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Doctoral Thesis:

Asthma, Caregiving and Mental Health: The Mind Keeps the Score

Malda-Castillo, Javier

Trainee Clinical Psychologist

Division of Health Research, Lancaster University

Total Word Count

Section	Text	Tables, Appendices and References	Total
Abstract	269	0	269
Systematic Literature Review	7,965	14,602	22,567
Outcome Paper	6,252	5,586	11,838
Critical Appraisal	3,844	1,562	5,406
Ethics Section	5,623	3,963	9,586
Total	**23,953**	**25,713**	**49,666**

Abstract

This thesis includes a systematic literature review, a research outcome paper and a critical appraisal.

The systematic literature review summarises 20 outcome papers that explore the use of Mentalisation-Based Treatment (MBT) in participants with different mental health presentations. The results suggest that MBT has strong evidence in the treatment of people with a diagnosis of Borderline Personality Disorder (BPD) and that MBT has the potential of improving clinical outcomes in people with diagnoses of eating disorders and depression, adolescents who self-harm and mothers enrolled in substance misuse treatments. As compared to other interventions, MBT yielded positive outcomes that were maintained over long follow-ups and thus should be increasingly available for people with a diagnosis of BPD. Future research addressing treatment fidelity, confounding and assessor's blindness bias is required.

The outcome paper explores the mental health of adult caregivers of asthmatic children living in the United Kingdom. Using an online designed questionnaire, the study collected information regarding participants´ socio-demographic characteristics, mentalising ability, family functioning, anxiety, depression and hypomanic symptoms. The aim was to further explore the association between caregivers´mentalising capacity and self-reported mental health symptoms. Sequential linear regression models showed that mentalising on its own was associated with 16%, and 14% of depressive and anxiety symptoms respectively. On the contrary, family functioning was not significantly associated with the independent variables in any of the regression models after mentalising was included. Psychological interventions targeting mentalising might be helpful in reducing anxiety and depression symptoms in this population. The critical appraisal includes the author´s personal reflections on the journey of writing a doctorate thesis along with the implications of the findings.

Declaration

The current doctorate thesis includes the work conducted between April 2017 and May 2018 for the Doctorate in Clinical Psychology at Lancaster University. This work is my own and has not been presented for the award of a degree elsewhere. In the cases where information pertaining the work of other authors has been described, this has been appropriately referenced.

Name: Javier Malda-Castillo

Signature:

Date:

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I am tremendously grateful for all the participants who devoted time and effort to participate in this study. Without their collaboration, this thesis would have never been possible. I would also like to thank my supervisors Dr Guillermo Perez-Algorta and Dr Claire Browne for their support, patience, praise and expertise, which were key ingredients in producing this piece of work.

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Section 1: Systematic Literature Review

1. Section One: Systematic Literature Review

Mentalisation-Based Treatment (MBT) and its Evidence-Base Status: A Systematic Literature Review

Malda-Castillo, Javier

Trainee Clinical Psychologist

Division of Health Research

Lancaster University

Correspondence should be addressed to:

Javier Malda-Castillo

Clinical Psychology

Lancaster University

Lancaster

LA1 4YG

Tel: +44 07514267419

Email: j.maldacastillo@lancaster.ac.uk

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Abstract

Purpose: This study has reviewed the evidence-base status of mentalisation-based treatment (MBT), along with its methodological quality, strengths and limitations. MBT is a manualised, time limited and attachment rooted psychotherapy. The aim was to pave the way for further MBT research.

Method: An electronic database search of papers published between 1999 and 2017 was conducted. Studies of any methodology and design that included pre and post outcome quantitative results were included. The quality of the studies and the risk of bias were determined using two validated checklist.

Results: Twenty studies were included in the review. This included seven randomised controlled trials, six uncontrolled pre-post effectiveness studies, three retrospective cohort studies, two uncontrolled randomised trials and two case studies. The methodological quality of almost half of the papers was assessed as fair (45%), followed by good (30%), poor (20%) and excellent (5%) ratings. Nevertheless, the review identified a risk of confounding bias across the majority of studies (70%), and fidelity to treatment was poorly reported in over half of the studies (40%). Most of the studies focused on borderline personality disorder (BPD) treatment, and the evidence base for other presentations was still developing. MBT produced positive clinical outcomes across all the presentations. The treatment of adolescents who self-harm and at-risk mothers in substance misuse treatment showed promising results, as these are client groups that had previously shown limited positive response to psychological interventions.

Conclusions: MBT has the potential of becoming an effective intervention for different clinical presentations, but further research should focus on increasing the quality and the quantity of the MBT evidence outside the treatment of BPD.

Practitioner points[1]

1.MBT can be a particularly effective intervention for the treatment of adults with a diagnosis of BPD, adolescents who self-harm and mothers enrolled in substance misuse treatments.

2.MBT can be an effective intervention for depression and eating disorders but the evidence is currently limited.

3.Professionals supporting mothers in substance misuse treatment may benefit from receiving training in the principles of MBT.

[1] Requirement of the target journal

Mentalisation-Based Treatment (MBT) and its Evidence-Base Status: A Systematic Literature Review

The concept of mentalisation was first described by Fonagy (1989) as an ability that helps make sense of one's own and others' states of mind regarding desires, intentions, thoughts, feelings and behaviour. An example of mentalising difficulty is becoming upset with someone else's behaviour and developing quick assumptions about their thoughts and intentions. Conversely, good mentalising would involve putting yourself in the other's position and thinking about alternative reasons for their behaviour (Fonagy & Luyten, 2009). Given that difficulties in mentalising seem to be present in people with a diagnosis of borderline personality disorder (BPD) (Bateman & Fonagy, 2010), this theory has strongly influenced a partial-hospitalisation psychoanalytic treatment programme for clients with BPD diagnoses (Bateman & Fonagy, 1999). The programme was manualised, labelled mentalisation-based treatment (MBT) and tested in a randomised controlled trial (RCT), which constituted the first published paper on MBT (Bateman & Fonagy, 1999).

MBT: Theoretical Foundations and Mentalising Practice

MBT is a time-limited psychodynamic treatment rooted in attachment, cognitive and neuropsychology principles (Bateman & Fonagy, 2016). One of the main strengths of MBT is its strong links with the neurosciences, as evidenced by the publication of a wide range of neuroimaging studies exploring the neuroanatomical correlates of mentalising (Denny et al., 2012; Frith & Frith, 2006; Stuss et al., 2001). For instance, Lombardo, Chakrabarti, Bullmore and Wheelwright (2010) demonstrated that overlapping neural circuits were involved in the process of mentalising of both self and others. Moreover, Nolte et al. (2013) concluded that when presenting healthy adult participants with an attachment-related stress condition, there was a reduction in the activation of the areas of the brain that collaborate in the process of mentalising, such as the superior temporal

sulcus, left inferior frontal gyrus and left temporo-parietal junction. Therefore, the theoretical principles of the model tap into complex levels of functioning that can be measured. This offers the possibility of widening the currently limited understanding of the biological pathways of therapeutic change.

A central assumption of MBT is that mentalising is a skill that develops as a result of early interactions with caregivers, and that it is a main contributor to the ability of orchestrating affect regulation and to the development of a sense of self (Fonagy, 1998). In order to develop full mentalising, Bateman and Fonagy (2016) "particularly emphasize the importance of marked mirroring" (p. 6) of attentive adults who are able to convey, hold and understand a baby's affect, states of mind and intentions. In contrast, neglectful, abusive or dysfunctional attachment experiences are likely to impair the development of robust mentalising, which could, in turn, lead to impulsivity, affect dysregulation, self-harm or anxiety, among other effects (Bateman & Fonagy, 2011; 2012; 2016).

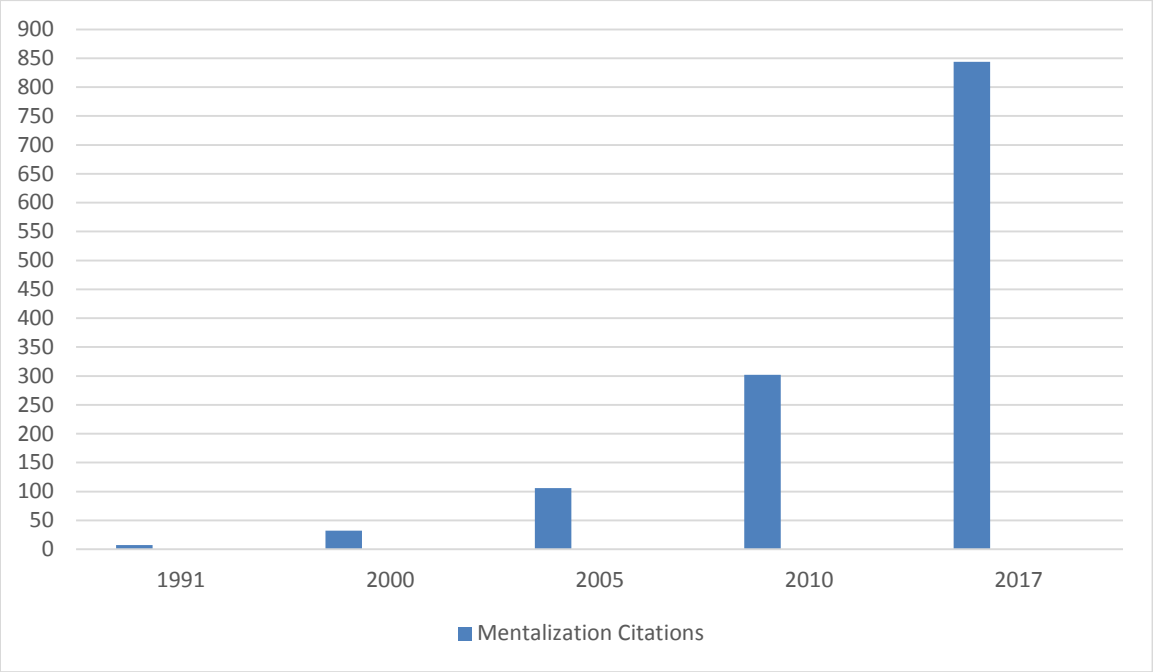
Initially, there were two different MBT treatment modalities, with different intensities. The first was implemented in the context of day hospital programmes, where service users received treatment for five days a week (Bateman & Fonagy, 2005) and the maximum length of the treatment ranged between 18 and 24 months. However, the intensive day hospital MBT approach is not currently offered in the UK (Bateman & Fonagy, 2016). One of the reasons is that over the last decade, mental healthcare provision in the UK has experienced major cuts (Davis, Lister & Wrigley, 2015; Lymbery, 2010), with a significant amount of day centres closing down as a result of the austerity policies (Pitt, 2010). Another reason is that outpatient, less intensive MBT has also proven to be efficacious (Bateman & Fonagy, 2009). Thus, in the UK service users receive the second type of MBT treatment, which consists of 18-month outpatient treatment with 50-minute individual and 75-minute group sessions each week (Bateman & Fonagy, 2016). The

structure of MBT can be divided in the following categories: assessment of mentalising difficulties, diagnosis and formulation, crisis plan and risk management, therapeutic contract and psychoeducation. A typical MBT session would involve a not-knowing therapeutic stance, where the therapist´s uses questions to promote reflective dialogue (Bateman & Fonagy, 2016). It would also include supporting the client to mentalise the narrative by using techniques such as "stop, re-wind, explore" in which the aim is to generate multiple perspective, to clarify how situations are felt and understood and how this is related with the attachment/relational patterns of the client (Bateman & Fonagy, 2016). Other MBT techniques include a constant focus on the client´s mind, monitoring relational misunderstandings and balancing the arousal levels with empathic validation and behavioural interventions (Bateman & Fonagy, 2016).

The main differences from other psychological interventions commonly implemented in the UK, such as cognitive behavioural therapy (CBT) or third wave CBT such as acceptance and commitment therapy (ACT), are that MBT is often more intensive (biweekly), has a longer duration, is well-integrated with other services available to the client, and uses both problem-solving skills and a specific focus on the therapeutic relationship as mediums of therapeutic change (Jørgensen et al., 2013; Ramires, Schwan & Midgley, 2012).

Clinical Implementation of MBT

In the last two decades, MBT has captured the interest of researchers and clinicians due to its novelty and ability to simplify and integrate attachment, psychodynamic and cognitive principles. According to the Thompson Reuter search tool Web of Science, the use of the term "mentalisation" increased from 7 to 844 between 1991 and 2017 (Web of Science, 2017).



Mental health professionals in particular have embraced MBT and have started to implement it for a wide range of clinical presentations (Bateman & Fonagy, 2013), such as eating disorders (Balestrieri et al., 2015; Robinson et al., 2016), depression (Jakobsen et al., 2014) and adolescents who self-harm (Rossouw & Fonagy, 2012), among others. Although some evidence has supported the efficacy of MBT in the treatment of BPD (Bateman & Fonagy, 1999; 2008; 2009; Jørgensen et al., 2013), it is still not recommended as a first-line treatment for personality disorders (PD) in the National Institute for Health and Care Excellence guidelines (NICE, 2009), and its evidence base for other psychological difficulties is still developing.

The charity Mind (2013) conducted a survey in the United Kingdom (UK) in which 1,639 adults with mental health difficulties who had accessed psychological therapies over the past two years took part. The survey indicated that CBT was the most commonly offered psychological intervention, accounting for 43% of all types of therapy. Given that specific MBT percentages were not reported and that psychodynamic therapies were offered to 19% of respondents, it can be inferred that MBT is often not available in

mainstream mental health services. These differences can be understood in the context of a significantly larger amount of published evidence in favour of CBT across a wide range of presentations (Hofman, Asnaani, Vonk, Sawyer & Fang, 2012) and the fact that MBT is often offered as a specialised intervention for PDs in the National Health Service (NHS).

Additionally, the Mind (2013) report also highlighted that 58% of the participants were not given a choice in the type of psychological intervention they accessed. These figures contrast with the Health and Social Care Act (2012) and with the Department of Health (2011) initiative of "no health without mental health", which prioritised the increase of service users' choice of treatment as a way of putting mental health on an equal footing with physical health, where choice of treatment is often available (Health and Social Care Information Centre, 2013). A plausible explanation is that the NICE guidelines are often dominated by widely established therapies such as CBT, which often means that service users lack the opportunity to choose between different therapeutic approaches (Mind, 2013).

Thus, in order to provide service users with the opportunity to make informed decisions around their choice of psychological treatments, clinical researchers have the responsibility of summarising and integrating the available outcome evidence for interventions that might be underrepresented in the guidelines and in current routine NHS provision, such as MBT.

Integrating New Evidence

In an attempt to coordinate and integrate the evidence base of psychological therapies, previous literature has proposed a wide range of models, such as the "hourglass model" (Salkovksis, 1995). The aim of the model is to provide an overarching framework that helps to establish whether the published literature around a specific psychological intervention includes efficacy and effectiveness studies (Barkham & Mellor-Clark, 2000).

Efficacy studies refer to those that are implemented under rigorous scientific conditions, such as RCTs (Barkhman & Mellor-Clark, 2000), and effectiveness studies refer to those implemented in standard settings with clinically representative populations. Although efficacy RCTs are considered to be the gold standard measure in assessing the evidence base of any psychological therapy, relatively few attempts have been made to translate and replicate the findings of controlled trials into routine clinical practice (Barkham & Mellor-Clark, 2000; Tajika, Ogawa, Takeshima, Hayasaka & Furukawa, 2015).

The "hourglass model" uses a three-stage evaluation process to examine the efficacy–effectiveness continuum. The first stage occurs when a new theoretical framework is proposed as a new alternative for treating a clinical problem that concerns a large number of practitioners (Barkham & Mellor-Clark, 2000; 2010). This approach is initially tested with small-scale methods such as case studies. The findings are then translated to the second stage, where more stringent methodology, such as RCTs, is employed as a way of testing the efficacy of the intervention (Barkham & Mellor-Clark, 2000). In the third stage, the treatment is implemented in settings that are closer to standard clinical practice to assess its effectiveness and external validity (Barkham & Mellor-Clark, 2000; Calvert & Kellet, 2014).

Current Review

Despite the novelty and limited implementation of MBT in routine clinical practice, there is a substantial amount of research on treatment efficacy and effectiveness that deserves attention. The efficacy and effectiveness of MBT treatment has so far only been systematically synthesised in literature reviews of PD treatment (Stoffers-Winterling et al., 2012). To date, no systematic review has focused on exploring the evidence base of MBT for other mental health presentations, such as eating disorders or depression.

Therefore, this review has three main objectives. First, it aims to describe and integrate all

of the published MBT outcome evidence, using the "hourglass model" as a framework to determine the status of such evidence. Second, it aims to establish whether MBT interventions lead to clinical improvements across different mental health presentations. Third, it attempts to assess the quality of such evidence and pave the way for further research in the field.

Method

This systematic review adheres to the guidelines specified by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (Liberati et al., 2009; Moher, Liberati, Tetzlaff & Altman, 2010).

Identification of Studies and Inclusion/Exclusion Criteria

The search was conducted with the support of a staff member of the academic liaison service of Lancaster University library. Papers were identified by searching six relevant databases: Medline, CINAHL, Psychinfo, Embase, Scopus and Web of Science. Databases were searched for studies published between 1999 (when the first MBT paper was published) and September 2017. All databases were searched using terms related to the treatment approach. Four terms relating to the same concept were combined using the Boolean operator "OR" ("Mentalis*ation based treatment" OR "Mentalis*ation based therapy" OR "Mentaliz*ation based treatment" OR "Mentaliz*ation based therapy"). These terms were searched for in the titles, abstracts and keywords of articles in the six databases, and full texts of relevant articles were retrieved accordingly. Furthermore, the reference lists of the retrieved articles were searched by hand in order to find any relevant articles not already included in the search.

Studies were deemed eligible based on the following criteria: 1) papers that reported pre- and post-outcome data; 2) published in English or Spanish in peer-reviewed

journals between 1999 and 20 September 2017; 3) participants received an intervention primarily informed by the main components of MBT; 4) papers both with and without comparison groups; 5) populations with any type of mental health presentation, including children, adolescents, adults, older adults and caregivers; 6) studies conducted within all types of healthcare settings; 7) at least one psychometric measure showing quantitative outcomes.

Papers were excluded from the current literature review according to the following criteria: 1) qualitative papers; 2) study protocols, theoretical discussions, unpublished articles, theses, dissertations or abstracts; 3) papers where MBT was limited to an adjunct component of another primary intervention (for example, a CBT intervention that had incorporated some MBT components).

Data Extraction and Methodological Quality Assessment

The present literature review employed a data extraction tool (see Appendix 1-A), which the author adapted from the data collection checklist of the "Cochrane Effective Practice and Organisation of Care Review Group" (EPOC, 2002).

The review employed a methodological quality assessment tool (Downs & Black, 1998) and a risk of bias assessment tool (Viswanathan et al., 2012). The methodological quality of each study was assessed using Trac et al.'s (2016) adaptation of the Downs and Black (1998) checklist tool. This 27- item instrument (Appendix 1-B) is considered as suitable for use in systematic reviews (Deeks et al., 2003) and allowed the calculation of a score that reflected the quality of each study, ranging from 0 to 28. Following the guidelines of a recently published comparative study (O'Connor et al., 2015) of the Downs and Black checklist tool (1998), the current review assessed the methodological quality of the included papers as follows: poor (<14 points), fair (14–18 points), good (19–23 points) or excellent (24–28 points). Five randomly selected papers also received scores from both

the author of this review and from an independent blind rater, which allowed for a calculation of an inter-rater reliability score.

However, methodological quality assessment tools use a single numerical value, which includes different elements such as ethical issues, statistical analyses or reporting strategy. These factors are not always directly associated with risk of bias (Wood et al., 2008) and thus papers with significant bias can receive high quality ratings if they are well reported.

In order to overcome this, the review also assessed the risk of bias, which plays an important role in establishing the robustness of evidence (Viswanathan et al., 2012) and is a requirement of the PRISMA guidelines (Liberati et al., 2009). The tool employed was developed by the Agency for Healthcare Research and Quality (AHRQ) (Viswanathan et al., 2012) and was constructed following the principles of the Cochrane "risk of bias" tool (Higgins & Green, 2011). Although independent ratings were not provided for this tool, the author clarified inconsistencies in the scoring with research supervisors.

Results

Figure 1 shows a flow diagram of the search process, which was divided into four separate stages: identification, screening, eligibility and inclusion (Moher et al., 2010). In the identification stage, the search generated 1,136 citations. These were exported to EndNote™, and screening identified 651 citations as duplicates, which were then removed. Subsequently, the titles and abstracts of the remaining 485 citations were screened.

Of these 485 citations, 463 were removed, and thus 22 studies were deemed appropriate for the eligibility stage. Full texts were retrieved and they were assessed, attending to the exclusion and inclusion criteria of the present review. After scrutiny, two articles were finally excluded from the present review according to the reasons presented in Figure 1.

An additional search of the 20 papers' reference lists was then conducted, and four new studies were identified (Bateman & Fonagy, 1999; 2008; Kvarstein et al., 2015; Suchman et al., 2010). Out of those 24 studies, three (Bateman & Fonagy, 2001; 2008; Jørgensen et al., 2014) were combined due to providing follow-up data for original trials (Bateman & Fonagy, 1999; Jørgensen et al., 2013), and one (Bateman, O'Connell, Lorenzini, Gardner & Fonagy, 2016) for presenting extended analyses of an original dataset from another article in this review (Bateman & Fonagy, 2009). Therefore, as presented in Figure 1, 20 studies were included in the current systematic review.

Data Synthesis

The papers are summarised in Table 1, which clusters them according to their design, consistent with the different stages of the "hourglass model" (Salkovskis, 1995). Given that this was the first systematic literature review of the evidence base of MBT, meta-analysis was discarded as only the studies concerning the treatment of BPD had enough number of trials for this approach, and a meta-analysis of the treatment BPD has already been conducted elsewhere (Stoffers-Winterling et al., 2012). On the contrary, this review aimed to synthesize the evidence of the treatment for the different mental health presentations, and thus narrative synthesis was employed, as recommended by the Cochrane guidelines (Ryan, 2014).

Study and Participant Characteristics

The N=20 studies were published between 1999 and 2017 and consisted of seven RCTs, six uncontrolled pre–post effectiveness studies, three retrospective cohort studies, two uncontrolled randomised trials and two case studies. These studies were conducted in a wide variety of countries, including the UK (N=6), Denmark (N=4), Netherlands (N=4), USA (N=2), Norway (N=2), Italy (N=1) and Brazil (N=1)

The total sample across the 20 studies was n=1,724. All the studies consistently reported a high proportion of female (ranging between 47% and 100%) and Caucasian (ranging between 68% and 85%) participants. The mean age ranged between 15.4 and 38.5. Although there was a relative degree of diversity in psychiatric diagnoses, a significant number of the studies (N=9) were focused on borderline personality disorder (BPD).

Intervention Characteristics

Almost half of the studies (N=9) followed the original 18-month MBT manualised approach (Bateman & Fonagy, 2004) and two of them (Balestrieri et al., 2015; Robinson et al., 2016) included the adaptations relevant for the treatment of eating disorders (MBT-ED). One study (Bateman & Fonagy, 1999) followed psychodynamic and mentalising principles but did not adhere to a treatment manual, as this was not available at the time. Similarly, another study adapted elements of the MBT treatment manual for adults in an intervention for maltreated children (Ramires et al., 2016). Two studies described shorter MBT interventions that lasted five and six months respectively (Jakobsen et al., 2014; Thomsen, Ruocco, Uliaszek, Mathiesen & Simonsen, 2017). Three studies explored the effectiveness of a one-year manualised MBT intervention for adolescents (MBT-A) (Bo et al., 2016; Laurenssen et al., 2014; Rossouw & Fonagy, 2012). One study (Griffiths, Noble, Duffy & Schwannauer, 2017) reported on the service utilisation of adolescent mentalisation-based integrative treatment (AMBIT), a systemic multi-agency liaison intervention organised around the concept of mentalising, which was originally developed to work with young service users that usually experience difficulties in accessing mental health services (Bevington, Fuggle, Fonagy, Target & Asen, 2013). Three studies described the adaptation of a short-term three-month MBT intervention for parents (Hertzmann et al., 2016; Suchman et al., 2010; 2017). The average number of offered clinical contacts varied significantly from six to 92 sessions.

Clinical Outcomes of MBT treatment

Table 1 presents the main clinical outcomes of MBT across different mental health presentations.

Personality Disorders

The status of evidence for MBT according to the hourglass model indicates one case study corresponding to stage one, two RCTs corresponding to stage two and six studies corresponding to stage three.

The first MBT published study (Bateman & Fonagy, 1999) tested treatment efficacy when applied to participants with a BPD diagnosis in a partially hospitalised setting (N=44). Self-harming behaviours were reduced significantly in the MBT arm [*Kendall's* W=0.21, $x^2(3)=11.9$, $p<.008$]. Furthermore, suicide attempts significantly decreased, from 95% at baseline to 5.3% at 18 months post-treatment (Bateman & Fonagy, 2001) in the MBT group [*Kendall's* W=.59, $x^2(3)=33.5$, $p<.001$], and they did not decrease significantly in the control group [*Kendall's* W=.04, $x^2(3)=2.4$, $p>.05$]. Medical record examinations at five years follow-up showed that the MBT group maintained a significantly lower suicidality (23% vs 74%), less access to psychiatric services and higher global assessment functioning (GAF) scores than the control group (Bateman & Fonagy, 2008). Although the five-year follow-up included records from all the participants (0% attrition), the study had a relatively small simple size (N=44) and did not follow a manualised approach.

In a subsequent RCT, Bateman and Fonagy (2009) examined the effectiveness of an outpatient MBT intervention when compared with structured clinical management (SCM, detailed in Bateman & Fonagy, 2009) in participants with diagnoses of antisocial PD (APD) and BPD. This paper employed a larger sample size (N=134) and included a manualised MBT intervention, which reduced performance bias. The results showed

medium and modest effect sizes for the reduction in rates of suicide attempts (*d*=.65, *95%, CI*=.58-0.73), self-harming behaviours (*d*=.62, *95% CI*=.28-.97) and depressive symptoms (*d*=.45, *95%, CI=.10-.79*) in the MBT group as compared with SCM. Results also showed significantly greater decreases in antisocial related features, such as anger (*t*=2.05, *p*<.05), paranoia (*t*=3.06, *p*<.01) and hostility (*t*=3.53, *p*<.001) in the MBT arm. Subsequently, a research group separate to the original authors of MBT (Jørgensen et al., 2013) developed the first uncontrolled clinical trial testing the effectiveness of MBT outside of the UK. This trial compared a two-year manualised MBT intervention with two years of supportive group therapy in Denmark (N=111). The pre–post analyses suggested that the psychiatric symptoms of both groups decreased significantly (*d*=.50–2.1, *p*<.001), although the differences between the two treatments were not statistically significant (*Fs*<2.9, *all ps>.13*). Although the therapists were not blind to the treatment condition, their ratings were compared with those of an independent assessor, showing very high reliability scores (*Cronbach's alpha*=.97 GAF-F and .95 GAF-S).

The number of participants without BPD diagnoses was significantly lower in the MBT arm (*d*=.58, *p*<.046) and although no significant changes were found between post-treatment and 18-month follow-up, the positive changes reported post-treatment were still maintained (Jørgensen et al., 2014). The study benefited from strong external validity, but internal validity was threatened because the same therapists delivered both interventions.

A prospective cohort study conducted by Bales et al. (2012) tested the applicability of a manualised MBT intervention in a day hospital setting in the Netherlands. The scores of depression, general symptom distress and quality of life improved significantly (*p*<.05) at 18 months posttreatment. This research study offered promising evidence regarding the generalisability of the results but lacked a control comparison group, which hinders the possibility of drawing conclusions about the efficacy of MBT.

Morken et al., (2014) reported on a case study from a clinic in Norway, which attempted to use MBT as part of a substance misuse treatment. The client, described by the authors as a 28-year-old female with features of borderline, schizotypal and avoidant PDs seemed to benefit from the treatment, although the only conclusion that can be extrapolated is that the intervention was helpful for that particular client.

Bales et al. (2015) developed a matched control study (N=204) for participants with a diagnosis of BPD. This paper compared a manualised MBT intervention with a heterogeneous group referred to as "other psychological treatments" (OPT), which included a wide range of therapeutic approaches, lengths and settings. Results suggested that psychiatric symptoms decreased in both groups post-treatment and after 18 months follow-up. Nevertheless, these improvements were higher in the MBT arm, as showed by the greater within-effect sizes (*d*=*-1.06* post-treatment and *d*=-1.42 18 months follow-up) than in the OPT group (*d*=-.35 post-treatment and *d*=-.57 18 months follow-up). The superiority of MBT was confirmed when exploring the large between-group effect sizes (-.71 post-treatment and -.85 at 18 months follow-up).

Similarly, a retrospective cohort study (Kvarstein et al., 2015) compared MBT (N=68) with psychodynamic psychotherapy (N=281) in Norway. The MBT group followed the Norwegian manual for the treatment (Karterud & Bateman, 2010), and the frequencies of self-harm, hospitalisation and suicide attempts decreased in both groups, whilst between group differences were not significant ($p>.05$). In MBT, pre–post analyses indicated that self-harm frequencies decreased from 89% to 27% and suicide attempts from 35% to 6% post-treatment. However, the long-term decrease of scores in the Brief Symptom Inventory (BSI) was significantly ($p<.001$) greater in the MBT group. The same pattern emerged for improvements in the GAF and in the circumplex of interpersonal problems (CIP) inventory ($p<.001$).

Thomsen et al. (2017) developed the first study testing neurocognitive functioning before and after an MBT intervention. This matched control study reported on the differences between an MBT group (N=18) of participants with a BPD diagnosis and a non-psychiatric control group (N=28), matched on parental education. Results showed a significant decrease in the Zanarini-BPD scale [$t(17)=5.19$, $p<.05$] and the Hamilton depression rating scale (HDRS) [$t(17)=2.71$, $p<.05$] post-treatment. Moreover, significant time X group interactions emerged for attention [$F(1,44)=8.98$, $p<.01$, $n^2_p=.17$] and perceptual reasoning [$F(1,44)=19.92$, $p<.001$, $n^2_{p=}.31$], such as that MBT improved more in perceptual reasoning [$t(44)=2.09$,$p<.05$, $d=0.61$], and that baseline group differences in attention were no longer significant post-treatment. Whilst improvements in episodic memory were associated with reductions in affective symptoms (*Spearman* $r=-.50$, $p<.05$), improvements in perceptual reasoning were correlated with improvements in interpersonal functioning (*Spearman* $r=.49$, $p<.04$). Although the results suggest that neuropsychological functioning can be associated with improvements in BPD-related symptoms, the non-controlled nature of the study does not allow attributing such improvements to MBT.

Finally, Bales et al. (2017) reported on the effectiveness of MBT in the treatment of BPD before and after a large reorganisation process. This retrospective cohort study (N=46) showed that psychiatric symptoms were reduced and personality functioning improved at 18 months follow-up for both groups ($p<.05$).

Overall, the summarised evidence corresponded to the three stages of the “hourglass model” and suggested that MBT has the potential of improving the clinical outcomes of people with a PD diagnosis, particularly BPD.

Depression

The status of MBT for the treatment of depression indicates that only evidence from the

second stage of the hourglass model is currently available. This review only identified one study exploring the benefits of MBT in depression. Jakobsen et al. (2014) developed a RCT (N=44) that compared the benefits of five months' third wave (non-specified) cognitive therapy (CT) with five months' MBT. The mean depression and psychiatric symptoms decreased for both conditions but the analyses indicated that the third wave CT group achieved significantly greater reduction in the scores of the HDRS than the MBT group (p=.039). Nevertheless, the treatment offered in this trial was limited to five months and only recruited 52% of the sample size that was estimated in the original power calculation. Thus, currently there is not enough available evidence of MBT outcomes in the treatment of depression.

Eating Disorders

The reviewed evidence of MBT for the treatment of eating disorders accumulated one study from the second, and one from the third stage of the hourglass model. Balestrieri et al. (2015) described the results of the first MBT matched control study (N=24) for eating disorders (MBT-ED). The paper compared the effectiveness of an 18-month manualised MBT-ED with a psychodynamic intervention, and the results indicated that all symptoms were reduced significantly in both groups (ps<.05), and the only significant between-group effects emerged in the GAF scores (p<.01), which favoured the MBT group.

A year later, Robinson et al. (2016) developed a RCT (N=68) that compared the outcomes of MBT-ED with an eating-disorders-adapted structural clinical management group (SCM-ED). The global scores in the eating disorder examination (EDE) improved at post-treatment, with a 1.2 point reduction in the MBT-ED condition (95% *CI* -1.81 to -.56, p<.001). Furthermore, the MBT-ED group showed a significantly (p<.05) greater reduction in shape concern and weight concern post-treatment than SSCM-ED. Given the limited available evidence, it is currently challenging to extrapolate conclusions regarding

the MBT outcomes in the treatment of eating disorders.

Children and Adolescents

The evidence of MBT for the treatment of children and adolescents accumulated five studies. Two corresponded to the first and second stage respectively, and three to the third stage of the hourglass model. A case study conducted by Ramires et al. (2012) reported on the outcomes of a six-month MBT intervention for a seven-year-old boy who had experienced early abuse and neglect in Brazil. The results showed a significant decrease in the child depression inventory (CDI), from 40 at baseline to 5 after six months of treatment. Despite the encouraging results for that individual at that particular time, no further conclusions can be drawn from this study.

Rossouw and Fonagy (2012) developed the first one-year manualised MBT intervention for adolescents (MBT-A), and tested its efficacy in the treatment of self-harm. This RCT (N=80) compared MBT-A with treatment as usual (TAU). Results post-treatment suggested significantly higher decreases in self-harming behaviour ($p<.01$), depression ($p<.04$) and self-reported BPD-related symptoms ($p<.05$) in the MBT-A arm than in the TAU arm. Moreover, mentalising was also enhanced in the MBT-A group ($d=.36$), whereas significant changes did not emerge in the TAU condition.

Laurenssen et al. (2014) further tested the implementation of MBT with adolescents in a practice-based effectiveness study. This uncontrolled research showed that adolescents from an inpatient unit benefited from a one-year MBT-A intervention. The findings indicated that scores in the Brief Symptom Inventory (BSI) decreased significantly ($p<.001$, $d=1.46$) and quality of life and personality functioning improved ($ps<.001$).

In a similar study, Bo et al. (2016) reported results from a fair-quality, uncontrolled, practice-based study. Their findings showed that after a one-year MBT group intervention, participants reported significant ($ps< .01$) reductions of general

psychopathology and depressive symptoms, as well as improved mentalising and peer and parent attachment.

More recently, Griffiths et al. (2017) reported on the implementation of the adolescent mentalisation-based integrative therapy (AMBIT) approach with regard to a tier-4 child and adolescent mental health service (CAMHS). This retrospective cohort study (N=302) showed consistently significant reductions in psychiatric symptoms (*ps*<.05) between admission and discharge. Furthermore, results suggested high overall attendance rates (80%) and higher professional involvement (x^2=5.26, *p*<.05) with those participants who experienced difficulties with engaging. Although the positive outcomes are consistent with the theoretical principles of AMBIT, whose principal aim is to be able to engage with young service users that are traditionally difficult to reach through services (Bevington et al., 2013), changes cannot be attributed to the implementation of AMBIT, since the design did not control for natural fluctuations in the self-reported distress.

Overall, currently there is promising evidence in the effectiveness of MBT-A for the reduction of self-harming behaviour, but the evidence for the treatment of children and other clinical presentations of adolescence still lacks robustness.

Parental Interventions

The reviewed evidence status of MBT parental interventions accumulated three studies and all of them corresponded to the second stage of the hourglass model. In line with prior research focused on attachment-based interventions with at-risk mothers, Suchman et al. (2010) developed the first MBT-based parental intervention (MIO). Its efficacy was tested in a RCT (N=47) that compared the effects of MIO with a control parent education (PE) group. The sample was comprised of mothers enrolled in a substance misuse treatment with children between birth and three years of age. The results were promising, with a significantly greater increase (*p*<.05) in reflective functioning (mentalising)

(*d*=.56) and caregiving behaviour (*d*=.41) in the MIO arm. Furthermore, the fidelity to the MIO intervention was correlated with improvements in reflective functioning, and small effect sizes suggested that the MIO group reported fewer psychiatric symptoms post-treatment. A subsequent RCT (N=87) developed by Suchman et al. (2017) further tested the efficacy of MIO in a sample of mothers enrolled in substance abuse treatment with children between one and five years of age. Similar results emerged, with higher reflective functioning (*d*=.36), mental coherent representation scores (*d*=.41) and engagement with their children (*d*=.21) in the MIO group than in the control PE group post-treatment. These two RCTs showed that a short (12 weeks) MBT intervention could reduce psychiatric symptoms as well as improve mentalising and caregiving behaviours in highly at-risk and vulnerable mothers presenting with substance misuse difficulties.

In addition, Hertzmann et al. (2016) reported on the only non-clinical study included in this review. This RCT compared the efficacy of an MBT-adapted intervention for parents in separation (entrenched) conflict (N=30) with a control parent group (PG). Although parental alliance and mentalising did not change significantly post-treatment, parents in both groups showed reduced scores in anger, stress and depression.

Hence, the studies summarised show that there is promising evidence for the use of MBT adapted parental interventions.

Methodological Quality and Risk of Bias

Methodological quality scores are presented in Table 1, and risk of bias judgements are described in Table 2. Regarding methodological quality, the two case studies were assessed as poor (M=5.5, range 4–7). Of a total of seven RCTs, five were rated as good, one as excellent and one as fair (M=20, range 17–24). Of a total of 11 practice-based effectiveness studies, eight were assessed to be fair, one as good and two as poor (M=14.9, range 11–19). Therefore, 45% of the included MBT studies (9/20) were considered to have

fair methodological quality, 30% good (6/20), 20% poor (4/20) and 5% excellent (1/20). An independent rater assessed five randomly selected papers with the Downs and Black (1998) checklist tool and the intraclass correlation coefficient was 0.82 (95% CI=.053-.98), suggesting excellent inter-rater reliability (Cichetti, 1994).

Similarly, selection bias ratings showed that five of the nine (55%) studies that conducted randomisation processes had low risk of bias, and that 11 studies had low risk of recruitment bias (55%). However, risk of confounding bias was present in 14 studies (70%). Performance risk of bias showed that eight studies (40%) had an unclear or high risk of fidelity to treatment bias. In contrast, the risk of bias due to attrition was assessed as low in 14 studies (70%). Judgments of detection bias showed that assessors' blindness was unclear for 13 papers (65%). All studies employed valid and reliable self-report measures, and 80% of the studies were rated with low risk of bias around their use of clinician- rated measures. In addition, almost half of the studies (45%) showed unclear risk of reporting bias.

Discussion

This systematic review is the first to analyse the outcome evidence base of published MBT studies. The review sought to achieve three main objectives. First, it aimed to describe the integration of MBT outcome evidence following the different stages of the "hourglass model" (Salkovskis, 1995). Second, it attempted to explore the potential of MBT to produce clinical improvements across different presentations, settings and populations. Third, this study sought to establish the quality of the published evidence for MBT.

Coherence of MBT Research

The ´hourglass model´ framework suggests that papers that measured treatment effects of MBT on participants with a diagnosis of BPD and on children and adolescents provide

evidence from the three stages of the model. Furthermore, MBT for eating disorders accumulated evidence from stages two and three. This indicates that MBT treatment for BPD, eating disorders and children and adolescents has accumulated evidence from highly controlled settings (Bateman & Fonagy, 1999; 2008; 2009; Jørgensen et al., 2013; Robinson, 2016, Rossouw & Fonagy, 2012), practice-based settings (Balestrieri et al., 2013; Bales et al., 2012; 2015; Kvarstein et al., 2015) and large service evaluations (Bales et al., 2017). On the contrary, studies on MBT treatment for depression and parental interventions failed to progress through the three stages of the model and only provided evidence from the second stage with studies in highly controlled settings (Jakobsen, 2013; Suchman et al., 2010; 2017).

Given that RCTs often assess psychological treatments in ideal conditions (Barkham, Hardy & Mellor-Clark, 2010), future research should aim to retrieve both efficacy and effectiveness evidence. This would help to clarify whether results obtained using MBT in highly controlled environments can be translated to the highly complex and heterogeneous population encountered in standard clinical practice and vice versa. By doing this, MBT can lay the foundations of accumulating a more consistent and robust evidence that attracts policy makers´ attention and funding.

Quality of MBT and Clinical Findings

The majority of published MBT evidence was assessed to be of fair quality (45%) or good quality (30%), with similar mean ratings for RCTs (M= 20) and practice-based effectiveness studies (M=15) to those reported by Calvert and Kellett (2014) when assessing the quality of Cognitive Analytic Therapy ([CAT] M=22 and M=16, respectively) with the same tool. However, quality checklist tools that rely on single numerical scales often fail to identify studies with increased risk of bias (O'Connor et al., 2015), and therefore this review also employed a risk-of-bias assessment tool. In fact,

reporting and attrition bias remained consistently low across the reviewed papers, although assessors' blindness was not clearly reported in 65% of the papers. Additionally, almost half of the studies presented with unclear or high risk of treatment fidelity bias (40%), risk of confounding bias were identified in a substantial amount of the included studies (70%) and almost half of the studies showed unclear risk of reporting bias.

This suggests that a substantial number of papers did not report adherence scales to the treatment manual, and that it was not clear whether the potential outcomes were pre-specified by researchers. It should be acknowledged that although some papers did not report the adherence scale results, they met inclusion criteria because they described clearly the MBT components employed. Additionally, they included live supervision by senior therapists, who assessed whether the interventions had the essential components to be defined as MBT.

Future studies would benefit from addressing these issues and from providing a clear description of the assessment procedure, with special attention to whether those involved in the assessment were blinded to the treatment condition or exposure status of participants, as this was also poorly described. Finally, a substantial amount of papers did not describe clearly whether the distribution of confounders in each group could affect the interpretation of the results, which requires attention.

Despite these methodological issues, the reported findings suggest that MBT was associated with positive clinical outcomes across the 20 studies and was superior to comparison groups, with the exception of supportive therapy and third wave CT (Jørgensen et al., 2013; Jakobsen et al., 2014). This was of particular relevance for BPD, as the therapy gains were maintained after long follow-up periods (Bateman & Fonagy, 1999; 2001; 2008). To date, no other psychological intervention has reported improvements of such endurance in the treatment of BPD (Levy, Ablon & Kächele,

2011). Although some of the studies reported particularly long follow-ups, 65% of the papers did not report any follow-up periods, and future studies should address this issue as positive therapy outcomes could dissipate after therapy terminated.

Nevertheless, the positive outcomes obtained by Bateman and Fonagy (2009; 2016) in the treatment of antisocial PD (APD) are also noteworthy given the very limited available evidence showing positive treatment results with this population (Gibbon et al., 2010; Yakeley & Williams, 2014). Despite the promising nature of the results, a note of caution should be made since some of these papers presented with limitations, such as unclear treatment fidelity or being underpowered. Nevertheless, it is important to take into account that three of the included studies (Hertzmann et al., 2016, Laurenssen et al., 2014 & Suchman et al., 2010) were feasibility studies with small sample sizes, because their aims were not to provide generalizable results but to determine whether a larger scale trial was warranted.

Regarding depression, a RCT demonstrated that participants receiving MBT improved in all the self-reported symptoms, although the improvements were greater for those receiving third wave CT. However, this trial lacked statistical power as it only included 52% of the originally calculated sample size and used the HDRS as the primary outcome measure, whose validity and ability to predict suicide attempts has been extensively questioned (Bagby, Ryder, Schuller & Marshall, 2004; Chakraborty & Chatterjee, 2006; Jakobsen et al., 2013). Additionally, the paper did not include any measure of mentalising, which is of particular relevance given that a previous paper identified mentalising deficits in female inpatient service users with diagnoses of major depressive disorder (Fischer-Kern et al., 2013). Therefore, more randomised trials that assess the efficacy of MBT in depression and that include measurements of mentalising are needed.

Similarly, the development of a new protocol of MBT for eating disorders (MBT-ED)

yielded positive results (Balestrieri et al., 2015; Robinson et al., 2016). In the trial of Robinson et al. (2016), changes in participants with a diagnosis of bulimia in the EDE instrument showed a mean effect size of 1.2, which is comparable to those reported by CBT-E (Fairburn et al., 2009; Mitchell et al., 2011), a first line treatment recommended in the NICE guidelines (2004). Despite the fact that this trial was well-designed, employed blind independent assessors and treatment adherence scales, the study lacked statistical power and the dropout rates were very high, with 70% of participants in the MBT-ED not finishing the treatment. Although the reasons for this were not apparent, the participants were described as highly complex and it was hypothesised that they might have found the trial very stressful. Thus, although the results were promising for those who remained in the trial, high levels of attrition limited the conclusions on the efficacy of MBT treatment for eating disorders.

The research concerning interventions with adolescents was ground breaking, with the MBT version for adolescents (MBT-A) (Rossouw & Fonagy, 2012) being one of the few psychological treatments that demonstrated to be efficacious in reducing self-harm among adolescents (Ougrin, Tranah, Leigh, Taylor & Asarnow, 2012). Although further research in standard clinical practices expanded on the effectiveness of MBT-A (Bo et al., 2016; Laurenssen et al., 2014) in outpatient and inpatient services, more randomised trials and practice-based effectiveness studies are required to draw definite conclusions.

Ultimately, the MBT intervention for parents with separation (entrenched) conflicts (Hertzmann et al., 2016) and mothers (MIO) (Suchman et al., 2010; 2017) at risk showed promising evidence. The results with mothers at risk in substance abuse treatment are deeply encouraging, as this is a population that has previously been overlooked by other programmes such as “The incredible years” (Webster-Stratton & Reid, 2010), and for whom treatment dropouts and lack of positive outcomes are very common (Kerwin, 2005;

Suchman et al., 2017). The next step could be to provide MBT training for professionals involved in the care and support of this population as well as to recognise the importance of including mentalising enhancement as one of the main treatment targets.

In addition, caution should be taken when interpreting the results. MBT is a long-term and intensive intervention, and therefore non-specific factors such as the treatment length could account for the positive outcomes. In order to overcome this, future literature should aim to establish whether positive treatment outcomes correlated with increasing mentalising function, as measured by validated mentalising scales. Participants in these studies were largely Caucasian female, which gives rise to questioning whether the same results would apply to male and ethnic minority service users. It is also noteworthy that few studies used a mentalising or reflective functioning measure, which hinders the ability to draw conclusions on the mechanisms of change. In spite of this, most of the participants included in this review presented with high diagnostic comorbidity, as MBT studies were often designed with very few exclusion criteria. Furthermore, research was conducted in a variety of countries, including the UK, Norway, Netherlands, Denmark, Brazil, Italy and the USA. The original authors were only involved in three studies (15%), suggesting that risk of research allegiance was minimal.

Taken together, these findings suggest that MBT is a favourable intervention across different presentations. Nevertheless, future research should address the risk of biases identified in this review, expand the selection of participants to male and minority client groups and increase the outcome evidence across all the presentations, especially for depression and eating disorders.

Strengths and Limitations of the Review

There are some limitations to this review. First, it was limited to articles written in English and Spanish, which could have impacted on the findings of this review,

particularly given the increasing body of MBT research conducted in Scandinavian countries (Bo et al., 2016; Jørgensen et al., 2013; 2014; Jakobsen et al., 2014; Kvarstein et al., 2015). Additionally, papers with non-significant results are less likely to be published in peer reviewed journals, or if they are published, is more likely to be in non-English journals (Egger et al., 1997), suggesting that this review might contribute to publication bias by not including such studies. Second, although inter-rater reliability was employed in the quality assessment, the review was primarily conducted by a single author, which could have impacted on the risk of bias rating, database search, inclusion and exclusion criteria assessment, as well as on the extraction of relevant data. In spite of this, the review presents with several strengths, such as including two well established and validated risk of bias and quality assessment tools. Moreover, the review adhered to the PRISMA guidelines and a priori identified the search strategy, as well as inclusion and exclusion criteria. Finally, this is the first review to systematically integrate the outcome evidence of MBT treatment and to employ the "hourglass model" as a framework to assess the status of such evidence.

Conclusions

In summary, although the studies included in this review suggest that MBT is a promising intervention for a wide range of presentations, there is currently insufficient evidence to consider MBT as a first line treatment. The reviewed evidence is of acceptable quality, but relevant risk of treatment, confounding and detection biases have been identified and should be taken into account in future studies. However, the results are promising and suggest that MBT has the potential to be a useful intervention for service users that have multifaceted presentations and high comorbidities and that often do not fit into a specific diagnostic category, making the treatment of choice difficult. In fact, MBT often provides long-term positive outcomes, which are often absent in other

established psychotherapies. Future research should aim to expand the currently available evidence on the effectiveness and efficacy of MBT across different presentations, with special emphasis on increasing the available number of controlled trials in BPD so that this treatment can be included in the future revision of NICE guidelines (2009) for the treatment and management of BPD.

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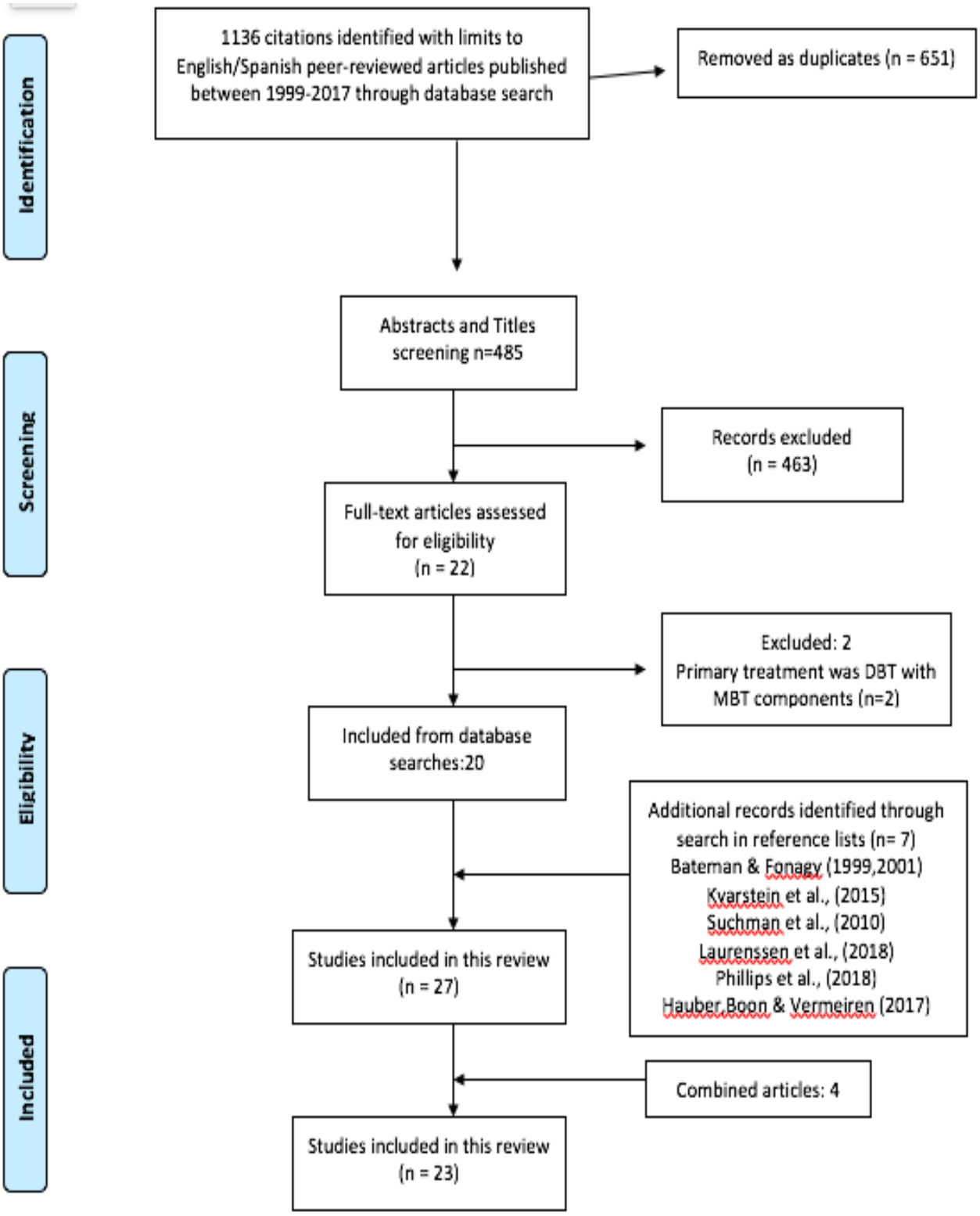

Figure 1. PRISMA flow diagram *Note.* DBT=Dialectical Behavioural Therapy, MBT=Mentalisation based treatment, PRISMA=Preferred Reporting Items for Systematic Reviews and Meta-Analyses

Tables

Table 1

MBT studies, characteristics and findings

Study (Country)	Design	N (att=attrition)	Sample	Demographics Age=M (SD)	Intervention	Follow-up	Outcome Measures	Downs & Black[1]	Main Findings
Stage 1 *Case Series*									
Ramires, Schwan & Midgley (2012) (Brazil)	Single case uncontrolled (pre-post)	1	Depression	7-year old child living in a residential home	6 months individual weekly MBT	Not reported	CDI[2]	7	Substantial decline in depressive symptoms with CDI scores dropping from 40 to 5
Morken,Karterud & Arefjord (2014) (Norway)	Single case uncontrolled (pre-post)	1	Disorganised attachment, BPD[3], SPD[4], substance misuse	28-year old woman	2-years weekly individual and group MBT	Not reported	GAF[5], SCL-90-R[6], GSI[7]	4	GAF scores changed by 15 points and SCL-90-R/GSI dropped from 1.50 to 0.68

Study (Country)	Design	N (att=attrition)	Sample	Demographics Age=M (SD)	Intervention	Follow-up	Outcome Measures	Downs & Black[1]	Main Findings
Stage 2 *Randomised Controlled Trials (RCT)* Bateman & Fonagy (1999; 2008) (UK)	RCT	MBT=22 SPC[8]=22 (12% attrition)	BPD	Age= 30.3 (5.86) and 68% females in MBT and age= 33.3 (6.60) and 47% females in SPC	18-months partial hospitalisation MBT program	36 months=0 % att MBT and 15% SPC 5 years= 0% att	SCL-90-R, BDI[9], STAI[10], SAS[11], IIP-C[12]	19*	Significantly greater decrease on suicide attempts (p<.01) and self-harm [*Kendall´s W*=.21, $x^2(3)$=11.9,p<.008] in the MBT group as compared to SPC group posttreatment. After 18 months clients in the MBT group showed being significantly lower scores in the BDI [$F(1,45)$=32.6, p<.001], SCL-90-R [$F(1,33)$=30.2, p<.001], SAS [F (1,36)=25.2, p<.001] and in the IIP [*Wilks´s lambda*=.87, $F(1,37)$=5.4, p<.001] than SCU group After 5 years the MBT group showed less suicidality (23% vs 74%), less access to psychiatric services, medication use and higher GAF (45% above 60 vs 10%) than SCU group.

Study (Country)	Design	N (att=attrition)	Sample	Demographics Age=M (SD)	Intervention	Follow-up	Outcome Measures	Downs & Black[1]	Main Findings
Bateman & Fonagy (2009; 2016) (UK)	RCT	134 MBT=71 (26% att) SCM[13]=63 (25% att)	BPD and APD[14]	Age=31.3 (7.6) 80% female, 76% white in MBT; age=30.9 (7.9) 79% female, 68% white SCM.	18 months MBT weekly individual and group treatment SCM=Case management, problem oriented	Not reported	GAF, SCL-90-R, BDI, SAS, IIP-C	21*	Self-harm (24% vs 44%) and suicide attempts (32% vs 47%) were significantly lower in MBT posttreatment. The reduction symptomatology was greater in MBT, with substantial effect sizes for IIP (*d*=.95, 95% *CI*=0.59-1.3), SAS (*d*=.72, 95% *CI*=0.37-1.06) and modest for BDI (*d*=.45, 95%, *CI*=0.10-0.79). Anger (*t*=2.05, *p*<.05) paranoia (*t*=3.06, *p*<.01) and hostility (*t*=3.53, *p*<.001) were significantly lower in MBT posttreatment.
Rossouw & Fonagy (2012) (UK)	RCT	80 MBT=40 (50% att) TAU[15] =40 (32% att)	Self-harm and depression	Age= 15.4 (1.3),82% female 75% Caucasian MBT; age=14.8 (1.2), 87% female and 75% Caucasian TAU	12 months individual MBT-A[16] weekly sessions and monthly MBT-F[17]sessions	Not reported	RTSHI[18], MFQ[19], BPFS-C[20], HIF[21], ECR[22]	24	Self-harm and depression reduced in both groups. Linear decrease was significantly greater in MBT-A for both self-harm (p<.001) and depression (*p*<.04). The reduction in self-reported BPD features (BPFS-C) was also greater for MBT-A (*d*=.36). Mentalisation (HIF) increased more in MBT-A (*d*=.38) and attachment avoidance decreased more in MBT-A (*d*=.42).

Study (Country)	Design	N (att=attrition)	Sample	Demographics Age=M (SD)	Intervention	Follow-up	Outcome Measures	Downs & Black[1]	Main Findings
Robinson et al., (2016) (UK)	RCT	68 MBT-ED[23]=34 (35% att) SSCM-ED[24]=34 (41% at)	Anorexia, bulimia, binge-eating disorder	Age=31.2(9.8), 94% female and 82% white in MBT-ED; age=30.8 (10.0), 91% female and 85% white in SSCM-ED	12 months weekly individual and group MBT-ED 12 months biweekly sessions of SSCM-ED	18 months (70% att MBT-ED and 73% in SSCM-ED in follow-up)	EDE[25], GAF, EQ-5D[26], DASS-21[27], BFI[28], ZAN-BPD[29]	21*	47% compliance in MBT-ED and 37% in SSCM-ED. No significant differences between interventions in the global EDE and ZAN-BPD at either 6, 12 or 18 months (p>0.05). Improvement at EDE global scores in the MBT-ED arm at 18 months with a -1.2 point reduction (95% *CI* -1.81 to 0.56, p<.001). The global ZAN-BPD scores also decreased for both MBT-ED (95% *CI* -12.68 to -4.95, p<.001) and SSCM-ED (95% *CI* -12.49 to -2.55 p<.003) at 18 months.
Hertzmann et al., (2016) (UK)	RCT	30 MBT-PT[30]=16 (6% att) PG[31]=14 (14%att)	Parents post-separation in entrenched conflict	93% heterosexual. Age of children=9.56 (2.92) MBT-T; age=7.71(3.54) for PG	MBT-PT 1 hour weekly sessions between 6 and 12 weeks PG= 4 hours	3 months (0% att)	STAXI[32], PFRQ[33], PDI[34], PSS[35], PAM[36], RAM[37], SDQ[38],SIMS-PR[39],PHQ-9[40]	17	STAXI scores reduced at 3 months follow-up (ß =-2.94, SE=1.06, <=-2.77, p<..01) along with PSS scores (ß =-1.21, SE=.53, <=-2.28, p<.05) and SDQ scores (ß =-1.97, SE=.61, z=-3.24, p<.01). There were no significant differences between treatments in the scores of the STAXI, PRFQ, PDI, PAM, RAM OR SDQ (p>.05).

Study (Country)	Design	N (att=attrition)	Sample	Demographics Age=M (SD)	Intervention	Follow-up	Outcome Measures	Downs & Black[1]	Main Findings
Suchman et al., (2010) (USA)	RCT	47 MIO[41]=23 PE[42]=24	Mothers in addiction treatment	Age=31.43 (6.46), 78% Caucasian MIO; age=28.88 (6.50), 62% Caucasian PE.	MIO (MBT based) 12-session individual therapy PE=12 sessions psychoeducation	Not reported	BDI, GSI, BSI[43], WMCI[44], NCAST[45], PDI	19	MIO mothers had significantly (p<0.05) higher reflective functioning (PDI) (d=.56) and higher caregiving behaviour scores (d=.41). Small differences showed that MIO mothers had less psychiatric symptoms and substance misuse PE mother posttreatment. Therapist fidelity to MIO model was associated with improvement in overall (R^2 =0.41, ß =0.74), highest ($R^{2\,\Delta}$=0.50, ß =0.81) and lowest reflective functioning scores ($R^{2\,\Delta}$=0.12, ß =0.41).
Suchman et al., (2017) (USA)	RCT	87 (20% attr) MIO=40 PE=47	Mothers in addiction treatment	Age=29.89 (5.10), 80% Caucasian MIO; age=29.43 (5.73), 74% Caucasian PE.	MIO (MBT based) 12-session individual therapy PE=12 sessions psychoeducation	3 months 22% did not complete treatment	BDI, BSI, SSP[46], CBP[47], PDI, TLFB[48], WMCI	20	MIO mothers had higher reflective functioning (PDI) scores (d=.36), higher mental coherent representation scores (d=.41) and higher engagement with their children (d=.21) than PE mothers at 3 month follow-up. PE mothers had less psychiatric symptom than MIO mothers (d=.54) at 3-month follow-up. MIO mothers decreased heroin use moderately (d=-.29) whereas PE mothers increased (d=.21).

Study (Country)	Design	N (att=attrition)	Sample	Demographics Age=M (SD)	Intervention	Follow-up	Outcome Measures	Downs & Black[1]	Main Findings
Stage 3 *Quasi Experimental Studies* Jørgensen et al., (2013;2014) (Denmark)	Uncontrolled Randomised Clinical Trial	85 MBT=58 (32% att) Control=27 (29% att)	BPD	Age= 29.5 (6.5) 97% females in MBT and age=29.7 (6.8) 93% females in control/supportive therapy (ST) group	MBT= 2 years individual and group weekly ST=2 years biweekly group therapy	18 months 4% attrition at MBT and 21% at ST	SLC-90-R, GSI, BDI, BAI[49], IIP, GAF	18	Psychiatric symptoms decreased significantly at 2-year posttreatment for both groups (p<.0001). Pre-post effect sizes were large or very large (d=.5-2.1) and significant (p<.01) for depression, anxiety, social functioning and general level of functioning but the differences between the two treatments were not statistically significant (Fs<2.9, all ps>0.13). Treatment gains were maintained at 18-month follow-up but no between group differences emerged.
Jakobsen et al., (2014) (Denmark)	Uncontrolled Randomised Clinical Trial	44 MBT=22 (9% att) CT[50]=22 (0% att)	Depression	Age= 38.5 (8.9) and 82% female third-wave CT; age=40.3 (6.8) and 91% female MBT	18 weeks MBT 18 weeks third wave CT	Not reported	HDRS[51], BDI, SCL-90-R, WHO-5[52]	19	No significant differences were found between the two groups regarding BDI, SCL-90-R OR WHO-5 at 18 weeks posttreatment. However, regarding HDRS scores, there was a significant difference (p<.03) favouring third wave-CT therapy.

Study (Country)	Design	N (att=attrition)	Sample	Demographics Age=M (SD)	Intervention	Follow-up	Outcome Measures	Downs & Black[1]	Main Findings
Effectiveness practice-based studies									
Laurenssen et al., (2014) (Netherlands)	Uncontrolled pre-post	13 (15% att)	Adolescents with BPD	Age=16.5 (1.57), 100% female	12 months MBT-A	Not reported	BSI, GSI, SIPP-118[53], EQ-5D	11	The BSI symptoms decreased significantly posttreatment (p<.001, d=1.46) and personality functioning improved with large effect sizes on self-control (p<.01, d=1.29), social concordance (p<.05, d=.70), identity integration (p<.01, d=1.42) and responsibility (p<.05, d=.58). Quality of life (EQ5D) scores also improved significantly (p<.05, d=1.11).
Bales et al., (2012) (Netherlands)	Uncontrolled pre-post	45 (26% att)	Severe BPD and substance use disorders	Age=30.1 (6.5) and 71% female	18-months day hospital MBT	Not reported	GSI, BDI, EQ-5D, IIP-C, BPDSI[54], SIIP-118	17	Scores of symptom distress, depression and quality of all improved during 18 months (d=.68 to 1.26) and reaching statistical significance at the 12-month measurement (p<.05). Borderline symptoms also improved significantly after 18 months (p<.001) with an effect size of d=1.23.

Study (Country)	Design	N (att=attrition)	Sample	Demographics Age=M (SD)	Intervention	Follow-up	Outcome Measures	Downs & Black[1]	Main Findings
Bales et al., (2015) (Netherlands)	Uncontrolled pre-post	204 MBT=29 OPD[55]=175	BPD	Age= 30.0 (6.17), 69% females in MBT; 30.3 (7.76) 82% females in OPD.	18-months day hospital MBT	18 months	BSI, GSI, SIPP-118	14	Both groups improved in all outcome measures after 36 months. Comparison of effect sizes showed greater improvements in the MBT group with large effects in the reduction of psychiatric symptoms (*d*=-.71 *d*=-.85 at posttreatment and follow-up respectively) and moderate effect sizes in improvement of personality functioning (*d*=.45 to .88 at 18 months and *d*=.34 to 1.09 at 36 months).
Balestrieri et al., (2015) (Italy)	Uncontrolled pre-post	24 MBT=12 (48.7% attrition) SPT[56]=12 (50% att)	Bulimia, anorexia nervosa	Not reported	18-months individual and group weekly MBT sessions 18-months individual weekly STP	Not reported	TAS-20[57], HAM-A[58], HAM-D[59], SCL-90, EDI-3[60], BES[61], BUT[62], CGI[63], SASS[64], SF-12[65] GAF, DES[66],	14	Only one client in the MBT group and two in the SPT group maintained an eating disorder diagnosis (x^2=.66; *p*<.042) posttreatment. Both treatments improved psychiatric symptoms in the HAM-D, HAM-A, TAS-20, GAF, SCL, CGI, SASS, DES, and BUT (*ps*<0.05). Analyses only differentiated between the two groups in the GAF (*p*<0.01; *partial eta squared*=.42) in favour of MBT.

Study (Country)	Design	N (att=attrition)	Sample	Demographics Age=M (SD)	Intervention	Follow-up	Outcome Measures	Downs & Black[1]	Main Findings
Kvarstein et al., (2015 (Norway)	Retrospective cohort study	345 MBT=68 (32% att) Psychodynamic=281 (22% att)	BPD	Age= 26.0 (6.0), 84% females in MBT; 30.0 (7.0) 83% females in OPD.	3 year MBT 18 months to 4 years psychodynamic (group and/or individual)	Not reported	BSI, IIP-C, GAF	15*	Both groups showed reductions in self-harming (89% to 27% in MBT) and suicide attempts (35% to 6% in MBT) posttreatment with no significant differences between groups (p>.05). BSI reductions were significantly (p<.001) better for MBT (reduction from M=2.0, SD=0.8 to M=0.8, SD=0.8) than for psychodynamic (reduction from M=2.1, SD=0.8, to M=1.4, SD=0.7). GAF improvements and interpersonal problem reduction were also significantly greater for MBT (p<.001) posttreatment.
Bo et al., (2016) (Denmark)	Uncontrolled pre-post	34 (26% att)	Adolescents with BPD	Age=16.4 (0.9), 100% female	12-months MBT group, 7-sessions of MBT-P[67] and 2 sessions of MBT-I[68]	Not reported	BPFS-C, PAI[69], YSR[70], BDI-Y[71], RTSHI-A, IPPA-R[72], RFQ-Y[73]	14	Significant reductions in borderline symptoms ([BPFS-C], p<.001) as well as significant reductions in the internalising psychopathology ([YSR], p<.005), peer and parent attachment (IPPA-R, p<.001). No between groups differences in the externalising psychopathology or risk-taking behaviour (RTSHI-A, p>.05) were found.

Study (Country)	Design	N (att=attrition)	Sample	Demographics Age=M (SD)	Intervention	Follow-up	Outcome Measures	Downs & Black[1]	Main Findings
Griffiths et al., (2017) (UK)	Retrospective cohort study	302	Tier 4 adolescent mental health service	Age (median years)= 16 (11-22), 64% female	AMBIT[74] (MBT based) 2-year implementation	Not reported	WHOQOL[75], BDI, PANSS[76], BYI[77],	10	All clinical outcomes improved after discharge. The differences were significant for anxiety, depression (p<.05), psychological quality of life and all PANSS scores (p<.001). High attendance rates (80%) were reported and professionals were highly involved (x^2=5.26, p<.022) with participants that struggled with engagement.
Thomsen et al., (2017) (Denmark)	Uncontrolled pre-post	90 MBT=30 (40% att) Control=60 (53% att)	BPD	Age=30.23 (7.77) and 100% psychiatric diagnoses in MBT ; age=30.59 (8.82) and 0% diagnoses in control	6 months weekly individual and group MBT	Not reported	ZAN-BPD, HDRS, GAF, WAIS-IV[78], CANTAB[79], HVLT[80]	14*	Improvements in the ZAN-BPD t(17)=5.19, p<.05 and HDRS t(17)=2.71 p<.05 posttreatment. Main effect of time for processing speed F (1,31)=5.56, p<.03, n^2_p =.15 with MBT improving posttreatment. Significant Time X Group interaction for sustained attention (1,44)=8.98, p<.01, n^2_p =0.17 and perceptual reasoning F(1,44)=19.92, p<.001, $n^2_{p=}$.31.MBT improved more in perceptual reasoning t(44)=2.09,p<.05, d=.61 and differences in attention were not significant posttreatment.

Study (Country)	Design	N (att=attrition)	Sample	Demographics Age=M (SD)	Intervention	Follow-up	Outcome Measures	Downs & Black[1]	Main Findings
Bales et al., (2017) (Netherlands)	Retrospective cohort study	46 PRE-REORG[81]30 REOR[82]=16	BPD	Age=29.8 (6.3) and 70% female PRE-REORG; 27.9 (5.7), 81% females REORG	18-months day hospital MBT +18 months maintenance MBT group	18 months	BSI, SCL-90-R, GSI, SIPP_118	18	Psychiatric symptoms decreased (BSI, SCL-90-R) and improvements in personality functioning at 18 month follow up in both groups (*ps*<.05). Outcomes decreased by half in the REORG group, (18 months, PRE-REORG *d*=.81-1.22 vs *d*=.03-.71 REORG) and these differences were significant posttreatment and at 18 month follow-up.

Note. *Papers that were assessed by two independent raters, [1]Downs and Black (1998) total score, [2]CDI=Children's depression inventory (Helsel & Matson, 1984),[3]BPD=Borderline Personality Disorder, [4]SPD=Schizotypal Personality Disorder, [5]GAF=Global Assessment Functioning, [6]SCL-90-R= Revised Symptom Checklist (Derogatis, 1977),[7]GSI=Global Severity Index (Derogatis & Melisaratos,1983), [8]SPC=Standard Psychiatric Care, [9]BDI=Beck Depression Inventory (Beck, Steer & Brown,1996), [10]STAI=State Trait Anxiety Inventory (Spielberger et al., 1983), [11]SAS=Social Adjustment Scale (Weissman,1999), [12]IIP-C=Inventory of Interpersonal Problems –Circumflex version (Alden et al., 1990), [13]SCM=Structured Clinical Management (Bateman & Krawitz, 2013), [14]APD=Antisocial Personality Disorder, [15]TAU=Treatment as Usual, [16]MBT-A=Mentalisation based treatment for adolescents, [17]MBT-F=Mentalisation based family therapy, [18]RTSHI=Risk Taking and Self-Harm Inventory (Vrouva, Fonagy, Fearon & Roussouw, 2010), [19]MFQ=Mood and Feelings Questionnaire (Angold et al., 1987), [20]BPFS-C=Borderline Personality Features Scale for Children (Crick et al., 2005), [21]HIF=How I Feel Questionnaire (Walden Harris & Catron, 2003), [22]ECR=Experience of Close Relationships Inventory (Fraley, Waller & Brenan, 2000), [23]MBT-ED= Mentalisation Based Treatment for Eating Disorders, [24]SSCM-ED=Supportive Clinical Management for Eating Disorders, [25]EDE=Eating Disorder Examination (Fariburn & Cooper, 1993), [26]EQ-5D=EuroQol-5D (EuroQoL, 1990), [27]DASS-21=Depression, Anxiety, Stress Scale-21 (Lovibond & Lovibond, 1995), [28]BFI=Big Five Inventory (John, Donahue& Kentle, 1991), [29]ZAN-BPD=Zanarini Rating for Borderline Personality Disorder (Zanarini et al., 2003), [30]MBT-PT=Mentalisation based treatment for parental conflict, [31]PG=Parent´s Group, [32]STAXI=State-Anger Expression Inventory (Spielberger, 1996), [33]PRFQ-1=Parental Reflective Function Questionnaire (Luyten et al., 2017),[34]PDI=Parent Development Interview (Aber et al., 1985), [35]PSS=Perceived Stress Scale (Cohen, Kamarck & Mermelstein,1983), [36]PAM=Parenting Alliance Measure (Abidin & Konold, 1999), [37]RAM=Relationship Attribution Measure (Finchman & Bradbury, 1992), [38]SDQ=Strengths and Difficulties Questionnaire (Goodman, 1997), [39]SIMS-PR=Security in the Marital-Subsystem Parent Report (Davies et

al, 2002), [40]PHQ-9=Patient Health Questionnaire (Spitzer, Kroenke & Williams, 1999), [41]MIO=Mothering from the Inside Out (Suchman & Bers, 2015), [42]PE=Parent Education, [43]BSI=Brief Symptom Inventory (Derogatis,1975),[44]WMCI=Working Model of the Child Interview (Zeanah & Benoit, 1993), [45]NCAST=Nursing Child Assessment Satellite Training (Barnard & Eyres, 1979), [46]SSP=Strange Situation Procedure (Ainsworth & Bell,1970), [47]CBP=Curiosity Box Paradign (Mayes, Carter & Stubbe,1993), [48]TFLB=Timeline Followback Interview (Sobell & Sobell,1992), BAI[49]=Beck Anxiety Inventory (Beck & Steer,1990) [50]CT=Cognitive Therapy, [51]HDRS=Hamilton Rating Scale for Depression (Hamilton, 1960), [52]WHO-5=Who Five Well-being Index (Bech, 2004),[53]SIPP-118=Severity Indices of Personality Problems (Verheur et al., 2008) [54]BPDSI=Borderline Personality Disorder Severity Index (Arntz, 1999), [55]OPD=Other Specialised Psychotherapeutic Treatment, [56]SPT=Short-Term Psychodynamic Treatment [57] TAS-20= Toronto Alexythimia Scale (Bagby et al.,1994), [58]HAM-A=Hamilton Anxiety Scale (Hamilton,1959) [59]HAM-D=Hamilton Depression Scale (Hamilton, 1960) [60]EDI=Eating Disorder Inventory (Garner,1991), [61]BES=Binge Eating Scale (Gormally et al.,1982) [62]BUT=Body Uneasiness test (Cuzzolaro et al.,2006) [63]CGI=Clinical Global Impression (Kadouri, Corruble & Falissard, 2007), [64]SASS=Social Adaptation Self-Evaluation Scale (Bosc, Dubini & Polin, 1997),[65]SF-12=Short-form Survey (Ware, Kosinski & Keller, 1996), [66]DES=Dissociative Experience Scale (Bernsteim & Putnam, 1986),[67]MBT-P=Mentalisation based treatment for parents, [68]MBT-I= Mentalisation based treatment (individual), [68]PAI=Personality Assessment Inventory (Morey & Suman 2008),[70]YSR=Youth Self Report (Achenbach,1991), [71]BDI-Y=Beck Depression Inventory for Youth (Beck, Beck & Jolly, 2005), [72]IPPA-R=Inventory of Parent and Peer Attachment-Revised (Armsden & Greenberg, 1987),[73]RFQ-Y=Reflective Functioning Questionnaire for Youth (Ha et al., 2013), [74]AMBIT=Adolescent Mentalisation-Based Integrative Treatment (Bevington et al., 2013), [75]WHOQOL= World Health Organisation Quality of life questionnaire (WHOQOL Group,1998), [76]PANSS=Positive and Negative Syndrome Scale (Kay, Fizbein & Opler, 1987), [77]BYI=Beck Youth Inventory (Beck et al., 2005), [78]WAIS-IV=Wechsler Adult Intelligence Scale Fourth Edition (Wechsler, 2010), [79]CANTAB=Cambridge Neuropsychological Test Automated Fray & Robbins,1998) [80]HVLT=Hopkins Verbal Learning Test, (Brandt, 1991), [81]PRE-REORG=Pre Reorganisation, [82]REOR=Reorganisation

Table 1.1

Summary of Primary Outcomes, Measures and Results

Study	Primary Outcomes	Measure	Results
Ramires, Schwan & Midgley (2012)	Depression	Children's Depression Inventory (CDI)	Reduction from 40 to 5
Morken,Karterud & Arefjord (2014)	General Psychopathology	Revised Symptom Checklist (SCL-90-R)	Reduction from 1.68 to 0.5
Bateman & Fonagy (1999;2008)	Depression	Beck Depression Inventory (BDI)	*F (1,45)*=32.6, *p*<.001
Bateman & Fonagy (2009;2016)	Depression	Beck Depression Inventory (BDI)	*d*=.45, 95%, *CI*=0.10-0.79
Rossouw & Fonagy (2012)	Self-harm	Risk taking and self-harm inventory (RTSHI)	Reduction favourable to MBT (p<.001)
Robinson et al., (2016)	BPD features, Eating disorder features	BPD Zanarini Scale, Eating Disorder Examination (EDE)	No significant differences in any scale (*p*>0.05).
Hertzmann et al., (2016)	Anger	Stat Trait Anger Expression Inventory (STAXI)	STAXI scores reduced at 3 months follow-up (ß =-2.94, SE=1.06, <=-2.77, p<..01)
Suchman et al., (2010)	Reflective Functioning, Caregiving Behaviours	Parent Development Interview (PDI)	Significantly (*p*<0.05) higher reflective functioning (*d*=.56) and caregiving behaviour scores (*d*=.41).

Study	Primary Outcomes	Measure	Results
Suchman et al., (2017)	Reflective Functioning, Caregiving Behaviours	Parent Development Interview (PDI)	Higher reflective functioning scores (*d*=.36), mental coherent representation scores (*d*=.41) and engagement with their children (*d*=.21)
Jørgensen et al., (2013;2014)	General Psychopathology, Depression	Revised Symptom Checklist (SCL-90-R) and Beck Depression Inventory (BDI)	Greater reduction of both in MBT (*p*<.0001).
Jakobsen et al., (2014)	Depression	Hamilton Depression Scale (HDRS)	Significant difference (*p*<.03) favouring third wave-CT therapy.
Laurenssen et al., (2014)	General Psychopathology	Brief Symptom Inventory (BSI)	Symptoms decreased significantly posttreatment (*p*<.001, *d*=1.46)
Bales et al., (2012)	Depression and General Psychopathology	Beck Depression Inventory (BDI) and Brief Symptom Inventory (BSI)	All improved during 18 months (*d*=.68 to 1.26)
Bales et al., (2015)	General Psychopathology	Brief Symptom Inventory (BSI) and General Symptom Inventory (GSI)	Large effects in the reduction of psychiatric symptoms (*d*=-.71 *d*=-.85 at posttreatment and follow-up respectively)
Balestrieri et al., (2015)	Eating Disorder Diagnosis	Structured Clinical Interview (SCID)	Only one client in the MBT group and two in the SPT group maintained diagnosis (x^2=.66; *p*<.042)

Study	Primary Outcomes	Measure	Results
Kvarstein et al., (2015)	Self-harm and Suicide Attempts	Medical Records, General Symptom Inventory (GSI)	Both groups showed reductions in self-harming (89% to 27% in MBT) and suicide attempts (35% to 6% in MBT).
Bo et al., (2016)	BPD features/symptoms	Borderline Personality Features Scale (BPFS)	Significant reductions in borderline symptoms ([BPFS-C], $p<.001$)
Griffiths et al., (2017)	Depression and Quality of Life	Beck Depression Inventory (BDI), WHO quality of life questionnaire (WHOQL)	Differences were significant for depression ($p<.05$), psychological quality of life
Thomsen et al., (2017)	BPD features	Zanarini BPD scale (ZAN-BPD)	Improvements in the ZAN-BPD $t(17)=5.19$, $p<.05$
Bales et al., (2017)	General Psychopathology	Brief Symptom Inventory (BSI), Revised Symptom Checklist (SCL-90-R)	All psychiatric symptoms improved ($ps<.05$).

Table 2

Risk of Bias Judgements

		Selection Bias			Performance Bias		Attrition Bias	Detection Bias			Reporting Bias
		Randomisation	Recruitment	Confounding	Fidelity	Concurrent Intervention	Attrition	Assessors Blinded	Self-report Outcomes	Clinician rated outcomes	Outcomes Reported
Study	Design										
Ramires et al., (2012)	Single case	N/A	−	−	+	+	+	?	+	+	N/A
Morken et al., (2014)	Single case	N/A	−	−	?	?	+	?	+	+	N/A
Bateman & Fonagy (1999)	RCT	?	+	−	−	+	+	?	+	−	?
Bateman & Fonagy (2009)	RCT	+	+	+	+	?	+	+	+	+	+
Rossouw & Fonagy (2012)	RCT	+	+	+	+	?	+	+	+	+	+
Robinson et al., (2016)	RCT	+	+	−	+	+	−	+	+	+	+
Hertzmann et al., (2016)	RCT	+	?	−	+	−	+	?	+	+	?
Suchman et al., (2010)	RCT	?	+	−	+	−	+	?	+	+	?
Suchman et al., (2017)	RCT	?	+	+	+	−	+	?	+	+	+
Jørgensen et al.,(2013)	Quasi-Experimental	?	+	−	−	+	−	−	+	+	+
Jakobsen et al., (2014)	Quasi-Experimental	+	+	−	+	+	+	+	+	−	+
Laurensen et al., (2014)	Uncontrolled pre-post	N/A	+	−	?	?	−	?	+	+	?
Bales et al., (2012)	Uncontrolled pre-post	N/A	?	?	+	−	+	?	+	+	?

		Selection Bias			Performance Bias		Attrition Bias	Detection Bias			Reporting Bias
		Randomisation	Recruitment	Confounding	Fidelity	Concurrent Intervention	Attrition	Assessors Blinded	Self-report Outcomes	Clinician rated outcomes	Outcomes Reported
Bales et al., (2015)	Uncontrolled pre-post	N/A	−	?	+	?	+	+	+	N/A	?
Balestrieri et al., (2015)	Uncontrolled pre-post	N/A	−	−	?	?	+	?	+	+	?
Kvarstein et al., (2015)	Retrospective cohort	N/A	−	−	+	?	−	?	+	+	?
Bo et al., (2016)	Uncontrolled pre-post	N/A	−	−	?	?	+	?	+	N/A	+
Griffiths et al., (2017)	Retrospective cohort	N/A	+	−	?	?	?	?	+	+	N/A
Thomsen et al., (2017)	Uncontrolled pre-post	N/A	−	−	+	?	?	?	+	+	+
Bales et al., (2017)	Retrospective cohort	N/A	+	+	?	?	+	+	+	+	?

Note. - Corresponds to a judgement of high risk; + corresponds to a judgement of low risk, ? represents that the judgement is unclear as there was not sufficient information, N/A corresponds to a judgment that did not apply, RCT=Randomised Control Trial, MBT=Mentalisation Based Treatment

Appendix 1-A: Data Extraction Form

Bibliographic information	
Publication year	
Country of origin	
Methods	
Study design	
Setting	
Intervention-Comparison Groups	
N total/ N MBT/ N control groups	
N total Attrition/ N attrition MBT/ N attrition control	
Follow-up months	
Inclusion/Exclusion Criteria	
Outcome Measures	
Mean Age, ethnicity and distribution of sex	
Clinical Presentation	
Inclusion/Exclusion Criteria	
Results	
MBT pre-outcomes	
MBT post outcomes	
MBT follow up	
Control follow-up	
Control pre-outcomes	
Control Post outcomes	
Implications of findings	

Appendix 1-B: Quality Assessment Checklist [2](Downs & Black, 1998; Trac et al., 2016[3])

	Ramires et al., (2012)	Morken et al., (2014)	Bateman & Fonagy (1999)[4]	Bateman & Fonagy (2009)[4]	Rossow & Fonagy (2012)	Robinson et al., (2016)[4]	Hertzmann et al., (2016)	Suchman et al., (2010)	Suchman et al., (2017)	Jørgensen et al., (2013)	Jakobsen et al., (2014)
1. Is the hypothesis/aim/objective of the study clearly described?	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2. Are the main outcomes to be measured clearly described in the Introduction or Methods section?	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
3.Are the characteristics of the patients included in the study clearly described ?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
4.Are the interventions of interest clearly described?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
5. Are the distributions of principal confounders in each group of subjects to be compared clearly described?	No	No	Yes	Yes	Yes	Yes	Partially	Yes	Yes	Yes	Partially
6. Are the main findings of the study clearly described?	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
7. Does the study provide estimates of the random variability in the data for the main outcomes?	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
8. Have all important adverse events that may be a consequence of the intervention been reported?	No	No	No	No No	No	Yes	No	No	Yes	Yes	No
9. Have the characteristics of patients lost to follow-up been described?	No	No	No	Yes	Yes	Yes	No	Yes	Yes	Yes	No
10. Have actual probability values been reported (e.g. 0.035 rather than <.05) for the main outcomes?	No	No	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes
External Validity											
11. Were the subjects asked to participate in the study representative of the entire population?	No	No	Yes	No	Yes	No	No	No	No	Unable	Unable
12. Were subjects prepared to participate representative of the population?	No	No	Yes	No	Unable	Unable	Unable	Unable	Unable	Unable	Unable
13. Were the staff, places, and facilities representative of the treatment the majority of patients?	No	No	Yes	Yes	Unable	Yes	Yes	Yes	Yes	Yes	Yes

Note Yes=1 point, except in question 5 is 2 points, Partially=1 point, Unable/No=0 points

[2]Further guidance on how to rate the Downs & Black (1998) scale can be found on http://jech.bmj.com/content/jech/52/6/377.full.pdf

[3] Question 27 was the only modified item by Trac et al., (2016) from the original Downs & Black (1998) checklist tool.

[4]Articles that were scored by an independent blind rater

Internal Validity-Bias											
14. Was an attempt made to blind study subjects to the intervention?	No	No	No	No	Yes	No	Unable	Unable	Unable	Unable	No
15. Was an attempt made to blind those measuring the main outcomes of the intervention?	No	No	No	No	Yes	Yes	Unable	Unable	Unable	Unable	Yes
16. If any of the results of were based on "data dredging", was this made clear?	N/A	N/A	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
17. In trials, do analyses adjust for different follow-ups, or in case-control, is the time period between the intervention and outcome the same?	N/A	N/A	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
18. Were the statistical tests appropriate?	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
19. Was compliance with the intervention/s reliable?	Yes	Yes	Unable	Yes	Yes	No	Yes	Yes	Yes	Unable	Yes
20. Were the main outcome measures used valid and reliable?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Internal Validity											
21. Were the patients in different intervention groups or were the cases and controls recruited from the same population?	Unable	Unable	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
22. Were study subjects in different intervention groups or were the cases and controls recruited over the same period of time?	No	No	Yes	Yes	No	No	Unable	Unable	Unable	Unable	Yes
23. Were study subjects randomised to intervention groups?	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
24. Was the randomised intervention assignment concealed from both patients and health care staff?	No	No	No	Yes	Yes	No	No	No	No	Unable	Unable
25. Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?	No	No	Yes	Yes	Yes	Yes	Unable	Yes	Yes	No	No
26. Were losses of patients to follow-up taken into account?	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Power											
27. Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%?	No	No	Unable	Unable	Yes	No	Unable	Unable	Unable	Unable	No
Total Score	**7**	**4**	**19**	**21**	**24**	**21**	**17**	**19**	**20**	**18**	**19**

	Laurenssen et al., (2014)	Bales et al., (2012)	Bales et al., (2015)	Balestrieri et al, (2015)	Kvarstein et al., (2015) [4]	Bo et al., (2016)	Griffiths et al., (2017)	Thomsen et al., (2017) [4]	Bales et al., (2017)
1. Is the hypothesis/aim/objective of the study clearly described?	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes
2. Are the main outcomes to be measured clearly described in the Introduction or Methods section?	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes
3.Are the characteristics of the patients included in the study clearly described ?	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
4.Are the interventions of interest clearly described?	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes
5. Are the distributions of principal confounders in each group of subjects to be compared clearly described?	Partially	Partially	Yes	Partially	Partially	No	No	Yes	Yes
6. Are the main findings of the study clearly described?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
7. Does the study provide estimates of the random variability in the data for the main outcomes?	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No
8. Have all important adverse events that may be a consequence of the intervention been reported?	No	No	No	No	No	No	No	No	No
9. Have the characteristics of patients lost to follow-up been described?	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes
10. Have actual probability values been reported (e.g. 0.035 rather than <.05) for the main outcomes?	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
External Validity									
11. Were the subjects asked to participate in the study representative of the entire population?	Unable	Unable	Unable	Unable	Unable	No	Yes	Unable	No
12. Were subjects prepared to participate representative of the population?	Unable	Unable	Unable	Unable	Unable	No	Unable	Unable	No
13. Were the staff, places, and facilities representative of the treatment the majority of patients?	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Internal Validity-Bias									
14. Was an attempt made to blind study subjects to the intervention?	No	No	No	No	No	No	No	No	No
15. Was an attempt made to blind those measuring the main outcomes of the intervention?	No	No	No	No	No	No	No	No	No
16. If any of the results of were based on “data dredging”, was this made clear?	Yes	Yes	Yes	Yes	Yes	Yes	Unable	Yes	Yes
17. In trials, do analyses adjust for different follow-ups, or in case-control, is the time period between the intervention and outcome the same?	Unable	Yes	Unable	Yes	Unable	Yes	Yes	Yes	Yes
18. Were the statistical tests appropriate?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes

19. Was compliance with the intervention/s reliable?	Unable	Yes	Unable	Unable	Yes	No	Yes	Unable	No
20. Were the main outcome measures used valid and reliable?	Unable	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Internal Validity									
21. Were the patients in different intervention groups or were the cases and controls recruited from the same population?	Yes	Unable	No	No	Yes	Yes	Yes	No	Yes
22. Were study subjects in different intervention groups or were the cases and controls recruited over the same period of time?	Yes	Yes	No	No	No	Yes	No	Unable	Yes
23. Were study subjects randomised to intervention groups?	No	No	No	No	No	No	No	No	No
24. Was the randomised intervention assignment concealed from both patients and health care staff?	No	No	No	No	No	No	No	No	No
25. Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?	Unable	Yes	Yes	Unable	Unable	No	No	No	Yes
26. Were losses of patients to follow-up taken into account?	No	Yes	Yes	No	Yes	No	No	Yes	Yes
Power									
27. Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%?	Unable	Unable	Unable	Unable	Unable	Unable	Unable	Unable	Unable
Total Score	**11**	**17**	**14**	**14**	**15**	**14**	**10**	**14**	**18**

Quality Assessment Checklist: Scores from an Independent Rater

	Bateman and Fonagy, 2009	Bateman and Fonagy, 1999	Kvarstein et al 2015	Robinson et al 2016	Thomsen et al. 2017
1. Is the hypothesis/aim/objective of the study clearly described?	1	1	1	1	1
2. Are the main outcomes to be measured clearly described in the Introduction or Methods section?	1	1	1	1	1
3.Are the characteristics of the patients included in the study clearly described?	1	1	1	1	1
4.Are the interventions of interest clearly described?	1	1	1	1	1
5. Are the distributions of principal confounders in each group of subjects to be compared clearly described?	2	1	0	2	1
6. Are the main findings of the study clearly described?	1	1	1	1	1
7. Does the study provide estimates of the random variability in the data for the main outcomes?	0	0	0	1	0
8. Have all important adverse events that may be a consequence of the intervention been reported?	0	0	0	1	0
9. Have the characteristics of patients lost to follow-up been described?	1	1	0	1	1
10. Have actual probability values been reported (e.g. 0.035 rather than <.05) for the main outcomes?	1	0	0	1	1
External Validity					
11. Were the subjects asked to participate in the study representative of the entire population?	0	0	0	1	0
12. Were subjects prepared to participate representative of the population?	1	1	1	1	1
13. Were the staff, places, and facilities representative of the treatment the majority of patients?	0	1	0	0	0
Internal Validity-Bias					
14. Was an attempt made to blind study subjects to the intervention?	0	0	0	0	0
15. Was an attempt made to blind those measuring the main outcomes of the intervention?	1	0	0	1	0
16. If any of the results of were based on “data dredging”, was this made clear?	1	1	1	1	1
17. In trials, do analyses adjust for different follow-ups, or in case-control, is the time period between the intervention and outcome the same?	1	1	0	1	1

18. Were the statistical tests appropriate?	1	1	1	1	1
19. Was compliance with the intervention/s reliable?	0	0	0	1	0
20. Were the main outcome measures used valid and reliable?	1	1	1	1	1
Internal Validity					
21. Were the patients in different intervention groups or were the cases and controls recruited from the same population?	1	1	1	1	1
22. Were study subjects in different intervention groups or were the cases and controls recruited over the same period of time?	1	1	0	1	1
23. Were study subjects randomised to intervention groups?	1	1	0	1	0
24. Was the randomised intervention assignment concealed from both patients and health care staff?	0	0	0	0	0
25. Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?	1	1	1	1	0
26. Were losses of patients to follow-up taken into account?	1	1	0	1	0
Power					
27. Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%?	**1**	**1**	**1**	**1**	**0**
Total Score	**21**	**19**	**12**	**25**	**15**

Appendix 1-C: Risk of Bias Judgements [4]

Ramires et al., (2012)		
Risk of Bias	**Judgement**	**Risk**
Selection Bias	Randomisation: Non-randomised study	N/A
	Recruitment: Explained that it was one of 14 but not explained differences with other cases or why this case chosen.	High
	Confounding: Confounding factors not reported.	High
Performance Bias	Intervention Fidelity: Therapy conducted by a trained therapist with 5 years of experience. Sessions were recorded and supervised by experienced therapists (>25 years) according to MBT principles.	Low
	Concurrent Intervention: No concurrent interventions were described.	Low
Attrition Bias	No attrition	Low
Detection Bias	Assessors blinded: Not reported	Unclear
	Self-reported outcomes: The outcome used was valid and reliable and used in a wide range of countries.	Low
	Clinician rated outcomes: The measure used was reliable and validated internationally.	Low
Reporting Bias	Not applicable	N/A
Morken et al., (2014)		
Risk of Bias	**Judgement**	**Risk**
Selection Bias	Randomisation: Non-randomised study	N/A
	Recruitment: Criteria why this case was chosen is not specified	High
	Confounding: Confounding factors not reported.	High
Performance Bias	Intervention Fidelity: Not reported	Unclear
	Concurrent Intervention: No concurrent intervention but substance abuse disorder (SUD) principles included	Unclear

[4] Further guidance on how to judge risk of bias can be found on https://effectivehealthcare.ahrq.gov/topics/methods-guidance-bias-individual-studies/methods/

Risk of Bias	Judgement	Risk
Attrition Bias	No attrition	Low
Detection Bias	Assessors blinded: Not reported	Unclear
	Self-reported outcomes: The outcome measures were valid and reliable	Low
	Clinician rated outcomes: The semi-structured, clinician rated measures were valid and reliable	Low
Reporting Bias	Not Applicable	N/A

Bateman & Fonagy (1999)

Risk of Bias	Judgement	Risk
Selection Bias	Randomisation: Not described clearly	Unclear
	Recruitment: All participants recruited from the same population. Source population described	Low
	Confounding: Baseline characteristics were introduced as covariates. Control group lacked coherence, included different interventions	High
Performance Bias	Intervention Fidelity: All interventions conducted by nurses with no formal psychotherapy qualifications. Did not follow manual.	High
	Concurrent Intervention: Participants could not receive any psychiatric or psychological intervention elsewhere.	Low
Attrition Bias	Three participants in treatment condition dropped out and three in the control group crossed over. Analyses showed non-significant differences compared with the rest of participants. Reasons were described.	Low
Detection Bias	Assessors blinded: Not reported	Unclear
	Self-reported outcomes: The self-report instruments were valid and reliable	Low
	Clinician rated outcomes: Non-validated semi-structured interview to determine self-harm and suicide attempts.	High
Reporting Bias	Protocol for the trial not published	Unclear

Bateman & Fonagy (2009)

Risk of Bias	Judgement	Risk
Selection Bias	Randomisation: Used stochastic minimisation program balancing for age, gender and presence of antisocial personality disorder	Low
	Recruitment: All participants recruited from the same hospital	Low
	Confounding: Covariates that could influence results based on previous literature were included in the analyses.	Low
Risk of Bias	**Judgement**	**Risk**
Performance Bias	Intervention Fidelity: Manualised MBT and adherence scales available upon request	Low

	Concurrent Intervention: No concurrent interventions described.	Unclear
Attrition Bias	99 participants of 134 completed treatment. Analyses were conducted following intention to treat principle. No significant differences between completers across the groups.	Low
Detection Bias	Assessors blinded: Assessors were blinded	Low
	Self-reported outcomes: The self-report instruments were valid and reliable	Low
	Clinician rated outcomes: Validated semi-structured interview	Low
Reporting Bias	All outcomes reported	Low

Rossouw & Fonagy (2012)

Risk of Bias	**Judgement**	**Risk**
Selection Bias	Randomisation: Independent statistician randomised participants using minimisation algorithm	Low
	Recruitment: Consecutive service users who presented with self-harming in community mental health care	Low
	Confounding: Baseline characteristics and number of clinical contact between groups did not differ significantly.	Low
Performance Bias	Intervention Fidelity: Manualised MBT-A and adherence scales available online. 22 therapists received six days MBT adolescent (MBT-A) training.	Low
	Concurrent Intervention: No concurrent interventions described.	Unclear
Attrition Bias	37 out of 80 participants completed treatment. No differences between groups. Analyses followed intention to treat principle.	Low
Detection Bias	Assessors blinded: Blinded to allocation	Low
	Self-reported outcomes: The self-report instruments were valid and reliable.	Low
	Clinician rated outcomes: Validated semi-structured interview to determine BPD symptoms in adolescence	Low
Reporting Bias	All outcomes reported	Low

Robinson et al., (2016)

Risk of Bias	**Judgement**	**Risk**
Selection Bias	Randomisation: Block randomisation stratified by BMI. Randomly varying block sizes were also implemented	Low
	Recruitment: Multi-centre study across three eating disorder and two personality disorder units. Strategy clearly described.	Low
	Confounding: Participants with BMI of less than 15 were excluded, potential confounder. Offered financial incentive to those completing follow-up questionnaires.	High

Performance Bias	Intervention Fidelity: Manualised MBT-ED and SCM-ED. Random recorded and transcribed sessions rated independently with MBT adherence scale.	Low
	Concurrent Intervention: Not allowed	Low
Attrition Bias	Out of 68 participants, 53 dropped out by 18 months	High
Detection Bias	Assessors blinded: Single blind (researchers and statisticians are blind)	Low
	Self-reported outcomes: The self-report instruments were valid and reliable.	Low
	Clinician rated outcomes: Mini International Neuropsychiatric Schedule and Adult Service Use Schedule valid and reliable.	Low
Reporting Bias	All outcomes reported	Low

Hertzmann et al., (2016)

Risk of Bias	Judgement	Risk
Selection Bias	Randomisation: Randomly allocated using minimisation criteria.	Low
	Recruitment: Different sources of referral including, solicitors, court judges and mediators. Strategy of recruitment unclear.	Unclear
	Confounding: No differences between groups in baseline characteristics. Ethnicity and socio-economic status were not reported. Number of significant differences between groups regarding number of sessions, and present or absence of the other parent in the session	High
Performance Bias	Intervention Fidelity: Manualised MBT for parental conflict (MBT-PT). MBT adherence scales were used.	Low
	Concurrent Intervention: More than half of the sample was receiving help or support elsewhere	High
Attrition Bias	3 participants out of 30 did not complete the post-treatment assessments.	Low
Detection Bias	Assessors blinded: Not reported	Unclear
	Self-reported outcomes: The instruments were valid and reliable.	Low
	Clinician rated outcomes: Valid and reliable semi-structured interviews	Low

Risk of Bias	Judgement	Risk
Reporting Bias	Not clear whether outcomes were reported a priori	Unclear

Suchman et al., (2010)

Risk of Bias	Judgement	Risk
Selection Bias	Randomisation: Process not described	Unclear
	Recruitment: Mothers enrolled in substance misuse treatment. Referrals from different professionals and recruited from same population.	Low
	Confounding: No differences between groups in baseline demographic and psychiatric characteristics apart from marital status. Mothers that were suicidal or disengaged from treatment were not included. Differences in number of clinical contacts between groups not reported.	High
Performance Bias	Intervention Fidelity: Manualised MBT for mothers with substance misuse difficulties and manualised parent education group (PE). Adherence scales were developed and used by independent raters. 4 therapists: 2 doctorate and 2 masters level provided therapy	Low
	Concurrent Intervention: Participants had access to CBT, counselling and substance misuse treatment among others	High
Attrition Bias	All analyses were conducted following intention to treat principle. 72% of the participants completed the intervention in both conditions.	Low
Detection Bias	Assessors blinded: Not reported	Unclear
	Self-reported outcomes: The instruments were valid and reliable.	Low
	Clinician rated outcomes: Valid and reliable instruments	Low
Reporting Bias	Not clear whether a prior outcomes were established	Unclear

Suchman et al., (2017)

Risk of Bias	Judgement	Risk
Selection Bias	Randomisation: Process not described	Unclear
	Recruitment: Mothers enrolled in substance misuse treatment. Both groups recruited from same population.	Low
	Confounding: No significant baseline differences in maternal, paternal or target children characteristics.	Low
Performance Bias	Intervention Fidelity: Manualised MBT for mothers with substance misuse difficulties and manualised PE. Adherence scales were and by independent raters.	Low
	Concurrent Intervention: Participants had access to substance misuse specialised treatment	High
Attrition Bias	Analyses following intention to treat principle.17/87-randomised participants did not start treatment and 3 dropped out during treatment.	Low
Risk of Bias	**Judgement**	**Risk**
Detection Bias	Assessors blinded: Not reported	Unclear
	Self-reported outcomes: The instruments were valid and reliable.	Low
	Clinician rated outcomes: Valid and reliable instruments	Low
Reporting Bias	All outcomes reported	Low

Jørgensen et al., (2013)		
Risk of Bias	**Judgement**	**Risk**
Selection Bias	Randomisation: Method not described	Unclear
	Recruitment: All participants recruited from the same population.	Low
	Confounding: Both treatments were conducted in the same clinic and by the same therapists. Baseline significant differences between groups in social security and axis I comorbidity.	High
Performance Bias	Intervention Fidelity: MBT and supportive psychotherapy were not manualised.	High
	Concurrent Intervention: No psychological intervention. All participants accessed a psycho educational program and medical treatment.	Low
Attrition Bias	85 participants out of 111 initiated treatment and 58 finished it. At follow-up data of 43 participants was available	High
Detection Bias	Assessors blinded: Not blinded	High
	Self-reported outcomes: The instruments were valid and reliable.	Low
	Clinician rated outcomes: Valid and reliable instruments.	Low
Reporting Bias	All outcomes reported	Low

Jakobsen et al., (2014)		
Risk of Bias	**Judgement**	**Risk**
Selection Bias	Randomisation: Generated block randomisation sequence unknown to the researchers.	Low
	Recruitment: All participants recruited from the same public psychiatric outpatient clinic during the same period of time	Low
	Confounding: One of the cognitive therapists was the principal investigator (researcher allegiance). Analyses adjusted for baseline differences between groups.	High
Risk of Bias	**Judgement**	**Risk**
Performance Bias	Intervention Fidelity: External assessors for treatment adherence of both MBT and third-wave cognitive therapy	Low
	Concurrent Intervention: Not reported	Low
Attrition Bias	0/22 participants dropped out of cognitive therapy and 2/22 participants were lost in the MBT group	Low
Detection Bias	Assessors blinded: Interviewers were blinded	Low
	Self-reported outcomes: The instruments were valid and reliable.	Low
	Clinician rated outcomes: Lack of reliable/valid clinican rated instruments	High

Reporting Bias	All outcomes reported	Low

Laurenssen et al., (2014)

Risk of Bias	Judgement	Risk
Selection Bias	Randomisation: Non-randomised study	N/A
	Recruitment: All participants recruited from the same hospital and referrals clearly described.	Low
	Confounding: Sample consisted entirely of adolescent girls, ethnicity was not reported, most of them going to school	High
Performance Bias	Intervention Fidelity: Adherence not reported although adherence scale used	Unclear
	Concurrent Intervention: Not reported	Unclear
Attrition Bias	2/15 dropped out of treatment and 2/13 did not complete posttreatment questionnaires. 4 out of 15 participants (26%) not included in analyses	High
Detection Bias	Assessors blinded: Unclear	Unclear
	Self-reported outcomes: The instruments were valid and reliable.	Low
	Clinician rated outcomes: Semi-structured validated interviews.	Low
Reporting Bias	A priori established outcomes not clear.	Unclear

Bales et al., (2012)

Risk of Bias	Judgement	Risk
Selection Bias	Randomisation: Non-randomised study	N/A
	Recruitment: All participants recruited from the same hospital. Clinicians referred the most severe "clients" to MBT program.	Unclear
	Confounding: Gender and age included as covariates in the analyses. Ethnicity is not reported and is potential confounder	Unclear
Performance Bias	Intervention Fidelity: Eight therapists with varying degree of experience, from junior psychologist to experienced clinical psychologists. Tapes sessions were regularly rated using MBT adherence scales	Low
	Concurrent Intervention: Between 13% and 16% of participants had additional treatments but these were not specified.	High
Attrition Bias	7 participants dropped out. Four left the treatment prematurely and three were discharged due to criminal activities. Their data was included in the analyses.	Low

Detection Bias	Assessors blinded: Unclear	Unclear
	Self-reported outcomes: The instruments were valid and reliable.	Low
	Clinician rated outcomes: Semi-structured validated interviews.	Low
Reporting Bias	No information regarding a priori established outcomes	Unclear

Bales et al., (2015)

Risk of Bias	Judgement	Risk
Selection Bias	Randomisation: Non-randomised study	N/A
	Recruitment: Participants in the MBT and in the matched control group were recruited from different settings/hospitals.	High
	Confounding: Five participants of the 41 invited for assessment could not be interviewed due to staff problems and thus did not participate. Their characteristics were not described. MBT and control participants were matched according to pre-treatment variables that were deemed potential confounders.	Unclear
Performance Bias	Intervention Fidelity: Therapists ranging in experience from junior psychologists to experienced psychotherapists. MBT adherence scale used.	Low
	Concurrent Intervention: No concurrent interventions were described.	Unclear
Attrition Bias	Attrition not reported but analyses were performed on the intention to treat sample	Low
Detection Bias	Assessors blinded: Independent raters conducted assessments	Low
	Self-reported outcomes: The outcome measures were valid and reliable.	Low
	Clinician rated outcomes: Not used	N/A
Risk of Bias	**Judgement**	**Risk**
Reporting Bias	No information regarding a priori established outcomes	Unclear

Balestrieri et al., (2015)

Risk of Bias	Judgement	Risk
Selection Bias	Randomisation: Non-randomised study	N/A
	Recruitment: Participants in the MBT and in the short-term psychodynamic treatment group recruited from two different settings.	High
	Confounding: Participants with substance and alcohol addiction excluded, potential confounding	High
Performance Bias	Intervention Fidelity: Not reported	Unclear
	Concurrent Intervention: No concurrent interventions were described.	Unclear

Attrition Bias	5/12 in MBT and 6/12 in short-term psychodynamic group dropped out the treatment. Those who drop out where not significantly different in demographic and clinical characteristics.	Low
Detection Bias	Assessors blinded: Not described	Unclear
	Self-reported outcomes: The outcome measures were valid and reliable.	Low
	Clinician rated outcomes: Well validated and reliable	Low
Reporting Bias	No information regarding a priori published protocol	Unclear

Kvarstein et al., (2015)

Risk of Bias	**Judgement**	**Risk**
Selection Bias	Randomisation: Non-randomised study	N/A
	Recruitment: All participants recruited from the same setting but where recruited over different years. Exclusion criteria not described	High
	Confounding: Participants received different treatment length and intensity in the different groups. Predictor analyses controlled for baseline variation.	High
Performance Bias	Intervention Fidelity: MBT was rated with adherence scale	Low
	Concurrent Intervention: No concurrent interventions were described.	Unclear

Risk of Bias	**Judgement**	**Risk**
Attrition Bias	Drop out defined as finishing treatment before the end of 3 months. 15% in psychodynamic group and 2% in MBT group dropped out. Drop outs continued as treatment advanced but characteristics of those who dropped out are not described.	High
Detection Bias	Assessors blinded: Not described	Unclear
	Self-reported outcomes: The outcome measures were valid and reliable.	Low
	Clinician rated outcomes: Well validated and reliable	Low
Reporting Bias	No information regarding a priori established outcomes	Unclear

Bo et al., (2016)

Risk of Bias	**Judgement**	**Risk**
Selection Bias	Randomisation: Non-randomised study	N/A
	Recruitment: Participants were recruited from three different clinics. 18 participants met criteria but chose not to participate. No reasons were given for this.	High

	Confounding: Anorexia, substance misuse and parents who were not willing to be involved in family treatment were exclusion criteria, potential confounders.	High
Performance Bias	Intervention Fidelity: No adherence scales were employed, but fidelity to the manual assessed through supervision	Unclear
	Concurrent Intervention: No concurrent interventions were described.	Unclear
Attrition Bias	9 participants dropped out before completion. No significant differences between completers and non-completers in any measured variables.	Low
Detection Bias	Assessors blinded: Not described	Unclear
	Self-reported outcomes: The outcome measures were valid and reliable and translated into Danish.	Low
	Clinician rated outcomes: All instruments were self-report based.	N/A
Reporting Bias	All outcomes were reported.	Low

Griffiths et al., (2017)

Risk of Bias	**Judgement**	**Risk**
Selection Bias	Randomisation: Non-randomised study	N/A
	Recruitment: Source population described. All data corresponded to three different teams within the same service.	Low
	Confounding: Baseline demographic characteristics were controlled for in the analyses. Different services used different self-report measures within the same study.	High
Performance Bias	Intervention Fidelity: Staff trained in the MBT systemic model (AMBIT) for 4 days. Adherence was not reported.	Unclear
	Concurrent Intervention: No concurrent interventions were described.	Unclear
Attrition Bias	Data did not correspond to psychotherapy but to a multimodal organisational approach. 80% of attendance for the appointments offered. Clinical differences between those who engaged more and those who engaged less described.	Unclear
Detection Bias	Assessors blinded: Not described	Unclear
	Self-reported outcomes: The outcome measures were valid and reliable	Low
	Clinician rated outcomes: Not reported	Low
Reporting Bias	Not applicable	N/A

Thomsen et al., (2017)

Risk of Bias	Judgement	Risk
Selection Bias	Randomisation: Non-randomised study	N/A
	Recruitment: MBT participants and controls were recruited from different sources	High
	Confounding: MBT participants were matched to non-psychiatric controls on parental education. The intervention group was heterogeneous with some participants receiving only group therapy, others receiving only individual therapy and others receiving both. Ethnicity was not reported.	High
Performance Bias	Intervention Fidelity: MBT intervention was conducted according to manualised principles.	Low
	Concurrent Intervention: Parental group therapy and psychoeducation groups were offered	Unclear
Attrition Bias	4/18 participants in the MBT group did not finish the treatment. Only 28/56 controls were re-contacted and reasons were not described.	Unclear
Detection Bias	Assessors blinded: Not described	Unclear
	Self-reported outcomes: The CANTABB might not measure adequately response inhibition	High
	Clinician rated outcomes: valid and reliable	Low
Reporting Bias	All outcomes are reported	Low

Bales et al., (2017)

Risk of Bias	Judgement	Risk
Selection Bias	Randomisation: Non-randomised study	N/A
	Recruitment: Both groups from the same service. Participants consecutively referred.	Low
	Confounding: No significant differences between the two cohorts at baseline	Low
Performance Bias	Intervention Fidelity: Both cohorts received 18 months of manualised MBT. Adherence was monitored qualitatively.	Unclear
	Concurrent Intervention: Not reported	Unclear
Attrition Bias	11 eligible participants did not take part. No dropouts during the treatment reported. Analyses performed following intention to treat principle.	Low
Detection Bias	Assessors blinded: Assessment conducted by treatment independent assessors	Low
	Self-reported outcomes: The outcome measures were valid and reliable	Low
	Clinician rated outcomes: low risk of bias	Low
Reporting Bias	Not clear if outcomes were a priori established	Unclear

Appendix 1-D: Guidelines for Authors

Journal: Psychology and Psychotherapy: Theory, Research and Practice

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Author Guidelines

Psychology and Psychotherapy: Theory Research and Practice (formerly The British Journal of Medical Psychology) is an international scientific journal with a focus on the psychological aspects of mental health difficulties and well-being; and psychological problems and their psychological treatments. We welcome submissions from mental health professionals and researchers from all relevant professional backgrounds. The Journal welcomes submissions of original high quality empirical research and rigorous theoretical papers of any theoretical provenance provided they have a bearing upon vulnerability to, adjustment to, assessment of, and recovery (assisted or otherwise) from psychological disorders. Submission of systematic reviews and other research reports, which support evidence-based practice, are also welcomed, as are relevant high quality analogue studies. The Journal thus aims to promote theoretical and research developments in the understanding of cognitive and emotional factors in psychological disorders, interpersonal attitudes, behaviour and relationships, and psychological therapies (including both process and outcome research) where mental health is concerned. Clinical or case studies will not normally be considered except where they illustrate particularly unusual forms of psychopathology or innovative forms of therapy and meet scientific criteria through appropriate use of single case experimental designs.

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• Qualitative papers: 6000 words

• Review papers: 6000 words
• Special Issue papers: 5000 words

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These should be limited to 1000 words and may include research studies and theoretical, critical or review comments whose essential contribution can be made briefly. A summary of not more than 50 words should be provided.

4. Submission and reviewing

All manuscripts must be submitted via Editorial Manager. The Journal operates a policy of anonymous (double blind) peer review. We also operate a triage process in which submissions that are out of scope or otherwise inappropriate will be rejected by the editors without external peer review to avoid unnecessary delays. Before submitting, please read the terms and conditions of submission and the declaration of competing interests. You may also like to use the Submission Checklist to help you prepare your paper. If you need more information about submitting your manuscript for publication, please email Melanie Seddon, Senior Editorial Assistant at papt@wiley.com or phone +44 (0) 1243 770 108

5. Manuscript requirements

• Contributions must be typed in double spacing with wide margins. All sheets must be numbered.

•Manuscripts should be preceded by a title page which includes a full list of authors and their affiliations, as well as the corresponding author's contact details. You may like to use this template. When entering the author names into Editorial Manager, the corresponding author will be asked to provide a CRediT contributor role to classify the role that each author played in creating the manuscript. Please see the Project CRediT website for a list of roles.
• The main document must be anonymous. Please do not mention the authors' names or affiliations (including in the Method section) and refer to any previous work in the third person.

• Tables should be typed in double spacing, each on a separate page with a self-explanatory title. Tables should be comprehensible without reference to the text. They should be placed at the end of the manuscript but they must be mentioned in the text.

• Figures can be included at the end of the document or attached as separate files, carefully labelled in initial capital/lower case lettering with symbols in a form consistent with text use. Unnecessary background patterns, lines and shading should be avoided. Captions should be listed on a separate sheet. The resolution of digital images must be at least 300 dpi. All figures must be mentioned in the text.

• For articles containing original scientific research, a structured abstract of up to 250 words should be included with the headings: Objectives, Design, Methods, Results, Conclusions. Review articles should use these headings: Purpose, Methods, Results, and Conclusions.

• All Articles must include Practitioner Points – these are 2-4 bullet points, in addition to the abstract, with the heading 'Practitioner Points'. These should briefly and clearly outline the relevance of your research to professional practice.

• For reference citations, please use APA style. Particular care should be taken to ensure that references are accurate and complete. Give all journal titles in full and provide DOI numbers where possible for journal articles.

• SI units must be used for all measurements, rounded off to practical values if appropriate, with the imperial equivalent in parentheses.

• In normal circumstances, effect size should be incorporated.

• Authors are requested to avoid the use of sexist language.

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6. Multiple or Linked submissions

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2. Section Two: Research Paper

Examining Mentalisation Ability in Caregivers of Asthmatic Children

Malda-Castillo, Javier
Trainee Clinical Psychologist
Division of Health Research
Lancaster University

Correspondence should be addressed to:

Javier Malda-Castillo
Clinical Psychology
Lancaster University
Lancaster
LA1 4YG
Tel: +44 07514267419
Email: j.maldacastillo@lancaster.ac.uk

Target Journal: *Development and Psychopathology*

Abstract

Background: The burden of caregiving for a child with asthma has long been documented worldwide. Caregivers of asthmatic children often report depressive and anxiety symptoms, low quality of life, demoralisation or high stress. To date, no study has explored the relationship between mentalising capacity and the mental health of caregivers of asthmatic children. **Method:** Caregivers of children with asthma residing in the United Kingdom (UK) were recruited using an online-designed survey. Participants recruited from social media support groups and the Asthma UK charity research bulletin completed self-report measures of mentalising (Reflective Functioning Questionnaire,RFQ-8), family functioning (Family Assessment Device, FAD) mood (7up and 7Down questionnaire, 7U7D) and anxiety (Beck Anxiety Inventory, BAI) difficulties. **Results:** A total of 88 participants completed the full survey. Results indicated that poorer mentalising capacity was significantly associated with poorer family functioning and increased mood and anxiety symptomatology. Mentalising was a significant predictor in all the regression models for depression, hypomania and anxiety, explaining 16% of variance in depression and 10% of variance in anxiety, whereas family functioning was not a significant predictor in any of the regression models after mentalising was included. Greater mentalising capacity was significantly associated with a reduction in mood and anxiety scores. **Conclusions:** These findings suggest that mentalising capacity might be a better predictor of the mental health of caregivers of asthmatic children than previously identified factors such as family functioning, asthma severity or income. Further investigation into the role of mentalising in the mental health of this population is warranted.

Key words: caregivers, asthma, children, mentalising, mental health

Have you ever unexpectedly started coughing, struggled to breathe or felt a tight chest? These are common symptoms of an asthma attack (British Lung Foundation, 2016). Imagine that the person experiencing these symptoms is a child. This scary situation would probably mobilise the family environment, and its satisfactory resolution may depend on the resilience of the child and the ability of the caregivers to understand the problem and provide a reliable response. Paradoxically, the incessant repetition of such a situation could increase the stress in the family unit and affect caregivers' mood and morale (Fagnano, Berkman, Wiesenthal, Butz & Halterman, 2012; Reyes et al., 2011).

Although its causes are still not well understood (Lazarus, 2010; Yangzong et al., 2012), asthma is one of the most common chronic diseases worldwide and is characterised by inflammation of the air passages, which can lead to several recurring symptoms such as wheezing, shortness of breath or difficulties in sleeping, among others (Global Initiative for Asthma, 2017). During the last two decades, the prevalence of childhood asthma has increased globally (Manning, Goodman, O'Sullivan & Clancy, 2007), and over one million children are currently receiving asthma treatment in the United Kingdom (UK) (National Health Service, 2017). The International Study of Asthma and Allergies in Childhood (ISAAC), the biggest epidemiological research study concerning asthma prevalence worldwide (Asher et al., 2006), showed that the prevalence of asthma in children living in the UK aged 13–14 was 24.7% and was 20.9% for children in the six to seven age group. This and further research have confirmed that the prevalence of childhood asthma in the UK constitutes one of the highest worldwide (British Lung Foundation, 2016; Mallol et al., 2013; Mukherjee et al., 2014).

There is a significant burden associated with asthma in the UK and in other Western countries, such as the United States (US), with extensive literature reporting on the negative economic effects of asthma in relation to healthcare, research, early mortality and partial or

permanent disability, among others (Gupta, Sheikh, Strachan & Anderson, 2004; Nunes, Pereira & Morais-Almeida, 2017). In the UK, the treatment and management costs of the illness have been estimated to be as high as one billion pounds annually (Asthma UK, 2016; Mukherjee et al., 2014). Although both the direct (visit to emergency services, medication, health consultations, etc.) and indirect (work/school days missed, disability, mortality, etc.) financial costs of asthma have been systematically studied and reported, this has not been carried out with respect to intangible costs, such as quality of life or psychological distress (Nunes et al., 2017).

Despite the scarce quantification of the intangible negative impact of asthma, previous research has identified that children with asthma are prone to experiencing psychological difficulties (McQuaid, Kopel & Nassau, 2001; Tibosch, Verhaak & Merkus, 2011). Similarly to other chronic diseases, asthma not only has an impact on those who experience it, but can also often pose a burden on caregivers (Easter, Sharp & Hunt, 2015). In fact, the mental health of asthma caregivers has captured the interest of researchers, as evidenced by the growing number of papers published on the topic in the last decade (Bellin et al., 2013; Fagnano et al., 2012; Halterman et al., 2004; Yamamoto & Nagano, 2015; Zhou, Yi, Zhang & Wang, 2014). In a recent systematic review and meta-analysis, Easter et al. (2015) concluded that caregivers of children with asthma reported higher prevalence of anxiety and depressive symptoms than caregivers of children without medical diagnoses.

In fact, several cross-sectional studies have suggested that caregivers of asthmatic children report more depressive symptoms (Bartlett et al., 2001; Brehaut et al., 2009; Fagnano et al., 2012) than caregivers of children without physical or mental health difficulties. In addition, previous research has also reported that caregivers of asthmatic children can experience high levels of perceived stress (Lange et al., 2011), low quality of life (Cerdan, Alpert, Moonie, Cyrkiel, & Rue, 2012; Halterman et al., 2004), maternal

demoralisation (Reyes et al., 2011) and reduced family functioning (Zhou et al., 2014). Given that mental health difficulties among caregivers of children with asthma are associated with poorer asthma outcomes (Bartlett et al., 2001; Tibosch et al., 2011), understanding the nature of this phenomenon is highly relevant. In fact, previous research has showed that caregivers' anxiety and depression predicts the incidence of asthma symptoms in their children (Martínez, Pérez, Ramírez, Canino & Rand, 2009).

As discussed earlier, family functioning would very likely impact on the resources available when responding to asthma episodes. Family functioning refers to the complex interaction between different qualities, such as family support, conflict resolution mechanisms, cohesion and adaptability (Lewandowski, Palermo, Stinson, Handley & Chambers, 2010). In fact, Sato et al. (2013) reported that children living in families who used ineffective responses to manage their asthma symptoms had poorer asthma outcomes. Furthermore, it has been suggested that family functioning can act as a mediator in the negative association between socio-economic status and the mental health of caregivers of asthmatic children (Zhou et al., 2014).

Because childhood asthma requires that caregivers respond effectively to the medical and emotional demands of the illness (Gibson-Young, Turner-Henson, Gerald, Vance & Lozano, 2014), poor family functioning could hinder such caregiving responses. Conversely, high levels of family functioning could facilitate caregivers to be able to make the necessary psychological adjustments (Drotar, 1997; Thompson, Gustafson, Hamlett & Spock, 1992) to respond flexibly and adaptively to the demands of a chronic illness like asthma.

Similarly, attachment theory (Bowlby, 1969) can offer an understanding of individual responses to stressful situations (Mikulincer & Shaver, 2012), such as caregiving for a child with asthma. Previous studies have suggested that mothers of children with asthma can display overprotective and anxious attachment styles

(Cassibba, van IJzendoorn, Bruno & Coppola, 2004; Hermanns, Florin, Dietrich, Rieger & Hahlweg, 1989; Madrid & Schwartz, 1991; Peri, Molinary & Taverna, 1991; Ravaccia & Fiorentini, 1997; Scobinger, Florin, Reichbauer, Lindemann & Zimmer, 1993; Tambelli, Zavattini & Pradarelli, 1993), which are associated with a higher risk of developing mental health difficulties (Mikulincer & Shaver, 2012).

In addition, there is some evidence that parental attachment style is a strong predictor of children's attachment style (Fonagy, Steele & Steele, 1995; Obegi, Morrison & Shaver, 2004; van IJzendoorn, 1995). Thus, understanding the ability of caregivers to model secure attachment patterns could have immediate and practical implications in supporting caregivers of asthmatic children, especially considering that they are responsible for dealing sensitively with the emotional and physical needs of their children (Easter et al., 2015; McQuaid et al., 2001). This necessary sensitivity of caregivers in order to promptly respond to their children's needs is closely linked with the concept of mentalisation (Meins, Fernyhough, Fradley & Tuckey, 2001; Sadler et al., 2013).

Mentalisation emerged over two decades ago in the context of understanding attachment interactions between parents and babies (Camoirano, 2017; Fonagy, Steele, Steele, Moran & Higgit, 1991). Fonagy (1989) first described it as an ability that allows awareness of one's own and others' mental states, which in turn facilitates the understanding of behaviours, intentions, thoughts and feelings.

Arguably, mentalisation and attachment are intertwined and cannot fully be separated. Mentalising is a key element of attachment interactions because it allows parents to develop alternative understandings of their children's needs, which in turn helps to provide them with attuned responses (Fonagy et al., 1991). Through this attachment process, and with the aid of mentalising ability, parents should be able to

provide their children with more insight into their internal world, including their emotional and physical needs. Caregivers' mentalising ability should be a tool that helps the children understand the connection between feelings, thoughts and behaviours (Claydon, Zerwas, Callinan & Smith, 2016). This enables contextualising behaviours as well as increasing their predictability.

Thus, whilst robust mentalising is associated with secure attachment and resilient responses in the face of stress (Bateman & Fonagy, 2013; Fonagy, Gergely, Jurist & Target, 2002), difficulties in mentalising among caregivers has been associated with disruptive communications with their children (Grienenberger, Kelly & Slade, 2005). Therefore, higher levels of mentalising may help caregivers cope with the demands and the uncertainty that a chronic disease such as asthma poses. An enhanced ability to make sense of their children's feelings and desires could help caregivers respond sensitively to the physical and emotional needs of the disease, which could in turn alleviate the children's suffering and subsequently reduce the stress that asthma may pose in the family unit. In fact, Grienenberger et al. (2005) suggested that maternal mentalising could reduce the risk of affect dysregulation among caregivers when their children were feeling distressed. In contrast, reduced levels of mentalising could place caregivers at an increased risk of being overwhelmed by the demands of asthma, feeling anxious or experiencing mood difficulties, which could in turn reduce their ability to respond adequately to the physical and emotional needs of their children. Noteworthy research published to date has not explored this construct with respect to caregivers of asthmatic children.

Given that mentalising is a malleable ability (Bateman & Fonagy, 2013), this has potential clinical implications. Previous literature has shown that mentalisation-based parental interventions have been efficacious in enhancing mentalising as well

as improving mental health outcomes among mothers (Suchman et al., 2010; 2017). Therefore, the results of this study may help to clarify the relationship between mentalising and the psychological distress that caregivers of asthmatic children may experience. Understanding this association is paramount to informing clinicians and mental health providers of possible treatment targets when working with caregivers of asthmatic children, or other chronic health conditions, that experience psychological difficulties.

Overall, previous research has identified that caregivers of asthmatic children are at risk of experiencing psychological distress and that family functioning might be a buffering agent (Zhou et al., 2014). To the best of our knowledge, previous literature has not explored the role of mentalising in the mental health and family functioning of caregivers of children with asthma.

The aims of the study were to (a) further explore mood difficulties, anxiety symptoms, family functioning and mentalising ability in a sample of caregivers of asthmatic children residing in the UK; (b) examine whether there were statistically significant associations between caregivers' mentalising scores and family functioning scores, as well as with caregivers' anxiety and mood difficulties; and (c) explore whether mentalising was a significant predictor of anxiety and mood difficulties after controlling for family functioning, income level and child asthma severity. In line with previous research, it was hypothesised that the mentalising "certainty about mental states" subscale (RFQ-C) would show a significant negative correlation with family functioning, mood and anxiety difficulties, whereas the mentalising "uncertainty about mental states" subscale (RFQ-U) would show a significant positive correlation with the same variables. Finally, it was predicted that mentalising would be significantly associated with caregivers' mood and anxiety

difficulties after controlling for other predictors in the models.

Method

Sample

In order to meet inclusion criteria, participants were at least 18 years old, understood written English and were caregivers of a child or an adolescent with an asthma diagnosis residing in the UK. Given the absence of a currently established definition of caregiver (Hermanns & Mastel-Smith, 2012), this paper defined caregivers as adults (>18) who were providing unpaid support and were taking the main responsibility (>4 hours daily) in caring for a child or adolescent that was under 18 years of age.

Design

The current paper was a quantitative cross-sectional study using an online survey design.

Measures

Mentalising: The reflective functioning questionnaire (RFQ-8) (Fonagy et al., 2016) was used as a self-report measure of mentalising. This is an eight-item likert scale, which provides two scores: one for the subscale regarding hypomentalising, which assesses the "uncertainty about mental states" (RFQ-U), and one for the subscale regarding hypermentalising, which assesses the "certainty about mental states" (RFQ-C). In the RFQ-C, very low scores (Mean <2.0) reflected difficulties in mentalising, with some agreement reflecting a more genuine mentalising. In contrast, in the RFQ-U, higher scores (Mean>4.0) reflected poor mentalising, with lower scores characterising greater ability to mentalise. This instrument has a 7-point Likert scale and has shown adequate internal consistency with *Cronbach's alphas*, ranging from .70 to .65 in clinical populations and from .63 to .67 in non-clinical populations (Fonagy et al., 2016). The test–retest reliability of the RFQ-8 is also good, with correlations ranging from r=.84 to .75 over a three-week period (Fonagy et al.,

2016). In the current study, the reliability analyses showed excellent internal consistency for the RFQ-C (*Cronbach's alpha*=.83) and poor internal consistency for the RFQ-U (*Cronbach's alpha*=.52). Both the RFQ-C and RFQ-U were employed in descriptive and correlational analyses. For the purpose of the regression analyses, RFQ-C subscale was employed as a measure of mentalising. Regression models using RFQ-U can be found in Appendix 2-A.

Family Functioning: The general functioning (GF) subscale of the Family Assessment Device (FAD) (Epstein, Baldwin & Bishop, 1983) was used as a measure of family functioning. This is a 12-item likert scale, where average scores above 2.2 indicate family disruption. Previous studies suggest that GF demonstrates high correlations with the overall FAD scores and can thus be used as an accurate measurement of family functioning on its own (Kabacoff, Miller, Bishop, Epstein & Keitner, 1990; Ridenour, Daley & Reich, 1999). This subscale has demonstrated adequate test–retest reliability (*r*=.71–.77) and internal consistency (*Cronbach's alpha*=.78–.92) scores (Akister & Stevenson-Hinde, 1991; Bihun, Wamboldt, Gavin & Wamboldt, 2002; Epstein et al., 1983; Shek, 2001), and has been previously employed in studies with caregivers of asthmatic children (Zhou et al., 2014). GF has also been able to discriminate between clinical and non-clinical populations, which provides further support to its discriminant validity (Miller, Epstein, Bishop & Keitner, 1985), and concurrent validity has been confirmed in a large epidemiological study (Byles, Byrne, Boyle & Offord, 1988). The FAD showed excellent internal consistency, with .91 *Cronbach's alpha* in the current sample.

Anxiety: Caregiver anxiety was measured using the Beck Anxiety Inventory (BAI) (Beck, Epstein, Brown & Steer, 1988). This 21-item self-report questionnaire has been widely used in research and clinical settings. The clinical cutoff point is indicated at scores above 10. It has demonstrated strong internal consistency (*Cronbach's alpha*=.92) as well as adequate

one-week test–retest reliability (*r*=.75) (Beck et al., 1988). The internal consistency of the BAI was excellent in the current sample (*Cronbach's alpha*= .92).

Mood Difficulties: The 7 Up 7 Down Inventory (7U7D) (Youngstrom, Murray, Johnson & Findling, 2013) was employed as a self-report measure of mood symptoms. Previous research has found clinical scores to be of Mean<5.0 in the 7U subscale and of Mean<6.5 in the 7 D subscale. This instrument was developed as a brief self-report questionnaire from the General Behaviour Inventory (GBI) (Depue et al., 1981), and measures depressive and hypomanic symptoms. The 7U7D has demonstrated high internal consistency (.83 to .95), high correlations with the original GBI scale and adequate construct validity (Youngstrom et al., 2013). The 7U7D showed excellent internal consistency, with *Cronbach's alphas* of .80 for the 7Up and .90 for the 7Down subscale in this sample.

Clinical and Socio-demographic Information: An electronic questionnaire was designed for the purpose of this study. The scales had a Likert design and collected clinical and socio-demographic characteristics of the participants, such as gender, ethnicity, age, number of children in the household and income, among others (see Appendix 4-D). The scale also collected information regarding asthma severity, using an adapted set of questions from the questionnaire of Halterman et al. (2004). For the purpose of the analyses, a caregiver report of the *number of asthma-free days over the last two weeks* was employed as a measure of asthma severity.

Procedure

Participants were recruited online between July and October 2017. The study was advertised on the Asthma Research UK bulletin, which is distributed monthly to the registered Research and Policy (RaP) patient volunteers. The study was also advertised on asthma support groups on Twitter and Facebook. The advert included a link to a REDCap (Harris et al., 2009) online platform. This is a secure online data-collection system licensed and approved by Lancaster

University. Following the link, a participant information sheet, containing a description of the study, its aims, exclusion and inclusion criteria, data management and confidentiality information, was displayed. Participants were then asked to provide consent by clicking a link at the end of the introductory section. Following completion of the online questionnaires, a debriefing section, with further information on the research team and sources of support, was displayed. The study received ethical approval by the University Research Ethics Committee (FHMREC). Copies of the information poster, participant information sheet, consent, questionnaires and debriefing section are included as appendices in the ethics section (Appendices 4-A, 4-B, 4-C & 4-D).

Statistical Analyses

All statistical analyses were conducted using IBM SPSS statistics software, version 22. Regarding missing data, comparisons on main demographic variables between caregivers with complete and non-complete survey data were conducted. Following traditional methods for handling missing data (Eekhout et al., 2014; Siddiqui, 2015), only cases with less than 25% of items missing in the RFQ-8, 7U7D and FAD questionnaires were included in the final sample. For the BAI questionnaire, only cases with less than 10% of items missing were included, following the strategy adopted by a previous paper on handling missing data in the BAI (Wetherell & Areán, 1997).

Descriptive analyses were conducted to explore and summarise the main demographic and clinical characteristics of the final sample. Correlation analyses were employed to assess the relationships between clinical and demographic variables. Sensitivity analyses were conducted to evaluate possible influential cases (multivariate outliers). The normal distribution of the data was confirmed through inspection of histograms. These analyses were followed by multiple linear regression analyses to examine whether candidate predictors (e.g. mentalising) were associated with mood difficulties and anxiety. Sequential linear regression

analyses were employed as the aim of the study was to examine whether previously identified predictors were still significant after introducing mentalising variable in the model. A priori sample size calculation indicated that in order to detect medium-to-large effect sizes in a multiple regression with four predictors at a probability of p=0.05 and with a power of 0.80, a minimum of 85 participants was required.

Results

A total of n=247 participants provided consent to take part in the current research, although only n=143 provided complete data in some of the survey sections. A final sample of n=88 participants fully completed the survey. When comparing those caregivers with complete data (n=88) with those with partial data not included in the final analyses (n=55), no significant differences were observed between groups in any of the variables (*ps*>.05) such as age, sex, ethnicity, income or qualifications among others (Table 1).

Insert Table 1

In terms of the demographic and clinical characteristics of the final sample (n=88), the mean age of caregivers was 36 (SD=7.13), 97% were female and 94% described themselves as white. All participants were mother or father of the child and 85% were married or cohabiting. Sixty-nine per cent of the caregivers reported a yearly income of £26,000 or more, and 57% had completed university education. Regarding the children, the mean age was six (SD=3.72), 45% were female and 91% were white.

In terms of clinical characteristics, the mean number of days over the past two weeks with daytime asthma symptoms was 5.92 (SD=3.93), the average number of days with night-time symptoms was 5.42 (4.13), and the mean number of asthma-free days was 6.72 (SD=5.09). Over the past two weeks, participants reported employing the rescue inhaler on an average of 5.68 (SD=4.41) days.

In terms of mentalising, the mean score in the uncertainty about mental states

subscale (RFQ-U, potential score range 0–12) was 2.48 (SD=2.54) and the score in the certainty about mental states subscale (RFQ-C, potential score range 0–18) was 7.37 (SD=5.13). The mean family functioning (FAD, potential score range 11–48) was 23.20 (SD=8.11). The mean hypomania (7U, potential score range 0–17) and depression (7D, potential score range 0–21) scores were 3.46 (SD=3.27) and 6.53 (SD=5.17) respectively. Finally, the mean anxiety score (BAI, potential score range 20–84) was 36.62 (SD=11.50).

Insert Table 2

Regarding the level of association between clinical and demographic characteristics (Table 2), asthma severity (number of asthma-free days in the past two weeks) was not significantly correlated with caregivers' and children's demographic characteristics, with the exception of qualifications (r=.27, p<.01), showing that families with higher education levels experienced a greater number of asthma-free days than those with less education.

Mentalising (RFQ-C or RFQ-U) did not show significant correlations with demographic variables (ps>.05). However, family functioning was significantly associated with income (r=.21, p<.05) and caregivers' qualifications (r=.22, p<.05), meaning that those with higher incomes and qualifications were more likely to experience greater family disruption.

Self-reported hypomanic symptoms were significantly correlated with children's age (r=.27, p<.05), suggesting that having older children was associated with greater chances of experiencing hypomanic symptoms. Depression (7Down) did not show any significant association with the other variables (ps>.05). Caregiver's anxiety symptoms were significantly associated with children's gender (r=-.26, p<0.01), suggesting that those with a female child were more likely to report greater anxiety scores.

Insert Table 3

Information about clinical variables is provided in Table 3. In terms of correlations

between predictors (e.g. mentalising with family function), most of the correlations were statistically significant, showing small and moderate effect sizes (r=0.01to -0.65) and running in the expected direction.

For example, certainty about mental states (RFQ-C) was negatively correlated with depression (r=-.49, p<.001), hypomania (r=-.24, p<.05), anxiety (r=-.44, p<.01) and family functioning (r=-.30, p<.01), whereas uncertainty about mental states (RFQ-U) was positively associated with depression (r=.50, p<.000) and anxiety (r=.28 p<.001). Given that low scores in the RFQ-C suggest poor mentalising (hypermentalising), and higher scores in the RFQ-U also suggest poor mentalising (hypomentalising), these correlations suggest that the poorer the mentalising scores, the more likely the reporting of family functioning difficulties, anxiety, and depressive and hypomanic symptoms. Similarly, family functioning (FAD) was positively correlated with self-reported depressive symptoms (r=.30, p<.01) and negatively with RFQ-C (r=-.30, p<.01), suggesting that those with higher difficulties in family functioning would be expected to report higher depressive symptoms and lower mentalising capacity.

When studying the association between clinical variables and asthma severity (Table 3), asthma-free days was negatively correlated with anxiety symptoms (r=-.22, p<=.05), whereas rescue inhaler use showed a positive correlation (r=.22, p<=0.05), meaning that caregivers who reported higher rescue inhaler use and fewer asthma-free days were more likely to report higher anxiety symptoms. In other words, high severity of asthma was associated with higher anxiety in caregivers. Moreover, asthma-free days showed a significant negative association with rescue inhaler use (r=-.65, p<=.001), as expected.

Insert Table 4

When exploring whether mentalising was significantly associated with anxiety and mood difficulties after controlling for confounders, mentalising (RFQ-C) was the only

variable significantly associated with caregivers' depressive symptoms. In the most stringent model (step 4, when all candidate predictors were present) mentalising explained 16% of variance in depression by itself (b=-.44, p<.001).

Insert Table 5

In the case of hypomanic symptoms, mentalising (RFQ-C) was the only predictor with a marginally significant contribution to the model (b=-.13, p=.05) (Table 5). These results suggest that a unit increase in mentalising (RFQ-C) was associated with a reduction in the self-reported depression and hypomanic symptoms scores.

Insert Table 6

In the last regression model, both mentalising (b=.89, p<.001) and asthma severity (b=-.42, p<.05) were significantly associated with anxiety, although mentalising explained 10% of the variance, compared with children's asthma severity, which only explained 3% of variance (Table 6). Similar to the regression models of depression and hypomania, increases in mentalising units (RFQ-C) were associated with reductions in anxiety scores. Moreover, increases in the number of asthma-free days were also associated with reductions in anxiety. When using RFQ-U as a predictor, similar results were observed (see Appendix 2-A).

Discussion

To our knowledge, this is the first study exploring mentalising ability in a sample of caregivers of asthmatic children. Overall, the findings show that poor mentalising was significantly associated with more disrupted family functioning and that it was significantly associated with anxiety and mood difficulties after controlling for other covariates.

In detail, regarding the first aim about exploring participants' socio-demographic characteristics, descriptive analyses indicated that the sample was almost entirely comprised of mothers (97%). The absence of fathers as informant caregivers in the current sample is consistent with asthma literature (Yamamoto & Nagano, 2015), where participants are

usually mothers. Given that this study targeted caregivers in general, this overwhelming majority suggests that mothers might assume most caregiving duties. Similarly, over half of the sample had completed university education, the majority of caregivers and their children identified themselves as white and 69% of the families reported having a yearly household income of £26,000 or more. This average income is above the median yearly household disposable income in the UK (Office for National Statistics, 2016). These results suggest that the participants of this study were mostly well-educated, middle class, white British females. Therefore, caution should be taken when generalising these results to service users from more deprived backgrounds and/or from non-white ethnic groups.

Interestingly, participants with higher income and qualifications were more likely to report greater family disruption. These correlations were unexpected and inconsistent with previous research, which suggests that family disruption is significantly associated with lower income (Zhou et al., 2014). Consequently, consideration of this inconsistency in future research is required.

In terms of clinical characteristics, participants reported that over the last two weeks, an average of 6.52 days (SD=5.09) were asthma-symptom-free. These results suggest an asthma severity of between the mild and moderate ranges (National Institute of Health, 2007). The results are also similar to a recent cross-sectional study (Gutiérrez, Fagnano, Wiesenthal, Koehler & Halterman, 2014) that reported an average of 7.67 asthma-free days (SD=5.0) in a sample of 194 asthma children attending primary care clinics. Moreover, the self-reported depression scores (mean=6.53, SD =5.17) were similar to those reported in a clinical sample using the same instrument (7D) (Youngstrom et al., 2013), and the average anxiety symptoms (mean=36.62, SD=11.50) level was in the moderate clinical range (Beck et al., 1988). These results are consistent with previous findings, which have indicated that caregivers of asthmatic children are prone to experiencing anxiety and depressive symptoms

(Easter et al., 2015; Fagnano et al., 2012; Zhou et al., 2014). However, caution is required when interpreting the results, as this study did not compare caregivers' scores with a control group, such as caregivers of non-asthmatic, healthy children.

The second aim was to analyse whether there were significant associations between mentalising and both self-reported mental health symptoms and family functioning. Initially, it was hypothesised that certainty about mental states (RFQ-C) would negatively correlate with family functioning, mood and anxiety difficulties, and uncertainty about mental states (RFQ-U) would positively correlate with the same variables. The results were mostly consistent with these hypotheses, such as that those with poorer mentalising scores (lower RFQ-C) were more likely to experience greater family disruption and greater symptoms of depression, anxiety and hypomania. Regarding RFQ-U, those with poorer mentalising, as measured by this scale (higher scores), were more likely to report greater anxiety and depression, but these scores were not significantly associated with family functioning difficulties or hypomanic symptoms. It is important to highlight here the poor reliability showed by the RFQ-U (*Cronbach's alpha*= .52), which warrants caution when interpreting these results. Nevertheless, these findings provide further support for the theoretical underpinnings of mentalising theory, such as that poor mentalising capacity is associated with greater mental health difficulties (Bouchard et al., 2008).

Finally, the study sought to examine whether mentalising was a significantly associated with anxiety, depressive and hypomanic symptoms after controlling for income, child asthma severity and family functioning. The final hypotheses were also confirmed, as mentalising was significantly associated with caregivers' depression (16% of variance), anxiety (13% of variance) and hypomanic (4% of variance) symptoms after controlling for income, asthma severity and family functioning. Mentalising was the most significant variable to all the models. After accounting for the contribution of the other variables,

mentalising alone showed a medium effect size for depressive (*r*=.40) and anxiety (*r*=.36) symptoms and a small effect size (*r*=.20) for hypomanic symptoms. These results indicated that higher levels of mentalising were significantly associated with a reduction in self-reported anxiety and mood difficulties. Although causality cannot be inferred, this supports the idea that mentalising might be a buffering agent against caregivers' mental health difficulties, as previous literature has identified when looking at other client groups (Bateman & Fonagy, 2013; Fonagy & Bateman, 2016).

Similarly, asthma severity was also able to contribute significantly to the final regression model of anxiety. However, asthma severity on its own only showed a small effect size (*r*=.17) suggesting that mentalising (*r*=.36) was the most important factor in understanding caregivers' mental health difficulties. This is important given that recent studies have focused on asthma severity as a significant predictor of poorer mental health outcomes amongst caregivers (Zaky, Fouda, Samir & Ahmed, 2016). In contrast, these results suggest that there are other significant factors, such as caregivers' mentalising ability, that require attention too. For instance, a mixed-method study suggested that losing control could be one of the significant dimensions associated with the burden of asthma (Guo, Gao, Guo, Wen & Zeng, 2015). It could be argued that losing control is intrinsically relevant to mentalising, which essentially supports affect regulation and helps in not "losing control" (Fonagy et al., 2002).

Furthermore, family functioning was not a significant variable in any of the final models. In fact, its contribution to the model of depressive and anxiety symptoms was no longer significant after mentalising was introduced to the model. This is particularly relevant given the extensive literature examining the significant association between disruptive family functioning and caregivers' mental health in both non-asthmatic (Brown, Lambert, Hsu & Eckman, 1998; Jackson, 1992; Kung, 2003) and asthmatic populations (Özkaya, Çetin,

Uğurad & Samanci, 2010; Schreier & Chen, 2010; Zhou et al., 2014).

A possible explanation is that none of the previous studies conducted statistical analyses including both family functioning and mentalising. Given that it is hard to imagine that positive family functioning can be constructed in a family unit where caregivers have difficulties with mentalising, it is possible that mentalising acts a mediating factor in the relationship between family functioning and asthmatic caregivers' mental health difficulties. Thus, future longitudinal studies should aim to test this hypothesis through mediation analyses. In addition, it is also important to acknowledge how maternal anxiety and depressive symptoms have showed to contribute to the incidence of asthma (Martinez et al., 2009), and how this might affect family functioning, thereby acting as a confounding factor. It is recommended that future studies further explore this issue.

Overall, these results are promising, as they suggest that mentalising could be an important factor in understanding caregivers' difficulties, irrespective of their income, family functioning and the asthma severity of their children. Theoretically, this can be understood in the context of mentalising being an essential component of affect regulation in emotionally charged situations (Migdley & Vrouva, 2013), which are often present in the context of asthma caregiving duties (Bellin et al., 2013).

Clinical Implications

Taken together, these findings suggest that mentalising could be a protective factor that allows these families to negotiate the social, financial and emotional demands that asthma may pose on their homes, without having such a significant impact on their mental health. Moreover, the results indicate that when caregivers' mentalising capacity is compromised, the likelihood of experiencing mental health difficulties increases.

Notably, most psychological interventions targeting asthmatic clients or caregivers of asthmatic children have focused on problem-solving, meditation, educational, family

functioning or environmental triggers, among other aspects (Canino et al., 2008; Ellis et al., 2014; Paudyal, Jones, Grindey, Dawood & Smith, 2017; Walders et al., 2006). It could be argued that learning skills or understanding the nature of asthma might be necessary but not sufficient to reduce caregivers' anxiety and mood difficulties if their mentalising is compromised. Therefore, interventions oriented towards mentalising enhancement could be an additional option for this population. In fact, short-term parental-based mentalisation interventions have yielded promising results for both clinical (Suchman et al., 2010; 2017) and non-clinical populations (Hertzmann et al., 2016). This MBT based intervention could constitute a short-term manualised intervention, especially designed for this population. It could contain elements of not knowing stance, mentalising dialogue and psychoeducation on asthma, responding to crisis, understanding asthma seasonal effects, as well as infant-caregiver interactions.

Limitations and Future Research

Although novel, the study presents some limitations. First, the study employed an online cross-sectional design and only obtained self-reported data. This is particularly relevant for variables such as asthma severity, where the inherent memory bias of retrospective self-report (Schwarz, 2007) could have affected the results. Although the asthma control test (ACT, NIH, 2007) or other systematically validated measures of asthma severity were considered in this study, it was finally decided to use shorter, less time consuming assessment procedures of asthma severity. By doing this, the current paper possibly avoided greater attrition, but possibly compromised the validity of asthma severity, which should be addressed in future studies.

Second, the study sample lacked diversity, especially regarding ethnicity and income. This suggests that the sample was not representative of the client group, which often affects people from minorities and deprived backgrounds. Given that asthma can pose significant

financial burdens in the family unit (Zhou et al., 2014) and that socio-economic status has been shown to predict worse anxiety, depression or quality of life outcomes in asthma caregivers (Annett, Bender, DuHamel & Lapidus, 2003; Celano et al., 2008; Erickson et al., 2003; Zhou et al., 2014), future studies should attempt to include a more diverse sample.

Third, the study was conducted in summer and autumn, whereas asthma seasonal effects have extensively documented that asthma severity increases in winter (NHS, 2017). This could have skewed our results and the impact of asthma severity on caregivers' symptoms. However, our results on asthma severity were very similar of those reported by Gutierrez et al., (2017) who recruited their sample over three years across different seasons, including winter.

Fourth, mentalising was measured using the short version of the reflective functioning questionnaire (RFQ-8). The RFQ-8 is a short screening questionnaire originally developed for research studies assessing mentalising capacity in clinical samples with severe mentalising difficulties (Fonagy et al., 2016). The use of a clinical scale in a community sample could partially explain the low internal consistency scores of the RFQ-U. Ideally, this study would have employed the recently developed parental reflective functioning questionnaire (PRFQ) (Luyten, Mayes, Nijjssens & Fonagy, 2017), but the first validated version of the PRFQ was not published until the data collection for this study was already ongoing. Thus, future studies aiming to examine mentalising capacity in asthma caregivers should employ the PRFQ instead.

Moreover, mentalising proponents have described the concept as a capacity that occurs largely at a more implicit or automatic level (Fonagy et al., 2002; Migdley & Vrouva, 2013), and thus it could be argued that it is hard for people to access it through self-report questionnaires. Future studies should therefore include both self-report questionnaires and semi-structured interviews, such as the parent development interview (PDI) (Slade, Aber,

Bresgi, Berger & Kaplan, 2004), which allow clinicians to potentially assess more implicit/automatic mentalising processes.

Conclusions

Despite its limitations, this study is the first to examine mentalising capacity in a sample of caregivers of children with asthma. The findings of this study suggest that mentalising was the most important factor in understanding caregivers' self-reported anxiety and mood difficulties. These results alert researchers and clinicians to the possible existence of an overlooked psychological construct that may influence caregivers' mental health. This could also be relevant to caregivers of other chronic illnesses, as the prevalence of depressive symptoms in this population has been extensively documented (Easter et al., 2015). The study paves the way for future research to develop a more comprehensive exploration of mentalising and its possible interrelatedness with other elements of caregiving for asthmatic children.

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Tables

Table 1.

Demographic and clinical characteristics

Caregivers	Excluded Cases (N=55)	Included Cases (N=88)	x^2/*t*
Age, Mean (SD)	35.19 (6.24)[a]	36.68 (7.13)	*t*=-.1.18
Sex female, n (%)	53 (98)[b]	85 (97)	x^2=.29
Ethnicity White, n (%)	46 (85)[b]	83 (94)	x^2=3.35
Relation to child (mother or father), n (%)	51 (94)[b]	87 (100)	x^2=4.93
Income, n (%)[c]			x^2=7.40
6,000 to >26,000	18 (34)	27 (30)	
26,000 to >48,000	17 (32)	30 (34)	
48,000 and above	18 (34)	21 (35)	
Qualifications, University Studies, n (%)	26 (48)[c]	50 (57)	x^2=5.11
Marital Status, Married or cohabiting, n (%)	34 (81)[d]	64 (84)	x^2=.20
Clinical Variables			
Mentalising scores (RFQ-U), Mean (SD)		2.48 (2.54)	
Mentalising scores (RFQ-C), Mean (SD)		7.37 (5.13)	
Anxiety scores (BAI), Mean (SD)		36.62 (11.50)	
Family Functioning Scores (FD), Mean (SD)		23.09 (8.15)	
Hypomania Scores (7Up), Mean (SD)		3.46 (3.27)	
Depression Scores (7Down), Mean (SD)		6.53 (5.17)	

Children	Excluded Cases (N=55)	Included Cases (N=88)	x^2/t
Age, Mean (SD)	5.94 (3.67)[e]	6.53 (3.72)	t=-.89
Sex female, n (%)	19 (36)[c]	39 (45)	x^2=1.09
Ethnicity White, n (%)	44 (80)	80 (91)	x^2=3.49
Asthma Severity			
Nº days with asthma daytime symptoms, M (SD)	5.93 (4.00)[b]	5.92 (3.93)	t=.00
Nº days with with asthma night-time symptoms, M (SD)	5.76 (4.03)	5.42 (4.13)	t=.48
Nº of asthma free days, M (SD)	6.20 (5.26)[c]	6.72 (5.09)	t=-.58
Nº days Use of rescue inhaler, M (SD)	5.51 (4.42)	5.68 (4.41)	t=-.22

Note *p< 0.05, **p< 0.01 ***p<0.001, x^2=Chi Square, t=Student´s t-test, [a]n=47, [b]n=54,[c]n=53, [d]n=42,[e]n=50

Table 2.

Pearson´s r correlations between demographic and clinical characteristics

Clinical Variables N=88	Asthma Free days[a]	Hypomania (7Up)	Depression (7Down)	Anxiety (BAI)[b]	Mentalising RFQ-U (RFQ-C)[c]	Family Functioning (FAD)[d]
Caregiver Demographics, r						
Age	.07	.15	.09	-.01	.03 (-.04)	.18
Gender	.01	.10	-.01	.08	.01 (-.16)	.15
Ethnicity	.00	-.05	-.17	-.16	-.06 (.18)	-.04
Relationship Status	.01	.11	.07	-.10	.09 (.11)	.08
Employment	-.19	.12	.02	.05	.08 (-.01)	-.04
Income	.15	-.18	-.00	-.05	-.05 (.00)	.21*
Qualifications	.27**	-.13	.07	-.15	-.07 (.12)	.22*
Children Demographics, r						
Age	.06	.27*	.11	.13	.01 (-.12)	.04

Gender	-.02	-.15	-.03	-.26*	-.19 (.11)	-.05
Ethnicity	-.06	.01	.03	-.01	-.07 (.01)	-.03

Note= *p<.05, **p<.01 ***p<.001, [a]=Refers to the amount of days without asthma symptoms over the last two weeks, [b]BAI=Beck Anxiety Inventory, [c]RFQ-C=Certainty About Mental States,RFQ-U=Uncertainty About Mental States, [d]FAD=Family Assessment Device

Table 3.

Pearson´s r correlations between clinical variables

N=88	Hypomania (7Up)	Depression (7Down)	Anxiety (BAI)	Family Functioning (FAD)	RFQ-U (RFQ-C)	Asthma Free days	Rescue Inhaler[a]
7Up, r		.33***	.49 ***	.09	.20 (-.24*)	-.09	.14
7Down, r	.33***		.47 ***	.30 **	.50*** (-.49***)	-.02	.04
BAI, r	.49***	.46***		.18	.28** (-.44**)	-.22*	.22*
FAD, r	.09	.30**	.18		.19 (-.30**)	.05	.01
RFQ-U (RFQ-C)	.20 (-.24*)	.50***(-.49***)	.28**(-.44***)	.19 (-.30**)	-.61***	-.09 (0.08)	.15 (-.10)
Asthma Free Days	-.09	-.02	-.22*	.05	-.09 (.08)		-.65**
Rescue Inhaler Use	.14	.04	.22*	.01	.15 (-.10)	-.65**	

Note= *p<.05, **p<.01 ***p<.001, [a]Rescue Inhaler= Refers to the number of days where rescue inhaler was needed in the last two weeks

Table 4

Sequential linear regression model of depressive symptoms (7D), asthma severity, family functioning and mentalising (N=88)

Variable	Step 1	Step 2	Step 3	Step 4	95% CI		Semipartial Correlation[2]
Depression (N=88)					Upper	Lower	
Constant[a]	6.56***	6.68***	2.74	7.54***	11.51	3.57	
Income[a]	-.01	.00	-.29	-0.17	.69	-1.05	.00
Asthma Severity[a]		-.02	-.03	.01	.20	-.18	.00
Family Functioning[a]			.20**	.11	.24	-.15	.02
Mentalising (RFQ-C)[a]				-.44***	-.24	-.64	.16
R^2	.00	.00	.09**	.27***			
F	.01	.02	3.01*	7.71***			
ΔR^2	.00	.00	.09*	.17***			
ΔF	.01	.04	9.00*	19.79***			

Note= *p<.05, **p<.01 ***p<.001, [a]All values are unstandardized Beta coefficients

Table 5

Sequential linear regression model of hypomanic symptoms (7U), asthma severity, family functioning and mentalising (N=88)

Variable	Step 1	Step 2	Step 3	Step 4	95% CI		Semipartial Correlation[2]
Hypomania (N=88)					Upper	Lower	
Constant[a]	4.66***	4.88***	3.77***	5.27***	8.06	2.48	
Income[a]	-.52	-.49	-.57	-.54	.07	-1.15	.03
Asthma Severity[a]		-.04	-.04	-.03	.10	-.16	.00
Family Functioning[a]			.05	.02	.11	-.06	.00
Mentalising (RFQ-C)[a]				-.13*	.00	-.27	.04
R^2	.03	.03	.05	.09*			
F	2.97	1.66	1.69	2.28			
ΔR^2	.03	.00	.01	.04*			
ΔF	2.97	.38	1.70	3.88*			

Note= *p<.05, **p<.01 ***p<.001, [a]All values are unstandardized Beta coefficients

Table 6

Sequential linear regression model of anxiety symptoms (BAI), asthma severity, family functioning and mentalising (N=88)

Variable	Step 1	Step 2	Step 3	Step 4	95% CI		Semipartial Correlation[2]
Anxiety (N=88)					Upper	Lower	
Constant[a]	37.84***	40.42***	34.53***	44.17***	53.19	35.15	
Income[a]	-.53	-.18	-.63	-.40	1.58	-2.38	.00
Asthma Severity[a]		-.50*	-.51**	-.42*	.01	-.86	.03
Family Functioning[a]			.30*	.12	.41	-.16	.00
Mentalising (RFQ-C)[a]				-.89 ***	-.44	-1.34	0.13
R^2	.00	.05*	.09*	.24***			
F	.24	2.28	2.93*	6.45***			
ΔR^2	.00	.04*	.04*	.14***			
ΔF	.24	4.30*	4.07*	15.47***			

Note= *p<.05, **p<.01 ***p<.001, [a]All values are unstandardized Beta coefficients

Appendices

Appendix 2-A

Sequential linear regression models with RFQ-U as covariate

Table 1

Sequential linear regression model of depressive symptoms (7D), asthma severity, family functioning and mentalising (N=88)

Variable	Step 1	Step 2	Step 3	Step 4	95% CI		Semipartial Correlation[2]
Depression (N=88)					Upper	Lower	
Constant[a]	6.56***	6.68***	2.74	1.19	4.53	-2.15	
Income[a]	-.01	.00	-.29	-.10	.75	-.97	.00
Asthma Severity[a]		-.02	-.03	.01	.19	-.17	.04
Family Functioning[a]			.20**	.13*	.26	.01	.02
Mentalising (RFQ-U)[a]				.93***	-.24	-.64	.19
R^2	.00	.00	.09**	.29***			
F	.01	.02	3.01*	8.73***			
ΔR^2	.00	.00	.09**	.19***			
ΔF	.00	.04	9.00**	23.48***			

Note= *p<.05, **p< 01 ***p<.001, [a]All values are unstandardized Beta coefficients

Table 2

Sequential linear regression model of hypomanic symptoms (7U), asthma severity, family functioning and mentalising (N=88)

Variable	Step 1	Step 2	Step 3	Step 4	95% CI		Semipartial Correlation[2]
Hypomania (N=88)					Upper	Lower	
Constant[a]	4.66***	4.88***	3.77***	3.41***	5.82	1.00	
Income[a]	-.52	-.49	-.57	-.53	.08	-1.15	.03
Asthma Severity[a]		-0.04	-0.04	-0.03	.10	-.17	.00
Family Functioning[a]			.05	.04	.13	-.04	.01
Mentalising (RFQ-U)[a]				.21	.49	-.05	.02
R^2	.03	.03	.05	.08			
F	2.97	1.66	1.69	1.90			
ΔR^2	.03	.04	.01	.02			
ΔF	2.97	.38	1.70	2.46			

Note= *p<.05, **p<.01 ***p<.001, [a]All values are unstandardized Beta coefficients

Table 3

Sequential linear regression model of anxiety symptoms (BAI), asthma severity, family functioning and mentalising (N=88)

Variable	Step 1	Step 2	Step 3	Step 4	95% CI		Semipartial Correlation[2]
Anxiety (N=88)					Upper	Lower	
Constant[a]	37.84***	40.42***	34.53***	32.82***	41.01	24.63	
Income[a]	-.18	-.63	-.42	-.17	1.68	-2.53	.00
Asthma Severity[a]		-.50*	-.51*	-.46*	-.00	-.93	.04
Family Functioning[a]			.30*	.23	.53	-.06	.02
Mentalising (RFQ-U)[a]				1.02*	1.96	.08	.04
R^2	.00	.05*	.09*	.14*			
F	.24	2.28	2.93*	3.48**			
ΔR^2	.00	.04*	.04*	.04*			
ΔF	.24	4.30*	4.07*	4.72*			

Note= *p<.05, **p<.01 ***p<.001, [a]All values are unstandardized Beta coefficients

Appendix 2-B

Journal: *Development and Psychopathology*

Instructions for Contributors

Development and Psychopathology strongly encourages contributions from a wide array of disciplines because an effective developmental approach to psychopathology necessitates a broad synthesis of knowledge. Manuscripts will be considered that address, for example, the causes and effects of genetic, neurobiological, biochemical, cognitive, or socioemotional factors in developmental processes with relevance to various risk or psychopathological conditions. The journal also seeks articles on the processes underlying the adaptive and maladaptive outcomes in populations at risk for psychopathology.

Manuscript Review Policy

Manuscripts will have a blind review by at least two scholars. Every effort will be made to notify authors within 90 days of submission concerning the reviewers' recommendations and comments. Development and Psychopathology has no page charges.

Manuscript Submission and Review

All manuscript submissions to Development and Psychopathology must be made electronically via ScholarOne Manuscripts: http://mc.manuscriptcentral.com/dpp Please follow the complete instructions on this website to avoid delays. The instructions will prompt the author to provide all necessary information, including the corresponding author's contact information, which includes complete mailing address, phone and fax numbers, and an e-mail address. The website also requests suggested reviewers. The website will automatically acknowledge receipt of the manuscript and provide a manuscript reference number. The Editor-in-Chief will assign the manuscript to an Editor who will choose at least two other reviewers. Every effort will be made to provide the author with a rapid review. If the Editor requests that revisions be made to the manuscript before publication, a maximum of 3 months will be allowed for preparation of the revision. For additional information on the new online submission and review system, please read the Tutorial for Authors or the Tutorial for Reviewers available from ScholarOne Manuscripts.

Manuscript Preparation and Style General.

All manuscripts must be provided in MSWord format in 12-point type with 1-in. margins on all sides. The entire manuscript must be double-spaced and numbered consecutively. The language of publication is English.

Style and Manuscript Order. Follow the general style guidelines set forth in the Publication Manual of the American Psychological Association (6th ed.). The Editor may find it necessary to return manuscripts for reworking or retyping that do not conform to requirements. Do not use embedded references, end notes, or

bookmarks.

Manuscripts must be arranged in the following order: Title Page. To facilitate blind review, all indication of authorship must be limited to this page, which should be submitted as a separate file. Other pages must only show the short title plus page number at the top right. The title page should include the (a) full article title; (b) name and affiliations of all authors; (c) acknowledgments; (d) mailing address and telephone number of the corresponding author; (e) address of where to send offprints, if different from the corresponding author; and (f) a short title of less than 50 characters.

Acknowledgments.

These should be placed below the affiliations. Use this section to indicate grant support, substantial assistance in the preparation of the article, or other author notes. Abstract Page. Include (a) a full article title, (b) an abstract of no more than 200 words, and (c) up to five keywords for indexing and information retrieval. Text. Use a standard paragraph indent. Do not hyphenate words at the ends of lines or justify right margins.

References.

Bibliographic citations in the text must include the author's last name and date of publication and may include page references. Examples of in-text citation style are Cicchetti (2002), Durston (2008, pp. 1133–1135), Hunt and Thomas (2008), (Hunt & Thomas, 2008), (Posner, Rothbart, Sheese, & Tang, 2007), and subsequently (Posner et al., 2007). If more than one, citations must be in alphabetical order. Every in-text citation must be included in the reference section; every reference must be cited in the text.

Examples of reference styles:

Journal Article

Haltigan, J. D., Roisman, G. I., & Fraley, R. C. (2013). The predictive significance of early caregiving experiences for symptoms of psychopathology through midadolescence: Enduring or transient effects? *Development and Psychopathology*, *25*, 209–221.

Book

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3. Critical Appraisal

Asthma, Caregiving and the Sense of Self

Malda-Castillo, Javier

Trainee Clinical Psychologist

Division of Health Research

Lancaster University

Correspondence should be addressed to:

Javier Malda-Castillo

Clinical Psychology

Lancaster University

Lancaster

LA1 4YG

Tel: +44 07514267419

Email: j.maldacastillo@lancaster.ac.uk

Overview

This thesis initially provided a systematic review of the evidence regarding the efficacy and effectiveness of mentalisation-based treatment (MBT), followed by presentation of a study exploring mentalising ability in a sample of caregivers of asthmatic children. Mentalising is in essence a conceptualisation of the development of a sense of self and how this impacts on an individual's ability to cope with the overwhelming demands of their social environment. Bearing this in mind, this paper addresses the opportunities and challenges that such a theory poses in the understanding of a caregiving experience. First, the main findings, limitations and strengths of the research paper are summarised. Second, the impacts of the findings on clinical practice are presented. Third, the current research context is described, along with future research directions. Finally, how mentalisation corresponds with my clinical curiosity, as well as the development of my professional identity in the context of clinical psychology training, is discussed.

Summary of Findings, Strengths and Limitations

The research paper sought to examine the mental health of caregivers of asthmatic children as well its relationship to their mentalising capacity. The results showed that participants reported anxiety and depressive scores similar to those of clinical populations, suggesting that this population might be at risk of experiencing mental health difficulties. Most previous literature has focused extensively on psychosocial and environmental predictors of caregivers' mental health, such as asthma severity, education, asthma management or life stress (Bellin et al., 2011; Clougherty, Kubzansky, Spengler & Levy, 2009; Halterman et al., 2004; Wood et al., 2002; Yamamoto & Nagano, 2015; Zhou, Yi, Zhang & Wang, 2014). These studies have contributed substantially to the understanding of the multiple factors involved in the mental health and quality of life of caregivers. This study took a step further by including mentalising capacity, an overlooked construct in the asthma

literature.

The results showed that mentalising was significantly associated with depression, anxiety and hypomanic symptoms, explaining more variance than any other variable included in the model. The findings are important because they confirm that caregivers of asthmatic children may experience emotional distress and that mentalising ability contributes to the understanding of such difficulties. Moreover, the parental-based mentalising interventions included in the systematic review showed good outcomes in both clinical (Suchman et al., 2010; 2017) and non-clinical populations (Hertzmann et al., 2016). Taken together, these findings might be especially attractive for policy-makers, clinicians and researchers who wish to further understand how mental health difficulties emerge in the context of caregiving and how it might be possible to prevent or treat them when necessary.

A particular strength of this study is its limited exclusion criteria, as participation was open to residents in the United Kingdom (UK) over 18 years old who were currently caregiving (>4 daily hours) for an asthmatic child. The study employed well-validated questionnaires and provided an a priori sample size and power calculation. Furthermore, the sequential linear regression included variables that previous studies had identified as associated with caregivers' mental health and quality of life, such as asthma severity, family functioning or income (Erickson et al., 2002; Schreier & Chen, 2010; Zaky, Fouda, Samir & Ahmed, 2016; Zhou et al., 2014). The study was further strengthened because it recruited participants from "Asthma UK", the biggest asthma charity in the UK, as well as from social media support groups.

However, there are caveats that deserve attention. Similarly to any cross-sectional study, the findings and their interpretations are limited by methodological considerations. Given that the study relied solely on self-report measures, common-method variance cannot

be disregarded as an explanation for the significant relationships between the variables. This is particularly relevant for the measurement of mentalising capacity. This is a complex, multifaceted and dynamic phenomenon, which is not static but rather fluctuates, especially under stressful circumstances (Fonagy, Gergely, Jurist & Target, 2002). In this research, mentalising was solely measured with a short self-report questionnaire, potentially significantly limiting the possibility of capturing its multidimensionality and dynamic components. This is particularly important in the context of difficulties obtaining internal consistency for the subscale measuring "uncertainty about mental states" (RFQ-U), a subscale designed to capture hypomentalising, defined as a significant lack of awareness about one's own and others' mental states (Fonagy et al., 2016). One possible explanation is that this scale was originally created to assess mentalising scores in clients with a diagnosis of Borderline Personality Disorder (BPD), who previous literature argues are likely to experience severe mentalising difficulties (Bateman & Fonagy, 2016). When employing the scale with a non-clinical sample, some items might have not been relevant for respondents, therefore compromising internal consistency.

Another possible limitation is that our regression model only included the mentalising subscale measuring "certainty about mental states" (RFQ-C). When conducting the same sequential linear regression with the "uncertainty about mental states" subscale (RFQ-U), the results were very similar but not identical (see Appendix 2-A). In the model using RFQ-U, both family functioning and mentalising were significant contributors to the final model of depression, whereas in the model using RFQ-C, only mentalising had a significant contribution. Nevertheless, whilst mentalising alone (RFQ-U) was associated with 19% of the depression symptoms, family functioning was only associated with 4%, suggesting that mentalising remained the strongest predictor in the model. Another significant difference is that whilst the model using RFQ-C as a mentalising measurement was significantly

associated with hypomanic symptoms, the model was no longer significant when RFQ-U was used as a measure of mentalising. These inconsistencies suggest possible differences in the subtypes of mentalising difficulties (hypomentalising and hypermentalising), which may or may not be associated with caregivers' mental health difficulties.

Nevertheless, this was the first study examining the concept of mentalising in a sample of caregivers of asthmatic children. It was beyond the scope of this research to provide a detailed explanation of the differentiating effects that different subtypes of mentalising difficulties could have on the caregivers, and this should be further explored in future studies.

Impact of the Study in Clinical Practice

The findings indicate that consideration should be given to mentalising when understanding the distress that caregivers of asthmatic children might experience. In a recent study, Riddle, Smith and Jones (2016) identified the need for accessible psychological interventions for caregivers in the UK. In the case of asthma caregivers, clinical psychologists could be embedded within respiratory teams and contribute to increasing the presence of mentalising principles in formulations, assessments and psychological intervention programmes. Another possibility would be to design mentalising-based group interventions delivered in primary care settings, where the first contact with caregivers is likely to occur. Finally, clinical psychologist could provide consultation to asthma charities, where staff working for helplines or support groups would be able to integrate and employ mentalising principles.

One of the main advantages of using a mentalising framework in the understanding of the mental health of asthma caregivers is its transdiagnostic nature. Mentalising is intrinsically related to the development of the sense of self (Migdley & Vrouva, 2013). Therefore, it would be expected that enhancing mentalising capacity can produce positive

outcomes, not only in specific symptoms but also in emotional regulation, positive self-appraisal and a more balanced view of oneself (Bateman & Fonagy, 2016). By targeting mentalising, clinicians would not be limited to dealing with anxiety or mood difficulties, but could also support caregivers experiencing other types of mental health difficulties.

Within my current clinical practice, this study has deepened my understanding of the importance of mentalising to construct secure attachment relationships, and the possible implications when this is absent or under threat. Moreover, this project has increased my awareness of the burden posed on my clients by caregiving, and how employing mentalising techniques might support them in dealing with such stressors.

Current Research Context and Future Research Directions

The application of mentalisation theory in understanding and treating mental health difficulties, personality development and caregiver–child interaction, among other areas, has rocketed over the past decade (Bateman & Fonagy, 2013; Kalland, Fagerlund, von Koskull & Pajulo, 2016; Hertzmann et al., 2016; Suchman et al., 2010). Concurrently, research exploring the mental health of caregivers of asthmatic children has also expanded rapidly over the past few years (Bellin et al., 2011; Easter, Sharpe & Hunt, 2015; Fagnano, Berkman, Wiesenthal, Butz & Halterman, 2012). Thus, it was only a matter of time until these two areas of research encountered each other.

To date, most psychological research examining asthma caregiving has focused on attachment (Yatsenko, Pizano & Nikolaidis, 2016), the impact of caregivers' mental health on children's asthma outcomes (Pak, 2012) or developing problem-solving and cognitive intervention programmes for families with asthma (Celano, Holsey & Kobrynski, 2012; Walders et al., 2006). Similarly, most asthma research exploring predictors associated with caregivers' mental health has taken a more sociological or medical perspective by focusing on factors such as income, asthma severity, caregivers' psychiatric diagnoses, family

functioning or education. Both lines of research have been tremendously helpful in increasing the understanding of mental health among caregivers. Yet it could be argued that introducing mentalising, a psychological construct previously overlooked in asthma research, would possibly expand the current understanding of the mechanisms that interplay with caregivers' mental health. On the basis of the findings of this thesis and its limitations, future directions for research are proposed.

First, participation in the study was limited to those who had Internet access. The sample mainly comprised white, female, well-educated participants, with a minimal representation from ethnic minorities. Future studies should aim to recruit a more diverse sample. A possible strategy would be to recruit participants from the National Health Service (NHS) by contacting general practitioners (GPs) and paediatric surgeries.

Second, the outcome study used a general mentalising ability measure (RFQ-8). Although parental and general mentalising are strongly correlated (Steele et al., 2008), authors have argued that these abilities are not exactly the same (Luyten, Mayes, Nikssenss & Fonagy, 2017). Thus, future studies should employ the recently developed parental reflective questionnaire (PRFQ) (Luyten et al., 2017) as a more accurate measure of assessing the mentalising capacity of caregivers.

Third, the sample size of the outcome paper was not big enough to detect significant differences in a regression with another independent variable, and thus RFQ-U and RFQ-C could not be included together. To examine the influence of different mentalising capacities on caregivers' mental health, future studies should aim to include different mentalising subscales in the regression analyses.

Fourth, the mental health of the children was not assessed in the current research. It is possible that caregiving for children who have both asthma and other mental health difficulties significantly increases the burden on the family unit, consequently increasing the

risk of emotional distress among caregivers. Future studies should therefore collect information regarding children's mental health in order to rule it out as a possible confounder.

Finally, future studies should aim to collect validated medical information regarding asthma. The outcome paper relied on participants' self-report to establish the severity of asthma. Incorporating confirmed medical diagnoses and information from medical records would increase the validity of the construct "asthma severity".

Mentalisation Theory and my Clinical Interests

What led me to develop a thesis on this subject?

Since childhood, I have questioned how human personality develops. Growing up with both parents trained in the area of psychiatry and psychotherapy, it is clear why this question accompanied me throughout my youth and possibly contributed to my decision to train as a clinical psychologist. In fact, one of the main premises when deciding on the topic of my thesis was to include a psychological theory relevant to personality development.

During a teaching session in the first year of training, the high prevalence of mental health difficulties and reduced quality of life amongst caregivers of chronic conditions were highlighted. Personally knowing several people with longstanding chronic health conditions, it had always struck me how illnesses like asthma were often examined and researched from purely medical lenses, even though, to date, medical science has not been able to clarify its causes (British Lung Foundation, 2016; Lazarus, 2010). Thus, I was genuinely interested in further understanding the psychological struggles that caregivers of children with such an illness may face. What could make the task of caregiving for asthma a less burdensome experience?

In attempting to answer this question, my mind travelled back to the start of my training in Spain, where my university studies were heavily influenced by attachment and

psychoanalytic theories. I remembered the lectures where we discussed the work of John Bowlby (1969), who demonstrated that early experiences play a fundamental role in shaping our sense of self. Attachment theory and the idea of an internal working model (Ainsworth, Blehar, Waters & Wall, 1978) that influences our behaviours, needs for intimacy and separation, loss and grief was not only very attractive, but also provided a wide range of research opportunities to understand caregiving experiences. Nevertheless, several studies had already examined the attachment experiences of caregivers of children with asthma (Cassiba, van IJzendoorn, Bruno & Coppola, 2004; Ravaccia & Fiorentini, 1997; Tambelli, Zavattini & Pradarelli, 1993) and thus I shifted my attention to mentalisation, which I considered a third-wave element of attachment theory.

As a clinician with a profound interest in psychoanalysis, the work of Bion (1962) and Winnicott (1971), on the role of caregivers who mirror and contain babies' feelings, has always inspired me. Nevertheless, psychoanalytic theories are often dense and more difficult to examine through quantitative research methodologies. Over the last two decades, Dr Fonagy and his collaborators have been able to expand on and deepen Winnicot's and Bion's concepts, incorporating them into the theory of mentalisation (Wallin, 2015). The integrative nature of mentalisation and its emphasis on the experience of early relationships in laying the foundations of the personality were what drew me to use mentalising as a key concept for my thesis.

Developing my Clinical Identity

The journey of conducting this research is an excellent representation of the science–practitioner model of clinical psychology. This model has not only contributed to developing an outstanding research-based culture but has also allowed professionals to make clinical decisions supported by the findings of a wide range of studies. Throughout my thesis journey, I have improved my understanding of research design and methodology, statistical analyses

and results interpretation, skills that will be of incalculable value for my professional development and identity, allowing me to critically understand quantitative research, its underlying assumptions and limitations, and the tremendous influence, both positive and negative, that research has in policy-making and service delivery.

Although very positive, this learning process has made me aware of an existing ethical dilemma between clinical psychology and research, which I believe has impacted on my clinical identity, and which I will try to address in the following pages. The dilemma concerns the allegiance of clinical psychology towards positivist paradigms of mental health.

For instance, when conducting my outcome paper, I realised that the interventions mostly studied for supporting families with asthmatic children were problem-solving and cognitive. Similarly, the literature appraised during the systematic review suggested that most clients who had accessed talking therapies in England were only offered cognitive behavioural therapy (CBT) (Mind, 2013). Although CBT has proven to be useful for some people with different mental health presentations (Hofman, Asnaani, Vonk, Sawyer & Fang, 2012), a significant amount of clients experience little or no benefit from this approach (Shedler, 2015). Furthermore, research conducted on predictors of therapeutic change has suggested that specific therapeutic models are not accurate predictors of positive therapy outcomes (Lambert, 2007; Martin, Garske & Davis, 2000; Wampold, 2001). Thus, overrelying on a limited number of therapeutic methods could suggest a misinterpretation of the clinical utility of the different available psychological therapies.

Conducting a quantitative thesis has made me more aware of the predominantly positivist epistemological position in clinical psychology and how this affects the identity of trainees like myself. Worryingly, I seem to have automatically incorporated some of the vocabulary belonging to a purely positivist approach, finding myself describing efficacy and effectiveness of psychological approaches with colleagues and supervisors without

questioning the underlying assumptions of such terms. These automatisms have been acquired after extensive hours devoted to understanding quantitative research and developing outcome papers written to a publishable standard.

One catchphrase that I have been regularly exposed to, both during training and throughout my thesis, has been "evidence-based". Originating from the field of medicine, this is often a synonym for manualised brief psychotherapies (Shedler, 2015) tested under stringent settings (i.e. randomised controlled trials [RCTs]). The appeal of evidence-based therapies is that they are meant to be the vehicle for providing the best quality of care for service-users. In theory, this is something that every clinician, including myself, would agree with. However, when looking closely at how the "evidence base" is constructed, one can start to understand some of the ambitious assumptions involved.

Publication bias or research allegiance, suggested by some authors to account for up to 40% of results of published trials (Duncan & Miller, 2006), are often unnoticed. In a significant number of research trials, a priori-established exclusion criteria can preclude up to 66% of clients from taking part (Westen, Novonty & Thompson-Brenner, 2004). This suggests that the clients whom clinical psychologists would see in their everyday practice are often excluded from such trials. In fact, psychotherapy research is currently experiencing a "replicability crisis", as most findings from RCTs are not translated into routine clinical practice (Tajika, Ogawa, Takeshima, Hayasaka & Furukawa, 2015). Replicating findings from high-controlled settings into naturalistic settings is an essential component of science (Rosenthal, 1990), yet this is not often acknowledged when discussing the evidence of "evidence-based therapies" (Shedler, 2015).

In the current context, it is often hard to challenge the "evidence-based" practice within clinical psychology settings (Mollon, 2009). Clinical psychologists have spent years producing robust evidence, thereby asserting the profession as compliant with the science–

practitioner model. This is admirable, but it remains unclear whether acquiring the status of science–practitioners has come with associated costs. Is equating "evidence-based" to RCTs freezing the ability of clinical psychologists to think and reflect on the limitations of such research?

Luckily, Lancaster's clinical training programme holds a more balanced perspective, welcoming different paradigms and acknowledging the limitations of dominant discourses. Yet over the past 18 months, I have experienced a sense of deflation and disappointment with some of the pathways taken by other clinical training programmes in understanding emotional distress. Almost mirroring the primary task crisis of the NHS, where providing quick-fix, cheap interventions seems to be the current priority, some clinical psychology circles seem to be moving towards a business model, where service-users are clients who "purchase" the seemingly best available ("evidence-based") approach in the market. The allegiance towards the National Institute for Clinical Excellence (NICE) guidelines can often produce a contradictory and confusing scramble of paradigms where, on the one hand, we tell ourselves that clinical psychologists employ a person-centred approach and, on the other hand, NICE guidelines are considered the bible of the profession, even though they blindly rely on psychiatric diagnostic categories that often lack adequate validity and utility (Jablensky, 2016).

Moreover, the tendency of our profession to rely excessively on *p* values when making clinical decisions can deceive professionals, service-users and policy-makers, as it can be used as discouragement from thinking, reflecting and acknowledging that psychotherapy is, in essence, a human relationship, and thus its complexity and multifaceted nature cannot be solely captured by statistical values. As Jacques Lacan put it in an interview in 1974 (Skinner, 2014):

> First off, let's get rid of this average Joe, who does not exist. He is a statistical

> fiction. There are individuals, and that is all. When I hear people talking about the guy in the street, studies of public opinion, mass phenomena, and so on, I think of all the patients that I've seen on the couch in forty years of listening. None of them in any measure resembled the others, none of them had the same phobias and anxieties, the same way of talking, the same fear of not understanding. Who is the average Joe: me, you, my concierge, the president of the Republic? (p.3)

It is important to acknowledge that I do not fully agree with Lacan's position, and that I believe that research is essential to progress in understanding how to best help our clients. That being said, I consider that Lacan's reflection touches on the identity crisis that I have experienced whilst developing my thesis. On the one hand, I value the attempt of clinical psychology to conduct research that helps to improve mental health care. This is the reason that I decided to conduct a quantitative project, as I believed that it could have a positive impact on caregivers of children with asthma who were struggling, and who had, to some extent, been overlooked by research. On the other hand, I disagree with the neglect of alternative mental health paradigms mainly because they have emerged from different epistemological positions, such as social constructionism, and therefore do not fit in easily with RCTs.

In fact, I consider that the currently established science–practitioner model in clinical psychology has become complacent. Under the umbrella of RCTs, too many questions have been foreclosed. Even though the mechanisms of therapeutic change are still largely unknown, certain therapies are being widely recommended (Mind, 2013), whilst others are largely disregarded. If the aim is for science to advance, neuroscientific evidence should be more readily incorporated into both routine decision-making and NICE guidelines. In fact, emerging evidence has suggested that psychotherapy can produce positive outcomes that are associated with brain functioning and structural changes (Frewen, Dozois & Lanius, 2008;

Wiswede et al., 2014).

Overall, the realisation that clinical psychology is, in my opinion, experiencing an identity crisis has been painful. However, this process has shaped my professional identity and allowed me to take on board the immense amount of skills, opportunities and knowledge that the thesis and training have offered me, whilst also preserving the values of clinical intuition, innovation and constructive criticism. In fact, I am grateful for the opportunity that clinical training and this thesis have provided me in terms of developing an independent judgement. Moreover, I highly value the opportunity that this process has granted in learning what research has allowed us to discover but also in reconnecting with the feelings of not understanding, which I believe are essential to help those in distress.

It is my hope that as my professional career develops, I am able to reconcile these disappointments and develop a practice that is transparent, honest and shaped by research, clinical judgement and clients' personal needs. The capacity of combining all these elements in an NHS that is often overstretched, risk-averse and strongly influenced by economic and political interests may seem utopic. However, as Fernando Birri, Argentinian filmmaker, said (Galeano, 2003):

> Utopia is on the horizon. I move two steps closer; it moves two steps further away. I walk another ten steps and the horizon then runs ten steps further away. As much as I walk, I'll never reach it. So what's the point of utopia? The point is this: to keep walking. (p.27)

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4. Ethics Section

Malda-Castillo, Javier

Trainee Clinical Psychologist

Division of Health Research

Lancaster University

Applicant: Javier Malda Castillo Supervisor: Guillermo Perez Algorta
Department: Health Research FHMREC Reference: FHMREC16112

11 July 2017

Dear Javier

Re: Examining mentalization ability in caregivers of asthmatic children

Thank you for submitting your research ethics application for the above project for review by the **Faculty of Health and Medicine Research Ethics Committee (FHMREC)**. The application was recommended for approval by FHMREC, and on behalf of the Chair of the Committee, I can confirm that approval has been granted for this research project.

As principal investigator your responsibilities include:

- ensuring that (where applicable) all the necessary legal and regulatory requirements in order to conduct the research are met, and the necessary licenses and approvals have been obtained;
- reporting any ethics-related issues that occur during the course of the research or arising from the research to the Research Ethics Officer at the email address below (e.g. unforeseen ethical issues, complaints about the conduct of the research, adverse reactions such as extreme distress);
- submitting details of proposed substantive amendments to the protocol to the Research Ethics Officer for approval.

Please contact me if you have any queries or require further information. Tel:- 01542 592838 Email:- fhmresearchsupport@lancaster.ac.uk

Yours sincerely,

Dr Diane Hopkins
Research Integrity and Governance Officer, Secretary to FHMREC.

Faculty of Health and Medicine Research Ethics Committee (FHMREC) Lancaster University

Application for Ethical Approval for Research[guidance1]

for additional advice on completing this form, hover cursor over ´guidance´

Guidance on completing this form is also available as a word document

Title of Project guidance 2]: Examining mentalisation ability in caregivers of asthmatic children

Name of applicant/researcher: JAVIER MALDA CASTILLO

ACP ID number (if applicable)*: **Funding source (if applicable)**

Grant code (if applicable):

***If your project has *not* been costed on ACP, you will also need to complete the Governance Checklist [link].**

Type of study

☐ Involves existing documents/data only, or the evaluation of an existing project with no direct contact with human participants. **Complete sections one, *two* and four of this form**

☒ Includes *direct* involvement by human subjects. **Complete sections one, *three* and four of this form**

SECTION ONE

1. Appointment/position held by applicant and Division within FHM Trainee Clinical Psychologist

2. Contact information for applicant:
E-mail: j.maldacastillo@lancaster.ac.uk **Telephone**: 07514267419 (please give a number on which you can be contacted at short notice)

Address: Clinical Psychology, Faculty of Health and Medicine, Furness Building, Lancaster University, Lancaster, LA1 4YG

3. **Names and appointments of all members of the research team (including degree where applicable)**

Principle Investigator (PI). Javier Malda Castillo Trainee in Clinical Psychology, Lancaster DclinPsych Research team
Dr Guillermo Pérez-Algorta:Lecturer in Mental Health, Lancaster DclinPsych Research team
Dr Claire Browne (field supervisor): Consultant Clinical Psychologist Central Manchester University Hospitals NHS Foundation Trust

3. If this is a student project, please indicate what type of project by marking the relevant box/deleting as
appropriate: (please note that UG and taught masters projects should complete **FHMREC form**

PG Masters by PhD PhD Pall.

PhD Pub. PhD Org. Health & Well PhD Mental M

DClinPsy Thesis

4. Project supervisor(s), if different from applicant: Dr Guillermo Pérez-Algorta

5. Appointment held by supervisor(s) and institution(s) where based (if applicable): Lecturer in Mental Health, Lancaster University, DClinpsych Research team.

SECTION TWO---Not relevant section for this project

Complete this section if your project involves existing documents/data only, or the evaluation of an existing project with no direct contact with human participants

1. Anticipated project dates (month and year [guidance 3])

Start date: End date:

2. Please state the aims and objectives of the project (no more than 150 words, in lay-person's language[guidance 4]):

Data Management

For additional guidance on data management, please go to Research Data Management *webpage, or email the RDM support email:* rdm@lancaster.ac.uk

3. Please describe briefly the data or records to be studied, or the evaluation to be undertaken.

4a. How will any data or records be obtained?

4b. Will you be gathering data from websites, discussion forums and online chats no
4c. If yes, where relevant has the permission been secured from the website moderator? **no**
4d. If you are only using those sites that are open access and do not require registration, have you made your intentions clear to other site users? **no**

4e. If no, please give your reasons

5. What plans are in place for the storage, back-up, security and documentation of data (electronic, digital, paper, etc[guidance5])? Note who will be responsible for deleting the data at the end of the storage period. Please ensure that your plans comply with the Data Protection Act 1998.

6a. Is the secondary data you will be using in the public domain? no
6b. If NO, please indicate the original purpose for which the data was collected, and comment on whether consent was gathered for additional later use of the data.

Please answer the following question *only* if you have not completed a Data Management Plan for an external funder

7a. How will you share and preserve the data underpinning your publications for at least 10 years e.g. PURE[guidance6]?

7b. Are there any restrictions on sharing your data[guidance7]?

8. Confidentiality and Anonymity

a. Will you take the necessary steps to assure the anonymity of subjects, including in subsequent publications? **yes**

b. How will the confidentiality and anonymity of participants who provided the original data be maintained?

9. What are the plans for dissemination of findings from the research[guidance 8]?

10. What other ethical considerations (if any), not previously noted on this application, do you think there are in the proposed study? How will these issues be addressed?

SECTION THREE

Complete this section if your project includes *direct* involvement by human subjects

1. Summary of research protocol in lay terms (indicative maximum length 150 words[guidance 9]):

The UK has one of the highest prevalence rates of asthma in children worldwide; with one in every 11 children suffering from asthma (Asthma UK, 2016). It has been suggested that caring for a child with a chronic illness can have a significant impact on the wellbeing of their caregivers (Julian et al. 2015) as well as increase their risk of experiencing mental health difficulties (Easter et al., 2015; Frankel & Wamboldt, 1998; Kaugars, Klinnert, & Bender,2004). In order to increase the understanding of the burden that asthma may have on caregivers of asthmatic children, we plan to collect online data using anxiety, mood disturbance, mentalisation and family functioning questionnaires. Overall, this research project will attempt to respond to three research questions:

1)Explore the levels of mentalisation in a sample of caregivers of asthmatic children

2)Is there an association between caregivers' mentalisation ability and family functioning?

3)I s there an association between caregivers' mentalisation levels and anxiety and mood difficulties (depression and/or hypomanic) symptoms?

2. **Anticipated project dates (month and year only**[guidance 10])

Start date: 20/08/2017 End date10/05/2018

Data Collection and Management

For additional guidance on data management, please go to Research Data Management *webpage, or email the RDM support email:* rdm@lancaster.ac.uk

3. Please describe the sample of participants to be studied (including maximum & minimum number, age, gender[guidance 11]):

Inclusion criteria: Be a caregiver (>18 years old) of a children or an adolescent with a confirmed asthma diagnosis in the United Kingdom. Currently there is not a consistent and agreed definition of caregiver (Hermanns & Mastel- Smith, 2012). This project will define caregiver as the adult who provides unpaid support and takes most responsibility (i.e. at least 4 hours per day) in caring for the wellbeing and health of the child. This can also include grandparents, relatives or legal guardians among others.

There is no specific exclusion criteria although participants who are unable to understand written English will not be able to take part in the study given that there will not be translators/interpreters available for the current research.

4. How will participants be recruited and from where? Be as specific as possible [guidance 12]. Ensure that you provide the *full versions* of all recruitment materials you intend to use with this application (eg adverts, flyers, posters).

The recruiting will be initially across the third sector, charitable organisations and online support groups of the United Kingdom. We plan to contact organisations such as: Asthma UK, British Lung foundation, or Allergy Uk and children centres such as Balmoral Children's Centre or Poulton Children's Centre. We also plan to contact asthma online support groups such as https://www.dailystrength.org/group/asthma or http://www.healthfulchat.org/asthma-chat-room.html. In addition, contacts of the supervisory team will support in the selection of participants through advertising the project in non-NHS special interest social media groups (i.e. Facebook or twitter). An official Facebook and Twitter account will be created for the purpose of this study. In order to advertise the research, potential participants will receive an information poster (see protocol), which outlines the research aims and contact details of the research team.

5. Briefly describe your data collection and analysis methods, and the rationale for their use.

The selection of the instruments to collect the information was made on the basis of previous literature around measuring anxiety, family functioning, mentalisation and mood disturbance in research settings. The selection of the questionnaires was also based on previous literature exploring mental health difficulties among caregivers of asthmatic children. The instruments that will be employed include the general functioning scale of the Family Assessment device, the reflective functioning questionnaire (RFQ-8), the 7up 7 down inventory (7U7D) and the Beck Anxiety Inventory (BAI). This research will also collect sociodemographic information (i.e. employment status, education etc.) with the aim of characterizing the sample, which would aid in understanding the generalizability of the results. These instruments will be included in an online e-survery that participants will be able to access through a link shared by the research team.

The independent variable in the current study will be the ability to mentalise and the three dependent variables will be anxiety , mood disturbance and family functioning. The aim of the current study is to clarify the possible effects of mentalisation in family functioning, anxiety levels and mood disturbances. Thus, correlation analyses between mentalisation and the three independent variables will be conducted. Descriptive statistics of sociodemographic (i.e. gender, ethnicity) and clinical characteristics (i.e. asthma severity) of the participants will also be conducted.

In order to control for potential confounders regression analyses will be conducted. Mentalisation will be included as predictor of family functioning, anxiety and mood disturbances and confounders will be caregivers´ gender, asthma severity (measured by adapted scale from Haterman et al., 2004) and income. These confounders were selected on the basis of previous research, which has suggested that there is a relationship between maternal demoralization, stress, depression and their children´s asthma (Yamamoto & Nagano, 2015). However, the interactions between paternal figures and asthmatic children have been overlooked. In addition, previous research has suggested that asthma severity of the child may impact on caregivers' quality of life (Haterman et al., 2004), which could then have effect on their mental health. Furthermore, income and health are strongly associated such as those from less privileged backgrounds are at increased risk of physical and mental health difficulties.
The current research hypothesizes that higher mentalisation levels will predict less anxiety and mood disturbance symptoms and better family functioning after controlling for these confounders. However of 0.80 and four predictors (mentalisation, gender, asthma severity and socio-economic status), a minimum sample size of 85 families will be required. Thus the minimum sample required will be of 85 and the maximum of 100.

6. What plan is in place for the storage, back-up, security and documentation of data (electronic, digital, paper, etc.)? Note who will be responsible for deleting the data at the end of the storage period. Please ensure that your plans comply with the Data Protection Act 1998[guidance 13].

Data will be collected via Redcap, which is a secure online system to build and manage online questionnaires. Redcap use is approved by Lancaster university (https://redcap.lancaster.ac.uk/ and one of its advantages compared to other programs such as Qualtrix is that you can provide access to your profile to other staff involved in the research. The data will be stored in the password protected Lancaster University internal server. During this time, the data will be anonymous and will only be available to the research team within a password-protected environment. When the data collection processes finishes, these data will be transferred into an excel database and stored in Javier Malda Castillo's personal password protected box system. This is an encrypted online support storage system. Participants will be able to withdraw their consent up until 15th February 2018. If participants withdraw their consent, their data will be destroyed. The investigators will be able to identify which participants have decided to withdraw their consent by using their date of birth as identifying information. Participants´ identifying information (their date of birth) will be kept in a separate password protected excel document and will be deleted after the thesis has been assessed. The database will be accessible to all members of the research team through box. After Javier Malda Castillo completes the course, Dr Guillermo Pérez-Algorta will be responsible for the storage and deletion of the data.

7. Will audio or video recording take place? ☒ no audio video
a. Please confirm that portable devices (laptop, USB drive etc) will be encrypted where they are used for identifiable data. If it is not possible to encrypt your portable devices, please comment on the steps you will take to protect the data.[guidance14]

b What arrangements have been made for audio/video data storage? At what point in the research will tapes/digital recordings/files be destroyed[guidance 15]?

No audio or video recording will take place.
Please answer the following questions *only* if you have not completed a Data Management Plan for an external funder

8a. How will you share and preserve the data underpinning your publications for at least 10 years e.g. [guidance16]PURE?
Once the thesis has been approved and the piece has been finished, the stored data will be transferred to the secure Lancaster University Server. As this is the last year of Javier Malda Castillo as a student, following his departure, maintenance of the data will be the responsibility of Dr Guillermo Perez-Algorta (supervisor). The data collected will be retained for 10 years as standard.
8b. Are there any restrictions on sharing your data [guidance17]?
We do not expect any restrictions in sharing the data and secondary analyses based on this data could be conducted. Information about this possibility will be provided to participants when obtaining consent .

9. Consent
a. Will you take all necessary steps to obtain the voluntary and informed consent of the prospective participant(s) or, in the case of individual(s) not capable of giving informed consent, the permission of a legally authorised representative in accordance with applicable law? yes

b. Detail the procedure you will use for obtaining consent[guidance 18]?
Participants will complete an online survey. Before starting to complete the questionnaires an introductory cover sheet will clearly inform participants that by completing the survey they consent to the use of the data for research purposes. However, this cover sheet will not require them to sign or type identifying information.
Therefore, participants will be asked to click into a link at the end of the introductory cover in order to provide consent. After they click on the link, they will be redirected to the completion of the online questionnaires.

10. What discomfort (including psychological e.g distressing or sensitive topics), inconvenience or danger could be caused by participation in the project? Please indicate plans to address these potential risks[guidance 19]. State the timescales within which participants may withdraw from the study, noting your reasons.[guidance 20]

It is possible that participants feel distressed when responding questions related to anxiety, mood disturbance or family functioning. At the end of the study, participants will be able to read a debriefing sheet and they will be informed about how to access emotional support if they need to. Participants will be given the opportunity to receive support from the PI and will be signposted to the appropriate service (i.e. mental health charity such as MIND) if further support is required. The field supervisor, Dr Clare Browne (Clinical Psychologist) will provide supervision and guidance to the PI on this matter.

11. What potential risks may exist for the researcher(s)? Please indicate plans to address such risks (for example, noting the support available to you; counselling considerations arising from the sensitive or distressing nature of the research/topic; details of the lone worker plan you will follow, and the steps you will take[guidance 21])

There are no potential risks identified for the principal investigator (PI). However, should the researcher feel distressed it will be agreed that he can have a conversation with his research supervisor. If this support is not sufficient, the research supervisor will guide the PI to access appropriate support. In fact, the Lancaster Doctorate in Clinical Psychology course offers 6 sessions of free Cognitive-Analytic therapy that the PI could access if he feels that he needs additional support.
12. Whilst we do not generally expect direct benefits to participants as a result of this research,

please state here any that result from completion of the study[guidance 22].

Participants will not gain any direct benefit from this study. However, this study will increase the understanding of the difficulties that caregivers of asthmatic children may experience. By exploring an overlooked construct in the area, this study will provide an opportunity for further research to develop in the area.

13. Details of any incentives/payments (including out-of-pocket expenses) made to participants[guidance 23]: No incentives/payments will be made to participants.

14. Confidentiality and Anonymity
a. Will you take the necessary steps to assure the anonymity of subjects, including in subsequent publications? yes
b. Please include details of how the confidentiality and anonymity of participants will be ensured, and the limits to confidentiality[guidance 24].
All information will be collected and stored anonymously. Participants will be informed about this prior to taking part in the study. No identifiable information will be collected for the current research.

15. If relevant, describe the involvement of your target participant group in the *design and conduct* of your research[guidance 25].

The project has consulted with two professionals with broad experience working with population with physical and mental health difficulties. The field supervisor has broad experience in working with children with chronic health conditions. An experienced stakeholder working in a children's hospital has also provided consultation on possible recruitment strategy.

16. What are the plans for dissemination of findings from the research? If you are a student, include here your thesis[guidance 26].

The results of this study will be part of a thesis in the Doctorate in Clinical Psychology program. Following the submission of the thesis, the results of this research will be submitted to an academic peer-reviewed journal.

17. What particular ethical considerations, not previously noted on this application, do you think there are in the proposed study[guidance 27]? Are there any matters about which you wish to seek guidance from the FHMREC? The current study will recruit participants primarily through online resources. Thus, caregivers who do not have access to the internet or who are not comfortable in providing online information may not take part in the study. This would mean that the current research may exclude a segment of the caregivers of asthmatic children. This is a potential ethical issue as this research aims to produce information that is generalizable for asthmatic caregivers in the UK. However, this will be acknowledged in the research paper and will provide the opportunity for future research to address this issue.

SECTION FOUR: signature

Applicant electronic signature Javier Malda Castillo
Date:17/05/2017

Student applicants: please tick to confirm that you have discussed this application with your

supervisor, and that they are happy for the application to proceed to ethical review ☒

Project Supervisor name Guillermo Perez-Algorta Date application discussed

Submission Guidance

1. Submit your FHMREC application by email to Diane Hopkins (d.hopkins@lancaster.ac.uk) as two separate documents:

   i. **FHMREC application form.**
   Before submitting, ensure all guidance comments are hidden by going into 'Review' in the menu above then choosing *show markup>balloons>show all revisions in line.*

   ii. **Supporting materials.**
   Collate the following materials for your study, if relevant, into a single word document:

   a. Your full research proposal (background, literature review, methodology/methods, ethical considerations).
   b. Advertising materials (posters, e-mails)
   c. Letters/emails of invitation to participate
   d. Participant information sheets[guidance 29]
   e. Consent forms
   f. Questionnaires, surveys, demographic sheets
   g. Interview schedules, interview question guides, focus group scripts
   h. Debriefing sheets, resource lists

   Please note that you DO NOT need to submit pre-existing measures or handbooks which support your work, but which cannot be amended following ethical review. These should simply be referred to in your application form.

2. Submission deadlines:

   i. Projects including direct involvement of human subjects **[section 3 of the form was completed]**. The *electronic* version of your application should be submitted to Diane Hopkins **by the committee deadline date.** Committee meeting dates and application submission dates are listed on the FHMREC website. Prior to the FHMREC meeting you may be contacted by the lead reviewer for further clarification of your application. Please ensure you are available to attend the committee meeting (either in person or via telephone) on the day that your application is considered, if required to do so.

   ii. The following projects will normally be dealt with via chair's action, and may be submitted at any time. **[Section 3 of the form has *not* been completed, and is not required].** Those involving:

   a. existing documents/data only;
   b. the evaluation of an existing project with no direct contact with human participants;
   c. service evaluations.

3. **You must submit this application from your Lancaster University email address, and copy your supervisor in to the email in which you submit this application**

Thesis Research Protocol

Title: *Examining* mentalization *ability in caregivers of asthmatic children*

Applicant: Javier Malda Castillo (Trainee Clinical Psychologist, Lancaster University)

Supervisors: Dr Guillermo Perez-Algorta (Mental Health Lecturer, Lancaster University) & Dr Claire Browne (Consultant Clinical Psychologist, Central Manchester University Hospitals NHS Foundation Trust)

Have you ever found yourself struggling to breath and being unable to speak or ask for help? That is what an asthma attack looks like. Asthma is the commonest long-term illness of childhood worldwide with prevalence rates ranging from 7-10% (Lazarus, 2010). The United Kingdom (UK) has one of the highest prevalence rates of asthma worldwide with over 8 million people currently experiencing this condition (British Lung Foundation, 2016) and the National Health Service (NHS) spends over a billion pounds every year in treating and supporting people with asthma (Asthma Uk, 2016).

The impact of this chronic illness is not limited to the children who suffer it, but has an effect in the family system, especially among caregivers (Easter, Sharp & Hunt, 2015). Previous literature has suggested that caring for a child with asthma can adversely affect parental mental health (Frankel & Wamboldt, 1998; Kaugars, Klinnert, & Bender,2004) and quality of life (Halterman et al., 2004). In fact, recent literature indicated that anxiety and mood difficulties (i.e. depressive symptoms) were higher in caregivers of asthmatic children than in caregivers of children without physical or mental health diagnoses (Easter et al., 2015) and other studies have reported that maternal demoralization (Reyes et al., 2011); perceived stress (Lange et al., 2011) and reduced quality of life (Halterman et al., 2004) are frequent among caregivers of asthmatic children.

Furthermore, it seems that family functioning is an important resource for caring for an asthmatic child (Drotar, 1997; Thompson, Gustafson, Hamlett & Spock, 1992). Family functioning refers to the interpersonal relationships within the family, including levels of cohesion, adaptability, conflict resolution and quality of communication (Lewandowski,Palermo, Stinson, Handley & Chambers, 2010). Families with higher levels of functioning can make flexible changes to deal with the stressors and uncertainties of a chronic illness like asthma (Zhou, Yi, Zhang & Wang, 2014). Although it has not been examined in the specific context of asthma, previous literature suggests that adequate family

functioning can help in reducing the effects of parental depressive symptoms related to childcare stress (Brown, Lambert, Hsu & Eckman, 1998). In contrast, families with lower levels of functioning can increase the stressors associated to having children with asthma and in turn impact on caregivers 'mental health (Zhou et al., 2014).

In contrast, the currently available literature has failed to explore mentalisation in this population, a concept originally developed by Fonagy (1991), defined as "the capacity to differentiate self from the other and to ascribe mental states to others so their behaviour can make sense and be predictable" (Roussow, 2012, p. 89). In interactions between caregivers and asthmatic children, mentalisation could help caregivers understand their children's emotional states, the potential stress of dealing with a chronic condition and how this could influence their behaviours. Understanding their children's mental states would help them support not only with the chronic condition but also with the emotional impact of it.

Since its origin, mentalisation has captured the interest of clinical research as is reflected by the wide array of clinical research papers that have explored it (Bateman & Fonagy, 2013). Although the concept was first introduced in the context of a treatment for personality disorders (Choi-Kain & Gunderson, 2008), its usage rapidly expanded into a wide array of clinical areas, including the treatment of families (Fearon et al., 2006), eating disorders (Skarderud, 2007), parent-infant dyads (Sadler, Slade & Mayes, 2006) and school-based community interventions (Twemlaw & Fonagy, 2006). Furthermore, robust mentalisation has been associated to secure attachment (Fonagy et al., 2002) and individuals with high levels of mentalisation show high significant resilience in the face of stressful situations (Bateman & Fonagy, 2013). In contrast, lack of mentalisation has been associated with different mental health difficulties (Roussow, 2012). Therefore, caregivers with greater levels of mentalisation may respond more adaptively to the demands of asthma and may experience higher levels of positive family functioning, whereas caregivers with lower mentalisation may be at risk of

experiencing mood difficulties, anxiety and reduced family functioning. This has potential clinical implications because mentalisation is not a static unitary trait, but instead a dynamic ability that can be enhanced through therapy (Bateman & Fonagy, 2013). Hence, exploring caregivers' ability to understand their own and their children´s feelings, desires and thoughts could contribute to the understanding of the impact that asthma has on the family unit. Furthermore, given that caregivers are primary responsible for monitoring children´s health and for making medical decisions regarding their asthma (McQuaid et al., 2003), understanding their possible mental distress is paramount both in terms of caregiver wellbeing and asthma outcomes (Easter, Sharp & Hunt, 2015).

Overall, previously available literature has suggested that caregivers of children with asthma may be at risk of experiencing mental health difficulties. However, the currently available literature has largely ignored a widely researched construct in clinical practice such as mentalisation. Therefore, this study aims to expand the currently available literature by exploring the mentalisation ability of the caregivers and its possible association with their mental health and family functioning. The results of the study could increase the understanding of the burden that caregivers of children with asthma may experience, which could in turn inform mental health providers in the design of prevention and intervention programs.

Method

Participants

Participants will be caregivers (>18 years old) of asthmatic children that in the United Kingdom. Currently there is not a consistent and agreed definition of caregiver in the literature (Hermanns & Mastel-Smith, 2012). This study will define caregiver as the adult who provides unpaid support and assumes most responsibility (i.e. at least 4 hours per day) in caring for the wellbeing and health of the child. This can also include grandparents, relatives

or legal guardians among others.

Sample Selection. Professional contacts of the supervisory team will help in identifying potential participants. In addition, participants will be recruited through advertising the project in non- NHS special interest social media groups (i.e. Facebook or twitter), online support groups, third sector organisations and charities. An official Facebook and Twitter account will be created for the purpose of this study. In order to advertise the research, potential participants will receive an information poster (see appendix 4-A), which outlines the research aims and contact details of the research team.

Design

The current study will follow a cross-sectional quantitative between subjects design. A quantitative survey design will be designed using the online secure survey design management system "Redcap".

Materials

-Clinical and sociodemographic information: An e-survey with forced response and Likert-scales will be employed to collect clinical and sociodemographic information such as: age, ethnicity, gender and asthma severity (adapted from Halterman et al., 2004) among others (see appendix 4-D). This will help characterizing the sample, which would aid in understanding the generalizability of the results.

-Family Functioning: The functioning of families in the current study will be assessed using the *general functioning scale* of the Family Assessment Device (Epstein, Baldwin & Bishop, 1983). This is a 12 item self-report questionnaire that provides rating of the overall functioning of a family. The score on this questionnaire can range from 0 to 4 with higher scores indicating more impaired family functioning. The average test-retest reliability of the scale is 0.71 and the average internal consistency is 0.78 (Akister and Stevenson-Hinde, 1991; Bihun et al., 2002). In addition, the concurrent validity was confirmed in a large

epidemiological study of children (Byles, Byrne & Boyle, 1998), as scores on the scale were significantly associated with other variables associated with impaired family functioning (e.g. alcoholism).

- Mentalisation: Reflective Functioning Questionnaire (Fonagy et al., 2016): The reflective functioning questionnaire (RFQ-8) is short screening 8-item version of the original RFQ which has 56 items . This is the most recently developed self-report screening measure for mentalizing, with a 7-point type Likert scale. Internal consistency of the scale ranged from 0.70 to 0.65 in a clinical sample and from 0.63 to 0.67 in a non-clinical sample. The test–retest reliability over a period of 3 weeks ranged from r= 0.84 to 0.75 (Fonagy et al., 2016). This questionnaire has been chosen because is easy to administer and because the aim of this research is not to capture the different dimensions of mentalizing, but rather explore the general ability of mentalisation of the participants.

-Mood difficulties: The 7 Up 7 Down Inventory (7U7D) is a recently developed self-report questionnaire that consists of 14 items (Youngstrom, Murray, Johnson and Findling, 2013). This scale measures hypomanic and depressive tendencies and has demonstrated high internal reliability ranging from .83 to .95 as well as adequate construct validity (Youngstrom et al., 2013).

-Anxiety: Beck Anxiety Inventory (BAI). This is a 21 item self-report questionnaire that can be used as a screening instrument for anxiety in research setting. The internal consistency for the BAI is as high as .92 and test-retest reliability scores of .75 have been reported after one week (Beck, Epstein and Brown, 1988).

Procedure

The recruiting will be initially across the third sector, charitable organisations and online support groups of the United Kingdom. We plan to contact organisations such as: Asthma Uk, British Lung foundation, or Allergy Uk and children centres in such as Balmoral

Children's Centre or Poulton Children's Centre. We also plan to contact asthma online support groups such as: https://www.dailystrength.org/group/asthma or http://www.healthfulchat.org/asthma-chat-room.html.

The study will be conducted online through the platform Redcap. Therefore, informed consent will be gained online (Appendix 4-B). Prior to completing the questionnaires, participants will be presented with an online participant information sheet. Informed consent will be gained by explaining to participants what are they consenting to such as: what will they be asked to do, what will their data be used for, how will the data be stored and what would they need to do if they wanted to withdraw from the study. Following consent, participants will be instructed on how to complete the online questionnaires. The order of the questionnaires will be the same that is described in the materials section above. After completing the questionnaires, participants will be able to read a debrief sheet (Appendix 4-E)

Proposed Analysis

In the current study, mentalisation will be the independent variable and anxiety, mood disturbances and family functioning will be the dependent variables. The aim of the current study is to clarify the possible effects of mentalisation in family functioning, anxiety levels and mood disturbances. Thus, correlation analyses between mentalisation and the three independent variables will be conducted. In order to control for potential confounders, regression analyses will be conducted in which mentalisation will be included as predictor of family functioning, anxiety and mood disturbances and caregivers' gender, income and child´s asthma severity will be included as confounders. These confounders were selected on the basis of previous research, which has suggested that there is a relationship between maternal demoralization, stress, depression and their children´s asthma (Yamamoto & Nagano, 2015). However, the interactions between paternal figures (male gender) and

asthmatic children have been overlooked. In addition, previous research has suggested that asthma severity of the child may impact on caregivers´quality of life (Haterman et al., 2004), which could then have an effect on their mental health. Furthermore, income and health are strongly associated such as those from less privileged backgrounds are at increased risk of physical and mental health difficulties (Marmot, 2010).The current research hypothesizes that higher mentalisation levels will be associated with less anxiety and mood disturbance symptoms and better family functioning after controlling for confounders. Therefore, according to power analysis guidelines (Miles & Shelvin, 2001) for a medium effect size, an alpha significance level of 0.05 and power of 0.80 and three predictors, this study will require a minimum sample size of 85 and a maximum sample size of 100.

Data Management Plan (DMP)

Data Collection

The data will be collected online through Redcap, which is an online secure e-survey design system. The data will be transferred to an excel document, which will be stored in a password-protected online secure system.

Storage, backup and security

The database will not contain any identifiable information from the participants. The principal investigator (PI) will be responsible for the data. The database will be held on the PI's Lancaster University personal file store. The PI personal file store is equipped with password-protected access. Field and research supervisor will be able to access the database using Lancaster University´s "Box system". This is a high-grade encryption online storage system. Participants will be able to withdraw their consent up until 15th February 2018. If participants withdraw their consent, their data will be destroyed. In order to be able to find out which participant has decided to withdraw their consent, their date of birth will be employed. Participants´ identifying information (their date of birth) will be kept in a separate

password protected excel document and will be deleted after the thesis has been assessed. After the thesis has been assessed and Javier completes the course, Dr Guillermo Pérez-Algorta will be responsible for the storage and deletion of the data. The data will be retained for ten years as standard.

Data Sharing

We do not expect any data restrictions to be necessary. Lancaster University Doctorate in Clinical Psychology administration team will store the data resulting from this project in an encrypted environment. Potential users will find out about the data through publication and/or other dissemination activities.

Ethical concerns

In the process of collecting information about anxiety or mood disturbance symptoms, caregiver may be in touch with distressing memories, feelings, emotions or thoughts. Thus, participants of the current research will be provided with the opportunity of receiving support from the principal investigator who is a trainee in Clinical Psychology. If this is not enough, they will be signposted to an appropriate service. Participants will be informed about the possibility of accessing support in the debrief sheet (appendix 4-E).

Timescale

June 2017: Ethical Approval

July 2017: Start data collection

November 2017: Systematic Literature Review

January 2018: Finish data collection

January 2018: Introduction and methods

February 2018: Statistical analysis and results

March 2018: Discussion

April 2018: Draft

May 2018: Final submission

July 2018: Inform the participants about the results

July 2018: Prepare for possible submission to a peer-reviewed journal

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Appendix 4-A: Information Poster

Exploring the wellbeing of caregivers of asthmatic children

My name is Javier Malda Castillo and I am a Trainee Clinical Psychologist at Lancaster University. As part of my doctorate I am conducting a research project about how caregiving for a child or an adolescent with an asthma diagnosis can have an effect on mental health.

Who can participate?

We are looking for caregivers who have children with an asthma diagnosis. By caregivers we mean parents, grandparents, step parents or any individual over 18 who has the main responsibility of caring for a child or an adolescent with an asthma diagnosis.

What is involved?

You will complete an online questionnaire about your mental health and family relationships.

Interested?

If you would like to participate please click on this link

_____

or alternatively contact **Javier Malda Castillo**
j.maldacastillo@lancaster.ac.uk. A member of the team will be in touch with you.

Appendix 4-B: Participant Information Sheet

Exploring the Wellbeing of Caregivers of Asthmatic Children

My name is Javier Malda Castillo and I am conducting this research as a student in the Doctorate in Clinical Psychology course at Lancaster University, Lancaster, United Kingdom.

What is the study about?

The purpose of this study is to explore the mental health and the family relationships of caregivers
of asthmatic children.

Why have I been approached?

You have been approached because the study requires information from caregivers of asthmatic children.

Do I have to take part?

No. It's completely up to you to decide whether or not you take part in this study.

What will I be asked to do if I take part?

If you decide you would like to take part, you would be asked to complete an online questionnaire that will take between 10 and 20 minutes.

Will my data be identifiable?

The information you provide is anonymous. The data collected for this study will be stored securely and researchers conducting this study will have access to this data. In addition, other researchers could use this data to develop more studies.
The files on the computer will be encrypted (that is no-one other than the research team will be able to access them) and the computer itself password protected.

Can I withdraw my consent?

Your participation is voluntary and you will be able to withdraw your consent up until 15th February 2018. This means that up until that date you can contact me to let me know that you no longer want to participate in the study. I will then delete all your data. In order to be able to find your anonymous data, we will use your date of birth and the child´s date of birth, which will be linked to your questionnaire responses.

What will happen to the results?

The results will be summarised and reported in a thesis and will be submitted for publication in an academic or professional journal.

Are there any risks?

There are no risks anticipated with participating in this study. However, if you experience any distress following participation you are encouraged to inform the researcher and contact the resources provided at the end of this sheet.

Are there any benefits to taking part?

Although you may find participating interesting, there are no direct benefits in taking part.

Who has reviewed the project?

This study has been reviewed and approved by the Faculty of Health and Medicine Research Ethics Committee at Lancaster University.

Where can I obtain further information about the study if I need it?

If you have any questions about the study, please contact the main researcher:

JAVIER MALDA CASTILLO

Clinical Psychology, Div. Of Health Research, Furness Building C34 Lancaster University, Lancaster,
LA1 4YG
aldacastillo@lancaster.ac.uk 01524 592754

Supervisors:

Dr Guillermo Pérez-Algorta
Clinical Psychology, Div. Of Health Research, Furness Building C73 ,Lancaster University, Lancaster, LA1 4YG
01524594711 g.perezalgorta@lancaster.ac.uk
Dr Claire Browne
Central Manchester University Hospitals NHS Foundation Trust 0161 701 0850
claire.browne@cmft.nhs.uk

Complaints

If you wish to make a complaint or raise concerns about any aspect of this study and do not want to speak to the researcher, you can contact:

Dr Bill Sellwood Tel: +44 1524 593998
Email: b.sellwood@lancaster.ac.uk Health Research Division, Lancaster University, Lancaster LA14YG

If you wish to speak to someone outside of the Doctorate Programme, you may also contact:

Professor Roger Pickup Tel: +44 (0)1524 593746
Associate Dean for Research Email: r.pickup@lancaster.ac.uk Faculty of Health and Medicine
(Division of Biomedical and Life Sciences) Lancaster University, LANCASTER LA14YG

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

Resources in the event of distress

Should you feel distressed either as a result of taking part, or in the future, you can contact a member of the research team who will provide you with support and guidance. If you do not feel comfortable about contacting the research team you can access free mental health support via your General Practitioner (GP) or MIND, which is a mental health charity

providing advice and support to anyone experiencing mental health problems.You can get in touch with MIND and find your nearest MIND service at https://www.mind.org.uk/about-us/local-minds/ or by phoning their central office at 020 8519 2122.

Appendix 4-C: Participant Consent

Study Title: Exploring the wellbeing of caregivers of asthmatic children

We are asking if you would like to take part in a research project that aims to increase the understanding of mental health and family relationships of caregivers of asthmatic children

Before you consent to participating in the study we ask that you read the participant information sheet. By clicking on the link below you will be consenting to take part in the current study. If you have any questions or queries before signing the consent form please speak to the principal investigator, Javier Malda Castillo.

By proceeding to the survey you confirm that:

1. I have read the information sheet and fully understand what is expected of me within this study
2. I have had the opportunity to ask any questions and to have them answered.
3. I understand that my participation is voluntary and that I am free to withdraw my consent up until 15th February 2018 without giving any reason, without my medical care or legal rights being affected.
4. I consent to information from my questionnaire responses being used in reports, conferences and training events.
5. I understand that the researcher will discuss data with their supervisor as needed.
6. I consent to Lancaster University keeping questionnaire responses for 10 years after the study has finished.
7. By clicking on this link, you consent to **taking part in the current study**.

Appendix 4-D: Questionnaires

Clinical and Socio-demographic Information

1) Your relationship to the child:

a) Mother or father

b) Grandmother or grandfather

c) Stepfather or stepmother

d) Legal guardian

e) Other

2) Your date of birth_____

3) How many hours do you approximately spend with the child over the course of a day?

4) What is your gender?

a)Male

b)Female

c)Other

5) What is your ethnicity?

a) White

b) Mixed/multiple ethnic groups

c) Asian/Asian British

d) Black/African/Caribbean/Black British

e) Other Ethnic group

Please specify_____

6)What is your marital status?

a) Married

b) Separated

c) Divorced

d) Widowed

e) Cohabiting

f) In a registered same sex civil partnership

g) Never married and never registered in a same sex civil partnership

6) Please tell us the total annual income of your household (before tax and deductions but including benefits/allowances)

a) £6.000 to less than £13,000 GBP
b) £13,000 to less than £19,000 GBP
c) £19,000 to less than £26,000 GBP
d) £26,000 to less than £32,000 GBP
e) £32,000 to less than £48,000 GBP
f) £48,000 to less than £64,000 GBP
g) £64,000 or more GBP

7) What is the highest qualification that you currently have?

a)No qualifications
b)Apprenticeship
c)GCSE
d)A levels
e)Degree (Bsc)
f) Masters´degree (Msc)
g) Doctorate

8) What is your employment status?

a)Full-time employed
b)Part-time employed
c)Self-employed or freelance
d)Student
e)Retired

9) How many people are there in your household including yourself? (Please write in)

a) Children 4 years and under
b) Children 5 to 16
c) Adults 17-64
d) Adults Over 65

11)What is the Child´s month and year of birth?_____

12) Child's gender Female

Male
Other

13) Child's race/ethnicity

a) White

b) Mixed/multiple ethnic groups

c) Asian/Asian British

d) Black/African/Caribbean/Black British

e) Other Ethnic group

Please specify_____

14) In the last two weeks, on how many days did the child experience the following symptoms?

a) Daytime asthma symptoms (i.e. coughing, wheezing, shortness of breath)_____

b) Nighttime asthma symptoms (i.e. coughing, wheezing, shortness of breath)_____

c) The need for rescue inhaler use

15) In the last two weeks, how many symptom free days did the child experience? (A symptom free day is a) a) 24 day-hour period with no symptoms of asthma

Family Assessment Device - General Functioning Scale

1. Planning family activities is difficult because we misunderstand each other.
   Strongly agree ___Agree ___Disagree___Strongly Disagree___ _

2. In times of crisis we can turn to each other for support.
   Strongly Agree __Agree __Disagree __Strongly disagree_

3. We cannot talk to each other about the sadness we feel.
   Strongly Agree __Agree __Disagree___Strongly Disagree _

4. Individuals are accepted for what they are.
   Strongly Agree __Agree __Disagree___Strongly Disagree ___

5. We avoid discussing our fears and concerns.
   Strongly Agree __Agree __Disagree___Strongly Disagree _

6. We can express feelings to each other.
   Strongly Agree __Agree__Disagree___Strongly Disagree _

7. There are lots of bad feelings in the family.
   Strongly Agree __Agree __Disagree___Strongly Disagree _

8. We feel accepted for what we are.
   Strongly Agree __Agree __Disagree___Strongly Disagree__

9. Making decisions is a problem for our family.
   Strongly Agree__Agree__Disagree___Strongly Disagree _

10. We are able to make decisions about how to solve problems.
    Strongly Agree __Agree __Disagree___Strongly Disagree _

11. We don't get along well together.
    Strongly Agree ___Agree__Disagree __Strongly Disagree _

12. We confide in each other.
    Strongly Agree __Agree __Disagree___Strongly Disagree _

The Reflective Functioning Questionnaire

Please work through the next 8 statements. For each statement, choose a number between 1 and 7 to say how much you disagree or agree with the statement, and write it beside the statement. Do not think too much about it – your initial responses are usually the best. Thank you.

Use the following scale from 1 to 7:

	Strongly disagree	1	2	3	4	5	6	7 Strongly agree

1. People´s thoughts are a mystery to me

2. I don´t always know why I do what I do

3.When I get angry I say things without really know why I am saying them

4. When I get angry I say things I later regret

5. If I feel insecure I can behave in ways that put others ‘back up

6. Sometimes I do things without really knowing why

7. I always know what I feel

8. Strong feelings often cloud my thinking

The 7 Up 7 Down Inventory

Below are some questions about behaviours that occur in the general population. Using the scale below, select the number that best describes how often you experience these behaviours.

1. Have you had periods of extreme happiness and intense energy lasting several days or more when you also felt much more anxious or tense (jittery, nervous. uptight) than usual (other than related to the menstrual cycle)?

0	1	2	3
Never or hardly ever	Sometimes	Often	Very often

2. Have there been times of several days or more when you were so sad that it was quite painful or you felt that you couldn't stand it?

0	1	2	3
Never or hardly ever	Sometimes	Often	Very often hardly ever

3. Have there been times lasting several days or more when you felt you must have lots of excitement, and you actually did a lot of new or different things?

0	1	2	3
Never or hardly ever	Sometimes	Often	Very often hardly ever

4. Have you had periods of extreme happiness and intense energy (clearly more than your usual self) when, for several days or more, it took you over an hour to get to sleep at night?

0	1	2	3
Never or hardly hardly ever	Sometimes	Often	Very often ever

5. Have there been long periods in your life when you felt sad, depressed, or irritable most of the time?

0	1	2	3
Never or hardly ever	Sometimes	Often	Very often hardly ever

6. Have you had periods of extreme happiness and high energy lasting several days or more when what you saw, heard, smelled, tasted, or touched seemed vivid or intense?

0	1	2	3
Never or hardly ever	Sometimes	Often	Very often hardly ever

7. Have there been periods of several days or more when your thinking was so clear and quick that it was much better than most other people's?

0 1 2 3

Never or hardly ever Sometimes Often Very often hardly ever

8. Have there been times of a couple days or more when you felt that you were a very important person or that your abilities or talents were better than most other people's?

0 1 2 3

Never or hardly ever Sometimes Often Very often hardly ever

9. Have them been times when you have hated yourself or felt that you were stupid, ugly, unlovable, or useless?

0 1 2 3

Never or hardly ever Sometimes Often Very often hardly ever

10. Have there been times of several days or more when you really got down on yourself and felt worthless?

0 1 2 3

Never or hardly ever Sometimes Often Very often hardly ever

11. Have you had periods when it seemed that the future was hopeless and things could not improve?

0 1 2 3

Never or hardly ever Sometimes Often Very often hardly ever

12. Have there been periods lasting several days or more when you were so down in the dumps that you thought you might never snap out of it?

0 1 2 3

Never or hardly ever Sometimes Often Very often hardly ever

13. Have you had times when your thoughts and ideas came so fast that you couldn't get them all out, or they came so quickly that others complained that they couldn't keep up with your ideas?

0 1 2 3

Never or hardly ever Sometimes Often Very often hardly ever

14. Have there been times when you have felt that you would be better off dead?

0	1	2	3
Never or hardly ever	Sometimes	Often	Very often hardly ever

Beck Anxiety Inventory (BAI)

Below is a list of common symptoms of anxiety. Please carefully read each item in the list. Indicate how much you have been bothered by that symptom during the past month, including today, by circling the number in the corresponding space in the column next to each symptom.

	Not At All	**Mildly but it didn't bother me much**	**Moderately - it wasn't pleasant at times**	**Severely – it bothered me a lot**
Numbness or tingling	□	□	□	□
Feeling hot	□	□	□	□
Wobbliness in legs	□	□	□	□
Unable to relax	□	□	□	□
Fear of worst happening	□	□	□	□
Dizzy or lightheaded	□	□	□	□
Heart pounding/racing	□	□	□	□
Unsteady	□	□	□	□
Terrified or afraid	□	□	□	□
Nervous	□	□	□	□
Feeling of choking	□	□	□	□
Hands trembling	□	□	□	□
Shaky / unsteady	□	□	□	□
Fear of losing control	□	□	□	□
Difficulty in breathing	□	□	□	□
Fear of dying	□	□	□	□
Scared	□	□	□	□
Indigestion	□	□	□	□
Faint / lightheaded	□	□	□	□
Face flushed	□	□	□	□
Hot/cold sweats	□	□	□	□

Appendix 4-E: Debrief

Thank you for taking the time to participate in this study. It has been suggested that caregivers of asthmatic children might be at increased risk of experiencing mental health difficulties. Thus, the purpose of this study is to explore whether caregivers of asthmatic children experience mental health difficulties and to better understand their family relationships.

The study also intends to explore the level of mentalisation among caregivers of asthmatic children. Mentalisation is the ability to understand others' emotions and be able to respond accordingly. For instance, understanding when someone is upset. High levels of mentalisation could be helpful when dealing with stressful situations. An example of mentalisation ability could be to understand when someone is upset and responding to it (i.e. nodding sympathetically if someone is describing an stressful experience or soothing a child if his/her non-verbal communication indicates that he/she is upset about something).

All the information that is collected for this study will be anonymous and there will be no way of identifying your responses in the dataset. If you have any questions about the study do not hesitate to contact me via email on j.maldacastillo@lancaster.ac.uk or my supervisor Dr Guillermo Perez-Algorta on g.perezalgorta@lancaster.ac.uk and we will be happy to answer any of your queries.

Sources of support
If you feel distressed as a result of participating in the study you can contact a member of the research team, who will provide you with support and guidance. Alternatively, you can also access free mental health support through your GP. You can also access free mental health support through the charity MIND. You can get in touch with MIND and find your nearest MIND service at https://www.mind.org.uk/about-us/local-minds/ or by phoning their central office at 020 8519 2122.

Javier Malda-Castillo

Trainee Clinical Psychologist