Title: The development and testing of joint crisis plans for people with borderline personality disorder
a feasibility study

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The development and testing of joint crisis plans for people with borderline personality disorder: a feasibility study

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Declaration

Some of the work described in this dissertation has been published elsewhere:

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2.) **Borschmann, R**, Hogg, J, Phillips, R, & Moran, P. (2011). Measuring self-harm in adults: a systematic review. *European Psychiatry, 27*, 176-180.

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The above publications are located in Appendix I. The results of this trial have been presented at the following international conferences:

1.) **Borschmann, R**., Moran, P., Flach, C., Barrett, B., Byford, S., Hogg, J., Leese, M., Sutherby, K.M., Henderson, C., Rose, D., Slade, M., Szmukler, G., & Thornicroft, G. (2011). The effectiveness of joint crisis plans for people with borderline personality disorder. International Society for the Study of Personality Disorders (ISSPD), XIIth International Congress; March 1-4, Melbourne, AUSTRALIA.

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I hereby declare that this dissertation, submitted in partial fulfilment of the requirements for the degree of Doctor of Philosophy and entitled “The effectiveness of joint crisis plans for people with borderline personality disorder: a pilot randomised controlled trial”, represents my own work and has not been previously submitted to this or any other institution for any degree, diploma or other qualification.

Dr Rohan Derek Borschmann

May 1st, 2014

ABSTRACT

Background: This dissertation focuses on effective crisis management for people with borderline personality disorder. The dissertation reports a single-blind randomised controlled trial investigating the effectiveness of joint crisis plans (JCPs; a type of advance statement regarding future treatment preferences for people with mental health problems) compared with treatment as usual for community-dwelling adults meeting research diagnostic criteria for borderline personality disorder.

Methods: During the developmental phase, three focus groups were held with mental health service users, clinicians and academics in order to adapt an existing joint crisis plan template, the utility of which was then tested in a small (N=13) pilot study. Participants in the resulting larger trial were recruited from community mental health teams in south London and randomised to receive either treatment as usual (TAU) or a joint crisis plan plus treatment as usual. Participants were assessed on a number of variables prior to randomisation and again at six-month follow-up and these included self-harm, engagement with services, therapeutic alliance and health-related quality of life.

Results: Eighty-eight adults out of the 133 referred were eligible and consented before being randomised to receive a joint crisis plan in addition to treatment as usual (n = 46) or TAU alone (n = 42). This represented approximately 75% of the target sample size. Follow-up data were collected on 73 (83.0%) participants. A modified intention-to-treat analysis revealed no significant differences in the

proportion of participants who reported self-harming (odds ratio (OR) = 1.9, 95% CI: 0.53–6.5, P=0.33) or the frequency of self-harming behaviour (rate ratio (RR) = 0.74, 95% CI: 0.34–1.63, P=0.46) between the two groups at follow-up. No significant differences were observed between the two groups on any of the secondary outcome measures. JCPs were viewed favourably by participants, who reported referring to their JCPs both during and between crises. Approximately half of participants (47%) reported a greater sense of control over their mental health problems and an improved relationship with their mental health team when using a JCP.

Conclusions: This dissertation expands the knowledge about effective crisis management for people with borderline personality disorder, a group who have traditionally been alienated from mainstream mental health services and are still perceived to be difficult to help. The study showed that it is possible to recruit and retain adult service users with borderline personality disorder to a trial of joint crisis plans. Although the intervention was not clinically effective, the findings suggest that the brief intervention was perceived as helpful to participants with borderline personality disorder. Future research - including a definitive trial with a more comprehensive process analysis - may provide further information about the potential benefits of JCPs to people with borderline personality disorder.

Table of Contents

CHAPTER 1. BACKGROUND **19**

Chapter 1.1. Borderline personality disorder **19**
1.1.1 Introduction to borderline personality disorder 19
1.1.2. Diagnostic features 20
1.1.3. Public health burden 22
1.1.4. History of the concept 24
1.1.5. Concerns about the diagnosis 25
1.1.6. Assessment 28
1.1.7. Epidemiology 28
1.1.8. Aetiology 30
1.1.9. Course 31

Chapter 1.2. Treatment of borderline personality disorder **34**
1.2.1. Psychosocial and psychological interventions 36
1.2.2. Psychological therapy programmes 37
1.2.3. Individual psychological therapies 42
1.2.4. Pharmacological therapies 48

Chapter 1.3. Borderline personality disorder and crisis management **56**
1.3.1. Systematic review of crisis interventions for BPD 62
1.3.2. Summary of BPD and remaining areas of uncertainty 64

Chapter 1.4. Self-harm **66**
1.4.1. Definition and terminology 66
1.4.2. Epidemiology 68
1.4.3. Economic costs 71
1.4.4. Association with suicide 72
1.4.5. Clinicians' attitudes towards self-harm 73
1.4.6. Functions of self-harm 74
1.4.7. Measurement issues 75
1.4.8. Management and prevention of self-harm repetition 77
1.4.8.1. Psychological interventions 80

1.4.8.2. Psychosocial interventions 83
1.4.8.3. Pharmacological interventions 86
1.4.9. Association with borderline personality disorder 87
1.4.10. Summary of self-harm and remaining areas of uncertainty 88

Chapter 1.5. Joint crisis plans 90
1.5.1. Introduction to shared decision-making 90
1.5.2. Introduction to joint crisis plans 92
1.5.3. Previous research 95
1.5.4. Summary and remaining areas of uncertainty 99

Chapter 1.6. Aims & hypotheses 101
1.6.1. Aims 101
1.6.2. Hypotheses 102

CHAPTER 2. METHODS 103

2.1 Feasibility study 103
2.2. The trial 109
2.2.1. Trial design 109
2.2.1.1. Choice of control group 110
2.2.2. Participants 111
2.2.2.1. Trial setting 111
2.2.2.2. Eligibility criteria 112
2.2.2.3. Identification of potential participants 113
2.2.3. Ethical approval and trial registration 114
2.2.4. Baseline data collection 114
2.3. Intervention 114
2.3.1. Intervention group: JCP plus TAU 114
2.4. Measures 116
2.4.1. Baseline measures 116
2.4.2. Rating instruments used 116
2.5. Outcome data collected at six-month follow-up 124
2.6. Sample size and power calculation 125

2.7. Randomisation 126
2.7.1. Stratification 127
2.7.2. Allocation concealment 128
2.7.3. Implementation 128
2.8. Data entry 128
2.9. Statistical analyses 129
2.9.1. Analysis of outcome measures 129
2.9.2. Analysis of JCP contents 130

CHAPTER 3. RESULTS 131

3.1. Results from developmental phase 131
3.2. Findings from the trial 133
3.3. Recruitment to the trial 133
3.4. Primary outcome measure 141
3.5. Secondary outcome measures 144
3.6. JCP content analysis 151

CHAPTER 4. DISCUSSION 156

4.1. Summary of main findings 156
4.2. General methodological considerations 156
4.3. External and internal validity of the trial 157
4.4. Strengths of the study 172
4.5. Discussion of hypotheses in light of trial findings 173
4.5.1. Primary outcome 173
4.5.2. Secondary outcomes 173
4.6. Qualitative findings 176
4.7. Possible reasons for negative findings 178
4.8. The trial in context 178
4.9. Implications 180
4.9.1. Implications for research 180
4.9.2. Implications for clinical practice 182

4.10. Summary and conclusions 185

REFERENCES 188

APPENDICES 265

Appendix I: Published papers from the trial 265
Appendix II: Materials and instruments used in the trial 267

List of tables

		Page
Chapter 1.	**Background**	
Table 1.	NICE recommendations for managing crises with people with BPD.	58
Table 2.	Risk and protective factors for self-harm (adapted from Skegg, 2005).	69
Table 3.	Functions of self-harm reported in the literature.	73
Table 4.	NICE guideline aims and objectives in the treatment of self-harm.	77
Chapter 2.	**Methods**	
Table 5.	Domains measured at baseline and instruments used to measure them.	116
Table 6.	Instruments used at different data collection points.	124
Chapter 3.	**Results**	
Table 7.	Number of participants recruited by borough.	135
Table 8.	Demographic characteristics of participants at baseline.	136
Table 9.	Number of SCID-II criteria endorsed by participants at baseline.	137
Table 10.	Substance misuse patterns reported at baseline.	139
Table 11.	Comparisons of the differences in self-harm at six months	141

between participants in the TAU and JCP arms.

Table 12. Summary of all secondary outcome measures data at baseline and follow-up for both trial arms. 144

Table 13. Mean HADS depression and anxiety scores (with standard deviations) reported by participants in the JCP and TAU arms 145

Table 14. Reported JCP use by participants in the JCP+TAU arm. 148

Table 15. Illustrative examples of situations and actions listed as being helpful and unhelpful by participants seeking to connect with, or disconnect from, other people during times of crisis. 151

Table 16. Illustrative examples of specific actions that participants stated they wanted mental health professionals to do during future crises. 153

Table 17. Individuals and services nominated by participants to receive a copy of their Joint Crisis Plans. 154

List of figures

		Page
Chapter 3.	**Results**	
Figure 1.	Pattern of participant recruitment to the trial.	132
Figure 2.	CONSORT diagram of participant flow through the trial.	134
Figure 3.	Proportion of participants in each trial arm who reported self-harming during the follow-up period.	142

Abbreviations & acronyms

The following abbreviations and acronyms are used in this dissertation:

95% CI	95% Confidence Intervals
A&E	Accident and Emergency Department
APA	American Psychiatric Association
AUDIT	Alcohol Use Disorders Identification Test
BPD	Borderline Personality Disorder
CBT	Cognitive Behaviour Therapy
CMHT	Community Mental Health Team
CONSORT	Consolidated Standards of Reporting Trials
CPA	Care Programme Approach
CSQ	Client Satisfaction Questionnaire
CTU	Clinical Trials Unit
DBT	Dialectical Behaviour Therapy
DSH	Deliberate Self-Harm
DSM	Diagnostic and Statistical Manual of Mental Disorders
DSM-III	Diagnostic and Statistical Manual of Mental Disorders (3rd Edition)
DSM-IV-TR	Diagnostic and Statistical Manual of Mental Disorders (4th Edition, Text Revision)
DSM-V	Diagnostic and Statistical Manual of Mental Disorders (5th Edition)

EQ-5D	European Quality of Life Scale
GP	General Practitioner
HADS	Hospital Anxiety and Depression Scale
HTA	Health Technology Assessment
ISRCTN	International Standard Randomised Controlled Trial Number
JCP	Joint Crisis Plan
MBT	Mentalization-Based Therapy
MRC	Medical Research Council
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NSSI	Non-Suicidal Self-Injury
PAG	Project Advisory Group
RCT	Randomised Controlled Trial
SAPAS	Standardised Assessment of Personality – Abbreviated Scale
SCID-II	Structured Clinical Interview for DSM Disorders (2nd Edition, Borderline Personality Disorder subsection)
SES	Service Engagement Scale
SLAM	South London and Maudsley NHS Trust
SPSS	Statistical Package for the Social Sciences
TAU	Treatment as Usual
TES	Treatment Experience Survey
TSC	Trial Steering Committee
UK	United Kingdom
WAI-C	Working Alliance Inventory (Client version)

WAI-T	Working Alliance Inventory (Therapist version)
WSAS	Work and Social Adjustment Scale
WEMWBS	Warwick-Edinburgh Mental Well-Being Scale
WHO	World Health Organization

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For Oriana:

Girlfriend at enrolment, fiancée during write-up,

wife at graduation

CHAPTER 1. BACKGROUND

Chapter 1.1. Borderline personality disorder

1.1.1 Introduction to borderline personality disorder

Borderline personality disorder (BPD) is a complex mental disorder of variable severity, characterised by a pervasive pattern of instability in interpersonal relationships and self-image, in addition to marked impulsivity and impaired functioning (1, 2). People with BPD are frequently in crisis (3, 4) and can have difficulties engaging in treatment (5-8). They have maladaptive personality styles which emerge in a variety of contexts and lead to distinct patterns of dysfunctional behaviour and interpersonal relationships (7-9). People with BPD often make what appear to many people to be bad decisions (10-12) and this may include a cycle of seeking out victim roles and manipulating others to inflict harm upon them (13, 14). People with BPD may also undermine themselves or sabotage their previous efforts when a goal is about to be attained (e.g. severely regressing after a discussion of recent progress in therapy) (15, 16), to be highly sensitive to perceived rejection from others (17, 18), to have difficulty dealing with emotions (19) and to misinterpret non-verbal cues from others in social interactions (20-30).

Research into the maladaptive psychological mechanisms underpinning BPD has indicated that people with the disorder have difficulties in appreciating other people's mental states such as beliefs, feelings, desires and intentions (31). Difficulties in problem-solving are often very pronounced in people with BPD and can contribute to them engaging in self-harming behaviour (32). Many people with BPD

also experience co-morbid mental health problems and symptoms such as paranoia, auditory hallucinations (33), alexithymia and chronic anhedonia are prevalent in this group of individuals (34-37). BPD is one of the most controversial Axis II diagnoses in the American Psychiatric Association (APA)'s Diagnostic and Statistical Manual (DSM-V) (38) and it presents some of the most difficult and challenging problems in all of psychiatry. The diagnosis has been the focus of considerable interest amongst researchers and clinicians in recent decades, with a more voluminous literature focusing on BPD than any other recognised personality disorder (39-41).

1.1.2. Diagnostic features

The current BPD diagnosis was largely developed in the late 1970s after the development of a reliable diagnostic method (42, 43) and it takes the form of a categorical diagnosis (i.e., one either receives the diagnosis or does not) (44). This method allowed clinicians to reliably distinguish people with BPD from those with other disorders including schizophrenia and depression, in addition to establishing a valid threshold for making a diagnosis and identifying seven highly distinguishing characteristics (45). These seven characteristics, along with the addition of 'identity disturbance', formed the basis of the BPD diagnostic criteria adopted in the third edition of DSM (the DSM-III) produced by the APA in 1980 and the only significant change since this time has been the addition of 'psychotic-like symptoms' to DSM-IV in 1994 (45). According to the DSM-IV-TR (Text Revision) (1), BPD is characterised by a pervasive pattern of instability of interpersonal relationships, self-image and affects, in conjunction with marked impulsivity. Additionally, at least five out of the following nine criteria need to be present for a definitive diagnosis to be made:

(1) Frantic efforts to avoid real or imagined abandonment;
(2) A pattern of unstable and intense interpersonal relationships characterised by alternating between extremes of idealization and devaluation;
(3) Identity disturbance: markedly and persistent unstable self-image or sense of self;
(4) Impulsivity in at least two areas that are potentially self-damaging (e.g. spending, sex, substance abuse, reckless driving, binge eating);
(5) Recurrent suicidal behaviour, gestures or threats, or self-mutilating behaviour;
(6) Affective instability due to a marked reactivity of mood (e.g. intense dysphoria, irritability, or anxiety usually lasting a few hours and only rarely more than a few days;
(7) Chronic feelings of emptiness;
(8) Inappropriate, intense anger or difficulty controlling anger (e.g. frequent displays of temper, constant anger, recurrent physical fights);
(9) Transient, stress-related paranoid ideation or severe dissociative symptoms.

These nine diagnostic criteria have an established research legacy and have thus far proven clinically valuable (45). Furthermore, all have been examined for their relative specificity, sensitivity and predictive power (45, 46). As the presence of any five of the nine criteria is sufficient for a diagnosis to be made, there is potential for extensive heterogeneity among people diagnosed with BPD (47, 48). It has been estimated that there are 256 different combinations of diagnostic criteria that all

confer the official DSM-IV-TR diagnosis (45, 49, 50). Additionally, two individuals with the same diagnosis may only share one of the nine diagnostic criteria (51). Grilo and colleagues (46) demonstrated that the combination of criterion two (intense unstable relationships) and criterion five (recurrent suicidal behaviours) were sufficient to accurately predict a diagnosis of BPD in a majority of cases. In light of the above, some researchers have suggested that such heterogeneity in presentation is a considerable barrier to effective research and clinical progress in the area (51, 52). Recent research has also suggested that psychiatric outpatients meeting just one of the nine BPD criteria displayed greater psychosocial morbidity than outpatients meeting none of the criteria (53). Furthermore, symptom severity (based on Axis II co-morbidity) has been identified as having some predictive power regarding treatment outcome (2). This evidence suggests that sub-threshold levels of severity are still of clinical significance.

1.1.3. Public health burden

Many people with BPD suffer considerably and can place a heavy burden on those around them (54-56). Due in part to the high degree of symptomatic distress often exhibited by people with BPD, they typically make frequent use of acute psychiatric and primary care services (50, 54, 57-65). It has been estimated that people with BPD commence an average of six different outpatient therapies over the course of their illness and that as many as two thirds cease attending the majority of these programs within the first three months (66, 67). Furthermore, in one study, 80 percent of participants with BPD were taking three or more medications simultaneously (68). At times, people with BPD can be extremely difficult to engage

in therapy in spite of efforts by therapists to keep them in active treatment and they can consequently use a disproportionate amount of therapeutic resources (61, 69). The impulsive and chaotic interpersonal functioning that is characteristic of BPD often makes the process of establishing a therapeutic relationship challenging (70, 71).

The overall societal and economic costs of BPD become even greater when the costs related to behaviours such as reckless driving, domestic violence, sexual risk behaviours, shoplifting, unplanned pregnancies, imprisonment and pathological gambling (behaviours which are more common among people with BPD than among those without it) are added to health service costs (72-82). People with BPD have less stable employment histories and are more likely to have been made redundant - or lost a job intentionally - than those without the diagnosis (83-85). Additionally, BPD negatively affects the course and treatment of coexisting medical (86-89), psychiatric (90-94) and substance use (95-98) disorders. The intensity and duration of treatment utilisation by people with BPD and their severe social dysfunction (and subsequent costs) underscore the disorder's public health significance (45, 99-101) and reduction in quality of life (102, 103). After conducting a national survey of more than 10,000 people in Australia, Jackson and colleagues (104) reported that a diagnosis of BPD was significantly more strongly associated with having one or more Axis I conditions, greater mental disability and greater functional impairment than having no diagnosis of personality disorder. People with BPD were also more likely to have sought prior mental health consultations from general practitioners (GPs),

psychiatrists and psychologists than those with an Axis I disorder or physical health condition (104).

1.1.4. History of the concept

The BPD diagnosis, and a developmental approach to understanding the disorder, is rooted in psychoanalytic theory and clinical observation (105). In 1938, Adolph Stern first used the term 'border line group' to describe a number of low-functioning, difficult-to-treat psychiatric patients whom he believed fitted into neither the psychotic nor the neurotic category (106). Observing that these patients presented with 'a fairly definite clinical picture and fairly definite clinical symptoms' (p.468), and intrigued by his inability to help these patients using the same methods that had proven so successful with neurotic patients, Stern compiled a list of features that were present in this patient group. He noted that they did not respond to standard psychotherapy and that their symptoms included inordinate hypersensitivity, insecurity, anxiety, rigid personality, deeply embedded feelings of inferiority and difficulties with reality testing in interpersonal relationships (106). However, it was not until Knight's seminal 1953 article (107) on 'borderline states' that the construct began to gain widespread attention in the literature. In this article, Knight described patients who had classic neurotic symptoms and intact areas of functioning, but whose ability to adapt to environmental demands or form meaningful relationships were severely impaired (105).

In modern healthcare settings, the term 'borderline' - based on Stern's old theory that such pathology lies on the border between psychosis and neurosis - is

considered by some to be a misnomer; rather, the disorder is a complex syndrome characterised by affective instability, poor impulse control and persistent interpersonal difficulties (108). Common clinical features of BPD include frequent intense mood swings, an inability to tolerate intimacy, chronic suicidality, perceiving others as being either entirely good or entirely bad (with no middle ground) and alternating between extreme dependency and sudden hostility (13). These features of the disorder interact with and reinforce each other, resulting in a pattern of behaviour and symptoms that has been described both as an 'unrelenting crisis' (109) and 'stable instability' (110). Despite this, the label is accompanied by considerable controversy; John Gunderson, himself an outspoken advocate of BPD research and treatment, once wrote that 'borderline personality disorder is to psychiatry what psychiatry is to medicine' (i.e., it remains far behind other major disorders in terms of awareness and research) (111).

1.1.5. Concerns about the diagnosis

In spite of the sizeable literature on BPD, its considerable public health impact and its high prevalence in hospital and community settings, the clinical construct of BPD is not without its opponents (112-114). Many criticisms have been levelled at the diagnosis from researchers, clinicians and members of the public alike, who state that it has little clinical utility, due in part to its flexible, unpredictable and heterogeneous presentation (38, 44, 45, 115, 116). In a 1985 article, reporting findings from a study in which they had examined 100 people with BPD from a phenomenological developmental perspective, Akiskal and colleagues (117) famously stated that the borderline diagnosis was 'an adjective in search of a noun'.

The BPD diagnosis has even been labelled 'the virus of psychiatry' applied erroneously as a negative catch-all to difficult clients (118). Until the 1980s, some clinicians and researchers viewed BPD with scepticism, often believing it was a sub-threshold variant of another disorder such as depression or bipolar disorder (117). More recently, it has been claimed that BPD symptoms and features do not identify a latent taxon or category and that, as such, the current categorical view of the disorder is inaccurate and inappropriate (44). Indeed, Tyrer (116) argued that BPD was *"neither borderline in nature, nor is it a personality disorder"* and that it is a pre-diagnosis rather than a fully formed one (115). He goes on to argue that BPD is incorrectly classified as a personality disorder and that it does an injustice to those who suffer from it, adding that it would be better classified as a condition of recurrent unstable mood and behaviour (116). Others have suggested that the diagnosis of BPD is essentially a heuristic for organising clinical information and guiding clinical decisions (119, 120).

However, despite such opposition, and as stated above, the nine criteria currently used to diagnose BPD have an established research legacy and have thus far proven clinically valuable (45). The BPD diagnostic criteria have remained essentially unchanged over the past three decades and a substantial body of research has now established the heritability, prevalence, developmental antecedents, markers of risk, course and treatment of the disorder (45). Furthermore, no changes were made in the recent DSM-V, published in 2013. As such, until the current polythetic algorithm used to diagnose BPD is improved upon and accepted widely by clinicians and

academics, it appears that the system retains significant clinical utility and will continue to be used in clinical and research settings alike (121).

Professional attitudes towards people with BPD are often negative and derogatory across mental health and emergency medicine service settings alike (57, 122-131). People with a diagnosis of BPD often attract more negative responses from staff members than those with a diagnosis of, for example, depression or schizophrenia (4, 143, 148). Perceptions of manipulative and threatening behaviour are common (132-135), with nurses in one study describing patients with BPD as powerful, dangerous, unrelenting forces that leave a trail of destruction in their wakes (133). Other research has shown that BPD appears to be associated with a greater likelihood of disruptive behaviours (such as yelling, screaming, verbally threatening, and refusing to talk with medical staff) in medical settings (136). It has also been suggested that receiving a diagnosis of BPD can lead to service users pre-emptively rejecting mental health services as a direct consequence of the stigma associated with the label. This, in turn, this leads to them being labelled as 'difficult' clients and a non-therapeutic vicious cycle then ensues (123, 137, 138). Consequently, many clinicians choose not to disclose the diagnosis to service users for fear of the above scenario playing out (139-141). However, much has been written about treatment considerations specific to people with BPD (142) and studies have shown that staff attitudes towards such service users can be improved as a result of education about BPD (122, 143-145).

1.1.6. Assessment

Assessment of BPD is best undertaken using a validated measure. Options are self-report questionnaires and structured clinical interviews (146), of which the latter are widely considered to be the gold standard for diagnosing BPD (147). Structured and semi-structured clinical interviews typically give more reliable results than unstructured clinical assessment and are thus preferred by many clinicians and academics (52). Instruments include the Structured Clinical Interview for DSM-IV Axis-II Personality Disorders (SCID-II) (148, 149), the McLean Screening Instrument for Borderline Personality Disorder (MSI-BPD) (150), the Diagnostic Interview for DSM-IV Personality Disorders (151), the Diagnostic Interview for Borderline Patients (DIBP) (43), the Borderline Personality Questionnaire (BPQ) (152), the Minnesota Borderline Personality Disorder Scale (153, 154), the Borderline Syndrome Index (155), the Borderline Personality Disorder Severity Index (156) and the International Personality Disorder Examination (157). Establishing a definitive diagnosis of BPD is time-consuming, often occurring over the course of multiple sessions, and is not without difficulties. As is the case when diagnosing other personality disorders, the issue of mental state bias may impact on the diagnostic process; in the case of BPD, people who are either depressed or in a manic episode can be wrongly labelled as having the affective instability associated with BPD (158, 159).

1.1.7. Epidemiology

BPD is the most prevalent Axis II disorder in both inpatient and outpatient mental health treatment settings (160). Approximately one to two percent of the general population, 10 percent of psychiatric outpatients, 20 percent of psychiatric

inpatients and 60-80 percent of forensic inpatients meet the diagnostic criteria for BPD (1, 52, 161). Additionally, between 30-60 percent of individuals with any other personality disorder meet the criteria for BPD (1). A recent national household study in the United Kingdom (UK) (54) reported a prevalence of 1.3 percent and a similar figure of 1.4 percent was reported in a comparable study from the USA (162), though other studies have reported prevalence figures as high as 5.9 percent of the general population in the USA (163). Torgersen and colleagues (164) suggested that BPD is not as prevalent as commonly assumed, reporting that just 0.7 percent of a representative community sample from Oslo, Norway, were diagnosed with the disorder.

The disorder is more prevalent in individuals with substance misuse disorders (165-169) and forensic populations (170) and it is frequently co-morbid with depression, anxiety and eating disorders (13, 48, 171-175). Two large-scale epidemiological surveys have reported greater physical and mental disability among people with BPD than among those without, after controlling for pre-existing medical conditions, socioeconomic status and Axis I disorders (102, 104). BPD is the most prevalent of all Axis II disorders treated in all clinical settings (99, 112). To a great extent, it is younger women who are diagnosed with BPD (161) and, accordingly, approximately 75-80 percent of individuals receiving therapy for BPD are women (50, 118), although the ratio is more even in community samples (162, 164, 171). The discrepancy in prevalence estimates might potentially be explained by several factors: a) women may be more likely than men to seek treatment for BPD; b) symptoms of BPD might cause more impairment in women relative to men; or c)

gender bias in the categorical description of BPD may result in women being more likely to be given the diagnostic label of BPD (176, 177). The disorder manifests itself in different ways between the sexes; whilst men with BPD are more likely to present with substance misuse disorders (178) and co-morbid personality disorders (including antisocial personality disorder), women with BPD are more likely to present with eating disorders and posttraumatic stress disorder (PTSD) (179).

1.1.8. Aetiology

Many people with a diagnosis of BPD have a background of early trauma (180); research has shown that approximately 40-50 percent of people with BPD report early sexual abuse by a non-family caregiver, 25 percent by their fathers (52), five percent from their mothers (52) and 33 percent report other severe forms of abuse (108). Other studies report a rate of sexual abuse as high as 91 percent and other childhood neglect as high as 92 percent (181). However, as physical and sexual abuse frequently co-occur, it is often difficult to determine whether one or both are necessary or sufficient for the development of BPD (52, 182, 183). It has also been reported that an association exists between the type of abuse experienced and specific borderline traits (184) and that multiple forms of trauma are associated with increased health service use and ongoing pharmacological interventions for people with BPD (185).

There is considerable research evidence to suggest that genetic factors have a role in the development of BPD (186, 187). Genetic studies have shown that the disorder is significantly heritable, with 42 to 68 percent of the variance associated with genetic

factors (95-98). Furthermore, the major components of BPD (i.e., interpersonal hypersensitivity, affective dysregulation, and impulsivity) have also been shown to be correlated within families (188) and BPD is five times more common among first-degree relatives of those with the disorder than in the general population . Factors relating to disorganised attachment systems, neurophysiological and neurobiological dysfunctions of emotional regulation and stress may also be contributing factors to the development of BPD (189).

1.1.9. Course

BPD is typically not diagnosed until a person is 18 years old (1). Although the diagnosis is given to adolescents on occasion (190-192), the practice remains somewhat controversial and is still in its infancy (193-196), with little evidence regarding effective treatments (197, 198). The course of BPD is considerably variable, but it is often the most debilitating during late teens and early twenties when mood instability, impulsivity and frequent self-harming behaviour are especially prominent (1, 170, 199). Although the disorder was once believed to be immutable, empirical research has demonstrated considerable plasticity (200). There is a large body of research suggesting that the symptoms of BPD begin to subside or reduce in severity from around the mid-twenties (201-203), although there is a subgroup (characterised by poor functioning and enduring suicidal ideation or attempts) who do not fare as well (204). In 2003, Gunderson and colleagues (205) suggested that people with a diagnosis of BPD can make significant rapid improvements within a period of two years that are of sufficient duration to be considered remissions. In 2004, Grilo and colleagues (206) showed that less than half

(44 percent) of their cohort met the diagnostic criteria for BPD at two year follow-up, whilst an Italian study from 2011 reported that one quarter (26%) of participants no longer met diagnostic criteria after two years (207).

The McLean Study of Adult Development (MSAD) commenced in 1993 and has charted prospectively the health outcomes of people with BPD since this time (208, 209). After the first six years, Zanarini and colleagues reported that remission rates were high (74 percent) and that these remissions were stable (210) and were comparable (78% - 99%) after 16 years (211). Independent ten-year follow-up studies (212, 213) have each reported that the course of BPD is characterised by high rates of remission and low rates of relapse, yet severe and persistent impairment in social functioning. Research evidence suggests that many people can remain functionally impaired even if they no longer meet the diagnostic criteria for BPD (214). In Gunderson's 2011 study (212), in which 175 participants with BPD, 312 participants with a cluster C personality disorder (either avoidant, dependent or obsessive-compulsive personality disorder) and 95 participants with major depressive disorder (and no personality disorder) were followed-up over a course of ten years, 85 percent of participants with BPD reached diagnostic remission. Additionally, only 12 percent of participants with BPD were classified as having relapsed after ten years. Zanarini's 2007 study (213) examined in greater detail the sub-syndromal phenomenology of BPD by assessing 24 symptoms occurring commonly in people with BPD (including affective instability, chronic anxiety, intolerance of aloneness and manipulative suicide efforts) over the course of ten years in a sample of 290 participants with BPD. Results showed that 12 of the 24

symptoms were reported at follow-up by less than 15 percent of participants who had reported them at baseline and that the remaining 12 symptoms also showed a pattern of reduction in severity, though with a less dramatic decline.

Longer-term outcome studies report that about two-thirds will be 'functioning well' when evaluated 10-25 years after initial contact (215-218), with the greatest decline in rates occurring typically after 44 years of age (216, 219). Such findings suggest that BPD may consist of some symptoms that are manifestations of acute psychiatric illness and other symptoms that represent more enduring aspects of the disorder (213, 220). After following a sample of 64 people with BPD over a 27-year period, Paris and colleagues (221) reported that approximately ten percent eventually went on to commit suicide. This figure is particularly high for young women, a group in whom the suicide rate is typically far lower (72). Against this, however, was the rate of four percent reported by Zanarini and colleagues in the MSAD (210).

There is a small body of research which suggests that BPD can persist - and even be first diagnosed - in people over the age of 50 and, indeed, in older adults (222-226). Research also suggests that the clinical presentation of older adults with BPD differs significantly from that of younger adults with BPD (227). Specifically, older adults with BPD are more likely to be impulsive, to self-harm and to display affective instability, whilst younger adults are more likely to present with co-morbid substance use disorders (228). However, when compared with other psychiatric conditions, BPD is typically associated with a relatively encouraging prognosis (39, 229, 230), though it may take a long time to achieve a positive outcome (211).

Predictors of poor prognosis include a history of childhood sexual abuse, young age at first psychiatric contact, symptom chronicity, affective instability, aggression, substance abuse and other psychiatric co-morbidity (161, 214).

Chapter 1.2. Treatment of borderline personality disorder

Although much has been learned in recent decades about the treatment of BPD, there are still few well-validated treatments for the disorder (231). People with BPD often present with complex pathology and associated problems, complicating clinical assessments and management as well as frequently posing considerable difficulties for clinicians endeavouring to establish or maintain a therapeutic relationship (70, 232). The literature contains numerous treatment options and interventions for BPD and these vary considerably in their theoretical approach, delivery format and amount of supporting evidence. According to Bateman and Fonagy (233), certain key principles underpin the management of BPD, irrespective of the treatment modality. Treatment needs to be carefully structured, with particular attention given to adherence, and the treatment model needs to be coherent to both service user and clinician (233).

Successful treatment of BPD is often measured in terms of quality of life, social functioning and service use (234). It can be challenging and many people with BPD discontinue treatment prematurely (137, 235, 236), with adverse effects on clinical outcomes (236). Regression in psychotherapy, countertransference issues, staff splitting and unstable one-to-one relationships are all likely to be experienced by

clinicians treating people with BPD (236, 237). The ever-present risk of threats of suicide, or indeed completed suicide, represents another common feature of treatment, bringing with it a range of clinical and ethical challenges for health professionals (47, 238). One factor mentioned frequently in relation to treatment for people with BPD is the common problem of early discontinuation from therapy. Previous studies have indicated that people with BPD who discontinue therapy programmes often have significantly higher levels of anger, greater Axis I co-morbidity and poorer therapeutic alliance - and have made significantly more suicide attempts - than those who complete treatment (239). Impulsiveness - a core feature of BPD - also plays a role in attrition from treatment. As such, it is likely that helping the individual to gain greater control of his or her impulsiveness early on in treatment is a critical issue in reducing such attrition (10, 236). It has been reported that as many as 60 percent of participants in trials of psychotherapy for BPD symptoms discontinue treatment prematurely (240). However, a 2011 systematic review and meta-analysis of treatment completion in psychotherapy for BPD (241) reported completion rates ranging from 36 to 100 percent, with an average of 75 percent of participants completing the full course of therapy. The authors stated that their findings challenged the long-held association between BPD and premature discontinuation from psychotherapy, suggesting that such an association may no longer be appropriate or evidence-based.

The treatment of people with personality disorder in the UK was, until recently, highly variable, with some parts of the country lacking any treatment services and with good practice concentrated in a few small centres of excellence. This situation

improved with the publication of national guidance from the Department of Health in 2003: “Personality disorder: no longer a diagnosis of exclusion” (242) which led to a raft of new service development and renewed enthusiasm for the management of personality disorders, and particularly BPD. In an attempt to ensure uniform treatment options across the National Health Service (NHS) for people with BPD, the UK National Institute for Health and Clinical Excellence (NICE) published a guideline on the long-term treatment and management of BPD (189) in 2009. The guideline incorporated a systematic review of the evidence base for psychological and pharmacological interventions for BPD. A brief description of these interventions is provided below.

1.2.1. Psychosocial and psychological interventions

It is widely acknowledged that some form of psychosocial intervention will be necessary in most cases (72, 243, 244). Psychosocial interventions cover a wide range of approaches, all of which include some form of talking therapy, but which differ in intensity, complexity and method. These interventions are delivered usually by mental health professionals with advanced training in the method being implemented (189). In a 2012 systematic review of psychological therapies for people with BPD, Stoffers and colleagues (245) stated that numerous psychologically-based therapeutic interventions are used for people with BPD and that these vary in both their theoretical approach and methods of practical application. The authors stated that many problems frequently encountered by people with BPD may be amenable to talking treatments, but that such therapies remain experimental and that studies in the literature are too few and too small to

inspire full confidence in their results (245). Furthermore, given that BPD is characterised by interpersonal difficulties and disturbances in relationships, it is perhaps not surprising that establishing a strong therapeutic relationship is central to most approaches to psychosocial interventions for BPD, and that many of these approaches also share some common structural features (233, 246, 247).

Brazier and colleagues (248) published a systematic review of psychological therapies for BPD, including dialectical behaviour therapy (DBT; see below) and concluded that, although the overall efficacy of psychological therapies appears to be promising, the current evidence is inconclusive. It has been claimed that research into effective interventions for BPD has not yet reached the stage where superiority over treatment as usual (TAU) can be assumed, particularly when the treatments being investigated have not previously demonstrated efficacy. During the course of a trial, rates of remission not due to the intervention may be significant, calling into question the conclusion that these interventions are responsible for a clinically significant improvement in the absence of a control group (249). More well-designed studies are both justifiable and urgently needed (5, 248).

1.2.2. Psychological therapy programmes

Dialectical behaviour therapy

Dialectical behaviour therapy (DBT) is a manualised, time-limited (12-month) treatment for BPD developed by Linehan to treat individuals with chronic suicidality, combining treatment strategies from behavioural, cognitive and supportive psychotherapies (243, 250). It is a variant of cognitive behavioural therapy with the

emphasis on behaviour, incorporating dialectics and mindfulness (251). Like many cognitive behavioural programs, DBT emphasises clear and precise definition of treatment targets, ongoing assessment of current behaviours and a collaborative working relationship between service user and therapist (252). The treatment is based on a combined motivation/capability deficit model of BPD, based on two assumptions; 1) people with BPD lack important skills in interpersonal interactions, emotion regulation, distress tolerance and self-regulation; and 2) various personal and environmental factors often inhibit the use of more appropriate behavioural skills that the person has and this reinforces ineffective borderline behaviours (253).

DBT includes weekly or twice-weekly group therapy and 60-90 minutes per week of individual therapy, in addition to the availability of out-of-hours telephone contact with a therapist. The group sessions consist of psychoeducational skills training, emphasising the acquisition of interpersonal effectiveness, distress tolerance, emotion regulation and self-management capabilities (254, 255). The individual therapy sessions consist of directive, problem-oriented techniques (such as behavioural skills training and contingency management) balanced with more supportive techniques (such as reflection, empathy and acceptance). The treatment goals of individual DBT sessions are organised hierarchically by importance in the following order: 1) reduction of self-harm and life-threatening behaviours; 2) reduction of any behaviours that interfere with the process of therapy; and 3) reduction of any behaviours that significantly interfere with the individual's quality of life (243). The first target is always high-risk self-harm behaviours because, as Linehan (254) stated, 'psychotherapy is not effective with dead patients' (p.239).

Whenever self-harm occurs, either part or whole of the next session is dedicated to discussing the event and of appropriate problem-solving strategies (254). Both during and between sessions, the DBT therapist actively teaches and reinforces adaptive behaviours (256). The overriding dialectic in DBT is its synthesis of validation and acceptance of the client on the one hand, set against persistent attention to behavioural change on the other (250).

Since Linehan's initial findings were published in 1991 (243), DBT has been widely implemented throughout multiple therapeutic settings and has been used successfully with a variety of client groups (257-271). It is currently the most frequently investigated intervention for BPD (255). There is some evidence to suggest that DBT is more effective than TAU (which is usually some form of case management from a community-based mental health team) for reducing the frequency and medical severity of suicide attempts and self-harm behaviour (272), the frequency and duration of inpatient psychiatric admissions, attrition from treatment, social maladjustment ratings and subjective ratings of anger in the treatment of women with BPD (208, 213, 214), especially when used in inpatient settings (273). As such, it should be considered as a treatment option if reducing self-harming behaviour is a priority (189). Also, results from a recent non-randomised trial (274) suggest that DBT can have a positive impact on self-esteem and self-concept, and thus on identity disturbance. An Australian quasi-experimental trial in 2010 (275) also reported that successful completion of a DBT programme was associated with reduced health service utilisation, particularly by participants with high previous service use histories. Some authors have speculated that the focus in

DBT on generalising certain skills to the individual's natural environment might account for some of the positive treatment outcomes (276).

It must be noted that treatment failures have also been reported with DBT (277, 278). In 2009, McMain and colleagues (278) conducted a randomised controlled trial of DBT versus general psychiatric management for BPD, using a sample of 180 people with a diagnosis of BPD. At one-year and two-year follow-ups, no significant differences were found between the two groups (266, 278), suggesting that people with BPD benefited equally from DBT and a well-specified treatment delivered by psychiatrists with expertise in treating BPD. This finding highlights the importance of clearly defining the control treatment in trials of interventions for BPD (e.g. TAU vs. best available practice). No findings were published regarding the cost-effectiveness of the two trial arms.

Such findings notwithstanding, the overwhelming majority of evidence supports the effectiveness of DBT for people with BPD, especially in reducing self-harm. Stoffers and colleagues (245) concluded that DBT was helpful on a range of outcomes (including reducing admissions to hospital and incarcerations), but the small sample sizes in the studies included in the review limits confidence in their results. The authors concluded that larger trials are urgently needed (245). The findings from a 2010 meta-analysis of 16 studies of DBT (eight RCTs and eight non-randomised trials) revealed a moderate global effect and a moderate effect size for reducing suicidal and self-injurious behaviours (255).

Mentalization-based treatment

The term 'mentalization' refers to a person's capacity to conceive of conscious and unconscious mental states in themselves and others (279-281). It is a preconscious, imaginative (as the person must imagine what other people might be thinking or feeling) mental activity which enables a person to perceive and interpret human behaviour in terms of intentional mental states such as the needs, desires, feelings, beliefs and goals of others (282, 283). Several factors can disrupt the development of mentalizing, including psychological trauma during childhood (281).

Mentalization-based treatment (MBT) is a psychodynamically-oriented treatment for people with BPD based on attachment and cognitive theory which aims to strengthen a person's capacity to understand their own and others' mental states in attachment contexts. This is in order to improve their interpersonal functioning, as well as their affect and impulse regulation, which may contribute to reducing or eliminating self-harming behaviour (189, 284). The focus of MBT is stabilising the sense of self (246) and the overall aims are threefold; 1) to promote mentalizing about oneself; 2) to promote mentalizing about others; and 3) to promote mentalizing of important interpersonal relationships (285). MBT for BPD is based on an understanding of BPD primarily as a disorder of the self, resulting from developmental disturbance of attachment in childhood and leading to a deficit in mentalization ability (246, 286).

Trials conducted by the creators of MBT (Bateman and Fonagy) have shown that the intervention - when delivered by generic mental health professionals as part of a

partial hospitalisation program - was cost-effective and superior to TAU over a period of three years (287-289) and that these treatment effects remained five years after the cessation of all index treatment (284, 288). Findings from a recent RCT comparing MBT with structured clinical management (284) showed that participants in the MBT group displayed a steeper decline of both self-reported and clinically significant problems, including suicide attempts and hospitalisation.

The creators of MBT have suggested that it may be useful for implementation in general mental health services both in the UK (284) and abroad (290). In light of early promising findings (291), further independent investigations of the efficacy of MBT are warranted.

1.2.3. Individual psychological therapies

Cognitive behaviour therapy (CBT)

Cognitive behaviour therapy (CBT) is a structured, time-limited, individual talking therapy focused on problems relating to dysfunctional emotions, behaviours and cognitions. It is one of the most extensively researched forms of psychotherapy and, although originally developed as a treatment for anxiety and depression, it has been adapted for an increasingly wider range of disorders and problems (189, 292, 293). CBT is typically less intensive in terms of clinician time than other forms of psychotherapy developed specifically for BPD (294). Despite this, relatively few randomised controlled trials (RCTs) examining the efficacy of CBT with BPD have been conducted (69, 294). Additionally, the cost-effectiveness of CBT for use within BPD populations has also been questioned (99). In one RCT by Davidson and

colleagues published in 2006 (69), participants receiving CBT in addition to TAU reported significantly reduced dysfunctional beliefs, state anxiety, psychiatric symptom distress and fewer suicidal acts; however no significant differences were observed on measures such as depression, social functioning, quality of life or interpersonal problems. Following these results, the authors conducted a prospective six-year follow-up study using this cohort of participants (295). The results indicated that the gains of CBT over TAU were maintained after six years and that 46 percent of the original total sample (44% of the CBT group vs. 48% of the TAU group) still met diagnostic criteria for BPD. Additionally, participants in the CBT group went on to have significantly fewer hospitalisations during the follow-up period than those in the treatment as usual group.

Problem-solving therapy

Problem-solving therapy (PST) is a brief psychological treatment based on cognitive behavioural principles originally designed for use with people with depression. The goal is for people to learn a structured method for overcoming problems that they believe have either precipitated their depressive state or have become increasingly difficult to solve as a result of their depressive state (189, 296). PST is a very structured and collaborative process, focussing on generating solutions to current problems (297). Applied to BPD, PST involves training participants in five major processes: problem orientation; problem definition and formulation; generation of alternatives; decision-making; and solution implementation and verification (298, 299). Cognitive modelling, prompting, self-instructions, and reinforcement are all used during these five stages (189). Additionally, since a variety of health and mental

health professionals can be trained to deliver PST, it is potentially a cost-effective treatment option for people with BPD receiving care from community-based mental health teams (CMHTs) (296).

PST has been used successfully with personality disordered male offenders (300) and was viewed in a positive light by many participants in this setting (301). However, the samples used in these studies with offenders were only partly made up of people with BPD. Further research would clarify the effectiveness of problem-solving therapy in an exclusively-BPD sample.

Schema-focused therapy

Schema-focused therapy (SFT) is a cognitive therapy that aims to effect structural change in a person's personality by altering maladaptive core beliefs and schemas (189, 302). The theory behind SFT suggests that people with BPD develop such schemas in the context of adverse events during childhood (303). In 2009, Farrell and colleagues (304) published findings from an RCT in which eight months of SFT were compared against TAU for 32 people diagnosed with BPD. Participants in the SFT group (which boasted a 100 per cent retention rate, a notable finding in itself) reported significantly greater reductions in BPD symptoms and global severity of symptoms than participants in the TAU group. Additionally, 94 per cent of participants in the SFT group no longer met diagnostic criteria for BPD after eight months of treatment, compared with 16 percent in the TAU group. The authors of a 2013 systematic review of the empirical foundations underpinning the effectiveness of schema therapy concluded that it is a promising and cost-effective intervention

for BPD (305). This small research base suggests that SFT may be an efficacious, disorder-specific treatment for BPD, although further research is required to establish its effectiveness (303).

Cognitive analytic therapy

Cognitive analytic therapy (CAT) is a time-limited, integrative psychotherapy developed in the UK by Ryle (306-309). CAT combines elements of object relations theory and cognitive psychology into an integrated model of development and psychopathology (310). Therapy involves a number of CBT methods, with attention to the therapeutic relationship as the vehicle of change, aiming to develop the motivation, skills and opportunities for learning new patterns of relating to oneself and others (189). There is a limited evidence base for the effectiveness of CAT in BPD, although results from a 2000 trial (311) suggest that shorter-term outpatient weekly psychotherapy is feasible and that CAT is a promising intervention for BPD which requires further research.

CAT has also been adapted for early intervention with adolescents and young adults with symptoms of BPD. Findings from an Australian RCT with participants aged 15-25 in 2008 (310) showed that CAT yielded greater symptom improvement than TAU over a two-year follow-up period. Additionally, participants in the CAT group showed a faster rate of improvement over time, and lower levels of externalising psychopathology, than participants receiving treatment as usual. However, caution must be exercised when drawing inferences from these findings, as some

participants in the sample met as few as two out of nine diagnostic criteria for BPD and thus did not have a definitive diagnosis.

Psychodynamic / psychoanalytic psychotherapy

Psychoanalytically-oriented forms of psychotherapy for people with BPD are based on the assumption that unconscious conflicts are responsible for the sharply polarised attitudes and extreme shifts in behaviour (such as switching rapidly from idealisation to devaluation) often seen in people with BPD (40). By addressing these conflicts directly, the goal is to reduce the problematic behaviours in question. Clinicians engaging in psychotherapy with BPD populations have adapted the methods in order to achieve treatment success (303). For example, whilst psychoanalytic therapists have traditionally maintained neutrality and allowed the patient to project their inner conflicts and wishes onto them, these methods have been modified in working with people with BPD so that the therapist provides more structure and is more active in the process (189). A recent systematic review of factors predicting a positive outcome in psychotherapy (312) indicated that pre-treatment symptom severity and client-rated therapeutic alliance were the two strongest predictors. There is limited evidence that long-term psychotherapy can be a useful form of treatment intervention for people with BPD (313), though more research is needed before substantive conclusions can be drawn from the findings.

Group therapy

One intervention format described frequently in the literature for the treatment of BPD symptoms is group therapy and its many variants (286-289, 314, 315). Several

types of group therapy for BPD have been trialled in both inpatient and outpatient settings and the potential advantages of these approaches are numerous; for example, the group format dilutes the potential for transference and countertransference issues commonly associated with people with BPD, thereby effectively reducing the anxiety associated with treating such individuals. Also, belonging to a group may provide its members with feelings of acceptance and commonality so often lacking in such populations (316, 317).

Despite some questions about the generalizability of findings, many studies suggest that group therapy can be an effective and valued treatment option for people with BPD (316, 318). Other non-randomised studies have reported that group therapy can also be an effective adjunctive treatment for enhancing self-esteem in females with BPD (319). Many studies of group therapy for BPD have focused heavily on female samples, using samples consisting either exclusively (194, 195, 197-199) or predominately (320) of female participants. Future research using mixed and/or exclusively male samples are urgently required in order to make reliable inferences about the efficacy of group therapy for BPD.

Summary of psychological interventions

The overall evidence base for psychological therapies in the treatment of BPD is relatively poor (189). The situation is further complicated by the fact that many trials to date have been underpowered and caution must therefore be exercised when interpreting any findings. There is some evidence for the efficacy of brief psychological interventions, manual-assisted cognitive therapy, cognitive behaviour

therapy, problem-solving therapy, schema-focused therapy, cognitive analytic therapy, psychodynamic psychotherapy, group therapy, mentalization-based treatment and dialectical behaviour therapy. At the time of writing, DBT represents the optimal treatment for women with BPD, where the treatment focus is on reduction of self-harm (255, 256, 278, 321). However, there is an urgent need to generate the missing evidence and to improve and expand upon the services available to people with BPD. Larger and better-designed trials need to be conducted before any strong recommendations can be made (5, 189, 248, 322).

1.2.4. Pharmacological therapies

There are currently no medications available in the UK which are indicated specifically for the treatment of BPD (189). However, many people with the diagnosis receive ongoing and long-term pharmacological treatment with antipsychotics, antidepressants and/or mood stabilisers (60, 189, 323-330) to manage state symptoms and trait vulnerability factors. Many people are prescribed multiple concurrent medications despite the lack of evidence supporting this practice (331). One longitudinal study found that 75 percent of participants with BPD were prescribed two or more different medications concurrently at some point in the six years following a hospital admission (209). This pattern of polypharmacy persists despite the associated heightened rate of obesity and related chronic illnesses, in addition to other side effects (88). Of particular note is that one of the few major studies of the effect of polypharmacy reported that, at follow-up, people with BPD fared approximately as well with one medication as they did with two (332).

The specific medications prescribed to people with BPD are selected typically due to their properties known from other psychiatric conditions such as depressive, psychotic, or anxiety disorders (a process termed 'off-label use'), which mostly target affective or impulsive symptom clusters (60, 326). The 2009 NICE guideline (189) recommended that pharmacological intervention should not be used specifically for the treatment of BPD, nor for the individual symptoms or behaviours associated with BPD. Furthermore, the guideline recommended that clinicians should aim to reduce and eliminate the unnecessary pharmacological treatment of people with BPD by reviewing the existing treatment of those individuals who do not have a diagnosed co-morbid mental or physical illness but who are prescribed medication (189).

It has been suggested in the literature that pharmacotherapy should not be used in the treatment of BPD as it presents unnecessary risks of harmful side effects (333). However, the impulsive behaviour of people with BPD, in addition to frequent distortions of thought and perception and lability of mood, provide some clear targets for pharmacotherapy (325). After conducting a systematic review of pharmacological interventions for BPD in 2010, Stoffers and colleagues (60) concluded that some beneficial effects have been observed with second-generation antipsychotics, mood stabilisers and dietary supplementation by omega-3 fatty acids. However, they noted that this evidence was based mostly on single study effect estimates and, as such, replicating such studies would be of considerable clinical and research utility (60). Despite conflicting opinions regarding a) the effectiveness, and b) the appropriateness of pharmacotherapy for people with BPD, it has been recommended as an adjunctive, symptom-targeted component of

treatment (334). Many other recent reviews (60, 303, 323, 326, 335-340) have indicated some evidence of effectiveness for certain medications including lamotrigine, topiramate, valproate, aripiprazole, olanzapine and omega-3 fatty acid supplementation.

Given that impulsivity and frequent attempts to engage in self-harm are two of the diagnostic criteria for BPD, there is a danger that such individuals may misuse - or overdose on - any form of prescribed medication. However, the medical consequences associated with an overdose of antipsychotics are typically less serious than those associated with other psychotropic drugs, such as tricyclic antidepressants (325). Another common concern relating to medication use and BPD is that of polypharmacy, which may occur when a person with BPD, or their doctor, wishes to continue or add medications despite a lack of demonstrable benefit. In one study (68), more than a third (37 percent) of participants with BPD were prescribed three or more psychotropic medications concurrently. Furthermore, one six-year follow-up study showed that polypharmacy was not affected by time, with 40 percent of participants prescribed three or more concurrent medications, 20 percent prescribed four or more and 10 percent of participants prescribed five or more medications at any follow-up period examined throughout the six-year duration of the study (341). The 2009 NICE guideline recommended that psychotropic medications with an unclear benefit should be discontinued prior to a new medication being initiated (189). A brief discussion of the main classes of psychotropic medications used commonly in the treatment of BPD is provided below.

Anticonvulsants and mood stabilisers

Affective instability is a core symptom of BPD and the co-occurrence of bipolar disorder in people with BPD is not uncommon (39, 158, 159, 241, 250, 313, 342, 343). Indeed, many symptoms of the onset of bipolar disorder (including impulsivity, wasteful spending and sexual promiscuity) are very similar to that of BPD (344-348) and this can frequently lead to misdiagnosis (349). Anticonvulsants and mood stabilisers such as lithium - common in the treatment of bipolar disorder - are therefore sometimes used in the treatment of mood-related symptoms in people with BPD (326, 350). There is limited evidence to suggest that mood stabilisers (in particular topiramate and lamotrigine) can be moderately effective against affective instability (189, 323). However, these effects are typically modest and side effects including obesity and associated hypertension are common. Thus, it is recommended that such medications should only be prescribed as adjuncts to psychotherapy (72).

Antipsychotics

Antipsychotics are often used to treat people with BPD, not only for their sedative effects (which may be desirable in BPD, as patients can experience high levels of arousal) but also because many of the licensed indications for antipsychotics are similar to some of the core features of BPD (e.g. cognitive and perceptual distortions, mood symptoms, irritability and aggression) (189, 324). RCTs have been conducted on classical neuroleptics and also on second generation - or atypical - antipsychotics (326). Some studies have reported that antipsychotics were slightly more effective than placebo in terms of impulsivity, interpersonal relationships and global

functioning (323, 351). However, other data have indicated that there may be an increase in self-harming behaviour in people treated with the antipsychotic olanzapine (60). There is also some evidence to suggest that injectable atypical antipsychotics (such as olanzapine or ziprasidone) may be effective, fast and safe for treating acutely agitated people with BPD (352). One recent trial comparing the impact of olanzapine and haloperidol on the management of mental and behavioural symptoms of people with BPD (353) reported that no significant differences were observed between the two medications. Another double-blind placebo-controlled RCT of olanzapine involving 451 people with BPD (351) reported a modest (but significant) benefit of olanzapine over placebo in relation to overall BPD psychopathology. However, as highlighted by the authors, such a benefit must be weighed against the risk of adverse metabolic effects associated with olanzapine, particularly weight gain and the subsequent health risks.

A recent meta-analysis of placebo-controlled RCTs of antipsychotics for people with BPD (324) showed that, in the short term, antipsychotics can have significant beneficial effects on cognitive-perceptual symptoms, anger, and mood lability, but that their long-term use with this population remains controversial. Similarly, the NICE guideline (189) advised against the use of antipsychotic drugs for the medium- and long-term treatment of BPD. The short-term side effects resulting from neuroleptic medication, including extrapyramidal symptoms such as dystonia and akathesia, often contribute to noncompliance and early termination of pharmacotherapy in people with BPD (325).

Antidepressants

Depression and symptoms of depression are common in people with BPD and many antidepressants, including selective serotonin reuptake inhibitors (SSRIs; antidepressant agents with a selective action on serotonin dysregulation), are often prescribed to people with BPD, though such medications have typically had little demonstrable benefit over placebo in controlled trials (354). For example, the results of an RCT published in 2002 (355) showed that no difference between the SSRI fluvoxamine and placebo was observed in the effect on impulsivity and aggression scores amongst female participants with BPD. There is some limited evidence to suggest that antidepressants, in particular fluoxetine, may have a modest effect against affective instability and impulsivity (323).

In their 2011 systematic review of double-blind RCTs of medications for the treatment of BPD published between 1990 and 2010 (comparing both 'active drugs versus placebo' and 'drugs versus drugs'), Bellino and colleagues (326) reported that there was some evidence that SSRIs may be effective in reducing affective symptoms including depression, anxiety and anger in people with BPD. However, most studies included in their review allowed for inclusion of participants with congruent mood and anxiety disorders and this affected the validity of findings, as SSRIs have been shown to be effective in the treatment of such disorders independently of BPD (326). As such, caution must be exercised when interpreting their findings. As with several other classes of medication, the NICE guideline (189) stated that more large clinical trials were needed to clarify the role of antidepressant medication in the treatment of people with BPD.

In summary, there are currently no medications available in the UK designed specifically for the treatment of BPD. However, studies have shown some evidence that pharmacological treatments can improve some aspects of the clinical picture by helping to reduce specific BPD symptoms including anger, anxiety, depression, hostility and impulsivity (326, 356). Other BPD features, including chronic feelings of emptiness, identity disturbance, avoidance of abandonment, and dissociation were not found to be affected significantly by any medication (189, 326). The overall evidence for the efficacy of pharmacotherapy is weak and it is often based on single studies (357). The long-term use of these medications has not been studied and current evidence does not support the effectiveness of any drug on the overall severity of BPD symptomatology (358). There is no strong evidence from any credible RCTs that any one medication reduces overall BPD severity in the short or long term. As such, a consensus about drug indications in the treatment of BPD is lacking and further research is urgently needed to provide reliable recommendations (22, 84, 241, 244).

Brief psychological interventions

In recent years, the average length of psychiatric hospitalisations has decreased and, consequently, effective brief inpatient treatments (defined as low intensity interventions lasting less than six months (189)) for people with BPD are in greater demand (359). Additionally, the often high rates of premature discontinuation (67) - combined with the typically modest effects of longer-term interventions - raise the possibility that briefer treatments, delivered following crises or during times of an

individual's heightened motivation to change, may prove to be more cost-effective than longer-term interventions or therapy for treating BPD (70, 231). There is some evidence that brief treatments for BPD may have the potential to facilitate meaningful change and increase the cost-effectiveness of treatment (70, 360). However, the effects of brief treatment on crisis management, early discontinuation from therapy and symptom reduction need to be further explored.

Although it has been suggested that most brief treatments are poorly-suited to people with BPD (as such treatments typically favour highly motivated and well-functioning participants), the aforementioned shift towards shorter inpatient admissions and increased community-based cared in the UK, as a result of resource constraints, dictates that effective short-term treatments need to be developed (314).

Manual-assisted cognitive therapy

Manual-assisted cognitive therapy (MACT) is a brief (up to six sessions), cognitively-oriented and problem-focused therapy, developed originally as a public health intervention for individuals engaging in repeated self-harming behaviour (361). As such, whilst it was not developed specifically for use with individuals with a diagnosis of BPD, many people in this population meet the diagnostic criteria for BPD and this subpopulation is therefore similar to that for which other psychological interventions were developed (189). The intervention is a six-session, manualised therapy that targets deliberate self-harm, incorporating elements of other cognitive-based interventions for BPD, with the option of a further two 'booster sessions' within six

months. The accompanying manual covers an evaluation of the specific self-harm attempt, crisis skills, problem solving, basic cognitive techniques to manage negative thinking, and relapse-prevention strategies (189).

A pilot study published in 1999 (361) showed that MACT was associated with a reduction in depressive symptoms and an increase in positive future thinking in a small sample of participants with repeated self-harm when compared to those in the treatment as usual condition. The authors went on to conduct a large-scale multi-centre randomised trial comparing MACT with treatment as usual in a sample of 480 participants with histories of repeated self-harm (179, 180). Results of this trial indicated that brief MACT was of limited efficacy in reducing self-harm, but the findings - taken in conjunction with the economic evaluation (362) - indicated that MACT was superior to TAU in terms of cost and effectiveness combined (363). The results regarding overall quality of life, however, were inconclusive. A small pilot study examining the efficacy of MACT as a stand-alone treatment for BPD published in 2010 (231) showed that, although MACT was associated with a significant reduction in both suicidal ideation and BPD features, less than half of the sample completed the full treatment.

Chapter 1.3. Borderline personality disorder and crisis management

People with BPD are at an increased risk of experiencing crises - many of which may include suicidal or homicidal threats, gestures or actions (364). It has been suggested that the DSM-IV diagnostic criteria for BPD read like an operational definition of a

crisis state; these include ‘frantic efforts’, ‘a pattern of unstable and intense personal relationships’, ‘impulsivity’, ‘recurrent suicidal behaviour’, ‘affective instability’ and ‘inappropriate intense anger’ (365). Factors commonly associated with the onset of a crisis for people with BPD include: a clear precipitating event causing acute anxiety and emotional suffering; an acute reduction in motivation and problem-solving ability; and an increase in help-seeking behaviour (366). People with BPD may present with a range of symptoms and behaviours, including behavioural disturbance, self-harm, impulsive aggression and short-lived psychotic symptoms, as well as with intense anxiety, depression and anger (189). Crises may be triggered by seemingly minor incidents or precipitated by threats of separation, fear of rejection, or expectations for which the person assumes responsibility (367). Several features associated with BPD are likely to increase the frequency of acute crisis events. These include:

- Alienation from lasting and meaningful relationships;
- Difficulty learning from previous experience;
- Inability to utilise support systems such as family and friends;
- A history of previously experienced crises that have not been effectively resolved; and
- Impulsive personality traits associated with impulsive and sometimes reckless behaviour (368).

Crises may be followed by social withdrawal, admission to hospital, self-harming behaviour, conflict in close relationships, or any combination of these. Goals of crisis interventions typically include returning the distressed individual to their pre-crisis level of functioning and mobilising both internal and external resources (365). The

2009 NICE guideline on the management of BPD (189) included a section on crisis management and, as shown in Table 1, this focused largely on empowering the individual.

Table 1. NICE recommendations for managing crises with people with BPD.

Crisis management strategies for people with BPD; adapted from NICE (189)
• Assess the level of risk to self or others; • Ask about effective management strategies used in the past; • Help the individual to manage anxiety by enhancing coping strategies; • Encourage the individual to identify manageable changes that will enable them to deal with the current crisis; • Offer a follow-up appointment to monitor progress; • Consider referral to a CMHT if the levels of distress and/or the risk of harm to self or others are a cause for concern

The guideline also recommended that short-term use of sedative medication during a crisis should be considered with caution and, if implemented, should not be prescribed for a period of longer than one week. An individual's capacity to consent to any form of treatment - including short-term medication - during times of crisis must also be considered in such circumstances (189). While these pragmatic recommendations are intended to assist clinicians in formulating a sensible and realistic response to crises occurring for people with BPD, empirical research in this area is lacking and little is known about what constitutes effective help for people with BPD in crisis (364, 369). In fact, one recent meta-analysis of 36 crisis intervention studies (370) contained no mention of BPD (or any other personality disorder), focusing instead on individuals with depressive disorders, PTSD and

suicidal ideation. A Cochrane review of crisis interventions for people with BPD published in 2012 by Borschmann and colleagues (371) revealed that there had been no completed RCTs of crisis intervention from which any firm conclusions could be drawn (see ***1.3.1. Systematic review of crisis interventions for BPD***, below). One ongoing randomised controlled trial was identified in which participants with BPD were provided with access to a 24-hour emergency crisis telephone line for 12 months or treatment as usual (372).

In recent years, several uncontrolled studies have examined the efficacy of various crisis interventions for people with BPD. In 2005, McQuillan and colleagues (373) examined the effectiveness of an intensive three-week version of DBT for 127 outpatients with BPD who were in crisis. Although the trial was not controlled and participants were not randomly allocated to the intervention arm, results showed that treatment completion was high and participants showed statistically significant improvements in both depression and hopelessness measures. Importantly, the authors also stated that this particular approach allowed therapists to treat a large number of people in a relatively short period of time (373).

In 2011, Berrino and colleagues (369) conducted a study to determine the efficacy of crisis intervention at a general hospital following self-harm (a common behavioural correlate of crises in BPD) in a sample of individuals meeting DSM-IV-TR criteria for BPD. Two hundred individuals presenting to an emergency department following self-harm were allocated to either TAU or crisis intervention and followed up after three months. The results showed that the rates of both repeated self-harm and

inpatient admissions were significantly lower in the intervention group than the TAU group. The authors concluded that crisis intervention may be a suitable management strategy for acutely suicidal people with BPD (369). However, this study was limited by its naturalistic and non-randomised design, preventing any reliable inferences being made about the comparative efficacy of the crisis intervention model tested.

In 2011, Linehan and colleagues (374) conducted a pilot study to examine the feasibility of a DBT software application (or 'app') for a smartphone, designed to enhance generalisation of a specific DBT skill amongst people with BPD and a co-morbid substance use disorder. One of the main attractions of such an app is that it is available to the person 24 hours a day. The results of the pilot study indicated that, although the smartphone app was not designed to replace the function or role of the individual therapist, such technology may be beneficial as an adjunct to standard DBT.

Short-term medications, such as sedatives, are used frequently in clinical practice to manage crises, even though there is no evidence for the use of any specific medication(s) in crisis management (189). In his 2011 article about the process of managing medication for people with BPD, Silk (328) recommended that, during acute crises, it is advisable not to commence or change medications whenever possible. He went on to state that crises, by their very nature, come and go; as such, the best approach is to encourage the individual to use skills or other behavioural cognitive approaches to get through the crisis.

1.3.1. Systematic review of crisis interventions for BPD

Objective

A systematic review was conducted to assess the evidence for the effectiveness of crisis interventions for adults with BPD in any setting. For the purposes of the review, a crisis intervention was defined as 'an immediate response by one or more individuals to the acute distress experienced by another individual, which is designed to ensure safety and recovery and lasts no longer than one month' (371).

Search methods

RB searched the following databases in September 2011: CENTRAL (*The Cochrane Library* 2011, Issue 3), MEDLINE (1948 to August Week 5 2011), MEDLINE In Process & Other Non-indexed Citations (8 September 2011), EMBASE (1980 to Week 36 2011), PsycINFO (1806 to September Week 1 2011), CINAHL (1937 to current), Social Services Abstracts (1979 to current), Social Care Online (12 September 2011), Science Citation Index (1970 to current), Social Science Citation Index (1970 to current), Conference Proceedings Citation Index - Science (1990 to current), Conference Proceedings Citation Index - Social Science and Humanities (1990 to current) and ZETOC Conference proceedings (12 September 2011). RB searched for dissertations in WorldCat (12 September 2011), Australasian Digital Theses Program (ADTP; 12 September 2011), Networked Digital Library of Theses and Dissertations (NDLTD), 12 September 2011 and Theses Canada Portal (12 September 2011). RB also searched for trials in the International Clinical Trials Registry Platform (ICTRP).

RB scrutinised the reference lists of published review articles in the area to locate additional relevant publications not already identified by the database searches. He then searched the complete archives of the six journals returning the largest number of relevant citations (*American Journal of Psychiatry*, *Archives of General Psychiatry*, *British Journal of Psychiatry*, *Journal of Clinical Psychiatry*, *Psychological Medicine* and the *Journal of Personality Disorders*). Finally, RB contacted the ten most published researchers in the field of BPD (as indexed by BioMed Experts; www.biomedexperts.com), in addition to contacting topic experts Marsha Linehan, Arnoud Arntz and Paul Links about ongoing trials and unpublished data.

Search terms

Databases were searched using variants of the terms 'borderline personality disorder' AND 'crisis' AND 'randomised controlled trial' (for a full list of search terms, see Appendix 1).

Results

A total of 3118 articles were identified via the online database search and a further 16 articles were located from other sources. After duplicates were removed, there were 1958 unique articles. The titles and abstracts of these 1958 were screened by two authors (RB and JH) and assessed against the inclusion criteria; 1943 were excluded as a result of clearly not being of relevance to the review topic. The full texts of the 15 articles that seemed likely to meet the inclusion criteria (or where this was unclear) were retrieved and read independently by RB and JH, after which 13 were excluded. Reasons for exclusion were: lack of randomisation [N=8; (58, 369,

373, 375-379)], retrospective design [N=2; (380, 381)], or the intervention was a complex psychological therapy lasting longer than one month [N = 3; (284, 382, 383)]. In addition to the present trial, one ongoing RCT that met the inclusion criteria was identified (372) with a predicted sample size of 600; this article was published in French and was translated in full by a native speaker.

Conclusion from the systematic review

A review of the literature did not identify any completed RCTs of crisis intervention compared with usual care or no intervention or a waiting list control for people with BPD. As such, it can be concluded that there is no evidence base to support any specific crisis intervention for people with BPD. In order to develop effective, evidence-based interventions, there is an urgent need for high-quality RCTs.

1.3.2. Summary of BPD and remaining areas of uncertainty

BPD is a chronic mental disorder marked by interpersonal difficulties and an unstable self-image. It is associated with high volumes of service use, frequent crises, self-harming behaviour and considerable distress. Longer-term interventions such as DBT and MBT appear to be promising and effective treatments for BPD (as reflected by the growing literature supporting their effectiveness) and, at the time of writing, DBT represents the optimal treatment for women with BPD, particularly where one focus of treatment is self-harm reduction (255, 256, 278, 321). However, several major criticisms have been levelled at both DBT and MBT, including that each of these treatments requires 1) a minimum of three to six months to produce a significant reduction in self-harming behaviour; 2) individual, group and, sometimes, additional

treatment modalities, and 3) expensive training of therapists (384). Also, service users in many geographical areas have limited access to such complex interventions; in the UK, the major limiting factor in providing access to psychological therapies is the very small proportion of National Health Service (NHS) staff members trained to deliver these to a competent standard (189, 385). Less complex and more affordable brief interventions are therefore urgently needed for the large proportion of people with BPD who are not referred to specialist services (386) and, as such, the prospect of finding a briefer and less expensive treatment offers considerable public health advantages (387). Additionally, investigation of the effectiveness of interventions designed to manage acute crises in people with BPD is both a clinical and an economic priority, as it may contribute to a reduction in suicide-related mortality, an improvement in the quality of life of people with BPD and a reduction in acute health services use and costs (364, 371).

Chapter 1.4. Self-harm

1.4.1. Definition and terminology

There is much debate about what constitutes self-harm and inconsistencies are evident in the literature. Although no universally recognised criteria exist regarding the definition of self-harm, the term refers typically to a person intentionally engaging in one or more behaviours which cause damage, mutilation or destruction of bodily tissue without suicidal intent and with a non-fatal outcome (251). The 2011 NICE guideline for the longer-term management of self-harm (388) stated that self-harm could be divided into two broad groups: self-poisoning and self-injury. Self-poisoning includes intentionally overdosing on licit or illicit substances. Self-injury includes such behaviours as cutting, bruising or biting skin, burning, scalding or picking/scratching skin, head-banging, hair pulling, swallowing objects or any combination of these (389, 390). It has been suggested that there is a spectrum of self-harming behaviours, with relatively minor acts intended to manage or communicate distress at one end and definite suicide attempts which are unsuccessful at the opposite end (32).

Numerous phrases are used interchangeably with the term 'self-harm' in the literature (391-393); these include 'self-mutilation', 'self-injury', 'deliberate self-harm' (DSH), 'suicidal behaviour', 'non-suicidal self-injury (NSSI)', 'non-fatal deliberate self-harm', 'self-poisoning', 'self-injurious behaviour', 'self-inflicted violence', 'self-wounding', 'non-fatal suicidal behaviour' and 'parasuicide'. In this dissertation, the term 'self-harm' will be used to refer to all behaviours captured by the above definition.

Self-harm is a significant problem, across the lifespan, for people engaging in such behaviour, their families, health services and the wider community (251, 394). It has appeared throughout recorded history but, as a result of increased prevalence in recent decades, there has been growing interest from scientists, clinicians and the public (393). Indeed, self-harm is documented as a global health problem and it is among the leading causes of death and injury worldwide (395). Self-harm is one of the strongest predictors of completed suicide (392, 396) and people who self-harm are at significantly increased risk of premature death than the general population (397, 398). It is perhaps not surprising, therefore, that a reduction in self-harm is part of the Health For All targets of the World Health Organisation (WHO) (399).

In May 2013, DSM-5 introduced the diagnostic category of 'non-suicidal self-injury (NSSI)' – a disorder of uncertain nosological status which DSM-5 recommends is the subject of future research (400-404). The term itself is controversial and has been criticised widely by European researchers (402) for a number of reasons. Firstly, NSSI refers to tissue damage and, therefore, repeated self-poisoning is excluded (somewhat arbitrarily). Secondly, suicidal intent is both difficult to measure reliably (405) and changeable between people and between episodes. Finally, people who self-harm repeatedly typically do so for multiple reasons (405) (see ***1.4.6. Functions of self-harm***, below).

Research over recent decades has helped to define self-harm as a health-related behaviour and not merely a sign of an underlying clinical disorder (406). This

behaviour can occur within the context of a broad range of personal and social circumstances (407, 408). A range of people engage in self-harm, including those with and without mental illness, those with substance misuse issues, physical illnesses and psychosocial difficulties (409).

1.4.2. Epidemiology

Self-harm is rare before puberty and becomes more common throughout early adolescence (410), with the first episode of self-harm occurring most commonly between the ages of 12 and 16 (392, 393). Although some self-harming behaviour occurs in a transient period of distress and is associated with no further risk, self-harm is often an important indicator of mental health problems and of an increased risk of suicide (411). A recent Australian longitudinal cohort study reported that, whilst most adolescent self-harming behaviour resolved by young adulthood, adolescent symptoms of depression and anxiety (which may persist) were significantly associated with self-harming behaviour in young adulthood (199).

Self-harm occurs in both clinical and nonclinical populations. In the general population it has been reported that approximately four percent of adults (412), 13-45 percent of adolescents (413-415) and 14-35 percent of college students (416-418) have a recent history of self-harm. It is more common in women than men, amongst gay and bisexual people (392, 419) and in certain subcultures such as 'goths' (32, 420). An elevated incidence of self-harm has also been reported in people with depression (421). It is particularly common among young people, a group in whom rates of repetitive and medically serious self-harm appear to be rising (199, 422-

426). Some differences in the nature and presentation of self-harm across ethnicities, in addition to differences in the methods most commonly used, have also been reported (427).

Approximately one third of people attending an emergency department after an episode of self-harm will be given a psychiatric diagnosis (usually depression) and about one third will have had previous contact with psychiatric services (428). Despite a common misconception, the majority of people who engage in self-harming behaviour do not meet diagnostic criteria for BPD. Haw and colleagues (407) reported that less than half of their sample of people who had self-harmed (46 percent) met the criteria for *any* personality disorder (and only 11 percent met the criteria for BPD), whilst affective disorders were identified in 72 percent of the sample. Most individuals with BPD, however, do engage in self-harming behaviour (429).

1.4.3. Risk factors associated with self-harm

There are many risk and protective factors associated with self-harming behaviours which may be related to personal, social or contextual factors (392, 428, 430-432). These are summarised in Table 1.

Table 2. Risk and protective factors for self-harm (adapted from Skegg, 2005 (392)).

Broad variable	Risk factors	Protective factors
Demographic profile	Adolescent	
	Female gender	
	Low socioeconomic status	
	Low level of education	
	Living in poverty	
	Unemployed	
	Divorced / separated	
	Homosexual / bisexual	
	Criminal record	
Social environment	Adverse childhood experiences	Social support and family activities
	Interpersonal difficulties in	Religious affiliation
	adolescence	Cultural norms
Psychiatric disorders	Depression	Lithium for people with bipolar disorder
	Substance abuse	
	Anxiety disorder	
	Personality disorder	
	Previous psychiatric hospitalisation	
Psychological characteristics	Impulsivity / poor problem-solving skills	Optimistic outlook
	Hopelessness	
	High suicidal intent	
Situational factors	Adverse life events	
	Media influence	
	Awareness of self-harm in others	
	Intoxication	
Physical illness	Epilepsy	
	HIV infection	

Various forms of abuse have been studied in relation to self-harm, with mixed findings. In 2011, Maniglio and colleagues published a review of four previous meta-analyses of 177 published studies (involving a total of 65,851 participants) investigating the relationship between childhood sexual abuse and subsequent self-harming behaviour (433). The authors concluded that childhood sexual abuse should be considered one of the major risk factors for both self-harming behaviour and completed suicide, stating that it may interact with personality traits and psychiatric disorders to contribute to such behaviours in people with a history of abuse.

As well as sexual abuse, bullying victimisation has emerged recently as a strong candidate risk factor for self-harm (434). Findings from a longitudinal study of a nationally representative cohort of 1116 pairs of twins in the UK, published in the BMJ in 2012, revealed that exposure to frequent childhood bullying was predictive of significantly higher rates of self-harm, even after controlling for emotional, behavioural and interpersonal variables (434). The authors concluded that greater effort needs to be invested in helping bullied children to cope more appropriately with the distress resulting from bullying if the rates of self-harm in young people are to be reduced (434).

1.4.3. Economic costs

Self-harm is a major source of public health costs, as it often results in presentations to the emergency department and subsequent psychiatric admissions (435). In the UK, self-harm is one of the five most common reasons for acute admission to

hospital (388, 436), with 200,000 hospital admissions annually resulting from self-harm (437), 40-50 percent of which are repeat episodes (438). Ninety percent of these admissions involve overdosing on licit or illicit substances (439), accounting for 14 percent of all medical admissions (440). Approximately 15 percent of individuals presenting at an emergency department following self-harm will present again within 12 months, adding further to healthcare costs (441). The wider indirect costs of self-harm are unknown; however, given its prevalence, they are likely to be substantial, particularly in terms of days absent from work and education (391).

1.4.4. Association with suicide

Self-harm is strongly associated with psychosocial distress, repetition of self-harm and subsequent completed suicide (442-445). The risk of suicide is at its highest in the first six months after an episode of self-harm and, by its nature, self-harm is also associated with an increased risk of accidental death by misadventure or permanent disability (388, 392). For every completed suicide in the UK, it is estimated that 30 acts of self-harm take place (446). Following an act of self-harm, the rate of suicide increases to between 50 and 100 times the rate of suicide observed in the general population (422, 444). Approximately one percent of individuals presenting to emergency departments following self-harm complete suicide within a year. This figure rises to approximately four percent within ten years, nine percent within 22 years and 10 percent across the lifespan (399, 447). Foster and colleagues (448) reported that between 28 percent and 41 percent of individuals who have engaged in self-harm have had prior suicidal ideation, with between 55 and 85 percent having made a previous suicide attempt. Approximately half of all people who commit

suicide have a history of self-harm, with approximately 20-25 percent having had an episode within the preceding year (399). Approximately one million people each year die by suicide worldwide and this figure is predicted to increase to an estimated 1.5 million by 2020 (449).

1.4.5. Clinicians' attitudes towards self-harm

People who self-harm are often viewed in a negative light by healthcare staff in emergency hospital and psychiatric settings. Research suggests that healthcare staff may feel unskilled, unconfident and anxious when providing care to people who self-harm (428, 440, 450-453). Service users frequently describe contact with health services as difficult and characterised by negative attitudes, ignorance and even punitive behaviour by health professionals (391). In addition, emergency practitioners report that they do not always have sufficient time or resources to provide appropriate care for people presenting with self-inflicted injuries, leading to feelings of frustration towards these individuals (454). Many emergency staff also believe that their function as healthcare professionals is to provide care for 'the deserving sick' and such a belief may cause them to deal with people who have self-harmed in a more judgemental manner (453). A previous NICE guideline regarding the treatment and management of self-harm (391) acknowledged that the experience of care for people who self-harm is often unacceptable and contained recommendations about how staff members should relate to them. These included: 1) treating people who have self-harmed with the same care, respect and privacy as any patient; 2) offering them a choice of male or female staff members (when possible); 3) involving people who have self-harmed in all discussions and decision-

making about their treatment and subsequent care; and 4) asking people who have self-harmed to explain their feelings and their understanding of their self-harm in their own words (391).

1.4.6. Functions of self-harm

The functions of self-harm are numerous and varied and may be related to the individual, to the outside world, or to both (32, 389, 392, 430, 455-463) (see Table 3). For many people, self-harm is an habitual coping mechanism and there is some evidence that these behaviours can continue even after personal problems have been resolved (464, 465). Other individuals use an act of self-harm as a form of 'trigger' for seeking help in the absence of more constructive coping strategies (466).

Table 3. Functions of self-harm reported in the literature.

Functions of self-harm.
• To punish oneself; • To express anger; • To elicit a caring response from, or to manipulate, others; • To avoid an even greater subjective harm (such as confronting the unbearable reality of one's inner experience); • To relieve tension; • To restore balance; • To regulate emotion; • To distract oneself from an intolerable situation; • To assert one's autonomy or establish a boundary between self and other; • To generate excitement.

Furthermore, people often report more than one motivation for self-harming and different forms of self-harm can serve different functions (392). For example, whilst taking an overdose often provides an escape from a difficult situation, cutting oneself may regulate dysphoric affect (467). Rodham and colleagues (468) reported that people who cut themselves think about self-harming for a shorter period than people who poison themselves before initiating the behaviour. They suggested that taking an overdose requires more time and planning than cutting and, as such, may indicate more serious intent and be more likely to require medical attention (468). Recent research by Hawton and colleagues (469) has also suggested that different forms of self-harm place people at different levels of risk for subsequent completed suicide, with methods classified as 'more dangerous' (e.g. self-cutting or road traffic-related behaviours) posing a greater risk than self-poisoning. Some researchers have advocated creating a distinction between direct and indirect forms of self-harm (470) and creating subtypes of BPD on the basis of different self-harming behaviours (471). The precipitants of self-harm are extremely wide-ranging (472-474), though common problems preceding self-harm include relationship difficulties, wider social problems and alcohol or drug misuse (32, 475, 476).

1.4.7. Measurement issues

Due in part to the multi-factorial nature of self-harm (477), measuring the behaviour accurately is difficult and much doubt has been raised about current methods of assessment (405, 478). At the time of writing, a versatile, easily applied 'gold standard' measure of self-harm does not exist (405, 479-481). Much of the published literature on the treatment of self-harm is therefore populated by studies which

have used un-validated measures (405). Additionally, individual items measuring self-harming behaviour can be found in many instruments designed for the assessment of broader psychopathology, developmental disorders and personality trait measures (482). In their 2011 systematic review of instruments to measure self-harm in adults, Borschmann and colleagues (405) suggested that, as with the measurement of violent behaviour, the most reliable way of capturing episodes of self-harm may be to triangulate multiple data sources including self-reported measures, clinician/observer reported measures, case records and possibly contemporaneous patient-held devices such as diaries and counters. The advantage of such an approach is that combining multiple sources of information allows for a more comprehensive measure of behaviour to be constructed (482, 483). The disadvantage is that such an approach is time-consuming and practical constraints limit the number of data sources that can be used in any single study.

Despite the aforementioned challenges, several instruments which purport to accurately capture self-harm events in a range of contexts and populations have been validated and published, with each possessing certain advantages and disadvantages (405, 484). These instruments include the Self-Harm Inventory (485), the Deliberate Self-Harm Inventory (417), the Self-Harm Behavior Questionnaire (479), the Suicide Attempt Self-Injury Interview (486), the Self-Injury Questionnaire (481), the Self-Injurious Thoughts and Behaviors Interview (480), the Self-Harm Information Form (487), the Inventory of Statements About Self-Injury (488), the Self-Harm Questionnaire (SHQ) (489) and Hawton's self-report measure of self-harming behaviours (424). Selection of the most appropriate instrument depends on

the client group, the method of administration required, the assessment setting and the time and resources available to complete the assessment. Irrespective of the instrument(s) used, the next step of measurement - predicting future acts of self-harm - has thus far proven difficult, with research suggesting that severity of previous self-harm acts and overall BPD symptomatology are the two most accurate predictors of future self-harm (490).

1.4.8. Management and prevention of self-harm repetition

Despite the scope and significance of the problems associated with self-harm, there are currently no evidence-based psychological or pharmacological treatments to reduce such behaviours (393). However, many interventions and guidelines for managing and preventing self-harm have been proposed (388, 399, 447). The common goals of such interventions typically include reducing repetition of self-harm, reducing the desire to self-harm, preventing suicide and improving social functioning and quality of life, whilst exerting minimal adverse effects (491). The 2011 NICE guideline on the management and prevention of self-harm (388) included key aims and objectives in the treatment of a person who has self-harmed. These are shown in Table 4.

Table 4. NICE guideline aims and objectives in the treatment of self-harm.

Aims and objectives:
• Prompt assessment of physical and psychological needs; • Effective engagement of the individual; • Prompt measures to minimise pain and discomfort; • Implementation of harm reduction strategies; • Prompt and supportive psychosocial assessment (including a risk assessment); • Provision of information about the long-term treatment, management and risks associated with self-harm; • Provision of six sessions of a psychological intervention specifically structured for people who self-harm with the specific aim of reducing self-harm; this intervention may include cognitive-behavioural, psychodynamic or problem-solving elements; • Psychological, pharmacological and psychosocial interventions for any associated conditions (including BPD, depression, bipolar disorder or schizophrenia); • Prompt referral for further psychological, social and psychiatric assessment and treatment when necessary.

The NICE guideline also recommended developing an integrated and planned approach to the problems precipitating self-harming behaviour. This includes the development of a care plan and a risk management plan in conjunction with the individual, their family, carers or significant others, with printed copies provided for the individual and other key healthcare professionals.

There is currently little convincing evidence for the efficacy of many interventions to reduce self-harm (399). Furthermore, recent studies have suggested that different

amounts of assistance are offered to individuals presenting at emergency departments with injuries resulting from different forms of self-harm. For example, hospital services tend to offer less help to people who have cut themselves - even though they are far more likely to repeat - than to those who have self-poisoned (492). In 1997, Lewis and colleagues (493) suggested that additional interventions following an episode of self-harm might reduce the rate of subsequent suicide by as much as 25 percent. However, a systematic review of psychosocial interventions following self-harm conducted in 2007 by Crawford and colleagues (447) found little evidence to support this contention. One major obstacle to any successful prevention of self-harming behaviour is the tendency of almost half of all people presenting to emergency departments following self-harm fail to attend subsequent follow-up appointments (494). Consequently, it has been recommended that any attendance to an emergency department following self-harm should result in a psychosocial assessment of needs, regardless of the method of self-harm used (492).

Effective interventions for managing and preventing self-harm must also take into account the subjective goals of the person engaging in self-harm, as these may vary considerably between individuals (495). For example, whilst one person's goal might be to permanently stop self-harming, recover from any underlying psychiatric disorder and achieve a good quality of life, another person's goal might be simply to reduce the frequency of self-harm or perhaps to reduce the harm associated with each act of self-harm (388). For others, the goal might be to improve social or occupational functioning. As such, interventions aimed at reducing the repetition of self-harm may focus on the actual behaviours themselves, or they may take a more

holistic approach by examining the individual's close relationships, cognitions and social factors (388). After a qualitative exploration of service users' views of treatment interventions for self-harm, Hume and colleagues (495) reported that there was a clear preference amongst service users for specialist community-based interventions focussing on the provision of immediate aftercare following self-harm, whilst simultaneously acknowledging that the management of self-harm may not necessarily involve its prevention.

Interventions can be divided into three main categories; psychological interventions, psychosocial interventions and pharmacological interventions. A brief summary of each is below.

1.4.8.1. Psychological interventions

As stated above, self-harm is a heterogeneous set of behaviours which can have different meanings and purposes for different people in different contexts (388). Self-harm is associated with a wide variety of psychiatric diagnoses and psychological problems and, as such, psychological interventions need to take account of this complexity. One key aim of many psychological interventions of self-harm is to increase understanding of the specific contributing factors in each individual (388). The rationale for this type of intervention is that an estimated 70 percent of self-harm episodes are precipitated by a personal problem (496). Psychological therapies, therefore, are often aimed at improving social functioning as well as reducing self-

harming behaviour (391, 497). Many different psychological interventions have been investigated in relation to self-harm, as outlined below.

Dialectical Behaviour Therapy (DBT)

DBT, discussed at length in section ***1.2.2. Psychological therapy programmes*** above, was developed for use with individuals with chronic suicidality and the first goal of DBT is to reduce or eradicate the repetition of self-harming behaviour (254). DBT is the psychological intervention with the strongest evidence base for its effectiveness in reducing repetition of both self-harm and suicide attempts (47, 243, 251, 257, 259, 388, 467, 498-500).

Mentalization-Based Treatment (MBT)

MBT is discussed at length in section ***1.2.2. Psychological therapy programmes*** above and there is a limited evidence base for its effectiveness in reducing self-harm behaviour. Findings from a recent RCT comparing MBT with structured clinical management (284) showed that participants in the MBT group displayed a steeper decline of suicide attempts and hospitalisation (among other clinically significant problems) than participants in the structured care group. It was noted, however, that participants in both groups showed substantial improvement over the course of the trial.

Cognitive Behaviour Therapy (CBT)

CBT is discussed at length in relation to BPD in section ***1.2.3. Individual psychological therapies*** above. There is some evidence that it can contribute to a reduction in self-

harm in adults (294, 501) but not in adolescents (502). A 2008 systematic review and meta-analysis examining the effectiveness of cognitive-behavioural interventions to reduce suicidal behaviour (502) found strong evidence to support the hypothesis that CBT can reduce suicide behaviour in the short-term. The authors acknowledged, however, that a publication bias (i.e., whereby non-significant results did not get published, subsequently biasing the available data in favour of treatment effects) may have contributed to this finding.

Randomised controlled trials of CBT treatments have yielded mixed results. In an RCT of brief CBT versus TAU in recurrent deliberate self-harm (the POPMACT study) (363), 480 self-harming participants were randomised to receive either TAU or a CBT-based intervention (manual-assisted cognitive therapy) in addition to TAU and followed up after 12 months. Results showed that there was no significant difference in the proportion of those repeating self-harm at follow-up between participants in the intervention group and those in the control group. The intervention was shown to be cost-effective when compared to treatment as usual after six months, although this difference was no longer significant after 12 months (363).

In another RCT published in 2006 (the BOSCOT trial) (69), 106 people with BPD were randomised to receive TAU alone or CBT plus TAU for 12 months and were followed up at 12 and 24 months. The results showed that there was a significant reduction in self-harm reported by participants in the intervention group, leading the authors to conclude that CBT can produce worthwhile and clinically important changes in self-harm behaviours. It is noted, however, that whilst the BOSCOT trial was focused on

the treatment of BPD, the POPMACT trial was focused on treating self-harm behaviour and the two trial samples may have differed considerably from each other as a result.

Summary of psychological interventions

Both DBT and MBT have been shown to be effective in reducing the incidence of self-harm and suicide attempts (467) in people with BPD. There is also some evidence that CBT may be effective in reducing self-harm in people with BPD. At the time of writing, DBT remains the psychological intervention with the strongest evidence base (47, 243, 259, 467, 500).

1.4.8.2. Psychosocial interventions

Many different psychosocial interventions to manage and reduce repetition of self-harm have been proposed and tested, although many of these trials have not included a sufficient number of participants on which to base firm recommendations (388, 399). Large definitive trials of interventions showing promise are needed to provide robust evidence (399). One goal of many psychosocial interventions is to improve contact and engagement with health services following presentation to an emergency department. This is important because adherence to outpatient treatment programmes after an episode of self-harm is typically poor (391).

In 1993, Morgan and colleagues (494) conducted an RCT randomising a sample of 212 people who had self-harmed for the first time to either the experimental group

(n = 111) or the control group (n = 101). The experimental group received a “green card”, which contained the contact details of a trainee psychiatrist who was available 24 hours a day via telephone if the participant experienced any further problems over the following 12-month period. The green card encouraged participants to seek help by contacting this number at an early stage, so long as no self-harm had already occurred on that occasion. No significant differences were observed in the reduction of self-harm between participants in the experimental group and those in the control group at one-year follow-up. Participants in the control group used more health services than those in the experimental group, although this difference did not reach statistical significance (494).

In 2005, Carter and colleagues (503) conducted an RCT designed to reduce the rate of repetition of hospital-treated deliberate self-poisoning. A total of 772 people referred from a hospital emergency department in Australia were included in the study; 378 in the intervention group and 394 in the control group. Participants in the intervention group were sent eight postcards over a one-year period following their presentation, while the control group received standard care. Results at one-year follow-up showed that no significant differences were observed in the number of participants who had one or more repeat episodes of deliberate self-poisoning in the intervention group compared to those in the control group (503). However, the total number of repeat episodes per individual was significantly lower in the intervention group than the control group, as was the total number of days spent in hospital. This low-cost intervention (approximately $AU15 per participant for stationary and postage) appeared to have substantial cost effectiveness, in light of the economic

implications of a large reduction in service use. In 2013, a five-year follow-up of this study indicated that the postcard intervention was associated with a 50 percent reduction in self-poisoning events and a one-third reduction in psychiatric admissions after five years (504). The authors noted that this translated into substantial savings in general hospital and psychiatric hospital bed days.

Other studies have also shown promising results for the use of a postcard intervention to reduce self-harming behaviour (505), whilst others have shown no effect (506). Many other psychosocial interventions have been examined in various trials (388, 399, 507, 508) and other low-cost interventions, including the prospect of a text message-based intervention to reduce self-harm (509), have also been raised in the literature as potential avenues to explore. However, the majority of completed trials have yielded insufficient evidence to determine clinically meaningful differences between interventions and standard care in the reduction of the proportion of participants who repeated self-harm (388). Considerable uncertainty therefore remains about which psychosocial interventions are the most effective for this population (399). In a pilot RCT from 2013 of a psychosocial intervention (which included information leaflets and a combination of phone calls and letters over a period of 12 months) after presenting to a hospital after an episode of self-harm, Kapur and colleagues (510) reported that a significantly higher proportion of participants who received the intervention self-harmed during the follow-up period when compared with participants in the control condition.

1.4.8.3. Pharmacological interventions

At the time of writing, no pharmacological interventions have clearly demonstrated a significant benefit in reducing rates of recurrent self-harm (491). The frequent use of pharmacological interventions for people who self-harm stems from the link between mental illness and self-harming behaviour; that is, although medications do not play a direct role in the management of self-harm per se, they play a considerable role in the management of associated conditions. Additionally, other co-existing physical conditions that may increase the risk of self-harm - such as chronic pain - may also lend themselves to pharmacological intervention(s). However, robust evidence for the efficacy of any pharmacological intervention to reduce self-harm is lacking (388). A retrospective study by Donovan and colleagues (511) compared the risk of self-harm by any method in 2776 individuals who had been prescribed either tricyclic antidepressants (TCAs) or SSRIs. Their results showed that significantly more self-harm events occurred following the prescription of SSRIs than TCAs, though the authors acknowledged that it is difficult to attribute the cause of such acts to any antidepressant medication in light of the complex clinical picture surrounding self-harm. The main limitation of the majority of such studies is that, as with the studies of psychosocial interventions discussed above, they have typically included far too few participants to detect clinically meaningful differences in rates of repetition of self-harm between the intervention and control groups (512). Larger trials, adequately powered to detect such differences, are therefore needed as a matter of urgency.

1.4.9. Association with borderline personality disorder

The fifth DSM criterion for BPD - "recurrent suicidal threats, gestures, or behaviours or self-mutilative behaviours" - is central to the borderline construct (390). Due to the very nature of the disorder, people with BPD are at an increased and ongoing risk of crises and self-harming behaviours (50, 278, 513). Within BPD populations, self-harm is a common - though often dangerous - coping strategy used by people in distress and who are unable to utilise more constructive strategies to manage this distress (443). Multiple suicide attempts and acts of self-harm are common in people with BPD and self-harm has been described as the 'behavioural specialty' of people with BPD (390, 514).

Naturalistic follow-up studies extending up to 27 years of people with BPD have reported that the overall suicide rate for this group is approximately ten percent (221). Long-term follow-up studies suggest that between three and 13 percent of those diagnosed with BPD go on to commit suicide (256, 429, 515) and, furthermore, that people with BPD account for between nine and 33 percent of all suicides (516). Recent research has produced more conservative figures, with one prospective six-year follow-up study in 2010 reporting two deaths by suicide from their sample of 106 people with BPD (1.9%) at follow-up (295). Predicting suicide in people with BPD is extremely challenging, not least because whilst self-harm is common in people with BPD, suicide is a comparatively rare event. Factors associated with completed suicide include co-occurring disorders, co-occurring symptoms of BPD (self-harm, affective reactivity and dissociation), adversity during adulthood and a family history of completed suicide (517). Further complicating the situation is the fact that people

with BPD are often excluded from clinical trials due to perceived risk (518). Cross-sectional studies have reported that childhood adversity, including bullying, sexual abuse and emotional neglect, is significantly associated with self-harm in individuals with BPD (430, 434, 519-522).

In light of the association between BPD and suicide, it is perhaps not surprising that people with BPD represent the greatest risk of suicide of any of the personality disorders recognised in the DSM (215). It has also been reported that, due to the frequency of suicidal crises observed in both inpatients and outpatients with BPD, clinicians may underestimate the seriousness of people's intent to die (523, 524).

1.4.10. Summary of self-harm and remaining areas of uncertainty

Self-harm is a significant problem across the lifespan and is the leading predictor of suicide, contributing to substantial public health costs. Many psychological, psychosocial and pharmacological interventions have been investigated in clinical trials which might reduce self-harming behaviour. However, due in part to the small numbers of participants included in many of the trials, there remains considerable doubt about which interventions are effective in reducing subsequent self-harming behaviour and/or suicide attempts (399, 512). At present, DBT (followed by MBT) appears to be the most effective psychological intervention for reducing self-harm among people with BPD. House and colleagues (428) recommended that future trials should be large enough to determine whether the intervention being tested reduces repetition of self-harm, whilst simultaneously examining other relevant outcomes such as levels of service use, quality of life, mood, social functioning and

interpersonal difficulties. Such large trials of substantial duration are required to provide definitive answers about which interventions are effective for which people, particularly in relation to the most important self-harm outcome measure, suicide (392).

Chapter 1.5. Joint crisis plans

1.5.1. Introduction to shared decision-making

Shared decision-making in healthcare refers generally to clinician(s) and service users working together to agree on the most appropriate treatment(s) for the service user. In 1997, Charles and colleagues (525) succinctly defined shared decision-making as "a mechanism to decrease the informational and power asymmetry between doctors and patients by increasing patients' information, sense of autonomy and/or control over treatment decisions that affect their well-being" (p.682). They also identified four key characteristics of true shared decision-making: 1) at least two partners (e.g. doctor and service user) are involved; 2) both partners share information about treatment options; 3) both partners take steps to build a consensus about the preferred treatment; and 4) an agreement is reached on the most appropriate treatment to implement. In the past two decades, the practice of implementing true shared decision-making, in which service users are given the opportunity to express their values and preferences and to participate in decisions about their care, has been increasingly advocated both in general medicine (525-529) and in psychiatry (most commonly with people with psychotic disorders) (530-534). Research has shown that there are many advantages and a robust rationale associated with this model of healthcare extending beyond the notions that service users will feel more empowered and will be more likely to adhere to treatment they have previously agreed to themselves. For example, advocates of shared decision-making argue that service users - more so than clinicians - understand the realities and impact of their condition and its treatment on their lives, as well as how services could be better designed to help them (535). Furthermore, there is some evidence to

indicate that engaging service users can reduce healthcare costs by avoiding unnecessary investigation and treatment (528) and, thus, shared decision-making may help health systems become more sustainable. Finally, it has been suggested that expertise in health and illness is not restricted to medical circles and that working alongside service users and their families is essential to improving healthcare (528).

In spite of the potential advantages associated with shared decision-making, many criticisms have also been levelled at the practice. Critics argue that many service users do not want to participate in decisions about their care and, rather, that they prefer simply to place their trust in the hands of the healthcare professionals to decide on the most appropriate course of action (536). Some have stated that revealing the uncertainties inherent in healthcare could be harmful to service users, whilst others have claimed that it is not feasible to provide service users with information about the numerous potential risks and benefits of all treatment options. Finally - and in contrast to the potential financial advantages mentioned above - critics have argued that increasing service user involvement in decision-making will actually lead to *greater* demand for unnecessary, costly or harmful procedures which could undermine the equitable allocation of health care resources (536). This argument has been supported by findings from recent studies indicating that an increase in shared decision-making may be associated with increased healthcare utilisation costs (537, 538).

The two main types of shared decision-making formats that have been implemented in psychiatric settings are advance statements and joint crisis plans (JCPs). Advance statements relating to mental health care aim to provide service users with more influence over future treatment decisions, thus reducing the occurrence of coerced treatment (530). One of the essential features of any advance statement is that it clearly documents a service user's treatment preferences in the event that he or she no longer has the capacity to make important decisions in the future, often as a result of accident or illness.

Issues of capacity are particularly relevant in the field of mental health, as service users - due to symptoms of their mental illness - can be deemed incapable of making rational decisions regarding their treatment preferences (530). As such, having the service user document his or her preferences clearly during a time of relative symptom stability can be of great benefit at a later time.

1.5.2. Introduction to joint crisis plans

A joint crisis plan (JCP) is an advance statement containing a service user's treatment preferences regarding mental health care during acute crises in the future. Psychiatric Advance Directives (PADs) (539) or Mental Health Advance Directives (MHADs) (540) are similar types of advance statements and are widely available in mental health care settings, though they are not widely used (530). JCPs are a variant of the PAD and research has indicated that they have the potential to reduce coercive treatment (541) and improve discussions between service users and clinicians which can enhance therapeutic relationships (542).

The JCP is created at a meeting between a service user and his or her treating mental health clinician, facilitated by an independent mental health practitioner (543). Carers, advocates, other support staff and family or friends may also be invited to the meeting at the service user's discretion. Several days before the meeting, the service user is provided with a blank template of a JCP, consisting of a list of subheadings that s/he may or may not wish to include in the final JCP. The service user is invited to note things they wish to include in their JCP in advance of the meeting, so that due consideration is given to each potential subsection of the plan. During the meeting, all parties present openly discuss with the service user the perceived advantages and disadvantages of the various subheadings selected for inclusion and the information entered under each, until a consensus is reached about the information to be entered. The facilitator remains neutral in the process and ensures that all parties have equal opportunity to discuss their opinions and preferences. The JCP is therefore produced collaboratively between the service user and his or her treatment team, with the aim being that the plan is consulted and followed during any future crises (387). Importantly, the final information included in the JCP is of the service user's choosing and is entered in his or her exact words. Within 24 hours of the meeting, the facilitator distributes a typed version of the JCP to all individuals specified by the service user and, with the service user's prior written permission, a copy of the JCP is also attached to his or her electronic psychiatric records in order to maximise dissemination of the plan within the local mental health Trust (544, 545). This approach has been used successfully with other forms of electronic care plans (546).

JCPs are designed to be folded up and to fit into the small plastic pocket provided (measuring 10cm x 8cm), so that they can be easily carried by the service user at all times, if so desired. JCPs improve the information available to clinical staff about the management of a crisis and empower service users by ensuring that they are actively involved in the generation of their own crisis plan (387, 531). While the main aim of creating and implementing a JCP is to enhance the service user's empowerment regarding their care, other benefits may be achieved. These include reduced levels of service use, reduced levels of perceived coercion, improved functioning and improved communication between service users, family members and service providers (530, 533, 539). Unlike PADs, however, JCPs do not carry any legal authority and the information contained within them is not legally binding (530); the one exception is the case of 'advanced refusals' (i.e., the service user refuses - in advance - a specific course of action) as this is covered by the Mental Capacity Act.

The rationale underlying the joint nature of crisis plans – including JCPs – is multi-factorial (547). Firstly, the service user may adhere to a treatment plan more closely if he or she has had substantial input into his or her crisis plan. Secondly, the treating mental health team will be considerably more likely to implement a chosen treatment or intervention if they themselves have previously agreed that it would be both feasible and in the best interests of the service user, and if they know they are also acting in accordance with the service user's wishes. Finally, the therapeutic relationship between the service user and the treating clinician may be substantially improved as a result of having the crisis plan meeting and detailed discussion about

the management of future crises. In light of this, although the JCP is developed collaboratively, it is imperative that the final content is determined by the service user. This includes deciding which sections from the template are to be included in the final plan and deciding the exact wording to be entered under each section (as the JCP may be of maximum value if service users choose to carry it with them because they feel it is their own plan and that it serves a useful function for them personally). The treating clinician's involvement during the creation of the JCP ensures that the service user's preferences are more likely to be acted upon (i.e., it is designed such that health practitioners can manage risk and crises in a manner more closely related to the individual preferences of the service user (543, 544)). It is essential that the individual facilitating the crisis planning meeting has had no prior relationship with the service user, so that he or she can remain impartial during the discussion and creation of the JCP. The facilitator must also be able to gain the trust of the service user in order to encourage him or her to discuss previous crises and episodes of treatment (both positive and negative) with the treatment team (544). As such, an experienced mental health clinician who has no direct relationship with the service user is the preferred choice.

1.5.3. Previous research

Sutherby and colleagues (548) assessed the feasibility of introducing JCPs to a community psychiatric service in the first descriptive study of the development and use of a form of collaborative mental health crisis plan. Forty service users assessed as having a high risk of future crises and a diagnosis of a psychotic illness participated in the uncontrolled study. An individual crisis planning meeting was attended by

each participant and his or her key worker and consultant psychiatrist, and participants were also encouraged to bring a relative or partner if they so desired. The aim of the meeting was to have a collaborative discussion about the contents of the participant's crisis plan. Each meeting was facilitated by one of the researchers. Sections of the plan to be discussed included: 1) "My mental health problem or diagnosis"; 2) "Circumstances that may lead to me becoming unwell or that have done in the past"; 3) "Treatments or other things that have been helpful during crises or relapses in the past"; and 4) "What I would like to be done when I first start to become unwell." After the meeting, a personalised crisis plan was typed up and provided to participants. Rates of hospital admissions over the following 12 months were reduced by 30 percent compared with the two years before the study commenced. A majority of participants reported consulting the plan either whilst experiencing a crisis or after being admitted to hospital (548). The study was not controlled and so the impact of potential confounding factors, such as the involvement of motivated and interested clinicians, could not be examined. In addition, validated rating instruments were not used. Despite these limitations, the authors concluded that the potential benefits of this relatively inexpensive and safe intervention warranted further investigation in an RCT.

Several members of the same research team went on to conduct a single blind RCT to determine whether creating a JCP could reduce use of inpatient services and compulsory admission or treatment under the Mental Health Act (1983) (541). One hundred and sixty patients from eight CMHTs and an operational diagnosis of psychotic illness or non-psychotic bipolar disorder with a recent history of hospital

admission took part in the trial. Eighty patients were randomised to the control and intervention arms. Participants in the intervention group attended a meeting, as described above, and created a personalised JCP (containing details of mental and physical illnesses, treatments, indicators for relapse and advance statements of preferences for care in the event of a future relapse, amongst other information). Participants in the control group received information leaflets about local services, mental illness and treatments, the Mental Health Act, local provider organisations and relevant policies. Results at 15-month follow-up showed that compulsory admissions and treatment were significantly less common in the intervention group than the control group and that a smaller proportion of the intervention group were admitted (though this difference did not reach significance). This trial provided the first evidence that a structured clinical intervention can significantly reduce compulsory admission and treatment under the Mental Health Act (1983) and, to date, it is the only structured intervention to have done so (541).

In the largest trial to date, Thornicroft and colleagues (549) conducted a three-centre, individual-level, single-blind, randomised controlled trial of JCPs compared with TAU for people with a history of relapsing psychotic illness. A total of 569 participants from 64 CMHTs were randomised either to the JCP (N=285) or TAU (N=284) arm of the trial and followed up 18 months post-randomisation. The primary outcome measure was psychiatric inpatient admissions. It was hypothesised that participants in the intervention arm would experience fewer inpatient admissions, fewer compulsory admissions and shorter inpatient stays than participants in the TAU arm (550). The results indicated that JCPs were not

significantly more effective than TAU, as no treatment effects were observed between the two groups for number of compulsory admissions or number of psychiatric admissions. However, there was a significant improvement in the therapeutic relationships reported by participants in the JCP arm compared to those in the TAU arm. The authors stated that the lack of significant findings may have resulted partly from the fact that the process of creating a JCP at a stand-alone meeting was not fully implemented in all sites. Results from an economic evaluation of the trial suggested a higher probability (more than 80 percent) of JCPs being the more cost-effective option and this value increased to 90 percent for Black ethnic participants (551). Thornicroft and colleagues posited that, due to the well-documented and disproportionately high rate of detention among Black service users, it is possible that such service users anticipate higher levels of discrimination than those from other ethnic groups do. As such, being afforded the opportunity to create a personalised JCP may have been associated with greater feelings of being respected and understood than those of service users from other ethnic backgrounds.

In 2009, Ruchlewska and colleagues (547) commenced an RCT in the Netherlands comparing the impact of two different types of crisis plan (facilitated by the service user's advocate or their treating clinician, respectively) with a control condition. The study sought to examine whether crisis plans could reduce the number of emergency hospital attendances and/or involuntary admissions in a sample of 240 outpatients with psychotic or bipolar disorders. They were also interested in investigating the possible mediator variables of the effects of the crisis plans,

including assessing participants' involvement in: 1) the creation of their crisis plan; 2) working alliances; 3) insights into illness; 4) recovery style; 4) presence of social support; 5) locus of control; 6) service engagement; and 7) crisis coping style. Although, at the time of writing, no definitive findings have been published, the authors have published some preliminary findings focusing on the quality of the plans produced in the two different conditions (552). Quality of the crisis plans was assessed using a checklist consisting of ten items corresponding to the items of the crisis plan, which comprised four domains: 1) Relapse indicators/daily functioning; 2) Advance statements on what to do during a future crisis; 3) Medical information; and 4) Information about personal contacts. The findings indicate that crisis plans created with the assistance of participants' advocates received significantly higher scores than those created with the assistance of participants' treating clinicians, indicating a higher quality of crisis plan in the advocate arm of the trial. The authors concluded that an even higher quality of crisis plan might be produced by involving an advocate, the participant's treating clinician and the participant in the discussion when creating each crisis plan. The forthcoming main results of the trial may shed light on the clinical effectiveness of different types of crisis plan.

1.5.4. Summary and remaining areas of uncertainty

BPD is a common condition of considerable public health importance. The clinical picture of BPD frequently involves severe functional impairment and can include unemployment, substance misuse and marked interpersonal instability. As these factors often impact on the service user's ability to commit to ongoing treatment, the task of keeping people with BPD in treatment depends primarily upon a strong

therapeutic alliance between the service user and his or her treating clinician (122). Therefore, maintaining a good working relationship is essential. However, considerable uncertainty still remains about what constitutes effective treatment for people with BPD, particularly with regard to effective crisis management.

One common feature of BPD is repeated self-harm and this is an important treatment outcome for this population because of the strong association with completed suicide. The 2011 NICE guideline on the management of self-harm (388) recommended developing a care plan and a risk management plan in conjunction with the individual who self-harms and their family, carers or significant others, with printed copies to be provided for the service user and other key healthcare professionals. This recommendation is closely aligned with the major features of JCPs.

Findings from previous JCP research using samples of people with psychosis have shown that JCPs may be associated with a reduction in compulsory admission to hospital, they are viewed favourably by mental health service users and that creating a JCP promotes a sense of self-determination and empowerment amongst service users (544). It is therefore possible that JCPs might also be an effective form of help for people with BPD when in crisis. To date, however, there have been no RCTs investigating the impact or effectiveness of crisis plans designed specifically for individuals with BPD (371). To address this gap in the literature, the aim of this trial was to develop and test the preliminary effectiveness of JCPs with a sample of

mental health service users who met the diagnostic criteria for BPD and had a recent history of self-harm.

Chapter 1.6. Aims & hypotheses

1.6.1. Aims

It was anticipated that the results of this trial would help to elucidate the potential beneficial effects of JCPs for people with BPD and also provide information to aid the design of a definitive trial (387). As a feasibility study for a future definitive RCT, the main goals of the study were to gather information about recruitment processes, consent and attrition rates and trial procedures. With that in mind, the trial had the following aims:

1.) To assess whether JCPs for people with BPD would have a beneficial effect on self-harming behaviour and to estimate the likely range of effects consistent with the use of JCPs;
2.) To assess the potential benefit of JCPs on other candidate outcome variables;
3.) To examine the feasibility of enrolling and retaining a pre-specified number of service users with BPD into a trial of JCPs;
4.) To assess the consent rate for service users entering the trial;
5.) To assess the acceptability of the concept of randomisation to participants;
6.) To examine the most appropriate methods of collecting self-harm data for use in a definitive trial of JCPs for people with BPD;

1.6.2. Hypotheses

As stated above, the aims of this trial were primarily to assess feasibility. However, the following exploratory hypotheses were formulated:

1. Participants in the JCP group would report significantly fewer self-harm events during the six-month follow-up period, when compared with participants in the control group;
2. Participants in the JCP group would report a significant improvement in engagement with mental health services at follow-up, compared with participants in the control group;
3. Participants in the JCP group would report a significant improvement in therapeutic alliance at follow-up, compared with participants in the control group;
4. Participants in the JCP group would report a significant improvement in satisfaction with care at follow-up, compared with participants in the control group;
5. Participants in the JCP group would report a significant improvement in quality of life at follow-up, compared with participants in the control group;

CHAPTER 2. METHODS

2.1 Feasibility study

Development of the intervention

Background

Recruitment and retention of participants is a significant problem in many clinical trials (553-557). In a 2006 review of trials funded by the UK Medical Research Council (MRC) and the Health Technology Assessment (HTA) programme, McDonald and colleagues (558) reported that less than one third (31%) of trials had achieved their original recruitment target within the allocated time period. Such shortfalls may lead to costly extensions or failure of the trial and may delay the introduction of effective interventions into routine clinical practice (556, 557). One approach to addressing this issue is to conduct a pilot or feasibility study to determine how members of the target population might react to the trial design and intervention (559). Pilot studies can play an important role by providing useful information for planning randomised controlled trials. In addition to supporting trial design, a pilot study can be treated as a 'dummy run' in preparation for a larger RCT. Pilots can also encourage methodological rigour (560).

The MRC framework for developing and evaluating complex interventions to improve health care states that, when designing a complex intervention, the best practice is to develop interventions systematically, using the best available evidence and appropriate theory, before testing them using a carefully phased approach (561, 562). The framework states:

> *'Complex interventions are built up from a number of components, which may act both independently and inter-dependently. The components usually include behaviours, parameters of behaviours (e.g. frequency, timing), and methods of organising and delivering those behaviours (e.g. type(s) of practitioner, setting and location). It is not easy precisely to define the "active ingredients" of a complex intervention.' (p.2)*

Complex interventions often include at least some of the following characteristics: several elements that may act both independently and inter-dependently; complex explanatory pathways, either physiological or psychosocial; an intervention that is difficult to describe and replicate; complex systems for the delivery of the intervention; and a degree of uncertainty about the active ingredient or mechanism of action of the intervention (562, 563).

Aims and objectives

The aims and objectives of the feasibility study were:

1.) To refine the existing JCP format to meet the needs of people with BPD;
2.) To obtain the views of service users and clinicians about the perceived clinical utility of JCPs for people with BPD;
3.) To determine the feasibility of recruiting and retaining CMHT service users to a study of JCPs;
4.) To determine the time required to administer a battery of health-related questionnaires at baseline and again at follow-up;

5.) To obtain the views of service users in relation to the randomisation process.

Method

The pilot work for the forthcoming trial consisted of four stages:

1.) Focus group consultation with mental health service users and clinicians;

2.) Refining the JCP for people with BPD;

3.) Questionnaire survey with mental health clinicians and clinical academics to obtain their views about the newly refined JCP;

4.) Pilot study of JCP for BPD and data collection procedures.

Focus group consultation

During the initial consultation process, purposive (non-random) samples of staff members and service users were recruited for three separate focus groups to discuss and refine the existing format of JCPs (i.e., for people with psychotic illnesses) used in Henderson and colleagues' 2004 trial (541). The first focus group consisted of six staff members from CMHTs and Accident and Emergency (A&E) departments and included consultant psychiatrists and community mental health nurses. The second focus group consisted of six clinicians working in specialist personality disorder services including forensic settings, eating disorders settings, intensive psychological treatment services and academic research. Seven service users from the Cawley Centre (a psychotherapeutic day hospital within the Maudsley Hospital for people with personality disorders) took part in the third and final focus group. Each group was co-facilitated by the chief investigator (PM) and the student (RB) and was 90 minutes in duration, during which time group members explored the

appropriateness of the language used in the extant JCP template. Participants were asked to suggest changes in language or format of the JCP, asked to provide their views about what constitutes a 'crisis', and whether self-harm would be a useful outcome measure for a trial of JCPs. All participants were also asked for their views about the methods to be used in the trial of JCPs for people with BPD, including a) the most effective methods of recruiting participants into the trial; b) the most accurate way to gather information about self-harming behaviour; and c) the acceptability of the randomisation process. Each of the three focus groups were facilitated using a topic guide, were audio-taped and fully transcribed. Content analysis was employed to analyse the resulting data.

Questionnaire survey

After the JCP was amended on the basis of the feedback from the three focus groups, the revised version was emailed to members of the focus groups for further feedback and refining. Staff members from the first and second focus groups forwarded their feedback by email (nine out of 12 [75%] provided feedback). Hard copies of the JCP were distributed to service users from the third focus group for their consideration (as many did not have email accounts) and four service users participated in individual feedback sessions with the student (RB) to provide more detailed feedback.

Delphi exercise

The revised version of the JCP was then distributed to the 12 staff members from the focus groups and an additional group of seven clinical academics working in the field

of personality disorders (identified from an electronic search of bibliographic databases) for a final round of feedback using a Delphi methodology. The aforementioned staff members and academics were emailed the revised version of the JCP, with the following amendment: inserted under each item was a brief scale and all respondents were asked to rate the relevance of the item on a scale from 1 (very irrelevant) to 5 (very relevant). Respondents were also encouraged to include any additional comments or suggested changes on the content or format of the JCP before returning it via email.

Feasibility study of JCPs and data collection procedures

In its guidance document for designing and evaluating complex interventions (561), the MRC recommends that sufficient piloting and feasibility work should be conducted to be confident that the intervention can be delivered as intended and that safe assumptions about effect sizes and recruitment/retention rates can be made for the subsequent main trial. With this is mind, a small feasibility study was conducted using the revised JCP template and all recruitment and data collection procedures to further inform the larger trial.

Recruitment of participants was conducted at three community mental health teams (CMHTs) within the South London and Maudsley (SLAM) NHS Trust. PM and RB approached each CMHT (usually at a weekly staff meeting) and conducted a brief presentation about the aims and underlying rationale of the study and allowed staff members to ask questions. Clinicians were then encouraged to identify any

potentially eligible service users from their caseloads and to approach these service users to discuss the study with them.

After each service user had stated that he or she was happy to be contacted by a member of the research team, RB contacted him or her and planned a baseline interview meeting at a convenient time. At this meeting, each client signed a consent form indicating their willingness to participate in the trial. During this meeting, all baseline assessments were conducted and RB then discussed the JCP template with the participant, answering any questions which arose. Each participant was also provided with a copy of the template to consider before a facilitated meeting with their care coordinator. RB then planned a date for the facilitated meeting with the participant and his or her care coordinator, as well as any significant others as nominated by the participant.

The second meeting was facilitated by RB. Prior to the meeting, the participant's care coordinator completed the Working Alliance Inventory (Therapist version [WAI-T]) (564) and the Service Engagement Scale (SES) (565) about their working relationship with the participant. During the meeting, detailed notes were taken by RB to ensure that the participant's exact wording was entered into his or her crisis plan. At the end of the meeting, the participant was provided with a copy of a brief self-harm diary (see Appendix 2), in which to document any episodes of self-harm between the facilitated meeting and the follow-up meeting. RB typed up the JCP and mailed a copy to the participant and a copy to any other party nominated by the

participant (this frequently included the care coordinator, GP, consultant and spouse/partner) within 24 hours.

RB contacted each participant approximately six weeks after the facilitated meeting to make an appointment for the follow-up interview. During this third and final meeting, all follow-up assessments were conducted and RB collected the participant's self-harm diary. Each participant was then asked whether he or she *would have* agreed to undergo randomisation if it had been required (for the purposes of the forthcoming RCT) in order to gauge participant opinion. Participants were also asked to provide feedback regarding their overall involvement in the study and were encouraged to suggest ways to improve the process for the trial.

2.2. The trial

2.2.1. Trial design

There are many different designs available to choose from when evaluating healthcare interventions, including naturalistic designs, experimental designs and quasi-experimental designs, with different designs suited to different research questions (566). However, randomised controlled trials (RCTs) are widely recognised as the most reliable method of determining the effectiveness of a healthcare intervention. This is because randomisation is the most robust method of ensuring the even distribution of known and unknown confounding factors that may impact on clinical outcomes (566, 567). As such, an RCT design was selected for the present

study, which was a single-centre exploratory RCT of JCPs compared with a TAU control condition for people with BPD and a recent history of self-harm.

2.2.1.1. Choice of control group

All RCTs require a control group against which the effectiveness of the intervention can be compared. This may be the best available package of care, standard care, or a placebo (567). Participants in this trial's control group received TAU, which was the standard treatment which they would have received from their CMHT had the trial not been conducted. This was chosen for two reasons: firstly, it provided a fair comparison with routine clinical practice. Secondly, the best available current treatment for BPD - dialectical behaviour therapy - requires specialist referral and can involve lengthy waiting lists. Additionally, the inclusion of a TAU group allows for comparisons with previous trials involving participants with BPD. Typical case management provided by a CMHT in the UK, as a part of the Care Programme Approach (CPA) for the most vulnerable service users, includes regular contact (one to four times per month) with a care coordinator or allocated member of the clinical team, in addition to the provision for service users to receive written copies of their care plan, including a prescriptive 'crisis contingency plan' (387, 568). The quality of these plans, however, has been shown to be poor. A recent analysis of 424 crisis contingency plans by Farrelly and colleagues (569) revealed that, despite clear government guidance regarding the importance of individualised crisis plans, their implementation has been less than optimal. They found that only 15 percent of the crisis plans contained any individualised information about the service user, such as interventions that had or had not been helpful in the past, who to contact in an

emergency, preferences or refusals for treatment in crisis, or practical arrangements (for securing a flat, looking after children, pets or plants, etc.) if admission to hospital were to be necessary. The remaining 85 percent of crisis plans contained only generic information, such as information about local emergency services. On the basis of their findings, the authors concluded that routine crisis planning in their sample was not influenced by clinical risk profiles (569).

In the trial, it was anticipated that the CPA arrangements above would be applied equally by CMHTs to both the intervention and control groups. However, it was acknowledged that standard care might not be consistent across sites, teams, or even individual clinicians within teams due to fluctuating clinical workloads and competing demands made on clinicians' time. As masking of participants and all researchers to treatment allocation in this trial was not possible (the senior researcher was not blinded to allocation, but the researcher collecting all follow-up data was blinded), care was taken to minimise bias by blinded assessment of all outcome measures, as recommended in the literature (570).

2.2.2. Participants

2.2.2.1. Trial setting

Participants were referred from 17 CMHTs and outpatient drug and alcohol treatment teams within the catchment area of either the South London and Maudsley (SLAM) Foundation Trust or the Oxleas Foundation Trust of the NHS. The CMHTs were based at 14 separate community health centres across five local

government boroughs in South East London. The UK Economic Deprivation Index (571) ranked the relative deprivation experienced by residents of each of the 354 local authorities in the UK in 2008, with each authority receiving a rank from one (most deprived) to 354 (least deprived). The relatively high level of deprivation experienced by residents in the five boroughs in the sample is highlighted by the rankings obtained by each: Lambeth, 12; Southwark, 19; Lewisham, 22; Greenwich, 24; and Croydon, 109.

2.2.2.2. Eligibility criteria

Individuals were eligible for the trial on the basis of the following inclusion and exclusion criteria:

Inclusion criteria

i) Aged 18 years or older;

ii) Current contact with a CMHT within SLAM or Oxleas NHS Foundation Trusts;

iii) Primary diagnosis of borderline personality disorder (or meeting the DSM-IV-TR diagnostic criteria);

iv) At least one self-reported episode of self-harm in the previous 12 months.

Exclusion criteria

(i) Aged less than 18 years;

(ii) Unable to give informed consent;

(iii) Unable to converse in English. Fluency in English was necessary to complete the assessment instruments (many of which have not been validated in other languages) and to fully participate in the development of a JCP if required;

(iv) Primary diagnosis of any psychotic illness;

(v) Currently an inpatient or subject to a compulsory community treatment order; service users in these groups were not recruited to avoid any perceived potential coercion to participate.

No other exclusions were made in order to maximise the external validity of the trial.

2.2.2.3. Identification of potential participants

Due to the duration of the recruitment phase being considerably longer during the RCT than during the feasibility study (i.e., 16 months instead of four months), members of the research team (RB, PM, and a junior research worker, JH) presented the trial at team meetings on more than one occasion at each site in an attempt to ensure that the trial remained prominent in the minds of relevant staff members throughout the entire recruitment period. After considering feedback from the Trial Steering Committee (TSC), a more proactive method of participant identification was employed; this involved the student (RB) and the junior research worker (JH) making appointments with individual clinicians within each team and reviewing their current caseload, in order to identify all potentially suitable participants for the trial. This process was repeated approximately every three months with individual clinicians over the 16 month recruitment period.

2.2.3. Ethical approval and trial registration

Ethical approval was gained from the South London Research Ethics Committee (reference number 09/H0803/113) and the trial was registered with the International Standard Randomised Controlled Trial registry (ISRCTN12440268).

2.2.4. Baseline data collection

Eighty-four baseline interviews (95.5%) were conducted at participants' treating CMHT bases and four (4.5%) were conducted at participants' homes after risk assessments and safety checks were performed.

2.3. Intervention

2.3.1. Intervention group: JCP plus TAU

Participants in the JCP condition were posted a blank JCP template, containing various subheadings relating to information they may have wished to include in their JCP (e.g. "Situations which can lead to a crisis", "Positive things which I have found helpful in the past" and "Details of current treatment and support from health professionals"). The JCP template is located in Appendix 2. Participants were encouraged to enter any information they wished to include in their JCP under the relevant subheadings prior to attending their crisis planning meeting, along with the help of carers, family members or friends if so desired.

Participants were then invited to attend a one-off joint crisis planning meeting at their local CMHT base which was facilitated by the student (RB) and attended by the participant and his or her treating CMHT clinician. Participants were also encouraged to bring a carer or friend to act as an advocate. At this meeting, all parties contributed to a discussion about the information which the participant wished to include his or her JCP, using the aforementioned template as a basis to structure the discussion. With the help of everyone present, the participant was encouraged to consider the advantages and disadvantages associated with the information he or she wished to include in his or her JCP and opposing opinions were discussed and resolved amongst the group.

After the meeting, RB produced a typed version of the JCP and distributed copies to all parties nominated by the participant during the meeting. With the participant's permission, a copy of the JCP was also uploaded onto his or her electronic psychiatric records. Research has indicated that uploading electronic care plans allows for immediate and effective dissemination of evidence-based good practice at the point of service delivery and eliminates many of the disadvantages associated with handwritten notes (546). An example of a completed (fictitious, but based on real statements) JCP is located in Appendix 2. All participants allocated to the JCP condition also continued to receive treatment as usual from their CMHT in addition to creating a JCP.

2.4. Measures

2.4.1. Baseline measures

Table 5 contains the domains that were assessed at baseline and the instruments used to measure them. Each instrument is described in greater detail below.

2.4.2. Rating instruments used

Demographics questionnaire (participant version)

A bespoke 11-item questionnaire was used to collect participants' demographic data including age, gender, ethnicity, employment status and geographical location. This questionnaire is located in Appendix 2.

Demographics questionnaire (clinician version)

A 10-item self-report questionnaire, developed by the researchers during the feasibility study, was used to collect socio-demographic data and information relating to professional qualifications and length of practice of each participant's care coordinator (see Appendix 2)**.**

Table 5. Domains measured at baseline and instruments used to measure them.

Domain	Instrument
Demographic variables	Demographic questionnaire
Work and social adjustment	Work and Social Adjustment Scale (WSAS): (572)
Working alliance (client rated)	Working Alliance Inventory – Client version (WAI-C): (564)
Working alliance (clinician rated)	Working Alliance Inventory – Therapist version (WAI-T): (564)
Perceived coercion	Treatment Experience Survey (TES)
Satisfaction with CMHT care	Client Satisfaction Questionnaire (CSQ): (573)
Alcohol misuse	Alcohol Use Disorders Identification Test (AUDIT): (574)
Substance misuse	Substance misuse questionnaire
Mental health wellbeing	Warwick-Edinburgh Mental Well-Being Scale (WEMWBS): (575)
Anxiety	Hospital Anxiety and Depression Scale (anxiety subscale; HADS-A): (576)
Depression	Hospital Anxiety and Depression Scale (depression subscale; HADS-D): (576)
Quality of life	EuroQoL Quality of Life measure (EQ-5D): (577)
Self-harm	Self-harm questionnaire: (424).
BPD psychopathology	Structured Clinical Interview for DSM-IV (SCID-II): (148, 149)
Personality disturbance	Standardised Assessment of Personality – Abbreviated Scale (SAPAS): (578)
Service engagement	Service Engagement Scale (SES): (565)

Work and Social Adjustment Scale (WSAS)

The WSAS (572) is a five-item self-report instrument to assess social functioning. Respondents are asked to indicate their responses to each item on a nine-point scale ranging from 'zero = no impairment at all' to 'eight = very severe impairment'. The WSAS is a valid and reliable instrument and that it offers the potential for readily interpretable comparisons across studies and across disorders (572). A total score is obtained by adding each of the five responses together, with higher scores indicating a higher level of impairment. Scores can range from zero to 40. The WSAS is located in Appendix 2.

Working Alliance Inventory – Client version (WAI-C)

The WAI-C (564) is a 12-item self-report instrument for measuring the quality of alliance between client and clinician, completed by the client. Each item is scored on a scale from 'one = never' to 'seven = always'. The WAI-C is reliably correlated with a variety of counsellor and client self-reported outcome measures and is widely used to assess alliance, with over 100 studies and several meta-analytic reviews focusing on the WAI-C (579). A total score is obtained by adding each of the 12 responses together (note that items four and 10 are reverse-scored), with higher scores indicating a more positive perception of working alliance. Scores can range from 12 to 84. The WAI-C is located in Appendix 2.

Working Alliance Inventory – Therapist version (WAI-T)

The WAI-T (564) is almost identical to the WAI-C (above), with the same items answered by the treating clinician. The scoring system is identical to that of the WAI-C. Scores can range from 12 to 84. The WAI-T is located in Appendix 2.

Treatment Experience Survey (TES)

The TES was adapted from the Admission Experience Survey (580), a 16-item instrument designed to assess the perceived level of coercion experienced by patients during hospital admission. The Admission Experience Survey has been used in many studies as a measure of perceived coercion (581). In the present study, the wording of each of the items was amended to reflect seeking treatment from a CMHT, as opposed to being admitted to hospital (e.g. "It was my idea to come into the hospital" became "It was my idea to seek treatment"). Respondents endorse each item as either 'true', 'false' or 'don't know'. Scores can range from zero to 45. The TES is located in Appendix 2.

Client Satisfaction Questionnaire (CSQ)

The CSQ (573) is an eight-item measure of clients' level of satisfaction with the treatment they are receiving. The CSQ takes approximately five minutes to complete and it possesses adequate psychometric properties (573). Respondents are encouraged to endorse each item on a scale from one to four and, thus, total CSQ scores can range between eight and 32 (with higher scores indicating a higher level of satisfaction with services). The CSQ is located in Appendix 2.

Alcohol Use Disorders Identification Test (AUDIT)

The AUDIT (574) is a 10-item self-report measure to identify problematic levels of alcohol consumption in respondents. Items one to three assess alcohol consumption, items four to six relate to alcohol dependence, items seven and eight measure adverse reactions and items nine and 10 assess alcohol-related problems. The AUDIT was developed by the World Health Organization (WHO) as a simple method of screening for excessive drinking and to assist in brief assessment. It was validated on primary health care patients from six countries (Australia, Bulgaria, Kenya, Mexico, Norway and the USA) and is the only screening test specifically designed for international use. The instrument has good psychometric properties (574) and is widely used by both clinicians and researchers in many countries. A total score is obtained by adding each of the 10 responses together (the total score ranges from 0 to 40), with higher scores indicating more problematic levels of alcohol consumption. The AUDIT is located in Appendix 2.

Substance misuse questionnaire

Respondents were asked about their recent substance use and asked to record any substances they had used recreationally in the preceding 12 months from a table in the questionnaire and the usual route of administration (i.e., oral, smoked) of each. Of those substances endorsed, respondents were then asked how many times, if any, they had used the substance in the preceding month. The substances listed in the inventory included both illicit substances (such as cannabis, cocaine and heroin) and licit substances (such as benzodiazepines and methadone) which were not prescribed and thus had been used recreationally. The substance misuse questionnaire is located in Appendix 2.

Warwick-Edinburgh Mental Well-Being Scale (WEMWBS)

The WEMWBS (575) is a 14-item measure of mental well-being over the preceding two weeks that focuses entirely on positive aspects of mental health. Each item is scored on a scale ranging from 'one = none of the time' to 'five = all of the time'. A total score is obtained by adding each of the 14 responses together and thus ranges from 14 to 70, with higher scores indicating a higher level of wellbeing. The WEMWBS is located in Appendix 2.

Hospital Anxiety and Depression Scale (HADS)

The HADS (576) is a 14-item self-report scale for measuring depression and anxiety in outpatients. Respondents receive separate scores for depression and anxiety by summing scores from the appropriate items, with higher scores indicating higher levels of depression/anxiety. Scores for each subscale can range from zero to 21 and combined scores can range from zero to 42. The HADS is useful for detecting change in a respondent's emotional state over repeated administrations, as well as for assessing presence or absence of clinically significant degrees of anxiety and depression (576). The HADS is located in Appendix 2.

EuroQoL Quality of Life measure (EQ-5D)

The EQ-5D (577) assesses respondents' subjective quality of life - in reference to the assessment date only - across five life domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Respondents are asked to endorse one of three options, ranging from 'one = I have no problems with (domain)' to 'three = I

am unable to (domain)'. A score is obtained by summing responses to the five items, with lower scores indicating a higher overall subjective quality of life. Overall health state is measured by a sixth item, which asks respondents to indicate their subjective health state on a scale from zero to 100 (where zero = 'the worst imaginable health state' and 100 = 'the best imaginable health state'). Respondents are asked to take into account both their physical health and mental health when indicating their overall health state. The EQ-5D is located in Appendix 2.

Self-harm questionnaire

Recent self-harming behaviour was measured at baseline and follow-up using a self-harm questionnaire used in Hawton and colleagues' 2002 survey of self-harm in young people (424). Participants were also encouraged to reflect on their most recent self-harm event and provide information relating to time spent delaying the act, help-seeking behaviour before and after the act and any medical consequences of the act. The self-harm questionnaire is located in Appendix 2.

Self-harm diary

Participants were provided with a simple self-harm diary upon completing their baseline assessment. This diary took the form of a brief (one-page) calendar commencing on the date of the baseline meeting and containing every day of the six-month follow-up period. Participants were encouraged to circle the day on which any episodes of self-harm occurred during the follow-up period and then to return the diary to the research worker (JH) at the follow-up assessment. The self-harm diary is located in Appendix 2.

Electronic psychiatric records

Each participant's electronic psychiatric records were also screened upon completion of their follow-up interview in order to establish the number of events of self-harm that had been recorded by clinicians during the follow-up period.

Structured Clinical Interview for DSM-IV (SCID-II) – Borderline Personality Disorder subsection

The SCID-II (148, 149) is a semi-structured interview for diagnosing the Axis II personality disorders of the DSM-IV-TR. It was designed with the primary goal of providing a rapid clinical assessment without sacrificing reliability or validity (149). The present study used only the BPD subsection, consisting of nine items. Respondents receive a score of either 'one = absent or false', 'two = sub-threshold' or 'three = threshold or definitely present'. A score for each respondent is calculated by summing the number of items rated as positive, with higher scores indicating a greater degree of personality disturbance. A score of at least five out of nine is required in order for the respondent to meet DSM-IV-TR criteria for BPD. Additionally, the total number of personality disorder items present may be an indication of overall personality pathology (149). The BPD subsection of the SCID-II is located in Appendix 2.

Standardised Assessment of Personality – Abbreviated Scale (SAPAS)

The SAPAS (578) is an eight-item screening interview to identify the presence and severity of personality disturbance. Each item is scored as either 'yes' or 'no' and a

total score (ranging from zero to eight) is calculated by summing the number of items rated as positive, with higher scores indicating a greater degree of personality disturbance. The SAPAS has satisfactory psychometric properties and, in the original validation study, a score of three or more positive responses on the SAPAS correctly identified the presence of a DSM-IV personality disorder in 90 percent of cases (578). The SAPAS has since been used successfully in a variety of populations (582-587) and a copy is located in Appendix 2.

Service Engagement Scale (SES)

The SES (565) is a 14-item self-report scale, completed by a service user's treating clinician - in this trial a care coordinator or key worker - to measure the service user's level of engagement with community mental health services. Each item is rated from "zero = Not at all or rarely" to "three = Most of the time". Positively worded items are reverse scored so that higher scores reflect a greater level of difficulty engaging with services (565). Scores can range from zero to 42. The Service Engagement Scale is located in Appendix 2.

2.5. Outcome data collected at six-month follow-up

Table 6 shows the instruments completed by participants and clinicians at the different data collection points during the trial.

Table 6. Instruments used at different data collection points.

Instrument	Baseline	JCP meeting	6-month follow-up
Participant Demographics	✓		
WSAS	✓		✓
WAI-C	✓		✓
TES	✓		✓
CSQ	✓		✓
AUDIT	✓		
Substance misuse	✓		
WEMWBS	✓		✓
HADS	✓		✓
EQ-5D	✓		✓
Self-harm	✓		✓
SCID-II	✓		
SAPAS	✓		
JCP template		✓	
Clinician Demographics	✓		✓
SES	✓		✓
WAI-T	✓		✓

2.6. Sample size and power calculation

Sample size calculations are not required for most pilot studies because the primary aim is to gather information about trial procedures, recruitment processes, and consent and attrition rates. Nevertheless, one aim of the trial was to determine whether it was feasible to recruit and retain a pre-determined number of people with borderline personality disorder into a trial of JCPs and, for this reason, a power calculation was undertaken in order to provide a target sample size for which to aim.

For the purposes of this power calculation, the variable 'proportion of each trial arm self-harming during the follow-up period' was selected as the primary outcome. In the POPMACT trial, a previous RCT of cognitive therapy versus TAU for people who self-harmed (363), 36 percent of participants in the TAU group reported an episode of self-harm in the first six months following randomisation. It was envisaged that the incidence of self-harm in participants in the trial's TAU arm would be similar to the POPMACT trial. In an RCT of 'green cards' versus TAU for individuals with a first presentation of self-harm, the proportion of participants who self-harmed in the green card group was one-third (33.3%) that observed in the TAU group (494). Given that the green card was not an individualised intervention (whereas the JCP is), it was envisaged that the JCP intervention would result in a larger effect, with a lower proportion (one third) of people at risk of self-harm after randomisation (33% risk ratio=0.33). Participants were followed up for six months with a predicted 36 percent and 12 percent of patients repeating self-harm in the TAU group and JCP group respectively. On the basis of these predictions, and accounting for 10 percent loss to follow-up, an overall sample of 120 participants (randomised 1:1 to TAU: JCP) would provide 80 percent power to detect an observed difference between the two groups based on a two-sided log-rank test at the five percent significance level.

2.7. Randomisation

Randomisation was performed at the individual participant level. All participants were informed about both arms of the trial and about the randomisation procedure. All participants were randomised to either the intervention (JCP+TAU) arm or the TAU arm of the trial at an approximate ratio of 1:1. Randomisation was managed

electronically by the Clinical Trials Unit (CTU) at the Institute of Psychiatry , King's College London. Confirmation of eligibility, written informed consent and baseline data were obtained prior to randomisation. Bias in the randomisation process was avoided by having randomisation performed electronically by the CTU (and without input from the research team), thereby also maintaining concealment from the research worker responsible for collecting all follow-up data.

2.7.1. Stratification

Stratification is used to ensure an approximately even balance of participant characteristics in the intervention arm and control arm of trials (588). This is because, by chance (and especially in smaller trials), the trial arms may not be well matched for important baseline characteristics. Stratification ensures that the numbers of participants allocated to each arm are closely balanced within each stratum, so that (for example) not all participants with high depression scores are entered into the intervention arm by chance. As alcohol misuse and depressive symptoms have been shown to be correlated with self-harm (35-38), it was thought that both depression and alcohol use were likely to be prognostically important variables in relation to self-harm. For this reason, participants were randomised using the method of minimisation with a random component stratified by alcohol misuse scores (as measured by the AUDIT: low<8; medium=8-15; high>15) and depression scores (as measured by the HADS depression subscale: low<8; medium=8-10; high>10). This methodology ensured equal allocation of participants to the two arms within each stratification category.

2.7.2. Allocation concealment

After each new participant was randomised into one of the treatment arms, the senior researcher on the study (RB) received an automated email containing the participant's initials, date of birth, study number, date of randomisation and treatment allocation. At the same time, the research worker (JH – responsible for collecting all six-month follow-up data) received an identical email minus the treatment allocation. RB was located in a different office to JH and used different storage facilities (i.e., locked filing cabinets, password-protected electronic files, locked offices) to ensure JH's allocation blindness was maintained throughout the study.

2.7.3. Implementation

Participants were informed of their treatment allocation via a letter mailed to their home address. Each participant's treating CMHT clinician (typically their care coordinator) was also advised of their allocation via email and reminded not to discuss this with the research worker collecting the follow-up data. Participants in the JCP group were contacted by telephone after the initial letter to make an appointment for the crisis planning meeting.

2.8. Data entry

Immediately following each participant's baseline meeting, and again after their six-month follow-up meeting, all data were entered into a MACRO database managed by the CTU. After the completion of follow-up data collection and entry, all data

were extracted by the senior data manager at the CTU and converted into SPSS 15.0 (Statistical Package for the Social Sciences) (589) format for data analyses.

2.9. Statistical analyses

All analyses were based on the modified intention-to-treat sample using a statistical analysis plan finalised by the trial statistician (JMH) and approved by the principal investigator (PM) in advance of conducting any analyses.

2.9.1. Analysis of outcome measures

All 88 participants randomised into the trial were retained in their allocated treatment arm for a modified intention-to-treat analyses. No interim analyses were conducted and all tests for significance were two-tailed. Continuous variables were summarised as mean (SD) and categorical variables as n (%). Self-harm (yes or no) was assessed with a logistic regression model with treatment and two stratification factors (alcohol misuse [AUDIT] and depression [HADS]) as covariates. Model assumptions were checked by the use of diagnostic plots. Models were undertaken with the assumption that data were missing at random. Categorical data were compared using Fisher's Exact test. Secondary outcomes were analysed in a generalised linear model (GLM) framework; covariates in the model were treatment group, baseline value of outcome, alcohol misuse and depression. For the frequency of self-harm at six-month follow-up, a negative binomial distribution was specified with a log link. Logistic regression was utilised for binary outcomes and clinical scales were analysed using the assumption of a normal distribution. Results of the

treatment effects were summarised as odds ratios (ORs; logistic and ordinal logistic regression), incidence rate ratios (RRs; negative binomial distribution GLM) and effect sizes (Gaussian models) at six-month follow-up with two-sided 95% confidence intervals.

2.9.2. Analysis of JCP contents

Data from all 41 joint crisis plans were analysed iteratively using a thematic analysis framework (590). Analysis began with two raters (RB and KT) independently conducting open coding of all JCPs, with the codes being rooted in the data. The two raters then compared their codes and a preliminary coding frame was constructed. This frame, and the initial categories, were scrutinised by two senior clinical researchers (CH and PM) and the coding frame was further developed. Some units of text were assigned several codes to reflect the multifarious nature of participants' statements. The two initial raters then actively searched for data that did not fit into the coding frame (i.e., deviant cases). Revisions to the coding frame were again cross-checked by senior clinical (CH, PM) and service user (DR) researchers and further refined through discussions of the appropriateness of each of the codes, with any initial disagreements resolved iteratively through consensus. Microsoft Word was used for indexing material and for retrieval of text chunks pertaining to the same or similar codes. This procedure ensured reliability of the analysis as it relied on the multiple coding and combined assessment of five raters (591). In terms of validity, this procedure was transparent and has been argued to be a proxy for validity in qualitative analysis (592).

CHAPTER 3. RESULTS

3.1. Results from developmental phase

Feedback from focus groups

Participants in the service users' focus group, without exception, endorsed the use of the term 'crisis', stating that they could personally identify with the term and it did not carry any negative connotations. They also discussed the acceptability of the randomisation process in the forthcoming trial and acknowledged that it was likely that there would be some people who would consent to the process and people who would not. During the consultation process, the section of the JCP under the heading "My mental health problems and diagnosis" was changed to "My mental health problems", then to "My difficulties", and finally to "My difficulties as I see them now." It was also suggested during the service user focus group that the information should be divided into two sections: one section for the service user and one section for health professionals. This amendment was implemented in all subsequent revisions. Members of all three focus groups agreed that it would be essential for the JCP to include a list of emergency telephone numbers for use in times of crisis, unlike the original JCP for people with psychotic illnesses.

After the focus groups, the title of the trial was changed from 'The effectiveness of joint crisis plans for people with borderline personality disorder: a pilot randomised controlled trial' to 'The effectiveness of joint crisis plans for people who have self-harmed: a pilot randomised controlled trial'. The decision to make this alteration

was well considered and emerged from the consultation work with mental health service users and professionals alike. It was suggested during the service user focus group that many participants in the study may not be aware that they have been given a diagnosis of personality disorder and that an interview with a research worker was not the appropriate forum in which to discover this. Given that all participants will, by definition, be aware of their own self-harm histories, the title of the study was amended to minimise any potential sources of conflict or disagreement. These changes were discussed with - and agreed upon by - the Project Advisory Group [PAG].

Delphi exercise feedback

Sixteen out of 19 (84.2%) professionals provided feedback about the relevance of items to be included in the JCP. The mean scores for items ranged from 4.4 to 4.9 out of five, suggesting that each item was highly relevant. On the basis of the above consultation work, the finalised version of the JCP was used in the feasibility study.

Feedback from feasibility study participants

Feedback about the JCPs - and the procedures of the overall forthcoming study - was mainly positive, with several participants stating that they believed all service users accessing CMHTs should be allowed to create their own JCPs. One participant stated that paramedic staff members had been unable to open his JCP as it was soaked through with blood following an episode of self-harm and suggested that it would be helpful to ensure that the JCP is protected somehow in the trial. In response to this, it was agreed that each JCP in the subsequent RCT would be placed inside a small

clear envelope to protect it from all liquid and other daily wear and tear. As the primary objective of the feasibility study was to determine the feasibility of recruiting and retaining CMHT clients to a study of JCPs, no data analysis was performed on the pre-intervention and post-intervention data obtained.

3.2. Findings from the trial

3.3. Recruitment to the trial

All participants were recruited over a 71-week period between December 2009 and April 2011 (see Figure 1). Follow-up data collection continued until October 2011.

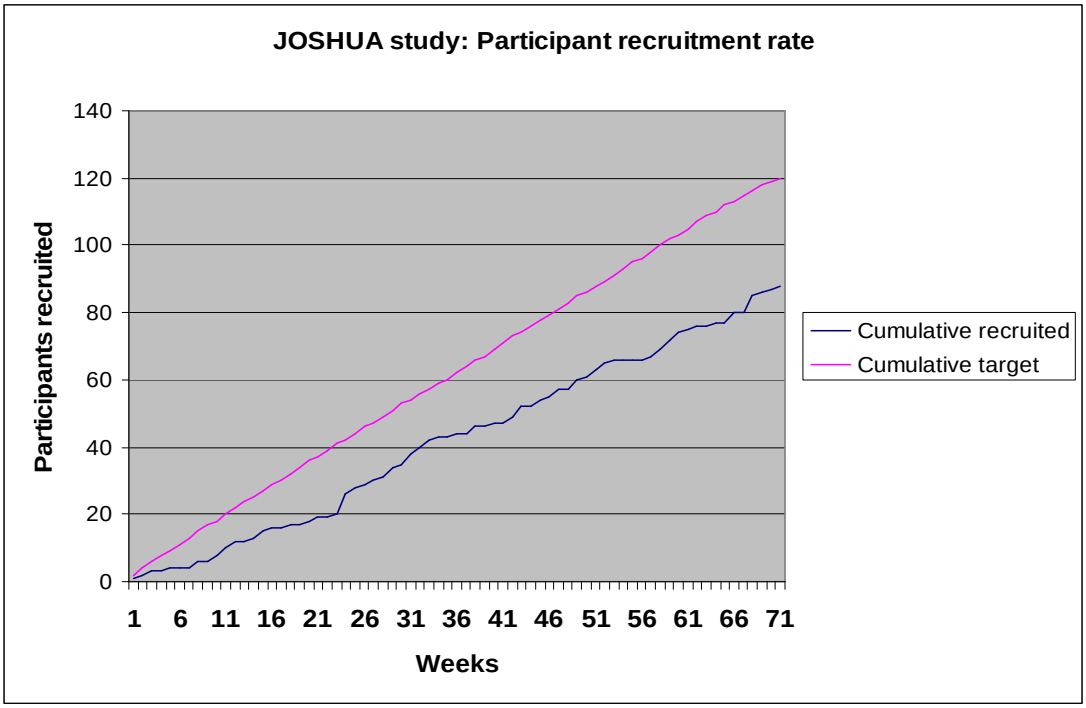


Figure 1. Pattern of participant recruitment to the trial.

A total of 133 potential participants were referred to the trial. Of these initial referrals, 30 people (22.6%) declined to take part in the study on the basis of a small number of recurring reasons (i.e., not interested in research, lack of insight into

mental disorder, unwillingness to acknowledge the possibility of a future crisis, or only willing to participate in the trial if they could be guaranteed to be placed into the intervention arm). Twelve people (9.0%) did not meet the inclusion criteria (five [3.6%] had not self-harmed in the preceding 12 months and seven [5.3%] did not meet the SCID-II diagnostic criteria for BPD). A further three individuals (2.3%) were excluded from participating as they required an interpreter. The remaining 88 people (66.2% of those initially referred) provided written informed consent to participate and were successfully recruited as participants into the trial (see Figure 2).

Figure 2. CONSORT diagram of participant flow through the trial.

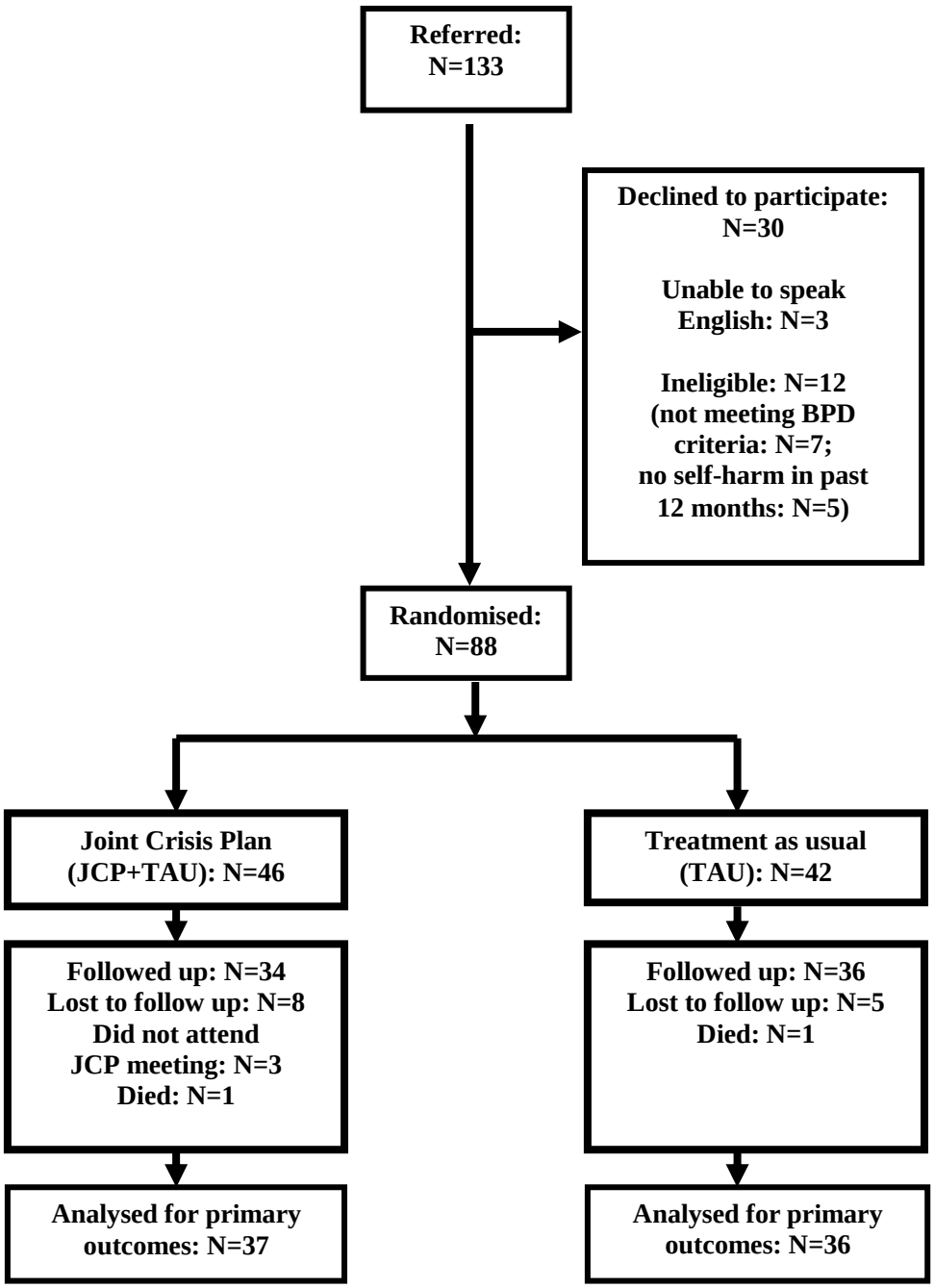


Table 7 shows the distribution of participants by recruitment borough.

Table 7. Number of participants recruited by borough.

Site	JCP group	TAU group	Total
Lambeth	4 (8.7%)	7 (16.7%)	10 (11.4%)
Southwark	18 (39.1%)	17 (40.5%)	36 (40.9)
Lewisham	7 (15.2%)	3 (7.1%)	10 (11.4%)
Croydon	10 (21.7%)	14 (33.3%)	24 (27.2%)
Greenwich	7 15.2%)	1 (2.4%)	8 (9.1%)
Total	46 (52.3%)	42 (47.7%)	88 (100.0%)

Of these 88 participants, 71 (80.1%) were female and the average age of participants was 35.8 years (*SD*=11.6). The demographic characteristics of participants are shown in Table 8.

Table 8. Demographic characteristics of participants at baseline.

Variable	Category	JCP group (N=46)	TAU group (N=42)	Total (N=88)
Gender	**Male**	10 (21.7%)	7 (16.7%)	17 (19.3%)
	Female	36 (78.3%)	35 (83.3%)	71 (80.7%)
Age	**Mean (*SD*)**	35.6 (11.1)	36.1 (12.4)	35.8 (11.6)
Ethnicity	**White**	34 (73.9%)	31 (73.8%)	65 (73.9%)
	Black	6 (13.0%)	3 (7.1%)	9 (10.2%)
	Asian	0 (0.0%)	1 (2.4%)	1 (1.1%)
	Mixed	3 (6.5%)	4 (9.5%)	7 (8.0%)
	Other	3 (6.5%)	3 (7.1%)	6 (6.8%)
Marital status	**Married**	2 (4.3%)	1 (2.4%)	3 (3.4%)
	Cohabiting	6 (13.0%)	4 (9.5%)	10 (11.4%)
	Widowed	0 (0.0%)	1 (2.4%)	1 (1.1%)
	Separated	2 (4.3%)	1 (2.4%)	3 (3.4%)
	Divorced	6 (13.0%)	2 (4.8%)	8 (9.1%)
	Single	30 (65.2%)	33 (78.6%)	63 (71.6%)
Employment status	**In paid employment**	6 (13.0%)	4 (9.5%)	10 (11.4%)
	Unemployed	11 (23.9%)	9 (21.4%)	20 (22.7%)
	Permanently sick / disabled	20 (43.5%)	2 (52.4%)	42 (47.7%)
	Homemaker	1 (2.2%)	1 (2.4%)	2 (2.3%)
	Student	0 (0.0%)	2 (4.8%)	2 (2.3%)
	Other	8 (17.4%)	4 (9.5)	12 (13.6%)
School leaving age	**< 17**	35 (76.1%)	34 (81.0%)	69 (78.4%)
	≥ 17	11 (23.9&)	8 (19.0%)	19 (21.6%)
Further education since school	**Yes**	31 (67.4%)	30 (71.4%)	61 (69.3%)
	No	15 (32.6%)	12 (28.6%)	27 (30.7%)

Forty-six participants (52.3%) were randomised to the intervention arm and 42 (47.7%) were randomised to the TAU arm. Of the 46 participants in the intervention arm, a total of 41 (89.1%) attended a JCP planning meeting within two weeks of randomisation. The remaining five participants (10.9%) did not create a JCP, due to

their treating clinicians or the participants themselves being unable to attend the crisis planning meeting as agreed. Eight participants (19.5% of those who created a JCP) attended their crisis planning meeting with a family member, carer or friend.

Covariates

BPD psychopathology

Participants endorsed an average of 6.9 of the nine diagnostic criteria on the SCID-II (*SD* = 1.3, range = 5-9) at baseline. All participants endorsed the self-harm criterion, as this was an inclusion criterion for the trial. Table 9 displays each criterion and how commonly it was endorsed.

Table 9. Number of SCID-II criteria endorsed by participants at baseline.

SCID-II item	TAU N (%)	JCP+TAU N (%)	Total N (%)
Have you often become frantic when you thought that someone you really cared about was going to leave you?	35 (83.3)	32 (69.6)	67 (76.1)
Do your relationships with people you really care about have lots of extreme ups and downs?	32 (76.2)	32 (69.6)	64 (72.7)
Does your sense of who you are and where you're headed often change dramatically?	25 (59.5)	31 (67.4)	56 (63.6)
Have you often done things impulsively?	32 (76.2)	34 (73.9)	66 (75.0)
Have you tried to hurt or kill yourself or ever threatened to do so?	42 (100.0)	46 (100.0)	88 (100.0)
Do you have a lot of sudden mood changes?	37 (88.1)	43 (93.5)	80 (90.9)
Do you often feel empty inside?	34 (81.0)	39 (84.8)	73 (83.0)
Do you often have temper outbursts or get so angry that you lose control?	23 (54.8)	26 (56.5)	49 (55.7)
When you are under a lot of stress, do you get suspicious of other people or feel especially spaced out?	31 (73.8)	33 (71.7)	64 (72.7)

The average number of SCID-II criteria endorsed by participants in the JCP group was 6.9 (*SD*=1.44, range=5-9) and the average number endorsed by the TAU group was

also 6.9 (*SD*=1.22, range=5-9), meaning that no significant difference was observed (t=0.12, p=.90).

Personality disturbance

At baseline, the mean (SD) SAPAS score was 5.21 (*SD*=1.66, range=1-8) for participants in the JCP group and 5.30 (*SD*=1.57, range=1-8) for those in the TAU group. This difference was not statistically significant (t=0.24, p=0.81).

Alcohol misuse

At baseline, participants obtained a mean score of 13.2 from a possible 40 on the AUDIT (*SD*=12.0, range=0-40). There was no significant difference in the AUDIT scores reported by participants in the JCP (M=13.5, *SD*=12.3) and TAU (M=12.8, *SD*=11.8) groups at baseline; t(85)=-2.4, p=0.81.

Illicit substance use

Table 10 shows the substance misuse patterns reported by participants at baseline. The most commonly used substance in the 12 months prior to baseline was cannabis, with 50% of participants from the TAU group and 39% of participants from the JCP+TAU group reporting that they had used it (more than half of whom had also used it in the preceding month). Other drugs that participants reported using (and the number who reported using them) were herbal highs (1), ketamine (2), mephedrone (1), 2CI (1), dimethyltryptamine (DMT) (1) and non-prescribed morphine (1).

Table 10. Substance misuse patterns reported at baseline.

Substance	JCP arm: Used in past 12 months; N(%)	JCP+TAU arm: Used in past 12 months; N(%)	Total: Used in past 12 months; N(%)
Cannabis	18 (39.1)	21 (50.0)	39 (44.3)
Amphetamine	1 (2.2)	6 (14.3)	7 (8.0)
Cocaine	9 (19.6)	11 (26.2)	20 (22.7)
Ecstasy / MDMA	5 (10.9)	5 (11.9)	10 (11.4)
Solvents / glue	0 (0.0)	1 (2.4)	1 (1.1)
Benzodiazepines	6 (13.0)	7 (16.7)	13 (14.8)
LSD	3 (6.5)	2 (4.8)	5 (5.7)
Methadone	2 (4.3)	5 (11.9)	7 (8.0)
Codeine / DF118	6 (13.0)	10 (23.8)	16 (18.2)
Crack cocaine	7 (15.2)	8 (19.0)	15 (17.0)
Heroin	4 (8.7)	7 (16.7)	11 (12.5)
Other	1 (2.2)	5 (11.9)	6 (6.8)

Follow-up data collection

Seventy-three participants (83.0%) were followed-up after approximately six months (participants in the JCP arm were followed up a mean of 190 days [SD = 12.9] post-randomisation and those in the TAU a mean of 192 days [SD = 11.6] post-randomisation). At six-month follow-up, 13 participants (14.8%) could not be contacted; eight from the JCP+TAU arm and five from the TAU arm. A further two (2.3%) participants (one from the JCP arm and one from the TAU arm) died between baseline and follow-up. The death of the participant in the intervention arm occurred after the participant suffered a heart attack (there was no evidence that self-harm was involved). The death of the participant in the TAU arm occurred after a fatal overdose of medication. No participants who were able to be contacted

declined to take part in the follow-up interview. The total attrition at six-month follow-up was therefore 17.0%.

3.4. Primary outcome measure

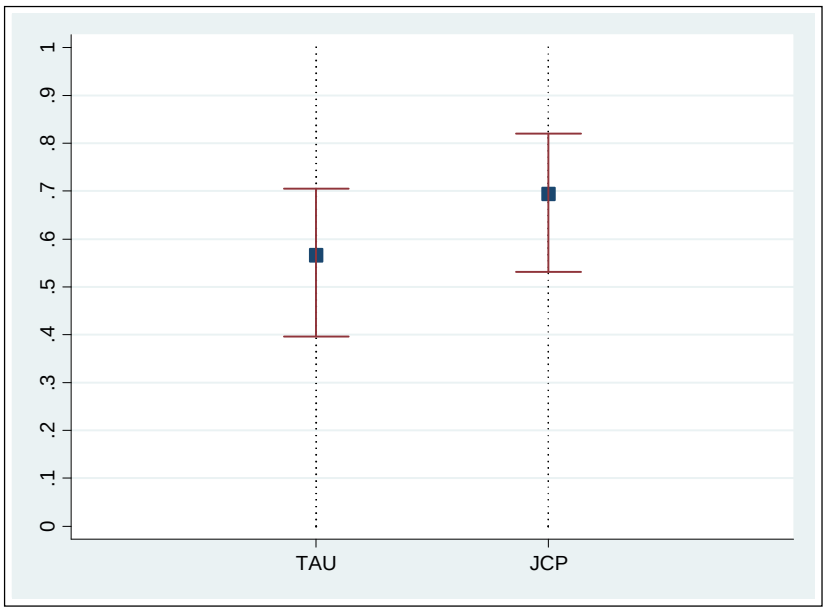
Self-harm

Table 11 shows the mean number of self-harm episodes reported by participants in each arm of the trial, along with the dichotomised self-harm data at baseline and six-month follow-up. At follow-up, the proportion of participants reporting self-harm had fallen in both trial arms. However, there was no significant difference in the proportion reporting self-harm between the JCP+TAU and TAU arms (OR 1.9, 95% CI: 0.53 - 6.5; p=0.33; see Figure 3). There were also no significant differences in the frequency of self-harm acts reported between the two groups (RR 0.74, 95% CI: 0.4 - 1.63; p=0.46).

Table 11. Comparisons of the differences in self-harm at six months between participants in the TAU and JCP arms.

	TAU			JCP+TAU		
Self-harmed in the past 12 months (baseline) / 6 months (follow-up)						
	N	**Self-harmed N (%)**		**N**	**Self-harmed N (%)**	
Baseline	42	42 (100%)		46	46 (100%)	
Month 6	36	20 (55.6%)		36	25 (69.4%)	
Odds ratio of self-harm in comparison to TAU (95% CI; p-value)						
Month 6				72	1.86 (0.53 to 6.51; p=0.33)	
Number of self-harm episodes in the past 12 months (baseline) / 6 month (follow up)						
	N	**Mean (SD)**	**Median (IQR)**	**N**	**Mean (SD)**	**Median (IQR)**
Baseline	42	56.2 (102.2)	5.5 (47)	46	51.2 (126.4)	6 (37)
Month 6	36	20.3 (67.0)	1 (3.5)	36	20.6 (89.7)	2 (7.0)
Rate ratio of frequency of self-harm in comparison to TAU (95% CI; p-value)						
Month 6				72	0.74 (0.34 to 1.63; p=0.46)	

Figure 3. Proportion of participants in each trial arm who reported self-harming during the follow-up period.



*** Figure shown with 95% confidence intervals. Unadjusted figure.**

Self-harm diaries

Fifteen participants out of 73 (20.5%) returned their self-harm diaries at six-month follow-up; the remaining 58 participants (79.5%) stated that they had either lost their diaries or had forgotten to complete them during the follow-up period. As the response rate was <50%, missing data were not imputed and no analyses were conducted.

Self-harm events recorded on electronic psychiatric records

There was a relative lack of information in participants' electronic psychiatric records regarding the incidence and prevalence of self-harming behaviour and, as such, it was not possible to subject these data to any quantitative or qualitative analysis. Episodes of self-harm were not recorded routinely in electronic records and, as

ethical permission to search participants' emergency department records had not been obtained, the trial was reliant on self-reported self-harm.

3.5. Secondary outcome measures

Table 12 contains a summary of the secondary outcome measures data at baseline and follow-up for both trial arms. There was no evidence of a statistically significant difference between the two arms at follow-up on any of the secondary outcome measures.

Table 12. Summary of all secondary outcome measures data at baseline and follow-up for both trial arms.

Variable	Clinical scale (range)	Time point	TAU		JCP+TAU	
			N	Mean (SD)	N	Mean (SD)
Highest score is most desired outcome						
Working alliance	**WAI-C (12-84)**	**Baseline**	33	63.4 (17.9)	38	58.5 (18.5)
		Month 6	30	60.5 (15.9)	33	58.9 (16.8)
Working alliance	**WAI-T (12-84)**	**Baseline**	37	61.3 (11.1)	40	63.7 (8.7)
		Month 6	25	63.0 (10.7)	29	64.7 (10.9)
Satisfaction with services	**CSQ (4-32)**	**Baseline**	37	18.6 (1.5)	41	19.9 (1.5)
		Month 6	36	19.6 (1.3)	37	20.0 (2.0)
Mental wellbeing	**WEMWBS (14-70)**	**Baseline**	23	31.7 (10.1)	26	29.7 (11.1)
		Month 6	35*	35.3 (10.3)	36*	34.3 (11.4)
Lowest score is most desired outcome						
Work and social adjustment	**WSAS (0-40)**	**Baseline**	42	27.0 (7.4)	46	27.0 (6.5)
		Month 6	36	26.1 (8.0)	36	25.8 (8.9)
Perceived coercion	**TES (0-45)**	**Baseline**	42	16.5 (2.8)	46	17.0 (3.0)
		Month 6	36	16.0 (3.1)	37	17.7 (3.1)
Depression	**HADS-D (0-21)**	**Baseline**	42	11.8 (4.3)	46	11.8 (5.0)
		Month 6	34	10.5 (3.5)	35	10.2 (5.0)
Anxiety	**HADS-A (0-21)**	**Baseline**	42	14.5 (5.6)	46	14.5 (4.1)
		Month 6	36	12.9 (4.6)	37	14.6 (3.8)
Engagement with services	**SES (0-42)**	**Baseline**	34	10.4 (7.1)	38	9.8 (6.0)
		Month 6	25	10.9 (5.6)	30	8.6 (6.1)

* Follow-up value is higher than baseline value as the WEMWBS was introduced mid-trial

Depression and anxiety

Table 13 shows the mean depression and anxiety scores, as measured by the HADS, reported by participants in each arm of the trial at baseline. None of the differences between the groups were statistically significant.

Table 13. Mean HADS depression and anxiety scores (with standard deviations) reported by participants in the JCP and TAU arms.

		JCP	TAU	Total	p-value
Baseline	**Depression**	11.8 (4.98)	11.8 (4.30)	11.8 (4.64)	0.98
	Anxiety	14.5 (4.08)	14.5 (4.49)	14.5 (4.25)	0.98
Follow-up	**Depression**	10.2 (4.96)	10.5 (3.54)	10.3 (4.29)	0.80
	Anxiety	14.6 (3.83)	12.9 (4.55)	13.8 (4.25)	0.10

Satisfaction with care

At baseline, participants in the TAU group obtained a mean score of 18.6 on the CSQ (*SD*=1.5, range=14-21) and the mean score in the JCP group was 19.9 (*SD*=1.5, range=17-23). At follow-up, participants in the TAU group obtained a mean score of 19.6 (*SD*=1.3, range=17-22) and those in the JCP group scored a mean of 20.0 (*SD*=2.0, range=17-27). None of these differences were statistically significant.

Working alliance (participant rated)

At baseline, participants in the TAU group obtained a mean score of 63.4 on the WAI-C (*SD*=17.9, range=12-84) and those in the JCP group scored an average of 58.5 (*SD*=18.5, range=19-81). At follow-up, participants in the TAU group obtained an average score of 60.5 (*SD*=15.9, range=26-82) and those in the JCP group scored an average of 58.9 (*SD*=16.8, range=14-84). None of these differences were statistically significant.

Mental wellbeing

An assessment of mental wellbeing was introduced after data collection had commenced and following consultation with the Project Advisory Group (PAG). A total of 40 out of 88 (45.4%) participants completed the WEMWBS at baseline. All participants who were followed-up completed the WEMWBS at 6-month follow-up. At baseline, participants in the TAU group reported an average score of 31.7 (*SD*=10.1, range=14-52), whilst participants in the JCP group reported an average of 29.7 (*SD*=11.1, range=14-51). The mean scores of participants from both groups increased at follow-up; participants in the TAU group reported an average score of 35.3 (*SD*=10.3, range=17-61), whilst participants in the JCP group reported an average of 34.3 (*SD*=11.4, range=14-57). The difference between the increased scores of the two arms was not significant (p=0.97).

Quality of life

At baseline, participants in the TAU group reported an average quality of life score of 45.2 out of 100 on the EQ-5D (*SD*=17.5, range=0-80) and those in the JCP group reported an average of 45.1 (*SD*=17.2, range=10-90). At follow-up, participants in the TAU group reported an average score of 53.1 (*SD*=21.7, range=5-90) and those in the JCP group reported an average of 47.0 (*SD*=19.0, range=5-85). None of these differences were statistically significant.

Working alliance (clinician rated)

At baseline, responding clinicians of participants in the TAU group obtained an average score of 61.3 on the WAI-T (*SD*=11.1, range=33-83) and those clinicians with participants in the JCP group scored an average of 63.7 (*SD*=8.7, range=44-78). At follow-up, the TAU clinician group obtained an average score of 63.0 (*SD*=10.7, range=40-84) and the JCP clinician group scored an average of 64.7 (*SD*=10.9, range=40-85). None of these differences were statistically significant.

Service engagement (clinician rated)

At baseline, responding clinicians of participants in the TAU group obtained an average score of 5.3 on the SES (*SD*=1.6, range=2-8) and those clinicians with participants in the JCP group scored an average of 5.2 (*SD*=1.7, range=1-8). At follow-up, the TAU clinician group obtained an average score of 10.9 (*SD*=5.6, range=0-23) and the JCP clinician group scored an average of 8.6 (*SD*=6.1, range=0-25). The difference between the increased scores of the two arms was not significant (p=0.16).

Use of JCPs

Participants were asked to provide details of how frequently (and in which context) they had used their JCPs during the follow-up period. Table 14 contains a summary of their responses.

Table 14. Reported JCP use by participants in the JCP+TAU arm.

Self-harm parameters	Month 6	TAU	JCP+TAU
Did you make a JCP?*	**No**	35 (97%)	3 (8%)
	Yes	1 (3%)	33 (89%)
Do you still have your JCP?	**No**	-	3 (9%)
	Yes	1	30 (91%)
If not, why not?	**Lost****		2
	Privacy concerns		-
Total n=3	**Disagreed with contents**		-
	Out of date**		1
	Other (become unhelpful)		1
Did you use your JCP in a crisis?	**No**		9 (26%)
	Yes		25 (74%)
If you used your JCP in a crisis, how did you use it?	**Looked at / referred to**		20 (80%)
	Number of times; mean (sd)		4.8 (4.4)
	Asked someone else to look at it		9 (36%)
Total n=25	**Number of times; mean (sd)**		2.8 (1.7)
	Care coordinator/other professional referred		8 (32%)
	Number of times; mean (sd)		5.1 (3.7)
	Carer/other person suggested referred		7 (28%)
	Number of times; mean (sd)		3.3 (2.6)
	Other		3 (12%)
	Number of times; mean (sd)		1 (-)
If you used your JCP in a crisis, how did you feel after looking at it?	**Felt better/ reassured**		10 (40%)
	Changed what I was doing and did what was agreed JCP		12 (48%)
Total n=25	**Care coordinator/other professional changed what they were doing and did what was agreed JCP**		3 (12%)
	Carer/other person changed what they were doing and did what was agreed JCP		5 (20%)
	No impact		3 (12%)
	Other		2 (8%)
Did you use your JCP in another situation (not a crisis)?	**No**		19 (56%0
	Yes		15 (44%)
If you used your JCP in another situation, how did you use it?	**Looked at / referred to**		9 (60%)
	Number of times; mean (sd)		4 (2.8)
	Asked someone else to look at it		7 (47%)
	Number of times; mean (sd)		5.4 (8.7)
Total n=15	**Care coordinator/other professional refer**		5 (33%)
	Number of times; mean (sd)		2.4 (1.1)
	Carer/other person suggested refer		2 (13%)
	Number of times; mean (sd)		1.5 (0.7)
	Other		1 (7%)
	Number of times; mean (sd)		-
Overall, did you follow your JCP?	**No**		3 (9%)
	Yes		16 (47%)
	Partly / somewhat		14 (41%)

Table 14. Reported JCP use by participants in the JCP+TAU arm (continued).

Overall, was your JCP followed by health professionals who saw it?	**No**		17 (50%)
	Yes		13 (38%)
	Partly / somewhat		3 (9%)
If you didn't refer to or use your JCP, why not? **Total n=10**	**Didn't need it / no crisis**		4 (12%)
	Lost it		3 (9%)
	Didn't agree with contents		1 (3%)
	Out of date		-
	Other		4 (12%)
As a result of creating your JCP, has there been any change in any of the following areas? **Total n=34**	**Relationship with mental health team**	**Much better**	4 (12%)
		A bit better	12 (35%)
		No change	14 (41%)
		A bit worse	3 (9%)
		Much worse	-
	Care you receive from mental health team	**Much better**	4 (12%)
		A bit better	9 (26%)
		No change	18 (53%)
		A bit worse	1 (3%)
		Much worse	1 (3%)
	Satisfaction with care	**Much better**	5 (15%)
		A bit better	8 (24%)
		No change	18 (53%)
		A bit worse	3 (9%)
		Much worse	-
	Control over problems	**Much better**	5 (15%)
		A bit better	11 (32%)
		No change	15 (44%)
		A bit worse	2 (6%)
		Much worse	1 (3%)
	How you feel about continuing contact with your mental health team	**Much better**	8 (24%)
		A bit better	6 (18%)
		No change	16 (47%)
		A bit worse	2 (6%)
		Much worse	-
Would you recommend a JCP to other service users?	**No**		1 (3%)
	Yes		29 (85%)
	Don't know		4 (12%)
Have you recommended a JCP to other service users?	**No**		29 (85%)
	Yes		5 (15%)

* Only those participants who answered yes are applicable to answer the remaining questions

** The same participant endorsed 'lost' and 'out of date'

3.6. JCP content analysis

Experience of crises

When reflecting on their experiences of previous crises, participants described a state of acute distress associated with a disruption in their daily functioning. When they were in this state, many reported failing to meet basic self-care requirements such as eating, drinking and bathing. Many reported withdrawing from 'the outside world' and avoiding all contact with friends and family members for the duration of the crisis. Additionally, it was common for such isolation to result in further complications (e.g. essential bills not being paid during times of crisis).

Connecting with / disconnecting from others during a crisis

Many participants emphasised the importance of having the opportunity to connect with people in their personal and/or professional networks during times of crisis and the benefits associated with this. Conversely, other participants preferred to disconnect completely from other people during a crisis. Table 15 displays illustrative examples of situations and actions perceived by participants as being helpful or unhelpful during crises.

Table 15. Illustrative examples of situations and actions listed as being helpful and unhelpful by participants seeking to connect with, or disconnect from, other people during times of crisis.

	Courses of action perceived as helpful during a crisis	Situations and circumstances perceived as unhelpful during a crisis
Participants seeking to connect with other people during a crisis	Seeking help from my community mental health team or the home treatment team	Isolating myself from the outside world
	Calling my care coordinator	Being trapped in my house and feeling alone
	Spending time with friends	Not having anyone to talk to
	Reaching out and asking for help, either from friends, my doctor or my sister	Withdrawing myself
	Spending time with my daughters	Being 'cooped up' in the house alone
	Calling the Samaritans[1] and talk with somebody about my feelings	Isolating myself (as this can make me feel worse)
Participants seeking to disconnect from other people during a crisis	Spending time on my own	Being forced to go out in public
	Taking a time-out by myself	Being forced to socialise
	Going to bed for a sleep	Being forced to talk when I don't want to talk
	Going out for a walk and giving myself some space	Not being left alone when I want to be alone
	Removing myself from the situation and going for a walk	Being surrounded by people
		Being around too many people

[1] Anonymous telephone counselling service in the UK.

Perpetuating factors

Many participants described situations and behaviours which had contributed to exacerbating previous crises and elected to include these in their JCPs as reminders of what to avoid in the event of a future crisis. These fell into one of two categories: "Interpersonal interactions" (such as seeing friends, family members or acquaintances that the participant did not wish to see or, conversely, being in isolation when the participant did not wish to be alone), or "Self-destructive behaviours" (such as self-harming, using or misusing drugs/alcohol, engaging in risky sexual behaviour or spending excessive amounts of money).

Interactions with mental health professionals during crises

Many participants recalled unhelpful interactions with mental health professionals during previous crises and expressed a desire to avoid similar interactions in the future. Phrases used to describe clinicians during previous crises included: 'judgmental', 'dishonest', 'dismissive', 'condescending', 'disrespectful', 'sarcastic', 'misleading', 'impatient', 'patronising', 'not taking [the participant] seriously' and 'treating [the participant] like a child'. Specific actions performed previously by clinicians that were deemed unhelpful during a crisis included 'not following through on promises' (including not returning telephone calls), 'not being discrete in front of others', 'comparing [the participant] to other clients' and 'giving [the participant] religious advice'. Table 16 displays illustrative examples of statements from participants' JCPs describing how they wanted clinicians to treat them during future crises.

Table 16. Illustrative examples of specific actions that participants stated they wanted mental health professionals to do during future crises.

	Specific action
Emotional support	'Talk to me; don't just sit there doing active listening.'
	'Be upbeat and positive.'
	'Reassure me that things will be alright.'
	'Don't force me to speak.'
Practical support	'Discuss options with me about where to go from here.'
	'Involve me in the decision-making process.'
	'Help me to plan out my next day.'
	'Ask me to hand over any excess medication.'
Respect	'Please don't speak to me so loudly that everyone in the room can hear my business; please respect my privacy.'
	'Non-judgmental responses.'
	'Please treat me with respect and don't be rude to me.'
	'Treat me as a person, not as a person with mental health problems.'

Specific refusals regarding treatment

Thirty-seven participants (90.2%) included at least one specific refusal regarding treatment during future crises. Preferences regarding medication and involuntary treatment were the two most common refusals. Medication refusals were most often based on: a) a preference to avoid being treated with specific medication(s) (56.1%); b) undesirable side effects of specific medication(s) (17.1%); or c) known allergies to certain medication(s) (12.2%). Eleven participants (26.2%) expressed a preference not to receive treatment involuntarily when in a crisis.

Dissemination of JCPs

At the request of participants, copies of their JCPs (either paper copies or electronic copies) were distributed to a range of health and statutory bodies involved in their care. The two most frequently requested recipients were community care coordinators and GPs (see Table 17).

Table 17. Individuals and services nominated by participants to receive a copy of their JCPs.

Recipient of JCP	N	%
Service user	41	100.0
CMHT care coordinator	39	95.1
GP	37	90.2
Electronic psychiatric records	23	56.1
Other health professional(s)	10	24.4
Parent(s)/child(ren)	8	19.5
Friend(s)	7	17.1
Partner/spouse	5	12.2
Social worker	3	7.3
Drug & alcohol worker	2	4.9
Emergency department at local hospital	2	4.9
Probation officer	1	2.4
Other family member(s)	1	2.4

CHAPTER 4. DISCUSSION

4.1. Summary of main findings

The trial investigated the impact of joint crisis plans on the self-harming behaviour of 88 community-dwelling adults recruited from community mental health teams in south London, all of whom met DSM-IV-TR diagnostic criteria for borderline personality disorder. The findings did not support any of the five hypotheses as there were no significant differences between the intervention and control groups on any primary or secondary outcome measures. Possible explanations for the negative findings are discussed in section ***4.2 General methodological considerations***, below.

4.2. General methodological considerations

Trial design & randomisation

Randomised controlled trials (RCTs) are widely recognised as the most reliable method of determining the effectiveness of healthcare interventions (593) and this is due to the randomisation process itself. Randomisation is the most robust method of ensuring the even distribution of all known and unknown confounding factors that may impact on clinical outcomes (566, 567). Without randomisation, treatment comparisons may be consciously or unconsciously prejudiced by selecting a particular participant to receive a particular intervention (588). For randomisation to be truly effective, two interrelated steps must occur; firstly, a sequence must be generated which is sufficient to prevent selection bias. Secondly, neither investigators nor participants should be able to foresee the result of any randomisation episode, thereby preventing detection bias (594). Each of these conditions was met in the trial as randomisation was conducted externally by the

Clinical Trials Unit at King's College London using a process of electronic stratified randomisation. As such, members of the research team could not have predicted the assignment of any given participant. Furthermore, randomisation was not an influential factor during the recruitment phase, as only one potential participant declined to participate because he could not be guaranteed of being randomised to the JCP+TAU arm of the trial.

The lack of statistically significant differences between the groups on primary or secondary outcomes in the face of high user acceptability was counterintuitive. However, significant clinical differences between the two groups may not have been detected for a number of reasons and the trial had several important limitations which may have impacted on the outcomes. Each of these is discussed below.

4.3. External and internal validity of the trial

When designing or interpreting a trial, the two main concerns of the researcher are the internal validity and external validity of the trial (595). Internal validity relates to the extent to which systematic error or bias is minimised, whilst external validity refers to the extent to which trial findings can be generalised to other circumstances (594).

Internal validity

The internal validity of a trial can be threatened by several types of bias, including a) selection bias, b) detection bias, and c) attrition bias and missing data. Each of these is discussed below in relation to the trial.

a) Selection bias

The risk of selection bias was minimised as a result of the centrally-operated stratified randomisation process used in the trial. The lack of selection bias was evidenced by the similarity of the intervention and control groups in both size and demographic characteristics.

b) Detection bias

When an investigator who should be blinded to participant allocation becomes unblinded, this is an example of detection bias, as the investigator's knowledge of the participant's allocation may (intentionally or otherwise) influence the assessment of outcome variables (594). The trial was a single-blind trial (i.e. follow-up data were collected by a research worker blinded to each participant's allocation). Due to the nature of the trial, it would not have been possible to use a double-blind methodology (i.e. it would have been impossible to keep participants and clinicians blinded to allocation status or to have a 'placebo JCP' condition). The research worker collecting all follow-up data was unblinded in eight (9.1%) cases; on seven occasions the unblinding was a result of the participant's actions and on one occasion it was a result of the actions of a CMHT clinician. All instances of unblinding occurred prior to follow-up data collection being conducted and, as a result, the research worker may have been unable to conduct the follow-up interview in an unbiased manner. Although this happened in only a small minority of cases, it may have impacted on the data obtained.

d) Attrition bias and missing data

The experience of recruiting from CMHTs was similar to that reported in the literature, as some clinicians were inherently more receptive to research and produced more referrals than others (555, 556). Other clinicians refused to complete the required measures either at baseline or follow-up (or both) and one clinician stated unambiguously that he disagreed with the trial's methodology and would not be completing any trial paperwork as a result. This stance by such clinicians, in addition to the participants who were lost to follow-up, resulted in a small amount of missing data throughout the trial. Missing data (particularly if differential between trial arms) can compromise internal validity and also lead to a loss of power in trials (596). However, as the amount of missing data in the trial was minimal, no substantial loss of power resulted. Additionally, rates of attrition from the trial and the subsequent amount of missing data were approximately even in the two groups. The impact of missing data was minimised by using modified intention-to-treat analyses throughout (see below).

Intention-to-treat analysis

Intention-to-treat refers to the process of all randomised participants, regardless of their outcome after randomisation, being retained within their original groups during data analyses (596). This is because participants who are not followed up (for any reason) are likely to be different from participants who go on to complete a trial (594) and intention-to-treat analyses helps to avoid selection bias. Although intention-to-treat analysis is likely to provide a reduced estimate of treatment effect

when adherence to treatment is low (299), this was not the case in this trial as adherence to treatment was high.

External validity

External validity relates to the extent to which the findings from a trial provide a robust basis for generalising the results to other populations, settings and variables – that is, its generalizability and applicability (588, 594). The findings of a trial with good external validity can more easily be applied to real clinical settings (597). External validity depends on the characteristics of the sample, the setting, the intervention, the outcome measures used and the social, economic and cultural environment in which the trial is conducted (588). Participants in the trial were recruited from inner-city CMHTs in south London and they all met DSM-IV diagnostic criteria for BPD. Most were white British, female, aged in their thirties, single, unemployed, and in receipt of long-term government disability benefits. A majority had left school prior to the age of 16, many were moderate to heavy consumers of alcohol and approximately half had used illicit substances in the previous 12 months. Demographically, the sample was broadly similar to those seen both in secondary care in the UK and in other trials in the field of BPD research (284, 302), indicating high external validity.

Choice of control group

Despite the existence of clinical guidelines, the concept of 'treatment as usual' for BPD can potentially vary greatly between CMHTs, between clinicians and between individual service users. Indeed, when the trial was conducted, there was no

standard definition of TAU specifically for people with BPD in the UK. Some participants reported not having seen their care coordinator during the six-month follow-up period despite still being registered as an active service user with the CMHT, whilst other participants reported being in contact with their care coordinator several times each week during the follow-up period. The net result of this was that participants in both trial arms received considerable variation in treatment. This is, however, consistent with previous research which states that different service users receive different levels of care from their treating clinicians (598-600).

Contamination of TAU group

It is possible that some participants in the TAU group may have received a generic, but equally efficacious, crisis contingency plan as part of their concurrent treatment as usual under the CPA, thereby potentially diluting the true impact of the JCP intervention. However, as stated earlier, recent findings published by Farrelly and colleagues (569) highlighted a low (15 percent) level of individualised crisis plan content amongst 424 CMHT service users, with the majority of crisis plans containing only generic information. Additionally, a 2007 audit of South London and Maudsley Trust service users who had attended the Maudsley emergency clinic (followed up nine months later) revealed that 42 percent of those under the standard CPA did not have a crisis contingency plan on their electronic records (unpublished data). Of those that did, only 37 percent of crisis plans contained any information which was specific to the service user, with the remaining plans consisting solely of generic information. It seems unlikely, therefore, that such generic crisis contingency plans

(which were written by the clinician, without input from the service user), would have contributed to the absence of a significant difference between intervention and control groups in this trial.

Lack of statistical power (Type II error)

Type II error occurs when a non-significant result is obtained and the null hypothesis is accepted incorrectly (597). There was a shortfall in predicted recruitment to the trial by approximately 30 participants (i.e., 25% of the initial target sample size) and this resulted in the trial being underpowered to detect a difference in self-harming behaviour. As such, there is a chance that the null hypothesis was accepted incorrectly (i.e., a Type II error was committed). Perhaps the most significant methodological limitation was that the trial was underpowered.

Additionally, it has been reported that less than one third of publicly funded trials manage to recruit according to their original plan (601) and the current under-recruitment may have reflected a generic problem relating to conducting research in the NHS, especially during a period of extensive service restructuring. Fewer referrals were made by clinicians and the rate of attrition was higher than anticipated when designing the trial. These findings emphasise the need to allow for a longer recruitment phase and larger inflation factors in the calculation of sample sizes for trials involving people with BPD. It is worth noting that, of the 30 individuals who declined the invitation to take part in the study, the majority stated that they did not wish to take part in research of any kind and only one stated that he disagreed with the trial's methodology.

Problems with measuring self-harm

Data collection via self-report methods

Data relating to the main outcome measure - self-harm - were obtained retrospectively via self-report. Although similar self-report methods have been used in previous RCTs aiming to reduce self-harming behaviour (286), there is an inherent risk associated with using this methodology for obtaining self-harm data, as it is dependant entirely upon respondents' candour, awareness and comprehension of questionnaire items (405). It may also be susceptible to reporting bias (unintentional or otherwise) and the occurrence of both false negatives and false positives is possible. Additionally, participant recall at six months may not have been accurate (602) and this may have impacted on the findings observed.

Severity and behavioural intention of self-harm

With the exception of the most recent act of self-harm, the medical severity of participants' self-harm was not measured and nor was their behavioural intention. Given that such intentions may vary considerably between individuals and even within the same individual at different times, these may have been important data to collect.

Challenges relating to data collection

Three methods of capturing self-harm events were used concurrently to maximise the accuracy of self-harm data collected: participant interviews, contemporaneous diaries and screening of participants' electronic psychiatric records. All participants

were provided with a brief (one-page) self-harm diary (see Appendix 2) at baseline and asked to record all episodes of self-harm during the follow-up period before bringing the diary to their follow-up appointment. Fifteen participants (20.5%) brought their diary to their follow-up appointment; the remaining 58 (79.5%) stated that they had either lost their diaries or had forgotten to complete them during the follow-up period. Although a minority of participants reported no self-harm events during the follow-up period (and, thus, returning their self-harm diary would not have provided any additional information), the majority of all trial participants (62.5 %) did self-harm during the follow-up period and their diaries may have provided valuable data.

Each participant's electronic psychiatric records were also screened upon completion of their follow-up interview in order to establish the number of events of self-harm recorded by clinicians during the follow-up period. Both the quantity and quality of information regarding participants' self-harming contained within their electronic records was poor, with episodes of self-harm reported by participants rarely featuring in their electronic records. There are two possible explanations for this finding; firstly, that participants were not informing their treating clinicians of the true extent of their self-harming behaviour or, secondly, that clinicians were aware of the true extent but did not, for various reasons, accurately document such behaviour. Given that self-harm is associated with considerable stigma and most self-harm is not associated with help-seeking behaviour (418, 603, 604), it is likely that the former explanation accounted for this finding.

In their 2011 systematic review of instruments designed to measure self-harm in adults, Borschmann and colleagues (405) posited that the most reliable way of capturing episodes of self-harm may be to triangulate multiple data sources such as self-report accounts, clinician/observer accounts, medical records and contemporaneous patient-held devices such as brief diaries. The findings from this trial suggest that participant diaries were not an effective method of capturing self-harm events contemporaneously, as they were misplaced frequently by participants. One alternative might be for participants to document episodes of self-harm using their phones (for example, by sending a text message to a pre-set number), as they may be less likely to lose their phone than a self-harm diary. Electronic records under-documented the incidence of self-harm and face-to-face follow-up interviews with participants appeared to provide the most complete account (i.e., the least missing data) of self-harming behaviour during the follow-up period. However, it must be noted that self-report is associated with recall bias and, as such, is also not without limitations.

Generalizability of findings

It is possible that eligible non-participants (i.e., those service users who declined to take part in the trial) may have differed significantly on key demographic or outcome measures from the participants who chose to enter the trial and this may have impacted on the results obtained. Previous studies have also reported that non-participants in health-related studies are more likely to be of lower socioeconomic status (i.e., worse living conditions, lower educational level and poorer employment status) (605), to have a lower level of functioning (as measured by global assessment

of functioning scores) (606), to have increased rates of substance misuse (607) and to have poorer general physical (608) and mental (609, 610) health than participants. It is therefore possible that potential participants who declined to be involved in the trial may have had poorer overall outcomes - including elevated rates of self-harming behaviour - than trial participants.

Seventy-three per cent of all referred service users were both eligible and willing to take part in the trial. The 30 service users who declined an offer to participate all cited one or more of the following reasons for their decision:

1) The client failed to acknowledge the possibility of future crises;
2) The client was unwilling to undergo the randomisation process;
3) The client did not agree with trial design;
4) The client stated s/he was too busy to participate;
5) The client had participated in a sufficient number of research studies prior to being approached about the trial.

Recruitment to the trial was facilitated with the assistance of local CMHT clinicians and, due to the conditions of the trial's ethical approval, no potential participant could be contacted by a researcher without having previously consented to such contact via their treating clinician. As such, researchers were limited to an extent in relation to a) the identification of potential participants, b) the initial approach of potential participants, and c) the provision of contact details for potential participants. Some sites - and some individual clinicians - were more productive in relation to the identification of potential participants than others and the practice of

'gatekeeping' (i.e., allowing or denying access to the study (556)) by some clinicians impacted adversely on the recruitment process throughout the trial. As the research team was, by definition, unaware of potentially suitable participants until notified by CMHT clinicians, this phase of the recruitment process was open to a range of selection biases (intentional or otherwise) on behalf of clinicians. It is possible that any potential participants who were not approached for the present study may have differed significantly from the group of participants who did take part.

Loss to follow-up

Fifteen participants (17.0%) could not be followed up; nine (19.6%) from the JCP arm and six (14.3%) from the TAU arm. Attrition can often be substantial when treating people with BPD (299) and, in light of the underlying psychopathology, this is perhaps understandable; difficulties with collaboration, flight from exploratory work and defence against change are observed frequently in this population (611). However, the attrition rate was considerably lower than rates observed in previous interventions involving this population. Reporting on a trial of psychotherapy for BPD, Gunderson and colleagues (240) reported that more than half (60%) of participants had dropped out of the study after six months. Skodol and colleagues (67) reported that 40 percent of participants with BPD had dropped out of their trial of outpatient treatment after three months, whilst Waldinger and Gunderson (612) reported a mean dropout rate of 47 percent after six months of people with BPD after a survey of private psychotherapy practices. Finally, de Panfillis and colleagues (6) reported a dropout rate of 33.3% within the first three months from outpatient care for people with BPD. By comparison, the dropout rate of 17.0% after six months

in the trial was low and may have reflected the relatively low intensity of the JCP intervention, in addition to participants being required to attend only one follow-up appointment after six months.

Barriers to recruitment

One prospective participant re-scheduled her baseline appointment five consecutive times, at which point she was excluded from entering the trial. Exactly one quarter of participants did not attend at least one appointment during the trial and a further seven potential participants were excluded after failing to attend three consecutive baseline appointments.

Barriers to intervention implementation

One clinician in the present trial was the care coordinator for two participants, both of whom were randomised into the JCP+TAU arm. However, as a result of the clinician being unable to attend the JCP planning meeting (on several occasions), neither of these participants was provided an opportunity to create their JCP. Both participants, however, did attend the follow-up appointment. Another participant delayed the completed version of her JCP being approved by more than two months, during which time more than 20 emails were sent between the research team and the participant. This resulted in her not having a JCP for more than one third of the follow-up period. Finally, one participant stated in her JCP the desire to attend the local emergency department when she was feeling at risk to herself but further stated that she did not wish to speak to any health professionals (and, rather, that she would feel safe simply by sitting there by herself). Unbeknownst to those

present at her JCP planning meeting, this wish directly contradicted the protocols of the local NHS emergency department and she was required (against her wishes) to speak with staff members the next time she attended in a crisis. This was not well received by the participant and she did not go on to participate in the follow-up interview several months later.

Barriers to data collection

The experience of recruiting from CMHTs was similar to that reported in the literature, as some clinicians were inherently more receptive to research and produced more referrals than others (555, 556). Other clinicians refused to complete the required measures either at baseline, follow-up or both. In contrast to this, the research team received a considerable amount of positive feedback from clinicians throughout the trial, in relation to both their clients' JCPs and the trial overall.

Problems relating to JCP content

Two participants stated during their JCP planning meetings that they wished to include the statement "If I overdose, I do not wish to be resuscitated" in their JCPs under the heading "Practical help in a crisis". It was agreed that this course of action would not be in keeping with the true ethos of an appropriate crisis plan and, after further discussion, both participants agreed to include the statement "However, I fully understand that treating health professionals may choose not to follow this wish in an emergency" after the initial statement.

Crisis definition and frequency

Although this was a trial of joint crisis plans, the number of crises experienced by participants during the follow-up period was not measured. This was because the JCPs were not designed to reduce the number of crises experienced by participants; rather, they were designed to help participants to better navigate future crises (however frequently or infrequently they may occur). Additionally, as highlighted in the literature review, there is no universally agreed definition of a 'crisis' and so it was not possible to operationalise this outcome for the trial. However, at follow-up, when reflecting upon their experiences, participants described similar emotional and contextual states that they regarded as crises; during previous crises, many participants reported that they had failed to meet their basic self-care requirements, including eating, drinking and bathing and had been unable to think or behave in a rational manner. As such, despite the absence of a clear definition of crises, it is reasonable to assume that participants were experiencing similar behavioural events.

Adherence to protocol and use of JCPs

Adherence to the protocol was high, as a total of 41 out of 46 participants in the JCP+TAU group (89.1%) attended their JCP planning meeting and consequently received the active intervention. There were relatively few protocol deviations and these are discussed below under "Deviations from protocol". Data gathered at follow-up indicated that JCPs were used both during and between crises and were viewed favourably by the majority of participants. More than 90 percent of participants were still in possession of their JCP at follow-up (two participants stated that they had lost their plans) and approximately three quarters stated that they had

used their JCP during a crisis. This is comparable to the findings by Henderson and colleagues (544), in which 36 out of 45 (80.0%) of participants were still in possession of their JCP at 15-month follow-up.

Forty-four percent of participants had referred to their plans in other (non-crisis) situations. Despite the lack of clinically significant results observed, the process of creating (and owning) a JCP appeared to have a positive impact on the experience of receiving mental health care. Many participants stated that, since creating their JCPs, there had been an improvement in their relationship with their treating mental health team (47%), they a greater feeling of control over their problems (47%), they had an increased satisfaction with the care they received (39%) and there was an improvement in the quality of mental health care they received (38%). A total of 85 percent of participants stated that they would recommend JCPs to other service users in similar circumstances.

Deviations from protocol

Addition of new outcome measure

The measure of mental wellbeing used in the trial (the WEMWBS) did not feature in the original protocol of the trial (387) and was introduced after data collection commenced, following consultation with the Project Advisory Group (PAG), whose view was that it was important to capture these additional data as part of the feasibility work. As such, less than half of participants (40; 45.4%) completed the WEMWBS at baseline and there were some missing data relating to mental

wellbeing. However, these were fully accounted for during analysis (see 'Missing Data', above).

4.4. Strengths of the study

In addition to the above limitations, the trial also had several strengths that warrant discussing. Firstly, it was conducted in routine NHS settings, with recruitment taking place across five separate and demographically disparate boroughs during a period of considerable service restructuring and efficiency savings. Despite this, approximately 75 percent of the target sample size was recruited and approximately 80 percent were retained at follow-up. The refusal rate (25 percent) was comparable with those reported in previous RCTs involving service users with BPD (286, 302) and, as stated above, the attrition rate was low when compared with previous BPD research (67, 240, 612). Also, the response rate of 75 percent was twice as high as that reported in a previous large scale RCT of joint crisis plans (541). The majority of service users (77.4%) who were invited to participate in the trial consented and were willing to undergo the randomisation procedure. Although a further nine percent later proved to be ineligible, such a high response rate was somewhat unexpected as the concept of randomisation has been discussed in the literature as a common difficulty associated with successfully recruiting people with BPD into trials (52, 233). Furthermore, this rate was considerably higher than the 53.2% response rate achieved in a recent large-scale RCT of JCPs for people with psychosis (550). Finally, in relation to data collection, although the trial could not have utilised a double-blind methodology, all follow-up data were collected by a research worker blinded to treatment allocation and this blindness was maintained in 62 of 73 (84.9%) cases.

4.5. Discussion of hypotheses in light of trial findings

This was primarily a feasibility (and not a hypothesis-testing) trial. However, five exploratory hypotheses were formulated and each of these is discussed below in relation to the findings obtained.

4.5.1. Primary outcome

Hypothesis 1: *Participants in the JCP group would report significantly fewer self-harm events during the six-month follow-up period, when compared with participants in the control group;*

Findings showed that there was no significant difference in the mean number of self-harm events reported over the follow-up period between participants in the JCP group and the TAU group. Although the mean frequencies were very similar, participants in the JCP group reported a marginally higher number of self-harm events during follow-up (20.6 vs. 20.3) and also a higher median number of events (two vs. one). Additionally, a higher proportion of participants in the JCP group reported self-harming during the follow-up period (69.4% vs. 55.6%), though this difference was also not significant.

4.5.2. Secondary outcomes

Although no specific hypotheses were formulated in relation to the secondary outcome measures investigated, several exploratory hypotheses were posited regarding secondary outcomes. A brief discussion of each is below.

Hypothesis 2: *Participants in the JCP group would report a significant improvement in engagement with mental health services at follow-up, compared with participants in the control group;*

Although the mean score of participants in the JCP group decreased over the follow-up period (indicating an improvement in engagement) and the mean score of participants in the TAU group increased (indicating a reduction in engagement), this difference was not statistically significant. As such, this hypothesis was not supported. It is possible that crisis plans which are integrated with a more detailed psychological treatment programme (i.e. those requiring greater engagement) may be required to help people with BPD who repeatedly self-harm (409, 613).

Hypothesis 3: *Participants in the JCP group would report a significant improvement in therapeutic alliance at follow-up, compared with participants in the control group;*

The results demonstrated that there was no significant difference in the change in mean therapeutic alliance scores at follow-up between participants in the two groups and, as such, this hypothesis was not supported. Despite this, the change in therapeutic alliance scores at follow-up was greater - and in the hypothesised direction - in the intervention group than in the control group. As with service engagement, the heterogeneity of care received by participants in both arms may have contributed to this finding.

Hypothesis 4: *Participants in the JCP group would report a significant improvement in satisfaction with care at follow-up, compared with participants in the control group;*

No significant differences were observed between the mean satisfaction scores by participants in the intervention and control groups. In Sutherby and colleagues' pilot study of crisis plans (548), a majority of participants reported that they felt more positive, more involved in their care and more in control of their mental health problems at follow-up as a result of developing their plans. It is noted, however, that satisfaction was not measured in the control group and, as such, no direct comparison can be made. Other forms of psychiatric advance directives have also resulted in increased feelings of empowerment and self-determination amongst mental health service users, as the service users believe that such directives have the potential to facilitate stronger client-service relationships (614).

Hypothesis 5: *Participants in the JCP group would report a significant improvement in quality of life at follow-up, compared with participants in the control group;*

Mean quality of life scores increased marginally across both groups at follow-up, although neither of these increases were significant and nor was the difference between the two groups. Previous studies have reported mixed findings regarding the impact of interventions on the health-related quality of life in people with BPD. Davidson and colleagues (294) reported no significant differences in quality of life at 12 or 24 months follow-up in a trial of CBT for BPD and McMain and colleagues (278) also showed no significant improvements in quality of life (using the same instrument that was used in this trial, the EQ-5D) in a trial of DBT. Against this, Giesen-Bloo and colleagues (302) showed significant improvements in health-related quality of life in outpatients with BPD receiving schema-focused therapy compared with those receiving transference-focused psychotherapy. Likewise, Carter and

colleagues (615) reported a significant improvement in quality of life scores of people with BPD receiving DBT in an Australian trial compared to those receiving treatment as usual.

4.6. Qualitative findings

Participants made considered choices to include useful information in their JCPs both for themselves and for health care professionals with whom they might interact during future crises. There is no standardised definition of a crisis (387), although participants clearly described a similar and coherent pattern of distress accompanied by a sudden disruption in functioning following an acute life event. During previous crises, participants reported that they had failed to meet their basic self-care requirements, including eating, drinking and bathing. Subsequently, many participants chose to include in their JCPs a reminder to themselves to address these basic needs during future crises, suggesting that thoughtfully constructed written advance statements such as JCPs can provide practical, immediate utility for people with BPD during acute crises.

Participants were divided on the issue of connecting with others (i.e., having a meaningful and reciprocal exchange with another person) whilst in a crisis. For many, having the opportunity to connect with others was seen as both vital and beneficial, whilst many others described it as unhelpful, instead preferring to be left alone when in a crisis. This discrepancy highlights the need for clinicians to actively discuss this issue with participants when reviewing crisis plans. The NICE guideline on the management of BPD (189) recommended that regular reviews of crisis plans

should be conducted with service users and their family members or carers if possible and that service user autonomy should be promoted at all times. For those seeking to be left alone during a crisis, 'being forced' into proximity with others (whilst sometimes being necessary as a last resort in order to manage risk) is also potentially traumatic and may increase underlying feelings of powerlessness which often play out in interactions with clinicians (616).

Treatment preferences regarding medication and involuntary treatment were the two most common treatment refusals. The NICE guideline (189) stated that, although medication is commonly started when a person with BPD presents in crisis, there is no evidence for the use of any specific drug or combination of drugs in crisis management. Additionally, at the time of writing, there are no medications licensed in the UK for the treatment of BPD. The choices expressed by participants in the trial regarding medication therefore appear to be choices that clinicians should not have difficulty following. In this regard, the findings are similar to research into the content of psychiatric advance directives produced in the US by people with severe mental illnesses (534, 614).

Goals of crisis interventions for people with BPD typically include returning people to their pre-crisis level of functioning by mobilising both internal and external resources (365). These were, for the most part, reflected by participants and mirror the goals of the recovery orientation which is central to mental health policy in the 21st century throughout the Western world (617, 618).

4.7. Possible reasons for negative findings

Intervention in isolation

It remains possible that crisis plans for people with BPD may be more successful when the crisis plan is more fully integrated with other components of comprehensive long-term treatment for BPD (233, 613), as opposed to the one-off intervention offered to participants in this trial.

Brief follow-up period

Finally, the follow-up period was limited to six months and it is possible that a longer follow-up period may have led to the detection of significant clinical change. Ultimately, it is possible that the findings may have been influenced by any of the aforementioned limitations - or a combination of them - or by other factors not yet understood.

4.8. The trial in context

Using the most recent MRC framework for developing and evaluating complex interventions (561) as a guide, the trial was designed iteratively after considering advice and input from service users with BPD, clinicians and academics working with people with BPD and the results of a brief pilot study. Although other intervention trials involving participants with BPD have included a crisis management component as an ingredient of treatment (243, 284), findings from Borschmann and colleagues' 2012 Cochrane review indicated that this was the first RCT of a crisis intervention specifically tailored to people with BPD (371). The findings from the trial revealed that it is feasible to recruit and retain people with BPD to a clinical trial of joint crisis

plans. Approximately three-quarters of the target sample size were recruited and more than 80 percent of participants were retained at follow-up. Moreover, the intervention appeared to have high face validity with participants as JCPs were used both during and between crises and were viewed favourably by participants. Approximately half of participants reported a greater sense of control over their problems and an improved relationship with their mental health team as a result of creating a JCP and the large majority of participants stated that they would recommend creating a JCP to other service users. At follow-up, the proportion of participants reporting self-harm had fallen in both groups; however, there was no significant difference in the proportions reporting self-harm between the groups, and no significant differences between the groups on any of the secondary outcome measures. Despite the lack of statistically significant differences between the two groups on any of the secondary outcome measures, the change in mean scores for several variables (including working alliance, mental wellbeing, work and social adjustment, perceived coercion, depression and engagement with services) was greater - and in the hypothesised direction - in the intervention group than in the control group. As the trial was underpowered (see ***'General methodological considerations'***, above), it remains a possibility that an adequately powered trial may have detected significant differences between the two groups on one or more of these outcome measures.

4.9. Implications

4.9.1. Implications for research

The trial highlights important implications for researchers working with people with BPD and/or people who self-harm. Firstly, the findings showed that it was possible to recruit and retain a sample of individuals with BPD to a trial of JCPs and that the intervention was viewed favourably by participants. The high face validity associated with JCPs observed in the trial mirrors that seen in previous large trials of JCPs for people with psychotic disorders (544, 550). Future studies would benefit from the inclusion of a robust process evaluation in order to help understand why the experience of receiving this intervention was so positive in this trial in the absence of clinically significant findings (545). This might include in-depth interviews with JCP recipients and also clinicians who attended the JCP planning meetings to explore their experiences of the intervention and the overall trial.

The current MRC guidance for developing and evaluating complex interventions (561) promotes an iterative model which involves the development, feasibility/piloting, evaluation and implementation of an intervention. Whilst these four elements can helpfully be thought of as stages, it is often the case that they do not follow a linear (or even cyclical) sequence (562). The guidance states that interventions are best developed systematically using a carefully phased approach and amended iteratively on the basis of previous findings. Applying this framework to the trial, one possibility is that future studies may benefit from re-visiting the 'development' stage mentioned above and - if the modelling suggests that other

outcomes should be measured - including additional outcome variables during the next 'feasibility/piloting' stage, as it remains possible that JCPs may influence other (as yet unmeasured) variables. Furthermore, future JCP research would be strengthened by the inclusion of a fidelity measure to assess how much variation there was in the creation of participants' JCPs, as this was identified as a possible limitation in previous large-scale JCP research (550).

One interesting finding from the trial was that, at six-month follow-up, the proportion of participants reporting self-harm had fallen in both the intervention arm and the control arm. It is possible that this is due in part to the Hawthorne effect (the commonly-observed phenomenon in health research whereby participants in an experimental study modify their behaviour simply in response to knowing they are being observed, rather than in response to any experimental manipulation). Another possibility is that there may have been a regression toward the mean (i.e., participants may have been highly motivated to enter the study as their recent levels of self-harm were relatively high and participants in both arms may have wished to address this). This finding has implications for future trials because it may represent an additional variable to consider when hypothesising about rates of self-harm over the course of an experimental trial or other type of study.

As stated earlier, people who self-harm do so typically as a result of multiple motivations and contextual factors (455, 458). As such, it is likely that one relatively brief intervention may not be sufficient to adequately address the motivations of a heterogeneous sample of people who self-harm.

4.9.2. Implications for clinical practice

The trial also highlights important implications for clinicians involved in the day-to-day care of people with BPD and/or those who self-harm. Firstly, the findings demonstrated that self-harm was substantially under-recorded in participants' electronic psychiatric records and this may reflect clinicians being unaware of the true extent of a given service user's patterns of self-harm. The consequences of this lack of awareness are potentially lethal, as clinicians may fail to refer appropriately or recommend the best available treatment to help service users address their self-harming. Secondly, it is possible that, during the process of collaboratively creating a JCP with a service user, clinicians may increase their awareness of that service user's extant self-management strategies. That is, by systematically discussing the JCP template subheadings together, clinicians may learn more about the coping strategies, resources and support mechanisms available to each individual service user. Thirdly, the findings from the trial highlight the difficulties of successfully implementing personalised care in the context of the non-personalised NHS framework. This concept was demonstrated in the case described above of the participant who wished to attend the local emergency department during times of crisis but, specifically, did not wish to be seen by any members of staff. Due to NHS duty of care requirements, this wish was not fulfilled and the participant later reported that she felt worse after attending the emergency department than she had felt beforehand.

Fourthly, qualitative analyses revealed that much of the content of participants' JCPs related to previous unsatisfactory interactions that participants had experienced with healthcare professionals and a desire to avoid such negative interactions in the future. There are clear staff training issues related to this; although people with BPD often elicit less empathic responses from clinicians than people with other diagnoses (125), research has shown that clinician attitudes toward this population can be improved as a result of targeted clinical education about BPD (143, 144). Future training could focus on providing clinicians with more detailed information about the aetiological factors and prognosis associated with BPD, in addition to therapeutic responses and attitudes toward BPD (122). The present findings underscore the importance of the Department of Health's Personality Disorder Capabilities Framework (619), which seeks to ensure that members staff working with people with personality disorders are equipped with the requisite education and experience to work effectively with this population. As the views of healthcare professionals regarding working with people with BPD can be negatively biased and unfavourable (57, 126), it could be argued that people with BPD have the greatest need for skilful professional care (143) and the findings from the trial demonstrated many participants' desire for meaningful interactions during times of acute crisis. This unambiguous finding provides a clear message to clinicians working with people with BPD about what is perceived as helpful and unhelpful during times of crisis.

At the request of participants, JCPs were distributed to a range of health and statutory bodies involved in their care. More than 90% of participants requested that their GP should be provided with a copy of their JCP. People with BPD are high

consumers of primary health care services (5) and often receive input from their GPs during acute crises. As such, advance statements that can be shared with GPs, such as JCPS, may be particularly valuable. Finally, the high face validity of JCPs with participants in this trial is an important finding during a period in healthcare in which shared decision-making (528) is becoming used more frequently.

Clinicians working with people with BPD may wish to make use of JCPs in routine practice as a method of discussing the differing risk factors, protective factors and treatment preferences of each individual service user. One of the strengths of JCPs is that they are written in the service user's own words and are, therefore, largely free of the medical jargon seen in electronic psychiatric records and earlier forms of crisis plan.

Participants included unambiguous and insightful statements in their JCPs, the majority of which related to a clear desire to recover from the crisis and continue living productive lives. This finding challenges misconceptions held by many clinicians that people with BPD either consistently make self-destructive life choices (10) or lack the requisite capacity to make sensible life choices (620-622). This highlights the fallacy whereby clinicians may sometimes make unfavourable generalisations about the level of functioning of people with BPD during their daily lives on the basis of their presentation during crises. The findings also demonstrate that the same issues of dignity, respect and autonomy identified in global surveys of discrimination amongst people with severe mental illness (623, 624) are important to people with

BPD and add further support to the NICE recommendations for improving the experience of care for people using NHS mental health services (625).

The qualitative analysis of 41 JCPs highlighted several important issues. Firstly, people with BPD do not (as many presume) make exclusively destructive life choices. Secondly, as highlighted by the statements relating to interactions with staff, the issues of dignity, respect and autonomy are as critically important to people with BPD as they are to people with severe mental illness. Thirdly, the variation observed in the treatment preferences of participants underscores the importance of involving service users with BPD in genuinely collaborative working relationships. In the UK, the NICE guideline for the treatment and management of BPD (189) recommends involving people with BPD in the decision-making process - including in relation to their crisis plans - regarding their future treatment. The findings highlight some clear domains in which people with BPD can be more involved in planning their future care during crises and also highlight important lessons for practitioners and policy-makers regarding future care planning for this population.

4.10. Summary and conclusions

Previous research using JCPs and other psychiatric advance statements has found that they promote self-determination and empowerment among service users (544) and that they have the potential to facilitate stronger relationships between service users and providers (614). Fostering collaborative relationships is essential in the treatment of people with BPD (189) and JCPs may provide one approach to ensuring that the values and treatment preferences of people with BPD remain central when

they experience crises. This trial, using data obtained from 88 self-harming outpatients receiving treatment from CMHTs in south London and meeting diagnostic criteria for BPD, showed that it is possible to recruit and retain adult service users with BPD to a research study of joint crisis plans. JCPs were used both during and between crises and were viewed favourably by participants. Approximately half of participants reported a greater sense of control over their mental health problems and an improved relationship with their mental health team as a result of creating their JCP. However, creating a JCP was not associated with a statistically significant reduction in self-harm at follow-up. The findings suggest that a brief and relatively simple intervention is perceived as helpful to people with BPD – a group who have traditionally been alienated from mainstream mental health services and are still perceived to be difficult to help (8). Reducing hospitalisation through improvements in outpatient services would reduce healthcare costs and benefit people with BPD (64).

Although JCPs had high face validity for people with BPD, evidence of clinical efficacy was not established and so the trial did not provide a robust justification to recommend the use of JCPs in clinical practice. Given the exploratory nature of this trial, the small sample size involved and the lack of significant improvements in the primary outcome measure, a decision to fund JCPs in addition to treatment as usual may be premature. However, as the trial was underpowered, it remains possible that the JCP is an effective intervention for people with BPD. Future research should include a robust process evaluation to help understand why the experience of receiving this intervention in this trial was rated so positively by participants. Such an

evaluation may also provide further useful information about the clinical and economic benefits of using joint crisis plans in a population of people with borderline personality disorder.

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APPENDICES

Appendix I: Published papers from the trial

1.) Moran, P., **Borschmann, R**., Flach, C., Barrett, B., Byford, S., Hogg, J., Leese, M., Sutherby, K.M., Henderson, C., Rose, D., Slade, M., Szmukler, G., & Thornicroft, G. (2010). The effectiveness of joint crisis plans for people with borderline personality disorder: protocol for a pilot randomised controlled trial. *Trials*, *11*, 18-25.

2.) **Borschmann, R**, Hogg, J, Phillips, R, & Moran, P. (2011). Measuring self-harm in adults: a systematic review. *European Psychiatry, 27*, 176-180.

3.) **Borschmann, R**., Henderson, C., Hogg, J., Phillips, R, & Moran, P. (2012). Crisis interventions for people with borderline personality disorder (Review). *Cochrane Database of Systematic Reviews,* Issue 6. Art. No.: CD009353. DOI: 10.1002/ 14651858.CD009353.pub2.

4.) **Borschmann, R.**, Barrett, B., Hellier, J.M., Byford, S., Henderson, C., Rose, D., Slade, M., Sutherby, K., Szmukler, G., Thornicroft, G., Hogg, J., & Moran, P. (2013). Randomised controlled trial of joint crisis plans for people with borderline personality disorder: feasibility and outcomes. *British Journal of Psychiatry, 202,* 357-364.

5.) **Borschmann, R.**, Trevillion, K., Henderson, C., Rose, D., Szmukler, G., Moran, P. (2013). Advance statements for people with borderline personality disorder: a qualitative study of service users' treatment preferences during future crises. *Psychiatric Services* (in press).

Appendix II: Materials and instruments used in the trial

1.) Joint Crisis Plan template

2.) Example of Joint Crisis Plan (fictional)

3.) Demographics questionnaire (participant version)

4.) Demographics questionnaire (clinician version)

5.) Work and Social Adjustment Scale (WSAS)

6.) Working Alliance Inventory (Client version) (WAI-C)

7.) Working Alliance Inventory (Therapist version) (WAI-T)

8.) Treatment Experience Survey (TES)

9.) Client Satisfaction Questionnaire (CSQ)

10.) Alcohol Use Disorders Identification Test (AUDIT)

11.) Substance misuse questionnaire

12.) Warwick Edinburgh Mental Wellbeing Scale (WEMWBS)

13.) Hospital Anxiety and Depression Scale (HADS)

14.) EuroQOL Quality of Life measure (EQ-5D)

15.) Self-harm questionnaire

16.) Self-harm diary

17.) The Structured Clinical Interview for DSM-IV (SCID-II) – Borderline Personality Disorder subsection

18.) Abbreviated Scale Standardised Assessment of Personality – Abbreviated Scale (SAPAS)

19.) Service Engagement Scale (SES)

My Joint Crisis Plan

We would like to help you put together a plan for you to use when you are in a crisis. By 'crisis', we mean urgent situations where you feel that you are not coping and may need some extra help.

The plan will be finalised at a meeting between you and key staff from your CMHT, which we will facilitate. The idea is that you might choose to use the plan when you encounter a health professional who doesn't know you well, for example a member of A&E staff.

This form is to help you decide what you would like to be included on your crisis plan. Some sections can be simply filled in by you if you want them included. Elsewhere you may want to select an item but wait to discuss the details with your treatment team at the facilitated meeting. You can include as much or as little information as you wish. Whatever you have chosen or agreed at your crisis planning meeting will then be made up into your own personal crisis plan.

It is important that your joint crisis plan is kept up to date. If you feel that it needs to be updated at any time please contact your treatment team. Please tick which of the following you would like on your crisis plan. Please provide details if at all possible.

☐ My name: .....
Address: .....
.....
Tel no.: .....

☐ GP's name: .....
Address: .....
.....
Tel no.: .....

☐ Consultant's name: .....
Address: .....
.....
Tel no: .....

- ❑ Care coordinator's name: .....
  Address: .....
  .....
  Tel no: .....

- ❑ Other (*e.g. social worker):*
  (please name) .....
  Address: .....
  .....
  Tel no: .....

- ❑ Do you have a friend or family member who might be willing to help and support you in a crisis? If so, it might be helpful if you could invite them along to the planning meeting. You can add their name and contact details below.

- ❑ Who to contact if I need extra support:

  Name .....
  Address .....
  .....
  Tel no: Home .....Work.....
  Mobile .....

My difficulties, and things which may help me in a crisis:

Please tick the boxes you would like on your crisis plan. You may want to fill in the details yourself or you can discuss them with your treatment team at your crisis planning meeting.

❑ **My difficulties as I see them now:**

.....
.....
.....

❑ **Situations which can lead to a crisis (e.g. relationship problems):**

.....
.....
.....

❑ **Positive things which I have found helpful when faced with problems or when I am distressed (e.g. go for a walk, listen to music, write, exercise, etc):**

.....
.....
.....

❑ **Things which have <u>not</u> been helpful when I have been faced with crises in the past:**

.....
.....
.....

❑ **Things I would like health professionals to do when I am in a crisis:**

.....
.....
.....

❑ **Things I sometimes forget to do when I am experiencing a crisis and which I would like to be reminded about:**

.....
.....
.....

INFORMATION WHICH HEALTH PROFESSIONALS MIGHT FIND USEFUL TO KNOW ABOUT ME:

My current treatment / support:

- ❑ **Details of any current treatment and support from professionals:**

.....
.....
.....

- ❑ **When I am distressed, I find it unhelpful if staff talk or relate to me in the following way:**

.....
.....
.....

- ❑ **Specific refusals regarding treatment during a crisis** (*Here you can describe what you <u>do not</u> want done if you are in a crisis).*

.....
.....
.....

- ❑ **Physical illnesses & medication:**

.....
.....
.....

- ❑ **Anything else that people need to know about me, or would be helpful to know when I encounter them in a crisis:**

.....
.....
.....

- ❑ **I do / do not have dependants (e.g. children, elderly relatives).**

If I am in a crisis, I may need extra support to care for them. The person named below can help with this (please provide phone number):

.....
.....
.....

- ❑ **Useful telephone numbers: (e.g. Samaritans, Crisis, Salvation Army, NHS Direct, local A&E department)**

.....
.....
.....

- ❑ **Agencies or people that I would like to have copies of this crisis plan** *(please tick)*

- ❑ myself
- ❑ treatment team – name, details
- ❑ out of hours team –name, details
- ❑ local A & E department – name, details
- ❑ GP – name, details
- ❑ my nominee (the person listed at the top of page 2; please name)
- ❑ other (please name) .....

Date of crisis planning meeting:.....

Present at meeting:

Name	**Role or profession** *(e.g. friend, relative, key-worker / CPN)*

Institute of Psychiatry, De Crespigny Park, London, SE5 8AF. Tel. 020-7848-5093

This **Joint Crisis Plan** has been developed by agreement between

John Paxson
and
_____ CMHT

Please make every effort to fulfil this agreement in the event of a crisis.

Advance statements regarding preferences for care included in a Joint Crisis Plan are not legally binding. Where a Joint Crisis Plan includes a valid advance refusal of treatment, that specific statement is legally binding, but may be over-ruled in certain circumstances such as treatment under the Mental Health Act. This plan is part of a research study designed to improve communication between the service user and professionals in the event of a crisis. For details about the study, please contact Dr. Rohan Borschmann at King's College on 020-7848-5093 or via this email address: Rohan.Borschmann@kcl.ac.uk

Checked by User: _____

Date: _____

*** EXAMPLE ONLY ***

My name: John Paxson
Address: 5 Nightingale Lane, Lewisham, SE13 5CB
Tel. no: 07936.XXX.XXX

My GP: Dr. Lance Patel
Address: 53 Livingstone street, Lewisham SE15 7FG
Tel. no: XXX-XXXX-XXXX

My psychiatrist: ....
Address: ....
Tel. no: ....

My CPN: ....
Address: ....
Tel. no: ....

In a time of crisis, I would like the person below to be contacted as soon as possible and to be informed of what is happening:

Name: Phil Paxson (father)
Address: 5 Nightingale Lane, Lewisham, SE13 5CB
Home tel: XXX-XXXX-XXXX
Work tel: XXX-XXXX-XXXX
Mobile: XXXXX.XXX.XXX

Information for me:

Positive things I can do when I am in a crisis:
Play music in my room
Walk my dog
Avoid contact with my ex-partner

Things which have <u>not</u> been helpful when I have been faced with crises in the past:
Getting into arguments
Using alcohol or drugs

Things I sometimes forget to do when I am in a crisis & may need to be reminded about:
Tell my college I won't be coming in
Remember that I have survived previous crises

Specific refusals regarding treatment during a crisis:
I do not want to be given any injections if possible please.

Useful telephone numbers:

Samaritans:	08457-90-90-90
NHS Direct:	0845-46-47
SLAM Helpline	0800-731-2864

Information for healthcare professionals:

My difficulties as I see them now:
Paranoia and mental health problems

Details of any current treatment / support from health professionals:
I see my CPN every Wednesday at Lewisham CMHT; I also see my GP every 4 weeks

Physical illnesses & medication:
I am asthmatic. My current medication is my Ventolin inhaler and Olanzepine: 10mg at night

Situations which can lead to a crisis:
Problems with money or with my ex-partner**.**

Things I would like professionals to do which may help me when I am in a crisis:
I'd like a quiet room if possible as noise makes me more likely to get distressed.

Things which professionals have said or done which have <u>not</u> been helpful in the past:
Increasing my medication; not listening to me when I am talking; not treating me with respect

When I am distressed, I find it <u>unhelpful</u> if staff talk or relate to me in the following way:
I like people to keep their distance while they're talking with me, as feeling closed in makes me get more distressed. Not being listened to.

Practical Help in a Crisis:

I have two daughters; when I am distressed, my ex-partner Helen (their mother) can take care of them. She can be reached on XXX-XXXX-XXXX.

I have a pet dog and my neighbour Tony (at number 91) is happy to look after him.

Agencies or people that I would like to have copies of this Joint Crisis Plan:

√ myself
√ my GP
√ my treatment team
√ my father, Phil Paxson (father)
√ other (please name)

Registration/Demographics Form (participant)

01.	**Participant Initials**	☐☐☐

02.	**Participant date of birth**	☐☐ / ☐☐ / ☐☐☐☐ **Day Month Year**

03.	**Gender**	**1**	**Female**
		0	**Male**

04.	**What is your <u>current</u> primary relationship status?**	**1**	**Married / civil partnership**	
		2	**Cohabiting**	
		3	**Spouse / partner deceased**	
		4	**Separated**	
		5	**Divorced**	
		6	**Single / non-cohabiting partner**	
		7	**Other (please specify)**	**Go to 04b**
		777	*Not available or not applicable*	
		888	*Not done*	
		999	*Unknown*	

04b.	**Other, please specify**	

05.	**Who do you usually live with?**	**1**	**Alone**	
		2	**Spouse/partner**	
		3	**Spouse/partner <u>and</u> child or children**	
		4	**Child or children (but no spouse/partner)**	
		5	**Other relatives**	
		6	**Other (unrelated)**	**Go to 5b**
		7	**Supervised/assisted living**	
		8	**Homeless**	
		9	**None of the above (please specify)**	**Go to 5b**
		777	*Not available or not applicable*	
		888	*Not done*	
		999	*Unknown*	

05b.	**Other, please specify**	

06a.	Which of the following ethnic groups do you consider you belong to? Circle ONE only:	1	Asian	
		2	Black	
		3	White	
		4	Mixed	
		5	Other – please specify:	Go to 6b
		777	*Not available or not applicable*	
		888	*Not done*	
		999	*Unknown*	

06b.	Other, please specify	

07a.	Which one of these best describes your current situation? Circle ONE only	1	In paid work (including self-employed)	
		2	Unemployed	
		3	Permanently sick or disabled	
		4	Retired	
		5	Looking after home or family	
		6	Full-time student	
		7	Other – please specify:	Go to 7b
		777	*Not available or not applicable*	
		888	*Not done*	
		999	*Unknown*	

7b.	Other, please specify	

08.	Please give the title of your present or most recent paid job:	(drop down list or text field?)	
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

09.	At what age did you leave school?		
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

10.	Have you been in further or higher education since you left school? Circle	1	Yes
		0	No
		777	*Not available or not applicable*
		888	*Not done*

	ONE only	*999*	*Unknown*

11a.	Site	1	Lambeth	
		2	Southwark	
		3	Lewisham	
		4	Croydon	
		5	Other, please specify	Go to 11b
		777	*Not available or not applicable*	
		888	*Not done*	
		999	*Unknown*	

11b.	Other, please specify	

Care Coordinator's Details

Please complete the following questions about <u>yourself</u>.

01.	**Your gender**	**1**	**Female**
		0	**Male**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

02.	**Which of the following ethnic groups do you consider you belong to? Circle ONE only:**	**1**	**Asian**
		2	**Black**
		3	**White**
		4	**Mixed**
		5	**Other – please specify:**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

02a.	**Other, please specify**	

03.	**Classification of your professional qualifications**	**1**	**Occupational therapist**
		2	**Community psychiatric nurse**
		3	**Psychologist**
		4	**Other**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

3a.	**Other (please Specify)**	

4.	**Length of your relationship with this client (in months)**		
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

5.	**Your date of birth**	/ /

		Day Month Year

6.	**Your age in years**	

7.	**Your initials**	

8.	**Length of time you have been working in this field (in months)**	

9.	**Your first language**	

10.	**Type of Care Co-ordinator/main contact**	**1**	**Temporary Care Coordinator**
		2	**Substantive/permanent Care Coordinator**
		3	**Psychiatrist**
		4	**Other** **Go to question 10b**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

10b.	**Other (please specify)**	

Work and Social Adjustment Scale

Rate each of the following questions on a 0 to 8 scale: 0 indicates no impairment at all and 8 indicates very severe impairment.

1.	**Because of my [disorder], my ability to work is impaired. 0 means not at all impaired and 8 means very severely impaired to the point I can't work.**	**0**	indicates no impairment at all
		1	
		2	
		3	
		4	
		5	
		6	
		7	
		8	indicates very severe impairment
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

2.	**Because of my [disorder], my home management (cleaning, tidying, shopping, cooking, looking after home or children, paying bills) is impaired. 0 means not at all impaired and 8 means very severely impaired.**	**0**	indicates no impairment at all
		1	
		2	
		3	
		4	
		5	
		6	
		7	
		8	indicates very severe impairment
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

3.	**Because of my [disorder], my social leisure activities (with other people, such as parties, bars, clubs, outings, visits, dating, home**	**0**	indicates no impairment at all
		1	
		2	
		3	
		4	
		5	
		6	
		7	

	entertainment) are impaired. 0 means not at all impaired and 8 means very severely impaired.	**8**	indicates very severe impairment
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

4.	**Because of my [disorder], my private leisure activities (done alone, such as reading, gardening, collecting, sewing, walking alone) are impaired. 0 means not at all impaired and 8 means very severely impaired.**	**0**	indicates no impairment at all
		1	
		2	
		3	
		4	
		5	
		6	
		7	
		8	indicates very severe impairment
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

5.	**Because of my [disorder], my ability to form and maintain close relationships with others, including those I live with, is impaired. 0 means not at all impaired and 8 means very severely impaired.**	**0**	indicates no impairment at all
		1	
		2	
		3	
		4	
		5	
		6	
		7	
		8	indicates very severe impairment
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

Working Alliance Inventory - Client

On the following pages there are sentences that describe some of the different ways a person might think or feel about his or her therapist (counsellor). As you read the sentences mentally insert the name of your therapist (counsellor) in place of _____ in the text.

Below each statement inside there is a seven point scale:

1 2 3 4 5 6 7
Never Rarely Occasionally Sometimes Often Very Often Always

If the statement describes the way you *always* feel (or think) circle the number 7; if it never applies to you, circle the number 1. Use the numbers in between to describe the variations between these extremes.

This questionnaire is confidential neither your therapist nor the agency will see your answers.

Work fast, your first impressions are the ones we would like to see. (PLEASE DON'T FORGET TO RESPOND TO EVERY ITEM.)

Thank you for your corporation.

1.	**_____ and I agree about the things I need to do in treatment to help improve my situation.** **1 2 3 4 5 6 7** **Never Rarely Occasionally Sometimes Often Very Often Always**	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*

2.	**What I am doing in treatment gives me new ways of looking at my problem.** **1 2 3 4 5 6 7** **Never Rarely Occasionally Sometimes Often Very Often Always**	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*

3.	**I believe _____likes me.** **1 2 3 4 5 6 7** **Never Rarely Occasionally Sometimes Often Very Often Always**	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*

4.	**_____does not understand what I am trying to accomplish in treatment** **1 2 3 4 5 6 7** **Never Rarely Occasionally Sometimes Often Very Often Always**	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*

5.	**I am confidant in _____ability to help me.** **1 2 3 4 5 6 7** **Never Rarely Occasionally Sometimes Often Very Often Always**	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*

6.	**_____and I are working toward mutually shared goals.** **1 2 3 4 5 6 7** **Never Rarely Occasionally Sometimes Often Very Often Always**	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*

7.	**I feel that _____ appreciates/ accepts me.** **1 Never 2 Rarely 3 Occasionally 4 Sometimes 5 Often 6 Very Often 7 Always**	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*

8.	**We agree what is important for me to work on.** **1 Never 2 Rarely 3 Occasionally 4 Sometimes 5 Often 6 Very Often 7 Always**	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*

9.	**_____and I trust one another.** **1 2 3 4 5 6 7** **Never Rarely Occasionally Sometimes Often Very Often Always**	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*

10.	**_____and I have different ideas on what my problems are** **1 2 3 4 5 6 7** **Never Rarely Occasionally Sometimes Often Very Often Always**	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*

11.	**We have established a good understanding of the kind of changes that would be good for me.** **1 2 3 4 5 6 7** **Never Rarely Occasionally Sometimes Often Very Often Always**	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*

12.	**I believe the way we are working with my problem is correct.** **1 2 3 4 5 6 7** **Never Rarely Occasionally Sometimes Often Very Often Always**	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*

Working Alliance Inventory – Therapist version

On the following pages there are sentences that describe some of the different ways a person might think or feel about his or her client. As you read the sentences mentally insert the name of your client in place of _____in the text.

Below each statement inside there is a seven point scale:

1 2 3 4 5 6 7
Never Rarely Occasionally Sometimes Often Very Often Always

If the statement describes the way you *always* feel (or think) circle the number 7; if it *never* applies to you circle the number 1.Use the numbers in between to describe the variations between these extremes.

Work fast, your first impressions are the ones we would like to see. (PLEASE DON'T FORGET TO RESPOND TO EVERY ITEM.)

Thank you for your corporation.

1.	**_____ and I agree about the steps to be taken to improve his/her situation.** **1 2 3 4 5 6 7** **Never Rarely Occasionally Sometimes Often Very Often Always**	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*

2.	**My client and I both feel confident about the usefulness of our current activity in therapy.** **1 2 3 4 5 6 7** **Never Rarely Occasionally Sometimes Often Very Often Always**	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*

3.	**I believe _____ likes me.** **1 2 3 4 5 6 7** **Never Rarely Occasionally Sometimes Often Very Often Always**	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*

4.	**I have doubts about what we are trying to accomplish in therapy.** **1 2 3 4 5 6 7** **Never Rarely Occasionally Sometimes Often Very Often Always**	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*
5.	**I am confident in my ability to help _____.** **1 2 3 4 5 6 7** **Never Rarely Occasionally Sometimes Often Very Often Always**	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*

6.	**We are working towards mutually agreed upon goals.** **1 2 3 4 5 6 7** **Never Rarely Occasionally Sometimes Often Very Often Always**	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*
7.	**I appreciate _____ as a person.** **1 2 3 4 5 6 7** **Never Rarely Occasionally Sometimes Often Very Often Always**	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*
8.	**We agree on what is important for _____ to work on.** **1 2 3 4 5 6 7** **Never Rarely Occasionally Sometimes Often Very Often Always**	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*
9.	**_____ and I have built a mutual trust.** **1 2 3 4 5 6 7** **Never Rarely Occasionally Sometimes Often Very Often Always**	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*

10.	**_____ and I have different ideas on what his/her real problems are.** **1 2 3 4 5 6 7** **Never Rarely Occasionally Sometimes Often Very Often Always**	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*
11.	**We have established a good understanding between us of the kind of changes that would be good for _____.** **1 2 3 4 5 6 7** **Never Rarely Occasionally Sometimes Often Very Often Always**	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*
12.	**_____ believes the way we are working with her/his problem is correct.** **1 2 3 4 5 6 7** **Never Rarely Occasionally Sometimes Often Very Often Always**	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*

Treatment Experience Survey

You are going to read some statements about your treatment. Please tick one box, either 'True' or 'False' or 'Don't know' for each question. To answer each question individually, no matter how similar it may sound to another.

1.	**I have felt free to do what I wanted about getting treatment**	**1**	**True**
		2	**False**
		3	**Don't know**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

2.	**People have tried to force me to get treatment**	**1**	**True**
		2	**False**
		3	**Don't know**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

3.	**I have had enough of a chance to say whether I wanted treatment**	**1**	**True**
		2	**False**
		3	**Don't know**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

4.	**I have chosen to get treatment**	**1**	**True**
		2	**False**
		3	**Don't know**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

5.	**I got to say what I wanted about getting treatment**	**1**	**True**
		2	**False**
		3	**Don't know**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

6.	**Someone threatened me to**	**1**	**True**
		2	**False**

	get me to come into treatment	**3**	**Don't know**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

7.	**It has been my idea to get treatment**	**1**	**True**
		2	**False**
		3	**Don't know**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*
8.	**Someone physically tried to make me come into treatment**	**1**	**True**
		2	**False**
		3	**Don't know**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

9.	**No one seemed to want to know whether I wanted to get treatment**	**1**	**True**
		2	**False**
		3	**Don't know**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

10.	**I was threatened with being sectioned**	**1**	**True**
		2	**False**
		3	**Don't know**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

11.	**They said they would make me get treatment**	**1**	**True**
		2	**False**
		3	**Don't know**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

12.	**No one tried to force me to get treatment**	**1**	**True**
		2	**False**
		3	**Don't know**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

13.	**My opinion about**	**1**	**True**

	getting treatment didn't matter	**2**	**False**
		3	**Don’t know**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

14.	**I have had a lot of control over whether I get treatment**	**1**	**True**
		2	**False**
		3	**Don't know**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

15.	**I have had more influence than anyone else on whether I get treatment**	**1**	**True**
		2	**False**
		3	**Don't know**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

Client Satisfaction Questionnaire

Please answer the following questions about your level of satisfaction with your CMHT. We are interested in your honest opinion, whether they are positive or negative. Please answer all of the questions.

1.	**How would you rate the quality of service you received?** **4 Excellent 3 Good 2 Fair 1 Poor**	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*

2.	**Did you get the kind of service you wanted?** **4 No, definitely not 3 No, not really 2 Yes, generally 1 Yes, definitely**	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*

3.	**To what extent has this CMHT met your needs?** **4 Almost all of my needs have been met 3 Most of my needs have been met 2 Only a few of my needs have been met 1 None of my needs have been met**	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*

4.	**If a friend were in need of similar help, would you recommend this CMHT to him or her?** **4 No, definitely not 3 No, not really 2 Yes, generally 1 Yes, definitely**	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*

5.	**How satisfied are you with the amount of help you have received?** **4 Quite dissatisfied 3 Indifferent or mildly 2 Mostly satisfied 1 Very satisfied**

	Dissatisfied	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*

6.	**Have the services you received helped you to deal more effectively with your problems?** **4 3 2 1** **Yes they have helped they seemed to make A great deal Yes they helped somewhat No they really didn't help No things worse**	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*

7.	**In an overall, general sense, how satisfied are you with the service you have received?** **4 3 2 1** **Very satisfied Mostly satisfied Indifferent or mildly dissatisfied Quite Dissatisfied**	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*

8.	**If you were to seek help again, would you come back to this CMHT?** **4 3 2 1** **No, definitely No, I don't think so Yes, I think so Yes, definitely**	
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*

AUDIT (Alcohol Use Disorders Identification Test)

PATIENT: Because alcohol use can affect your health and can interfere with certain medications and treatments, it is important that we ask some questions about your use of alcohol. Your answers will remain confidential so please be honest.

Place an X in one box that best describes your answer to each question.

01.	**How often do you have a drink containing alcohol**?	**0**	**Never**
		1	**Monthly or less**
		2	**2-4 times a month**
		3	**2-3 times a week**
		4	**4 or more times a week**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

02.	**How many drinks containing alcohol do you have on a typical day when you are drinking?**	**0**	**1 or 2**
		1	**3 or 4**
		2	**5 or 6**
		3	**7 to 9**
		4	**10 or more**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

03.	**How often do you have six or more drinks on one occasion?**	**0**	**Never**
		1	**Less than monthly**
		2	**Monthly**
		3	**Weekly**
		4	**Daily or almost daily**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

04.	**How often during the last year have you found that you were not able to stop drinking once you had started?**	**0**	**Never**
		1	**Less than monthly**
		2	**Monthly**
		3	**Weekly**
		4	**Daily or almost daily**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

05.	**How often during the last year have you failed to do what was normally expected of you because of drinking?**	**0**	**Never**
		1	**Less than monthly**
		2	**Monthly**
		3	**Weekly**
		4	**Daily or almost daily**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

06.	**How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?**	**0**	**Never**
		1	**Less than monthly**
		2	**Monthly**
		3	**Weekly**
		4	**Daily or almost daily**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

07.	**How often during the last year have you had a feeling of guilt or remorse after drinking?**	**0**	**Never**
		1	**Less than monthly**
		2	**Monthly**
		3	**Weekly**
		4	**Daily or almost daily**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

08.	**How often during the last year have you been unable to remember what happened the night before because of your drinking?**	**0**	**Never**
		1	**Less than monthly**
		2	**Monthly**
		3	**Weekly**
		4	**Daily or almost daily**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

09.	**Have you or someone else been injured because of your drinking?**	**0**	**No**
		2	**Yes, but not in the last year**
		4	**Yes, during the last year**
		777	*Not available or not applicable*

		888	*Not done*
		999	*Unknown*

10.	**Has a relative, friend, doctor, or other health care worker been concerned about your drinking or suggested you cut down?**	**0**	**No**
		2	**Yes, but not in the last year**
		4	**Yes, during the last year**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

11.	**Total**		
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

Drug Misuse:

We are asking everybody some questions about specific drugs they may have used within the past year. As with the rest of this interview, your answers are treated with strict confidence. In the past twelve months, have you used:

1. Drug	2. Used in last year? Coded as: Yes = 1 No = 0	3. If yes, no. of times used in last month? (e.g. daily, 20x, 10x, etc.) Coded as: 1. Once daily 2. Twice daily 3. Three times daily 4. four times daily 5. As required 6. Other, please specify	4. Other, please specify	5. Usual route (po; iv; s/c) Coded as: 1. PO 2. IV 3. S/C 4. Inhaled 5.Intermuscular 6. Sublingual 7.Other	6. Other, please specify
Cannabis	☐ *Insert Number*	☐ *Insert Number*		☐ *Insert Number*	
Amphetamine	☐ *Insert Number*	☐ *Insert Number*		☐ *Insert Number*	
Cocaine	☐ *Insert Number*	☐ *Insert Number*		☐ *Insert Number*	
Ecstasy	☐ *Insert Number*	☐ *Insert Number*		☐ *Insert Number*	
Solvents/glue	☐ *Insert Number*	☐ *Insert Number*		☐ *Insert Number*	
Benzodiazepines	☐ *Insert Number*	☐ *Insert Number*		☐ *Insert Number*	

LSD	☐ *Insert Number*	☐ *Insert Number*		☐ *Insert Number*	
Methadone	☐ *Insert Number*	☐ *Insert Number*		☐ *Insert Number*	
Codeine / DF118	☐ *Insert Number*	☐ *Insert Number*		☐ *Insert Number*	
Crack	☐ *Insert Number*	☐ *Insert Number*		☐ *Insert Number*	
Heroin	☐ *Insert Number*	☐ *Insert Number*		☐ *Insert Number*	
Other	☐ *Insert Number*	☐ *Insert Number*		☐ *Insert Number*	
7. Comments					

The well-being scale

Please circle the number that best describes your experience of each over the last 2 weeks.

STATEMENTS	None of the time	Rarely	Some of the time	Often	All of the time
I've been feeling optimistic about the future	1	2	3	4	5
I've been feeling useful	1	2	3	4	5
I've been feeling relaxed	1	2	3	4	5
I've been feeling interested in other people	1	2	3	4	5
I've had energy to spare	1	2	3	4	5
I've been dealing with problems well	1	2	3	4	5
I've been thinking clearly	1	2	3	4	5
I've been feeling good about myself	1	2	3	4	5
I've been feeling close to other people	1	2	3	4	5
I've been feeling confident	1	2	3	4	5
I've been able to make up my own mind about things	1	2	3	4	5
I've been feeling loved	1	2	3	4	5
I've been interested in new things	1	2	3	4	5
I've been feeling cheerful	1	2	3	4	5

Hospital Anxiety and Depression Scale

INSTRUCTIONS: Doctors are aware that emotions play an important part in most illnesses. If your doctor knows about these feelings he or she will be able to help you more. This questionnaire is designed to help your doctor know how you feel. Read each item and indicate the reply which comes closest to how you have been feeling in the PAST WEEK. Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought out response.

1.	**I feel tense or 'wound up'**	**3**	**Most of the time**
		2	**A lot of the time**
		1	**Time to time, occasionally**
		0	**Not at all**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

2.	**I feel as if I am slowed down**	**3**	**Nearly all of the time**
		2	**Very often**
		1	**Sometimes**
		0	**Not at all**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

3.	**I still enjoy the things I used to enjoy**	**0**	**Definitely as much**
		1	**Not quite so much**
		2	**Only a little**
		3	**Not at all**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

4.	**I get sort of a frightened feeling like 'butterflies in the stomach'**	**0**	**Hardly at all**
		1	**Occasionally**
		2	**Quite often**
		3	**Very often**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

5.	**I get a sort of frightened feeling**	**3**	**Very definitely and quite badly**
		2	**Yes, but not too badly**

	as if something awful is about to happen	**1**	**A little, but it doesn't worry me**
		0	**Not at all**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

6.	**I have lost interest in my appearance**	**3**	**Definitely**
		2	**I don't take as much care as I should**
		1	**I may not take quite as much care**
		0	**I take just as much care as ever**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

7.	**I can laugh and see the funny side of things**	**0**	**As much as I always could**
		1	**Not quite so much now**
		2	**Definitely not so much now**
		3	**Not at all**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

8.	**I feel restless as if I have to be on the move**	**3**	**Very much indeed**
		2	**Quite a lot**
		1	**Not very much**
		0	**Not at all**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

9.	**Worrying thoughts go through my mind**	**3**	**A great deal of the time**
		2	**A lot of the time**
		1	**Not too often**
		0	**Very little**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

10.	**I look forward with enjoyment to**	**0**	**As much as I ever did**
		1	**Rather less than I used to**

	things	**2**	**Definitely less than I used to**
		3	**Hardly at all**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

11.	**I feel cheerful**	**3**	**Never**
		2	**Not often**
		1	**Sometimes**
		0	**Most of the time**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

12.	**I get sudden feelings of panic**	**3**	**Very often indeed**
		2	**Quite often**
		1	**Not very often**
		0	**Not at all**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

13.	**I can sit at ease and feel relaxed**	**0**	**Definitely**
		1	**Usually**
		2	**Not often**
		3	**Not at all**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

14.	**I can enjoy a good book or radio or television programme**	**0**	**Often**
		1	**Sometimes**
		2	**Not often**
		3	**Very seldom**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

15.	**Depression score total**	☐☐☐

16.	**Anxiety score total**	☐☐☐

EuroQoL (EQ-5D)

For <u>each</u> group below, please indicate which statements best describe your own health state TODAY.

1.	**Mobility**	**1**	**I have no problems in walking about**
		2	**I have some problems in walking about**
		3	**I am confined to bed**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

2.	**Self Care**	**1**	**I have no problems with self-care**
		2	**I have some problems washing or dressing myself**
		3	**I am unable to wash or dress myself**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

3.	**Usual Activities** **(e.g. work, study, housework, family or leisure activities)**	**1**	**I have no problems with performing my usual activities**
		2	**I have some problems with performing my usual activities**
		3	**I am unable to perform my usual activities**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

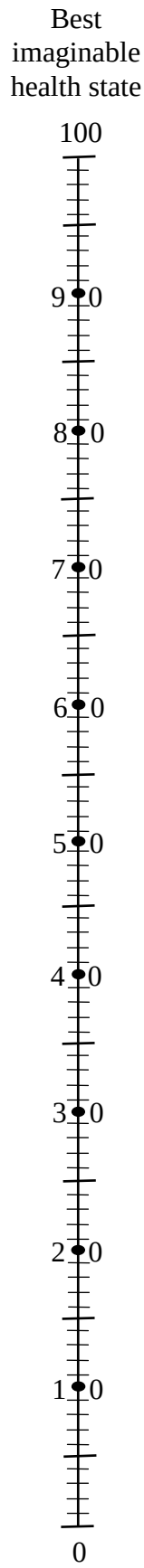
4.	**Pain/Discomfort**	**1**	**I have no pain or discomfort**
		2	**I have moderate pain or discomfort**
		3	**I have extreme pain or discomfort**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

5.	**Anxiety/Depression**	**1**	**I am not anxious or depressed**
		2	**I am moderately anxious or depressed**
		3	**I am extremely anxious or depressed**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

6.	**Your own he state today:**	**Your own health state today**	
			available or not icable
		888	*Not done*
		999	*Unknown*



Self-harm questionnaire

There may be times in a person's life when they become very low and depressed and may feel like taking drastic action because of these feelings.

1.	Have you ever deliberately taken an overdose (eg of pills or other medication) or tried to harm ? *Please tick the box which applies to you*	**0**	**No**
		1	**Yes, once**
		2	**Yes, more than once**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

2.	In the past year, have you deliberately taken an overdose (eg. of pills or other medication) or tried to harm yourself in some other way (such as cut yourself)? *Please tick the box which applies to you*	**0**	**No**	
		1	**Yes, once**	
		2	**Yes, more than once**	**Go to Question 2a**
		777	*Not available or not applicable*	
		888	*Not done*	
		999	*Unknown*	

2a.	If so, how many times?		
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

The following questions are about the LAST TIME you took an overdose or tried to harm yourself.

3.	When was the **LAST TIME** you took an overdose or tried to harm yourself?	**0**	**less than a month ago**
		1	**between a month and a year ago**
		2	**more than a year ago**
		777	*Not available or not applicable*
		888	*Not done*

		999	*Unknown*

3a.	Describe what you did to yourself **on that occasion:** Please give as much detail as you can (for example, the name of the drug taken in an overdose)	

4.	How long before you took the overdose or tried to harm yourself **on that occasion** had you started to think about doing it?	**0**	**less than an hour**
		1	**more than an hour but less than a day**
		2	**more than a day but less than a week**
		3	**more than a week but less than a month**
		4	**a month or more**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

5. Did you talk or try to get any help beforehand from any of the following people or sources?	Yes	No
Someone in your family		
Friend		
Teacher		
GP (family doctor)		
Social worker		
Psychologist or psychiatrist		
Telephone help line		
Drop-in/advice centre		
Other source (eg internet, book, magazine, other person etc)		

If yes, please specify:	

6.	Did you try to get any help afterwards for the problems that led you to take an overdose or try to harm yourself **on that occasion**?	**0**	**No**	**Go to Question 6a**
		1	**Yes**	
		777	*Not available or not applicable*	
		888	*Not done*	
		999	*Unknown*	

6a.	If 'no', please say why you didn't try to get any help.	

7.	Did you go to hospital because of **this** overdose or attempt to harm yourself?	**0**	**No**
		1	**Yes**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

8. On that occasion, did you receive help from any of the following people or sources?	**Yes**	**No**
Someone in your family		
Friend		
Teacher		
GP (family doctor)		
Social worker		
Psychologist or psychiatrist		
Telephone help line		
Drop-in/advice centre		
Other source (eg internet, book, magazine, other person etc)		
If yes, please specify:		

9.	Have you **EVER** gone to hospital because you took an overdose or harmed yourself?	**0**	**No**
		1	**Yes**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

10.	Have you EVER seriously wanted to kill yourself when you have taken an overdose or tried to harm yourself in some other way?	**0**	**No**
		1	**Yes**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

11.	Have you **EVER** told someone you were going to harm or kill yourself?	**0**	**no**
		1	**once**
		2	**a few times**
		3	**often**

		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

Harm to others

12.	Have you ever intentionally tried to harm or injure another person?	**0**	**No**	
		1	**Yes**	**Go to question 13**
		777	*Not available or not applicable*	
		888	*Not done*	
		999	*Unknown*	

13.	If yes, how often?	**0**	**Once**
		1	**Twice**
		2	**More than twice**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

14.	What methods have you used to harm/injure others?	**0**	**Hitting**	
		1	**Stabbing**	
		2	**Shooting**	
		3	**Strangling**	
		4	**Poisoning**	
		5	**Other - Specify**	**Go to question 14a**
		777	*Not available or not applicable*	
		888	*Not done*	
		999	*Unknown*	

14a	Other, please specify	

15.	Was the harm to others 'major'?**	**0**	**No**
		1	**Yes**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

** **Major**: homicide, sex attacks, attempted or actual serious assault
Non-major incidents requiring attendance of police or on-ward seclusion or special civil-law admissions to a place of safety

16.	In the past year, have you ever intentionally tried to harm or injure another person?	**0**	**No**	
		1	**Yes**	**Go to question 17**
		777	*Not available or not applicable*	
		888	*Not done*	
		999	*Unknown*	

17.	If yes, how often?	**0**	**Once**
		1	**Twice**
		2	**More than twice**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

18.	What methods have you used to harm/injure others?	**0**	**Hitting**	
		1	**Stabbing**	
		2	**Shooting**	
		3	**Strangling**	
		4	**Poisoning**	
		5	**Other - Specify**	**Go to question 18a**
		777	*Not available or not applicable*	
		888	*Not done*	
		999	*Unknown*	

18a	Other, please specify	

19.	Was the harm to others 'major'?**	**0**	**No**
		1	**Yes**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

** **Major**: homicide, sex attacks, attempted or actual serious assault
Non-major incidents requiring attendance of police or on-ward seclusion or special civil-law admissions to a place of safety

Self-harm diary

April 2011

M	T	W	T	F	S	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	

May 2011

M	T	W	T	F	S	S
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

June 2011

M	T	W	T	F	S	S
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30			

July 2011

M	T	W	T	F	S	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

August 2011

M	T	W	T	F	S	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

September 2011

M	T	W	T	F	S	S
			1	2	3	4
5	6	7	8	9	10	11

12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

The Structured Clinical Interview for DSM-IV (SCID-II)

personality disorders: BPD subsection

Borderline Personality Disorder: A pervasive pattern of instability of interpersonal relationships, self-image, and affects and marked impulsivity beginning by early adulthood and present in a variety of contexts, as indicated by **five (or more)** of the following:

1.	**Have you often become frantic when you thought that someone you really cared about was going to leave you?**	**1**	**absent or false**
		2	**sub threshold**
		3	**threshold or true**
		0	**inadequate information**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

2.	**Do your relationships with people you really care about have lots of extreme ups and downs?**	**1**	**absent or false**
		2	**sub threshold**
		3	**threshold or true**
		?	**inadequate information**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

3.	**Does your sense of who you are and where you're headed often change dramatically?**	**1**	**absent or false**
		2	**sub threshold**
		3	**threshold or true**
		0	**inadequate information**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

4.	**Have you often done things impulsively?**	**1**	**absent or false**
		2	**sub threshold**
		3	**threshold or true**
		0	**inadequate information**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

5.	**Have you tried to hurt or kill yourself or ever threatened**	**1**	**absent or false**
		2	**sub threshold**
		3	**threshold or true**

	to do so?	**0**	**inadequate information**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

6.	**Do you have a lot of sudden mood changes?**	**1**	**absent or false**
		2	**sub threshold**
		3	**threshold or true**
		0	**inadequate information**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

7.	**Do you often feel empty inside?**	**1**	**absent or false**
		2	**sub threshold**
		3	**threshold or true**
		0	**inadequate information**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

8.	**Do you often have temper outbursts or get so angry that you lose control?**	**1**	**absent or false**
		2	**sub threshold**
		3	**threshold or true**
		0	**inadequate information**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

9.	**When you are under a lot of stress, do you get suspicious of other people or feel especially spaced out?**	**1**	**absent or false**
		2	**sub threshold**
		3	**threshold or true**
		0	**inadequate information**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

Standardised Assessment of Personality – Abbreviated Scale (SAPAS)

I'd like to ask you some questions about yourself. Your answers will help me better understand what you are usually like. If the way you have been in recent weeks or months is different from the way you usually are, please look back to when you were your usual self.

1.	***In general*, do you have difficulty making and keeping friends?**	**0**	**0. No**
		1	**1. Yes**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

2.	**Would you *normally* describe yourself as a loner?**	**0**	**0. No**
		1	**1. Yes**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

3.	***In general*, do you trust other people?**	**1**	**1. No**
		0	**0. Yes**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

4.	**Do you *normally* lose your temper easily?**	**0**	**0. No**
		1	**1. Yes**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

5.	**Are you *normally* an impulsive sort of person?**	**0**	**0. No**
		1	**1. Yes**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

6.	**Are you *normally* a worrier?**	**0**	**0. No**
		1	**1. Yes**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

7.	***In general*, do you depend on others a**	**0**	**0. No**
		1	**1. Yes**

	lot?	*777*	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

8.	***In general*, are you a perfectionist?**	**0**	**0. No**
		1	**1. Yes**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

Service Engagement Scale (SES)

Please complete the following questions about <u>this client</u>.

1.	**The client seems to make it difficult to arrange appointments**	**0**	**Not at all or rarely**
		1	**Sometimes**
		2	**Often**
		3	**Most of the time**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

2.	**When a visit is arranged, the client is available**	**0**	**Not at all or rarely**
		1	**Sometimes**
		2	**Often**
		3	**Most of the time**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

3.	**The client seems to avoid making appointments**	**0**	**Not at all or rarely**
		1	**Sometimes**
		2	**Often**
		3	**Most of the time**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

4.	**If you offer advice, does the client usually resist it?**	**0**	**Not at all or rarely**
		1	**Sometimes**
		2	**Often**
		3	**Most of the time**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

5.	**The client takes an active part in the setting of goals or treatment plans**	**0**	**Not at all or rarely**
		1	**Sometimes**
		2	**Often**
		3	**Most of the time**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

6.	**The client actively participates in managing his/her illness**	**0**	**Not at all or rarely**
		1	**Sometimes**
		2	**Often**
		3	**Most of the time**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*
7.	**The client seeks help when assistance is needed**	**0**	**Not at all or rarely**
		1	**Sometimes**
		2	**Often**
		3	**Most of the time**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*
8.	**The client finds it difficult to ask for help**	**0**	**Not at all or rarely**
		1	**Sometimes**
		2	**Often**
		3	**Most of the time**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

9.	**The client seeks help to prevent a crisis**	**0**	**Not at all or rarely**
		1	**Sometimes**
		2	**Often**
		3	**Most of the time**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

10.	**The client does not actively seek help**	**0**	**Not at all or rarely**
		1	**Sometimes**
		2	**Often**
		3	**Most of the time**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

11.	**The client agrees to take prescribed medication**	**0**	**Not at all or rarely**
		1	**Sometimes**
		2	**Often**
		3	**Most of the time**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

12.	**The client is clear about what medications he/she is taking and why**	**0**	**Not at all or rarely**
		1	**Sometimes**
		2	**Often**
		3	**Most of the time**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

13.	**The client refuses to co-operate with treatment**	**0**	**Not at all or rarely**
		1	**Sometimes**
		2	**Often**
		3	**Most of the time**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

14.	**The client has difficulty in adhering to the prescribed medication**	**0**	**Not at all or rarely**
		1	**Sometimes**
		2	**Often**
		3	**Most of the time**
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*