The Family Connections Programme: A Feasibility Study

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Thesis declaration form

I confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

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Overview

The focus of this thesis is Borderline Personality Disorder (BPD), including childhood experiences of emotional invalidation (EI) and an intervention for family members of adults with BPD. This thesis consists of three parts.

The first part of this thesis is a systematic literature review that explored the relationship between childhood experiences of EI and adult psychopathology. Research to date has focused on overt abuse as a risk factor in the development of BPD, but less attention has been focused on emotionally invalidating responses in transactions between parents and children, and the development of BPD. The review aimed to explore research that investigated this association, as well as whether it is present across a range of adult psychopathologies. The clinical and research implications of the findings are discussed.

The second part of this thesis is an empirical paper on the feasibility of the Family Connections programme, a group intervention developed for family members who have a relative with BPD, in the USA. The results indicated that the programme is feasible in the UK, that participants can be recruited to, and retained for the 12-week programme. The results provide tentative support that the Family Connections programme is an effective and acceptable intervention.

The third part of this thesis is a critical appraisal that reflects on some of the issues and reflections that arose during the research. This critical appraisal focuses on four areas: the difficulty of collecting data on EI in individuals with BPD, the contents of the Family Connections programme, possible mechanisms underpinning change in family members, and working with mental health professionals who support individuals with BPD.

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Part One: Literature Review

Childhood Emotional Invalidation and Adult Psychopathology: A Systematic Review

Abstract

Aim: This systematic literature review aimed to assess the evidence investigating the association between childhood experiences of EI and adult psychopathology.

Method: A systematic literature search was conducted across PsycINFO, Medline and Embase databases to identify studies appropriate for review. The relevant studies were quality assessed and a sub-sample were rated by an independent assessor.

Results: 12 studies met inclusion criteria to be included in the review and the quality of these was mostly moderate to high. The studies suggested an association between childhood experiences of EI and adult psychopathologies, including symptoms of Borderline Personality Disorder, eating disorders, anxiety and depression. Generally this relationship was mediated by difficulties managing emotions.

Conclusions: The findings of the review illustrated the relationship between childhood experiences of EI and adult psychopathology. Methodological issues within the studies highlights the need for further research to improve understanding of this relationship. Most importantly, the development of psychometrically evaluated tools to measure EI are required.

Introduction

Understanding the development and course of psychopathology has become increasingly important in recent years for informing our understanding of the prevention and treatment of mental illness (Hollinger, 2000). There is a wealth of research implicating the role of adverse early experiences in the development of mental health difficulties across the lifespan (Dube et al., 2001). This research has primarily focused on the characteristics of early childhood experiences, particularly in the relationship between the child and their primary caregiver (Fonagy & Target, 1997; Fonagy, Target, Gergely, Allen & Bateman, 2003). A consistent finding is that early relationships with caregivers characterised by abuse, neglect, separation and criticism are documented in the histories of individuals who present with mental health difficulties (Horwitz, Widom, McLaughin & White, 2001; Molnar, Buka, & Kessler, 2001; Springer, Sheridan, Kuo & Carnes, 2007).

The need to understand the early experiences which lead to the development of psychopathology is especially important for disorders characterised by severe symptoms that significantly impact on the individual and that are costly for National Health Services (NHS). One example of this is Borderline Personality Disorder (BPD), a severe mental illness characterised by dysfunctional patterns of emotion instability, impulsivity and difficulties in interpersonal relationships (APA, 2013). Individuals with BPD are at increased risk of deliberate self-harm, attempted and completed suicide (Goodman, Roiff, Oakes & Paris, 2012) and often have co-occurring diagnoses such as depression, anxiety, substance misuse and eating disorders (Lieb, Zanarini, Schmahl, Linehan & Bohus, 2004; Zanarini, Frankenburg, Hennen, Reich & Silk, 2004). The prevalence of BPD ranges between 0.7-2% in the general population (Coid, Yang, Tyrer, Roberts & Ullrich, 2006) and in clinical settings 10% of outpatients and 15-25% of inpatients have a diagnosis (Coid et al., 2006). As a result, BPD is associated with significant financial implications for health services (Zanarini, Frankenburg, Hennen & Silk, 2003).

The majority of research studies in this area have focused on the development of treatment for the condition and Dialectical Behavioural Therapy (DBT) is now considered the gold standard psychological therapy for BPD (NICE, 2009). DBT has been shown to be effective in reducing suicide attempts, admissions to psychiatric hospital, and to emergency departments (Kliem, Kröger & Kosfelder, 2010; Linehan et al., 2006). Research has focused less on understanding the development of BPD and validating the theories that guide treatment.

The Linehan biosocial theory of BPD

The biosocial theory by Linehan (1993) is currently one of the most influential aetiological theories of BPD. The theory identifies two variables: emotional vulnerability and emotional invalidation (EI) as being central in the development of the disorder. Emotional vulnerability refers to an individual's innate, biological predisposition for emotion sensitivity, meaning that they become emotionally dysregulated more easily. This may be a vulnerability that a child is born with or may develop as a result of early experiences in childhood that impact on brain structures that govern emotion (Fonagy & Luyten, 2009). Emotional vulnerability has three important qualities: 1) low threshold for triggering emotions, 2) heightened emotional response, and 3) slow return to baseline.

The second factor deemed important is exposure to an emotionally invalidating environment, defined by Linehan (1987) as: *"one in which communication of private experiences is met by erratic, inappropriate, and extreme responses. In other words, the expression of private experiences is not validated; instead, it is often punished, and/or trivialized. The expressions of painful emotions, as well as the factors that to the emotional person seem causally related to the emotional distress, are disregarded."* (pg 49). In her theory, Linehan further described three types of family environment deemed emotionally invalidating to the individual: chaotic, typical and perfect. In the 'chaotic family' environment caregivers are preoccupied with their own problems of mental illness, substance use disorders and may be receiving input from social services. As a result, little attention is paid to the child and their needs are often ignored and invalidated. The second type of invalidating family environment is the ‘typical family’, where the environment emphasizes and rewards over-control of a child’s emotions, yet does not acknowledge that this may be difficult for them. Additionally, there is a focus on achievement as a marker of success. In the third type of emotionally invalidating family environment, the ‘perfect family’, negative emotions are not tolerated due to the inability of the caregivers to manage the expression of emotions.

Linehan (1993) identified four consequences of childhood EI: firstly, a child fails to learn how to recognise and label their emotions. Secondly, they do not develop skills to tolerate their emotional distress. Thirdly, in order to elicit a reaction to their emotions from their caregivers a child may display ‘extreme’ emotional reactions. The positive reinforcement of such displays as well as ignoring, minimizing or punishing appropriate displays of emotion is highly confusing and teaches a child to oscillate between emotional inhibition and over-expression. Finally, in the absence of emotional validation, a child is left to cope with their emotions alone and thus may develop maladaptive ways of managing these uncomfortable and confusing experiences (Shenk & Fruzzetti, 2014). A child is likely to adopt the characteristics of their environment and ‘self-invalidate’ their internal experiences (Brown, Comtois & Linehan, 2002).

The biosocial model suggests that there is a transaction between the biological emotional vulnerability of the child with EI from their environment (Linehan, 1993). A child who experiences strong emotions but who has not been able to seek support from caregivers in regulating these is left in a state of emotional dysregulation. Thus, the environment intensifies the emotional vulnerability of the child and repetition of this leads to increased emotional dysregulation over time. Gratz & Roemer (2004), have defined four aspects of emotional dysregulation: *“(a)* *lack of awareness, understanding, and acceptance of emotions; (b) lack of access to adaptive strategies for modulating the intensity and/or duration of emotional responses; (c) an unwillingness to experience emotional distress as part of pursuing desired goals; and (d) the inability to engage in goal-directed behaviors when experiencing distress"* (p.43).

In response to emotional dysregulation an individual will develop maladaptive ways to modulate and escape their emotional experiences in the absence of adaptive distress tolerance skills. The problem behaviours that characterise BPD, such as suicide attempts and deliberate self-harm, are therefore understood as responses to manage emotion dysregulation. When an individual becomes emotionally dysregulated, behaviours such as self-harm become a solution which gives them temporary relief from their painful experiences which become negatively reinforced over time. However, the consequences of self-harm can be further painful emotions including guilt and shame, which can lead to further emotional dysregulation and self-invalidation (Feigenbaum, 2010).

Evidence in support of the biosocial model

It is important to acknowledge that Linehan developed the biosocial theory to guide treatment of BPD, however since its inception, research has explored and supported the putative aetiology and developmental pathways to BPD. Studies investigating subjective emotional sensitivity and reactivity in BPD samples using self-reports have consistently found that individuals report higher negative emotional intensity than non-clinical samples (Rosenthal, Cheavens, Lejuez & Lynch, 2005). Exploration of emotional vulnerability at the neurological and biological level has shown differences in BPD and non-BPD samples in brain areas that govern emotions (Domes, Schulze & Herpertz, 2009; Schmahl et al., 2014). Individuals with BPD had decreased activity in pre-orbital frontal regions and increased activity in their amygdala and limbic systems, thus providing evidence for biological markers underpinning individual’s sensitivity to emotions (Donegan et al., 2003; Kuo & Linehan, 2009).

Conversely there is a lack of research into the construct of EI (Crowell, Beauchaine & Linehan, 2009). Based on the definition provided by Linehan (1993), EI is a broad construct and as such there are many different experiences in childhood that can be experienced as emotionally invalidating. Childhood sexual abuse (CSA) is an example of an experience in childhood that is highly emotionally invalidating in which the physical and emotional needs of the child are clearly ignored or neglected, and the emotional responses to CSA are often denied or punished (Rosenthal et al., 2005). The incidence of CSA is a prevalent risk factor in the development of BPD. Indeed, 66-75% of individuals with BPD have experienced CSA (e.g. Bandelow et al., 2005) and the severity of CSA correlates positively with severity of symptoms (Zanarini et al., 2002). Other forms of overt abuse, including physical and emotional abuse and neglect are also high in BPD samples (Kuo, Khoury, Metcalfe, Fitzpatrick, Goodwill, 2015). In a sample of individuals with BPD, 92% had experienced neglect and 25-73% had been physically abused in childhood (Zanarini et al., 2000). These experiences all communicate a powerful message to a child: that their needs, distress and pain are not relevant or important. However, there are a number of individuals with diagnoses of BPD who report no abuse (Lieb, Zanarini, Schmahl, Linehan & Bohus, 2004) and many individuals who have experienced abuse do not develop BPD (Grover et al., 2007). Therefore the current consensus is that even though a history of abuse is common, it is not necessary to the development of BPD (Zanarini, Williams, Lewis & Reich, 1997).

Other disorders of emotional dysregulation

The biosocial theory offers an explanation of the development of emotional dysregulation and how this may lead to the development of BPD symptoms. However, emotion dysregulation is not unique to BPD and has been deemed a ‘transdiagnostic’ difficulty (Fernandez, Jazaieri & Gross, 2016). A transdiagnostic process can be understood as something that causes or maintains pathology, which is present across a number of different clinical diagnoses (Aldao & Nolen-Hoeksema, 2010). Emotion regulation difficulties are associated with a range of psychopathologies including other personality disorders, major depressive disorder, anxiety disorders, substance misuse disorders and eating disorders (Aldao, Nolen-Hoeksema & Schweizer, 2010). The identification of transdiagnostic processes can also explain high comorbidity across these psychopathologies (Gratz & Tull, 2010; Mennin, Heimberg, Turk & Fresco, 2005; Gunderson et al., 2014).

Of the psychopathologies listed, there is a wealth of research on the association between emotion dysregulation and eating pathology. Research indicates that individuals who present with eating disorders have difficulties tolerating and regulating their emotions (Harrison, Sullivan, Tchanturia & Treasure, 2010; Haynos, Roberto, Martinez, Attia & Fruzzetti, 2014) and make attempts to avoid their emotions (Serpell & Treasure, 2002). The transdiagnostic approach suggests that eating disordered behaviours across diagnoses (restriction, binging, purging, exercising) are maladaptive ways of managing emotion dysregulation in the absence of more adaptive distress tolerance skills (Mountford, Corstorphine, Tomlinson & Waller, 2007), similar to the self harm and suicide attempts exhibited by individuals with BPD.

In terms of early experiences, the prevalence of CSA and physical neglect in eating disorder populations is high, (Johnson, Cohen, Kasen & Brook, 2002) yet similar to BPD, a substantial number of individuals report no overt abuse. Research into the quality of the interactions and relationships with caregivers has indicated that parental criticism and relationships characterized by enmeshment and intrusiveness are common in the histories of individuals with Anorexia Nervosa (AN) and Bulimia Nervosa (BN) (Polivy & Herman, 2002). It is also well established that early messages about the desirability of thinness from family and western culture are influential in the development of eating difficulties (Abramovitz & Birch, 2000; Dohnt & Tiggermann, 2006). Although early interactions in relationships with caregivers are deemed important in the development of eating difficulties, it is unclear whether invalidation of emotions during interactions with caregivers in childhood is related to the levels of emotional dysregulation and eating disordered psychopathology.

The measurement of emotional invalidation (EI)

Based on the definition of EI (Linehan, 1993) there are three self-report measures that exist which measure retrospective recall of the experience of EI in interactions with primary caregivers. These measures focus on the way in which an individual recalls how their parents responded to their emotions but do not assess experiences of overt abuse. The first is the ‘Invalidating Childhood Environment Scale’ (ICES; Mountford et al., 2007), which is comprised of 14-items that assess themes of an emotionally invalidating environment as defined by Linehan (1993): ignoring thoughts and judgements, ignoring emotions, negating thoughts and judgements, negating emotions, over-reacting to emotions, overestimating problem solving, overreacting to thoughts and judgments, and over simplifying problems. Individuals are asked to rate their experience of the behaviour of caregivers, up to the age of 18, on a 5-point scale ranging from 1 (‘never) to 5 (‘all the time’). The scale is completed twice, reflecting both maternal and paternal levels of EI. Within the measure, 4 items reflect the different ‘types’ of family invalidating environment (‘typical’, ‘chaotic’, ‘perfect’ and ‘validating’).

A subsequent measure is the ‘Socialisation of Emotions Scale’ (SES, Krause et al., 2003), which was adapted from the ‘Coping with Children’s Negative Emotions Scale’ (CCNES; Fabes, Poulin, Eisenberg & Madden-Derdich, 2002). The SES is an 72-item questionnaire, which presents respondents with 12 childhood scenarios, each with seven different caregiver responses. Respondents are asked to identify their primary caregiver from childhood and provide a response to each scenario based on their experience of how their caregiver responded to their emotions on a scale of 0 (‘very unlikely’) to 6 (‘very likely’). The SES is comprised of 3 subscales corresponding to the concepts of EI: ‘distress reactions’, ‘punitive reactions’ and ‘minimization’. Higher scores indicate greater perceived experience of emotionally invalidating responses. The scale is completed twice, reflecting both maternal and paternal experiences of EI. The final measure, the ‘Invalidating Environment Child Scale’ (IE-Child; Sauer and Baer, 2010) is a 33-item measure of EI developed from the SES. Individuals are asked to read six scenarios of instances of distress in childhood and rate how their caregivers would have responded on a 7 -point scale- 0 (‘very unlikely’) to 6 (‘very likely’). The scale provides an overall score for both maternal and paternal invalidation.

Summary

Currently, understanding of the relationship between parental emotionally invalidating responses and clinical outcomes is lacking beyond the context of overt abuse (Shenk & Fruzzetti, 2014). It is unclear what type of impact EI may have had on the individual and the mechanisms that underlie development of psychopathology. Given that emotional dysregulation is a transdiagnostic phenomena (Aldao et al., 2010; McLaughlin, Hatzenbuehler, Mennin & Nolen-Hoeksema, 2011) is it important to consider whether the experience of having ones emotions invalidated in childhood is associated with a range of psychopathologies. The aim of the current review is to answer the following question:

> Is the experience of EI in childhood, in the absence of overt abuse, associated with adult psychopathology?

Method

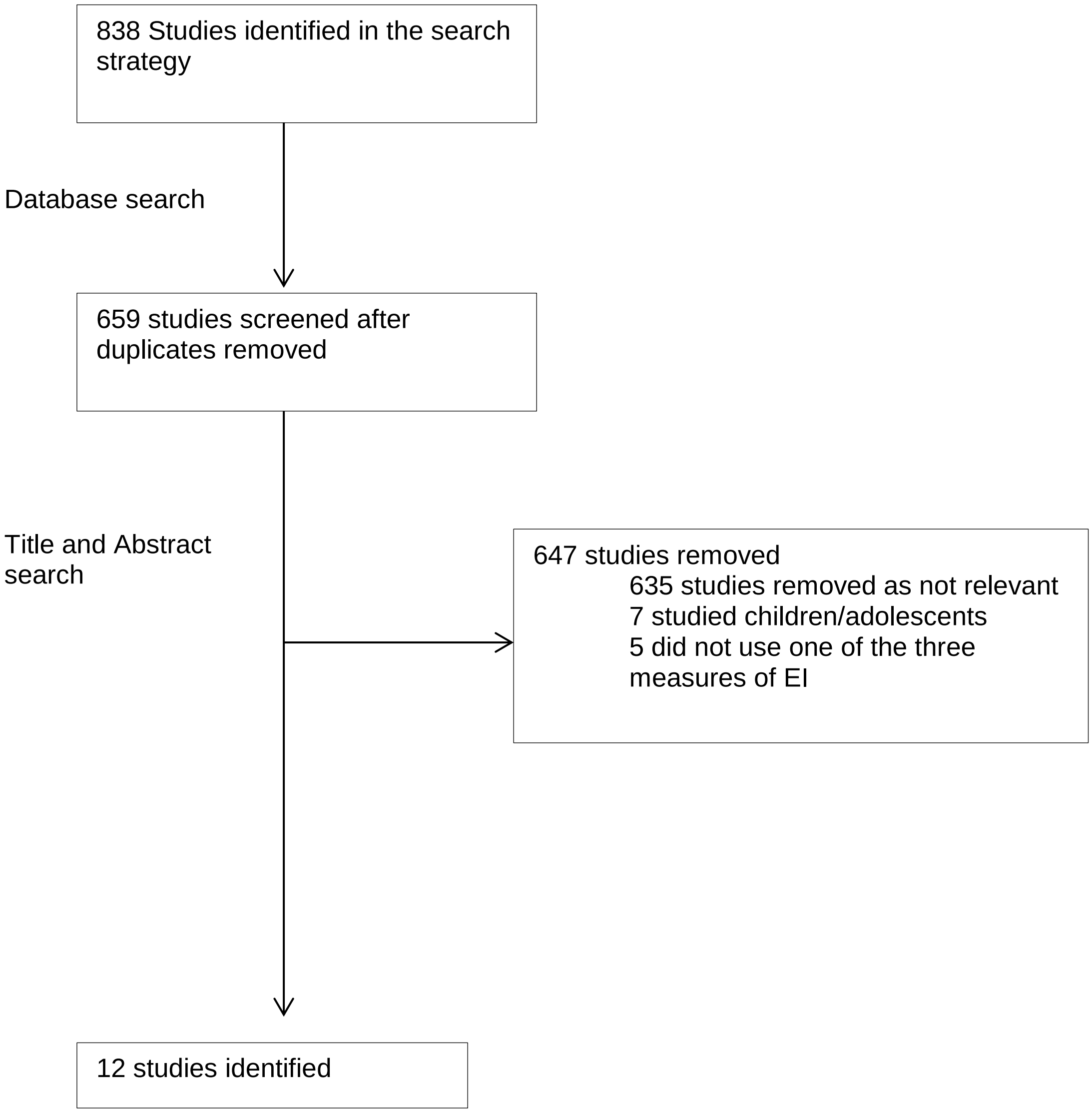
Search strategy

The search strategy and reporting for this systematic review were based on the guidelines from the PRISMA statement (Liberati et al., 2009). The search strategy was applied to three databases: PsycINFO, Medline and Embase. Search terms were _‘child*’_ OR ‘_infant’_ OR ‘_infancy’_ AND _‘emotion*’_ AND _‘invalid*._ Limitations placed on the search were as follows: (i) English language (ii) Peer reviewed journal (iii) human studies and (iv) from 1980 to present, as Linehan introduced the term EI in 1987 (Linehan, 1987) and therefore it was not anticipated that there would be a significant number of relevant studies identified before this. Studies were included in the review if they met the following criteria:

1. Recruited adults over the age of 18, as psychopathology such as BPD is rarely diagnosed before the age of 18 years old (Crowell et al., 2009).
2. Utilised one of the three measures of EI (ICES, SES, IE-Child).
3. Utilised a psychometrically evaluated tool for the measurement of psychopathology.

Initially 838 studies were identified and once duplicates were removed 659 studies remained. Titles and abstracts of the remaining studies were then screened and if a study clearly did not meet the inclusion criteria (e.g. child participants were used) it was excluded. If a study appeared to meet the inclusion criteria (e.g. stated that it measured EI) the full paper was screened (n= 51). Of these, reference lists were hand-searched. Throughout the process, reasons for exclusion were documented (Figure1).

Figure 1: Flow chart depicting the process of identifying studies



Critical Appraisal tool

The 14 –item 'Standard quality assessment criteria' tool (Kmet, Lee & Cook, 2004) was used to guide the appraisal of the quality of the selected studies (Appendix A). A quality appraisal tool was used to determine the weight to be given to the studies included in the review. The tool addresses: study objectives, design, method, quality of data analysis and the degree of similarity between results and discussion. Items were rated using the 3-point scale (2= criteria met, 1= criteria were partially met, 0= criteria not met) and an overall score was derived for each study. Three items were removed from the quality appraisal, as these were deemed not relevant as they relate to intervention studies (see Table 1). An independent researcher rated a selection of the studies to ensure inter-rater reliability using the same rating scale. Both researchers discussed their ratings and any differences were resolved by discussion.

Items excluded from quality appraisals	Reasons for exclusion
Item 5; If interventional and random allocation was possible, was it described?	None of the studies were interventional nor had random allocation.
Item 6; If interventional and blinding of investigators was possible, was it reported?	None of the studies were interventional nor required blind investigators.
Item 7; If interventional and blinding of subjects was possible, was it reported?	None of the studies were interventional nor required blinding of subjects.

Table 1: Items excluded from quality appraisal tool and reasons for exclusion

Study	1. Question/ objective sufficiently described?	2. Study design evident and appropriate?	3. Method of subject/comparison group selection or source of information/input variables described and appropriate?	4. Subject characteristics sufficiently described	8. Outcome and (if applicable) exposure measure (s) well defined and robust to measurement/ misclassification bias? Means of assessment reported?	9. Sample size appropriate	10. Analytic methods described/justified and appropriate?	11. Some estimates of variance is reported for the main results?	12. Controlled for confounding?	13. Results reported in sufficient detail?	14. Conclusions supported by results?	Total
DeShong et al., (2015)	2	2	2	2	2	1	1	0	0	2	1	0.68
Gill & Warburton (2014)	2	2	1	1	2	2	1	0	0	1	1	0.59
Haslam et al., (2008)	2	2	1	1	2	2	2	0	0	1	1	0.63
Haslam et al., (2012)	2	2	0	1	1	2	2	0	0	1	2	0.68
Krause et al., (2003)	2	1	1	2	2	2	2	2	1	2	2	0.86
Mountford et al., (2007)	2	2	2	2	2	2	2	2	1	2	2	0.95
Robertson et al., (2013)	2	2	2	2	2	2	2	2	1	2	2	0.95
Sauer & Baer (2009)	2	2	2	2	1	2	2	0	0	1	2	0.77
Sauer & Baer (2010)	2	2	2	2	2	2	2	0	2	1	2	0.86
Sauer-Zavala, Geiger & Baer (2013)	2	2	1	2	1	2	2	0	2	2	1	0.77
Sturrock et al, (2009)	2	2	1	2	2	2	2	0	1	2	2	0.81
Sturrock et al., (2014)	2	1	1	2	2	2	2	1	2	2	1	0.81

Summary scores are calculated by summing the total score and dividing it by the total possible score

Table 2: Breakdown of quality ratings for included studies

Results

Quality of studies

Across the majority of studies, the quality was moderate to high (see Table 2). All papers described their research questions clearly, implemented appropriate methodological designs, employed suitable analytic methods, and presented the results clearly. Main reasons for studies scoring lower was the lack of control for confounding variables, failure to report estimates of variance in the results, and when claims were made about the clinical applicability of results despite the use of non-clinical samples. Generally, sample sizes recruited were large, however the use of non-clinical participants limits the generalisability of the findings.

Study	Final rating (max=22)
Mountford, Corstorphine, Tomlinson & Waller (2007)	21 (0.95)
Robertson, Kimbrel & Nelson-Gray (2013)	21 (0.95)
Krause, Mendelson & Lynch, (2003)	19 (0.86)
Sauer & Baer (2010)	19 (0.86)
Sturrock, Francis & Carr (2009)	18 (0.81)
Sturrock & Mellor (2014)	18 (0.81)
Sauer & Baer (2009)	17 (0.77)
Sauer- Zavala, Gieger & Baer (2013)	17 (0.77)
DeShong, Lengel, Sauer-Zavala, O’Meara & Mullins-Sweatt, (2015)	15 (0.68)
Haslam, Arcelus, Farrow & Meyer (2012).	15 (0.68)
Haslam, Mountford, Meyer & Waller (2008)	14 (0.63)
Gill & Warburton (2014)	13 (0.59)

Table 3: final quality ratings for included studies

Reliability and validity of scales

Table 3 displays reliability statistics for the measurement of childhood EI provided by the studies selected. For the majority of studies Cronbach's alphas were high, indicating good scale reliability. None of the childhood EI scales selected for review have undergone full psychometric evaluation. Exploratory factor analysis was reported in two studies to consider the structure of the SES (Sauer & Baer, 2010 & Robertson et al., 2013). Sauer and Baer (2010) found that a 33-item, 2 factor structure reflecting both emotional invalidation and validation was a better fit to the data, which later became the IE-Child scale. Robertson et al. (2013) used a confirmatory factor analysis to explore factor structure in the ICES (Mountford et al., 2007) in a non-clinical sample. The results indicated that the maternal and paternal invalidation sub-scales demonstrated poor fit when all 14-items were included and a 9-item scale demonstrated improved fit to the data.

Scale	Paper	Sample	Reliability statistics
ICES	Mountford et al. (2007)	Clinical sample of eating disorder patients and non clinical sample of university students	Clinical group: α = 0.80 for paternal invalidation, α = 0.77 for maternal invalidation; Non clinical group: α = 0.59 for paternal invalidation, α = 0.66 for maternal invalidation.
	Haslam et al. (2008)	Clinical sample of eating disorder patients	α = 0.91 for paternal invalidation, α = 0.90 for maternal invalidation
	Haslam et al. (2012)	Non clinical sample of university students	Not reported
	Sturrock et al. (2009)	Non clinical sample of university students and individuals recruited from general population	α = 0.56 for paternal invalidation, α = 0.53 for maternal invalidation
	Sturrock & Mellor (2014)	Non clinical sample of university students and individuals recruited from general population	α = 0.84 for paternal invalidation, α = 0.82 for maternal invalidation
	Robertson et al. (2013)	Non clinical sample of university students	α = 0.90 for paternal invalidation, α = 0.88 for maternal invalidation
SES	Sauer & Baer (2009)		Not reported
	DeShong et al. (2015)	Non clinical sample of university students	α = 0.90 for paternal invalidation, α = 0.95 for maternal invalidation
	Krause et al. (2003)	Non clinical sample of university students	α = 0.85 for parental invalidation distress scale, α = 0.80 for parental invalidation punitive scale, α = 0.78 for parental invalidation minimisation scale
IE-Child	Sauer & Baer (2010)	Non clinical sample of university students	α = 0.90 for paternal invalidation, α = 0.88 for maternal invalidation
	Sauer- Zavala et al. (2013)	Non clinical sample of university students	α = 0.89 for overall parental invalidation

Table 4: *Reliability of scales used in the studies selected for review*

Results of studies

The relationship between IE and BPD

Three studies established a relationship between self-reported experiences of EI during childhood and current symptoms of BPD (DeShong et al., 2015; Robertson et al., 2013; Sauer & Baer, 2010), Robertson et al. (2013) recruited 212 self-selecting female undergraduate psychology students (mean age= 18.9 years, SD= 3.08) who completed the ICES and Borderline Personality Index (BPI, Conte, Plutchik, Karasu & Jerrett, 1980). Scores for both overall maternal (*r* =. 45, *p*<. 05) and paternal invalidation (*r* =. 35, *p*<. 05), were positively correlated with symptoms of BPD. The three types of family invalidating environments were also correlated with BPD scores: typical (*r* =. 27, *p*<. 05), perfect (*r* =. 40, *p*<. 05) and chaotic (*r* =. 50, *p*<. 01). Hierarchical regression analysis tested whether ICES scores predicted BPD symptoms when controlling for age, family income and ethnicity. Maternal invalidation (b = .24, *p*<. 05) and chaotic family type (b = .38, *p*<. 05) significantly predicted BPD symptoms. The study scored a high quality rating of 0.95 as the authors controlled for confounding variables of reported anxiety and depression, and recruited a large sample size. However, the study was cross-sectional and relied on retrospective reports of EI. Additionally, the non-clinical female sample limits the generalisability of the results beyond this population. There is also a potential bias amongst self-selecting participants who may represent a different group of individuals from those who did not choose to take part.

Sauer and Baer (2010) also recruited a large sample of undergraduate students (n= 519, female n=336) with an average age of 19.11 years. Participants completed the SES, PAI-BOR (Personality Assessment Inventory; Morey, 1991) and the Depression Anxiety Stress Scale (DASS; Lovibond & Lovibond, 1995), during their lectures (n=177) or online (n=342). Parental EI correlated with BPD symptoms (*r*=. 30, *p*<. 01). Each subscale positively correlated with EI: affective instability, (*r*=.

25, p<. 01), negative relationships (*r*=. 23, p<. 01), identity problems (*r*=. 17, p<. 01) and self-harm (*r*=. 21, p<. 01). When severity of depression and anxiety scores, were controlled for, the association between EI and overall PAI-BOR score decreased (*r* =. 15, *p*<. 01). The childhood caregivers of participants were also asked to complete the CCNES (Fabes et al., 2002), a measure that assessed the way in which they responded to expressions of negative emotion in their child. This measurement of EI was used to explore agreement between parent- child reports in order to assess accuracy of retrospective reports of EI provided by the child. Of the 177 parents who were invited to take part, 104 responded and the majority of these were from mothers (n=92). Statistically significant correlations were found between parent and child reports of EI (*r* =. 29, *p*<. 01). This study was deemed to be a high quality study and received a quality rating of 0.86, despite the use of a non-clinical population to explore clinical constructs. The study utilised a cross sectional design and participants completed retrospective measures at a single time point. Although attempts were made to test the reliability of participant's retrospective accounts of EI, parents are unlikely to acknowledge invalidating responses towards their children. Furthermore, the age of the parent, presence of mental illness, and inaccuracy of memory may impact on the accuracy of recall. The reasons why parents who did not take part in the study were not provided which is important because non-responders may be different from those that responded which suggests there may have been some selection bias.

In a subsequent study that also recruited university psychology students, DeShong et al. (2015) measured maternal and paternal EI and BPD as part of a larger study investigating measurement of BPD symptoms. Participants completed an online screening questionnaire and those who reported that they had self-harmed in the past year were invited to complete further questionnaires, including the SES (n=160). Of these, 85 subsequently took part (mean age = 19.24 years, SD= 1.59). Total maternal EI (*r* =. 35, *p*<. 001) and paternal EI (*r* =. 46, *p*<. 01) were positively correlated with total scores of BPD symptoms, measured on the Five Factor Borderline Inventory (FFBI, Mullins-Sweatt et al., 2012). Specifically, paternal invalidation was significantly associated with dysregulated anger (*r* =. 44, *p*<. 001), despondence (*r* =. 37, *p*<. 001), affective dysregulation (*r* =. 34, *p*<. 001), dissociative tendencies (*r* =. 40, *p*<. 001), distrust (*r* =. 45, *p*<. 001) and oppositional subscales (*r* =. 38, *p*<. 001). Maternal invalidation was associated with dysregulated anger (*r* =. 43, *p*<. 001) and oppositional tendencies (*r* =. 35, *p*<. 001). This study received a moderate quality rating of 0.68. The screening and recruitment process was unclear and no rationale was provided for excluding non self-harming individuals. The study was cross sectional and self-reports were collected retrospectively at a single time point. Additionally, no data was provided on participants who dropped out of the study (i.e. the rate of self-harm that they had reported). Finally, correlation analyses did not control for degree of anxiety or depression, which may contribute to the associations reported.

Factors explaining the relationship between childhood EI and symptoms of BPD

Five studies explored the importance of mediating variables in the relationship between IE and BPD (Gill & Warburton, 2014; Sauer & Baer, 2009; Sauer-Zavala et al., 2013; Sturrock et al., 2009; Sturrock & Mellor, 2014). Sturrock et al. (2009) studied whether the pathway between childhood EI and BPD symptoms could be explained by the degree of emotional avoidance. Individuals from the general population and university students (n= 141, 89 females) self-selected into the study (mean age= 35.17, SD= 13.89). Participants completed the ICES, the BPD subscale of the Personality Diagnostic Questionnaire- 4th edition (PDQ-4; Hyler, 1994) and the Distress Tolerance Scale (DTS; Corstorphine, Mountford, Tomlinson, Waller & Meyer, 2005) as a measure of ability to tolerate emotions. This measure consists of three scales: anticipate and distract (neutral), avoidance of affect (maladaptive), and accept and manage (adaptive). Results showed that symptoms of BPD were unrelated to paternal EI (*r* =. 11, *p*>. 05). A mediation analysis explored the hypothesis that the relationship between maternal EI and BPD symptoms was mediated by avoidance of emotions (see Figure 2). The relationship between maternal EI and symptoms of BPD (b= 19, *p*= .038) was no longer significant when emotional avoidance was added into the model as a mediator (b= 11, *p*= .22). A high quality rating of 0.81 was given to this study, however they did not screen nor control for Axis I and II disorders. All measures were collected retrospectively at a single time point.

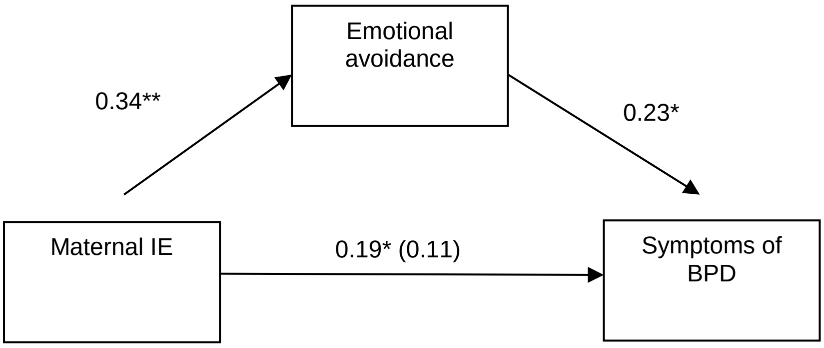


*Figure 2: Meditational model of maternal EI, avoidance of emotions, and symptoms of BPD. The value in parentheses shows the relationship between maternal EI and BPD symptoms when the mediator was included in the model. All values are beta coefficients, * p < 0.05 ** p < 0.01.*

Emotional avoidance was investigated further by Sturrock and Mellor (2014) who investigated the different contributions of past parental, current parental and current partner EI on symptoms of BPD. A large sample of 186 participants (female n=143) were recruited from the general population and were invited to take part if they were between 18 to 55 years old and were in current contact with their childhood caregivers. The sample was comprised of 43 males (mean age 37.02 years, SD=11.89) and 143 females (mean age= 32.10, SD=10.42). Participants completed the ICES, Current Parental Invalidation Scale (CPIS; Sturrock et al., 2014), the Validating and Invalidating Responses Scale – Couples (VIRS; Fruzzetti, 2007), the BPD subscale of the Personality Diagnostic Questionnaire- 4th edition (PDQ-4; Hyler, 1994), the Difficulties in Emotion Regulation Scale (DERS; Gratz &

Roemer, 2004) and the DTS. Results indicated that self-reported EI in the relationship with participant’s current partner, poor emotion regulation, and poor distress tolerance mediated the relationship between childhood experiences of parental EI and current symptoms of BPD (see Figure 3). The model accounted for 38% of the variance in adult BPD symptoms.

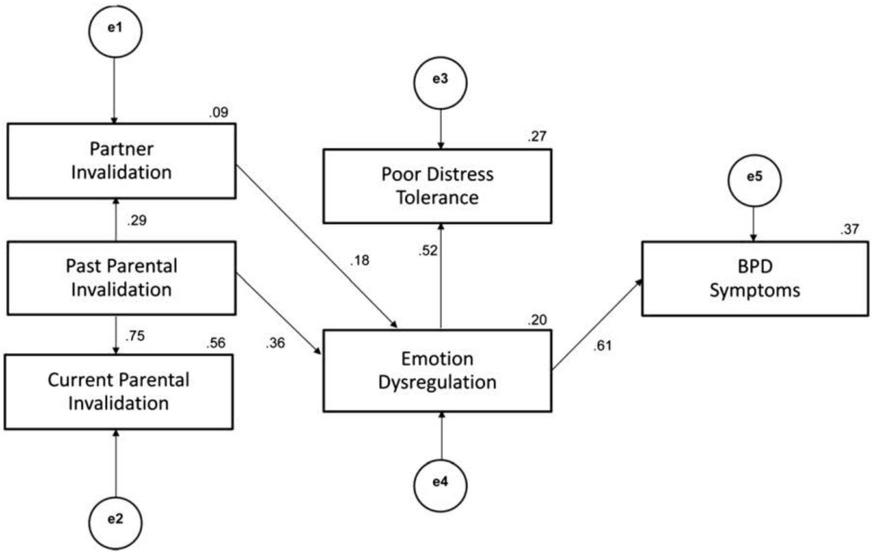


Figure 3: Path model of relationship between parental EI and BPD symptoms as mediated by current partner invalidation, emotional dysregulation and distress tolerance.

This study received a high quality rating of 0.81. Limitations included an unclear screening protocol for participants, recruitment of a non-clinical sample, and use of a cross sectional design to explore the proposed development pathway. By excluding participants who were not in contact with caregivers, individuals who experienced high levels of EI during childhood may not have been captured in the current research. Additionally, the authors did not control for confounding variables, such as anxiety and depression, in their analyses.

Sauer and Baer (2009) investigated the presence of theoretically derived mechanisms of thought suppression and fear of emotions as contributing to the relationship between biosocial precursors of BPD and current BPD symptomology. A non-clinical sample of psychology undergraduate students completed the PAI-BOR and groups of participants scoring in the low, medium and high range of symptoms were invited to complete additional questionnaires. Selected participants completed the SES, The White Bear Suppression Inventory (WBSI; Wenger & Zanakos, 1994) and the Affective control scale (ACS; Williams, Chambless & Ahrens, 1997). The final sample was comprised of 104 individuals, aged between 18 and 34 years old (mean= 19.10 years). The direct effect of EI on BPD symptoms (b=*.* 24, *p*= <. 005) was reduced when both mediators were added into the regression model and was no longer significant, (b=*.* 13, *p*= n.s) as shown in Figure 4.

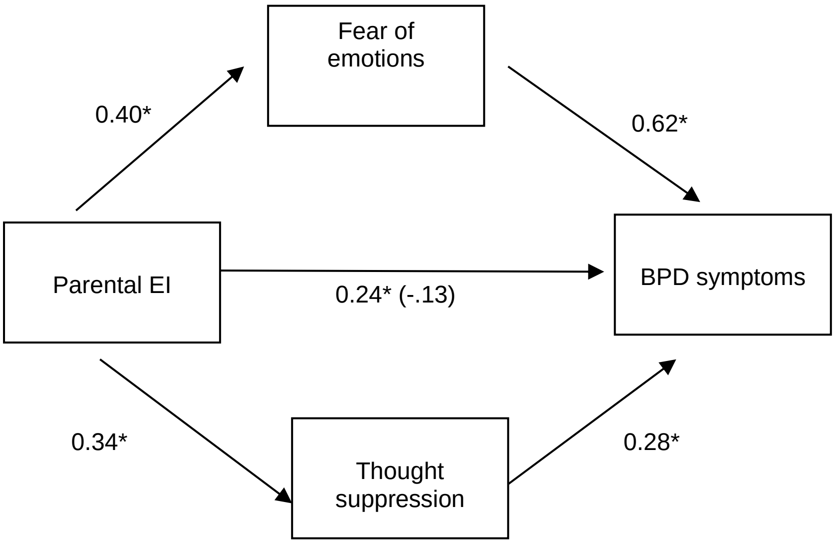


*Figure 4: Meditational model of parental EI, fear of emotions, thought suppression and symptoms of BPD. The value in parentheses shows the relationship between parental EI and BPD symptoms when both mediators were included in the model. All values are beta coefficients, * p < 0.05.*

This study received a high quality rating of 0.81. A strength of the study was the careful selection of a sample that reflected varying levels of BPD symptoms. A power analysis was also provided which indicated that the sample size was appropriate. The use of a cross sectional design limits the conclusions that can be drawn regarding the developmental pathway between EI, BPD and hypothesised mediating variables. Finally, no attention was paid to the influence of confounding variables in this study, such as anxiety or depression.

Sauer-Zavala et al. (2013) examined the relationship between theoretical precursors of BPD (emotional vulnerability and EI), BPD symptoms, and the tendency to ruminate in response to anger. A non-clinical sample of 342 psychology undergraduate students (females= 194; males = 148), aged between 18 to 30 years old (mean = 19.52 years, SD = 2.95), volunteered to take part in an online survey. The sample was a subsample of participants recruited into the study by Sauer and Baer (2010). Participants completed the IE-Child, PAI-BOR, ARS (Anger Rumination Scale; Sukhodolsky, Golub & Cromwell, 2001) and the DASS. EI significantly correlated with symptoms of BPD, (r= .27, *p*<. 01), anger rumination, (r=. 28, *p*<. 01), and depression, (r= .28, *p*<. 01). Contrary to their hypothesis, parental EI did not predict BPD symptoms, nor the degree of anger rumination when controlling for current depressive symptomology. However, no statistics were provided on this non-significant result and therefore the direction and strength of the relationship is unknown. Due to the non-significant regression analysis, further planned exploration of the hypothesised relationship between variables using mediation analyses was not conducted (as recommended by Baron & Kenny, 1986). The results of a non-significant relationship between EI and BPD when level of depression was controlled for contradicts those described in the study by Sauer and Baer (2010). As the current study explored a smaller selection of the original sample, there may not have been sufficient power to detect a significant effect. Additionally, some of the statistics were not reported in full and it was therefore given a moderate quality rating of 0.72. The sample was recruited from a non-clinical population and a cross sectional design was used to explore the relationship between variables.

Gill and Warburton (2014) examined the relationship between theoretical precursors of BPD (emotional vulnerability and EI), BPD symptoms, and emotion dysregulation. A non-clinical sample (mean age= 32.06) comprised of undergraduate psychology students (n=100) and individuals from the general population (n=150) completed an online survey that included the following measures: IE-Child, DRES and Borderline Personality Questionnaire (BPQ, Poreh et al, 2006). Of interest to the current review question, authors concluded EI was associated with emotion dysregulation, which predicted symptoms of BPD (see Figure 5). However, the results were presented as part of a larger model including variables that were not relevant to the review question. As a result, the pathway between emotion dysregulation and BPD takes account of other parts of the model and therefore the precise amount of variance between the variables relevant to this review are unknown. The study was given an overall quality rating of 0.59. Details on measures, participant characteristics and recruitment were only partially provided. The study did not control for Axis I or II disorders and the results were unclear. The study relied on retrospective measures, a cross sectional design, and a non- clinical sample to examine clinical constructs.

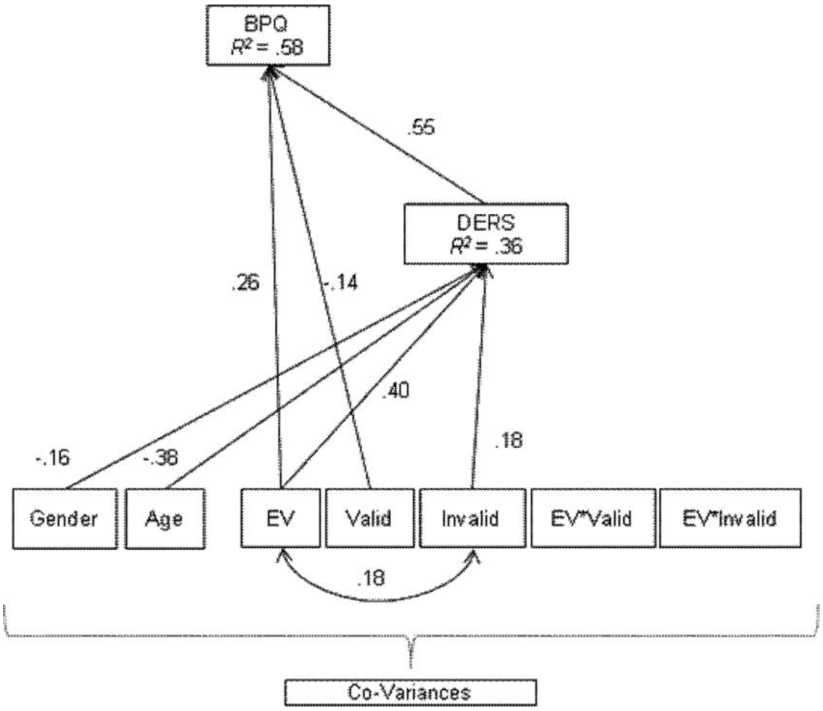


Figure 5: Model of the relationships between pre cursors to BPD, difficulties regulating emotions and BPD symptoms.

The relationship between IE and eating pathology

Three studies explored the relationship between IE and eating pathology (Haslam et al., 2008; Haslam et al., 2012; Mountford et al., 2007). Haslam et al,

(2008) investigated the association between childhood EI and clinical diagnoses of an eating disorder (AN and BN), eating disorder behaviours (bingeing, vomiting, laxatives, exercise) and eating attitudes (restraint, weight concern, shape concern, or eating concern). A clinical group of 58 individuals, 55 of whom were female (Mean age = 27, SD = 6.10) with diagnoses of either AN (n=21) or BN (n= 37), were recruited to the study during routine clinical assessment from a specialist eating disorder service. Participants completed the ICES and the Eating Disorder Examination Questionnaire (EDE-Q, Fairburn & Beglin, 1994). The EDE-Q has four subscales: restraint, eating, body shape and body weight concern. A between-subjects MANCOVA analysis explored whether level of IE varied between diagnosis when controlling for age and BMI. The BN group reported significantly greater levels of perceived paternal EI (M = 2.22, SD = 0.69) compared to the AN group (M = 1.86, SD = 0.47), F = 7.67, p<. 01). No significant differences were found between diagnosis for maternal invalidation (F= 0.73, *p*>.01), chaotic family type (F= 1.40*,* *p*>.01), perfect family type (F = 0.02, p> .01), and typical family type (F= 1.25*, p<.* 01). A further set of MANCOVAs explored the relationship with eating behaviours (bingeing, vomiting, use of laxatives and exercising) and indicated that participants with a diagnosis of BN and who engaged in vomiting reported greater levels of perceived invalidation by their fathers (F= 3.84, p<. 05). Participants with a diagnosis of BN, who reported high levels of exercise reported higher levels of a 'typical family style' (an emotionally controlled, high achieving style), (F= 8.12, p<. 001). There were no associations between ICES scores and other behaviours (e.g. use of laxatives and bingeing). Finally, regression analyses indicated no associations between ICES and eating attitudes: restraint (F= 0.40, p=. 89), weight concern (F= 1.30, *p*= .029), shape concern (F= 1.18, *p*=*.* 33), nor eating concern (F= 1.31, *p*=. 27).

This study was given a quality rating of 0.63. Strengths of this study were use of a clinical sample and the use of a well-validated tool to assess the presence of eating pathology. However the sample was small and limited to two eating disorder diagnoses, therefore the results may not represent other eating disorder presentations, or sub clinical levels of pathology. Little detail was provided on how the participants were recruited and whether any exclusion criteria were applied. The study was cross sectional and all data was collected at a single time point. Although the study did control for age and BMI in the analysis, no attention was given to the presence of further confounding variables. A series of non-significant results were reported, however estimates of variance were not recorded therefore the direction and trend of these results are unknown.

Factors explaining the relationship between childhood EI and eating pathology

Two studies explored mediating variables to understand the relationship between EI and eating disorder pathology (Haslam et al., 2012; Mountford et al., 2007). In a case control study, Mountford et al. (2007) explored whether low distress tolerance explained this relationship. All participants completed the ICES, Eating Disorder Inventory (EDI; Garner, Olmsted & Polivy, 1983) and the DTS. A group of eating disordered females with diagnoses of either AN, BN or Eating Disorder Not Otherwise Specified (EDNOS) (n=73, mean age= 28.5, SD = 7.80) were compared with a group of university students (n=62, mean age= 28.4, SD = 5.78). The clinical group was collapsed into a single group for the initial analysis. Overall, the group of eating-disordered females perceived significantly greater levels of childhood EI by both mothers (M = 31.68, SD = 7.22), t = 3.03*,* *p*= .003) and fathers (M = 34.70, SD = 8.88) (t = 5.12, *p*<. 001), across three measures of EI family styles: Typical (M = 2.58, SD = 1.26) (t= 3.24, *p*=. 002), Chaotic (M = 1.81, SD = 1.12), (t = 3.21, *p*=. 002), and Perfect (M = 2.14, SD = 1.28), (t= 4.01*,* *p*< .001) compared to the non-clinical group. Mediation analysis (see Figure 6) revealed that a direct effect between paternal EI and eating disorder symptoms (b=0.57, *p*<. 001) reduced when distress tolerance was added into the regression model (b=. 04, *p*<. 001). This indirect effect remained significant therefore poor distress tolerance was deemed a partial mediator between paternal invalidation and eating disorder symptoms.

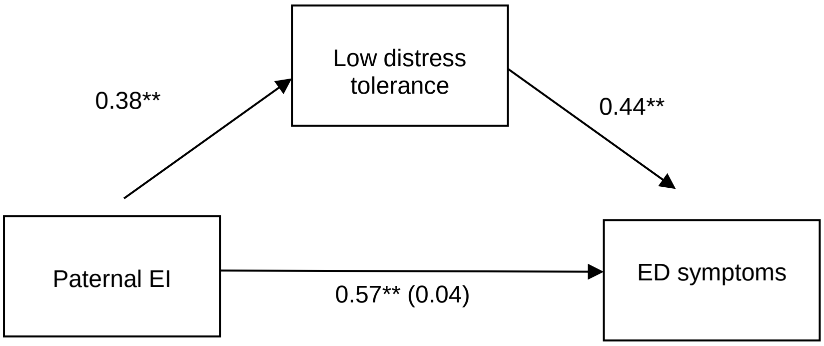


*Figure 6: Meditational model of paternal EI, distress tolerance, and eating disorder symptoms. The value in parentheses shows the relationship between paternal EI and eating disorder symptoms when the mediator was included in the model. All values are beta coefficients, * $p < 0.05$ ** $p < 0.01$.*

This study received a high quality rating (0.90) and utilised a clinical sample to explore psychopathology. The cross sectional design limits the exploration of the developmental pathway between EI, distress tolerance and eating pathology. It was unclear when eating disorder participants completed the questionnaires and whether there was any standardisation of this across the sample. It is possible that reported EI and eating pathology might vary through therapy and therefore the absence of this information lowered the quality rating.

In a subsequent study exploring EI and eating pathology, Haslam et al. (2012) investigated associations between EI, beliefs about expressing emotions, and eating attitudes. The non-clinical sample was comprised of 200 female university students (mean age= 21 years, SD= 3.70) who completed the ICES, EDE-Q and Attitudes to Emotional Expression Scale (AEE; Joseph, Williams, Irwing & Cammock, 1994). The AEE is a self-report measure of the belief that emotions are a sign of weakness (weakness subscale), that emotions should be kept under control (control subscale), that others will reject emotional expression (social subscale), and the tendency to keep emotions to oneself (non-expression subscale). Spearman's rank correlation analysis identified that paternal EI was associated with weight concern (*r=.* 177, *p* < .001). The results also suggested that both maternal EI (*r=.* 128, *p*< .05) and paternal EI (*r=.* 169, *p*< .001) were associated with high scores on the eating concern subscale, which contrasts to findings in a clinical sample (Haslam et al., 2008). Mediation analysis revealed that the direct effect between maternal EI and eating concern (b= 0.17, *p* <. 001) became non significant when the belief that expressing emotions as a sign of weakness was added as a mediator, (b=. 14, *p* >.005), indicating this fully mediated the relationship between variables (see Figure 7).

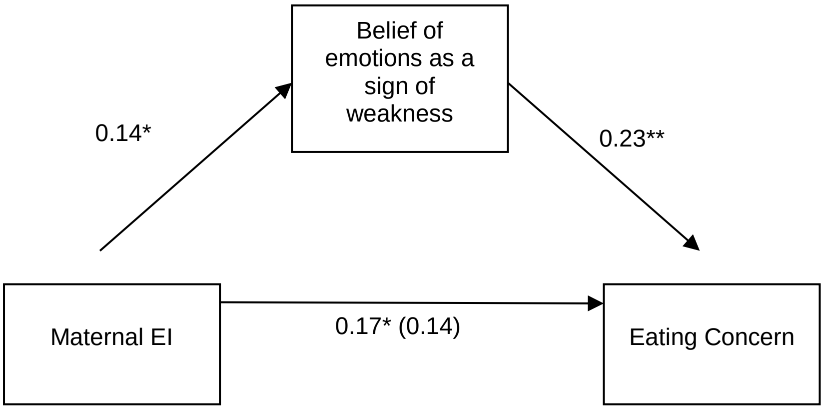


*Figure 7: Meditational model of maternal EI, beliefs about emotions, and eating concern. The value in parentheses shows the relationship between maternal EI and eating concern when the mediator was included in the model. All values are beta coefficients, * p < 0.05 ** p < 0.01.*

This study received a quality rating of 0.63. No information was provided on how the sample was recruited including the relevant inclusion and exclusion criteria. A series of non-significant results were not provided in the results section. The use of a non-clinical, female sample limits the generalisability of the results, as does the use of a cross sectional design to explore the developmental pathway of eating pathology based on childhood EI.

The relationship between IE, depression and anxiety

Data from two studies established an association between EI and symptoms of depression and anxiety (Krause et al., 2003; Sauer- Zavala et al., 2013). Krause et al. (2003) recruited 127 undergraduate students, between 18 and 30 years old who completed the SES, the Beck Depression Inventory (BDI; Beck, Rush, Shaw & Emery, 1979) and the Beck Anxiety Inventory (BAI; Beck, Epstein, Brown & Steer, 1988). Participants who reported that their parents responded to their emotions with distress (SES distress subscale) reported higher levels of both depression (*r* =. 37, *p* <. 01) and anxiety (*r* =. 30, *p* <. 01). No significant associations were found between reported experiences of parental minimization of emotions (SES minimising subscale) in childhood and current symptoms of depression (*r* =. 12, *p* >. 05) and anxiety (*r* =. 15, *p* >. 05). A similar pattern of non-significant associations between parental punishment of emotions (SES punishing subscale) and current depression (*r* =. 15, *p* >.05) and anxiety (*r* =. 12, *p* >.05) was also found. This study received a high quality rating of 0.86. The study relied on retrospective measures, a cross sectional design and a non- clinical sample to examine clinical constructs. There was also a potential bias of self-selecting participants who may represent a different group of individuals from those who did not choose to take part. In a subsequent and previously discussed study, Sauer- Zavala et al. (2013) reported a correlation (*r* =. 28, *p*<. 01) between EI and depression and anxiety, as measured on the DASS.

Discussion

Summary of results

The aim of this review was to review the evidence for the association between childhood EI and adult psychopathology. Across the 12 studies selected for review, self-reported experiences of childhood EI from both parents were found to be significantly associated with BPD symptoms (DeShong et al., 2015; Gill & Warburton, 2014; Robertson et al., 2013; Sauer & Baer, 2009; Sauer & Baer, 2010; Sauer-Zavala et al., 2013; Sturrock et al., 2009; Sturrock & Mellor, 2014;) eating pathology, (Haslam et al., 2008; Haslam et al., 2012; Mountford et al., 2007) and depression and anxiety (Krause et al., 2003; Sauer- Zavala et al., 2013). However, the size of this effect was generally small to medium.

Across BPD and eating disorder studies, difficulties with regulating emotions was found to mediate the relationship between reported EI in childhood and outcome variables that measured psychopathology. Findings are supportive of the biosocial model of Linehan (1993), which suggests that the experience of childhood EI leads to difficulties tolerating emotions, which underpins the problem behaviours associated with BPD. The results point to an experience, other than overt abuse, that is associated with symptoms of BPD in adulthood. Additionally, the findings suggest that EI is a transdiagnostic experience, associated with disorders characterised by difficulties regulating emotions including eating pathology, depression and anxiety.

Although a transdiagnostic pattern between EI and psychopathology emerged, an unexpected finding was the differential impact of maternal and paternal invalidation on the development of psychopathology in some of the studies. In the studies exploring EI in clinical groups of eating disordered participants, paternal EI was more strongly associated with pathology (e.g. Haslam et al., 2008; Mountford et al., 2007). There is some evidence to suggest the differential impact of paternal and maternal interaction style on the development of eating disorders beyond EI. In a sample of children with eating disorders, Enten and Golan (2009) found that child EDI scores were significantly associated with a paternal authoritarian parenting style (e.g. a coercive, hostile and punitive style), which was not observed for mothers. In a systematic review of family functioning in eating disorders, fathers were found to be more critical compared to mothers, who were more emotional overinvolved (Anastasiadou, Medina-Pradas, Sepulveda & Treasure, 2014). In the current review, no clear pattern for maternal or paternal EI emerged within studies investigating BPD, anxiety or depression. More broadly, sufficient research evidence is lacking on the differential impact of maternal and paternal parenting characteristics and their contribution to the development of psychopathology (Phares, Fields, Kamboukos & Lopez, 2005).

Limitations

The limited research in areas other than BPD, eating pathology, depression and anxiety limits the conclusions that can be made about whether childhood EI is a transdiagnostic factor, which underpins a range of adult psychopathologies. As only two of the studies included in this review employed clinical samples, the generalisability of the findings of this review are limited. Only one study that employed a non-clinical sample provided details of the number of participants that scored within the clinical range of symptoms. Specifically, Sauer & Baer (2010) reported that 17.1% of their sample of undergraduate students scored above the clinical cut off for BPD. Although this increases generalisation of findings to clinical populations, students currently enrolled in university courses reflect a group of individuals who are unlikely to represent the patients typically seen in mental health services, who report significant distress associated with symptoms of BPD (Meaney, Hasking & Reupert, 2016).

All studies reviewed measured childhood EI using retrospective self-reports. There are inherent difficulties when data is collected in this way; namely that they are highly subjective (Austin, Gibson, Deary, McGregor & Dent, 1998; Paulhus & Vazire, 2007) and subject to social desirability bias (Barker & Pistrang, 2015). Relevant to the current review, it is well documented that individuals with symptoms of BPD and eating disorders may be biased in their self- reported aversive early experiences (Huang et al., 2012; Zanarini et al., 2000), and therefore the results from studies may be an over estimation of EI. It is also important to acknowledge the impact of adult experiences of EI and how this would impact on the level of childhood EI reported by the individual. In the current review, only one study measured this (e.g. Sturrock et al., 2014).

All studies measured EI using one of three measures, none of which have undergone full psychometric evaluation. This is a major limitation of the studies and therefore the research base in this area. A further limitation of the identified research was that there were no longitudinal studies that assessed the impact of EI, measured in childhood on adult psychopathology. It is therefore difficult to make conclusions about the casual relationship between EI and the dependent variables described, as well as the variables that mediated this relationship.

Finally, the studies selected for review utilised measures which reflected Linehan's definition of EI and a small number of studies were excluded, as the way in which EI was measured did not reflect Linehan's conceptualisation. For example, one of these studies measured parental bonding and early attachment as an indicator of EI (e.g. Martin, Bureau, Cloutier & Lafontaine, 2011). Despite these being key processes know to underpin healthy child development, these do not specifically measure an individual's recall of the way in which their parents responded to their emotions. This review also excluded studies that investigated overt abuse, an experience deemed highly invalidating, and frequently reported in BPD samples (e.g. Bandelow, et al., 2005; Zanarini et al., 2002). Although investigating the early experiences of individuals who have not experienced overt abuse is important, it is highly likely that individuals who experienced overt abuse would also have experienced EI during interactions with their parents. This has recently been indicated in research by Hong, Ilardi and Lishner (2011) and Hong and Lishner (2016), who explored EI in response to disclosures of CSA and 'general EI' in childhood. Although the review excluded studies that explored overt abuse to focus on the way in which a child experienced how their parents responded to their emotions, it is likely that across samples explored there may have been instances of overt abuse that were not controlled for.

Clinical implications

The findings of this review point to the importance of early intervention such as targeting caregivers who may be ‘at risk’ of providing an emotionally invalidating environment for their children. One example of this already in place is Mellow Parenting (MacBeth, Law, McGowan, Norrie, Thompson & Wilson, 2015; Stepp, Whalen, Pilkonis, Hipwell & Levine, 2012), an intervention that targets the quality of interactions between mothers and their young children, and more recently between fathers and their children (MacBeth et al., 2015). Within transactions, parents are aided in recognising their child’s preferences and needs, linked to their emotional states. The recognition of emotional states is imperative to be able to validate these. Such interventions are important given the evidence to indicate the trans-generational nature of mental health difficulties (Hosman, Doesum & van Santvoort, 2009), particularly BPD (Barnow, Spitzer, Grabe, Kessler & Freyberger, 2006; Stepp et al., 2012). One example of this is provided by Buckholdt, Parra and Jobe-Shields (2014), who provided evidence to suggest that parents who report high levels of emotion dysregulation, invalidated their adolescent’s emotions more often. These adolescents were found to have difficulties regulating their own emotions. One key way of preventing this transmission may be to identify mothers who have emotional regulation difficulties, particularly those with BPD, and offer psychoeducational programmes on EI and support the development of skills for providing a more validating environment (Fallow, 2009).

Research implications

Given the promising findings of this review, further research into this area is warranted to determine the reliability of findings as well as to improve the generalisability to clinical samples and to a wider range of psychopathologies. To improve the validity of further research, the limitations identified need to be addressed and a psychometrically validated measure EI is necessary, based on a clear definition of EI. Following this, larger scale studies across clinical samples including a range of psychopathologies would enable more robust conclusions to be made. In order to suggest that childhood EI has a ‘causal’ impact on adult psychopathology, longitudinal studies are needed. This would involve employing a large cohort of children and their parents, where there is likely to be EI and frequently measuring this across their course of development and then assessing psychopathology in the child in adulthood. Given the small to medium associations between EI and psychopathology found in this review, the measurement of other known risk and protective factors is necessary. A key variable would be experience of overt abuse, given the evidence to suggest that overt abuse is strongly associated with a range of psychopathologies (Bandelow et al., 2005). A second variable would be biological emotional vulnerability, deemed important in the biosocial model by Linehan (1986). Other environmental variables to be included could be parental bonding, parental criticism, parenting style, peer relationships and family social economic status, all of which have been explored as key in the development of psychopathology.

Conclusions

This review found a small association between self-reported childhood EI and symptoms of BPD, eating disorders, anxiety and depression in adults. There is some evidence that this may be mediated by difficulties with emotion regulation. This has implications for the identification and intervention in emotionally invalidating environments, particularly to help prevent trans-generational transition of these difficulties. Given the infancy of the research in this area, in order to determine how valid and reliable these findings are, further research is needed. In particular, it is recommended that larger scale, longitudinal studies are conducted across a broader range of psychopathologies

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Part Two: Empirical Paper

Family Connections: A Feasibility Study

Abstract

Aims: Being a family member to an individual with Borderline Personality Disorder (BPD) is associated with high levels of burden, grief, depression and low levels of personal mastery. The aim of the study was to assess the feasibility of the Family Connections programme in the UK. The programme offers education, skills training and support to family members supporting an individual with BPD over 12-weekly group sessions.

Method: Family members of individuals with BPD were recruited from an NHS trust. Recruitment, retention and the acceptability of the intervention were recorded to assess feasibility. Burden, grief, mastery, depression, mindfulness and emotional invalidation (EI) were measured at pre, post and at one month follow up to assess preliminary effectiveness of the programme.

Results: 31 participants started the programme and three of these dropped out. At the end of the programme there were significant reductions in family members levels of burden, grief, mastery, depression, mindfulness and EI. Participants reported that the intervention was acceptable.

Conclusions: The Family Connections programme is a promising intervention for family members of individuals with BPD that requires further study.

Introduction

Borderline Personality Disorder (BPD) is a severe and pervasive mental illness characterised by dysfunctional patterns of emotion instability, impulsivity and difficulties in interpersonal relationships (APA, 2013). Individuals with BPD are at increased risk of deliberate self-harm and attempted or completed suicide (Goodman, Roiff, Oakes & Paris, 2011). 73% of BPD patients will attempt suicide and 10% will be successful (Lieb, Zanarini, Schmahl, Linehan & Bohus, 2004). The prevalence of BPD ranges between 0.7-2% in the general population, and in clinical settings 10% of outpatients and 15-25% of inpatients have the diagnosis (Coid, Yang, Tyrer, Roberts & Ullrich, 2006)

The role of early experiences has been highlighted as important in the development of BPD (Linehan, 1987), discussed extensively in Chapter one of this thesis. The key premise of the biosocial model is that early experiences of EI, where ones emotions are ignored, minimized or dismissed, transact with an individual's innate emotional vulnerability in the development of pervasive emotion dysregulation, a core difficulty in BPD (Linehan, 1993). Fruzzetti, Shenk and Hoffman (2005) have extended this theory to explain the importance of ongoing problematic transactions that occur in the family environment, which may continue to intensify emotion dysregulation in individuals with BPD (see Figure 1). When an individual with BPD is emotionally dysregulated they are unable to accurately express their thoughts and emotions, referred to as 'inaccurate expression' (Fruzzetti et al., 2005, Fruzzetti & Shenk, 2008). This 'inaccurate expression' is difficult for family members to understand, and therefore their responses are likely to be experienced as emotionally invalidating, leading to further emotional dysregulation in the individual and further 'inaccurate expression'. The individual with BPD may then withdraw from others, escape emotionally or behave in an aggressive way to manage their emotions (Fruzzetti et al., 2005). As a consequence, the individual with BPD may feel angry and alone, their family more hopeless, and the relationship between them more strained (Fruzzetti & Worrall, 2010).

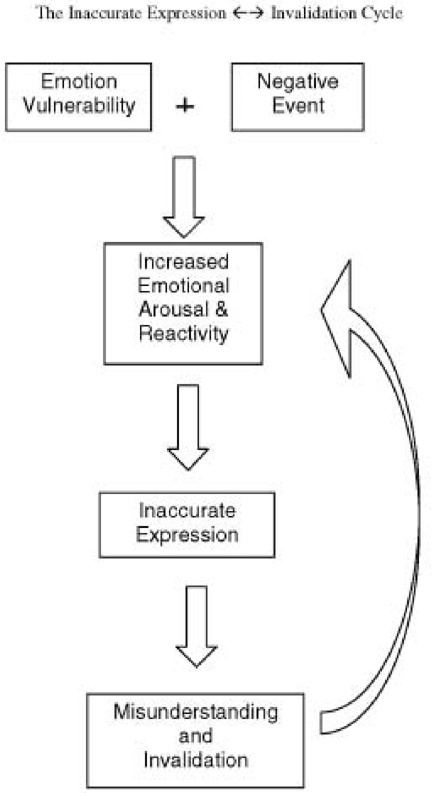


Figure 1: The transactional model of emotional dysregulation and invalidating responses (Fruzzetti et al., 2005).

Treatment for BPD

The biosocial model by Linehan (1993) underpins Dialectical Behavioural Therapy (DBT), an extensively validated treatment for BPD (Linehan et al., 2006; McMain, Guimond, Streiner, Cardish & Links, 2012). The aim of DBT is to target key difficulties associated with BPD, including emotional instability, impulsivity, interpersonal difficulties and identity disturbance. DBT is based on the principle that individuals with BPD lack adaptive skills to regulate their emotions and therefore the therapy emphasises the acquisition of skills to increase an individual's capacity to regulate their emotions and the consequent behaviours. DBT is delivered across five modes: weekly (group-based) skills training, weekly individual therapy, telephone coaching, therapist consultation meetings, and consultation to the environment. DBT skills training is comprised of four modules: 1) mindfulness skills, which encourage individuals to observe, describe and participate in the present moment, effectively without judgment; 2) emotion regulation skills, which teach individuals to recognize, manage, and respond differently to emotions; 3) interpersonal effectiveness skills, which help individuals balance their needs, objectives, and self respect in an assertive and non-aggressive manner; and, d) distress tolerance skills, which increase ways of managing strong emotions and control impulsive urges and behaviours. The primary aim of weekly individual therapy is to maintain commitment to use skills and address motivation to change. Within this, skills are related to specific problem areas linked to therapy goals. Individuals are encouraged to seek support from their therapist via telephone coaching to aid identification of skills to manage distress and to increase skills generalization to their environment. Consultation to the individual's environment, including to families and other professionals involved in their care increases opportunities for further generalization and reinforcement of skills use. The DBT consultation team meeting functions to enhance therapist skills and motivation.

Traditional DBT for adults focuses on the individual as a priority but makes little attempt to directly modify the family environment. Through treatment, individuals are encouraged to practice and use their skills in a range of environments so that following completion of DBT they are more able to manage difficult relational and environmental challenges (Swales, Heard & Williams, 2000). However, this generalisation of skills can be challenging as their families may continue to have very little knowledge of their loved ones difficulties (Hayes, 1991; Hoffman, Fruzzetti & Buteau, 2007).

The impact on family members

The difficulties that an individual with BPD experiences, including emotional instability, impulsivity and difficulties in interpersonal relationships are not only painful for the individual but also for the system around them, including family members. Family members are often present during periods of chaos and crisis (Stobie & Tromski-Klingshirn, 2009) and may witness an array of risk behaviours, including self-harm and suicide attempts (Rajalin, Wickholm-Pethrus, Hursti & Jokinen, 2009), which can be highly anxiety provoking and traumatising (Griffin, 2008; Gunderson, 2009). The relational difficulties individuals with BPD experience include sensitivity to abandonment and rejection, which are often associated with intense anger towards family members (Gunderson & Lyoo, 1997). In these times family members may receive verbal and physical abuse (Penny & Woodward, 2005). Individuals may also oscillate between idealisation and devaluation of significant others, including their families (Linehan, 1993), leading to frequent shifts in the quality of the relationship.

Family members often face difficulties accessing suitable services and report receiving very little information on BPD from health care professionals (Griffin, 2008; Hoffman, Fruzzetti & Buteau, 2007). In a qualitative study, parents of individuals under a specialist personality disorder service took part in focus groups that explored their experience of their caring role and experiences of mental health services supporting their relatives. Family members expressed concern about how to appropriately manage their loved-ones behaviour as well as where to access support for managing the risk behaviours (Griffin, 2008). Families have frequently described poor relationships with mental health services, characterised by poor communication and lack of consistency (Dunne & Rogers, 2013; Lawn & McMahon, 2015). Qualitative findings suggest that once psychiatric support was provided to the individuals with BPD, families often feel excluded from their loved ones care, resulting in them feeling neglected and abandoned (Ekdahl, Idvall, Samuelsson & Perseius, 2011; Ekdahl, Idvall & Perseius, 2014). Additionally, they were often fearful that their relative was being judged negatively by psychiatric services (Buteau, Dawkins & Hoffman, 2008) as well as fearing they were also being judged (Lawn & McMahon, 2015). In terms of knowledge, Hoffman et al. (2003) found that one third of family members had no knowledge of BPD or the associated symptoms, and that they felt confused, ignorant and incompetent in managing their loved ones difficulties. A subsequent study found that only one third of parents had had the diagnosis explained to them (Lawn & McMahon, 2015). Linked to this, parents of individuals with BPD frequently report their concern that they are the ‘cause’ of their loved ones difficulties (Penny & Woodward, 2005).

Unsurprisingly, high levels of burden have been observed in family members of individuals with BPD. Overall burden has two dimensions: objective, the daily responsibilities placed upon the family (e.g. financial concerns and disruption in the home) and subjective, how the family feels their roles are impacted (e.g. feeling guilty, resenting their relative and feeling trapped and isolated by their care-giving role), (Goodman et al., 2011).

In a recent systematic review, family members who cared for relatives with BPD were found to score highly on measures of objective and subjective burden, grief, depression and anxiety and low on perceived empowerment. These scores were higher than for families supporting a relative with a diagnosis of schizophrenia (Bailey & Grenyer, 2013). Schiers and Bok (2007) found that family members scored highly on all dimensions of the Symptom Check List (SCL; Arrindell & Ettema, 2003), a screening measure of psychopathology. When compared to the general population, family members of individuals with BPD self reported significantly higher levels of anxiety, agoraphobia, depression, somatisation, distrust and interpersonal sensitivity, insufficiency in thinking and acting, hostility and sleep problems. Bailey and Grenyer (2014) found that family members scored highly on measures of emotional dysregulation, which was found to be associated with high levels of burden, anxiety and depression.

Overall satisfaction in relationships is low in both parent-child (Fruzzetti & Worrell, 2010) and romantic relationships (Bouchard & Sabourin, 2009; Bouchard & Sabourin, Lussier & Villeneuve, 2009) when compared to a sample of non-BPD dyads. It is unsurprising that the difficulties family members develop may compromise functioning within relationships and lead to difficulties in communication with their loved one (Fruzzetti et al., 2005). Importantly, emotional involvement of family members is associated with positive treatment outcomes in BPD (Hooley & Hoffman, 1999). This contrasts with research findings of families of individuals with psychosis, where 'high expressed emotion' and 'over involvement' were found to have a negative impact on the illness course and recovery (Hooley, 2007). Conversely, emotional 'over involvement', characterised by worry and concern was experienced as supportive and validating to individuals with BPD. This is an interesting distinction and highlights the interpersonal nature of the difficulties in BPD. Although this may contribute to therapeutic improvement in the individual with BPD, it is associated with higher levels of burden, anxiety and depression in family members (Bailey & Grenyer, 2014).

The Family Connections Programme

Although the literature has indicated the helpfulness of family members involvement to the individual with BPD, empirical data has consistently highlighted the negative impact that this may have on family members. The need for interventions aimed at supporting families to manage the impact of their loved ones difficulties has now been recognised. The 'Family Connections programme' was developed in consultation with family members of individuals with BPD (Hoffman et al., 2005). The programme draws on DBT skills (Linehan, 1993) and relationship and family skills underpinned by the transactional model of the maintenance of BPD described in Figure 1 (Fruzzetti et al., 2005). To the current author's knowledge, the Family Connections Programme is the only intervention developed for family members that has been subject to evaluation.

The aims of the Family Connections programme are to increase knowledge of symptoms, behaviour and treatment of BPD and to help family members understand their own responses to their loved one. The programme promotes communication and adaptive problem solving strategies to enhance family members own mental health. This is achieved in the context of a supportive environment among others in similar situations (Fruzzetti, Santisteban, Hoffman, Dimeff & Koerner, 2007). The Family Connections programme runs over 12 weekly sessions, covering 6 modules that include in-session and homework exercises. In America the group is run by family members of individuals who have BPD who have undergone extensive training in the delivery of the programme.

Empirical support for the Family Connections Programme

There have been two evaluation studies in the USA (Hoffman et al., 2005; Hoffman, et al., 2007), which have provided promising results for the effectiveness of the programme. In the first study, 44 participants (27 mothers, 12 fathers, 4 partners and 1 sibling) were assessed at pre and post intervention for levels of burden, grief, depression and mastery. Both burden and grief scores decreased and mastery increased significantly from pre to post measurement (Cohen's d= .28, .45, .58 respectively). At follow up, burden continued to decrease (Cohen's d= .65) and changes in grief and mastery were maintained. Unfortunately, depression scores did not change following the intervention. In a replication study by Hoffman et al. (2007) with a larger sample of 55 participants (31 mothers, 12 fathers, 6 partners and 4 siblings), the results for burden, grief and mastery were replicated from pre to post intervention (Cohen's d= .56, .32, -.95 respectively). Depression scores were found to decrease (Cohen’s d= .28), which researchers concluded related to higher statistical power and higher depression scores at baseline. At follow up, grief continued to decrease (Cohen’s d= .18) and mastery increased (Cohen’s d= .23).

Justification for the current study and aims

To date the research evaluating the Family Connections programme has been conducted in America, however there are important considerations regarding recruitment of family members and programme delivery which would vary in the UK. In America, family members of individuals with BPD are trained in the approach and deliver the programme. This is not possible in an UK as no family members have been trained to deliver the group programme, nor would it be possible for family members to run the group in an NHS setting without trained professionals. Subsequently, in America family members may attend the programme without their family member receiving their own treatment. In the UK, access and recruitment of family members is dependent on their relative having been referred to a specialist personality disorder NHS service and being diagnosed with BPD. Given these differences, the aim of the current research was to conduct a UK based feasibility study of the Family Connections programme.

The Medical Research Council (MRC; Craig et al., 2008) suggests that feasibility studies are the first step to evaluating complex interventions. The study aimed to explore the feasibility of recruitment to the programme, dropout, appropriateness of outcome measures selected, and acceptability of the intervention. The study also aimed to explore preliminary effectiveness of the programme in a UK population. Primary outcomes were those explored in the USA (burden, grief, mastery, and depression) and two further outcomes, mindfulness and EI, given the focus of these in the programme.

Method

Participants

Participants were recruited from a large NHS Foundation Trust in Greater London between April 2016 and December 2016. To be included in the study participants had to: (a) have a family member under the local Personality Disorder (PD) service with a diagnosis of BPD (for the purpose of the research, ‘family member’ was defined as a person who was biologically or non-biologically related to the individual with BPD), (b) have at least monthly contact with the individual with a diagnosis of BPD, and (c) be over the age of 18. Participants were excluded if they: (a) were unable to communicate in conversational English, (b) had a learning disability, (c) were experiencing current psychotic disorder, or (d) were known to engage in violent behaviour.

All clinicians in the PD service were asked to review their caseloads and speak to their clients to identify family members who may be eligible. They then asked the clients if it would be acceptable to contact their family members to tell them about the study and invite them to participate. The research team contacted potential participants and invited them to take part. Participants were sent a Participant Information sheet (Appendix B) by post and completed a consent form before the group commenced.

Measures

Burden Assessment Scale (BAS, Reinhard, Gubman, Horwitz & Minsky, 1994): the BAS is a 20-item likert scale which assesses subjective and objective levels of burden including personal distress, disrupted activities, social functioning and guilt. Example items include: ‘Because of your relative’s mental health difficulties, to what extend have you found it difficult to concentrate on your own activities?’ and ‘Because of your relative’s mental health difficulties, to what extent have you felt guilty because you were not doing enough to help your relative'. Individuals are required to tick how much they agree with a statement ('Not at all', 'A little', 'Some', 'A lot'). A higher score indicates a greater experience of burden. The scale produces an overall score for level of burden and two further scores for subjective and objective levels of burden. Cronbach's alpha has been reported as ranging from 0.86-0.90 (Horwitz & Reinhard, 1995). Bailey and Greyner (2014) reported that the measure had strong internal consistency of 0.88 when used with family members of individuals with a diagnosis of BPD.

Grief Assessment Scale (GAS, Struening et al., 1995): the GAS is a 15-item likert scale which assesses current level of grief associated with the mental illness of a loved one. Example items include: 'It is painful to see what my relative is going through', and 'It is painful for me to accept my relative's condition'. Items are rated on a 5-point scale ranging from 1 ('always true') to 5 ('never true'). A total grief score is attained, with a higher score indicating a greater experience of grief. Bailey and Greyner (2014) reported that the measure had strong internal consistency of 0.92 when used with family members of individuals with a diagnosis of BPD.

Personal Mastery Scale (PMS, Dixon, 2001): the PMS is a 7-item likert scale, which assesses the perceptions of an individual's mastery in their life. Example items include: 'I have little control over the things that happen to me', and 'I often feel helpless in dealing with the problems of life'. Items are rated on a 4-point scale ranging from 1 ('strongly agree') to 4 ('strongly disagree'). A total mastery score is attained with a higher score indicating higher perceived mastery. Cronbach's alpha has been reported as 0.88 (Bibou-Nakou et al., 1997), indicating good internal consistency.

Centre for Epidemiological Studies Depression Scale revised (CES-D, Struening et al., 1995): the CES-D is a 20-item likert scale, which assess current depressive symptomology over the past week. Example items include: 'During the past week I felt depressed', and 'During the past week I had crying spells'. Items are rated on a scale ranging from ‘rarely or none of the time (less than one day)’ to ‘most or all of the time (5-7 days)’. A higher score indicates the presence of more depressive symptomology. The CES-D has been widely used in studies of caregiving strain and demonstrated high internal consistency with a Cronbach’s alpha of 0.93 (Bookwala, Yee & Schulz, 2000).

Five-Facet Mindfulness Questionnaire (FFMQ, Baer, Smith, Hopkins, Krietemeyer & Toney, 2006): the FFMQ is a 39-item likert scale that assesses mindfulness across five subscales (observing, describing, acting with awareness, accepting without judgement and non-reactivity). Example items include: ‘I find it difficult to stay focused on what’s happening in the present’, and ‘I pay attention to how my emotions affect my thoughts and behaviour’. Items are rated on a 5-point scale ranging from 1 (‘never or very rarely’) to 5 (‘very often or always true’). The five facets can be combined to give a global measure of mindfulness, with a higher score indicating a higher level of mindfulness. Good internal consistency has been found, with Cronbach’s alphas being reported as between 0.77 and 0.93 (Williams, Dalgleish & Kuyken, 2014) where the psychometric properties of the scale were examined in both clinical and non-clinical samples. These Cronbach’s alphas were similar to those found by Baer et al. (2006) and Baer et al. (2008) in earlier explorations of the psychometric properties of the scale.

Adult Invalidating Environment Scale (AIES; Feigenbaum, unpublished): the AIES is an adapted version of the Invalidating Childhood Environment Scale (ICES; Mountford, Corstorphine, Tomlinson and Waller, 2007). Example items include: ‘When I am anxious my family ignore me’, and ‘When I am miserable my partner asks me what is happening, so that they can help me’. The scale has 14- items and assesses the level of perceived EI in current relationships. Participants must select ‘family’, ‘partner’ or ‘friend’ dependent on their relationship with the individual who has BPD. The measure reflects themes evident within invalidating environments: ignoring thoughts and judgements; ignoring emotions;

negating thoughts and judgement; negating emotions; over reacting to emotions; over estimating problem solving; over–react to thoughts, and judgements and over-simplifying problems (Linehan, 1993). A higher score reflects a greater perception of invalidation in the relationship. This scale has been used in one previous study (Seal, 2012), and its psychometric properties are currently under evaluation.

Follow up interviews

A semi-structured interview schedule was developed for this study (see Appendix C), which asked questions related to the acceptability and usefulness of the programme. Either CP or a research assistant from the service from which participants were recruited completed the follow up interviews.

Procedure

During the first and final session participants completed the BAS, GAS, PMS, CES-D, FFMQ, and AIES. These questionnaires were repeated one month following the end of the programme during a follow up appointment with each participant or by post if they could not attend. Participants who attended the follow up appointment took part in a brief semi-structured interview regarding the acceptability of the programme. During the course of the intervention, in sessions four and eight, participants completed the primary outcome variables that were used in the USA research into the programme: BAS, GAS, PMS and CES-D. The purpose of this was to be able to use these scores as the last available data point for any participants who dropped out during the course of the programme (Mazumdar, Liu, Houck & Lii, 1999).

Intervention

The programme ran over 12 weekly sessions, each lasting 2.5 hours. The group followed the Family Connections 12-week manualized protocol developed by

Fruzzetti et al. (2005) outlined in Table 1. All groups were led by a trained facilitator (ML) and were co-facilitated by one of the developers of this research (CP), a Trainee Clinical Psychologist, who had experience of facilitating DBT skills groups.

Ethics

The acceptability of this study was discussed in consultation with service users who attended an in-service research and development meeting. All service users had a diagnosis of BPD and reported that the design was acceptable. The study was reviewed by the research committee at University College London, the NHS trust research and development department and received a favourable opinion from the North West Greater Manchester West Research Ethics Committee (Appendix D). The main ethical consideration was whether this research was a burden to participants filling out large numbers of questionnaires. Because of this, and in order to encourage completion, participants were offered a £5 voucher for completing the questionnaires in session one and a £10 voucher for completing the questionnaires at the follow-up appointment.

Module	Title	Aim	Content and skills
1	Introduction to the programme	Orientation to the programme	Sharing family perspectives and experiences
2	Family Education	Increase knowledge of BPD	Psychoeducation on BPD diagnosis, heterogeneity and treatment options The Biosocial model (Linehan, 1987) The Transactional model of emotional dysregulation and invalidating responses (Fruzzetti et al., 2005)
3	Relationship mindfulness skills	Enhance emotionally validating responses within the family Enhance accurate expression of thoughts and feelings Address emotional reactivity in the family member	Relationship mindfulness skills DBT ‘what’ and ‘how’ mindfulness skills (Linehan, 2014) Increasing awareness of emotions using mindfulness DBT acting opposite skill (Linehan, 2014)
4	Family environment skills	Improve the quality of relationships and interactions within the family.	Impact of strong beliefs and judgments (e.g. blame) Basic assumptions of relationship effectiveness Radical acceptance (Linehan, 2014)
5	Validation skills	Improve communication between family members Increase family members interpersonal effectiveness skills	Validation Self –invalidation Observing limits Interpersonal effectiveness skills- DEARMAN GIVE FAST skills (Linehan, 2014)
6	Problem management skills	Increase family members problem management skills	How to identify the problem Solutions to the problem

Table 1: Content of the Family Connections programme

Statistical analysis

Power analysis for this study was informed by the prior work of Hoffman et al., (2007). The largest effect size obtained in this study was used to inform the effect size for this power calculation. The power calculation was carried out using the "G*Power3" computer programme (Faul, Erdfelder, Lang and Buchner, 2007), specifying alpha= 0.01% and desired power= 80%. The minimum number of participants needed for this study was 34.

Each variable to be analysed was checked for normality by calculating the z-score for skewness and kurtosis and by using the Kolmogorov-Smirnov test. There was no evidence that would mean non-parametric tests should be used in this study (according to the to Kolmogorov-Smirnov test at $p < 0.01$).

Analysis was conducted in three stages. The first stage compared pre, post, and follow-up scores to ascertain whether there were any significant changes on the outcome measures deployed. Scores on the BAS, GAS, PMS, CES-D, FFMQ and the AIES were compared using one way- repeated measures ANOVAs. The pre-treatment measures were obtained from the start of the first session of the programme, the post-treatment measures were obtained at session 12, and follow up measures were collected one month following programme completion. All individuals who completed the 12- session programme (attended at least 8 sessions) were entered into the analysis. For individuals who completed the programme but were unable to attend the follow up appointment, their post-intervention scores were carried forward (n=5).

The second stage of the analysis considered whether the type of relationship between the participant and individual with BPD influenced any of the outcome variables. The analysis planned to split participants into groups, based on whether they were a ‘parent’ or a ‘partner’. A 2x3 repeated measures ANOVA (two levels of the independent variable; parent and partner and three levels of each dependent variable; pre, post and follow-up) was planned to see if there were any differences between these groups.

The third stage of analysis evaluated the qualitative data from semi-structured interviews that took place at one-month follow up to assess the acceptability and usefulness of the programme. A thematic analysis was conducted using the 6- step process recommended by Braun and Clarke (2006). This process involved the following steps: 1) familiarisation of the data by listening to, and reading transcripts, 2) the development of initial codes that identified features of the data, 3) drawing of these codes together by themes, as well as discarding codes that did not reach sufficient saturation, 4) reviewing all themes together to ensure there was no repetition, 5) naming the final themes, 6) dissemination of themes into the results.

Results

Participant characteristics

A total of 31 participants were recruited and 28 participants completed the group during the course of the study. Three groups were run between April 2016 and April 2017 with between seven and 13 participants in each group. Group attendance was high with an average of 89.28% of sessions attended. The participants who attended the programme were aged between 30 and 72 years old with a mean age of 53.63 years (SD = 10.91). The majority of the participants were White British (90.3%) and 9.60% were Asian British. 70.9% of participants were parents, 54.50% of these were mothers and 45.50% were fathers. 22.50% were partners, 3.20% were a child (n=1), 3.20% were an aunt (n=1). 51.60% attended with another member of their family. 80.60% lived with their relative. The age of the BPD relative ranged from 18-51 years old with a mean age of 26.38 years (SD=9.40).

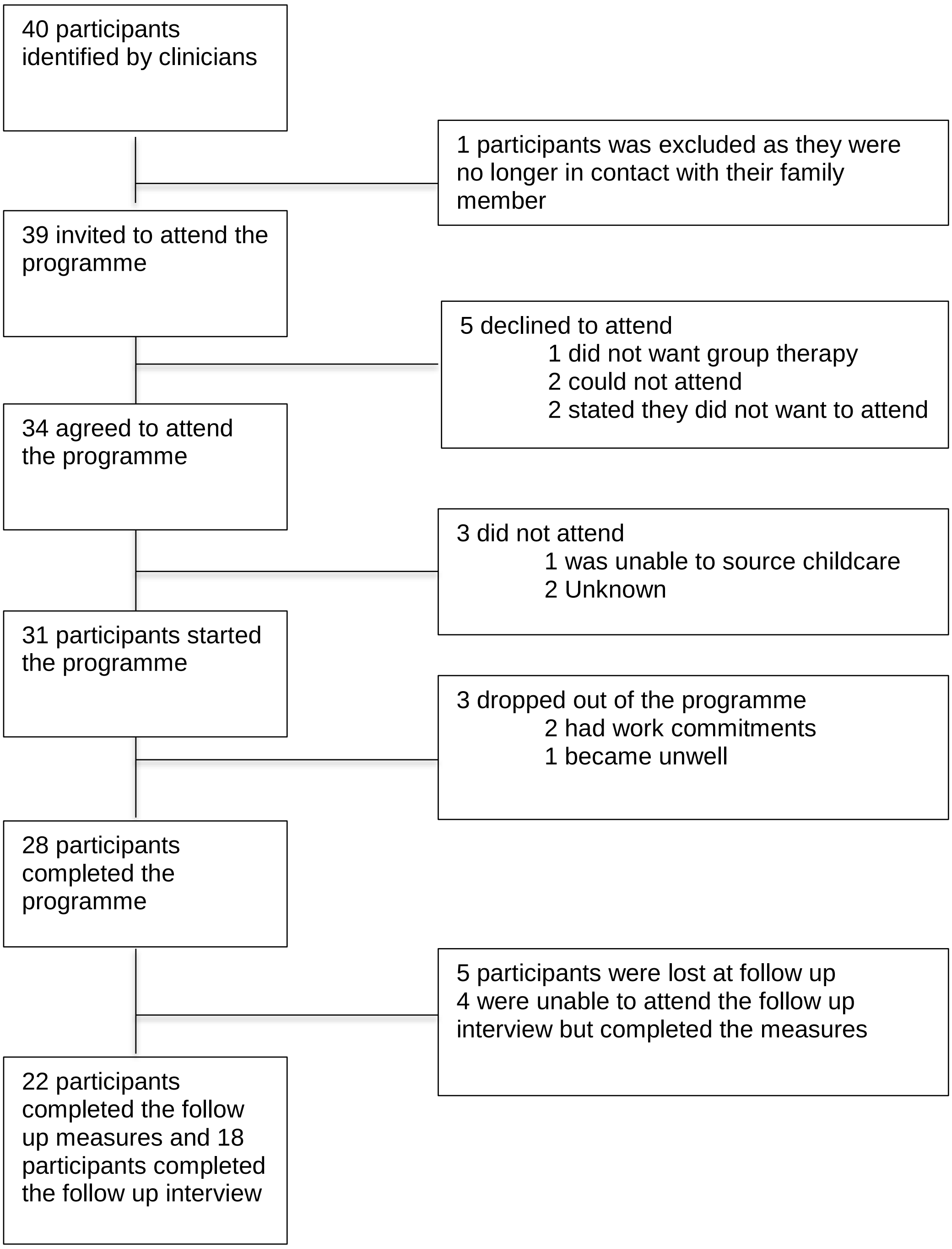
Recruitment and dropouts

Figure 2 depicts participant flow through the study, indicating reasons for non-attendance and dropout. The study invited 39 participants to attend the Family Connections programme, of which 34 agreed to attend. Of those who agreed to attend, 3 did not attend the first session. 31 participants started the intervention and three dropped out (all before session 4) which is a drop out rate of 9.6%. Pre treatment measures were compared for dropouts and participants who completed the intervention using independent sample t-tests. There were no significant differences on any pre treatment variables apart from objective burden, which was significantly higher for participants who completed the programme (M= 27.86, SD= 7.07) compared to dropouts (M=20.67, SD= 2.08), t (8.861) = 4.02, p = .003.

Reliability of scales

In line with best practice, the reliability of the scales for this sample were explored using Cronbach’s alpha. All variables demonstrated excellent ($\alpha \geq 0.9$) or good ($0.9 > \alpha \geq 0.8$) internal reliability, with the exception of AEIS scale which demonstrated questionable ($0.7 > \alpha \geq 0.6$) to poor ($0.6 > \alpha \geq 0.5$) and unacceptable ($0.5 > \alpha$) reliability.

Figure 2: Flow chart depicting participant flow through the study



Scale	Items	Cronbach's alpha		
		Pre (n-28)	Post (n-28)	Follow up (n-22)
BAS Overall	20	.912	.933	.915
BAS Subjective	10	.866	.920	.882
BAS Objective	10	.848	.879	.863
GAS	15	.930	.959	.966
PMS	7	.806	.823	.872
CES-D	20	.900	.918	.916
FFMQ	39	.906	.925	.941

Table 2: Cronbach's alphas for outcome measures for this sample. Note: BAS: Burden Assessment Scale, GAS: Grief Assessment Scale, PMS: Personal Mastery Scale, CES-D: Centre of Epidemiological Studies. Depression Scale, FFMQ: Five Factor Mindfulness Scale.

Scale	Items	Cronbach's alpha								
		Pre (n-28)			Post (n-28)			Follow up (n-22)		
AEIS	14	Parent (n-21)	Partner (n-5)	Other (n-2)	Parent (n-21)	Partner (n-5)	Other (n-2)	Parent (n-16)	Partner (n-5)	Other (n-1)
		.942	.849	.868	.901	.439	.703	.749	.892	NA

Table 3: Cronbach's alphas for outcome measures for the AIES for type of relationship. Note: AIES: Adult Invalidating Environment Scale

Outcome analyses

Repeated measures ANOVAs were used to compare the pre- treatment, post- treatment and follow-up scores for all outcome measures.

Outcome	Pre-treatment Mean *(SD)*	Post-treatment Mean *(SD)*	Follow-up Mean *(SD)*	*F*	*P*	Effect size partialh2
BAS Overall	56.60	44.07	44.60	20.69	.001	.434
	(12.12)	(12.90)	(12.28)			
BAS Subjective	28.75	22.29	22.86	17.74	.001	.397
	(6.34)	(6.78)	(6.42)			
BAS Objective	27.85	21.99	21.75	17.02	.001	.387
	(7.02)	(7.31)	(7.11)			
GAS	57.18	43.79	45.46	16.85	.001	.384
	(12.38)	(13.58)	(15.11)			
PMS	17.75	19.82	19.64	10.63	.003	.283
	(4.51)	(4.69)	(4.56)			
CES-D	24.43	17.75	18.28	10.11	.004	.272
	(12.60)	(12.27)	(13.27)			
FFMQ	116.93	126.21	128.04	7.27	.002	.212
	(21.46)	(23.32)	(26.16)			
AIES	31.92	26.54	27.46	5.41	.013	.167
	(13.73)	(8.80)	(8.53)			

Table 4: Differences Between Pre-Treatment, Post-Treatment and Follow-Up for all outcome measures

BAS scores decreased from 56.60 at pre-treatment to 44.07 at post-treatment, and increased very slightly to 44.60 at follow-up. A one-way repeated measures ANOVA found the change in participants level in overall burden across the intervention was significant, F (2, 54) = 20.69, p = .001, with a very large effect size (partialh2 = .434). Planned comparisons, using a Bonferroni correction, found a significant reduction between pre-treatment and post-treatment scores, and between pre-treatment and follow-up scores, but a non- significant change between post-treatment and follow-up scores.

Planned comparison	Mean difference	*p*	95% confidence interval for difference
Pre- Post	12.53	.000*	6.50-18.54
Pre- FU	12.00	.000*	5.88-18.12
Post- FU	-.53	1.000	-5.10-4.022

Table 5: Planned comparisons for Overall BAS. Note. Pre= pre-treatment, Post= post-treatment, FU= follow-up. * denotes the differences that remain significant following a Bonferroni correction (p < 0.01)

Subjective burden scores decreased from 28.75 at pre-treatment to 22.29 at post-treatment, and increased slightly to 22.85 at follow-up. A one- way repeated measures ANOVA found the change in subjective burden across the intervention was significant, F (2, 54) = 17.74, p = .001, with a very large effect size (partialh2 = .397). Planned comparisons, using a Bonferroni correction, found a significant reduction between pre-treatment and post-treatment scores, and between pre-treatment and follow-up scores, but a non- significant change between post-treatment and follow-up scores.

Planned comparison	Mean difference	*p*	95% confidence interval for difference
Pre- Post	6.46	.000*	3.13-9.80
Pre- FU	5.89	.000*	2.57-9.22
Post- FU	-.57	1.000	-3.03-1.89

Table 6: Planned comparisons for BAS Subjective. Note. Pre= pre-treatment, Post= post-treatment, FU= follow-up. * denotes the differences that remain significant following a Bonferroni correction (p < 0.01)

Objective burden scores decreased from 27.85 at pre-treatment to 21.99 at post-treatment, and further reduced slightly to 21.75 at follow-up. A one-way repeated measures ANOVA found the change in objective burden across the intervention was significant, F (2, 54) = 17.02, p = .001, with a very large effect size (partialh2 = .387). Planned comparisons, using a Bonferroni correction, found a significant reduction between pre-treatment and post-treatment scores, and between pre-treatment and follow-up scores, but a non- significant change between post-treatment and follow-up scores.

Planned comparison	Mean difference	*p*	95% confidence interval for difference
Pre- Post	6.07	.000*	2.75-9.40
Pre- FU	6.11	.000*	2.85-9.36
Post- FU	.036	1.000	-2.6-2.64

Table 7: Planned comparisons for BAS Objective. Note. Pre= pre-treatment, Post= post-treatment, FU= follow-up. * denotes the differences that remain significant following a Bonferroni correction (p < 0.01)

GAS scores decreased from 57.18 at pre-treatment to 43.79 at post-treatment, and increased to 45.46 at follow-up. A one-way repeated measures ANOVA found the change in level of grief across the intervention was significant, F

(2, 54) = 16.85 p = .001, with a very large effect size (partialh2 = .384). Planned comparisons, using a Bonferroni correction, found a significant reduction between pre-treatment and post-treatment scores, and between pre-treatment and follow-up scores, but a non- significant change between post-treatment and follow-up scores.

Planned comparison	Mean difference	*p*	95% confidence interval for difference
Pre- Post	13.39	.000*	7.02-19.77
Pre- FU	11.71	.001*	4.43-18.99
Post- FU	-1.68	.939	-5.85-2.49

Table 8: Planned comparisons for GAS. Note. Pre= pre-treatment, Post= post-treatment, FU= follow-up. * denotes the differences that remain significant following a Bonferroni correction (p < 0.01)

Personal mastery increased from 17.75 at pre-treatment to 19.82 at post-treatment, and decreased slightly to 19.64 at follow-up. A one-way repeated measures ANOVA found the change in level of mastery across the intervention was significant, F (2, 54) = 10.63, p = .003, with a large effect size (partialh2 = .283). Planned comparisons, using a Bonferroni correction, found a significant reduction in level of mastery between pre-treatment and post-treatment scores, and between pre-treatment and follow-up scores, but a non- significant change between post-treatment and follow-up scores.

Planned comparison	Mean difference	*p*	95% confidence interval for difference
Pre- Post	-2.07	.012*	-3.75- -.396
Pre- FU	-1.89	.009*	-3.37- -.411
Post- FU	0.18	1.000	-1.12-1.47

Table 9: Planned comparisons for PMS. Note. Pre= pre-treatment, Post= post-treatment, FU= follow-up. * denotes the differences that remain significant following a Bonferroni correction (p < 0.01)

CES-D scores decreased from 24.43 at pre-treatment to 17.75 at post-treatment, and then increased slightly to 18.28 at follow-up. A one-way repeated measures ANOVA found the change in level of depression across the intervention was significant, F (2, 54) = 10.11, p = .004, with a large effect size (partialh2 = .271). Planned comparisons, using a Bonferroni correction, found a significant reduction in level of depression between pre-treatment and post-treatment scores, and between pre-treatment and follow-up scores, but a non- significant change between post-treatment and follow-up scores.

Planned comparison	Mean difference	*p*	95% confidence interval for difference
Pre- Post	6.68	.005*	1.82-11.54
Pre- FU	6.14	.011*	1.22-11.07
Post- FU	-.54	1.000	-4.12- 3.05

Table 10: Planned comparisons for CES-D. Note. Pre= pre-treatment, Post= post-treatment, FU= follow-up. * denotes the differences that remain significant following a Bonferroni correction (p < 0.01)

FFMQ scores increased from 116.93 at pre-treatment to 126.21 at post-treatment, and further increased to 128.04 at follow-up. A one-way repeated measures ANOVA found the change in level of mindfulness across the intervention was significant, F (2, 54) = 7.27, p = .002, with a large effect size (partialh2 = .212). Planned comparisons, using a Bonferroni correction, found a significant increase in level of mindfulness between pre-treatment and post-treatment scores, a significant increase between pre-treatment and follow-up scores, but a non- significant change between post-treatment and follow-up.

Planned comparison	Mean difference	*p*	95% confidence interval for difference
Pre- Post	9.29	.038*	.41- 18.16
Pre- FU	11.11	.011*	2.19- 20.02
Post- FU	1.82	1.000	-3.89- 7.53

Table 11: Planned comparisons for FFMQ. Note. Pre= pre-treatment, Post= post-treatment, FU= follow-up. * denotes the differences that remain significant following a Bonferroni correction (p < 0.01)

EI scores decreased from 31.92 at pre-treatment to 26.54 at post-treatment, and then slightly increased to 27.46 at follow-up. A one-way repeated measures ANOVA found the change in EI across the intervention was significant, F (1.54, 41.61) = 5.41, p = .013, with a small effect size, (partialh2 = .167). Planned comparisons, using a Bonferroni correction, found a significant decrease in level of EI between pre-treatment and post-treatment scores, a non-significant decrease between pre-treatment and follow-up scores, and a non- significant change between post-treatment and follow-up.

Planned comparison	Mean difference	*p*	95% confidence interval for difference
Pre- Post	-5.39	.037*	10.53- -.25
Pre- FU	-4.47	.088	-9.411-.48
Post- FU	.93	1.000	-2.09- 3.95

Table 12: Planned comparisons for AIES. Note. Pre= pre-treatment, Post= post-treatment, FU= follow-up. * denotes the differences that remain significant following a Bonferroni correction (p < 0.01)

The effect of the type of relationship

Participants were split into two groups, parents (n= 21) and partners (n=5) to explore the effect of the type of relationship on treatment outcomes. Participants who did not fit into these categories (n=2) were excluded from the analysis, as the size of this group would be too small. There were no significant differences between outcomes for parents and partners, shown in Table 13. It is important to note the particularly small group size (n=5) for partners. In light of this, the following analyses should be interpreted with caution.

Acceptability

The acceptability of the intervention was measured using a semi- structured interview one month following completion of the programme. 18 participants took part in the semi-structured interviews at follow up. Themes were generated inductively from the data and were divided into six domains: Individuals own wellbeing, usefulness of skills, increased understanding, the group environment, changes in the relationship with relative and wanting more. Themes and corresponding quotes are presented in Table 14

Outcome	Relationship	Pre treatment mean (SD)	Post treatment mean (SD)	Follow up mean (SD)	*F*	*P*	Effect size partialh2
BAS Overall	Parent	59.95 (12.51)	44.38 (13.47)	44.95 (12.95)	.166	.687	.007
	Partner	61.20 (11.60)	37.00 (3.53)	39.80 (4.02)			
BAS Subjective	Parent	27.81 (6.68)	22.42 (7.00)	22.81 (6.88)	.093	.763	.004
	Partner	31.40 (5.27)	18.40 (3.05)	20.800 (3.19)			
BAS Objective	Parent	27.14 (7.23)	21.95 (7.75)	22.13 (7.23)	.178	.739	.005
	Partner	29.80 (7.36)	18.60 (3.21)	19.00 (4.53)			
GAS	Parent	56.05 (13.32)	44.42 (12.22)	46.19 (13.82)	.113	.739	.005
	Partner	63.60 (6.27)	37.00 (14.31)	40.20 (17.11)			
PMS	Parent	17.86 (5.14)	19.67 (4.53)	19.62 (4.68)	.346	.562	.014
	Partner	17.60 (1.67)	22.20 (3.70)	21.00 (1.58)			
CES-D	Parent	24.85 (13.14)	17.24 (12.15)	17.66 (12.83)	.026	.874	.001
	Partner	24.80 (6.90)	17.60 (10.31)	20.00 (12.10)			
FFMQ	Parent	118.10 (23.34)	125.90 (21.42)	128.61 (23.85)	.205	.655	.008
	Partner	109.00 (15.57)	124.60 (33.69)	124.20 (34.38)			
AIES	Parent	29.48 (13.93)	26.19 (9.60)	27.19 (8.24)	.237	.631	.010
	Partner	37.40 (11.67)	25.20 (5.40)	27.00 (11.27)			

Table 13: Differences between parents and partners across outcome measures at Pre-Treatment, Post-Treatment and Follow-Up.

Domain	Themes	N	Quotes
Individuals own wellbeing	The importance of self-care	11	‘I’ve learnt that I have to put the oxygen mask on myself first and only then will I be able to help others- that’s a huge benefit’ (p14) ‘..my feeling matter, they are important. (p1)
	Decreased stress and worry	7	‘I am so much calmer. Others have commented on how calm I am. I’m able to deal with stress and put it into perspective. I haven’t got constant not sleeping. I don’t have the feeling that I am so stressed out that I can’t deal with anything. I can be calm and think straight.’ (p6) ‘I’m not frightened to approach her now, even when she’s not feeling well’ (p17)
	Decreased blame and guilt	9	‘It’s helped me see it’s not my fault, it’s nobody’s fault, it’s just the way it is’ (p12) ‘My personal feeling was that it was somehow my fault. I always felt really guilty. If I hadn’t done the course I think I would have carried that guilt around with me for the rest of my life.’ (p14)
Usefulness of skills	Validation	4	‘it’s part of everyday life’ (p17) ‘Validation makes a massive different when speaking to her’ (p4)
	Mindfulness and increased awareness	9	‘….noticing the impact that I have on him’ (p3)
	Radical Acceptance	6	‘…at week eight I was getting understanding but not feeling much change. At week eight it was a bang, the penny dropped, light bulb moment. It made me feel so much better and everything flowed in after that’ (p6) ‘The acceptance part, that really sticks in my mind and that has helped me’ (p7)

Increased understanding	Usefulness of the Biosocial model	10	‘I understand now exactly where she is coming from. We didn’t know what her condition was, what the treatment was and how to be with her’. (p7)
	Understanding the condition	10	‘It was like a jigsaw, it was so informative to be learning about how she worked.’ (p13)
The group environment	Finding support from others	16	‘It was powerful- that was a real connection. That was probably the driving force for turning up the next week’ (p15)
	Learning from each other	13	‘Certainly peace of mind listening to other people- that I wasn’t by myself, that there were other people in the same predicament, same situation as us. They were all going through similar emotions, similar fears. That always helps (p7)’.
Changes in the relationship with relative	Improvements in relationship	9	‘We are communicating more on a more effective level’ (p14)
	Acceptance of illness	6	‘Its part of our life, its something we accept now. Probably because of that we are happier’ (p14) ‘I’m not stressed anymore, what will happen will happen. We will support her to do whatever she wants to do’ (p16).
	Confidence in responding in relationship	7	‘I no longer see myself as someone who needs to find a solution. I’ll be there along the way’ (p2)

	Balancing autonomy versus dependence	9	‘I use to push her all the time. I realise now that I cant- I have to let her get on with it. In the past it was always a battle’. (p7) ‘I do allow him to make more decisions now. I’ve got to a place where he needs to do it and learn’. (p3)
	Reduced judgment	9	‘In the shock of the moment you can really react, but I’m really trying to be aware now’ (p20) ‘Listening to what she’s got to say, not making judgments on it. Before, I was very quick to make a judgment.’ (p17) ‘If we are having a crisis at home, try and stay calm, step back, don’t judge. There have been a few times we have put them into practice.’ (p10)
Wanting more	Wish for more sessions	8	‘I could have carried on learning, some of it was rushed’ (p20) ‘It’s a lot to cram in, perhaps longer’ (p4)

Table 14: qualitative feedback. Note: n = number of participants endorsing this theme

Discussion

Summary of findings

This study aimed to assess the feasibility of the Family Connections programme in the UK, including recruitment, dropout, the appropriateness of outcome measures, acceptability of the intervention and preliminary effectiveness.

This study suggests that it is feasible to run the Family Connections programme in the UK and that family members can be recruited to and retained in the programme. Of the 31 individuals recruited to the programme, 28 participants completed the intervention (9.6% drop out rate) and attended on average 89.28% of sessions. Those who dropped out did not report dissatisfaction with the programme. These findings are consistent with previous evaluations in different settings and cultural contexts. Hoffman et al. (2005) reported that participants attended on average 83% of sessions and 12% of participants dropped out of the programme. Hoffman et al. (2007) reported that participants attended on average for 83.5% of sessions and 7% of participants dropped out.

Data indicated that participants who attended the programme reported significant changes in their level of burden, grief, depression, mastery, mindfulness and EI. The findings regarding level of burden, grief, depression and mastery are consistent with research evaluating the programme in the USA with similar effect sizes (e.g. Hoffman et al., 2005; Hoffman et al., 2007). There were no significant differences on any of the outcome measures between the end of the programme and the one-month follow up. This indicates that treatment gains remain static following completion of the programme. However, it is possible that the treatment outcomes may change over a longer follow-up period. Previous evaluations of the programme have conducted a 3-month follow up and found that level of burden (Hoffman et al., 2005) and grief (Hoffman et al., 2007) continued to decrease over time.

Neither mindfulness nor EI had been explored in family members of individuals with BPD prior to this research. This study suggests that participants level of mindfulness increases over the course of the programme. Mindfulness is introduced to help family members become more aware of their thoughts and feelings in themselves and their loved one, particularly in transactions. The study also found that the amount of EI experienced by family members significantly decreased throughout the programme. It is useful to consider the transactional model (Fruzzetti et al., 2005), which highlights the presence of problematic transactions between family members and the individual with BPD in maintaining their emotional dysregulation. The programme aimed to increase the level of validating responses in the relationship with the individual with BPD to promote understanding and decrease triggers to emotional reactivity (Shenk & Fruzzetti, 2011). The suggestion that family members may then experience this relationship as more emotionally validating themselves was based on the principle that increasing the level of validating responses in the environment by the family member may impact on the level of validation they then receive from the individual with BPD (Hayes, 1991). The observed decrease in level of invalidation in the family member is important because if they feel their experiences are understood by their loved ones, their emotional reactivity and distress may be lower, meaning they are more able to support them.

Qualitative feedback that was collected to explore acceptability of the programme identified support from other group members as being highly valued by participants. Relevant to this, it was fedback that to ensure that they had support following programme completion, participants who took part in the second group had set up an on-going monthly meet up. Many participants spoke of their increased awareness of the need to look after their own wellbeing before being able to effectively support the individual with BPD. A subsequent theme was the positive changes that participants perceived within their relationship with their loved one. Finally, many participants stated that they would have liked the programme to be longer. The feedback suggests that the programme was acceptable to participants and should continue to be delivered as a group programme.

Limitations

A major strength of the study was that it was conducted within an NHS setting, as part of the PD service, thus the study has good external validity. However, the study has a number of limitations that are important to consider. Although suitable for a feasibility study, the one-group pre- post-test design has a number of limitations. The absence of a control group means that it is not known how much of the change observed in outcome measures is attributable to the programme and how much is attributable to factors independent of the programme. An example of this is social support, provided by the group environment, deemed to be an important coping resource for individuals who are under stress (Burlingame, McClendon & Alonso, 2011). Social support created by group environments is key to significant treatment outcomes and therapeutic change in a number of clinical settings, including survivors of domestic violence (Iverson, Shenk & Fruzzetti, 2009), depressed older adults (Lynch, Morse, Mendelson & Robins, 2003) and for individuals with Schizophrenia (Orfanos, Banks & Priebe, 2015) and their families (Gruber, Kajevic, Agius & Martic-Biocina, 2006). The literature on the experiences of family members of individuals with BPD highlights the isolation and stigma they experience (Bailey & Grenyer, 2014; Goodman et al., 2011; Griffin, 2008). It is unsurprising that the development of positive bonds with other family members and a sense of belonging were highly valued by participants in the current study. It is possible that the social support provided to participants through being part of a group contributed to positive treatment outcomes above and beyond the content of the programme.

The significant changes observed in family members may be attributable to positive changes that their relative with BPD was making in their own therapy. The majority of individuals with BPD were in treatment (n=17) and it is likely that as the treatment for the individual with BPD progresses, they would develop skills to manage their emotions, leading to a reduction in risk behaviours (e.g. self-harm, suicide attempts). Given that these behaviours are key in leading to family members level of distress, the reduction in these may decrease family members difficulties in the areas that the programme targets. The DBT programme also teaches validation skills, which means that the relatives with BPD may have become more aware of, and validating of their family members, improving overall relationship satisfaction.

Another limitation of the current study is that EI in family members was measured using a tool that currently lacks psychometric evaluation. Reliability statistics indicated that the internal consistency for the scale was poor for partners and that this was not stable across time points. However, the due to the small sample of partners, estimates of internal consistency may lack precision.

A further limitation of this study was the lack of independence between the delivery of the programme and data collection. One of the group facilitators (CP) conducted the majority of follow-up interviews and therefore it is possible that participants may have not felt able to give negative feedback. Individuals may have wanted to provide feedback that they thought would please the facilitator (King & Bruner, 2000; Van de Mortel, 2008). A further compounding issue with the qualitative analysis was that there was no independent rater employed to explore and code a subset of this data to minimise the impact of subjective bias on the process. A final limitation was the short follow- up period employed due to the time constraints in this study. It is therefore not known whether the significant treatment gains would be maintained over a longer period.

Research implications

A key aim of a feasibility study is to assess how feasible the research is in preparation for conducting a large scale Randomised Control Trial (RCT). Within the current study no a-priori threshold for feasibility was set to determine whether an RCT would be indicated. It is therefore useful to reflect on guidance from Eldridge et al. (2016) to form a decision regarding whether future research should aim to conduct an RCT. Among areas of feasibility reported in the results of the current study, Eldridge et al. (2016) specifically highlight the importance of a study being able to successfully recruit and retain participants and collect sufficient outcome data. Specifically, that 50% of participants who are invited to take part must be successfully recruited, that 70% of participants of the recruited sample are retained in the research, and that the level of missing data does not surpass 10% (Eldridge et al, 2016). In the current feasibility study, the results exceed these thresholds: 70.50%, 90.30% and 3.73% respectively, and therefore progression to an RCT is indicated.

The aim of an RCT would be to test the effectiveness of the Family Connections programme and to include a control group (Bowen et al., 2009; Craig et al., 2008). A suitable control group that could be considered would be a support group for family members of individuals with BPD. This would allow researchers to draw conclusions on effectiveness and to possibly identify mechanisms of change. Although exploration and identification of possible mechanism of change were not the aim of the current feasibility study, the qualitative data may inform preliminary hypotheses about these. Given the emphasis placed on the importance of social support, increased knowledge of BPD and decreased guilt and self- blame to family members, these areas could be measured in an RCT.

To further support the exploration of effectiveness and mechanism of change, it would be important to collect and analyse outcome data more frequently between sessions to explore rates of change across the programme. Use of Hierarchical Linear Modelling would allow for control over slopes and intercepts in the statistical model, which would permit understanding of the trajectories of change. Furthermore, this analysis would not violate the assumptions of independence and would allow for nesting which is important given that data is collected across a number of different groups. In addition, it is necessary to take account of nesting of family members at different time points and family members within families (e.g. both a mother and father who support the same individual with BPD). Finally, use of Hierarchical Linear Modelling would allow inclusion of missing data, which is lost when analysis such as repeated measures ANOVA's are employed.

A subsequent aim of a feasibility study is to consider the appropriateness of outcome measures for future research (e.g. an RCT) (Craig et al, 2008). The high rate of completion of the questionnaires in this study indicates that participants found these acceptable. The BAS, GAS, PMS, CES-D and FFMQ demonstrated excellent internal consistency and therefore future research should continue to employ these measures. The internal consistency of the AIES partner scale at post measurement was poor and further exploration of the psychometric properties of this scale is required. A possible area that was not captured by the questionnaires deployed in this research was family member's knowledge of BPD. Qualitative data collected during the follow up interviews indicated that knowledge and understanding of BPD increased during the programme. However, previous research has indicated that Family members who have more knowledge of the condition have been found to score highly on measures of depression, anxiety, burden and hopelessness (Hoffman, Buteau, Hooley, Fruzzetti & Bruce, 2003). Providing education on BPD alone does not provide family members with a framework that guides them in changing their responses to their relative's difficulties, nor does it help family members to consider and care for their own wellbeing. Given that this is a key aim of the programme, in addition to providing knowledge, future research would benefit from exploring whether increasing family members knowledge is associated with positive outcomes as the qualitative data suggests. A suitable measure of knowledge may be the Knowledge Assessment Interview (KAI; Hooley & Hoffman, 1999) that has previously been administered to family members of individuals with BPD.

As some participants said they would have liked the group to be longer, further research could investigate whether a longer programme could be implemented. This would allow more time for content to be explained and for group members to have the opportunity to discuss more example scenarios and practice, using role-plays. However, extending the number of sessions may increase the dropout rate or lead to non-attendance, as this commitment may be too much to expect of family members.

Finally, future research should aim to carry out an economic evaluation of the Family Connections Programme, often requested by research funding providers alongside a full RCT (Sheaner & Byford, 2015). Economic cost evaluations guide decision-making about the availability of interventions, which is important with regard to increasing the availability of the Family Connections programme within the current NHS climate. An economic evaluation should calculate the cost of the group programme including cost of facilitators, training, supervision, rooms and administrative support. These costs need to be balanced against the benefits to family members (Sheaner, McCrone & Romeo, 2016).

Clinical implications

The results of this study provide tentative support for the suggestion that the Family Connections programme is an effective and acceptable intervention for family members of individuals with BPD in the UK NHS. This has clinical implications for services that provided treatment to adults with BPD and underscores the need to consider families in this work. However, the financial implications of this are important, given the current climate of the NHS and limited resources. For services that are unable to provide the full Family Connections programme, alternative methods of programme delivery could be considered. One example of this could be creating a self-help for families booklet based on the contents of the group in collaboration with family members who have attended. This could include mindfulness practice exercises and provide examples of how to apply these in relationships. Increasing the level of EI in the family environment could be targeted in family or couples work as part of the individual with BPD's own treatment.

Conclusion

This study provides evidence for the feasibility of the Family Connections programme for family members of individuals with BPD. The programme had a low dropout rate, employed appropriate measures that captured the difficulties and improvements amongst the family members, and was acceptable to participants. It also provided preliminary evidence for significant treatment outcomes.

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Part Three: Critical Appraisal

Critical reflection

The intention of this critical appraisal is to reflect on key issues and reflections that arose during the study and to suggest recommendations for further research. Four key issues will be discussed: (i) the difficulty in collecting data on Emotional Invalidation (EI) in individuals with Borderline Personality Disorder (BPD), (ii) the content of the Family Connections programme, (iii) possible mechanisms underpinning change in family members, (iv) working with mental health professionals who support individuals with BPD.

Measurement of EI in individuals with BPD

An original aim of this research was to measure EI in individuals with BPD at the start and end of the programme that their family member attended. The rationale for this was that through attending the Family Connections programme the family member would learn about the role of EI in the development and maintenance of emotion dysregulation in BPD. A key aim of the programme was to increase validating responses by family members towards the individual with BPD to improve the quality of interactions within the family environment. Although the programme was focused on the well-being of family members, it was considered likely that any changes in the level of validation in the environment would impact on the individual with BPD (Linehan, 2014; Hayes, 1991). Specifically, I was interested in whether the individual with BPD would perceive the relationship with their family member to be less emotionally invalidating following their family member attending the programme. Anecdotally, family members discussed in sessions that as their knowledge of BPD and the importance of validating responses increased, they perceived that the relative was also changing.

Unfortunately recruitment into this part of the study did not work out as planned and only two participants completed the Adult Invalidating Environment Scale (AIES) when their family member began the programme (hence this part of the research was not able to be included in the empirical paper) so there is no data to corroborate what family members reported. It is important to consider why this was the case in terms of the appropriateness of the methodology used to collect this data and the acceptability of this measure and process for BPD participants. The method of recruiting individuals with BPD was through contacting their 1:1 therapists working in the PD service. The first issue with this recruitment method is the burden to therapists. The second issue was that not all individuals with BPD were assigned to an individual therapist; some individuals were in DBT skills training group alone and were on the waiting list for individual therapy.

Patel, Douku & Tennakoon (2003) have highlighted the challenges of recruiting psychiatric participants into research and make a number of recommendations on how to improve this that are relevant to the current study. Several of these recommendations are targeted at how to engage clinicians who are responsible for identifying participants. Patel et al. (2003) suggest that it is important to establish relationships with clinicians working with potential participants at recruitment locations. Clear information should be provided to clinicians on the research rationale, requirements of them and the participant, and the inclusion and exclusion criteria of the study. In the current study, once family members were recruited to the Family Connections programme and attended the first session, I contacted the clinicians of the corresponding potential participants by email. Within this email I explained the rationale of this part of the research and asked for their assistance in recruiting the individual with BPD into the study. I provided them with an information sheet to give to the potential participants, a consent form and the measure of EI for completion. On reflection there are several reasons why this method of recruitment may have been unsuccessful. As I did not meet any of the clinicians in person there was a limited opportunity to engage them in the research. Although contacting them by email was deemed a quick and non-evasive method to support recruitment of individuals with BPD, the clinicians were all very busy and it is likely that this email was not prioritised.

If I were to repeat this study in the future I would consider changing the method of recruitment for the individuals with BPD. In line with recommendations of Patel et al. (2003), I would visit recruitment locations and meet with clinicians to talk about the research, explaining why EI was being measured. I would discuss with them whether they felt able to take on the recruitment themselves and come up with a collaborative plan to support this, including for the recruitment of individuals who do not have an allocated 1:1 therapist. I would also plan to attend regular staff meetings as each 12-week programme started and provide feedback on the research as it progressed to maintain enthusiasm and motivation of clinicians.

Alternatively, I would also consider the possibility of this part of the research being conducted by the research team who would engage directly with the individual with BPD. Due to the limited time frame in which the current research took place within, priority was given to recruiting family members to the 12-week programme. Due to the trainee’s clinical placements and teaching schedule, there was not enough time to be allocated to this part of the study. Patterson, Duhig, Connell & Scott (2014) recommend that successful recruitment of individuals from psychiatric populations is supported by building a therapeutic relationship with the individual in order to engage them in the research. Patel et al. (2003) recommends that researchers should be flexible in engaging their participants, including offering a range of options for meeting to complete the research or offering a number of methods to complete measures. Future research should therefore build an extended amount of time into the research protocol to support recruitment into this part of the research.

Aside from the practicalities of recruitment of individuals with BPD, a second reason for poor recruitment into this part of the study may have been that individuals with BPD did not deem this acceptable. The acceptability of the collection of AIES scores at the beginning and end of the programme for individuals with BPD was discussed with a service user group who stated that they would be willing to consent to take part in the research. However, participants who were actually eligible to take part may have not found this part of the study to be acceptable and may not have wanted to complete a measure on the relationship with their family. Unfortunately no data or feedback was provided to the trainee on reasons why participants refused to take part, however there are several reasons why this may be. EI is very painful; the experience of having ones emotions ignored, minimized or dismissed leaves an individual vulnerable to emotional dysregulation (Fruzzetti & Worrall, 2010; Linehan, 1987). Individuals with BPD may not want to consider that the responses they receive from significant family members in their life are emotionally invalidating and that this may lead them to feel distressed. It is also possible that this may be compounded by their knowledge of the commitment that their family member is making in attending the Family Connections programme and being fearful of ‘blaming’ their family member. Finally, many individuals with BPD report very positive relationships with their families and therefore may not perceive that they experience EI in these relationships. Indeed in each of the groups run during the study many parents reported being extremely close with their children. Further research would benefit from exploring individuals with BPD’s experience of EI in their current relationship with their family member, and perhaps exploring the association between current EI and therapeutic outcomes in BPD. This would extend research by Hooley (2007) who found that emotional ‘over involvement’, characterised by worry and concern is experienced as supportive and validating to individuals with BPD.

A subsequent option to support the collection of data on EI in individuals with BPD would be to adopt an observational approach to the measurement of invalidation within the interactions between the individual with BPD and their family member. To support this, the Validating and Invalidating Behaviours Coding Scale (VIBCS; Fruzzetti, 2001) could be used to rate the number of validating and invalidating responses at the beginning and end of the programme during interactions. The benefits of this approach would be that it would include both the individual and their family member and that the scenario selected to be rated would be standardised across all dyads. However, the weaknesses in this approach would be the resources needed to support this data collection, including independent trained assessors. Secondly, it would increase the number of tasks expected of participants taking part in the research, which may result in poorer recruitment or attrition.

The content of the group programme

An identified limitation of the study referred to in part two of this thesis was that the therapist who had run the intervention administered the questionnaires throughout the programme and conducted some of the follow up interviews. When the protocol for the study was written it was agreed that to ensure independence between the delivery of the programme and data collection an independent assessor would be recruited to the research team to collect this data. Unfortunately, at the time when the first group commenced, this was not feasible due to service constraints and the group taking place in the evening.

A factor related to lack of dependence between programme delivery and data collection that may bias the results is social desirability bias (King & Bruner, 2000; Van de Mortel, 2008). As a clinician I instinctively aimed to develop a therapeutic rapport with participants who attended the programme but this may have meant that participants chose to provide data that was favourable to me. Future studies, particularly an RCT should employ methods that reduce such threats to internal validity. To ensure dependence between programme delivery and data collection, a research assistant could be employed or an online method of data collection could be used at each time point outside of the actual programme.

Despite this limitation, it is also important to acknowledge the benefit of being present in the programme. Being part of the delivery of the programme meant that I gained unique insight into the participant's experiences. This is especially important to the current study, which assessed feasibility as there were several aspects of the contents of the programme that are linked to this, but that may not have been captured by the questionnaires or post –programme feedback. The first of my observations is the potential gap in the linking of treatment between family members and the individual with BPD. The literature on the experience of family members to individuals with BPD indicates that once psychiatric support is involved, they often feel abandoned and are unaware of what treatment their relative is receiving (e.g. Ekdahl, Idvall, Samuelsson & Perseius, 2011). This was a common theme discussed by family members across the three groups that were run in this study. Family members, particularly parents shared their experience of feeling left out of their relative's treatment, specifically wanting to understand what they were going through and wanting to be involved in their recovery. In part, the Family Connections programme addresses both of these areas: 1) families are informed of the treatment options available for individuals with diagnoses of BPD as part of the psychoeducation module of the programme; 2) family members are encouraged to develop a balance between being involved in their relative's treatment and recovery whilst balancing their own needs. Indeed, the latter point fits with the aim of the Family Connections programme that is for the family member to address and prioritise their own wellbeing, often compromised as a result of their caring role. Frequent discussions were held regarding family members wish to be involved in treatment, which typically resulted in facilitators and other group members encouraging these individuals to allow their relative the space for their own therapy and develop independence in their own recovery.

As a facilitator this was often challenging as although I supported this sentiment, behind these family members concerns of not being involved appeared to be a genuine wish to identify the ways in which they could help their relative. As a facilitator, I often felt that the Family Connections programme was running parallel to the treatment that the individual with BPD was receiving and what was missing was the joining up of the people involved in the relationship (e.g. the individual with BPD and their mother, father or partner). Given the focus on the transactional model within the programme and EI in maintaining emotional dysregulation (Fruzzetti, Shenk & Hoffman, 2005), it may be helpful to explore how this occurs in families with both parties present. To support this, it may be beneficial to offer an optional family session that could focus on this. This approach has been suggested as highly important in therapy for adolescents who have been diagnosed as having traits of BPD (Adshead, Brodrick, Preston & Deshpande, 2012). The suggestion of families coming together in this way is based on my observation of what family members may benefit from as a result of being a facilitator of the programme. However, exploration of the acceptability and desire for this would need to be discussed with the individual with BPD, as well as it's efficacy and effectiveness being explored in further research.

Possible mechanisms of change

Frequently, research questions are focused on whether an intervention 'works' and whether it is 'effective', in leading to changes in an identified outcome variable (Roth & Fonagy, 2013). A further question relevant to research that evaluates an intervention, are the mechanisms of the observed change, which is 'how' and 'why' it works (Kazdin, 2007). Mechanisms of change refer to key processes within a therapy that are necessary, and impact on the dependent variable of interest, and are referred to as mediating or moderating variables. Research of this kind has increased, including in the area of treatment for adult BPD (e.g. Forster, Berthollier & Rawlinson, 2014; Lynch, Chapman, Rosenthal, Kuo & Linehan, 2006). The identification of mediators and moderators of therapy outcomes is important in the development and refinement of treatment programmes and therefore this is a useful area to consider in further research trials that evaluate the Family Connections programme.

Based on my observations of the group programme as a facilitator and through reviewing the qualitative data provided by participants, I have two preliminary hypotheses regarding aspects of the programme central to change that could be evaluated in further research. The first is the role of social support, provided by and between family members through the programme. The research literature indicates that family members feel very alone in managing their loved-ones difficulties and they predict others, including their own families judge them negatively as a result of their relative having BPD (Ekdahl et al., 2011; Lawn & McMahon, 2015). As indicated in the results from the study discussed in part two, the delivery of the intervention in a group format was acceptable and participants felt the support that was provided by other family member’s was one of the most important aspects of the programme. Participants cited that support from the group had led them to feel less judged, less alone, and provided opportunities to learn. Social support has frequently been cited as mediating the positive impact of psychological interventions in family members who support adolescents with BPD traits (Woodberry, Miller, Glinski, Indik & Mitchell, 2002) with Schizophrenia (Szmukler et al., 2003) and with dementia (Roth, Mittelman, Clay, Madan & Hayley, 2005).

The second factor identified by participants as highly important was the psychoeducation provided on the development of BPD, specifically the biosocial model of Linehan (1993). When reading any academic journal on BPD, the high prevalence of overt abuse, including physical, sexual and emotional abuse in the histories of individuals is almost always reported. Statistics suggest that 66-75% of individuals with BPD have experienced CSA (Bandelow et al., 2005), 92% have experienced neglect and 25-73% have experienced physical abuse (Zanarini et al., 2000) and that the perpetrator of such abuse is often a family member (Bandelow et al., 2005; Silk, Lee & Hill 1995). Many individuals with a diagnosis of BPD do not report experiences of overt abuse and although it is common, it is not necessary to the development of the disorder (Zanarini, Williams, Lewis & Reich, 1997).

In all groups that were run, there were parents who shared that they had felt judged by professionals, despite their child not having been abused in any of these ways (a key assumption is that parents attending the programme were not abusive to the individual with BPD). Lawn and McMahon (2015) found that family members who perceived that they were being judged negatively by mental health professionals scored highly on measures of distress and that this led to difficulties in their relationships with these services. The key aim of the presentation of the biosocial model of Linehan (1987) within the Family Education module (module two) was to explain that the development of BPD is underpinned by a transaction between biological and environmental factors. The purpose of this was to challenge concerns in those attending the programme that they had ‘caused’ their relatives difficulties. During the programme participants who were parents shared their sense of relief as they gained reassurance that they had not ‘caused’ their child’s difficulties and were therefore not to blame. Providing psychoeducation is a key focus of other interventions offered to family members with relatives who have diagnoses of Schizophrenia (McFarlane, Dixon & Lukens, 2003), Bipolar (Reinares et al., 2008) and Major Depressive Disorder (Sanford et al., 2006).

It is important that future research that evaluates the effectiveness of the Family Connections programme also gives attention to the components of the programme that mediate change, and that enhance improvements in family members reported levels of burden, grief, depression, mastery, mindfulness and EI. Further research could explore the preliminary observations stated above in two related ways. Kazdin (2007) recommends that one approach to identification of possible mediators in therapy is to conduct in-depth qualitative interviews to explore the participant's experience of the programme and the processes that they experience within this. Although the current research employed a short qualitative interview, this was focused on the acceptability of the intervention to assess feasibility. An in-depth interview focused on the areas of social support and psychoeducation may provide evidence to support my hypotheses regarding the key components of the programme that are central to change. Secondly, these hypothesised mechanisms could also be measured throughout the programme in future evaluations (Kazdin, 2007). For example, measures of social support, knowledge and understanding of BPD and its ateiology could be monitored session-by – session to assess whether these are associated with changes in dependent variables during the programme.

Motivations for the research project

Prior to commencing my clinical training I worked with individuals with established diagnoses of BPD, their families and the staff who supported them in their community treatment programmes, during admission to a psychiatric hospital, and during crises, managed by a Home Treatment Team. My observation was that a great deal was expected of individuals with BPD, that they were expected to commit to treatment which would involve them learning skills to manage their strong and painful emotions and to reduce their risk behaviours (self-harm and suicide attempts). Subsequently, they had to develop these skills across a range of contexts and relationships: with their families, friends, and many mental health professionals. I observed that the major barriers to the generalisation of skills was the limited knowledge that families and mental health staff had of BPD, how to help them effectively, whilst managing their own emotional reactions and wellbeing. This led to an appreciation of the need for clinicians to consult with the individual’s environment, a key treatment mode in DBT (Linehan, 1993). I was therefore incredibly grateful that I was able to conduct research in the area of families of individuals with BPD, and that I was able to devote my time to exploring an area I felt was lacking.

However, as my experience has suggested it is not only family members who are in need of support and the research literature mirrors this concern. Within services who care for individuals with BPD, mental health staff have been found to hold a number of unhelpful views, including individuals being ‘difficult’, ‘attention seeking, and ‘unmotivated’. Mental health staff are responsible for the management of high levels of risk, including self-harm and suicide attempts, which leads to high anxiety and difficulty in maintaining hope of recovery (Bodner et al., 2015), particularly in services that are highly pressurised (Soeteman et al., 2011). Professionals have described difficulties in building and maintaining a therapeutic relationship when the individual is highly sensitive to feelings of rejection and who may frequently oscillate between idealising and devaluing them.

The emotional impact of working with individuals with BPD on health care professionals includes high levels of distress, poor self-care, fatigue and emotional exhaustion, and burn out (e.g. Cotes, 2004). A wealth of literature has highlighted the lack of knowledge about BPD among nursing staff (Clarke, Usick, Sanderson, Giles-Smith & Baker, 2014; O’Connell & Dowling, 2013) and lack of training in specific skills to work with the condition (James & Cowman 2007; Woollaston & Hixenbaugh, 2008). However, improved attitudes towards individuals with BPD have been observed when a clear framework was provided to work from (Stroud & Parsons, 2012).

Along with the need to offer support to family members, NICE guidelines for BPD (2009) state the need for clinicians with specialist knowledge to provide consultation and advice to primary and secondary care mental health services, who provide support to individuals with BPD. Subsequent to this is the recommendation that training should be provided on the diagnosis and its management. There is limited research on training and support for staff that work with individuals with BPD and therefore future research is required to generate a clear framework for this.

Certain aspects of the Family Connections programme may be helpful in forming this training and support. Firstly, professionals should be provided with information on BPD, including aetiology, with the aim of promoting understanding and compassion for the individual they are working with. A description of the transactional model, outlined by Fruzzetti et al., (2005) is also important to make sense of the difficulties in the relationships between individuals with BPD and their support systems. Key to this would be providing staff teaching on EI, emotional validation and validating responses as a tool to manage emotional dysregualtion in the individual with BPD. In my own clinical practice I have used the model to help a variety of health care professionals make sense of emotional dysregulation they observe in individuals with BPD. Specifically, how quickly interactions can result in further dysregulation and conflict, leading to the break down in relationships and engagement in risk behaviours. Finally, it is important that mental health staff are supported to manage their own wellbeing when working with individuals who present with complex needs and risk behaviours seen in individuals with BPD. A key avenue to explore would be the role of self-care and the development of mindfulness skills to aid staff to become aware of their own emotional responses and how to manage these.

Conclusions

A number of further questions and research ideas have emerged out of this study, both in response to methodological limitations and clinical observations. The process of reflection has highlighted to me the power of both evidence-based practice and practice-based evidence, the latter which was key in guiding me to this research project in the first place and keeps me invested in this research area for the foreseeable future.

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Appendices

Appendix A

Quality Assessment Tool

Item	Criteria	Yes (2)	Partial (1)	No (0)
1	Question / objective sufficiently described?			
2	Study design evident and appropriate?			
3	Method of subject/comparison group selection or source of information/ input variables described and appropriate?			
4	Subject (and comparison group, if applicable) characteristics sufficiently described?			
8	Outcome and (if applicable) exposure measure(s) well defined and robust to measurement / misclassification bias? Means of assessment reported?			
9	Sample size appropriate?			
10	Analytic methods described/justified and appropriate?			
11	Some estimate of variance is reported for the main results?			
12	Controlled for confounding?			
13	Results reported in sufficient detail?			
14	Conclusions supported by the results?			

Appendix B

Participant Information Sheet

North East London NHS
NHS Foundation Trust
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Goodmayes Hospital
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IG3 8XJ

RESEARCH DEPARTMENT OF CLINICAL,
EDUCATIONAL AND HEALTH PSYCHOLOGY
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Participant Information Sheet
Researcher: Christy Pitfield

A Feasibility Study of the Family Connections programme (Student study)

We would like to invite you to take part in our research study. Before you decide whether you would like to take part, we would like you to understand why the research is being done and what it would involve for you. Please take some time to read this sheet, and to discuss it with other people if you wish. You are also very welcome to ask us any further questions about the study, or if you find anything on this sheet unclear.

Part 1 of the information sheet

What is the purpose of this study?

This is a feasibility study assessing the effectiveness of a group programme for family members of individuals with Borderline Personality Disorder (BPD). The programme is formally know as 'Family Connections' and was developed in the USA. Family members of individuals with BPD are often present during periods of chaos and crisis associated with this diagnosis and as a result will often assume multiple roles, which they may be unprepared for. Family members may also witness an array of behaviours including self-harm or suicide attempts. Furthermore, families may face difficulties relating and interacting with their loved one as relationships are typically characterised by cycles of idealising and devaluing others.

Unfortunately, carers often face difficulties accessing suitable services and report receiving very little information on BPD from health care professionals. The impact of being a family member to an individual with a diagnosis of BPD appears to be a heavy burden, with several research studies indicating a risk of family members developing their own mental health difficulties as a result of their caring role. **Importantly though, research has found the involvement of families to be highly important in BPD treatment outcomes**. Family interventions for BPD have become popular and interventions of this kind are accumulating empirical support. However, the research to date is based on individuals engaged in the programme in America, where the health system is very different to the NHS. This study is therefore investigating the feasibility of running Family Connections within the UK. We will be investigating whether the 12-week programme is an acceptable intervention for Family members of individuals with BPD and whether it is effective in reducing depression, grief, burden and increasing mastery as observed in two USA evaluation studies.

Why have I been invited to take part?

You have been invited to take part in this study because you have been identified as someone who is a family member (parent, sibling, partner) or friend of a person with a diagnosis of BPD who has been referred to the IMPART service.

Do I have to take part?

No. Taking part in the study is entirely voluntary. It is your choice whether or not you would like to participate. Deciding not to take part in the study will not affect whether you can attend the programme or the care your family member receives from services either now or in the future.

If you do decide to participate, you will be given this information sheet to keep, and you will later be asked to sign a consent form stating that you wish to take part. If you do give consent to take part in the study, you are still free to leave the study at any point, without giving a reason. This will not affect whether you can attend the programme or the care your family member receives from services either now or in the future. If you decide to withdraw from the study, you can request that all of the information that you have provided to be removed by the researcher.

What will happen to me if I take part?

We will be attending a session to discuss the research with you, giving you a chance to ask any questions. We will then give you an information sheet containing this information that you are welcome to take away and read in more detail. If you would like to then take part, we ask that you sign a consent form stating that you wish to take part in the study. If you have any questions at any point, you can email us- markjohn.leach@nelft.nhs.uk or christypitfield@nhs.net. When you have signed the consent forms you will then be asked to complete a series of questionnaires.

As you are already doing, you will be asked to attend sessions of the group, which will run weekly, every Thursday from 6.30pm- 9.00pm. Each group session will last for 2.5 hours. However we understand that people sometimes have to miss sessions, due to unforeseeable circumstances, and you will not be excluded from the study if this happens.

We will ask you to complete four of the questionnaires you completed during the first session every 4 weeks (this will take approximately 20 minutes). One month after the group has finished we will invite you back for a follow-up session in which we will ask for feedback about the group and ask you to fill in the same questionnaires you filled out in your first assessment. The main aim of the follow-up session is to find out how you experienced the group and what you found helpful. Your opinions and experiences will help inform the conclusions of our research. As a result we would like to record the follow-up sessions. Again, this is not compulsory.

As an acknowledgement of your time, we will be offering you a £5 voucher for your participation in the initial questionnaires and a £10 voucher for your participation in the follow-up session. The meetings and the groups will take place at NHS settings used by the IMPART personality disorder service. We will be conducting the research until September 2017.

What will I have to do?

If you decide to take part in our research you will be expected to attend the Family Connections programme which runs over 12 sessions and then one follow-up appointment. Furthermore, you will be required to complete questionnaires about your mood, experience of being a family member to person with BPD and mindfulness (the questionnaires will take approximately 30 minutes to complete). Six of these will be given to you during the first, last and follow up sessions. 4 of these will be given to you every 4 sessions (a total of 5 times over the course of the study).

What are the possible disadvantages and risks of taking part?

Some people can find it upsetting to talk about their personal experiences. However, we will support you if you become upset because this is often an important part of the intervention. Facilitators will be available after the group should you want to discuss anything which arises during the session. We will also signpost you to other support services if you need further support. You can get further support from your GP, Mental Health Direct and the Samaritans.

People may find filling out a number of questionnaires time consuming and inconvenient. We will ask you to complete six questionnaires at the assessment and follow-up appointments, this will take approximately 30 minutes. We will ask you to complete four of these questionnaires every 4 sessions, this will take approximately 20 minutes.

What are the possible benefits of taking part?

The research has indicated that family members of individuals with a diagnosis of BPD are at risk of developing their own mental health difficulties, feel burdened by and unsupported in their caring role. The benefits of attending the programme are that you will gain information on symptoms, behaviour and treatment of BPD, learn communication and adaptive problem solving strategies and have access to a supportive environment with others in similar situations.

What does Family Connections involve?

The programme includes in-session exercises as well as homework tasks to be completed between sessions. The programme content is split into 6 modules:

1. Current information and research on BPD such as symptoms and illness course.
2. Psychoeducation around the development of BPD and available treatments
3. A focus on individual and relationship skills to promote wellbeing in family members, such as emotion self management, mindfulness, letting go of judgements, decreasing vulnerability to negative emotions and skills to decrease emotional reactivity.
4. Skills to improve the quality of family relationships and interactions such as acceptance skills in relationships and letting go of blame and anger.
5. Validation skills including accurate and effective expression.
6. Problem management skills, including defining problems effectively, collaborative problem solving, knowing when to focus on acceptance and when to focus on change.

The information gathered during this study will help to inform our understanding of treatment for Family members of individuals with BPD, which will hopefully be a step towards improving the availability of these interventions in the future.

What happens when the research study stops?

The results of the research study will be written up as part of Christy Pitfield's thesis for the Clinical Psychology Doctorate at University College London (UCL). The report of the study could also be published in relevant journals outside UCL. As mentioned, you will not be identifiable from these results. At the end of data collection we will invite you to a meeting to review the results and help us make sense of what we found. In addition we will send you a copy of the report of the study.

What if there is a problem?

Every care will be taken in the course of this study to protect you. Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

Part 2 of the information sheet

What if relevant new information becomes available?

If this happens, your research therapist might consider you should withdraw from the study. They will explain the reasons and arrange for your care to continue.

What if there is a problem?

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff, you should initially contact Dr Janet Feigenbaum, who is the Chief Investigator for the research, and is based both in NELFT and University College London. If she is not able to resolve the complaint or you are not satisfied with her actions then the normal National Health Service complaints mechanisms are available to you. Please ask the programme facilitators if you would like more information on this at any point.

If you suspect that harm is the result of UCL or the hospital's negligence then you may be able to claim compensation. After discussing with your research therapist please make the claim in writing to the Dr Janet Feigenbaum, Chief Investigator at IMPART Goodmayes Hospital, Barley Lane, Ilford, IG3 8XP. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this. In the unlikely event that you are injured by taking part, compensation may be available. If you suspect that the injury is the result of the Sponsor's (University College London) or the hospital's negligence then you may be able to claim compensation. If this is the case you may make the claim in writing to Dr Janet Feigenbaum, who is the Chief Investigator for the research. She will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

Will my taking part in the study be kept confidential?

Your consent form will be kept in a separate location from your questionnaires, ensuring that this remains anonymous. All data will be stored in secure locations and on computers or flash drives which are password protected. Any published data will also be entirely anonymous meaning individuals cannot be identified. The data from this study will be stored in accordance with the UCL and NHS Data Protection and Records Management policies.

Who is organising and funding the research?

The research has been organised by Christy Pitfield, Trainee Clinical Psychologist. The study is part of their Clinical Psychology Doctorate. The research will be funded by UCL.

Who has reviewed this study?

This study has been reviewed by the research committee in the clinical psychology department at UCL, by the NELFT research and development department and by North West Greater Manchester West Research Ethics Committee.

Further information

Patient Advice and Liaison Service (PALS); they are an independent contact that you can address questions to about taking part in this research: King Georges' Hospital, Barley Lane, Ilford, Essex IG3 8YB (Telephone: 0800 389 8324)

Contact Details of Researchers

If you wish to contact us to discuss any of the information further or any concerns you have about the study, then please do so by ringing 0300 555 1213 or sending us an email at IMPART@nelft.nhs.uk or christypitfield@nhs.net. If you feel that we have not addressed your questions adequately or if you have any concerns about our conduct, then please contact our supervisor Dr. Janet Feigenbaum (Strategic and Clinical Lead for Personality Disorder Services, North East London NHS Foundation Trust and Senior Lecturer, Research Department of Clinical, Educational and Health Psychology, UCL) on 0300 555 1213 or by email at janet.feigenbaum@nhs.net.

Thank you very much for taking the time to read this information sheet.

Christy Pitfield
Trainee Clinical Psychologists
IMPART
Goodmayes Hospital
Barley Lane
Ilford
IG3 8XP
[redacted]

Dr. Janet Feigenbaum
Consultant Clinical Psychologist
IMPART

Mark Leach
IMPART
Goodmayes Hospital
Barley Lane
Ilford
IG3 8XP
[redacted]

Appendix C

Follow-up Semi-structured Interview

North East London NHS
NHS Foundation Trust

IMPART
Goodmayes Hospital
Barley Lane
Ilford Essex
IG3 8XJ

RESEARCH DEPARTMENT OF CLINICAL,
EDUCATIONAL AND HEALTH PSYCHOLOGY
UNIVERSITY COLLEGE LONDON
GOWER ST
LONDON
WC1E 6BT

UCL

A Feasibility Study of the Family Connections programme (Student study)

Semi-structured Interview schedule for Family Connections programme

This interview will take place by an independent researcher and the questions below should be used as a guide.

1. How did would you describe your experience of the programme overall?

2. Did the group meet your expectations?

3. What was most useful to you about the programme?

    a. Are there any aspects of the programme that have stood out in your mind?
    b. Have any of the skills that were discussed within the intervention been helpful to you? Do you have any examples of this?

4. What do you anticipate that you will take away from the programme?
    a. Do you foresee any barriers to this?
    b. Is there anything you may need more of in order to do this?

5. What were the difficult aspects of the programme?
    a. Are there any ways that you consider these could be addressed- both for you and groups in the future?
    b. Was there anything that was not useful to you?

6. What was your experience of being part of a group and meeting others in this setting?

7. We are interested in specifically how this intervention impacts on your overall wellbeing for those who attend. Have you been aware of anything changing as a result of your attendance?

8. Has the relationship with your family member changed in any way as a result of you attending the programme?

Appendix D

Ethical Approval Letter

North West - Greater Manchester West Research Ethics Committee
Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

18 March 2016

Dr Janet Feigenbaum
Consultant Clinical Psychologist
UCL and North East London NHS Foundation Trust
Research Department of Clinical, Educational and Health Psychology
University College London
1-19 Torrington Place
WC1E 7HB

Dear Dr Feigenbaum

Study title:	**Family Connections: A feasibility study**
REC reference:	**16/NW/0168**
IRAS project ID:	**191869**

Thank you for your submission, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this 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, Anna Bannister, nrescommittee.northwest-gmwest@nhs.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

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

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

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk 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 management permissions 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

NHS 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" below).

Non-NHS sites

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Copies of advertisement materials for research participants	1	25 January 2016

Copies of advertisement materials for research participants [Intervention and evaluation Flyer]	V1.1	12 March 2016
Covering letter on headed paper		02 February 2016
Covering letter on headed paper [Covering letter to REC]		12 March 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [ ]		13 July 2015
GP/consultant information sheets or letters [BPD Participant GP Letter]	V1.0	04 January 2016
Interview schedules or topic guides for participants [Semi structured interview questions]	V1.0	06 January 2016
IRAS Checklist XML [Checklist_14032016]		14 March 2016
Letter from sponsor		22 January 2016
Letter from statistician [Discussion with Statistician]		01 January 2016
Other [Data Protection UCL form]		01 September 2015
Other [Christy Pitfield GCP]		10 January 2016
Other [Therapist Participant information sheet]	V1.1	04 January 2016
Other [Initial Research Proposal]	1.1	05 October 2015
Other [Second Research Proposal]	1.1	11 November 2015
Participant consent form [Family participant consent form]	1.4	15 March 2016
Participant consent form [BPD Participant consent form]	1.4	15 March 2016
Participant information sheet (PIS) [Family member participant information sheet]	1.2	12 March 2016
Participant information sheet (PIS) [BPD Participant Information sheet]	1.2	12 March 2016
REC Application Form	5.2.1	03 February 2016
Referee's report or other scientific critique report [Initial research proposal research review form]	1.1	23 October 2015
Referee's report or other scientific critique report [Letter to reviewer]	1.1	11 November 2015
Referee's report or other scientific critique report [Research proposal version 2]	1.1	11 November 2015
Referee's report or other scientific critique report [Research proposal 2 review form]	1.1	12 November 2015
Research protocol or project proposal [Family Connections Protocol]	V1.2	12 March 2016
Summary CV for Chief Investigator (CI) [Janet Feigenbaum]		
Summary CV for student [Christy Pitfield]		
Validated questionnaire [Measures for Family Connections]	1.1	01 December 2015

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.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received 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/

HRA Training

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

16/NW/0168	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

[redacted]

On behalf of Dr Lorraine Lighton (Chair)
Chair

Email: nrescommittee.northwest-gmwest@nhs.net

Enclosures:	After ethical review – guidance for Researchers
Copy to:	*Ms Suzanne Emerton* *Ms. Fiona Horton, North East London NHS Foundation Trust*