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J Brazier, I Tumur, M Holmes, M Ferriter, G Parry, K Dent-Brown and S Paisley

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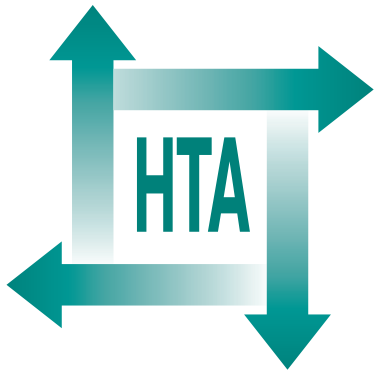



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The research reported in this monograph was commissioned by the HTA Programme as project number 04/52/01. The contractual start date was in January 2005. The draft report began editorial review in September 2005 and was accepted for publication in February 2006. 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.

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# Abstract

## Psychological therapies including dialectical behaviour therapy for borderline personality disorder: a systematic review and preliminary economic evaluation

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**Objectives:** To summarise the available evidence on the clinical effectiveness and cost-effectiveness of psychological therapies including dialectical behaviour therapy (DBT) for borderline personality disorder (BPD).

**Data sources:** Electronic databases were searched up to March 2005.

**Review methods:** Relevant studies were assessed using standard checklists and data were abstracted by two reviewers using standardised forms. Separate economic evaluations were undertaken for six selected randomised controlled trials (RCTs). Cost-effectiveness was assessed in terms of cost per parasuicide event avoided in all six trials and cost per quality-adjusted life-year (QALY) in four of them. All results are at 2003–4 prices and for 12 months follow-up.

**Results:** Nine RCTs and one non-RCT of moderate to poor quality were identified in the clinical effectiveness review. They provided some evidence that DBT is more effective than treatment as usual (TAU) for the treatment of chronically parasuicidal and drug-dependent borderline women; that DBT-orientated therapy is more effective than client-centred therapy (CCT) for the treatment of BPD; and that DBT is as effective as comprehensive validation therapy plus 12-Step for the treatment of opioid-dependent borderline women. There was also some evidence that partial hospitalisation is more effective than TAU in the treatment of BPD, good evidence that manual-assisted cognitive behavioural therapy (MACT) is no more effective than TAU in the treatment of BPD and some evidence that interpersonal group therapy is no more effective than individual mentalisation-based partial hospitalisation (MBT) for the treatment of BPD. However, these results should be interpreted with caution as not all studies were primarily targeted to borderline symptoms and there were considerable differences between the studies. The assessment of cost-effectiveness found a mix of results in the four trials of DBT, along with the high levels of uncertainty and the limitations in the analyses. The findings do not support the cost-effectiveness of DBT though they suggest it has the potential to be cost-effective. The results for MBT are promising, though again surrounded by a high degree of uncertainty and for MACT, the analysis suggests that the intervention is unlikely to be cost-effective.

**Conclusions:** The overall efficacy of psychological therapies is promising; however, at this stage the evidence is inconclusive. The cost-effectiveness of the intervention in six RCTs examined, however, does not support the cost-effectiveness of DBT although potential is suggested. There is a need for considerable research in this area. This research should involve appropriately powered head-to-head RCTs of psychological therapies; a survey of current practice and the use of the full range of services by people with BPD to inform future economic analyses; full resource-use data collected in the context of pragmatic clinical trials; psychometric assessment of the validity of the EQ-5D or other generic and condition-specific preference-based measures in BPD, and the development of a more formal cost-effectiveness model using the above data.

# Contents

# Glossary and list of abbreviations

Technical terms and abbreviations are used throughout this report. The meaning is usually clear from the context, but a glossary is provided for the non-specialist reader. In some cases, usage differs in the literature, but the term has a constant meaning throughout this review.

## Glossary

**Client-centred therapy** Model of supportive therapy based on Carkuff's model which emphasises empathic understanding of the patient's sense of aloneness and provides a supportive attitude on an individual basis.

**Cognitive behaviour therapy** The pragmatic combination of concepts and techniques from cognitive and behaviour therapies common in clinical practice.

**Comprehensive validation therapy with 12-Step** A manualised approach that provides the major acceptance-based strategies such as therapeutic warmth, responsiveness and empathy in combination with the 12-Step programme.

**Dialectical behaviour therapy** Combination of standard cognitive behavioural techniques with acceptance-based strategies and strategies designed to keep the therapy balanced between change and acceptance (dialectical strategies).

**Manual-assisted cognitive behaviour therapy** A 70-page manual that consists of a brief form of cognitive behaviour therapy combined with dialectical behaviour therapy techniques potentially suitable for widespread use in routine healthcare settings.

**Mentalisation-based partial hospitalisation** Integrates individual and group psychoanalytic psychotherapy within a limit-setting, structured, flexible and reliable partial hospitalisation. The mentalisation-based partial hospitalisation reflects both the therapeutic and management difficulties, with an emphasis on the relational aspects of the disorder.

**Psychodynamic therapy** Emphasises personality structure and development and aims to provide insight for people, allowing them to understand their feelings and to find better coping mechanisms.

## List of abbreviations

| | |
|---|---|
| A&E | accident and emergency |
| AUC | area under the curve |
| BAI | Beck Anxiety Inventory |
| BDI | Beck Depression Inventory |
| BHS | Beck Hopelessness Scale |
| BPD | borderline personality disorder |
| BPDSI | Borderline Personality Disorder Severity Index |
| BPRS | Brief Psychiatric Rating Scale |
| BSI | Brief Symptom Inventory |
| CASP | Critical Appraisal Skills Programme |
| CBT | cognitive behavioural therapy |
| CCDAN | Cochrane Collaboration Depression and Anxiety Neurosis Review Group |
| CCT | client-centred therapy |
| CEAC | cost-effectiveness acceptability curve |

*continued*

## List of abbreviations *continued*

| | |
|---|---|
| CI | confidence interval |
| CRD | Centre for Reviews and Dissemination |
| CSRI | Client Service Receipt Inventory |
| CVT+12S | comprehensive validation therapy with 12-Step |
| DBT | dialectical behaviour therapy |
| DES | Dissociative Experiences Scale |
| df | degree of freedom |
| DIB | Diagnostic Interview for Borderlines |
| DSH | deliberate self-harm |
| DSM | Diagnostic and Statistical Manual of Mental Disorders |
| EQ-5D | EuroQol 5 Dimensions |
| EuropASI | European Addiction Severity Index |
| GAF | Global Assessment of Functioning |
| GAS | Global Adjustment Scale |
| GSA | Global Social Adjustment |
| GSI | Global Symptom Index |
| HADS | Hospital Anxiety and Depression Scale |
| HAM-D | Hamilton Depression Rating Scale |
| HARS | Hamilton Anxiety Rating Scale |
| HSC-90 | Hopkins Symptom Checklist |
| HSRS | Health Sickness Rating Scale |
| ICD-10 | International Classification of Diseases 10 |
| IGP | interpersonal group psychotherapy |
| IQR | interquartile range |
| IRT | interpersonal reconstructive therapy |
| ITT | intention-to-treat |
| LAAM | levo-alpha acetyl methadol |
| LOS | length of stay |
| LPC | Lifetime Parasuicide Count |
| MACT | manual-assisted cognitive behavioural therapy |
| MBT | mentalisation-based partial hospitalisation |
| NA | not applicable |
| NICE | National Institute for Health and Clinical Excellence |
| NR | not reported |
| ns | not significant |
| OBI | Objective Behaviours Index |
| ONS | Office for National Statistics |
| PD | personality disorder |
| PDE | Personality Disorders Exam |
| PDQ | Personality Diagnostic Questionnaire |
| PH | partial hospitalisation |
| PHI | Parasuicide History Interview |
| POPMACT | Prevention of Parasuicide by Manual-Assisted Cognitive Behaviour Therapy |
| PS | parasuicide |
| PSA | probabilistic sensitivity analysis |
| QALY | quality-adjusted life-year |
| RCT | randomised controlled trial |
| SAS | Social Adjustment Scale |
| SCID | Structured Clinical Interview for DSM |
| SCL-90-R | Symptom Checklist 90–Revised |
| SD | standard deviation |
| SE | standard error |
| SFQ | Social Functioning Questionnaire |
| SHI | Social History Interview |
| SSRI | selective serotonin reuptake inhibitor |
| TAU | treatment as usual |
| TFT | transference-focused therapy |
| TLFB | Timeline Follow-Back |

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices in which case the abbreviation is defined in the figure legend or at the end of the table.

# Executive summary

## Background

Borderline personality disorder (BPD) is a severe and complex mental disorder characterised by pervasive instability in moods, interpersonal relationships, self-image and behaviour. In the DSM-IV system, the criterion for a diagnosis of BPD is five of nine presenting symptoms. The Office for National Statistics 2000 survey of psychiatric morbidity in private households identified seven people per 1000, which indicates that for a primary care trust of 500,000, there would be 3500 individuals meeting the criteria for BPD.

Psychological therapies for BPD have many factors in common, such as a high level of structure, consistency, theoretical coherence, taking account of the relationship problems (including the difficulty in engaging positively with the therapist), and taking a flexible and individualised approach to care. Within these general principles, several specific therapies have been applied to, and developed for use with, patients with BPD. Mental health practitioners specifically trained in the methods described deliver these treatments. The practitioners may have a qualification in psychiatry, mental health nursing, clinical psychology or another mental health profession (e.g. occupational therapy or mental health social work).

## Objective

The aim of this project was to summarise the available evidence on the clinical effectiveness and cost-effectiveness of psychological therapies including dialectical behaviour therapy (DBT) for BPD.

More specifically, the review aimed to:

- evaluate clinical effectiveness in terms of reductions in self-harm and suicide
- evaluate effectiveness in terms of improved psychological functioning (e.g. in terms of dissociation and mood)
- evaluate effectiveness in terms of interpersonal and social functioning
- evaluate effectiveness in terms of quality of life
- evaluate effectiveness in terms of presentation to mental health and other services (including accident and emergency attendance and psychiatric hospital admission)
- evaluate the cost-effectiveness of the therapies compared with treatment as usual
- identify the important areas of ignorance or uncertainty.

## Methods

### Clinical effectiveness

A systematic review of the literature aimed to identify all references related to the clinical and cost-effectiveness of psychological therapies including DBT for BPD.

Twenty electronic bibliographic databases were searched, covering biomedical, health-related, science and social science literature. In addition, attempts were made to identify 'grey' literature by searching appropriate databases (e.g. Health Management Information Consortium, Index to Theses, Dissertation Abstracts), current research registers (e.g. National Research Register, Current Controlled Trials) and the Internet (e.g. by searching Google and relevant websites, such as the British Association for Behavioural and Cognitive Psychotherapies, British Psychological Society and Royal College of Psychiatry). Citation searches of included studies were undertaken using the Science Citation Index and Social Sciences Citation Index citation search facility, and the reference lists of included studies and relevant review articles were also checked.

The study quality of relevant studies was assessed using standard checklists and data were abstracted by two reviewers using standardised forms.

### Cost-effectiveness

The cost-effectiveness assessment was in two parts. The first was a review of the literature. The second was an original assessment undertaken by the review team using evidence from the clinical trials and other sources.

It was not possible to apply a formal decision modelling approach given the complex care pathways for patients with BPD and the lack of evidence. It was decided instead to undertake separate economic evaluations for the six randomised controlled trials (RCTs) that had sufficient data using a combination of data reported in published papers, trial data sets sent by the investigators, a cost model using data from the POPMACT study and a utility mapping exercise. Cost-effectiveness was assessed in terms of cost per parasuicide event avoided in all six trials and cost per quality-adjusted life-year (QALY) in four of them, (which was done by mapping BDI results onto the EQ-5D for three. All results are at 2003–4 prices and for 12 months follow-up.

# Results

## Number and quality of studies, and direction of evidence

### *Clinical effectiveness*

Ten studies met the inclusion criteria of DBT, mentalisation-based partial hospitalisation (MBT), manual-assisted cognitive behavioural therapy (MACT), comprehensive validation therapy (CVT) and client-centred therapy (CCT), along with treatment as usual (TAU). Of these, nine were RCTs and one was a non-randomised comparative study. The quality of the studies ranged from moderate to poor.

### *Cost-effectiveness*

The review of published studies identified one cost-effectiveness analysis of psychological therapy for BPD. This was based on data from an RCT comparing DBT with TAU for the treatment of BPD. Participants were women who were clinically referred to a psychotherapy outcome study. The review of published studies also identified an economic evaluation of psychological therapies of partial relevance to BPD. This was a cost-effectiveness analysis of data from an RCT comparing MACT with TAU for the treatment of people with recurrent episodes of deliberate self-harm. A subgroup analysis was published but this did not present a full economic evaluation (although one was undertaken by the review team).

## Evidence of effectiveness

### *Clinical effectiveness*

Nine RCTs and one non-RCT of moderate to poor quality were identified in the clinical effectiveness review. There is some evidence to support the effectiveness of psychological therapies for BPD:

- There is some evidence that DBT is more effective than TAU for the treatment of chronically parasuicidal and drug-dependent borderline women.
- There is some evidence that DBT-orientated therapy is more effective than CCT for the treatment of BPD.
- There is some evidence that DBT is as effective as CVT with 12-Step (CVT+12S) for the treatment of opioid-dependent borderline women.
- There is some evidence that partial hospitalisation is more effective than TAU in the treatment of BPD.
- There is good evidence that MACT is no more effective than TAU in the treatment of BPD.
- There is some evidence that interpersonal group therapy is no more effective than individual MBT for the treatment of BPD.

However, these results should be interpreted with caution as not all studies were primarily targeted to borderline symptoms and there were considerable differences in patient characteristics, comparison groups and outcomes between the studies.

### *Cost-effectiveness*

**Review**

One cost-effectiveness analysis used data from an RCT that compared DBT with TAU for the treatment of BPD. The participants were women who were clinically referred to a psychotherapy outcome study. Those receiving DBT ($n$ = 22) incurred significantly higher psychotherapy costs, lower psychiatric inpatient costs and lower emergency room costs compared with TAU ($n$ = 22). The two treatment groups did not differ significantly with respect to median medical or total healthcare costs. The cost-effectiveness measures used were cost per week employed and cost per point of global adjustment, and no significant difference was found in either of these measures for DBT compared with TAU. This study had limitations concerning the lack of important cost data and the fact that it was undertaken using data from a small, underpowered trial with a high dropout rate.

The cost-effectiveness analysis comparing MACT with TAU for the treatment of people with recurrent episodes of deliberate self-harm found no significant differences between the groups in the total costs across all patients or among those with BPD ($n$ = 62). The cost per 1% reduction in the proportion of patients with a

repeat self-harm episode was £120, with more than a 90% chance of being cost-effective, but this analysis was not undertaken for the BPD subgroup. The incremental mean effect as measured by EQ-5D was negative for MACT (–0.01118). The incremental cost per QALY gained from TAU was therefore £66,000, but the authors argued that this was probably a chance finding given that the difference in EQ-5D was not significant.

**Assessment**
In three of the four DBT trials, the intervention dominated the control groups in terms of parasuicide events or achieved a cost per event avoided below £50. However, in a fourth DBT trial the estimated cost per event avoided was £43,124. Although these studies seem favourable to DBT in terms of mean incremental cost-effectiveness, the probability of being cost-effective at £5000 per parasuicide event avoided was around just 60% in each case. Only two DBT trials could be subjected to a cost per QALY analysis, and for one the intervention again dominated and the other had a cost per QALY of £273,801. The probabilistic sensitivity analysis showed substantial uncertainty surrounding these results; the most favourable study had a probability of DBT being cost-effective of around 85%.

The MBT study group achieved a low cost per parasuicide event avoided, with a probability of being cost-effective at £5000 per parasuicide event avoided of 80%. While the cost per QALY was modest at £7242, there was substantial uncertainty, with a probability of being cost-effective at £20,000 per QALY of less than 60%. For the POPMACT, the BPD subgroup analysis found that the intervention was dominated in terms of cost per parasuicide event avoided. There was an insignificant incremental QALY gain in BPD, with an associated cost per QALY of £84,032. These assessments of MACT were both associated with a high degree of uncertainty, where the probability of being cost-effective was less than 50% in each case.

These assessments must be viewed with great care. The trials on which they were based were often of poor quality, using a mixture of methods for costing and assessing outcome (including QALYs) and of doubtful generalisability to the NHS for many of the studies. This mixture of results, high levels of uncertainty and the limitations in methods provides very limited support for the cost-effectiveness of DBT, but the results suggest that DBT could be cost-effective.

## Conclusions

The overall efficacy of psychological therapies is promising; however, at this stage the evidence is inconclusive.

This study attempted to examine the cost-effectiveness of the intervention in six RCTs. The mixture of results for the four trials of DBT, plus the high levels of uncertainty and the limitations of the analyses, do not support the cost-effectiveness of DBT, although they suggest that it could have the potential to be cost-effective. The results for MBT are promising, although again surrounded by a high degree of uncertainty, and for MACT, the analysis suggests that the intervention is unlikely to be cost-effective. There is a need for considerable research in this area.

## Recommendations for research

The results from existing studies in this field have produced a body of evidence that has been largely inconclusive. BPD is an important condition with a number of resource-intensive therapies available and it should be a priority area for future research. Suggestions for further research in terms of pragmatic trials and studies to inform economic evaluation are presented below.

### Pragmatic controlled trials

Appropriately powered head-to-head RCTs of psychological therapies are needed. The key features of these trials include:

- Where possible, a trial should have more than one psychological therapy being compared.
- Studies must be designed with adequate statistical power taking into account expected dropouts.
- Patients from a variety of ethnic and socio-economic backgrounds must be included, with an age and gender mix comparable to those receiving treatment on the NHS.
- The level of severity and dysfunction must be well defined.
- The definition of 'dropout' must be standardised and reduced where possible in the RCTs examining psychological therapies for BPD. Where patients drop out of therapy considerable effort must still be undertaken to collect data on them.
- The different therapies need to be properly described, including a TAU arm (e.g. medication must be taken into account).

- The longest follow-up has been for 18 months, and 6 months was more common. Given the high cost of the interventions, longer term follow-ups should be undertaken.
- Data should be collected on outcomes, including recognised generic measures of health-related quality of life, including preference-based measures to permit comparisons across programmes (see below).
- Data should be collected on resource-use services (see below).
- Research teams should include independent researchers.

## Studies to inform future economic analyses

- A survey of current practice and the use of the full range of services (including number of sessions attended and type of therapist) by people with BPD is needed to inform future economic analyses.
- Full resource-use data must be collected in the context of pragmatic clinical trials.
- A psychometric assessment is needed of the validity of the EQ-5D and other generic preference-based measures in BPD.
- If the generic measures are found wanting, then a more condition-specific preference-based measure that captures the impact of BPD on people's lives should be developed.
- A more formal cost-effectiveness model needs to be developed using the above data.

# Chapter 1

## Aim of the review

Borderline personality disorder (BPD) is a severe and complex mental disorder characterised by pervasive instability in moods, interpersonal relationships, self-image and behaviour. There are several psychological therapies, including dialectical behaviour therapy (DBT), and there is an emerging evidence base on their efficacy. The aim of this project is to summarise the available evidence on the effectiveness and cost-effectiveness of psychological therapies including DBT for BPD.

More specifically, the review aims to:

- evaluate clinical effectiveness in terms of reductions in self-harm and suicide
- evaluate effectiveness in terms of improved psychological functioning (e.g. in terms of dissociation or mood)
- evaluate effectiveness in terms of interpersonal and social functioning
- evaluate effectiveness in terms of quality of life
- evaluate effectiveness in terms of presentation to mental health and other services including accident and emergency (A&E) attendance and psychiatric hospital admission)
- evaluate cost-effectiveness of the therapies compared with treatment as usual (TAU)
- estimate the possible overall cost in England and Wales.
- identify the important areas of ignorance or uncertainty.

In undertaking to achieve the above aims the review will consider factors such as the setting and process of therapy, including the professional background of therapists involved, impact on the use of other services, co-morbidity, and co-medication and patient characteristics including chronicity and severity of the condition. Therapies will be compared against any control or comparator.

# Chapter 2
# Background

## Description of underlying health problem

BPD, one of nine or ten personality disorder diagnoses [according to International Classification of Disease-10 (ICD-10) or Diagnostic and Statistical Manual of Mental Disorders IV (DSM-IV)], is characterised by instability of self-image, interpersonal relationships and mood. The person has an uncertain sense of identity, feelings of inner emptiness and often a fear of being alone. Interpersonal relationships tend to be intense but stormy, and there may be an intense fear of abandonment and strenuous efforts to avoid abandonment, real or imagined. The person has difficulty regulating their emotions, with extreme and sudden shifts of mood to intense depression or anxiety, often lasting for a few hours. The individual may be prone to respond to some situations with intense anger, or with impulsive, often self-harming, behaviour. Under stress, the person may dissociate or become paranoid. Self-harm can include attempted suicide, overdosing or self-mutilation (e.g. through cutting or burning).

### Epidemiology

The classification of personality disorders remains controversial and the borderline diagnosis in particular has been criticised on scientific grounds.[1] There are high levels of co-morbidity between different personality disorder diagnoses and difficulties in reliable assessment, factors that should be taken into account when considering epidemiological estimates.

Prevalence data for the UK are available from the Office for National Statistics (ONS) 2000 survey of psychiatric morbidity in private households. This survey suggests that the prevalence of borderline disorder was 7 per 1000, which indicates that for a primary care trust serving a population of 175,000 there would be 1250 individuals meeting the criteria for BPD.

The ONS survey can be compared with international estimates of prevalence. These suggest a greater prevalence of BPD in women, but the ONS survey found lower rates for women (4 per 1000 women compared with 10 per 1000 men). This discrepancy may reflect differences in sampling and instrumentation, and it is possible that the excess prevalence in women has been overestimated in some studies. An implication for research is that findings from intervention studies with all-women samples may not generalise to the full population.

The overall prevalence in the UK study is at the lower end of the range of 0.7–4.6% reported in other studies.[2–7]

### Aetiology

The cause of BPD is complex, with adverse experiences in childhood, such as neglect and abuse, including sexual abuse,[8–11] interacting with a genetic predisposition for emotional dysregulation.[12,13]

### Prognosis

Early studies suggested that over 5-year follow-up, symptomatic patterns change little,[14–16] but that by middle age, many people will no longer meet BPD criteria, mainly through a reduction in impulsivity, self-harm and aggression, although other borderline features, such as inner emptiness and affective instability, may continue.[17–19]

More recent studies suggest that this may be too negative a picture, with 75–80% losing the diagnosis over 4–10 years of follow-up.[20–22] There has been replication of the finding that the change is in the behavioural and reactive criteria such as self-harm, rather than in negative affectivity and anger.[23]

### Significance in terms of ill-health

BPD represents a significant burden of ill-health, with reduced levels of functioning, difficulty maintaining relationships, difficulty maintaining employment, high levels of service use, including attendance at A&E departments and admission to psychiatric hospitals, and rates of suicide more than 50 times higher than in the general population.[13,21,24,25]

## Description of new intervention

### Identification of patients and subgroups

There are wide variations in presentation and in severity. In the DSM-IV system, the criterion for a

diagnosis of BPD is five of the following nine presenting symptoms:

- inappropriate intense anger or difficulty controlling anger
- chronic feelings of emptiness
- affective instability
- transient stress-related paranoid ideation or severe dissociative symptoms
- identity disturbance: striking and persistent unstable self-image or sense of self
- recurrent suicidal behaviour, gestures or threats; or self-mutilating behaviour
- impulsivity in at least two areas that are self-damaging that do not include suicidal or self-mutilating behaviour
- frantic efforts to avoid real or imagined abandonment
- a pattern of unstable and intense interpersonal relationships characterised by alternating between extremes of idealisation and devaluation.

This means that two individuals may meet criteria for the disorder with only one of five symptoms in common. The implications of this for research are important, as some treatments [e.g. DBT, manual-assisted cognitive behavioural therapy (MACT)] were primarily developed for deliberate self-harm (DSH), which although commonly found, is neither a necessary nor a sufficient criterion for the diagnosis of BPD. In addition, the wide range of possible presentations means that interventions for BPD are complex, which generates problems in designing research and interpreting findings.

## Criteria for treatment

In addition to meeting criteria as above, all psychological therapies rely on a minimum willingness to attend regular sessions and form a working relationship with the therapist. For people who have severely problematic drug or alcohol dependence, coexisting psychotic symptoms, severe and intense suicidal behaviour or intellectual impairment, this may not be possible.

## Intervention

Psychological therapies for BPD have many factors in common, such as a high level of structure, consistency, theoretical coherence, and taking account of the relationship problems (including the difficulty in engaging positively with the therapist), and taking a flexible and individualised approach to care. Within these general principles, a number of specific therapies has been applied to, and developed for use with, patients with BPD.

Psychodynamic therapies used with BPD include transference-focused therapy (TFT[26]) and mentalisation-based therapy.[27] Cognitive and behavioural approaches include DBT,[28] schema-focused therapy,[29] and MACT[30] [an adapted form of cognitive behavioural therapy CBT)].[31] Integrative (relational) approaches include cognitive analytic therapy[32] and interpersonal reconstructive therapy (IRT). Evidence from randomised trials has not yet been published for all of these modalities, and the interventions described here are those for which trial data are reported, namely DBT, MACT and mentalisation-based partial hospitalisation (MBT).

### *DBT*

DBT[33] was developed for women who self-harm. Five stages of treatment are outlined, but most literature and all research focuses on stage 1, which aims to help the patient to develop motivation to stay in treatment and achieve behavioural control over urges to self-harm. Weekly individual therapy and a weekly psychoeducational and skills training group are offered concurrently over 1 year. The aim is to achieve behavioural control, stability and connection with the care provider. Patients move to the second stage (emotional experience and reprocessing of past trauma) when behavioural control has been achieved. The key principles of treatment include moving flexibly between acceptance and validation and behavioural change strategies; this includes behavioural analysis, solution analysis and strategies, skills training, contingency management, exposure, cognitive modification and psychoeducation. The DBT package also includes weekly supervision and consultation meetings for the therapists, who work as a team, and telephone consultation, where therapists are available to patients outside office hours for coaching.

### *MACT*

MACT therapy[30] was developed as a public health intervention for the large numbers of people who repeatedly attempt suicide (parasuicide) rather than for BPD per se. However, a high proportion of people in this population meet criteria for BPD, and this subpopulation is therefore similar to that for which DBT was developed. The intervention is a brief, cognitively orientated and problem-focused therapy comprising up to five sessions within 3 months of an episode of self-harm, with the option of a further two booster sessions within 6 months. Bibliotherapy, in the form of a 70-page booklet, is used to structure the treatment sessions and to act as an *aide-mémoire* between sessions. The manual covers an evaluation of the self-harm

attempt, crisis skills, problem solving, basic cognitive techniques to manage emotions and negative thinking, and relapse prevention strategies.

### *MBT*

MBT[27] also termed psychoanalytically orientated partial hospitalisation, is based on an understanding of BPD as a disorder of the self resulting from a failure in mentalisation, with intervention aimed at increasing the self-reflective capacity of the patient. Treatment is in the context of a day hospital and comprises many elements, including weekly individual therapy, thrice-weekly group analytical therapy, weekly expressive therapy with psychodrama and a weekly community meeting, for a maximum of 18 months.

## Personnel involved

These treatments are delivered by mental health practitioners specifically trained in the methods described. The practitioners may have a qualification in psychiatry, mental health nursing, clinical psychology or other mental health profession (e.g. occupational therapy, mental health social work). Training routes vary, but after the core professional qualification, usually involve a 1- or 2-year part-time course followed by supervised practice.

# Current evidence

Twelve systematic reviews reporting at least some information regarding BPD, personality disorder, DSH and suicide attempters as populations and psychological treatments as interventions were identified (*Table 1*). They were aimed either at broad strategies such as dissemination of guidelines[34–37] or at particular target groups and problem areas related to personality disorders.[38–45] Most primary studies were included in more than one review. There was a lack of common approach accepted between the reviews and the inclusion and exclusion criteria varied considerably. Interventions were classified differently in different systematic reviews. The characterisation of BPD was also complicated. Because the BPD is a subcategory of personality disorder with DSH/suicide attempts as a main feature, the reviews on personality disorders and DSH often include borderline patients and there are very few reviews conducting BPD subgroup analyses or reviews on BPD on its own.

No systematic reviews published before 1997 were identified. Four reviews conducted meta-analyses of the results of the studies identified.[36,38,39,40] Because of the broad inclusion criteria and heterogeneity of the studies included in the reviews the appropriateness of meta-analyses is uncertain. *Table 1* presents the overlap in information of identified systematic reviews. Among the reviews only one high-quality systematic review[38] was designed to look at studies on BPD. This review was completed by the Cochrane Collaboration on behalf of the NHS National R&D Programme on Forensic Mental Health, UK. The authors were contacted and gave their permission for the review to be used in this report before its official publication. The reviewers searched large number of electronic databases supplemented by citation tracking of included articles and keywords. Only published data were included in this review.

To assess the effectiveness the authors limited the type of study to randomised controlled trials (RCTs). The quality of studies was assessed according to the Cochrane Collaboration Handbook[46] and only trials in category A and B were included. The outcomes were data from assessment scales such as global state, behaviour and mental state. The engagement with services, satisfaction with treatment, acceptance of treatment and quality of life were also assessed. Meta-analyses were performed on relevant outcomes using a random effects model. The authors described in detail the methods of testing heterogeneity and sensitivity analyses. Although a wide range of psychological therapies is used to treat BPD, many were omitted from the review owing to a lack of RCT evidence.

The review by Adams and colleagues[38] suggests that some problems of BPD patients may be treated by behavioural therapies. However, the authors note that all reviewed therapies are currently at the experimental stage and the number and size of the trials are too small to come to clear conclusions.

The scope of Adams' review[38] overlapped with the current review in all aspects of inclusion criteria. Trials identified by Adams and colleagues[38] are also included in the current review and described in the section 'Results' (p. 8). The populations, interventions and outcomes of the Adams review[38] were compared with the scope of the present HTA review to assess the degree of overlap and identify areas not covered. The current review differs in that non-RCT evidence is also included.

***TABLE 1*** *Summary of systematic reviews of BPD*

| Study | Type of evidence | | Condition | | | Psychological therapy intervention | BPD reported | Main outcome |
|---|---|---|---|---|---|---|---|---|
| | RCT | Non-RCT | PD | DSH | BPD | | | |
| Binks *et al.*, 2005 (NHS National R&D Programme on Forensic Mental Health)[38] | Yes | – | – | – | Yes | Yes | Yes | Improvement of symptoms<br>Suicide and repetition of DSH<br>Treatment retention<br>Treatment duration |
| Bateman and Fonagy, 2000[45] | Yes | Yes | Yes | | | Yes | Yes | Effectiveness of the treatment |
| Boyce *et al.*, 2003, (Australian and New Zealand clinical practice guideline)[34] | Yes | Yes | – | Yes | – | Yes | Yes | Improvement of symptoms<br>Suicide and repetition of DSH |
| Cornah *et al.*, 1997 (NHS R&D Directorate Report)[37] | – | Yes | – | – | Yes | Therapeutic community | Yes | Improvement of symptoms<br>Effectiveness of therapeutic community |
| Hawton *et al.*, 1998[39] | Yes | – | – | Yes | – | Yes | Yes | Improvement of symptoms<br>Suicide and repetition of DSH |
| Lees *et al.*, 1999 (NHS, CRD Report)[36] | Yes | Yes | Yes | – | – | Therapeutic community | Yes | Improvement of symptoms<br>Effectiveness of therapeutic community |
| Leichsenring, 2002[42] | Yes | Yes | Yes | – | – | Psychodynamic therapy | Yes | Effectiveness of psychodynamic therapy |
| Perry *et al.*, 1999[41] | Yes | Yes | Yes | – | – | Yes | Yes | Improvement of symptoms<br>Treatment retention<br>Treatment duration |
| Sanislow and McGlashan, 1998[43] | – | Yes | Yes | – | – | Yes | Yes | Effectiveness of the treatment |
| Van der Sande *et al.*, 1997[40] | Yes | – | – | Yes | – | Yes | Yes | Suicide and repetition of DSH<br>Effectiveness of therapy |
| Warren *et al.*, 2003 (Home Office Report)[35] | Yes | Yes | Yes | – | – | Yes | Yes | Improvement of symptoms<br>Suicide and repetition of DSH<br>Treatment retention<br>Treatment duration |
| Woods and Richards, 2003[44] | Yes | Yes | Yes | – | – | Nursing | Yes | Effectiveness of nursing interventions |

CRD, Centre for Reviews and Discrimination; PD, personality disorder.

# Chapter 3

# Effectiveness

## Methods for reviewing effectiveness

### Identification of studies

#### *Aim of the search strategy*

One set of searches was undertaken to inform the review of clinical effectiveness. The aim of these searches was to identify all studies relating to psychological therapies for BPD. A second set of searches was undertaken to inform the two economic aspects of the assessment. The scope of these searches was broader, to satisfy the inclusion criteria of the cost-effectiveness review and to inform the broader requirements of the economic assessment. The aim of these searches therefore was to identify all economic studies relating to BPD (i.e. not restricted by intervention).

#### *Sources searched*

Twenty electronic bibliographic databases were searched, providing coverage of the biomedical, health-related, science, social science and grey literature (including theses and conference abstracts). The publications lists and current research registers of health services research, social care and mental health organisations were consulted via the World Wide Web. Keyword searching of the World Wide Web was undertaken using the Google search engine. The reference lists of included studies and relevant review articles were also handsearched. A list of the sources searched is provided in Appendix 1.

#### *Search terms*

Sensitive keyword strategies using free-text and, where available, thesaurus terms were developed to search the electronic databases. The selection of keywords was informed by DSM-III, DSM-IV, ICD-10 and clinical members of the assessment team. For the review of clinical effectiveness synonyms relating to the intervention (e.g. psychological therapies, dialectical behaviour therapy) were combined with synonyms relating to the population (e.g. borderline personality disorder, Axis II, Cluster B). For the economic searches synonyms relating to the population only were used. Keyword strategies for all electronic databases are provided in Appendix 2.

#### *Search restrictions*

The clinical effectiveness searches were not restricted by terms relating to study design. The economic searches were restricted by terms relating to cost and economics. The search of PubMed was restricted to the last 180 days to capture recent and unindexed MEDLINE records. Date limits were not used on any other database. Language restrictions were not used on any database. Searches were undertaken in March 2005.

### Inclusion and exclusion criteria

Eligibility for this review was determined by the following criteria:

- **participants:** adults with BPD (diagnosed according to DSM-III/DSM-III-R, DSM-IV or ICD-10 criteria for BPD), with or without co-morbidity; studies on people with any personality disorder and DSH were also included, where subgroup analysis of BPD was available
- **intervention:** psychological therapies, including DBT
- **comparators:** any psychiatric or psychological treatment, or no treatment
- **outcomes:** self-harm, suicide, interpersonal and social functioning, crisis presentations to mental health services, quality of life, patient preference, satisfaction, acceptability of treatment and cost
- **study type:** published papers were assessed according to the accepted hierarchy of evidence, whereby systematic reviews of RCTs are taken to be the most authoritative forms of evidence, with uncontrolled observational studies the least authoritative
- **exclusion criteria:** papers on personality disorder and DSH without separate BPD subgroup analyses.

*Figure 1* shows a summary of study selection and exclusion.

### Quality assessment strategy

Systematic reviews were assessed according to the Users' guides to evidence-based practice.[47] The quality of RCTs was assessed using the Critical Appraisal Skills Programme (CASP) checklist for appraising RCTs (http://www.phru.nhs.uk/casp/rcts.htm). The ten questions in CASP tool are

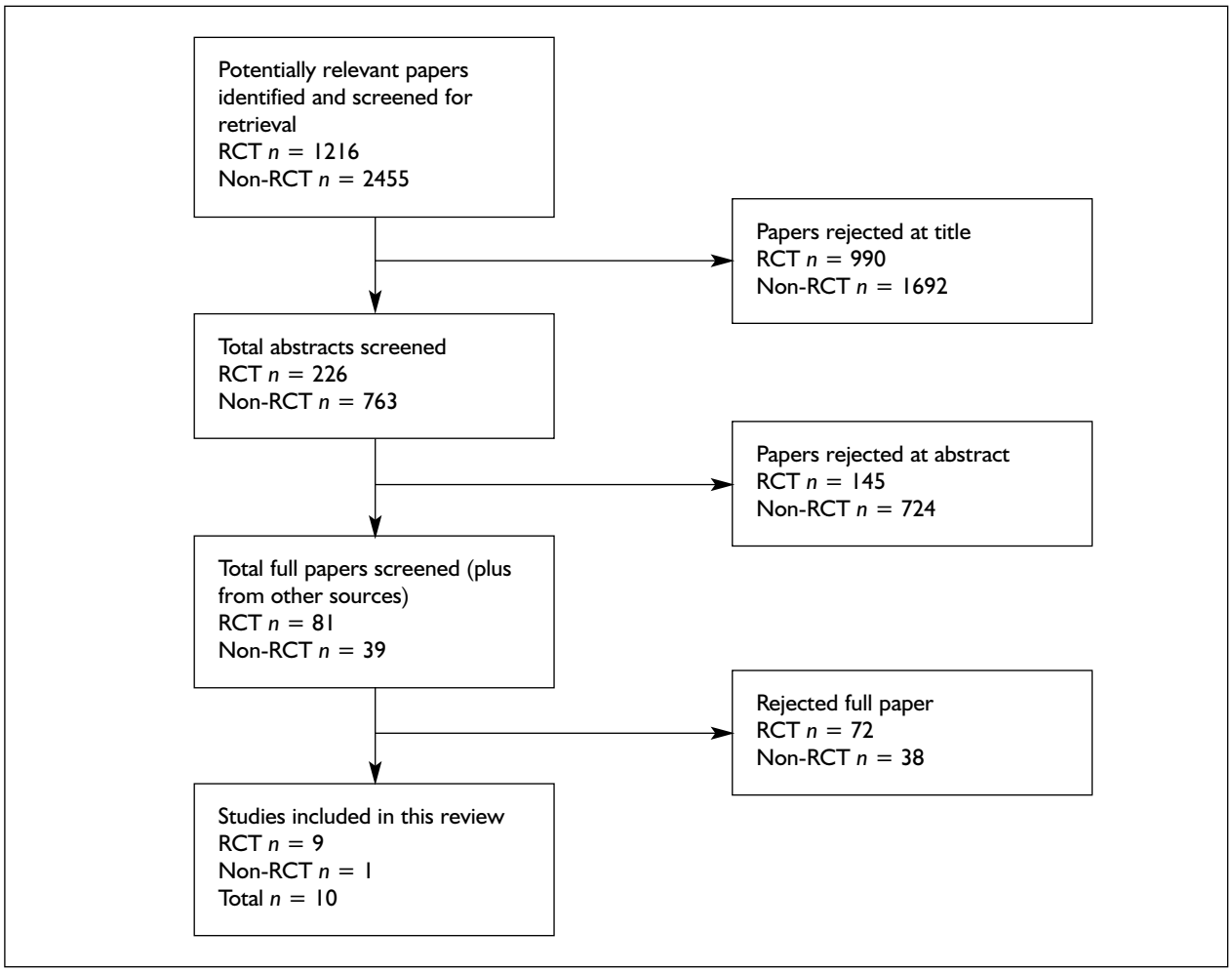


***FIGURE 1*** *Summary of study selection and exclusion*

adapted from the users' guides to the medical literature.[48,49]

The non-randomised study using quantitative data was assessed with respect to validity using the CASP checklist for cohort studies (http://www.phru.nhs.uk/casp/cohort_studies.htm). It contains 12 questions for assessing the types of study in terms of their validity, results and applicability. The quality of the economic literature was assessed according to the Guidelines for authors and peer reviewers of economic submissions to the BMJ.[50]

Key components of quality assessment are listed in Appendix 3 (*Tables 18* and *19*).

## Data extraction strategy

Data were extracted by one researcher and checked by another using the Reference Manager database. Any disagreements were resolved by discussion. The authors aimed to cover as many as possible types of psychotherapy and find the best available evidence on each treatment. Where there were no RCTs available on a certain type of intervention, lower level (comparative) studies were considered.

## Data synthesis

The suitability of pooling data across studies was assessed by examining study populations, comparators, outcomes and study type. Studies were found to be too heterogeneous in these respects for meta-analysis to be appropriate, and it was not undertaken. The results are therefore presented in tabulated format with narrative synthesis of the results.

# Results

## Quantity and quality of research available

Ten trials were identified, of which nine were RCTs and one was a non-randomised trial. *Table 2*

***TABLE 2*** *Studies included in the review*

| Study | Sample size | Intervention | Comparator | Population | Primary outcome |
|---|---|---|---|---|---|
| **RCTs** | | | | | |
| Bateman and Fonagy, 1999[51a] | 38 | PH | TAU | Patients with severe parasuicidal BPD | Effectiveness of psychoanalytically orientated PH for the BPD symptoms |
| Koons *et al.*, 2001[57] | 20 | DBT | TAU | Women Veterans with BPD | Effectiveness of DBT for the treatment of BPD |
| Linehan *et al.*, 1991[53a] | 44 | DBT | TAU | Chronically parasuicidal women with BPD | Effectiveness of DBT for the treatment of BPD women with BPD |
| Linehan *et al.*, 1999[54] | 28 | DBT | TAU | Substance abusing women with BPD | Effectiveness of DBT for the treatment of drug-dependent women with BPD |
| Linehan *et al.*, 2002[55] | 23 | DBT | CVT+12S | Heroin-dependent women with BPD | Effectiveness of DBT for the treatment of heroin-dependent women with BPD |
| Munroe-Blum and Marziali, 1995[56] | 48 | Time –limited (psychodynamic) IGP | Individual psychotherapy | Patients with BPD | Effectiveness of IGP for the treatment of BPD |
| Turner, 2000[57] | 24 | DBT-orientated therapy | CCT | Patients with BPD | Effectiveness of a DBT-orientated therapy for BPD |
| Tyrer *et al.*, 2003[58a] | 480 (PD $n = 391$ BPD $n = 67$) | MACT | TAU | Patients with recurrent DSH (including BPD) | Effectiveness of MACT in reduction of depressive symptoms and the rate of parasuicide events |
| van den Bosch *et al.*, 2002[59a] | 34 | DBT | TAU | Female borderline patients with or without co-morbid substance abuse | Effectiveness of the DBT for the BPD and substance use problems |
| **Non-RCT** | | | | | |
| Wilberg *et al.*, 1998[60] | 43 | Day hospital treatment (TAU) plus post-discharge group analytical therapy | Day hospital treatment (TAU) | Patients with BPD | Effectiveness of the day treatment with subsequent outpatient group therapy for the BPD |

[a] The follow-up and other relevant studies were assessed as part of the main studies, and only the main paper is cited in the current report. All other relevant references can be found from the reference list. Linehan *et al*. (1993)[61] was the 12-month post-treatment follow-up report of Linehan *et al.*, (1991)[53] and Bateman and Fonagy (2001)[62] was the 18-month post-treatment follow-up report of Bateman and Fonagy (1999).[51] Tyrer *et al.* (2004)[63] was part of Tyrer *et al*. (2003)[58] and Verheul *et al*. (2003)[64] was included as part of van den Bosch *et al.* (2003).[59]

CVT+12S, comprehensive variation therapy with 12-Step; IGP, interpersonal group psychotherapy; PH, partial hospitalisation.

summarises the studies included in this review. (Excluded studies are listed in Appendix 4.)

Appendix 3 contains the evidence tables with data extracted from the ten studies included in this report. RCTs and non-randomised trials are presented in separate tables.

### *Study characteristics*

Study characteristics for the ten studies are described in Appendix 3 (*Tables 18* and *19*).

### Description of psychotherapies

*RCTs* The studies report problem-focused psychotherapies administered in the outpatient

***TABLE 3*** *Study qualities assessed using the CASP checklist*

| Study | Description of randomisation method | Blinded assessment | Power calculation | Reason for loss to follow-up | ITT |
|---|---|---|---|---|---|
| Bateman and Fonagy, 1999[51] | N | NR | N | N | N |
| Koons *et al.*, 2001[52] | N | NR | Y | Y | N |
| Linehan *et al.*, 1991[53] | Y | Blinded independent assessor | N | Y | N |
| Linehan *et al.*, 1999[54] | Y | Blinded independent assessor | N | N | Y |
| Linehan *et al.*, 2002[55] | Y | Blinded independent assessor | N | N | Y |
| Munroe-Blum and Marziali, 1995[56] | Y | NR | Y | N | N |
| Turner, 2000[57] | N | Blinded independent assessor | N | N | Y |
| Tyrer *et al.*, 2003[58] | Y | NR | Y | Y | Y |
| van den Bosch *et al.*, 2002[59] | Y | Independent assessor[a] | N | Y | Y |

[a] Independent assessors were not informed about the treatment condition of the interviewees; however, patients might have given the information about treatment.
N, no; NR, not reported; Y, yes.

setting using various methods. Five RCTs, by Linehan,[53–55] Koons[52] and van den Bosch and colleagues,[59] assessed the effectiveness of DBT, the therapy that balances problem-orientated techniques with supportive techniques such as reflection, empathy and acceptance of patient's inherent ability. One RCT[57] used a form of integrative therapy based on DBT, where psychodynamic techniques were incorporated to conceptualise patients' behavioural, emotional and cognitive relationship schema and the skills groups were omitted. Instead, group sessions in both the treatment and control groups emphasised interpersonal relationships. One trial[51] used the psychoanalytically orientated partial hospitalisation method, where the partially hospitalised group received a combination of individual and group MBT along with community meetings. One trial[56] looked at the time-limited group therapy approach, which addresses the interpersonal problems and focuses on observing and processing the meaning of within-therapy enactment of interpersonal communication and behaviour, among patients and between patients and co-therapists. One RCT[58] on DSH used MACT, where patients were given a booklet covering problem solving, basic cognitive techniques to manage emotions, negative thinking and relapse prevention strategies.

*Non-RCT* The study by Wilberg and colleagues[60] used day hospital treatment followed by postdischarge, group analytical therapy.

**Study quality**

*RCTs* The quality of RCTs was assessed using the CASP checklist for appraising RCTs (http://www.phru.nhs.uk/casp/rcts.htm), which covers five main categories: randomisation method (description of the randomisation method), blinded assessment, power calculation, reason for loss for follow-up and intention-to-treat (ITT) analysis (*Table 3*).

Because people with BPD have difficulty forming and sustaining collaborative interpersonal relationships, psychological therapy is often difficult to deliver. A high dropout rate, failure to meet power calculation estimates and impossibility of blinding are typical for the studies examining psychological interventions, and assessment of their quality with the standard criteria seems inadequate. Therefore, the authors used an additional modified Lackner's checklist based on the Cochrane Collaboration Depression and Anxiety Neurosis Review Group (CCDAN) scale, which covers a wider area of design issues specifically for psychological studies.

Lackner and colleagues[65] adapted the CCDAN 23-item coding scheme (CCDAN criteria are on www.iop.kcol.ac.uk/IoP/ccdan/index.htm) specifically to rate the methodological quality of psychological treatment trials. They incorporated six additional items into the measure, so that the final 29-item coding scheme reflected both

general, evidence-based medicine guidelines for rating the quality of clinical trials (e.g. post-treatment follow-up for all groups, declared allegiance or therapy, avoidance or equality of co-interventions) and recommendations.

Appendix 3 (*Tables 18* and *19*) and Appendix 5 show quality scores for each of the trials. All trials were described as randomised with treatment lasting from 6 months[52] to over 18 months,[51] and all trials except for Turner[57] and Munroe-Blum and Marziali[56] gave a description of the randomisation method. No studies were double blind. It is impossible to blind patients and therapists in psychological treatments as both are aware that therapy is taking place. Therefore, assessments were conducted by independent assessors who were not aware of patients/treatment conditions. Only three trials[52,56,58] reported that they did a power calculation; however, the sample sizes were too small in most of them to detect the true effect of the treatment. All reported the number of withdrawals, but only five trials reported the reasons for dropouts.[52–54,58,59] Dropout rates were high, up to one-third of the total sample, often with no apparent reason, with patients starting to dropout immediately after randomisation and pretreatment assessment and throughout the active treatment period and post-treatment follow-up. ITT analysis is a strategy for the analysis of RCTs that compares participants in the groups to which they were originally assigned including all patients regardless of whether they received the treatment or withdrew from the trial. Clinical effectiveness may be overestimated if an ITT analysis is not done.[66] Three trials[51–53] reported data only for completers and assumed that patients who left the trial had poor outcomes. The rest of the studies reported the use of an ITT analysis. Most studies had a follow-up period of at least 4 months, except for three trials.[52,57,58] Two trials[56,58] had more than 50 participants in each arm. Most participants were women. Most of the trials gave full demographic details. All trials clearly reported details of the inclusion/exclusion criteria, diagnostic criteria and therapy conditions. However, important aspects such as allocation concealment, therapy credibility and expectancy were omitted in all studies. No trial gave details on side-effects. All described outcome measures clearly and/or used validated instruments, and gave sufficient information on comparability of groups. The presentation of results was inadequate for later data synthesis in two trials.[56,58] All trials were considered to have 'mainly appropriate' statistics, with some exceptions, such as the inappropriate use of one-tailed tests. Conclusions were partially justified and all but two[51,57] acknowledged support and/or funding sources.

*Non-RCT* The Wilberg study[60] was a comparative study with an active treatment period lasting for up to 1 year and had over 50 participants in each arm. The study[60] reported some information on socio-economic background, but unclear information regarding participants' gender. The study had a small sample size, different baseline comparability between two groups and retrospective assessment of diagnoses and some measurements [i.e. Health Sickness Racing Scale (HSRS)], which may lead to a serious bias in measuring outcomes.

**Co-therapy or medication**

*RCTs* The use of co-therapies was described in most of the studies. Participants from the trials conducted by the Linehan group[53–55] aimed to terminate, taper off or replace psychotropic medications. One trial[51] reported that polypharmacy was discouraged, three trials[52,57,59] reported the type of pharmacotherapy used by participants, and two trials[56,58] did not provide any information about co-therapy.

*Non-RCT* Wilberg and colleagues[60] did not report co-therapy administration.

**Comparators**

*RCTs* Six trials had TAU as a comparator, although the TAU was not always clearly described. Koons and colleagues[52] described TAU as 60 minutes of weekly individual therapy. All patients were additionally offered one or more of several supportive and psychoeducational groups. Linehan and colleagues[53] report that patients in the TAU group were given alternative referrals. Nine patients received individual psychotherapy for an average of 34.87 hours. The TAU condition was naturalistic and allowed participation in any type(s) of therapy available in the community. Linehan and colleagues[67] referred TAU patients to alternative substance abuse and mental health counsellors and programmes in the community, or they continued their existing treatment. Van den Bosch and colleagues[59] report that TAU consisted of principal management from the original referral source: addiction treatment centre, psychiatric services with no more than two sessions per month with a psychologist, psychiatrist or social worker. Tyrer and colleagues,[63] report that TAU patients were offered the standard treatment in the area concerned or the continuation of existing treatment. This varied from problem-

solving approaches, through dynamic psychotherapy, GP or voluntary group referral, to short-term counselling.

According to Bateman and Fonagy[51] TAU consists of general psychiatric services with regular psychiatric review, hospitalisation as appropriate with treatment focused on problem solving and outpatient community follow-up. One trial[55] on heroin-dependent women with BPD had CVT+12S as a control therapy. CVT+12S is designed to control for provision of support, validation and general therapeutic acceptance, and other components of treatment not covered by DBT. One trial[57] used client-centred therapy (CCT). CCT is the model of supportive therapy based on Carkhuff's model,[114] which emphasises empathic understanding of the patient's sense of aloneness and provides a supportive attitude on an individual basis. One study[56] used an individual dynamic psychotherapy as a comparator, which is open-ended, individual therapy.

*Non-RCT* The Wilberg[60] study design was TAU plus postdischarge group analytical therapy versus TAU, with TAU being day hospital treatment. Some of the control group participants were untreated postdischarge. Thus, in reported trials members of the control group were not receiving the same care.

**Sample size**

*RCTs* Sample sizes were generally small (less than 50). Only two trials[56,58] included more than 100 patients. Three studies[51,53,57] included from 30 to 60 patients, and four trials[52,54,55,57] had fewer than 30 participants. Although three studies[52,56,58] reported a power calculation being used to determine sample size, only two of these[56,58] reached adequate power.

*Non-RCT* In the Wilberg trial[60] the sample size was small (less than 50 in each arm).

### *Therapy details*

Appendix 3 describes the details of therapy (*Tables 20* and *21*).

**Recruitment**

*RCTs* Most trials recruited patients from psychiatric hospitals or mental health centres, or patients were referred by independent clinicians. The Linehan group[55] also included participants with substance abuse from methadone maintenance clinics and HIV/AIDS prevention organisations treating underserved minority populations. One study[57] recruited participants from emergency services and community health outpatient clinics.

*Non-RCT* In the Wilberg study[60] recruitment was from patients at a day hospital.

**Number and length of sessions**

*RCTs* The number of sessions of DBT ranged from 48 to 56 (weekly for 1 year) according to standard BPD treatment.[53] In one study[52] DBT was administered for 6 months. A maximum of 84 weekly sessions were administered for DBT-orientated therapy.[57] Partial hospitalisation[51] was also administered weekly over an average of 1.45 years. Patients in IGP[56] had 30 sessions (25 weekly sessions, followed by five twice-weekly sessions). The study on DSH[58] reported that patients received six sessions according to six chapters of the manual, but there is no indication of the duration of the sessions.

*Non-RCT* In the Wilberg study[60] the sessions were once a week for 1.5 hours over 1–33 months (mean length of treatment 12 months).

**Therapist contact between sessions and professional background of therapist**

*RCTs* Most studies reported that patients were allowed to make a telephone call[52–55,59] or have a face-to face[57] consultation with therapists in a crisis situation. It was unclear whether there was similar access to therapists for comparator groups. Patients who used MACT were given the first chapter of the manual by the therapist and in the later sessions sought the therapist's help only for specific problems. More details are provided in *Table 4* and Appendix 3 (*Table 20*). There is no information regarding the frequency and duration of the crisis situations and additional between-session consultations did not seem to be included in the therapist time.

*Non-RCT* Therapist time was not reported.

**Therapist's professional background**

*RCTs* The therapist's professional background varied from a psychotherapist with an average of 22 years of experience[57] to experienced graduate psychology students[53] and psychiatric nurses without a formal psychotherapy qualification.[51] All studies report that therapists were trained in the intervention therapies. The details of the therapists are given in Appendix 3 (*Table 20*).

*Non-RCT* In the Wilberg study[60] the majority of therapists (six out of eight) had a background in

***TABLE 4*** *Therapist time*

| Study | Psychological therapy | Control therapy |
|---|---|---|
| **RCTs** | | |
| Bateman and Fonagy, 1999[51] | Individual group session 1 hour per week<br>Thrice-weekly group 1 hour per week<br>Once-a-week expressive therapy 1 hour per week<br>Weekly community meeting 1 hour per week<br>Meeting with case administrator 1 hour per month | NR |
| Koons *et al.*, 2001[52] | 1.5 hours per week | 1 hour individual session per week |
| Linehan *et al.*, 1991[53] | Individual session 1 hour per week<br>Group session 2.5 hours per week | Nine patients received individual psychotherapy for an average of 34.87 hours |
| Linehan *et al.*, 1999[54] | Individual session 1 hour per week<br>Group session 2.5 hours per week<br>plus 15-minute wind-down | NR |
| Linehan *et al.*, 2002[55] | Individual session 40–90 minutes per week<br>Group session 150 minutes per week | Individual CVT+12S 40–90 minutes per week<br>'12-and-12' Narcotics Anonymous group 120 minutes per week |
| Munroe-Blum and Marziali, 1995[56] | 30 sessions<br>25 weekly sessions for 1.5 hours<br>5 biweekly sessions for 1.5 hours | Individual session once or twice per week. Total 210 hours for 30 sessions |
| Turner *et al.*, 2000[57] | NR | NR |
| Tyrer *et al.*, 2003[58] | NR | NR |
| van den Bosch *et al.*, 2002[59] | 2–2.5 hours per week | NR |
| **Non-RCT** | | |
| Wilberg *et al.*, 1998[60] | Once a week for 1.5 hours over a period of 1–33 months (mean 12 months) | NR |

group analytical training. The details of the therapists are given in Appendix 3 (*Table 21*).

### *Study site, follow-up and inclusion/exclusion criteria*

Appendix 3 (*Tables 22* and *23*) describes the study site, follow-up and inclusion/exclusion criteria of all included studies.

#### Study site and setting

*RCTs* Five studies were conducted in the USA,[52–55,57] two in the UK,[51,58] one in Canada,[56] and one in The Netherlands.[59] One of the trials[58] in the UK was a multicentre RCT. In terms of setting, three studies were conducted in university-based research clinics,[53–55] one[59] was based in an addiction treatment centre and five studies took place in outpatient psychiatric units, either a hospital or a psychiatric centre.[51,52,56–58] Patients in one study[51] were partially hospitalised.

*Non-RCT* The Wilberg study[60] took place in Norway and was carried out in a day psychiatric unit of a university hospital.

#### Follow-up

*RCTs* The length of follow-up ranged from 12 months[57,58] up to 36 months[51] (*Table 5*). Three studies[52,57,58] did not follow up the patients after the active treatment period. Although the number of patients lost to follow-up was reported in all trials, the reasons were not always given.[55–57] Where reported, loss to follow-up was mainly caused by patients dropping out before, during or after treatment in both groups. Other reasons included death,[54,48] distance and problems with transportation,[52] refusal of treatment allocation[52] or assessment.[58] The non-acceptance of the treatment and/or dropout rate was relatively high, with an average of one in three patients not completing their treatment.

***TABLE 5*** *Study follow-up*

| Study | Active treatment period (months) | Post-treatment follow-up (months) | Total follow-up (months) |
|---|---|---|---|
| **RCTs** | | | |
| Bateman and Fonagy, 1999[51] | 18 | 18 | 36 |
| Koons *et al.*, 2001[52] | 6 | No | 6 |
| Linehan *et al.*, 1991[53] | 12 | 12 | 24 |
| Linehan *et al.*, 1999[54] | 12 | 4 | 16 |
| Linehan *et al.*, 2002[55] | 12 | 4 | 16 |
| Munroe-Blum and Marziali, 1995[56] | 12 | 12 | 24 |
| Turner, 2000[57] | 12 | No | 12 |
| Tyrer *et al.*, 2003[58] | 12 | No | 12 |
| van den Bosch *et al.*, 2002[59] | 12 | 6 | 18 |
| **Non-RCT** | | | |
| Wilberg *et al.*, 1998[60] | 12 | 34 | 46 |

*Non-RCT* Wilberg and colleagues[60] reported that the follow-up information was available for 92% of the participants, of whom two were dead at follow-up, and the final results are based on 88% of the participants.

**Inclusion and exclusion criteria**

*RCTs* All studies clearly stated the inclusion and exclusion criteria using standardised criteria or scales for BPD. Exclusion criteria were similar in all trials and included schizophrenia, bipolar disorder, and organic mental or physical impairment. A primary diagnosis of alcohol and drug addiction was also an exclusion criterion in some studies.[53,56,58]

*Non-RCT* Wilberg and colleagues[60] used DSM-III/DSM-III-R criteria for BPD as inclusion criteria.

### *Patient characteristics*

Patient characteristics are described in Appendix 3 (*Tables 24* and *25*).

**Diagnosis of disorder**

All studies reported the methods used to diagnose BPD. The most common criteria were:

- DSM-III/DSM-III-R
- DSM-IV
- Structured Clinical Interview for DSM (SCID)-I
- SCID-II
- Personality Disorder Exam (PDE)
- Diagnostic Interview for Borderlines (DIB)
- ICD-10
- European Version of the Addiction Severity Index (EuroASI)
- Personality Diagnostic Questionnaire (PDQ-R).

**Age, gender, ethnicity, background and patient history**

*RCTs* Five studies were done only on women.[52–55,59] The other studies also included considerably more women than men. The age of participants ranged between 16 and 70 years; however, the mean age was not always reported. Six trials[52,54,55,57–59] reported the ethnicity, although some of them reported only the nationality of the participants. At least some information on education and socio-economic background, including level of education, employment, income, marital status and living conditions, was reported in all but one trial.[54]

All studies reported explicitly the history of patients. The common elements in patient history included history of parasuicide, psychiatric hospitalisation and alcohol or drug abuse. Two trials[51,52] reported history of childhood sexual and physical abuse. Three studies[52,54,59] reported that patients had a lifetime history of parasuicide. Four trials[52,53,56,59] reported that patients had a history of therapy or medication for BPD or other psychiatric problems.

Overall, the participants were mainly white, unemployed and single, and had graduated from high school or college. There were, however, some distinct differences between studies. For example, Linehan and colleagues' 1999[54] study included

only women, who were relatively young and wealthy, whereas Bateman and Fonagy's[51] participants included men and women, who were older and mainly unemployed.

*Non-RCT* The information presented in the Wilberg paper[60] was unclear. However, it provided some information on participants' education, marital and occupational background, and data on their clinical history.

**Baseline comparability**

*RCTs* All studies reported that there were no statistically significant differences for important variables between two groups[51,52,55–59] or that participants were matched on age, severity of the symptoms and number of psychiatric hospitalisations.[53,54]

*Non-RCT* Wilberg and colleagues[60] reported that the control group were significantly younger than the treatment group and had spent less time in the day hospital. Participants in the treatment group had also been married less often than those in the control group.

### *Outcomes and results*

Treatment outcome measures and instruments are presented in Appendix 3 (*Tables 26* and *27*).

Outcomes to be reported in this review are:

- clinical effectiveness in terms of improvement in psychological symptoms (parasuicide, suicidal ideation, mood and emotional dysregulation)
- effectiveness in terms of interpersonal and social functioning (impulsive behaviour)
- effectiveness in terms of preference, satisfaction and acceptability of treatment
- effectiveness in terms of quality of life
- cost (see Chapter 4).

**Instruments and measurement periods**

*RCTs* Outcomes were measured by a variety of validated instruments for BPD, depression and anxiety, suicide ideation, treatment history and social functioning, at baseline, during and at the end of treatment. Most studies also reported the results of post-treatment follow-up. The list of the instruments is presented in *Table 6*.

*Non-RCTs* Outcomes were measured by a variety of validated instruments. The list of instruments is presented in *Table 6*.

Descriptions of the most common scales are as follows.

- The *Borderline Syndrome Index* is a 52-item forced choice questionnaire that measures borderline psychopathology associated with borderline states and borderline personality organisation.
- The *Parasuicide History Interview (PHI)* is a semi-structured interview that is used to collect details regarding the time, circumstances, motivations and treatment of each parasuicide event that a participant can recollect.
- The *Beck Depression Inventory (BDI)* is a 21-item self-report scale used to determine depression severity. Items are scored on a 0–3 scale giving a total range of 0–63. Total scores within the 1–9 range indicate minimal depression, 10–18 mild depression, 19–29 moderate and 30–63 severe depression.
- The *Beck Anxiety Inventory (BAI)* is also a 21-item self-report scale. Patients rate symptoms from 0 to 3 according to severity. A score of 0–9 reflects normal levels of anxiety, 10–18 mild to moderate anxiety, 19–29 moderate to severe anxiety and 30–63 severe anxiety.
- The *Beck Hopelessness Scale (BHS)* is a 20-item true/false test that examines three aspects of hopelessness: feelings about the future, loss of motivation and expectations. It is designed for use with people aged from 17 to 80 years, and takes 5–10 minutes to administer.
- The *Beck Scale for Suicide Ideation* is a 21-item scale that assesses any potential suicidal intent and the severity of suicidal ideation.
- The *Borderline Personality Disorder Severity Index (BPDSI)* is a semi-structured interview assessing the frequency and severity of manifestations of BPD during a circumscribed period.
- The *Hamilton Rating Scale for Depression (HAM-D, HRSD)* is designed to be used on patients already diagnosed as suffering from an affective disorder of depressive type. There are 17 variables measured on either a five-point or a three-point rating scale.
- The *Hospital Anxiety and Depression Scale (HADS)* is a self-assessment instrument for measuring depression and anxiety independently. It was developed for use with physically ill patients. It is limited to 14 items and scored on a four-point scale from 0 to 3.
- The *Social Adjustment Scale (SAS)* is a 54-item self-report measure, using a five-point Likert scale. It is a comprehensive scale available for assessing detailed role performance within the family, as a parent and at work. Six major areas of functioning are covered: work (paid or unpaid), social and leisure activities, relationships with extended family, role as marital partner, parental role and role within

***TABLE 6*** *Instruments and scales used as outcome measures*

| Instrument | Abbreviation | Studies |
|---|---|---|
| **RCTs** | | |
| Beck Anxiety Inventory | BAI | Turner, 2000[57] |
| Beck Depression Inventory | BDI | Linehan *et al.*, 1991;[53] Koons *et al.*, 2001;[52] Bateman and Fonagy, 1999;[51] Turner, 2000;[57] Munroe-Blum and Marziali, 1995[56] |
| Beck Hopelessness Scale | | Linehan *et al.*, 1991;[53] Koons *et al.*, 2001[52] |
| Beck Scale for Suicide Ideation | | Linehan *et al.*, 1991;[53] Koons *et al.*, 2001;[52] Turner, 2000[57] |
| Borderline Personality Disorder Severity Index | BPDSI | van den Bosch *et al.*, 2002[59] |
| Brief Psychiatric Rating Scale | BPRS | Turner, 2000[57] |
| Brief Symptom Inventory | BSI | Linehan *et al.*, 2002[55] |
| Client Service Receipt Inventory | CSRI | Tyrer *et al.*, 2003[58] |
| Dissociative Experiences Scale | DES | |
| Global Adjustment Scale | GAS | Linehan *et al.*, 1999;[54] Linehan *et al.*, 2002[55] |
| Global Assessment of Functioning | GAF | Linehan *et al.*, 2002;[55] Tyrer *et al.*, 2003[58] |
| Global Social Adjustment | GSA | Linehan *et al.*, 1999;[54] Linehan *et al.*, 2002[55] |
| Hamilton Anxiety Rating Scale | HARS | Koons *et al.*, 2001[52] |
| Hamilton Depression Rating Scale | HAM-D | Koons *et al.*, 2001;[52] Turner, 2000[57] |
| Hopkins Symptom Checklist | HSC-90 | Munroe-Blum and Marziali, 1995[56] |
| Hospital Anxiety and Depression Scale | HADS | Tyrer *et al*., 2003[58] |
| Inventory of Interpersonal Problems | | Bateman and Fonagy, 1999[51] |
| Lifetime Parasuicide Count | LPC | van den Bosch *et al*., 2002[59] |
| Longitudinal Interview Follow-Up Evaluation Base Schedule | | Linehan *et al.*, 1999;[54] Linehan *et al.*, 2002[55] |
| Objective Behaviours Index | OBI | Munroe-Blum and Marziali, 1995[56] |
| Parasuicide History Interview | PHI | Linehan *et al.*, 1991;[53] Linehan *et al.*, 1999;[54] Linehan *et al.*, 2002;[55] Koons *et al.*, 2001;[52] Tyrer *et al.*, 2003[58] |
| Generic Health Related Qualities of Life (EuroQol 5 Dimensions) | EQ5D | Tyrer *et al.*, 2003[58] |
| Social Adjustment Scale | SAS | Linehan *et al.*, 1999;[54] Linehan *et al.*, 2002;[55] Bateman and Fonagy, 1999;[51] Munroe-Blum and Marziali, 1995[56] |
| Social Functioning Questionnaire | SFQ | Tyrer *et al.*, 2003[58] |
| Social History Interview | SHI | Linehan *et al.*, 1999;[54] Linehan *et al.*, 2002[54] |
| Spielberg State–Trait Anger Expression Inventory | | Linehan *et al.*, 1999;[54] Koons *et al*., 2001[52] |
| Spielberg State–Trait Anxiety Inventory | | Bateman and Fonagy, 1999[51] |
| Structured Clinical Interviews | | Linehan *et al.*, 1999[54] |
| Suicide and Self-Harm Inventory | | Bateman and Fonagy, 1999[51] |
| Survival and Coping Scale | | Linehan, 1991[53] |
| Symptom Checklist | SCL-90-R | Bateman and Fonagy, 1999[51] |
| Target Behaviour Ratings | | Turner, 2000[57] |
| The Reasons for Living Inventory | | Linehan *et al.*, 1991[53] |
| Timeline Follow-Back | TLFB | Linehan *et al.*, 2002[55] |
| Treatment History Interview | THI | Linehan *et al.*, 1999[54] |
| **Non-RCT** | | |
| Health and Sickness Rating Scale | HSRS | Wilberg *et al.*, 1998[60] |
| Global Symptom Index | GSI | Wilberg *et al.*, 1998[60] |

family unit (including perceptions about economic functioning).
- The *Global Assessment of Functioning (GAF)* is a 100-point tool rating overall psychological, social and occupational functioning of people aged 18 years and older. It excludes physical and environmental impairment.
- The *Global Adjustment Scale (GAS)* is a 100-point scale for measuring the overall level of impairment.
- The *Global Social Adjustment (GSA)* is a five-point scale that is more specifically related to social functioning.
- The *Global Symptom Index* is measured using the SCL-90-R.
- The *Symptom Checklist 90–Revised (SCL-90-R)* is a 90-item self-report inventory assessing current levels of mental symptoms patterns. Each item is a description of a mental symptom rated on a five-point scale, and rates the degree of 'distress/discomfort' during the week before its administration.
- The *Ad hoc semi-structured interview for DSM-III criteria for BPD* is a semi-structured interview based on a 27-point scale made up of all the items in each criterion category for BPD in DSM-III.
- The *Health and Sickness Rating Scale (HSRS)* includes a structured diagnostic interview, SCID-I and SCID-II, assessment of employment, social contact, suicide attempts and treatment.

**Results for behaviour (self-harm, alcohol and drug abuse), affect scales (BDI), therapy maintenance and hospitalisation outcomes**

The results for improvement in psychological symptoms and interpersonal and social functioning outcomes are presented in Appendix 3, (*Tables 28* and *29*). The results for the included studies are described below by comparator.

*RCTs* Of the included nine RCTs seven were of CBT: five of them were DBT,[52–55,59] one was DBT orientated[57] and one was MACT.[58] The comparators were TAU,[52–54,58,59] CVT+12S,[55] and CCT.[57] One study[51] compared psychoanalytically orientated partial hospitalisation therapy with individual therapy and one study[56] compared psychodynamic structured IGP with individual therapy (*Table 2*).

**Cognitive behaviour therapy**

*DBT versus TAU* Of the four studies comparing DBT with TAU, three studies[52–54] reported significantly greater improvement of borderline symptoms such as parasuicide and/or suicide attempts and drug abuse. However, one study[59] did not find significant differences between DBT and TAU groups. This may have occurred because three studies[52–54] were targeted to specific populations such as chronic parasuicidal or drug-abusing women, whereas the fourth study[59] was a mixed group of parasuicidal and non-parasuicidal women with severe or less severe disorder. The study by van den Bosch and colleagues[59] was larger and conducted in Europe, in comparison with other smaller studies from the USA. Thus, a different setting[59] and a larger sample size may have influenced the less favourable outcome. All trials reported that maintenance in the DBT group was greater than in the TAU group. Koons and colleagues[52] analysed the data of 20 (ten in each group) out of the original 28 randomised participants. Linehan and colleagues[53] looked at the data on 44 (22 in each group) out of 63 randomised patients. In the second Linehan study,[54] of 28 randomised participants seven in the DBT group and five in the TAU group were lost to follow-up. Van den Bosch and colleagues[59] reported that they lost almost 50% of the study participants during the treatment period (in the DBT group ten out of 27 and in the TAU group 24 out of 34). Three studies[52–54] reported that DBT patients received more therapy hours per week. One study[53] reported that control subjects had significantly more psychiatric days per person hospitalised than patients who were receiving DBT. Two studies[52,54] found no difference between DBT and TAU groups in terms of hospital admission and one study[59] did not report data on therapy contact and hospital admission. The details of these studies are presented below.

**Study: Linehan and colleagues (1991)[53]**

*Sample size:* randomised $n = 63$; analysed as completers $n = 44$ (22 in each group); follow-up parasuicide assessment $n = 39$ (DBT $n = 19$, TAU $n = 20$); all other follow-up assessments $n = 20$ (DBT $n = 9$, TAU $n = 11$).

*Efficacy:* the Linehan study[53] looked at the parasuicide rate of chronically parasuicidal women, and found that the likelihood of any parasuicide (DBT 63.6%, TAU 95.5%; $p < 0.005$) and medical risk scores (DBT mean 9.21, SD 8.22, $n = 14$; TAU mean 17.86, SD 20.94, $n = 21$; $t = 1.70$, df = 28.01, $p < 0.05$) were significantly higher for the TAU group. In the follow-up year the suicide repeat rate ($p < 0.01$)

and the likelihood of psychiatric hospitalisation ($p < 0.07$) were lower in the participants completing DBT.

*Maintenance in therapy:* 83.3% and 42% of patients completed the entire treatment year in the DBT and TAU groups, respectively.

*Therapy contact:* DBT patients had more group ($z = 5.51$, $p < 0.001$) and individual ($z = 2.00$, $p < 0.01$) therapy hours per week, and the control group reported more day treatment hours per week ($z=1.83$, $p < 0.05$). No significant relationship was found between the number of individual and group therapy hours and parasuicidal behaviour, independent of treatment.

*Hospital admission:* TAU participants tended to have more hospital admissions per person (DBT median 0, interquartile range (IQR) 1; TAU median 1, IQR 4, $z = 1.47$, $p < 0.07$). Control subjects also had significantly more psychiatric days per person hospitalised than patients who were receiving DBT. It is unclear whether these hospital admissions were voluntary or involuntary.

**Study: Linehan and colleagues (1999)[54]**
*Sample size:* $n = 28$ (DBT $n = 12$; TAU $n = 16$).

*Efficacy:* the second study by Linehan and colleagues[54] was conducted on borderline drug-dependent women and their primary outcome was reduction of drug abuse. The proportion of drug abstinence was significantly higher for DBT participants during the 4–8-month period and during the 12–16-month period (DBT mean 0.94, SD 0.17; TAU mean 0.58, SD 0.36, $F = 4.04$, $p < 0.05$). However, there were no between group differences on other psychopathology outcome measures (e.g. parasuicide episodes, GSA, GAS or anger). At the 16-month follow-up DBT participants showed better social and global adjustment, with significantly lower (better) scores on the GSA (DBT mean 2.25, SD 0.75; TAU mean 2.92, SD 0.71, $F_{1,12} = 3.98$, $p < 0.05$ for best scores) and higher scores on the GAS (DBT mean 69, SD 12; TAU mean 49, SD 10, $F_{1,12} = 22.24$, $p < 0.001$ for best scores).

*Maintenance in therapy:* 64% in the DBT group and 27% in the TAU group remained in treatment (Fisher's exact test, $p = 0.1$). In DBT, a subject was considered a dropout if 4 consecutive weeks of scheduled individual sessions were missed for any reason. In TAU, a subject was considered a dropout from therapy if the participant either never went to therapy or dropped out of therapy any time following a first session.

*Therapy contact:* DBT participants received significantly more psychological therapy (the hours are not reported) than did TAU participants (DBT mean 43.14, SD 10.67; TAU mean 21.88, SD 32.32; $F_{1,15} = 2.07$, $p < 0.05$). TAU was analysed by summing hours of psychotherapy and sessions spent with a case manager that were provided to TAU participants. This total was then compared with DBT individual psychotherapy sessions.

*Hospital admission:* no between-group differences were found in types and number of medical and inpatient psychiatric treatments received.

**Study: Koons and colleagues (2001)[52]**
*Sample size:* randomised $n = 28$ (DBT $n = 13$, TAU $n = 15$); analysed as completers $n = 20$ (10 in each group).

*Efficacy:* Koons and colleagues[52] found that the proportion of patients who reported any intentional self-harm (including suicide attempt) during the previous 3 months dropped from 50% at pretreatment to 10% post-treatment in DBT, and from 30% to 20% in TAU ($p = 0.07$). The differences between groups at pre-treatment are not reported. Participants in DBT changed significantly more than did patients in TAU with regard to suicidal ideation ($p = 0.008$), hopelessness ($p = 0.004$), Beck Depression ($p = 0.012$) and Spielberg Anger Expression Scale anger out ($p = 0.005$).

*Maintenance in therapy:* 20 out of 28 patients completed the treatment. Three patients in the TAU group dropped out either before treatment or after the first appointment. Three participants in the DBT group and two in the TAU group were lost to follow-up during the treatment period.

*Therapy contact:* DBT patients received more hours of group therapy than did TAU patients (DBT mean 32.1, SD 9.6; TAU mean 11.8, SD 11.2; $t_{18} = 4.35$, $p < 0.001$), while the TAU participants attended more hours of 30-minute medication-management visits (DBT mean 2.7, SD 2.2; TAU mean 7.6, SD 4.2; $t_{18} = 3.27$, $p < 0.01$). There were no differences in individual therapy hours.

*Hospital admission:* the proportion of patients with any admission during the prior 3 months was relatively low at pretreatment. Neither group

showed a significant change in this proportion by the end of treatment (DBT group had 30% of pretreatment hospital admissions and 10% post-treatment admissions; TAU group had 20% of pretreatment admissions, which reduced to 10% after the treatment).

**Study: van den Bosch and colleagues (2002)[59]**
*Sample size:* randomised $n = 58$ (DBT $n = 27$, TAU $n = 31$); analysed as completers and followed up: $n = 34$ (DBT $n = 10$, TAU $n = 24$).

*Efficacy:* van den Bosch and colleagues[59] reported that the frequency and course of suicidal behaviours were not significantly different across treatment conditions: neither treatment condition ($p = 0.866$) nor the interaction between time and treatment condition ($p = 0.639$) reached statistical significance. Fewer patients in DBT (7%) than in the control group (26%) attempted suicide. This difference was not statistically significant ($p = 0.064$) A significant effect was observed for the interaction term-time × treatment condition ($p = 0.003$), but not for treatment condition alone ($p = 0.055$). In terms of self-mutilating impulsive behaviour, participants in the DBT group significantly improved over time (interaction term time × treatment condition), but not for treatment condition alone ($p = 0.315$).

*Maintenance in therapy:* significantly more patients assigned to DBT (63%) were retained in therapy than patients in the control group (23%) for the entire treatment year ($p = 0.002$).

*Therapy contact:* not reported.

*Hospital admission:* not reported.

*DBT versus CVT+12S*
One study compared DBT with CVT+12S.

**Study: Linehan and colleagues (2002)[55]**
*Sample size:* $n = 23$ (DBT $n = 11$, CVT+12S $n = 12$).

*Efficacy:* Linehan and colleagues[55] found that participants in both treatment groups showed significant improvements. BSI (pretreatment mean 1.78, SD 71; post-treatment mean 1.17, SD 0.60; $z = 3.17$, $p < 0.002$) and GAS (pretreatment mean 37.6, SD 5.6; post-treatment mean 47.4, SD 10.7; $z = 3.59$, $p < 0.001$) scores were statistically significant in both groups and maintained at 12 months. At the 16-month follow-up point, BSI scores continued to improve but were not reliably different from the 12-month point (mean 0.98, SD 0.74, $z = 1.76$, $p < 0.08$) in both treatments. No difference appeared between treatment groups on GSA rating. The parasuicidal behaviour during the treatment year was low (17.4% of patients), but did not significantly differ by treatment.

*Maintenance in therapy:* there were three dropouts (36%). in the DBT group. There were no dropouts in the CVT+12S group.

*Therapy contact:* there was no statistical difference in the mean number of individual sessions received across the treatment year between treatments.

*Hospital admission:* the incidence of psychiatric and drug-related visits to emergency rooms and inpatient units was low over the year, but not significantly different between groups.

*DBT-orientated therapy versus CCT*
One study compared DBT-orientated therapy with CCT.

**Study: Turner (2000)[57]**
*Sample size:* $n = 24$ (DBT-oriented therapy $n = 12$, TAU $n = 12$).

*Efficacy:* Turner[57] found that suicide/self-harm behaviour (rate of parasuicide, BSI, number of suicide and self-harm attempts) significantly improved in patients for both treatments ($F_{6,84} = 26.8$, $p = 0.001$, $R^2 = 0.657$, repeated measures multivariate analysis of variance). However, the DBT-orientated therapy patients' gains were greater than those receiving CCT at both 6 months and 12 months ($F_{6,84} = 5.1$, $p = 0.001$, $R^2 = 0.268$). In addition, the rating of parasuicide [95% confidence interval (CI) 0.559 to 2.83], the BSI (95% CI 3.1, 11.3) and the number of suicide/self-harm attempts (95% CI 0.24 to 5.7) favoured DBT at 6 months and 12 months. Both treatments also improved patients' emotional functioning, but patients receiving DBT-orientated therapy had significantly lower scores than those receiving CCT on impulsiveness, anger and depression at 12 months. Global mental health functioning was also statistically significantly improved for both treatments ($p = 0.005$). There were no significant differences between two groups on anxiety.

*Maintenance in therapy:* 15 out of 24 patients were still in treatment at 12 months. Four DBT and six CCT participants withdrew from treatment. Of these patients one participant in the DBT group returned to DBT treatment after a 5-week break.

*Therapy contact:* there were no significant differences between groups regarding the average number of treatment sessions.

*Hospital admission:* number of days of psychiatric hospitalisation was not significant ($p = 0.08$).

*MACT versus TAU*
One study compared MACT with TAU.

**Study: Tyrer and colleagues (2003)[58]**
*Sample size:* randomised $n = 480$ (MACT $n = 239$, TAU $n = 241$). Participants with personality disorder $n = 391$, participants with BPD $n = 67$.

*Efficacy:* the Tyrer study,[58] which was a large trial, found no significant improvement between the groups in terms of parasuicide events. There were no statistically significant treatment effects of MACT according to centre ($p = 0.48$), baseline parasuicide risk score ($p = 0.64$) or personality status ($p = 0.66$). The trial included participants with different types of personality disorder and the severity and type of disorder influenced the repetition of the self-harm. Many patients had more than one personality disorder; however, the authors managed to examine each disorder separately. Of the 67 borderline patients, 44.8% made no parasuicide attempt during the follow-up. Of the 55.2% who had made at least one parasuicide attempt, the 25th percentile time to parasuicide event (in days) was 89 and the frequency of self-harm (rate per year) was 3.15. It was evident that participants with personality disorder, especially BPD, had a greater incidence of repetition of self-harm, compared with participants without a personality disorder; however, there were no differences between treatment conditions.

*Maintenance in therapy:* 40% of patients in MACT were lost to follow-up during the treatment period. The results of the TAU group are not reported.

*Therapy contact:* in many cases the amount of therapeutic time given in TAU exceeded that of MACT considerably.

*Hospital admission:* there was no difference in the proportion of self-harm in the year after randomisation, between MACT and TAU.

**Mentalisation-based partial hospitalisation**
*MBT versus TAU* One study compared MBT with TAU.

**Study: Bateman and Fonagy (1999)[51]**
*Sample size:* randomised $n = 44$ ($n = 22$ in each group); analysed $n = 38$ ($n = 19$ in each group).

*Efficacy:* Bateman and Fonagy[51] found a highly significant reduction in self-mutilating behaviour in the MBT group (Kendall's $W = 0.21$, $\chi^2 = 11.9$, df = 3, $p < 0.008$) compared with the TAU group (Kendall's $W = 0.05$, $\chi^2 = 2.4$, df = 3, $p$ = ns) and the number of participants who were no longer parasuicidal was significantly greater by 18 months in the MBT group than in the control group ($\chi^2 = 7.0$, df = 1, $p < 0.08$). Anxiety scores decreased significantly in the MBT group ($p < 0.005$) while remaining unchanged in the TAU group. Beck depression scores also significantly decreased in the MBT group ($p < 0.0001$). The SAS score was significantly lower in the MBT group (mean = 2.8) than in the TAU group (mean = 3.3, $p < 0.006$).

*Maintenance in therapy:* there was a 12% dropout rate in the MBT group. Three patients in the TAU group crossed over to the MBT group and were not included in the analyses.

*Therapy contact:* patients in the control group received considerably more staff time during follow-up than did patients in the MBT arm.

*Hospital admission:* no patient who completed the MBT programme was admitted to hospital within 6 months after discharge. Within 1 year after the end of the trial one patient from the MBT group and 14 patients from the TAU group had been admitted to hospital.

**Psychodynamic therapy**
*IGP versus individual therapy* One study compared IGP with individual therapy.

**Study: Munroe-Blum and Marziali (1995)[56]**
*Sample size:* randomised $n = 79$ (IGP $n = 38$, individual psychotherapy $n = 41$); analysed $n = 48$ (IGP $n = 22$, individual psychotherapy $n = 26$).

*Efficacy:* Munroe-Blum and Marziali[56] reported no statistically significant differences in outcomes between the two treatment groups. However, both treatment groups experienced significant improvements over time on outcomes such as behaviour, social adjustment, global symptoms and depression from baseline.

*Maintenance in therapy:* 31 participants withdrew from the study at the point of randomisation.

*Therapy contact:* patient–therapist contact time was considerably lower in the IGP group (90 hours) than in the individual group (120 hours).

*Hospital admission:* the use of mental health and social services decreased significantly by the end of 12 months of follow-up ($p < 0.038$) for the total cohort.

*Non-RCT* Appendix 3 (*Table 29*) presents the results of improvements in psychological symptoms and interpersonal and social functioning. The trial reviewed in the current report[56] was day hospital treatment (TAU) plus postdischarge group analytical therapy versus TAU.

*Day hospital treatment (TAU) plus postdischarge group analytical therapy versus day hospital treatment (TAU)*
One non-RCT compared TAU plus postdischarge group analytical therapy with TAU alone.

**Study: Wilberg and colleagues (1998)[60]**
*Sample size:* $n = 43$ (day treatment plus subsequent outpatient group therapy $n = 12$, day treatment only group $n = 31$).

*Efficacy:* Wilberg and colleagues[60] found significantly ($p < 0.05$, two-tailed) higher (better) HSRS scores at discharge and follow-up for the treatment group compared with the control group. They also found a significantly lower (better) GSI score at follow-up for the treatment group compared with control ($p < 0.05$), although not at discharge. Eight per cent ($n = 1$) of participants in the treatment group attempted suicide compared with 18% ($n = 5$) in the control group ($p$ = ns); 75% ($n = 6$) of the participants in the treatment group showed remission from substance use disorder compared with 41% ($n = 7$) in the control group.

*Maintenance in therapy:* two participants died, one from suicide and one from natural causes. Four patients refused to participate in the follow-up. The results were available from the data of 43 patients (88%).

*Therapy contact:* between-group differences were not reported.

*Hospital admission:* one participant (8%) in the treatment group was rehospitalised, compared with 12 participants (43%) in the control group. The difference did not reach significance ($p = 0.06$, Fisher's exact test, two-tailed).

**Patient preference, satisfaction and acceptability**
Information on patient preference, satisfaction and acceptability of treatment is presented in Appendix 3 (*Tables 30* and *31*).

*RCTs* One trial of DBT[53] reported that treatment success did not improve general satisfaction, despite significant improvements in anger reduction and social adjustment.

One DBT study[59] reported that all participants who continued in therapy viewed the programme as helpful and judged the treatment as very important.

*Non-RCT* These aspects were not reported.

**Quality of life**
Only one study[58] comparing MACT with TAU reported utilisation of a specific quality of life scale (EQ-5D). The EQ-5D scores were more favourable at 6 and 12 months than at baseline (for both groups); however, they showed no differences between MACT and TAU (*Table 7*).

## Summary of the assessment of effectiveness

*Table 8* presents a brief summary of the clinical effectiveness results. Ten studies were included in this review, nine of which were RCTs and one was a non-RCT. Active treatments included DBT, MBT, MACT and IGP. Comparators were TAU, CCT, CVT+12S, individual and day hospital therapies.

*RCTs* The results of the included studies are summarised as follows. Three studies[52–54] compared DBT with TAU and one study[57] compared psychodynamically modified DBT with CCT. Three showed significant improvements in the DBT group compared with the TAU and CCT groups. One study[59] found improvement in both DBT and TAU groups; however, DBT was not more efficacious than the TAU group and both groups were equally effective.

Comparison of DBT with another active treatment, CVT+12S,[55] showed that both groups were significantly effective; however, there were no differences between the two therapies. Comparison of MACT with TAU[58] found MACT to be no more effective than TAU. One study[51] found MBT to be more effective than TAU, and one study[56] found IGP to be no more effective than individual therapy.

*Non-RCT* The study by Wilberg and colleagues[60] found day hospital plus postdischarge group analytical therapy to be more effective than day hospital on its own.

***TABLE 7*** *EuroQol scores[a] at 6 and 12 months in MACT and TAU groups (by Tyrer* et al.*, 2003)[58]*

| Baseline | | | 6-month scores | | | Difference (MACT – TAU) | |
|---|---|---|---|---|---|---|---|
| *n* | MACT (SD) | TAU (SD) | *n* | MACT | TAU | Unadjusted (SE) | Adjusted (SE) |
| 476 | 0.5 (0.3) | 0.5 (0.3) | 390 | 0.7 | 0.7 | –0.01 (0.03) | –0.01 (0.03) |
| **Baseline** | | | **12-month scores** | | | **Difference (MACT-TAU)** | |
| *n* | MACT (SD) | TAU (SD) | *n* | MACT | TAU | Unadjusted (SE) | Adjusted (SE) |
| 476 | 0.5 (0.3) | 0.5 (0.3) | 400 | 0.7 | 0.7 | 0.00 (0.03) | 0.00 (0.03) |

[a] Higher scores represent better states

***TABLE 8*** *Summary of clinical effectiveness*

| Study | Study quality | Study size (total analysed) | Intervention | Comparisons | Evidence of clinical effectiveness for BPD symptoms |
|---|---|---|---|---|---|
| **RCTs** | | | | | |
| Bateman and Fonagy, 1999[51] | Moderate to poor | 38 | MBT | TAU | Improvement in both groups, but MBT more effective than TAU |
| Koons *et al.*, 2001[52] | Moderate | 20 | DBT | TAU | Improvement in both groups, but DBT more effective than TAU |
| Linehan *et al.*, 1991[53] | Moderate to poor | 44 | DBT | TAU | Improvement in both groups, but DBT more effective than TAU |
| Linehan *et al.*, 1999[54] | Moderate to poor | 28 | DBT | TAU | Improvement in both groups, but DBT more effective than TAU |
| Linehan *et al.*, 2002[55] | Moderate to poor | 23 | DBT | CVT+12S | Improvement in both groups, but DBT group maintained the efficacy longer than CVT+12S |
| Munroe-Blum and Marziali, 1995[56] | Moderate to poor | 48 | IGP | Individual psychotherapy | Improvement in both groups, but IGP no more effective than individual psychotherapy |
| Turner, 2000[57] | Moderate to poor | 24 | DBT-orientated | CCT | Improvement in both groups, but DBT more effective than CCT |
| Tyrer *et al.*, 2003[58] | Moderate | 480 (PD $n = 391$, BPD $n = 67$) | MACT | TAU | Improvement in both groups, but MACT no more effective than TAU |
| van den Bosch *et al.*, 2002[59] | Moderate | 34 | DBT | TAU | Improvement in both groups, but DBT no more effective than TAU |
| **Non-RCT** | | | | | |
| Wilberg *et al.*, 1998[60] | Poor | 43 | Day hospital treatment (TAU) plus postdischarge group analytical therapy | Day hospital treatment (TAU) | Treatment plus TAU more effective than TAU |

# Chapter 4
# Cost-effectiveness

This chapter is in two parts. The first part is a review of the literature on the cost-effectiveness of psychological therapies for BPD. The second part presents original cost-effectiveness analyses of the psychological therapies based on data collected in the RCTs described in the last chapter. The results are presented in terms of cost per unit of effect, where the unit of effect is determined by the outcomes measured in the trials. The results are presented as a series of incremental cost-effectiveness analyses and the uncertainty is summarised graphically using cost-effectiveness acceptability curves (CEACs).

## Systematic review of existing economic literature

### Search

Studies were identified using the search methods reported in the section 'Identification of studies' (p. 7) and Appendix 2.

Economic evaluations assessing the cost-effectiveness of any psychological therapy for BPD were selected for inclusion. Studies were included if both costs and benefits were reported and either a cost-effectiveness ratio was reported or sufficient detail was reported to enable a cost-effectiveness ratio to be calculated. Studies where BPD subjects were only partially represented were excluded unless a subgroup analysis was performed on the BPD subjects. The references retrieved by the economic searches ($n$ = 1748) and the references tagged as being RCTs from the clinical effectiveness searches ($n$ = 1216) were assessed for inclusion in the review of cost-effectiveness. An initial title sift was carried out by one reviewer and 2458 references were excluded. Two reviewers read abstracts of the remaining 506 references. Although some studies did contain relevant information, only one met the inclusion criteria as being suitable for review.[68]

One other study has been reviewed. The study by Byford and colleagues[69] was an economic evaluation alongside a clinical trial of MACT that collected costs and outcome data, but it was concerned with self-harming patients. Although BPD patients were a subgroup in this study, full economic evaluation was not undertaken for this subgroup and so it should have been excluded from this review. However, an exception has been made for several reasons. First, it was the only cost-effectiveness study identified that was published in a peer-reviewed journal. Secondly, the trial data from this study form an integral part of the cost-effectiveness analyses presented in this chapter. The study is therefore considered of sufficient interest to be included in the review.

### Review

The quality of the studies identified by the search was assessed using the *British Medical Journal* checklist[50] for economic evaluations (Appendix 6).

#### *Cost-effectiveness studies*

**Heard (2000). Cost-effectiveness of dialectical behavior therapy in the treatment of borderline personality disorder[68]**

This dissertation by Heard presents the cost-effectiveness results of two psychotherapy outcome trials involving DBT. The first study is included in the effectiveness review;[53] however, the second study is unpublished. In the first study subjects were randomly assigned to receive 1 year of DBT ($n$ = 22) or to receive TAU in the community ($n$ = 22). Analyses suggested that at the end of 1 year of treatment, subjects receiving DBT had incurred significantly higher psychotherapy costs, lower psychiatric inpatient costs and lower emergency room costs compared with TAU. The two groups did not differ significantly with respect to mean medical costs (DBT US$1161, 95% CI $589 to 1733; TAU $1799, 95% CI $710 to 2888) or total healthcare costs (DBT $9856, 95% CI $7292 to 12,420 (1988 prices); TAU $19,745, 95% CI $11,144 to 28,345). Analyses also revealed important differences in variance between the two conditions, with the TAU arm having significantly greater variance in terms of psychotherapy, inpatient, emergency room and total healthcare costs. The two arms also did not differ in terms of employment or global functioning cost-effectiveness ratios.

In the second study the DBT subjects from the first study were compared with subjects whose existing therapists in the community had agreed to

provide them with 1 year of stable psychotherapy ($n$ = 16). At the end of 1 year of treatment, subjects receiving DBT had incurred significantly lower psychiatric inpatient costs and had a trend towards better global functioning cost-effectiveness ratios. The mean costs and cost-effectiveness ratios did not differ significantly between the two groups on any of the remaining variables. Finally, the TAU again had significantly greater variance in terms of psychotherapy, inpatient and emergency room costs.

*Comment* This was a good-quality study that scored highly on the *BMJ* checklist for economic evaluations. The cost-effectiveness analysis did not support the hypothesis that DBT is a more cost-effective treatment than TAU, though it suffered from small numbers. Another shortcoming of this study is the choice of economic outcome measures. Cost-effectiveness measured in terms of cost per number of weeks worked and cost per one-point improvement in global functioning is not comparable to other disease areas and is of little use to decision-makers. A limitation of the study is the lack of societal cost data and the cost of consultation that therapists receive for working with these patients. Societal costs are relevant for this population and team consultation is strongly emphasised in DBT. Excluding these costs may have given the DBT group an unfair advantage.

**Byford and colleagues (2003). Cost-effectiveness of brief cognitive behaviour therapy versus treatment as usual in recurrent deliberate self-harm: a decision-making approach[69]**

The Byford study is a cost-effectiveness analysis of data from an RCT [Prevention of Parasuicide by Manual-Assisted Cognitive Behaviour Therapy (POPMACT)] comparing MACT with TAU for the treatment of people with recurrent episodes of DSH. The trial was conducted by Tyrer and colleagues,[58] in five centres in Glasgow, Edinburgh, Nottingham, West London and South London. The economic outcomes were cost per 1% reduction in the proportion of patients with a self-harm episode and cost per quality-adjusted life year (QALY) gained. The study took a broad societal perspective and included costs of hospital, community, voluntary and social services, community accommodation, the criminal justice system and productivity losses due to time taken off work. The time horizon was the length of the trial (12 months) and costs and benefits (self-harm episodes and EQ-5D) were therefore not discounted. An interim cost analysis at 6 months was also conducted. Unit costs for hospital services were based on local costs; all other unit costs were based on national sources. The analysis was performed on an ITT basis. Mean costs in the two groups were compared using standard $t$-tests with ordinary least squares regression for adjusted analysis. Bootstrapping techniques were used to confirm the validity of the results.

Univariate sensitivity analysis was conducted by replacing local unit costs with national ones, adjusting productivity costs, excluding community accommodation and including a mean cost for court appearances. Probabilistic sensitivity analysis (PSA) was conducted (based on repeated sampling using bootstrapping techniques) and reported by means of CEACs.

*Mean cost of treatment* The overall mean cost per patient was £13,450 and £14,288 (mean difference –£834, 95% CI –£2142 to 466) for the MACT and TAU groups, respectively. No statistically significant differences between the groups were found in the total costs or in the individual resource-use categories. No statistically significant cost difference was found between the MACT and TAU groups in any of the univariate sensitivity analyses.

*Cost-effectiveness analysis* The cost per 1% reduction in the proportion of patients with a repeat self-harm episode was £120. However, the incremental mean effect as measured by the EQ-5D instrument, was negative for MACT (–0.01118). MACT was therefore cheaper but less effective than TAU using EQ-5D, although not significantly so. The incremental cost per QALY gained from TAU was £66,000, but this can possibly be dismissed as a chance finding as the confidence intervals for the mean difference in cost are large.

PSA showed that the probability of cost-effectiveness of MACT compared with TAU using the percentage reduction in repeat self-harm was over 90%, whatever the willingness to pay. Using QALYs based on the EQ-5D, MACT was more cost-effective than TAU up to a willingness to pay of £60,00 per QALY.

*Comment* This was a good-quality study that scored highly on the *BMJ* checklist for economic evaluations. For the primary outcome measure of cost per 1% reduction in the proportion of patients with a self-harm episode, MACT was cheaper and more effective than TAU. However, this unit of measurement is difficult to interpret since it is a relative measure and so cannot be compared between studies. Furthermore, there are

questions about its appropriateness as the primary outcome for patients with BPD. Another limitation is that this outcome cannot be compared with other disease areas and so is not helpful to decision-makers.

The cost per QALY gained of £66,000 of TAU is higher than is generally accepted by the National Institute for Health and Clinical Excellence (NICE), but tells us little about the potential cost-effectiveness of MACT since it is based on a small and non-significant difference in EQ-5D scores (–0.0118). This small difference, and one that was in the opposite direction to the primary outcome, may have been the result of chance or the lack of sensitivity of the EQ-5D to changes in this patient group.

An important limitation of this study, as far as this review is concerned, is that it covers far more than BPD, since it includes people with recurrent self-harm and most of these people were not diagnosed with BPD. In subgroup analysis of the same trial data the authors report the cost of care for patients with personality disorders.[63] In patients with BPD, the average societal costs of care were higher for patients in the MACT group (£16,144) than in the TAU group (£14,185). Outcomes were not reported by treatment for BPD.

### Studies assessing the cost of therapies

Only two studies were identified that investigated the cost of therapy specifically for BPD patients. The Bateman study[70] estimated the annual healthcare utilisation costs for BPD patients receiving either partial hospitalisation or general psychiatric care. The setting was the Halliwick Day Unit at St Ann's Hospital in the UK. Costs were reported in US dollars and have been converted back to pounds sterling using the exchange rate quoted in the publication. The year of unit costs is not stated. The mean (SD) cost of care at 18 months was £19,000 (£11,000) in the partial hospitalisation group and £22,000 (£18,000) in the general psychiatric care group.

The Hall study[71] compared the cost of 1 year of psychotherapy in 30 BPD patients with the cost of the previous year in which the same patients received no formal psychotherapy. The mean cost of care for 1 year of psychotherapy was AUS$ 7309 (1998 unit costs). This includes the cost of inpatient stay, outpatient visits, ambulatory care, diagnostics, medications and psychotherapy treatment.

Further details of these studies can be found in Appendix 7.

## Cost-effectiveness and cost–utility analysis

The aim of this section is to assess the cost-effectiveness of different psychological therapies in the treatment of BPD. This assessment of cost-effectiveness is not based on a conventional decision-analytic model owing to the complex nature of BPD and the lack of evidence. The approach has been to undertake a cost-effectiveness analysis for each of the nine RCTs reviewed in Chapter 3 using a combination of data reported in published papers, trial data sets sent by the investigators and a cost model using data from the POPMACT study. Cost-effectiveness has been assessed in terms of cost per parasuicide event avoided in six trials and cost per QALY has also been undertaken in four of the six studies (by mapping BDI results onto the EQ-5D in the case of three trials; see Appendix 8).

### Overall methods

#### *Modelling*

The NICE guidelines for economic evaluation[72] recommend undertaking a formal decision-analytic modelling approach. This was not felt to be useful in BPD owing to the lack of evidence for a well-defined treatment pathway. The application of models to synthesise evidence was also inhibited by the inability to conduct any meta-analysis of the clinical studies reviewed. As argued in the section on clinical effectiveness, the nine RCTs and one non-RCT were too different in terms of their patient populations and interventions to permit a formal meta-analysis. For these reasons it was decided to undertake a series of economic evaluations on those trials that contain sufficient data, namely six of the nine RCTs reviewed in Chapter 3.[51–53,57–59] The study-specific approach limits the generalisability of the results and makes comparison between interventions difficult, but it does at least provide some evidence on the potential cost-effectiveness of the interventions (where currently so little exists).

**Technique of economic evaluation**

The form of economic evaluation was limited by the data collected in the clinical studies. For all six RCTs, cost-effectiveness analyses are undertaken using parasuicidal events as the unit of effect. As described later in some detail, this is a very limited measure of outcome since it does not reflect the overall health-related quality of life of

the patient. The ideal approach would be to conduct cost–utility analysis, where the outcomes are expressed in the form of QALYs to permit comparison with other health service interventions. However, only one trial used a preference-based measure of health (POPMACT) and of the remainder, just three used outcome measures that could be mapped onto the EQ-5D. A cost-effectiveness analysis using events avoided has been undertaken in all six RCTs and a cost–utility analysis in four out of the six.

#### *Economic perspective*

The NICE perspective is limited to the NHS and Personal Social Service (PSS). However, the high consumption by BPD patients of other government services, such as the criminal justice system, makes a broader government perspective more relevant. The base case was therefore taken from a government perspective, with NICE and societal perspectives being presented in the univariate sensitivity analyses.

#### *Time horizon*

The length of the follow-ups undertaken in the published studies limited the time horizon for these analyses. Most studies were 12 months in length and this has been applied in all studies. Studies of different durations have been converted to 12 months by a simple pro-rata approach.

#### *Outcome measure*

To compare cost-effectiveness between studies, a common outcome measure is required. The outcome measure most commonly reported across the studies is the number of parasuicide events. The cost-effectiveness analysis by Byford and colleagues,[69] identified from the literature review, was based on the POPMACT study and used this measure. However, cost-effectiveness was expressed in terms of cost per 1% reduction in the proportion of patients with a self-harm episode.

There are several problems with this outcome measure. One is the use of a 1% reduction. This is problematic because it is a relative measure and may not mean the same between studies. Therefore, the absolute number of parasuicide events was used as the main outcome measure, which provides a measure that is more meaningful to decision-makers making comparisons across studies. A more fundamental problem is the focus on just one outcome rather than a fuller measure of health-related quality of life, particularly since the relationship between the patient's quality of life and levels of parasuicide is not necessarily linear. Parasuicide events are nonetheless comprehensible to clinicians and decision-makers and although there is no willingness-to-pay figure for this outcome, decision-makers may be able to come to some judgement about a reasonable figure.

The other problem with using parasuicide activity or related outcomes such as attempted self-harm is that they have been defined in slightly different ways and may not be comparable between studies. We have attempted to standardise this where possible.

The QALY is used by NICE to undertake comparisons across programmes and this would have been a better measure to compare the cost-effectiveness of psychological therapies for BPD. In this appraisal, only the Tyrer study[58] was found to have used a preference-based measure of health that could be used to generate QALYs. An alternative method is to use another self-report measure of health and map that onto a preference-based measure. Three of the trials used the BDI, which has been previously mapped onto the EQ-5D (Appendix B).[73] This mapping function was applied to BDI data in three trials to generate QALYs.

The BDI is typically reported at several trial time-points. To summarise these measurements and also to take into account the between-group differences at baseline, a mean QALY gain (or loss) has been calculated to be the area under the curve (AUC).

## Costs

The costs implications of the interventions are more than the cost of the psychotherapy provided to patients in the experimental arm. BPD patients are heavy users of resources across a large range of services[69] and a successful therapy is likely to have knock-on implications for the use of services well beyond the specific intervention being evaluated in the trial. All resource consequences have been costed. Costs were inflated to 2003/04 prices using the Hospital and community health services pay and prices index (Office for National Statistics).[74]

#### *Costs of psychological therapy*

**Sessional costs**

The costs of the interventions were estimated from descriptions provided in the published papers of the trials and other available documentation on the number and type of sessions and the therapists providing the therapy.

***TABLE 9*** *Unit costs*

| Personnel and services | National average unit cost | Service |
|---|---|---|
| Consultant psychiatrist | £272 | Per 1-hour contact |
| Community psychiatric nurse | £72 | Per 1-hour contact |
| Clinical psychologist | £136 | Per 1-hour contact |
| Social worker | £99 | Per 1-hour contact |
| Occupational therapist | £44 | Per 1-hour contact |
| Other therapists | £118 | Per 1-hour contact |
| GP visit | £85 | Per 1-hour contact |
| Mental health services (inpatient) adult acute care | £190 | Per bed-day |
| A&E | £83 | Per first attendance |

The main concern with this approach is that the resources devoted to the interventions in the trials, particularly those undertaken in other countries, may not be typical of what would be provided in the NHS. The dilemma is that in conducting an economic evaluation alongside a clinical trial, it is important to retain the internal validity from a direct link between the resources costed and the study outcomes since a different level of resource is likely to have achieved a different outcome. However, the trial resource level may be unrealistic. The solution adopted here has been to use published trial data on the numbers of sessions (individual and group), but to cost the sessions using UK estimates of the types of therapist likely to be taking the sessions.

Estimates for the types of therapist conducting both group and individual sessions are based on a survey of DBT practitioners by the Psychological Therapies Research Centre at the University of Leeds.[75] All practitioners registered on the Leeds DBT Practice Research Network (PRN) database were sent a postal survey. The aim of the survey was to address questions of how DBT was implemented, which clients and patients received DBT, and how services were being monitored and researched. The percentage breakdown of professionals delivering DBT was clinical psychologists (48%), nurses (26%), psychiatrists (8%) and occupational therapists (8%). The remaining 10% were psychologists, psychotherapists, forensic psychologists or social workers (classed as 'other therapists' in *Table 9*).

Unless stated otherwise in the trial publications, it is assumed that two staff members[76] deliver the group therapy to an average of seven or eight patients (Rees A, Psychological Therapies Research Centre, University of Leeds: personal communication) and that sessions last on average for 2.25 hours.[76] Individual therapy sessions are assumed to last for 1 hour,[76] unless indicated otherwise in the trial publications.

Staff time has been costed using national average hourly costs for therapists taken from Curtis and Netten (2003),[77] which include the full employment costs of the therapists, along with related costs such as general training (*Table 9*). The only exception to this is the cost of a clinical psychologist, which in Curtis and Netten is £69 per hour of clinical contact. This seems to be unrealistically low and appears to be so because it does not include the costs of qualifications. The cost of qualifications is considerable for professionals at this level; for example, the cost of a consultant psychiatrist includes qualification costs of £26,000 per year. In the absence of an alternative data source the cost of a psychologist was based on expert opinion (Dent-Brown K, University of Sheffield: personal communication) and was estimated at half the cost of a consultant psychiatrist.

### *Training*

There is an extra cost associated with training people in the specific therapies evaluated in the RCTs. The cost of DBT training, for example, is between £1350 and £1925 per person depending on the number of staff attending (British Isles DBT training. www.capricorn.uk.net). To include this in the cost of DBT would require an assumption as to an annuity period and the number of patients treated in this period. The resulting annual mean cost per patient of training would be small and have little effect on the overall results, and has therefore not been included.

### *Telephone consultation*

Although DBT requires therapists to be available for telephone consultations, the only study that reported telephone contact reported no statistically significant difference between the DBT and TAU groups. Patients receiving TAU in the UK also have telephone contact with their therapist. The contrast is one of differently structured methods of delivering telephone

***TABLE 10*** *Resources used by BPD patients*

| Hospital services | Community health services | Social services | Voluntary sector services | Community accommodation | Criminal justice system | Productivity |
|---|---|---|---|---|---|---|
| Psychiatric inpatient | Community psychiatry psychology | Day centre/ drop-in centre | Helpline | Staffed | Police officer | Days off work |
| Other inpatient | Community counselling | Specialist education facility | Advice | Unstaffed | Prison/police cell | |
| A&E | Community mental health nurse/team | Sheltered workshop | Support | | Psychiatric assessment in custody | |
| Psychiatric/ psychology outpatient | Community physical therapy | Social worker | Counselling | | | |
| Other outpatient | Primary care | Home help | Group therapy | | | |
| Day hospital | Other community health services | Other social services | | | | |
| Medication | | | | | | |

Source: Byford *et al.*[69]

contact, rather than one of cost, and so the cost of telephone contact has not been included in this analysis.

### *Staff supervision*

DBT is a team effort, and an integral and essential part of the therapy is support for the therapist through regular supervision meetings with the other therapists. This constitutes a major cost element in the overall cost of DBT. Of the four DBT studies, three[52,59,78] report the frequency, number of hours and number of staff involved in supervision meetings, and this information has been used to estimate a cost of supervision per patient.

Staff delivering TAU may also receive supervision; however, no data were found to enable the resource implications to be quantified. To take TAU staff supervision into account it was assumed that TAU supervision is less resource-use intensive by a factor of 0.5 compared with DBT supervision. This supervision cost has been added to all TAU arms. It was also assumed that there is no difference in the supervision costs between the groups in the non-DBT studies and the cost of TAU supervision.

### *Other resource consequences*

The full range of additional resource consequences of BPD patients is shown in *Table 10*.

For three trials most of the resource-use data were available from the published articles or the individual-level data provided by the authors.[51,58,68] Resource-use data were converted into current UK prices using methods described in the section below on study-specific methods. In two other studies,[57,59] resource-use data were only available for length of inpatient hospital stay, and for the remaining study[52] no resource-use data were available. It has been shown that inpatient length of stay is the largest element of resource cost[79] and so the potential for modelling total resource-use cost from inpatient hospital stay was investigated. The relationship between the number of parasuicide events and resource-use costs was also investigated to estimate a cost for the study that did not have inpatient data.[52]

A key component in the costings was a cost model relating length of stay and parasuicide events to costs. This required UK patient-level trial data and the only trial data available that collected costs in all of the main resource categories (i.e. hospital, community health, social services, voluntary sector, community accommodation, criminal justice and productivity), which can be combined to represent the perspectives of the government, NICE and society, was the Tyrer study.[58]

In the Tyrer study,[58] no significant differences were found between the MACT and TAU arms and it

***TABLE 11*** *Results of the cost regression model based on parasuicide and length of stay (LOS)*

| | $R^2$ | Coefficient | SE |
|---|---|---|---|
| **Government perspective** | **0.66** | | |
| (Constant) | | 3,767 | 818 |
| Parasuicide events | | 55 | 109 |
| Inpatient psychiatric LOS (days) | | 244 | 41 |
| **NICE perspective** | **0.76** | | |
| (Constant) | | 3,136 | 627 |
| Parasuicide events | | 18 | 84 |
| Inpatient psychiatric LOS (days) | | 256 | 32 |
| **Societal perspective** | **0.63** | | |
| (Constant) | | 13,414 | 643 |
| Parasuicide events | | 198 | 86 |
| Inpatient psychiatric LOS (days) | | 162 | 33 |

was therefore considered appropriate to combine both arms for the purposes of this investigation. The study had 480 self-harming patients randomised and with a reasonable proportion being BPD patients ($n$ = 62). The cost modelling was conducted on the BPD subgroup of patients. Since the Tyrer data also contain the cost of therapy there may be an element of double-counting with the therapy costs. However, the average number of MACT sessions in the trial was so low (4.3) that double-counting of therapy cost is expected to have a minimal impact on overall cost.

A regression analysis was performed with inpatient length of stay and parasuicide events as the independent variables and total government cost as the dependent variable. Both variables were found to have significant coefficients. The analysis was repeated from the NHS and societal perspectives. The government perspective included all resources except for the voluntary sector services group, unstaffed community accommodation and productivity cost. For the NICE perspective, hospital services, community health services, social services and the cost of staffed accommodation were included. For the societal perspective all items were included. From *Table 11*, it can be seen that inpatient stay and parasuicide events account for around two-thirds of the variation.

As reported above, the Koons study[52] did not provide data on inpatient stay. Therefore a regression model based on parasuicide events alone was used to estimate costs (*Table 12*). The explanatory ability of this model is poor ($R^2$ = 0.1); however, in the absence of better data it gives some indication of the expected relative costs of the treatment and control groups.

## Analysis

The cost-effectiveness results are presented in terms of incremental cost per parasuicide event avoided and cost per QALY. PSA is used to investigate the impact of the uncertainty around parameters. It permits an analysis of the effect of joint uncertainty in all of the variables simultaneously. A distribution is attached to the range associated with each of the variables in the analysis and Monte Carlo simulation simultaneously selects values from the specified ranges and distributions. The simulations are run 10,000 times to generate a distribution of values. The results of this have been shown graphically on a cost-effectiveness plane for each study.

The cost and effectiveness distributions for each intervention are then combined to form a series of net benefit distributions, one for each intervention and at each level of willingness-to-pay. Finally, the probability that the intervention of interest is optimal is quantified and plotted for every value of the willingness-to-pay threshold. PSA was used to examine the probability that the intervention is cost-effective compared with the control arm at different levels of willingness to pay for avoiding parasuicide events and per QALY. This has been presented graphically in the form of CEACs and in terms of the specific likelihood of an intervention being cost-effective compared with the control arm at an arbitrary cut-off of £5000 per suicidal event avoided and a cost per QALY of £20,000.

The PSA does not capture all of the uncertainty in the results. One source of uncertainty is the perspective of the evaluation, which can include NICE, government or societal. The impact of this is explored in a univariate analysis. The other

*TABLE 12* *Cost regression model based on parasuicide events alone*

| | $R^2$ | Coefficient | SE |
|---|---|---|---|
| **Government perspective** | **0.1** | | |
| (Constant) | | 4,518 | 1010 |
| Parasuicide events | | 320 | 124 |
| **NICE perspective** | **0.1** | | |
| (Constant) | | 3,924 | 891 |
| Parasuicide events | | 296 | 110 |
| **Societal perspective** | **0.22** | | |
| (Constant) | | 13,913 | 751 |
| Parasuicide events | | 374 | 92 |

factors explored in the univariate analyses are the relative size of the supervision costs of TAU and the costing of DBT.

## Methods by study

The methods used to analyse each study vary depending on the availability and source of data and are therefore presented separately in this section.

### DBT trials

#### *Turner (DBT versus CCT)[57]*

This study attempted to keep the levels of therapy in DBT and CCT equal in terms of therapy contact hours and as a result no significant differences were reported between treatment arms in the number of therapy sessions. However, there was a cost difference between DBT and CCT sessions and so the mean number of individual therapy sessions for each arm was needed, but this was not reported. The number was estimated from the reported minimum (49) and maximum (84) number of therapy sessions. Six group therapy sessions were also provided for each group.

Supervision costs were estimated from the number of supervisors (two), the number of therapists (four) and the frequency of meetings (weekly in two separate sessions). The length of the meetings was not reported and was assumed to be 1 hour. Supervision costs were added to the CCT group by the method described above.

Resource-use costs were estimated by applying the regression cost model to the number of parasuicide events and the inpatient psychiatric length of stay.

The definition of parasuicide is unclear in this study. The authors state that "patients also maintained daily logs of suicide urges and attempts", but the analysis assumed that it is comparable to the other studies. The BDI was reported at baseline, 6 months and 12 months, and these data were converted to the EQ-5D preference-based index using the mapping function and used to calculate QALYs using the AUC.

#### *Linehan (DBT versus TAU)[53]*

Costs were not provided in the published trial paper for this study; however, costs are available from a cost-effectiveness dissertation by Heard.[68] The cost of therapy was reported separately for individual therapy, group therapy and day treatment. Resource-use costs were reported for psychiatric inpatient stay, emergency room visits, physician visits and medical inpatient days. The costs reported in the Heard dissertation are reproduced in *Table 13*.

Heard reported unit costs alongside mean costs and so the mean hours of therapy and resource use could be estimated. These resource-use figures have been recosted using current UK unit costs. Several assumptions are made in this costing: first, that sessional input will be delivered in the UK at the same level as in the Linehan study; secondly, that the efficacy rates will be similar given the differences in service delivery in the UK compared with the Linehan study; and thirdly, that the amounts of psychiatric inpatient stay and other medical treatment are the same in the UK as in the USA. Since the Linehan team pioneered DBT, it is reasonable to expect efficacy rates to be higher for them than for DBT delivered in the UK. The first two assumptions, therefore, would probably result in a larger

***TABLE 13*** *Costs (1998 US$) reported by Heard*[80]

| | | DBT | | TAU | |
|---|---|---|---|---|---|
| **Treatment mode** | **Unit cost** | **Mean** | **SE** | **Mean** | **SE** |
| **Outpatient psychotherapy** | | | | | |
| Individual hours | $88 | $3,885 | $232 | $2,915 | $927 |
| Group hours | $35 | $1,514 | $128 | $147 | $7 |
| Day treatment hours | $77 | $10 | $10 | $876 | $167 |
| **Psychiatric inpatient** | | | | | |
| Days | $309 | $2,612 | $1,086 | $12,079 | $3,692 |
| **Emergency room** | | | | | |
| Visits | $144 | $226 | $43 | $569 | $90 |
| **Medical treatment** | | | | | |
| Physician visits | $91 | $783 | $198 | $650 | $160 |
| Medical inpatient days | $360 | $360 | $212 | $1,096 | $542 |

difference in efficacy between treatments and control than would be achieved in the UK and so exaggerate the difference. For the third assumption, inpatient stay is generally considered to be used less in the USA than in the UK and the analysis is likely to underestimate the cost savings. The overall impact of these differences is unknown.

Insufficient data were reported on supervision costs and therefore the average of the other three DBT studies was used.

In the Linehan study,[53] parasuicides were measured using the PHI. Although the BDI was measured in this study, the values at 12 months were not reported and so QALYs could not be estimated.

### *Van den Bosch (DBT versus TAU)*[59]

The annual mean hours of therapy for individual and group sessions were estimated from the number of patients in therapy, the proportion continuing therapy and the frequency of sessions reported in the trial publication. In order to include the length of time that dropouts received therapy, it is assumed that, on average, they withdrew halfway through the trial.

Supervision costs were estimated based on the types of therapist delivering treatment and the frequency of supervision meetings reported in the trial publication. It was assumed that supervision sessions last for 1 hour. Supervision costs were added to the TAU group by the methods described above.

No other resources were reported in the study, so these were estimated by applying the regression cost model to the number of parasuicide events and the inpatient psychiatric stay.

Parasuicide was measured with the LPC instrument. The number of parasuicide events was calculated from LPC trial data provided by the authors. The BDI was not used in this study.

### *Koons (DBT versus TAU)*[52]

The mean hours of individual therapy, group therapy and medication management visits were reported in the trial publication. These were multiplied by the appropriate unit costs described in the section 'Costs' (p. 26). Supervision costs were estimated for the types of therapist delivering treatment and the frequency and length of supervision meetings reported in the trial publication.

No other resource-use costs were reported, nor was length of stay. Other resource costs were therefore estimated using the regression cost model with number of parasuicide events as the only independent variable. This is a very crude model and its estimates should be viewed with extreme caution.

Parasuicide was measured in this trial using the PHI, which is the same instrument used by Linehan's group.[53] The number of parasuicide attempts was reported at 3 and 6 months. For the purposes of comparison with the other studies, these event rates were multiplied by a factor of 2 to represent 12-month event rates. The BDI was

reported at baseline, 3 months and 6 months. To estimate a QALY over 12 months, the assumption was made that the mean BDI scores remain constant between months 6 and 12.

### MBT trials

#### *(Bateman MBT versus TAU)*[51]

This study was conducted over an 18-month period. It was converted to a 12-month period pro rata to make it comparable to the other studies. The 18-month study results are presented in the sensitivity analysis.

Therapy and other resource-use costs were reported in a cost analysis performed by the author. Other resource-use costs reported in the study were psychiatric inpatient and outpatient care, medication and emergency room treatment. Social and other government costs were not included. Although twice-weekly supervision of therapists was provided, the number of therapists involved was not reported. The level of supervision appears comparable to DBT and the average supervision cost of DBT was therefore assumed. Supervision costs were added to the TAU group by the method described above. Costs were reported in US dollars and were converted back to UK pounds using the exchange rate reported.

Suicide and self-harm acts were measured using the Suicide and Self-Harm Inventory. This instrument is available from the trial authors and no further details were reported.

The number of suicide and self-harm events was calculated from individual-level trial data supplied by the authors. The BDI was reported at baseline and 3-month intervals thereafter. A mean QALY gain for both groups was estimated for 12 months pro rata.

#### *Tyrer (MACT versus TAU)*[58]

The intervention therapy, other resource-use costs, parasuicide events and EQ-5D scores were available from trial data supplied by the authors.[69] From this data set the reviewers were able to undertake an analysis of the BPD subgroup. The cost categories used to calculate costs from the government, NICE and societal perspectives are the same as those described above in the regression cost modelling. Supervision of therapists was not described in the trial publication. It was assumed that supervision for both groups was similar to TAU. The cost of TAU supervision (estimated by the method described above) was therefore added to both groups.

Parasuicide was measured using the PHI, the same instrument used by Linehan's group.[53] The EQ-5D was directly used in the study and this was used to estimate QALYs.

## Cost-effectiveness results

The costs of the interventions and their study control arms are shown in *Table 14*.

The mean therapy costs for DBT across the four DBT trials were between £10,372 and £16,903 and in all cases exceeded the therapy costs in the control arm, whether TAU or CCT. There was a lower length of psychiatric inpatient stay and there were fewer parasuicide events than in the control arms. In two of the studies, the decrease in government costs associated with the reduction in use of services was sufficient to outweigh the cost of the additional therapy[53,57] and nearly to outweigh the cost in another study.[59] Only in the fourth study was there still a large incremental cost for the DBT arm.

For MBT and MACT, therapy costs were not recorded separately. The mean total costs of the MBT patients (£18,174) were within the range of the DBT intervention groups, while the MACT patients' costs were somewhat lower (£9580). The costs of the control patients were roughly the same for the MBT trial, but lower in the POPMACT study (£7563). The large cost difference between patients in the POPMACT study and three of the other studies may be partly due to a degree of double counting, since it was not possible to exclude therapy costs from the cost model (since the POPMACT data set did not separate these out). However, overall those categories of costs most likely to contain therapy, hospital psychiatric outpatients and community NHS services, together only account for 23% of total cost. Therefore, double-counting does not account for the order of difference between the three DBT studies by Turner,[57] Linehan[53] and van den Bosch[59] compared with POPMACT. It also cannot account for any of the differences from the Linehan and Bateman studies,[51,53] where actual other resource-use data collected in the trial were used. The reason for the lower costs of MACT patients is not clear.

*Tables 15* and *16* present the key constituents of the cost-effectiveness analyses: total numbers of parasuicidal events, total QALYs and total costs associated with each arm of the trials, along with the number of events avoided or QALYs gained

***TABLE 14*** *Cost implications of psychological therapy*

| | Intervention arm | | | Control arm | | |
|---|---|---|---|---|---|---|
| **Study** | **Therapy costs** | **Other costs** | **Total** | **Therapy costs** | **Other costs** | **Total** |
| Turner (DBT vs CCT)[57] | £10,372 | £5,371 | £15,743 | £9,428 | £11,557 | £20,985 |
| Linehan (DBT vs TAU)[53] | £13,033 | £2,658 | £15,691 | £7,958 | £8,941 | £16,898 |
| van den Bosch (DBT vs TAU)[59] | £11,996 | £5,434 | £17,430 | £6,060 | £10,646 | £16,706 |
| Koons (DBT vs TAU)[52] | £16,903 | £6,536 | £23,439 | £8,206 | £6,609 | £14,815 |
| Bateman (MBT vs TAU)[51] | | | £18,174 | | | £17,743 |
| Tyrer (MACT vs TAU)[58] | | | £9,580 | | | £7,563 |

and the incremental costs. The incremental cost-effectiveness results are presented in three ways depending on the results: where the intervention is both cheaper and more effective than the control it is considered to dominate the control arm; where the intervention is both more expensive and less effective than the control it is considered dominated by the control arm; and where the intervention costs more and is more effective the results are presented as an incremental cost per unit of benefit. The detailed results are now described by therapy and study in the same order as the Methods section.

## DBT

### *Turner*[57]

The incremental cost per patient of DBT over CCT was –£5242 and the incremental benefit was 9.4 events avoided. At the mean level, DBT was more effective and cheaper than CCT and this is reflected in the plot on the cost-effective plane (*Figure 2*). The CEAC shows that DBT would have a probability of more than 80% of being cheaper and more effective and the probability that it would be preferable at a threshold of £5000 per event avoided was around 85% (*Figure 3*).

The incremental QALY gain from DBT was 0.12 and the domination of DBT is again reflected in the cost-effectiveness plane (*Figure 4*). The CEAC suggests that DBT would have a probability of 85% of being cheaper and more effective than CCT and the probability that it would be preferable at a threshold of £20,000 was around 90% (*Figure 5*).

### Linehan[53]

The incremental cost per patient of DBT over TAU was –£1207, with 26.7 events avoided. Although at the mean level DBT dominated TAU, there is rather more uncertainty surrounding this result than for the Turner study. The scatterplot on the cost-effectiveness plane is clustered around all four quadrants (*Figure 6*). DBT had a probability of around 53% of being cheaper and more effective, and the probability that it would be preferable at a threshold of £5000 was around 60% (*Figure 7*).

### *van den Bosch*[59]

The incremental cost per patient of DBT over TAU was £724 and the incremental number of events avoided 18.1. This results in an incremental cost per event avoided of £724. The plot on the cost-effectiveness plane suggests a linear relationship between events avoided and cost (*Figure 8*), which may reflect the fact that the cost model used events avoided as one of the independent variables. The CEAC is very flat, reflecting the uncertainty in this analysis; the probability that DBT is cost-effective was around 65% at all thresholds (*Figure 9*).

### *Koons*[52]

The incremental cost per patient of DBT over CCT was £8625, with just 0.2 events avoided. The incremental cost per event avoided was £43,124 (*Figure 10*). The higher incremental cost may be a consequence of using the simpler cost model based on events avoided, which did not take any reduction in inpatient cost directly into account. However, the trial report indicates that there was little difference between the arms in hospital admissions. The probability of being cost-effective at £5000 per event avoided was below 40% (*Figure 11*).

The incremental QALY gain was 0.03 and this resulted in an incremental cost per QALY of £273,801. This reflected the higher incremental cost of DBT in this study. The cost-effectiveness plane reflects the high probability that DBT will cost more than TAU (*Figure 12*). The CEAC suggests that TAU would have a probability of around 95% of being the treatment of choice (*Figure 13*) at a willingness to pay of £20,000.

***TABLE 15*** *Cost per parasuicide event avoided*

| Study | Parasuicide events, mean (95% CI) | | Cost, mean (95% CI) | | Events avoided | Incremental cost | Cost per event avoided |
|---|---|---|---|---|---|---|---|
| | Intervention arm | Control arm | Intervention arm | Control arm | | | |
| Turner (DBT vs CCT)[57] | 2.92 (1.6 to 4.2) | 12.33 (7.8 to 16.8) | £15,743 (£14,000 to 20,000) | £20,985 (£17,000 to 28,000) | 9.4 | –£5,242 | Intervention dominates |
| Linehan (DBT vs TAU)[53] | 6.82 (1.7 to 12) | 33.54 (4.3 to 62.8) | £15,691 (£13,000 to 18,000) | £16,898 (£9,000 to 25,000) | 26.7 | –£1,207 | Intervention dominates |
| van den Bosch (DBT vs TAU)[59] | 16 (0 to 34.6) | 34.1 (9.4 to 58.8) | £17,430 (£15,000 to 23,000) | £16,706 (£11,000 to 28,000) | 18.1 | £724 | £40 |
| Koons (DBT vs TAU)[52] | 4 (0 to 8.4) | 4.2 (0.7 to 7.7) | £23,439 (£20,000 to 27,000) | £14,815 (£11,000 to 18,000) | 0.2 | £8,625 | £43,124 |
| Bateman (MBT vs TAU)[51] | 6.1 (2.3 to 10) | 17.5 (10.7 to 24.2) | £18,174 (£16,000 to 21,000) | £17,743 (£14,000 to 22,000) | 11.3 | £432 | £38 |
| Tyrer (MACT vs TAU)[58] | 4.9 (1.1 to 8.7) | 1.7 (0.7 to 2.7) | £9,580 (£6,000 to 14,000) | £7,563 (£4,000 to 11,000) | –3.2 | £2,017 | Intervention dominated by control |

***TABLE 16*** *Cost per QALY*

| Study | QALY gain | | Cost | | Incremental QALY (95% CI) | Incremental cost | Cost per QALY |
|---|---|---|---|---|---|---|---|
| | Intervention arm | Control arm | Intervention arm | Control arm | | | |
| Turner (DBT vs CCT)[57] | 0.17 | 0.05 | £15,743 | £20,985 | 0.12 (–1.2 to 1.4) | –£5,242 | Intervention dominates |
| Koons (DBT vs TAU)[52] | 0.07 | 0.04 | £23,439 | £14,815 | 0.03 (–1.3 to 1.3) | £8,625 | £273,801 |
| Bateman (MBT vs TAU)[51] | 0.04 | –0.01 | £18,174 | £17,743 | 0.06 (–1.2 to 1.3) | £432 | £7,242 |
| Tyrer (MACT vs TAU)[58] | 0.19 | 0.14 | £9,580 | £7,563 | 0.02 (0 to 0.09) | £2,107 | £84,032 |

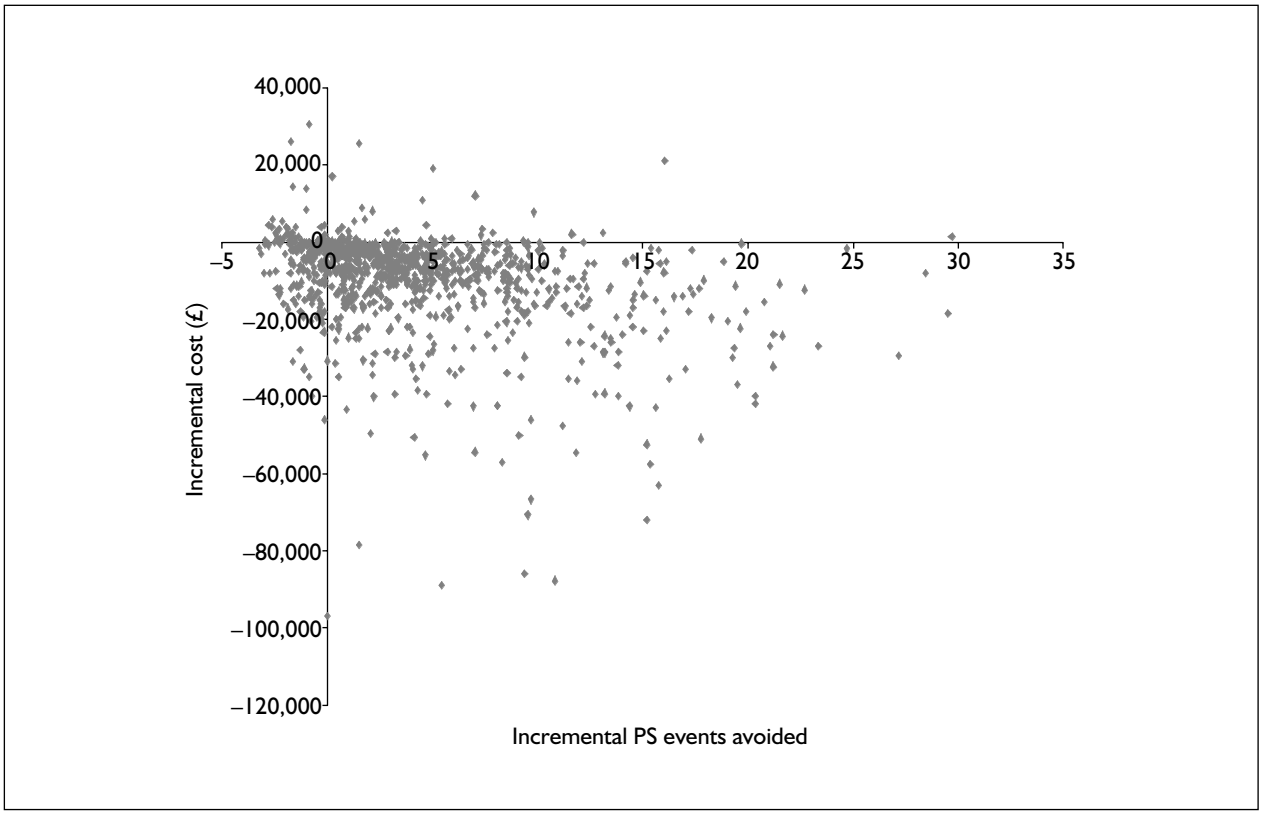


***FIGURE 2*** *Turner: cost-effectiveness plane of parasuicide (PS) events avoided*

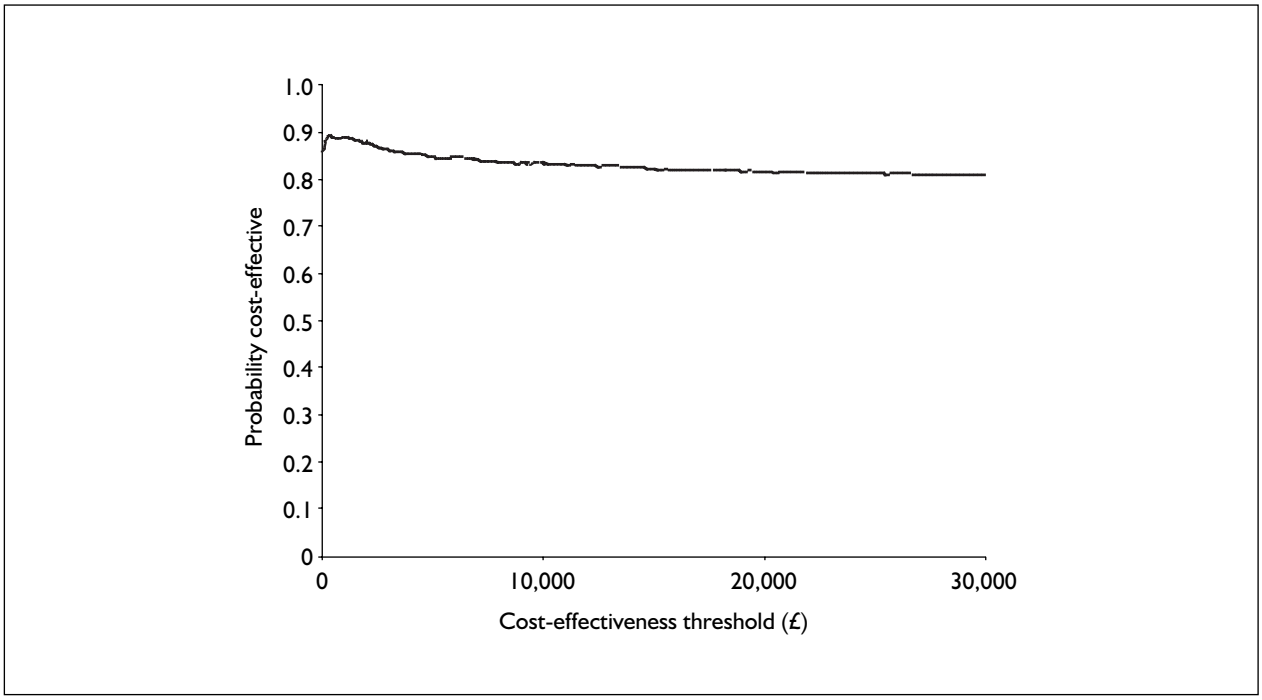


***FIGURE 3*** *Turner: CEAC of PS events avoided*

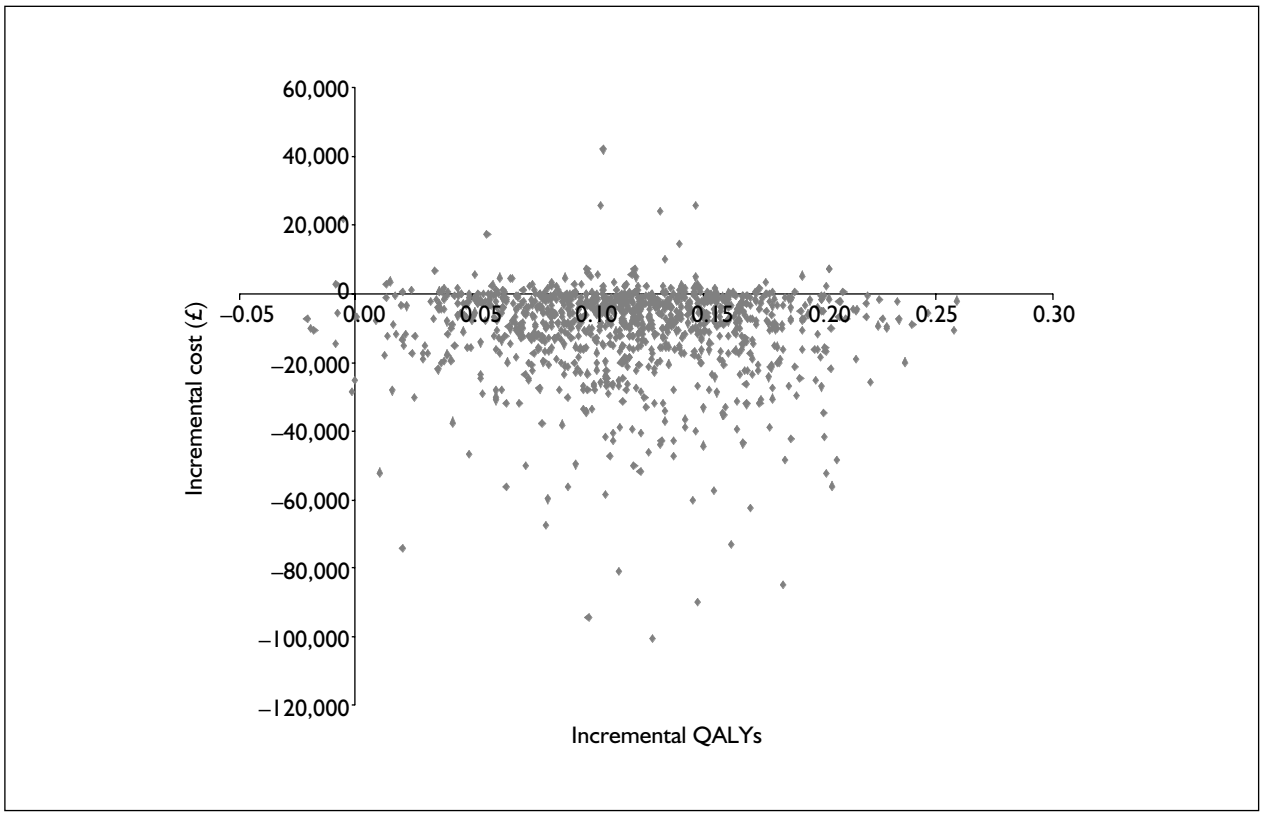


***FIGURE 4*** *Turner: cost-effectiveness plane of QALYs*

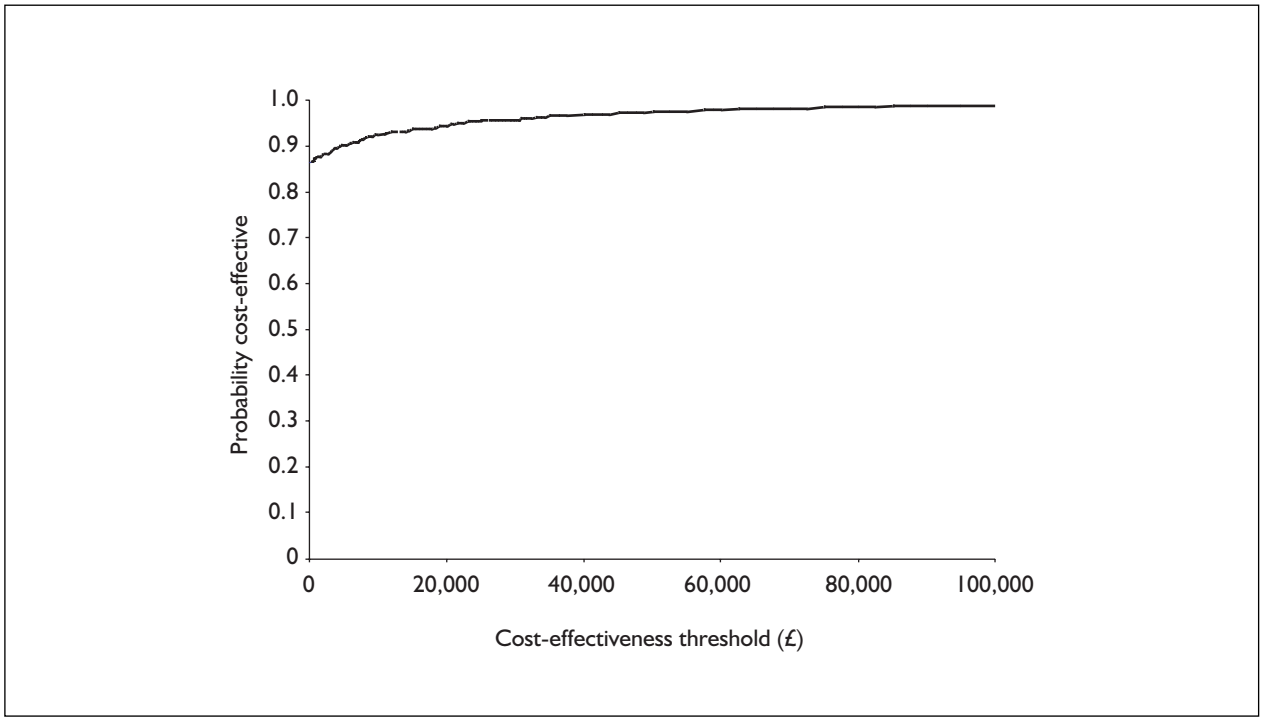


***FIGURE 5*** *Turner: CEAC of QALYs*

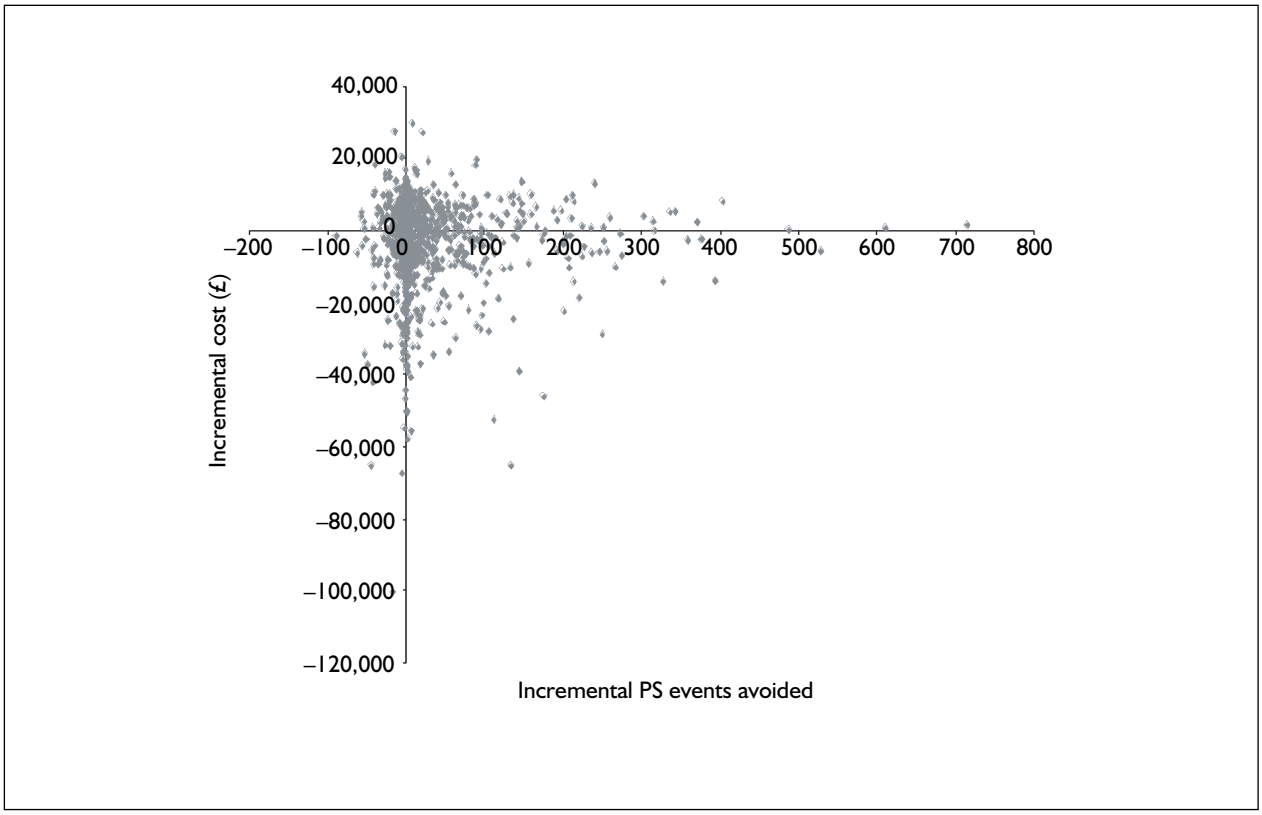


***FIGURE 6*** *Linehan: cost-effectiveness plane of PS events avoided*

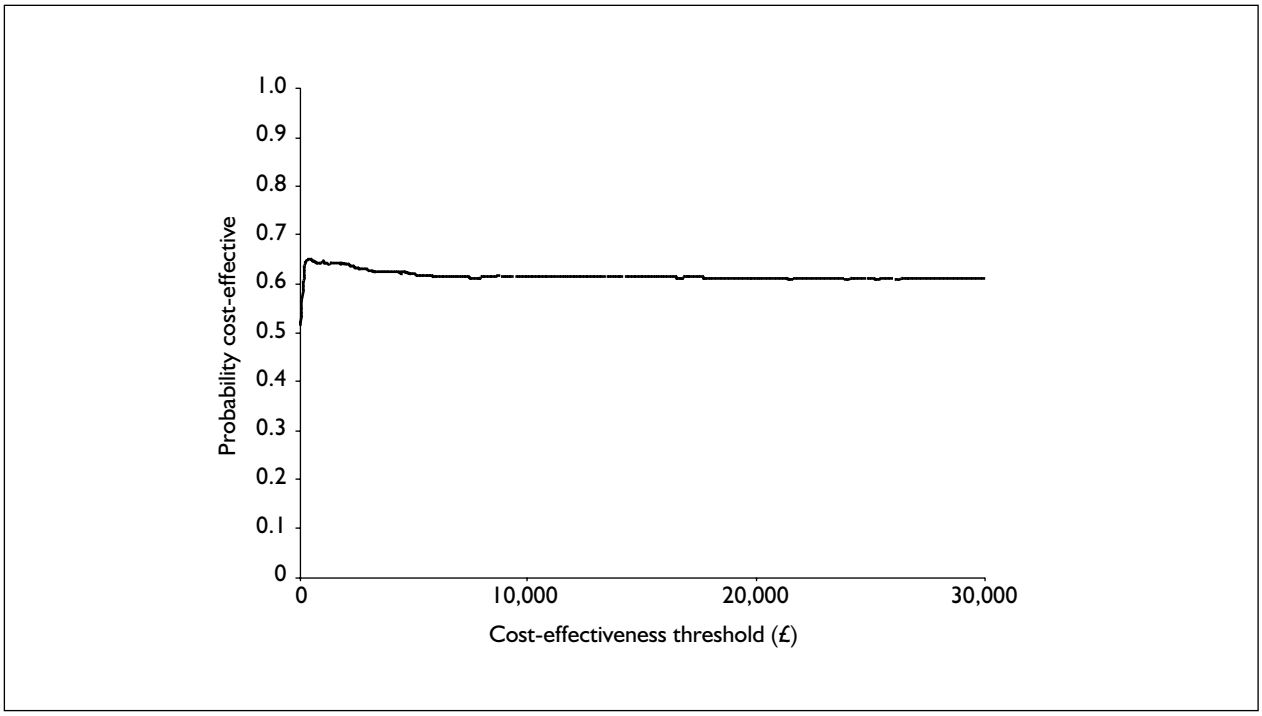


***FIGURE 7*** *Linehan: CEAC of PS events avoided*

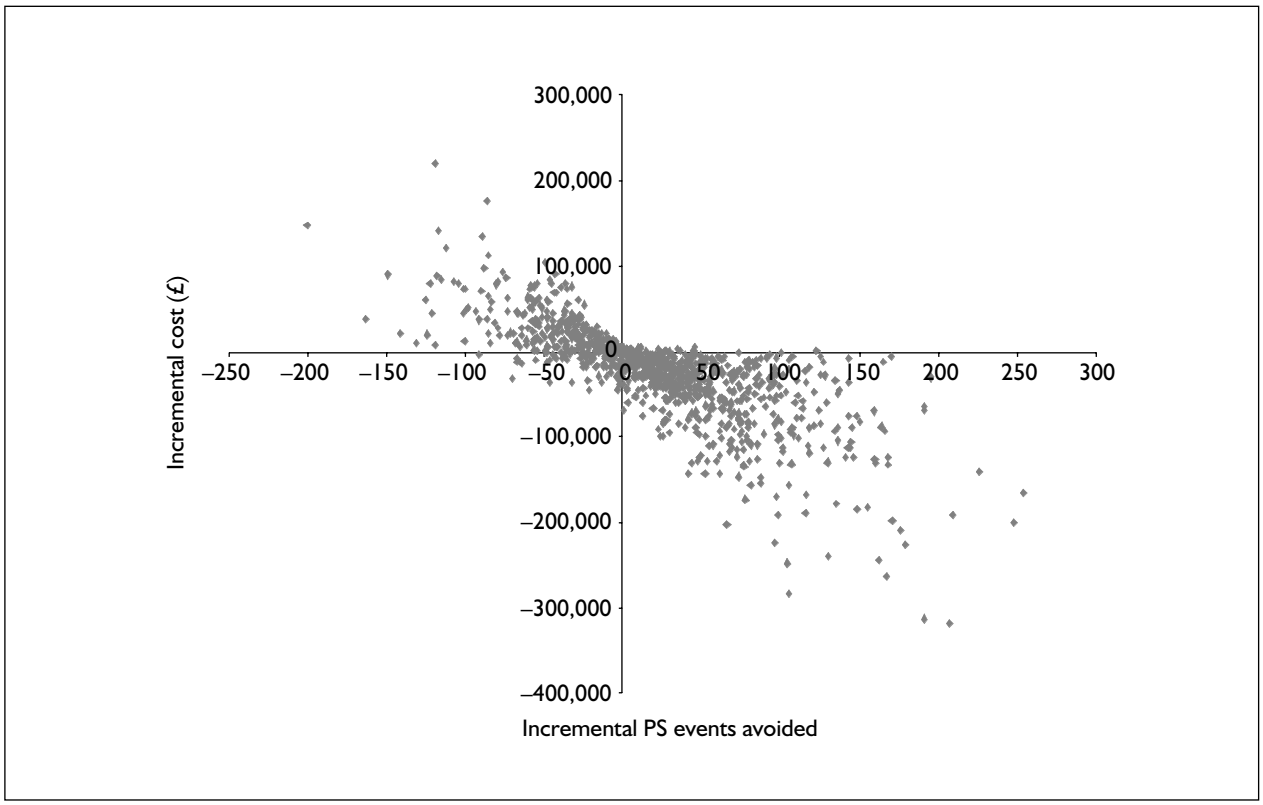


***FIGURE 8*** *van den Bosch: cost-effectiveness plane of PS events avoided*

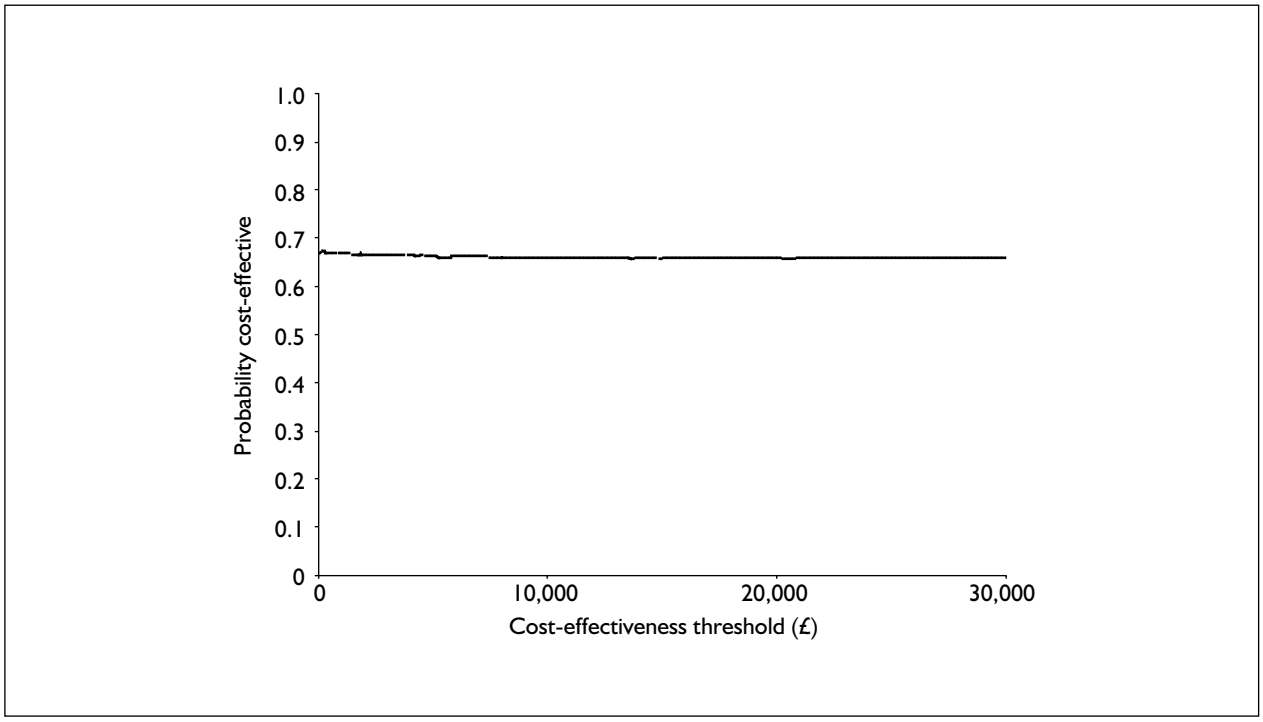


***FIGURE 9*** *van den Bosch: CEAC of PS events avoided*

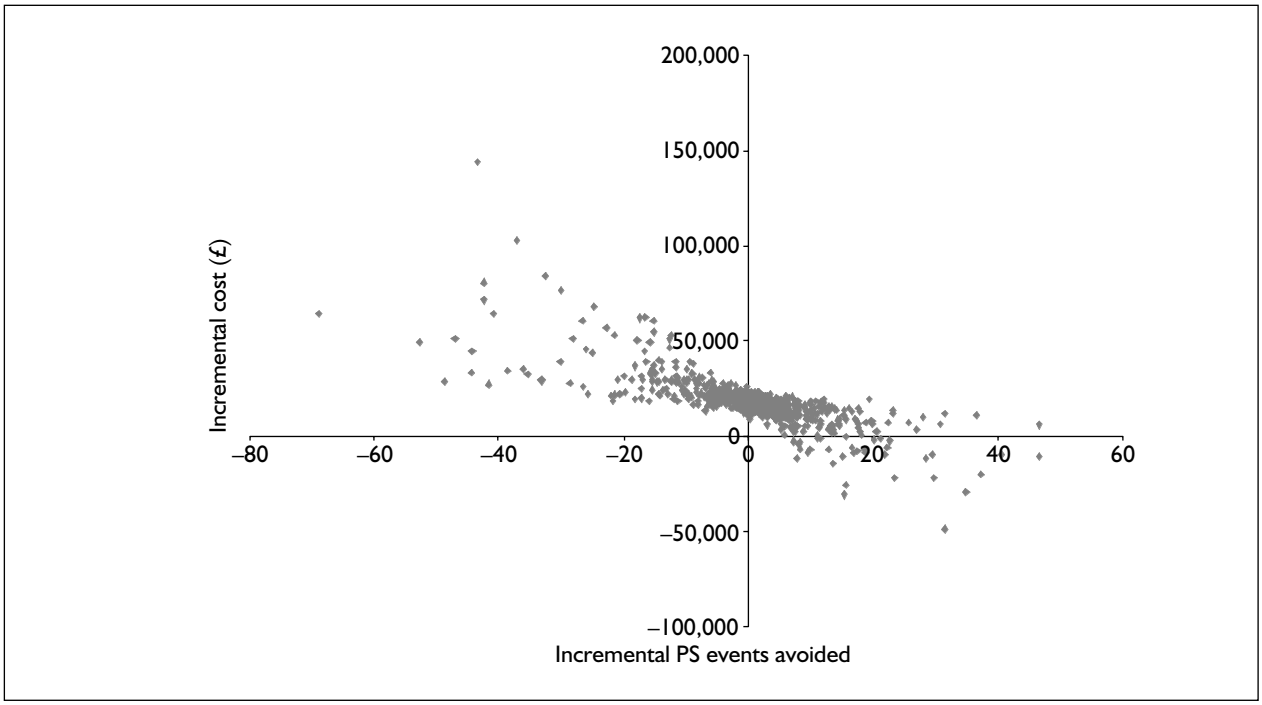


***FIGURE 10*** *Koons: cost-effectiveness plane of PS events avoided*

## MBT

### *Bateman*[51]

In the baseline 12-month analysis, the central estimate of the incremental cost per patient was £432 and number of events avoided was 11.3, resulting in a cost per event avoided of £38. There was a strong tendency for the intervention to be more effective with little cost difference (*Figure 14*). At a threshold of £5000 there was an 80% chance that the intervention would be cost-effective (*Figure 15*).

The cost per QALY was £7242. The cost-effectiveness plane demonstrates the uncertainty in this analysis (*Figure 16*). This is also reflected in the CEAC, which demonstrates that below a threshold of £20,000 there was a 55% chance that TAU was more cost-effective than partial hospitalisation (*Figure 17*).

At 18 months 17 parasuicide events were avoided, at an incremental cost of £647, resulting in a cost per event avoided of £38, as before, and little reduction in uncertainty, with an 80% probability that the intervention would be cost-effective at £5000 per event avoided (*Figures 18* and *19*). The cost per QALY was reduced from £7000 to £3000, but there was considerable uncertainty around the result (*Figure 20*). MBT had a probability of around 40% to 50% of being cheaper and more effective than TAU and the probability that it was cost-effective at a threshold of £20,000 per QALY was around 55% (*Figure 21*).

## MACT

### *Tyrer*[58]

The central estimate for the incremental cost of MACT over TAU was £2017 in BPD patients, with 3.2 more events. MACT was dominated by TAU in BPD. However, the uncertainty is such that the cost-effectiveness could range from TAU dominating MACT to MACT dominating TAU (*Figure 22*). The CEAC demonstrates that there was around a 60% chance that TAU would be more cost-effective than MACT (*Figure 23*).

The incremental QALY gain of MACT was 0.02 and this resulted in a cost per QALY of £84,032. The direction of the gain in QALY contradicts the primary outcome of parasuicide events (which were higher in the MACT group). However, there was considerable uncertainty surrounding this figure and this is reflected in the plots on the cost-effectiveness plane (*Figure 24*). The probability of being cost-effective at £20,000 was around 45% (*Figure 25*).

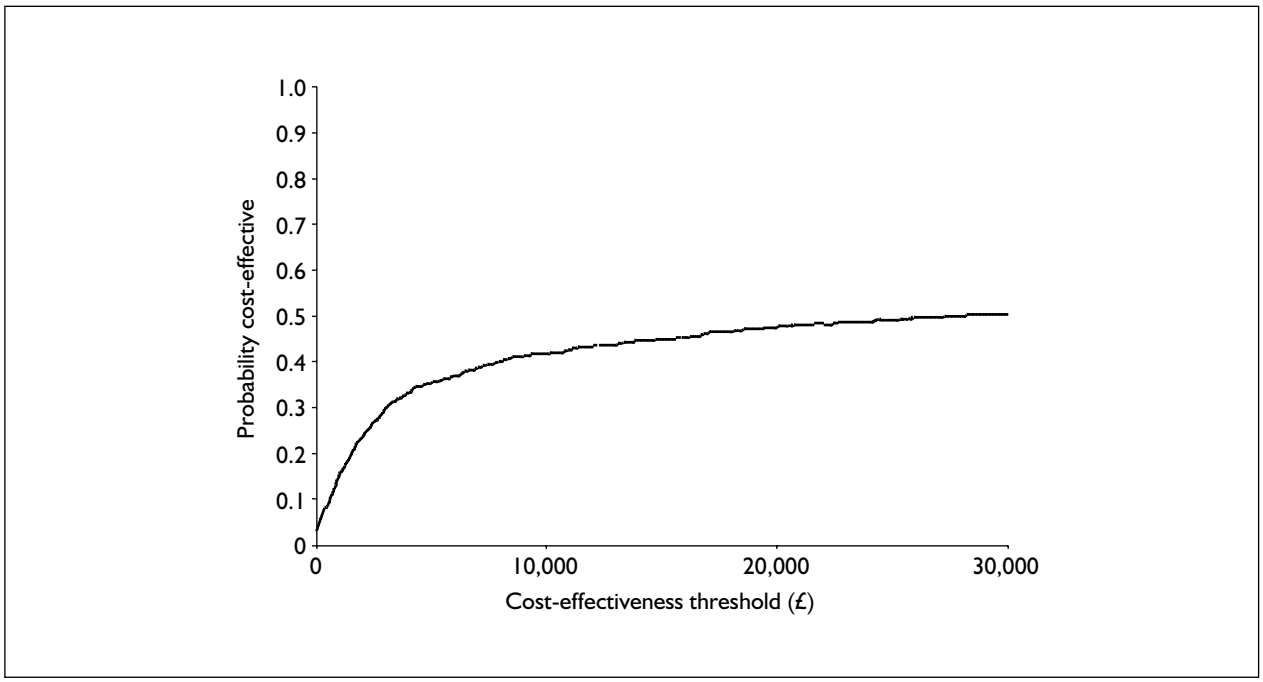


***FIGURE 11*** *Koons: CEAC of PS events avoided*

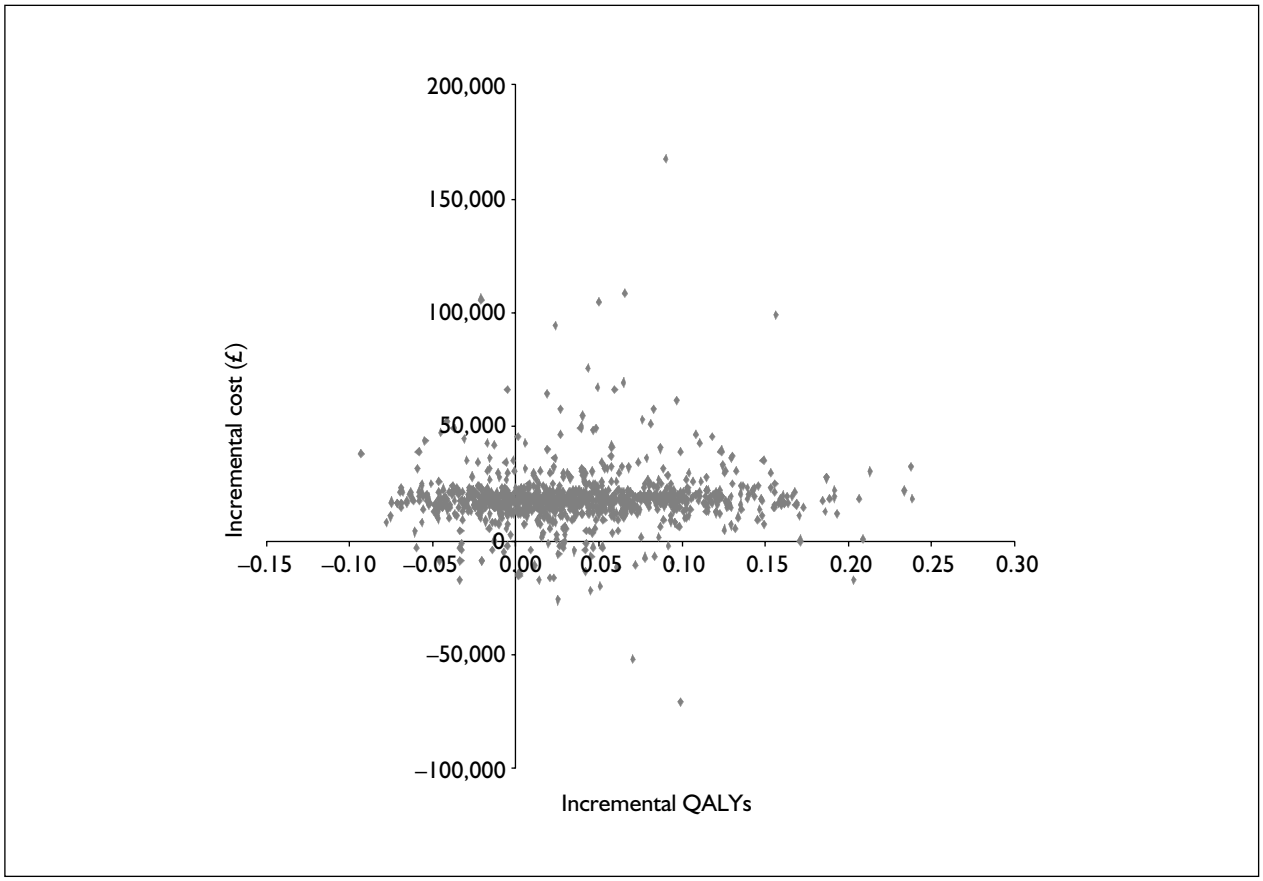


***FIGURE 12*** *Koons: cost-effectiveness plane of QALYs*

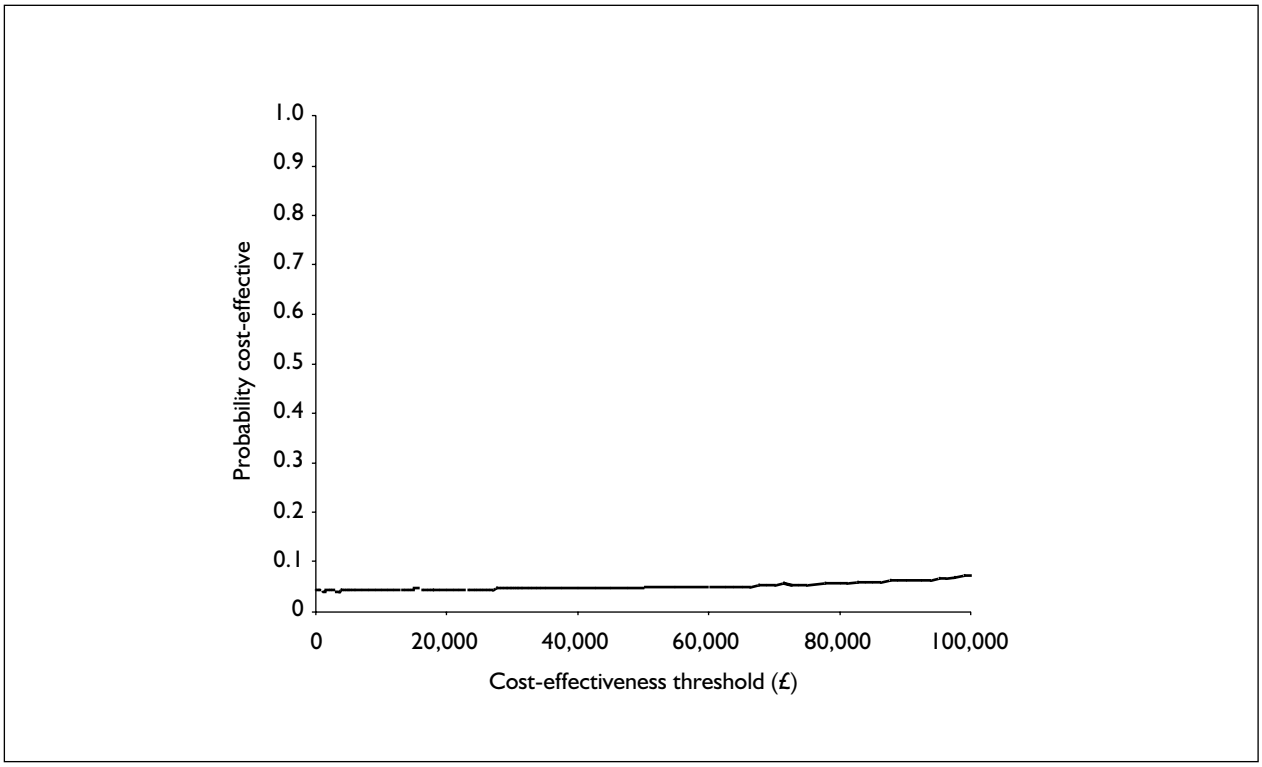


***FIGURE 13*** *Koons: CEAC of QALYs*

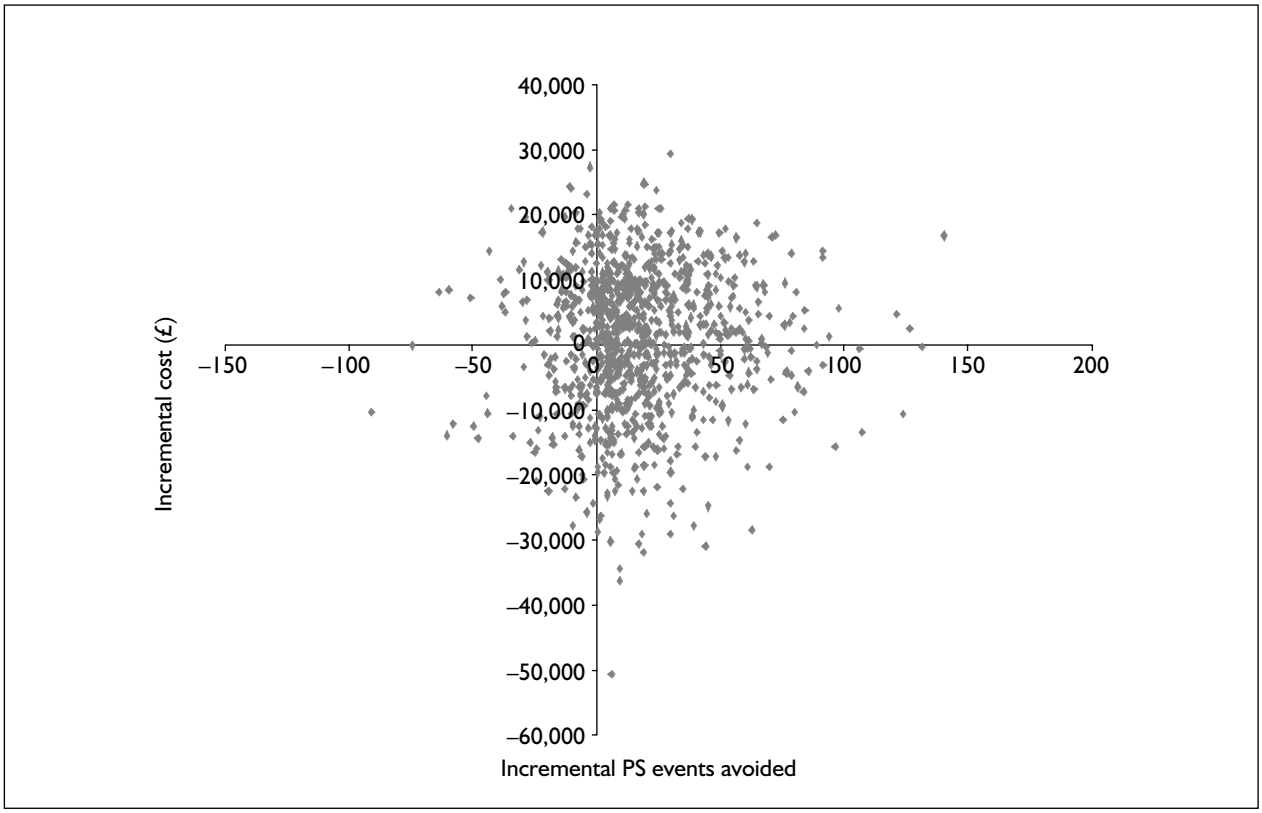


***FIGURE 14*** *Bateman: cost-effectiveness plane of 12-month PS events avoided*

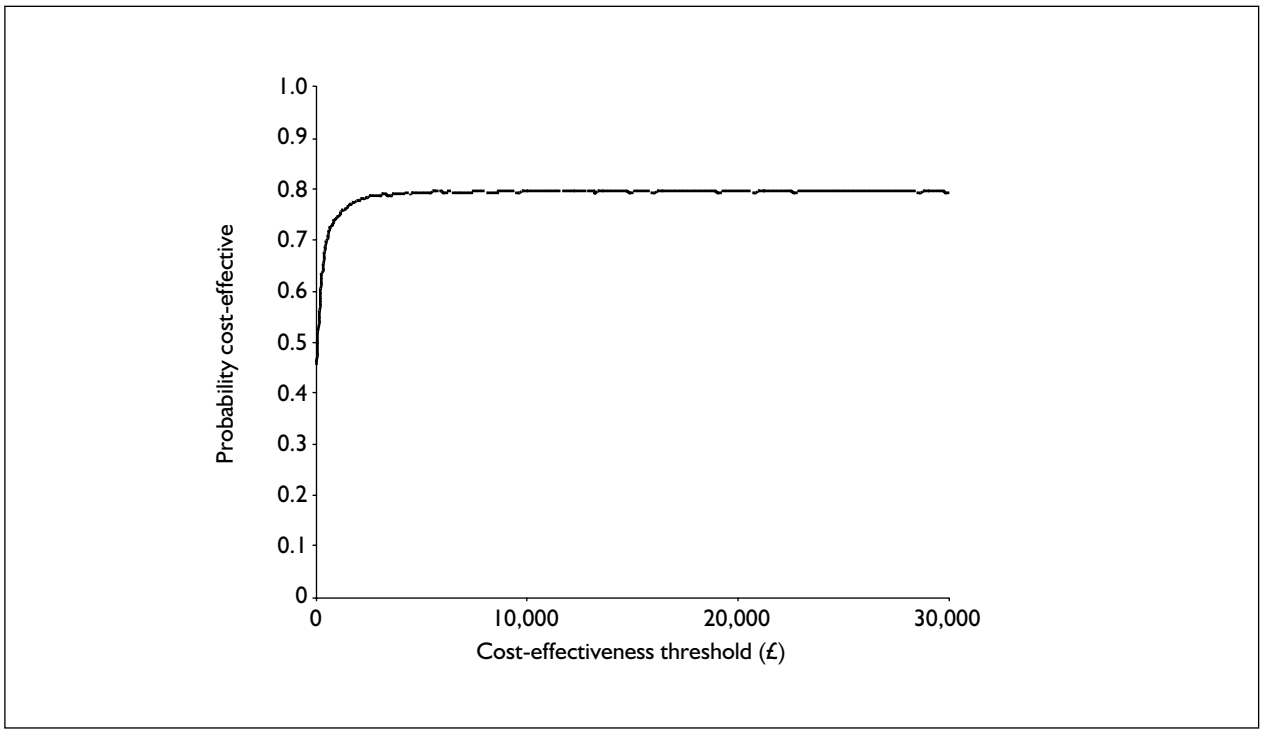


***FIGURE 15*** *Bateman: CEAC of 12-month PS events avoided*

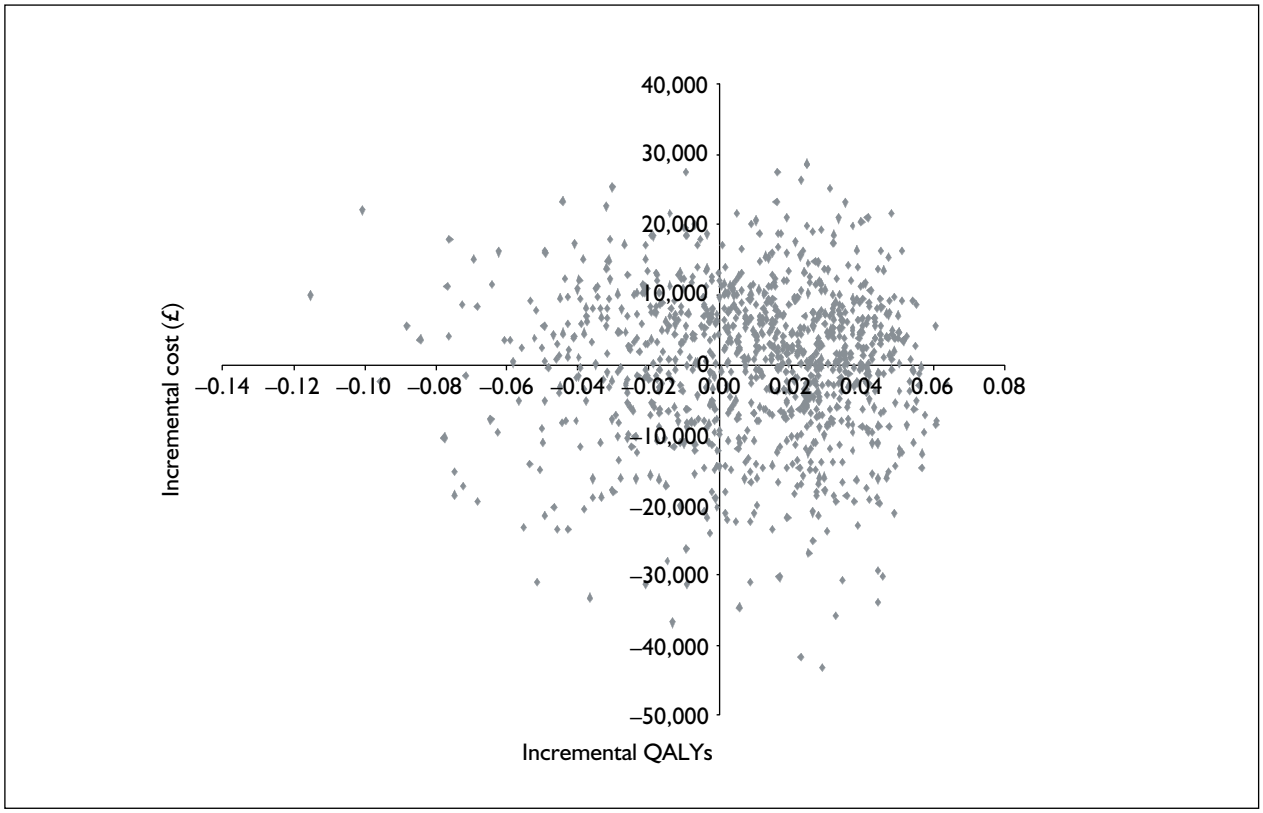


***FIGURE 16*** *Bateman: cost-effectiveness plane of 12-month QALYs*

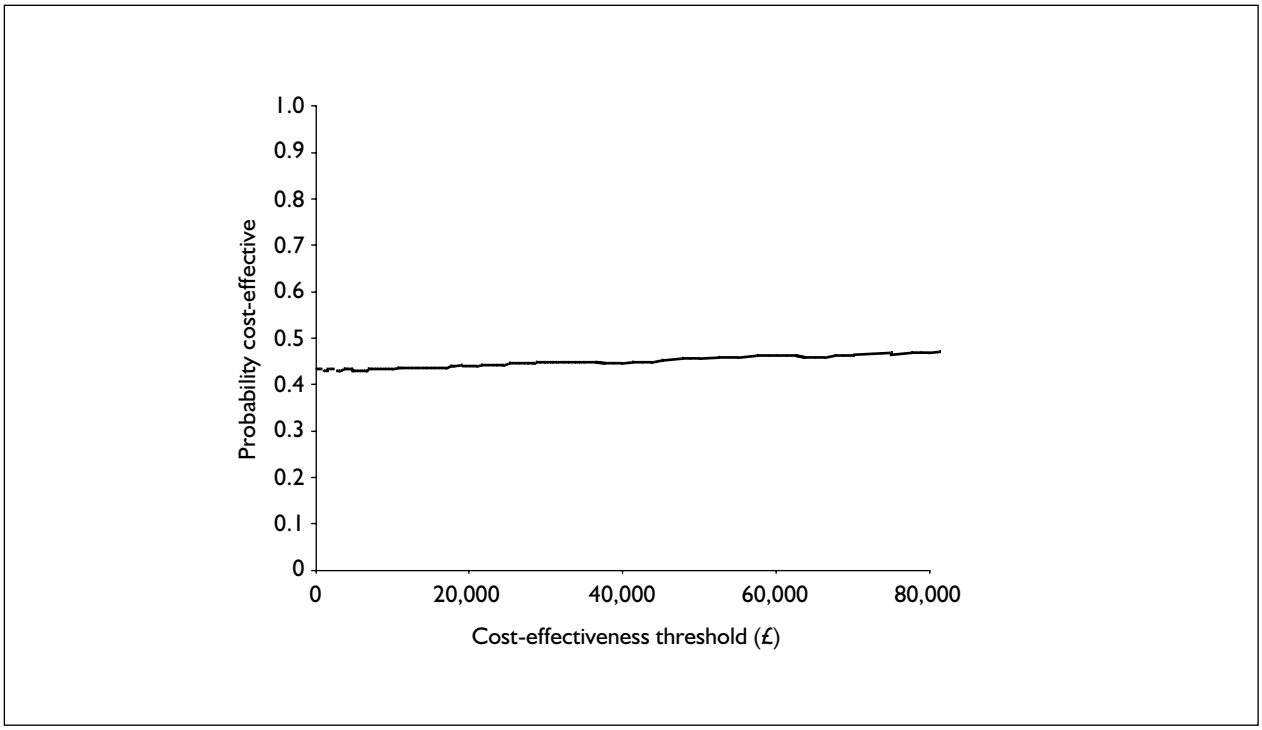


***FIGURE 17*** *Bateman: CEAC of 12-month QALYs*

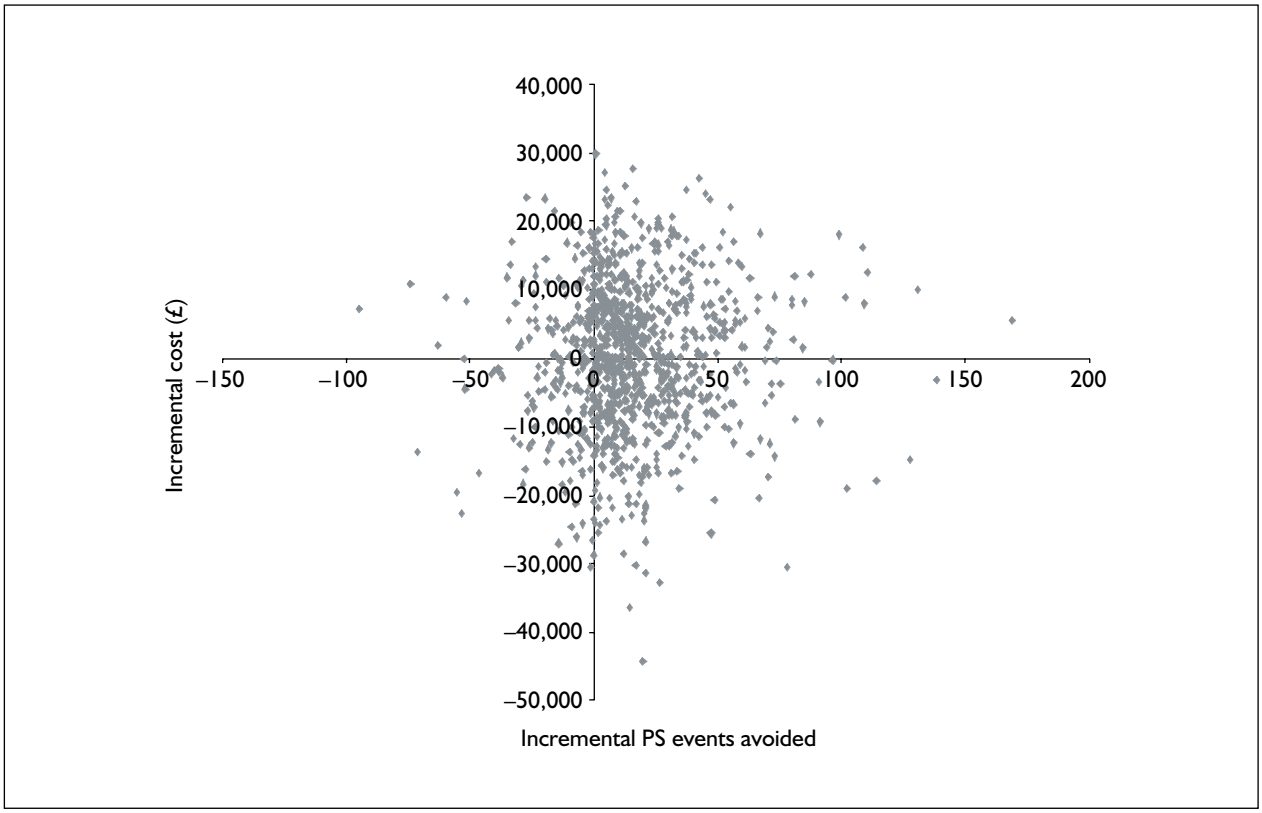


***FIGURE 18*** *Bateman: cost-effectiveness plane of 18-month PS events avoided*

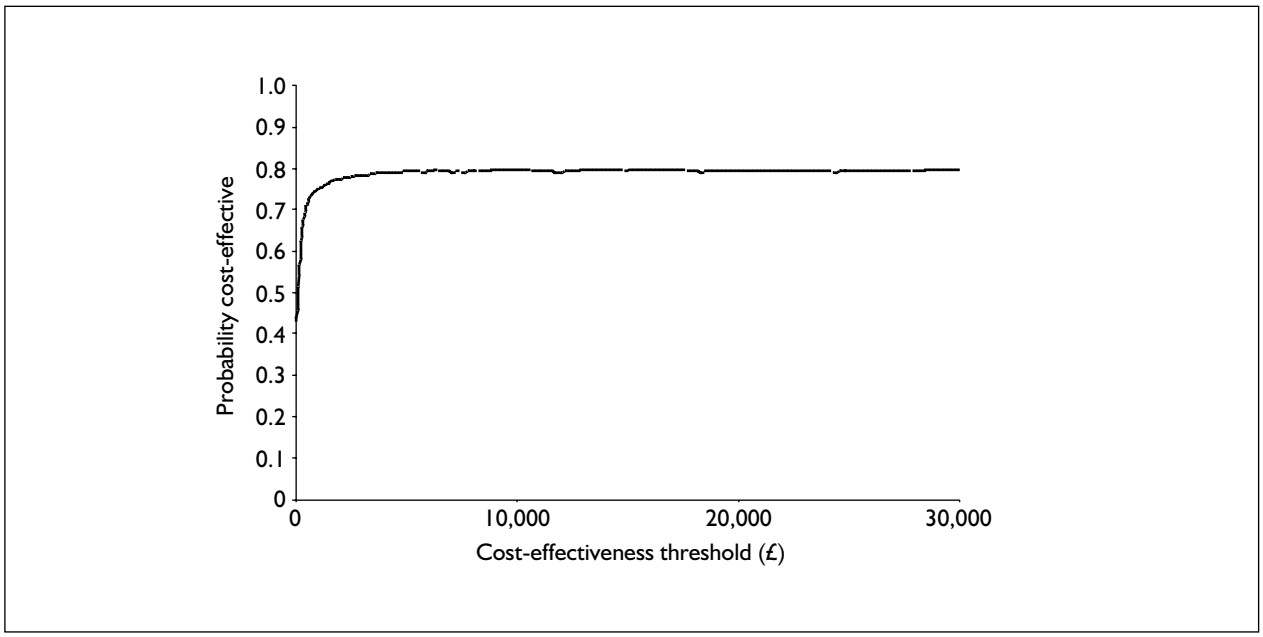


***FIGURE 19*** *Bateman: CEAC of 18-month PS events avoided*

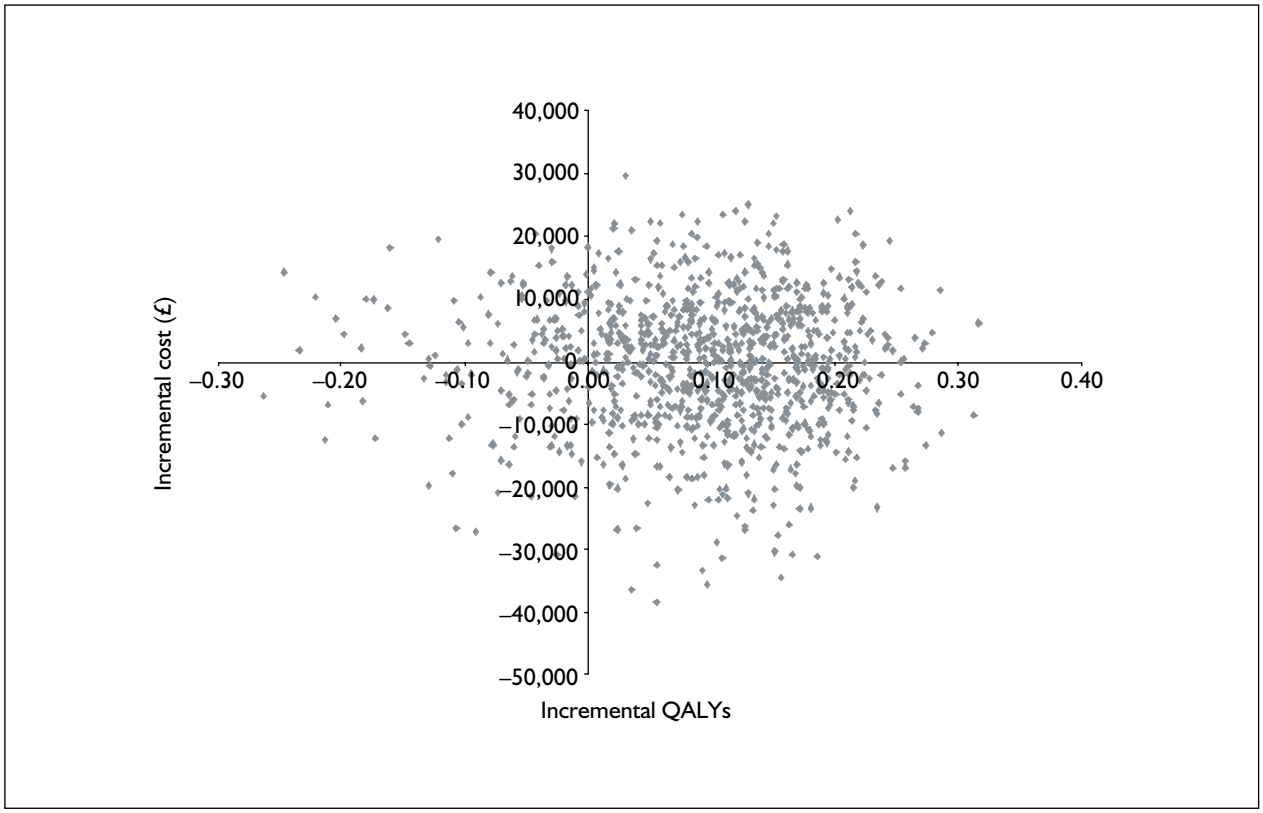


***FIGURE 20*** *Bateman: cost-effectiveness plane of 18-month QALYs*

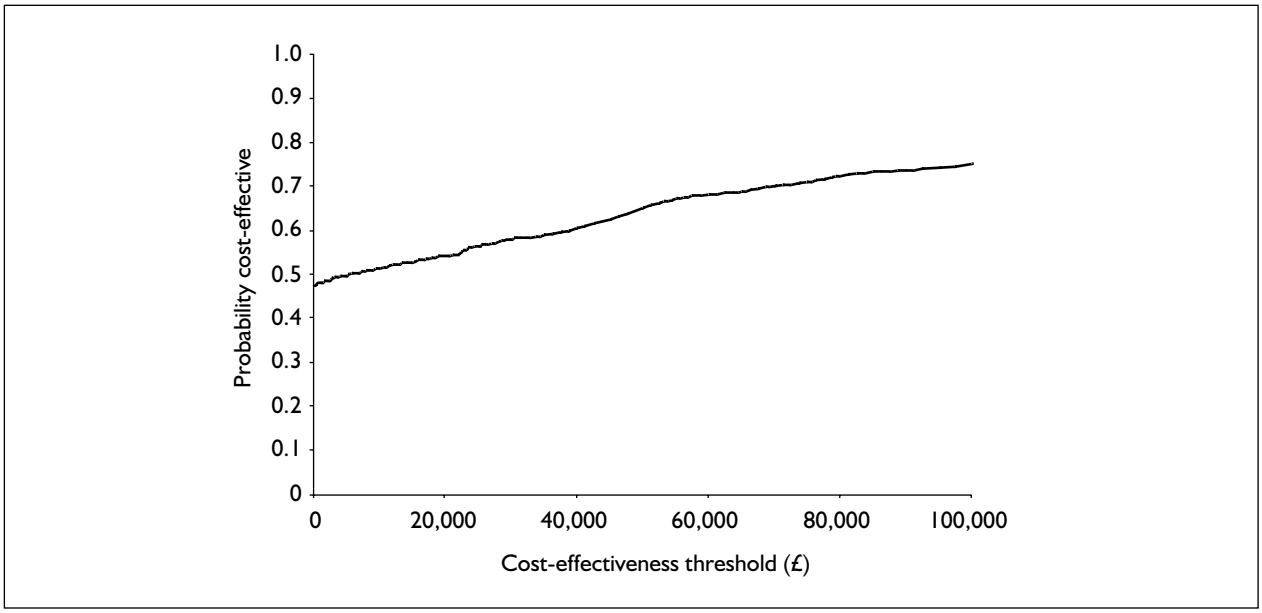


***FIGURE 21*** *Bateman: CEAC of 18-month QALYs*

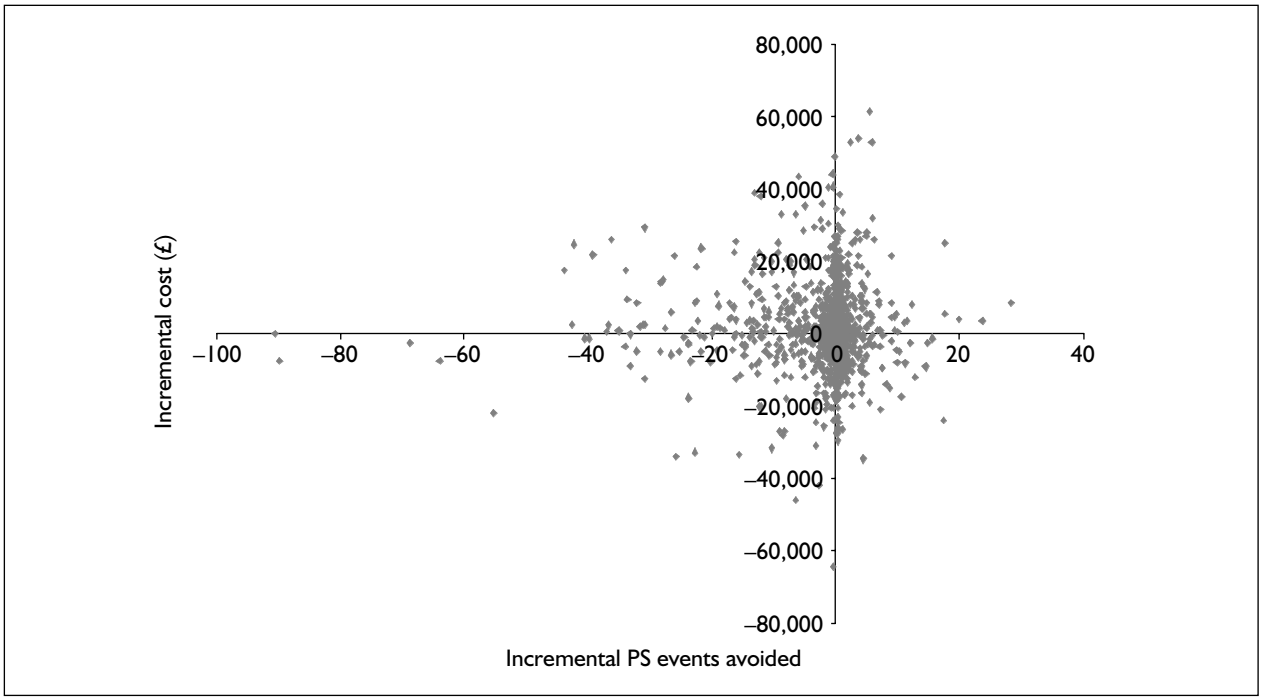


***FIGURE 22*** *Tyrer: cost-effectiveness plane of PS events avoided*

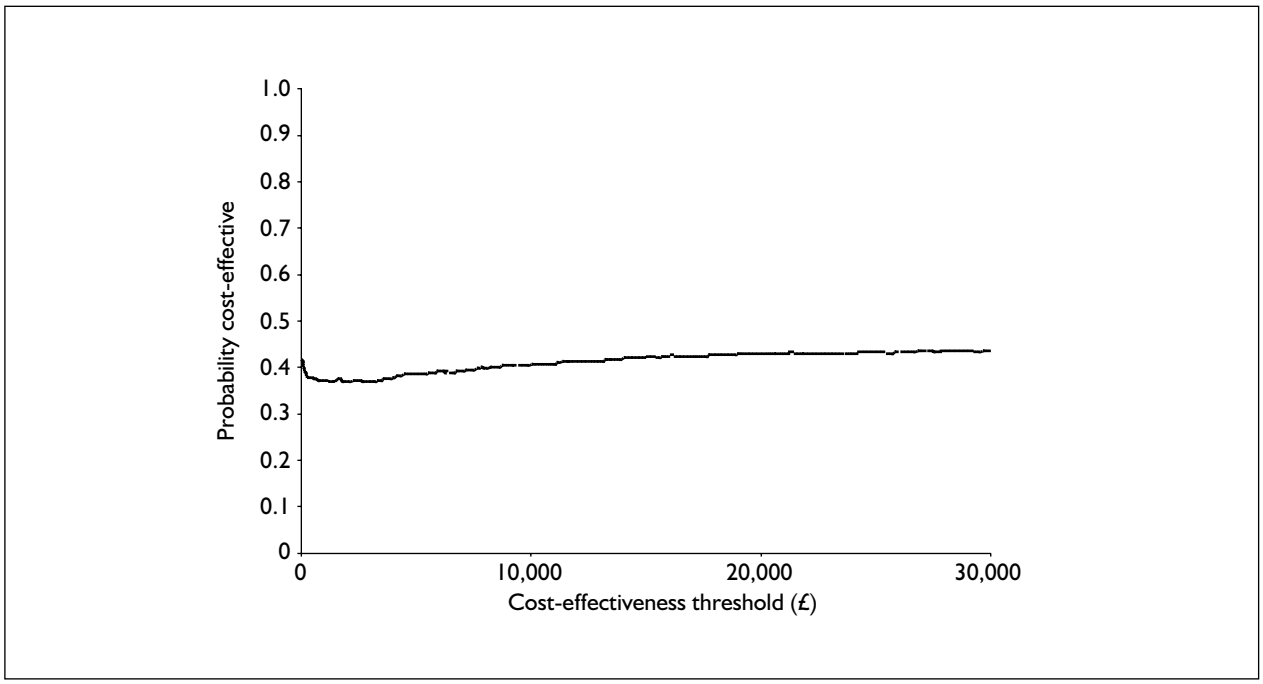


***FIGURE 23*** *Tyrer: CEAC of PS events avoided*

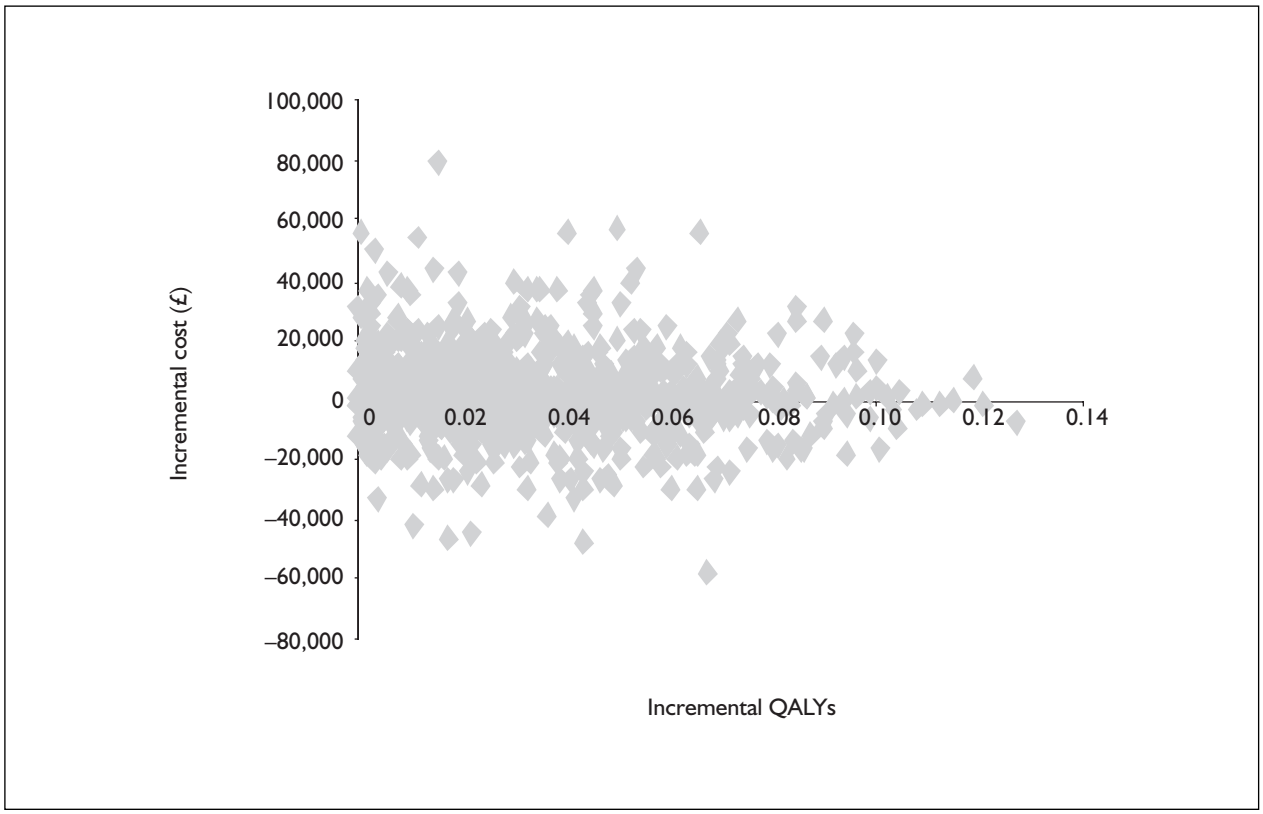


***FIGURE 24*** *Tyrer: cost-effectiveness plane of QALYs*

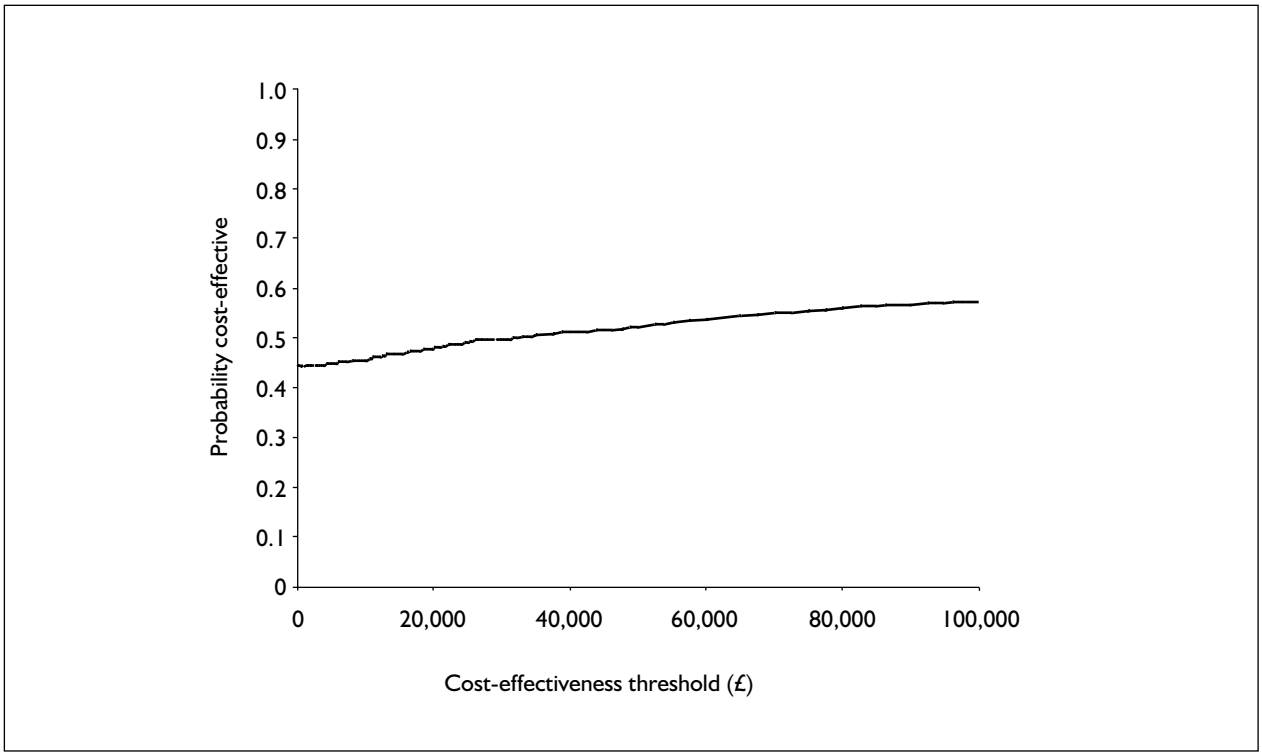


***FIGURE 25*** *Tyrer: CEAC of QALYs*

## Univariate sensitivity analysis

### NICE economic perspective

For those studies where the costing for other resources was based on the regression model, the NICE perspective did not alter the direction or magnitude of the cost-effectiveness results. This may be due to the fact the regression coefficients in the government and NICE models had a similar order of magnitude. The direction and magnitude of the Tyrer results[58] were also similar when costs were estimated from the trial data from a NICE perspective.

### Societal perspective

The societal model has the effect of increasing the magnitude of costs in both arms by a factor of approximately 75%. The van den Bosch study[59] was the only one in which the societal model resulted in a change in the direction of the results. Using the societal model the incremental cost in this study became –£818, and the intervention dominated TAU.

### Supervisor costs

In the baseline analysis TAU supervision costs were assumed to be less than DBT supervision costs by a factor of 0.5. This factor was increased to 0.75 (increasing control arm costs) and decreased to 0.25 (decreasing control arm costs). For the Bateman (MBT) and van den Bosch (DBT) studies,[51,59] a factor of 0.75 resulted in the intervention arm becoming cheaper than the control arm and therefore DBT dominated TAU. A factor of 0.25 resulted in small increases in the cost per QALY or events avoided for van den Bosch[59] and Koons,[52] and a three- to four-fold increase for Bateman.[51]

# Chapter 5
# Discussion

## Main results: clinical effectiveness

Nine RCTs and one non-RCT of moderate to poor quality were identified in the clinical effectiveness review. Of these ten studies, six show that there is some evidence that psychological therapies for BPD may be effective, whereas the evidence from four trials suggests that psychological therapies are no more effective than the alternatives. However, these results should be interpreted with caution as not all studies were primarily targeted to borderline symptoms and there were considerable differences in patient characteristics, comparison groups and outcomes between the studies.

## Main results: cost-effectiveness

The review of published studies identified one cost-effectiveness analysis of data from an RCT comparing DBT with TAU for the treatment of BPD. Subjects were women who were clinically referred to a psychotherapy outcome study. Subjects receiving DBT ($n$ = 22) incurred significantly higher psychotherapy costs, lower psychiatric inpatient costs and lower emergency room costs than those receiving TAU ($n$ = 22). The two treatment groups did not differ significantly with respect to median medical or total healthcare costs. The cost-effectiveness measures used were cost per week employed and cost per point of global adjustment and no significant difference was found in either of these measures for DBT compared with TAU.

The review of published studies also identified an economic evaluation of psychological therapies of partial relevance to BPD. This was a cost-effectiveness analysis of data from an RCT comparing MACT with TAU for the treatment of people with recurrent episodes of DSH. There were no significant differences between the groups in the total costs across all patients or among those with BPD ($n$ = 62). The cost per 1% reduction in the proportion of patients with a repeat self-harm episode was £120, with more than 90% chance of being cost-effective, but this analysis was not undertaken for the BPD subgroup. The incremental mean effect as measured by the EQ-5D instrument was negative for MACT (–0.01118). The incremental cost per QALY gained from TAU was therefore £66,000, but the authors argued that this was probably a chance finding given that the difference in EQ-5D was not significant.

A formal decision modelling approach could not be applied given the complex care pathways for patients with BPD and the lack of evidence. It was decided instead to undertake separate economic evaluations for the six RCTs that had sufficient data using a combination of data reported in published papers, trial data sets sent by the investigators, a cost model using data from the POPMACT study and a utility mapping exercise. Cost-effectiveness was assessed in terms of cost per parasuicide event avoided in all six trials and cost per QALY in four of them (this was done by mapping BDI results onto the EQ-5D for three trials). All results are at 2003/04 prices and for 12 months follow-up.

In three of the four DBT trials the intervention dominated the control groups in terms of parasuicide events (Turner[57] and Linehan[53]) or achieved a cost per event avoided below £50 (van den Bosch[59]). However, in a fourth DBT trial the estimated cost per event avoided was £43,124. While the studies by Linehan[53] and van den Bosch[59] seem favourable to DBT in terms of mean incremental cost-effectiveness, the probability of being cost-effective at £5000 per parasuicide event avoided was around just 60% in each case. Only two DBT trials were subjected to a cost per QALY analysis, and for one the intervention again dominated (Turner[57]) and the other had a cost per QALY of £273,801. The PSA showed substantial uncertainty surrounding these results. For Koons,[52] the probability of DBT being cost-effective was very low (at less than 10%). This mixture of results, high levels of uncertainty and the limitations described in the next section do not support the cost-effectiveness of DBT, although they suggest that DBT could potentially be cost-effective.

The MBT study group achieved a very low cost per event avoided, with a probability of being cost-effective at £5000 per parasuicide event avoided of 80%. While the cost per QALY was modest at £7242, there was substantial uncertainty,

with a probability of being cost-effective at £20,000 per QALY of less than 60%. For POPMACT, the BPD subgroup analysis undertaken by the assessment team found that the intervention was dominated in terms of cost per parasuicide event avoided. There was an insignificant incremental QALY gain in BPD, but the associated cost per QALY was £84,032. These assessments of MACT were both associated with a high degree of uncertainty, where the probability of being cost-effective was less than 50% in each case.

## Assumptions, limitations and uncertainties

### Clinical effectiveness

The size of the studies was small. Therefore, a lack of power was a major problem for the majority of trials. Bias was likely in some trials owing to a lack of blind outcome assessment, unclear allocation concealment and high dropout rates. Most trials included only women or predominantly women, limiting their generalisability.

A significant number of BPD patients usually do not complete the programme; thus, greater therapist involvement is necessary.[53] The degree of therapist involvement in most intervention groups was high. Therapists in experimental groups tend to have a more effective and supportive approach, with flexible relationships with patients, than therapists in control groups, which may have led to the lower attrition rates in the intervention arms.

The level of training and supervision of the therapist as well as therapist beliefs may have influenced the treatment outcomes. The therapists with special training, previous experience and a particular interest in working with patients with BPD may have achieved more success in the treatment than would be achieved in a routine setting. For example, the trials by Linehan's group were conducted in research clinics, which specialised in these patients. Personnel made considerable efforts to keep patients in treatment, which is not usual in normal practice. Although the principle of BPD therapies is based on developing a strong working alliance between therapist and client to prevent withdrawal and consequently to provide a complete treatment course, this requires considerable skills, effort and time from therapists and may not be a practical approach for busy mental health settings.

One trial[52] compared two active psychological treatment conditions where the same pharmacotherapy was administered in both groups. Although both groups significantly improved at the end of the treatment, there were no differences between the two treatments and the authors assumed that the effect might have occurred because of the drug. Therefore, it is important to consider drug administration in studies examining psychosocial therapies.

The long-term efficacy of psychological therapies is unclear, since the longest reported follow-up was 36 months,[51] at which time significant reductions in clinical symptoms of the intervention arm not only were maintained but continued to decline and were associated with low hospital admission rates.

DBT was one of the more successful treatments, with significant positive outcomes in relation to reducing self-harm and improving behavioural control in women. However, most studies come from a single group of investigators who developed the method and have a strong allegiance to it. More recent and more independent replication of these trials with a larger sample in Europe found that DBT is not significantly more effective than TAU.

There was insufficient evidence to examine whether any particular type of psychological treatment is more effective than others.

Most of the BPD participants in trials were referred by tertiary care settings and described as "(severely) parasuicidal" or "substance abusing", which omitted the rest of the (less severe, non-parasuicidal or non-substance-abusing) BPD patients. Such patients cannot fully represent the BPD population.

The need for a common scale for major clinical outcomes derives from the considerable heterogeneity of measures for assessing similar variables. Also, there is a need for more generic health-related quality of life measures.

Little information has been provided in the studies regarding patient preference. Research is still needed in these areas.

Finally, the authors are confident that they have not missed any important RCTs; however, the review of the non-RCTs might not have been sufficiently thorough. The reason for this uncertainty is that BPD can be included as a subgroup in general personality disorder, parasuicide/self-harm, suicide attempts, A&E and

forensic studies. These would require a large number of studies to be reviewed and would have been beyond the resources available for this review.

### Cost-effectiveness

The two studies that provided a cost-effectiveness analysis were of good quality, but the Heard study[68] had limitations concerning the lack of important cost data and the Byford study[69] was concerned with DSH and not just BPD. A published subgroup analysis did not replicate the full economic analysis. Indirectly, however, the Byford study provided important evidence on the likely cost-effectiveness of MACT, which was used in a subgroup analysis undertaken by this assessment team, and the trial provided data for the economic analyses undertaken for the other RCTs presented in this report.

The assessments of cost-effectiveness undertaken for each of the six trials presented in this report must be interpreted with great care. The trials were conducted in different settings in patients with varying baseline disease conditions. In addition, the methods and types of staff used to deliver the therapy differed, as did the length, frequency and type of sessions delivered. These differences make comparisons between the trials problematic. The comparability of TAU between the trials is also questionable. For two of the studies, the analysis only uses parasuicide events avoided, which limits the generalisability of the results and makes comparison between interventions difficult. Comparison between studies even using this outcome is limited because the studies used different definitions of the outcome measure.

The methods for assessing outcome used in the economic analysis are also subject to limitations. The cost-effectiveness analysis used the number of parasuicide events avoided and, as reported earlier, there was some variation between studies in the recording of these events. Furthermore, this is not an outcome that captures all of the consequences of the interventions for patients and is not a useful outcome for decision-makers concerned with allocating resource across programmes. This review attempted to estimate QALYs to try to capture a more patient-focused outcome that provides a more generic assessment of benefit. However, only one study directly measured QALYs and for three others a mapping from the BDI to the EQ-5D that was, inevitably, not completely accurate.

There are more general concerns with the use of QALYs in this condition and specifically QALYs that use the EQ-5D preference-based measure. The EQ-5D may not capture all of the consequences for health-related quality of life of people with BPD. There have been no validation studies of EQ-5D in BPD. Suggestions for further work in this area are suggested below.

The methodology to estimate costs differs between the trials. Some trials reported costs in detail, whereas others had to be estimated using simple regression models. The estimation of resource use for the Koons study[52] is particularly weak, since it was based on a poor association between parasuicide events and total costs. However, the number of parasuicide events was similar for both arms in this trial and the use of this model probably had little influence on the cost-effectiveness results.

The cost-effectiveness estimates are also dependent on the quality of the trials, which were small and suffered from high dropout rates. This would suggest that in many cases the results exaggerate the cost-effectiveness of the interventions. There must also be doubts about the generalisability of the results from these trials. Most of the DBT studies, for example, were undertaken in countries outside the UK and there must be doubts as to whether the results are transferable to the NHS. These results merely indicate the potential cost-effectiveness of DBT and MBT.

## Need for further research

Research into psychological interventions for BPD has tended to comprise either uncontrolled studies where it is impossible to interpret the findings, or small, poor-quality RCTs with high rates of dropouts that have not been properly followed up. At the same time, little thought has been given to the needs of contemporary economic analysis, although there are some notable exceptions. The results have produced a body of evidence that has been largely inconclusive. BPD is an important condition with a number of resource-intensive therapies available and it should be a priority area for future research. Here, more detailed suggestions are made for further research in terms of pragmatic trials and studies to inform economic evaluation.

### Pragmatic controlled trials

The basic evidence of clinical efficacy was poor. Appropriately powered, head-to-head RCTs of

psychological therapies are needed. The key features of these trials include the following:

- Where possible, a trial should have more than one psychological therapy being compared.
- Studies must be designed with adequate statistical power, taking into account expected dropouts.
- Patients from a variety of ethnic and socio-economic backgrounds must be included, with an age and gender mix comparable to those receiving treatment in the NHS.
- The level of severity and dysfunction must be well defined in future surveys and trials.
- The definition of dropout must be standardised and reduced where possible in the RCTs examining psychological therapies for BPD. Where patients drop out of therapy considerable effort must still be undertaken to collect data on them.
- The different therapies need to be properly described, including a TAU arm. Medication, for example, must be taken into account.
- Studies comparing active intervention with TAU need to be designed so that TAU is indeed that and not minimal intervention to maximise the benefits associated with intervention psychological therapies.
- The longest follow-up was for 18 months, and 6 months was more common. Given the high cost of the interventions, longer term follow-ups should be undertaken.
- Data should be collected on outcomes, including recognised generic measures of health-related quality of life, as well as preference-based measures to permit comparisons across programmes (see below).
- Data should be collected on resource-use services (see below).
- Research teams should include independent researchers.

### Studies to inform future economic analysis

The lack of data and complexity of the care pathway of BPD meant that a conventional economic model that synthesised a range of evidence could not be constructed for this report. This makes it difficult to conduct an estimate of the value of information to provide evidence on the size of investment needed and the priorities for future research. However, based on the analyses presented here the authors are able to recommend the following (in addition to the above on clinical effectiveness).

- Conducting cost-effectiveness analyses was in part limited by the complexity of the condition, but also the absence of good data on current practice. Survey work is needed into current practice in terms of pathways of care to begin to be able to model the longer term benefits using a more formal decision modelling approach.
- A survey of current practice and the use of the full range of services (including number of sessions attended and type of therapist) by people with BPD is needed to inform future economic analyses.
- Full resource-use data must be collected in the context of pragmatic clinical trials.
- A psychometric assessment is needed of the validity of the EQ-5D and other generic preference-based measures in BPD.
- If the generic measures are found wanting, then a more condition-specific preference-based measure must be developed that captures the impact of BPD on people's lives.

### Related to the above research recommendations

It must be recognised that BPD is not a homogeneous condition and it often occurs alongside other psychological co-morbidities.

Research is needed to determine the relationship of BPD and co-occurring major disorders to develop an optimal multicomponent programme, which will be targeted not only to BPD-specific symptoms but also to the coexisting problems.

# Chapter 6
# Conclusions

There is some evidence to support the clinical effectiveness of psychological therapies for BPD.

- There is some evidence that DBT is more effective than TAU for the treatment of chronically parasuicidal and drug-dependent women with BPD.
- There is some evidence that DBT-orientated therapy is more effective than CCT for the treatment of BPD.
- There is some evidence that DBT is as effective as CVT+12S for the treatment of opioid-dependent women with BDP.
- There is some evidence that MBT is more effective than TAU in the treatment of BPD.
- There is good evidence that MACT is no more effective than TAU in the treatment of BPD.
- There is some evidence that IGP is no more effective than individual MBT for the treatment of BPD.
- There is some evidence that TFP is more effective than TAU.

The overall efficacy of psychological therapies is promising; however, at this stage the evidence is inconclusive.

In terms of cost-effectiveness, this review attempted to examine the cost-effectiveness of the intervention in six RCTs. The mix of results between the four trials of DBT, along with the high levels of uncertainty and the limitations of the analyses, do not support the cost-effectiveness of DBT, although they suggest that it has the potential to be cost-effective. The results for MBT are promising, although again surrounded by a high degree of uncertainty, and for MACT the analysis suggests that the intervention is unlikely to be cost-effective.

Although the results do not support the cost-effectiveness of any psychological intervention over the rest, or of psychological therapy as a whole, the results do offer the hope that such interventions could be cost-effective. What is needed now are well-designed, pragmatic RCTs of the leading therapies in head-to-head comparisons with appropriate patient-focused outcomes (including an appropriate preference-based measure) and resource-use data collection, with formal modelling of the longer term consequences.

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## Contribution of authors

Indra Tumur (Research Fellow) and Michael Ferriter (Research Fellow) compiled the clinical effectiveness section. John Brazier (Professor of Health Economics) and Michael Holmes (Research Analyst) wrote the economic evaluation section. Glenys Parry (Professor of Applied Psychological Therapies) and Kim Dent-Brown (Postdoctoral Research Fellow) provided the background information and Suzy Paisley (Research Scientist) did the literature searching.

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# Appendix 1

## Identification of studies

This appendix contains information on the sources and keyword strategies used in the identification of studies.

### Electronic databases searched

Addiction Abstracts

ASSIA (Applied Social Sciences Index and Abstracts)

CareData

CDSR (Cochrane Database of Systematic Reviews)

CENTRAL (Cochrane Central Register of Controlled Trials)

Diss Abs (Dissertation Abstracts)

EconLIT

EMBASE

IBSS (International Bibliography of the Social Sciences)

Index to Theses

ISIP (Institute for Science Information Proceedings)

MEDLINE

NHS DARE (NHS Database of Abstract of Reviews of Effectiveness)

NHS EED (NHS Economic Evaluation Database)

HTA (Health Technology Assessment Database)

NCJRSA (National Criminal Justice Reference Service Abstracts)

OHE HEED (Office of Health Economics Health Economic Evaluations Database)

PsycINFO

PUBMED

Soc Abs (Sociological Abstracts)

SSA (Social Services Abstracts)

UKOP (United Kingdom Official Publications)

WOS (Web of Science)

### Sources consulted via the World Wide Web

AHRQ (Agency for Healthcare Research and Quality)

AIHW (Australian Institute of Health and Welfare)

AHFMR (Alberta Heritage Foundation for Medical Research)

APA (American Psychiatric Association)

APA (American Psychological Association)

Bandolier

BPD Research Foundation

BIGSPD (British and Irish Group for the Study of Personality Disorders)

Campbell Collaboration

CCOHTA (Canadian Co-ordinating Office for Health Technology Assessment)

CCT (Controlled Clinical Trials)

CEMH (Centre for the Economics of Mental Health)

CenterWatch

CHE (Centre for Health Economics)

Chestnut Lodge Hospital

CRD (Centre for Reviews and Dissemination)

DoH PRP (Department of Health Policy Research Programme)

DACEHTA (Danish Centre for Evaluation and Health Technology Assessment)

DPHE (Department of Public Health and Epidemiology, University of Birmingham)

DTB (Drug and Therapeutics Bulletin)

Harvard CEA Registry (Harvard Cost Effectiveness Analysis Registry)

HCNA (Health Care Needs Assessment epidemiological reviews)

HEBE (Health Boards Executive)

HERC (Health Economics Research Centre)

HERG (Health Economics Research Group)

HERU (Health Economics Research Unit)

Home Office

HSPSCB (High Security Psychiatric Services Commissioning Board)

HSRU (Health Services Research Unit)

ICSI (Institute for Clinical Services Improvement)

INAHTA Clearing House (International Network of Associations for Health Technology Assessment)

Institute of Psychiatry

ISSPD (International Society for the Study of Personality Disorders)

MIHSR (Monash Institute for Health Services Research)

MIND (National Association for Mental Health)

mRCT (Meta Registers of RCTs)

MSAC (Medical Services Advisory Committee)

NGC (National Guideline Clearinghouse)

NPC (National Prescribing Centre)

NCCHTA (National Co-ordinating Centre for Health Technology Assessment)

NHS QIS (NHS Quality Improvement, Scotland)

NHS R&D Programmes (including forensic mental health)

NHSC (National Horizon Scanning Centre)

NIH (National Institutes of Health)

NIH Clinical Trials Database

NIMHE (National Institute for Mental Health in England)

North of England Guidelines

NSF Mental Health (National Service Framework for Mental Health)

NZHTA (New Zealand Health Technology Assessment)

PDI (Personality Disorders Institute)

PSSRU, Kent (Personal and Social Services Research Unit)

RAND Corporation

RCP (Royal College of Physicians)

RCPsych (Royal College of Psychiatrists)

SBU (Swedish Health Technology Assessment)

SIGN (Scottish Intercollegiate Guidelines)

SPR (Society for Psychotherapy Research)

Thames Valley Initiative

Therapeutics Initiative (Vancouver)

WPA (World Psychiatric Association)

# Appendix 2

# Database keyword strategies

All searches were undertaken in March 2005.

## Addiction Abstracts

1996 onwards
MetaPress version

Personality disorder or personality disorders or borderline

## ASSIA

1987 onwards
Via Cambridge Scientific Abstracts (CSA)

### Clinical effectiveness search

Last Search Query: ((((DE="Borderline personality disorder") or (DE="Personality disorders") or (otherwise specified) or (axis ii) or (behavi*ral dyscontrol) or bpc or (cluster b) or (borderline and (personality or disorder*)) or (severe personality dysfunction) or (unstable personality) or ((dissocial or dramatic or emotional* or erratic or flamboyant or impulsivity or instability) within 3 (personality or disorder*))) and ((DE=("Psychotherapy" or "Analytical psychotherapy" or "Child analytical psychotherapy" or "Art therapy" or "Behaviour therapy" or "Aversion therapy" or "Cognitive behaviour therapy" or "Covert sensitization" or "Selfreevaluation therapy" or "Stress inoculation training" or "Verbal satiation" or "Contingency contracts" or "Habit reversal" or "Implosive therapy" or "Interruption prompting" or "Stimulus control" or "Subconscious retraining" or "Behavioural psychotherapy" or "Cognitive behavioural psychotherapy" or "Bibliotherapy" or "Brief therapy" or "Solutions based brief therapy" or "Child psychotherapy" or "Posttraumatic child therapy" or "Psychoanalytic child psychotherapy" or "Cognitive psychotherapy" or "Countertransference" or "Couple therapy" or "Systemic couple therapy" or "Dialogical psychotherapy" or "Drama therapy" or "Duo therapy" or "Existential psychotherapy" or "Experiential psychotherapy" or "Experimental psychotherapy" or "Family therapy" or "Behaviour family therapy" or "Brief family therapy" or "Cognitive behaviour family therapy" or "Contextual therapy" or "Developmental family therapy" or "Family play therapy" or "Medical family therapy" or "Multiple family therapy groups" or "Structural family therapy" or "Systemic family therapy" or "Feminist therapy" or "Forensic psychotherapy" or "Gestalt therapy" or "Group psychotherapy" or "Analytical group psychotherapy" or "Sociotherapy groups" or "Forensic group psychotherapy" or "Psychodynamic group psychotherapy" or "Individual psychotherapy" or "Interpersonal psychotherapy" or "Milieu therapy" or "Mother-Infant psychotherapy" or "Multimodal therapy" or "Music therapy" or "Primal therapy" or "Psychoanalytic supportive psychotherapy" or "Psychodrama" or "Psychodynamic therapy" or "Brief psychodynamic therapy" or "Psychosynthesis" or "Psychotherapeutic techniques" or "Mirroring" or "Rational-Emotive therapy" or "Reality therapy" or "Social economy therapy" or "Supportive psychotherapy" or "Therapeutic communities" or "Transactional analysis" or "Transference" or "Self-Object transference" or "Validation therapy")) or (DE=("Psychotherapeutic techniques" or "Mirroring")) or (DE=("Psychotherapists" or "Analytical psychotherapists" or "Child psychotherapists" or "Group psychotherapists" or "Analytical

group psychotherapists")) or (DE="Psychological services") or
(DE="Psychological intervention") or
(DE=("Psychoanalysis" or "Castration
anxiety" or "Psychological splitting" or "Seduction theory" or
"Selfobjects" or "Selfpsychology")) or
(DE=("Psychoanalysts" or "Social
work psychoanalysts")) or (DE=("Group therapy" or "Brief group therapy"
or "Cognitive group therapy" or "Feminist group therapy" or "Group focal
conflict theory" or "Psychoanalytic group therapy" or "Psychoeducational
group therapy" or "Sensitivity training" or "Crosscultural sensitivity
training")) or psychotherap* or boscot or cat or cbt or dbt or
(democratic within 2 communit*) or (therapeutic communit*) or (henderson
hospital*) or psychoanaly* or psycho-analy* or psycho-therap* or ipt or
mact or popmact or linehan or stepps or (crisis intervention) or
((therap* or treatment* or strateg* or approach* or system* or
intervention* or program* or oriented or focus* or framework) within 2
(analytic or autogenic or behavi*r* or bio-cognitive or biocognitive or
brief or dynamic* or cognitive or client cent*red or outpatient or
individual or validation or day patient or dialectic* or eclectic or
expressive or family or inpatient or insight or intensive or
interpersonal or interpretive or long term or longterm or intermittent
or
manuali?ed or mentali?ation or partial hospitali?ation or psychodynamic*
or psycho-dynamic* or supportive or talk* or time limited or short term
or transference or framework or psychoeducational or psychological or
psychosocial)))))

### Cost-effectiveness search

Last Search Query: ((DE="Borderline personality disorder") or
(DE="Personality disorders") or (otherwise specified) or (axis ii) or
(behavi*ral dyscontrol) or bpc or (cluster b) or (borderline and
(personality or disorder*)) or (severe personality dysfunction) or
(unstable personality) or ((dissocial or dramatic or emotional* or
erratic or flamboyant or impulsivity or instability) within 3
(personality or disorder*))) and ((cost* or economic* or qaly*) or
(quality adjusted))

## CareData

1993 onwards
Electronic Library for Social Care

Borderline in ti
Borderline in ab
Personality disorder not borderline in ti
Personality disorder not borderline in ab

## Cochrane Library (CDSR and CENTRAL)

Issue 1, 2005
Wiley version

Borderline in All Fields and personality in All Fields

## Dissertation Abstracts

1861 onwards
ProQuest

Borderline personality and (therapy or treatment or psychotherapy)
Borderline personality and (cost* or economic* or qaly* or quality adjusted)

## EconLIT

1969 onwards
SilverPlatter WebSPIRS Version 4.3

#1 borderline and (personality or disorder*)

## EMBASE

1980 onwards
SilverPlatter WebSPIRS Version 4.3

### Clinical effectiveness search

#44 #18 and #43
#43 #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 or #39 or #42
#42 #40 near2 #41

#41 analytic or autogenic or behavio?r* or bio-cognitive or biocognitive or brief or dynamic* or cognitive or client cent?red or outpatient or individual or validation or day patient or dialectic* or eclectic or expressive or family or inpatient or insight or intensive or interpersonal or interpretive or long term or longterm or intermittent or manuali?ed or mentali?ation or partial hospitali?ation or psychodynamic* or psycho-dynamic* or supportive or talk* or time limited or short term or transference or framework or psychoeducational or psychological or psychosocial
#40 therap* or treatment* or strateg* or approach* or system* or intervention* or program* or oriented or focus* or framework
#39 crisis intervention*
#38 counsel*
#37 stepps
#36 popmact
#35 linehan
#34 mact
#33 ipt
#32 psychoanaly* or psycho-analy*
#31 henderson hospital*
#30 therapeutic communit*
#29 democratic near2 communit*
#28 dbt
#27 cbt
#26 cat
#25 boscot
#24 psychotherap* or psycho-therap*
#23 'counseling-' / all subheadings in DEM,DER,DRM,DRR
#22 explode 'psychodynamics-' / all subheadings in DEM,DER,DRM,DRR
#21 'psychological-and-psychiatric-procedures-techniques-and-concepts' / all subheadings in DEM,DER,DRM,DRR
#20 'psychoanalysis-' / all subheadings in DEM,DER,DRM,DRR
#19 explode 'psychotherapy-' / all subheadings in DEM,DER,DRM,DRR
#18 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17
#17 instability near3 (personality or disorder*)
#16 impulsivity near3 (personality or disorder*)
#15 flamboyant near3 (personality or disorder*)
#14 erratic near3 (personality or disorder*)
#13 emotional* near3 (personality or disorder*)
#12 dramatic near3 (personality or disorder*)
#11 dissocial near3 (personality or disorder*)
#10 unstable personality
#9 severe personality dysfunction
#8 borderline and (personality or disorder*)
#7 cluster b
#6 bpc
#5 behavio?ral dyscontrol
#4 axis ii
#3 otherwise specified
#2 'personality-disorder' / all subheadings in DEM,DER,DRM,DRR
#1 'borderline-state' / all subheadings in DEM,DER,DRM,DRR

### Cost-effectiveness search

#20 #18 and #19
#19 explode 'economic-aspect' / all subheadings in DEM,DER,DRM,DRR
#18 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17
#17 instability near3 (personality or disorder*)
#16 impulsivity near3 (personality or disorder*)
#15 flamboyant near3 (personality or disorder*)
#14 erratic near3 (personality or disorder*)
#13 emotional* near3 (personality or disorder*)
#12 dramatic near3 (personality or disorder*)
#11 dissocial near3 (personality or disorder*)
#10 unstable personality
#9 severe personality dysfunction
#8 borderline and (personality or disorder*)
#7 cluster b
#6 bpc
#5 behavio?ral dyscontrol
#4 axis ii
#3 otherwise specified
#2 'personality-disorder' / all subheadings in DEM,DER,DRM,DRR
#1 'borderline-state' / all subheadings in DEM,D

## IBSS

1951 onwards
Via BIDS (Bath Information and Data Services)

### Clinical effectiveness search

((Borderline and (personality or disorder*)) or personality disorder*) and (treatment* or therap* or psychotherapy*)

### Cost-effectiveness search

((Borderline and (personality or disorder*)) or personality disorder*) and (cost* or economic* or qaly* or quality adjusted)

## Index to Theses

1716 onwards
Expert Information

(borderline and (personality or disorder*)) or (personality disorder*)

## ISIP

1990 onwards
Web of Knowledge

### Clinical effectiveness search

#1 TS=borderline and TS=(personality or disorder*)
#2 TS=(otherwise specified or axis ii or behavio*ral dyscontrol or bpc or borderline state or cluster b or severe personality dysfunction or unstable personality or personality disorder*)
#3 TS=(dissocial* or dramatic or emotional* or erratic or flamboyant or impulsivity or instability) same TS=(personality or disorder*)
#4 #1 or #2 or #3
#5 TS=(psychotherap* or psycho-therap* or psychoanaly* or psycho-analy* or counsel*ing or boscot or cat or cbt or democratic communit* or therapeutic communit* or henderson hospital* or ipt or mact or linehan or popmact or stepps or crisis intervention)
#6 TS=(therap* or treatment*) same TS=(analytic or autogenic or behavio*r* or bio-cognitive or biocognitive or brief or dynamic* or cognitive or client cent*red or individual or validation or dialectic* or eclectic or expressive or family or group or insight or intensive or interpersonal or interpretive or long term or longterm or intermittent or manuali?ed or mentali?ation or partial hospitali?ation or psychodynamic* or psycho-dynamic* or supportive or talk* or time limited or short term or transference or framework or psychoeducational or psychological or psychosocial)
#7 #5 or #6
#8 #4 and #7

### Cost-effectiveness search

#1 TS=borderline and TS=(personality or disorder*)
#2 TS=(otherwise specified or axis ii or behavio*ral dyscontrol or bpc or borderline state or cluster b or severe personality dysfunction or unstable personality or personality disorder*)
#3 TS=(dissocial* or dramatic or emotional* or erratic or flamboyant or impulsivity or instability) same TS=(personality or disorder*)
#4 #1 or #2 or #3
#5 TS=(cost* or economic* or qaly* or quality adjusted)
#6 #4 and #5

## MEDLINE

1966 onwards
Ovid Online version 9.3

### Clinical effectiveness search

1 Borderline Personality Disorder/
2 Personality Disorders/
3 otherwise specified.tw.
4 axis ii.tw.
5 behavio?ral dyscontrol.tw.
6 BPC.tw.
7 cluster b.tw.
8 (borderline and (personality or disorder$)).tw.
9 severe personality dysfunction.tw.
10 unstable personality.tw.
11 (dissocial adj3 (personality or disorder$)).tw.
12 (dramatic adj3 (personality or disorder$)).tw.
13 (emotional$ adj3 personality disorder$).tw.
14 (erratic adj3 (personality or disorder$)).tw.
15 (flamboyant adj3 (personality or disorder$)).tw.
16 (impulsivity adj3 (personality or disorder$)).tw.
17 (instability adj3 (personality or disorder$)).tw.
18 or/1-17
19 exp Psychotherapy/
20 Psychoanalysis/
21 exp Psychological Techniques/
22 Counseling/
23 (psychotherap$ or psycho-therap$).tw.
24 boscot.tw.
25 cat.tw.
26 cbt.tw.
27 dbt.tw.
28 (democratic adj2 communit$).tw.
29 therapeutic communit$.tw.
30 henderson hospital$.tw.
31 (psychoanaly$ or psycho-analy$).tw.
32 ipt.tw.
33 mact.tw.
34 linehan.tw.
35 popmact.tw.
36 stepps.tw.
37 counsel$.tw.
38 crisis intervention.tw.
39 (therap$ or treatment$ or strateg$ or approach$ or system$ or intervention$ or program$ or oriented or focus$ or framework).tw.
40 (analytic or autogenic or behavio?r$ or bio-cognitive or biocognitive or brief or dynamic$ or cognitive or client cent?red or outpatient or individual or validation or day patient or dialectic$ or eclectic or expressive or family or inpatient or insight or intensive or interpersonal or interpretive or long term or longterm or intermittent or manuali?ed or mentali?ation or partial hospitali?ation or

psychodynamic$ or psycho-dynamic$ or supportive or talk$ or time limited or short term or transference or framework or psychoeducational or psychological or psychosocial).tw.
41 ((therap$ or treatment$ or strateg$ or approach$ or system$ or intervention$ or program$ or oriented or focus$ or framework) adj2 (analytic or autogenic or behavio?r$ or bio-cognitive or biocognitive or brief or dynamic$ or cognitive or client cent?red or outpatient or individual or validation or day patient or dialectic$ or eclectic or expressive or family or inpatient or insight or intensive or interpersonal or interpretive or long term or longterm or intermittent or manuali?ed or mentali?ation or partial hospitali?ation or psychodynamic$ or psycho-dynamic$ or supportive or talk$ or time limited or short term or transference or framework or psychoeducational or psychological or psychosocial)).tw.
42 or/19-38,41
43 18 and 42

### Cost-effectiveness search

1 Borderline Personality Disorder/
2 Personality Disorders/
3 otherwise specified.tw.
4 axis ii.tw.
5 behavio?ral dyscontrol.tw.
6 BPC.tw.
7 cluster b.tw.
8 (borderline and (personality or disorder$)).tw.
9 severe personality dysfunction.tw.
10 unstable personality.tw.
11 (dissocial adj3 (personality or disorder$)).tw.
12 (dramatic adj3 (personality or disorder$)).tw.
13 (emotional$ adj3 personality disorder$).tw.
14 (erratic adj3 (personality or disorder$)).tw.
15 (flamboyant adj3 (personality or disorder$)).tw.
16 (impulsivity adj3 (personality or disorder$)).tw.
17 (instability adj3 (personality or disorder$)).tw.
18 or/1-17
19 Economics/
20 exp "Costs and cost analysis"/
21 Economic value of life/
22 exp Economics, hospital/
23 exp Economics, medical/
24 Economics, nursing/
25 exp models, economic/
26 Economics, pharmaceutical/
27 exp "Fees and charges"/
28 exp Budgets/
29 ec.fs.
30 (cost or costs or costed or costly or costing$).tw.
31 (economic$ or pharmacoeconomic$ or price$ or pricing).tw.
32 Quality-adjusted life years/
33 (qaly or qalys).af.
34 (quality adjusted life year or quality adjusted life years).af.
35 or/19-34
36 18 and 35

## NCJRSA

1975 onwards
Via CSA

### Clinical effectiveness search

(((personality disorder*) or (borderline and (personality or disorder*))) and (treatment* or therap* or psychotherap*))

### Cost-effectiveness search

((personality disorder*) or (borderline and (personality or disorder*))) and ((cost* or economic* or qaly*) or (quality adjusted))

## NHS DARE, NHS EED, HTA

Date coverage not known (approx. 1994–2005)
CRD website version

Borderline and personality

## OHE HEED

Date coverage not known
CD-ROM version

Borderline or personality

## PsycINFO

1887 onwards
SilverPlatter WebSPIRS Version 4.3

### Clinical effectiveness search

#44 #19 and #43
#43 #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 or #39 or #42
#42 #40 near2 #41
#41 analytic or autogenic or behavio?r* or bio-cognitive or biocognitive or brief or dynamic* or cognitive or client cent?red or outpatient or

individual or validation or day patient or dialectic* or eclectic or expressive or family or inpatient or insight or intensive or interpersonal or interpretive or long term or longterm or intermittent or manuali?ed or mentali?ation or partial hospitali?ation or psychodynamic* or psycho-dynamic* or supportive or talk* or time limited or short term or transference or framework or psychoeducational or psychological or psychosocial
#40 therap* or treatment* or strateg* or approach* or system* or intervention* or program* or oriented or focus* or framework
#39 crisis intervention*
#38 counsel*
#37 stepps
#36 popmact
#35 linehan
#34 mact
#33 ipt
#32 psychoanaly* or psycho-analy*
#31 henderson hospital*
#30 therapeutic communit*
#29 democratic near2 communit*
#28 dbt
#27 cbt
#26 cat
#25 boscot
#24 psychotherap* or psycho-therap*
#23 explode 'Psychotherapeutic-Processes' in MJ,MN
#22 explode 'Psychotherapeutic-Techniques' in MJ,MN
#21 'Cognitive-Therapy' in MJ,MN
#20 explode 'Psychotherapy-' in MJ,MN
#19 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18
#18 instability near3 (personality or disorder*)
#17 impulsivity near3 (personality or disorder*)
#16 flamboyant near3 (personality or disorder*)
#15 erratic near3 (personality or disorder*)
#14 emotional* near3 (personality or disorder*)
#13 dramatic near3 (personality or disorder*)
#12 dissocial near3 (personality or disorder*)
#11 unstable personality
#10 severe personality dysfunction
#9 borderline and (personality or disorder*)
#8 cluster b
#7 bpc
#6 behavio?ral dyscontrol
#5 axis ii
#4 otherwise specified
#3 'Personality-Disorders' in MJ,MN
#2 'Borderline-States' in MJ,MN
#1 'Borderline-Personality' in MJ,MN

### Cost-effectiveness search

#19 and #20
#20 cost* or economic* or qaly* or quality adjusted
#19 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18
#18 instability near3 (personality or disorder*)
#17 impulsivity near3 (personality or disorder*)
#16 flamboyant near3 (personality or disorder*)
#15 erratic near3 (personality or disorder*)
#14 emotional* near3 (personality or disorder*)
#13 dramatic near3 (personality or disorder*)
#12 dissocial near3 (personality or disorder*)
#11 unstable personality
#10 severe personality dysfunction
#9 borderline and (personality or disorder*)
#8 cluster b
#7 bpc
#6 behavio?ral dyscontrol
#5 axis ii
#4 otherwise specified
#3 'Personality-Disorders' in MJ,MN
#2 'Borderline-States' in MJ,MN
#1 'Borderline-Personality' in MJ,MN

## PUBMED

September 2004 onwards
Version not known

### Clinical effectiveness search

#5 Search #3 and #4 Limits: 180 Days
#4 Search treatment* or therap* or psychotherap* or psycho-therap*
#3 Search #1 or #2
#2 Search personality disorder*
#1 Search borderline and (personality or disorder*)

### Cost-effectiveness search

#5 Search #3 and #5 Limits: 180 Days
#4 Search cost* or economic* or qaly* or quality adjusted
#3 Search #1 or #2
#2 Search personality disorder*
#1 Search borderline and (personality or disorder*)

## SSA

1980 onwards
Via CSA

### Clinical effectiveness search

(((personality disorder*) or (borderline and (personality or disorder*))) and (treatment* or therap* or psychotherap*))

### Cost-effectiveness search

((personality disorder*) or (borderline and (personality or disorder*))) and ((cost* or economic* or qaly*) or (quality adjusted))

## Soc Abs

1963 onwards
Via CSA

### Clinical effectiveness search

(((personality disorder*) or (borderline and (personality or disorder*))) and (treatment* or therap* or psychotherap*))

### Cost-effectiveness search

((personality disorder*) or (borderline and (personality or disorder*))) and ((cost* or economic* or qaly*) or (quality adjusted))

## UKOP

1980 onwards
The Stationery Office

Borderline or personality

## WOS

1981 onwards
WOK

### Clinical effectiveness search

#1 TS=borderline and TS=(personality or disorder*)
#2 TS=(otherwise specified or axis ii or behavio*ral dyscontrol or bpc or borderline state or cluster b or severe personality dysfunction or unstable personality or personality disorder*)
#3 TS=(dissocial* or dramatic or emotional* or erratic or flamboyant or impulsivity or instability) same TS=(personality or disorder*)
#4 #1 or #2 or #3
#5 TS=(psychotherap* or psycho-therap* or psychoanaly* or psycho-analy* or counsel*ing or boscot or cat or cbt or democratic communit* or therapeutic communit* or henderson hospital* or ipt or mact or linehan or popmact or stepps or crisis intervention)
#6 TS=(therap* or treatment*) same TS=(analytic or autogenic or behavio*r* or bio-cognitive or biocognitive or brief or dynamic* or cognitive or client cent*red or individual or validation or dialectic* or eclectic or expressive or family or group or insight or intensive or interpersonal or interpretive or long term or longterm or intermittent or manuali?ed or mentali?ation or partial hospitali?ation or psychodynamic* or psycho-dynamic* or supportive or talk* or time limited or short term or transference or framework or psychoeducational or psychological or psychosocial)
#7 #5 or #6
#8 #4 and #7

### Cost-effectiveness search

#1 TS=borderline and TS=(personality or disorder*)
#2 TS=(otherwise specified or axis ii or behavio*ral dyscontrol or bpc or borderline state or cluster b or severe personality dysfunction or unstable personality or personality disorder*)
#3 TS=(dissocial* or dramatic or emotional* or erratic or flamboyant or impulsivity or instability) same TS=(personality or disorder*)
#4 #1 or #2 or #3
#5 TS=(cost* or economic* or qaly* or quality adjusted)
#6 #4 and #5

# Appendix 3

## Evidence tables for BPD studies

This appendix contains the evidence tables with data extracted from the 10 studies included in this review.

***TABLE 17*** *Studies included in the review*

| Study | Funding, location | Intervention | Study type | Patient population |
|---|---|---|---|---|
| Bateman and Fonagy, 1999[51] | NR, UK | Partial hospitalisation (MBT) | RCT | Patients with severe parasuicidal BPD |
| Koons *et al.*, 2001[52] | VA Research Advisory Group grant, USA | DBT | RCT | Women Veterans with BPD |
| Linehan *et al.*, 1991[53] | Grant MH34486, National Institute of Mental Health, Bethesda, USA | DBT | RCT | Chronically parasuicidal women with BPD |
| Linehan *et al.*, 1999[54] | Grant DA08674, National Institute of Drug Abuse, Bethesda, USA | DBT | RCT | Substance-abusing women with BPD |
| Linehan *et al.*, 2002[55] | Grant DA 08674, National Institute of Drug Abuse, National Institute of Health, USA | DBT | RCT | Heroin-dependent women with BPD |
| Munroe-Blum and Marziali, 1995[56] | Ontario Mental Health Foundation; Grant 88-87-89, grants 6606-4232-MH and 6606-4232-64, National Health Research and Development Program, Canada | Time-limited IGP | RCT | Patients with BPD |
| Turner, 2000[57] | NR, USA | DBT-orientated therapy | RCT | Patients with BPD |
| Tyrer *et al.*, 2003[58] | Medical Research Council, UK | MACT | RCT | Patients with recurrent DSH (including BPD) |
| van den Bosch et al., 2002[59] (Verheul *et al.*, 2003[64]) | Province of Noord-Holland and ZAO Health Insurance Company in Amsterdam, The Netherlands | DBT | RCT | Female BPI with or without comorbid substance abuse |
| Wilberg *et al.*, 1998[60] | Norwegian Research Council, S and JP Sommer's Foundation and Maja-Jonn-Nilsen's Foundations | Group psychotherapy | Non-random controlled study (naturalistic follow-up study) | Patients with BPD |

***TABLE 18*** *Study characteristics: RCTs*

| Study | Description of psychotherapy | Study quality | Co-therapy or medication | Comparator | Sample size |
|---|---|---|---|---|---|
| Bateman and Fonagy, 1999[51] | MBT consisted of: (1) once-weekly individual psychoanalytical psychotherapy; (2) thrice-weekly group analytical psychotherapy; (3) once-a-week expressive therapy orientated towards psychodrama techniques; (4) a weekly community meeting; (5) once-a-month meeting with case administrator; (6) medication review by the resident psychiatrist | Randomisation method: NR<br>Blinded assessment: NR<br>Power calculation: NR<br>Loss to follow-up: yes<br>*Lackner Quality Rating Scale items*<br>Patient selection: 12/14<br>Intervention: 4/8<br>Outcome measurement: 7/12<br>Data presentation and statistical analysis: 6/12<br>Investigator: 0/4<br>Miscellaneous: 5/8<br>Total: 34/58 | Antidepressants and antipsychotic drugs prescribed as appropriate; polypharmacy was discouraged. Unclear whether this relates to both groups | TAU: (1) regular psychiatric review with a senior psychiatrist when necessary; (2) inpatient admission as appropriate; (3) outpatient and community follow-up (every 2 weeks by a community psychiatric nurse) | Randomised: $n = 44$ (MBT $n = 22$, TAU $n = 22$)<br>Analysed: $n = 38$ (MBT $n = 19$, TAU $n = 19$) |
| Koons *et al.*, 2001[52] | DBT based on balance and synthesis of acceptance of the patient as he/she is currently, using validation strategies, with the attempt to get the patient to change, using behaviour therapy strategy (for details see Linehan *et al.*, 1991[53]) | Randomisation method: computerised random number generation<br>Blinded assessment: NR<br>Power calculation: yes<br>Loss to follow-up: yes<br>*Lackner Quality Rating Scale items*<br>Patient selection: 12/14<br>Intervention: 4/8<br>Outcome measurement: 8/12<br>Data presentation and statistical analysis: 8/12<br>Investigator: 2/4<br>Miscellaneous: 3/8<br>Total: 37/58 | Pharmacotherapy: SSRIs, mood stabiliser and/or low-dose neuroleptic | TAU: 60 minutes of weekly individual therapy with a clinician. Patients were also offered one or more of several supportive and psychoeducational groups that they could attend | Randomised $n = 28$ (DBT $n = 13$, TAU $n = 15$)<br>Analysed: $n = 20$ (DBT $n = 10$, TAU $n = 10$) |

*continued*

***TABLE 18*** *Study characteristics: RCTs (cont'd)*

| Study | Description of psychotherapy | Study quality | Co-therapy or medication | Comparator | Sample size |
|---|---|---|---|---|---|
| Linehan *et al.*, 1991[53] | DBT is a manualised 12-month treatment that combines four modules: (1) weekly individual cognitive behavioural psychotherapy sessions with the primary therapist; (2) weekly skills training groups lasting for 2–2.5 h per session; (3) weekly supervision and consultation meetings for the therapists; and (4) telephone consultation, where patients are encouraged to obtain coaching in the appliance of new effective skills by telephoning their primary therapists either during or outside office hours. Individual therapy focuses primarily on motivational issues, including the motivation to stay alive and to stay in treatment. Group therapy teaches self-regulation and change skills, and self and other acceptance skills. Among the central principles is DBT's simultaneous focus on applying both acceptance and validation strategies and change (behavioural) strategies to achieve a synthetic (dialectical) balance in patient functioning | Randomisation method: participants were matched on the number of lifetime parasuicides and psychiatric hospitalisation, age and good vs poor clinical prognosis<br>Blinded assessment: blind independent assessor<br>Power calculation: NR<br>Loss to follow-up: yes<br>*Lackner Quality Rating Scale items*<br>Patient selection: 9/14<br>Intervention: 4/8<br>Outcome measurement: 9/12<br>Data presentation and statistical analysis: 6/12<br>Investigator: 2/4<br>Miscellaneous: 4/8<br>Total: 34/58 | Participants had to terminate other individual psychotherapies and taper off psychotropic medication (antidepressants, neuroleptics, anxiolytics, anticonvulsants, sedatives, lithium) | TAU: control participants were given alternative therapy referrals, usually by the original referral source, from which they could choose | Randomised: $n = 63$ (DBT $n = 32$, TAU $n = 31$)<br>Analysed: $n = 44$ (DBT $n = 22$, TAU $n = 22$)<br>Followed up: $n = 39$ (DBT $n = 19$, TAU $n = 20$) |

*continued*

***TABLE 18*** *Study characteristics: RCTs (cont'd)*

| Study | Description of psychotherapy | Study quality | Co-therapy or medication | Comparator | Sample size |
|---|---|---|---|---|---|
| Linehan *et al.*, 1999[54] | DBT with replacement medication. "Several modifications and additions were added to standard DBT for use with substance abusing population. A new set of "attachment strategies" were added to DBT. These strategies consisted of a set of organised interventions designed to increase the positive balance of therapy and the therapist, as well as to reach out to and brick back 'lost' patients." A 'transitional maintenance' replacement medication pharmacotherapy protocol was added for individuals with stimulant or opiate dependence | Randomisation method: participants were matched on age, severity of drug dependence, readiness to change and global adjustment<br>Blinded assessment: blind independent assessor<br>Power calculation: NR<br>Loss to follow-up: Yes<br>*Lackner Quality Rating Scale items*<br>Patient selection: 12/14<br>Intervention: 4/8<br>Outcome measurement: 8/12<br>Data presentation and statistical analysis: 8/12<br>Investigator: 2/4<br>Miscellaneous: 6/8<br>Total: 40/58 | Several modifications and additions were added to standard DBT for use with substance-abusing population<br>Four months of drug maintenance (to provide time for skills acquisition), 4 months of drug tapering (for skills strengthening) and 4 months of no drug replacement (for skills generalisation). Illicit stimulants were replaced with methadone. The maximum dose of methylphenidate given was 20 mg daily, and the maximum dose of methadone given was 70 mg daily | TAU participants were either referred to alternative substance abuse and/or mental health counsellors and programmes in the community, or allowed to continue with their individual psychotherapists if they were receiving service at the time of pretreatment assessment | $n = 28$ (DBT $n = 12$, TAU $n = 16$) |

*continued*

***TABLE 18*** *Study characteristics: RCTs (cont'd)*

| Study | Description of psychotherapy | Study quality | Co-therapy or medication | Comparator | Sample size |
|---|---|---|---|---|---|
| Linehan *et al.*, 2002[55] | DBT for substance abusers. Treatment requires a synthesis of validation to strengthen self-trust validation, reduce fear of self-generated (intrinsically motivated) response patterns, and maintain working alliance, behaviour therapy to teach emotional regulation, self-validation and skilful responses to problems in living, and to extinguish or punish BPD behaviours (including illicit drug use), and dialectics to counteract rigid and extreme response patterns | Randomisation method: participants were matched on severity, drug dependence, presence/absence of PD and global assessment of functioning<br>Blinded assessment: blind independent assessor<br>Power calculation: NR<br>Loss to follow-up: yes<br>*Lackner Quality Rating Scale items*<br>Patient selection: 11/14<br>Intervention: 4/8<br>Outcome measurement: 8/12<br>Data presentation and statistical analysis: 8/12<br>Investigator: 4/4<br>Miscellaneous: 6/8<br>Total: 41/58 | Opiate-replacement medication: LAAM (methadone alternative); dosing: 90/90/130 mg; the maximum schedule was 110/110/180 mg | CVT+12S requires a synthesis of validation to strengthen self-trust, reduce fear of self-generated response patterns, decrease arousal, increase the experience of control, and maintain working alliance and fellowship of similar community such as 12-Step to validate both sense of self and recovery | $n = 23$ (DBT $n = 11$, CVT+12S $n = 12$) |
| Munroe-Blum and Marziali, 1995[56] | IGP based on manualised training procedure; its strategies reflect an interpersonal group treatment approach geared to addressing a central feature of the BPD | Randomisation method: randomised over five waves (unclear)<br>Blinded assessment: independent assessor<br>Power calculation: yes<br>Loss to follow-up: yes<br>*Lackner Quality Rating Scale items*<br>Patient selection: 11/14<br>Intervention: 4/8<br>Outcome measurement: 7/12<br>Data presentation and statistical analysis: 6/12<br>Investigator: 2/4<br>Miscellaneous: 4/8<br>Total: 34/58 | NR | Individual psychodynamic psychotherapy consisting of open-ended, individual, dynamic psychotherapy; the typical model of treatment offered to patients with BPD | Randomised $n = 79$ (IGP $n = 38$, individual $n = 41$)<br>Analysed: $n = 48$ (IGP $n = 22$; individual $n = 26$) |

*continued*

***TABLE 18*** *Study characteristics: RCTs (cont'd)*

| Study | Description of psychotherapy | Study quality | Co-therapy or medication | Comparator | Sample size |
|---|---|---|---|---|---|
| Turner, 2000[57] | DBT-orientated therapy which had two modifications made to Linehan's DBT approach: (1) psychodynamic techniques were incorporated to conceptualise the patient's behavioural, emotional and cognitive relationship schema; (2) in order to keep treatment conditions equal with regard to clinical contact hours, the authors did not run a separate DBT skills training group, but provided skills during the course of individual therapy | Randomisation method: NR<br>Blinded assessment: blind independent assessor<br>Power calculation: NR<br>Loss to follow-up: none<br>*Lackner Quality Rating Scale items*<br>Patient selection: 12/14<br>Intervention: 4/8<br>Outcome measurement: 8/12<br>Data presentation and statistical analysis: 8/12<br>Investigator: 0/4<br>Miscellaneous: 5/8<br>Total: 37/58 | 19 patients were taking prescribed psychotropic medications at the beginning of the study. There was no consistent pattern of medication types | CCT based on Carnuff's models of CCT, emphasising emphatic understanding of the patient's sense of aloneness and providing a supportive atmosphere for individuation. CCT did not use a structured agenda. Instead, therapists instructed patients to express what was on their minds at each session | *n* = 24<br>(DBT *n* = 12, TAU *n* = 12) |
| Tyrer *et al.*, 2003[58] | MACT is 70-page booklet, offering up to seven treatment sessions with a therapist who has been trained in advance in the MACT methods | Randomisation method: stratified by centre and baseline parasuicide risk score and allocated randomly by telephone/fax<br>Blinded assessment: NR<br>Power calculation: yes<br>Loss to follow-up: yes<br>*Lackner Quality Rating Scale items*<br>Patient selection: 12/14<br>Intervention: 4/8<br>Outcome measurement: 8/12<br>Data presentation and statistical analysis: 12/12<br>Investigator: 2/4<br>Miscellaneous: 4/8<br>Total: 42/58 | NR | TAU patients normally receive an initial psychiatric assessment followed by psychiatric outpatient care, occasional day-patient care or referral back to the GP, depending on the arrangements of the hospital. If patients were already under psychiatric care any further treatment was permitted, apart from MACT | *n* = 480<br>(MACT *n* = 239, TAU *n* = 241)<br>Of these,<br>PD *n* = 391,<br>BPD *n* = 67 |

*continued*

***TABLE 18*** *Study characteristics: RCTs (cont'd)*

| Study | Description of psychotherapy | Study quality | Co-therapy or medication | Comparator | Sample size |
|---|---|---|---|---|---|
| van den Bosch *et al.*, 2002[59] | DBT (for details see Linehan *et al.*, 1991[53]) | Randomisation method: minimisation method matched by age, alcohol, drug and social problems<br>Blinded assessment: independent assessors[a]<br>Power calculation: NR<br>Loss to follow-up: yes<br>*Lackner Quality Rating Scale items*<br>Patient selection: 12/14<br>Intervention: 4/8<br>Outcome measurement: 8/12<br>Data presentation and statistical analysis: 9/12<br>Investigator: 2/4<br>Miscellaneous: 5/8<br>Total: 40/58 | Three-quarters of the patients reported use of medication from one or more of the following categories: benzodiazepines, SSRIs (DBT 52%, TAU 61%), tricyclic antidepressants, mood stabilisers and neuroleptics | TAU consisted of clinical management from the original referral source (addiction treatment centres $n = 11$, psychiatric services $n = 20$). Patients attended no more than two sessions per month with a psychologist, a psychiatrist or a social worker | Randomised: $n = 58$ (DBT $n = 27$, TAU $n = 31$)<br>Analysed: $n = 47$ (DBT $n = 23$, TAU $n = 24$) |

[a] Independent assessors were not informed about the treatment condition of the interviewees; however, patients might have given the information about treatment.
LAAM, levo-alpha acetyl methadol; SSRI, selective serotonin reuptake inhibitors.

***TABLE 19*** *Study characteristics: non-RCT*

| Study | Description of psychotherapy | Study quality | Co-therapy or medication | Comparator | Sample size |
|---|---|---|---|---|---|
| Wilberg *et al.*, 1998[60] | Day hospital treatment and, postdischarge, group analytical therapy. The day treatment programme consists of a combination of individual and group psychotherapies and pharmacotherapy, conducted in accordance with therapeutic community principles. The subsequent outpatient group therapy was conducted in accordance with group analytical principles | Comparator and dropouts described. Baseline comparability not justified. Analyses done retrospectively<br>*Lackner Quality Rating Scale items*<br>Patient selection: 9/14<br>Intervention: 4/8<br>Outcome measurement: 8/12<br>Data presentation and statistical analysis: 3/12<br>Investigator: 2/4<br>Miscellaneous: 4/8<br>Total: 30/58 | NR | Day hospital treatment and, postdischarge, TAU "ranging from no treatment to psychotherapy twice weekly" | $n = 43$ (treatment group $n = 12$, control group $n = 31$) |

***TABLE 20*** *Therapy details: RCTs*

| Study | Recruitment | Number of sessions | Length of sessions | Therapist contact between sessions | Professional background of therapist |
|---|---|---|---|---|---|
| Bateman and Fonagy, 1999[51] | Patients from general psychiatric services referred during 1993 and 1994 | (1) Once-weekly individual psychoanalytical psychotherapy; (2) thrice-weekly group analytical psychotherapy; (3) once-a-week expressive therapy orientated towards psychodrama techniques; (4) a weekly community meeting; (5) once-a-month meeting with case administrator; (6) medication review by the resident psychiatrist | (1) 1 hour; (2) 1 hour each; (3) 1 hour; (4) 1 hour; (5) 1 hour. The average length of stay was 1.45 years<br>TAU: (1) regular psychiatric, review by senior psychiatrist when necessary (twice per week); (2) inpatient admission as appropriate (admission rate 90%, average stay 11.6 days); (3) outpatient and community follow-up (visit every 2 weeks by a community psychiatrist) | Partial hospitalisation: therapies and patient–staff contact were organised in accordance with the psychoanalytical model | All therapy was given by psychiatric nurses who were members of the partial hospitalisation programme's team, but who had no formal psychotherapy qualification |
| Koons *et al.*, 2001[52] | Durham VA Medical Centre and Veterans Readjustment and Counselling Centre in one case | DBT: weekly for 6 months;<br>TAU: weekly individual therapy for 6 months | DBT: 90 minutes/week;<br>TAU: 60 minutes per week | Telephone calls with the primary therapist (when needed) | DBT: psychiatrist, two psychologists, a clinical social worker and a clinical nurse specialist in psychiatry. Clinicians had a mean of 8.2 years of clinical experience. All except one attended intensive training in DBT<br>TAU: three psychologists, two resident psychiatrists, two clinical social workers and a clinical nurse specialist in psychiatry. They had a mean of 10.6 years of clinical experience. Four described themselves as cognitive behavioural, two as psychodynamic and two as eclectic in their primary orientation |

*continued*

***TABLE 20*** *Therapy details: RCTs (cont'd)*

| Study | Recruitment | Number of sessions | Length of sessions | Therapist contact between sessions | Professional background of therapist |
|---|---|---|---|---|---|
| Linehan *et al.*, 1991[53] | Participants were clinically referred and voluntarily enrolled in the study | DBT: individual therapy was scheduled for weekly 1-hour session. Group therapy was scheduled once each week for 2.5 hours (for 1 year); control group: NR | Individual session 1-hour; group session 2.5 hours | Telephone contact with the individual therapist between sessions was part of DBT. The group therapist did not accept telephone calls from patients, and patient crises were referred to the individual therapist | Experienced graduate psychology students, therapists with master's level training and clinical psychologists |
| Linehan *et al.*, 1999[54] | Participants were referred to the programme by area clinicians | Weekly individual psychotherapy (1 hour), group skills training session (2 hours plus a 15-minute wind-down) (for 1 year) | Individual session 1-hour; group session 2 hours plus a 15-minute wind-down | Skills coaching telephone calls with the primary therapist (when needed) | DBT: two psychologists, one psychiatrist and two master's level clinicians<br>TAU: of 15 therapists interviewed, five were psychotherapists, eight master's level therapists and two had no or unknown health degree (two behavioural, three cognitive, five CCT or supportive, one psychodynamic, one eclectic) |

*continued*

***TABLE 20*** *Therapy details: RCTs (cont'd)*

| Study | Recruitment | Number of sessions | Length of sessions | Therapist contact between sessions | Professional background of therapist |
|---|---|---|---|---|---|
| Linehan *et al.*, 2002[55] | Participants were recruited from mental health clinics, needle exchange programmes, substance abuse clinics, methadone maintenance clinics and non-profit HIV/AIDS prevention organisations treating underserved minority populations | DBT or CVT+12S plus an opiate medication for approximately 1 year (48–56 weeks) | DBT: individual DBT 40–90 minutes per week; group skills training 150 minutes per week; individual skills coaching 30 minutes per week (recommended); 12S and other supportive group meetings (recommended); DBT case management throughout 1 year (48–56 weeks)<br>CVT+12S: individual CVT+12S 40–90 minutes per week; '12-and-12' Narcotics Anonymous group 120 minute per week; 12S sponsor meeting; 12S meeting (recommended); CVT+12S case management (as needed) throughout 1 year (48–56 weeks) | Telephone consultation and crisis interventions | Five therapists (one male, four female; three DBT and two CVT+12S): two doctoral level and one master's level behaviour therapist delivered DBT, and two master's level therapists with chemical dependency certification and 12S experience delivered CVT+12S. Each therapist had a minimum of 8 month training, and had supervised training clients in their respective modalities before seeing their research clients. Therapists in each condition met weekly with supervisors to discuss case materials and review session videotapes |
| Munroe-Blum and Marziali, 1995[56] | Participants were recruited from the inpatient and outpatient psychiatry units of the teaching hospitals of a large Canadian urban university | IGP: 30 sessions of treatment (25 weekly sessions followed by five twice weekly sessions leading into termination) | Each session scheduled for 1.5 hours | NR | All therapists were trained to use IGP |

*continued*

***TABLE 20*** *Therapy details: RCTs (cont'd)*

| Study | Recruitment | Number of sessions | Length of sessions | Therapist contact between sessions | Professional background of therapist |
|---|---|---|---|---|---|
| Turner, 2000[57] | Patients from local hospital emergency services were referred to the community mental health outpatient clinic | Minimum 49 and maximum 84 sessions<br>Six group sessions were provided to patients in both treatment conditions<br>CCT: treatment was scheduled for 12 months. Sessions were scheduled twice per week when possible | NR | In CCT group during the crisis management phase, the therapist met patients as often as three times a week | Therapists conducting both treatments had an average 22 years of experience, with theoretical backgrounds in family system, client-centred and psychodynamic treatments. DBT training lasted for 3 months (12 sessions, each session lasted for 90 minutes) |
| Tyrer *et al.*, 2003[58] | Participants were recruited in nine A&E departments in five UK study centres: Glasgow, Edinburgh, Nottingham, West London and South London | Up to five sessions within 3 months after a self-harm episode, with the option of two additional booster sessions within 6 months | NR | Between sessions, the manual acts as an *aide-mémoire* and can be used for homework tasks by the patient | NR |
| van den Bosch *et al.*, 2002[59] | Referrals originated from addiction treatment services, psychiatric hospitals, centres for mental healthcare, independently working psychologists and psychiatrists, GPs and self-referral | Weekly session during 12 months | DBT: 2–2.5 hours; TAU: no more than two sessions per month (length of sessions not reported) | Telephone calls with the primary therapist (when needed) | Four psychiatrists and 12 clinical psychologists (two with master's degrees and one a PhD). Group training was conducted in three separate groups led jointly by social workers and clinical psychologists. A core group of three therapists was sent to Seattle to be trained in DBT |

***TABLE 21*** *Therapy details: non-RCT*

| Study | Recruitment | Number of sessions | Length of sessions | Therapist contact between sessions | Professional background of therapist |
|---|---|---|---|---|---|
| Wilberg *et al.*, 1998[60] | Patients being treated at the Day Unit, Ullevål University Hospital | Once a week for a mean period of 12 months (range 1–33 months) | 1.5 hours | NR | "Six of the eight therapists were in group analytical training at the time" |

***TABLE 22*** *Study site, follow-up and inclusion/exclusion criteria: RCTs*

| Study | Study site | Length of follow-up | Numbers lost to follow-up | Reasons for loss to follow-up/dropout | Inclusion criteria | Exclusion criteria |
|---|---|---|---|---|---|---|
| Bateman and Fonagy, 1999[51] | Halliwick Psychotherapy Unit, which is part of the general psychiatric services, UK (PH) | 18 months | Of 44 eligible patients, 6 dropped out during the study. No loss to follow-up in PH group and three in TAU | Within the first month three patients from the control group crossed over into the PH group after serious suicide attempt. Within 6 months three patients dropped out from the PH group (reason NR) | BPD patients who scored 7 or more on (1) SCID for DSM-III-R and (2) the Diagnostic Interview for BPD | Schizophrenia, bipolar disorder, substance misuse, mental impairment or organic brain disorder |
| Koons *et al.*, 2001[52] | Medical Centre, USA (outpatient setting) | No follow-up | Two did not attend the first appointment, one dropped out after first appointment, two in TAU and three in DBT dropped out of treatment after attending more than one session | Loss of transportation and distance from the medical centre. One dropped out when she realised she would only be paid for assessments, not for attending treatment | Women veterans who met DSM-III-R criteria for BPD | Schizophrenia, bipolar disorder, substance dependence or antisocial personality disorder |
| Linehan *et al.*, 1991[53] | Research clinic, USA (outpatient setting) | 1 year | 19 (dropouts during the treatment period)<br>Five (during 1 year of follow-up) | Ten (DBT $n = 5$, TAU $n = 5$) dropped out during pretreatment assessment; Seven (DBT $n = 3$, TAU $n = 4$) dropped out owing to refusal or inability to meet study conditions; two (DBT) quit after four or fewer sessions | (1) Scored at least 7, out of a maximum of 10, on the DIB; (2) Met DMS-III criteria for BPD; (3) had at least two incidences of parasuicide in the past 5 years, with one during the past 8 weeks; (4) women aged 18–45 years | Men; parents who met DSM-III criteria for schizophrenia, bipolar disorder, substance dependence or mental retardation |
| Linehan *et al.*, 1999[54] | Research clinic, USA (outpatient setting) | 16 months (4 months post-treatment) | 12 | Six (DBT $n = 1$, TAU $n = 5$ ) participants dropped before or immediately after pretreatment assessment; two (DBT) participants dropped out by the sixth session; two (DBT) provided no data after pretreatment; one dropped out of treatment after the sixth session; one died of accidental drug overdose during the 4-month assessment | Participants who met criteria for BPD on both PDE and the SCID-II and met criteria for substance use disorder for opiates, cocaine, amphetamines, sedatives, hypnotics, anxiolytics or polysubstance use disorder on the SCID | Participants who met criteria for schizophrenia and other psychotic disorder, or bipolar mood disorder on the SCID, or mental retardation on the Peabody Picture Vocabulary Test–Revised |

*continued*

***TABLE 22*** *Study site, follow-up and inclusion/exclusion criteria: RCTs (cont'd)*

| Study | Study site | Length of follow-up | Numbers lost to follow-up | Reasons for loss to follow-up/dropout | Inclusion criteria | Exclusion criteria |
|---|---|---|---|---|---|---|
| Linehan *et al.*, 2002[55] | Research clinic, USA (outpatient setting) | 16 months (4 months post-treatment) | DBT: 36% loss to follow up<br>CVD+12S: no loss to follow-up | NR | (1) Women aged 18–45 years; (2) diagnosis of BPD according to two structured interviews: PDE and SCID-II; (3) diagnosis of current opiate dependence according to SCID-I | Bipolar disorder, psychosis, seizure disorder, or mental retardation; pregnancy or any other medical condition in which the use of opiate-replacement medication was contraindicated; indications of coercion (e.g. court ordered/agency ordered to retain housing) |
| Munroe-Blum and Marziali, 1995[56] | Outpatient hospitals, Canada (outpatient setting) | 24 months | 31 withdrew at the point of randomisation | NR | (1) Men and women aged 18–65 years; (2) had at least one prior psychiatric contact and met BPD criteria on the DIB, cut-off score ≥7 | Language difficulty; neurological impairment or mental retardation; a primary diagnosis of alcohol or drug addiction; physical disorders with known psychiatric consequences |
| Turner, 2000[57] | Outpatient clinic, USA (outpatient setting) | 12 months | DBT: $n = 4$,<br>CCT: $n = 6$ | NR (one patient in DBT group returned after 5-weeks break) | (1) Met diagnostic criteria for BPD; (2) gave informed consent; (3) accepted random assignment | Schizophrenia, schizoaffective disorder, bipolar disorder, organic mental disorder or mental retardation |
| Tyrer *et al.*, 2003[58] | Patients from the hospitals in Glasgow, Edinburgh, Nottingham, West London and South London between May 1988 and April 2000, UK (outpatient setting) | 12 months | MACT $n = 40$,<br>TAU $n = 38$ | MACT TAU<br>$n = 3$ $n = 5$ died<br>$n = 14$ $n = 13$ not traced<br>$n = 9$ $n = 10$ refused assessment<br>$n = 4$ $n = 0$ withdrew<br>$n = 3$ $n = 6$ did not attend<br>$n = 7$ $n = 4$ other reason | (1) Patients who had had a previous episode of DSH; (2) gave informed written consent; (3) did not require inpatient psychiatric treatment; (4) aged between 16 and 65 years, (5) presented to A&E after an episode of DSH | Psychotic or bipolar disorder; primary diagnosis of substance dependence; insufficient knowledge of English; temporary residence |

*continued*

***TABLE 22*** *Study site, follow-up and inclusion/exclusion criteria: RCTs (cont'd)*

| Study | Study site | Length of follow-up | Numbers lost to follow-up | Reasons for loss to follow-up/dropout | Inclusion criteria | Exclusion criteria |
|---|---|---|---|---|---|---|
| van den Bosch *et al.*, 2002[59] | Jellinek Addiction Treatment Centre in Amsterdam, The Netherlands (outpatient setting) | 18 months | Of 58 eligible patients, six dropped out during the study | DBT: $n = 4$ refused to start treatment<br>TAU: $n = 2$ did not accept TAU condition | (1) Met DSM-IV criteria for BPD; (2) currently in outpatient psychiatric or substance abuse treatment; (3) women aged 18–70 years; (4) residence within 40-km circle around Amsterdam | DSM-IV criteria for bipolar disorder or (chronic) psychotic disorder; insufficient command of Dutch language; severe cognitive impairments |

***TABLE 23*** *Study site, follow-up and inclusion/exclusion criteria: non-RCT*

| Study | Study site | Length of follow-up | Numbers lost to follow-up | Reasons for loss to follow-up/dropout | Inclusion criteria | Exclusion criteria |
|---|---|---|---|---|---|---|
| Wilberg *et al.*, 1998[60] | Day Psychiatric Unit in University Hospital, Oslo, Norway | An average of 34 months postdischarge from day hospital | None. Retrospective study | NR | Met DSM-III/DSM-IIIR criteria for BPD | Patients with schizotypal personality disorder; patients who had stayed for less than 3 weeks at the day hospital |

***TABLE 24*** *Patient characteristics: RCTs*

| Study | Methods for diagnosis of disorder | Age (years) | Gender | Ethnicity | Education/socio-economic background | Patient history | Baseline comparability |
|---|---|---|---|---|---|---|---|
| Bateman and Fonagy, 1999[51] | (1) SCID for DSM-III;<br>(2) Diagnostic Interview for BPD | 16–65 | F *n* = 22<br>M *n* = 16 | NR | College: PH *n* = 7, TAU *n* = 3<br>Unemployed: PH *n* = 19, TAU *n* = 19<br>Single: PH *n* = 17, TAU *n* = 16<br>Sheltered accommodation: PH *n* = 3, TAU *n* = 2<br>With family of origin: PH *n* = 6, TAU *n* = 3<br>Alone: PH *n* = 10, TAU *n* = 14 | Early maternal loss: PH *n* = 10, TAU *n* = 14<br>Reported sexual abuse: PH *n* = 7, TAU *n* = 8<br>Reported rape: PH *n* = 5, TAU *n* = 2<br>Reported physical abuse: PH *n* = 9, TAU *n* = 8 | There were no significant differences on any of the baseline measures between the two groups |
| Koons *et al.*, 2001[52] | BPD and antisocial personality disorder sections of the SCID-II for DSM-III-R for Axis II, and the substance abuse, bipolar disorder, and schizophrenia sections of the SCID for DSM-III-R for Axis II | Mean 35 (21–46) | F | Caucasian 75%; African–American 25% | College 80%; bachelor's degree or equivalent 20%; income >$20,000 pa 70%; lives with partner 55% | 75% had a lifetime history of parasuicide, defined as any intentional self-injury, including suicide attempts; 40% reported parasuicidal behaviour in the 6 months before the study. 55% had at least one lifetime psychiatric admission; 25% had an inpatient psychiatric admission in the past 6 months. All had at least one psychiatric outpatient visit in the previous 6 months. 25% met criteria for substance abuse, but not dependence; 60% reported sexual abuse before the age of 13, 65% reported being battered by a partner and 85% reported being raped as an adult, 46% while on active military duty | None of the variables differed significantly between groups |

*continued*

***TABLE 24*** *Patient characteristics: RCTs (cont'd)*

| Study | Methods for diagnosis of disorder | Age (years) | Gender | Ethnicity | Education/socio-economic background | Patient history | Baseline comparability |
|---|---|---|---|---|---|---|---|
| Linehan *et al.*, 1991[53] | (1) Scored at least 7 out of a maximum of 10 on the DIB; (2) DMS-III criteria for BPD; (3) had at least two incidences of parasuicide in the past 5 years, with one during the past 8 weeks | 18–45 | F | NR | NR | Patients with a history of parasuicide and psychiatric hospitalisation on the ground of BPD | Participants were matched on the number of lifetime parasuicides and psychiatric hospitalisation, age, and good vs. poor clinical prognosis |
| Linehan *et al.*, 1999[54] | Participants were given a screening interview that included SCID for DSM-III and the PDE | Mean 30.4±6.6 (18–45) | F | European 78%; African–American 7%; Latina 4%; other 11% | High school graduate 22%, college graduate 63%; income: <$5000 54%, $5000–19.999 35%, $20,000 <12%; single 63% | 74% met SCID criteria for substance dependence for more than one drug, 58% for current cocaine abuse or dependence, and 52% for alcohol dependence. Eight participants primarily abused cocaine, six opiates, four marijuana, one methamphetamine, one halucinogens, and one both cocaine and methamphetamine. Participants commonly suffered Axis I non-substance use disorder (79% lifetime; 50% current) and post-traumatic stress disorder (38% current and lifetime). 12% were diagnosed with antisocial personality disorder | Participants were matched on age, severity on drug dependence (based on SCID ratings), readiness to change and global adjustment (Axis V, DSM-IV) using a minimisation random assignment procedure |

*continued*

***TABLE 24*** *Patient characteristics: RCTs (cont'd)*

| Study | Methods for diagnosis of disorder | Age (years) | Gender | Ethnicity | Education/socio-economic background | Patient history | Baseline comparability |
|---|---|---|---|---|---|---|---|
| Linehan *et al.*, 2002[55] | (1) PDE; (2) SCID-II for DSM-IV; (3) opiate dependence according to SCID-I | Mean 36.1±7.3 (18–45) | F | Caucasian 66%; African–American 26%; Mixed 4% | Divorced 52%, married 4%; never been married 44%; high school 96%; business/technical school 48%; college 4%; graduate or professional school without graduating 18%; employed 52% | Dependence on: cocaine 52%, sedatives 13%, cannabis 8.7%, alcohol 26%<br>Co-morbidity: major depressive disorder or dysthymia 39%, anxiety disorder 52%, eating disorder 18%<br>65% of the sample reported a history of at least one suicide attempt or intentional self-injury | No significant between-group differences were detected for diagnoses, level of general functioning or parasuicide acts prior to treatment |
| Munroe-Blum and Marziali, 1995[56] | DIB | 18–52 | F $n = 89$; M $n = 21$ | NR | Most had completed high school. Most were currently unmarried, but had had a prior marriage or live-in relationship. Over half had children, who often were not residing with them. Most had a history of some form of employment, albeit intermittent | One-third of the sample experienced significant behavioural and social dysfunction in the 6 months before treatment; about half had reported problems with the law and substance abuse. 85% reported problems with impulse control. All participants used mental health/social services | There were no statistically significant differences on clinical and socio-demographic factors between two groups or between patients who remained in the study and those who withdrew |
| Turner, 2000[57] | (1) 90-minute screening interview based on the DIB and SCID for DSM-III; (2) PDE to cross-validate the BPD diagnosis and determine the presence of additional Axis II disorders | 22 (18–27) | F $n = 19$; M $n = 5$ | Caucasian $n = 19$; African–American $n = 4$; Asian–American $n = 1$ | Average level of education 13.3 years (range 12–16) | 23 patients met criteria for a co-morbid Axis I disorder; eight patients had a history of brief psychotic or paranoid episodes | Baseline difference was not statistically significant, $\chi^2(1) = 2.27$, $p = 0.132$ |

*continued*

***TABLE 24*** *Patient characteristics: RCTs (cont'd)*

| Study | Methods for diagnosis of disorder | Age (years) | Gender | Ethnicity | Education/socio-economic background | Patient history | Baseline comparability |
|---|---|---|---|---|---|---|---|
| Tyrer *et al.*, 2003[58] | ICD-10 diagnostic criteria of the personality schedule | Mean 32 | M 32% | White 90% (English, Scottish, Welsh) | Marital status: single 55%, married 24%, other (divorced, separated, widowed) 21%; living alone 34%<br>Simple disorder 26%, diffuse disorder 16% | Years since first ever parasuicide 8.8 (SD 8.7) | There were no important differences in baseline characteristics between two groups and those with and without 12-month assessment |
| van den Bosch *et al.*, 2002[59] | DSM-IV diagnosis for BPD SCID-II, screening device (PDQ-4+). Substance abuse problems were assessed with EuropASI | Mean 34.9 (18–70) | F | Dutch nationality 97% | Education: DBT 12.6 years, TAU 13.6 years<br>Unemployed: DBT 26%, TAU 16%<br>Never married: DBT 56%, TAU 68%<br>Living alone: DBT 33%, TAU 39%<br>Disability pension: DBT 56%, TAU 61% | Number of BPD criteria (mean): DBT $n = 7.3$, TAU $n = 7.3$<br>History of suicide attempts: DBT $n = 70\%$, TAU $n = 71\%$<br>History of self-mutilation: DBT $n = 93\%$, TAU $n = 94\%$<br>Lifetime self-mutilation acts (median): DBT $n = 13.1$, TAU $n = 14.4$<br>Addictive problems: DBT $n = 59\%$, TAU $n = 52\%$<br>Average number of days in residential treatments in the past 4 years = 74 days per year; average number of admissions in the past 4 years ranged from four to 58 | There was no significant difference between treatment conditions on socio-demographic variables, number of DSM-IV criteria for BPD, history of suicide attempts, number of self-mutilating acts, or prevalence of clinically significant alcohol and/or drug use problems |

F, female; m, Male.

***TABLE 25*** *Patient characteristics: non-RCT*

| Study | Methods for diagnosis of disorder | Age (years) | Gender | Ethnicity | Education/socio-economic background | Patient history | Baseline comparability |
|---|---|---|---|---|---|---|---|
| Wilberg *et al.*, 1998[60] | DSM-III (DSM-III-R), HSRS, SCID-I and SCID-II | Treatment group: mean 27±5<br>Control group: mean 32±9 | Treatment group: unclear, the text states that there was only one male out of 12 in the group, but the sample characteristics table shows that 92% of the group were male<br>Control group: 71% M, (22/31) | NR | Mean number of months in work in the last year before admission: treatment group 8±3 and for the control group 7±5<br>Three of the patients in the treatment group (25%) and 20 in the control group (65%) had ever been married | Treatment group: nine patients had previous hospitalisations; nine had a history of suicide attempts; three had an anxiety disorder, eight a mood disorder and 8 a substance use disorder<br>Control group: 17 patients had previous hospitalisations; 13 had a history of suicide attempts; 13 had an anxiety disorder, 12 a mood disorder and 20 a substance use disorder | The control group was significantly younger than the treatment group ($p < 0.001$) and had less often been married ($p < 0.05$). The treatment group had a significantly longer stay in the day hospital (11 vs 6 months, $p < 0.05$) |

***TABLE 26*** *Outcomes and analysis information: RCTs*

| Study | Outcomes | Instruments | Measurement periods | ITT analysis |
|---|---|---|---|---|
| Bateman and Fonagy, 1999[51] | (1) Engaging the patients in treatments; (2) reduction in general psychiatric symptoms; (3) decrease in the number of self-destructive acts and suicide attempts; (4) improvement in social and interpersonal functions; (5) prevention of reliance on prolonged hospital stays | (1) Suicide and Self-Harm Inventory; (2) SCL-90-R; (3) BDI; (4) Spielberg State-Trait Anxiety Inventory; (5) modified SAS; (6) Inventory of Interpersonal Problems | Baseline, 3, 6, 9, 12, 15 and 18 months | No; cross-over and dropout patients were not included in the analyses |
| Koons *et al.*, 2001[52] | (1) Whether research therapist of current study could conduct DBT with adequate adherence; (2) outcomes of the DBT are superior to those of usual care in the same setting and system: parasuicide, suicidal ideation and hopelessness, mood and emotion, dissociation, psychiatric inpatient admission, BPD criteria | (1) PHI; (2) Beck Scale for Suicide Ideation; (3) BHS; (4) BDI; (5) HAM-D; (6) HARS; (7) Spielberg Anger Expression Scale; (8) DES | Pretreatment, 3 and 6 months | No |
| Linehan *et al.*, 1991[53] | (1) Parasuicide; (2) maintenance in the therapy; (3) psychiatric inpatient treatment | (1) PHI; (2) self-report form of the Scale for Suicide Ideators; (3) BDI; (4) BHS; (5) Reasons for Living Inventory, Survival and Coping Scale | Pretreatment, 4, 8 and 12 months | No |
| Linehan *et al.*, 1999[54] | (1) Adaptation of the original DBT manual for a population of substance-abusing women with BPD; (2) comparison of its efficacy to a control (TAU) condition: drug abuse; treatment initiation, exposure and retention; psychopathology | (1) Structured clinical interviews; (2) urine analyses; (3) treatment history interview; (4) PHI; (5) SHI; (6) SAS; (7) Longitudinal Interview Follow-Up Evaluation base schedule; (8) GSA; (9) GAS; (10) Spielberg State–Trait Anger Expression Inventory | Pretreatment, 4, 8, 12 and 16 months | Yes |
| Linehan *et al.*, 2002[55] | (1) Decrease in opiate dependence; (2) decrease in BPD symptoms: treatment initiation, exposure and retention; drug use outcomes; psychopathology | (1) Urine analyses<br>Interview and self-report measures: (2) TLFB; (3) PHI; (4) SHI; (5) SAS; (6) Longitudinal Interview Follow-up Evaluation; (7) GAS; (8) GSA; (9) GAF; (10) BSI | Pretreatment, 4, 8, 12 and 16 months | Yes |

*continued*

***TABLE 26*** *Outcomes and analysis information: RCTs (cont'd)*

| Study | Outcomes | Instruments | Measurement periods | ITT analysis |
|---|---|---|---|---|
| Munroe-Blum and Marziali, 1995[56] | (1) Behaviours related to social dysfunction; (2) behaviours related to social performance; (3) symptom status | (1) OBI; (2) SAS; (3) BDI; (4) HSC-90 | Baseline, 6, 12, 18 and 24 months | No |
| Turner, 2000[57] | (1) Suicide/self-harming behaviour; (2) emotional dysregulation; (3) impact of treatment indicators; (4) hospitalisation | (1) HAM-D; (2) BPRS; (3) Target Behaviour Ratings; (4) BDI; (5) BAI; (6) Beck Scale for Suicide Ideation | Pretreatment, 6 and 12 months | Yes |
| Tyrer *et al.*, 2003[58] | (1) Parasuicide events (including suicide) in the following year; (2) uptake of MACT sessions; (3) symptom improvements (DSH, anxiety, depression and social functioning) at 1 year; (4) Other outcomes | (1) HADS; (2) GAF; (3) SFQ; (4) EQ-5D; (5) CSRI; (6) PHI | Baseline, 6 and 12 months | Yes |
| van den Bosch *et al.*, 2002[59] | (1) Treatment retention; (2) high-risk behaviour, including suicidal, self-mutilating and self-damaging impulsive behaviours; (3) whether the efficacy of DBT is modified by baseline severity of parasuicide | (1) BPDSI (semi-structured interview). BPDSI consists of nine sections, one for each of the DSM-IV criteria for BPD. The parasuicide section includes three items; the impulsive section includes 11 items; (2) LPC | Baseline, 11, 12, 33, 44 and 52 weeks; 18 months follow-up | Yes |

***TABLE 27*** *Outcomes and analysis information: non-RCTs*

| Study | Outcomes | Instruments | Measurement periods | ITT analysis |
|---|---|---|---|---|
| Wilberg *et al.*, 1998[60] | Reduction of substance misuse, suicide attempts, mental state | HSRS, GSI | At admission, discharge and follow-up | No |

GSI, Global Symptom Index.

***TABLE 28*** *Results of reported outcomes (psychological symptoms and interpersonal and social functioning: RCTs*

| Study | Results | Other outcome information |
|---|---|---|
| Bateman and Fonagy, 1999[51] | (1) Spielberg Inventory score | (5) In the PH group, there was a clear reduction of suicide attempts from 94.7% on admission to 5.3% (mean 0.16) at 18 months. This trend was highly significant (Kendall's $W = 0.59$, $\chi^2 = 33.5$, df = 3, $p < 0.001$). No significant trend for the control group (Kendall's $W = 0.04$, $\chi^2 = 2.4$, df = 3, ns). |
| | (2) Beck Depression Scale | Group differences emerged by 6 months. The number of individuals who were no longer parasuicidal was significantly greater in the PH group than in the TAU group by 12 months ($\chi^2 = 4.3$, df = 1, $p < 0.05$) |
| | (3) Global Severity Index score | |
| | (4) Positive Symptom total score | |

(1) Spielberg Inventory score

| | Baseline | | | End-point (18 months) | | | Follow-up (36 months) | | |
|---|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Adjusted mean | Mean | SD | Adjusted mean | Mean | SD | Adjusted mean |
| **State** | | | | | | | | | |
| PH | 68.4 | 7.0 | – | 52.5 | 11.5 | 51.3 | 32.6 | 5.9 | 32.3 |
| TAU | 63.2 | 6.8 | – | 65.5 | 9.3 | 66.6 | 52.4 | 10.3 | 52.9 |
| **Trait** | | | | | | | | | |
| PH | 66.5 | 6.1 | – | 56.8 | 9.1 | 55.2 | 34.4 | 6.1 | 34.1 |
| TAU | 62.0 | 9.9 | – | 61.0 | 7.6 | 36.0 | 42.7 | 10.1 | 43.4 |

(2) Beck Depression Scale

| | Baseline | | | End-point (18 months) | | | Follow-up (36 months) | | |
|---|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Adjusted mean | Mean | SD | Adjusted mean | Mean | SD | Adjusted mean |
| PH | 36.0 | 7.6 | – | 20.6 | 7.0 | 20.3 | 11.9 | 3.3 | 11.9 |
| TAU | 34.9 | 7.4 | – | 35.2 | 7.4 | 35.7 | 20.4 | 10.5 | 20.6 |

(3) Global Severity Index score

| | Baseline | | | End-point (18months) | | | Follow-up (36 months) | | |
|---|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Adjusted mean | Mean | SD | Adjusted mean | Mean | SD | Adjusted mean |
| PH | 2.50 | 0.58 | – | 2.10 | 0.82 | 2.1 | 0.8 | 0.6 | 0.8 |
| TAU | 2.30 | 0.71 | – | 2.40 | 0.70 | 2.4 | 2.0 | 0.5 | 2.0 |

(4) Positive Symptom total score

| | Baseline | | | End-point (18 months) | | | Follow-up (36 months) | | |
|---|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Adjusted mean | Mean | SD | Adjusted mean | Mean | SD | Adjusted mean |
| PH | 74.1 | 14.5 | – | 70.7 | 17.3 | 72.0 | 40.6 | 19.6 | 40.2 |
| TAU | 72.3 | 15.2 | – | 73.1 | 15.0 | 73.5 | 74.5 | 9.6 | 75.3 |

*continued*

***TABLE 28*** *Results of reported outcomes (psychological symptoms and interpersonal and social functioning: RCTs*

| Study | Results | | | | | | | | | | Other outcome information |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Pre | | Mid | | Post | | Pre–mid *F* | Pre–post *F* | Pre vs Post effect size[a] | Group × Time $F_{2,36}$ | |
| | | Mean | SD | Mean | SD | Mean | SD | | | | | |
| Koons *et al.*, 2001[52] | Parasuicides past 3 months | | | | | | | | | | | The proportion of patients with any admissions during the prior 3 months was relatively low at pretreatment, and neither group showed significant change in this proportion by the end of treatment |
| | DBT | 5.1 | 13.2 | 1.6 | 3.7 | 0.4 | 1.3 | 2.5 | 4.75† | 0.35 | 2.44† | |
| | TAU | 0.7 | 1.3 | 1.1 | 2.3 | 1 | 2.2 | 0.03 | 0.01 | 0.28 | | |
| | Suicidal ideation | | | | | | | | | | | |
| | DBT | 36.2 | 13.5 | 34.9 | 13.5 | 26.2 | 8 | 0.89 | 9.64* | 0.98 | 3.71* | |
| | TAU | 44.6 | 11.4 | 41.9 | 13.3 | 41.5 | 14.3 | 1.61 | 2.89 | 0.54 | | |
| | Hopelessness | | | | | | | | | | | |
| | DBT | 11.9 | 6.7 | 0.4 | 7.5 | 5.1 | 5.3 | 1.63 | 17.08** | 1.31 | 8.03** | |
| | TAU | 13.6 | 6.8 | 12 | 7.8 | 14.2 | 7.3 | 1.25 | 0.3 | –0.18 | | |
| | Hamilton Depression | | | | | | | | | | | |
| | DBT | 29.7 | 13.7 | 24.7 | 10.1 | 17.1 | 5.7 | 4.67† | 12.40** | 1.12 | 0.71 | |
| | TAU | 32.6 | 9.7 | 31.1 | 11.3 | 24.3 | 7.8 | 0.88 | 9.09* | 0.95 | | |
| | Beck Depression | | | | | | | | | | | |
| | DBT | 22.8 | 11.1 | 21.3 | 13.4 | 13.4 | 7.5 | 0.25 | 9.35* | 0.96 | 3.70* | |
| | TAU | 34.7 | 14.6 | 27 | 14.6 | 29.3 | 17.7 | 25.40** | 5.93* | 0.77 | | |
| | Hamilton Anxiety | | | | | | | | | | | |
| | DBT | 18.4 | 7.3 | 18.1 | 8.4 | 19.1 | 7.5 | 0.02 | 0.13 | –0.31 | 1.32 | |
| | TAU | 27.7 | 9.3 | 25.8 | 10.7 | 32.2 | 12.4 | 1.07 | 1.79 | –0.42 | | |
| | Anger in | | | | | | | | | | | |
| | DBT | 22.9 | 5.7 | 19.3 | 5.4 | 17.3 | 4 | 6.19* | 11** | 1.04 | 1.71 | |
| | TAU | 20.5 | 4.7 | 18.2 | 5.4 | 19.2 | 6.2 | 6.99** | 0.31 | 0.17 | | |
| | Anger out | | | | | | | | | | | |
| | DBT | 18.2 | 5.7 | 17.3 | 4.8 | 14.5 | 3.9 | 0.67 | 13.38** | 1.16 | 5.89** | |
| | TAU | 17.2 | 5.8 | 14.6 | 3.1 | 17.9 | 6.1 | 3.16 | 0.16 | –0.12 | | |
| | Dissociation | | | | | | | | | | | |
| | DBT | 22.3 | 15.2 | 20 | 16.2 | 13.2 | 12 | 0.79 | 13** | 1.13 | 1.21 | |
| | TAU | 41 | 22.4 | 29.5 | 22.5 | 30.6 | 23.3 | 3.05 | 2.4 | 0.48 | | |
| | BPD criteria | | | | | | | | | | | |
| | DBT | 6.8 | 1.1 | | | 3.6 | 1.6 | | 79.45** | 2.83 | 0.79[b] | |
| | TAU | 6.7 | 0.8 | | | 4.2 | 2.3 | | 12.64** | 1.13 | | |

†$p < 0.1$; *$p < 0.05$; **$p < 0.01$.

[a] Effect size computed as (mean pre-mean post) (SD pre-post).

[b] BPD criteria were assessed only at pretreatment and posttreatment. Degrees of freedom for F test are (1,18).

*continued*

***TABLE 28*** *Results of reported outcomes (psychological symptoms and interpersonal and social functioning: RCTs (cont'd)*

| Study | Results | Other outcome information |
|---|---|---|
| Linehan *et al.*, 1991[53] | (1) Parasuicide<br>Likelihood of any parasuicide:<br>DBT 63.6%, TAU 95.5%, $z$ 2.26, $p < 0.005$<br><br>Medical risk scores:<br>DBT mean 9.21, SD 8.22, $n = 14$<br>TAU mean 17.86, SD 20.94, $n = 21$<br>($t = 1.70$, df = 28.01, $p < 0.05$)<br><br>Participants who received DBT had a median of 1.5 parasuicide acts per year compared with nine acts per year for control participants<br><br>(2) Maintenance in therapy<br>DBT patients were significantly more likely to start individual therapy than were control participants, all of whom were referred for treatment (100% and 73% for participants assigned to DBT and control participants, respectively, $z = 2.75$, $p < 0.003$)<br><br>(3) Psychiatric inpatient treatment<br>Number of hospitalised participants | (4) Throughout the follow-up year, both the parasuicide repeat rate (DBT 26%, TAU 60%, $z = 2.12$, $p < 0.01$) and the likelihood of any psychiatric hospitalisation (DBT 11%, TAU 40%, $z = 1.43$, $p < 0.07$) were lower for participants completing DBT than for participants remaining in TAU<br><br>(5) Psychiatric inpatient days during the 18–24-month period were lower for participants completing treatment<br><br>(6) At the end of the 24-month time-point, participants completing DBT were rated significantly higher on overall social adjustment by the interviewer |

| | DBT (*n*) | Control (*n*) | *z* | *p* |
|---|---|---|---|---|
| 0–4 months | 6 | 9 | 2.54 | <0.005 |
| 4–8 months | 5 | 7 | | |
| 8–12 months | 3 | 7 | 1.49 | <0.10 |
| Year | 8 | 12 | 1.70 | <0.05 |

*continued*

***TABLE 28*** *Results of reported outcomes (psychological symptoms and interpersonal and social functioning: RCTs (cont'd)*

| Study | Results | Other outcome information |
|---|---|---|
| Linehan *et al.*, 1999[54] | (1) Drug abuse (ITT analyses, $n = 28$) | (4) Psychopathology. There were no between-group differences on other outcome measures (e.g. parasuicide episodes, GSA, GAS or anger) during treatment or at the 12-month post-treatment follow-up |

| | DBT | | TAU | | | |
|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | *F*-value (*p*-value) | Effect size |
| Pretreatment assessment | 0.36 | 0.26 | 0.22 | 0.28 | | |
| Pretreatment to 4 months | 0.63 | 0.34 | 0.32 | 0.37 | 3.16 ($p < 0.05$) | 0.80 |
| 4–8 months | 0.62 | 0.35 | 0.38 | 0.34 | 1.50 | 0.65 |
| 8–12 months | 0.67 | 0.38 | 1.39 ($n = 8$) | 0.44 | 1.67 | 0.64 |
| Year total ($n = 10$) | 0.63 | 0.33 | 0.35 | 0.34 | 2.83 ($p < 0.05$) | 0.93 |
| 12–16 months | 0.94 | 0.17 | 0.58 | 0.36 | 4.04 ($p < 0.05$) | 0.59 |

(2) Treatment initiation, exposure and retention: DBT mean 43.14±10.67; TAU mean 31.6±27.88, $F_{1,15} = 1.07$, ns
When case management hours are excluded from these analyses, DBT participants receive significantly more psychotherapy than do TAU participants
DBT: mean 43.14±10.67; TAU: mean 21.88±32.32, $F_{1,15} = 2.07$, $p < 0.05$. TAU participants rarely participated in group psychotherapy

(3) Participants as a group showed significant reductions over time on frequency of parasuicide episodes and state and trait anger

At the 16-month follow-up assessment DBT participants showed better social and global adjustment, with significantly lower (better) scores on the GSA:
DBT: mean 2.25±0.75; TAU: mean 2.92±0.71, $F_{1,12} = 3.98$, $p < 0.05$ for best week scores

DBT: mean 3.04±0.89; TAU: mean 3.74±0.67, $F_{1,12} = 2.94$, $p = 0.056$ for last month scores and higher scores on the GAS

DBT: mean 69±12; TAU: mean 49±10, $F_{1,12} = 22.24$, $p < 0.001$ for best week scores

DBT: mean 62±10; TAU: mean 44±10, $F_{1,12} = 22.19$, $p < 0.001$ for last week scores

*continued*

***TABLE 28*** *Results of reported outcomes (psychological symptoms and interpersonal and social functioning: RCTs (cont'd)*

| Study | Results | Other outcome information |
|---|---|---|
| Linehan *et al.*, 2002[55] | (1) Treatment initiation, exposure and retention. | (5) Global adjustment improvements were maintained, but did not improve further. The incidents of parasuicidal behaviour and psychiatric or drug-related visits to emergency rooms and inpatient units were low, but there were no significant between-condition differences |

| Year total | DBT Mean | DBT SD | CVT+12S Mean | CVT+12S SD | $t_{21}$ | $p$ |
|---|---|---|---|---|---|---|
| Mean number of individual sessions received | 33.2 | 20.4 | 33.0 | 9.6 | 2.62 | <0.05 |
| Number of skills group sessions | 26.6 | 15.9 | 10.8 | 12.8 | | |

(2) Urinanalysis
By week 52 (end of 12 months); DBT participants had a significantly lower percentage of opiate-positive urinanalyses than CVT+12S participants ($t = 2.32$, $p < 0.02$)
At 16 months percentage of positive urinanalyses in both conditions: DBT 27%, CVT+12S 33%

(3) Self-report

| Year total | DBT Mean (%) | DBT SD | CVT+12S Mean (%) | CVT+12S SD |
|---|---|---|---|---|
| **Self-report** | | | | |
| Heroin | 66.26 | 67.01 | 91.14 | 91.86 |
| Cocaine | 83.12 | 80.93 | 78.90 | 72.08 |
| Amphetamines | 99.97 | 99.92 | 100.00 | 100.00 |
| Barbiturates | 99.97 | 99.92 | 99.92 | 99.84 |
| Sedatives | 99.82 | 99.39 | 99.83 | 99.48 |
| **Urinanalyses** | | | | |
| Heroin | 46.43 | 68.34 | 53.30 | 83.40 |
| Cocaine | 70.86 | 80.66 | 72.27 | 78.58 |
| Amphetamines | 88.07 | 89.87 | 91.72 | 88.68 |
| Barbiturates | 88.46 | 90.11 | 92.45 | 88.14 |
| Sedatives | 86.36 | 89.24 | 90.92 | 88.22 |

(4) Psychopathology
in both groups:

| | Pretreatment Mean | Pretreatment SD | 12 months Mean | 12 months SD | $Z$ | $p$ |
|---|---|---|---|---|---|---|
| BSI | 1.78 | 71 | 1.17 | 0.60 | 3.17 | <0.002 |
| BSI (16-month follow-up) GAS | 37.6 | 5.6 | 47.4 | 10.7 | 3.59 | <0.001 |

BSI (16-month follow-up): $z = 1.76$, $p < 0.08$, mean 0.98±0.74).

*continued*

***TABLE 28*** *Results of reported outcomes (psychological symptoms and interpersonal and social functioning: RCTs (cont'd)*

| Study | Results | Other outcome information |
|---|---|---|
| Munroe-Blum and Marziali, 1995[56] | There were no significant findings with respect to the major outcome variables under study; however, both treatments did experience significant improvements over time reflected on behavioural indicators, social adjustment, global symptoms and depression<br>Cohort analysis of variance | There were no significant differences in outcome between the two treatment-time exposure groups; the low exposure group made gains comparable to those of the high exposure group on all of the outcome measures |

| | Scale means (SD) at three points in time | | | |
|---|---|---|---|---|
| | OBI | SAS | HSC-90 | BDI |
| Pretreatment | 32.01 (10.88) | 2.13 (0.42) | 1.76 (0.68) | 25.9 (9.89) |
| 12 months | 30.99 (12.67) | 1.91 (0.50) | 1.26 (0.69) | 18.4 (12.46) |
| 24 months | 23.61 (10.58) | 1.89 (0.59) | 1.03 (0.78) | 14.6 (12.29) |
| *n*[a] | 48 | 43 | 45 | 46 |
| | $F_{2.94}$ =10<br>0.76[b] | $F_{2.84}$ = 7<br>0.04 | $F_{2.88}$ = 16<br>0.42 | $F_{2.90}$ = 17<br>0.93 |

[a] Numbers vary because of missing data.
[b] $p = 0.0001$.

| Study | Results | Other outcome information |
|---|---|---|
| Turner, 2000[57] | (1) Measures | (2) Assessment of treatment credibility<br>The analysis found no significant difference between treatments regarding credibility, ($t_{22}$ = 1.63, $p$ = 0.116)<br>(3) Assessment of helping alliance differences<br>Helping Relationship Questionnaire (HRQ) showed no significant difference between treatments ($F_{1,16}$ = 1.10, $p$ = 0.31) |

| | CCT ($n$ = 12) | | | DBT ($n$ = 12) | | |
|---|---|---|---|---|---|---|
| | Pretreatment | 6 months | 12 months | Pretreatment | 6 months | 12 months |
| Rating of parasuicide | 7.25 (0.75) | 4.33 (1.92) | 4.25 (2.18) | 7.17 (0.83) | 2.08 (2.02) | 1.50 (1.98) |
| Beck Suicide Ideation Scale | 23.53 (3.34) | 13.33 (9.79) | 11.58 (9.21) | 24.08 (3.73) | 2.83 (3.49) | 3.83 (8.03) |
| Number of suicide/ self-harm attempts | 13.58 (3.34) | 6.75 (5.97) | 5.58 (5.28) | 14.08 (3.73) | 2.17 (1.95) | 0.75 (1.23) |
| Rating of impulsiveness | 7.58 (0.51) | 6.67 (0.78) | 6.08 (1.08) | 7.42 (0.51) | 5.83 (0.83) | 4.58 (1.62) |
| Rating of anger | 7.08 (0.90) | 5.92 (0.79) | 5.67 (1.15) | 7.33 (0.65) | 5.00 (1.21) | 4.67 (1.30) |
| BDI | 27.75 (6.11) | 24.75 (4.94) | 24.08 (5.55) | 27.58 (5.30) | 18.08 (7.91) | 14.92 (8.26) |
| HAM-D | 17.42 (4.46) | 13.67 (2.93) | 12.58 (3.90) | 20.75 (4.33) | 8.58 (6.58) | 7.50 (5.96) |
| BAI | 20.42 (3.45) | 17.08 (5.82) | 14.83 (6.34) | 19.25 (3.55) | 12.58 (4.89) | 10.17 (6.53) |
| BPRS | 30.83 (6.00) | 25.83 (8.40) | 25.33 (3.94) | 30.33 (6.56) | 18.42 (7.33) | 18.17 (7.90) |
| Hospitalisation days | 10.00 (8.11) | 10.75 (16.27) | 13.00 (15.34) | 10.20 (3.37) | 2.67 (6.58) | 0.75 (1.96) |

*continued*

***TABLE 28*** *Results of reported outcomes (psychological symptoms and interpersonal and social functioning: RCTs (cont'd)*

| Study | Results | Other outcome information |
|---|---|---|
| Tyrer *et al.*, 2003[58] | Results related to BPD are only reported where it is possible to differentiate | (3) The psychometric assessment outcomes showed no difference between MACT and TAU |

(1) Proportions of total 430 patients experiencing a repeat self-harm (parasuicide) episode over 1 year, incidence rate and frequency of self-harm episodes in those separated by category of PD (ICD-10 categories)

| Parasuicide events during follow-up | BPD ($n$ = 67) | PD ($n$ = 117) | Diffuse ($n$ = 69) | No PD ($n$ = 39) |
|---|---|---|---|---|
| None | 30 (44.8%) | 57 (48.7%) | 31 (44.9%) | 31 (79.5%) |
| At least one | 37 (55.2%) | 60 (51.3%) | 38 (55.1%) | 8 (20.5%) |
| Sample size[a] | ($n$ = 60) | | | |
| Incidence rate[a] | | | | |
| First episode per person-year follow-up | 0.762 | 0.634 | 0.659 | 0.229 |
| 25th percentile time to parasuicide event (days)[a] | 89 | 132 | 162 | |
| Frequency of self-harm (per year) | 3.15 | | | |

[a] These figures refer to the original 400 patients for whom detailed information on first self-harm was available.

(2) Proportion of 430 patients experiencing a repeat self-harm (parasuicide) episode over 1 year

| | MACT (PD) | | TAU (PD) | |
|---|---|---|---|---|
| Parasuicide events during follow-up | 0–6 months ($n$ = 91) | 6–12 months ($n$ = 88) | 0–6 months ($n$ = 90) | 6–12 months ($n$ = 83) |
| Incidence rate[a] | | | | |
| None | 57 (62.2%) | 55 (62.5%) | 49 (54.4%) | 61(73.5%) |
| At least one | 34 (37.4%) | 33 (37.5%) | 41 (45.6%) | 22(26.5%) |
| First episode per person-year follow-up | 0.584 | | 0.71 | |
| 25th percentile time to parasuicide event (days)[a] | 212 | 89 | | |
| Frequency of self-harm (per 6-month period) | 1.65 | 1.18 | 3.74 (1.63[b]) | 3.61 (0.88[b]) |
| Frequency of self-harm (per year) | 2.84 | | 7.36 (2.54[b]) | |

[a] These figures refer to the original 400 patients for whom detailed information on first self-harm was available.
[b] Excluding patients with 420 episodes.

*continued*

***TABLE 28*** *Results of reported outcomes (psychological symptoms and interpersonal and social functioning: RCTs (cont'd)*

<table>
<tr><th>Study</th><th>Results</th><th>Other outcome information</th></tr>
<tr><td>van den Bosch et al., 2002[59]<br>(Verhaul et al., 2003[64])</td><td>(1) Treatment retention<br>Significantly more patients who were receiving DBT ($n$ = 17; 63%) than patients in the control group ($n$ = 7; 23%) continued in therapy with the same therapist for the entire year ($\chi^2_1$ = 9.70, $p$ = 0.002)<br><br>(2) High-risk behaviours<br>The frequency and course of suicidal behaviours were not significantly different across treatment groups ($t_{1,137}$ = 0.03, $p$ = 0.866) and the interaction between time and treatment condition ($t_{1,166}$ = 0.22, $p$ = 0.639) did not reach statistical significance<br>Self-mutilating behaviours in DBT patients gradually diminished over the treatment year, whereas patients in TAU group gradually deteriorated: a significant effect was Time x Treatment condition ($t_{1,44.4}$ = 10.24, $p$ = 0.003), but not for treatment condition alone ($t_{1,69.1}$ = 3.80; $p$ = 0.055). The most common self-mutilating acts were cutting, burning, pricking and head banging<br><br>(3) Impact of DBT on severity of substance use problems at 18-month follow-up<br><table><tr><th rowspan="2">EuropASI item (a)</th><th colspan="2">DBT, mean±SD</th><th colspan="2">TAU, mean±SD</th><th colspan="2">Comparison at 18-month follow-up corrected for baseline[b]</th></tr><tr><th>Baseline ($n$ = 27)</th><th>Follow-up[a] ($n$ = 20)</th><th>Baseline ($n$ = 31)</th><th>Follow-up[a] ($n$ = 24)</th><th>$F$</th><th>$p$</th></tr><tr><td>Days ≥5 drinks past months 0–30</td><td>7.1±10.3</td><td>6.1±9.8</td><td>6.2±9.2</td><td>3.8±7.8</td><td>0.9</td><td>0.34</td></tr><tr><td>Days medication use past months 0–30</td><td>14.2±14.0</td><td>7.9±12.2</td><td>13.5±14.5</td><td>11.5±13.9</td><td>0.4</td><td>0.54</td></tr><tr><td>Days cannabis use past months 0–30</td><td>6.5±11.2</td><td>9.2±13.3</td><td>2.3±5.8</td><td>5.9±11.5</td><td>0.1</td><td>0.73</td></tr><tr><td>Days alcohol problems past months 0–30</td><td>8.7±12.3</td><td>7.0±11.3</td><td>9.0±12.9</td><td>6.7±11.3</td><td>0</td><td>0.89</td></tr><tr><td>Days drug problems past months 0–30</td><td>8.1±11.4</td><td>9.5±13.2</td><td>9.0±12.6</td><td>4.5±10.0</td><td>2</td><td>0.17</td></tr><tr><td>Severity of alcohol problems 0–9</td><td>2.7±2.3</td><td>2.8±2.6</td><td>3.0±2.5</td><td>2.4±2.1</td><td>1.1</td><td>0.31</td></tr><tr><td>Severity of drug problems 0–9</td><td>3.3±2.0</td><td>2.8±2.2</td><td>3.6±2.3</td><td>2.3±1.8</td><td>0.5</td><td>0.47</td></tr></table>[a] Follow-up scores at 18 months since start of treatment.<br>[b] Using the General Linear Model Module of SPSS 8.0, with EuropASI scores at 18-month follow-up as dependent variables, treatment condition as fixed factor and baseline scores on EuropASI as covariates.</td><td>(4) Impact of baseline severity on effectiveness<br>For suicidal behaviour an almost significant effect was evident for the three-way interaction term Time x Treatment x Condition ($t_{1,170}$ = 4.81, $p$ = 0.029), indicating a trend towards greater effectiveness of DBT in severely affected individuals. For self-mutilating behaviours a significant effect was evident for the 3-way interaction term Time × Severity × Treatment condition ($t_{1,404}$ = 16.82, $p$ = 0.000) and the interaction term Severity × Treatment condition ($t_{1,67.6}$ = 9.63, $p$ = 0.003), indicating that DBT was superior to TAU in the high-severity group, but not for their lower severity counterparts. No differential effectiveness was found for self-damaging impulsivity</td></tr>
</table>

***TABLE 29*** *Results of reported outcomes (psychological symptoms and interpersonal and social functioning): non-RCTs*

| Study | Results | Other outcome information |
|---|---|---|

Wilberg *et al.*, 1998[60]

(1) Status dimensions at admission, discharge and follow-up

| | Total sample ($n$ = 43) | Treatment group ($n$ = 12) | Control group ($n$ = 31) |
|---|---|---|---|
| HSRS admission | 38.6±5.1 | 36.9±5.1 | 39.2±5.1 |
| HSRS discharge | 43.5±7.8 | 47.3±5.4 | 42.0±8.1* |
| HSRS follow-up | 51.2±11.9 | 57.4±9.0 | 48.8±12.1* |
| GSI admission | 1.84±0.55 ($n$ = 42) | 1.67±0.48 | 1.92±0.56 ($n$ = 30) |
| GSI discharge | 1.28±0.65 ($n$ = 35) | 1.11±0.49 | 1.37±0.72 ($n$ = 23) |
| GSI follow-up | 1.37±0.67 ($n$ = 36) | 1.02±0.50 | 1.55±0.67 ($n$ = 24)* |
| Rehospitalisation | 13 (33%) ($n$ = 40) | 1 (8%) | 12 (43%) ($n$ = 28) |
| Suicide attempts | 6 (15%) ($n$ = 44) | 1 (8%) | 5 (18%) ($n$ = 28) |
| Remission from substance use disorder | 13/25 (52%) | 6/8 (75%) | 7/17 (41%) |

*$p < 0.05$ ($t$-test, two-tailed)

(2) Multiple regression models for HSRS at follow-up (95% CI)

| Independent variable | $B$ | SE $B$ | β | Min. | Max. | Significance |
|---|---|---|---|---|---|---|
| HSRS at admission | 0.638 | 0.326 | 0.274 | –0.023 | 1.298 | 0.058 |
| Continuous treatment | 0.196 | 0.010 | 0.266 | –0.006 | 0.398 | 0.057 |
| Work before admission | 0.899 | 0.327 | 0.365 | 0.238 | 1.561 | 0.009 |
| Outpatient group therapy | 7.537 | 3.464 | 0.288 | 0.524 | 14.549 | 0.036 |

$R^2 = 0.39$, $F = 6.15$, significance $F = 0.0006$

(3) Multiple regression models for GSI at follow-up (95% CI)

| Independent variable | $B$ | SE $B$ | β | Min. | Max. | Significance |
|---|---|---|---|---|---|---|
| GSI at admission | 0.162 | 0.178 | 0.140 | –0.201 | 0.525 | 0.370 |
| Continuous treatment | 0.006 | 0.007 | 0.142 | –0.008 | 0.021 | 0.362 |
| % of follow-up period on medication | 0.005 | 0.003 | 0.320 | 0.0002 | 0.010 | 0.041 |
| Outpatient group therapy | –0.552 | 0.214 | –0.410 | –0.989 | –0.115 | 0.015 |

$R^2 = 0.35$, $F = 4.08$, significance $F = 0.009$

***TABLE 30*** *Patient preferences and conclusions: RCTs*

| Study | Patient preference, satisfaction and acceptability of treatment | Conclusions |
|---|---|---|
| Bateman and Fonagy, 1999[51] | NR | Patients treated with PH for 18 months showed significant improvement on both symptomatic and clinical measures. Treatment was effective for both men and women |
| Koons *et al.*, 2001[52] | NR | This study demonstrates that DBT can be conducted with reasonably good adherence by a group of therapists at a site independent of the treatment's developer. The treatment was associated with clinically significant changes in the symptoms and functions of borderline patients, changes that were significantly greater than those associated with TAU on a number of measures. Efficacy of DBT is not limited only to patients with recurrent suicidal and self-injurious behaviour |
| Linehan *et al.*, 1991[53] | No treatment specific gains in general satisfaction despite significant improvements in anger reduction and social adjustment | (1) The authors found a significant reduction in the frequency and medical risk of parasuicidal behaviour among patients who received DBT compared with that for control participants<br>(2) DBT effectively retained patients in therapy<br>(3) Days of patients' psychiatric hospitalisation were fewer for participants who received DBT than for control participants<br>(4) DBT was not differentially effective in improving patients' depression, hopelessness, suicide ideation or reasons for living |
| Linehan *et al.*, 1999[54] | NR | (1) The authors found a significant reduction in substance abuse among participants assigned to DBT compared with those assigned to TAU<br>(2) DBT more effectively retained participants in treatment<br>(3) Improvements in social and global adjustment in the DBT condition were observed and reached significance compared with TAU at follow-up |
| Linehan *et al.*, 2002[55] | NR | (1) Both treatments when combined with LAAM were effective in reducing opiate use and maintaining the reduction during the 4-month follow-up period<br>(2) CVT+12S was remarkably effective in maintaining participants in treatment; 100% stayed for the entire year<br>(3) Participants assigned to DBT were significantly more accurate in self-reporting opiate use than were those assigned to CVT+12S |

*continued*

***TABLE 30*** *Patient preferences and conclusions: RCTs (cont'd)*

| Study | Patient preference, satisfaction and acceptability of treatment | Conclusions |
|---|---|---|
| Munroe-Blum and Marziali, 1995[56] | NR | IGP showed significant improvements on all major outcomes (as well as TAU) at follow-up. The group therapy appears more cost-effective than individual therapy |
| Turner, 2000[57] | NR | DBT-orientated therapy can be more effective than providing only the supportive components of psychotherapy. DBT-orientated patients showed greater improvements than patients receiving CCT on measures of suicide and self-harm behaviour, suicide ideation, depression, impulsiveness, anger and global psychological functioning, and a reduction in days spent in psychiatric hospitals |
| Tyrer *et al.*, 2003[58] | NR | The results showed no difference with regard to the outcomes between the two groups. However, the MACT intervention was cheaper, led to somewhat fewer episodes of self-harm and was associated with fewer suicides than in the TAU group |
| van den Bosch *et al.*, 2002[59] | Both subgroups (BPD and BPD with substance abuse) of patients appeared to get along easily by the second week. Through the discussion of homework, the substance-abusing and non-substance-abusing participants realised that they shared most of the essential borderline problems. All participants judged the programme as validating and helpful. They felt acknowledged as borderline patients and judged the treatment as very important. Session attendance for the total group was 81% | (1) DBT had a substantially lower 12-month attrition rate than TAU<br>(2) DBT resulted in greater reductions in self-mutilating behaviours and self-damaging impulsive acts than TAU<br>(3) The beneficial impact on the frequency of self-mutilating behaviours was far more pronounced in participants who reported higher baseline frequencies than in those reporting lower baseline frequencies |

***TABLE 31*** *Patient preferences and conclusions: non-RCT*

| Study | Patient preference, satisfaction and acceptability of treatment | Conclusions |
|---|---|---|
| Wilberg *et al.*, 1998[60] | NR | "The results support the clinical experience that a treatment model combining day treatment and outpatient group psychotherapy may be favourable for selected patients with BPD" |

# Appendix 4

## Excluded studies

***TABLE 32*** *Excluded studies*

| Study | Population | Reason for exclusion |
|---|---|---|
| **RCTs** | | |
| Allard *et al.*, 1992[81] | Suicide attempters | No BPD subgroup analysis |
| Chiesa *et al.*, 2004[82] | PD | No BPD subgroup analysis |
| Clarkin *et al.*, 2004[83] | BPD | Ongoing trial, no evaluable data |
| Evans *et al.*, 1999[30] | DSH | No BPD subgroup analysis |
| Manning, 1997[84] | BPD | Abstract, no evaluable data |
| Piper *et al.*, 1993[85] | PD | No BPD subgroup analysis |
| Simpson *et al.*, 2004[86] | BPD | Combination of drug with DBT |
| Sloane *et al.*, 1975[87] | PD | No BPD subgroup analysis |
| Springer *et al.*, 1996[88] | PD | No BPD subgroup analysis |
| Stiwne *et al.*, 1994[89] | BPD | Therapist assessment |
| Winston *et al.*,1994[90] | PD | No BPD subgroup analysis |
| **Non-RCTs** | | |
| Bohus *et al.*, 2000[91] | BPD | DBT |
| Bohus *et al.*, 2004[92] | BPD | DBT |
| Brobin *et al.*, 1987[93] | BPD | Case study |
| Battegay and Klaui, 1986[94] | BPD | Qualitative study |
| Buzov *et al.*, 1985[95] | BPD | Qualitative study |
| Chiesa *et al.*, 2000[96] | PD | Qualitative study |
| Clarkin *et al.*, 1991[97] | BPD | Review |
| Clarkin *et al.*, 1994[98] | BPD | No comparison |
| Clarkin *et al.*, 2001[26] | BPD | No comparison |
| Damman *et al.*, 2001[99] | BPD | Review |
| Dolan *et al.*, 1997[100] | PD | Not eligible comparison (admitted vs not admitted patients) |
| Hirvas, 1987[101] | BPD | No comparison |
| Karterud *et al.*, 2004[102] | BPD | Not eligible comparison (day hospital vs Bateman's MBT) |
| Kent and Hartstone, 2000[103] | BPD | Abstract, no data |
| Kern *et al.*, 1997[104] | BPD | Case series |
| Koenigsberg, 1982[105] | BPD | Diagnostic paper |
| Lopez *et al.*, 2004[106] | BPD | No comparison |
| Meares *et al.*, 1999[107] | BPD | Not eligible comparison (treatment vs waiting list) |
| Pfitzer *et al.*, 1990[108] | BPD | No comparison |
| Rathus and Miller, 2002[109] | Suicide attempters | Adolescents |
| Ryle and Golynkina, 2000[110] | BPD | No comparison |
| Schane and Kovel, 1988[111] | BPD | Case series |
| Ushijima, 1994[112] | BPD | Case series |
| Wildgoose *et al.*, 2001[113] | BPD | No comparison |

# Appendix 5

## Consensus trial quality ratings according to Lackner's quality checklist

***TABLE 33*** *Quality ratings*

| | Bateman and Fonagy, 1999[51] | Koons *et al.*, 2001[52] | Linehan *et al.*, 1991[53] | Linehan *et al.*, 1999[54] | Linehan *et al.*, 2002[55] | Munroe-Blum and Marziali, 1995[56] | Turner 2000[57] | Tyrer *et al.*, 2003[58] | van den Bosch *et al.*, 2002[59] | Wilberg *et al.*, 1998[60] |
|---|---|---|---|---|---|---|---|---|---|---|
| Q1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| Q2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| Q3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 0 |
| Q4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Q5 | 2 | 2 | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 2 |
| Q6 | 2 | 2 | 0 | 2 | 2 | 1 | 2 | 2 | 2 | 1 |
| Q7 | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| Q8 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| Q9 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| Q10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Q11 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Q12 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| Q13 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| Q14 | 0 | 1 | 1 | 1 | 1 | 0 | 1 | 0 | 0 | 0 |
| Q15 | 1 | 2 | 2 | 1 | 1 | 1 | 1 | 2 | 2 | 2 |
| Q16 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Q17 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| Q18 | 0 | 2 | 0 | 0 | 0 | 2 | 0 | 2 | 0 | 0 |
| Q19 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 2 | 1 | 0 |
| Q20 | 2 | 2 | 2 | 2 | 2 | 1 | 2 | 1 | 2 | 1 |
| Q21 | 2 | 2 | 2 | 2 | 2 | 0 | 2 | 2 | 2 | 1 |
| Q22 | 2 | 2 | 2 | 2 | 2 | 1 | 2 | 2 | 2 | 1 |
| Q23 | 0 | 0 | 0 | 2 | 2 | 0 | 2 | 2 | 2 | 0 |
| Q24 | 0 | 2 | 2 | 2 | 2 | 2 | 0 | 2 | 2 | 2 |
| Q25 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 |
| Q26 | 2 | 0 | 0 | 2 | 2 | 2 | 2 | 2 | 2 | 1 |
| Q27 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 1 |
| Q28 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 |
| Q29 | 1 | 1 | 2 | 2 | 2 | 0 | 1 | 0 | 1 | 0 |
| **Total** | **34** | **37** | **34** | **40** | **41** | **34** | **37** | **41** | **40** | **30** |

Q1. Were exclusion criteria specified and number of exclusion/refusals reported?
Q2. Were formal diagnostic criteria used to confirm [BPD] and/or inclusion criteria specified?
Q3. What was the method (e.g. randomisation) and adequacy of the method by which patients were allocated to treatment arms?
Q4. Was allocation concealed from those involved in patient recruitment?
Q5. Were patients comparable on prognostic variables, and were statistical procedures used to adjust for differences in analyses?
Q6. How well were sample demographics and clinical characteristics described?
Q7. What was the source and representativeness of participants?
Q8. Was compliance with experimental procedure (e.g. attendance and checks for adherence with behavioral assignments) conducted?
Q9. How clearly was the content of therapeutic and control conditions (e.g. manualised treatment procedures) operationalised?
Q10. Were participants blind to treatment allocation, and, if so, was integrity test

conducted? (replaced with credibility criterion)
Q11. Were therapy credibility and expectancy for improvement assessed? (Credibility criterion)
Q12 .Were the objectives and main outcomes specified a priori?
Q13. Were outcome measures clearly described and/or psychometrically sound outcome measure used?
Q14. Was a blind assessor used, and, if so, was integrity of blinding tested?
Q15. Were the number and reasons for withdrawal by group recorded?
Q16. Were details on side effects recorded by group?
Q17. What was the planned duration of trial including follow-up?
Q18. Were power calculations stated a priori?
Q19. Was sample size (number per group) adequate?
Q20. Were appropriate statistical analyses conducted (including correction for multiple tests where applicable)?
Q21. Did presented results include data for reanalysis of main outcomes (e.g. point estimates and measures of variability for each primary outcome such as standard deviations, 95% confidence interval)?
Q22. Were conclusions justified?
Q23. Were withdrawals included in analyses?
Q24. Was declaration of interests (e.g. source of funding) stated?
Q25. Was declaration of allegiance to therapy stated?
Q26. Was a post-treatment follow-up conducted for all groups?
Q27. Were cointerventions avoided or equal across conditions?
Q28. Were consecutive participants recruited?
Q29. Was concurrent drug use recorded?

# Appendix 6

## *British Medical Journal* checklist for economic evaluations[50]

***TABLE 34*** *Heard study*[68]

| | Item | Assessment |
|---|---|---|
| **The study design** | | |
| 1. | The research question is stated | The economic hypothesis was that DBT is more cost-effective than TAU in the treatment of BPD |
| 2. | The economic importance of the research question is stated | The disease is costly in terms of resources used. An intervention that reduces outcomes may impact on these costs |
| 3. | The viewpoint(s) of the analysis are clearly stated and justified | A societal perspective was taken, including hospital inpatient and outpatient visits and physician visits. Costs incurred in the community or the criminal justice system were not included |
| 4. | The rationale for choosing the alternative programmes or interventions compared is stated | TAU is a relevant measure for evaluating the opportunity cost of the new treatment |
| 5. | The alternatives being compared are clearly described | DBT and TAU therapy is clearly described |
| 6. | The form of economic evaluation used is stated | Cost-effectiveness |
| 7. | The choice of form of economic evaluation is justified in relation to the questions addressed | Yes |
| **Data collection** | | |
| 8. | The source(s) of effectiveness estimates are used as stated | Yes |
| 9. | Details of the design and results of effectiveness study are given (if based on a single study) | Brief description of design, no results |
| 10. | Details of the method of synthesis or meta-analysis of estimates are given (if based on an overview of a number of effectiveness studies) | Based on a single trial |
| 11. | The primary outcome measure(s) for the economic evaluation are clearly stated | Yes (employment or global functioning cost-effectiveness ratios) |
| 12. | Methods to value health states and other benefits are stated | Health states not valued |
| 13. | Details of the subjects from whom valuations were obtained are given | NA |
| 14. | Productivity changes (if included) are reported separately | Yes |
| 15. | The relevance of productivity changes to the study question is discussed | Yes |
| 16. | Quantities of resources are reported separately from their unit costs | Yes |
| 17. | Methods for the estimation of quantities and unit costs are described | Yes |

*continued*

***TABLE 34*** *Heard study[68] (cont'd)*

| | Item | Assessment |
|---|---|---|
| 18. | Currency and price data are recorded | Yes |
| 19. | Details of currency of price adjustments for inflation or currency conversion are given | Yes (Employment Cost Index used to inflate prices to 1999 levels) |
| 20. | Details of any model used are given | No model used |
| 21. | The choice of model used and the key parameters on which it is based are justified | NA |
| **Analysis and interpretation of results** | | |
| 22. | Time horizon of costs and benefits is stated | Trial period (12 months) |
| 23. | The discount rate(s) is stated | NA |
| 24. | The choice of rate(s) is justified | NA |
| 25. | An explanation is given if costs or benefits are not discounted | NA |
| 26. | Details of statistical tests and confidence intervals are given for stochastic data | *t*-Test, ordinary least squares regression, bootstrapping. CIs for overall results not given, only SDs for individual resources reported |
| 27. | The approach to sensitivity analysis is given | One-way and PSA |
| 28. | The choice of variables for sensitivity analysis is justified | Yes |
| 29. | The ranges over which the variables are varied are stated | Local costs converted to national costs. No other sensitivity analysis on costs reported |
| 30. | Relevant alternatives are compared | Yea |
| 31. | Incremental analysis is reported | Yes |
| 32. | Major outcomes are presented in a disaggregated as well as aggregated form | Yes |
| 33. | The answer to the study question is given | Yes |
| 34. | Conclusions follow from the data reported | Yes |
| 35. | Conclusions are accompanied by the appropriate caveats | Yes |

***TABLE 35*** *Byford study*[69]

| | Item | Assessment |
|---|---|---|
| **Study design** | | |
| 1. | The research question is stated | The economic hypothesis was that MACT is more cost-effective than TAU in the treatment of DSH |
| 2. | The economic importance of the research question is stated | The disease is costly in terms of resources used. An intervention that reduces outcomes may impact on these costs |
| 3. | The viewpoint(s) of the analysis are clearly stated and justified | A broad societal perspective was taken, including hospital, community and social services and the criminal justice system |
| 4. | The rationale for choosing the alternative programmes or interventions compared is stated | TAU is a relevant measure for evaluating the opportunity cost of the new treatment |
| 5. | The alternatives being compared are clearly described | MACT is not well described here. However, it is described in the trial publication[58] |
| 6. | The form of economic evaluation used is stated | Cost-effectiveness |
| 7. | The choice of form of economic evaluation is justified in relation to the questions addressed | Yes |
| **Data collection** | | |
| 8. | The source(s) of effectiveness estimates are used as stated | Yes |
| 9. | Details of the design and results of effectiveness study are given (if based on a single study) | Brief description of design, no results |
| 10. | Details of the method of synthesis or meta-analysis of estimates are given (if based on an overview of a number of effectiveness studies) | Based on a single trial |
| 11. | The primary outcome measure(s) for the economic evaluation are clearly stated | Yes (cost per QALY) |
| 12. | Methods to value health states and other benefits are stated | Yes (EQ-5D) |
| 13. | Details of the subjects from whom valuations were obtained are given | Yes |
| 14. | Productivity changes (if included) are reported separately | Yes |
| 15. | The relevance of productivity changes to the study question is discussed | Yes |
| 16. | Quantities of resources are reported separately from their unit costs | Yes |
| 17. | Methods for the estimation of quantities and unit costs are described | Yes |
| 18. | Currency and price data are recorded | Yes |
| 19. | Details of currency of price adjustments for inflation or currency conversion are given | Yes (Hospital and Community Health Services Pay and Prices Index) |
| 20. | Details of any model used are given | No model used |
| 21. | The choice of model used and the key parameters on which it is based are justified | NA |

*continued*

***TABLE 35*** *Byford study[69] (cont'd)*

| Item | Assessment |
|---|---|
| **Analysis and interpretation of results** | |
| 22. Time horizon of costs and benefits is stated | Trial period (12 months) |
| 23. The discount rate(s) is stated | NA |
| 24. The choice of rate(s) is justified | NA |
| 25. An explanation is given if costs or benefits are not discounted | NA |
| 26. Details of statistical tests and confidence intervals are given for stochastic data | *t*-Test, ordinary least squares regression, bootstrapping. CIs for overall results not given, only SDs for individual resources reported |
| 27. The approach to sensitivity analysis is given | One-way and PS |
| 28. The choice of variables for sensitivity analysis is justified | Yes |
| 29. The ranges over which the variables are varied are stated | Local costs converted to national costs. No other sensitivity analysis on costs reported |
| 30. Relevant alternatives are compared | Yes |
| 31. Incremental analysis is reported | Yes |
| 32. Major outcomes are presented in a disaggregated as well as aggregated form | Yes |
| 33. The answer to the study question is given | Yes |
| 34. Conclusions follow from the data reported | Yes |
| 35. Conclusions are accompanied by the appropriate caveats | Yes |

# Appendix 7
## Case studies

***TABLE 36*** *Table of cost studies*

| Study | Subjects | Setting | Study length | Treatments | Resources costed | Costs, mean (SD) | Comment |
|---|---|---|---|---|---|---|---|
| Bateman, 2003[70] | BPD | Halliwick Unit, UK | 18 months | (a) Partial hospitalisation; (b) general psychiatric services (TAU) | Inpatient/outpatient psychiatry, partial hospitalisation, medication | (a) £19,364 (£10,966) (b) £21,969 (£17,985) | Healthcare utilisation of all BPD patients who participated in a previous trial of partial hospital treatment compared with TAU was assessed using information from case notes and service providers. Costs were compared for the 6 months before treatment, 18 months of treatment and an 18-month follow-up period |
| Hall, 2001[71] | BPD | Westmead Hospital, Australia | 12 months | No formal psychotherapy 12 months before with 12 months of psychotherapy | Any hospital admission | Average cost per patient AUS$7309 | The stated aim of this study was to conduct a preliminary cost–benefit study of the effect of outpatient psychotherapy, twice a week for 1 year, in 30 borderline patients . However, this is not a true cost–benefit study |

# Appendix 8

## Mapping BDI to EQ-5D

This mapping uses data from a recently published RCT of supervised self-help CBT in primary care for patients with depression[115] that incorporated EQ-5D and CORE (Clinical Outcomes in Routine Practice). These patients were recruited from 17 primary healthcare teams in the NHS. It used CORE rather than the BDI, but CORE is a depression-specific questionnaire that is similar in many ways to the BDI and it has been mapped onto the BDI by the developer of the CORE (Barkham: personal communication). The mapping function was fitted to these data to provide BDI data on each case.

This provided 62 patients with predicted BDI scores and EQ-5D data. The BDI score has been fitted to EQ-5D data using a simple linear model by ordinary least squares. The model produced in SPSS is summarised in *Tables 37–39*.

The interpretation of the constant at over 1 only presents problems for patients with BDI scores below 5.0, which does not arise in the mean BDI scores to which it is applied in the studies reported here. More complex models such as curvilinear ones did not greatly improve the fit of the model.

A better model would have fitted the original item responses (e.g. Brazier[116]), but because these BDI scores were derived from the CORE, item-level data were not available. The adjusted *R*-squared suggests at best a moderate fit and, more importantly, its dependence on the BDI means that many of the quality of life consequences for people suffering from BPD are not considered. The quality of life score probably under-represents the impact of BPD Nonetheless, the BDI does focus on affect, so at least reflects the way in which it impacts on the feelings and happiness of people with BPD.

***TABLE 37*** *Model summary*[a]

| Model | *R* | $R^2$ | Adjusted $R^2$ | SE of the estimate |
|---|---|---|---|---|
| 1 | 0.534[b] | 0.285 | 0.273 | 0.262183 |

[a] Dependent variable: EQ-5D overall utility (tariff).
[b] Predictors: (constant), BDIPRED.

***TABLE 38*** *ANOVA*[a]

| Model | | Sum of squares | df | Mean square | *F* | Significance |
|---|---|---|---|---|---|---|
| 1 | Regression | 1.645 | 1 | 1.645 | 23.937 | 0.000[b] |
| | Residual | 4.124 | 60 | 0.069 | | |
| | Total | 5.770 | 61 | | | |

[a] Dependent variable: EQ-5D overall utility (tariff).
[b] Predictors: (constant), BDIPRED.

***TABLE 39*** *Coefficients*[a]

| Model | | Unstandardised coefficients | | Standardised coefficients | *t* | Significance |
|---|---|---|---|---|---|---|
| | | *B* | SE | β | | |
| 1 | (Constant) | 1.110 | 0.111 | | 9.954 | 0.000 |
| | BDI score | –0.021 | 0.004 | –0.534 | –4.893 | 0.000 |

[a] Dependent variable: EQ-5D overall utility (tariff).

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