Data supplement to McCabe et al. Training to enhance psychiatrist communication with patients with psychosis (TEMPO): cluster randomised controlled trial. Br J Psychiatry doi: 10.1192/bjp.bp.115.179499

Online supplement

Table DS1 Examples of psychiatrist–patient communication after the training

Topic	Psychiatrist–patient communication
Understanding the patient with psychotic experiences	<u>EAR skills</u> (**E**xplore, listen **A**ctively, **R**espond) <u>Explore</u> 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 <u>Respond</u> Dr And have you ever done what that voice or that person has told you to do? P No 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 symptoms	<u>Eliciting strong beliefs</u> Dr When you think about these voices, what do you make of it? 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? <u>Realistic goal-setting (negative symptoms)</u> 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 as well. Shall we start to think about a time frame? When do you think 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 *Care coordinator
Empowering the patient	<u>Agenda-setting</u> Dr Well the main thing would be perhaps today to understand what <u>you</u> would like from coming to meet with me today, what things did you want to talk about? <u>Normalising symptoms</u> 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 when …. you 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	<u>Information provision</u> 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 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. <u>Double sided reflection</u> Dr We're in bit of a dilemma here, and then I come back and say well perhaps we should think about clozapine again, but you would have to - its difficult coz then you'd have to overcome your fears about it being poisoning, but on the plus side it might, well, treat some of your symptoms much better than the injection has been able to.

Table DS2 CONSORT checklist

Section/topic	Item no.	Standard checklist item	Extension for cluster designs	Page 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 trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	See Table 3	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 to the cluster level, the individual participant level or both	5
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	10
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with 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	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Whether outcome measures pertain to the cluster level, the individual participant level or both	8-9
	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	6

			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	
	7b	When applicable, explanation of any interim analyses and stopping guidelines		n/a
Randomisation				
Sequence generation	8a	Method used to generate the random allocation sequence		10?
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	10
Allocation concealment 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 complete enumeration, random sampling)	9
	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
Masking	11a	If done, who was masked after assignment to interventions (e.g. participants, care		10

		providers, those assessing outcomes) and how		
	11b	If relevant, description of the similarity of interventions		n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		10
Results				
Participant flow (a diagram is strongly recommended)	13a	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
	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	14a	Dates defining the periods of recruitment and follow-up		11
	14b	Why the trial ended or was stopped		n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Baseline characteristics for the individual and cluster levels as applicable for each group	20
Numbers 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 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 unintended effects in each group (for specific guidance see		n/a

		CONSORT for harms)		
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		13
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	13
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		13-15
Other information				
Registration	23	Registration number and name of trial registry		3
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