

# Implementing the role of the primary care mental health worker: a qualitative study

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## ABSTRACT

### Background

Primary care mental health workers are a new role recently introduced into primary care in England to help manage patients with common mental health problems.

### Aim

To explore the views of GPs, primary care teams and patients on the value and development of the new role of primary care mental health workers in practice.

### Design of study

Qualitative study.

### Setting

The Heart of Birmingham Primary Care Teaching Trust in the West Midlands, UK.

### Method

Thirty-seven semi-structured interviews involving seven primary care mental health workers, 21 patients and 11 focus groups involving 38 members of primary care teams were held with six teams with a worker. Two teams asked for the worker to be removed. Six practice managers also took part in the study.

### Results

A number of different approaches were used to implement this new role. Strategies that incorporated the views of primary care trust senior management, primary care teams and workers' views appeared most successful. Rapid access to a healthcare professional at times of stress and the befriending role of the worker were also highly valued. Workers felt that their role left them professionally isolated at times. A number of workers described tension around ownership of the role.

### Conclusion

Primary care mental health workers appear to provide a range of skills valued by patients and the primary care teams and can increase patient access and choice in this area of health care. Successful implementation strategies highlighted in this study may be generalisable to other new roles in primary care.

### Keywords

health personnel; mental health; primary health care; primary care mental health workers.

## INTRODUCTION

Ninety per cent of all patients with mental health problems are seen and treated in primary care.<sup>1</sup> Approximately 40% of primary care consultations have a mental health component and 30% are purely for a mental health issue.<sup>2</sup> However, patients are not always offered optimal care, with reported significant levels of unmet need.<sup>3</sup> Recent strategies to improve the quality of primary care mental health include targeted education programmes,<sup>4</sup> case management,<sup>5</sup> and the deployment of additional workers including counsellors to support service delivery.<sup>6</sup>

Primary care mental health workers described in *The NHS Plan*<sup>7</sup> as helping GPs manage and treat people with common mental health problems may also have an important role to play in improving primary care mental health care. Their generic role description, based on Department of Health Best Practice Guidance<sup>8</sup> is described in an accompanying paper in this issue.<sup>9</sup> Primary care mental health workers offer brief evidence-based interventions to patients, develop practice infrastructure and establish links with the wider mental health community including the voluntary sector. There has, however, been little formal evaluation of the impact or effectiveness of the role. This paper reports the findings of a qualitative study, exploring the implementation of, and views about, the role from multiple stakeholder perspectives.

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## METHOD

### Participants

The participants are described more fully in the accompanying paper.<sup>9</sup> Seven workers were placed in practices across the Heart of Birmingham PCT. The components of the role closely followed the Department of Health Guidance.<sup>10</sup> Each GP could refer patients of working age (18–65 years) diagnosed as having a new or ongoing common mental health problem such as depression, anxiety, stress and sleep problems (using ICD-10 criteria) to their worker. Alternatively, GPs were free to treat patients by themselves and/or to refer to the voluntary sector or the local secondary mental healthcare team instead of, or as well as, involving the workers.

Senior partners of the 10 practices that had or used to have a worker were contacted. Six practices with a worker agreed to participate. Two practices declined citing staffing problems and time constraints. Two practices that asked for their worker to be withdrawn after 6 months also agreed to participate in a focus group. Reasons for the worker being withdrawn were explored within these focus groups. Eight 1-hour focus groups were conducted in primary care settings (group size between four and eight participants). Participants in the primary care team focus groups are identified in Table 1.

The seven workers in post at the time of the qualitative study and all six senior managers involved in developing and implementing the primary care mental health worker policy at a primary care trust (PCT) level were also interviewed. Workers identified voluntary sector organisations that they regularly referred to and leads for six of these organisations were invited to participate in a focus group with their wider team. The first 200 patients seen by the seven primary care mental health workers were sent a letter by the study team describing the study. Sixty-six patients replied indicating an interest in being interviewed and were purposively sampled using practice, age, sex, ethnicity and mental health diagnosis as the important variables. In total, 21

**Table 1. Primary care team focus group participants.**

Focus group	Participants				Total
	GPs	Practice nurses	Administrative staff	Practice manager	
1	1	2	1	1	5
2	1	1	2	1	5
3	4	1	1	1	7
4	2	1	1	1	4
5	2	1	1	1	5
6	1	1	2	0	4
7	2	1	0	0	3
8	1	2	1	1	5
Total	14	9	9	6	38

patient interviews were carried out (Table 2).

### Topic guide

Topic guides were constructed for each set of interviews and/or focus groups reflecting the different expertise of stakeholders but core questions included the value and scope of the role, issues related to fidelity of the role to national policy guidance and barriers and

**Table 2. Patient demographic characteristics.**

Sex	Age (years)	Ethnicity	Previous experience of using mental health services	Mental health diagnosis <sup>a</sup>
F	50	White, British	Yes	Depression, agoraphobia, anxiety
F	60	White, Irish	Yes	Depression
F	42	White, British	Yes	Depression, anxiety
F	50	White, British	Yes	Depression, anxiety
F	28	Asian, British	No	Postnatal depression
F	37	Asian, Pakistani	Yes	Stress, depression
F	47	Asian, British	Yes	Depression
F	23	Asian, British	Yes	Depression
F	64	Black, Caribbean	No	Anxiety
F	22	Asian, British	No	Depression
F	34	White British	Yes	Anxiety
M	50	White, British	Yes	Work-related stress and depression
M	50	White, British	Yes	Depression
M	33	Asian, Pakistani	No	Depression, anxiety
M	40	White, British	No	Work-related stress
M	63	White, Irish	No	Depression
M	56	White, Irish	No	Bereavement
M	26	Asian, British	Yes	Panic attacks
M	58	White, British	Yes	Anxiety
M	27	White, British	No	Depression
M	31	Asian, British	Yes	Depression, anxiety

<sup>a</sup>This was made by the GP at the time of referral.

## How this fits in

Patients and primary care teams value the new role of primary care mental health workers, particularly the speedy access, befriending and increased choice of non-medical treatments they can offer. Workers themselves may feel frustrated and professionally isolated by their role. Horizontal synthesis methods of implementation that include multiple stakeholder perspectives appear critical in successful implementation of the role.

facilitators to implementing the role. Each interview and focus group was audiotaped, fully transcribed and field notes were written.

### Analysis

The constant comparative method, guided by the Framework analytical approach was used to analyse the data.<sup>11</sup> This method is based on a grounded theory approach to data analysis in which theories are generated from the data. Each transcript was read and read again with the field notes and analysed concurrently with data collection. Disconfirming evidence was sought throughout and emerging themes modified in response. Data collection continued until data saturation was achieved and no new themes were emerging.<sup>12</sup> Separate analyses were carried out depending on the background of the interviewees. All responders were invited to comment on a summary of their transcript, and these views were then incorporated into the analysis. Quotations have been chosen on grounds of representativeness.

## RESULTS

Interviews and focus groups took place between September 2003 and March 2004, approximately 18 months after the workers started in post. Thirty-seven semi-structured interviews were carried out involving 21 patients (quotes represented as sex, age in years), three voluntary sector leads, six senior PCT executives (PCTE) and seven primary care mental health workers (PCMHW). Eleven focus groups (FG) were held (eight with primary care teams involving a total of 38 participants (Table 1) and three with voluntary sector organisations (VOL) involving 15 participants). In addition six practice managers (PM) took part. Two responders commented on their transcript but these were not significant comments. This paper discusses the two key themes emerging from the data: the perceived focus of the role and tensions around how the role should be implemented.

### Perceived focus of the role

Many patients described how their time with the worker seemed to have a different quality compared with other consultations they had experienced. Several patients described particular characteristics of the consultation which differed including a lack of 'time rationing', how the consultation was perceived as an informal, relaxed experience, and how the worker seemed prepared to listen to their life problems and help normalise their situation:

*'There was more time, not necessarily more understanding because my GP is very understanding but with her there was more time to explain things in more depth and detail.'* (M, 58)

*'The word that springs to mind is "non-threatening", which I liked, it helps when you talk. My psychiatrist is nice but so professional and formal, it feels a bit inhibitory at times.'* (M, 50)

*'She didn't sit there and try and analyse me and use lots of big words. She just sat there and talked to me like a friend would.'* (M, 29)

Several patients had regular follow-up sessions and were given additional support and information between appointments with GPs and/or secondary care:

*'She made an appointment to see the psychologist but in the interim she was like a break for me. I sort of haven't got to carry it around for 2 months until I get my appointment and that was good for me.'* (M, 58)

*'She acted as a liaison between me and the GP and helped to sort out an appointment with the psychiatrist. She sort of helped move things along.'* (M, 50)

*'In the meantime everyone has agreed it seems like a good idea for me to go back and see her in between appointments with the psychiatrist and psychologist and GP, just so I'm seeing somebody.'* (F, 60)

A number of patients commented on how perceived immediate or prompt access to the worker helped them keep their appointments and be followed up. The worker also seemed to provide a 'safety net' if patients did not turn up for appointments, so that they were not 'lost' in the system:

*'I think it's better to be able to see someone straight away because I know we don't live in an ideal world but well it's just better. Even if you've got the referral you lose the momentum when you come away and think about it.'* (F, 37)

*'Now I know her I don't find it difficult to make appointments, but the first time when I was feeling really bad, I don't think I would have been able to take that first step so it was just easier to go round and see her straight away with the GP.'* (F, 50)

*'She could have a role like she did with me. If she did that with other people it would be like a safety net. You know, if you don't go and see her, she chases you. I didn't like that at first, but then when I thought about it I thought it could be a good thing. So you don't get forgotten or lost.'* (F, 23)

For other patients and many GPs, the workers offered an alternative choice to refer patients to other than secondary care:

*'I think from our point of view she has filled a gap. There has always been this gap in services between us and secondary care and now patients have a choice of accessing somebody who can keep them going or help them without having to go and see a psychiatrist or whatever.'* (FG4, GP2)

*'We really we don't need designated specialist psychiatric input for many of these patients. Many of these patients have broader issues and they don't fit into the mental health team or the general practice team skills, they don't need the medication but they need some form of support and that's where I think the mental health worker has a role.'* (FG6, GP1)

*'Is it necessarily cost-effective to go and see a psychiatrist or someone who's had all that training as a psychologist when someone in this position is much better, not just on a cost level but generally. It just makes more sense.'* (M, 27)

Most practices and patients valued the workers ability to advise patients about the most appropriate local voluntary service:

*'She acted as a signpost and pointed me in directions of help I hadn't thought about. I was caring alone for my 90-year-old mother-in law and she helped get social services involved.'* (M, 58)

*'I mean I know through years of working in general practice some of the bigger organisations like Cruse [Bereavement Care] and Alcoholics Anonymous but I haven't got time to go and look up every local thing.'* (FG2, GP1)

However the two practices that asked for their worker to be withdrawn did not see the value of this role, describing the workers as little more than 'walking Yellow Pages':

*'My feedback is that the patients aren't getting anything except dishing out some leaflets which you can pick up from the front of the surgery or anywhere. I can give them those.'* (FG4, GP1)

*'It appeared to be more of a living catalogue of agencies rather than a listening ear, somebody who will help. It was more or less like a "Yell", which is physically there, you know like the Yellow Pages or something sitting there with you.'* (FG5, GP1)

[Talking about patients] *'Some of them said it was a waste of time and it wasn't what they were expecting. They wanted a ready-made answer that kind of thing; a short thing ready-made, no effort thing.'* (FG1, GP1)

All workers reported that patient contacts were the most enjoyable aspect of the role for them:

*'I'd have to say it was the patient contact, you know. I quite enjoy doing that plus liaising for people, that kind of thing.'* (PCMHW4)

*'I suppose I feel comfortable with this role because part of my previous job involved talking and counselling people. I like that interaction, that's what I should be doing.'* (PCMHW7)

*'Previously I worked in Birmingham as a counsellor. I think that long-term contact is good, you build up relationships and get to know your clients which makes the job feel more valuable.'* (PCMHW6)

Only three workers were actively pursuing the practice infrastructure aspect of the job, by leading mental health audits. Barriers included the relatively limited support from their practices, and workers' perceptions that there was little personal gain from the role:

*'I'm trying to do an audit at the moment on Seroxat® [GSK] but it's difficult because of the way things are entered onto the computer to pull the information out, they're not as stringent as, say, diabetes notes.'* (PCMHW4)

*'At the other practice I couldn't do it [audit]. I wasn't allowed to look at the written notes or have access to the computer.'* (PCMHW2)

*'The second role, the audit role, hasn't really existed for me. I started to do an audit but in terms of getting support on that, the GPs are really limited on what they can and can't support you with. So I just left it and thought, well I can't do everything myself.'* (PCMHW1)

Worker and patient interaction from the voluntary sector also appeared variable. Only two of the six voluntary organisations interviewed were aware of this new role. Those organisations with greater knowledge of the workers had more formal historical links and good channels of communication with the PCT:

*'I have had no involvement with the workers or*

*received reports or met them so my knowledge is exceedingly limited.'* (VOL3)

*'No we haven't noticed any perceptible impact yet, but it may happen with time, although our contract is with the GP so we wouldn't necessarily notice.'* (VOL2)

*'I think because we are an established organisation we already knew about the workers from the PCT with whom we have a permanent contract. Plus I had asked them to come and visit our agency.'* (VOL4)

### **Tensions in implementing the primary care mental health workers' role**

PCT executives, primary care teams and workers expressed conflicting ideas on how best to implement the primary care mental health workers' role. Most Trust executives felt that the role was best implemented by the PCT taking a lead and determining issues of expected fidelity to national policy guidance, recruitment and placement of the workers:

*'I think there's a lot of anecdotes and hearsay about GPs knowing what's best and so on. If they're offered a service and it increases their capacity and access and so forth, then that's meeting the targets and providing them with a service.'* (PCTE3)

*'The main barrier in some practices is that the GPs don't want what they've got. They wanted a counsellor or something. They didn't want a prescription [on] how to use the workers or have restrictions placed on them and we've got to refocus that way of thinking.'* (PCTE1)

*'The main barrier has been the expectation of the workers and people wanting to use them as they want. They don't want to have restrictions placed on them.'* (PCTE1)

Communication between the primary care team and Trust was seen as key to implementation, as was the assumption that primary care teams would implement the role in the way prescribed by the Trust (which closely followed national guidance). However, some of the PCT executives reported difficulties in creating effective lines of communication:

*'We spent an awful lot of time going round to practices, having evening events and daytime events. Also we've written to them [the GPs] to try and reinforce their roles [the worker's roles] and try and educate practice staff but a lot of them*

*wanted something specific and it didn't seem to filter down to other staff in the practices ... things sometimes broke down I think, partly because of a misunderstanding of why workers were there and what their role was.'* (PCTE2)

*'One of the main problems was around communication and some GPs just didn't get involved or enter into discussion about the worker. So in essence they were getting second-hand information from their practice managers and so on.'* (PCTE5)

From the primary care teams perspective, the Trust's controlling approach created tensions for some practices. This was a particular issue for the two practices that asked for the worker to be withdrawn, since they saw the worker as being 'owned' by the PCT. They felt frustrated that the mental health workers were working in the practice, using practice facilities and seeing 'their' patients, yet were neither directly accountable nor answerable to them:

*'In terms of responsibility in that case, in terms of if something were to go wrong then I know who it would come down to if questions were asked, say, if this is a referral from a non-clinician and the patient committed suicide and they said "Can you tell me how this happened?" And I would have said "Oh, well I didn't know [who] they were".'* (FG4, GP1)

*'I think the real disappointment was that they were employed by the PCT. We had very little to do with their work or sort of how they worked or behaved in practice, which led to very unsatisfactory behaviour and unsatisfactory work.'* (FG5, GP)

Two workers tried to influence the development of the role by adapting and responding to their local environment and population needs:

*'I've often thought if I could do anger management I would because then I wouldn't have to send so many people through secondary care services, which is the whole idea of this role.'* (PCMHW5)

*'I've been thinking that part of the role could be health promotion that sort of thing. I think it would pay for us to go into schools, maybe the sixth form and do some health promotion sort of around anxiety, depression, maybe teenage pregnancy; sort of more outreach work. Also I could help to set up a good mental health website for the practice, I don't know, lots of things really.'* (PCMHW4)

Three of the workers described feeling neither part of primary care nor secondary mental health services, which led to feelings of professional isolation. It was this aspect of the workers' role that appealed to patients, as workers were not seen as part of what was sometimes perceived as the stigmatising mental health services:

*'The difficulty is that I'm based in two practices, supervised somewhere else, line managed somewhere else ... When I make referrals or try and discuss things with the local community mental health team, they're not really interested "Who are you again? What do you do?" I get that lots. They don't see us as part of primary care and here [the practice] doesn't see us as part of them, so we're in like this third non-existent place, limbo ...'* (PCMHW5)

*'We don't really fit that seems to be the problem. We're not really part of the practice, we're certainly not part of the community mental health team, we're just us really, which can be difficult.'* (PCMHW7)

*'I preferred seeing her because I thought she was less formal. You feel there's an air of authority when you sit in front of a counsellor or a doctor but to talk to somebody on a level where there is no formality or superiority, gives you an opportunity to express yourself more, there's no stigma with it. It's not like going to see someone with the label 'Mental Health.'* (M, 29)

Some workers discussed how they felt there was conflict around their role. Priorities and goals for this role are specified by the Department of Health and workers are employed and managed by the PCT. However, workers were expected to fully integrate into the primary care team, involving paying attention to the practice and practice populations goals and priorities:

*'It was really hard at one stage. We had input from all different sides and each lot thought they were telling us what to do for the best. So I had the psychiatry department telling me one thing, the PCT and HOB [Heart of Birmingham PCT] who were concerned with the funding and then the day to day work side of it in surgery.'* (PCMHW2)

*'We get stuff coming through from different people all the time that sometimes conflicts and we're not really sure who we should follow. It isn't always clear who has the priority.'* (PCMHW6)

*'For mental health issues we need someone with a whole person approach, a holistic approach but*

*I think she came with certain ideas from the other workers or the PCT and that wasn't what we got.'* (FG4, PM1)

Those practices and workers, who reported mutual satisfaction with the role, appeared to share a number of distinct working practices. The most important of these included clear communication between the worker and at least one senior member of the practice team and protected time for the worker to discuss issues with the practice. These practices also encouraged a sense of belonging by ensuring workers had a suitable working environment and inviting the worker to practice meetings and team events:

*'They've both been very mature in their outlook and the practice has tried to meet them halfway to check they had all the things they needed for the infrastructure role like computers, actual physical help and support.'* (FG3, GP3)

*'I think in terms of where we placed her in the practice, we took a conscious decision that we would place her near those people she'd use most so she wasn't isolated and we hoped that would help facilitate that team-building atmosphere.'* (FG3, PM1)

*'I told her she could always have access to me because I knew she would need help but it would have been better if we'd had a designated time which I think would have helped her more.'* (FG6, GP1)

## DISCUSSION

### Summary of main findings

This focused evaluation suggests that workers can provide a different more accessible approach to treatment valued by both patients with common mental health problems and primary care teams. It also highlights key issues that PCTs and primary care teams need to address in implementing the role.

### Strengths and limitations of the study

This study is important as it adds to the limited body of evidence evaluating the implementation of new roles into primary care settings. In addition, few studies have explored the value of the role of primary care mental health workers from a multiple-stakeholder perspective using qualitative methodology which is particularly important when seeking patient's opinions. A number of limitations affect the utility of the results. The stakeholders were from a single inner-city PCT which could limit the generalisability of the findings to other areas. The study only includes the views of seven workers. Of the

200 patients contacted, only 66 agreed to participate in a face-to-face interview and it is possible that those who did were more positive about the experience of seeing a primary care mental health worker. A number of authors have suggested that the background of an interviewer may have an effect on the information divulged.<sup>13,14</sup> There is also potential for a power imbalance to develop between the interviewer and patient interviewees when the interviewer is a practising health professional.<sup>15</sup>

### **Comparison with existing literature**

The importance of giving time, provision of information and ability to talk to a friend in an informal non-medicalised way were highly valued by patients in this study and reflect the findings of the literature on the benefits of befriending for people with depression in primary care.<sup>16</sup> Essential aspects of befriending previously reported by patients include opportunities for empathic and sensitive contact; an holistic approach taking into account the complexity of peoples' problems; being allowed to talk; being listened to like a friend and having someone take an interest in them.<sup>17,18</sup> Befriending has more recently been found to be a credible option in psychosis<sup>19</sup> and has also been described as a method of strengthening social ties and promoting mental wellbeing.<sup>20</sup>

Establishing effective contacts and referring patients on to the appropriate service in the voluntary sector has been widely recognised as challenging for some primary care teams, despite the evidence describing the benefits of effective primary care and voluntary sector partnerships. Patients have positively described their experience when referred to a referral facilitation service signposting them to the appropriate voluntary sector service, which is reflected in this study.<sup>21</sup> The difficulties experienced by the two practices who asked for their worker to be removed mirrors some of the experiences of implementing counselling services in primary care settings in the 1990s. Disputes over counsellors' roles and responsibilities and professional accountability<sup>22</sup> led to difficulties in embedding the role in some practices. Conversely, good communication between counsellors and the primary care team was found to help promote integration of counsellors into primary care teams.<sup>23</sup>

### **Implications for developing the role**

From the perspective of most of the primary care teams, workers offered an alternative avenue of care for patients who did not need a referral to secondary mental health care services. From the patients' perspective, workers were seen as an opportunity to be listened to in an atmosphere free of stigma by someone who would help ensure they were not lost to follow up and could access relevant aspects of the voluntary

sector. However, while this role may be beneficial to primary care teams and patients, it raises a number of issues around how best to develop the workers to allow them a degree of autonomy within the NHS system. There are already signs that recruitment to and retention in this role is problematic and perceptions of professional isolation or even 'deprofessionalisation' through an essentially befriending role may further exacerbate this issue. Some PCTs appear to be seeking to overcome this problem by situating workers in secondary care, but this may create its own set of problems in terms of access to primary care and fidelity to the original job description.<sup>24</sup>

Recent initiatives to encourage greater partnership working between statutory and non-statutory sectors aim to make the voluntary sector part of mainstream health service provision.<sup>25</sup> Developing the primary care mental health workers role to work at the interface of the voluntary and health sectors could help to reinforce and strengthen this emerging partnership. Within primary care, recent guidelines advocate the use of the stepped care model for the management of depression.<sup>26</sup> There are a number of studies supporting this, which suggest case management, one facet of the stepped model of care, may help improve delivery of care.<sup>27,28</sup> This could be a potential role for the new mental health workers in helping offer patients additional options for the management of depression.

### **Implications for implementing the role**

The recent 5-year review of the National Service Framework for Mental Health suggests that: 'progress with the new graduate primary care workers has been slower than anticipated'.<sup>29</sup> This study highlights the importance of having an agreed transparent implementation strategy that includes multiple stakeholder perspectives if progress is to be made. Top-down theories of implementation suggest that policy is best implemented in a hierarchical fashion, with policy formulators at the top of the chain and those who implement the policy at the grass roots level at the bottom.<sup>29</sup> Top-down policy relies heavily on control and assumes that those at the bottom will carry out instructions unquestioningly. This study, however, suggests that some primary care teams were unhappy with the top-down approach taken by the PCT, and were concerned about issues of ownership, autonomy and clinical responsibility.

A bottom-up approach also raises potential problems. Lipsky's concept of 'street level bureaucrats' suggests that in terms of implementation, it is the workers on the ground who develop their roles from the 'bottom-up,' adapting and responding to the human dimensions of the environment they work in.<sup>31</sup> The findings in this study support this. Some of the mental health workers, for example, responded to the needs of

their practice, (as they perceived them), by setting up anger or anxiety management groups. However, from a broader policy perspective, changes to a job description at an early stage in the evolution of a role can make cost effectiveness analyses difficult and potentially lead to the birth of a post with an inadequate underpinning evidence base.<sup>32</sup> It could also lead to workers adopting clinical responsibilities beyond their capabilities.

In the majority of practices, in effect, a 'horizontal method' of policy implementation appeared to evolve.<sup>26</sup> Horizontal implementation theory suggests that policy is implemented as a result of continuing interactions between a number of players who negotiate until a consensus is achieved. Horizontal methods often include an element of leadership, with a named individual managing the relatively autonomous individual stakeholders thus facilitating communication. In this evaluation, practices that set time aside for in-house support, recognised the importance of communication between all stakeholders and acknowledged that although the workers were funded by the PCT, they were part of the primary care teams, and were, in practice, adopting aspects of horizontal synthesis theory.

In summary, this study suggests that a prescriptive and hierarchical or a disproportionately local approach to implementation may create tensions and difficulties in implementation. However, if implemented in ways that recognise 'horizontal synthesis' methods, offering access to a primary care mental health worker, who is able to offer befriending, increases patient choice and potentially improves patients' experiences of primary care mental health.

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#### Ethics committee

The West Birmingham Ethics committee granted ethical approval (02/07/462)

#### Competing interests

The authors have stated that there are none

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