Child Psychiatry Hum Dev
DOI 10.1007/s10578-016-0675-y

ORIGINAL ARTICLE

Augmenting Cognitive Behavior Therapy for School Refusal with Fluoxetine: A Randomized Controlled Trial

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Abstract This study investigates whether the augmentation of cognitive behavior therapy (CBT) with fluoxetine improves outcomes in anxious school refusing adolescents (11–16.5 years). Sixty-two participants were randomly allocated to CBT alone, CBT + fluoxetine or CBT + placebo. All treatments were well tolerated; with one suicide-attempt in the CBT + placebo group. All groups improved significantly on primary (school attendance) and secondary outcome measures (anxiety, depression, self-efficacy and clinician-rated global functioning); with gains largely maintained at 6-months and 1-year. Few participants were anxiety disorder free after acute treatment. During the follow-up period anxiety and depressive disorders continued to decline whilst school attendance remained stable, at around 54 %. The only significant between-group difference was greater adolescent-reported treatment satisfaction in the CBT + fluoxetine group than the CBT alone group. These results indicate the chronicity of school refusal, and the need for future research into how to best improve school attendance rates.

This trial is registered with the Australian New Zealand Clinical Trials Registry (www.anzctr.org.au; Trial Number: ACTRN12606000103561; Trial Name: Treatment of School Refusal).

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Keywords School refusal · Anxiety disorders · Cognitive behavior therapy · Fluoxetine

Introduction

Attendance at school to gain an education is a key developmental task of childhood and adolescence achieved by most but not all students. Refusal to attend school disrupts emotional, social, and educational development and is predictive of further problems in later adolescence and adulthood [1, 2]. Berg [3] defines school refusal as severe emotional upset that precipitates persistent difficulty attending school. Students remain at home with parental knowledge, while resisting their attempts to enforce school attendance. While adolescents may be oppositional and even aggressive towards those who try to enforce school attendance they typically lack antisocial behavior problems. School refusal is equally common in boys and girls [4] and has been reported in all countries in which there is mandatory education [1]. While school refusal is not a diagnostic entity found in psychiatric classification systems such as the DSM-5 [5], it is typically associated with one of three diagnostic profiles, characterized by separation anxiety disorder, phobic anxiety, and a combination of anxiety and depressive disorder [4].

To date, cognitive behavior therapy (CBT) interventions appear to be the most evidence-based treatment for school refusal, and typically involve treatment components such as psychoeducation, relaxation training, cognitive restructuring, graded exposure, and social-skills training [6]. However, few randomized controlled trials (RCT) evaluating the efficacy of CBT have been reported and a substantial proportion do not respond [7]. CBT has been shown to be superior to a waitlist control (CBT: 94 %

Published online: 02 August 2016

attendance vs. WL: 56 %) in children and adolescents [8] and equivalent to an education support treatment control (CBT: 67 vs. 60 % Ed. Support) in a trial in which both interventions resulted in significant improvements in attendance [9]. A CBT components-analysis study [10] indicated that involving parents and school personnel in CBT treatment is important for earlier success of treatment. Further, some evidence suggests that CBT may be more effective for younger children than adolescents which is also consistent with reports by others that adolescents are harder to treat [9]. The authors suggested that this difference may have been due to the presence of depressive disorders in adolescents compared with children. Adolescent developmental issues have also been suggested to interfere with engagement in CBT for school-refusing adolescents [11]. In response, Heyne and colleagues developed and successfully evaluated a developmentally sensitive treatment in an open trial ($N = 20$) demonstrating significant improvement in attendance and reductions in internalizing symptoms. Longer term outcomes of treatment of school refusal are largely unknown with CBT studies reporting modest follow up periods of 2–4.5 months [8, 10, 11].

Given the modest attendance rates following psychosocial treatment for school refusal, Bernstein et al. [12] investigated CBT treatment augmented with antidepressant medication in 63 school refusing adolescents (12–18 years) with anxiety and depressive disorders. The authors compared 8 sessions of CBT in conjunction with either placebo or imipramine. Significantly more adolescents in the CBT + imipramine group (54 %) achieved 75 % school attendance than those in the CBT + placebo group (17 %). While the Bernstein et al. [12] study demonstrated the benefit of augmenting CBT with a tricyclic antidepressant, this type of medication has potential cardiotoxic effects, is lethal in overdose [13, 14] and is not superior to placebo in the treatment of depressive disorder in adolescents [15]. The selective serotonin reuptake inhibitors (SSRIs), and fluoxetine specifically, have been recommended as a pharmacological treatment of choice for anxiety and depressive disorders in children and adolescents given their safety and evidence of efficacy [16, 17], but require evaluation in their role in the treatment of school refusal. Some studies [18, 19] but not all [20, 21], indicate that combined pharmacotherapy and psychotherapy treatment is more effective than either treatment alone for young people suffering from anxiety or depressive disorders. Therefore, it is possible that SSRIs may be effective in augmenting CBT treatment of anxious school refusing adolescents. Hence, the aim of the current study is to investigate whether CBT combined with a widely used antidepressant, fluoxetine, improves response to treatment in school refusing adolescents beyond CBT alone. Fluoxetine was chosen due to evidence of its therapeutic effect in treating both anxiety and depressive disorders in adolescents [e.g. 22, 23]. First, it was hypothesized that adolescents in all of the treatment groups (CBT + fluoxetine, CBT + placebo, CBT alone) would show improved school attendance, and improved short and longer-term outcomes in terms of reductions in anxious and depressive symptomatology. Second, adolescents in the CBT + fluoxetine (CBT + FLX) group were expected to show superior outcomes on primary and secondary outcome measures, compared to CBT only and CBT + placebo (CBT + PLA) groups. Third, school refusing adolescents with anxiety alone were expected to show better school attendance than those with comorbid depressive disorders.

Materials and Methods

Participants

Adolescents aged between 11 and 16.5 years who met Berg's criteria [3] for school refusal were invited to participate in the study between March 2006 to July 2011. The upper age limit was extended from 15.5 to 16.5 in 2007 in line with the change to the age of mandatory school attendance in Australia. Berg's criteria were operationalized as: severe difficulty attending school (less than 50 % attendance for the past 4 weeks), severe emotional upset (DSM-IV-TR diagnosis of social phobia, specific phobia, generalized anxiety disorder, separation anxiety disorder or panic disorder) [24], at home during the school day with parent's knowledge, absence of antisocial characteristics (operationalised as absence of conduct disorder) and reasonable efforts by parents to enforce attendance. Prior mental health treatment had been received by 80.6 % (n = 50) of participants and 58.1 % (n = 36) were experiencing their first episode of school refusal.

A number of exclusion criteria were applied for research and ethical reasons including physical illness that precluded school attendance, psychotropic medication use, pregnancy, intellectual disability or insufficient English language skill that precluded CBT, current inpatient admission, primary behavior disorder (e.g., conduct disorder), substance use disorder, bipolar disorder, obsessive compulsive disorder (OCD) and post-traumatic stress disorder (PTSD). Sixty-two participants were randomized to treatment (see Fig. 1); participant demographic information is depicted in Table 1. Participant ethnicity was determined with 93.5 % of the sample as non-hispanic white, and 6.5 % Asian.

Study Design

This study was a randomized controlled trial with two control groups (CBT, CBT + PLA). The CBT control allowed

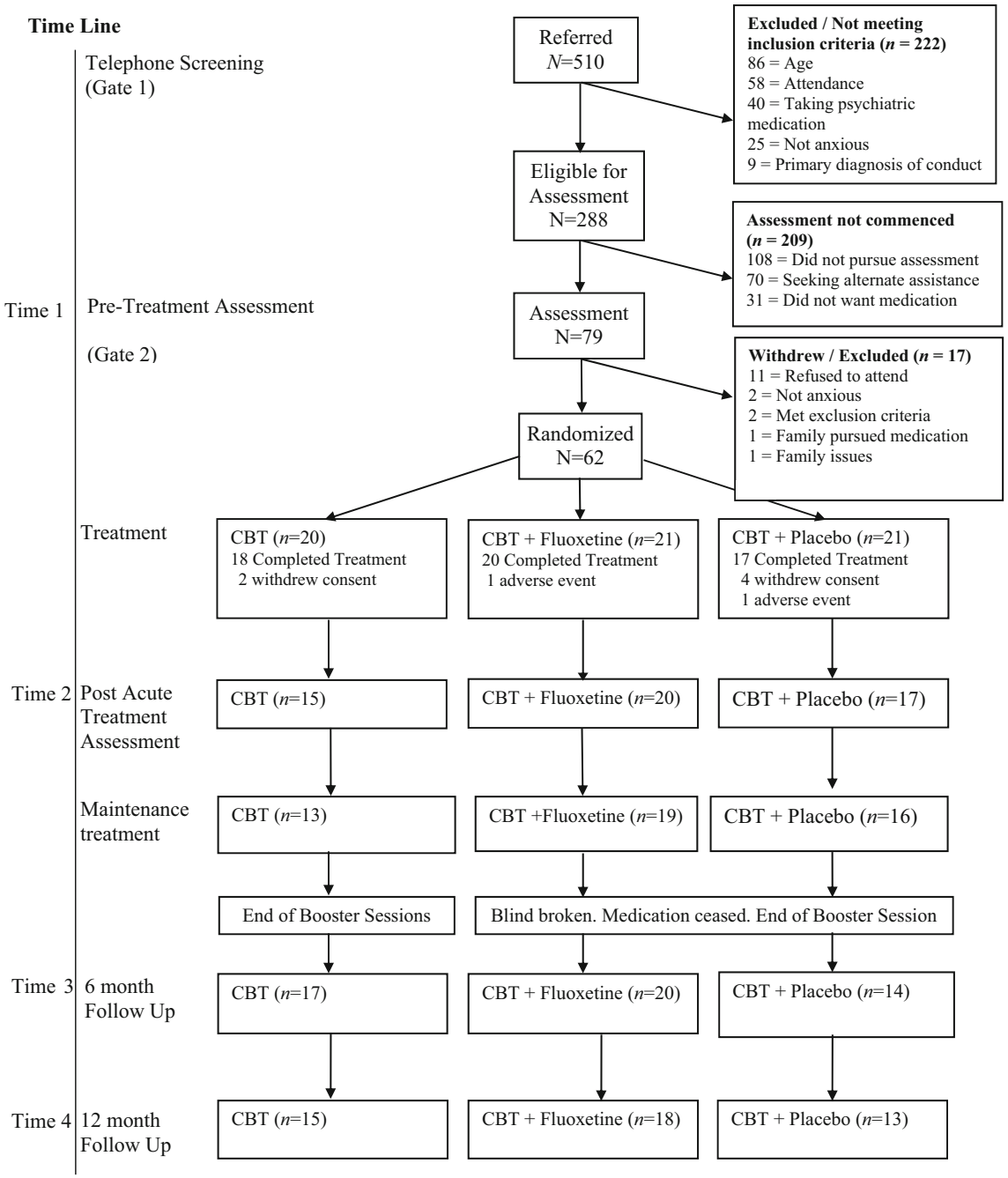

Fig. 1 Participant flow

the impact of adding fluoxetine to be determined. The CBT + PLA treatment controlled for the non-specific effect of taking a tablet. A double blind was maintained for fluoxetine/placebo groups but it was not possible to blind participants in the CBT alone treatment. The study was approved by both Monash University and Monash Health human research ethics committees. The trial was registered with the Australian New Zealand Clinical Trials Registry (www.anzctr.org.au; Trial Number: ACTRN1260600010 3561; Trial Name: Treatment of School Refusal).

Measures

Multiple outcome measures were administered during the pre-treatment assessment period (baseline, time 1), following acute treatment (time 2), and at two follow up assessments at approximately 6 and 12 months (times 3 and 4) that were subsequent to a naturalistic observation period after the end of treatment. Treatment was continued until the requisite number of sessions was completed (which varies from our initial protocol that prescribed the number of weeks

Table 1 Baseline demographics and clinical characteristics

	CBT $n = 20$	CBT + placebo $n = 21$	CBT + fluoxetine $n = 21$	Total $N = 62$
Age[a]	14.0 (0.8)	13.4 (1.3)	13.3 (1.0)	13.6 (1.0)
Male	10 (50 %)	10 (47.6 %)	14 (66.7 %)	34 (54.8 %)
Single parent family	7 (35 %)	6 (28.6 %)	7 (33.3 %)	20 (32.2 %)
School type[b]				
Government	15 (75 %)	14 (66.7 %)	9 (42.9 %)	38 (61.3 %)
Catholic/private	5 (25 %)	5 (23.8 %)	12 (57.1 %)	22 (35.5 %)
Alternative	–	2 (9.5 %)	–	2 (3.2 %)
First school refusal	9 (45 %)	11 (52.4 %)	6 (28.6 %)	26 (42.0 %)
Primary diagnosis				
Social Phobia	12 (60.0 %)	11 (52.4 %)	8 (38.1 %)	31 (50.0 %)
Separation anxiety disorder	2 (10.0 %)	4 (19.1 %)	3 (14.3 %)	9 (14.5 %)
Generalized anxiety disorder	3 (15.0 %)	4 (19.1 %)	8 (38.1 %)	15 (24.2 %)
Anxiety disorder NOS	3 (15.0 %)	2 (9.5 %)	2 (9.5 %)	7 (11.3 %)
Comorbid disorder				
Any disorder	15 (75.0 %)	16 (76.2 %)	17 (81.0 %)	48 (77.4 %)
Anxiety disorder	4 (20.0 %)	9 (42.9 %)	7 (33.3 %)	20 (32.2 %)
Depressive disorder	13 (65.0 %)	10 (47.6 %)	13 (61.9 %)	36 (58.1 %)
ODD or ADHD	5 (25.0 %)	7 (33.3 %)	3 (14.3 %)	15 (24.2 %)
Other	1 (5.0 %)	2 (9.5 %)	2 (9.5 %)	5 (8.1 %)

[a] CBT > CBT + PLA, CBT > CBT + MED

[b] CBT + FLX > CBT + PLA, CBT + FLX > CBT

between pre and post assessment) in acknowledgment of the common occurrence of missed appointments (e.g., clinic refusal), and there was no impact on the analysis plan.

Measures were selected based on their sound psychometric properties and previous use in similar trials. Clinicians that completed assessments were independent evaluators, blind to participants' treatment assignment.

School Attendance

The single primary outcome measure was attendance for the prior four weeks (20 days) of regular school (e.g., excluding holidays/ vacation) which was collected at each time point using official records of attendance collected by the school. Daily attendance was measured as a proportion of the school periods attended each day (e.g., 4 periods attended of 6 was recorded as 67 %). As used in recent comparable study [11], ≥80 % attendance was used as a marker of acceptable attendance, and thus represents clinically significant change from baseline (attendance <50 %).

The Anxiety Disorders Interview Schedule for DSM-IV Child Version (ADIS-C)

The ADIS-C [25] is a structured interview for children and adolescents 7–17 years old includes child and parent interview schedules. The ADIS-C includes sections for assessing child and adolescent psychiatric disorders including those relevant to the study selection criteria. Test–retest reliability is satisfactory (r = 0.71), while inter-rater reliability for diagnoses had an overall kappa = 0.75 [26].

The Global Assessment of Functioning (GAF)

The GAF is a psychometrically sound, clinician reported 100 point hypothetical continuum of mental health—illness used to rate current level of psychological, social and occupational functioning [23]. Reliability for a single rater is = 0.72, randomly chosen rater is = 0.56 [27].

The Clinical Global Impressions Scale—Improvement (CGI-I)

The CGI-I is an established measure of clinician-rating of improvement was administered [28]. Improvement is measured on a seven-point scale, ranging from very much improved (1) to very much worse (7). It has been shown to have an inter-rater reliability of 0.51 [29] and good concurrent validity with the Hamilton Rating Scale for Depression (r = 0.42) and the Liebowitz Social Anxiety Scale (r = 0.74) in individuals with social anxiety disorder [30].

Children's Depression Inventory (CDI)

The CDI is a measure of depressive symptoms for use in children and adolescents from 7 to 17 years [31]. It is a 27 item measure that has good internal consistency (alpha = 0.83–0.89) and adequate test–retest reliability (r = 0.41–0.77) [32].

Revised Children's Manifest Anxiety Scale (RCMAS)

The RCMAS is a 37-item anxiety rating scale for children aged between 6 and 19 years. Internal consistency estimates are 0.80 and above [33], and test–retest reliability is 0.88 [34].

The Self-Efficacy Questionnaire for School Situations (SEQSS)

The SEQSS is a 12-item questionnaire assessing children's perceived ability to manage specific anxiety-provoking situations associated with school attendance [35]. It has an internal consistency reliability of 0.85 and good test–retest reliability (r = 0.41–0.77) [35].

Child Behavior Checklist (CBCL)

The CBCL is a very well established parent completed 118-item checklist that measures behavior and emotional problems in children and adolescents aged between 6 and 18 years [36]. The CBCL has subscales that measure internalizing and externalizing problems. Both subscales have high test–retest reliability of above 0.9.

School Refusal Program Consumer Satisfaction Questionnaire (SRP-CSQ)

This measure assesses adolescent- and parent-report desire for adolescent to return to school (1 item) and satisfaction with the treatment program (5 items) on a five point scale ranging from not at all (score = 0) to very much (score = 4) [37]. In addition, the measure asked the respondent receiving CBT + PLA or CBT + FLX to guess whether they were taking fluoxetine or placebo. Cronbach alpha of the 5 item consumer satisfaction subscale with the current sample ranged from 0.81 (mother) to 0.9 (adolescent).

Procedures

Recruitment was achieved by providing information about the study to schools, health professionals, and child and adolescent mental health services and inviting referrals. The study was conducted at two locations; a hospital-based Monash University child and adolescent outpatient clinic and a government child and adolescent mental health service, both in suburban Melbourne, Australia.

Adolescents with parental consent who met selection criteria were randomly allocated to CBT alone, CBT + FLX, or CBT + PLA. The clinic randomization officer (JT), prepared the random sequence using a computer-generated blocking procedure to ensure similar numbers in each treatment group. Treatment allocation occurred after selection criteria were met. The blind was protected by use of medication capsules identical in appearance, taste and packaging, as prepared by an independent compounding pharmacy which was paid for this work.

Cognitive Behavior Therapy

CBT was administered twice weekly for the first four sessions (50–60 min duration), and then weekly for a remaining eight sessions. After acute treatment, monthly booster sessions were offered for three months in the treatment maintenance phase. Attendance of at least 8 (67 %) sessions was required for qualifying as having completed treatment.

Two clinicians worked with each family, one with the adolescent and the other with the parents. Clinicians were eight registered psychologists and six masters and doctoral level students working under supervision. Clinicians received a 2-day training workshop from a senior clinician and the study investigators (AD, GM, BT) and undertook one or two training cases under supervision. They were required to demonstrate a level of competence before providing treatment independently and received weekly supervision from study investigators.

The CBT was a manualized child, parent and teacher program based on an existing evidence-based CBT intervention for school refusal [38], that was adapted to include a greater emphasis on social skills training and the treatment of depressive symptoms.

Child therapy sessions comprised both core and optional treatment components. Core components were provided to all participants and included psychoeducation on anxiety and school refusal, goal-setting, relaxation training (e.g. breathing retraining and progressive muscle relaxation), social skills training (i.e., practicing responding to questions regarding school absence, assertiveness training), problem solving skills, cognitive therapy (i.e., challenging unhelpful thinking about school, developing coping statements), graded exposure, and a review of treatment. Following skills training and about 4–5 treatment sessions, a return to school plan was developed in conjunction with the adolescent, parents and school staff. The plan included graded steps (fear hierarchy) towards full time attendance

that used a systematic desensitization paradigm. Optional treatment components included mood management (e.g., coping with depressed mood, activity scheduling, cognitive restructuring), and further social skills training. Depending on treatment progress, the final sessions focused on relapse prevention that aimed to maintain attendance or exploring strategies to assist with school return.

Parent therapy sessions included content that mirrored adolescent therapy including, psychoeducation, problem solving skills, awareness of adolescent social skills training, and communication training to enhance parent skill and family functioning. Treatment also included parent-oriented therapy sessions that focused on behavior management and communication skills that aimed to improve parent capacity in returning the adolescent to school (e.g., identifying factors reinforcing non-attendance, giving clear messages regarding school return, planned ignoring of somatic complaints associated with anxiety, modeling confidence in the child, and positive reinforcement for attendance plan achievements). Parents were informed about the principles behind graded exposure to enable them to assist in exposure tasks. Finally, challenging parent's own unhelpful thoughts in regards to their child's anxiety/school refusal was undertaken along with relapse prevention skills.

At least one meeting with relevant school staff took place to discuss plans for school return and the role of school staff in facilitating this process. Regular telephone and written correspondence was undertaken with school staff in monitoring the student's progress towards attendance.

Fluoxetine/Placebo Medication

A child psychiatrist or a supervised child psychiatry registrar, who was blind to medication allocation, saw the child/adolescent with their parents for weekly to fortnightly reviews, in order to monitor dose and adverse events. To systematically monitor for adverse events, a modified version of the New York State Psychiatric Institute Side Effects Form for Children and Adolescents (SEFCA) [39] was administered at each appointment. The frequency and severity of side-effects were assessed using the measure's 58 items to which items about suicidal and non-suicidal self-injury (NSSI) ideation and behaviors were added due to concern about suicidal adverse events [40].

A flexible-dose design was used allowing adjustment for clinical response and tolerability. Dosing was also dependent on level of pubertal development. Level of pubertal development was determined by adolescent selecting the gender appropriate Tanner Stage [41] sketch that corresponded to the stage of pubertal development. Fluoxetine dosing ranged from 10 to 20 mg for pre-pubescent participants (Tanner stage 1, $n = 2$) and 10–60 mg for pubescent participants (Tanner stage ≥ 2; $n = 19$). The dose range is consistent with prior studies [18, 22]. Medication was prescribed until the end of the third booster (or equivalent time if the family did not attend), after which the blind was broken. Medication adherence for 3 months was required for qualifying as having completed that treatment component.

Treatment Integrity

A random selection of 10 % of participant files (n = 7) were audited by an independent Masters level researcher to assess completion of core activities in the treatment. The audit showed that the core activities of psychoeducation, goal setting, relaxation, cognitive therapy, social skills, problem solving, exposure and reviewing achievements were all administered to all participants with the exception of problem solving which was administered in 5/7 (71 %) cases.

Data Analyses

Random effects regression analyses were used to address study hypotheses with generalized least squares estimation. This analysis technique is an intent-to-treat approach with the advantage of allowing the analysis of incomplete participant data without the use of the overly conservative last observation carried forward method. Given that the post treatment assessments were conducted following the requisite number of sessions rather than a set time period, the time variable 'number of days from baseline to assessment date' was used within regression analyses. There was no significant difference between treatment groups in the average time between pre and post-treatment ($M = 136.8$ days $SD = 30.1$), and post-treatment assessment and the first ($M = 221.7$ days $SD = 38.8$) and second ($M = 227.0$ days $SD = 77.6$) follow-up assessments. Change in the outcome variables was expected to occur rapidly during the intensive twelve session treatment program before stabilizing during the follow up period with treatment gains maintained over time. Given this, we chose to use a non-linear (logarithmic) transformation of the time variable (days since baseline). To answer the hypotheses, longitudinal regression analyses were used to model both primary (school attendance) and secondary (RCMAS, CGAS, CDI, CGI and SEQ-SS, anxiety and depressive diagnosis) outcome variables as a function of time, treatment group, time x treatment group, age and gender (Hypotheses 1 and 2). To assess whether comorbid depressive disorder was associated with school attendance, we used a longitudinal regression analysis to model school attendance as a function of depressive diagnosis as well as time,

treatment group, time x treatment group, age and gender (Hypothesis 3). The purpose of the time x group interaction was to investigate whether the magnitude of change in the outcome variables was associated with treatment group. There was no evidence of treatment x time interaction in any of the analyses, so simpler models without interaction terms are presented.

Statistical Power

Power to detect the difference between CBT + fluoxetine and CBT + placebo was estimated using the figures provide by Bernstein et al [12] (54 % CBT + Imipramine and 17 % CBT + Placebo attending ≥75 %) with adjustment for our 80 % attendance goal (51 and 16 %) and our protocol of one pre- and three post-treatment assessments. We estimated that with our sample size that power to detect such a difference between groups would be 0.84. Data were analyzed with Stata Version 13 [42].

Results

During the recruitment period, 510 enquiries were received regarding participation in the trial, about half of whom were ineligible due to not meeting selection criteria, primarily for being too young or having missed less than 50 % of school in the last month (see Fig. 1). Of those who were eligible for assessment after telephone screening (Gate 1, $n = 288$) almost one third did not pursue an assessment, while a small minority ($n = 31$) discontinued due to stated concerns about antidepressant medication. Of those who commenced an assessment ($n = 79$), 62 met selection criteria (Gate 2) and were randomly allocated to treatment. Mean number of treatment sessions did not differ between groups for CBT (11.3 CBT, 12.2 CBT + PLA, 12.2 CBT + FLX), or booster sessions (1.8 CBT, 2.5 CBT + PLA, 2.5 CBT + FLX). The mean medication dose after acute treatment, at post-assessment was 22.50 mg ($SD = 6.39$) per day (range 10–30 mg) in the CBT + FLX group, and 23.53 mg ($SD = 9.96$) per day (10–40 mg) in the CBT + PLA group.

Baseline Characteristics

Differences between treatment groups on baseline demographic and clinical variables were examined using t tests and Chi square analyses. Two significant differences were found, with the CBT group being older by about 6 months, than the other two groups, and the school type was unevenly distributed with more participants from the CBT + FLX group attending non-government schools (see Table 1).

At baseline the participants were, on average, attending school less than 1 day per week (mean = 15 %). Social phobia was the most common primary diagnosis. For the majority, their current episode of school refusal was not their first with the mean age of first school refusal episode being 10.86 years ($SD = 2.71$) with onset ranging from 4 (pre-school) to 14 years. About three quarters (77.4 %) experienced one or more comorbid disorder with depressive disorders being most common ($n = 36$, 58.1 %) followed by another anxiety disorder ($n = 20$, 32.2 %). Rating of global functioning (GAF) was, on average, on the cusp of moderate and severe symptoms and functional impairment.

Primary Outcome Measure—School Attendance

In Fig. 2, the proportion of school attendance is graphically represented for each participant by treatment group and by percentage of attendance at the final assessment (≥80 % attendance, <80 and ≥50 % attendance and <50 % attendance). General patterns of attendance can be discerned. In the CBT alone group (Fig. 2a) a sub-group demonstrated rapid improvement and maintained these gains with attendance of ≥80 %. A small group ($n = 5$) appeared to receive little benefit from this treatment and were attending less than 50 % at the last observation. The CBT + PLA group (Fig. 2b) demonstrated scattered trajectories of change over time, with those who made rapid improvement by post-treatment assessment experiencing a subsequent decline, with attendance less than 80 % at their final observation.

The CBT + FLX group (Fig. 2c) largely improved between pre- and post-treatment albeit with a wide range of upward trajectories. Only three cases were attending less than 50 % at their final assessment.

Using regression analysis, significant improvement in mean school attendance averaged across treatment groups was observed over time (see Table 2). The effect size was medium ($d = 0.59$, 95 % CI 0.46–0.72). While fluctuation in trajectories can be observed in Fig. 2, on average, gains were maintained over the follow-up period. Regression analyses conducted to determine whether fluoxetine had an augmenting effect on CBT found no difference in treatment × time trajectories between groups, contrary to our hypothesis. Older participants had significantly worse attendance (see Table 3). The regression analysis assessing the association between comorbid depression and school attendance revealed that school attendance was not significantly lower in those with depressive disorder, again contrary to our hypothesis (see Table 3). We assessed clinically significant change by examining the proportion in each group who reached 80 % attendance (see Table 2),

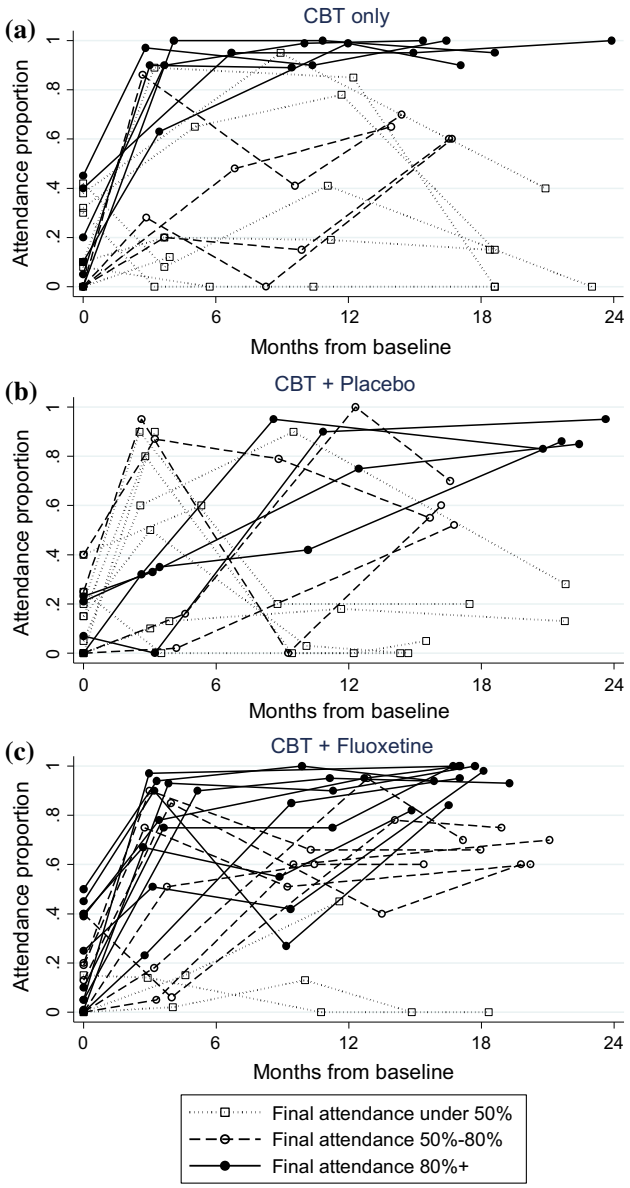

Fig. 2 Proportion of school attendance over time by treatment group

and conducted a logistic regression but found no difference in treatment x time trajectories between groups.

Secondary Outcome Measures

Mean scores on all self-, parent- and clinician-rated secondary outcome measures (see Table 2) improved across time for all outcomes. Regression analyses were conducted to compare change in secondary outcome measures between groups across time while controlling for age and gender. No significant differences between treatment groups were found on any self- or clinician-reported measure. Parent-reported CBCL internalizing and externalizing subscales improved over time but did not differ between treatment groups. As well as being associated with poorer attendance, older age was associated with more parent-reported externalizing problems. The mean effect size for these secondary outcome measures was 0.35 (range 0.23–0.58).

Adverse Events

All treatments were well tolerated. Two participants withdrew from treatment due to adverse events. One participant from the CBT + PLA group made a suicide attempt (placebo pill overdose) after 7 weeks of treatment and was discontinued from the study and referred to a psychiatrist for treatment. This participant had reported passive suicidal ideation at pre-treatment assessment and had made two prior suicide attempts. The second participant was from the CBT + FLX group and chose to discontinue after self-reporting weight gain, sore veins, difficulties speaking as well as a distrust of the study doctors and tablets.

The most common adverse events were difficulty falling asleep, difficulty arousing in the morning, outbursts of anger (all treatments), headache (CBT + FLX, CBT + PLA), irritability (CBT, CBT + PLA), drowsiness (CBT), lethargy, and apathy (CBT + FLX). ANOVA analyses found significant differences between groups on suicidal $F(2,623) = 3.64$, $p < 0.05$) and NSSI ideation ($F(2,623) = 4.94$ $p < 0.01$) and NSSI ($F(2,623) = 5.67$ $p < 0.01$). Games-Howell post-hoc tests for unequal variances at the $p < 0.05$ level confirmed that mean scores for both suicidal ideation and NSSI were significantly lower in the CBT + FLX group compared with the CBT group and mean scores for NSSI ideation were significantly lower in the CBT + FLX compared with both other groups.

Blinding

After 12 sessions of treatment, adolescents who were taking tablets and their parents were asked to guess which treatment (FLX or PLA) that they were receiving. Adolescents (sensitivity = 0.58; specificity = 0.73) and parents (sensitivity = 0.67; specificity = 0.71) guessed their treatment allocation at better than chance.

Consumer Satisfaction

Mean item score on the five-point consumer satisfaction scale (0–4 range, ranging from not at all satisfied to very much satisfied) was 2.6 for adolescents ($n = 49$), 3.2 for mothers ($n = 48$) and 3.1 for fathers ($n = 32$). Satisfaction varied ($p < 0.05$) between treatment groups with adolescents treated with CBT + FLX (mean item score = 3.1) more satisfied than those receiving CBT (mean item

Table 2 Outcome measure scores over time

	CBT *M*(SD) *n* (%)	CBT + placebo *M*(SD) *n* (%)	CBT + fluoxetine *M*(SD) *n* (%)	Overall *M*(SD) *n* (%)
School attendance				
Baseline	0.14 (0.17)	0.15 (0.14)	0.16 (0.17)	0.15 (0.16)
Post treatment	0.55 (0.39)	0.44 (0.35)	0.56 (0.36)	0.52 (0.36)
6 months	0.58 (0.40)	0.40 (0.40)	0.63 (0.29)	0.54 (0.37)
12 months	0.49 (0.40)	0.38 (0.36)	0.72 (0.31)	0.54 (0.38)
≥80 % attendance				
Baseline	0	0	0	0
Post treatment	7 (41 %)	5 (29 %)	7 (35 %)	19 (31 %)
6 months	8 (47 %)	4 (24 %)	7 (35 %)	19 (35 %)
12 months	5 (29 %)	4 (24 %)	10 (50 %)	19 (35 %)
RCMAS				
Baseline	53.0 (9.0)	56.0 (8.0)	51.3 (12.1)	53.5 (9.9)
Post treatment	47.4 (7.8)	43.9 (14.2)	46.5 (16.4)	45.8 (13,8)
6 months	45.6 (13.6)	45.5 (11.3)	46.8 (17.9)	46.1 (14.8)
12 months	50.0 (14.8)	44.0 (7.9)	33.2 (15.5)	43.1 (15.4)
CDI				
Baseline	16.9 (8.1)	16.6 (8.9)	12.8 (9.3)	15.4 (8.9)
Post treatment	13.7 (10.0)	8.2 (8.0)	7.3 (8.5)	9.2 (8.9)
6 months	9.5 (6.3)	8.5 (7.0)	7.2 (7.9)	8.2 (7.1)
12 months	11.5 (9.5)	5.6 (2.6)	3.4 (5.6)	6.8 (7.7)
GAF				
Baseline	51.3 (5.7)	51.3 (3.9)	50.6 (4.9)	51.1 (4.8)
Post treatment	58.5 (9.0)	58.7 (10.8)	59.7 (9.4)	59.0 (9.6)
6 months	64.6 (9.2)	61.8 (10.0)	63.4 (10.8)	63.4 (9.9)
12 months	60.3 (13.2)	65.2 (8.7)	68.5 (12.6)	64.9 (12.2)
SEQSS				
Baseline	56.9 (10.9)	56.3 (9.1)	58.9 (11.0)	57.3 (10.2)
Post treatment	58.6 (10.1)	61.5 (14.6)	65.5 (9.7)	62.6 (11.8)
6 months	63.3 (10.3)	63.6 (10.0)	64.5 (14.2)	64.1 (12.0)
12 months	63.4 (10.6)	63.0 (10.9)	74.4 (5.8)	67.2 (10.5)
CGI-I rating 1 or 2				
Post treatment	5 (36 %)	6 (35 %)	9 (50 %)	20 (40.8)
6 months	10 (59 %)	7 (54 %)	13 (68 %)	30 (61.2)
12 months	9 (60 %)	9 (75 %)	13 (72 %)	31 (68.9)
CBCL—Internalizing				
Baseline	74.3 (6.7)	71.0 (8.4)	72.1 (9.6)	72.5 8.3
Post treatment	64.3 (12.5)	62.5 (8.7)	63.6 (11.3)	63.5 10.7
6 months	62.7 (12.5)	60.2 (9.5)	65.8 (8.2)	63.2 10.2
12 months	63.5 (13.5)	62.2 (8.7)	59.5 (14.0)	61.6 12.4
CBCL—Externalizing				
Baseline	64.9 (11.8)	60.3 (9.1)	60.0 (9.9)	61.8 (10.5)
Post treatment	58.0 (12.8)	54.7 (6.0)	53.9 (9.1)	55.3 (9.4)
6 months	55.8 (11.3)	53.4 (9.4)	56.8 (7.1)	55.5 (9.2)
12 months	56.7 (10.5)	52.7 (9.8)	52.0 (14.0)	53.8 (11.7)
Anxiety diagnosis				
Baseline	20 (100 %)	21(100 %)	21(100 %)	62 (100 %)
Post treatment	12 (80 %)	14 (82 %)	19 (95 %)	45 (86.5 %)
6 months	11 (65 %)	10 (77 %)	13 (68 %)	34 (69.4 %)
12 months	6 (40 %)	5 (42 %)	7 (39 %)	18 (40.0 %)

Table 2 continued

	CBT *M*(SD) *n* (%)	CBT + placebo *M*(SD) *n* (%)	CBT + fluoxetine *M*(SD) *n* (%)	Overall *M*(SD) *n* (%)
Depression diagnosis				
Baseline	13 (65 %)	10 (48 %)	13 (62 %)	36 (58.1 %)
Post treatment	8 (53 %)	6 (35 %)	9 (45 %)	23 (44.2 %)
6 months	6 (35 %)	4 (31 %)	7 (37 %)	17 (34.7 %)
12 months	5 (33 %)	1 (8 %)	5 (28 %)	11 (24.4 %)

CBCL child behavior checklist, *CDI* Children's Depression Inventory, *CGI-I* Clinical Global Impression—Improvement, *GAF* Global Assessment of Functioning, *OR* odds ratio, *RCMAS* Revised Children's Manifest Anxiety Scale, *SEQSS* Self Efficacy Questionnaire School Situations

Table 3 Regression of attendance on treatment type, age, gender and depressive disorder and clinical outcomes on treatment type, age and gender. Logistic regression of anxiety and depressive diagnosis on treatment type, age and gender

	Attendance	RCMAS	CDI	SEQSS	GAF	CGI-I	CBCL-INT	CBCL-EXT	Diagnosis[c]	
									Anxiety OR	Depression OR
Time [Log (1 + days)][a]	0.30**	−6.32**	−4.77**	3.95**	8.54**	−0.45**	−6.21**	−3.35**	0.002**	0.07**
Treatment[b]										
CBT	0.02	2.68	4.41	−6.10	−0.65	0.20	1.53	6.14*	0.23	1.37
CBT + PLA	−0.11	2.04	1.39	−4.02	−1.34	0.12	−0.60	0.68	0.64	0.13
Age	−0.08**	1.62	0.91	−2.78	−1.80	0.06	0.60	−0.65*	1.38	1.70
Male	0.09	1.78	0.01	−2.78	−0.71	−0.11	1.77	5.50	0.23	1.00
Depressive disorder	−0.04	–	–	–	–	–	–	–	–	–
Constant	−0.05	57.18**	22.0*	22.97	38.19**	4.24**	90.16**	79.60**	4.55×10^{15}**	510.38

CBCL child behavior checklist, *Int* internalising subscale, *Ext* externalizing subscale, *CDI* Children's Depression Inventory, *CGI-I* Clinical Global Impression—Improvement, GAF Global Assessment of Functioning, *OR* odds ratio, *RCMAS* Revised Children's Manifest Anxiety Scale, *SEQSS* Self Efficacy Questionnaire School Situations

[a] Time under observation was expressed using a curvilinear expression to reflect the rapid improvement between pre- and post-treatment assessments

[b] CBT + FLX was the reference treatment

[c] Logistic regression

* $p < 0.05$; ** $p < 0.01$

score = 2.2). Neither parent satisfaction scores differed between treatments.

Discussion

The current study investigated whether the augmentation of CBT with fluoxetine improves response to treatment in adolescents with school refusal. The results indicated that on average, treatments resulted in improvements of medium effect size in school attendance and a reduction in anxiety and depressive symptoms (on average of small effect size, but ranging from small to medium). There were no significant differences between treatment groups on primary and secondary outcome measures. Thus findings did not support the hypothesis that augmentation of CBT with fluoxetine improves treatment response. However, the CBT + FLX group had a better side-effect profile in terms of suicidal and NSSI ideation and NSSI. In addition, adolescent-reported, but not parent-reported, consumer satisfaction was greater in the CBT + FLX group. School refusing adolescents with an anxiety disorder did not show better school attendance than those with comorbid anxiety and depressive disorder.

The current sample was highly impaired and often exhibited chronic difficulties with school attendance and multiple psychiatric disorders. Nevertheless, all three treatments resulted in improved school attendance, with attendance rates increasing from 15 to 52 % attendance after acute treatment. This improvement was maintained

6 months (54 %), and 12 months after acute treatment (54 %). Similar improvements were evident in terms of self-rated anxiety and depression scores, despite most (73 %) participants still having an anxiety disorder diagnosis after treatment. Similarly, significant clinician-rated improvements in global functioning were reported, as well as significant improvements in parent-rated internalizing and externalizing problems (CBCL). It is noteworthy that despite these improvements, the average level of attendance reached did not meet the level required for a full time education.

Improvement in attendance rate was comparable to another recent adolescent school refusal study, where adolescents treated with CBT [11] improved their school attendance from 15 to 48 %. However, the proportion reaching more than 80 % attendance (34 % on average post baseline across treatments) was somewhat lower than the 45 % achieved by Heyne and colleagues [11]. While attendance rates for the CBT + PLA group (44 %) were higher than the 28 % reported by Bernstein and colleagues [12], our drug treatment attendance rate of 56 % was lower than the 70 % of Bernstein et al.'s [12] CBT and imipramine group. The lower placebo treatment response rate in Bernstein and colleagues [12] study may be attributable to the higher rate of comorbid depression (100 vs. 58 % in the current study), the lower dose of CBT (8 sessions vs. 12 sessions in the current study), differences in the content of CBT treatments provided, and/or the greater parent participation in the current study (12 parent treatment sessions).

Only 27 % of participants did not have an anxiety disorder post treatment, compared with 45 % at 6-month follow-up and 71 % at 12 months. In addition, the percentage with a depressive disorder declined steadily over time with the proportion almost halving from baseline (58 %) to 12-month follow-up (24 %). These data are comparable to those of Heyne et al. [11] who found 30 % of their sample had no anxiety diagnosis following CBT treatment, 50 % of their sample had no anxiety at follow up, and 75 % of their sample no longer met criteria for a depressive disorder following treatment and at 2 month follow up. The high remission rate from anxiety disorder (71 %) and depressive disorder (58 %) at 12 months post treatment might reflect a natural process of return to mental health, although it more probably suggests a longer term benefit of treatment and the durability of diagnostic outcomes, because it is better than the rate of recovery from psychiatric disorders reported at the 1 year follow up of Bernstein et al.'s [12] sample. This study found that despite good school attendance in the CBT and imipramine group at 8 weeks (although diagnostic data were not reported post treatment), over 70 % had an anxiety and/or depressive disorder at one-year follow-up. Unfortunately, school attendance rates were not measured at the follow up so it is not clear whether the sample also showed poorer school attendance at this time point.

Taken altogether, available treatment studies of adolescent school refusal indicate that while important gains are made with CBT based treatments in terms of attendance and diagnosis, many require further improvement to achieve satisfactory attendance level. Moreover, the halving of the rate of anxiety disorders during the follow up period (55 % at 6 months and 29 % at 12 months post treatment) contrasts with the largely stable rates of school attendance of 54 % at 6 and 12 months post-acute treatment. Heyne et al. [11] reports a similar pattern with improvements in anxiety, yet stable school attendance rates, after post treatment assessment. The stability of school attendance in conjunction with the improvement in anxiety disorder raises the possibility that other factors may be maintaining school refusal behaviors, for example, adolescent factors such as autonomy-development, family factors such as family acceptance, or psychological factors such as adjustment to long term school refusal [43]. Study of these psychosocial interactions is necessary to inform future research on phenomenology and treatment.

The current study was unable to demonstrate the superiority of CBT + FLX in the management of school refusal in adolescents on the primary (school attendance) or on secondary outcome measures. This finding contrasts the Bernstein et al. [12] finding that CBT + imipramine was superior to CBT + placebo. However, Bernstein et al.'s treatments and sample differ somewhat to those of the present study, as mentioned above. While other studies [19], have shown the superiority of combined CBT and sertraline treatment for children suffering from anxiety disorders, further comparison is difficult because school refusing children were excluded.

The current findings must also be interpreted, in light of the study's modest sample size. It is thus noteworthy, that despite non-significant differences between groups, attendance in the fluoxetine group appeared to continue to improve over time, with 72 % school attendance at 12 months post treatment. This might suggest the possibility of a delayed treatment effect on school attendance in this group.

Interestingly, there was a group difference on adolescent-reported consumer satisfaction measures, with greater treatment satisfaction reported by adolescents in the CBT + FLX group. This however, may just reflect the perception that "two treatments are better than one". The fact that this effect was not seen in the CBT + PLA group may be explained by the participants being able to correctly identify their treatment group at a rate better than chance, despite double blinding.

The finding that older school refusers are less responsive to treatment than younger school refusers [44] has been interpreted in terms of the greater incidence of comorbid depression in older samples. Consistent with this, previous studies have indicated that comorbid depression increases

the risk for anxiety treatment failure among young people [45]. The current study however, did not find any evidence that comorbid depressive disorder impacted upon school attendance. Depressive disorder responded to treatment over time. However, older age was significantly associated with poorer treatment outcome. It is possible that older age may be associated with longer illness duration, or that anxiety-related difficulties may be particularly troublesome in older adolescence when young people are facing developmental tasks such as autonomy development. Older school refusers may prefer to decide for themselves about whether, when and how they return to school due to the drive towards independence which may fuel a defiance of external control and authority [46]. Perhaps not inconsistent with this interpretation, is the finding that older age was not only associated with lower school attendance, but also more parent-reported externalizing problems.

Treatments were rated on average as very satisfactory by parents and somewhat satisfactory by adolescents, with higher adolescent-reported satisfaction for CBT + FLX than CBT treatment. The rate of discontinuation was 12.9 %, which is substantially lower than the 25.4 % reported by Bernstein et al. [12]. All treatments were well tolerated. The most common adverse events reported for all treatments were difficulty falling asleep, difficulty arousing in the morning, and outbursts of anger. The CBT + FLX group had a better side effect profile in terms of suicidal and NSSI ideation and NSSI, which is consistent with a conclusion that fluoxetine has a more favorable risk profile than placebo. This finding contrasts the conclusion of a past meta-analysis of pediatric clinical trial data which suggested that antidepressants are associated with a greater risk of suicidal adverse events compared with placebo [47]. However this meta-analysis was based on analysis of spontaneously recorded adverse event data collected in a non-standardized manner [40] which may, in part, explain the difference.

The findings of this study might be influenced by several limitations. Study sample size was modest and may have impacted on capacity to determine a difference between groups. The variability in the main outcome measure of school attendance (range 0–100) also meant wide standard deviations which reduces statistical power. The CBT participants were not blind to treatment allocation, however adding another form of psychotherapy treatment as a control was not feasible due to resource limitations, given the increase in sample size required.

Summary

Results underline the seriousness of school refusal and the important need for effective treatments. While important gains are made with CBT-based treatments in terms of attendance and recovery of mental health, post-treatment attendance rates were below that required for a full time secondary education. Thus there is a great need for further innovation and novel approaches to the management of school refusal, along with definition of the optimal duration of current treatments. Improvements in anxiety but not school attendance with time after acute-treatment, raises the possibility that factors other than anxiety may be maintaining school refusal behavior. Studies investigating the contribution of adolescent (e.g., autonomy-development), family (e.g., family acceptance or adjustment to long term school refusal) and other contributing psychosocial factors to treatment outcome are of great importance. In addition, long term follow up studies are necessary to determine the longitudinal course of this disabling behavior.

Acknowledgments The authors acknowledge the National Health and Medical Research Council (545968), beyondblue The National Depression Initiative and Financial Markets Foundation for Children. The authors thank A/Prof Neville King (retired) who made a substantial contribution to establishment of this study, the team of clinicians, Slade Pharmacy for preparation of the fluoxetine and placebo and all the participating adolescents and their families.

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