

## ADAPT STUDY

## adolescent depression antidepressants and psychotherapy trial

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## Background

Major depression in adolescence is associated with significant mortality and morbidity

Response rates to single therapies is low

ADAPT is the first UK study to compare combined treatment to antidepressant alone in depressed youths

ADAPT is a pragmatic trial with few exclusion criteria, and thus representative of a typical NHS child and adolescent mental health service (CAMHS) population

ADAPT incorporates a health economics analysis to fully assess costs and benefits of treatment

## Question

What is the most effective and most cost-effective treatment for adolescent major depression?

## Hypothesis

When compared to fluoxetine alone the additional costs of CBT will be offset by improvements in i) quality of life ii) depressive symptoms iii) financial savings in the use of health, social and educational services

## Method

## Participants

208 adolescents, aged 11-17, with a diagnosis of unipolar depressive disorder entered the study between autumn 2000 and autumn 2004. Subjects were from CAMHS clinics in Manchester and Cambridge. Adolescents with current or past suicidality were included, even if they were deemed to be at high risk.

## Exclusion criteria

Need for hospitalisation; pregnant, or possibility of; learning disability; medial illness cause for depression; schizophrenia; bipolar disorder; inability to complete questionnaires; sensitivity to SSRIs, potential drug interactions, SSRI medically contraindicated; past adequate treatment with both an SSRI and CBT with no effect.

## Randomisation

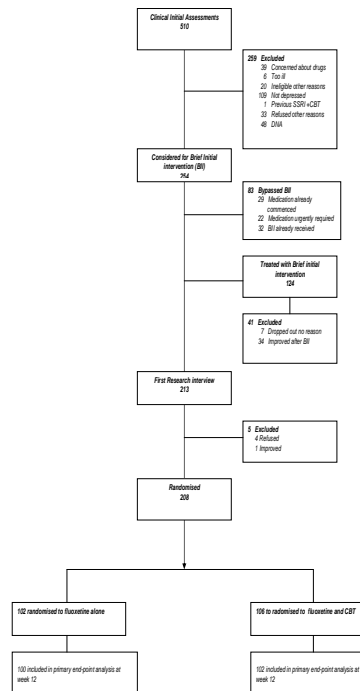
After a brief psychosocial intervention those with persisting depression underwent baseline research assessment and were randomised via an independent remote telephone centre. Participants were randomised to SSRI plus CBT or SSRI alone. Minimisation was used to ensure balance on severity, centre, sex, and co-morbid behavioural disorder.

## Interventions

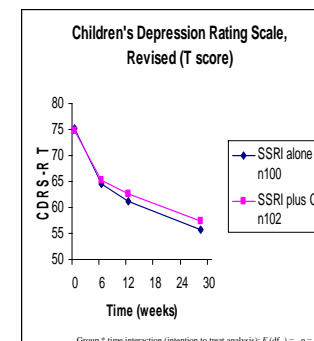
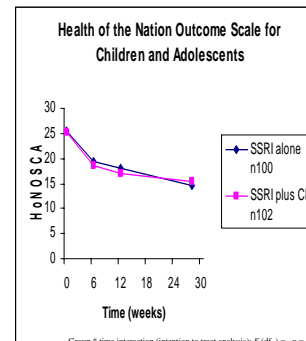
All other forms of ongoing psychiatric treatment were permitted during the study period except for CBT in the SSRI alone arm. Treatment was manualised for both arms. Subjects were seen regularly for monitoring of medication (weekly initially). Fluoxetine was the primary SSRI used (10-60mg per day). Other SSRIs were considered on a case-by-case basis. Subjects in the combined arm were offered weekly CBT for 12 weeks, followed by 2 weekly maintenance sessions. Sessions were audiotaped to assess quality of therapy.

## Outcome Measures

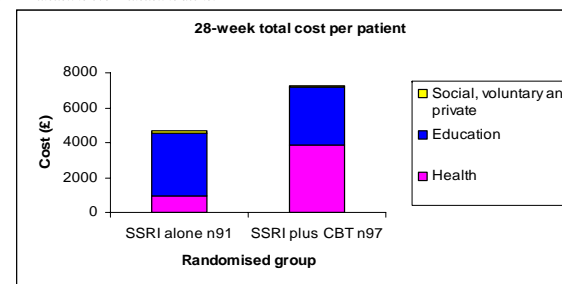
Assessments with subjects and carers were done by independent evaluators blind to treatment assignment at baseline, 6, 12 and 28 weeks. Psychiatric diagnoses were assessed by the K-SADS-PL. The primary outcome measure was the Health of the Nation Outcome Scale for Children and Adolescents (HoNOSCA). Secondary measures included: the Children's Depression Rating Scale, Revised (CDRS-R); the Mood and Feelings Questionnaire (MFQ); the Strengths and Difficulties Questionnaire (SDQ); the Children's Global Assessment Scale (CGAS) and the Clinical Global Impression Improvement Scale (CGI-I).



## Results



Statistical analysis of the clinical outcome measures was based on a linear random coefficient model of 6 week, 12 week and 28 week scores. Time from randomisation to assessment in days, the baseline value of the outcome measure, continuous variables corresponding to the categorical variables used in minimization, age and gender were included as covariates in the model. For all outcome measures there was no evidence of a time-treatment interaction. There was no significant benefit over time for CBT+Fluoxetine over Fluoxetine alone.



## Discussion

Depression and global functioning improved in both groups over the duration of the trial.

There was no extra benefit of CBT in the combined group in terms of depression outcomes or global functioning.

Combined treatment was more expensive with no additional gains, although no differences were statistically significant.

## Conclusions

The additional costs of CBT were not offset by any significant improvements in depression or quality of life. Fluoxetine plus treatment as usual is more cost-effective than fluoxetine+CBT plus treatment as usual in adolescents with moderate-severe depression presenting to CAMHS outpatient services within the NHS.

## Limitations

This study did not compare medication with CBT alone.

## Acknowledgements

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