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Training to Enhance Psychiatrist Communication with Patients with Psychosis (TEMPO): A Cluster Randomized Controlled Trial

Running Title: Enhancing Psychiatrist-Patient Communication

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#### **Abstract**

#### **Background**

A better therapeutic relationship predicts better outcomes. However, there is no trial based evidence on how to improve therapeutic relationships in psychosis.

## **Aims**

To test the effectiveness of communication training for psychiatrists on improving shared understanding and the therapeutic relationship.

#### Methods

In a cluster randomized controlled trial in the U.K., 21 psychiatrists were randomized. 97 (51% of those approached) outpatients with schizophrenia/schizoaffective disorder were recruited. 64 (66% of the sample recruited at baseline) were followed up after 5 months. The intervention group received four group and one individualized session. The primary outcome, rated blind, was psychiatrist effort in establishing shared understanding, self-repair. Secondary outcome was the therapeutic relationship.

#### Results

Psychiatrists receiving the intervention used 44% more self-repair than the control group (6.4, 95% CI 1.46 to 11.33, p<.011, a large effect) adjusting for baseline self-repair. Psychiatrists rated the therapeutic relationship more positively (0.20, 95%CI 0.03 to 0.37, p=.022, a medium effect), as did patients (0.21, 95% CI 0.01 to 0.41, p=.043, a medium effect).

#### **Conclusions**

Shared understanding can be successfully targeted in training and improves relationships in treating psychosis.

#### **Trial Registration**

Current Controlled Trials ISRCTN94846422

#### Introduction:

A better therapeutic relationship in the treatment of psychosis predicts better treatment adherence, less severe symptoms, better social functioning and fewer hospitalisations.<sup>1–4</sup> A recent meta analysis found the odds of a patient adhering to treatment to be 2.16 times greater if there is a good doctor-patient relationship.<sup>5</sup> However, although patients rate the therapeutic relationship as the most important component of psychiatric care,<sup>6</sup> currently there are no trial based interventions for how psychiatrists can improve the therapeutic relationship.

The psychiatrist-patient therapeutic relationship is negotiated in psychiatrist-patient communication and psychiatrists consider effective communication skills to be one of the most important characteristics of a good psychiatrist. 1.7 Hence, improving communication is central to improving the relationship. Using conversation analysis, a method increasingly applied to medicine which analyses what people do rather than what they say they do<sup>8,9</sup>, previous research identified a lack of shared understanding in psychiatrist-patient communication in the treatment of psychosis. This often centred on exchanges about psychotic symptoms in the context of mental state assessment. Patients repeatedly attempted to discuss the content and emotional consequences of their hallucinations and delusions, whilst psychiatrists tended to avoid engaging with these concerns in an attempt to avoid disagreement. This led to patients asking direct questions about these experiences (e.g. "Why don't people believe me?" "Do you believe me?") in an attempt to establish a shared understanding. 10

One specific index of good communication is 'self-repair', explained in detail elsewhere.<sup>11–12</sup> This is a conversation analytic term, which reflects attempts to achieve shared understanding. It refers to the 'online' processes of editing or reworking an utterance while it is being produced. Self-repairs are ubiquitous in natural, unscripted dialgoue and have proved to be a useful measure of how hard people are working to make their talk understandable and acceptable to the listener in conversation generally and in psychiatric encounters.<sup>13,14</sup> For example, in the following excerpt, the psychiatrist asks the patient about reducing or stopping his procyclidine, reformulating the utterance as he produces it.

I mean (1) what if we- ah er hhh (2) what would your thoughts be about- (3) what if I said to you well we should look about reducing them or stopping them, what would you think about that?

His first formulation "what if we-" is abandoned and reworked as "what would your thoughts be about-". This is reworked again as "what if I said to you well we should look about reducing or stopping them?". The final formulation presents a hypothethical proposal for the patient to consider, indicating that the subsequent action will take the patient's position into account. In a previous observational study of psychiatrist-patient communication, more psychiatist self-repair was associated with a better patient rated therapeutic relationship. In non-medical interaction, self-repair has also been identified as an index of effort by conversational partners in sustaining mutual intelligibility in dialogue.

Currently mental health professionals receive little specific training, beyond basic communication and counselling skills, in how to communicate effectively with patients with psychosis. We developed a brief training programme for psychiatrists based on research findings that psychiatrist-patient shared understanding – assessed by means of psychiatrist 'self-repair' – is associated with better relationships <sup>14,15</sup>. The training was novel as it was developed from micro-analysis of psychiatrist-patient communication in previously recorded routine psychiatric encounters. It focused on the challenges of communicating in this therapeutic context along with effective ways of overcoming these challenges and empowering patients. This trial tested whether the novel training programme would increase psychiatrist self-repair and improve therapeutic relationships.

#### Methods

#### Study design

This was a cluster randomized control trial. Psychiatrists were randomized to the training or control group.

Data was collected from psychiatrists and their patients at two time points: baseline, i.e. before psychiatrists received the training, and follow-up, i.e., at the first outpatient encounter after the training for each psychiatrist-patient pair (approximately 5 months after baseline). At baseline and follow-up, encounters

between participating psychiatrists and their patients were video recorded in the clinic as usual. Researchers set up the camera and left the room. Psychiatrists and patients completed questionnaires.

#### Sample size

The target sample size was 72 patients (and 12 psychiatrists), i.e., 36 patients in each group, providing 85% power at the 5% significance level to detect an effect size of 1 (a doubling in the rate of repair) based on an assumed correlation between pre and post training measures of 0.7 and an intracluster correlation coefficient (ICC) of 0.65 in a previous study. The As there was more psychiatrist turnover than anticipated during recruitment, additional participants were recruited so that the final sample size was 97 patients and 21 psychiatrists.

### **Participants**

Recruitment took place between September 2011 and October 2012.

Psychiatrist inclusion criteria were: specialist psychiatric trainees working in outpatient clinics or community mental health teams. Psychiatrists working at this level have basic knowledge and experience in psychiatry gained through at least three years core psychiatric training and practice without direct supervision.

Patient inclusion criteria were: adults aged 18-65; meeting ICD-10 criteria for a diagnosis of schizophrenia or schizoaffective disorder; currently attending psychiatric outpatients or being cared for by community mental health teams; capable of giving informed consent. Exclusion criteria were: organic impairment or an encounter requiring an interpreter.

#### Intervention

The training was developed over one year by specialists in communication in psychiatry (RM, DK and PJ) and general medicine (AC) with input from service users. It was fully manualized (available in print/ DVD on request or online

http://medicine.exeter.ac.uk/media/universityofexeter/medicalschool/profiles/TEMPO\_full\_manual.pdf). Four

sessions focused on (1) understanding the patient with psychotic experiences: reflecting on the patient's experience and the professional and emotional response to psychotic symptoms; (2) communication techniques for working with positive and negative symptoms; (3) empowering the patient: agenda setting at the start of the meeting and explaining/ normalising psychosis; and (4) involvement in decision making about medication.<sup>2</sup>

The programme was based on previous research highlighting: engaging with the patient to acknowledge their distressing experience without an underlying goal of changing the patient's beliefs;<sup>10,18</sup> negative symptoms as protective and working with patients with long standing negative symptoms to set their own, albeit small, treatment goals;<sup>19</sup> and, involving the patient in decisions about treatment.<sup>2</sup>

The training was administered in four consecutive weekly group sessions lasting three hours each and one individualized feedback session where participants reflected on their video-recorded communication with patients in the clinic. Each session was run by two facilitators (RM, AC, DK, PB). The weekly interval facilitated practicing new skills with different patients and feeding back positive and negative experiences in the next session. The sessions were delivered to groups of up to 9 participants. Each session included transcripts and video-clips of each topic (e.g. delusions, agenda setting, decision making) in previously recorded psychiatrist-patient encounters using high levels of self-repair for each topic. 1,2,10,17 Clips of excerpts, previously micro-analysed using conversation analysis, were played and then stopped to ask participants how they would respond to a particular patient utterance. This stimulated group discussions reflecting on alternative ways of communicating. This was followed by role-play trying out new ways of communicating with each other and simulated patients (professional actors) along with the use of real time video-feedback. The role-plays used actual scenarios from video-recorded encounters, e.g., an exchange where a patient wants to come off medication but the psychiatrist does not support this.

In the first session, psychiatrists participated in a simulated 'hearing voices exercise'.<sup>20</sup> Psychiatrists performed various tasks (e.g. a cognitive assessment) while listening to simulated voices. This exercise was

highly rated by the participants, with most commenting on how distressing it was and that they now understood why patients feel a need to make sense of such experiences.

#### **Control condition**

Psychiatrists in the control condition did not receive the training and delivered treatment as usual.

#### Framework for evaluating the training

The framework for evaluating the training was that psychiatrists would feel more confident in communicating with patients with psychosis at the end of the training, apply the new communication skills - reflected behaviourally in increased use of self-repair - leading to improved therapeutic relationships from both psychiatrist and patient perspectives. Each of these outcomes was assessed.

#### **Outcome measures**

### **Primary Outcome**

Self-repair

The pre-determined primary outcome was psychiatrist self-repair in outpatient encounters with participating patients after the training, reflecting engagement with the patient and effort in establishing shared understanding. All pre- and post-training encounters were transcribed and self-repair was automatically annotated on the transcripts using a computer programme STIR to detect self-repair. STIR detects the presence and extent of self-repairs, including repetitions, substitutions and deletions by detecting key phrases that indicate repair ("er", "sorry", "I mean" etc.), and using statistical measures of fluency and likely sentential sequence. The STIR programme has been validated in clinical and non-clinical data and with people for whom English is not a first language. <sup>21,22</sup> The accuracy (i.e. F-score) of the STIR algorithms' classifications of self-repairs applied to psychiatric data was 0.68. <sup>21</sup> To adjust for number of words spoken by each psychiatrist, self-repair was normalized by calculating mean number of self-repairs per 1000 words.

## Secondary Outcomes

#### **Psychiatrist Confidence**

A self-rated questionnaire to assess psychiatrist self-confidence in communicating with patients with psychosis before and after the training was developed. Ten items (rated from 0 to 10) relating to each area in the training (e.g. I feel comfortable communicating with patients with negative symptoms, I feel comfortable explaining psychotic illness to patients). A mean score was calculated, ranging from 0 to 10, a higher score indicating higher self-confidence.

#### Therapeutic relationship

The therapeutic relationship was assessed using the Scale To Assess Therapeutic Relationship (STAR),<sup>23</sup> by each patient and psychiatrist at baseline and follow-up. The STAR scale was developed in a four year study beginning with Item generation from interviews with patients and professionals and existing therapeutic relationship scales before rigorous psychometric validation. <sup>23</sup> STAR has a patient and professional version. Each version has 12 items and 3 distinct factors: positive collaboration, positive clinician input and non-supportive clinician input and emotional difficulties. The total score range is 0-48 (a higher score=a better relationship). Length of therapeutic relationship was documented.

Originally, a further follow-up point was planned, six months after the post-training encounters were recorded. However, this turned out to be impractical because many of the psychiatrists rotated posts after one year and so were no longer treating the patients in the trial.

#### **Procedure**

Consent was sought from individual psychiatrists prior to randomization by the researchers on the study (PJ and JD). Specialist psychiatric trainees working in outpatient clinics in East and North East London were identified. The number of eligible trainees was lower than anticipated. Hence, the inclusion criteria were widened to include fully qualified psychiatrists, i.e., Staff and Associate Specialist Grade (SASG) and consultant psychiatrists. Information letters were sent to 35 psychiatrists. Participating psychiatrists identified eligible patients in outpatient clinics. Eligible patients were approached by an independent researcher before their appointment with the psychiatrist, and were blind to whether their psychiatrist was part of the

intervention or control group. Patients who provided written informed consent had their encounter video-recorded. When the training was complete, the next time each participating patient attended the clinic, this follow-up encounter was video-recorded. Ethical approval was granted by East London Research Ethics Committee 1 (10/H0703/12).

Psychiatrists and patients' age, sex and ethnicity was recorded along with length of time psychiatrists had been qualified. Data was collected on patients' employment status and treatment history.

Researchers assessed symptoms on the 30-item Positive and Negative Syndrome Scale (PANSS) at baseline and follow-up.<sup>24</sup> Researchers were trained in the assessment and inter-rater reliability was good (ICC=.90).

#### Randomisation and masking

Consenting psychiatrists were randomly allocated using simple radomization in a 1:1 ratio to the control or intervention group. This was generated by the statistician (SB) using a sequence generated in Excel with the RAND function. There was no allocation concealment. Each psychiatrist was assigned to the next allocation in the sequence. The primary outcome, self-repair, was masked. For the secondary outcome, the therapeutic relationship, patients were masked but it was not possible to mask psychiatrists.

## Data analysis

Data analysis was conducted in Stata 12.0.

Data were summarised as numbers and percentages or means and standard deviations. Using all available cases, the adjusted treatment differences (intervention vs. control group) along with 95% confidence intervals and p values were estimated following intention to treat principles. The ICCs were estimated for each outcome using an adaptation of one-way analysis of variance which does not truncate negative ICCs at zero.<sup>25</sup>

For the primary outcome, self-repair, and for STAR psychiatrist linear mixed effects regression models were fitted by restricted maximum likelihood, adjusting for baseline measure of the outcome and including a random effect (random intercept) for psychiatrist. Additionally, for STAR psychiatrist, patient-reported number of months under the care of their psychiatrist was adjusted for.

For STAR patient, the estimated ICC was negative. Hence, a linear regression model ignoring clustering was fitted so as not to bias the standard error of treatment effect downwards. Baseline STAR patient score was adjusted for along with baseline PANSS total score based on previously reported negative associations between the PANSS and STAR patient<sup>22</sup>.

#### Results

### **Psychiatrists**

Twenty-five psychiatrists agreed to participate out of 35 approached (71%). One psychiatrist was excluded before randomization due to changing post. Twenty-five were randomized. Four psychiatrists (2 control and 2 intervention) had to be excluded after randomization because they had too few eligible patients/changed post, leaving 10 psychiatrists in the intervention and 11 in the control group. All ten psychiatrists in the intervention group participated in training.

Participant flow can be seen in the CONSORT diagram (Figure 1).

Psychiatrist characteristics are presented in Table 1.

## **Patients**

407 patients were eligible. 191 did not attend their appointment. Twenty-five were not approached (considered too ill to approach for consent or appointment overlapped with another participant). Ninety-three did not consent. Ninety-seven patients, 51% of those approached, were recruited. An average of 4.6

(SD=1.9, range= 1-7) patients were recruited per psychiatrist: 5.0 (SD 1.6) patients per psychiatrist in the intervention and 4.3 (SD 2.1) patients per psychiatrist in the control group.

At baseline, patient data was collected from 97 patients. Ninety-six encounters were video-recorded, one was missing due to equipment malfunction. Sixty-four patients were followed up and had the second encounter video-recorded. Patients could only be followed up if they were seeing the same psychiatrist again. Reasons for loss to follow up are provided in Figure 1.

There was an average of 152 days (approximately 5 months) between baseline and follow-up recordings (SD = 80.2, range = 47.2-500 days). The average baseline encounter length was 18.9 minutes (SD = 7.6, range = 7.3–37.1) and at follow-up was 18.4 minutes (SD=8.7, range = 4.0–43.5).

Patient characteristics are summarised in Table 1.

Associations between clinical characteristics and outcomes

At baseline, the Spearman correlation between patient rated therapeutic relationship on the STAR and the patient reported length of relationship with the psychiatrist was r = -0.02 (p=0.85) The Spearman correlation between psychiatrist rated therapeutic relationship on the STAR and the length of the relationship was r=0.27 (p=0.02).

## **Primary outcome**

Psychiatrist self-repair

Psychiatrist self-repair was significantly higher in the intervention than the control group (Table 2, adjusted mean difference 6.4 self-repairs per 1000 words, 95% CI 1.46 to 11.33, p<.011). The model based ICC for self-repair was 0.03: 3% of the variability in psychiatrist self-repair could be attributed to differences between psychiatrists. This corresponded to a large effect, Cohen's d=0.91.

## **Secondary outcomes**

#### Psychiatrist Self-confidence

Self-confidence in communicating with patients with psychosis increased. Paired t-tests showed a significant difference between before and after the training (t = 5.19, 95% CI 1.0 to 2.4, p<.01). The mean score increased by 1.7 points (0-10 scale) from 6.9 (SD=1.4) at baseline to 8.5 (SD=1.2) at follow-up.

#### Therapeutic relationship

The quality of the therapeutic relationship improved significantly more in the intervention group than in the control group (Table 2), both on psychiatrist ratings (STAR mean difference 0.20, 95% CI 0.03 to 0.37, p=.022) and patient ratings (STAR mean difference 0.21, 95% CI 0.01 to 0.41, p=.043). The ICC for the psychiatrist rated STAR was 0.3, i.e., 30% of the total variability in psychiatrists' ratings of the quality of the therapeutic relationship with their patients can be attributed to differences between psychiatrists. The ICC on the patient rated STAR was negative, which, given the large sampling variation of ICCs, is most likely due to chance. The effect size for psychiatrist ratings of the relationship was d=0.81, a large effect. The effect size for patient ratings of the relationship was d=0.36, a medium effect.

#### Feedback on the training

Attendance at the training was good (100% participated in at least 3 of 4 sessions). Psychiatrists who could not attend a specific session received the session later or watched a video of the session. Psychiatrists rated the training as highly beneficial (mean score 8.9) on 0-10 scale (see Box 1 for participant quotes).

## Change in communication

Table 3 shows examples of psychiatrist communication after the training for each of the four areas covered. For example, agenda setting was one aspect of empowering the patient by asking him/her what s/he wanted to talk about at the beginning of the meeting rather than "Any questions" when wrapping up. The following question was posed 40 seconds into the meeting "well the main thing would be perhaps today to understand what you would like from coming to meet with me today, what things did you want to talk about?".

#### Discussion

This study found that a brief intervention to enhance psychiatrist-patient communication in the treatment of psychosis was effective. Psychiatrists' effort in establishing shared understanding with their patients was significantly higher after training. Both psychiatrists' and patients' views of the therapeutic relationship improved, corresponding to a large and medium effect size respectively.

The strengths of the study were that psychiatrist encounters in the clinic were video-recorded before and after training so that the change in communication could be compared between the control and the intervention group, adjusting for baseline communication. There was a range of experience among the psychiatrists and also varying lengths of relationships with their patients. The limitations were that the follow-up sample was smaller than at baseline because some psychiatrists changed post or were on sick leave. The participating patients may not be representative of all patients as they are likely to be more engaged in services and agreeable to participate in research. Moreover, the psychiatrists who participated may not be representative as they are likely to be more motivated than those who did not participate.

The findings are in line with the theoretical model that guided the training and the trial. Psychiatrists' confidence in communicating with psychotic patients improved. Communication was better after the training and the therapeutic relationship improved. This is the first communication intervention in mental health care to show these effects. Training in communication skills may benefit from an underlying theoretical model. The focus on self-repair may appear rather technical. However, with psychiatrists in the intervention group using 44% more self-repair than the control group, it appears to be a valid index of communicative interest in and engagement with the patient. The psychiatrists were not made aware that self-repair is considered to be positive or that self-repair would be assessed as an outcome. Hence, they are unlikely to have been consciously trying to do more of it in their communication. We would predict that trying to do more self-repair per se would, in itself, not be helpful. Rather, repairs are symptomatic of the effort a speaker is investing in producing an utterance that is tailored for their recipient. As such, they are likely to reflect a shift in thinking about the role of communication and genuine adjustments to find the best possible expression.

To illustrate the kinds of self-repairs used in practice and the different ways in which they can take a listener's needs into account, some examples are provided. In the following utterance, the psychiatrist states "I mean it would be good if you can keep up with the healthy life style, I mean er, not to take the medication if not really necessary". Here healthy life style is qualified (repaired) to "not to take the medication" as a number of life style factors have previously been discussed including diet and exercise. In this example, the self-repair clarifies a referent and prevents a possible misunderstanding by the patient. In the next example, the psychiatrist has proposed that it may be worth exploring how the patient could gain some more control over his overpowering voices rather than taking such a high dose of medication. The patient is somewhat resistant to the term 'control'. In line 5, the psychiatrist amends 'control' in a sensitive adjustment to the patient's perspective.

- 1. P: But isn't controlling wrong in a sense? strange
- 2. Dr:
- 3. Dr: It it it
- 4. P: You can actually control er
- 5. Dr: Er when I say control I I I I'm, I I think more in living, in terms of living with them, yeah?

Finally, in the excerpt below, the psychiatrist and patient have been discussing the patient's mother's recent death and the general question format "How have things been in the last few months?" is revised quickly to "I mean I know that your day, kind of revolved around" [your mother] displaying sensitivity to the patient's particular circumstances. Not revising the question from it's first version would be hearable as insensitive to how the patient's life has been affected by his mother's death. Revising it in this way indicates a senstive affective stance towards the patient.

- Dr: So how, how, how, how, how have things been in the last few months, I mean I know that
   your day, kind of revolved around
- 3. P: My day revolves- my day revolves around seeing my brother and sister a lot now, now my
- 4. Mum's no longer with us.

It is interesting that psychiatrist communicative engagement decreased in the control group but was maintained in the intervention group. This is consistent with psychiatrists' reports in the training on the challenges of communicating about psychotic experiences over time, i.e. when they first meet patients, they are more engaged in their experiences but that this can be challenging to maintain when patients are keen to talk about experiences repeatedly. A focus on self-repair, as an index of engagement with patients, may be

useful in training and in research. Psychiatrists identified the training as filling a gap in their training. In research, the current theoretical model could be applied in other disorders and treatment settings to advance the field of communication skills in psychiatry and medicine.

Psychiatrists' ratings of the therapeutic relationship improved considerably (a large effect size) and improved more than the patients' rating. While the confidence intervals are reasonably wide, possibly due to the sample size, this is the first study to show an improvement of the therapeutic relationship through training and suggests that the proposed mechanism of effect, i.e., increased communicative enagement with the patient, does indeed improve the quality of the therapeutic relationship. This finding is encouraging given that, in psychiatric treatment, the professional's rating of the relationship appears to be a stronger predictor of outcome than the patients' rating,<sup>26</sup> the reverse of psychotherapy. Given that the odds of having adherent patients are twice as high if there is a good doctor-patient relationship<sup>5</sup>, this is an important locus of intervention in improving longer-term outcomes. The current study was designed to investigate the effect of the intervention on process outcomes. Future studies would be required to investigate longer term outcomes such as symptoms, quality of life and social functioning.

There is increasing interest in harnessing the potential of the therapeutic relationship in psychiatry<sup>32</sup>. Two interventions have focused on helping patients to prioritise what they wish to discuss with their clinician.

Priebe et al.<sup>27</sup> found that a computer-mediated intervention to structure care coordinator-patient communication improved quality of life, reduced unmet needs for care and improved treatment satisfaction.

Van Os et al.<sup>31</sup> used a checklist which patients completed before seeing their psychiatrist, which improved patient-reported quality of the communication and increased changes in management. Meanwhile, there is considerably more research in other fields such as primary care and oncology.<sup>28</sup> As Fallowfield et al. have noted, senior oncology doctors acknowledge that lack of communication training in complex medical contexts contributes to psychological morbidity, emotional burnout and depersonalisation.<sup>29</sup> Psychiatrists are also at risk of these negative outcomes. Many psychiatrists are highly skilled communicators addressing complex problems and some of the training was based on identifiying what they are doing in everyday

practice. Specifying these skills and integrating them in psychiatric training would address the need within the profession to define the skills that psychiatrists use in treating complex mental health problems.<sup>8,30,33</sup>

## Conclusions

This is the first study to test an intervention for psychiatrists to enhance communication with patients with psychosis. It suggests that shared understanding, which can be challenging in the treatment of psychosis, can be targeted in training and is important for improving the quality of the communication and the therapeutic relationship.

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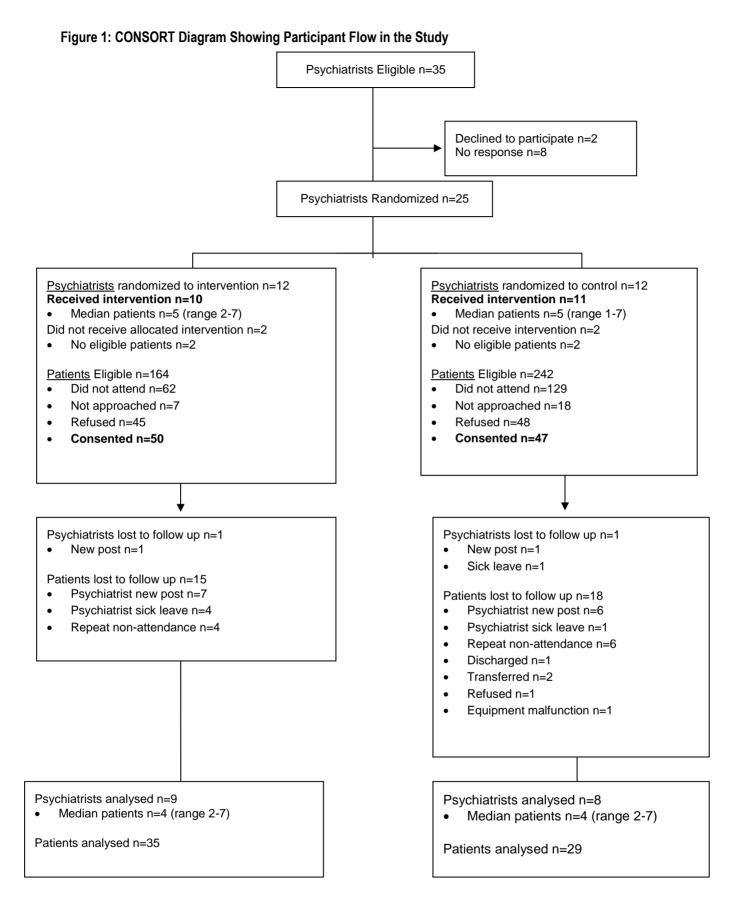


Table 1: Participant Socio-demographic and Clinical Characteristics

|  |                       | Intervention group | Control group    |
|--|-----------------------|--------------------|------------------|
|  |                       | N (%)/ Mean (SD)   | N (%)/ Mean (SD) |
| Patient Characteristics                        |                       | N=50               | N=47             |
| Age  |                       | 43.8 (SD=10)       | 42.8 (SD=10.4)   |
| Gender   | Male                  | 32 (64%)           | 34 (72%)         |
|  | Female                | 18 (36%)           | 13 (28%)         |
| Marital Status                                 | Single                | 36 (72%)           | 36 (76.5%)       |
|  | Married/Partnership   | 10 (20%)           | 7 (15%)          |
|  | Other                 | 4 (8%)             | 4 (8.5%)         |
| Ethnicity                                      | White                 | 21 (42%)           | 13 (28%)         |
|  | Black                 | 10 (20%)           | 16 (35%)         |
|  | Asian                 | 12 (24%)           | 11 (24%)         |
|  | Mixed/Other           | 7 (14%)            | 6 (13%)          |
| First language                                 | English               | 36 (74%)           | 37 (80%)         |
|  | Other                 | 13 (26%)           | 9 (20%)          |
| Highest level of education                     | School                | 24 (51%)           | 19 (40%)         |
|  | Further Education     | 15 (32%)           | 15 (32%)         |
|  | Higher Education      | 8 (17%)            | 13 (28%)         |
| Employment Status                              | Unemployed            | 30 (61%)           | 32 (70%)         |
|  | Employed              | 11 (22%)           | 7 (15%)          |
|  | Student/Retired/Other | 8 (17%)            | 7 (15%)          |
| Number of hospital admissions                  | Total previous        | 3.3 (SD=4.2)       | 3.6 (SD=7.5)     |
|  | Compulsory admissions | 1.2 (SD=1.4)       | 2.0 (SD=2.4)     |
| Length relationship with psychiatrist (months) |                       | 24.1 (39.9)        | 8.0 (13.6)       |
| Symptoms (PANSS)                               | Total                 | 60.3 (SD=21.8)     | 59.5 (SD=15.2)   |
|  | Positive              | 15.5 (SD=7.1)      | 14.9 (SD=6.8)    |
|  | Negative              | 13.8 (SD=6.2)      | 13.5 (SD=4.9)    |
|  | General               | 31.0 (SD=10.8)     | 31.0 (SD=8.5)    |
| Psychiatrist Characteristics                   | S                     | N=10               | N=11             |
| Age  |                       | 42.4 (SD=9.8)      | 41.5 (SD=10.4)   |
| Gender   | Male                  | 8 (80%)            | 7 (64%)          |
|  | Female                | 2 (20%)            | 4 (36%)          |
| Grade  | Trainee (ST4-6)       | 6 (60%)            | 6 (55%)          |
|  | SASG                  | 3 (30%)            | 4 (36%)          |
|  | Consultant            | 1 (10%)            | 1 (9%)           |
| Ethnicity                                      | White                 | 4 (20%)            | 4 (36%)          |
|  | Black                 | 1 (5%)             | 2 (18%)          |
|  | Asian                 | 4 (20%)            | 5 (45%)          |
|  | Mixed/Other           | 1 (10%)            | 0 (0%)           |
| First language                                 | English               | 3 (30%)            | 6 (55%)          |
|  | Other                 | 7 (70%)            | 5 (45%)          |
| Years in Psychiatry                            |                       | 11.3 (SD=7.9)      | 8.7 (SD=5.7)     |

Ethnicity was missing for 1 patient, first language was missing for 2 patients, highest level of education was missing for 3 patients and employment status was missing for 2 patients

Table 2: Adjusted Differences in Means Between the Intervention and Control Groups on the Primary and Secondary Outcomes

|                    |                       |            | Intervention grou | ıp   |      | Control group |      |      |                              |                         |         |                         |
|--------------------|-----------------------|------------|-------------------|------|------|---------------|------|------|------------------------------|-------------------------|---------|-------------------------|
| Outcomes           | Scoring               | Time point | N-patients        | Mean | SD   | N-patients    | Mean | SD   | Adjusted difference in means | 95% confidence interval | p-value | Model<br>based<br>ICC * |
| Primary outcome    |                       |            |                   |      |      |               |      |      |                              |                         |         |                         |
| Self-repair        | frequency per         | baseline   | 31                | 32.5 | 14.5 | 28            | 25.0 | 12.4 |                              |                         |         |                         |
|                    | 1,000 words           | follow-up  | 31                | 32.1 | 12.2 | 28            | 22.2 | 9.1  | 6.39                         | 1.46 to 11.33           | 0.011   | 0.03                    |
| Secondary outcomes |                       |            |                   |      |      |               |      |      |                              |                         |         |                         |
| STAR patient ^     | 0 [worst] to 4 [best] | baseline   | 33                | 2.6  | 0.5  | 30            | 2.7  | 0.4  |                              |                         |         |                         |
|                    |                       | follow-up  | 33                | 2.8  | 0.4  | 30            | 2.6  | 0.3  | 0.21                         | 0.01 to 0.41            | 0.043   | n/a                     |
| STAR psychiatrist  | 0 [worst] to 4 [best] | baseline   | 25                | 2.5  | 0.3  | 23            | 2.5  | 0.3  |                              |                         |         |                         |
|                    |                       | follow-up  | 25                | 2.5  | 0.2  | 23            | 2.4  | 0.3  | 0.20                         | 0.03 to 0.37            | 0.022   | 0.3                     |

Each model is adjusted for the outcome measure at baseline, treatment group and, additionally for STAR-patient, PANSS negative score at baseline, and for STAR-psychiatrist, patient-reported number of months under the care of their psychiatrist.

<sup>^</sup> Model fitted by linear regression without a random effect for psychiatrist, n/a not applicable

<sup>\*</sup> Intracluster correlation coefficient

Table 3: Examples of Psychiatrist-Patient Communication After the Training

| France                         | Described to Defend Occurred to  |
|--------------------------------|--|
| Topic                          | Psychiatrist-Patient Communication   |
| Understanding the patient with | EAR skills (Explore, listen Actively, Respond)   |
| psychotic experiences          | Explore  |
|                                | Dr What's that about? Explain that one to me again what happened?  |
|                                | , , , , , , , , , , , , , , , , , , ,  |
|                                | <u>Listen Actively</u>   |
|                                | P At the moment (0.60)   |
|                                | Dr I see, I see P Erm It's got a lot to do with things so that area could be covered er that   |
|                                | area is a quick- a short area  |
|                                | Dr I see   |
|                                |  |
|                                | Respond  |
|                                | Dr And have you ever done what that voice or that person has told you to do?   |
|                                | P No Dr No vou've always fought it   |
|                                | Dr No you've always fought it P Yeah yeah  |
|                                | Dr So that's very strong of you isn't it?"   |
|                                | ,  |
| Techniques for working with    | Eliciting strong beliefs   |
| symptoms                       | Dr When you think about these voices, what do you make of it?  |
|                                | De lleve de ver feel thet ver heel de net richt? De ver whet what een ver feel?  |
|                                | Dr How do you feel that your body's not right? Do you, what what can you feel?   |
|                                | Dr And how do they affect you?   |
|                                | 7 and now do they direct you:  |
|                                | Realistic Goal setting (Negative symptoms)   |
|                                | Dr So you said not now but you would like to go to gym, why not? What  |
|                                | do you think needs to change for you to start going gym?   |
|                                | P I don't know I don't think things can change   |
|                                | Dr Ok is there a gym nearby where you live? P No   |
|                                | CC* There is some in (place).  |
|                                | Dr Gym is a very good idea because it'll er keep you healthy and er also   |
|                                | keep you busy  |
|                                | P Yeah   |
|                                | Dr And I think it's a good idea for your mental health aswell. Shall we start to   |
|                                | think about a timeframe? When do you think you you you could start to  |
|                                | go to gym? P Maybe now   |
|                                | Dr So you're happy to give it a go now?  |
|                                | P Yeah   |
|                                | CC We'll look for a gym nearby and we can give some information  |
|                                |  |
| Francisco de action            | * Care Coordinator   |
| Empowering the patient         | Agenda setting Dr Well the main thing would be perhaps today to understand what you  |
|                                | would like from coming to meet with me today, what things did you  |
|                                | want to talk about?  |
|                                |  |
|                                | Normalising symptoms   |
|                                | Dr So that's a flashback when people have had in the past traumatic  |
|                                | experiences you know I mean unfortunately one cannot erase it from   |
|                                | memory but over a period of time you have dealt with it and it was pushed aside ok? but it's still there and whenyou are under stress all these sort |
|                                | of past unpleasant memories comes to the surface and then obviously  |
|                                | you get really distressed about it and it can cause a minor relapse.   |
|                                |  |
| Involvement in decision making | Information provision  |
|                                | Dr I can give you a brochure on the medication that I'm thinking of which is in  |
|                                | the same category at the same group of anti psychotics as as the medication that you were on and you can read it and see if you want it              |
|                                | and let me know if you want me to prescribe that for you.  |
|                                | and lot the falow if you want the to prosence that for you.  |
|                                | Double sided reflection  |
|                                | Dr We're in bit of a dilemma here isn't it, a- and then I come back and say  |
|                                | well perhaps we should think about Clozapine again, but y- you would   |
|                                | have to f- its difficult coz then you'd have to overcome your fears about it   |
|                                | being poisoning, an but on the plus side it might well u-a- treat some of  |
|                                | your symptoms much better than than the injection has been able to.  |
|                                |  |



#### Box 1: Participant Perspectives on the Training

"The hearing voices exercise was very powerful. I now understand why patients want to talk about their voices"

"How to explore in depth patient's concerns and listen actively with more attention to patient's cues"

"EAR (<u>Explore, Active Listening and Respond</u>) and GUNS (<u>G</u>ive overview of options, <u>U</u>nderstanding check, <u>N</u>egotiate, <u>S</u>ummarise decision) were excellent!"

"I learned useful approaches and insight into my abilities (both strength and weaknesses) as a psychiatrist"

"Understanding that I need to explore patients' concerns before coming to a decision making stage "

"The art of discussion and negotiation in sharing decisions"

"Paying more attention to the patient's agenda and their priorities...reduces the feeling of yet another routine" "Goal setting with patients with negative symptoms – realistic and achievable"

"Thinking about the patient perspective of psychosis"

"Advanced techniques for explaining psychotic symptoms"

"Even more of a focus on conflict and disagreement could be good"

"I thought I knew a lot about the story of his delusions, but going through the 'voices checklist' makes me realise that I don't really how and when it started and so on."

"I've never realised how much taking notes in the consultation affects the connection with the patient."

"It sounds as if I'm just going through a checklist, rather than talking to the patient."

"I should invite the patient to ask more questions."

## Appendix One: CONSORT checklist

| Section/Topic             | Item | Standard Checklist item  | Extension for  | Page |
|---------------------------|------|--|--|------|
|                           | No   |  | cluster designs  | No * |
| Title and abstract        |      |  |  |      |
|                           | 1a   | Identification as a randomised trial in the title  | Identification as a cluster randomised trial in the title  | 1    |
|                           | 1b   | Structured summary of<br>trial design, methods,<br>results, and conclusions<br>(for specific guidance<br>see CONSORT for<br>abstracts) | See table 2  | 2    |
| Introduction              |      |  |  |      |
| Background and objectives | 2a   | Scientific background and explanation of rationale   | Rationale for using a cluster design   | 4-5  |
|                           | 2b   | Specific objectives or hypotheses  | Whether objectives pertain<br>to the cluster level, the<br>individual participant level<br>or both | 5    |
| Methods                   |      |  |  |      |
| Trial design              | 3a   | Description of trial<br>design (such as parallel,<br>factorial) including<br>allocation ratio  | Definition of cluster and description of how the design features apply to the clusters             | 10   |
|                           | 3b   | Important changes to<br>methods after trial<br>commencement (such as<br>eligibility criteria), with<br>reasons                         |  | 9    |
| Participants              | 4a   | Eligibility criteria for participants  | Eligibility criteria for clusters  | 6    |
|                           | 4b   | Settings and locations where the data were collected   |  | 9    |
| Interventions             | 5    | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered  | Whether interventions pertain to the cluster level, the individual participant level or both       | 6-7  |
| Outcomes                  | ба   | Completely defined pre-<br>specified primary and<br>secondary outcome<br>measures, including how<br>and when they were                 | Whether outcome measures pertain to the cluster level, the individual participant level or both    | 8-9  |

|  |     | assessed  |   |     |
|--|-----|---|---|-----|
|  | 6b  | Any changes to trial outcomes after the trial commenced, with reasons   |   | n/a |
| Sample size                            | 7a  | How sample size was determined  | Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or k), and an indication of its uncertainty | 6   |
|  | 7b  | When applicable,<br>explanation of any<br>interim analyses and<br>stopping guidelines   |   | n/a |
| Randomisation:                         |     |   |   |     |
| Sequence<br>generation                 | 8a  | Method used to generate the random allocation sequence  |   | 10? |
|  | 8b  | Type of randomisation;<br>details of any restriction<br>(such as blocking and<br>block size)  | Details of stratification or matching if used   | 10  |
| Allocation<br>concealment<br>mechanism | 9   | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned | Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both                      | 10  |
| Implementation                         | 10  | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions   | Replace by 10a, 10b and 10c   | 10  |
|  | 10a |   | Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions   | 10  |
|  | 10b |   | Mechanism by which individual participants were included in clusters for the purposes of the trial (such as   | 9   |

| 1  | 10c  | complete enumeration, random sampling)  |     |
|--|--|---|-----|
| 1  | 10c  |   |     |
|  |  | From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation | 9   |
|  |  |   |     |
| Blinding 1   | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how       |   | 10  |
| 1  | If relevant, description of the similarity of interventions  |   | n/a |
| Statistical 1 methods                                  | 12a Statistical methods used<br>to compare groups for<br>primary and secondary<br>outcomes   | How clustering was taken into account   | 10  |
| 1  | Methods for additional<br>analyses, such as<br>subgroup analyses and<br>adjusted analyses  |   | 10  |
| Results  |  |   |     |
| Participant flow 1 (a diagram is strongly recommended) | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome | For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome                         | 19  |
| 1  | 13b For each group, losses and exclusions after randomisation, together with reasons   | For each group, losses and exclusions for both clusters and individual cluster members  | 19  |
| Recruitment 1  | Dates defining the periods of recruitment and follow-up  |   | 11  |
| 1  | 14b Why the trial ended or was stopped   |   | n/a |
| Baseline data  | 15 A table showing baseline demographic and clinical characteristics for each  | Baseline characteristics for the individual and cluster levels as applicable for each   | 20  |

|                         |     | group   | group  |       |
|-------------------------|-----|---|--|-------|
| N 1                     |     |   |  | 10    |
| Numbers<br>analysed     | 16  | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups           | For each group, number of clusters included in each analysis   | 19    |
| Outcomes and estimation | 17a | For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) | Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome | 12    |
|                         | 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended   |  | n/a   |
| Ancillary<br>analyses   | 18  | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory         |  | n/a   |
| Harms                   | 19  | All important harms or<br>unintended effects in<br>each group (for specific<br>guidance see CONSORT<br>for harms)                                 |  | n/a   |
| Discussion              |     |   |  |       |
| Limitations             | 20  | Trial limitations,<br>addressing sources of<br>potential bias,<br>imprecision, and, if<br>relevant, multiplicity of<br>analyses                   |  | 13    |
| Generalisability        | 21  | Generalisability<br>(external validity,<br>applicability) of the trial<br>findings  | Generalisability to clusters and/or individual participants (as relevant)  | 13    |
| Interpretation          | 22  | Interpretation<br>consistent with results,<br>balancing benefits and<br>harms, and considering<br>other relevant evidence                         |  | 13-15 |
| Other information       |     |   |  |       |
| Registration            | 23  | Registration number and   |  | 3     |

|          |    | name of trial registry  |    |
|----------|----|---|----|
| Protocol | 24 | Where the full trial protocol can be accessed, if available                     | 5  |
| Funding  | 25 | Sources of funding and other support (such as supply of drugs), role of funders | 16 |

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#### **Author Contributions:**

RM (principal investigator) conceived and designed the study, with input from SP, DK and PH. RM, AC and DK developed and delivered the training. PJ and JD collected the data. SB and PJ conducted the data analysis, with input from RM. RM drafted the manuscript, with input from SP, and all authors contributed to writing and critically reviewing the final manuscript. RM is the guarantor. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health. All authors had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis.

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