

# Selective serotonin reuptake inhibitors (SSRIs) and routine specialist care with and without cognitive behaviour therapy in adolescents with major depression: randomised controlled trial

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## ABSTRACT

**Objective** To determine whether a combination of a selective serotonin reuptake inhibitor (SSRI) and cognitive behaviour therapy (CBT) together with clinical care is more effective in the short term than an SSRI and clinical care alone in adolescents with moderate to severe major depression.

**Design** Pragmatic randomised controlled superiority trial.

**Setting** 6 outpatient clinics in Manchester and Cambridge.

**Participants** 208 adolescents, aged 11-17, with moderate to severe major or probable major depression who had not responded to a brief initial intervention. Adolescents with suicidality, depressive psychosis, or conduct disorder were included.

**Interventions** 103 adolescents received an SSRI and routine care; 105 received an SSRI, routine care, and CBT. The trial lasted 12 weeks, followed by a 16 week maintenance phase.

**Main outcome measures** Change in score on the Health of the Nation outcome scales for children and adolescents (primary outcome) from baseline with 12 weeks as the primary and 28 weeks as the follow-up end point. Secondary measures were change in scores on the mood and feelings questionnaire, the revised children's depression rating scale, the children's global assessment scale, and the clinical global impression improvement scale.

**Results** At 12 weeks the treatment effect for the primary outcome was  $-0.64$  (95% confidence interval  $-2.54$  to  $1.26$ ,  $P=0.50$ ). In a longitudinal analysis, there was no difference in effectiveness of treatment for the primary (average treatment effect  $0.001$ ,  $-1.52$  to  $1.52$ ,  $P=0.99$ ) or secondary outcome measures. On average there was a decrease in suicidal thoughts and self harm. There was no evidence of a protective effect of cognitive behaviour therapy on suicidal thinking or action. By 28 weeks, 57% were much or very much improved with 20% remaining unimproved.

**Conclusions** For adolescents with moderate to severe major depression there is no evidence that the combination of CBT plus an SSRI in the presence of routine clinical care contributes to an improved outcome by 28 weeks compared with the provision of routine clinical care plus an SSRI alone.

**Trial registration** Current Controlled Trials ISRCTN 83809224.

## INTRODUCTION

Adolescent depression is a serious disorder with a high risk of suicidality, recurrence, and chronicity.<sup>1,2</sup> Selective serotonin reuptake inhibitors (SSRIs) are used in treatment, although there are concerns regarding both efficacy and raised risk of suicide.<sup>3,4</sup> The National Institute for Health and Clinical Excellence (NICE) has proposed cognitive behaviour therapy (CBT) as one of the primary treatments of choice.<sup>5</sup> Specifically, their guidelines recommend that SSRIs be prescribed only in conjunction with a specialised psychological treatment such as CBT, based on the results from the treatment of adolescent depression study (TADS) in the United States.<sup>6</sup> The US randomised controlled trial showed that fluoxetine in combination with CBT was superior to fluoxetine alone and might reduce suicidality. Results of secondary analyses, however, were equivocal, and a subsequent study reported no benefit for combined treatment over SSRIs alone.<sup>7</sup>

The adolescent depression antidepressant and psychotherapy trial (ADAPT) was designed as a pragmatic randomised controlled superiority trial of combination therapy for moderate to severe major depression in routine patients referred to NHS child and adolescent mental health services.

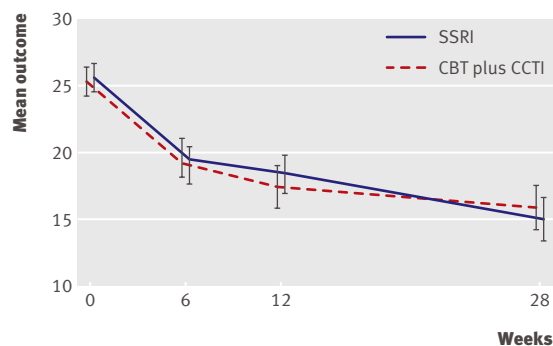
## METHODS

### Protocol, design, and objectives

We used a pragmatic randomised superiority trial to determine whether, in those who did not respond to a brief initial intervention but were continuing to receive routine care, the addition of combined specialist therapy (SSRI plus CBT) was superior to the addition of an SSRI alone in improving general functioning and depression. After an initial assessment by trial psychiatrists, participants were offered a brief initial intervention based on principles of routine clinical care for a minimum of two sessions, if they had not had such a procedure before referral. We excluded those already taking antidepressants or those thought to require immediate treatment with antidepressants. If participants did not improve after the brief initial intervention, they were randomised to SSRI alone or SSRI plus CBT for 12 weeks, followed by a maintenance phase to 28 weeks.

### Participants

Adolescents aged 11-17 were recruited from six specialist child and adolescent mental health services



Mean outcome by treatment group (95% confidence interval) for the Health of the Nation outcome scale (SSRI=selective serotonin reuptake inhibitor, CBT=cognitive behaviour therapy)

(CAMHS) in Manchester and Cambridge. All participants met criteria for major or probable major depression (four symptoms with psychosocial impairment).<sup>8</sup> Patients with active suicidal intent, self harm, depressive psychosis, or conduct disorder were included.

Participants were randomised to SSRI alone or SSRI plus CBT by an equal allocation ratio using stochastic minimisation balancing for severity (children's global assessment scale  $\leq 40$ ), centre, sex, concurrent comorbid conduct disorder, and age. Research staff from the clinical sites enrolled patients, and an independent telephone randomisation centre allocated treatment.

#### Interventions

Trial psychiatrists treated participants in outpatient settings in the context of ongoing clinical care. Treatment was conducted in an empathic and reflective framework with monitoring of mental state, psychoeducation, parental support, problem solving, attention to comorbidity, and liaison with other agencies. Family therapy was kept to a minimum (up to three sessions) in the first 12 weeks. The focus of usual care was an explanation of depression and attention to recent family or peer group conflicts. Comorbidity problems were also attended to when required, including liaison with schools and other agencies.

**Drug treatment**—The primary SSRI was fluoxetine 10 mg daily for one week, increasing to 20 mg for five weeks. If there was no response by six weeks, a further increase was considered to a maximum of 60 mg. Patients in the SSRI only arm were offered nine outpatient sessions of usual care over 28 weeks; more could be offered depending on clinical need.

**Therapy**—CBT was offered weekly for 12 weeks, then fortnightly for 12 weeks with a final session at 28 weeks (total 19 sessions). Further details are on [bmj.com](http://bmj.com). Core interventions were engagement and goal setting, emotional recognition, self monitoring, self reinforcement and activity scheduling, challenging negative thinking and cognitive restructuring, social problem solving, and communication skills. Parental participation at the end of each session was encouraged.

#### Outcomes

All assessment measures were given at baseline, 6, 12, and 28 weeks. The Kiddie Schedule for affective disorders and schizophrenia present and lifetime version (K-SADS-PL)<sup>9</sup> established the presence of diagnoses for depression and all concurrent comorbid psychiatric disorders. The Health of the Nation outcome scale was the primary outcome measure<sup>10</sup> with 12 weeks as the primary and 28 weeks as the follow-up end point. Secondary measures were the participant rated mood and feelings questionnaire,<sup>11</sup> the observer rated revised children's depression rating scale (CDRS-R, the (t) score being reported),<sup>12</sup> the children's global assessment scale (CGAS),<sup>13</sup> and the clinical global impression improvement scale (CGI-I),<sup>14</sup> scores being obtained from combining participants' and parents' reports. We used the suicidality items from the K-SADS-PL depression section as a secondary measure to rate suicidality at each research assessment. These included all acts of self harm, including attempted suicide and non-suicidal self cutting, as well as suicidal thoughts.

Treating clinicians could not be blind to treatment; research assistants blind to treatment assignment assessed outcome.

#### Sample size

We used the outcome score to determine sample size. Data from the development study<sup>10</sup> and the overdose study<sup>15</sup> suggested that 3 points on the total score scale was a clinically important difference. With a sample size of 100 in each arm we would have 94% power to detect a difference of this magnitude with a two tailed 0.05 significance level, assuming a common SD of 6.0 points.

#### Statistical analysis

Full details are on [bmj.com](http://bmj.com). Analysis was by intention to treat subject to the availability of the data. For each outcome measure we used a random effects model to compare the two treatments in a longitudinal analysis.<sup>16</sup> We used statistical models to estimate the difference in the rate of improvement between the two treatments using a time-treatment interaction.

## RESULTS

#### Participants

From 2000 to 2004, 510 patients were assessed, of whom 249 (49%) met inclusion criteria (see [bmj.com](http://bmj.com)). Of 211 available for first research interview, three dropped out, 103 were randomised to SSRI alone, and 105 were randomised to CBT plus SSRI (see [bmj.com](http://bmj.com)). Twelve patients were formally withdrawn from the study for clinical reasons and the families of 18 patients formally withdrew them from study treatment.

#### Medication

The mean dose of fluoxetine was 30 mg for both groups. Two patients received the maximum dose of 60 mg. Of those randomised, 26 were taking other

SSRIs on entry to the trial and three switched to fluoxetine. Eleven changed from fluoxetine to another SSRI. Compliance with medication was measured on a Likert scale of 1-8, with 8 representing total compliance: 160 (77%) participants had a median score greater than 6, with no difference between arms ( $P=0.83$ ). Over the course of the trial, 14 patients received additional psychotropic medication.

#### Attendance

Compared with SSRI alone, at 28 weeks the mean number of clinical sessions attended was significantly greater in the SSRI plus CBT arm (6.5 (SD 4.0) *v* 10.6 (SD 5.7); Mann-Whitney,  $P<0.0001$ ). Typical durations of clinical trial sessions were 30 (SSRI alone) and 55 (CBT plus SSRI) minutes.

#### Clinical outcomes

We had data at one or more assessment points over the 28 weeks for 204 (98%) patients. Primary endpoint data were available for 202/208 (97%) at 12 weeks and 193/208 (93%) at 28 weeks. The table shows the summary statistics for the primary and secondary outcome measures. The figure displays the profile of the unadjusted means for the Health of the Nation outcome scale.

Mean values for the two treatments were similar at corresponding assessments. At the primary end point (12 weeks) the treatment effect for the primary outcome was  $-0.64$  (95% confidence interval  $-2.54$  to

$1.26$ ,  $P=0.50$ ) after adjustment for age, sex, site, behavioural disorder, and baseline score. In the random effects model (table) there were no differences in either the time-treatment interaction or the average treatment effect of the follow-up time points. For the Health of the Nation outcome scale, the treatment effect (between groups) averaged across follow-up time points was  $0.001$  ( $-1.52$  to  $1.52$ ,  $P=0.99$ ). There was no evidence of an interaction between treatment and baseline severity for primary (interaction  $0.78$ ;  $-2.38$  to  $3.92$ ,  $P=0.63$ ) or any secondary outcome (children's depression rating scale (t)  $P=0.37$ , mood and feelings questionnaire  $P=0.37$ , children's global assessment scale  $P=0.44$ ).

For the clinical global impression improvement scale the proportion of patients in each category was similar between treatment arms (see [bmj.com](#)).

By 28 weeks 57/94 (61%) of those in the SSRI alone group and 52/98 (53%) of the CBT plus SSRI group were much or very much improved; 16/94 (17%) of those in the SSRI alone group and 24/98 (25%) of those in the CBT plus SSRI group reported no response or worsening of symptoms.

#### Suicidality and self harm

Symptoms of suicidality and self harm reduced over time for both treatments for most outcomes so that the odds reduced over time (see [bmj.com](#)). For non-suicidal self harm there was evidence of a time-

Comparison of groups for primary and secondary outcome measures according to allocated treatment with selective serotonin reuptake inhibitors (SSRIs) alone or in combination with cognitive behaviour therapy (CBT)

| Outcome   | SSRI        |                | CBT plus SSRI |                | Time-treatment interaction* (95% CI); P value | Treatment effect† (95% CI); P value |
|---|-------------|----------------|---------------|----------------|---|-------------------------------------|
|   | Mean (SD)   | No of patients | Mean (SD)     | No of patients |   |                                     |
| <b>Primary</b>  |             |                |               |                |   |                                     |
| Health of the Nation outcome scales for children and adolescents: |             |                |               |                |   |                                     |
| Base  | 25.5 (5.6)  | 103            | 25.1 (5.5)    | 105            |   |                                     |
| 6 weeks   | 19.2 (7.6)  | 98             | 18.7 (7.0)    | 98             | 0.048 (-0.059 to 0.155);<br>0.38              | 0.001 (-1.519 to 1.521);<br>1.00    |
| 12 weeks  | 18 (7.5)    | 101            | 17.1 (8.3)    | 101            |   |                                     |
| 28 weeks  | 14.5 (8.3)  | 95             | 15.4 (8.6)    | 98             |   |                                     |
| <b>Secondary</b>  |             |                |               |                |   |                                     |
| Children's revised depression rating scale (t score):             |             |                |               |                |   |                                     |
| Base  | 75.3 (6.7)  | 103            | 75.1 (6.7)    | 105            |   |                                     |
| 6 weeks   | 64.6 (10.1) | 97             | 65.3 (9.3)    | 98             | -0.023 (-0.189 to 0.143);<br>0.79             | 1.432 (-0.709 to 3.572);<br>0.19    |
| 12 weeks  | 61 (11.8)   | 99             | 62.8 (12.4)   | 100            |   |                                     |
| 28 weeks  | 55.8 (12.7) | 94             | 57.3 (13.5)   | 98             |   |                                     |
| Mood and feelings questionnaire:                                  |             |                |               |                |   |                                     |
| Base  | 38.2 (12.7) | 103            | 37.9 (11.9)   | 105            |   |                                     |
| 6 weeks   | 25.4 (13.8) | 97             | 25.5 (13.0)   | 98             | 0.087 (-0.108 to 0.287);<br>0.37              | 1.271 (-1.256 to 3.797);<br>0.32    |
| 12 weeks  | 21.6 (14.8) | 99             | 22.7 (15.4)   | 100            |   |                                     |
| 28 weeks  | 15.5 (15.0) | 93             | 18.9 (15.5)   | 98             |   |                                     |
| Children's global assessment scale:                               |             |                |               |                |   |                                     |
| Base  | 40.3 (6.3)  | 103            | 41.6 (6.0)    | 105            |   |                                     |
| 6 weeks   | 48 (10.2)   | 98             | 48.9 (10.7)   | 98             | -0.029 (-0.218 to 0.160);<br>0.76             | 0.162 (-2.535 to 2.860);<br>0.91    |
| 12 weeks  | 50.7 (12.1) | 100            | 52.1 (14.3)   | 101            |   |                                     |
| 28 weeks  | 57.8 (14.5) | 94             | 57.2 (16.4)   | 98             |   |                                     |

\*Adjusted for time, sex, age, site, behavioural disorder, and baseline value of outcome measure.

†Refers to estimated mean across three follow-up time points.

**WHAT IS ALREADY KNOWN ON THIS TOPIC**

There is no clear cut optimal treatment for major depression in adolescents  
 Treatment can be effective in the short term, though use of selective serotonin reuptake inhibitors (SSRIs) might be associated with suicidality  
 NICE guidelines advocate specific psychological therapy, such as cognitive behaviour therapy, in conjunction with SSRIs

**WHAT THIS STUDY ADDS**

For referred patients in a specialist service setting the addition of CBT to treatment with an SSRI and routine specialist clinical care does not confer any additional benefit in clinical outcomes

treatment interaction ( $P=0.070$ ) and a mean treatment effect across follow-up time points ( $P=0.023$ ). This was probably because few participants in the SSRI alone group reported threshold levels of self harm at the six week assessment. When we removed this time point from the longitudinal analysis the interaction ( $P=0.57$ ) and mean treatment effect ( $P=0.24$ ) were no longer present.

**Adverse events**

Some 59% (61/103) in the SSRI alone group and 62% (65/105) in the CBT plus SSRI group reported side effects (adjusted odds ratio 1.05, 0.58 to 1.91,  $P=0.87$ ). In one participant this was severe. The commonest reported adverse events or side effects were headaches, nausea, tiredness, dry mouth, and reduced appetite. Irritability was reported in 4% (8/208) and disinhibition in less than 1% (1/208).

**DISCUSSION****Principal findings**

In these adolescents in routine specialist clinic care with moderate to severe depression the addition of cognitive behaviour therapy to treatment with an SSRI had no benefit over treatment with an SSRI alone. Around one in five patients improved with a brief psychosocial intervention, consistent with previous reports.<sup>17,18</sup> Eighty six (43%) by 12 weeks and 109 (57%) by 28 weeks reported being much or very much improved, indicating an increasing proportion of patients showing recovery by the secondary end point. These findings are consistent with those of one recent trial that tested the effects of combined treatment against SSRIs alone<sup>7</sup> but differed from the results of the US treatment of adolescent depression study, which showed combined treatment to be more effective than fluoxetine alone on some but not all of their outcome measures. This was true only for patients with moderate but not severe depression.<sup>6,19</sup> In our study neither severity nor comorbidity influenced the results and SSRI plus CBT was no more effective in relatively milder cases, bearing in mind that our participants were probably the most severely impaired in any randomised controlled trial to date.<sup>6,7,17</sup> Importantly, we did not exclude any cases on the basis of suicidality.

The US study suggested that compared with fluoxetine alone, combined treatment with CBT was

protective against suicidality.<sup>6</sup> We found no evidence to support this, nor did we find an increase in suicidality associated with SSRI use, though our study was not powered to detect such a difference. Overall all forms of suicidal thoughts and actions and self harm reduced over the study period.

**Strengths and weaknesses**

Our participants were typical of adolescents with major depression in the NHS and included those with severe illness with considerable impairment, active suicidality, and self harm. In addition, we excluded adolescents who responded to the brief initial intervention, ensuring that we randomised only those with persistent depression. The US study also found no greater response to combined treatment than to fluoxetine alone in their subgroup of more severely affected patients.<sup>19</sup> Taken with the current findings this implies that psychiatrists who treat adolescents should consider prescribing fluoxetine in severe cases characterised at diagnosis by greater than eight symptoms, suicidal ideas, self harm, or psychotic thoughts.

Low attendance rates for CBT may have reduced response, despite the intensive efforts made to maintain therapeutic contact. Whether the use of fully trained CBT therapists together with more sessions and longer treatment duration would influence rate of response is unclear and deserves further investigation. Although ratings of audiotaped sessions showed that trained CBT therapists delivered somewhat better treatment in this study than those who delivered CBT under supervision, this did not result in improved outcome. Active specialist clinical care delivered in both arms may have been of a higher quality than general family support and contained more psychologically effective components than would be found in routine care delivered in most hard pressed NHS clinics. If this were true for the active clinical care in this study it might have reduced treatment effects of adding CBT. The US findings showed that CBT without active clinical care was no better than placebo, which supports the lack of added effect of CBT in our study. Our study was powered to detect only superiority of one treatment over the other, and not equivalence, so although there is no difference in outcome we can not say there is evidence that treatments are equally effective. In addition there was insufficient power to detect differences in suicidality and self harm between the treatment arms. We examined only short term effects of treatment and longer term outcomes should be used in future studies.

**Policy implications**

Current guidelines from the National Institute for Health and Clinical Excellence (NICE) recommend that SSRIs should be given only to moderate to severely depressed adolescents in combination with a psychological therapy.<sup>5</sup> Consideration of previous and current study data suggests that, for depressed patients referred from community settings, the addition of CBT

adds little to specialist active clinical care in conjunction with an SSRI in the short term. Lack of response to treatment in adolescents deserves much closer attention.

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**Competing interests:** BD has been reimbursed for attending educational meetings sponsored by Lilly.

**Ethical approval:** Multi-centre research ethics committee and all relevant local research ethics committees.

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## My first time on call

It was my first time on call, and I was to cover the emergency room from 4 pm until 8 am the next morning. The early part of my shift was uneventful, and I successfully cleared the minor cases of malaria, colds, and catarrhs. My great fear had long been of being accosted by a patient and not knowing what to do, so that night I retired to bed with hopes and prayers for a sweet sleep, dreaming of nothing related to medicine.

My ordeal started at about 11 pm. The first inkling of trouble came from shouts at the hospital gate, which rapidly progressed to the emergency room. After a brief knock on my room door, a nurse's head appeared: "Doctor, we have accident victims," she said.

I stepped rather timidly into the emergency room to find it full of passengers from a bus. I could see only one potential patient, a man clutching his chest and making a lot of noise, while the other people added to the increasing bedlam. To make matters worse, the National Electric Power Authority had decided that working in pitch darkness was preferable to having light, so I had the extra burden of examining a possibly seriously injured patient by lantern light.

My worst fears had not just materialised, they had multiplied. I was so confused. I am sure the people in that room smelt my fear and indecision. "Nurse, nurse where is the doctor?" (This was to my memory the only time I denied my profession.)

"He is coming," I replied, for in that moment I suddenly remembered there was a second doctor on call, the registrar. I immediately told the orderlies to run to call him, and, as an extra measure, I sent the ambulance driver too.

Meanwhile, I tried to make the patient comfortable; he did not assist me but proceeded to shout with increased vigour that he was going to die. The minutes before the registrar arrived seemed like hours; "Where is he? Oh, where is he?" I continued to lament.

Suddenly he appeared. Looking at my face and then around the room, he summed up the situation. The first thing he did was to send everyone except the patient and one other passenger out of the room to make more space and reduce the chaos. Then, very calmly, he said, "Dr Lamikanra, ABC of resuscitation."

Immediately I felt so stupid. How had I forgotten the most basic facts? In a few minutes the examination was over, and the patient who had been about to die had calmed down considerably.

I finished my shift the next morning knowing that, even if you have forgotten everything, starting from the basics is always the best thing to do.

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