Treatments for adolescent anorexia nervosa – the TOuCAN trial

A randomised controlled multicentre trial of treatments for adolescent anorexia nervosa including assessment of cost-effectiveness and patient acceptability – the TOuCAN trial

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Executive summary

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Executive summary

Background

Anorexia nervosa (AN) is a complex disorder generally developing in adolescence, with high rates of morbidity and occasional mortality. It often continues into adult life with a range of adverse physical and psychosocial outcomes. Although interventions to treat the disorder have been devised, evaluation of them has been limited. Inpatient psychiatric treatment is often employed, but this is expensive, has been poorly evaluated and never in randomised controlled trials involving adolescents using NHS facilities. Similarly, although treatment in specialist centres is often advocated, this is often confused with treatment in exclusive eating disorder inpatient units. No trials have examined the effectiveness or cost-effectiveness of specialist services for adolescents. Generic Child and Adolescent Mental Health Services (CAMHS) are well equipped to offer individual and family-based psychological therapies and may offer effective treatment for adolescent AN.

Objectives

The aim of the study was to determine if at 1, 2 and 5 years, young people treated in specialist services (inpatient and outpatient) enjoyed advantages over those attending general CAMHS. In addition, it aimed to evaluate whether inpatient management conferred advantages over outpatient treatment. The specific hypotheses were that:

- inpatient treatment would be more effective than outpatient treatment
- specialist treatment would be more effective than general treatment
- outpatient treatment would be more cost-effective than inpatient treatment
- specialist outpatient treatment would be more cost-effective than general CAMHS treatment
- carers would have higher expectations of treatment and would be more satisfied with it than young people with the disorder
- satisfaction would be higher with specialist treatment than with generalist treatment.

In addition we anticipated that:

- for the total series, few patients would fully recover by 1 year after the start of treatment, but overall outcomes would improve at the 2-year and 5-year time points
- for those remitting, relapse would be unusual during the course of the study.

To achieve these objectives a randomised controlled trial of inpatient management against a specialist outpatient programme and treatment as usual in general CAMHS was undertaken.

Method

A pragmatic randomised controlled trial was conducted on young people between the ages of 12 and 18 years presenting to community CAMHS with AN. Inclusion criteria comprised food restriction plus or minus compensatory behaviours; weight below 85% of that expected based on age and height; intense fear of gaining weight or undue influence of weight or shape on self-evaluation; primary or secondary amenorrhoea of at least 3 months in females, or menstruation only while on the contraceptive pill.

The only exclusion criteria employed were severe learning difficulties or the presence of severe chronic comorbid physical conditions affecting digestion or metabolism. No exclusions were made on grounds of clinical severity.

Setting

Thirty-five CAMHS in the north-west of England (total population 7.5 million), co-ordinated through specialist centres in Manchester and Liverpool, UK.

Interventions

Participants were randomised to either treatment as usual within community CAMHS, a specialist outpatient programme (delivered in two centres)

comprising individual cognitive behaviour therapy, dietary advice, parental counselling and feedback of self-report measures, or inpatient treatment within one of four specialist but not exclusive inpatient units. Outpatient treatment spanned a minimum of 6 months. Inpatient treatment was at the service's discretion with outpatient follow-up to a minimum of 6 months.

Baseline and outcome measures

Participants received a comprehensive baseline assessment and follow-up assessments at 1, 2 and 5 years. The main outcome measure was the Morgan–Russell Average Outcome Scale (MRAOS), a validated and frequently used measure for AN. This, and the Health of the Nation Outcome Scales for Children and Adolescents (HoNOSCA) (recently validated in a number of research trials), demonstrated good inter-rater reliability.

Secondary outcome measures included diagnosis and self-reported abnormal eating cognitions (Eating Disorders Inventory 2), mood (Mood and Feelings Questionnaire), family functioning (Family Assessment Device) and physical measures of weight, height and body mass index (BMI). Information on resource use was collected in interviews at 1, 2 and 5 years using the Child and Adolescent Service Use Schedule (CA-SUS). Participant and carer satisfaction was measured by a satisfaction questionnaire devised for this study and supplemented by qualitative data from user and carer focus groups.

Results

Of the 167 young people randomised, 67% adhered to allocated treatment, with lower adherence to inpatient management. Every subject was traced at both 1 and 2 years, (the main outcome point) with the main outcome measure completed by 94% at 1 year, 93% at 2 years but only 47% at 5 years. A valid outcome category was assigned for 98% at 1 year, 96% at 2 years and 60% at 5 years. There was significant improvement in all groups at each time point, with the number achieving a good outcome being 19% at 1 year, 33% at 2 years and 64% (of those followed up) at 5 years. Analysis by intention to treat demonstrated no difference in effectiveness (on the main outcome measure), for inpatient compared with outpatient treatment, or specialist over generalist treatment at any time point controlling for baseline characteristics; but specialist treatment had advantages with increasing time. Patients receiving inpatient treatment showed poor results, among those failing to make progress with outpatient treatment and transferring to it on clinical grounds.

Generalist treatment was slightly more expensive over the first 2 years, largely because greater numbers were subsequently admitted to hospital after the treatment phase. The cost-effectiveness analysis revealed that specialist outpatient services were dominant in terms of incremental cost-effectiveness (as they were more effective and less costly). Specialist outpatient services had a higher probability of being cost-effective than general CAMHS and outpatient services had a higher probability of being cost-effective than inpatient services.

The satisfaction study showed overall, good levels of satisfaction with young people being twice as likely to express positive as negative views of their treatment. Parents were much more satisfied, with five times as many expressing positive than negative views of treatment. Parents were consistently more satisfied than young people with each treatment but both parents and young people were more satisfied with specialist than general treatments, largely on account of their confidence in 'expertise' and their ability to forge a good relationship with an individual therapist, working either on an inpatient or outpatient basis.

Conclusions

Implications for health care

For moderately to severely ill adolescents with AN, outpatient services delivered by experienced, expert professionals, supported by medical management of physical complications as required, offer the most cost-effective treatments. Lengthy psychiatric inpatient treatment does little to add to positive outcomes and is cost-ineffective. Treatment in specialist services with experience and expertise in managing the condition is to be preferred owing to its cost-effectiveness and higher levels of satisfaction in both young people and carers. Where young people with AN are managed in community CAMHS, a consultation and advice link with a specialist service may enable the team to contain anxiety and reduce unnecessary hospital admissions, thereby leading to greater user satisfaction. This needs further investigation.

The findings are broadly consistent with the National Institute for Clinical Excellence [now

National Institute for Health and Clinical Excellence (NICE)] guidelines on the treatment of AN. Although physical risk should not be underestimated and may require urgent and active intervention, this trial does not lend support to the advantages of managing this within a psychiatric service.

Recommendations for future research

Further research is recommended in the following areas.

Clarify the positive and negative aspects of inpatient care

Physical and psychological risk, parental anxiety and social and educational withdrawal often result in inpatient admission. The opportunities for intensive psychological therapies, general support, refeeding and respite from external stresses make specialist inpatient care a logical step. Satisfaction (particularly among parents) is quite good. However, research outcomes are consistently disappointing, suggesting that adverse effects are under-recognised. Some are likely to be associated with the specifics of inpatient care, such as reinforcement of feelings of ineffectiveness; some to do with difficulties negotiating discharge and continuity of care. These need further clarification.

Clarify the optimum length of stay for inpatient care

Some of the adverse effects of inpatient care may relate to 'institutionalisation', reinforcement of the sick role, or a deskilling effect on both young people and their carers. A study comparing brief stays to stabilise physical health and initiate normal eating, with longer more comprehensive treatment, would help to clarify these issues. Again, user views and a health economic component should be incorporated into such a study, given the high cost of inpatient care.

Evaluation of the efficacy and cost-effectiveness of individual psychological therapies

The current findings lent only modest support to the specialist programme used in this study comprising cognitive behaviour therapy with dietary therapy and parental counselling. As AN is a psychological disorder based on abnormal cognitions, further research is required to evaluate the effect of different approaches on the specific (weight and shape) and non-specific cognitions underlying the disorder. This research in adults is ongoing, but untested in (particularly younger) adolescents.

Evaluation of co-ordinated individual psychological therapies with family-based treatments

Since this project started, research into family-based treatments has been productive and indicated that these can be effective. However, they have not been adequately tested against individual approaches. For pragmatic as well as theoretical reasons, (supported by our user views), adolescents should receive individual therapies and involvement of the family. The specific components of combined therapies and how these should be co-ordinated to produce cognitive as well as behavioural change, requires further testing.

Trial registration

This trial is registered as NRR N0484056615 and ISRCTN39345394.

Publication

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The research reported in this issue of the journal was commissioned by the HTA programme as project number 97/42/02. The contractual start date was in January 2000. The draft report began editorial review in July 2009 and was accepted for publication in October 2009. As the funder, by devising a commissioning brief, the HTA programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

The views expressed in this publication are those of the authors and not necessarily those of the HTA programme or the Department of Health.

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