
T3	341	15.2	585	40.3	3.75	2.65 – 5.32*	3.78	2.63– 5.45*
T4	392	11.7	657	44.4	6.01	4.97 – 7.28 *	5.98	4.96 – 7.22*
T5	437	13.3	693	39.3	4.22	3.01 – 5.90 *	4.13	2.94 – 5.79*

C4C, consent for contact. OR, odds ratios. Adj. OR, adjusted odds ratios. CI, confidence interval. *p<0.001

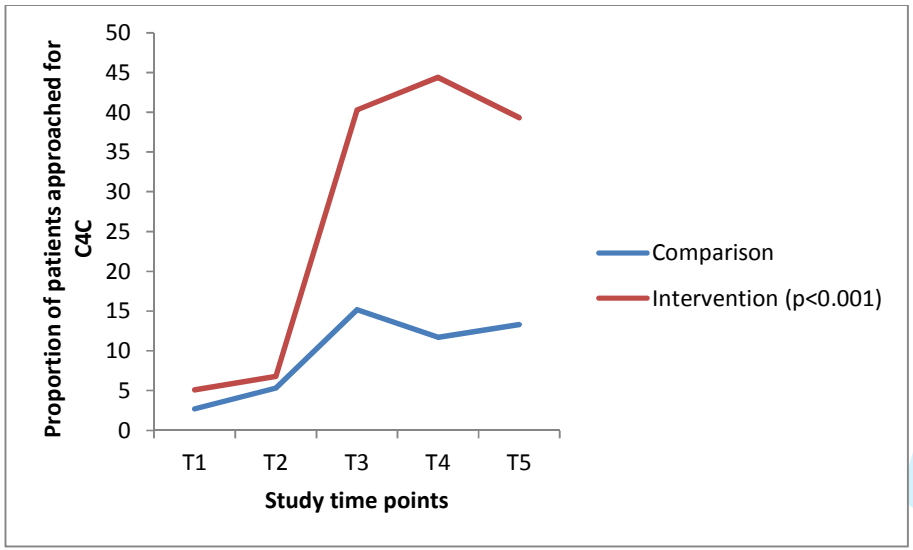

Figure 1: comparison between control and intervention group for proportion of patients asked C4C

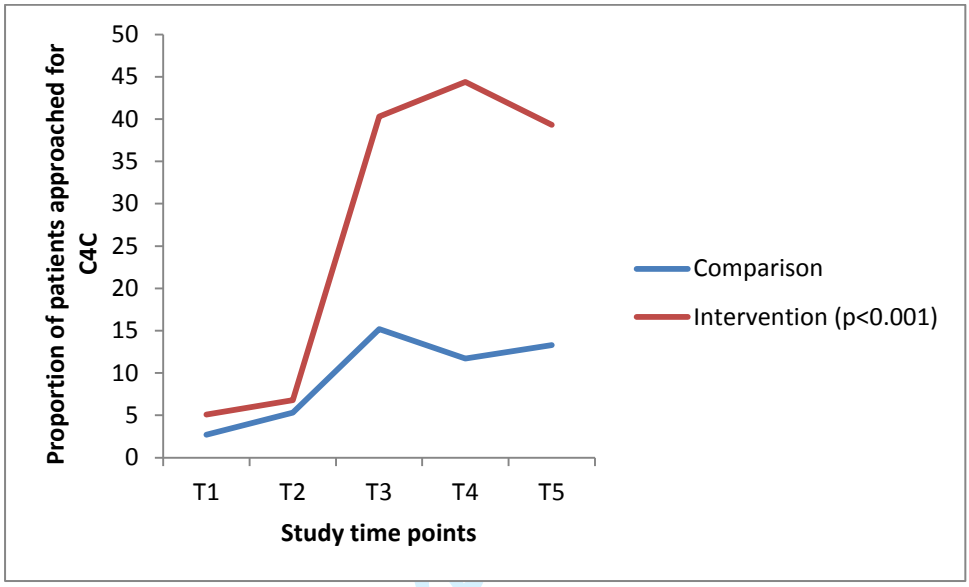

Figure 1: comparison between control and intervention group for proportion of patients asked C4C

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No.
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any pre specified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	5
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5/6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*6*
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8
		(*b*) Describe any methods used to examine subgroups and interactions	
		(*c*) Explain how missing data were addressed	
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods	

		taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	

Continued on next page

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed 8	8
		(b) Give reasons for non-participation at each stage	9
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8/9
		(b) Indicate number of participants with missing data for each variable of interest	9
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	*8/9*
Main results9	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	14
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	9
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	10
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	10
Generalisability	21	Discuss the generalisability (external validity) of the study results	11
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	13

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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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

- Describes how research activity can be embedded as part of routine clinical care.
- Highlights the importance of investing in clinical staff to promote and drive research in clinical settings.
- Quasi-experimental study evaluates the relationship between service-level intervention and opportunities for patients to hear about and engage in clinical research studies.
- Lack of randomisation may have led to the introduction of bias.

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 with the understanding that they have autonomy over their participation [5] and are reassured of confidentiality of their personal information [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 upon 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 juggle 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 are recorded in electronic health records. 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 to take and record consent on patients electronic health records 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 [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 (i.e. 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.

Methods

Study design and participants

We employed a before and after quasi-experiment 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]. To support the implementation, a dedicated team of clinicians and project workers referred to as 'C4C implementation team' coordinated C4C activities. 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 which 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 one-day event on 20th May to acknowledge and celebrate the International Clinical Trials Day (National Institute of 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. 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 electronic health records (EHR).

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 research champions to work in each borough.

Of the four boroughs, clinical services in two boroughs (Southwark and Lewisham) took up the opportunity to employ research champions 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 research champions (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 ten 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 e.g. nursing, social work or occupational therapy; extensive clinical experience; broad knowledge of mental disorders and treatment models; excellent communications, computer and organisational skills. These qualities were assessed in an interview. Two nurses were employed as RCs; they were allocated to spend two weeks in each intervention team at 37.5hrs per week. An average unit cost of £35 per hour for the year 2013/14 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 one 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 electronic health records. 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 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 1st March and 30th June 2014.

Source of data

Data were drawn from the Maudsley Biomedical Research Centre (BRC) Clinical Records Interactive Search tool (CRIS) (Stewart et al., 2009). 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 follow:

T1 = 3 month before intervention (1st Dec 2013)

T2 = Start of intervention (1 March 2014)

T3 = End of intervention (30 June 2014)

T4 = 3 months post intervention (30 Sep 2014)

T5 = 6 months post intervention (31 Dec 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. Socio-demographic information (gender and age) were collected at patient level as covariates for logistic regression analysis.

Data were analysed using STATA version 12 [22]. Chi-squared 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 association 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]

Ethical approval

The SLaM BRC 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) which 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).

Results

Consent for contact approaches

In total, fifteen community mental health teams participated in the study (10 in intervention (n=2684); 5 in comparison (n=1771) group). A total of 4,455 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 and 1115 in intervention group) and 2584 men (1014 in comparison; 1570 in intervention group). 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.

[Insert Table 1 and Figure 1]

Table 1 shows the breakdown of patients active to teams in the intervention and comparison groups who are recorded as having been approached for C4C by study time-point along with 95% confidence intervals (CI). 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 – 5.45, p<0.001). The evidence was stronger and sustained three months later at T4 when patients were six times more likely to be asked (adj. OR= adj. OR= 5.98; 95% CI= 1.96 – 7.22, p<0.001). The association of increased likelihood of being asked C4C remained robust in the intervention group at six month post intervention (adj. OR=4.13, 95% CI =2.93 – 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 research champion intervention had a positive and sustained impact on the proportion of patients asked about consent for contact compared to recruitment as usual.

During the three month 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.

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

The observed growth in the comparison group overtime supports previous findings that suggest C4C is an acceptable infrastructure for research recruitment [9, 10]. However, the slight drop (4%) in proportion of patients approached in the intervention group at six month may hint at washout effect of end of research champions' 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/ Limitation

A number of research studies have investigated factors associated with participating in consent for contact [5, 6]. 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 4,455 patients at team and individual level to investigate impact of service related intervention in facilitating research recruitment. Further, 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, 25]

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 who may be more likely to attend appointments at clinics and therefore have more opportunity to see the research champions. Another limitation is that we only considered assessment of the intervention up to six months, therefore we have not accounted for trends over longer 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.

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AUTHOR CONTRIBUTIONS

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

COMPETING INTERESTS

None declared

DATA SHARING

No additional data are available.

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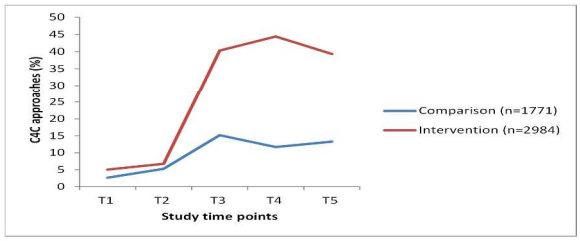
Tables and figures

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

Time points	Control		Intervention		Odds ratios with 95% confidence intervals			
	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 – 10.31	1.71	0.45 – 10.26
T2	301	5.3	355	6.8	1.29	0.28 – 5.86	1.32	0.32 – 5.39
T3	341	15.2	585	40.3	3.75	2.65 – 5.32*	3.78	2.63– 5.45*
T4	392	11.7	657	44.4	6.01	4.97 – 7.28 *	5.98	4.96 – 7.22*
T5	437	13.3	693	39.3	4.22	3.01 – 5.90 *	4.13	2.94 – 5.79*

C4C, consent for contact. OR, odds ratios. Adj. OR, adjusted odds ratios. CI, confidence interval. *p<0.001

Figure 1: Comparison between control and intervention group for the proportion of patients asked C4C



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254x142mm (300 x 300 DPI)

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No.
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any pre specified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	5
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5/6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*6*
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8
		(*b*) Describe any methods used to examine subgroups and interactions	
		(*c*) Explain how missing data were addressed	
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods	

		taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	

Continued on next page

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed 8	8
		(b) Give reasons for non-participation at each stage	9
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8/9
		(b) Indicate number of participants with missing data for each variable of interest	9
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	*8/9*
Main results9	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	14
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	9
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	10
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	10
Generalisability	21	Discuss the generalisability (external validity) of the study results	11
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	13

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

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

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Secondary Subject Heading:	Health services research
Keywords:	recruitment, consent, psychosis, research participation, MENTAL HEALTH

Title:

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Key words: recruitment, mental health, consent, psychosis, research participation.

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: Quasi-experiment before and after study.

Setting: South London and Maudsley NHS Foundation Trust (SLaM).

Participants: 4,455 patients receiving care from fifteen community mental health teams between 1st December 2013 and 31st December 2014.

Outcome measures: The proportion of patients approached for research participation in clinical services where research champions were present (intervention group) and comparison group where there were no research champions present.

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 – 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 quasi-experimental 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 six 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 upon 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 juggle visits across multiple community clinic sites. The upshot is persistent, if understandable failures to recruit to target and on time [7, 8].

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Study design and participants

We employed a before and after quasi-experiment 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 which 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 one-day event on 20th 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 electronic health records (EHR).

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 research champions to work in each borough.

Of the four boroughs, clinical services in two boroughs (Southwark and Lewisham) took up the opportunity to employ research champions 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 research champions (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 ten 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 e.g. nursing, social work or occupational therapy; extensive clinical experience; broad knowledge of mental disorders and treatment models; excellent communications, computer and organisational skills. These qualities were assessed in an interview. Two nurses were employed as RCs; they were allocated to spend two weeks in each intervention team at 37.5hrs per week. An average unit cost of £35 per hour for the year 2013/14 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 one 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 electronic health records. 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 1st March and 30th 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 follow:

T1 = 3 month before intervention (1st Dec 2013)

T2 = Start of intervention (1 March 2014)

T3 = End of intervention (30 June 2014)

T4 = 3 months post intervention (30 Sep 2014)

T5 = 6 months post intervention (31 Dec 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. Socio-demographic information (gender and age) were collected at patient level as covariates for logistic regression analysis.

Data were analysed using STATA version 12 [22]. Chi-squared 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]

Ethical approval

The SLaM BRC 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) which 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).

Results

Consent for contact approaches

In total, fifteen community mental health teams participated in the study (10 in intervention (n=2684); 5 in comparison (n=1771) group). A total of 4,455 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 and 1115 in intervention group) and 2584 men (1014 in comparison; 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 – 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.

[Insert Table 1 and Figure 1]

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% confidence intervals (CI). 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 – 5.45, p<0.001). The evidence was stronger and sustained three months later at T4 when patients were six times more likely to be asked (adj. OR= adj. OR= 5.98; 95% CI= 1.96 – 7.22, p<0.001). The association of increased likelihood

of being asked C4C remained robust in the intervention group at six month post intervention (adj. OR=4.13, 95% CI =2.93 – 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 research champion intervention had a positive and sustained impact on the proportion of patients asked about consent for contact compared to recruitment as usual.

During the three 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 six 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 six month may hint at washout effect of end of research champions' 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 consent for contact [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 4,455 patients at team and individual level to investigate impact of service related intervention in facilitating research recruitment. Further, 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 research champions. Another limitation is that we only considered assessment of the intervention up to six 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.

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AUTHOR CONTRIBUTIONS

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

COMPETING INTERESTS

None declared

DATA SHARING

No additional data are available.

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Tables and figures

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

Time points	Control		Intervention		Odds ratios with 95% confidence intervals			
	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 – 10.31	1.71	0.45 – 10.26
T2	301	5.3	355	6.8	1.29	0.28 – 5.86	1.32	0.32 – 5.39
T3	341	15.2	585	40.3	3.75	2.65 – 5.32*	3.78	2.63– 5.45*
T4	392	11.7	657	44.4	6.01	4.97 – 7.28 *	5.98	4.96 – 7.22*
T5	437	13.3	693	39.3	4.22	3.01 – 5.90 *	4.13	2.94 – 5.79*

C4C, consent for contact. OR, odds ratios. Adj. OR, adjusted odds ratios. CI, confidence interval. *p<0.001

Figure 1: Comparison between control and intervention group for the proportion of patients asked C4C

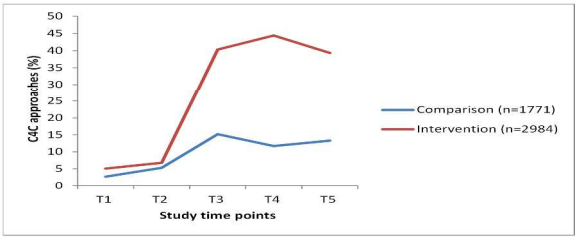

Figure 1: comparison between control and intervention group for the proportion of patients asked C4C

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254x142mm (300 x 300 DPI)

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No.
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any pre specified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	5
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5/6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*6*
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8
		(*b*) Describe any methods used to examine subgroups and interactions	
		(*c*) Explain how missing data were addressed	
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods	

		taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	

Continued on next page

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed 8	8
		(b) Give reasons for non-participation at each stage	9
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8/9
		(b) Indicate number of participants with missing data for each variable of interest	9
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	*8/9*
Main results9	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	14
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	9
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	10
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	10
Generalisability	21	Discuss the generalisability (external validity) of the study results	11
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	13

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.