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Dallimore, Sian

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Abstracts

Main Research Project

An investigation of perceptions of OCD, caregiver burden, distress and accommodation

Caring for someone with Obsessive Compulsive Disorder has a demonstrated impact on psychological distress and quality of life. Relatives often struggle to know how best to help and it has been suggested that most engage in some form of accommodation of symptoms. Given the impact of OCD on carers, and the potentially detrimental effects of symptom accommodation and interpersonal difficulties on treatment outcome, it seems appropriate to include family members in treatments, but it is not yet fully understood which factors contribute to these interpersonal difficulties. The self-regulation model suggests that carers’ perceptions of an individual’s difficulties will have implications for both emotional and behavioural responses. For this purpose, individuals with OCD and their caregivers completed questionnaires to assess their appraisals of OCD, psychological distress, perceived criticism, caregiver burden and family accommodation. Caregiver perceptions of severe consequences of OCD were associated with increased perceived burden, whereas perceptions of chronicity and consequences were both independently associated with higher levels of caregiver psychological distress. Caregiver appraisals of OCD were not associated with levels of accommodation, but the appraisals of personal control held by the individual with OCD were, with lower perceived control associated with more accommodation. These findings suggest that aspects of the self-regulation model can be used to understand that appraisals of the chronicity, consequences and control one has over OCD can influence the distress of caregivers and also the extent to which they engage in potentially unhelpful accommodating behaviours. It is hoped that this model can help therapists to fine-tune the already efficacious treatments available.

Service Improvement Project

Improving Multidisciplinary Clinical Discussion on an Inpatient Mental Health Ward

Purpose – Multidisciplinary team (MDT) clinical supervision is being used in many mental health services but at present has not received adequate attention by researchers in order to generate evidence based approaches. This paper aims to explore the utility and staff perspectives of an MDT model of clinical supervision in the form of a “Clinical Discussion Group” (CDG) on an acute inpatient mental health ward within the context of
the current literature on the components of effective supervision in order to make recommendations for practice.

**Design/Methodology/Approach** – Twelve members of staff working on the ward were interviewed to gather their perspective on attendance, helpful aspects, outcomes, unhelpful aspects, and changes. Interview transcripts were analysed using thematic analysis.

**Findings** - eleven themes were identified, three within “The Group and how it operates” (Attendance, Discussion Topics and Facilitation), five within “Impact and Usefulness” (Valued by Staff, Understanding a Case, Emotional Benefit, Learning and Working together as a Team) and three within “Changes to the Group” (Organisation, Discussion Topic and Group Outcomes).

**Originality/Value** – This paper explores the benefits and challenges of a CDG from the perspective of the staff who attend. It presents some recommendations for good practice which should be of use to managers and supervisors who wish to use team supervision to improve patient outcomes and also makes suggestions for future research in this field.

**Critical Review of the Literature**

*Involving the wider system in skills-based treatments for Borderline Personality Disorder: A systematic review*

The transactional model of Borderline Personality Disorder (BPD) describes how both individual factors and systemic factors influence each other reciprocally to contribute towards the development and maintenance BPD. As such, treatments involving family members or carers have the potential to result in better outcomes. This paper reviews evidence for the effectiveness of involving family systems in skills based treatment approaches for BPD. A systematic search yielded 17 studies of 3 different skills based interventions that included members of the patients’ system: Dialectical Behaviour Therapy- Adolescents (DBT-A); Systems Training for Emotional Predictability and Problem Solving (STEPPS); and Family Connections. Each of the 3 types of intervention were effective in significantly reducing symptoms of BPD. However the heterogeneity of the research available limits the conclusions that can be drawn regarding the additive benefit of involving the wider system. More rigourous research designs focusing on the comparison of skills based interventions with and without systemic components will enable the identification of the mechanisms through which systemic involvement can improve outcomes for people with BPD.
Involving the wider system in skills-based treatments for Borderline Personality Disorder: A systematic review

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*Dr Emma Griffith*

Critical Review of the Literature, May 2015

Word Count 8017

Journal to be targeted

This paper is to be targeted towards Clinical Psychology Review. This journal publishes substantive reviews of topics relevant to the field of clinical psychology and covers a diverse range of issues including psychopathology, psychotherapy, cognitive therapies and behavioural therapy. As a paper which advances the scientific field regarding evidence based therapies for individuals with Borderline Personality Disorder, the scope of this journal is very relevant and will allow for the wide dissemination of this paper.
Abstract
The transactional model of Borderline Personality Disorder (BPD) describes how both individual factors and systemic factors influence each other reciprocally to contribute towards the development and maintenance BPD. As such, treatments involving family members or carers have the potential to result in better outcomes. This paper reviews evidence for the effectiveness of involving family systems in skills based treatment approaches for BPD. A systematic search yielded 17 studies of 3 different skills based interventions that included members of the patients’ system: Dialectical Behaviour Therapy- Adolescents (DBT-A); Systems Training for Emotional Predictability and Problem Solving (STEPPS); and Family Connections. Each of the 3 types of intervention were effective in significantly reducing symptoms of BPD. However the heterogeneity of the research available limits the conclusions that can be drawn regarding the additive benefit of involving the wider system. More rigourous research designs focusing on the comparison of skills based interventions with and without systemic components will enable the identification of the mechanisms through which systemic involvement can improve outcomes for people with BPD.

Introduction
Borderline Personality Disorder (BPD) is characterised by impairment in self functioning, interpersonal dysfunction, negative affectivity, disinhibition and hostility (American Psychiatric Association, 2013). Onset of these difficulties is usually in adolescence or early adulthood with symptoms the most severe in the late teens and early twenties (Widiger & Frances, 1989). Individuals meeting the criteria for this diagnosis often engage in self-injurious behaviours and suicide attempts, with Zanarini et al. (2007) showing that, worryingly, 4% of people followed up over ten years took their own life.

Several evidence based treatments for BPD have emerged including Dialectical Behaviour Therapy (DBT; Linehan, 1993); Mentalization-Based Therapy (MBT; Bateman & Fonagy, 2004); Transference Focused Psychotherapy (TFP; Clarkin, Yeomans, & Kernberg, 1999), Schema Focused Therapy (SFT; Young, 1999) and Systems Training for Emotional Predictability and Problem Solving (STEPPS; Blum, Bartels, St John, & Pfahl, 2012). Many of these specific treatment approaches for BPD share common features in that they are manualised, have a clear therapeutic focus, actively promote compliance with the treatment, focus on the therapeutic relationship and assign the therapist an active role in the
treatment (Alesiani, Boccalon, Giarolli, Blum, & Fossati, 2014). However, there are two distinct mechanisms within these different therapies with some (such as MBT, TFP and SFT) emphasising and using the therapeutic relationship as a model for the patients’ personal relationships, and others (such as DBT and STEPPS) aiming to help patients acquire new self-management skills and new experiences (Stoffers et al., 2012). A recent review of randomised controlled trials concluded that these disorder specific treatments are more effective than non-specific treatment models such as Cognitive Behaviour Therapy (CBT), client-centred therapy (CCT) and interpersonal therapy (IPT) in reducing BPD pathology (Stoffers et al., 2012).

**Family involvement in BPD**

There are clear recommendations to involve family members or carers in treatment for individuals with BPD (NICE, 2009). A key reason for this is the core problem of interpersonal difficulties. The transactional model for BPD (Linehan, 1993) describes how both individual factors and systemic factors influence each other reciprocally to contribute towards the development and maintenance BPD. The model suggests that an individual with BPD has vulnerabilities to negative emotions and emotion regulation difficulties as a result of biological factors, temperament and early experiences. These difficulties interact within an invalidating family environment consisting of negative judgement, communication of elevated negative emotion and reinforcement of dysfunctional behaviours resulting in symptoms of BPD.

![Biological Emotion Regulation Dysfunction](Transactional Model of BPD (Linehan, 1993))

**Figure 1.1** Transactional Model of BPD (Linehan, 1993)

This model emphasises that the quality of relationships can have an important role to play in outcomes for individuals with BPD (Gunderson et al., 2006; Hooley & Hoffman, 1999). This importance is recognised by treatment guidelines which emphasise establishing a
caring environment in which clinicians build a trusting, open and non-judgemental relationship with the individual within a consistent multi-disciplinary team approach (NICE, 2009). These therapeutic principles are also important within the family environment. In particular, the ongoing intensive support of families can enable people with BPD to make a better recovery as families scoring highly on measures of emotional over-involvement have been shown to be associated with more positive outcomes for the individual with BPD (Hooley & Hoffman, 1999; Zanarini, 2002).

Although involving family members in the care and treatment for individuals with BPD is endorsed by theory and research, caring for a relative with BPD is a difficult and stressful task. Family members often report experiencing distress and burden with feelings of loss, grief and depression (Berkowitz & Gunderson, 2002; Hoffman & Hooley, 1998). As a result, family psychopathology is higher than found in controls, with an increased risk of affective disorders (Goldman, D'Angelo, & DeMaso, 1993; Gould, Greenberg, Velting, & Shaffer, 2003; Silverman et al., 1991) and personality disorders (Riso, Klein, Anderson, & Ouimette, 2000). This is likely to limit the capacity of family members to provide the support needed by individuals with BPD to achieve a positive outcome.

Evidently, treatments involving family members could benefit not just the individual with BPD by addressing the context within which the disorder exists, but also the family member by providing support and reducing burden (Hoffman, Fruzzetti, & Swenson, 1999). Potential targets for treatment have included increasing validation and emotion management within the family (Hoffman & Hooley, 1998; Hooley & Gotlib, 2000), altering attributions of patient illness and control (Hooley & Gotlib, 2000) and providing reinforcement of helpful behaviours by developing consistent responses from the family and professional systems (Blum, Pfohl, St John, Monahan, & Black, 2002). Adaptations to existing evidence based self-management skills treatments have attempted to integrate a systemic component and new interventions have been developed with the transactional model of BPD in mind, but it is unclear what the clinical benefits are of combining skills based and systemic approaches.

**Objectives and Importance of the Current Review**
This review aims to identify, synthesise and critically evaluate research on the involvement of family systems in skills based treatment approaches for BPD. Interventions with components targeting the development of self-regulation skills within the system and
reinforcement of adaptive coping for the individual with BPD psychopathology are emerging for both adults and adolescents, suggesting that such a review is timely. Whilst there has been a recent Cochrane review of psychological therapies for people with BPD (Stoffers et al., 2012), this focused on randomised controlled trials and did not specifically evaluate the implications of the transactional model of BPD and the efficacy of interventions targeting both individual and systemic outcomes. The current review aims to ascertain:

- the effectiveness of skills based interventions with systemic components, focussing on BPD symptoms
- the efficacy of these interventions for alleviating distress for families and other members of the system
- whether involving the system in skills based interventions improves outcomes for people with BPD.

**Method**

The review used the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA; Moher, Liberati, Tetzlaff, & Altman, 2009). See Appendix A.2 for review protocol.

**Inclusion Criteria**

A number of criteria were used to determine the selection of original research studies for inclusion in the review:

1. Participants were patients or family members of patients diagnosed with, or meeting a large portion of the diagnostic criteria for, Borderline Personality Disorder. Meeting the full diagnostic criteria was not a requirement given the inclusion of participants of all ages. Historically there has been a reluctance to give adolescents a diagnosis of personality disorder due to concerns that the instability of adolescent behaviour may affect validity of the diagnosis (Shapiro, 1990). Recent evidence however has demonstrated the reliability and validity of BPD in this age group (Bondurant, Greenfield, & Tse, 2004; Chanen, Jovev, & Jackson, 2007; Miller, Muehlenkamp, & Jacobson, 2008) and therefore it is important to include this cohort in the review.

2. The treatment modality was either individual or group psychotherapy focusing on acquiring skills for self-management.
3. The treatment included a systemic component which aimed to influence BPD psychopathology.

Conference abstracts themselves were excluded, although they were used to identify further relevant papers. Dissertations were considered for inclusion. Papers not written in the English language were excluded due to the unavailability of resources for translation.

Given that this is a relatively new area of research, all study designs were included in the review in order to evaluate the strengths and weaknesses of the existing evidence and examine the case for undertaking further research. Consideration was given to the possibility that non-randomised trials may be affected more by publication biases given the lower requirement to register pre-specified protocols (Reeves, Deeks, Higgins, & Wells, 2011) and as such, evidence generated from studies of different designs were considered separately rather than attempting to synthesise potentially heterogeneous outcomes.

**Literature Search**

The following databases were used to perform searches of titles and abstracts: PsycINFO, PsychEXTRA, EMBASE, PubMed and Cochrane Library. The final search was conducted on 5\(^{th}\) January 2015. The search words used were terms to describe BPD including behaviours associated with the diagnosis: “Borderline Personality Disorder”, “Emotionally Unstable Personality Disorder” “BPD”, “Emerging Personality Disorder”, “Self Injurious Behaviour” or Suicide”, in combination with terms related to the system: “family” or “systemic”, and also combined with terms used to define skills based psychological therapy: “skills therapy”, “skills treatment”, skills intervention”, “skills training”, “skills program”, “Dialectical Behaviour Therapy”, “diallectic”, “DBT”, “STEPPS”, “Family Connection”. Search terms and syntax were modified as needed for each database (Appendix A.3).

The references of included studies, relevant review papers and grey literature such as conference abstracts and editorials were screened to identify further relevant studies. In addition, authors were contacted via email where appropriate to request any further published or unpublished studies.
Selection of Studies
The titles and abstracts of all studies identified in the literature search were independently screened by two reviewers the author (SD) and a masters graduate (NM) and the full texts of any potentially relevant studies were obtained. Additional studies were identified through manual searching of reference lists of relevant reviews, related papers and contacting researchers. The full texts were then assessed by both reviewers (SD and NM) to determine eligibility for the review. Any discrepancies were resolved by discussion between reviewers. Supervision with an experienced Clinical Psychologist (EG) could have been called upon, but this was not necessary. Data on study characteristics and outcomes was extracted by the author (SD).

Assessment of Risk of Bias of included studies
Study level risk of bias was assessed using the Cochrane Collaboration’s tool for assessing risk of bias (Higgins, Altman, & Sterne, 2011). This tool directly assesses the extent to which outcomes of studies could be influenced by bias as a result of the methodology used and is recommended by Cochrane in preference to assessing “quality” as it recognises that quality does not preclude the presence of biases and overcomes ambiguities between the quality of reporting and quality of research (Higgins et al., 2011). As the risk of bias tool focused on randomised controlled trials, aspects were adapted where appropriate to consider the inclusion of non-randomised studies and uncontrolled (Appendix A.4). Assessments included ratings of the likelihood for selection bias (random sequence generation, concealment of allocation), detection bias (blinding of outcome assessment), attrition bias, reporting bias and performance bias (integrity of the intervention based upon adherence to treatment protocol, attention bias, programme differentiation, quality of delivery and participant responsiveness).

The risk of bias protocol was applied independently by two researchers (SD and NM). Inter-rater agreement was good (kappa= 0.557) and discrepancies were discussed in order to reach a consensus.

Results
Study Selection
Figure 1.2 provides a flow chart for the selection of eligible studies. The systematic literature search using the specified criteria generated 756 studies, of which 163 were
identified as duplicates. After screening of titles and abstracts, 72 studies were considered eligible for further inspection. Manual searching of reference lists of relevant reviews, related papers and contacting researchers identified a further 16 studies. Assessment of full texts resulted in the exclusion of 71 studies: 51 were not original research (e.g. conference abstracts, reviews, opinion articles); 6 did not include participants with BPD; 8 did not have interventions with a systemic component; 3 were not skills-based interventions; 2 were not written in the English language and 1 was excluded on the ground that it did not contain outcome data for the intervention.

**Figure 1.2 Flow Chart for the selection of eligible studies**
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<tr>
<th>Study; Location</th>
<th>Participant Characteristics</th>
<th>Intervention</th>
<th>Study Design</th>
<th>Outcome Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Age M (SD)</td>
<td>Diagnostic Criteria</td>
<td>Type</td>
</tr>
<tr>
<td>Alesiani et al. (2014); Milan, Italy</td>
<td>32</td>
<td>44.41 (9.29)</td>
<td>DSM-IV-TR BPD diagnosis <em>OR</em> Severe PD with prominent borderline traits &amp; history of suicide attempts or self-harm, and emotional and behavioural dysregulation <em>AND</em> Comorbid mood disorder</td>
<td>STEPPS</td>
</tr>
<tr>
<td>Black et al. (2008); USA</td>
<td>12</td>
<td>34.8</td>
<td>DSM-IV criteria for BPD</td>
<td>STEPPS</td>
</tr>
<tr>
<td>Black, Blum, McCormick, and Allen (2013); USA</td>
<td>77</td>
<td>31.4 (8.6)</td>
<td>DSM-IV criteria for BPD</td>
<td>STEPPS</td>
</tr>
<tr>
<td>Blum et al. (2002); USA</td>
<td>52</td>
<td>33 (9)</td>
<td>DSM-IV criteria for BPD</td>
<td>STEPPS</td>
</tr>
<tr>
<td>Blum et al. (2008); USA</td>
<td>165</td>
<td>31.5 (9.5)</td>
<td>DSM-IV criteria for BPD</td>
<td>STEPPS</td>
</tr>
<tr>
<td>Study; Location</td>
<td>Participant Characteristics</td>
<td>Intervention</td>
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<tr>
<td>(Bos, van Wel, Appelo, &amp; Verbraak, 2010); Netherlands</td>
<td>N: 79; Age M (SD): 32.4 (7.5); Diagnostic Criteria: DSM-IV criteria for BPD as per SCID-II and Personality Diagnostic Questionnaire (PDQ-4)</td>
<td>STEPPS Group + Individual 2 hour session for “reinforcement team”</td>
<td>RCT vs. TAU</td>
<td>SCL-90; BPD-40; WHOQOL-B</td>
</tr>
<tr>
<td>Bos, van Wel, Appelo, and Verbraak (2011); Netherlands</td>
<td>N: 168; Age M (SD): 32.6; Diagnostic Criteria: Diagnosed as having BPD by a clinician</td>
<td>STEPPS Group + Individual 2 hour session for “reinforcement team”</td>
<td>RCT vs. TAU</td>
<td>SCL-90; BPD-40; WHOQOL-B; BPDSI-IV</td>
</tr>
<tr>
<td>Fleischhaker et al. (2011); Germany</td>
<td>N: 12; Age M (SD): 37 (8.1); Diagnosis of BPD: ≥3 DSM-IV BPD criteria</td>
<td>DBT-A Group + Individual Multi-family skills training group- 2 hours per week</td>
<td>Pilot No comparison group</td>
<td>SCID-II diagnostic criteria; LPC; GAF; CGI; ILC; SCL-90-R; CBCL; YSR; DIKJ</td>
</tr>
<tr>
<td>Harvey, Black, and Blum (2010); West Sussex, UK</td>
<td>N: 62; Age M (SD): 55.5 (10.0); Participant Characteristics: Family member of someone with BPD</td>
<td>Family Connections Group 12-week multiple family education program</td>
<td>Pilot No comparison group 3 mo f-up</td>
<td>BAS; PBS; CES-D; Grief Scale; Mastery Scale</td>
</tr>
<tr>
<td>Hoffman et al. (2005); USA</td>
<td>N: 44; Age M (SD): 53.4 (8.84); Participant Characteristics: Family member of someone with BPD</td>
<td>Family Connections Group 12-week multiple family education program</td>
<td>Pilot No comparison group 3 mo f-up</td>
<td>BAS; PBS; CES-D; Grief Scale; Mastery Scale</td>
</tr>
<tr>
<td>Hoffman, Fruzzetti, and Buteau (2007); USA</td>
<td>N: 55; Age M (SD): 53.4 (8.84); Participant Characteristics: Family member of someone with BPD</td>
<td>Family Connections Group 12-week multiple family education program</td>
<td>No comparison group 3 mo f-up</td>
<td>BAS; PBS; CES-D; Grief Scale; Mastery Scale</td>
</tr>
<tr>
<td>Study; Location</td>
<td>Participant Characteristics</td>
<td>Intervention</td>
<td>Study Design</td>
<td>Outcome Measures</td>
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<tr>
<td>James, Winmill, Anderson, and Alfoadari (2011); UK</td>
<td>N: 25, Age M (SD): 15.5 (1.5), Diagnostic Criteria: DSM-IV criteria for BPD</td>
<td>DBT-A Group + Individual Skills training for those working with young person (e.g. carer, staff, school)</td>
<td>No comparison group</td>
<td>BDI; BHS; Attachment Style; CATS; Comprehensive Quality of Life Scale; GAF; Episodes of self-harm</td>
</tr>
<tr>
<td>Mehlum et al. (2014); Norway</td>
<td>N: 77, Age M (SD): 15.6 (1.5), Diagnostic Criteria: ≥2 episodes of self-harm, 1 within the last 16 weeks AND ≥2 DSM-IV BPD criteria OR 1 criterion + ≥2 subthreshold-level criteria</td>
<td>DBT-A Group + Individual Multi-family skills training group- 2 hours weekly for 19 weeks</td>
<td>RCT vs. EUC</td>
<td>No. self-harm episodes; SIQ-JR; SMFQ; MADRS; BHS; BSL; No. hospitalisations</td>
</tr>
<tr>
<td>Neiditch (2010); USA</td>
<td>N: 67, Age M (SD): 52.3 (8.8), Participant Characteristics: Family member of someone with BPD diagnosis or exhibiting symptoms of BPD</td>
<td>Family Connections Group 12-week multiple family education program</td>
<td>No comparison group</td>
<td>BAS; PBS; CES-D; BDI-II; Grief Scale; Mastery Scale; FES; STAXI-2 trait anger subscale; Family Experience Interview Schedule-worry subscale; FAD general functioning subscale; FTF; Hopefulness</td>
</tr>
<tr>
<td>Rathus and Miller (2002); NY, USA</td>
<td>N: 111, Age M (SD): 15.3 (1.7), Diagnostic Criteria: ≥3 DSM-IV BPD criteria AND suicide attempt within last 16 weeks or current suicidal ideation</td>
<td>DBT-A Group + Individual Multi-family skills training twice weekly for 12 weeks</td>
<td>Controlled trial vs. TAU</td>
<td>LPI; SSI; SCL-90-R; No. psychiatric hospitalisations; No. suicide attempts</td>
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<tr>
<td>Study; Location</td>
<td>Participant Characteristics</td>
<td>Intervention</td>
<td>Outcome Measures</td>
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<tr>
<td><strong>Ulasczek, Wilson, Mayberry, Cox, and Maslar (2014); Canada</strong></td>
<td>N=13; Age M (SD) = 15 (1.63), Symptoms and behaviours associated with borderline and externalizing pathology</td>
<td>DBT-A Group + Individual Multi-family skills training weekly for 16 weeks</td>
<td>IPDE; CBCL; YSR; SCL-90-R</td>
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<tr>
<td><strong>Woodberry and Popenoe (2008); USA</strong></td>
<td>N=46; Age M (SD) = 16 (1.4), Behavioural patterns of BPD: history of suicide attempts, self-injury, and/or intense and unstable affect or relationships within past 3-6 months</td>
<td>DBT-A Group + Individual Multi-family skills training 1.75hrs weekly for 15 weeks</td>
<td>RADS; BASIS-32; AAS; TSCC; CBCL; BDI</td>
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</table>

Measures: AAS = Adult Attachment Scale; AQ = Aggression Questionnaire; ASQ = Attachment Style Questionnaire; BAS = Burden Assessment Scale; BASIS-32 = Behavior and symptom Identification Scale; BDI = Beck Depression Inventory; BEST = Borderline Evaluation of Severity Over Time; BHS = Beck Hopelessness Scale; BIS = Barratt Impulsiveness Scale; BIS-11 = Barratt impulsiveness Scale-11; BPDSI-IV = Borderline Personality Disorder Severity Index-IV; BPD-40 = Borderline Personality Disorder checklist-40; BSL = Borderline Symptom List; CATS = Children’s Automatic Thoughts Scale; CBCL = Child Behavior Checklist CES-D = Revised Center for Epidemiologic Studies Depression Scale; CGI = Clinical Global Impression severity scale; CORE-OM = Clinical Outcomes in Routine Evaluation-OM; DIKI = Depression Inventory for Children and Adolescents; EIC = Emotional Intensity Continuum; FAD = McMaster Family Assessment Device; FES = Family Empowerment Scale; FTF = Family-to-family outcome survey; GAF = Global Assessment Scale of Functioning; GAS = Global Assessment Scale; HASS = Harkavy-Asnis Suicide Survey; HSNS = Hyper-Sensitive Narcissism Scale; ILC = Inventory of Life Quality in Children and Adolescents; IPDE = International Personality Disorder Examination; K-SADS = Schedule for Affective Disorders and Schizophrenia, child version; LPC = Lifetime Parasuicide Count; LPI = Life Problems Inventory; MADRS = Montgomery-Asberg Depression Rating Scale; NPI-40 = Narcissistic Personality Inventory-40; PANAS = Positive and Negative Affectivity Scale; PANAS-X = Positive and Negative Affectivity Scale-Expanded Version; PBS = Perceived Burden Scale; RADS = Reynolds’ Adolescent Depression Scale; SAS = Social Adjustment Scale; SCL-90-R = Symptom Checklist-90-Revised; SII-JR = Suicidal Ideation Questionnaire; SMFQ = Short Mood and Feelings Questionnaire; SSI = Scale for Suicidal Ideation; STAXI-2 = State Trait Anger Expression Inventory-2; TCI-R = Temperament and Character Inventory- Revised; TSCC = The Trauma Symptom Checklist for Children; WHOQOL-B = World Health Organization Quality of Life Assessment-Bref; YSR = Youth-Self-Report; ZAN-BPD = Zanarini Rating Scale for Borderline Personality Disorder

Note: TAU = treatment as usual; STEPPS = Systems Training for Emotional Predictability and Problem Solving; DBT = Dialectical Behaviour Therapy; DBT-A = Dialectical Behaviour Therapy- Adolescents; EUC = Enhanced Usual Care; f-up = Follow-up
Summary of Study Characteristics

The 17 included studies are summarised in Table 1.1. The studies were published between 2002 and 2014. 9 were conducted in the United States of America, 1 in Canada and the remainder in Europe (2 in the UK, 2 Netherlands, 1 Norway, 1 Italy and 1 Germany). The majority (n = 14) were conducted in community outpatient settings with 1 in an inpatient setting and 2 others in prisons.

Participants

The sample sizes ranged from n = 12 to n = 168. Altogether n = 931 participants with BPD were included (mean = 66.5, SD = 51.7). 3 studies examined an intervention exclusively for systemic participants and did not include participants with BPD. The studies varied in how BPD was diagnosed and the criteria used for inclusion. 7 required a DSM-IV diagnosis of BPD, 3 included participants partially meeting diagnostic criteria, 3 required BPD traits and 1 relied upon clinician judgement. Studies involving both adults (n = 8) and adolescents (n = 6) were included in the review with a mean age across all studies of 27.62 years. Only half of the studies reported ethnicity. Where it was reported, the majority of participants were Caucasian, with the exception of Rathus and Miller (2002) where 67.6% were Hispanic, 17.1% African American, 8.1% Caucasian, 0.9% Asian American and 6.3% Other.

Members of the patients’ systems involved in interventions included parents, step-parents, caregivers, foster carers, spouses, partners, siblings, adult children, staff and friends. Only four of the seventeen included studies provide information for the systemic participants. These studies have samples ranging from n = 16 to n = 67 (mean = 45.5, SD = 21.8) with a total of 182 participants.

Study Design

4 of the 17 studies comprised randomised controlled trials (RCTs) and one utilised a control group but no randomisation. All of these controlled trials compared the target intervention with a form of usual care, but the format of this varied. Rathus and Miller (2002) was the only study to specify that the control treatment consist of an equivalent dose of both individual and family sessions. Bos et al. (2010) and Bos et al. (2011) used treatment as usual consisting of individual therapy only, excluding any participants who had included their family in sessions. The remaining two trials (Blum et al., 2008; Mehlum et al., 2014) used treatment as usual but did not specify whether members of the
participants’ systems could be involved. Two of the RCTs reported follow-up data at 12 months post intervention with the other two providing no follow-up.

The remaining 13 studies are pilot studies, one of which was a precursor to larger trials also included in this review (Blum et al., 2002).

*Interventions*

All of the 17 studies utilised a group form of skills-based intervention, some of which (n = 9) were augmented by individual sessions. Three different treatment programs with a systemic component featured: Systems Training for Emotional Predictability and Problem Solving (STEPPS; Blum et al., 2002), Dialectical Behaviour Therapy for Adolescents (DBT-A; Rathus & Miller, 2002), and Family Connections (Hoffman et al., 2005).

STEPPS is a 20 week treatment program consisting of weekly 2-hour sessions as well as a 2 hour session for system members. The treatment includes psycho-education, emotion management skills and behaviour management skills for patients with BPD. The systems component also includes psycho-education and aims to encourage members of the patients’ systems to reinforce and support their new skills and manage interpersonal conflict. The STEPPS program is designed to complement an individual’s ongoing treatment and support, rather than being a standalone treatment, so those engaging in STEPPS may also receive psychiatry interventions, support from mental health teams, or other individual psychological treatment. Four of the included studies utilised the original manualised STEPPS intervention (Black et al., 2008; Black et al., 2013; Blum et al., 2002; Blum et al., 2008), one used an “open group” adaptation to allow new patients to join at any time and also changed the format to 45 minute sessions twice weekly for 6-8 months (Alesiani et al., 2014), and three studies augmented the STEPPS program with individual sessions focused on reinforcing and enhancing the newly acquired skills (Bos et al., 2010, 2011; Harvey et al., 2010).

DBT-A is an adolescent adaptation of Linehan’s (1993) DBT intervention. Treatment targets, in order of importance: life-threatening behaviours, therapy-interfering behaviours, quality-of-life interfering behaviours, and increasing adaptive behaviours. The intervention is delivered via group skills training where patients learn mindfulness, interpersonal effectiveness, emotion regulation and distress tolerance. In addition, individual therapy sessions provide opportunity for validation, reinforcement of skills and problem solving.
Another key element of the DBT approach is the use of therapist consultation to ensure a consistent approach and provide supervision. The main adaptations within the studies included in this review are the length of delivery, 12-19 weeks rather than 12 months, shortening sessions, simplified materials, additional skills specific to adolescents, and the inclusion of multi-family skills training sessions. Other adaptations included an assertive outreach approach (James et al., 2011) and offering adjunctive family therapy (Woodberry & Popenoe, 2008).

Family Connections is an intervention for family members of BPD only, based upon the rationale of “supporting family members in their efforts to be emotionally involved with their relative in effective ways, to increase their own wellbeing and also to have a salutary effect on the relative with BPD” (Hoffman et al., 2007, p. 71). The intervention is delivered by trained family members following a standardised 12 week manual. The program covers psycho-education regarding current research, development of BPD and available treatments as well as building skills in emotional self-management, mindfulness, improving relationships emotional expression, validation and problem solving. All three studies included in this review were led by the founders of the intervention and therefore followed this original protocol.

Outcome Measures
A total of 55 different measures were used across the studies, and these were classified into four main categories: BPD symptoms, risk behaviours, mood and overall improvement, and systemic outcome.

The majority of studies (n = 14) used measures of BPD symptom change. These included overall measures of symptomatology as well as more specific outcomes such as impulsivity, social adjustment, attachment and emotional intensity. Typically these were self-report and standardised with good psychometric properties, but some were new measures designed for measuring outcomes for the particular intervention and therefore lacked reliability and validity data (e.g., Emotional Intensity Continuum).

Eight studies utilised measures of risk behaviours such as suicide attempts, self-harm, hospitalisations and prison infractions. These are often the target behaviours of interventions for BPD and therefore can be a good way of assessing change. Some of the measures used in the studies were self-report questionnaires, but the majority were
objective ratings either counting the occurrences of such behaviour or a dichotomous scale indicating the presence of the behaviour or not.

Fourteen studies included measures of mood or general symptomatology for the individual with BPD, including quality of life scales. The most common of these was the Beck Depression Inventory (BDI & BDI-II; Beck, 1979; Beck, Steer, & Brown, 1996).

A small number of studies (n = 5) assessed outcomes for the member of the system. Three of these were studies in which participants were exclusively family members. They included measures of general symptomatology, depression, burden, grief, mastery knowledge and family functioning. Of all the studies included in this review of interventions with systems components, only 2 assessed outcome measures for both the individual with BPD and the member of the system.

**Outcomes**

Table 1.2 gives an overview of the key findings by outcome category and details of drop-out rates for each study.

**BPD Symptoms**

Eleven studies included a global measure of BPD symptoms. Each of these reported a statistically significant change in score from pre to post intervention. Three of the four RCTs found that scores for participants in the intervention groups improved significantly more than those in the control conditions. Bos et al. (2010) and Bos et al. (2011) utilised a STEPPS intervention for a research sample and clinical sample respectively compared with treatment as usual. In both trials, BPD specific psychopathology as measured by the Borderline Personality Disorder Checklist (BPD-40) decreased from pre-treatment to 6 month follow-up for both groups, but more so for the STEPPS group (F=11.7, p=0.001; F=14.1, p<0.0001). This represents a clinically significant difference as demonstrated by medium effect sizes at the end of treatment (d=0.68; d=0.57) and follow-up (d=0.53; d=0.42). Blum et al. (2008) also reported significantly greater improvements in the STEPPS group relative to treatment as usual using the Zanarini Rating Scale for Borderline Personality Disorder (ZAN-BPD) (F=11.0, p=0.001) representing a large effect size (d=0.84) which was maintained at follow-up. However a secondary outcome measure in this study, the Borderline Evaluation of Severity over Time (BEST; reference) showed greater improvement in thoughts, feelings and behaviours associated with BPD for the
treatment group but did not reach significance. The final RCT examined the efficacy of DBT-A for adolescents (Mehlum et al., 2014) versus enhanced usual care. In this study DBT-A did lead to a reduction in BPD symptoms according to the Borderline Symptom List (BSL) (p<0.001, d=0.89), however this was not a significantly greater improvement that the active control group.

The remaining seven studies measuring global BPD symptom outcomes reported within group data. STEPPS interventions resulted in significant decreases in overall BPD symptoms as measured by the BEST (Black et al., 2008; Black et al., 2013; Blum et al., 2008; Harvey et al., 2010) and the ZAN-BPD (Harvey et al., 2010). Studies of DBT-A interventions also achieved significant improvements according to SCID diagnosis (Fleischhaker et al., 2011), Life Problems Inventory (Rathus & Miller, 2002) and International Personality Disorder Examination (IPDE) (Uliaszek et al., 2014).

Other measures of BPD related outcomes such as emotional intensity, cognitions, impulsivity and relationships were included by ten studies. Significant improvements were found on measures of emotion with a reduction in emotional intensity (Alesiani et al., 2014) and reductions in negative affect (Black et al., 2008; Black et al., 2013; Blum et al., 2002; Blum et al., 2008; Harvey et al., 2010) but not an improvement in positive affect with four of five studies measuring this attaining non-significant findings. Neither of the two studies that included measures of BPD specific cognitions (Alesiani et al., 2014; James et al., 2011) found a significant change.

Three studies included a measure of impulsivity, but only one found a significant improvement with Blum et al. (2008) finding scores on the Barratt Impulsiveness Scale-II (BIS-II; reference) reduced significant more in the STEPPS intervention group than the treatment as usual controls with a moderate effect size (F=9.0, p=0.004, d=0.54). Five studies assessed outcomes for relational measures including attachment style (Alesiani et al., 2014; James et al., 2011; Woodberry & Popenoe, 2008), social adjustment (Blum et al., 2008) and social aspects of life quality (Fleischhaker et al., 2011). Only one found a significant improvement with Alesiani et al. (2014) finding a significant reduction on the ‘comfort depending’ subscale of the Adult Attachment Scale (AAS), but not for other subscales, following DBT-A intervention for adolescents.
Risk Behaviours

Eight studies used measures of risk behaviours, namely suicidal and self-harm behaviours (Alesiani et al., 2014; Black et al., 2013; Fleischhaker et al., 2011; James et al., 2011; Mehlum et al., 2014; Rathus & Miller, 2002), hospitalisations (Alesiani et al., 2014; Blum et al., 2008; Mehlum et al., 2014), crisis contacts (Blum et al., 2008) and disciplinary infractions (Black et al., 2013).

Suicidal and self-harm behaviours were consistently found to significantly reduce following both STEPPS and DBT-A interventions. Only two of these studies compared the interventions with a control. Mehlum et al. (2014) found that the number of self-harm episodes reduced significantly more for adolescents randomly assigned to the DBT-A group compared with enhanced usual care (Δslope=0.92, p=0.021). Conversely Rathus and Miller (2002) found that the number of suicide attempts did not differ between adolescents who received DBT-A compared with treatment as usual. However, as this study did not randomise participants, the two groups differed considerably with those with more severe pre-treatment symptoms, including suicidality, selectively allocated to the DBT-A group.

Across the studies which analysed utilisation of crisis service and hospitalisations, results for these outcomes were inconclusive. Two studies reported a significant effect in hospitalisations. The first of these reported a significant decrease in hospitalisations from pre to post STEPPS intervention ($\chi^2=18.69$, p<0.001; Alesiani et al., 2014) and the other reported that the number of hospitalisations during the intervention was significantly lower for a DBT-A group than treatment as usual ($\chi^2=4.16$, p=0.041; Rathus & Miller, 2002). Other studies however found no significant improvements in the need for hospitalisations or crisis service involvement from pre to post intervention when compared to a control treatment (Blum et al., 2008; Mehlum et al., 2014).

Disciplinary infractions were used as an outcome measure by Black et al. (2013) as the study setting was a prison or community correctional facility. The proportions of participants making disciplinary infractions reduced significantly from 26% at baseline to 17% at the end of the STEPPS intervention ($t=-2.06$, p=0.043). Combined with the improvements in symptoms associated with BPD, this outcome suggests that the STEPPS intervention may enable participants to regulate their emotions in a way that allows them to refrain from engaging in rule-breaking behaviours.
**Mood and Overall Improvement**

Nine studies included outcomes on measures of depression for participants with BPD, all of which found significant reduction in symptoms of depression following the intervention. Two of these compared improvement in depressive symptoms with participants in a control treatment, finding that symptoms improved significantly more for those in the skills based interventions with system members. Outcome measures for other emotions were less frequently used and therefore do not provide any substantial evidence for the efficacy of systemic skills based interventions on outcomes such as anger.

Measures of general and overall functioning were utilised by ten of the eleven studies examining the efficacy for participants with BPD and overwhelmingly showed that skills based interventions with systemic components result in overall improvements from baseline to post intervention and follow-up. These improvements were found to be significantly greater than those achieved by control treatments in all four of the RCTs.

**Systemic Outcomes**

A small number of studies (n=5) measured outcomes for the systemic participant. Three of these were studies investigating an intervention solely for family members and did not measure outcomes for the individual with BPD although the intervention aimed to have a salutary effect on BPD symptoms. These studies reported significant improvements in burden, grief and mastery. Two of the three studies also reported a significant reduction in depressive symptoms.

A further two studies included measures for family members who participated in an intervention alongside the individual with BPD (Ulíaszek et al., 2014; Woodberry & Popenoe, 2008). Both investigated DBT-A for adolescents. Woodberry and Popenoe (2008) found a large effect for depressive symptoms reduction in parents attending the intervention (t=3.06, p=0.007, d=0.72) suggesting that they are able to benefit from the systemic approach to skills training. On the other hand, Ulíaszek et al. (2014) found no statistically significant changes in mean parental scores of depression, anxiety, hostility and interpersonal sensitivity but some caregivers did report clinically significant change using the reliable change index (RCI). The authors suggest that the small sample size and low pre-treatment scores could have introduced a floor effect which did not allow the analyses to detect subtle changes.
<table>
<thead>
<tr>
<th>Study</th>
<th>Analysis</th>
<th>BPD Symptoms</th>
<th>Risk Behaviour</th>
<th>Mood &amp; Overall Improvement</th>
<th>Member of System</th>
<th>Drop Outs (definition; n (%); analysis)</th>
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<tbody>
<tr>
<td>Alesiani et al. (2014)</td>
<td>WG</td>
<td>↓EIC*** $\chi^2 = 73.96$, p&lt;0.001</td>
<td>Non-Significant Findings Filters questionnaire. BIS-11 ASQ</td>
<td>↓Hospitalisations*** pre, 4.11; post, 0.33, $\chi^2 = 18.69$, p=0.001</td>
<td>Non-Significant Findings AQ</td>
<td>Not completing the program including 12mo f-up. 15/32 (47%). Dropouts not included in analysis.</td>
</tr>
<tr>
<td>Black et al. (2008)</td>
<td>WG</td>
<td>↓BEST** pre, 28.0; post, 16.9, F(1,10) = 10.5, p= 0.009</td>
<td>↓PANAS –ve* pre, 24.6; post, 19.5, F(1,10) = 7.5, p= 0.021</td>
<td>↓BDI** pre, 19.3; post, 11.8, F(1,10)= 15.0, p= 0.003</td>
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<td>Not completing program. 2/12 (17%). Dropouts not included in analysis.</td>
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<tr>
<td>Black et al. (2013)</td>
<td>WG</td>
<td>↓BEST*** pre, 34.3; post, 19.5, F = 78.1, p&lt;0.001</td>
<td>↓PANAS –ve*** pre, 27.6; post, 20.5, F= 23.8, p&lt;0.001</td>
<td>↓BDI*** pre, 25.5; post, 30.2, F= 85.7, p&lt;0.001</td>
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<td>Not completing program. 36/ 67 (47%), Dropouts weekly data included in analysis.</td>
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<tr>
<td>Blum et al. (2002)</td>
<td>WG</td>
<td>↓BEST* F(18,392)=.94, p=0.01</td>
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<td>Attended &lt;10 sessions. 24/52 (46%). Dropouts weekly data included in analysis.</td>
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<tr>
<td>Study</td>
<td>Analysis</td>
<td>Outcomes</td>
<td>Drop Outs (definition; n (%)</td>
<td>Analysis</td>
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<td>Drop Outs (definition; n (%)</td>
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<tr>
<td>Blum et al.</td>
<td>BG: STEPPS vs. TAU</td>
<td>BPD Symptoms</td>
<td>Risk Behaviour</td>
<td>Mood &amp; Overall Improvement</td>
<td>Member of System</td>
<td>(definition; n (%)</td>
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<td>[ZAN-BPD]** pre, 18.9 vs. 17.3; post, 9.8 vs. 13.4, F(1,89)=11.0, p=0.001</td>
<td>[A&amp;E visits* (No. months per year with utilisation), 0.97 vs. 1.52, p=0.040</td>
<td>[BDI* pre, 29.0 vs. 29.7; post, 22.0 vs. 25.8, F(1,377)=4.6, p=0.033</td>
<td>[40/164 (24%)] dropped out following randomisation. 16/164 (10%) did not complete program: 8/93 (9%) (STEPPS and 8/72 (11%) TAU. 20/164 (12%) lost to follow up: 12/93 (13%) STEPPS and 8/72 (11%) TAU.</td>
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<td>PANAS –ve* pre, 28.9 vs. 29.9; post, 23.6 vs. 26.1, F(1,376)=4.3, p=0.038</td>
<td>Non-Significant Findings</td>
<td>Non-Significant Findings</td>
<td>Non-Significant Findings</td>
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<td>BIS-11** pre, 80.6 vs. 16.8; post, 72.7 vs. 76.8, F(1,80)=9.0, p=0.004</td>
<td>Crisis contacts (No. months per year with utilisation), 2.49 vs. 2.31</td>
<td>BPD symptoms</td>
<td>[BPD symptoms]</td>
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<td>Non-Significant Findings</td>
<td>Hospitalisations. (No. months per year with utilisation), 1.13 vs. 1.24</td>
<td>Mood &amp; Overall Improvement</td>
<td>Mood &amp; Overall Improvement</td>
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<td>BEST pre, 39.0 vs. 39.8; post, 31.8 vs. 34.1, F(1,364)=3.5, p=0.063</td>
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<td>[SCL-90-R* pre, 16.0 vs. 16.8; post, 12.5 vs. 14.9, F(1,78)=4.8, p=0.031</td>
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<td>PANAS+ve pre, 21.6 vs. 22.3; post, 23.4 vs. 22.4, F(1,374)=0.6, p=0.440</td>
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<td>[CGI severity*** pre, 5.1 vs. 4.9; post, 4.4 vs. 4.7, F(1,398)=14.1, p&lt;0.001</td>
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<td>SAS pre 27.8 vs. 28.2; post, 24.6 vs. 26.3, F(1,80)=3.5, p=0.065</td>
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<td>[CGI improvement*** pre, 3.8 vs. 4.9; post, 4.4 vs. 4.7, F(1,277)=11.6, p&lt;0.001</td>
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<td>GAS*** pre, 39.7 vs. 39.6; post, 50.5 vs. 43.5, F(1,84)=12.1, p=0.001</td>
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<td>[GAS*** pre, 39.7 vs. 39.6; post, 50.5 vs. 43.5, F(1,84)=12.1, p=0.001</td>
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<td>Pre, 106.8 vs. 101.1; post, 79.7 vs. 95.1; f-up, 78.2 vs. 88.6, F(1,56)=11.7, p=0.001</td>
<td></td>
<td>[SCL-90** pre, 263.4 vs. 247.4; post, 205.8 vs. 248.5; f-up, 199.2 vs. 222.7, F(1,58)=11.9, p=0.001</td>
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<tr>
<td>Bos et al.</td>
<td>BG: STEPPS vs. TAU</td>
<td>BPDSI-IV parasuicide (above cut-off) pre, 18 vs. 20; post, 16 vs. 13; f-up, 13 vs. 13, Wald χ²=0.31, p=0.578</td>
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<td>[BPDSI-IV parasuicide (above cut-off) pre, 29 vs. 31; post, 19 vs. 22; f-up, 20 vs. 22, Wald χ²=0.65, p=0.420</td>
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<td>BPDSI-IV impulsivity (proportion above cut-off) pre, 29 vs. 31; post, 19 vs. 22; f-up, 20 vs. 22, Wald χ²=0.65, p=0.420</td>
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40/164 (24%) dropped out following randomisation. 16/164 (10%) did not complete program: 8/93 (9%) (STEPPS and 8/72 (11%) TAU. 20/164 (12%) lost to follow up: 12/93 (13%) STEPPS and 8/72 (11%) TAU.

Not completing intervention. 13/79 (16.5%): 9/42 (21.4%) STEPPS, 4/37 (10.8%) TAU. Dropouts not included in analysis.
<table>
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<tr>
<th>Study</th>
<th>Analysis</th>
<th>Outcomes</th>
<th>Drop Outs (definition; n (%); analysis)</th>
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<tbody>
<tr>
<td>Bos et al. (2011)</td>
<td>BG: STEPPS vs. TAU</td>
<td>BPD Symptom: ↓BPD-40*** pre, 99.4 vs. 92.7; post, 75.9 vs. 85.8; f-up, 74.1 vs. 81.5, F(1, 118)=14.1, p&lt;0.001</td>
<td>Not completing, 38/168 (22.6%); 22/84 (26.2%) STEPPS, 16/84 (19.0%) TAU. Available data included in analysis.</td>
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<tr>
<td>Fleischhaker et al. (2011)</td>
<td>WG</td>
<td>SCID-II diagnostic criteria**: No. of BPD diagnostic met pre, 5.8; f-up, 2.75, p=0.003</td>
<td>Non-Significant Findings ILC Family; Social contact with peers.</td>
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<tr>
<td>Harvey et al. (2010)</td>
<td>WG</td>
<td>↓ZAN-BPD*** pre, 21.8; post, 10.7, t=7.4, p&lt;0.001</td>
<td>Not completing intervention. 3/12 (25%).</td>
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<td>Study</td>
<td>Analysis</td>
<td>Outcomes</td>
<td>Drop Outs (definition; n (%) ; analysis)</td>
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<td>Hoffman et al. (2005)</td>
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<td>Hoffman et al. (2007)</td>
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<tr>
<td>James et al.</td>
<td>WG</td>
<td>Non-Significant Findings</td>
<td>↓Episodes of self-harm*** mean change = -2.4, t = 4.7; p &lt; 0.001</td>
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<td>Attachment Style CATS</td>
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<tr>
<td>Mehlum et al.</td>
<td>BG: DBT- A vs. EUC</td>
<td>Non-Significant Findings BSL pre, 38.47 vs. 40.18; post, 21.34 vs. 34.75, Δslope = -0.50, p = 0.050</td>
<td>↓No. self-harm episodes* baseline-wk9, 4.1 DBT-A vs. 4.7 EUC; wk10-wk15, 1.2 vs. 3.3, Δslope = 0.92, p = 0.021</td>
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<td>Study</td>
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<td>Neiditch (2010)</td>
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<td>BPD Symptoms</td>
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<td>Rathus and Miller (2002)</td>
<td>WG: DBT &amp; BG: DBT vs. TAU</td>
<td>BPD Symptoms:</td>
<td>Risk Behaviour</td>
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<td>[LPI]** pre, 170.6; post, 108.0, t= 3.44, p= 0.009</td>
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<td>No. psychiatric hospitalisations* throughout intervention, 0% vs. 13%, $\chi^2 = 4.16, p=0.041$</td>
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<td>Non-Significant Findings</td>
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<td>No. suicide attempts, 3.4% DBT vs. 8.6% TAU, ns.</td>
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<td>Study</td>
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<td>BPD Symptoms</td>
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<tr>
<td>Uliaszek et al. (2014)</td>
<td>WG</td>
<td>↓IPDE borderline** pre, 5.10; post, 1.10, t=4.00, p = 0.003</td>
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<td>Woodbery and Popenoe (2008)</td>
<td>WG</td>
<td>↓AAS comfort depending* depending pre, 2.84; post, 3.13, t=2.17, p=0.040</td>
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Note: ↑↓ direction of change in outcome measure; WG = within groups; BG = between groups
Levels of statistical significance: * = p<0.05, ** = p<0.01, *** = p<0.001
Assessment of Risk of Bias

Risk of bias was assessed using The Cochrane Collaboration’s tool for assessing risk of bias (Higgins et al., 2011) with adaptations for considering non-randomised and uncontrolled studies. Figures 1.3 and 1.4 summarise the risk of bias for each study. Figure 1.5 shows the review authors’ judgements about each risk of bias item across all studies.

Although not formally assessed, the inclusion of non-randomised and uncontrolled studies necessitated the consideration of publication bias. During the literature search process unpublished studies were purposefully sought by the inclusion of grey literature and authors contacted in order to obtain reports or data. One intervention potentially meeting the review criteria was identified in the correspondence of the British Journal of Psychiatry (Flewett, Bradley, & Redvers, 2003), but having contacted the author it was ascertained that this intervention had not been evaluated. It is possible that further interventions have been developed but not researched or published, and given the susceptibility of non-randomised and uncontrolled studies to bias in the direction of publishing more favourable outcomes, this must be considered when interpreting the results of the current review.

<table>
<thead>
<tr>
<th>Study</th>
<th>Random Sequence Generation</th>
<th>Allocation Concealment</th>
<th>Detection Bias-Outcome Blinding</th>
<th>Attrition Bias</th>
<th>Reporting Bias</th>
<th>Adherence</th>
<th>Attention Bias</th>
<th>Programme Differentiation</th>
<th>Quality of Delivery-Allegiance Effect</th>
<th>Participant Responsiveness</th>
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<tr>
<td>Blum et al. (2008)</td>
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<td>Bos et al. (2010)</td>
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<td>Mehlum et al. (2014)</td>
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[Figure 1.3 Risk of Bias Summary for controlled studies (randomised and non-randomised)]
Selection Bias

Studies with control groups were judged on their method of randomisation by considering how the randomised sequence was generated and also how the selection was concealed from those delivering the interventions. 60% of studies described adequate randomisation, with one study providing insufficient information (Mehlum et al., 2014) and another purposefully selecting more severe cases for the intervention group (Rathus & Miller, 2002). Those that described an allocation procedure in which selection was performed by researchers not involved in intervention delivery were considered low risk (60%).
For non-controlled studies, the judgement of selection bias was made depending on the presence of possible confounding factors. Six studies (50%) were considered to have low risk of bias as they included selection procedures such as consecutive referrals, open referrals or secondary analysis of an intervention conducted in a clinical setting. The remaining studies did not provide sufficient information to make a judgement about selection bias.

Detection Bias
Detection bias due to inadequate blinding of patients and personnel was not assessed due to the unfeasibility of this in psychotherapy outcome research as both need to be informed about the nature of the intervention in order to fully engage (Stoffers et al., 2012). Detection bias due to knowledge of allocated interventions or desired outcome by outcome assessors was considered. The majority of all studies (67%) used self-rated outcomes and were therefore considered to be low risk. Only one study was judged to have high risk of bias due to lack of blinding of interviewer rated outcomes (Fleischhaker et al., 2011). The other studies lacked sufficient information to assess.

Attrition Bias
Attrition bias was assessed based upon the proportion of participants dropping out of the study and also the nature of the data analysis. Risk of attrition bias was lower in the controlled trials with 80% deemed to have low risk compared with 58% for the uncontrolled studies. The reason for this lower risk was a higher proportion of studies presenting intention to treat analyses in addition to analyses for participants completing the study. Two studies were deemed to have unclear risk of attrition bias as they did not provide sufficient information about the participants who dropped out for a judgement to be made as to whether this was likely to influence the outcome.

Reporting Bias
For three studies study protocols were available either from trial registers or directly from the authors. For the study of Mehlum et al. (2014) there was no indication of selective reporting. However for Bos et al. (2010) and Bos et al. (2011) the protocol indicates several outcome measures that are not reported in the study leading to a rating of high risk of selective reporting bias.
For the remaining studies, no protocols were available and therefore the risk of bias was deemed to be unclear.

**Intervention Integrity**

Ten studies (59%) specified either regular supervision or objective methods of assessing adherence to the intervention protocol. Alesiani et al. (2014) in further information provided for this review stated that adherence to the manual was not formally assessed and therefore risk of bias was rated as likely. The other six studies did not provide enough information for the potential risk to be assessed.

For controlled trials only one study (20%) (Rathus & Miller, 2002) was rated as providing equal amounts of attention to both treatment groups. One other trial Bos et al. (2011), although providing more sessions to the experimental group, conducted analyses controlling for number of treatment contacts which determined that the increased attention did not affect the outcome and therefore was deemed to have a low risk of bias. The other three trials provided more attention (number and frequency of sessions, additional group treatments) to the experimental group and were judged to have a high risk of attention bias.

Three studies (Black et al., 2008; Bos et al., 2010, 2011) had safeguards employed to ensure that participants received only the planned interventions and were rated as low risk of programme differentiation. Twelve studies did not address this issue and the risk was rated unclear. Harvey et al. (2010) reported that participants continued to receive other interventions during the study period and the extent of this was not measured resulting in a high risk of bias. Although participants in the study by Woodberry and Popenoe (2008) did not engage in other treatments during the study period, the authors described that pre-treatment measures were collected at inconsistent times, with some collected after group sessions had been initiated which was considered by the review authors to introduce a high risk of bias.

A high proportion (41%) of studies had main investigators who had developed the treatment and as such were deemed to possess a high risk of allegiance bias. Five studies considered the implications of clinician training and enthusiasm towards each of the treatment groups which was judged to be sufficient to receive a rating of low risk of bias. The remaining five studies did not give enough information for allegiance bias to be assessed.
Six studies were rated a low risk of bias due to participant responsiveness as they had low drop-out rates, high attendance rates or high participant satisfaction. Studies providing insufficient information regarding satisfaction or reasons for drop-out were judged to have unclear risk (n = 8). Three studies were rated as having a high risk of bias. Black et al. (2008) reported a high drop-out rate with some participants dropping out due to lack of programme efficacy. Also contributing to this study’s high risk rating was that participant satisfaction was rated as significantly higher in the experimental group suggesting that participants in the treatment as usual group may have been less responsive. Blum et al. (2002) also reported a high drop-out and gave no reasons for these which may have biased the results. Finally, Black et al. (2013) reported a 47% drop-out rate which the study authors acknowledged could have compromised the findings resulting in a high risk of bias rating.

**Figure 1.5** Risk of Bias Graph: review authors’ judgements about each risk of bias item presented as percentages across controlled trials (randomised and non-randomised) (top) and uncontrolled studies (bottom).
Discussion

This paper aimed to synthesise and evaluate evidence for the efficacy of involving a person with BPD’s wider system in skills based treatments. The transactional model of BPD (Linehan, 1993) suggests that individual and systemic factors are involved in the development and maintenance of the disorder. Thus, treatments targeting both may improve outcomes. At present the literature is in its early stages, but as more studies are emerging it is important to consider the current status of the evidence and establish what is needed from future research. The current review aimed to ascertain the effectiveness of skills based interventions with systemic components, focusing on BPD symptoms; determine the efficacy of these interventions for alleviating distress for families and other members of the system; and find out whether involving the system in skills based interventions improves outcomes for people with BPD.

The literature search identified three different skills based interventions with a systemic component that had been evaluated. The majority employed a skills group for people with BPD symptomatology with some including families in these group sessions (DBT-A for adolescents) and others offering a separate session for those in the patients’ system (STEPPS). Three studies evaluated an intervention with a different approach. Family Connections is a group skills intervention for family members only, aiming to reduce distress and improve skills and as such result in improved outcomes for the person with BPD.

Each of the studies included in this review reported significant improvements in BPD symptoms and risk of self-harm or suicide, with those reporting effect sizes finding moderate to large effects. These results suggest that skills based interventions with systemic components may be an efficacious treatment for individuals with BPD. However this conclusion is limited by the heterogeneity of the included studies with regards to participant characteristics, interventions applied, study design and outcome measures used, each of which are explored below.

Many of the studies implemented differing inclusion criteria for BPD, some using strict adherence to DSM-IV diagnosis whilst others used partial diagnosis or symptomatology. To establish a rigorous evidence base, it is often important that research applies consistent criteria in order to reduce the interference of possible confounding factors. However, this
can compromise the generalisation of results to clinical practice so a strength of the evidence included in this review is it’s applicability to real clinical presentations.

This review included participants of all ages given the small number of studies and the move to recognising the reliability and validity of BPD in this age group (Bondurant et al., 2004; Chanen et al., 2007; Miller et al., 2008). As a result, ages of participants ranged from twelve to sixty-three years. On inspection, there didn’t appear to be any differences in the number of significant findings between those studies evaluating interventions for adolescents and those with adult participants. However it is possible that the phenomenology and treatment of adolescents and adults is different, particularly regarding the importance of a systemic approach to learning and applying skills. Future research needs to explore whether involving families, and the nature of this involvement, is differentially important with regards outcomes for adults and adolescents.

Within the three different intervention approaches, there were many variations in the treatment administered. Within an intervention type the session length, session frequency and treatment duration differed as well as having differing formats of augmented individual therapy and varying means of involving family members. This makes it difficult to compare the approaches and establish the most effective way of delivering the intervention in practice.

This review also aimed to establish the outcomes of these interventions for members of the system. Caring for someone with BPD is often a difficult and stressful experience (Berkowitz & Gunderson, 2002; Goldman et al., 1993; Gould et al., 2003; Hoffman & Hooley, 1998; Silverman et al., 1991), and given that the support of family members is associated with outcomes for individuals with BPD (Hooley & Hoffman, 1999; Zanarini, 2002) it is important that systemic interventions address this need. The results of this review indicated that members of the system involved in interventions benefited from significant improvements in outcome such as mood, burden and mastery for four of the five studies that included this data, with the remaining study limited by small sample size and low ratings on initial pre-intervention measures. Eleven studies included in the review did not measure outcomes for family members, limiting the capacity of this review to draw conclusions regarding the benefits to the wider system of involving them in skills based interventions for BPD.
The final goal of this review was to examine whether skills-based interventions involving the system are more effective than those providing treatment just for the individual with BPD. The majority of included studies employed a pilot study design without a control group. Of the five studies with a comparison group, four were RCTs. Comparison groups used were all alternative treatment approaches rather than wait-list controls which is an asset to the overall evidence as it allows us to conclude that these interventions are more effective than the usual supportive treatments offered to people with BPD within clinical practice. There are some limitations within these studies however. Firstly, comparison groups tended to comprise of much less clinician contact than the experimental interventions, introducing a considerable risk of bias to the findings. Secondly, none of the studies compared the systemic skills based intervention with an equivalent intervention without a systemic component. As such, it is not possible to ascertain from the evidence available to date whether involving the system in skills based interventions improves outcomes for people with BPD.

**Research implications**

As is apparent by the small number of studies evaluating these interventions, development is still in the early stages and the majority of studies have small numbers of participants and have not included a comparison group. Future studies should focus on larger scale and more rigorous designs in order to establish the evidence for including members of the system in interventions for BPD.

The current research available on systemic skills based interventions is not sufficient to answer the question of whether involving members of the system contributes towards better outcomes for people with BPD. For this to be established, RCTs comparing skills based interventions with and without systemic components is needed. Given that the transactional model of BPD (Linehan, 1993) postulates that a family environment consisting of negative judgement, elevated negative emotion and reinforcement of dysfunctional behaviours is involved in the maintenance of BPD symptoms, targeting these aspects should lead to a greater improvement in BPD symptoms and risk outcomes when compared to interventions providing the skills to the individual with BPD alone, particularly over long term follow-up when the intensive support from clinicians is withdrawn.
Only two studies collected outcome data for both the participants with BPD and the members of the system. The majority of studies measured outcomes for people with BPD only, whilst three studies measured only the family member outcomes. An important goal for future research would be to identify which aspects of the systemic component may be effective in improving BPD outcomes, and the mechanism through which they achieve change. By collecting outcome data for both participants with BPD and members of the system, research can identify which changes for family members predict improved outcomes for people with BPD. For example, the transactional model suggests that improvements in family member distress, criticism and reinforcement pattern may predict improvements in BPD symptoms.

Finally, many of the studies were conducted by the developers of the intervention leading to a high risk of allegiance bias. Whilst most studies are likely to have some allegiance effect due to the nature of intervention studies which requires therapists to be invested in the treatment approach in order to deliver it effectively, research by independent researchers is needed in order to reduce the likelihood that the evidence base is biased by studies conducted by those who are invested in its success.

**Strengths and limitations of these findings**

This review used a rigorous and comprehensive search strategy to identify eligible studies, including dissertations, conference abstracts and hand searching of reference lists in order to reduce the likelihood of publication bias. It was not possible however to include foreign language studies due to limited resources, and therefore several studies that may have been relevant to the review had to be excluded. To improve the reliability of the application of inclusion and exclusion criteria, studies were screened by two independent researchers and reliability checks conducted.

Detailed data on the precise methodology, interventions and systemic components of the included studies was not always available. Authors of the studies were contacted and asked for access to the study protocol and additional information but only 3 of the 10 authors responded and thus is a limiting factor.
Assessing the efficacy of skills based interventions with systemic components using a meta-analytic approach was not possible due to the small number and heterogeneity of studies included. Therefore synthesis of the results relied upon qualitative analysis.

An important strength of the current review was the comprehensive assessment of the risk of bias and integrity of the intervention of each of the included studies. The Cochrane risk of bias tool is a domain-based evaluation rather than a scale or checklist which are not supported by empirical evidence (Emerson, Burdick, Hoaglin, Mosteller, & Chalmers, 1990; Schulz, Chalmers, Hayes, & Altman, 1995). Therefore the assessment reported on the risk of bias for various aspects of methodological rigour, allowing the reader to evaluate the overall quality of the evidence.

**Conclusions**

Research investigating the application of the transactional model of BPD (Linehan, 1993) in involving systems in skills based interventions is still in its early stages and more research is needed. To date, the outcomes for people with BPD and their family members are promising, but there is no empirical basis to suggest that the addition of systemic components to skills based treatment approaches improves outcome. Future research should focus on the comparison of skills based interventions with and without systemic components and identifying the mechanisms through which systemic involvement improves outcomes for people with BPD in order to target these in treatment.

**References**


Neiditch, E. R. (2010). *Effectiveness and moderators of improvement in a family education program for borderline personality disorder.* (71), ProQuest Information & Learning, US.


Improving Multidisciplinary Clinical Discussion on an Inpatient Mental Health Ward

Sian Dallimore

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External Supervisor
Dr Katharine Christie

Internal Supervisors
Dr Maria Loades

Service Improvement Project, September 2014
Word Count 5081

Journal to be targeted
This paper is to be targeted towards the Mental Health Review Journal. The scope of this journal includes work that focuses the delivery and evaluation of mental health services in the UK, with particular attention to innovation, implementation and service user experience. Given this study’s focus on the role of Clinical Psychology in delivering effective multidisciplinary supervision, it falls within the remit of this journal.
Abstract

Purpose – Multidisciplinary team (MDT) clinical supervision is being used in many mental health services but at present has not received adequate attention by researchers in order to generate evidence based approaches. This paper aims to explore the utility and staff perspectives of an MDT model of clinical supervision in the form of a “Clinical Discussion Group” (CDG) on an acute inpatient mental health ward within the context of the current literature on the components of effective supervision in order to make recommendations for practice.

Design/Methodology/Approach – Twelve members of staff working on the ward were interviewed to gather their perspective on attendance, helpful aspects, outcomes, unhelpful aspects, and changes. Interview transcripts were analysed using thematic analysis.

Findings - eleven themes were identified, three within “The Group and how it operates” (Attendance, Discussion Topics and Facilitation), five within “Impact and Usefulness” (Valued by Staff, Understanding a Case, Emotional Benefit, Learning and Working together as a Team) and three within “Changes to the Group” (Organisation, Discussion Topic and Group Outcomes).

Originality/Value – This paper explores the benefits and challenges of a CDG from the perspective of the staff who attend. It presents some recommendations for good practice which should be of use to managers and supervisors who wish to use team supervision to improve patient outcomes and also makes suggestions for future research in this field.

Introduction

Clinical supervision is empirically defined as “the formal provision by senior/qualified health practitioners of an intensive relationship-based education and training that is case focussed and which supports, directs and guides the work of colleagues” (Milne, 2007). Staff working on inpatient psychiatric (or mental health) wards have access to several formats of supervision including formal group or individual case discussions, managerial, case conferences, handovers, daily reviews and peer discussions (Buus, Angel, Traynor, & Gonge, 2011). Clinical Psychologists are well placed to provide clinical supervision within staff teams, a position which is recognised by various government and professional body documents (British Psychological Society, 2001; National Institute for Mental Health in England, 2007). Multidisciplinary team supervision offers an opportunity for members of different professions to work together to enhance the quality of patient care (Mullarkey, Keeley, & Playle, 2001).
One format of team clinical supervision explored recently in the literature takes the form of psychological formulation within teams. Various authors have described innovations and case examples of team formulation from a range of different perspectives (Christofides, Johnstone, & Musa, 2012) including Cognitive-Behavioural (Kennedy, Smalley, & Harris, 2003; Lake, 2008), Psychodynamic (Davenport, 2002), Attachment (Lake, 2008) and Systemic, all reporting a positive impact on guiding patient interventions, improving staff-patient relationships and improving team cohesion. However, this approach has been recognised as particularly challenging as although it is possible to create an environment to share problems, open communication and slow progress can create tensions in the team (Hyrkäs & Appelqvist-Schmidlechner, 2003). The challenges of working in this way are perhaps reflected by the lack of empirical research into clinical outcomes of team clinical supervision, so it is necessary to draw on the wider literature to explore the purpose and components of effective supervision.

The purpose of clinical supervision
Proctor (1987) proposed a framework for clinical supervision incorporating three key objectives or functions. This framework has been used to shape supervision structure and direct further research.

1. Formative (educative) – developing skills and abilities through sharing knowledge pertinent to current practice and enhancing self-awareness.
2. Normative – maintaining safe practice and adequate standards of care through discussion with experienced and knowledgeable clinicians who can offer suggestions for change and continuous improvement.
3. Restorative – ensures clinicians maintain the stability and personal resources to be effective in their work through peer review and sharing anxieties.

Research has aimed to establish the effect supervision has on supervisees. Formative benefits include a broader knowledge base rather than a solely neurobiological understanding of mental health (Crowe, Carlyle, & Farmar, 2008), increased creativity (Brunero & Stein-Parbury, 2008) and a lasting influence on professional confidence (Arvidsson, Baigi, & Skarsater, 2008). Normative benefits have been found to include increased empathy (Brunero & Stein-Parbury, 2008), autonomy (Hallberg, Welander-Hansson, & Axelsson, 1994) and improved cooperation between staff and patients (Severinsson & Hallberg, 1996). The restorative effects of supervision have been most
commonly researched, indicating that supervisees experience less strain and burnout (Berg, Hansson, & Hallberg, 1994; Edwards et al., 2006; Hallberg, 1994; Hallberg & Norberg, 1993; Hyrkas, 2005), improved coping (Berg & Hallberg, 1999) and are more able to maintain their strength and energy (Arvidsson et al., 2008).

**Components of effective supervision**

In a review of empirical studies, Buus and Gonge (2009) concluded that methodological weaknesses in the available literature allowed for only tentative conclusions regarding the effectiveness of clinical supervision. The research that is available relies upon small sample sizes, has insufficient consideration of confounding factors and often uses qualitative accounts of supervisees’ perspectives. The following components have been discussed as being important: length and frequency of sessions; session content; supervision environment; supervisee involvement, preparation and follow-up (Table 2.1).

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<thead>
<tr>
<th>Table 2.1</th>
<th>Summary of components considered important for effective clinical supervision</th>
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<tr>
<td><strong>Component</strong></td>
<td><strong>Evidence</strong></td>
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<tr>
<td><strong>Length and Frequency of Sessions</strong></td>
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<tr>
<td>At least an hour duration</td>
<td>Edwards et al. (2005)</td>
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<tr>
<td>Frequent Attendance</td>
<td>Edwards et al. (2005)</td>
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<tr>
<td>Frequent Attendance</td>
<td>Gonge and Buus (2011)</td>
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<td>Frequent Attendance</td>
<td>Buus et al. (2011)</td>
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<tr>
<td>Frequent Attendance</td>
<td>Hyrkäs and Appelqvist-Schmidlechner (2003)</td>
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<td><strong>Content of Sessions</strong></td>
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<tr>
<td>Formulation-Based</td>
<td>Milne, Sheikh, Pattison, and Wilkinson (2011)</td>
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<tr>
<td>Formulation-Based</td>
<td>Buus et al. (2011)</td>
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<td>Formulation-Based</td>
<td>Summers (2006)</td>
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<tr>
<td>Modelling</td>
<td>Kavanagh, Spence, Wilson, and Crow (2002)</td>
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<td>Modelling</td>
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<td>Modelling</td>
<td>Milne et al. (2011)</td>
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<tr>
<td>Feedback</td>
<td>Kavanagh et al. (2002)</td>
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<td>Feedback</td>
<td>Dodenhoff (1981)</td>
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<td>Feedback</td>
<td>Milne et al. (2011)</td>
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<tr>
<td>Problem Solving</td>
<td>Kavanagh et al. (2002)</td>
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<tr>
<td>Supervisee Involvement</td>
<td>Preparation</td>
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<td>Supervisee Involvement</td>
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<tr>
<td>Supervision Environment</td>
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<td>Supervision Environment</td>
<td>Supportive</td>
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<td>Supervision Environment</td>
<td>Challenging</td>
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</tbody>
</table>

**Barriers to effective supervision**

Some of the barriers affecting the effectiveness of clinical supervision include supervisee beliefs that supervision will increase their stress and be anxiety provoking, uncertainty about the confidentiality, feeling threatened and finding it to be unproductive (Butterworth,
Bell, Jackson, & Pajnikihar, 2008). In addition, the nature of shift work makes it difficult to achieve regular attendance (Buus et al., 2011) and professionally trained staff are more likely than unqualified staff to attend case formulation sessions (Summers, 2006), perhaps due to hierarchies within teams or greater perceived ability to contribute.

Aims
As identified by Buus and Gonge (2009), previous research has relied upon small, convenience samples in generating evidence for the features of effective supervision and has yet to bring a focus to multidisciplinary team supervision. This study aims to:

- Explore the utility of a multidisciplinary model of clinical supervision in the form of a “Clinical Discussion Group” on an acute inpatient mental health ward
- Identify supervision needs from the perspective of the staff themselves, and
- Make recommendations to enhance effective team working.

The study’s objectives are to address the following questions:

1) Does the current format of the Clinical Discussion Group incorporate the components of effective supervision identified in the literature?

2) In what ways do staff find the Clinical Discussion Group helpful and unhelpful; and what do they perceive are the barriers to regular attendance?

3) Taking into consideration evidence from the supervision literature and the views of the staff, in what ways can the group be improved in order to more effectively meet the needs of the service.

Method

Ethical Considerations
This study was reviewed and approved by the University of Bath Department of Psychology Ethics Committee and the local NHS trust Research and Development Department.

Description of the Service
The acute inpatient service provides mental health care to adults whose needs are complex, intense and unpredictable. The multidisciplinary staff team consisting of medics, nurses, health care assistants, occupational therapists, psychologists and art therapists provide evidence based interventions within a recovery model of care. Clinical supervision takes
the form of a “Clinical Discussion Group” (CDG) facilitated fortnightly by a Clinical Psychologist.

The aims of the CDG are to provide time and space for staff to talk about clinical cases, and to increase psychological thinking. This is achieved through conversations between staff members facilitated by the psychologist who tries to pull together the information, introduce psychological models and encourage problem solving and interventions for the staff to take forward. These sessions take place fortnightly during an extended handover period between shifts, lasting 45 minutes. At present staff attending the sessions have little involvement in the preparation for discussions and it is unclear how the CDG is influencing the quality of work on the ward.

**Participants**
All members of clinical staff were invited to take part in the study. Twelve participants were recruited in total from a diverse range of profession including six nurses, four Health Care Assistants, one Occupational Therapist and one Medic. Nine participants were female and three were male.

**Procedure**
Staff were invited to participate in an individual interview via email, poster advertisement and by the primary author (SD) in person. Informed consent was obtained prior to participation. Interviews took place in private rooms located within the inpatient ward, lasted between fifteen and thirty minutes and were all conducted by SD.

Data was collected with the help of a semi-structured interview schedule that focused on five areas: attendance; helpful aspects; outcomes; unhelpful aspects; and changes (Table 2.2). The interviews were digitally recorded and transcribed verbatim by SD.
Table 2.2  Semi-Structured Interview Questions

1. How often do you attend the CDG? What encourages/ discourages you from attending?
2. Can you recall/describe a group discussion that you found particularly important or helpful?
   o What aspects of that discussion made it helpful?
3. Are there other aspects of the discussion groups that you find helpful?
4. In what ways does the group help with your work on the ward?
   o How does the group select the topic for the discussion? How effective do you think this is?
   o How are topics/actions/discussions in the group followed up by staff?
5. Is there anything about the group that you find unhelpful?
6. What changes would you like to see to help the group be more beneficial to you?

Analysis
Themes were identified from the transcribed interview data using Thematic Analysis as described by Braun and Clarke (2006). The analysis used an essentialist (realist) theoretical framework in order to reflect the experiences and meanings of the participants as they were articulated in the interview. NVivo software was used to organise and manage the data.

First the data was read carefully to identify text segments relevant to the research questions. Second, segments of text were systematically given codes. The same segment of text could be given more than one code. Third, coded segments were sorted into potential themes. In order to successfully answer the specific research questions, a broadly deductive approach was considered to be the most useful in forming the main themes. Therefore codes pertaining to the format and procedures of the CDG (Questions 1), impact and usefulness (Question 2) and changes (Question 3) were identified and used to guide the process of generating themes. Finally, the themes were reviewed and refined to ensure they adequately capture the meaning of the data.

To ensure a degree of coherence and reliability of the themes, a second researcher (ML) independently coded and generated themes for a portion (25%) of the data and reviewed the final themes for a consensus to be reached.

Position of the Author
The primary author and data analyser (SD) was a trainee clinical psychologist with two years’ experience working in an acute inpatient mental health ward. In the development of the study, SD liaised closely with the psychologist facilitating the CDG (KC) and therefore
had some ideas about the potential areas for development of the group prior to data collection.

Results

Within the three areas pertaining to the research questions, eleven themes were identified, three within “The Group and how it operates” (Attendance, Discussion Topics and Facilitation), five within “Impact and Usefulness” (Valued by Staff, Understanding a Case, Emotional Benefit, Learning and Working together as a Team) and three within “Changes to the Group” (Organisation, Discussion Topic and Group Outcomes) (Table 2.3). Themes considered to be of greatest significance to the aims and objectives of the study are presented below. More detailed descriptions of all themes are presented in Appendix B.2.

<table>
<thead>
<tr>
<th>1. The Group and how it operates</th>
<th>2. Impact and Usefulness</th>
<th>3. Changes to the Group</th>
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<tbody>
<tr>
<td>Attendance</td>
<td>Valued by Staff</td>
<td>Organisation</td>
</tr>
<tr>
<td>Discussion Topics</td>
<td>Understanding a Case</td>
<td>Discussion Topic</td>
</tr>
<tr>
<td>Facilitation</td>
<td>Emotional Benefit</td>
<td>Group Outcomes</td>
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<td></td>
<td>Learning</td>
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<td></td>
<td>Working Together as a Team</td>
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</tbody>
</table>

The Group and how it operates

Three main themes were identified that related to the operation of the CDG: Attendance; Discussion Topics; and Facilitation.

Attendance

All twelve participants discussed whether they had attended the group. Staff tended to attend one group session per month, with some staff able to attend fortnightly and the least frequent attender just once in five months. Many aspects of the nature of inpatient ward work were suggested in preventing staff from being able to attend, including shift work rotations and having cover for the ward.

P1: “Just that it’s every other Thursday and if you are not working a Thursday you don’t get to go.”

P6: “if you invite everyone in, then suddenly there is no one on the ward…. You can’t really leave a 23 bed acute ward with no staff.”
Some participants acknowledged other barriers to attending the group. Being unaware that
the group is scheduled (Participants 7, 10 and 11) was highlighted as a problem and two
participants suggested that there could be staff reticence due to a lack of knowledge of the
purpose or the group or disinterest.

P8: “in a staff team you are gonna get a group of people who maybe have been here a
long time and say “nothing stresses me, I don’t need to go in” or “I don’t need to do
that, I’m alright” ...in that way you get the same people coming in and the same
people staying out and whether it’s about education or something like that.”

The combination of factors which encourage and prevent staff from attending results in
different individuals being present at each group.

**Discussion Topics**

Eleven of the participants were in agreement that the main focus of CDGs was a clinical
case from the ward. In particular, the emphasis was on complex or difficult cases where
staff wanted ideas for their work.

P12: “there are a few suggestions and we usually say the name which for us is maybe
more difficult...most difficult person or if you know, if behaviour of the person or
patient is challenging really and it is good to discuss that person really. If everybody
can get a better knowledge of how to actually treat the person.”

P9: “which one we think is the best, the one that is most difficult, you know the
most...that we are struggling the most with I suppose.”

Sometimes organisational issues such as management changes and staff relationships were
discussed within CDG sessions (Participants 10 and 11) but this was acknowledged as
being infrequent.

The choice of topic for each group session was decided through discussion at the start of a
session with staff coming to an agreement (11 participants) but a few participants raised
some difficulties with this process, namely spending too long trying to decide (Participant
1) and balancing the priorities of different team members (Participants 1, 6 and 7).

P1: “Um.....I mean it’s difficult isn’t it....coz obviously there is 23 patients and
everyone’s got their own things that they want to deal with, especially now that we are
in teams so you focus on your 7 or 8 patients....so stuff that I probably want to discuss
with my patients, the other nurses wanna discuss their patients.”
Impact and Usefulness

Responses relating to the ways in which participants found the group useful were organised into five main themes which were: Valued by Staff; Understanding a Case; Emotional Benefit; Learning; and Working together as a Team.

Understanding a Case

The benefits of coming together as a group to discuss and generate a greater understanding of a case was raised by all participants but only three explicitly mentioned the use of psychological models such as formulation. In particular, participants talked about the group being an opportunity to hear different perspectives from the staff attending.

P3: “We come to a common understanding of the problem I guess, through putting all our ideas into the pot, and a richer understanding of the problem.”

P2: “...giving you different ways of how.....of why a person might be feeling that way, and maybe going a little bit into formulation and looking at the reasons why they might do that, and that’s good...it’s like the whole of us talking about it, you can sort of gather a different picture.”

As a multidisciplinary team, hearing from all members of the team was valued, especially hearing from members that might otherwise lack opportunity to share their views such as Health Care Assistants (Participants 2, 3, 6 and 11). However, many of the Health Care Assistants included in this study identified some difficulties feeling able to contribute to the discussions.

P10: “I think if some of the other people aren’t confident speaking in the groups, coz I know that there’s a couple of us that aren’t 100% about sharing stuff in the group, you might not get the benefit from it that you need. So you might not say what you are thinking or feeling, or you might not get chance to discuss a particularly area that you would like to, unless someone else brings it up.”

In contrast to the view that it was helpful to gather different perspectives of a case, one participant indicated that the difference could be unhelpful.

P11: “the group sometimes I find have very individual views expressed which are not team views, which is something I am concerned about, that we work as a team, we need to see more of what the teams views are..... what I am trying to say is polarised views sometimes exist and these groups can sometimes make that worse.”
Emotional Benefit

Eleven participants talked about the emotional benefits of attending the group. Talking about the way that they are feeling about a particular issue seemed to be important for staff members’ own emotional wellbeing. Seven participants identified that the most helpful thing about sharing emotions was having these validated and acknowledged by colleagues experiencing the same.

P2: “I think that it’s not….you know it doesn’t go back onto the way we practise, but we relieve…it’s that validation of someone listening to you and understanding you that it’s frustrating and I think it gives us opportunity to look at other ways of, how we feel about it....”

The CDG sessions provided staff with an opportunity to support one another with the difficult nature of the work (six participants).

P1: “um... but also it just made me feel better, better about my job, not necessarily making me a better nurse, or nurse that person in a different way, just sort of supportive.”

Working together as a team

There was discussion from all participants about the ways in which the CDG enabled them to work together to get the best outcomes for patients, six of whom gave specific examples. It was acknowledged that ideally the group would lead to an agreement about how to approach patient care and “come up with a solution” (participant 8), but over half of participants suggested that the group did not manage to achieve this outcome for patients.

P1: “but yeah we never come out of CDG with like a strategy or a plan or anything like that. Not in the ones that I have been in anyway.”

P2: “but I don’t know how much we take on of it afterwards as such....as how we then deal with patients as such, I think that’s maybe something we need to look at.”

It seemed important to disseminate the information and outcomes from the group sessions with other staff involved in the patient’s care. Some participants thought that a summary would be documented in clinical notes or minutes from the meeting (Participants 2, 3, 6, 7 and 8) whereas others highlighted that those staff not in attendance would usually not be made aware of the information.
P9: “I think it can get lost though, with it only being a few members of the team here and then if it’s not handed over sufficiently then you know, we need to be working as a team and I think that that cannot always go as well as it should do here.”

Changes to the group
All participants made suggestions for changes that could be made to improve the CDG: Organisation; Discussion Topic; and Group Outcomes.

Organisation
The need for more frequent CDGs was a common response to questions about change.

P2: “I think weekly would be great, even if we all couldn’t go in weekly. It’s a shame that we don’t have psychology input on a constant basis really.”

But one participant felt that they were too frequent.

P11: “although it is helpful, they should talk about that in their supervision, rather than use the valuable clinical psychology time when we are so under resourced for psychology on the ward.”

Promoting the group to ensure that all staff are aware of not only the presence and schedule of the sessions, but also have an accurate understanding of the purpose and aims was suggested as a way of increasing participation.

P8: “I think it’s about that education isn’t it, that actually it’s more about, well not solely about coming in a talking about what is stressing me out, it’s about finding a solution and finding a way of dealing with that. It’s not…it’s a group thing, it’s not a personal kind of....”how are we gonna help you then”, it’s about.... ....promoting the idea that it’s kind of patient centred and that it’s for the benefit of the actual patients. And I think sometimes the focus goes away from that kind of thing and all the people that don’t come to the meeting don’t feel that that is what it’s there for.”

Five participants wanted to expand on the involvement of different professional groups, particularly medics, and wanted more involvement of psychology on the ward.

P3: “I think it would be very nice if the consultants came in more, they don’t come in enough, only occasionally.”
P2: “So I can see the benefit of it and I think that the perception is that in the acute phase psychology isn’t helpful, and that’s actually not true, it can be helpful and I know that within other trusts, they have psychology input a lot more than our trust do and I think that maybe that is something that we are lacking really.”

Discussion Topic

Although participants had agreed that discussing complex and difficult cases was important, one participant (Participant 5) raised an idea that less prominent “under the radar” cases should have more attention within CDG as there could be scope for helpful approaches that might normally be overlooked.

Selecting the topics of discussion also received suggestions for change. Four participants wanted to consider choosing the topic before the session to save time and also bring more information about the case to the session.

P8: “if we were to say that well OK then these people are going into the meeting, print off the formulation from Rio, and you have got the first ¼ of an hour done, if you know what I mean, so now we can get on with the nitty gritty.”

Outcome from the Group

Seven participants thought that more emphasis could be put on using the group discussions to inform patient care. Being able to have a provision for following up a case discussion was also mentioned to ensure that the group is having an impact on staff work.

P11: “If you are working to a recovery model then we need to look at more of what would help, what are the things that will help this person be discharged from hospital and how they can maintain safety or whatever it is, so that those sort of things need to be discussed from the start.”

The impact of the group on patient care was also limited by the small number of staff able to attend any one session. Five participants suggested that it would be helpful to have a system for sharing session outcomes with the entire ward team which would enhance the consistency and enable the staff to work better together as a team.

P9: “I don’t know if there could be someone who could….if there was someone who would have time to write up what had happened and email everyone what we had
Discussion

This study aimed to determine the extent to which the evidence based components of effective supervision were met by a Clinical Discussion Group on an acute inpatient mental health ward and the views of the staff regarding the helpfulness of the groups for their clinical work. The findings from this analysis have shown that multidisciplinary team supervision in the form of a CDG can be a successful and valuable way of bringing members of different professions together to enhance patient care. As highlighted in previous literature, this approach can be challenging for supervisees (Hyrkäs & Appelqvist-Schmidlechner, 2003) so this study sought participants’ views in order to find out what aspects they find helpful and unhelpful, and develop some guidelines to improve the impact this group has on patient care.

Components of Effective Supervision in the Clinical Discussion Group

In this case, the group sessions took place fortnightly and were of 45 minutes duration. The results showed that many staff members viewed this as inadequate given shift rotations, the potential number of cases to discuss and limited direct psychological input for patients. This is supported by previous research which suggests that more frequent clinical supervision has a greater impact on the work of supervisees (Buus et al., 2011; Gonge & Buus, 2011) with recommendations of hourly sessions attended at least monthly (Edwards et al., 2005).

Of particular importance to the majority of participants in this study, coming together to discuss a complex case enabled them to integrate medical and psychological models to develop a better understanding of a patient’s difficulties. Group case discussion for multidisciplinary teams such as the CDG have an additional advantage of drawing upon many more different personal and professional perspectives in order to come to a useful understanding. This is consistent with a substantial amount of literature indicating that supervision is most successful when it is based upon theoretically informed formulations (Berry et al., 2009; Gonge & Buus, 2011; Milne et al., 2011).

The collaborative understanding achieved through formulations helped staff in this study to remain empathic toward patients in the face of challenging behaviours and maintain a
sense of hopefulness in their work. A supportive supervision environment has been described as essential for psychiatric nurses to aid them in coping with the emotional difficulties of their work (Buus et al., 2011; Scanlon & Weir, 1997). These benefits of supervision have been acknowledged previously as normative functions according to Proctor (1987's) model and evidenced by Brunero and Stein-Parbury (2008) and Severinsson and Hallberg (1996) who found that staff-patient relationships were improved as a result.

Supervisee involvement in the planning and preparation for sessions has been identified as an important component of clinical supervision (Aston & Molassiotis, 2003; Kavanagh et al., 2002; Sloan, 1999). However, the results here showed that although staff took responsibility for choosing a case for discussion, there was no preparation in advance of the sessions and rarely was the summary and outcome documented. Some participants acknowledged that this was an inefficient use of time and suggested that more preparation, although difficult in a busy ward environment, would be a valuable change.

**Impact and Outcomes of the group**

As in previous research (Christofides et al., 2012; Mullarkey et al., 2001), the majority of participants commented that the group had many benefits. There was however a disparity between this perspective and the view of one participant who felt that the group was an unhelpful use of a psychologist’s time and therefore should be reduced, which appeared to be as a result of a misinterpretation of the purpose and aims of the group. This particular participant had thought the group was for staff to make complaints and discuss their disagreements rather than focus on case understanding and patient care. It is possible that this misunderstanding prevents some clinicians from attending through beliefs that it will be unhelpful or involve revealing personal feelings. This raises the importance of promoting the aims of CDG and providing an evidence base for the benefits of team formulation based supervision.

The intention of the CDG was to enable staff to use the new understanding to solve problems in their work and provide effective interventions for patients. Six participants were able to identify occasions where a care plan was put forward and implemented but many others spoke about the group having little impact on their practice. This is a concerning finding given that inpatient ward staff are required to work intensively with
patients and often have limited opportunities for clinical supervision beyond discussion groups.

**Clinical Implications**
Adequate frequency, a well-defined purpose, and preparation for sessions are aspects of clinical supervision deemed to be essential by the Division of Clinical Psychology (Division of Clinical Psychology, 2014). In their policy on supervision, formalised supervision contracts are advocated to make clear the function, format and responsibilities of each member. Multidisciplinary team supervision as described in this study may not lend itself to this form of contract, but a documented version of the aims, purpose, arrangements, format and member responsibilities would be good practice, would resolve the misunderstandings identified in this research and would help orientate new members of the team to the approach.

Putting into practice the understanding gained from supervision is a key element of learning. According to Kolb (1984), learning is achieved through discovery and experience, in a cycle beginning with being actively involved in a situation; then taking time to reflect, review and discuss with others; making sense of the experience by drawing upon theories and advice from those with expertise; and finally planning and implementing the new information. Essentially, within this model learning is a continuous process meaning that ideas implemented through supervision generate further learning when reviewed and evaluated.

![Kolb's Experiential Learning Cycle](image)

**Figure 2.1 Kolb’s Experiential Learning Cycle**

In order for multidisciplinary team clinical supervision to be effective in introducing evidence driven interventions, emphasis must be placed on actively using the
conceptualisation achieved through case discussion. In an inpatient ward environment, this presents many challenges as staff rotations, time restrictions and demanding workloads often overshadow the advances made in supervision sessions. This study would suggest that time set aside to plan the actions to be taken, including how to share the information with staff who were unable to be present, would be a helpful approach to CDGs. Furthermore, CDG’s should aim to revisit and review actions from previous sessions in order to facilitate the cycle of learning which would enable staff to generalise their understanding of one case to situations in the future and ensure the longer term development of service provision.

Strengths and Limitations
This study explored the views of a diverse range of participants including representatives from each profession within the multidisciplinary team. There may however be some bias in sampling given that participation was voluntary and therefore members of staff who did not attend the group, or held more negative views of its purpose and usefulness, may have been less likely to participate. The study sought to encourage everyone to participate, regardless of their views and provided individual interviews rather than focus groups in order to offer an opportunity to be honest and uninhibited by colleagues who may hold different views.

A particular strength of this research is the checks of credibility, using a second analyst to code a portion (25%) of the transcripts and identify themes. The final themes were consistent with those identified within the credibility sample. In addition, as more of the twelve transcripts were coded, saturation was reached with no new themes being identified. Although this indicates a degree of reliability and validity for these results, it is important to note that this study explored the views of staff members from a single acute mental health inpatient ward and therefore the findings may not be generalizable to other settings, though they are consistent with findings discussed in the wider supervision literature.

Future Directions
This study has highlighted themes that should be considered for offering clinical supervision in the form of multidisciplinary case discussion groups for staff working in acute inpatient mental health services. Table 2.4 summarises good practice for such groups that can be drawn from the results.
Table 2.4  

Implications for Practice

To be effective in increasing psychological thinking and improving patient outcomes in acute inpatient mental health wards, Clinical Discussion Groups should:

- Occur frequently, perhaps weekly, to provide adequate opportunity for staff attendance
- Have well-defined and well-promoted aims and purposes
- Encourage supervisee preparation in advance of sessions
- Allow a space for emotional expression and validation
- Set time aside within sessions to plan the approach to be taken by staff for that case
- Share a summary and the outcome of sessions with all staff who were unable to attend
- Review and reflect upon actions implemented in forthcoming sessions

This research has explored the benefits and challenges of a CDG from the perspective of the staff who attend. Although this has generated some ideas for improving the impact of this form of supervision on patient outcomes, further research is needed to objectively measure this. One method of achieving this was described by Green (1999) who employed a “critical incident analysis” methodology (Kemppainen, 2000) to measure staff behavioural changes following clinical supervision. CDG’s should in the future aim to develop and routinely use outcome measures in order to evaluate their efficacy and justify their importance within acute inpatient mental health services.

References


An investigation of perceptions of OCD, caregiver burden, distress and accommodation

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Journal to be targeted

This paper is to be targeted towards Behaviour Research and Therapy. The scope of this journal: “theoretical and experimental analyses of psychopathological processes with direct implications for treatment” and “predictors, moderators and mechanisms of behaviour change” encompasses the aims and clinical impact of this study. In addition, recent research on the impact of OCD for carers as well as carer factors influencing symptoms and treatment outcome in OCD have been published in this journal.
Abstract
Caring for someone with Obsessive Compulsive Disorder has a demonstrated impact on psychological distress and quality of life. Relatives often struggle to know how best to help and it has been suggested that most engage in some form of accommodation of symptoms. Given the impact of OCD on carers, and the potentially detrimental effects of symptom accommodation and interpersonal difficulties on treatment outcome, it seems appropriate to include family members in treatments, but it is not yet fully understood which factors contribute to these interpersonal difficulties. The self-regulation model suggests that carers’ perceptions of an individual’s difficulties will have implications for both emotional and behavioural responses. For this purpose, individuals with OCD and their caregivers completed questionnaires to assess their appraisals of OCD, psychological distress, perceived criticism, caregiver burden and family accommodation. Caregiver perceptions of severe consequences of OCD were associated with increased perceived burden, whereas perceptions of chronicity and consequences were both independently associated with higher levels of caregiver psychological distress. Caregiver appraisals of OCD were not associated with levels of accommodation, but the appraisals of personal control held by the individual with OCD were, with lower perceived control associated with more accommodation. These findings suggest that aspects of the self-regulation model can be used to understand that appraisals of the chronicity, consequences and control one has over OCD can influence the distress of caregivers and also the extent to which they engage in potentially unhelpful accommodating behaviours. It is hoped that this model can help therapists to fine-tune the already efficacious treatments available.

Introduction
Obsessive-Compulsive Disorder (OCD) is defined by the presence of recurrent and persistent intrusive thoughts, images or impulses (obsessions) and/or excessive repetitive mental or physical behaviours performed in an attempt to reduce anxiety (compulsions) (American Psychiatric Association, 2013). Because OCD often affects aspects of daily functioning and home life (such as bathing, eating, working, being with family members) it can disrupt social and interpersonal functioning, particularly within a family context but also within other relationships. This interpersonal impact has been demonstrated by a wealth of research showing that caring for someone with OCD is associated with significant caregiver burden, psychological distress and reduced quality of life (Abreu Ramos-Cerqueira, Torres, Torresan, Negreiros, & Vitorino, 2008; Cicek, Cicek, Kayhan,

Knowing how to respond to someone’s OCD is particularly challenging for their friends and family (Futh, Simonds, & Micali, 2012; Stengler-Wenzke, Trosbach, Dietrich, & Angermeyer, 2004). This is because relatives both want to reduce distress, but also want to avoid worsening the OCD through encouraging it. Much of the research exploring family involvement in OCD has thus focused on symptom accommodation. Accommodation is defined as “the participation of family member(s) in the ritual(s) of a child or adult with OCD” (Amir, Freshman, & Foa, 2000) and includes aiding in completion of rituals, facilitating avoidance, giving reassurance or modifying one’s own activities in response to the individual’s OCD symptoms. Given that family members are naturally motivated to help their loved ones to reduce their distress and decrease the time spent on rituals or compulsions (Calvocoressi et al., 1995) it is understandable that they would engage in accommodation behaviours. Studies have repeatedly shown that up to 96.9% of carers accommodate their family members’ OCD symptoms to some extent (Amir et al., 2000; Calvocoressi et al., 1995; Stewart et al., 2008; Vikas et al., 2011).

Although accommodation may be an effective strategy for carers in reducing their family member’s immediate distress, in the longer term it is thought likely to enable the individual with OCD to avoid confronting their obsessional thoughts, strengthening the obsessional beliefs and increasing the need for further accommodation. Studies have certainly found that accommodation is associated with the severity of OCD symptoms (Abreu Ramos-Cerqueira et al., 2008; Boeding et al., 2013; Stewart et al., 2008), poorer treatment outcome (Boeding et al., 2013; Calvocoressi et al., 1995) relationship difficulties (Boeding et al., 2013) and increased carer distress (Abreu Ramos-Cerqueira et al., 2008; Calvocoressi et al., 1995). The direction of causality is however unclear.

Relationships between individuals with OCD and their caregivers can understandably become strained. OCD symptoms are associated with difficulties with intimacy in romantic relationships (Abbey, Clopton, & Humphreys, 2007) and decreased marital satisfaction (Boeding et al., 2013). Communication between individuals with OCD and family members OCD has been explored using the concepts of Perceived Criticism and Expressed Emotion. Criticism from a family member has been associated with worse treatment outcome (D. L. Chambless & Steketee, 1999; Cherian, Pandian, Math, Kandavel, &
Reddy, 2014; Renshaw, Chambless, & Steketee, 2003; Van Noppen & Steketee, 2009) and increased anxiety and depression for the individual with OCD (Steketee, Lam, Chambless, Rodebaugh, & McCullouch, 2007). It is not yet fully understood which factors lead to interpersonal difficulties in adult relationships, but a study with children and their families found that parental depression was associated with high Expressed Emotion and that parents who held appraisals of blame and responsibility for their child’s symptoms were more likely to be critical (Peris, Benazon, Langley, Roblek, & Piacentini, 2008).

Given the impact of OCD on carers, and the potential effect of symptom accommodation and interpersonal difficulties on treatment outcome, it seems appropriate to include family members in treatments. The National Institute for Health and Care Excellence have recognised this by clearly recommending that family members should be included in the treatment of OCD, particularly in childhood OCD (NICE, 2005). A recent meta-analytic review by Thompson-Hollands, Edson, Tompson, and Comer (2014) identified seven family inclusive treatments for adults with OCD, some providing psychoeducation to families, and others delivering more targeted skills training to consider how aspects of the environment might contribute towards the perpetuation of OCD. All family inclusive treatments resulted in a large effect on OCD symptoms but treatments specifically addressing family accommodation achieved larger effects (ES: Pooled d=1.09) on functioning than those not focusing on accommodation (ES: Pooled d=0.58; Q_{between}=7.14, p<0.001). To date, studies have yet to directly compare family inclusive treatments with individual treatment but Abramowitz et al. (2013) found that a pilot couples intervention obtained an effect size greater than that of individual CBT reported in a meta-analysis by Eddy, Dutra, Bradley, and Westen (2004) (2.68 vs. 1.53) suggesting that this is an encouraging area for improving psychological treatments for OCD.

The Self-Regulation model as applied to caregivers (Leventhal & Diefenbach, 1991; Leventhal, Nerenz, & Steel, 1984) suggests that carers’ perceptions of an individual’s difficulties will have implications for their emotional and behavioural responses. Nine components of illness perceptions have been empirically supported with the use of the Revised Illness Perceptions Questionnaire (IPQ-R): beliefs about the number of symptoms attributed to the illness; chronicity; cyclical nature, severity of the consequences; personal controllability; potential for treatment; personal understanding of the condition; emotional representations; and causes (Moss-Morris et al., 2002). The link between these components of caregivers’ appraisals and their psychological and behavioural responses has been
demonstrated extensively within the physical health field (Hagger & Orbell, 2003). Areas of mental health research have also begun to find that carer responses are regulated to some extent by their appraisals of their family members’ condition. Within the psychosis literature perceptions of lack of patient control of their symptoms are associated with increased caregiver distress, depression and lower self-esteem (Kuipers et al., 2007), and pessimistic beliefs about chronicity associated with more stress (Fortune, Smith, & Garvey, 2005; Kuipers et al., 2007). Carer appraisals of patient lack of control or cure (Barrowclough, Lobban, Hatton, & Quinn, 2001) and blame or responsibility (Grice et al., 2009) have both been found to be associated with elevated levels of critical behaviour. In the eating disorder field, Whitney, Haigh, Weinman, and Treasure (2007) found that carers who perceived more negative consequences and believed that the problems were attributable to the sufferer’s personality were more likely to look upon their caregiving role negatively.

It is possible that discrepancies between patient and carer perceptions of their condition may also contribute towards interpersonal difficulties because by their nature, relationships are defined by the interaction between two people (Lobban, Barrowclough, & Jones, 2006). For example previous work in this area has shown that discrepancies in the perceptions of the consequences of psychosis are associated with more anxiety, depression and low self-esteem for the patient, whereas differences in perception of control had an impact on carer distress.

Research purposely focussing on carer perceptions has yet to be extended to OCD. However, caregiver appraisals have been indirectly alluded to but not specifically researched. In particular, Torres et al. (2012) speculated that family members who believe that the patient has control over behaviours (washing, ordering, checking, hoarding, avoidance) and do not do so because they “don’t want to”, “lack the will to” or want everything to be done “their own way” to “get attention” would feel irritated or intolerant and experience more burden. Control and predictability have also appeared to be important in studies examining coping in parents of children with OCD (Futh et al., 2012; Storch et al., 2009). Understanding the caregiver appraisals which contribute towards accommodation and criticism may help to identify approaches to reduce these maladaptive behaviours. Given that appraisals of patient control over compulsions has been hypothesised to be a significant predictor of caregiver burden and coping behaviours in OCD, and the findings in other mental health disorders that carer appraisals of chronicity
and consequence severity play a significant role in caregiver distress and criticism, these three components of illness perceptions were selected for investigation in this study. Table 3.1 summarises the hypotheses to be tested, together with the measures used to examine them.

**Table 3.1 Summary of Study Hypotheses and corresponding measures**

<table>
<thead>
<tr>
<th>Hypothesis</th>
<th>Dependent Variable</th>
<th>Independent Variables</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hypothesis 1:</strong> Carer perceived burden will be associated with carer perceptions of their relative’s control over OCD; perceptions of chronicity; and perceptions of severity of consequences of OCD</td>
<td>ECI Total Negative subscale</td>
<td>Carer IPQ-R Personal Control Carer IPQ-R Timeline Acute/Chronic Carer IPQ-R Consequences OCI-R</td>
</tr>
<tr>
<td><strong>Hypothesis 2:</strong> Carer psychological distress will be associated with carer perceptions of their relative’s control over OCD; perceptions of chronicity; and perceptions of severity of consequences of OCD</td>
<td>Carer Distress-Combined PHQ-9 and GAD-7</td>
<td>Carer IPQ-R Personal Control Carer IPQ-R Timeline Acute/Chronic Carer IPQ-R Consequences OCI-R</td>
</tr>
<tr>
<td><strong>Hypothesis 3:</strong> Accommodation will be associated with carer perceptions of their relative’s control over OCD; perceptions of chronicity; and perceptions of severity of consequences of OCD</td>
<td>FAS-SR</td>
<td>Carer IPQ-R Personal Control Carer IPQ-R Timeline Acute/Chronic Carer IPQ-R Consequences OCI-R</td>
</tr>
<tr>
<td><strong>Hypothesis 4:</strong> Perceived criticism of the OCD sufferer by the carer will be associated with carer perceptions of their relative’s control over OCD; perceptions of chronicity; and perceptions of severity of consequences of OCD</td>
<td>PC- Individual with OCD perception of OCD specific criticism from relative</td>
<td>Carer IPQ-R Personal Control Carer IPQ-R Timeline Acute/Chronic Carer IPQ-R Consequences OCI-R</td>
</tr>
<tr>
<td><strong>Hypothesis 5:</strong> Carer and Individual with OCD Depression will be associated with discrepancies between perceptions of control over OCD; perceptions of chronicity; and perceptions of severity of consequences of OCD</td>
<td>Carer PHQ-9 Individual with OCD PHQ-9</td>
<td>Carer IPQ-R Personal Control Carer IPQ-R Timeline Acute/Chronic Carer IPQ-R Consequences</td>
</tr>
</tbody>
</table>
Method

Statement of ethical approval
This study was reviewed and given favourable opinion by the Bradford Leeds Research Ethics Committee (ref.14/YH/0179) and the University of Bath Department Of Psychology Ethics Committee.

Participants
Participants were dyads consisting of one individual with OCD and one family member or friend who could be considered to be a caregiver. To be included in the study, individuals had to meet DSM-IV diagnostic criteria for OCD, be over 18 years of age and English speaking. Caregivers were defined as any family member or friend over the age of 18 whom, at the time of the study, was living with the individual with OCD or providing care or support on a regular basis either in person or via telephone. Figure 3.1 shows recruitment into the study.

<table>
<thead>
<tr>
<th>Recruitment from:</th>
<th>Contacted Researcher to indicate interest-sent full study information 105</th>
<th>No Further contact 66</th>
</tr>
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<tbody>
<tr>
<td>OCD support groups</td>
<td>Agreed to Participate 39</td>
<td>No Further contact 1</td>
</tr>
<tr>
<td>Website Advertisements</td>
<td>SCID completed by phone 38</td>
<td>Questionnaires not completed 3</td>
</tr>
<tr>
<td>NHS Services</td>
<td></td>
<td>Partial Questionnaires Completed 4 (3 OCD complete, carer incomplete; 1 carer complete, OCD incomplete)</td>
</tr>
<tr>
<td>Social Media</td>
<td></td>
<td>Questionnaires Completed 31</td>
</tr>
</tbody>
</table>

Figure 3.1 Consort Diagram of the recruitment of participant dyads

Statistical Power
Previous research investigating the impact of carer perceptions on affect and behaviour in the field of psychosis has obtained large effect sizes (Barrowclough et al., 2001; Fortune et
Therefore, using g*power a sample size of 26 dyads was determined to be necessary to achieve sufficient power determined (power = 0.8; effect size = 0.5; α error prob. = 0.05). Given the analytic method used, the study over recruited participants in order to be able to achieve enough power to conduct regression analyses without ‘overfitting’, assuming a requirement of ten participants for each independent variable (Babyak, 2004; Casson & Farmer, 2014; Green, 1991; Peduzzi, Conato, Feinstein, & Holford, 1995).

Table 3.2 Demographic characteristics of the sample (N = 31 dyads)

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>%</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual with OCD</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>31.5</td>
<td>9.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>10</td>
<td>32.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>21</td>
<td>67.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
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<td></td>
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<tr>
<td>White British</td>
<td>27</td>
<td>87.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other White</td>
<td>2</td>
<td>6.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Black or Black British</td>
<td>1</td>
<td>3.2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>3.2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>42.2</td>
<td>13.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>16</td>
<td>51.6</td>
<td></td>
<td></td>
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<tr>
<td>Female</td>
<td>15</td>
<td>48.4</td>
<td></td>
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<tr>
<td>Ethnicity</td>
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<td></td>
</tr>
<tr>
<td>White British</td>
<td>29</td>
<td>93.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White Other</td>
<td>1</td>
<td>3.2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>3.2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relationship to individual with OCD</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spouse</td>
<td>11</td>
<td>35.5</td>
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<tr>
<td>Partner</td>
<td>9</td>
<td>29.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parent</td>
<td>9</td>
<td>29.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sibling</td>
<td>1</td>
<td>3.2</td>
<td></td>
<td></td>
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<tr>
<td>Friend</td>
<td>1</td>
<td>3.2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Co-habiting with individual with OCD</td>
<td>22</td>
<td>71.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amount of caregiving (hours/week)*</td>
<td>13.2</td>
<td>15.9</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Some missing values if participant did not disclose this information

Procedure

Participants were recruited through website, email and social media advertisements; study coordinator attendance at support groups; and via clinicians working in NHS mental health services. OCD-Carer dyads responding to the advertisements were screened over the telephone by the primary researcher where appropriate (i.e., if diagnosis by NHS clinician unknown). During this telephone interview the OCD scale of Structured Clinical Interview
for DSM-IV (SCID; First, Spitzer, Gibbon, & Williams, 1996) was administered to establish that DSM-IV diagnostic criteria were met. Diagnostic reliability was assessed by inter-rating of a random sample of 15% of telephone interviews by a senior supervisor. Inter-rater agreement was 100%. Any questions about whether an individual met criteria for OCD were discussed during supervision. If the dyad met all eligibility criteria following this interview, they were enrolled in the study and allocated matched participant numbers.

OCD-Carer dyads completed online questionnaires independently of one another. Participants who preferred to complete paper questionnaires were sent hard copies in the post with a pre-paid envelope in order to return them. Upon completion participants were offered a £5 voucher as a token of our appreciation.

**Measures**

For the individual with OCD:

- **Obsessive Compulsive Inventory- Revised (OCI-R).** This 18-item self-report scale (Foa et al., 2002) measures the degree of distress experienced as a result of OCD symptoms. The scale generates a total score and scores for six subscales of OCD symptoms. The OCI-R has good psychometric properties for both clinical and control populations with good construct validity, internal consistency and diagnostic predictability (Abramowitz & Deacon, 2006; Foa et al., 2002; Hajcak, Huppert, Simons, & Foa, 2004; Huppert et al., 2007) making it ideally suited for research.

- **Patient Health Questionnaire- 9 item version (PHQ-9).** This nine-item self-report depression module is used as a brief diagnostic and severity measure in research and clinical practice (Kroenke, Spitzer, Williams, & Löwe, 2010). The measure has demonstrated good sensitivity, specificity and reliability (Kroenke et al., 2010) and in comparison to other established depression screening tools, has superior criterion validity (Löwe et al., 2004).

- **Generalised Anxiety Disorder- 7 item version (GAD-7).** The GAD-7 is a self-report scale to measure severity of anxious feelings. Originally developed as a diagnostic tool for Generalised Anxiety Disorder, the GAD-7 has also been shown to have good psychometric properties as a screening tool for other anxiety disorders including panic, social anxiety and post-traumatic stress disorder (Kroenke et al., 2010).
• Perceived Criticism (PC) (Hooley & Teasdale, 1989). The original single-item PC has demonstrated construct validity and convergent validity with observer measures of criticism and relatives’ own report of criticism and has good test-retest reliability (Dianne L Chambless & Blake, 2009; Dianne L Chambless, Bryan, Aiken, Steketee, & Hooley, 1999; Hooley & Teasdale, 1989). A modified version of the PC scale was used in this study. The scale was adapted by Boeding et al. (2013) in order to specifically measure OCD related criticism in patient-carer relationships. The scale has four items; two relating to general perceptions of criticism and two for criticism related to OCD symptoms. Boeding et al. (2013) found that this adapted measure had good reliability with Cronbach’s alphas of 0.78 and 0.89 for the patient and relative total scores respectively. For the purpose of the analyses, the patient report item for OCD criticism was used individually rather than a summed total scale as proposed by Boeding et al. (2013).

• Revised Illness Perceptions Questionnaire (IPQ-R) (Moss-Morris et al., 2002). The IPQ-R has nine subscales each with good internal reliability with Cronbach’s alphas between 0.78 to 0.89 (Moss-Morris et al., 2002), namely: identity, timeline, consequences, personal control, treatment control, illness coherence, timeline cyclical, emotional representations and cause. The questionnaire is designed to be adapted for use in different illnesses, and has been utilised for research with participants with mental health problems (e.g., Holliday, Wall, Treasure, & Weinman, 2005; Lobban, Barrowclough, & Jones, 2004) but as yet has not been used to explore the illness perceptions of those with OCD. In order to address the research questions this study used three subscales: personal control, timeline and consequences (table 3.1).

Caregiver measures:

• Revised Illness Perceptions Questionnaire (IPQ-R) (Moss-Morris et al., 2002). As the measure was designed to assess patient perceptions of their difficulties, minor adaptations were made to the wording of all items (e.g., “my OCD” became “my friend/relative’s OCD”).

• The Experience of Caregiving Inventory (ECI) (Szmukler et al., 1996). This 66 item self-report questionnaire is a measure of stress, appraisal and coping in carers of an individual with a severe mental illness. The measure has eight negative focus and two positive focus subscales. Given the problem in operationalising the concept of burden (Schene, Tessler, & Gamache, 1996), the ECI was selected in favour of
other measures of burden as it addresses the problem of defining burden by measuring instead caregiver appraisals of the total caregiving experience. The ECI has been shown to have good construct validity, predicting scores on the General Health Questionnaire (Joyce, Leese, & Szmukler, 2000; Szmukler et al., 1996). It also has good internal consistency with Cronbach’s alphas for the subscales between 0.74 to 0.91 (Szmukler et al., 1996).

- Family Accommodation Scale-Self Rated (FAS-SR) (Pinto, Van Noppen, & Calvocoressi, 2013). A 19-item self-report measure of the nature and frequency of a family member’s accommodating behaviours towards a relative with OCD including; participation in OCD symptom-related behaviour, modification of functioning of the carer, distress caused by accommodating and consequences of not participating in symptom-related behaviours. Initial psychometric examination of the scale have shown that it strongly agrees with the interview rated version, has good convergent validity with other measures of family functioning and has excellent internal consistency (Cronbach’s alpha =0.90) making it an accurate and efficient measure of accommodation (Pinto et al., 2013).

- Patient Health Questionnaire- 9 item version (PHQ-9).

- Generalised Anxiety Disorder- 7 item version (GAD-7).

- Perceived Criticism (PC) (Hooley & Teasdale, 1989).

**Analysis**

First, missing data were identified and dealt with. If there was only one missing item for a scale, this item was replaced with the median of other items of the scale for this participant. In the case of more than one missing item, the scale of this participant was not used in the analysis.

Analyses were conducted using SPSS for Windows (version 22.0.0.1). Stepwise linear regression analyses were used to examine the association between the dependent variables (caregiver burden, caregiver psychological distress, perceived criticism and accommodation) with the independent variables (appraisals of chronicity, consequences and personal control, and OCD severity). Pearson’s Correlations were used to test relationships between OCD sufferer and caregiver appraisals. Differences between the means of the appraisals for each dyad member were tested using mixed design analysis of variance (ANOVA).
Results

Missing data analyses

Two participants had one item missing from a subscale of the OCI-R which was then imputed using the median of the remaining subscale items for the participant; no questionnaires had more missing data.

Table 3.3 Mean and standard deviations for all study variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Individual with OCD</th>
<th>Carer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>General Psychopathology</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PHQ-9</td>
<td>14.3</td>
<td>6.7</td>
</tr>
<tr>
<td>GAD-7</td>
<td>14.0</td>
<td>4.8</td>
</tr>
<tr>
<td>Psychological Distress (sum of PHQ-9 and GAD-7)</td>
<td>28.3</td>
<td>10.6</td>
</tr>
<tr>
<td>IPQ-R (average item score)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Timeline (acute/chronic)</td>
<td>4.1</td>
<td>0.7</td>
</tr>
<tr>
<td>Consequences</td>
<td>4.1</td>
<td>0.6</td>
</tr>
<tr>
<td>Personal Control</td>
<td>3.7</td>
<td>0.8</td>
</tr>
<tr>
<td>Perceived Criticism</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PC 1: In general, how much do you feel you criticise your family member or friend?</td>
<td>3.7</td>
<td>2.5</td>
</tr>
<tr>
<td>PC 2: In general, how much do you feel your family member or friend criticises you?</td>
<td>4.2</td>
<td>2.9</td>
</tr>
<tr>
<td>PC 3: How much do you feel your family member or friend criticises you regarding OCD issues?</td>
<td>4.2</td>
<td>2.6</td>
</tr>
<tr>
<td>PC 4: How much do you feel you criticise your family member or friend regarding OCD issues?</td>
<td>3.5</td>
<td>2.2</td>
</tr>
<tr>
<td>OCI-R</td>
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<td></td>
</tr>
<tr>
<td>Total Severity</td>
<td>31.6</td>
<td>11.1</td>
</tr>
<tr>
<td>Hoarding</td>
<td>2.5</td>
<td>3.0</td>
</tr>
<tr>
<td>Checking</td>
<td>6.0</td>
<td>3.4</td>
</tr>
<tr>
<td>Ordering</td>
<td>5.5</td>
<td>3.3</td>
</tr>
<tr>
<td>Neutralising</td>
<td>3.3</td>
<td>3.6</td>
</tr>
<tr>
<td>Washing</td>
<td>4.7</td>
<td>4.5</td>
</tr>
<tr>
<td>Obsessing</td>
<td>9.5</td>
<td>3.0</td>
</tr>
<tr>
<td>ECI (average item score)</td>
<td></td>
<td></td>
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<tr>
<td>Total Negative</td>
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<tr>
<td>Total Positive</td>
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<tr>
<td>Difficult Behaviours</td>
<td></td>
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<tr>
<td>Negative Symptoms</td>
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<tr>
<td>Stigma</td>
<td></td>
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<tr>
<td>Problems with Services</td>
<td></td>
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<tr>
<td>Effects on Family</td>
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<td>Need to Back Up</td>
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<td>Dependency</td>
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<td>Loss</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive Personal Experience</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good Aspects of Relationship</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FAS</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Overview

The importance of OCD sufferer and caregiver appraisals for caregiver burden distress, criticism and accommodation was analysed. First, descriptive statistics for each of the study variables are shown. Secondly the contribution of caregiver appraisals of OCD in explaining the variance in perceived burden and psychological distress is presented. Next the association between these appraisals and perceived criticism and accommodation is investigated. Lastly, the discrepancies between OCD appraisals of the suffer and caregiver are established and the association between discrepancies and distress and perceived criticism is presented.

Descriptive Statistics

Means and standard deviations for all study variables are reported in table 3.3.

Caregiver appraisals of OCD, perceived burden and psychological distress

As the primary analysis, stepwise linear regression analyses were conducted as planned (a priori) to examine the association of caregiver appraisals of OCD chronicity, severe consequences and personal control (independent variables) with two separate dependent variables: caregiver perceived burden (ECI Total Negative subscale) and caregiver psychological distress. Due to the ratio of participants to variables, two consecutive analyses were used. First, the three appraisal subscale predictors (timeline-chronic, consequences and personal control) were entered stepwise. Significant variables were then re-entered into a further analysis along with OCD severity as measured by the OCI-R total score in order to control for the contribution of OCD severity. Tables 3.4 and 3.5 summarise the results of the linear regression analyses.

For perceived burden, perceptions of consequences of OCD (IPQ-R Consequences) entered first into the regression model, explaining 44.0% of the variance (F(1,29)=22.788, p<0.001). Perceptions of chronicity (IPQ-R Timeline (acute/chronic)), perceptions of personal control (IPQ-R Personal Control) and OCD severity (OCI-R Total Severity) were not independently associated with perceived burden. Thus greater caregiver perceptions of consequences of OCD were associated with greater perceived burden.
Table 3.3 Mean and standard deviations for all study variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Individual with OCD</th>
<th>Carer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>General Psychopathology</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PHQ-9</td>
<td>14.3</td>
<td>6.7</td>
</tr>
<tr>
<td>GAD-7</td>
<td>14.0</td>
<td>4.8</td>
</tr>
<tr>
<td>Psychological Distress (sum of PHQ-9 and GAD-7)</td>
<td>28.3</td>
<td>10.6</td>
</tr>
<tr>
<td>IPQ-R (average item score)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Timeline (acute/chronic)</td>
<td>4.1</td>
<td>0.7</td>
</tr>
<tr>
<td>Consequences</td>
<td>4.1</td>
<td>0.6</td>
</tr>
<tr>
<td>Personal Control</td>
<td>3.7</td>
<td>0.8</td>
</tr>
<tr>
<td>Perceived Criticism</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PC 1: <em>In general,</em> how much do you feel you criticise your family member or friend?</td>
<td>3.7</td>
<td>2.5</td>
</tr>
<tr>
<td>PC 2: <em>In general,</em> how much do you feel your family member or friend criticises you?</td>
<td>4.2</td>
<td>2.9</td>
</tr>
<tr>
<td>PC 3: How much do you feel your family member or friend criticises you regarding OCD issues?</td>
<td>4.2</td>
<td>2.6</td>
</tr>
<tr>
<td>PC 4: How much do you feel you criticise your family member or friend regarding OCD issues?</td>
<td>3.5</td>
<td>2.2</td>
</tr>
<tr>
<td>OCI-R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Severity</td>
<td>31.6</td>
<td>11.1</td>
</tr>
<tr>
<td>Hoarding</td>
<td>2.5</td>
<td>3.0</td>
</tr>
<tr>
<td>Checking</td>
<td>6.0</td>
<td>3.4</td>
</tr>
<tr>
<td>Ordering</td>
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<td>3.3</td>
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<tr>
<td>Neutralising</td>
<td>3.3</td>
<td>3.6</td>
</tr>
<tr>
<td>Washing</td>
<td>4.7</td>
<td>4.5</td>
</tr>
<tr>
<td>Obsessing</td>
<td>9.5</td>
<td>3.0</td>
</tr>
<tr>
<td>ECI (average item score)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Negative</td>
<td>1.6</td>
<td>0.7</td>
</tr>
<tr>
<td>Total Positive</td>
<td>2.3</td>
<td>0.7</td>
</tr>
<tr>
<td>Difficult Behaviours</td>
<td>1.3</td>
<td>0.8</td>
</tr>
<tr>
<td>Negative Symptoms</td>
<td>1.8</td>
<td>0.9</td>
</tr>
<tr>
<td>Stigma</td>
<td>1.4</td>
<td>0.8</td>
</tr>
<tr>
<td>Problems with Services</td>
<td>1.4</td>
<td>1.0</td>
</tr>
<tr>
<td>Effects on Family</td>
<td>1.4</td>
<td>0.9</td>
</tr>
<tr>
<td>Need to Back Up</td>
<td>1.4</td>
<td>0.8</td>
</tr>
<tr>
<td>Dependency</td>
<td>2.5</td>
<td>1.1</td>
</tr>
<tr>
<td>Loss</td>
<td>1.6</td>
<td>0.9</td>
</tr>
<tr>
<td>Positive Personal Experience</td>
<td>1.9</td>
<td>0.8</td>
</tr>
<tr>
<td>Good Aspects of Relationship</td>
<td>2.8</td>
<td>0.7</td>
</tr>
<tr>
<td>FAS</td>
<td>16.2</td>
<td>13.8</td>
</tr>
</tbody>
</table>

For caregiver psychological distress (sum of PHQ-9 and GAD-7) perceptions of chronicity and consequences both entered into the regression model, explaining a total of 27.3% (15.2% chronicity, 12.1% consequences) of the variance (F(2,28)=5.253, p=0.012). Perceptions of personal control and OCD severity were not independently associated with
caregiver psychological distress. Thus greater caregiver perceptions of OCD chronicity and consequences were associated with higher levels of psychological distress.

Table 3.4 Summary of stepwise linear regression analysis predicting caregiver perceived burden measured by the ECI Total negative subscale

<table>
<thead>
<tr>
<th>Predictor</th>
<th>Unstandardised Coefficients</th>
<th>β</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carer IPQ-R Consequences</td>
<td>5.024</td>
<td>1.052</td>
<td>0.663</td>
<td>4.774</td>
</tr>
</tbody>
</table>

Note. $R^2=0.440$

Table 3.5 Summary of stepwise linear regression analysis predicting caregiver psychological distress

<table>
<thead>
<tr>
<th>Predictor</th>
<th>Unstandardised Coefficients</th>
<th>β</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carer IPQ-R Timeline Acute/Chronic</td>
<td>0.799</td>
<td>0.358</td>
<td>0.361</td>
<td>2.229</td>
</tr>
<tr>
<td>Carer IPQ-R Consequences</td>
<td>0.698</td>
<td>0.323</td>
<td>0.349</td>
<td>2.159</td>
</tr>
</tbody>
</table>

Note. $R^2=0.273$

Appraisals of OCD, perceived criticism and accommodation

Stepwise linear regression analyses were conducted as described above with separate analyses for each of the dependent variables (OCD specific perceived criticism, general perceived criticism and accommodation) a priori.

None of the predictors entered into the regression model for either of the perceived criticism measures. Therefore, the level of caregiver criticism perceived by the individual with OCD was not associated with caregiver appraisals of OCD chronicity, consequences or personal control, or the severity of OCD symptoms.

For accommodation (FAS) none of the three caregiver OCD appraisal scales entered into the regression model. OCD severity did enter into the model explaining 13.3% of the variance ($F(1,29)=4.453$, $p=0.044$). Thus when these variables were considered, greater symptom severity was associated with greater family accommodation.
Given that caregiver appraisals appeared not to be associated with their degree of accommodating behaviours and OCD severity accounted for a relatively small proportion of the variance, a post hoc stepwise regression analysis of the association between the appraisals of the individual with OCD regarding chronicity, consequences and personal control and family accommodation was conducted. Personal control entered into the model, whereas the other appraisal scales and OCD severity did not (F(1,29)=5.872, p=0.22). In this model, appraisals of personal control of OCD made by the sufferer accounted for 16.8% of the variance with appraisals of higher control associated with less caregiver accommodation.

**Discrepancy between appraisals**

A mixed design ANOVA was conducted to investigate whether appraisals made by the caregiver were different to those made by the sufferer. Mauchly’s test of sphericity was not significant indicating that there were no autocorrelation problems. Levene’s test also indicated that there were no problems with equality of variance (p>0.05). The mixed ANOVA indicated that there was no significant effect of Illness Perceptions (Chronicity, Consequences, Personal Control) (F(2,120) = 2.83, p>0.05). There was also no effect of dyad member (Individual with OCD vs. Carer) (F(1,60) = 2.26, p>0.05), nor were there any indication of interaction (F(2,120) = 0.86, p>0.05).

**Discussion**

This study aimed to explore the importance of appraisals of OCD in explaining the variance in caregiver burden, psychological distress, critical behaviours and accommodation. This is the first study to apply the self-regulation model (Leventhal & Diefenbach, 1991; Leventhal et al., 1984) to the distress and behaviours of carers of people with OCD.

Caregiver perceptions of the severity of consequences of OCD for the patient were associated with greater perceived burden, whereas perceptions of chronicity and severity of consequences were associated with greater caregiver psychological distress. This is consistent with Torres et al. (2012)’s hypothesis that caregiver appraisals may play a role in determining their emotional response and experience of burden. However, contrary to Torres et al. (2012)'s prediction, it was not appraisals of control over OCD that was associated with perceived burden, but a perception that the consequences of OCD for their
friend or relative were severe, above and beyond the effect of actual OCD severity. This finding is consistent with literature in the eating disorders field where carers who perceived more negative consequences were more likely to look upon their caregiving role negatively (Whitney et al., 2007). In the present study, caregiver appraisals of chronicity and consequence severity were together associated with caregiver distress. This association is different to those found in other mental health problems such as psychosis where although pessimistic beliefs about chronicity have been associated with more stress as in this study (Fortune et al., 2005; Kuipers et al., 2007), perceptions of lack of patient control of their symptoms have been found to have more of a role in caregiver distress, depression and self-esteem (Kuipers et al., 2007). Thus it appears that there is perhaps something about the nature of OCD that, unlike in psychosis, appraisals of their friend or relatives’ personal control over their symptoms are not a significant factor in the degree of distress experienced by a caregiver whereas appraisals of chronicity and severe consequences are.

The examination of the association of caregiver appraisals of OCD on critical behaviours found that the variance in perceived criticism of the individual with OCD from the carer could not be explained by any of the appraisal measures, nor OCD severity. This is in contrast with findings of studies with caregivers of patients with psychosis where caregiver appraisals of control, responsibility or blame were related to criticism (Barrowclough et al., 2001; Grice et al., 2009).

In the present study, accommodation of OCD symptoms by the caregiver was not found to be associated with any of the caregiver appraisal measures. As in other research (Abreu Ramos-Cerqueira et al., 2008; Boeding et al., 2013; Stewart et al., 2008), results in this study showed that OCD severity was associated with greater accommodation. However this accounted for only a small proportion of the variance. Interestingly, when the appraisals of the individual with OCD were considered, their perception of their own control over OCD symptoms was associated with their caregivers’ accommodation accounting for more of the variance than OCD severity. Given the cross-sectional nature of this study, the directionality of this association cannot be determined. Perceptions of a lack of control over symptoms could lead individuals with OCD to seek more accommodation from their family members or friends in an attempt to reduce distress. On the other hand, accommodation by caregivers could in turn lead the individual with OCD to develop an appraisal of reduced control.
As an additional question, the present study also looked at discrepancies between the appraisals of people with OCD and their caregivers. The results showed that appraisals of chronicity, consequences and personal control for each member of the dyad did not differ significantly from one another suggesting that people with OCD and their caregivers tend to share the same perceptions on these measures.

This study makes four key contributions to the understanding of the interpersonal impact of OCD. Firstly, factors that protect caregivers against the experience of burden and psychological distress include their appraisals of the chronicity and consequences of their relative or friends’ OCD. Those who hold more optimistic perceptions in these areas may be better able to cope with the challenge of supporting their loved one. This raises an important consideration for services who should consider the use of these findings in relation to aspects of the self-regulation model in providing support for carers of individuals with OCD.

Secondly, this study advances previous research in considering the contribution of cognitive appraisals of OCD to the degree of accommodation engaged in by the caregiver. Previously, research has shown that there is a potentially bi-directional relationship between OCD severity and accommodation (Boeding et al., 2013). However, this study has shown that the appraisals of personal control over symptoms made by the individual with OCD have a greater association with caregiver accommodation than both OCD severity and caregiver appraisals. Given the recent development of family inclusive interventions, this finding has potential implications for the identification of methods for reducing maladaptive accommodating behaviours. Depending upon the direction of this association, helping the individual with OCD to develop appraisals of increased control might lead them to seek less support from their caregiver. On the other hand, interventions to help caregivers reduce their accommodating behaviour in a way that enhances the individual with OCD’s sense of control could see a benefit in terms of treatment outcome.

Thirdly, contrary to research in other fields (e.g., psychosis and eating disorders), perceived criticism from the caregiver was not found to have an association with any appraisals of OCD, nor with OCD severity. This result cannot be explained by current models. Thus we are yet to find factors specific to the relationship between people with OCD and their caregivers which could be targeted by interventions to reduce interpersonal difficulties arising from OCD.
The final contribution to the literature made by this study is in the consideration of discrepant appraisals of people with OCD and their caregivers. It seems that both members of the dyad tend to hold the same views of OCD. These findings show that family members and friends have the potential to be a huge support throughout the process of treatment.

There are a number of limitations to consider when interpreting the results of this study. Firstly, the association between carer perceptions of OCD consequences and their experience of caregiving burden was found to have a relatively large $R^2$ value of 0.44 which could be indicative of a conceptual overlap between burden and perceived consequences. The use of the Experience of Caregiving Inventory (ECI) rather than other available measures of burden was intended to ensure that the two concepts were conceptually distinct, one measuring caregiver appraisals of the consequences of OCD for their relatives (IPQ-R) and the other measuring appraisals of the personal impact of caring for their relative with OCD (ECI). Although these two measures have face validity, the results need to be interpreted with caution. Another limitation of this study is the small sample size which limits the statistical power available. However, to account for this the number of variables entered into the regression analyses was reduced and theoretically derived, so the significant findings can be considered as likely to be valid. The study utilised a convenience sample of participants which is typical of research in this field. Although a variety of sources were used to recruit participants, which is preferable to relying solely upon internet methods, it is possible that the sample used in this study is not representative of the all sufferer-caregiver dyads. In addition, this study did not restrict participation to dyads in which the caregiver resided with the individual with OCD. It is important to consider the impact of OCD on non-residing caregivers, but the small sample size meant that these two groups could not be separated in the analysis which may be a limiting factor. The mean scores for accommodation in this study appear to be lower than those found in other research which may indicate problematic sampling. However, there appeared to be adequate variance in scores and scores were similar to those found in research by Torres et al. (2012). Lastly, as previously noted, this study is cross-sectional in nature and therefore directionality of associations cannot be inferred, warranting future research with longitudinal data.
Future avenues for research include the exploration of other OCD appraisals that might be important influences on caregiver and sufferer distress and behaviours in order to directly target unhelpful appraisals and nurture those which lead to more positive outcomes. This study considered only three of the eight dimensions of appraisals measured by the Illness Perceptions Questionnaire-Revised (Moss-Morris et al., 2002) as these appeared to be most theoretically relevant but there may be further appraisals important for our understanding of the interpersonal aspects of OCD. Ultimately, the purpose of this type of research into appraisals of OCD is to develop effective interventions potentially including family members or loved ones. In the future, it will be important to determine to what extent the appraisals of individuals with OCD and their caregivers have an impact on the outcomes of interventions, both for interventions directly targeting accommodation and also those aimed at treating OCD.

This study suggests that we can use aspects of the self-regulation model to understand that appraisals of the chronicity, consequences and control one has over OCD can influence the distress of caregivers and also the extent to which they engage in potentially unhelpful accommodating behaviours. It is hoped that this model can help therapists to fine-tune the already efficacious treatments available.

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emotion. *Behaviour Research and Therapy, 47*(9), 783-789. doi: 10.1016/j.brat.2009.06.004


Executive Summary: An investigation of perceptions of OCD, caregiver burden, distress and accommodation

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Internal Supervisors

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*Dr Claire Lomax*

*Bryjar Halldorsson*

Executive Summary: Main Research Project, May 2015

Word Count 870
OCD within families: can what they think affect how they cope?
Sometimes the way that we think about a problem can make our experience of it better or worse. Researchers wondered whether the way families think about Obsessive-Compulsive Disorder (OCD) is linked to how stressful they find it and what they do to help someone with OCD.

What do we know already?
Obsessive–Compulsive Disorder (OCD) is a mental health problem which causes someone to have intrusive and unwanted obsessive thoughts which makes them feel extremely anxious. This often makes the person do repetitive actions or mental rituals to try to relieve the anxiety. OCD can have a huge cost for the individual and their family.

Lots of families struggle to work out how to best help their loved one with OCD. One way that many family members try to help is through making changes in their own lives to make it easier for their loved one to continue with their obsessional behaviours, referred to as “accommodation”. Accommodation is when they help or actually take part in OCD rituals such as helping someone to do rituals, doing things for them so they don’t feel anxious, reassuring them or changing the way they do things. This might help in the short term, but unfortunately it can become a vicious cycle which can make it harder to overcome OCD.

Some psychological treatments now include family members, but we don’t yet know what the best way to do this is.

What did we do in this study?
Thirty-one people (aged 18+) with OCD and their family member or friend volunteered to take part by completing questionnaires. The questions asked what people thought about how long OCD was going to last, how severe the consequences were, and whether the person with the condition had control over the symptoms. There were also questions about depression, anxiety, family member burden, accommodation and criticism.
What did the study say?

- Family and friends who thought that their loved ones’ OCD would not have severe consequences found the experience of supporting them less difficult.
- Family and friends who thought that their loved ones’ OCD would last a long time and have severe consequences experienced more depression and anxiety.
- If the person with OCD thought that they had no control over their OCD symptoms, family and friends tended to do more “accommodation” to try to help, even if the symptoms were less severe.
- Most people with OCD and their family member or friend thought the same way about whether OCD would last a long time and whether the person with OCD could have control. Sometimes views about the severity of the consequences of OCD were different to the family member or friend.

What does this mean for how we can help people with OCD and their families?
Having hopeful views for the future of someone with OCD can help families to feel less overwhelmed and be more able to cope. We think that it is really important to help people with OCD and their families to understand more about the condition and the treatments available so that they are encouraged to get help. NHS services, charities, support groups and inspirational recovery figures who work really hard can use this study to think about the best way to support families.

People with OCD who think that they have little personal control over symptoms tend to have family members who become more involved in rituals, help them avoid or change the way they do things to accommodate OCD. We know from other research that accommodation can get in the way of treatment so these findings can help us to find new ways to help families reduce how much they accommodate. We don’t know yet which direction this link goes. Helping people with OCD to have more sense of control over symptoms might mean that they don’t need their families to assist as much with rituals, but on the other hand, helping families to work together to reduce accommodation might increase someone’s control.
How reliable are the findings?

Studies like this are the most common method of exploring links between what people think about mental health problems and the impact it has on them. But there are a few problems which may affect the reliability of these findings.

- We used a relatively small number of people
- The way we found people to take part (internet advertisement, visiting support groups, contacting NHS services) might mean that participants are not representative of all families with someone who has OCD.
- We didn’t look at whether results were different for those living or not living with the person with OCD.
- We asked people questions at one point in time, so we can’t determine whether one factor causes another, only that they are related.

What can we do next?

The next steps for research to help families with a person who has OCD could be to look at whether there are other ways of thinking about OCD that influences how stressed families are and what they do to cope. Eventually we hope that research will find out how certain ways of thinking about OCD affect treatment, and how we can use this to improve how effective treatments are.
Connecting Narrative

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Clinical Tutor
Dr Maria Loades

May 2015
Word Count 2937
Much of my experience of psychological therapies pre-training had been on an individual basis, but I had begun to recognise the limitations of this approach, particularly when reflecting on the role of relationships between clients, families and services in maintaining difficulties. Alongside conversations with experienced clinicians, this inspired my interest in the integration of systemic and individual theories and therapies.

This interest is reflected in each of the three core research projects I have undertaken to fulfil the requirements of the Doctorate in Clinical Psychology. The Critical Review of the Literature investigates the benefits of involving family members or other members of the system in treatment for Borderline Personality Disorder. The Main Research Project explores the impact of caregiver perceptions of OCD on distress and behaviours including those which may have an impact on the outcomes for their relatives with OCD. The Service Improvement Project takes a different approach to systemic working, exploring the utility of group clinical supervision for staff on an inpatient mental health ward and working to improve this approach in order to best help the patients.

Through the process of conducting these projects, I have learnt much about the importance of including families and wider systems in psychological interventions. The experience has encouraged me to consider systems in my clinical work and has enhanced my practice. Conducting these projects has also developed my skills in planning, conducting, analysing and disseminating research. A narrative account of the process of research follows below.

**Critical Review of the Literature**

*Involving the wider system in skills-based treatments for Borderline Personality Disorder: A systematic review*

**Study Selection and Development**

The process of selecting a topic for literature review required a broad investigation of existing literature on a number of topics. As a trainee with limited clinical experience and knowledge this process was challenging as it required the identification of a topic which had heuristic value, had not yet been reviewed, and had sufficient literature to be able to answer the research question. In my case, I began with a very broad topic and narrowed the focus to a specific area of this.
A systematic review was selected over a narrative review in order to bring a level of methodological rigour that should be used to produce research evidence. This involved producing a review protocol which pre-defined each of the processes involved including the terms used to search for papers, search strategy, identification of papers for inclusion, data extraction and assessment of study quality. In order to develop this protocol, I referred to the Cochrane Handbook for Systematic Reviews of Interventions as well as other reviews published in my target journal. As the research tutor for this project changed several times during the study period, much of the protocol development was done independently with tutors answering specific questions when needed.

**Collaborating with other Reviewers**

In conducting a systematic literature review, it is important to include more than one reviewer. Therefore, I recruited the help of a Psychology Masters Graduate who was keen to gain experience in conducting clinically relevant research. This second reviewer was involved in several stages of the review: identifying papers for inclusion, assessment of study quality, and verifying the accuracy of the data extraction. This process was particularly useful and ensured that the review was to the highest quality possible.

**Challenges and Personal Learning**

Conducting literatures reviews is a common task for Assistant Psychologists, and as such I had conducted many informal reviews prior to commencing training. Systematic reviews of publishable quality which are of value to the evidence base are far more complex. There are many different systematic methodological approaches and it was my task to find the most appropriate one for the topic I was reviewing. Through this process I have learned that it may be less important which method to use but rather more important to justify the one selected. To be able to do this, I have needed to know the variation in methods (e.g., tools for assessing the quality of the evidence) and in which cases they are more or less appropriate.

Conducting research in a systematic way is an essential skill, but is not only limited to literature reviews. This research project has helped me to develop skills in searching for literature for clinical purposes as well as research, and has enabled me to refine my organisational abilities- something which will be particularly important when juggling the various demands of a Clinical Psychologist.
Service Improvement Project

Improving Multidisciplinary Clinical Discussion on an Inpatient Mental Health Ward

Study Selection and Development
Having worked in the role of Health Care Support Worker on an acute inpatient mental health ward early in my career, I feel strongly about the often limited psychological care available. As most inpatient wards do not have a dedicated Psychologist, the provision of clinical supervision for staff working on the wards can be an important indirect way of providing psychological interventions for patients. With my interest in this area, I approached a Clinical Psychologist working in this way to explore the scope of conducting some research. In developing an idea for service related research, it is important to be led by the needs of that service, so I worked closely with the Psychologist and Ward Manager-them bringing knowledge of the service, and me guided by the literature, evidence base, local policy and research tutor.

One of the difficulties I faced in the development of this project was balancing the needs of the service, and my workload capacity. There were many interesting ideas that were not feasible for a trainee project and even when the project took shape, there was a pressure to recruit larger numbers of participants than was practical given the time restraints. This was resolved through discussion and by consulting the existing literature to establish an appropriate number of participants for the qualitative methodological approach.

Ethics
This project fell under the definition of service evaluation and audit and therefore did not require review by an NHS Research Ethics Committee. Permission was however sought from the University of Bath Psychology Department Ethics Board and the local NHS trust’s Clinical Auditing Committee.

Recruitment
Recruiting members of staff working on the inpatient ward was supported by the ward manager, but was challenging due to the busy nature of this working environment. The project was advertised via posters displayed in staff areas and also by email. However, I was not approached by any staff members volunteering to take part, and instead scheduled time to be present on the ward, inviting staff to participate whenever they had the opportunity to take a break from their hectic work schedule. Using this more assertive approach
approach required clear guidance that participation was voluntary and I made sure to give potential participants the opportunity to decline to participate so that they did not feel under any pressure.

**Data Collection and Analysis**

Data collection involved semi-structured interviews with the Psychologist facilitating the group, Ward Manager and members of staff. Interviews were audio recorded and transcribed by myself, a time consuming activity, but one which was helpful for immersing myself in the data in preparation for analysis.

Qualitative research relies upon the research coding data and interpreting themes which potentially could be influenced by their prior experiences and knowledge of the study aims. As such it is important to involve more than one coder in the process to increase the reliability of the findings. The role was undertaken by the research tutor for this project, who independently coded twenty-five percent of the transcript data which was then discussed and compared with the themes identified by my own coding process.

**Challenges and Personal Learning**

Conducting service based research in an important role for Clinical Psychologists. I had gained experience of this prior to training in services within which I was employed. The Service Improvement Project conducted during training was for a service within which I had no previous ties, and I found that the ideas were not always accepted by staff members, who perhaps not knowing my previous experience of working on a ward, may have thought that I did not understand the nature of ward working and found it difficult to consider a new psychological approach. This experience has taught me the value of enlisting the support of team leaders who are active and enthusiastic about opportunities for change.

**Main Research Project**

*An investigation of perceptions of OCD, caregiver burden, distress and accommodation*

**Study Selection and Development**

The process of selecting this project was a difficult one. As previously mentioned, my clinical interest in systemic approaches influenced my interest in topics for research and I
initially hoped to conduct research exploring the mechanisms of change in systemic family therapy. Although I had some ideas for research projects, as a trainee new to this therapeutic approach it was important to have the input of experienced clinicians and researchers to shape my ideas into a viable project. With the University of Bath course still in its infancy, and local systemic practitioners more experienced in qualitative rather than quantitative research, it was difficult to develop the idea further and instead I had to explore other projects which were perhaps more suited to a quantitative methodology. Whilst holding true to my interest in systemic approaches, I came across a volume of research examining the impact of caregiver perceptions on their relationships with their relative with a mental health difficulty and wondered whether this model could be applied to other mental health problems where caregivers have an important role. I found that this had not yet been considered in the literature for OCD, where family member accommodation of symptoms was known to have significant impact on treatment outcome and so the idea of this particular project was chosen.

I was fortunate to work with experts in the field of OCD treatment and research in developing the project and have also had the support of OCD-UK, a charitable organisation run by people with personal experience of OCD, one of whom helped in the development stage by trailing the questionnaire measures and providing feedback.

Ethics
The process of gaining ethical approval for this study was threefold.

- NHS Research Ethics Committee approval was sought via the use of the Integrated Research Application System. This process is very thorough and requires the careful planning of all aspects of the project including purpose, research questions, recruitment process, maintenance of confidentiality, data protection, data collection, analysis and dissemination. Although time consuming the procedure was particularly useful in the design of the project as it encouraged me to consider areas that I may have otherwise not thought to plan in advance.
- University of Bath Psychology Department ethics approval was also sought.
- In order to advertise the project to NHS service users, local NHS trust research and ethics approval was sought.
Recruitment

Finding participants to take part in this research project was a challenge given that it required both members of the OCD sufferer-caregiver dyad to participate. Thus to be included in the study, one member of the dyad needed to respond to the advertisement, liaise with the other member and both agree to take part. Participation then involved the individual with OCD engaging in a short telephone screening interview, followed by both dyad members completing a pack of questionnaires. This process inevitably resulted in a high rate of drop-out. Sixty-four percent of people who initially contacted the researcher to show their interest in participating were lost to the study at this stage. Following screening, a further three percent of the initial contactors did not return the questionnaire packs and four percent of dyads returned only one half of the questionnaires. As a result of this proportion of drop-out, it was necessary to invest a significant amount of time and resource into follow-up communication with potential participants to improve the rate of questionnaire completion.

Participants were recruited from a variety of sources in order to maximise the reach of the research project. The more successful avenues were via advertisements on charitable organisation websites and social media. These forms of advertisement have the potential to be wide reaching and appeal to those with a particular interest in taking part in research, perhaps purposefully looking for opportunities to participate. Less fruitful was advertisement through NHS services. There are a few of possible reasons for the unsuccessful use of NHS services in the recruitment of participants for this project.

- Firstly, several service managers declined the offer to invite users of their service to take part citing their concern that other projects had already been advertised and they did not wish to promote others.
- Services which did support the research required clinicians to pass on the details of the project to appropriate service users. Given the increasing pressures on NHS staff at present, it is possible that clinicians were too busy and stressed to be able to consider the additional request of research.
- Clinicians working in NHS services may have felt that it was inappropriate to ask service users who are distressed by their mental health difficulties to take part in research.
- Finally, those who have sought help from NHS services are perhaps more likely to be struggling with their mental health difficulties at the time of being asked to take
part in research and this may mean that they feel it is too difficult to manage the demands of research.

Though these are reasonable and valid reasons for not taking part in research, it is possible that being located within or closer to these services may have allowed me to liaise further with clinicians and increase their responsiveness to requests to share the study information with service users. Unfortunately, balancing the demands of clinical placements in a different geographical area, attendance at teaching and other research commitments compromised my ability to undertake this.

**Data Collection**

Questionnaire data for this study was mostly collected via a secure online questionnaire which enabled participants to enter their responses using a unique participant identification number. This method was satisfactory to most participants as it was convenient and easily accessible, and also allowed for rapid and accurate data management as completed questionnaire data could be automatically exported into data analysis software.

**Challenges and Personal Learning**

Conducting research at this scale within a clinical population required a large resource, particularly in terms of time, experience and contacts within services and organisations. It was particularly useful to work alongside experts in the field when planning and implementing the project. I have learnt to make a thorough evaluation of the feasibility of research projects early in the development stage, taking into consideration the availability of other professionals who could be involved in some of the stages.

Statistical analyses were, and to some extent still are, a complicated area in which I lack confidence. As research methodologies become more complex, the statistics needed to evaluate do so too. I think it is important to understand the process behind statistical analyses in order to use them appropriately, but in order to do this I will perhaps need to seek further advanced training.

**Case Studies**

**Case Selection**

It was a requirement of each clinical placement to select a case to write up as a case study. Early identification of suitable cases proved to be the best approach, but given that one of
the assets of Clinical Psychology is the focus on evidencing outcomes, approaching every case in this way enabled me to select work which had the potential to add to the literature.

**Selection of Outcome Measures**
Selecting outcome measures for case studies is particularly important in order to effectively capture the change being targeted by the intervention. This was relatively easier where referral information gave clear indication of the presenting problem and the goals of the client. Most useful was when services had in place generic or broad measures of difficulties that were routinely given to clients, such as the Children and Young Persons Service (CYPS) who were involved in an ongoing research project monitoring outcomes.

More difficult was the selection of outcome measures for experimental designs. These needed to be easily administered on a repeat basis. For the final case study in the series, the measure used was chosen as a clinically relevant, idiosyncratic way to monitor the immediate impact of each therapy session. It was mostly by chance that this approach led to very interesting outcome data which could be used to contribute to a much debated research question, highlighting to me the value in considering all cases as having the potential to further psychological knowledge.

**Personal Learning**
The experience of conducting case studies has taught me ways in which to systematically evaluate clinical practice so that it can contribute towards further understanding of the assessment and treatment of mental health difficulties. Although the requirement to write case reports to this extent won’t be present in my qualified work, the processes involved are useful not only to evaluate my work, but also for the client to observe change so will continue to inform my work.

**Continuing Research Post-Qualification**
Research is a continuing feature in the work of a Clinical Psychologist. Post-qualification I will ensure that I remain aware of developments in research in order to provide the most effective treatments possible for the clients I am working with. Clinical Psychologists are ideally located with NHS services to lead service developments. I aim to use my skills to evaluate and improve services, hopefully innovating new service approaches. At present, my goals for my career post-qualification focus primarily on clinical practice, but as I
become more experienced, I anticipate becoming involved in more research activities, possibly in collaboration with future Clinical Psychology Trainees.
Appendix A.1

Author Guidelines for Clinical Psychology Review

CLINICAL PSYCHOLOGY REVIEW

AUTHOR INFORMATION PACK

ISSN: 0272-7358

DESCRIPTION

Clinical Psychology Review publishes substantive reviews of topics germane to clinical psychology. Papers cover diverse issues including: psychopathology, psychotherapy, behavior therapy, cognition and cognitive therapies, behavioral medicine, community mental health, assessment, and child development. Papers should be cutting edge and advance the science and/or practice of clinical psychology.

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Citations in the text should follow the referencing style used by the American Psychological Association. You are referred to the Publication Manual of the American Psychological Association, Sixth Edition, ISBN 1-4338-0559-6, copies of which may be ordered from http://books.apa.org/books.cfm?id=4200067 or APA Order Dept., P.O.B. 2710, Hyattsville, MD 20784, USA or APA, 3 Henrietta Street, London, WC3E 8LU, UK. Details concerning this referencing style can also be found at http://humanities.byu.edu/linguistics/Henrichsen/APA/APA01.html

Citation in text

Please ensure that every reference cited in the text is also present in the reference list (and vice versa). Any references cited in the abstract must be given in full. Unpublished results and personal communications are not recommended in the reference list, but may be mentioned in the text. If these references are included in the reference list they should follow the standard reference style of the journal and should include a substitution of the publication date with either 'Unpublished results' or 'Personal communication'. Citation of a reference as 'in press' implies that the item has been accepted for publication.

Web references

As a minimum, the full URL should be given and the date when the reference was last accessed. Any further information, if known (DOI, author names, dates, reference to a source publication, etc.), should also be given. Web references can be listed separately (e.g., after the reference list) under a different heading if desired, or can be included in the reference list.

References in a special issue

Please ensure that the words 'this issue' are added to any references in the list (and any citations in the text) to other articles in the same Special Issue.

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http://open.mendeley.com/use-citation-style/clinical-psychology-review

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Reference style

References should be arranged first alphabetically and then further sorted chronologically if necessary. More than one reference from the same author(s) in the same year must be identified by the letters "a", "b", "c", etc., placed after the year of publication. References should be formatted with a hanging indent (i.e., the first line of each reference is flush left while the subsequent lines are indented).


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submit the material in electronic format together with the article and supply a concise and
descriptive caption for each file. For more detailed instructions please visit our artwork

3D neuroimaging
You can enrich your online articles by providing 3D neuroimaging data in NIfTI format.
This will be visualized for readers using the interactive viewer embedded within your
article, and will enable them to: browse through available neuroimaging datasets; zoom,
rotate and pan the 3D brain reconstruction; cut through the volume; change opacity and
color mapping; switch between 3D and 2D projected views; and download the data. The
viewer supports both single (.nii) and dual (.hdr and .img) NIfTI file formats.
Recommended size of a single uncompressed dataset is maximum 150 MB. Multiple
datasets can be submitted. Each dataset will have to be zipped and uploaded to the online
submission system via the '3D neuroimaging data' submission category. Please provide a
short informative description for each dataset by filling in the 'Description' field when
uploading a dataset. Note: all datasets will be available for downloading from the online
article on ScienceDirect. If you have concerns about your data being downloadable, please
provide a video instead. For more information see:
http://www.elsevier.com/3DNeuroimaging.

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The following list will be useful during the final checking of an article prior to sending it to
the journal for review. Please consult this Guide for Authors for further details of any item.
Ensure that the following items are present:
One author has been designated as the corresponding author with contact details:
• E-mail address
• Full postal address
All necessary files have been uploaded, and contain:
• Keywords
• All figure captions
• All tables (including title, description, footnotes)
Further considerations
• Manuscript has been 'spell-checked' and 'grammar-checked'
• References are in the correct format for this journal
• All references mentioned in the Reference list are cited in the text, and vice versa
• Permission has been obtained for use of copyrighted material from other sources (including the Internet)
Printed version of figures (if applicable) in color or black-and-white
• Indicate clearly whether or not color or black-and-white in print is required.
• For reproduction in black-and-white, please supply black-and-white versions of the figures for printing purposes.
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http://dx.doi.org/10.1016/j.physletb.2010.09.059
When you use a DOI to create links to documents on the web, the DOIs are guaranteed never to change.

Online proof correction

Corresponding authors will receive an e-mail with a link to our online proofing system, allowing annotation and correction of proofs online. The environment is similar to MS Word: in addition to editing text, you can also comment on figures/tables and answer questions from the Copy Editor. Web-based proofing provides a faster and less error-prone process by allowing you to directly type your corrections, eliminating the potential introduction of errors. If preferred, you can still choose to annotate and upload your edits on the PDF version. All instructions for proofing will be given in the e-mail we send to authors, including alternative methods to the online version and PDF. We will do everything possible to get your article published quickly and accurately. Please use this proof only for checking the typesetting, editing, completeness and correctness of the text, tables and figures. Significant changes to the article as accepted for publication will only be considered at this stage with permission from the Editor. It is important to ensure that all corrections are sent back to us in one communication. Please check carefully before
replying, as inclusion of any subsequent corrections cannot be guaranteed. Proofreading is solely your responsibility.

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**AUTHOR INQUIRIES**


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Appendix A.2

Systematic Protocol for Critical Review of the Literature

Search Protocol

1. Input all search combinations into the following databases: PubMed, Cochrane Library, Embase, PsychInfo.
2. Record Total number of papers found through database searching
3. Record number of papers after duplicates deleted
4. Screen titles and abstracts of all articles and remove studies not directly related to the review
5. Reliability check with 2nd researcher (masters graduate)
6. Record number of papers excluded, with reasons.
7. Record number of full texts articles assessed for eligibility.
8. Check reliability with 2nd researcher (masters graduate)
9. Record number of full text articles excluded, with reasons.
10. Record number of additional papers found via reference lists or other ad hoc sources that have been assessed for eligibility and are to be included in the review.
11. Record number of papers to be included in the review
12. Any issues regarding inclusion/exclusion will be discussed with EG

Search Terms

Borderline Personality Disorder (MeSH/Index Term) OR "borderline personality disorder" OR “BPD” OR "emotionally unstable personality disorder" OR Self Injurious Behavi*r (MeSH/Index Term) OR "self harm" OR "self-harm" OR "self injury" OR “self-injurious behavi*r” OR “self injurious behavi*r” OR “deliberate self-harm” OR “deliberate self harm” OR “parasuicide” OR suicid* OR “NSSI” OR "emerging personality disorder"

AND
Famil* OR “system*”

AND
“dialectical behavi*r therapy” OR “dialectic*” OR “dbt” OR “stepps” OR "family connection*” OR (“skill*” AND (“therapy” OR “treatment” OR “intervention” OR “training” OR “program”))
Inclusion Criteria

- Written in English
- Studies with primary outcome data
- Diagnosis of BPD, or meets partial diagnostic criteria for BPD. (e.g. described as emotional regulation disorder for adolescents: nssi, parasuicide, suicidality)
- Experimental intervention is skills based
- Has a systemic component

Exclusion Criteria

- Not written in English
- Reviews or book extracts
- Did not use primary data
- Primary diagnosis is not BPD (or other emotion regulation disorder for adolescents- NSSI, parasuicide, suicidality). E.g. Depression, substance misuse, eating disorder.
- Not having a skills based intervention
- Not including a systems component i.e. families, schools, employer, other staff.
### Appendix A.3

**Search Terms by database for Critical Review of the Literature**

<table>
<thead>
<tr>
<th>Database</th>
<th>Search Fields</th>
<th>Terms</th>
</tr>
</thead>
</table>
| PubMed       | Title and Abstract                | MeSH Term: Borderline Personality Disorder OR "borderline personality disorder" OR “BPD” OR "emotionally unstable personality disorder" OR MeSH Term: Self Injurious Behavi*r OR suicid* OR “NSSI” OR "emerging personality disorder"

AND

Famil* OR “system*”

AND

“dialectical behavi* therapy” OR “dialectic*” OR “dbt” OR “stepps” OR "family connection*” OR (“skill*” AND (“therapy” OR “treatment” OR “intervention” OR “training” OR “program”))

| Cochrane Library | Title, Abstract and Key words                  | "borderline personality disorder" OR “BPD” OR "emotionally unstable personality disorder" OR “Self Injurious Behavi*r” OR “self harm” OR "self-harm" OR "self injury" OR “self-injurious behavi*r” OR “deliberate self-harm” OR “deliberate self harm” OR “parasuicide” OR suicid* OR “NSSI” OR "emerging personality disorder"

AND

Famil* OR “system*”

AND

“dialectical behavi* therapy” OR “dialectic*” OR “dbt” OR “stepps” OR "family connection*” OR (“skill*” AND (“therapy” OR “treatment” OR “intervention” OR “training” OR “program”))

| PsychInfo     | Title and Abstract                  | [Index Term:] Borderline Personality Disorder OR "borderline personality disorder" OR “BPD” OR "emotionally unstable personality disorder" OR [Index Term:] Self Injurious Behavi*r OR suicid* OR “NSSI” OR "emerging personality disorder"

AND

Famil* OR “system*”

AND

“dialectical behavi* therapy” OR “dialectic*” OR “dbt” OR “stepps” OR "family connection*” OR (“skill*” AND (“therapy” OR “treatment” OR “intervention” OR “training” OR “program”))

| Embase        |                                    | "borderline personality disorder" OR “BPD” OR "emotionally unstable personality disorder" OR “Self Injurious Behavi*r” OR “NSSI” OR "emerging personality disorder" OR “self harm” OR "self-harm" OR "self injury" OR “self-injurious behavi*r” OR “deliberate self-harm” OR “parasuicide” OR suicid* OR “NSSI” OR "emerging personality disorder" OR “dialectical behavi* therapy” OR “dialectic*” OR “dbt” OR “stepps” OR "family connection*” OR (“skill*” AND (“therapy” OR “treatment” OR “intervention” OR “training” OR “program”)) |
"self harm" OR "self-harm" OR "self injury" OR “self-injurious behavi*" OR “deliberate self-harm” OR “deliberate self harm” OR “parasuicide” OR suicid* OR “NSSI” OR "emerging personality disorder"

AND

Famil* OR “system*”

AND

“dialectical behavi* therapy” OR “dialectic*” OR “dbt” OR “stepps” OR "family connection*" OR ("skill*" AND (“therapy” OR “treatment” OR “intervention” OR “training” OR “program”))
### Appendix A.4

**Risk of Bias Protocol for Critical Review of the Literature**

**Selection Bias (including confounders)**

*RANDOM SEQUENCE GENERATION*

Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence.

<table>
<thead>
<tr>
<th>Judgement</th>
<th>Criteria</th>
<th>Source</th>
</tr>
</thead>
</table>
| “Low Risk”      | The investigators describe a random component in the sequence generation process such as:  
• Referring to a random number table;  
• Using a computer random number generator;  
• Coin tossing;  
• Shuffling cards or envelopes;  
• Throwing dice;  
• Drawing of lots;  
• Minimization*.
  
*Minimization may be implemented without a random element, and this is considered to be equivalent to being random. | Cochrane Handbook for Systematic Reviews of Interventions, Version 5.1.0. (March 2011) http://handbook.cochrane.org/ |

*For non-randomised studies with control groups:*

The study applied inclusion/exclusion criteria uniformly to all groups.

Cases and controls selected according to appropriate diagnostic criteria.

Strategy for recruiting participants does not differ across groups.

*For all designs:*

The design accounts for other confounding factors in selection e.g. matching, stratification, multivariate analysis, consecutive referrals etc.

| “High Risk”   | The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example:  
• Sequence generated by odd or even date of birth;  
• Sequence generated by some rule based on date (or day) of admission; | Cochrane Handbook for Systematic Reviews of Interventions (2011) |
- Sequence generated by some rule based on hospital or clinic record number.

Other non-random approaches happen much less frequently than the systematic approaches mentioned above and tend to be obvious. They usually involve judgement or some method of non-random categorization of participants, for example:
- Allocation by judgement of the clinician;
- Allocation by preference of the participant;
- Allocation based on the results of a laboratory test or a series of tests;
- Allocation by availability of the intervention.

**For non-randomised studies with control groups:**
Inclusion/exclusion criteria not applied uniformly to all groups.
Cases and controls selected according to inappropriate diagnostic criteria.
Strategy for recruiting participants differs across groups.

**For all designs:**
The design does not account for other confounding factors in selection.

<table>
<thead>
<tr>
<th>“Unclear Risk”</th>
<th>Insufficient information about the sequence generation process to permit judgement of ‘Low risk’ or ‘High risk’.</th>
<th>Viswanathan et. al. (2012)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Cochrane Handbook for Systematic Reviews of Interventions (2011)</td>
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</tbody>
</table>
**Allocation Generation**
Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment.

<table>
<thead>
<tr>
<th>Judgement</th>
<th>Criteria</th>
<th>Source</th>
</tr>
</thead>
</table>
| “Low Risk”      | Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation:  
  - Central allocation (including telephone, web-based and pharmacy-controlled randomization);  
  - Sequentially numbered drug containers of identical appearance;  
| “High Risk”     | Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on:  
  - Using an open random allocation schedule (e.g. a list of random numbers);  
  - Assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or non-opaque or not sequentially numbered);  
  - Alternation or rotation;  
  - Date of birth;  
  - Case record number;  
  - Volunteering/Self-Selection  
| “Unclear Risk”  | Insufficient information to permit judgement of ‘Low risk’ or ‘High risk’. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgement – for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed. | Cochrane Handbook for Systematic Reviews of Interventions (2011) |
| N/A             | Non controlled as concealment not possible.                                                                                                                                                    |                                                                      |
Detection Bias

*Blinding of Outcome Assessment*

Detection bias due to knowledge of the allocated interventions by outcome assessors.

<table>
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<tr>
<th>Judgement</th>
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<th>Source</th>
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<tbody>
<tr>
<td>“Low Risk”</td>
<td>Any one of the following:</td>
<td>Cochrane Handbook for Systematic Reviews of Interventions (2011)</td>
</tr>
<tr>
<td></td>
<td>• No blinding of outcome assessment, but the review authors judge that</td>
<td>Stoffers (2012)</td>
</tr>
<tr>
<td></td>
<td>the outcome measurement is not likely to be influenced by lack of</td>
<td></td>
</tr>
<tr>
<td></td>
<td>blinding;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Blinding of outcome assessment ensured, and unlikely that the</td>
<td></td>
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<tr>
<td></td>
<td>blinding could have been broken.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• All measures are self-report.</td>
<td></td>
</tr>
<tr>
<td>“High Risk”</td>
<td>Any one of the following:</td>
<td>Cochrane Handbook for Systematic Reviews of Interventions (2011)</td>
</tr>
<tr>
<td></td>
<td>• No blinding of outcome assessment, and the outcome measurement is</td>
<td></td>
</tr>
<tr>
<td></td>
<td>likely to be influenced by lack of blinding;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Blinding of outcome assessment, but likely that the blinding</td>
<td></td>
</tr>
<tr>
<td></td>
<td>could have been broken, and the outcome measurement is likely to</td>
<td></td>
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<tr>
<td></td>
<td>be influenced by lack of blinding.</td>
<td></td>
</tr>
<tr>
<td>“Unclear Risk”</td>
<td>Any one of the following:</td>
<td>Cochrane Handbook for Systematic Reviews of Interventions (2011)</td>
</tr>
<tr>
<td></td>
<td>• Insufficient information to permit judgement of ‘Low risk’ or ‘High</td>
<td></td>
</tr>
<tr>
<td></td>
<td>risk’;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• The study did not address this outcome.</td>
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</tr>
</tbody>
</table>
### Attrition Bias

**Incomplete Outcome Data**

Attrition bias due to amount, nature or handling of incomplete outcome data.

<table>
<thead>
<tr>
<th>Judgement</th>
<th>Criteria</th>
<th>Source</th>
</tr>
</thead>
</table>
| “Low Risk”       | Any one of the following:  
- No missing outcome data;  
- Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias);  
- Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups;  
- For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate;  
- For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size;  
- Missing data have been imputed using appropriate methods. | Cochrane Handbook for Systematic Reviews of Interventions (2011)        |
| “High Risk”      | Any one of the following:  
- Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups;  
- For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate;  
- For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size;  
- ‘As-treated’ analysis done with substantial departure of the intervention received from that assigned at randomization;  
| “Unclear Risk”   | Any one of the following:  
- Insufficient reporting of attrition/exclusions to permit judgement of ‘Low risk’ or ‘High risk’ (e.g. number randomized not stated, no reasons for missing data provided);  
- The study did not address this outcome.                                                                                                      | Cochrane Handbook for Systematic Reviews of Interventions (2011)        |
**Reporting Bias**

*Selective Reporting*

**Reporting bias due to selective outcome reporting.**

<table>
<thead>
<tr>
<th>Judgement</th>
<th>Criteria</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Low Risk”</td>
<td>Any of the following:</td>
<td>Cochrane Handbook for Systematic Reviews of Interventions (2011)</td>
</tr>
<tr>
<td></td>
<td>• The study protocol is available and all of the study’s pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon).</td>
<td></td>
</tr>
<tr>
<td>“High Risk”</td>
<td>Any one of the following:</td>
<td>Cochrane Handbook for Systematic Reviews of Interventions (2011)</td>
</tr>
<tr>
<td></td>
<td>• Not all of the study’s pre-specified primary outcomes have been reported;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• One or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect);</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• The study report fails to include results for a key outcome that would be expected to have been reported for such a study.</td>
<td></td>
</tr>
<tr>
<td>“Unclear Risk”</td>
<td>Insufficient information to permit judgement of ‘Low risk’ or ‘High risk’. It is likely that the majority of studies will fall into this category.</td>
<td>Cochrane Handbook for Systematic Reviews of Interventions (2011)</td>
</tr>
</tbody>
</table>
## Intervention Integrity (Performance Bias)

### Adherence

The extent to which specified intervention components were delivered as prescribed

<table>
<thead>
<tr>
<th>Judgement</th>
<th>Criteria</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Provision of clinical supervision</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Objective means of assessment</td>
<td></td>
</tr>
<tr>
<td>“Unclear Risk”</td>
<td>Any one of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Insufficient reporting of adherence to permit judgement of ‘Low risk’ or ‘High risk’</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• The study did not address this outcome.</td>
<td></td>
</tr>
</tbody>
</table>

### Attention Bias (Exposure)

Equality of the Number, length and frequency of implementation of intervention components across groups.

<table>
<thead>
<tr>
<th>Judgement</th>
<th>Criteria</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Low Risk”</td>
<td>Each intervention group is exposed to the same level of attention (i.e. equivalent number of contact hours and type)</td>
<td>Cochrane Handbook for Systematic Reviews of Interventions (2011)</td>
</tr>
<tr>
<td>“High Risk”</td>
<td>The intervention groups have unequal levels of attention or type of contact.</td>
<td>Cochrane Handbook for Systematic Reviews of Interventions (2011) Stoffers (2012)</td>
</tr>
<tr>
<td>“Unclear Risk”</td>
<td>Insufficient reporting of equivalence of attention to permit judgement of ‘Low risk’ or ‘High risk’</td>
<td></td>
</tr>
<tr>
<td>Not Applicable</td>
<td>Studies where there is no comparison group</td>
<td></td>
</tr>
</tbody>
</table>
**Programme Differentiation**

Safeguard checks against the diffusion of treatments, that is, to ensure that the subjects in each experimental group received only the planned interventions.

<table>
<thead>
<tr>
<th>Judgement</th>
<th>Criteria</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Low Risk”</td>
<td>The author has described how they assessed whether the participants’ received any other unintended interventions during the study period. or Other interventions unlikely to have biased outcome of the study.</td>
<td>Cochrane Handbook for Systematic Reviews of Interventions (2011)</td>
</tr>
<tr>
<td>“High Risk”</td>
<td>Participants’ likely to have engaged in other interventions during the study period. Author reports that participant engagement in other interventions was not monitored.</td>
<td>Cochrane Handbook for Systematic Reviews of Interventions (2011)</td>
</tr>
<tr>
<td>“Unclear Risk”</td>
<td>Unclear whether participants’ could have engaged in other interventions.</td>
<td></td>
</tr>
</tbody>
</table>

**Quality of Delivery (Allegiance Effect)**

Aspects of intervention delivery that are not directly related to the implementation of prescribed content that introduce bias.

<table>
<thead>
<tr>
<th>Judgement</th>
<th>Criteria</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Low Risk”</td>
<td>Qualitative aspects of intervention delivery: • Study includes measure of facilitator enthusiasm • Author describes the details of facilitator training • Comments on leader attitude towards intervention</td>
<td>Cochrane Handbook for Systematic Reviews of Interventions (2011)</td>
</tr>
<tr>
<td>“High Risk”</td>
<td>Intervention facilitators or main investigator is the treatment developer.</td>
<td>Stoffers (2012)</td>
</tr>
<tr>
<td>“Unclear Risk”</td>
<td>Insufficient reporting of allegiance/quality to permit judgement of ‘Low risk’ or ‘High risk’</td>
<td></td>
</tr>
</tbody>
</table>

**Participant Responsiveness**

Aspects of participant response to the intervention which could introduce bias.

<table>
<thead>
<tr>
<th>Judgement</th>
<th>Criteria</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Low Risk”</td>
<td>Authors report measures of: • High Attendance/Low drop-out frequency • High participant enthusiasm/satisfaction</td>
<td>Cochrane Handbook for Systematic Reviews of Interventions (2011)</td>
</tr>
<tr>
<td>“High Risk”</td>
<td>Author reports: • High drop-out rates due to participant dissatisfaction or lack of improvement • Measures of enthusiasm/satisfaction that indicate low participant responsiveness.</td>
<td>Cochrane Handbook for Systematic Reviews of Interventions (2011)</td>
</tr>
<tr>
<td>“Unclear Risk”</td>
<td>Insufficient reporting of participant responsiveness to permit judgement of ‘Low risk’ or ‘High risk’</td>
<td></td>
</tr>
</tbody>
</table>
## Appendix A.5

### Risk of Bias Assessment for each Study included in Critical Review of the Literature

Alesiani, R., Boccalon, S., Giarolli, L., Blum, N., & Fossati, A. (2014)

<table>
<thead>
<tr>
<th>Risk of Bias Assessment</th>
<th>Author's judgement</th>
<th>Support for Judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Selection Bias</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Random Sequence</td>
<td>Unclear Risk</td>
<td>Unclear whether participants were recruited consecutively from the inpatient ward or purposefully selected by clinicians</td>
</tr>
<tr>
<td>Generation</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Selection Bias</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Allocation</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td>Concealment</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Detection Bias</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blinding of</td>
<td>Low Risk</td>
<td>Outcome measures collected by the researcher so not blind to research aims. However, all measures were self-report so lack of blinding deemed not to introduce bias.</td>
</tr>
<tr>
<td>Outcome Assessment</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Attrition Bias</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incomplete</td>
<td>High Risk</td>
<td>‘As-treated’ analysis done with substantial departure of the intervention received from that assigned at randomization</td>
</tr>
<tr>
<td>Outcome Data</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Reporting Bias</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>selective reporting</td>
<td>Unclear Risk</td>
<td>No protocol available</td>
</tr>
<tr>
<td><strong>Intervention Integrity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adherence</td>
<td>High Risk</td>
<td>&quot;Facilitators were expert clinical psychologists specialized in the treatment of PD patients. They read the manual and they attended some e-meetings with Nancee Blum.&quot; (Alesiani- email to author) &quot;We didn’t formally assess the adherence to the manual.&quot; (Alesiani- email to author)</td>
</tr>
<tr>
<td><strong>Intervention Integrity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attention Bias (exposure)</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Intervention Integrity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Programme Differentiation</td>
<td>Unclear Risk</td>
<td>Unclear if participants' monitored for participation in other co-occurring interventions. &quot;patients participating to STEPPS received a drug treatment provided by their psychiatrists.&quot; (Alesiani-email to author)</td>
</tr>
<tr>
<td><strong>Integrity of Intervention</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quality of Delivery</td>
<td>Unclear Risk</td>
<td>No assessment of facilitator enthusiasm/satisfaction. &quot;Facilitators were expert clinical psychologists specialized in the treatment of PD patients. They read the manual and they attended some e-meetings with Nancee Blum.&quot; (Alesiani- email to author)</td>
</tr>
<tr>
<td>(Allegiance Effect)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Integrity of Intervention</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participant Responsiveness</td>
<td>Unclear Risk</td>
<td>No measure of participant satisfaction. No assessment of reasons for drop out.</td>
</tr>
<tr>
<td><strong>Integrity of Intervention</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bias Type</td>
<td>Author's judgement</td>
<td>Support for Judgement</td>
</tr>
<tr>
<td>------------------------------</td>
<td>--------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Selection Bias</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Random Sequence Generation</td>
<td>Low Risk</td>
<td>&quot;Subjects were assigned by coin toss to either the STEPPS plus treatment as usual group or treatment as usual alone group. Whenever eight to 12 subjects were assigned to STEPPS plus treatment as usual, they were notified that a group would begin.&quot; (Blum 2008, p.469)</td>
</tr>
<tr>
<td>Allocation Concealment</td>
<td>Unclear Risk</td>
<td>Unclear who was responsible for performing random allocation and what method was used to conceal allocation.</td>
</tr>
<tr>
<td><strong>Detection Bias</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blinding of Outcome Assessment</td>
<td>Low Risk</td>
<td>Author considered the impact of this risk and deemed it to be low. &quot;While we intended to conduct blind assessments, we found it nearly impossible to maintain blindness. The convergence of both rater- and patient-administered scales suggests that this may not have been an important deficiency.&quot; (Blum et al. 2008, P.477)</td>
</tr>
<tr>
<td><strong>Attrition Bias</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incomplete Outcome Data</td>
<td>Low Risk</td>
<td>Missing data have been imputed using appropriate methods. &quot;By utilizing the correlation of subjects’ responses over time, this model accommodates subjects with incomplete data.&quot; (Blum et al. 2008, p.471)</td>
</tr>
<tr>
<td><strong>Reporting Bias</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Selective reporting</td>
<td>Unclear Risk</td>
<td>No protocol available</td>
</tr>
<tr>
<td><strong>Intervention Integrity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adherence</td>
<td>Low Risk</td>
<td>“Adherence to the manual was rated on a 5-point scale [...] A score of 4 (good) or higher was considered acceptable. Two Ph.D.-level psychologists who were not involved with the randomized controlled trial but familiar with STEPPS rated 43 randomly selected video-taped session. The mean adherence score was 4.4 (SD = 0.8).” (Blum et al. 2008, p.470)</td>
</tr>
<tr>
<td>Attention Bias (exposure)</td>
<td>High Risk</td>
<td>STEPPS is 20 x 2hr sessions weekly + 2 hr session for system whereas TAU had no prescribed contact and is likely to entail less exposure/attention.</td>
</tr>
<tr>
<td>Programme Differentiation</td>
<td>Unclear Risk</td>
<td>&quot;Subjects received no instructions or advice about other pharmacologic or psychotherapeutic treatments.&quot; (Blum et al. 2008, p.470) Participants in the STEPPS group were encouraged to share the treatment approach with their TAU clinicians. &quot;Subjects assigned to TAU could not attend any STEPPS group until they completed the 20-week trial.&quot; (p.470). Unclear whether they were able to participate during the follow up period.</td>
</tr>
<tr>
<td>Quality of Delivery</td>
<td>High Risk</td>
<td>Authors give no indication for an allegiance effect. However, as some authors are founders of STEPPS, the treatment actually used in the experimental group, an allegiance effect seems not improbable</td>
</tr>
</tbody>
</table>
Participant Satisfaction Questionnaire showed significantly higher satisfaction with STEPPS group. Author described high discontinuation rate with reasons for drop out including low small proportion due to lack of efficacy.


<table>
<thead>
<tr>
<th>Integrity of Intervention</th>
<th>Support for Judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant Responsiveness</td>
<td>High Risk</td>
</tr>
<tr>
<td></td>
<td>Participant Satisfaction Questionnaire showed significantly higher satisfaction with STEPPS group. Author described high discontinuation rate with reasons for drop out including low small proportion due to lack of efficacy.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Author's judgement</th>
<th>Support for Judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Risk</td>
<td>&quot;viewed as 'secondary analysis' of data previously collected by and stored at the IODC.&quot; (Black et al 2008, p.883).</td>
</tr>
<tr>
<td>Not Applicable</td>
<td>&quot;... viewed as a secondary analysis of data previously collected by and stored at the IODC.&quot; (Black et al 2008, p.883) Clinicians collecting the data were not blind to desired outcome. However, all measures were self report so deemed not to introduce bias.</td>
</tr>
<tr>
<td>Low Risk</td>
<td>Missing data have been imputed using appropriate methods.</td>
</tr>
<tr>
<td>Unclear Risk</td>
<td>No protocol available</td>
</tr>
<tr>
<td>Low Risk</td>
<td>&quot;Adherance to the model was rated as &quot;excellent&quot;(4.9 out of 5).&quot; (p.883) Supervised by founder of intervention.</td>
</tr>
<tr>
<td>Not Applicable</td>
<td>&quot;None received concurrant psychotherapy&quot; (p.884). Authors considered possible confounder of psychotropic medication but unlikely to introduce bias.</td>
</tr>
<tr>
<td>High Risk</td>
<td>Lead authors are founders of STEPPS, and were involved in the training &amp; supervision, an allegiance effect seems not improbable.</td>
</tr>
<tr>
<td>Low Risk</td>
<td>&quot;mean CSQ-8 scores were 27.0±4.5, indicating high levels of satisfaction with the program.&quot; (Black et al 2008, p.884) Drop out accounted for. &quot;One subject dropped out after baseline assessment and another dropped out after week 12 because both were released from prison.&quot; (p.884)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bias Type</th>
<th>Risk Level</th>
<th>Support for Judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selection Bias-</td>
<td>Low Risk</td>
<td>&quot;Participation in STEPPS has been considered part of an offender’s routine mental health care within the IDOC.” (Black et al. 2013, p.124).</td>
</tr>
<tr>
<td>Random Sequence Generation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Allocation Concealment</td>
<td>Not</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Detection Bias-</td>
<td>Low Risk</td>
<td>&quot;considered a “secondary analysis” of data collected by and stored at the IDOC.” (pg.125) so not blind to desired outcome. However, all measures were self report so lack of blinding deemed not to introduce bias.</td>
</tr>
<tr>
<td>Blinding of Outcome Assessment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attrition Bias-</td>
<td>Low Risk</td>
<td>Missing data have been imputed using appropriate methods.</td>
</tr>
<tr>
<td>Incomplete Outcome Data</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reporting Bias-</td>
<td>Unclear</td>
<td>No protocol available</td>
</tr>
<tr>
<td>selective reporting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention Integrity-</td>
<td>Low Risk</td>
<td>Therapists received 2 days training, direct supervision during initial 4-5 sessions &amp; teleconference supervision thereafter by the treatment developer. Therapist adherence measured as excellent for first group at each site.</td>
</tr>
<tr>
<td>Adherence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention Integrity-</td>
<td>Not</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Attention Bias (exposure)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention Integrity-</td>
<td>Unclear</td>
<td>Unclear whether participants’ could have engaged in other interventions.</td>
</tr>
<tr>
<td>Programme Differentiation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Integrity of Intervention-</td>
<td>High Risk</td>
<td>Authors give no indication for an allegiance effect. However, as some authors are founders of STEPPS, and were involved in the training, supervision and were present at several intervention sessions, an allegiance effect seems not improbable.</td>
</tr>
<tr>
<td>Quality of Delivery (Allegiance Effect)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Integrity of Intervention-</td>
<td>High Risk</td>
<td>Participant satisfaction measured as high. High level of drop out (47%). &quot;the dropout rate was high, and this may have compromised the integrity of the findings.” (Black et al. 2013, p.128) No reasons given for drop out.</td>
</tr>
<tr>
<td>Participant Responsiveness</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Selection Bias</strong></th>
<th><strong>Author’s judgement</strong></th>
<th><strong>Support for Judgement</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Random Sequence Generation</td>
<td>Unclear Risk</td>
<td>&quot;the data were collected as an integral part of the STEPPS treatment program&quot; (Blum et al 2002, p.306). Unlear whether any bias could exist in the selection of participants by clinicians.</td>
</tr>
<tr>
<td>Allocation Concealment</td>
<td>Not Applicable</td>
<td></td>
</tr>
</tbody>
</table>

### Detection Bias

| **Blinding of Outcome Assessment** | **Low Risk** | No blinding of outcome assessment, but outcome measurement is entirely self report so is not likely to be influenced by lack of blinding |

### Attrition Bias

| **Incomplete Outcome Data** | **Unclear Risk** | Insufficient reporting of attrition/exclusions to permit judgement of ‘Low risk’ or ‘High risk’- unclear how missing data was treated in the analysis. |

### Reporting Bias

| **selective reporting** | **Unclear Risk** | No protocol available |

### Intervention Integrity

| **Adherence** | **Unclear Risk** | Comprehensive training and supervision offered to all therapists by intervention developers. |
| **Attention Bias (exposure)** | **Not Applicable** | |
| **Programme Differentiation** | **Unclear Risk** | Did not report whether participants' engaged in other interventions. |

### Integrity of Intervention

| **Quality of Delivery (Allegiance Effect)** | **High Risk** | Authors give no indication for an allegiance effect. However, as some authors are founders of STEPPS, and were involved in the training, supervision, an allegiance effect seems not improbable. |

| **Participant Responsiveness** | **High Risk** | "Although response rates for the surveys were suboptimal, they show that among those who responded STEPPS has high levels of acceptance for both efficacy (i.e. self-harm) and process (i.e. amount of materials, length of session) variables. (Blum et al 2002, p.308) However, high levels of drop out with no reasons provided for this. |


<table>
<thead>
<tr>
<th><strong>Selection Bias</strong></th>
<th><strong>Author’s judgement</strong></th>
<th><strong>Support for Judgement</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Random Sequence Generation</td>
<td>Low Risk</td>
<td>Allocation randomised by drawing of lots. (Study Protocol provided by Bos)</td>
</tr>
<tr>
<td>Allocation Concealment</td>
<td>Low Risk</td>
<td>Centralised randomisation (Study protocol provided by Bos)</td>
</tr>
<tr>
<td>Detection Bias - Blinding of Outcome Assessment</td>
<td>Author's judgement</td>
<td>Support for Judgement</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>--------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td></td>
<td>Unclear Risk</td>
<td>Data collected by researchers separate to the facilitators. Insufficient information about blinding to permit judgement of risk of bias.</td>
</tr>
</tbody>
</table>

| Attrition Bias - Incomplete Outcome Data | Low Risk | "Intention-to-treat analyses, in which also patients are included who did not receive the intervention as intended, were performed as well. The perprotocol and intention-to-treat analyses yielded similar results." (Bos et al 2010, p.300) |

| Reporting Bias - selective reporting | High Risk | According the the measures suggested in the protocol, not all of the study’s pre-specified primary outcomes have been reported |

| Intervention Integrity - Adherence | Low Risk | "STEPPS trainers met twice a year under the supervision of expert trainers to evaluate the procedure and preserve uniformity. After each session, individual therapists completed a self-report questionnaire by which the content and frequency of the therapy contacts could be checked." (Bos - email to author) |

| Intervention Integrity - Attention Bias (exposure) | High Risk | Participants in STEPPS received 18 x weekly group session plus weekly individual sessions. Participants in TAU received weekly sessions every 1-4 weeks which is likely to be significantly less than treatment group. |

| Intervention Integrity - Programme Differentiation | Low Risk | Provided specific STEPPS individual therapy to afind confounding with TAU. Monitored contact with professionals in both groups to ensure integrity of interventions. |

| Integrity of Intervention - Quality of Delivery (Allegiance Effect) | Low Risk | "STEPPS therapists met twice a year under the supervision of expert trainers to evaluate the procedure and to preserve uniformity." (Bos et al 2010, p.300) |

| Integrity of Intervention - Participant Responsiveness | Unclear Risk | No method of measuring participant satisfaction. Four of 42 in STEPPS condition dropped out due to factors related to the programme. |

---


| Selection Bias - Random Sequence Generation | Low Risk | Allocation randomised by drawing of lots. (Study Protocol provided by Bos) "16–24 sealed envelopes were prepared containing a paper with the patient’s enrolment number, stratified by BPD status." (Bos et al 2011, p.175) |

<p>| Selection Bias - Allocation Concealment | Low Risk | Centralised randomisation (Study protocol provided by Bos) &quot;The envelopes were then handed over to a research assistant in random order.&quot; (Bos et al 2011, p.175) |</p>
<table>
<thead>
<tr>
<th>Bias Type</th>
<th>Risk Level</th>
<th>Support for Judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detection Bias - Blinding of Outcome Assessment</td>
<td>Low Risk</td>
<td>All self-report</td>
</tr>
<tr>
<td>Attrition Bias - Incomplete Outcome Data</td>
<td>Low Risk</td>
<td>&quot;We present the results for the intention-to-treat (ITT) analyses, unless otherwise indicated. In the ITT analyses, all available data of the patients who started with the intervention (n = 168) were used.&quot; (Bos et al 2011, p.176)</td>
</tr>
<tr>
<td>Reporting Bias - selective reporting</td>
<td>High Risk</td>
<td>According to the measures suggested in the protocol, not all of the study’s pre-specified primary outcomes have been reported</td>
</tr>
<tr>
<td>Intervention Integrity - Adherence</td>
<td>Unclear Risk</td>
<td>&quot;STEPPS trainers met twice a year under the supervision of expert trainers to evaluate the procedure and preserve uniformity. After each session, individual therapists completed a self-report questionnaire by which the content and frequency of the therapy contacts could be checked.&quot; (Bos - email to author)</td>
</tr>
<tr>
<td>Intervention Integrity - Attention Bias (exposure)</td>
<td>Low Risk</td>
<td>Participants in STEPPS received 18 x weekly group session plus weekly individual sessions. Participants in TAU received weekly sessions every 1-4 weeks which is likely to be significantly less than treatment group. However, authors included additional analysis which showed no significant effect of length or frequency of contact (Bos et al 2011, p179)</td>
</tr>
<tr>
<td>Intervention Integrity - Programme Differentiation</td>
<td>Low Risk</td>
<td>Provided specific STEPPS individual therapy to avoid confounding with TAU. Monitored contact with professionals in both groups to ensure integrity of interventions. Two cases were excluded due to breaching criteria regarding treatment integrity.</td>
</tr>
<tr>
<td>Integrity of Intervention - Quality of Delivery (Allegiance Effect)</td>
<td>Unclear Risk</td>
<td>Insufficient reporting of allegiance/quality to permit judgement of 'high/low' risk</td>
</tr>
<tr>
<td>Integrity of Intervention - Participant Responsiveness</td>
<td>Unclear Risk</td>
<td>No method of measuring participant satisfaction. 11 out of 84 STEPPS condition dropped out due to factors related to the programme.</td>
</tr>
</tbody>
</table>

Fleischhaker et al. (2011)

<table>
<thead>
<tr>
<th>Bias Type</th>
<th>Risk Level</th>
<th>Support for Judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selection Bias - Random Sequence Generation</td>
<td>Low Risk</td>
<td>&quot;Participation in our pilot study on DBT-A was proposed to all families with adolescent females exhibiting nonsuicidal self-injurious and suicidal behavior.&quot; (Fleischhaker et al 2011, p.2)</td>
</tr>
<tr>
<td>Selection Bias - Allocation Concealment</td>
<td>Author's judgement</td>
<td>Support for Judgement</td>
</tr>
<tr>
<td>----------------------------------------</td>
<td>--------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td></td>
<td>Not Applicable</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Detection Bias - Blinding of Outcome Assessment</th>
<th>Author's judgement</th>
<th>Support for Judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Risk</td>
<td></td>
<td>No blinding of outcome assessment. p9</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Attrition Bias - Incomplete Outcome Data</th>
<th>Author's judgement</th>
<th>Support for Judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Risk</td>
<td></td>
<td>Missing data have been imputed using appropriate methods.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reporting Bias - selective reporting</th>
<th>Author's judgement</th>
<th>Support for Judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unclear Risk</td>
<td></td>
<td>No protocol available.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Intervention Integrity - Adherence</th>
<th>Author's judgement</th>
<th>Support for Judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unclear Risk</td>
<td></td>
<td>This paper did not include information to permit the judgement of risk of bias.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Intervention Integrity - Attention Bias (exposure)</th>
<th>Author's judgement</th>
<th>Support for Judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Intervention Integrity - Programme Differentiation</th>
<th>Author's judgement</th>
<th>Support for Judgement</th>
</tr>
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<tbody>
<tr>
<td>Unclear Risk</td>
<td></td>
<td>Insufficient reporting of equivalence of attention to permit judgement of ‘Low risk’ or ‘High risk’</td>
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<table>
<thead>
<tr>
<th>Integrity of Intervention - Quality of Delivery (Allegiance Effect)</th>
<th>Author's judgement</th>
<th>Support for Judgement</th>
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<tbody>
<tr>
<td>Unclear Risk</td>
<td></td>
<td>Insufficient reporting of allegiance/quality to permit judgement of 'high/low' risk</td>
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<thead>
<tr>
<th>Integrity of Intervention - Participant Responsiveness</th>
<th>Author's judgement</th>
<th>Support for Judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Risk</td>
<td></td>
<td>Low drop out rate- those that dropped out did so for reasons other than dissatisfaction.</td>
</tr>
</tbody>
</table>

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Harvey, R., Black, D. W., & Blum, N. (2010)

<table>
<thead>
<tr>
<th>Selection Bias - Random Sequence Generation</th>
<th>Author's judgement</th>
<th>Support for Judgement</th>
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<tbody>
<tr>
<td>Unclear Risk</td>
<td></td>
<td>Insufficient information to determine whether there could be any confounding factors in the pattern of referrals to the study. &quot;Referrals were received from community teams in six areas of West Sussex.&quot; (Harvey et al 2010, p.226).</td>
</tr>
</tbody>
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<table>
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<tr>
<th>Selection Bias - Allocation Concealment</th>
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<th>Support for Judgement</th>
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<tbody>
<tr>
<td>Not Applicable</td>
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<td></td>
</tr>
<tr>
<td>Bias Type</td>
<td>Risk Level</td>
<td>Support for Judgement</td>
</tr>
<tr>
<td>---------------------------</td>
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</tr>
<tr>
<td>Detection Bias - Blinding of Outcome Assessment</td>
<td>Low Risk</td>
<td>&quot;Assessments were carried out by the head researcher assisted by professional colleagues (all clinical psychologists). Strict protocols for test administration were followed to assure standardised procedures according to the test authors’ specifications. Data collected was handed to a research assistant not connected with the running of groups, for data input, and analysis.&quot; (Harvey et al 2010, p.228)</td>
</tr>
<tr>
<td>Attrition Bias - Incomplete Outcome Data</td>
<td>High Risk</td>
<td>&quot;An intention-to-treat analysis may have helped guard against a type 1 error, but was not done.&quot; (Harvey et al 2010, p.230)</td>
</tr>
<tr>
<td>Reporting Bias - selective reporting</td>
<td>Unclear Risk</td>
<td>No protocol available.</td>
</tr>
<tr>
<td>Intervention Integrity - Adherence</td>
<td>Low Risk</td>
<td>&quot;Each of the programs were also attended by one or two ‘‘observers,’’ who provided additional assistance, monitored adherence to the model (according to a protocol provided by the author, NB), or were there for training purposes.&quot; (Harvey et al 2010, p.227)</td>
</tr>
<tr>
<td>Intervention Integrity - Attention Bias (exposure)</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td>Intervention Integrity - Programme Differentiation</td>
<td>High Risk</td>
<td>Participants’ continued to other interventions during the study period and the extent to this was not measured.</td>
</tr>
<tr>
<td>Integrity of Intervention - Quality of Delivery (Allegiance Effect)</td>
<td>High Risk</td>
<td>&quot;The close involvement of strong supporters of the model in running the programs and conducting the research are important to bear in mind&quot; (Harvey et al 2010, p.231)</td>
</tr>
<tr>
<td>Integrity of Intervention - Participant Responsiveness</td>
<td>Unclear Risk</td>
<td>No assessment of reasons for drop out &amp; no measure of participant satisfaction.</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Bias Type</th>
<th>Risk Level</th>
<th>Support for Judgement</th>
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<tbody>
<tr>
<td>Selection Bias - Random Sequence Generation</td>
<td>Low Risk</td>
<td>Participants recruited through various sources including self-selection. Participants not excluded.</td>
</tr>
<tr>
<td>Selection Bias - Allocation Concealment</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td>Detection Bias - Blinding of Outcome Assessment</td>
<td>Low Risk</td>
<td>Unclear blinding of outcome assessment, but outcome measurement is entirely self-report so is not likely to be influenced by lack of blinding.</td>
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<td><strong>Author's judgement</strong></td>
<td><strong>Support for Judgement</strong></td>
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</tr>
<tr>
<td><strong>Attrition Bias</strong>- Incomplete Outcome Data</td>
<td>Low Risk</td>
<td>Missing data have been imputed using appropriate methods.</td>
</tr>
<tr>
<td><strong>Reporting Bias</strong>- selective reporting</td>
<td>Unclear Risk</td>
<td>No protocol available.</td>
</tr>
<tr>
<td><strong>Intervention Integrity</strong>- Adherence</td>
<td>Unclear Risk</td>
<td>The paper did not address this issue, but comments that it is a replication of earlier study that did employ measures of adherence.</td>
</tr>
<tr>
<td><strong>Intervention Integrity</strong>- Attention Bias (exposure)</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Intervention Integrity</strong>- Programme Differentiation</td>
<td>Unclear Risk</td>
<td>No further information given regarding participants' involvement in other interventions, but given referrals from variety of sources, very likely that some participants would have received input from other services.</td>
</tr>
<tr>
<td><strong>Integrity of Intervention</strong>- Quality of Delivery (Allegiance Effect)</td>
<td>High Risk</td>
<td>Lead authors are founders of Family Connections, and were involved in the training &amp; supervision, an allegiance effect seems not improbable.</td>
</tr>
<tr>
<td><strong>Integrity of Intervention</strong>- Participant Responsiveness</td>
<td>Low Risk</td>
<td>&quot;Dropout rate for the program, as defined by missing more than three sessions in the 12- week series, was 7%. Group attendance was high with an average of 83.25% sessions attended.&quot; (p.74)</td>
</tr>
</tbody>
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<tr>
<td><strong>Detection Bias</strong>- Blinding of Outcome Assessment</td>
<td>Low Risk</td>
</tr>
<tr>
<td><strong>Attrition Bias</strong>- Incomplete Outcome Data</td>
<td>Low Risk</td>
</tr>
<tr>
<td><strong>Reporting Bias</strong>- selective reporting</td>
<td>Unclear Risk</td>
</tr>
<tr>
<td>Intervention</td>
<td>Author's judgement</td>
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<tr>
<td><strong>Intervention Integrity</strong>-Adherence</td>
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</tr>
<tr>
<td><strong>Intervention Integrity</strong>-Attention Bias (exposure)</td>
<td>Not Applicable</td>
</tr>
<tr>
<td><strong>Intervention Integrity</strong>-Programme Differentiation</td>
<td>Unclear Risk</td>
</tr>
<tr>
<td><strong>Integrity of Intervention</strong>-Quality of Delivery (Allegiance Effect)</td>
<td>High Risk</td>
</tr>
<tr>
<td><strong>Integrity of Intervention</strong>-Participant Responsiveness</td>
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<tbody>
<tr>
<td><strong>Selection Bias</strong>-Random Sequence Generation</td>
<td>Unclear Risk</td>
<td>Unclear whether confounding factors exist in referral to research study.</td>
</tr>
<tr>
<td><strong>Selection Bias</strong>-Allocation Concealment</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Detection Bias</strong>-Blinding of Outcome Assessment</td>
<td>Unclear Risk</td>
<td>&quot;Independent audit outcome measures were carried out at the start of full treatment and end of treatment.&quot; (James et al 2011, p.10) unclear what independent means.</td>
</tr>
<tr>
<td><strong>Attrition Bias</strong>-Incomplete Outcome Data</td>
<td>Low Risk</td>
<td>Missing data have been imputed using appropriate methods. &quot;Importantly, these findings maintained after an intention-to-treat analysis (ITT).&quot; (p.11)</td>
</tr>
<tr>
<td><strong>Reporting Bias</strong>-selective reporting</td>
<td>Unclear Risk</td>
<td>No protocol available.</td>
</tr>
<tr>
<td><strong>Intervention Integrity</strong>-Adherence</td>
<td>Low Risk</td>
<td>Therapist consultation meetings aiming to &quot;Enhancing therapist capabilities, ensure adherence to the DBT model and support&quot; (p.10)</td>
</tr>
<tr>
<td><strong>Author's judgement</strong></td>
<td><strong>Support for Judgement</strong></td>
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<td>Not Applicable</td>
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<td></td>
</tr>
<tr>
<td><strong>Integrity of Intervention</strong>- Participant Responsiveness</td>
<td>Unclear Risk</td>
<td></td>
</tr>
</tbody>
</table>

The study did not address this outcome.

Insufficient reporting of allegiance/quality to permit judgement of ‘Low risk’ or ‘High risk’

Insufficient reporting of participant responsiveness to permit judgement of ‘Low risk’ or ‘High risk’

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</tr>
<tr>
<td><strong>Selection Bias</strong>- Allocation Concealment</td>
<td>Low Risk</td>
</tr>
<tr>
<td><strong>Detection Bias</strong>- Blinding of Outcome Assessment</td>
<td>Low Risk</td>
</tr>
<tr>
<td><strong>Attrition Bias</strong>- Incomplete Outcome Data</td>
<td>Low Risk</td>
</tr>
</tbody>
</table>

Insufficient information about the sequence generation process to permit judgement of ‘Low risk’ or ‘High risk’

"daily management of the randomization procedures was performed by an external group” (p.1083)

"Two child and adolescent psychiatrists and 2 doctoral level clinicians, blinded to treatment allocation, conducted the baseline interviews. Ten independent assessors, blinded to treatment allocation and to results from baseline interviews, conducted interviews at trial completion. To ensure the integrity of blinding, a non-blinded project coordinator made all of the practical arrangements for follow-up interviews and collected treatment history data. All patients were instructed not to disclose any information about their treatment. When asked after completion of interviews which treatment they thought each patient received, assessors’ responses were correct for 44.2% of patients (Cohen’s k=0.12), indicating that blinding was successful.” (p. 1085)

"A separate series of analyses was conducted with only those patients who had dropped less than 4 treatment sessions (n = 47). The differences between the 2 treatment conditions remained significant for all 3 primary outcome variables." (p.1088)
| Reporting Bias- selective reporting | Low Risk | The study protocol is available ([https://clinicaltrials.gov/ct2/show/record/NCT00675129?term=NCT00675129&rank=1](https://clinicaltrials.gov/ct2/show/record/NCT00675129?term=NCT00675129&rank=1)) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way. |
| Intervention Integrity- Adherence | Low Risk | "Adherence to DBT continued to be assessed throughout the trial. For each patient–therapist dyad in individual therapy, 5 videotaped sessions (first 2 sessions and 3 random) were rated by an independent rater (S.L.) trained to and maintaining reliability with the treatment developer group in the use of the DBT Global Rating Scale... On average, 1 randomly selected videotaped skills training session per group was rated per month." (p. 1084-1085) Although authors state that control treatment not monitored for adherence, therapists were not trained in DBT and therefore the risk of overlap in treatments is low. |
| Intervention Integrity- Attention Bias (exposure) | High Risk | "Only DBT-A patients received skills-training group sessions; this implied a significant difference in the treatment intensity between interventions." (p.1090) |
| Intervention Integrity- Programme Differentiation | Unclear Risk | The study did not address this outcome. |
| Integrity of Intervention- Quality of Delivery (Allegiance Effect) | Low Risk | "Fifteen psychologists and psychiatrists previously unfamiliar with DBT were recruited for the purpose of the trial and were trained through an 80-hour seminar with an additional 12 months of supervised practice on clinical training cases, and were rated for adherence to DBT-A treatment principles." (p.1084) |
| Integrity of Intervention- Participant Responsiveness | Low Risk | "Treatment retention in this study was generally good, with no differences between the 2 treatment conditions." (p.1088-1089) |

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<tr>
<td>Detection Bias</td>
<td>Low Risk</td>
<td>Outcome assessment is entirely self report so not likely to be influenced by lack of blinding.</td>
</tr>
<tr>
<td>Blinding of Outcome Assessment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attrition Bias</td>
<td>Low Risk</td>
<td>&quot;Follow up analyses were conducted on only those participants who had complete data (i.e., the set of 29 participants at pre- and post-participation) and yielded similar results as those described above....&quot; (Neiditch 2010, p.29)</td>
</tr>
<tr>
<td>Incomplete Outcome Data</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reporting Bias</td>
<td>Unclear Risk</td>
<td>No protocol available</td>
</tr>
<tr>
<td>selective reporting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention Integrity-</td>
<td>Unclear Risk</td>
<td>The study did not address this outcome.</td>
</tr>
<tr>
<td>Adherence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention Integrity-</td>
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<td></td>
</tr>
<tr>
<td>Attention Bias (exposure)</td>
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<td></td>
</tr>
<tr>
<td>Intervention Integrity-</td>
<td>Unclear Risk</td>
<td>The study did not address this outcome.</td>
</tr>
<tr>
<td>Programme Differentiation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Integrity of Intervention-</td>
<td>Unclear Risk</td>
<td>Insufficient reporting of allegiance/quality to permit judgement of 'Low risk' or 'High risk'</td>
</tr>
<tr>
<td>Quality of Delivery (Allegiance Effect)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Integrity of Intervention-</td>
<td>Unclear Risk</td>
<td>&quot;As a result, there are 38 participants for whom data is missing at the post-participation assessment. Also missing are further details regarding numbers of participants who were recruited and who dropped out during the program.&quot; (Neiditch 2010, p.17)</td>
</tr>
<tr>
<td>Participant Responsiveness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Selection Bias</td>
<td>High Risk</td>
<td>Allocation by clinician judgement.</td>
</tr>
<tr>
<td>Random Sequence Generation</td>
<td></td>
<td>&quot;This group of patients was assigned to DBT based on a triage model, with those patients who met criteria indicating the greatest need for this treatment (i.e., suicidality plus borderline personality features) assigned to it. Participants who met criterion A or criterion B but not both were assigned to TAU.&quot; (Rathus &amp; Miller 2002, p.148-149)</td>
</tr>
<tr>
<td>Selection Bias</td>
<td>High Risk</td>
<td>Allocation by clinician judgement.</td>
</tr>
<tr>
<td>Allocation Concealment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Detection Bias - Blinding of Outcome Assessment</td>
<td>Low Risk</td>
<td>Unclear blinding of outcome assessment, but outcome measurement is entirely self-report or objective so is not likely to be influenced by lack of blinding.</td>
</tr>
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<td>-----------------------------------------------</td>
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</tr>
<tr>
<td>Attrition Bias - Incomplete Outcome Data</td>
<td>Unclear Risk</td>
<td>The study did not address this outcome.</td>
</tr>
<tr>
<td>Reporting Bias - selective reporting</td>
<td>Unclear Risk</td>
<td>No protocol available.</td>
</tr>
<tr>
<td>Intervention Integrity - Adherence</td>
<td>Low Risk</td>
<td>&quot;To enhance DBT adherence, all therapists followed a formally modified skills training protocol (Miller, Rathus, Landsman &amp; Linehan, 1995), and skills groups were videotaped for teaching and supervision purposes. In addition, individual therapists audiotaped therapy sessions for individual supervision, and participated in weekly therapist consultation team meetings which included group supervision and didactic instruction in DBT.&quot; (p.149)</td>
</tr>
<tr>
<td>Intervention Integrity - Attention Bias (exposure)</td>
<td>Low Risk</td>
<td>&quot;DBT treatment was comprised of 12 weeks of twice weekly individual and multi-family skills training.&quot; &quot;TAU condition was comprised of 12 weeks of twice weekly individual and family sessions.&quot; (p.149)</td>
</tr>
<tr>
<td>Intervention Integrity - Programme Differentiation</td>
<td>Unclear Risk</td>
<td>The study did not address this outcome.</td>
</tr>
<tr>
<td>Integrity of Intervention - Quality of Delivery (Allegiance Effect)</td>
<td>Low Risk</td>
<td>Authors considered this risk. &quot;the possibility exists that differences between groups could be accounted for by differential enthusiasm conveyed to patients regarding the two treatments..... our TAU condition was delivered in a teaching hospital with supervisors committed to the short-term psychodynamic model and trainees eager to learn it. Thus, we feel this threat is minimized.&quot; (p.155)</td>
</tr>
<tr>
<td>Integrity of Intervention - Participant Responsiveness</td>
<td>Unclear Risk</td>
<td>High drop-out rate with no reasons given. Difference between groups in drop-out. Insufficient reporting of participant responsiveness to permit judgement of ‘Low risk’ or ‘High risk’</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bias Type</th>
<th>Author's judgement</th>
<th>Support for Judgement</th>
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<td><strong>Selection Bias</strong>&lt;br&gt;Allocation Concealment</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Detection Bias</strong>&lt;br&gt;Blinding of Outcome Assessment</td>
<td>Unclear Risk</td>
<td>The paper did not address this outcome.</td>
</tr>
<tr>
<td><strong>Attrition Bias</strong>&lt;br&gt;Incomplete Outcome Data</td>
<td>High Risk</td>
<td>&quot;The following results are based on participants with complete data. Of the 13 adolescents who participated in group, 9 had complete interview data and 8 had complete questionnaire data. Concerning the 16 caregivers who participated in the study, only 10 had full questionnaire data. This was due to two families leaving (two adolescents and three caregivers), as well as the failure to obtain full assessments on the remaining participants.&quot; (p.210)</td>
</tr>
<tr>
<td><strong>Reporting Bias</strong>&lt;br&gt;selective reporting</td>
<td>Unclear Risk</td>
<td>No protocol available</td>
</tr>
<tr>
<td><strong>Intervention Integrity</strong>&lt;br&gt;Adherence</td>
<td>Unclear Risk</td>
<td>The study did not address this outcome.</td>
</tr>
<tr>
<td><strong>Intervention Integrity</strong>&lt;br&gt;Attention Bias (exposure)</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Intervention Integrity</strong>&lt;br&gt;Programme Differentiation</td>
<td>Unclear Risk</td>
<td>The study did not address this outcome.</td>
</tr>
<tr>
<td><strong>Integrity of Intervention</strong>&lt;br&gt;Quality of Delivery (Allegiance Effect)</td>
<td>Low Risk</td>
<td>&quot;There were four trained clinical psychology graduate students who were involved in leading groups throughout this study. For each individual group, two to four of these group leaders were present. In all groups, at least one of the group leaders had previously coled groups with doctoral level clinicians, completed an intensive DBT training, and had consistently practiced DBT at both the group and the individual treatment level independent of the present study. All group leaders attended a weekly DBT team consultation meeting and were supervised by a doctoral level clinician with approximately 15 years of experience administering DBT and leading skills groups.&quot; (p.209)</td>
</tr>
<tr>
<td><strong>Integrity of Intervention</strong>&lt;br&gt;Participant Responsiveness</td>
<td>Low Risk</td>
<td>No participating families missed more than four group sessions, meaning that the attendance rate was 75% or higher for all families. p209</td>
</tr>
<tr>
<td>Bias</td>
<td>Author's judgement</td>
<td>Support for Judgement</td>
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<tr>
<td><strong>Selection Bias</strong></td>
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</tr>
<tr>
<td>Random Sequence Generation</td>
<td>Low Risk</td>
<td>Participants recruited through various sources including self-selection. p278</td>
</tr>
<tr>
<td>Allocation Concealment</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td><strong>Detection Bias</strong></td>
<td></td>
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<tr>
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<td>Low Risk</td>
<td>Unclear blinding of outcome assessment, but outcome measurement is entirely self-report so is not likely to be influenced by lack of blinding.</td>
</tr>
<tr>
<td><strong>Attrition Bias</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incomplete Outcome Data</td>
<td>High Risk</td>
<td>Potentially inappropriate application of simple imputation- high drop out and no ITT analysis.</td>
</tr>
<tr>
<td><strong>Reporting Bias</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>selective reporting</td>
<td>Unclear Risk</td>
<td>No protocol available.</td>
</tr>
<tr>
<td><strong>Intervention Integrity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adherence</td>
<td>Low Risk</td>
<td>&quot;One-hour weekly consultation team supervision was the primary check on DBT treatment adherence and included review of session videotapes. Many clinicians also completed checklists of the DBT components and strategies they used in individual sessions to self-monitor adherence.&quot; (p.280)</td>
</tr>
<tr>
<td>Attention Bias (exposure)</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td>Pre-treatment measures collected before the first skills group session, but some participants had already begun individual DBT treatment prior to this.</td>
<td></td>
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</tr>
<tr>
<td>Programme Differentiation</td>
<td>High Risk</td>
<td></td>
</tr>
<tr>
<td>Quality of Delivery (Allegiance Effect)</td>
<td>Low Risk</td>
<td>Comprehensive training package described. &quot;The context of voluntary but committed participation among our diverse group of clinicians fostered dialectical discussions and creativity.&quot; (p.280)</td>
</tr>
<tr>
<td>Participant Responsiveness</td>
<td>Unclear Risk</td>
<td>High drop-out rate with no reasons given. Insufficient reporting of participant responsiveness to permit judgement of ‘Low risk’ or ‘High risk’</td>
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<td><strong>Integrity of Intervention</strong></td>
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Appendix A.6

Inter-rater Reliability for Assessment of Risk of Bias

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Appendix B.1

Author Guidelines for Mental Health Review Journal

Mental Health Review Journal
Research, Policy and Practice
ISSN: 1361-9322

Journal Information

*Mental Health Review Journal (MHRJ)* is a vital source of current thinking on the research, policy and practice of mental health service delivery, bringing together research and practice perspectives.

This double blind peer-reviewed journal focuses on the delivery and evaluation of mental health services in the UK, with particular attention to innovation, implementation and service user experience. International contributions are welcomed where these apply innovation and best practice to, or draw out the context for, the UK.

*MHRJ* includes research and practitioner papers, discussion/commentary papers, policy reviews, case studies and book reviews covering, but not limited to:

- Contemporary issues in the mental health field
- The design and management of services
- Service evaluation, research and methodology
- Innovations in service developments
- New practice models (including clinical practice) and their implications
- Good practice in relation to issues of ethnic diversity
- Contributions from mental health service users and carers

*MHRJ* is a valuable source of information for everyone involved in mental health service research and delivery, including academics, researchers, students, commissioners, front-line practitioners, policy-makers, managers, health boards, education providers, local authorities, NHS and primary care trusts, the voluntary and community sectors, service users and carers.
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CINAHL, CPA’s AgeInfo, Illustrata, PsycINFO, Scopus, Social Care Online, ZETOC.

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<td>Headings must be concise, with a clear indication of the distinction between the hierarchy of headings. The preferred format is for first level headings to be presented in bold format and subsequent sub-headings to be presented in medium italics.</td>
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<td>Notes/Endnotes</td>
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e.g. Harrow, R. (2005), *No Place to Hide*, Simon & Schuster, New York, NY
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Appendix B.2

Additional Results for Service Improvement Project

Results not presented in the main body of the paper are presented here.

The Group and how it operates

Facilitation

Ten participants talked about the current format of the group. They debated the balance of having a flexible format where staff were free to talk the way they wanted but at the same time wondering if it would be more helpful to have a more structured way of operating.

P1: “I wouldn’t want to make it too structured, I quite like the flexibility of it.”

P11: “It needs a structure. What is discussed there, why are we discussing it there, what we here for, what is our expectations? So if you know that, then these groups are good, otherwise I’d say it is a waste of [Facilitating Psychologist's] time.”

They also valued the role of the facilitating psychologist in coordinating the discussion from an impartial perspective.

P8: “[Facilitating Psychologist] is really good at getting the discussion going about kind of about you know “what do you think”, “what's the formulation”, “what's…””

P6: “So I think it is good to have someone from outside. And in many ways [Facilitating Psychologist] is from outside coz she isn’t...there’s no...there’s nobody really who she manages from that respect on the ward.”

Impact and Usefulness

Valued by Staff

Nine participants talked in general about how they valued the group, with most viewing the group positively.

P2: “I think they are really valuable, I’ve got no criticism of them at all, I find them very useful. I don’t know if all my colleagues do but I do.”

P8: “I find it quite useful to go, I do yeah.”

But one participant spoke about the group perhaps being an unnecessary use of resources (11)

“I think it is a luxury having a clinical discussion group if I am honest.” (11)

“No no, I think it is very helpful, but I think it adds more strain to what we already have...resources.” (11)
In addition, two participants described the work carried out by managers and psychology in order to create an environment where the group is valued.

P3: “there has been quite a lot of work in the background, to get the sort of people to turn up, and it’s happening slowly….sorry I am now talking about the sort of stuff that happens outside the room in order to get the people into the room, but there is… there has been…I have worked here 10 years or something ridiculous, no its not quite 10 years…well it is nearly 10 years…and there have been lots of groups that haven’t worked, similar groups which haven’t worked, and it’s important to do the work outside the room, to get the people into the room”

Learning

Four participants talked about learning something from attending the group.

P1: “Because you can learn anything from any discussion couldn’t you, regardless whether it’s specifically your interest or not.”

P5: “it’s helping me because it’s helping me broaden my knowledge and it’s helping me understand why people might put certain things in place with regards to patient care”

One participant noted that the group had also led them to do further research.

P6: “I looked up assessment tools and had a better conversation with her…”

Responsibility for Follow Up

The responsibility for following up any actions from the group was discussed with many participants describing the difficulty finding time in the busy work schedule to do this effectively.

P10: “… then someone would say “well I will make it my responsibility to try to get them up” sort of thing. And that is kind of the only thing, unless it is like nurses to follow up stuff. It is just, sort of like, just those basics…ummm…yeah.”

P9: “It should happen. Sometimes it just gets forgotten about, it’s so busy. But I will try and take that forward. It is something that I have discussed with the ward manager before so it is something ….it’s just making it happen, yeah it can be forgotten.”
Appendix B.3

Service Description for Service Improvement Project

Avon and Wiltshire Mental Health Partnership NHS Trust (AWP) provides mental health services covering Bath and North East Somerset (B&NES), Bristol, North Somerset, South Gloucestershire, Swindon and Wiltshire.

Sycamore ward is an acute inpatient service located in Bath for adults whose health care needs are complex, intense and unpredictable. The service is based upon a recovery model of care (National Institute for Mental Health in England, 2005) which is provided by a multidisciplinary team. The key outcomes of the service are to:

- Care for adults in an inpatient setting, building on patients' strengths, maintaining levels of independence and promoting well-being;
- Use evidence based therapeutic interactions within a multidisciplinary approach;
- Provide inpatient treatment 24/7 for people with mental health problems;
- Support service users experiencing an acute psychiatric crisis of such severity that they cannot be managed at home with the involvement of the intensive team. (Avon and Wiltshire Mental Health Partnership NHS Trust, n.d.)

Nurses, Health Care Assistants and Medics provide 24 hour care for inpatients with a shift rotation allowing for information handover between staff changes. Other therapeutic staff provide input within working hours on weekdays and weekends.

Clinical supervision is an essential forum for professional development, quality control and personal support. As such, it is recognised by Avon and Wiltshire Partnership NHS Trust as a requirement for all practitioners (Staff Supervision Policy- P044: (Avon and Wiltshire Mental Health Partnership NHS Trust, 2012) with a minimum standard set at one hour bi-monthly or an amount sufficient to maintain registration. A recent initiative, “Information of Quality”, established by Avon and Wiltshire Partnership Trust has introduced supervision as one of seven important areas for ensuring high quality service provision.
Appendix B.4

Dissemination of the project to the service for the Service Improvement Project

Dissemination to the service consisted of three phases:

- Feeding back the result to Katharine Christie, the facilitating psychologist;
- Feeding back the results to the staff and ward manager at Sycamore ward via a presentation;
- Gathering responses from the feedback to determine acceptability and feasibility of the recommendations.

Feeding back the result to Katharine Christie, the facilitating psychologist

Having shared the results with KC, there was further discussion regarding the changes that could be made to the CDG. It was encouraging that the research found many strengths and helpful aspects of the group and KC agreed that it would be important to continue offering those things that staff found most helpful. With regards to the suggested changes, it was discussed that these could be of benefit to the ward, but some (e.g. weekly sessions) may be difficult to implement given funding and time constraints. Other changes, such as preparation for the sessions by both supervisees and supervisor would require further discussion and negotiation with the staff team in order to reach an agreement as to which member hold responsibility for this.

Feeding back the results to the staff and ward manager at Sycamore ward via a presentation

I delivered a presentation to the ward manager and six staff members on 18th September 2014 (Appendix 5). This was accompanied by a summary hand-out (Appendix 4).

Gathering responses from the feedback to determine acceptability and feasibility of the recommendations

Following the presentation staff were invited to share their views on the results and recommendations and to come up with ideas of how they could be implemented. In general, the comments were positive, particularly around the recognition of the usefulness of the group. Some suggestions were made regarding implementation:

- Increasing CDG sessions to once per week was viewed as helpful as more patients could be included in the team formulation, enhancing collaborative care.
• Choosing a discussion topic in advance, although viewed as time consuming, received positive feedback. Staff suggested that this would allow staff not working on that day to decide if they wanted to attend the group anyway. The manager was in support of this and suggested that those staff could be given time off in lieu for this. Advanced preparation would also be possible as the ward had been improving staff office space which in the near future would include a room where electronic notes and projectors would be available.

• Staff were in agreement that focusing on outcomes and action for the patients was important although not all discussion topic lent themselves to this. It was also agreed that revisiting any agreed plans in the following session would be helpful.

• Disseminating the group outcomes appeared to be important for the staff who attended the feedback session. Several challenging aspects to this were raised though, including potential disagreements about what information should go in the summary and who would be responsible for this. Suggestions regarding these issues were to spend a few minutes at the end of the CDG session summarising and agreeing what to disseminate and that this should be led by KC as the group facilitator to be emailed to all staff.
Appendix B.5
Summary hand-out of project for the service for Service Improvement Project

An evaluation of a Clinical Discussion Group for Inpatient Staff

As you may be aware I am a Trainee Clinical Psychologist from the University of Bath and have been working alongside Dr Katharine Christie (Clinical Psychologist) to complete a research project exploring ways in which the Clinical Discussion Group could best meet the needs of the staff working on Sycamore Ward. Below is a summary of the research and outcomes.

Introduction
The Clinical Discussion Group on Sycamore ward is one place where members of different professions can discuss their work and enhance the quality of patient care. Recently AWP has introduced an “Information for Quality” (IQ) initiative whereby supervision is one of seven areas monitored to ensure high quality service provision. The Clinical Discussion Group contributes towards this target.

Previous research has shown that clinical discussion helps to:

- broaden knowledge of a variety of models and approaches (Crowe, Carlyle, & Farmar, 2008)
- increase professional confidence (Arvidsson, Baigi, & Skarsater, 2008)
- increase empathy (Brunero & Stein-Parbury, 2008)
- improve cooperation between staff and patients (Severinsson & Hallberg, 1996)
- reduce strain and burnout (Berg, Hansson, & Hallberg, 1994; Edwards et al., 2006; Hallberg, 1994; Hallberg & Norberg, 1993; Hyrkas, 2005)

Although the benefits of clinical discussion are numerous, multidisciplinary approaches have been recognised as particularly challenging (Hyrkäs & Appelqvist-Schmidlechner, 2003) and more research is needed to consider the perspectives of staff members in order to shape and improve services.

Method
All members of clinical staff were invited to take part in the study. Twelve people volunteered from a diverse range of profession including six nurses, four Health Care
Assistants, one Occupational Therapist and one Medic. Nine participants were female and three were male.

Those taking part were asked questions about their views of the Clinical Discussion Group including attendance; helpful aspects; outcomes; unhelpful aspects; and changes they would like to see. The views of the participants were analysed using Thematic Analysis (Braun & Clarke, 2006) in order to identify common themes.

**Results**

<table>
<thead>
<tr>
<th>Themes generated by analysis of the data</th>
<th>1. The Group and how it operates</th>
<th>2. Impact and Usefulness</th>
<th>3. Changes to the Group</th>
</tr>
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<tr>
<td>Attendance</td>
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<td>Organisation</td>
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<td>Understanding a Case</td>
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<td>Group Outcomes</td>
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</table>

**Recommendations**

- **Increased Frequency** – to once per week to enable staff to attend more often.
- **Promotion** – of the group purpose and aims to encourage a greater diversity of attenders, particularly medics, and giving reminders to staff for upcoming groups.
- **Choosing a discussion topic in advance** – to reduce the time taken in the group session to do this allowing more time for the discussion. It was highlighted that it would be beneficial for staff to prepare more for the discussions by bringing information about a particular case, including care plans, formulations and case notes. This would also enable the facilitating psychologist to research background information about the case.
- **Focus on case discussion** – in order to influence clinical practice, the focus should remain on the discussion of a case. As such, the role of the facilitating psychologist is to facilitate discussions enabling psychological understanding and formulation. However, it could be important to retain a space for staff to discuss other team issues that have an impact on their work e.g. staff conflicts.
- **Continue to encourage all members to contribute** – as many people really valued the contribution of staff that often don’t have an opportunity to voice their views such as Health Care Assistants who spend the most time with patients and therefore have a wealth of information.
• **Retain space for emotional release and support** – to help staff remain able to form therapeutic relationships with patients and cope with the difficult and emotionally demanding nature of work on an inpatient mental health ward.

• **Focus on outcomes for patient care** – perhaps by setting time aside at the end of each discussion group session to consider how best to use the understanding gained through discussion to be helpful to patients and plan a way forward. Although this already appears to be in place in some instances, these agreements are not consistently followed through so a strategy for follow up should be implemented, perhaps via a review at the start of the subsequent group session.

• **Dissemination** – of a summary of the group outcome via patient case notes and staff handover. This will enable all staff to consistently implement any plans from the group and have a greater impact on clinical work.
AN EVALUATION OF A CLINICAL DISCUSSION GROUP FOR INPATIENT STAFF

Siân Dallimore
Dr Katharine Christie
Dr Maria Loades

Clinical Discussion Group
- Multidisciplinary group for staff working on Sycamore Ward
  - Nurses
  - Health Care Support Workers
  - Occupational Therapists
  - Psychiatrists
  - Art Therapists
- Takes place fortnightly
- Facilitated by Dr Katharine Christie (Clinical Psychologist)

Aims of the Clinical Discussion Group
- Provide time and space for staff to talk about clinical cases
- Increase psychological thinking
- Solve problems and generate ideas for interventions

Rationale for Service Improvement Project
- “Information for Quality” (IQ): Clinical Discussion Group contributes towards the target of monitoring of supervision.
  - Research has shown that clinical discussion helps to:
    - broaden knowledge of models and approaches
    - increase professional confidence
    - increase empathy
    - improve cooperation between staff and patients
    - reduce strain and burnout
- But multidisciplinary approaches have been recognised as particularly challenging (Hyrkäs & Appelqvist-Schmidlechner, 2003)
- Research needed to consider perspectives of staff in order to shape and improve services.

Method
- All members of clinical staff were invited to take part.
  - Twelve people volunteered from a diverse range of profession including:
    - 6 x Nurses
    - 4 x Health Care Assistants
    - 1 x Occupational Therapist
    - 1 x Medic
  - Nine participants were female and three were male.

Results

<table>
<thead>
<tr>
<th>Themes generated by analysis of the data</th>
<th>1. The Group and how it operates</th>
<th>2. Impact and Usefulness</th>
<th>3. Changes to the Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attendance</td>
<td>Valued by Staff</td>
<td>Understanding a Case</td>
<td>Organisation</td>
</tr>
<tr>
<td>Discussion Topics</td>
<td>Emotional Benefit</td>
<td>Facilitation</td>
<td>Discussion Topic</td>
</tr>
<tr>
<td>Facilitation</td>
<td>Learning</td>
<td>Work Together as a Team</td>
<td></td>
</tr>
</tbody>
</table>

The group and how it operates
- Attendance
  - Average one group session per month
  - Some staff able to attend fortnightly
  - Least frequent attender just once in five months.
  - Barriers to attending include shift patterns, cover for the ward & being unaware of group taking place
- Discussion Topics
  - A complex of difficult case
  - Rarely discuss organisational issues
  - Discussion topic decided at the start of each session
Results

Impact and Usefulness
- Understanding a Case
  - Better, multidisciplinary understanding
  - Psychological models
- Emotional Benefit
  - Sharing feelings
  - Validation
  - Supporting each other
- Working together as a team
  - Specific examples of how group influenced work
  - Not always resulting in an outcome for patients
  - Lack of dissemination

Results

Changes to the Group
- Organisation
  - More frequent
  - Promotion
  - More multidisciplinary involvement
- Discussion Topics
  - Some discussion of less prominent cases needed
  - Prepare in advance
- Outcome for the group
  - More focus on outcomes for patient care
  - Follow up the actions from the group
  - Share with the rest of the team

Recommendations

Increased Frequency
- to once per week to enable staff to attend more often.

Promotion
- of the group purpose and aims to encourage a greater diversity of attenders, particularly medics
- giving reminders to staff for upcoming groups.

Choosing a discussion topic in advance
- to reduce the time taken in the group session allowing more time for the discussion.
- it would be beneficial for staff to prepare more for the discussions by bringing information about a particular case, including care plans, formulations and case notes. This would also enable the facilitating psychologist to research background information about the case.

Recommendations

Focus on case discussion
- in order to influence clinical practice
- the role of the facilitating psychologist is to facilitate discussions enabling psychological understanding and formulation.
- important to retain a space for staff to discuss other team issues that have an impact on their work e.g. staff conflicts.

Continue to encourage all members to contribute
- valued the contribution of staff that often don’t have an opportunity to voice their views such as Health Care Assistants

Retain space for emotional release and support
- to help staff remain able to form therapeutic relationships with patients and cope with the difficult and emotionally demanding nature of work on an inpatient mental health ward.

Recommendations

Focus on outcomes for patient care
- by setting time aside at the end of each discussion group session to consider how best to use the understanding gained through discussion to be helpful to patients and plan a way forward.
- a strategy for follow-up should be implemented, perhaps via a review at the start of the subsequent group session.

Dissemination
- of a summary of the group outcome via patient case notes and staff handover.
Appendix C.1

Author guidelines for Behaviour Research and Therapy

BEHAVIOUR RESEARCH AND THERAPY

AUTHOR INFORMATION PACK

ISSN: 0272-7358

DESCRIPTION

Behaviour Research and Therapy encompasses all of what is commonly referred to as cognitive behaviour therapy (CBT). The focus is on the following: theoretical and experimental analyses of psychopathological processes with direct implications for prevention and treatment; the development and evaluation of empirically-supported interventions; predictors, moderators and mechanisms of behaviour change; and dissemination and implementation of evidence-based treatments to general clinical practice. In addition to traditional clinical disorders, the scope of the journal also includes behavioural medicine. The journal will not consider manuscripts dealing primarily with measurement, psychometric analyses, and personality assessment.

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*Behaviour Research and Therapy* encompasses all of what is commonly referred to as cognitive behaviour therapy (CBT). The focus is on the following: theoretical and experimental analyses of psychopathological processes with direct implications for prevention and treatment; the development and evaluation of empirically-supported interventions; predictors, moderators and mechanisms of behaviour change; and dissemination and implementation of evidence-based treatments to general clinical practice. In addition to traditional clinical disorders, the scope of the journal also includes behavioural medicine. The journal will not consider manuscripts dealing primarily with measurement, psychometric analyses, and personality assessment.

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• All references mentioned in the Reference list are cited in the text, and vice versa
• Permission has been obtained for use of copyrighted material from other sources (including the Internet)

Printed version of figures (if applicable) in color or black-and-white
• Indicate clearly whether or not color or black-and-white in print is required.
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AFTER ACCEPTANCE

Use of the Digital Object Identifier

The Digital Object Identifier (DOI) may be used to cite and link to electronic documents. The DOI consists of a unique alpha-numeric character string which is assigned to a document by the publisher upon the initial electronic publication. The assigned DOI never changes. Therefore, it is an ideal medium for citing a document, particularly 'Articles in press' because they have not yet received their full bibliographic information. Example of a correctly given DOI (in URL format; here an article in the journal Physics Letters B):
http://dx.doi.org/10.1016/j.physletb.2010.09.059

When you use a DOI to create links to documents on the web, the DOIs are guaranteed never to change.

Online proof correction

Corresponding authors will receive an e-mail with a link to our online proofing system, allowing annotation and correction of proofs online. The environment is similar to MS
Word: in addition to editing text, you can also comment on figures/tables and answer questions from the Copy Editor.

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Appendix C.2

Evidence of NHS Ethical Approval for Main Research Project

Health Research Authority
NRES Committee Yorkshire & The Humber - Bradford Leeds
Jarrow REC Centre
Jarrow
Business
Centre Room
002
Rolling Mill Road
Jarrow
NE32 3DT
Telephone: 0191 428 3565

15 July 2014

Mrs Sian Dallimore
Doctorate in Clinical Psychology
6 West 0.9
University of Bath
Bath
BA2 7AY

Dear Mrs Dallimore

Study title: The Impact of Perceptions of OCD on Carers’ Affective and Behavioural Responses
REC reference: 14/YH/1079
IRAS project ID: 151223

The Proportionate Review Sub-committee of the NRES Committee Yorkshire & The Humber - Bradford Leeds reviewed the above application on 11 July 2014.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager Ms Gillian Mayer, nrescommittee.yorkandhumber-bradfordleeds@nhs.net .

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

A revised consent form needs to be submitted to include the mandatory paragraph (minus the reference to medical records).
The participant invitation letters to be revised to clarify that there is more than one questionnaire involved.

Additional conditions specified by the REC

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission (“R&D approval”) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation’s role in the study is limited to identifying and referring potential participants to research sites (“participant identification centre”), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites
The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see “Conditions of the favourable opinion”).

Ethical issues raised, noted and resolved in discussion:

The Sub-Committee raised the following issues and the chief investigator responded accordingly as follows:

Recruitment arrangements and access to health information, and fair participant selection

Confirmation was requested if the participants have already been diagnosed with OCD (and therefore receiving relevant services). Clarification was also requested if it is possible that people recruited through the charity could be self-diagnosed as OCD and then having applied the SCID found not to be.

You clarified that the potential participants will not be receiving a diagnosis as a result of completing the SCID questions with the researcher. The SCID is used to determine whether the person meets the criteria for inclusion in the study. You stated this would be made clear during the conversation with the potential participants.

Informed consent process and the adequacy and completeness of participant information

The consent forms need to include the mandatory paragraph (as appropriate to this study) – ‘I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from regulatory authorities as relevant to this study. I give permission for these individuals to have access to my medical records’.

The sub-committee were informed that you will not be accessing medical records for this research. Participants recruited from the University of Bath clinic will have already completed a full diagnostic interview using the SCID and therefore it would not be necessary or appropriate to repeat the questions.

The Sub-Committee noted that the consent form would still need to include the mandatory paragraph and omit the reference to medical records.

Suitability of supporting information

The participant invitation letters mention “a questionnaire” however this should clarify that there is more than one questionnaire involved.

You agreed to amend the invitation letter accordingly and would forward this revised document to the REC in the next few days.

Approved documents

The documents reviewed and approved were:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td>Copies of advertisement materials for research participants</td>
<td>1</td>
<td>23 May 2014</td>
</tr>
<tr>
<td>Covering letter on headed paper [Covering Letter]</td>
<td>1</td>
<td>23 May 2014</td>
</tr>
<tr>
<td>Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [University of Bath Indemnity]</td>
<td></td>
<td>15 July 2013</td>
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<tr>
<td>Letter from sponsor [Letter from Sponsor]</td>
<td></td>
<td>18 June 2014</td>
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<tr>
<td>Letters of invitation to participant [Participant Invitation Letter- Patient Version]</td>
<td>1</td>
<td>23 May 2014</td>
</tr>
</tbody>
</table>
Letters of invitation to participant [Participant Invitation Letter-Carer] 1 23 May 2014
Non-validated questionnaire [Perceived Criticism- Patient] 1 23 May 2014
Non-validated questionnaire [Perceived Criticism- Carer Version] 1 23 May 2014
Non-validated questionnaire [Illness Perceptions Questionnaire- Carer Version] 1 04 June 2014
Non-validated questionnaire [Illness Perceptions Questionnaire- Patient Version] 1 04 June 2014
Non-validated questionnaire [Demographic Questions- Carer Version] 1
Non-validated questionnaire [Demographic Questions- Patient Version] 1 23 May 2014
Participant consent form [Carer Consent Form] 1 23 May 2014
Participant information sheet (PIS) [Participant Information Sheet- Carer Version] 1 23 May 2014
Participant information sheet (PIS) [Participant Information Sheet- Patient Version] 1 23 May 2014
REC Application Form [REC_Form_01072014] 1 01 July 2014
Research protocol or project proposal [Protocol] 1 23 May 2014
Summary CV for Chief Investigator (CI) [Sian Dallimore CV] 1 23 May 2014
Summary CV for supervisor (student research) [Claire Lomax CV] 1 23 May 2014
Summary, synopsis or diagram (flowchart) of protocol in non-technical language [Flowchart of Protocol] 1 23 May 2014
Validated questionnaire [Patient Health Questionnaire-9] 1
Validated questionnaire [Obsessive Compulsive Inventory] 1
Validated questionnaire [Family Accommodation Scale] 1
Validated questionnaire [Generalised Anxiety Disorder-7] 1
Validated questionnaire [Experience of Caregiving Inventory] 1

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.
Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

We are pleased to welcome researchers and R & D staff at our NRES committee members’ training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee’s best wishes for the success of this project

14/YH/1079 Please quote this number on all correspondence

Yours sincerely pp

Dr Janet Holt
Chair

Email: nrescommittee.yorkandhumber-bradfordleeds@nhs.net
Enclosures: List of names and professions of members who took part in the review

“After ethical review – guidance for researchers”

Copy to: Dr Claire Lomax –
Appendix C.3

Revised Illness Perceptions Questionnaire (IPQ-R): OCD Version


We are interested in your own personal views about how you now see your OCD.

Please indicate how much you agree or disagree with the following statements about your OCD by ticking the appropriate box.

<table>
<thead>
<tr>
<th></th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neither Agree nor Disagree</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>My OCD will last a short time.</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>2</td>
<td>My OCD is likely to be permanent rather than temporary.</td>
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<tr>
<td>3</td>
<td>My OCD will last a long time.</td>
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<tr>
<td>4</td>
<td>My OCD will pass quickly.</td>
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<tr>
<td>5</td>
<td>I expect to have OCD for the rest of my life.</td>
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</tr>
<tr>
<td>6</td>
<td>My OCD is a serious condition.</td>
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<td></td>
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<tr>
<td>7</td>
<td>OCD has major consequences on my life.</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>OCD does not have much effect on my life</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>OCD strongly affects the way others see me.</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>10</td>
<td>My OCD has serious financial consequences.</td>
<td></td>
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<tr>
<td>11</td>
<td>My OCD causes difficulties for those who are close to me.</td>
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<tr>
<td>12</td>
<td>There is a lot which I can do to control my OCD symptoms.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>What I do can determine whether my OCD gets better or worse.</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>14</td>
<td>The course of my OCD depends on me.</td>
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<td></td>
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<tr>
<td>15</td>
<td>Nothing I do will affect my OCD.</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>16</td>
<td>I have the power to influence my OCD.</td>
<td></td>
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<tr>
<td>17</td>
<td>My actions will have no effect on the outcome of my OCD.</td>
<td></td>
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<td></td>
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</tbody>
</table>
Please indicate how much you agree or disagree with the following statements about your OCD by ticking the appropriate box.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>18</td>
<td>My OCD will improve over time.</td>
</tr>
<tr>
<td>19</td>
<td>There is very little that can be done to improve my OCD.</td>
</tr>
<tr>
<td>20</td>
<td>My treatment will be effective in curing my OCD.</td>
</tr>
<tr>
<td>21</td>
<td>The negative effects of OCD can be prevented (avoided) by my treatment.</td>
</tr>
<tr>
<td>22</td>
<td>My treatment can control my OCD.</td>
</tr>
<tr>
<td>23</td>
<td>There is nothing that can help my OCD.</td>
</tr>
<tr>
<td>24</td>
<td>The symptoms of my OCD are puzzling to me.</td>
</tr>
<tr>
<td>25</td>
<td>My OCD is a mystery to me.</td>
</tr>
<tr>
<td>26</td>
<td>I don't understand my OCD.</td>
</tr>
<tr>
<td>27</td>
<td>My OCD doesn't make any sense to me.</td>
</tr>
<tr>
<td>28</td>
<td>I have a clear picture or understanding of my OCD.</td>
</tr>
<tr>
<td>29</td>
<td>The symptoms of my OCD change a great deal from day to day.</td>
</tr>
<tr>
<td>30</td>
<td>My symptoms come and go in cycles.</td>
</tr>
<tr>
<td>31</td>
<td>My OCD is very unpredictable.</td>
</tr>
<tr>
<td>32</td>
<td>I go through cycles in which my OCD gets better and worse.</td>
</tr>
<tr>
<td>33</td>
<td>I get depressed when I think about my OCD.</td>
</tr>
<tr>
<td>34</td>
<td>When I think about my OCD I get upset.</td>
</tr>
<tr>
<td>35</td>
<td>My OCD makes me feel angry.</td>
</tr>
<tr>
<td>36</td>
<td>My OCD does not worry me.</td>
</tr>
<tr>
<td>37</td>
<td>Having OCD makes me feel anxious.</td>
</tr>
<tr>
<td>38</td>
<td>My OCD makes me feel afraid.</td>
</tr>
</tbody>
</table>
Appendix C.4

Revised Illness Perceptions Questionnaire (IPQ-R): Carer Version


We are interested in your own personal views about how you now see your family member/friend’s OCD.

Please indicate how much you agree or disagree with the following statements by ticking the appropriate box.

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<th></th>
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<tbody>
<tr>
<td>1</td>
<td>My family member/friend's OCD will last a short time.</td>
<td>Strongly Disagree</td>
<td>Disagree</td>
<td>Neither Agree nor Disagree</td>
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<tr>
<td>32</td>
<td>My family member/friend goes through cycles in which their OCD gets better and worse.</td>
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<tr>
<td>33</td>
<td>My family member/friend gets depressed when they think about their OCD.</td>
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<tr>
<td>34</td>
<td>When my family member/friend thinks about their OCD they get upset.</td>
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<tr>
<td>35</td>
<td>My family member/friend's OCD makes them feel angry.</td>
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<tr>
<td>36</td>
<td>My family member/friend's OCD does not worry them.</td>
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<tr>
<td>37</td>
<td>Having OCD makes my family member/friend feel anxious.</td>
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<tr>
<td>38</td>
<td>My family member/friend's OCD makes them feel afraid.</td>
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</tbody>
</table>
Appendix C.5

Perceived Criticism Scale (PC)

*Hooley & Teasdale (1989)*

These questions are about your relationship with the family member or friend you have identified for this project.

1. In general, how much do you feel you criticise your family member or friend?

   ![Rating Scale](1-10)

   1 (Not at All)  2  3  4  5  6  7  8  9  10 (All the Time)

2. In general, how much do you feel your family member or friend criticises you?

   ![Rating Scale](1-10)

   1 (Not at All)  2  3  4  5  6  7  8  9  10 (All the Time)

3. How much do you feel your family member or friend criticises you regarding OCD issues?

   ![Rating Scale](1-10)

   1 (Not at All)  2  3  4  5  6  7  8  9  10 (All the Time)

4. How much do you feel you criticise your family member or friend regarding OCD issues?

   ![Rating Scale](1-10)

   1 (Not at All)  2  3  4  5  6  7  8  9  10 (All the Time)