

Quality of life outcomes for intensive versus standard community mental health services

PRISM Psychosis Study 9

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Background We report the impact on the quality of life (QOL) of people with psychosis of an intensive compared with a standard model of community care.

Method People with psychosis, in two sectors in south London, were interviewed with a variety of measures at baseline, and at two-year follow-up ($n=138$). After baseline, services within one sector were reorganised, and a more intensive model of community care was introduced. QOL was measured using the Lancashire Quality of Life Profile.

Results The two overall QOL measures, global QOL and the average of the domain-specific scores, were remarkably stable over time. There was weak evidence for an improvement in living situation domain in the intensive sector; this may be accounted for by a large drop in in-patient admissions. In both sectors objective QOL was poor, and there was little change in any of the objective indicators except in-patient admissions, and a suggestion of increased social activity in the intensive sector.

Conclusions We failed to find an effect of intensive community care on QOL in people with psychosis. This may indicate an insensitivity to change in QOL measures, or that the intervention failed to produce the kind of changes in mental health and functioning which would be reflected in improved QOL.

Declaration of interest Funding provided by the Bethlem & Maudsley NHS Trust.

Quality of life (QOL) has become an important outcome of mental health services. Early studies in the USA focused on describing QOL in people with chronic mental illness receiving care in a variety of community settings (Baker & Intagliata, 1982; Lehman *et al*, 1982). Quality of life has also been used in evaluating the policy of deinstitutionalisation by comparing hospitalised patients with those receiving community care (Okin *et al*, 1983; Gibbons & Butler, 1987). These studies have demonstrated the feasibility of measuring QOL in people with severe mental illness, and the psychometric properties of some measures, for example Lehman's Quality of Life Interview, have been well established (Lehman, 1988). A consistent finding is that QOL in common with other subjective measures such as satisfaction, is higher in community compared with the hospitalised groups. In contrast other outcomes such as symptoms or social function are often unchanged. Quality of life measures have therefore proved their worth in being one of the major justifications for pursuing the move from hospital care and toward community integration.

EVALUATING MODELS OF COMMUNITY MENTAL HEALTH SERVICES

As this move is now nearly complete in many Western countries it is clear that this function of QOL studies is now almost redundant. The new challenge for outcome measures in this field is to discriminate between different models of community mental health services. The randomised controlled trial has been used as a method of comparing service delivery and in a few studies QOL has been employed as an outcome (Stein & Test, 1980). Olfson (1990) reviewed evaluations of assertive community treatment models, and found

that where QOL measures had been used, only in one (Stein & Test, 1980) was there a difference in QOL between experimental and control groups. Barry & Crosby (1996) have highlighted the question of sensitivity to change of QOL measures when used as outcome measures in service evaluations. Their repeated measures study of 65 long-stay patients pre- and post-discharge found remarkable stability of subjective QOL across the three baseline hospital measures and the three post-discharge measures. This was in contrast to significant objective changes in the domains of living situation, social contact and leisure activities. The problem of a weak relationship between subjective and objective measures within particular life domains has been well described (Pinkney *et al*, 1991; Sullivan *et al*, 1991). Patients with chronic mental illness included in Lehman's early studies rated remarkably high QOL despite high levels of economic and social disadvantage (Lehman, 1983). While this methodological issue is well described but unresolved, the recent concerns that QOL measures are insufficiently sensitive to change to be useful outcome measures in repeated measures evaluations remain unconfirmed. In their recent review Barry & Zissi (1997) emphasise the dearth of studies employing QOL as an outcome in repeated measures evaluations of different models of community services, and those that do exist involve small numbers. They conclude that there is need for more research on the sensitivity of QOL measures, and call for longitudinal studies using multiple measures and large sample sizes. The present paper reports the results of exactly such a study.

The study reported here has used QOL along with several other outcome measures in a repeated measures design with relatively large numbers of subjects. The main aim of the study as a whole was to examine prospectively the impact of the introduction of an intensive versus a standard model of community mental health services. QOL was employed as one of the main outcome measures in comparing the experimental intensive care sector with the control standard care sector. We were interested in whether QOL changed over time, and whether there were sector differences in QOL. The specific hypotheses tested were: (a) at Time 2 the intensive intervention would result in patients experiencing a higher subjective QOL than a Time 1; and (b) for a given initial level there would be a significant effect of sector on

QOL favouring the intensive intervention sector.

METHOD

The methodology for the evaluation has been described in detail earlier (Davies *et al*, 1996; Becker *et al*, 1997). A case finding technique identified all people with psychosis in two socio-demographically similar sectors in south London. A total of 514 people were identified who fulfilled strict criteria for psychosis using the Operational Criteria Checklist (OPCRIT; McGuffin *et al*, 1991) system of rating case notes. A random sample of people from each sector was interviewed at baseline and at two-year follow-up. The intervention consisted of the introduction, shortly after baseline interviews, of an intensive model of community mental health care in the experimental sector. In the control sector the introduction of community mental health care developed along standard lines.

The intervention is described in detail in Becker *et al* (1998a, paper 2 in this series). The main features of the intensive service were that it aimed to offer acute home-based care, to decrease hospital admissions, to provide assertive outreach, and to develop primary care liaison. In practical terms there was a reduction in beds with increase in community staff, provision of care by the mental health team beyond office hours, and provision of non-hospital crisis and respite beds.

Measures

This study focuses on the outcome of the intervention in terms of QOL, which was measured using the Lancashire Quality of Life Profile (LQOLP; Oliver, 1991). The LQOLP is an interviewer-administered questionnaire which provides objective and subjective ratings of QOL for the following areas: work, leisure, religion, finances, legal and safety issues, family relations, social relations and health. Objective ratings are made from direct questioning about patients' lives, while subjective QOL is measured by asking patients to rate their satisfaction with each separate life domain on a seven-point scale as follows: 1 – Can't be worse; 2 – Displeased; 3 – Mostly dissatisfied; 4 – Mixed; 5 – Mostly satisfied; 6 – Pleased; 7 – Can't be better. An average score across all nine domains is calculated, and there is

also a global well-being rating made at the beginning and end of the interview where patients are asked to rate their life overall.

A number of other measures were used at baseline and repeated at follow-up, including the Brief Psychiatric Rating Scale (Ventura *et al*, 1993a,b), the Global Assessment of Functioning scale (American Psychiatric Association, 1987) and the Severe Behaviour Score (Wykes & Sturt, 1986).

Analysis

The data were analysed using SPSS and STATA (version 4). Only patients with QOL data at both Time 1 and Time 2 were included in the outcome analysis ($n=138$; 68 in intensive sector; 70 in standard sector). Repeated measures analysis was used to explore gender and ethnic differences in QOL scores. Comparisons of mean QOL scores between sectors were made using independent *t*-tests, and for comparisons of QOL scores within a sector between Time 1 and Time 2, paired *t*-tests were employed. The effect of sector on subjective QOL scores was examined using analysis of covariance (ANCOVA) in which the Time 1 value was entered as a covariate along with the following other potential confounding variables: age, gender, marital status, ethnic group, diagnosis, total Brief Psychiatric Rating Scale score and total Severe Behaviour Score. This analysis aims to test whether the type of intervention has a significant effect on the Time 2 QOL scores after controlling for the Time 1 QOL value, and the other potential confounding variables. To examine this sector effect on objective QOL indicators, a logistic regression was used in which the Time 2 objective QOL indicator was entered as the dependent variable, controlling for the Time 1 value.

RESULTS

Subject numbers and characteristics

Three hundred and two people were selected for interview in the study as a whole, and some QOL data were obtained in 217 people. There were 138 people who had completed QOL data at both Time 1 and Time 2, and a remainder of 79 people who had QOL data at one but not both time points. It is this sample of 138 people that is used in the analysis. The characteristics of this sample of 138 people are

described in Table 1, and they are compared with the interviewed sample of 217 in whom some QOL data were available. Table 1 shows that the sample of 138 with both Time 1 and Time 2 data available is very similar to the rest of the interviewed sample. Independent *t*-tests of the sample of 138 compared to the 79 people who had some QOL data but not data at both time points, revealed no significant differences on any of the variables displayed in Table 1. Neither were there any differences between the sectors in the characteristics of those people who were lost to the paired analysis. The QOL scores of people who completed Time 1 data but dropped out before Time 2, or who had no Time 1 data but completed Time 2 data, did not differ significantly from those with data at both time points.

QOL scores at baseline and follow-up for each sector

Subjective QOL indicators

At both time points and in both sectors the subjective scores were between 4 and 5 (between mixed and satisfied). The relative scores between domains remain the same over time, indicating that none of the interventions impacted on particular domains and changed them relative to others. Only in two domains, work and finance, did the mean fall just in the dissatisfied range. There were no baseline differences in the overall subjective QOL scores, that is the global QOL score and the average of the domain-specific scores. At the level of individual domains there were only three significant differences between sectors at baseline. The employed domain was higher in the intervention sector (mean intensive sector=4.9, mean control sector=3.9, $P=0.005$). On both living situation and health, the QOL scores were higher in the standard sector at baseline (living situation: mean intensive sector=4.26, standard sector=4.78, $P=0.009$; health: mean intensive sector=4.40, standard sector=4.82, $P=0.03$). There were no gender differences in either the global or the average domain-specific score.

Objective QOL data

The objective data collected are displayed in Table 1. The biggest objective differences between sectors were in sheltered employment and sheltered accommodation. These differences were expected as they arise from

Table 1 Comparison of the people with Time 1 and Time 2 quality of life (QOL) scores ($n=138$ unless indicated otherwise) with the remainder of the study sample ($n=217$ unless indicated otherwise)

Variable	Complete pairs		Interviewed sample	
Sector (n (%))				
Nunhead	68	(49)	105	(48)
Norwood	70	(51)	112	(52)
Gender (n (%))				
Male	75	(54)	108	(50)
Marital status (n (%))				
Married or cohabiting	24	(17)	43	(20)
Ethnic group (n (%))				
White	87	(64)	137	(63)
Black Caribbean	39	(28)	57	(26)
Employment status (n (%))				
Unemployed	98	(71)	139	(64)
Diagnosis (n (%))				
Schizophrenia	86	(62)	121	(56)
Accommodation (n (%))				
Unsupported	112	(81)	171	(79)
Supported	21	(15)	34	(16)
Ever on MHA section (n (%))				
Yes	68	(49)	108	(50)
Criminal history (n (%))				
Yes	44	(32)	62	(29)
Age in years (mean (s.d.))	41	(14.7)	42.1	(15.8)
Years contact with services (mean (s.d.))	17.3	(12.4) ¹	16.6	(12.7) ²
GAF score (mean (s.d.))	60.9	(16.74) ³	59	(14.1) ⁴
Severe behaviour score (mean (s.d.))	1.24	(1.86) ⁵	1.3	(1.9) ⁵
Total BPRS score (mean (s.d.))	35.1	(11.1) ⁶	35.2	(11.3) ⁷
Global QOL score Time 1 (mean (s.d.))	4.4	(1.4)	4.39	(1.43) ⁸
Average domain specific QOL score Time 1 (mean (s.d.))	4.5	(0.8)	4.45	(0.81) ⁸

GAF, Global Assessment of Functioning; BPRS, Brief Psychiatric Rating Scale; MHA, Mental Health Act.

1. $n=133$.

2. $n=209$.

3. $n=126$.

4. $n=182$.

5. $n=188$.

6. $n=136$.

7. $n=194$.

8. $n=196$.

the differences in provisions of these services between sectors. The intensive sector has two hostels providing sheltered accommodation, a facility that does not exist in the standard sector. The standard sector has an established sheltered work programme for which there is no equivalent in the intensive sector. These differences were part of the existing service provision in the two sectors, and did not relate to the intervention. The differences on these two indicators were significant at baseline (baseline sheltered employment: $\chi^2=8.67$, $d.f.=1$, $P=0.004$; baseline sheltered accommodation: $\chi^2=9.53$, $d.f.=1$, $P=0.003$), and these differences persisted at follow-up. The other indicator on which

there was a significant baseline difference between sectors was in visiting with a friend in the past week. This was higher in the standard sector at baseline but not at follow-up (baseline visited with friend $\chi^2=9.28$, $d.f.=1$, $P=0.004$). The data paint a picture of quite poor objective QOL. Only about a fifth of patients are in any form of employment (including sheltered). This is slightly higher in the standard sector than in the intensive sector because of the greater provision of sheltered employment there. Only about a third live with any family, though contact with family is quite high with about three-quarters having daily or weekly contact.

Testing of hypotheses and further analysis of results

Hypothesis: intensive intervention improves QOL over time

Table 3 presents the mean QOL scores for the two main subjective QOL measures at both time points in each sector. The difference over time in both sectors is very small and paired t -tests showed no significant increase in QOL in either sector. There were only two significant differences in any of the individual domains, and both were in the intensive sector. There was a significant increase in scores on the living situation domain (mean change score, Time 2 minus Time 1, 0.34, 95% CI, 0.59–0.10, $P=0.007$), and a significant decrease in scores in the religion domain (mean change score -0.75 , 95% CI, -0.23 to -1.27 , $P=0.006$). However, on the basis of Simes' test (Simes, 1986), which adjusts for multiple testing, in neither sector is there evidence at $P=0.05$ for overall changes over time.

Hypothesis: time-adjusted QOL is better in the intensive intervention sector

Table 4 presents the difference in Time 2 QOL between the intensive sector and the standard sector, adjusted for the Time 1 value and for possible confounding variables. There was no significant sector effect on any of the main subjective QOL measures. There was one significant difference in the subscales, in which the intensive sector had an apparently significant effect of decreasing satisfaction with the religion domain. However, the sample size for this variable is low as many participants did not feel the question was relevant to them, and Simes' test again showed no significant sector effect when the variables are taken as a group. It can be seen from the positive and negative signs on the changes that there is no consistent trend of scores favouring either sector.

Living situation domain

Within the intensive sector there was a significant increase in the subjective QOL on the living situation domain. Although the ANCOVA results were not significant, showing that this finding could not definitely be attributed to the intervention, the direction of the effect was in favour of the intensive sector. We considered whether this could be related to two objective indicators: the much greater provision and

Table 2 Objective quality of life (QOL) data for each sector at baseline and follow-up

Objective QOL measure	Intensive sector (n=68) ¹		Standard sector (n=70) ¹		P ²
	Baseline	Follow-up	Baseline	Follow-up	
Employed					
Yes	15 (22.1%)	12 (17.6%)	25 (35.7%)	17 (24.3%)	0.86
Supported work					
Yes	2 (2.8%)	5 (6.9%)	16 (21.9%)	14 (19.2%)	0.50
Supported accommodation					
Yes	20 (27.8%)	23 (31.9%)	5 (6.8%)	7 (9.6%)	0.16
Played or watched sport					
Yes	17 (25.4%)	8 (11.9%)	12 (17.1%)	12 (17.1%)	0.27
Been shopping					
Yes	54 (79.4%)	57 (83.8%)	60 (85.7%)	57 (81.4%)	0.37
Travel, bus, train, car					
Yes	55 (80.9%)	60 (88.2%)	66 (94.3%)	53 (75.7%)	0.03
Listened to TV/radio					
Yes	64 (97.0%)	62 (93.9%)	68 (97.1%)	66 (94.3%)	0.94
Accused of a crime					
Yes	7 (10.8%)	1 (1.5%)	5 (7.1%)	3 (4.3%)	0.33
Assaulted					
Yes	4 (6.2%)	10 (15.4%)	10 (14.3%)	5 (7.1%)	0.12
Frequency of relative contact					
Daily/weekly	45 (69.4%)	48 (77.4%)	52 (76.5%)	51 (75.0%)	0.32
Close friend					
Yes	42 (65.6%)	39 (60.9%)	50 (72.5%)	51 (73.9%)	0.16
Friend for help					
Yes	37 (56.9%)	36 (54.4%)	50 (73.5%)	51 (75%)	0.09
Visited with a friend past week					
Yes	25 (38.5%)	32 (49.2%)	42 (63.6%)	43 (65.2%)	0.25
Doctor for physical illness					
Yes	37 (56.9%)	35 (53.8%)	34 (48.6%)	47 (67.1%)	0.05
Medication for nerves					
Yes	49 (75.4%)	53 (81.5%)	64 (91.4%)	64 (91.4%)	0.67
In-patient in care previous six months					
Yes	22 (30.6%)	14 (19.4%)	12 (16.4%)	13 (17.8%)	0.53

1. Maximum sample size: some missing values for individual measures.

2. Significance for comparison of sectors on Time 2 proportion, controlling for the Time 1 proportion (See text; 'Objective QOL Data').

use of sheltered accommodation, and the decrease in in-patient admissions in the intensive compared with the standard sector.

The subjective QOL on the living situation domain increased from hospital living through supported accommodation to unsupported accommodation (Table 5). This trend persisted, though was less significant, after controlling for symptoms. However, the suggestion that increased use of sheltered accommodation in the intensive sector accounts for lower QOL on the living situation domain was not supported,

as the sector difference remained after controlling for living situation, and also after controlling for age, gender, diagnosis, and ethnicity. A further relevant finding is that the living situation domain in the intensive sector was the only domain to show a significant increase between Time 1 and Time 2. A major change brought about by the intervention was that in-patient admissions fell markedly in the intensive service (from 30% in the six months before Time 1 to 19% in the six months before Time 2) whereas admissions remained constant in the standard sector at about

16% (Table 2). It is suggested that the reduction in use of in-patient admissions in the intensive sector might explain the improved QOL scores in the living situation domain; however, it was not possible to examine this further with the current data.

Objective QOL data

Table 2 displays the results of the logistic regression analysis of objective QOL indicators, showing the significance of differences at Time 2, controlling for Time 1 values. The most striking thing about these data is the stability of people's objective situation over time for most measures. Furthermore, in only two domains is there evidence for a sector effect on objective indicators, having adjusted for the Time 1 level. The failure to detect other significant sector effects is probably due to low power, and for only two was there evidence for a sector effect at $P=0.05$ (not adjusting for multiple testing). This is an increase in travel favouring the intensive sector, and an increase in people on medication in the standard sector. The baseline sector differences in sheltered work and sheltered accommodation persist at Time 2. There are increases (although not significant) in the proportion of people in the intensive sector who have visited with a friend, and who have relative contact, in the intensive sector and there was also significantly more travelling. This may indicate increased social activity, and is in keeping with findings of increased relative contact in the social network data (Becker *et al*, 1998b, paper 7 this series). There is a marked decrease in in-patient care in the intensive sector.

DISCUSSION

The mean scores on individual domains and in global QOL are comparable with those of other studies in people with psychosis (Simpson *et al*, 1989; Oliver *et al*, 1997). In common with other studies (Lehman *et al*, 1982) we see that despite having a major mental illness, these people rated themselves as broadly satisfied across all life domains and globally. The only areas in which the mean scores fell in the dissatisfied range were employment, which involved small numbers as only 40 were employed, and finances. The lower score on employment may be partially explained by the relatively high numbers in sheltered

Table 3 Quality of life (QOL) scores: changes in mean from Time 1 to Time 2 in each sector

QOL variable	Time 1	Time 2	Mean difference (95% CI)	P ¹
Intensive sector (n=68)				
Average of domains	4.41	4.44	0.03 (−0.20–0.15)	0.76
Global QOL	4.35	4.40	0.05 (−0.39–0.30)	0.80
Standard sector (n=70)				
Average of domains	4.55	4.59	0.04 (−0.18–0.11)	0.61
Global QOL	4.49	4.50	0.01 (−0.34–0.32)	0.97

1. Significance of change in QOL score between Time 1 and Time 2 using paired t-test (within sector).

Table 4 Estimated effect of the intensive service on quality of life (QOL) scores

QOL variable	n	Adjusted difference ¹	95% CI	P
Average domain-specific QOL	138	−0.01	−0.22 to 0.19	0.88
Global QOL	138	0.10	−0.34 to 0.55	0.65
Sub-scales				
Employed	19	0.13	−0.59 to 2.86	0.16
Unemployed	78	−0.49	−1.19 to 0.21	0.17
Work	122	−0.21	−0.64 to 0.40	0.64
Leisure	138	−0.23	−0.55 to 0.09	0.16
Religion	76	−0.65	−1.23 to −0.06	0.03
Finance	138	−0.03	−0.49 to 0.42	0.88
Living situation	137	0.16	−0.13 to 0.46	0.27
Legal and safety	135	−0.10	−0.50 to 0.30	0.63
Family relations	131	0.21	−2.0 to 0.62	0.31
Social relations	135	0.05	−0.33 to 0.42	0.81
Health	131	0.10	−0.25 to 0.45	0.56

1. Difference (intensive – standard) after adjusting for the Time 1 QOL value and the other possible confounders, i.e. age, gender, marital status, ethnic group, diagnosis, total Brief Psychiatric Rating Scale score and total severe behaviour score.

employment, which seemed to be a factor reducing satisfaction with employment. The lower QOL on the finances domain needs to be interpreted in the light of the low average income in this group, as additional analysis revealed a significant correlation between income and QOL on the finance domain.

We found a remarkable stability in QOL measures over time, with only small variations in the scores across the domains and on the overall measures of average of domains, and global QOL the scores were

virtually identical at Time 1 and Time 2. The possible explanations for this are that QOL measures are insufficiently sensitive to change to be useful as outcome indicators, or alternatively the mental health services offered by either sector did not make the changes necessary to impact on mental health.

Considering within-sector QOL comparison, the only scores that showed a significant sector effect, adjusting for initial level, were in the intensive sector, where there was an estimated reduction in satis-

faction with religion and an estimated increase in satisfaction with living situation. Neither of these effects are significant when we take an adjustment for multiple testing into account. Little weight can be placed on the religion subscale as the numbers responding on this domain were low. It is suggested that the living situation finding is partly explained by the number of admissions in the six months before interview falling from Time 1 to Time 2 in the intensive sector, while admission rates remained stable in the standard sector. This finding of a change on the living situation domain related to being out of hospital has been reported in earlier papers which looked at people moving from long-stay institutions into the community (Barry & Crosby, 1996). Our findings confirm in another setting that people are more satisfied with their living situation when living in the community.

The changes that were found in the objective indicators (i.e. significant increase in travel and a trend towards increasing social contact), although modest, were in keeping with the findings of other studies that community-focused care improves social relations and leisure activities (Gibbons & Butler, 1987; Barry & Crosby, 1996).

Calculation of effect size is suggested as a way of examining QOL outcome data and is produced by dividing the difference between the post-treatment and pre-treatment QOL scores by the standard deviation of the pre-treatment score (Fletcher, 1995). The effect sizes for QOL scores in all the domains varied between negligible and small, and none reached the level of 0.4 which would be regarded as a moderate effect size. Changes on the overall measure of global QOL were particularly small, perhaps because very little has changed objectively. However, it would appear that there is little direct relationship between subjective QOL and objective indicators within the same domain.

None of the QOL measures differed significantly between sectors after taking account of initial differences, so we were unable to show an advantage in improved QOL to the intensive service. The changes in organisation and delivery of mental health services in the intensive sector represented a big change for those working within it, with a major shift in orientation from hospital to community. However, it seems from the perspective of the service users that there were few changes, either in their objective

Table 5 Subjective satisfaction with living situation by receipt of supported accommodation, and in-patient status

	Subscale for satisfaction with living situation ¹ Mean (95% CI)
Hospital in-patient (n=7)	3.71 (3.11–4.30)
Supported accommodation (n=32)	4.26 (3.82–4.70)
Unsupported accommodation (n=156)	4.60 (4.41–4.79)

1. P=0.07 (test for trend)

situation or in their subjective QOL. Furthermore there were few differences in any of the other outcome measures used in the study (i.e. symptoms, disability, or satisfaction with services; Wykes *et al*, 1998; Leese *et al*, 1998, papers 4 and 8 this series). Although the numbers in this study are larger than those in many QOL studies, the differences in QOL ratings were too small to detect significant differences. This problem of lack of power should be considered by others planning future research as studies with larger sample sizes are needed.

In conclusion this study has not been able to either support or refute the utility of QOL measures as outcome measures in evaluating mental health services. The failure to find a change in QOL does not necessarily mean that QOL scores are insensitive to change. It would appear the intervention itself was ineffective, as there were few changes in any of a wide range of outcome measures. More work is needed in understanding QOL and the factors that affect it. We need to understand which of the factors amenable to change by mental health services impact on QOL. Services need to be targeted at specific areas of deficit in patients' lives, and then we can consider whether this leads to improved QOL in those life domains. In such a complex area multiple measures of outcome will always be necessary to build up an overall picture. However, we need much more research which enables us to understand the relationship between our different measures, for example between need, symptoms and disability and QOL.

ACKNOWLEDGEMENTS

We are pleased to acknowledge the invaluable contributions that the following colleagues have made towards the PRISM Psychosis Study: Thomas Becker, Sara Bixby, Liz Brooks, Sara Davies, Graham Dunn, Ruth Fermo, Julie Grove, Hilary Guite, Andrew Higginbotham, Sonia Johnson, Frank Kelly, Julia Kleckham, David Nathaniel-Jones, Linda Loftus, Paul McCrone, Wendy Ojurongbe, Dominic O'Ryan, Sue Parkman, Michael Phelan, Laura Ponti-Sgargi, Mike Slade, Geraldine Strathdee, George Szmuckler, David Turner, Rozalia Wojcik, Til Wykes. We would also like to acknowledge the sustained and invaluable assistance of the users, carers and clinical staff of the Nunhead and Norwood sectors of the Bethlem and Maudsley NHS Trust.

CLINICAL IMPLICATIONS

- Objective improvement in quality of life does not necessarily affect subjective quality of life.
- Major changes in mental health services may not impinge greatly on quality of life.
- Intensive interventions which succeed in looking after patients at home, and reducing admissions, may have a positive effect on subjective assessment of living situation.

LIMITATIONS

- Large baseline differences between sectors make interpretation difficult.
- The sample sizes may be too small to detect subtle changes in quality of life.
- The association between objective and subjective quality of life, and the sensitivity to change of quality of life scores, require further exploration.

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(First received 5 January 1998, final revision 2 June 1998, accepted 3 July 1998)

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