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Use of intensive case management to reduce time in hospital in people with severe mental illness: systematic review and meta-regression

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ABSTRACT

Objectives To explain why clinical trials of intensive case management for people with severe mental illness show such inconsistent effects on the use of hospital care.

Design Systematic review with meta-regression techniques applied to data from randomised controlled trials.

Data Sources Cochrane central register of controlled trials, CINAHL, Embase, Medline, and PsychINFO databases from inception to January 2007. Additional anonymised data on patients were obtained for multicentre trials.

Review methods Included trials examined intensive case management compared with standard care or low intensity case management for people with severe mental illness living in the community. We used a fidelity scale to rate adherence to the model of assertive community treatment. Multicentre trials were disaggregated into individual centres with fidelity data specific for each centre. A multivariate meta-regression used mean days per month in hospital as the dependent variable.

Results We identified 1335 abstracts with a total of 5961 participants. Of these, 49 were eligible and 29 provided appropriate data. Trials with high hospital use at baseline (before the trial) or in the control group were more likely to find that intensive case management reduced the use of hospital care (coefficient −0.23, 95% confidence interval −0.36 to −0.09, for hospital use at baseline; −0.44, −0.57 to −0.31, for hospital use in control groups). Case management teams organised according to the model of assertive community treatment were more likely to reduce the use of hospital care (coefficient −0.31, −0.59 to −0.03), but this finding was less robust in sensitivity analyses and was not found for staffing levels recommended for assertive community treatment.

Conclusions Intensive case management works best when participants tend to use a lot of hospital care and less well when they do not. When hospital use is high, intensive case management can reduce it, but it is less successful when hospital use is already low. The benefits of intensive case management might be marginal in settings that have already achieved low rates of bed use, and team organisation is more important than the details of staffing. It might not be necessary to apply the full model of assertive community treatment to achieve reductions in inpatient care.

INTRODUCTION

Modern mental health services try to ensure that people with severe mental illness spend the minimum amount of time in hospital because unnecessary hospital care is wasteful, stigmatising, and disliked by patients. To achieve this goal, mental health services increasingly use intensive case management to care for severely mentally ill people at high risk of readmission. In the United Kingdom, the national service framework has authorised the setting up of 170 high fidelity assertive outreach teams.[1] Assertive outreach was previously referred to in the UK as intensive case management, a somewhat broader term emphasising small caseloads. It is the term used for the UK application of the North American service assertive community treatment, a carefully specified approach to case management,[2] which includes daily team meetings, case sharing, 24 hour availability, and multidisciplinary working with doctors as full team members.

Under intensive case management, each person with severe mental illness at high risk of readmission is allocated a nurse, social worker, or other clinician (a "case manager") who carries a small caseload of between 10 and 20 patients. This case manager takes primary responsibility for keeping contact with the patient, assessing their needs, and ensuring that these needs are met.[2] Intensive case management is one of the most thoroughly evaluated non-pharmaceutical interventions in psychiatry, but numerous trials over the past 35 years have failed to show that it consistently reduces the use of hospital care. While some trials have shown a large reduction, others have found no effect, and some have shown a significant increase.

We applied meta-regression techniques to try to explain why clinical trials of intensive case management for people with severe mental illness have shown inconsistent effects on the use of hospital care.

METHODS

Data sources

We identified randomised controlled trials available for review by January 2007 that had compared

intensive case management (caseload up to and including 20) with standard care (from a community mental health team or outpatient clinic) or low intensity case management (caseload greater than 20) in people with severe mental disorder living in the community. We defined severe mental disorder as schizophrenia or schizophrenia-like disorder, bipolar disorder, or depression with psychotic features. We excluded trials in which the experimental intervention was an acute crisis team or if the control condition was hospital admission, remaining in hospital, or an alternative form of intensive case management. Full details of the methods are on bmj.com and www.psychiatry.ox.ac.uk/socpsych/bmjmrtable.

Data extraction

The dependent variable in the meta-regression was time in hospital, defined as mean number of days per month in hospital. We also noted the degree of low intensity case management in the control group; the country where the trial took place; mean days per month in hospital for participants in the two years before the study began (baseline hospital use); the year the study began; trial size; and a rating of fidelity of the intervention to assertive community treatment on the "team membership" and "team structure and organisation" subscales of the index of fidelity to assertive community treatment (IFACT).[3] This index was derived from a survey of 20 clinical experts in assertive community treatment and validated in a survey of 18 programmes. The team membership subscale comprises four items: ratio of patients to staff, total size of the team, and the extent of psychiatric and nursing input to the team. The structure and organisation subscale comprises seven items: whether the team is the primary source of care for its patients, is situated away from the hospital, meets daily, shares responsibility for caseloads, is available 24 hours a day, has a team leader who is also a case manager, and offers unlimited time for its services. We chose the index because the subscales are brief and can be completed from published data. For each item on the index, a score of 1 indicates high fidelity to the model.

Relation between hypotheses tested and covariates used in the meta-regression (shown in parentheses)

Variation in the outcome of hospital use between trials of intensive case management is explained by:

- Lack of team working as recommended in assertive community treatment in the case management team in the trial (team structure and organisation subscale of IFACT)
- Lack of personnel resources as recommended in assertive community treatment in the case management team in the trial (team membership subscales of IFACT)
- Factors related to trial context such as:
  - Control treatments improving over time (year the study started)
  - Control treatment from US healthcare system (country in which study took place)
  - High rates of hospital use in the setting where the trial was conducted (mean days per month in hospital for all participants in the two years before trial)
  - Case management practices present in control group (degree of low intensity case management in control group)
- Publication bias (size of trial)

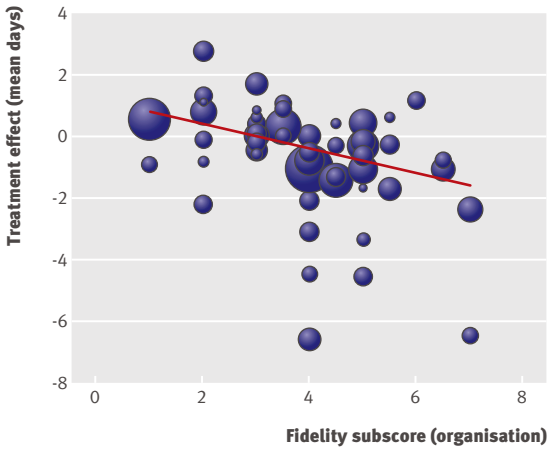

Fig 1 | Scatter plot of IFACT organisation subscore *v* mean days per month in hospital. Each circle is proportional to size of centre it represents. Negative treatment effect indicates that intensive case management achieved reduction in mean days in hospital relative to control

Fidelity data were obtained from published and unpublished trial reports; direct contact with trialists; and data previously obtained directly from trialists by a previous review.[4,5] Two raters independently combined these data into a single fidelity score. Multicentre trials of intensive case management often struggle to implement a uniform approach,[6] with centres operating at different degrees of fidelity to assertive community treatment. We exploited this to increase the power of the meta-regression by disaggregating multicentre studies into component centres with outcome and fidelity data for each. Trialists provided data either in summary form or as anonymous data on individual patients with the permission of their institutional review boards. We verified independently calculated centre data against original trial reports.

Data synthesis

The box shows the relation between the covariates and the hypotheses tested. We also included trial size as a covariate to check for publication bias. We used Stata to carry out a random effects meta-analysis with random effects for variation between centres and between studies using a three level random effects model with a numerical constraint on the level 1 variation. This was fitted with generalised linear latent and mixed models (GLLAMM).[7]

Initially, we excluded baseline hospital use as a covariate as this was not available for all centres. Subsequently, we repeated the meta-analysis including

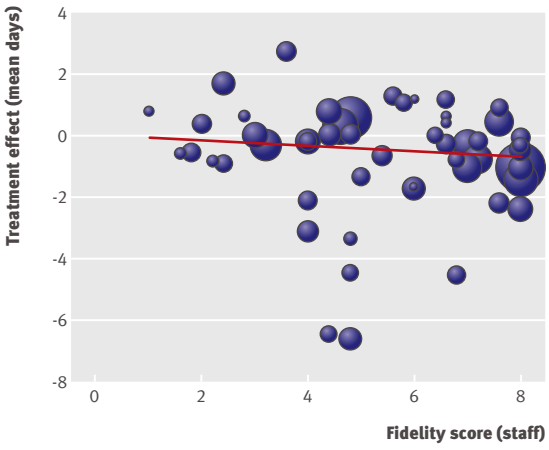

Fig 2 | Scatter plot of IFACT team membership subscore *v* mean days per month in hospital. Each circle is proportional to size of centre it represents. Negative treatment effect indicates that intensive case management achieved reduction in mean days in hospital relative to control

only centres for which we had baseline data on hospital use. To reduce the possibility of type 2 errors, this second analysis included only covariates that were found to have a significant association with mean number of days in hospital in the first analysis.

We then carried out two sensitivity analyses on the full dataset to verify our findings. Firstly, we included the mean of the control group as a covariate instead of the baseline measure of hospital use. We carried out a second sensitivity analysis by modelling the means of the treatment group rather than the intervention effect. Finally, we performed two further sensitivity analyses: the first excluded trials with imputed SDs; and the second excluded trials where the Cochrane randomisation category was B.

RESULTS

The selection of studies for inclusion is summarised on bmj.com. The initial search detected 1335 abstracts from which 42 eligible trials, involving 5961 participants, were identified. Twenty nine of these trials provided data on mean days per month in hospital (see www.psychiatry.ox.ac.uk/socpsych/bmjmrtable).[w1-w29]

The mean age of participants was 37.9 years, 37% were female, 66% had schizophrenia or schizophrenia-like disorder, and 37% were from ethnic minorities. The mean attrition rate was 4%. Only three included trials had a caseload of more than 15 patients per case manager and 21 had a caseload of 1:10 or less.

A preliminary meta-analysis showed a small but significant effect in favour of intensive case management but with significant heterogeneity between centres (pooled intervention effect −0.46, 95% confidence interval −0.84 to −0.08, P=0.019; variation between centres 0.32, variation between trials 0.32).

Meta-regression on days in hospital

The table shows the meta-regression of mean difference in days per month in hospital (unstandardised) against all covariates except baseline days in hospital. It shows that the more a case management team is organised like an assertive outreach team, the better it is at reducing time spent in hospital. The regression coefficient for team organisation indicates a decrease of 0.44 (95% confidence interval 0.72 to 0.17) days in hospital per month for each one point increase on the index organisation scale. The scatter plot of organisation subscore versus mean days in hospital (fig 1) shows that the effect of intensive case management on hospital use is negligible if the team organisation fidelity score is low. No other covariates were significant, including the index team membership subscale (fig 2), and there was no evidence of variation within trials between centres. There was, however, continuing evidence of variation between trials, suggesting that differences on the organisation subscore did not entirely explain the heterogeneity between trials.

When we included the covariate of mean days per month in hospital for participants before the trial, baseline levels of hospital use and index team organisation subscore were both significant, although the strength of the association between index score and hospital use was reduced compared with that observed in the previous model (see bmj.com). There was negligible variation between trials.

In the first sensitivity analysis (see www.psychiatry.ox.ac.uk/socpsych/bmjmrtable) we replaced baseline levels of hospital use with mean in the control group as

Summary of meta-regression analysis of days in hospital per month (52 centres) based on estimates of treatment effect

	Coefficient* (days/month)	SE	95% CI for coefficient	P value
Fidelity score				
Staffing	0.03	0.16	−0.29 to 0.34	0.862
Organisation	−0.444	0.14	−0.72 to −0.17	0.002
Case management				
11-89% in control	−0.05	0.53	−1.09 to 0.99	0.929
≥90% low intensity	0.44	0.54	−0.62 to 1.51	0.414
Trial size	0.00	0.001	−0.002 to 0.001	0.615
Year (-1990)	0.07	0.06	−0.05 to 0.19	0.257
Country (1=US, 0=otherwise)	−0.03	0.62	−1.24 to 1.19	0.965
Constant	1.32	0.61	0.13 to 2.51	0.030

*No variation between centres. Variation between trials was 0.47.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Intensive case management is designed to reduce unnecessary admissions to hospital in severely mentally ill people

Randomised controlled trials of intensive case management have conflicting findings: some have shown reductions in hospital care, while others have found no effect

WHAT THIS STUDY ADDS

Intensive case management works best in trials where participants tend to use a lot of inpatient care

The effectiveness of intensive case management teams is increased as their organisation reflects the assertive community treatment model, but there is less evidence for the benefits of increased staffing levels

a covariate. This analysis showed a strong effect of control group mean (−0.44; 95% confidence interval −0.57 to −0.31, P<0.001), with no other covariates being significant. In our second sensitivity analysis, which modelled means of treatment group rather than the treatment effect with a random intercept and a random coefficient for treatment at the centre and trial level (see www.psychiatry.ox.ac.uk/socpsych/bmjmrtable) there was evidence of a strong correlation between the treatment effect and the underlying level of hospital use. The treatment effect was estimated to decrease by 0.31 bed days for each mean bed day difference between centres, in the analysis within studies. The treatment effect decreased by 0.11 bed days for each difference of one bed day between studies. Index organisation score affected the intervention (−0.47, −0.78 to −0.17, P=0.002). No other covariates had significant interactions with intervention group.

When we dropped centres with an imputed SD from the analysis, index organisation score and baseline level of hospital use were no longer significant (see bmj.com and www.psychiatry.ox.ac.uk/socpsych/bmjmrtable for details).

DISCUSSION

For severely mentally ill patients, intensive case management works best in trials where participants tend to use a lot of hospital care and less well in trials where they do not. When hospital use is high, intensive case management tends to succeed in reducing it, but it is less successful when hospital use is already low. This is the main reason why the findings of trials on case management are inconsistent. We also found that fidelity to the structure and organisation aspect of the assertive community treatment model explained some of the variation in hospital use between trials. In sensitivity analyses, however, this finding was less robust than explanations based on participants' use of hospital care. Fidelity to the staffing practices of the assertive community treatment model did not, moreover, explain variation between trials. It is precisely these extra staffing features that have been authorised in the NHS plan[1] for assertive outreach teams. Some of the control groups in trials of assertive outreach teams with high fidelity might have shared some of their organisational features, which may account for the limited effect on the use of inpatient care in some studies.[8 9]

Strengths and weaknesses

We made maximum use of the available data, not only by identifying all eligible randomised trials but also by obtaining previously unpublished fidelity data directly from trialists and substantial amounts of data on individual patients to facilitate the disaggregation of multicentre trials into their component centres. However, our fidelity data were only 95% complete. Nine of 14 trials with missing fidelity items had lower hospital use in the intervention arm, so if all these items had received a positive rating, this could have strengthened the relation between fidelity to the model and reduction of days in hospital. We also found it necessary to use imputed SDs for the data provided by 16 of the 52 centres, and a sensitivity analysis without these centres reduced the strength of some of the observed associations.

Implications of findings

Why is it that the level of hospital use among a trial's participants is so important in determining the effectiveness of intensive case management? We think that low levels of hospital use are a proxy for good community services. Where community services are good, hospital care is used sparingly and only when absolutely necessary. Under such circumstances even intensive case management teams find it difficult to have an impact on hospital use. When community services are poor, it is usually fairly easy for patients to spend long periods of time in hospital, and intensive case management teams find it relatively easy to reduce such wastefulness. There are, however, other explanations. Firstly, low levels of hospital use might indicate that a trial's participants are less severely ill and hence less likely to benefit from intensive case management. Secondly, low levels of hospital use may indicate that it is difficult to obtain admission within the setting in which the trial is being conducted, leaving little scope for the intensive case management team to achieve further reductions.

The main clinical implication of our study is that the introduction of intensive case management teams will not lead to substantial reductions in hospital use in settings where average hospital use is already low. Teams can optimise their ability to reduce hospital use by organising themselves in the manner recommended for assertive community treatment, and by focusing on patients with a history of high hospital use. Replicating staffing requirements of assertive community treatment does not confer measurable benefits. Our study confirms a growing recognition that we should research the practices of teams rather than their labels.[10 w29]

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Probiotics for treatment of acute diarrhoea in children: randomised clinical trial of five different preparations

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ABSTRACT

Objective To compare the efficacy of five probiotic preparations recommended to parents in the treatment of acute diarrhoea in children.

Design Randomised controlled clinical trial in collaboration with family paediatricians over 12 months.

Setting Primary care.

Participants Children aged 3-36 months visiting a family paediatrician for acute diarrhoea.

Intervention Children's parents were randomly assigned to receive written instructions to purchase a specific probiotic product: oral rehydration solution (control group); *Lactobacillus rhamnosus* strain GG; *Saccharomyces boulardii*; *Bacillus clausii*; mix of *L delbrueckii* var *bulgaricus*, *Streptococcus thermophilus*, *L acidophilus*, and *Bifidobacterium bifidum*; or *Enterococcus faecium* SF68.

Main outcome measures Primary outcomes were duration of diarrhoea and daily number and consistency of stools. Secondary outcomes were duration of vomiting and fever and rate of admission to hospital. Safety and tolerance were also recorded.

Results 571 children were allocated to intervention. Median duration of diarrhoea was significantly shorter (P<0.001) in children who received *L rhamnosus* strain GG (78.5 hours) and the mix of four bacterial strains (70.0 hours) than in children who received oral rehydration solution alone (115.0 hours). One day after the first probiotic administration, the daily number of stools was significantly lower (P<0.001) in children who received *L rhamnosus* strain GG and in those who received the probiotic mix than in the other groups. The remaining preparations did not affect primary outcomes. Secondary outcomes were similar in all groups.

Conclusions Not all commercially available probiotic preparations are effective in children with acute diarrhoea. Paediatricians should choose bacterial preparations based on effectiveness data.

Trial registration number Current Controlled Trials ISRCTN56067537.

INTRODUCTION

Several probiotic micro-organisms are effective in reducing the severity and duration of acute diarrhoea in children: *Lactobacillus rhamnosus* (formerly "*Lactobacillus casei* strain GG" or "*Lactobacillus* GG"), *L plantarum*, several strains of bifidobacteria, *Enterococcus faecium* SF68, the yeast *Saccharomyces boulardii*, and preparations containing a mix of strains. Several trials with probiotic preparations have been conducted in different settings and with different end points. Meta-analyses of probiotic efficacy are also available,[1-4] though few meet the criteria of properly controlled trials.[4]

In a study of Italian children with diarrhoea, probiotics were the most commonly prescribed treatment.[5] With the increasing availability and widespread use of probiotics, it is important to identify the most effective preparations. We evaluated the efficacy of five probiotic preparations for the treatment of acute diarrhoea in children.

METHODS

The study was a prospective single blind randomised controlled trial in which parents of children with acute diarrhoea received written instructions to purchase a specific brand of probiotic. Diarrhoea was defined as three or more outputs of loose or liquid stools a day. Eligible children were those aged 3-36 months who were seen in family paediatricians' offices from October 1999 to September 2000 because of diarrhoea. We included in the study all