Supplementary appendix

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

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## Reasons for ineligibility

| Reason                                                                 | n         |
|------------------------------------------------------------------------|-----------|
| **After patients identified**                                           | N=79      |
| No current positive symptoms of psychosis or problems                   | 21 (26·6%)|
| Dose of clozapine below 400mg and not limited due to side effects      | 16 (20·3%)|
| Lacking capacity to consent                                            | 9 (11·4%) |
| Current CBT or CBT in past year                                        | 8 (10·1%) |
| Never taken clozapine                                                   | 7 (8·9%)  |
| Diagnosis not schizophrenia spectrum                                   | 7 (8·9%)  |
| Discontinued clozapine > 2 years ago                                   | 6 (7·6%)  |
| Moved out of area                                                      | 2 (2·5%)  |
| Diagnosis of a developmental disability                                | 1 (1·3%)  |
| Not English speaking                                                   | 1 (1·3%)  |
| Deceased before consented                                              | 1 (1·3%)  |
| **After patients found to be eligible**                                | N=47      |
| Below threshold on the Positive and Negative Syndrome Scale            | 40 (85·1%)|
| Diagnosis not schizophrenia spectrum                                   | 2 (4·3%)  |
| Lacking capacity to consent                                            | 2 (4·3%)  |
| Dose of clozapine below 400mg and not limited due to side effects      | 1 (2·1%)  |
| No current positive symptoms of psychosis or problems                  | 1 (2·1%)  |
| Unable to complete the baseline assessment                              | 1 (2·1%)  |
| Number of sessions attended | CBT N=242 |
|-----------------------------|-----------|
| 0                           | 12 (5.0%) |
| 1-5                         | 17 (7.0%) |
| 6-10                        | 20 (8.3%) |
| 11-20                       | 48 (19.8%)|
| 21-30                       | 124 (51.2%)|
| >31                         | 21 (8.7%) |
| Median (25th, 75th centile); n | 23 (13, 28); 242 |
### PANSS outcome by symptom severity based on inclusion criteria

|                        | CBT N = 242 | TAU N = 245 |
|------------------------|-------------|-------------|
| **PANSS total**        |             |             |
| Delusions < 4          | 73·5 (11·7); 34 | 75·9 (13·2); 38 |
| Delusions ≥ 4          | 84·3 (13·4); 208 | 84·7 (13·7); 207 |
| Hallucinatory behaviour < 4 | 80·6 (12·0); 53 | 81·0 (10·7); 42 |
| Hallucinatory behaviour ≥ 4 | 83·4 (14·1); 189 | 83·8 (14·6); 203 |
| Grandiosity < 5        | 81·4 (13·2); 207 | 82·1 (13·8); 208 |
| Grandiosity ≥ 5        | 90·7 (13·9); 35 | 90·4 (13·1); 37 |
| Suspiciousness persecution < 5 | 77·3 (11·8); 119 | 78·0 (13·5); 113 |
| Suspiciousness persecution ≥ 5 | 88·0 (13·3); 123 | 87·9 (12·8); 132 |
| **PANSS positive**     |             |             |
| Delusions < 4          | 17·6 (4·1); 34 | 18·4 (3·0); 38 |
| Delusions ≥ 4          | 25·9 (5·3); 208 | 26·4 (5·2); 207 |
| Hallucinatory behaviour < 4 | 23·3 (4·4); 53 | 23·0 (3·7); 42 |
| Hallucinatory behaviour ≥ 4 | 25·1 (6·2); 189 | 25·6 (6·0); 203 |
| Grandiosity < 5        | 23·6 (5·5); 207 | 24·1 (5·1); 208 |
| Grandiosity ≥ 5        | 31·1 (4·0); 35 | 31·4 (4·9); 37 |
| Suspiciousness persecution < 5 | 21·5 (5·2); 119 | 21·8 (4·8); 113 |
| Suspiciousness persecution ≥ 5 | 27·8 (4·7); 123 | 28·1 (4·8); 132 |
| **PANSS negative**     |             |             |
| Delusions < 4          | 19·6 (5·4); 34 | 20·4 (7·7); 38 |
| Delusions ≥ 4          | 19·3 (6·2); 208 | 19·2 (6·1); 207 |
| Hallucinatory behaviour < 4 | 19·3 (6·4); 53 | 19·2 (5·8); 42 |
| Hallucinatory behaviour ≥ 4 | 19·3 (6·0); 189 | 19·5 (6·5); 203 |
| Grandiosity < 5        | 19·8 (6·1); 207 | 19·6 (6·4); 208 |
| Grandiosity ≥ 5        | 16·7 (4·9); 35 | 18·4 (5·9); 37 |
| Suspiciousness persecution < 5 | 18·2 (5·4); 119 | 18·5 (6·9); 113 |
| Suspiciousness persecution ≥ 5 | 20·4 (6·5); 123 | 20·2 (5·8); 132 |
|--------------------------------|----------------|----------------|
| **PANSS disorganised**          |                |                |
| Delusions < 4                   | 21·9 (6·5); 34 | 23·3 (7·4); 38 |
| Delusions ≥ 4                   | 25·2 (6·4); 208| 25·1 (6·4); 207|
| Hallucinatory behaviour < 4     | 25·3 (6·2); 53 | 24·8 (6·2); 42 |
| Hallucinatory behaviour ≥ 4     | 24·6 (6·6); 189| 24·8 (6·6); 203|
| Grandiosity < 5                 | 24·0 (6·1); 207| 24·3 (6·4); 208|
| Grandiosity ≥ 5                 | 29·1 (7·5); 35 | 27·7 (6·7); 37 |
| Suspiciousness persecution < 5  | 24·2 (6·5); 119| 23·9 (7·2); 113|
| Suspiciousness persecution ≥ 5  | 25·3 (6·5); 123| 25·6 (5·8); 132|
| **PANSS excitement**            |                |                |
| Delusions < 4                   | 15·2 (3·7); 34 | 15·9 (3·9); 38 |
| Delusions ≥ 4                   | 18·5 (4·4); 208| 18·3 (4·3); 207|
| Hallucinatory behaviour < 4     | 18·4 (4·4); 53 | 18·2 (3·7); 42 |
| Hallucinatory behaviour ≥ 4     | 17·9 (4·5); 189| 17·8 (4·5); 203|
| Grandiosity < 5                 | 17·4 (4·2); 207| 17·4 (4·3); 208|
| Grandiosity ≥ 5                 | 21·4 (4·5); 35 | 20·8 (3·3); 37 |
| Suspiciousness persecution < 5  | 16·6 (3·9); 119| 16·6 (4·0); 113|
| Suspiciousness persecution ≥ 5  | 19·4 (4·6); 123| 19·0 (4·3); 132|
| **PANSS emotional distress**    |                |                |
| Delusions < 4                   | 23·6 (5·2); 34 | 24·8 (5·2); 38 |
| Delusions ≥ 4                   | 27·6 (5·5); 208| 27·9 (5·5); 207|
| Hallucinatory behaviour < 4     | 25·9 (5·1); 53 | 27·2 (4·6); 42 |
| Hallucinatory behaviour ≥ 4     | 27·3 (5·8); 189| 27·5 (5·7); 203|
| Grandiosity < 5                 | 27·0 (5·7); 207| 27·5 (5·5); 208|
| Grandiosity ≥ 5                 | 27·0 (5·0); 35 | 27·2 (6·0); 37 |
| Suspiciousness persecution < 5  | 23·8 (4·6); 119| 24·8 (4·9); 113|
| Suspiciousness persecution ≥ 5  | 30·2 (4·7); 123| 29·7 (5·1); 132|
## PANSS outcomes using multiple imputation

|               | MD    | 95% CI          | p-value |
|---------------|-------|-----------------|---------|
| **PANSS total** |       |                 |         |
| 9 months      | -2·50 | (-4·98, -0·02)  | 0·048   |
| 21 months     | -0·63 | (-3·22, 1·96)   | 0·63    |
| **PANSS positive** |     |                 |         |
| 9 months      | -1·64 | (-2·65, -0·63)  | 0·002   |
| 21 months     | -0·74 | (-1·80, 0·33)   | 0·17    |
| **PANSS negative** |     |                 |         |
| 9 months      | -0·43 | (-1·44, 0·59)   | 0·41    |
| 21 months     | 0·28  | (-0·77, 1·32)   | 0·60    |
| **PANSS disorganised** |    |                 |         |
| 9 months      | 0·05  | (-0·88, 0·98)   | 0·92    |
| 21 months     | 0·22  | (-0·75, 1·19)   | 0·66    |
| **PANSS excitement** |    |                 |         |
| 9 months      | -1·14 | (-1·84, -0·44)  | 0·001   |
| 21 months     | -0·51 | (-1·25, 0·23)   | 0·18    |
| **PANSS emotional distress** |    |                 |         |
| 9 months      | -1·04 | (-2·02, -0·05)  | 0·040   |
| 21 months     | -0·10 | (-1·14, 0·94)   | 0·85    |
### PANSS outcomes after removing participants who discontinued clozapine due to side effects

|                         | CBT (N=242) | TAU (N=245) | Mean difference | 95% CI               | P Value |
|-------------------------|-------------|-------------|-----------------|----------------------|---------|
| **PANSS total**         |             |             |                 |                      |         |
| Baseline                | 82·8 (14·0); 226 | 82·8 (13·7); 222 |                 |                      |         |
| 9 months                | 75·6 (15·5); 204 | 77·1 (14·0); 203 | -1·84 (-4·27 to 0·58) | 0·14 |         |
| 21 months               | 73·1 (16·8); 195 | 73·8 (14·8); 196 | -1·05 (-3·53 to 1·43) | 0·41 |         |
| **PANSS positive**      |             |             |                 |                      |         |
| Baseline                | 24·7 (6·0); 226 | 24·9 (5·7); 222 |                 |                      |         |
| 9 months                | 21·8 (6·6); 204 | 23·2 (6·1); 204 | -1·25 (-2·25 to -0·25) | 0·014 |         |
| 21 months               | 21·2 (6·9); 195 | 22·3 (6·1); 196 | -0·94 (-1·96 to 0·08) | 0·071 |         |
| **PANSS negative**      |             |             |                 |                      |         |
| Baseline                | 19·3 (6·2); 226 | 19·4 (6·3); 222 |                 |                      |         |
| 9 months                | 18·2 (7·0); 206 | 18·8 (6·7); 205 | -0·63 (-1·63 to 0·38) | 0·22 |         |
| 21 months               | 17·7 (6·7); 197 | 17·6 (6·1); 196 | 0·03 (-1·00 to 1·06) | 0·95 |         |
| **PANSS disorganised**  |             |             |                 |                      |         |
| Baseline                | 24·8 (6·6); 226 | 24·7 (6·5); 222 |                 |                      |         |
| 9 months                | 23·4 (6·5); 204 | 23·0 (5·9); 204 | 0·16 (-0·77 to 1·09) | 0·74 |         |
| 21 months               | 22·9 (6·7); 196 | 22·4 (6·3); 196 | 0·21 (-0·74 to 1·16) | 0·67 |         |
| **PANSS excitement**    |             |             |                 |                      |         |
| Baseline                | 17·9 (4·4); 226 | 17·8 (4·3); 222 |                 |                      |         |
| 9 months                | 16·2 (4·1); 206 | 17·2 (4·1); 206 | -1·07 (-1·77 to -0·37) | 0·003 |         |
| 21 months               | 15·4 (4·0); 196 | 15·9 (3·9); 196 | -0·65 (-1·37 to 0·06) | 0·074 |         |
| **PANSS emotional distress** |           |             |                 |                      |         |
|          |       |       |       |       |
|----------|-------|-------|-------|-------|
| Baseline | 27.1 (5.7); 226 | 27.3 (5.5); 222 |       |       |
| 9 months | 24.2 (6.2); 206 | 25.1 (6.2); 206 | -0.82 | (-1.78 to 0.14) |
| 21 months| 23.3 (6.5); 196 | 23.9 (6.0); 196 | -0.40 | (-1.38 to 0.59) |

0.095

0.43
CACE analysis estimates for PANSS outcomes using a minimum of 6 sessions of CBT attendance

|                          | Mean difference | 95% CI          | p-value |
|--------------------------|-----------------|-----------------|---------|
| **9 months PANSS**       |                 |                 |         |
| PANSS total              | -2·50           | (-5·10 to 0·11) | 0·060   |
| PANSS positive           | -0·52           | (-1·60 to 0·56) | 0·35    |
| PANSS negative           | -1·67           | (-2·68 to -0·67)| 0·001   |
| PANSS disorganised       | 0·00            | (-0·97 to 0·97) | 0·99    |
| PANSS excitement         | -1·28           | (-2·05 to -0·50)| 0·001   |
| PANSS emotional distress | -1·17           | (-2·21 to -0·13)| 0·028   |
| **21 months PANSS**      |                 |                 |         |
| PANSS total              | -0·87           | (-3·69 to 1·96) | 0·55    |
| PANSS positive           | 0·36            | (-0·76 to 1·48) | 0·53    |
| PANSS negative           | -0·95           | (-2·10 to 0·19) | 0·10    |
| PANSS disorganised       | 0·17            | (-0·87 to 1·22) | 0·74    |
| PANSS excitement         | -0·56           | (-1·32 to 0·20) | 0·15    |
| PANSS emotional distress | -0·33           | (-1·47 to 0·80) | 0·57    |
### Potential unwanted effects of trial participation

**Forms returned**
313 of 487 = 64.2%

**Forms returned by group**
- CBT 146 of 242 (60.3%)
- TAU 167 of 245 (68.1%)

**Participants endorsing at least one item 3 or 4**
- CBT n=40/146 (27.3%)
- TAU n=42/167 (25.1%)

**Total counts for all participant responses (i.e. TAU and CBT plus TAU)**

| Item | 0 Not at all | 1 Very little | 2 A little | 3 Quite a lot | 4 Very much | Responses n=313 | Missing |
|------|--------------|---------------|------------|---------------|-------------|----------------|---------|
| Q1   | 114          | 43            | 79         | 54            | 21          | 311            | 2       |
| Q2   | 243          | 45            | 17         | 3             | 3           | 311            | 2       |
| Q3   | 165          | 66            | 65         | 12            | 2           | 310            | 3       |
| Q4   | 221          | 49            | 34         | 8             | 1           | 313            | -       |
| Q5   | 225          | 45            | 33         | 6             | 2           | 311            | 2       |
| Q6   | 256          | 36            | 15         | 2             | 1           | 310            | 3       |
| Q7   | 190          | 58            | 45         | 11            | 7           | 311            | 2       |
| Q8   | 147          | 62            | 65         | 24            | 14          | 312            | 1       |
| Q9   | 262          | 31            | 14         | 5             | -           | 312            | 1       |
| Q10  | 211          | 59            | 34         | 8             | 1           | 313            | -       |
| Q11  | 219          | 61            | 22         | 10            | 1           | 313            | -       |
| Q12  | 280          | 19            | 11         | 3             | -           | 313            | -       |
| Q13  | 279          | 21            | 8          | 3             | 2           | 313            | -       |
| Q14  | 253          | 39            | 16         | 1             | 1           | 310            | 3       |
| Q15  | 289          | 15            | 5          | 2             | -           | 311            | 2       |
| Q16  | 259          | 33            | 13         | 5             | -           | 310            | 3       |
| Q17  | 283          | 17            | 6          | 2             | 1           | 309            | 4       |
| Q18  | 263          | 21            | 7          | 6             | 6           | 303            | 10      |
| Q19  | 155          | 59            | 64         | 21            | 4           | 303            | 10      |
| Q20  | 282          | 12            | 7          | 1             | -           | 302            | 11      |
| Q21  | 229          | 43            | 19         | 9             | 3           | 303            | 10      |
| Q22  | 273          | 17            | 8          | 5             | -           | 303            | 10      |
| Q23  | 228          | 39            | 25         | 8             | 1           | 301            | 12      |
| Q24  | 196          | 43            | 43         | 16            | 4           | 302            | 11      |
| Q25  | 286          | 7             | 2          | 2             | 1           | 298            | 15      |
| Q26  | 237          | 38            | 22         | 3             | 2           | 302            | 11      |
| Q27  | 171          | 42            | 61         | 15            | 7           | 296            | 17      |

*For item description see subsequent tables*
**CBT plus TAU Group Responses**

| Taking part -                                                                 | 0 | 1 | 2 | 3 | 4 | Resp. n=146 |
|------------------------------------------------------------------------------|---|---|---|---|---|--------------|
| 1 hasn’t helped me with my problems                                          | 58| 16| 38| 24| 9 | 145 1       |
| 2 made my problems worse                                                      | 117| 17| 7 | 2 | 1 | 144 2       |
| 3 made me feel more anxious                                                  | 82 | 26| 31| 6 | - | 145 1       |
| 4 took up too much time                                                       | 105| 24| 13| 4 | - | 146 -       |
| 5 led to my mood becoming very low                                            | 103| 22| 15| 3 | 2 | 145 1       |
| 6 made me feel more angry and irritable                                       | 121| 13| 9 | 2 | - | 146 -       |
| 7 I didn’t feel ready to talk about my problems                              | 91 | 24| 19| 6 | 6 | 146 -       |
| 8 made me think too much about bad things that have happened in the past     | 71 | 25| 29| 11| 9 | 145 1       |
| 9 meant I stopped looking after myself properly                              | 121| 15| 7 | 2 | - | 145 1       |
| 10 made me feel more suspicious                                              | 100| 31| 11| 4 | - | 146 -       |
| 11 required too much energy or motivation                                     | 100| 33| 7 | 5 | 1 | 146 -       |
| 12 increased my thoughts of killing myself                                   | 132| 8 | 6 | - | - | 146 -       |
| 13 I didn’t feel listened to or believed by FOCUS staff                      | 131| 10| 3 | 2 | - | 146 -       |
| 14 made my voices or visions worse                                           | 121| 15| 6 | 1 | 1 | 144 2       |
| 15 was making me fall out with my family or friends                          | 137| 6 | 1 | 1 | - | 145 1       |
| 16 was having a bad effect on my self-esteem                                 | 120| 16| 4 | 4 | - | 144 2       |
| 17 was making me want to harm myself                                         | 136| 8 | - | 1 | - | 145 1       |
| 18 I didn’t like or feel I could trust the FOCUS team members                | 127| 6 | 5 | 2 | 2 | 142 4       |
| 19 I felt embarrassed talking about my problems with people I had not met before | 77 | 24| 31| 8 | 2 | 142 4       |
| 20 made me have thoughts of harming other people                            | 137| 2 | 2 | - | - | 141 5       |
| 21 was making me feel hopeless about the future                              | 102| 25| 8 | 5 | 2 | 142 4       |
| 22 meant I had to increase my medication in order to cope                    | 131| 5 | 3 | 3 | - | 142 4       |
| 23 involved too much hard work.                                              | 108| 17| 14| 2 | 1 | 142 4       |
| 24 made me worry that people would think badly of me because of my diagnosis | 98 | 16| 18| 8 | 1 | 141 5       |
| 25 made me fall out with my doctor or care team                              | 133| 5 | 1 | 1 | 1 | 141 5       |
| 26 made me worry about losing control of my mind                             | 107| 21| 10| 2 | 2 | 142 4       |
| 27 My problems have improved to the point I no longer feel I need help       | 73 | 17| 35| 12| 3 | 140 6       |
| Response                                                                 | Level 0 | Level 1 | Level 2 | Level 3 | Level 4 | Total | Average |
|--------------------------------------------------------------------------|---------|---------|---------|---------|---------|-------|---------|
| Hasn't helped me with my problems                                        | 56      | 27      | 41      | 30      | 12      | 166   | 1       |
| Made my problems worse                                                   | 126     | 28      | 10      | 1       | 2       | 167   |         |
| Made me feel more anxious                                               | 83      | 40      | 34      | 6       | 2       | 165   | 2       |
| Took up too much time                                                    | 116     | 25      | 21      | 4       | 1       | 167   |         |
| Led to my mood becoming very low                                         | 122     | 23      | 18      | 3       | -       | 166   | 1       |
| Made me feel more angry and irritable                                    | 135     | 23      | 6       | -       | 1       | 165   | 2       |
| Didn't feel ready to talk about my problems                              | 99      | 34      | 26      | 5       | 1       | 165   | 2       |
| Made me think too much about bad things that have happened in the past   | 76      | 37      | 36      | 13      | 5       | 167   | -       |
| Meant I stopped looking after myself properly                            | 141     | 16      | 7       | 3       | -       | 167   | -       |
| Made me feel more suspicious                                             | 111     | 28      | 23      | 4       | 1       | 167   | -       |
| Required too much energy or motivation                                    | 119     | 28      | 15      | 5       | -       | 167   | -       |
| Increased my thoughts of killing myself                                  | 148     | 11      | 5       | 3       | -       | 167   | -       |
| Didn't feel listened to or believed by FOCUS staff                       | 148     | 11      | 5       | 1       | 2       | 167   | -       |
| Made my voices or visions worse                                          | 132     | 24      | 10      | -       | -       | 166   | 1       |
| Was making me fall out with my family or friends                         | 152     | 9       | 4       | 1       | -       | 166   | 1       |
| Was having a bad effect on my self-esteem                               | 139     | 17      | 9       | 1       | -       | 166   | 1       |
| Was making me want to harm myself                                       | 147     | 9       | 6       | 1       | 1       | 164   | 3       |
| Didn't like or feel I could trust the FOCUS team members                 | 136     | 15      | 2       | 4       | 4       | 161   | 6       |
| Felt embarrassed talking about my problems with people I had not met before | 78      | 35      | 33      | 13      | 2       | 161   | 6       |
| Made me have thoughts of harming other people                           | 145     | 10      | 5       | 1       | -       | 161   | 6       |
| Was making me feel hopeless about the future                             | 127     | 18      | 11      | 4       | 1       | 161   | 6       |
| Meant I had to increase my medication in order to cope                   | 142     | 12      | 5       | 2       | -       | 161   | 6       |
| Involved too much hard work                                              | 120     | 22      | 11      | 6       | -       | 159   | 8       |
| Made me worry that people would think badly of me because of my diagnosis | 98      | 27      | 25      | 8       | 3       | 161   | 6       |
| Made me fall out with my doctor or care team                             | 153     | 2       | 1       | 1       | -       | 157   | 10      |
| Made me worry about losing control of my mind                            | 130     | 17      | 12      | 1       | -       | 160   | 7       |
| My problems have improved to the point I no longer feel I need help      | 98      | 25      | 26      | 3       | 4       | 156   | 11      |
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