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Full Title:

Randomised controlled trial of assertive community treatment in intellectual disability: the TACTILD study

Short Running Title:

Randomised controlled trial in intellectual disability services

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Abstract

Background

There has been a policy shift away from hospital to community in the services of all those with psychiatric disorders, including those with intellectual disability, in the last fifty years. This has been accompanied recently by the growth of assertive outreach services, but these have not been evaluated in intellectual disability services.

Method

In a randomised controlled trial we compared assertive outreach with 'standard' community care, using global assessment of function (GAF) as the primary outcome measure, and burden and quality of life as secondary measures.

Results

We recruited thirty patients, considerably less than expected; no significant differences were found between the primary and secondary outcomes in the two groups. The differences were so small that a Type II error was unlikely.

Conclusions

Reasons for this lack of specific efficacy of the assertive approach are discussed and it is suggested that there is a blurring of the differences between standard and assertive approaches in practice.

Introduction

It is well recognised that the shift from hospital to community services has been at least as dramatic in ID services as in general psychiatry, with key changes to service delivery and the comprehensive development of CTLDs (Community Learning Disability Teams), which provide services for both physical and mental health problems (Aspray et al. 1999). Within this model, mental health professionals provided specialist input for those with dual diagnosis (Alexander et al. 2002). In some areas specialist assertive outreach teams have also been established. This paper evaluates the effectiveness of such teams.

In a large randomised controlled trial (the UK 700 Study) it was found that people with severe mental illness did not benefit preferentially from intensive case management compared with standard case management (Burns et al. 1999). However, the outcomes in the subset with borderline intelligence (nearly one in five of the total) were significantly superior ($P < 0.003$ for primary outcome) in those allocated to intensive case management (Tyrer et al. 1999; Hassiotis et al. 2001). It was therefore considered appropriate to ask whether this finding extended to intellectual disability (ID) services in general.

This led to the development of TACTILD (Trial of Assertive Community Treatment in Learning Disability), a research proposal designed to evaluate the effectiveness of community interventions using a similar randomised design. There are already a number of community teams that purport to work assertively in the UK which offer specialist input for behavioural and psychiatric difficulties, and our study was designed to evaluate their effectiveness.

Methods

Specific hypotheses

Three hypotheses were tested in the trial:-

- (a) that global improvement of clinical and social functioning of those with learning disability, dual diagnosis and/or challenging behaviour, would be superior in those treated by an assertive community team compared with those in a standard team;
- (b) that improvement in quality of life in this population would be superior in those treated by an assertive community team compared with the standard team;
- (c) that the burden of care on carers in this population would be no different in those treated by an assertive community team compared with the standard team.

Design of study

A simple parallel design with randomised allocation to two arms; assertive outreach and standard teams with baseline assessments at the point at which additional service input was considered for patients with a psychiatric disorder or challenging behaviour, and repeat assessments 12 weeks later. The trial was pragmatic in design with an intention-to-treat analysis of data of all randomised patients. The inclusion criteria included patients with mild or moderate intellectual disability who had either (i) serious mental health problems or (ii) challenging behaviour, or both (i) and (ii), (iii) were living in community homes with professional carers or in family homes with relatives, (iv) were aged between 18-65 years, and (v) gave consent and assent for the trial. Exclusion criteria included clients with an IQ more than 75, had severe learning disability and/or whose problems are assessed as sufficiently severe to need assertive

treatment and for whom the risk of randomisation would be unethical. The trial had an external randomisation officer based at a different site in London from either of the recruitment centres; randomisation was generated using a random number list.

Definition of assertive community treatment

A preliminary review of services within the areas considered for the study showed that ‘assertive treatment’ was interpreted differently, ranging from a full-integrated team working long-term with patients to visits which were additional to standard care at times of crisis. Consequently it was agreed that ‘assertiveness’ was best measured in terms of frequency and types of contact rather than by team structure, and thereby differed from similar trials in adult psychiatry (Tyrer et al. 1998; Creed et al, 1999). The “assertive” group was therefore defined as those who received more than one visit per week from one or more professionals and the “standard” group that received no more than one visit per week from any one professional in a week. This reflected actual practice in most teams when an assertive model was employed, and helped to justify distribution of resources (Oliver et al. 2002).

Ethical and logistical issues

The trial was regarded as a dramatic new venture and debate among providers and commissioners lasted a year before the design was finalised. Initially ten intellectual disability services in North London expressed interest in the study but this quickly reduced to six, essentially because of ethical concerns (Oliver et al 2002). The eventual study design received London multi-centre research ethical committee (MREC) approval as well as their local research ethical committee (LREC) approval. In order to overcome the reservations by some centres previously reported (Oliver et

al. 2002) it was decided that following referral to services there would be a two-week assessment and service users would be placed into one of three groups;

A) Needing assertive treatment and would be unethical to randomise;

B) Could be randomised;

C) Failed to satisfy inclusion and exclusion criteria.

Only Group B patients were randomised but as Group A qualified for inclusion in principle they are included in the CONSORT flow chart (Figure 1).

Assessment measures and procedure

After referral to specialist mental health services and a two-week clinical assessment, suitable patients were randomly assigned to assertive community treatment (ACT) or standard community treatment (SCT) in one of three centres; two within the London area (Brent and Harrow) and one from North Leicestershire. The following assessments were made at baseline:-

- (i) Multi-axial diagnosis (including level of intellectual disability, 'serious mental health problems' and 'challenging behaviour' were assessed at baseline using the DSM IV multi-axial assessment with ICD 10 codes (Cooray et al. 2000);
- (ii) Global assessment of function (GAF) with 'symptomatology' and 'social function and performance' separately assessed (Tyrer & Casey, 1993) in order to improve reliability of the measure, which has particular problems of assessment in intellectual disability (Oliver et al, 2003);
- (iii) Burden on carers using the Uplift/Burden scale (Pruchno, 1990);
- (iv) Quality of life (QOL) using the WHOQOL Bref (WHOQOL Group, 1995).

Of these the psychiatrist made the diagnostic assessments and a research associate (PO) the other assessments. All non-diagnostic assessments were repeated after 12 weeks by the research associate masked to knowledge of treatment.

The WHOQOL-Bref is a standardised quality of life assessment tool for the general population, which has been applied to the intellectual disability population (WHOQOL Group, 1995). The uplift/burden scale was selected as it has good psychometric properties amongst carers of Alzheimer's patients, who can be considered a similar population to carers of people with intellectual disability and mental health problems (Pruchno, 1990).

The GAF 'symptomatology' and 'social function and performance' (Tyrer & Casey, 1993), consists of two continuous scales ranging from 1 – 90 in which the anchor points were only guides, all forms of disability and symptomatology were assessed, and some allowances would normally be made for the intellectual level of the subject concerned when scoring an individual's function. The quality of life assessment was completed by interview with capable patients, however all assessments were completed by interview with the primary carer if the patient is incapable. Repeat measures were made after three months by an independent researcher blind as to allocation of treatment. For the WHOQOL Bref questions standard procedures were used to convert scores to a total score of quality of life (WHOQOL Group, 1995).

For the Carer Uplift/Burden scale 6 questions were used to compute the total score for 'uplift', each question in this scale had scores ranging from 1 to 3, where 1 indicates a poor rating 'not at all', 2 'some of the time', and 3 a better rating 'most of the time'.

The Carer Uplift/Burden scale has 17 questions used to compute the total score for 'burden', the burden scale questions were negatively reversed and ranged from 3 to 1, with the poor rating of 3 'often', 2 'sometimes' and 1 the better rating of 'never' (Pruchno, 1990). Statistical analysis used the intention to treat principle and used analysis of covariance and variance with the STATA package.

Results

Main Findings [Figure 1 and Table 1 near here]

Thirty patients were recruited to the trial over a period of 25 months. Fifteen (50%) came from two centres (B and C) with the remaining 15 (50%) coming from centre A. Thirteen patients were male and seventeen were female. The mean age of patients was 40.53 and the range 46 (20-66). Fourteen patients lived in 24 hour staffed community homes, seven in <24 hour staffed or un-staffed community homes and the remaining nine patients lived with family in owner occupied or rented housing from local authority. Twenty-one patients were of white (English, Scottish or Welsh) ethnicity and nine patients included other white, Black Caribbean, Indian and Pakistani ethnicity. All of the 30 patients were followed up after three months successfully. The flow diagram (Figure 1) and clinical characteristics (table 1) of the two groups followed recommended procedure for randomised trials (Altman et al. 2001).

In the analysis of results for the 30 randomised patients who completed all stages of treatment mean scores for total GAF 'symptomatology' and 'social function', WHOQOL-Bref (QOL) social, physical, environmental and psychological, carer uplift and burden, showed no difference in outcome (table 2).

Using two way analysis of variance in which differences in outcome were measured by time/treatment model interaction there was no significant difference in gains for clinical symptomatology ($p=0.80$) and social functioning ($p=0.79$) between assertive and standard groups, nor were there any significant differences in reduction of burden ($p=0.84$) to primary carers, uplift ($p=0.84$) of primary carers, or improvement in quality of life ($p=0.18$). The WHOQOL-Bref physical subscale ($P=0.05$) and psychological subscale ($P=0.06$) were not major outcomes but showed differences between the groups that favoured standard care.

Fidelity to Assertive Treatment Model

The number of contacts and duration of time of the clinical professionals, psychiatrist, psychologist/counsellor, and community nurse and outreach team illustrate the fidelity to the treatment models for assertive community treatment and standard community treatment in table 3. Table 3 shows a significant difference between the two treatment groups for the number of psychologist/counselling contacts and the total number of contacts for all professionals. However, it is important to note that while thirteen out of fifteen (87%) of the assertive treatment group were treated assertively, five out of fifteen (33%) of the standard treatment group were also treated assertively in relation to the fidelity treatment model (i.e. more than 12 health professional contacts over the 3-month intervention period). Thus, there was a significant degree of overlap in the fidelity of the treatment groups for the number of contacts and duration of time.

Discussion

This study has demonstrated that 30 patients have statistically shown no difference between the two treatment groups of ‘assertive community treatment’ and ‘standard

community treatment'. In a heterogeneous sample of 30 patients with varied mental health diagnosis and behaviour problems it could still be possible that there were significant differences between the two treatment groups. However, the small differences demonstrated between the treatment groups make a Type II error unlikely, as such an error is normally associated with a moderate but non-significant difference that would become significant with larger numbers. In fact, the differences that were found favoured standard rather than assertive treatment and it could be argued that if a Type II error was present standard treatment would be the beneficiary of any doubt.

The overlap between the two complex interventions was substantial and the lack of difference in outcome could be explained as much by lack of fidelity to the assertive model as by a genuine equivalence of the treatments. The GAF can be criticised as a primary outcome in view of concerns about its assessment (Oliver et al, 2003) but its reliability is better in general psychiatric patients in a clinical setting, situations which were representative of the TACTILD study patients with serious mental health problems (Oliver et al. 2003, Loevdahl & Friis 1996, Rey et al 1995, Jones et al 1995).

With the difficulties that Oliver et al. 2002 encountered, TACTILD became a pilot study that was as much concerned with establishing the feasibility of randomised controlled trial methodology within the ID services, as with measuring the effectiveness of the two types of intervention. McGrew et al. (1994) showed that response to ACT correlated with programme fidelity in a mental health program model, but this may not be a satisfactory way forward for ACT in intellectual

disability. Under these circumstances it is justifiable to use a pragmatic definition for ACT as in the TACTILD study.

Published literature, particularly from outside the UK has highlighted the superiority of assertive community treatment models over standard care (Burns & Santos 1997; Drake & Burns 1995). It is fair to assume that this superiority would depend, quite substantially, on the quality of the standard care itself. The three centres from where patients were recruited for this trial have had a long ethos of multi-disciplinary working, well established CTLDs and intellectual disability registers, good accessibility to professionals and a tradition of following evidence based practice methods (McGrother et al. 2002; Fernando et al. 1997; Cooray & Tolmac, 1998). It is therefore quite possible that within these teams, professionals are working 'assertively' whether or not they visit patients once or more than once per week. Thus, the difference between the two approaches may be more apparent than real in these settings.

What appears to be crucial is the presence of a well established and motivated community team rather than the particular label, 'assertive' or 'standard'. Perhaps the only way to establish the need or otherwise of assertive community treatment in intellectual disability would be to repeat this study in centres which do not have separate well established CLDTs; centres where service provision for this group is “ad hoc’ and dependent on goodwill and personal commitment of professionals” (Bouras et al. 2000, p.215) and to combine formal qualitative and quantitative methodology in evaluation (Crawford et al, 2002). As this study has shown, simple randomisation can be achieved ethically and safely in this population and there is no reason why such

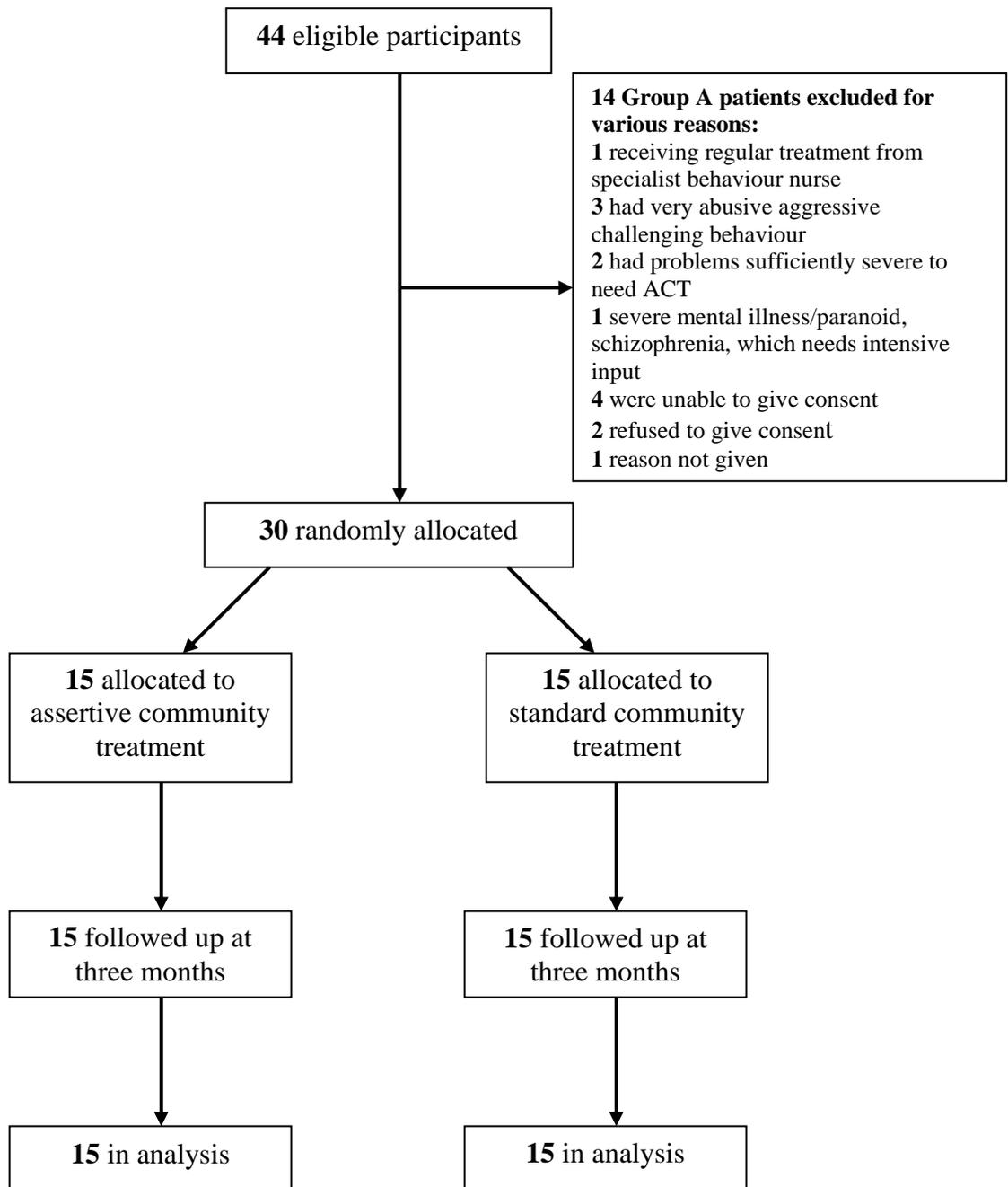
studies should not be replicated in the future. Despite possible limitations in the choice of primary outcome measure (Oliver et al, 2003) and absence of any measures that might improve care (e.g. adherence to medication) we feel that this study was an accurate and valid attempt to record the effects of a difficult complex intervention in intellectual disability and hope it will stimulate other studies with larger numbers.

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Figure 1. Flow Diagram of a trial of assertive community treatment in intellectual disability



The diagram includes the number of patients actively followed up during the trial. Adapted from reference Altman et al. 2001.

Table 1 – Clinical Characteristics of Patients

	Type of Community Intervention		
	Assertive Community Treatment (%)	Standard Community Treatment (%)	Total
Total Sample	15 (50)	15 (50)	30
Study Centre			
Centre A	7 (47)	8 (53)	15
Centre B	3 (20)	3 (20)	6
Centre C	5 (33)	4 (27)	9
DSM IV Axis 1 Mental Disorders (Using ICD 10 Codes)			
Organic Including Symptomatic Mental Disorders	0 (0)	2 (13)	2
Schizophrenia, Schizotypal and Delusional Disorder	5 (33)	3 (20)	8
Mood Affective Disorder	3 (20)	2 (13)	5
Neurotic, Stress-related and Somatoform Disorders	2 (13)	1 (7)	3
Behavioural Syndromes	0 (0)	2 (13)	2
Disorders of Psychological Development	1 (7)	1 (7)	2
Behavioural and Emotional Disorders from Childhood	1 (7)	1 (7)	2
Not Applicable (Intellectual Disability Only)	3 (20)	3 (20)	6
DSM IV Axis 2 (A) Intellectual Disability (Using ICD 10 Codes)			
Mild Intellectual Disability	12 (80)	11 (73)	23
Moderate Intellectual Disability	3 (20)	4 (27)	7
DSM IV Axis 2 (B) Personality Disorders (Using ICD 10 Codes)			
Specific Personality Disorders	3 (20)	1 (7)	4
Mixed and Other Personality Disorders	0 (0)	1 (7)	1
Not Applicable	12 (80)	13 (86)	25

Table 2 – Mean ratings for total GAF symptomatology and social function and performance, WHOQOL-Bref social, physical, environmental and psychological, carer uplift and burden in patients allocated to assertive community treatment (ACT) and standard community treatment (SCT)

Rating	Community Intervention	No. of Patients	Assessment Period Mean Ratios [Standard Deviation] (Range)		F ratio & degrees of freedom	P Value
			Baseline (0)	Follow-up (3 months)		
GAF						
Symptomatology*	ACT	15	39.87 [15.30] (20 - 71)	69.07 [8.40] (55 - 90)	F = 0.07; df= 1	P = 0.80 ns
	SCT	15	40.13 [14.64] (15 - 61)	69.80 [10.90] (40 - 85)		
Social Function and Performance*						
	ACT	15	41.33 [10.99] (30 - 60)	69.40 [10.47] (50 - 90)	F = 0.07; df= 1	P = 0.79 ns
	SCT	15	41.20 [12.42] (21 - 60)	70.33 [10.70] (50 - 85)		
WHOQOL –Bref						
Physical*						
	ACT	15	67.14 [12.09] (46 - 86)	60.00 [13.58] (32 - 82)	F = 3.88; df=1	P = 0.05 ns
	SCT	15	56.43 [13.97] (29 - 82)	65.24 [17.10] (36 - 96)		
Psychological*						
	ACT	15	55.28 [18.59] (21 - 92)	57.22 [16.48] (25 - 79)	F = 3.63; df = 1	P = 0.06 ns
	SCT	15	45.00 [18.64] (8 - 67)	64.44 [18.36] (25 - 88)		
Social*						
	ACT	15	53.33 [17.76] (25 - 83)	63.33 [20.19] (25 - 100)	F = 0.13; df = 1	P = 0.72 ns
	SCT	15	49.44 [26.81] (8 - 100)	55.56 [16.86] (25 - 75)		
Environmental*						
	ACT	15	67.71 [12.03] (53 - 88)	66.46 [16.64] (34 - 94)	F = 0.43; df= 1	P = 0.51 ns
	SCT	15	61.67 [11.48] (34 - 78)	67.92 [15.65] (38 - 91)		
Carer Uplift/Burden						
Uplift*						
	ACT	15	14.93 [1.91] (11 - 18)	15.53 [2.45] (9 - 18)	F = 0.04; df=1	P = 0.84 ns
	SCT	15	13.93 [2.05] (11 - 18)	14.20 [2.43] (9 - 18)		

Burden #	ACT	15	26.33 [3.68] (22 – 35)	25.80 [5.19] (19 – 35)	F = 0.04; df = 1	P = 0.84 ns
	SCT	15	32.40 [6.22] (22 – 44)	30.00 [8.65] (17 – 44)		

*** For all these ratings a higher score indicates improvement.**

For this rating a lower score indicates improvement.

Table 3 – Mean number of professional contacts and duration of time (minutes) in assertive community treatment (ACT) and standard community treatment (SCT) groups.

Number of Contacts	Standard Community treatment (SCT)	Psychiatrist	Psychologist and Counsellor	Community Intellectual Disability Nurse	Outreach Team	Total	
	Mean	2.00	2.00	7.79	6.50	9.87	
	Range	Min	1	1	1	1	
		Max	4	4	18	12	25
	Assertive Community treatment (ACT)						
	Mean	2.64	7.75	12.57	16	16.80	
	Range	Min	1	1	2	16	2
		Max	8	12	40	16	41
P-value		t = 0.66; df = 16 P = 0.52, ns	t = 2.88; df = 8 P = 0.02, significant	t = 1.67; df = 26 P = 0.11, ns	t = 0.99; df = 1 P = 0.50 ns	t = 2.25; df = 28 P = 0.03, significant	
Duration of Time (Minutes)	Standard Community treatment (SCT)						
	Mean	112.86	82.50	340.71	367.50	452.67	
	Range	Min	30	30	30	15	30
		Max	360	135	1440	720	1800
	Assertive Community treatment (ACT)						
	Mean	82.73	390	388.57	4860	851.33	
	Range	Min	30	60	80	4860	80
		Max	240	720	1200	4860	5010
P-value		T = -0.69; df = 16 P = 0.51, ns	t = 2.19; df = 3.09 P = 0.11, ns	t = 0.37; df= 26 P = 0.72, ns	t = 7.36; df=1 P = 0.09 ns	t = 1.18; df = 28 P = 0.25 ns	