

# A qualitative study exploring the barriers and facilitators of implementing a cardiovascular disease risk reducing intervention for people with severe mental illness into primary care contexts across England: the 'PRIMROSE' trial.

Suzan Hassan (✉ [suzan.hassan@ucl.ac.uk](mailto:suzan.hassan@ucl.ac.uk))

University College London

Samira Heinkel

University College London

Alexandra Burton

University College London

Ruth Blackburn

University College London

Tayla McCloud

University College London

Jamie Ross

University College London

David Osborn

University College London

Kate Walters

University College London

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## Research article

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# Abstract

**Background:** People with severe mental illness (SMI) are at greater risk of earlier mortality due to physical health problems including cardiovascular disease (CVD). There is limited work exploring whether physical health interventions for people with SMI can be embedded and/or adopted within specific healthcare settings. This information is necessary to optimise the development of services and interventions within healthcare settings. This study explores the barriers and facilitators of implementing a nurse-delivered intervention ('PRIMROSE') designed to reduce CVD risk in people with SMI in primary care, using Normalisation Process Theory (NPT).

**Methods:** Semi-structured interviews were conducted between April-December 2016 with patients with SMI at risk of CVD who received the PRIMROSE intervention, and practice nurses and healthcare assistants who delivered it in primary care in England. Interviews were audio recorded, transcribed and analysed using thematic analysis. Emergent themes were then mapped on to constructs of NPT.

**Results:** 15 patients and 15 staff participated. The implementation of PRIMROSE was affected by: 1) Coherence, where both staff and patients expressed an understanding of the purpose and value of the intervention, 2) Cognitive participation, including mental health stigma, staff confidence levels, staff knowledge and staff perceptions of the compatibility of the intervention to primary care contexts, 3) Collective action, including lack of patient engagement despite flexible appointment scheduling. Limited time and resources hindered implementation. Positive relationships between staff and patients facilitated implementation, and access to 'in-house' staff support was considered important. Staff skills, knowledge and training facilitated implementation. However, perceptions of the applicability of the intervention to real-world contexts and accessibility of resources sometimes prevented collective action. 4) Reflexive monitoring, where the staff commonly appraised the intervention by reporting its value and identifying ways of improving it.

**Conclusions:** Future interventions for physical health in people with SMI could consider the following items to improve implementation: 1) training for practitioners covering interpersonal skills, mental and physical health, in order to overcome stigma, increase knowledge, confidence and facilitate positive relationships with patients and 2) enabling access to resources including specialist services, additional staff and time.

## Background

It is well established that people with a diagnosis of severe mental illness (SMI) are at greater risk of early mortality compared to the general population due to physical health problems including cardiovascular disease (CVD) (1, 2), and this gap is widening (3). The causes of this health disparity are multi-factorial and interrelated (2). Higher cholesterol, blood pressure, blood glucose and obesity are apparent in people with SMI as well as poorer health behaviours such as smoking, excessive alcohol intake, poor diet and physical inactivity (2). Restricted access to appropriate healthcare has also been reported as a potential

contributing factor, with barriers to access including difficulties around patients attending appointments, knowledge, stigma, lack of interpersonal skills displayed by healthcare professionals (HCPs) and lack of continuity between HCPs (4-7). Current clinical guidance in the United Kingdom (UK) states that both primary and secondary care services should take a more active role in detecting and preventing health problems in people with SMI (8).

There is an emerging body of research investigating the effects of different interventions to reduce physical health problems in people with SMI. Systematic reviews have reported nutrition interventions to be effective at preventing and treating weight gain, bupropion and varenicline to be effective at improving smoking quit rates in the medium and long term, and inconsistencies in the literature on interventions aimed at improving sedentary behaviour and physical activity levels (9-11). It is however unclear whether these interventions are replicable, can be embedded and/or adopted within different healthcare contexts and whether factors related to setting may impact the effectiveness of interventions.

There is limited existing research on factors that affect the delivery of physical healthcare for people with SMI in healthcare settings. Studies conducted in Australia report that the availability of services, geographic location, waiting time, staffing levels, mental health stigma, lack of role responsibility, lack of training, lack of primary care links and increased workload all affect delivery (12, 13). Research in the UK has reported that having appropriate knowledge and skills amongst staff, prioritising this area, information sharing systems, access to time and shared agreement of roles and responsibilities were important (14). Factors preventing healthcare delivery included challenges accessing General Practitioner (GP) and community-based services, challenges adopting healthy behaviours, patients not attending appointments and a lack of awareness among HCPs of CVD risk in people with SMI (15).

We developed a pragmatic behavioural intervention (PRIMROSE) delivered by primary care nurses and healthcare assistants (HCAs) in primary care practices across England to people with SMI, with the aim of reducing their CVD risk (16, 17). The intervention was delivered across 8-12 sessions over 6 months and targeted those from 30-75 years of age. Nurses and HCAs were trained by a team of behavioural psychologists in supporting patients achieve healthy behavioural changes. Nurses and HCAs were given a manual to follow in sessions comprising of eight behavioural strategies: goal setting, making an action plan, recording progress, providing positive feedback, involving supportive others, reviewing progress, coping with setbacks and habit formation. Goals included taking physical health medication, increasing physical activity, improving diet, alcohol or smoking reduction. Nurses and HCAs supported these behaviours using the training they had received and the PRIMROSE manual. The findings from the cluster randomised trial in 76 practices has been published (16, 17). While the intervention was associated with lower costs due to reduced psychiatric admissions, there was no effect on the primary outcome (total cholesterol) and other secondary outcomes compared to usual treatment (16). It is important to understand factors that impeded and/or assisted intervention implementation into primary care contexts to further elucidate findings. There is a lack of work in this area and evidence is needed to help inform future services, clinical guidelines and commissioning groups working to implement physical health interventions for people with SMI in primary care settings.

Qualitative methods are advocated in guidance related to assessing the implementation of complex interventions (18). Additionally, the use of theory is thought to strengthen knowledge and explanations regarding why interventions may or may not work well within specific contexts (18, 19). One theory that explains the dynamics of embedding or 'normalising' a complex intervention within settings is Normalisation Process Theory (NPT) (20, 21). NPT has been applied widely in different populations and healthcare settings, but not yet to a physical health primary care intervention for people with SMI. Applying NPT may facilitate understanding as to whether an intervention to reduce CVD risk in people with SMI can be implemented in primary care. The purpose of the current study was to explore the barriers and facilitators of implementing the PRIMROSE intervention into primary care across England, applying NPT to facilitate a deeper understanding of the factors that affected implementation

## Methods

### *Participants and recruitment*

A random 20% sample of practices randomised to deliver the PRIMROSE intervention in the trial were identified (n=8/38); from which thirty patients receiving the PRIMROSE intervention were invited to participate. Staff were selected if they had delivered at least one PRIMROSE session, attended PRIMROSE training and were not part of the internal PRIMROSE pilot phase (n=31/41 health providers). Staff and patients were approached for participation by researchers (S.He and A.B) via email and letter. Ethical approval for the study was granted by the London - City Road & Hampstead Research Ethics Committee NRES committee, REC ref 12/LO/1934.

### *Data collection*

Face-to-face semi-structured interviews were conducted with participants by two members of the research team (S.He and A.B). None of the researchers had any prior contact with patients. There was prior contact between researchers and staff in terms of training and answering queries or concerns related to the PRIMROSE trial.

Staff interviews took place between April – August 2016, approximately 6-18 months after conducting the final appointment with their last PRIMROSE patient. Patient interviews took place between October – December 2016, approximately 6-9 months after their final intervention appointment. Interviews took place in primary care practices.

Two topic guides aimed at patients and staff were used to guide interviews. These contained open-ended questions on the impact of the intervention on patients, benefits and disadvantages of the intervention, fitting the intervention into current roles and primary care contexts and factors impacting this. Corresponding prompts were added to questions to gain more clarity or detail regarding responses.

Questions in staff and patient topic guides were developed through discussion with the core research team (S.He, A.B, K.W and D.O). The topic guide was piloted on members of the research team and an HCP

to check the relevance of topics and legibility of questions and adapted accordingly.

Before the start of the interview, researchers explained the purpose of the study and encouraged participants to share both negative and positive experiences of receiving and delivering the PRIMROSE intervention. Staff were required to complete a form to ascertain demographic details, whilst patient characteristics were collected during the PRIMROSE trial (16, 17).

All interviews were audio-recorded and transcribed verbatim by an external transcription company. The transcripts were checked against audio-recordings for accuracy by the researchers. Researchers anonymised transcripts by removing all identifiable content.

### ***Data analysis***

Anonymised and corrected transcripts were stored and analysed on NVivo (Version 11) software. The analysis was conducted by researchers with a background in qualitative research, health psychology, psychiatry and mental health research. In the initial analysis researchers (S.He, A.B, R.B and T.M) familiarised themselves with the data by reading the transcripts and then coded the data descriptively to represent emerging topics. The codes were developed through discussion with the research team (S.He, A.B, R.B, T.M, D.O and K.W). This process was iterative and researchers continuously revised and adapted codes until they felt satisfied that the codes represented the data. Once coded, the data were then analysed thematically (22) by S.He and A.B. Two further researchers (S.H & J.R) with an interest in mental health research, process evaluations and implementation science were involved in further developing the themes. These researchers had previously not been involved with the trial or data collection. Themes were identified inductively by searching for commonalities, discordant views and underlying meanings behind the derived codes. The themes were derived iteratively through discussion with the research team (S.H, J.R, A.B, S.He, K.W and D.O).

Following agreement on themes, NPT was applied to move the analysis beyond description and toward explanation. The four main constructs include coherence (i.e. sense-making of the intervention), cognitive participation (i.e. commitment to and engagement with intervention), collective action (i.e. the work that is conducted to facilitate delivery) and reflexive monitoring (i.e. an evaluation of the costs and benefits). Each construct contains sub-components; however, we were particularly interested in the sub-components of collective action, including: interactional workability, contextual integration, skill-set workability and relational integration as this is one of the most defined and used of the subconstructs and particularly helpful in explaining implementation (20, 21). One researcher (S.H) mapped the inductively derived themes to NPT constructs. Details regarding how the NPT constructs were operationalised are provided in Table 1. The mapping process was iterative, moving backward and forward between the emergent themes and the NPT definitions. The mapping process was discussed among researchers (S.H, J.R, A.B and K.W) and revised iteratively until we were satisfied that the themes had been mapped correctly onto the NPT constructs.

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**Table 1. Operationalisation of Normalisation Process Theory.**

## NPT constructs

## Operationalisation of constructs\*

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Coherence	Whether patients and staff were able to understand the purpose of the intervention. Exploring participants views on the meaning of the intervention including whether staff and patients perceived the intervention as beneficial in terms of reducing health problems.
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Cognitive participation	Whether patients and staff were prepared and willing to commit to and engage with the intervention.
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Collective action	Establishing what work was carried out in terms of interactional workability, relational integration, skill-set workability and contextual integration in order to facilitate delivery. This is further explained below.
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*Interactional workability*

How staff encouraged patient interaction with the intervention in the context of primary care practices in terms of accessibility and flexibility of delivery.

*Relational integration*

How the work that was done to facilitate the delivery of the intervention was understood across staff within practices (even if they were not responsible for delivering the intervention) and whether there was cohesion between staff and patients.

*Skill-set workability*

Whether staff and patients perceived that staff possessed the skills, training and knowledge to deliver the intervention.

The practices' ability to support the intervention as well as the fit of the intervention into practice contexts.

*Contextual integration*

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Reflexive  
monitoring

Whether staff and patients reflected on the intervention by appraising it in terms of the benefits and disadvantages and evaluated ways to adapt intervention.

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*\*NPT constructs were operationalised according to NPT construct definitions (20, 21)*

## Results

### *Participant characteristics*

Thirty participants, including 15 nurses and HCAs who delivered PRIMROSE and 15 patients with SMI who received it, took part in the current study. Out of 30 patients approached, six patients did not give a reason for not wanting to take part. Reasons for patient non-participation were: unable to contact (n=3), not feeling well enough to take part (n=2), one patient expressed lack of time, another expressed language difficulties, one was not interested and one suggested they were unable to offer feedback.

Out of 31 staff approached, nine staff did not respond to the invitation to take part. Reasons for staff non-participation included: unable to find time due to demands of current roles (n=2), not yet finished delivering the intervention (n=2) and not being interested (n=3).

The characteristics of staff and patients are presented in Table 2. The sample comprised of both practice nurses and HCAs of different age ranges (25-65 years) with varying degrees of professional experience (from 1 to 30 years). Staff were all White British ethnicity and female. Most staff were previously not involved in research.

The patient sample comprised of participants who were diagnosed with either bipolar disorder or schizophrenia. The age of patients ranged from 30 to 70 years. Patients were mostly male and White ethnicity.

**Table 2. Staff and patient characteristics in the qualitative sample**

	Staff characteristics	Patient characteristics
	N (%)	N (%)
<b>Age group (n, %)</b>		
25-35	3 (20%)	2 (13%)
36-45	1 (6%)	3 (20%)
46-55	7 (47%)	4 (27%)
56-65	4 (27%)	4 (27%)
66-75	-	2 (13%)
<b>Gender (n, %)</b>		
Female	15 (100%)	6 (40%)
Male	-	9 (60%)
<b>Marital Status</b>		
Single	N/A	8 (53%)
Married or cohabiting		7 (47%)
Separated or divorced		-
Widowed		-
<b>Ethnicity (n, %)</b>		
White British*/ White	15* (100%)	13 (87%)
Black	-	-
Asian	-	2 (13%)
Other	-	-
<b>Provider type (n, %)</b>		
Healthcare Assistant	6 (40%)	N/A
Practice Nurse	9 (60%)	

<b>Length of experience</b>		
<b>as a nurse/HCA (years)</b>		N/A
1 to 2	1 (6%)	
3 to 5	3 (20%)	
6 to 10	4 (27%)	
11 to 15	2 (13%)	
16 to 20	1 (7%)	
21 to 30	4 (27%)	
<b>Previous experience</b>		
<b>of research (n, %)</b>		N/A
Yes	6 (40%)	
No	9 (60%)	
<b>Diagnosis</b>		
Schizophrenia/ schizo-affective disorder	N/A	6 (40%)
Bipolar affective disorder		7 (47%)
Other Psychosis		2 (13%)

## ***Findings***

The themes derived from the data are provided in Table 3. These are presented alongside the NPT constructs that themes were mapped to. The themes were discussed with specific reference to, and organised by, the NPT constructs in the written presentation of findings. Some themes mapped on to more than one NPT construct. In these instances, the relevance of the theme regarding different NPT constructs were discussed within each NPT heading.

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**Table 3. Inductively derived themes mapped to NPT constructs**

Themes identified in the raw data	Broad theme/NPT constructs
Clarity of purpose	Coherence
Value of intervention	Coherence
Mental health stigma	Cognitive participation
Confidence to engage	Cognitive participation Skill-set workability (Collective action)
Motivation to engage	Cognitive participation Reflexive monitoring
Compatibility with existing practice	Cognitive participation Interactional workability Contextual integration (Collective action)
Accessibility of intervention	Interactional workability
Engagement with intervention	Interactional workability (Collective action)
Intervention materials	Interactional workability (Collective action)
Resource availability and benefits	Interactional workability Contextual integration (Collective action) Reflexive monitoring
The level of 'in-house' support	Relational integration (Collective action)

Patient – staff alliance	Relational integration (Collective action)
Knowledge	Skill-set workability (Collective action) Reflexive monitoring
Training	Skill-set workability (Collective action) Reflexive monitoring
Skills	Skill-set workability (Collective action)
Modifiability through accessibility	Reflexive monitoring

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## Coherence

The intervention was mostly perceived by patients as coherent in terms of the aim of the intervention. Both staff and patients reported a shared understanding of the benefits of the intervention.

### *Clarity of purpose*

Patients mostly reported a clear understanding of the purpose of the intervention, acknowledging the focus on health improvement in people with SMI to reduce CVD risk. Patients reported that their understanding was facilitated by staff who provided relevant information sheets and explained the purpose.

*“...I thought it was to get an insight into how I was going from time to time, seeing people you know, getting weighed, taking blood pressure and things like that ...I got the original pamphlet and I read that and that kind of told me everything I wanted to know.”* (Patient 12, female, 70’s)

A minority of patients expressed confusion regarding the purpose of the intervention. One patient believed that the intervention was designed to improve mental health outcomes rather than physical health. The lack of understanding appeared to be caused by the GP’s description of the intervention.

*“As I understood it, it was basically, with early intervention, or regular intervention, by your local GP practice, the nurse, normally, then it can offer stability and assistance so people like myself don’t*

*relapse... I was approached by the GP practice, basically saying, would I be happy to take part in a project related to mental health.” (Patient 81, male, 60’s)*

### *Value of intervention*

The intervention was perceived as valuable by patients and staff. Staff reported that they understood the intervention could prevent patients from experiencing later health problems and increase quality of life, as well as reduce financial burden for future health services.

*“I think it would benefit people. Because it’s a positive thing, and it’s working towards improving people’s health and their lifestyles.” (Staff 8, Nurse, 50’s)*

Most patients additionally reported that the intervention would provide an opportunity to make changes and improvements to their health.

*“I thought it would be a good idea to just look at my healthcare and try and make some necessary adjustments so that my health can be improved...” (Patient 112, female, 50’s)*

### **Cognitive participation**

Although most staff and patients understood the purpose and value of the intervention (i.e. coherence), the extent to which staff were cognitively willing to participate, engage and commit to the intervention varied. Stigma surrounding perceptions of people with SMI in some cases resulted in a lack of confidence among staff in their ability to deliver the intervention. In some cases, an understanding (i.e. coherence) of the value of the intervention in terms of helping patients become healthier, motivated staff to deliver the intervention. In other cases, difficulties arising from the contextual environment (collective action/contextual integration) affected cognitive participation.

### *Mental health stigma*

Staff held different views regarding their preconceptions of mental health. There were some prior concerns regarding working with people with SMI. Some staff anticipated problems around the impact of mental health symptoms on attendance and engagement difficulties.

*“We can deal with somebody with diabetes and all of that, and we can tell them this, that and the other, but somebody with mental health, when they’ve got that problem they may not have that understanding. They may not engage for a long period of time. It’s really very difficult... I prefer people who can engage with me.” (Staff 5, Nurse, 40’s)*

However, other staff felt positive about working with patients with SMI and in some cases prior experience within nursing roles enabled staff to feel open toward delivering the intervention.

*“I think you have to be open-minded, as a nurse, to be a good nurse. So I wasn’t intimidated at all, initially” (Staff 4, HCA, 50’s)*

### *Confidence to engage*

Prior concerns regarding working with patients with SMI resulted in a minority of staff lacking confidence in their own ability to provide the intervention, resulting in cognitive disengagement. A lack of confidence appeared to arise from skill-set workability (discussed later).

*"I was out of my depth because it's not my zone at all, and mental health never has been because I don't understand it... It makes me nervous and it makes me unsure, and it makes me feel less confident"* (Staff 5, Nurse, 40's)

This was supported by a minority of patients who had noticed that staff appeared to be lacking in confidence providing the intervention.

*"... she was kind of paddling in the dark to some degree... the impression I got is that, you know, she was just given a pile of information and she had to do her best to interpret..."* (Patient 81, male, 60's)

### *Motivation to engage*

Despite some negative attitudes towards mental illness in some individuals, it was clear that most staff had the motivation and desire to help patients achieve their goals and therefore engage with the intervention. This appeared to stem from the understanding of the its purpose and potential benefits (i.e. coherence).

*"I think probably knowing that you could be a part of helping them, I think that probably influenced us as well, and knowing that if you just gave them that little bit of help then they could improve. I think that's probably the motivation in that."* (Staff 15, Nurse, 60's)

### *Compatibility with existing practice*

Some issues related to cognitive participation were also underpinned by difficulties related to contextual integration (discussed later). Some staff questioned the applicability of the intervention to real-world contexts (cognitive participation) and suggested that the intervention would not fit in within a busy GP practice which subsequently affected their willingness to deliver the intervention going forward.

*"I'm not sure how it would fit in easily in a surgery that's already quite packed. We've got ever-growing lists, so whether it could be done in more of a mental health environment, it may be more appropriate..."* (Staff 13, Nurse, 30's)

### **Collective action**

Several barriers surrounding the work that was needed to facilitate delivery of the intervention were identified. There were some problems related to interactional workability, contextual integration, skill-set

workability and, in some cases, relational integration.

### 1. *Interactional workability*

Despite some prior reluctance to engage in the intervention by staff, most staff made substantial efforts to encourage patient engagement by facilitating accessibility to the intervention. This finding was also reported by patients, and staff arranged appointments to suit their preferences. Despite efforts to facilitate accessibility, staff did face barriers regarding patient engagement. Additionally, both staff and patients found some of the intervention written materials including the use of written health plans, difficult and time-consuming to implement. However, patients reported mixed views about the use of health plans. It was also difficult to operationalise the intervention into routine practice due to the need for adequate time to facilitate engagement and accessibility despite lacking access to time in primary care. Despite this, staff made use of administration support within such contexts to facilitate delivery.

#### 1a. *Accessibility of intervention*

Most staff acknowledged that intervention appointments would sometimes take longer than the time they had available. Difficulties were centred mainly on fitting appointments around additional responsibilities. Despite these difficulties however, staff demonstrated flexibility and scheduled appointments accordingly to increase accessibility.

*“Something, finding slots when we’re so busy, that, that would be a thing as well, so sometimes you think to yourself, well, you know, this patient needs extra time, but actually we haven’t got a slot...to fit her in”*  
(Staff 1, HCA, 40’s)

The flexibility in scheduling appointments was also reported by patients who suggested that staff would arrange appointments when it would suit them and were understanding even if patients did not attend.

*“She suggested dates on the telephone, and sometimes I would phone and say, I’m not available on that day, so an alternative appointment was made, so it had to be mutually convenient for both of us. Obviously, she has other jobs... in the surgery to do as well, so it had to be convenient for her as well.”*  
(Patient 112, female, 50’s)

#### 1b. *Engagement with intervention*

Despite attempts to make the intervention accessible to patients through flexible appointment scheduling, staff reported difficulties related to patient attendance. Staff commonly reported being disappointed when patients were disengaged from the intervention given the time invested to facilitate accessibility.

*"...it was the patients that didn't come. You just get frustrated; you put all of this time and effort into the first appointment and then you never saw them again."* (Staff 10, Nurse, 40's)

### *1c. Intervention materials*

Staff reported that the materials designed for the intervention including the health plans, in some cases acted as barriers to providing the intervention. Some staff reported that patients sometimes struggled in terms of understanding and completing the required documentation and reported it was time-consuming and negatively impacted on the consultation process.

*"I think using the book for something like that, you do need a lot of time to go through it with them...I think maybe the book made it feel too formulized... I don't find that book a very easy layout so I think that was almost a stumbling block. Maybe I didn't understand the book particularly and the patients didn't particularly find it helpful"* (Staff 11, Nurse, 60's)

Patients' views regarding the value of health plans were mixed. Some patients reported that they were sometimes problematic to use in practice. It was suggested that documents were repetitive and were sometimes difficult to fill in. Conversely, others reported that the health plans helped them keep track of the changes they had made.

*"That was okay. A bit repetitive at times because, you know, you were... obviously, the food for four weeks, you tended to be writing a little bit of the same thing..."* (Patient 9, female, 50's)

*"... That booklet or a personal diary would help, because sometimes you can't remember exactly what have you done a week ago, two weeks ago, so it's good to write down some notes. But it's difficult sometimes. One of the difficulties, I found it's difficult to do it on the day sometimes."* (Patient 112, female, 50's)

### *1d. Compatibility with existing practice*

Most staff were concerned about patient engagement issues with intervention appointment attendance. As a result, they suggested that the practicalities of getting patients with SMI to engage within a GP practice would be difficult. They also suggested there would be a need for additional nurse time to facilitate engagement and accessibility. However, the availability of additional nurse time was questionable.

*"I think if we were going to deliver that care in that format and at that intensity, I think it would be quite difficult. Not so much the face-to-face time, but certainly the getting people in... Ringing them once wasn't a problem, just ringing them again and again...if that was going to be part of how we would deliver the care, that could provide difficulties if it was down to me"* (Staff 10, Nurse, 40's)

### *1e. Resource availability and benefits*

Staff frequently commented that another barrier to implementation was the lack of time to complete additional paperwork and administration resource to facilitate this. In other cases, it was clear that staff were engaging with the right people (i.e. interactional workability) to facilitate implementation (i.e. collective action). Some staff accessed support from administration to facilitate intervention delivery.

*“...there were times where I used to go home and I was tearing my hair out...If there was an interested member, perhaps, of admin staff that you could work alongside and say, these are the things that I would like you to do.... Then I don't see any obstacles to run it in general practice.”* (Staff 10, Nurse, 40's)

## *2. Relational integration*

Relationships between practice staff and staff delivering the intervention and patients were considered as important in the implementation of the intervention. The availability of team support within some practices facilitated intervention delivery, whilst the lack of availability hindered progress. A positive relationship between patient and staff members encouraged confidence and trust in staff members to deliver the intervention.

### *2a. The level of 'in-house' support*

Most staff suggested that they required support from team members within practices to deliver the intervention. There was a need for access to health advice for difficult cases when staff were unsure. However, there was a variation between the level of teamwork within different practices to facilitate intervention delivery. This sometimes acted as a barrier to providing the intervention, particularly in cases where permission was required for prescribing medications and senior staff members were unavailable.

*“I did feel as if I was on my own a little bit in the surgery... There was just not support as in, I'm worried about this patient, but it was maybe just reading consultation notes, that sort of thing.”* (Staff 10, Nurse, 40's)

The differences between team working across different practices were apparent when other staff reported that senior members within their practice were willing to provide advice regarding patients, which facilitated intervention delivery.

*“I've always got backup. I wouldn't have hesitation in asking any of the senior and the qualified staff. I think that we've got the backup here to do a really good job”* (Staff 14, Nurse, 50's)

### *2b. Patient – staff alliance*

It was apparent that some patients and staff had formed close therapeutic relationships. Most staff were aware that in order to ensure that patients felt comfortable engaging with the intervention, and instil

confidence in their ability of providing it, it was important to establish connections with patients.

*“Making them feel comfortable by making a relationship with them to start with... And that is making a relationship with them to come back and encouraging them in their own way.”* (Staff 11, Nurse, 60's)

As a result of the relationships patients had formed with staff, most patients felt positive about interacting with staff and found that this increased their willingness to engage with the intervention.

*“...we had quite a good relationship, she's very supportive and I think she understood about me personally, obviously having my medical record, that it was the medication that stopped me losing weight ....”*

(Patient 12, female, 70's)

### 3. Skill set workability

Staff knowledge regarding mental health were both barriers and facilitators to intervention delivery. Most staff appeared knowledgeable regarding physical health. Once staff had received the PRIMROSE study intervention training, it was clear that they developed valuable skills that aided intervention delivery.

#### 3a. Knowledge

Most staff reported a lack of experience working with patients with mental health problems resulting in a lack of knowledge in this area. As a result, they felt anxious about delivering the intervention (i.e. lack of confidence to engage, cognitive participation). One staff member suggested that the intervention was not in keeping with her knowledge and therefore it would be more appropriate that patients were seen in mental health settings.

*“I just think better in a mental health environment, with the nurses that already have that knowledge of conditions. Because they were very limited on what knowledge we do know about mental health.”* (Staff 13, Nurse, 30's)

In contrast, staff with prior experience with mental health patients were more knowledgeable about interacting with people with mental health and less anxious delivering the intervention. In some cases, this prior experience facilitated their knowledge on delivering the intervention to this population.

*“Maybe I was using the tools and the skills I used for really poorly mentally ill patients that were having to be put on a ward for their own safety.”* (Staff 14, Nurse, 50's)

Whilst there was a mixture of staff that had knowledge of mental health, it was clear that most staff had some form of knowledge of physical health as a result of their prior experience.

*“... I do the NHS health checks here, if their risk is high and their total cholesterol is high or their ratio is high, I will actually go and initiate a start on the total statin 20mg...if the patient was coming to me*

wanting to lower their cholesterol or lower their blood pressure, then I have the tools that I can, advise them on that” (Staff 14, Nurse, 50’s)

### *3b. Training*

Most staff reported that the training delivered prior to the intervention was essential in increasing their knowledge of how the intervention could be delivered. In most cases staff reported that the training increased their confidence and prepared them in terms of how to engage with people with SMI.

*“...the training you gave us was amazing, very helpful, I wouldn’t have been able to do it without it, just as a background of the different illnesses and going back to basics for us...And also we had some training on communication and body language and things like that, which was a good refresher, because you forget.”* (Staff 2, HCA, 50’s)

However, not all patients believed that staff had been trained adequately. One patient felt that HCAs had less training and were consequently unable to deliver the intervention.

*“We had to use Health Care Assistants, who maybe didn’t have quite as much training...”* (Patient 17, male, 40’s)

### *3c. Skills*

Some patients reported on the skills that staff members used when delivering the intervention. It was evident that staff provided advice when necessary, displayed patience when interacting with patients, were clear, encouraging and positive.

*“...sometimes I wasn’t sure, but then <practice nurse> would kind of give me a bit of hand with ideas, and then we’d kind of come up with it together...it was good...”* (Patient 6, female, 30’s)

This in some cases was reinforced by staff who commonly reported attempts to make appointments engaging by interacting with patients and providing guidance when required.

*“...when a patient comes in, I try to make it as much fun as possible as well, because doing that... it makes it more comfortable for the patient, I think.”* (Staff 1, HCA, 40’s)

## *4. Contextual integration*

The integration of the intervention into practice contexts contained challenges. There was a lack of compatibility between the intervention and real-world contexts. Additionally, resources including time

were required to successfully implement the intervention and the availability and time taken to identify this in some cases acted as a barrier to delivering the intervention.

#### *4a. Compatibility with existing practice*

Although staff understood the purpose and value of the intervention (i.e. coherence) and were mostly willing to deliver it (i.e. cognitive participation), a minority of staff questioned the applicability of the intervention to real-world contexts. One staff member questioned the structured nature of the intervention and reported that it sometimes felt unnatural.

*"...we need to follow these questions and we need to do it this way, but that's not real life and that's not how we would speak to our ordinary patients that don't have a mental health illness... you had to follow this stream of questioning, and that didn't work...It wasn't comfortable because that's not the normal of working...."* (Staff 5, Nurse, 40's)

The difference between GP and intervention appointments was further highlighted by patients. Patients expressed that more time was available in intervention appointments with care that felt holistic compared to GP appointments.

*"This was totally different. This is very patient-centred... From my view is that it's very much based on a holistic approach of the patient. So it's patient-centric and in looking at everything whereas a normal GP appointment is five minutes and it's transactional..."* (Patient 17, male, 40's)

#### *4b. Resource availability and benefits*

Staff described that one of the main intervention functions involved searching for available local services that patients could be referred to for additional support in reducing physical health problems. However, one of the barriers to implementing the intervention was finding the time required to look for such resources as well as the lack of availability of local services.

*"...part of the Primrose it was to look what was available in the area, and to be perfectly honest I didn't have time. We did some of it but you just don't... you haven't always got time to sit and read through a directory of things and see what's around in the city."* (Staff 5, Nurse, 40's)

The need for external resources to implement the intervention was highlighted where staff had successfully located resources. They suggested that this facilitated easier access to resources which appeared to help patients achieve specific health goals.

*"Another person was referred to a dietician. As I said, that was in regard to his cholesterol, and he was referred to a specialist, as well. And I think that probably happened a bit more quickly than it might have done... I think we're quite lucky, out here, that you can refer people on different groups, clubs..."* (Staff 4, HCA, 50's)

## Reflexive monitoring

In some cases, staff appraised the value of the intervention by reflecting on the knowledge they had gained from implementing it and the potential benefits of it (cognitive participation). When evaluating ways to adapt the intervention, it was suggested that there was a need for a PRIMROSE designated clinic within future practices, further training and technology to make the intervention more workable.

### *Knowledge*

As a result of the intervention, staff developed increased knowledge of physical health problems. Staff perceived the knowledge they gained as valuable and some reported that they used the knowledge they developed from the intervention and applied it to other patients they saw within their practice.

*“As I say, already with the diabetics it’s just made me have a slightly different approach. When I did my prescribing training that had a bit of an impact as well.”* (Staff 10, Nurse, 40’s)

### *Modifiability through accessibility*

As apparent in interactional workability (accessibility), staff made necessary adjustments to fit intervention appointments into routine practice in settings where time was limited. Some staff suggested that a designated timeslot could be developed for patients within GP surgeries to better integrate the intervention and allow more time for appointments.

*“...rather than have the appointments scattered, have an actual little clinic for it, and then let, let people know what day that you’re running and to come in...”* (Staff 1, HCA, 40’s)

### *Training*

There was evidence that staff were evaluating the intervention and suggesting changes to make it more workable and sustainable as they delivered it. This was highlighted in requests for additional training where some staff suggested the training could be reinforced during the intervention.

*“... it seemed to sort of suit what we had to do but, like you say, perhaps something in the interim would be good”* (Staff 12, HCA, 30’s)

### *Resource availability and benefits*

Some patients suggested that there was a need for current digital technology in order to track their progress during the intervention. However, the intervention did not facilitate access to these types of tools, and GP practices in routine settings do not have access to such facilities.

*“I have an apple iPhone and I track my weight and my BMI and my measurements on my phone. And I would have liked something like that could have tracked it, not necessarily that it was always on paper.”*

(Patient 17, male, 40's)

## Discussion

The aim of this study was to explore the barriers and facilitators of implementing a behavioural CVD risk-reducing intervention for people with SMI in primary care, using NPT. We identified several factors that affected the 'normalisation' of this type of intervention into primary care contexts as defined by NPT. Cognitive participation among staff and patients was variable, despite both groups perceiving the intervention as coherent. This was influenced by stigma, confidence levels, prior knowledge, the prospect of helping patients become healthier and the perception of whether the intervention could be applied in primary care. It was also apparent that elements of interactional workability, relational integration, skill-set workability and contextual integration affected collective action (i.e. work that was done to implement the intervention). Interactional workability of the intervention was affected by the engagement of patients with the intervention, despite efforts to increase accessibility. Limited time and resources acted as barriers to implementation. Relational integration, including access to support within practices and the relationships between staff and patients both facilitated and hindered intervention delivery. Skill-set workability including skills, knowledge and training, facilitated implementation. Most staff questioned the applicability to real-world contexts (coherence) and accessibility of resource (contextual integration). Staff and patients commonly appraised the value of the intervention both positively and negatively (i.e. reflexive monitoring) and acknowledged that the intervention could be further developed. Suggestions to facilitate implementation included having a designated time slot within practices, more training and the use of digital technology.

A common finding in the literature is that mental health stigma negatively impacts the delivery and implementation of physical healthcare to patients with SMI (12, 15). We also found that staff willingness to deliver PRIMROSE (i.e. cognitive participation) was in some cases affected by negative perceptions of mental health, which subsequently influenced confidence to deliver the intervention. This appeared to stem from skill-set workability and a lack of knowledge in mental health. This suggests that more work is needed to instil confidence in primary care professionals in terms of engaging with people with SMI and tackling stigma. This notion was further supported where some staff reported that prior experience and knowledge in mental health meant that they were more willing to deliver the intervention, and PRIMROSE training further increased confidence. Thus, mental health specific training for primary care

professionals (practice nurses and health care professionals) could help to facilitate the implementation of physical health interventions in people with SMI. Recent work supports the value of training primary care professionals in mental health, with findings suggesting improvements to knowledge, attitudes and practice (23). We also found that having physical health knowledge played an important role in facilitating implementation, which mirrored previous findings (13-15). Therefore, training of primary care teams in both physical and mental health-specific knowledge could facilitate the implementation of physical health interventions in people with SMI.

Previous work reported that patients with SMI find it difficult to access appointments in primary care, consequently affecting the uptake of physical health interventions (7, 15). In contrast, despite efforts to maximise accessibility through flexible appointment scheduling, it appeared that patients were in some cases still unwilling to engage, which subsequently negatively impacted implementation. This was consistent with previous work that suggested that lack of engagement with appointments impeded physical health intervention delivery (15).

It was previously reported that a lack of interpersonal skills displayed by HCPs and lack of continuity of care between different HCPs impeded access to and implementation of physical health interventions for people with SMI (6, 7, 14, 15). We also found that relational integration, in terms of the relationships formed between staff and patients was particularly integral to the implementation of the PRIMROSE intervention. There was a continuity of care for those that did attend appointments frequently which subsequently facilitated positive relationships with staff. It is possible that one-to-one contact with the same HCP enabled patients to feel more comfortable, more trusting of primary care professionals and therefore more likely to engage with the intervention. The value of continuity of care for people with SMI is supported in other work where ongoing personal relationships facilitate trust and are central for mental health recovery (24). This may explain findings from the trial that the PRIMROSE intervention was associated with lower costs due to reduced psychiatric admissions (16).

A common finding was that staff questioned the contextual integration of the intervention; most staff did not perceive the intervention as applicable to real-world practice, which was influenced by a lack of access to resources, time, and staff support. These findings are well cited in previous work where the lack of availability of services, appointment waiting times, staffing levels and challenges surrounding increased workload affect the delivery and implementation of physical healthcare for people with SMI (12-14). Conversely, we found that when staff did have access to specialist resources and designated PRIMROSE appointment slots, this facilitated intervention delivery. However, primary care is often an over-stretched service and if interventions of this kind are to be implemented in such settings, more consideration must be given to the resources required to facilitate successful delivery.

## **Implications for practice**

In light of our findings, we recommend that the following should be taken into account when implementing physical health interventions for people with SMI in primary care: a) tailored mental and physical health training for primary care professionals to change negative attitudes, overcome stigma

and increase knowledge and confidence in engaging with patients with SMI, b) application of interpersonal skills when engaging with patients, and access to the same HCPs to increase continuity of care and facilitate positive relationships and trust between staff and patients and c) increasing accessibility to resources including specialist services, more staff and designated time-slots for people with SMI in primary care settings.

## **Limitations and strengths**

Overall, the sample that took part in the current study was representative of both staff and patients that took part in the PRIMROSE study, in terms of age, gender, job role (staff), years of experience (staff) and mental health diagnosis (patients). However, in terms of the generalisability of the study to the wider population, there was a lack of diversity among participants in terms of ethnicity (both groups) and gender (staff). Patients and staff were also interviewed sometime after they had delivered and received the intervention, which may have affected recall in some cases.

Further, the role of the researchers (S.He, A.B) should also be considered when interpreting the findings. Researchers had prior involvement in PRIMROSE and prior contact with staff delivering PRIMROSE. The same researchers were also responsible for conducting staff interviews and coding transcripts. It is possible that researchers' pre-conceptions of staff and knowledge about PRIMROSE may have influenced their interpretation of findings. However, attempts to minimise this possibility included discussion with the wider research team (D.O and K.W). Further, two other researchers (S.H & J.R) not involved in the PRIMROSE trial, data collection or data coding contributed toward the identification of themes and therefore approached the data afresh. Additionally, prior relationships between staff and researchers (S.He, A.B) may have influenced staff responses in terms of social desirability. However, researchers clarified at the start of interviews that all perspectives including both negative and positive views were important and ensured that non-leading questions were posed.

Finally, a further strength is that the use of the NPT facilitated a greater understanding of explaining implementation. We applied the NPT using an inductive data-driven approach, whereby themes were identified in the raw data first and then mapped to NPT constructs. Further, we consulted an expert in implementation science with experience in the application of the NPT during the mapping process (J.R) and held discussion meetings among the broader team (S.H, J.R, A.B, D.O and K.W) until we were satisfied that the findings had been mapped to the NPT correctly.

## **Conclusions**

To our knowledge, this is one of the first studies to explore the implementation of a behavioural physical health intervention delivered by primary care staff to patients with SMI in primary care practices using NPT. Successful implementation hinged on staff preconceptions, experience and knowledge of mental health, training, physical health knowledge, continuity of care and relationships between staff and

patients, interpersonal skills displayed by staff and contextual factors including resource. Our findings should be used as basis for informing the implementation of future interventions into primary care settings.

## Abbreviations

CVD Cardiovascular disease

SMI Severe mental illness

HCA Healthcare assistant

HCP Healthcare professional

NPT Normalisation process theory

UK United Kingdom

PRIMROSE Prediction and management of cardiovascular disease risk for people with severe mental illnesses: A research programme and trial in primary care

GP General Practitioner

## Declarations

### *Ethics approval and consent to participate*

Both staff and patients were provided with information sheets detailing the purpose of the study. All participants provided their written consent prior to taking part in the study. The study was approved by the London - City Road & Hampstead Research Ethics Committee NRES committee, REC ref 12/LO/1934.

### *Consent for publication*

Not applicable.

### *Availability of data and materials*

The data are not publicly available as they contain confidential information.

### *Competing interests*

None.

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### *Authors' contributions*

DO and KW conceived the study. DO, KW, S.He and A.B developed the protocol, S He and AB collected and inductively coded the data. T.M and R.B coded the data. S.H wrote the paper, analysed the data in terms of thematic interpretation and mapped themes to NPT constructs. The following authors discussed the data, the thematic interpretation and mapping of the themes to the NPT: S.H, A.B, J.R, D.O and K.W. All authors read and approved the manuscript.

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### *Authors' information*

S.H is undertaking a PhD at University College London.

S.He was the Trial Coordinator on the PRIMROSE study at University College London.

A.B is a Senior Research Fellow at University College London and was the Trial Manager of the PRIMROSE study

T.M is a PhD student at University College London and was a Research Assistant on the PRIMROSE study.

R.B is a Research Fellow at University College London and undertook her PhD as part of the PRIMROSE study team

J.R is a Senior Research Fellow Implementation Scientist at University College London.

D.O was the Chief Investigator of the PRIMROSE study and Professor of Psychiatric Epidemiology at University College London. K.W was deputy lead on the PRIMROSE study and Professor of Primary Care and Epidemiology at University College London

## **References**

1. Correll CU, Solmi M, Veronese N, Bortolato B, Rosson S, Santonastaso P, et al. Prevalence, incidence and mortality from cardiovascular disease in patients with pooled and specific severe mental illness: a large-scale meta-analysis of 3,211,768 patients and 113,383,368 controls. *World Psychiatry*. 2017;16(2):163-80.
2. De Hert M, Correll CU, Bobes J, Cetkovich-Bakmas M, Cohen D, Asai I, et al. Physical illness in patients with severe mental disorders. I. Prevalence, impact of medications and disparities in health care. *World Psychiatry*. 2011;10(1):52-77.
3. Hayes JF, Marston L, Walters K, King MB, Osborn DPJ. Mortality gap for people with bipolar disorder and schizophrenia: UK-based cohort study 2000-2014. *Br J Psychiatry*. 2017;211(3):175-81.
4. Lawrence D, Kisely S. Inequalities in healthcare provision for people with severe mental illness. *Journal of Psychopharmacology*. 2010;24(11):61-8.
5. Wright CA, Osborn DP, Nazareth I, King MB. Prevention of coronary heart disease in people with severe mental illnesses: A qualitative study of patient and professionals' preferences for care. *BMC Psychiatry*. 2006;6:16:1-16.
6. Hardy S, Deane K, Gray R. The Northhampton Physical Health and Wellbeing project: the views of patients with severe mental illness about their health check. *Mental Health Family Medicine*. 2012;9:2:33-40.
7. McCabe M, Leas L. A qualitative study of primary health care access, barriers and satisfaction among people with mental illness. *Psychology, Health & Medicine*. 2008;13:303-12.
8. The Five Year Forward View for Mental Health. In: Strategy MHT, editor. England 2016. p. 1-81.
9. Teasdale SB, Ward PB, Rosenbaum S, Samaras K, Stubbs B. Solving a weighty problem: systematic review and meta-analysis of nutrition interventions in severe mental illness. *Br J Psychiatry*. 2017;210(2):110-8.
10. Peckham E, Brabyn S, Cook L, Tew G, Gilbody S. Smoking cessation in severe mental ill health: what works? an updated systematic review and meta-analysis. *BMC Psychiatry*. 2017;17(1):252.
11. Ashown-Franks G, Williams J, Vancampfort D, Firth J, Schuch F, Hubbard K, et al. Is it possible for people with severe mental illness to sit less and move more? A systematic review of interventions to increase physical activity or reduce sedentary behaviour. *Schizophrenia Research*. 2018;202:3-16.
12. Ehrlich C, Kendall E, Frey N, Kisely S, Crowe E, Crompton D. Improving the physical health of people with severe mental illness: Boundaries of care provision. *International Journal of Mental Health Nursing* 2013;23.
13. Organ B, Nicolson E, Castle D. Implementing a physical health strategy in a mental health service. *Australasian Psychiatry*. 2010;18(5):456-9.
14. McBain HB, Mulligan K, Lamontagne-Godwin F, Jones J, Haddad M, Flood D, et al. Implementation of recommended type 2 diabetes care for people with severe mental illness - a qualitative exploration with healthcare professionals. *BMC Psychiatry*. 2016;16:222.

15. Burton A, Osborn D, Atkins L, Michie S, Gray B, Stevenson F, et al. Lowering Cardiovascular Disease Risk for People with Severe Mental Illnesses in Primary Care: A Focus Group Study. *PLoS One*. 2015;10(8):e0136603.
16. Osborn D, Burton A, Hunter R, Marston L, Atkins L, Barnes T, et al. Clinical and cost-effectiveness of an intervention for reducing cholesterol and cardiovascular risk for people with severe mental illness in English primary care: a cluster randomised controlled trial. *Lancet Psychiatry*. 2018;5(2):145-54.
17. Osborn D, Burton A, Walters K, Nazareth I, Heinkel S, Atkins L, et al. Evaluating the clinical and cost effectiveness of a behaviour change intervention for lowering cardiovascular disease risk for people with severe mental illnesses in primary care (PRIMROSE study): study protocol for a cluster randomised controlled trial. *Trials*. 2016;17:80.
18. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ*. 2015;350:h1258.
19. Nilsen P. Making sense of implementation theories, models and frameworks. *Implement Sci*. 2015;10:53.
20. May C, Finch T. Implementing, Embedding, and Integrating Practices: An Outline of Normalization Process Theory. *Sociology*. 2009;43(3):535-54.
21. May CR, Mair F, Finch T, MacFarlane A, Dowrick C, Treweek S, et al. Development of a theory of implementation and integration: Normalization Process Theory. *Implementation Science*. 2009;4:29.
22. Braun V, Clarke V. Using thematic analysis in psychology. *Qualitative Research in Psychology*. 2006;3(2):77-101.
23. Ayano G, Assefa D, Haile K, Chaka A, Haile K, Solomon M, et al. Mental health training for primary health care workers and implication for success of integration of mental health into primary care: evaluation of effect on knowledge, attitude and practices (KAP). *Int J Ment Health Syst*. 2017;11:63.
24. Biringer E, Hartveit M, Sundfor B, Ruud T, Borg M. Continuity of care as experienced by mental health service users - a qualitative study. *BMC Health Serv Res*. 2017;17(1):763.