The Psychological Impact of Trauma on Preschool Children and their Parents

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Thesis portfolio abstract

Aims: The aim of this thesis portfolio was to examine the psychological impact of experiencing a traumatic event in young children and parents. Factors that may predict an individual's psychological response following a traumatic event were also explored.

Design: This portfolio contains two main papers and supporting chapters. The first paper, a meta-analysis, reviewed the prevalence of post-traumatic stress disorder (PTSD) in preschool-aged children. The second paper, an empirical study, examined the impact of a child's admission to a Paediatric Intensive Care Unit (PICU) on parents. In both papers, factors contributing to higher emotional distress were explored. The additional chapters include further information and an overall discussion and critical review.

Results: The meta-analysis revealed that a significant minority of preschool-aged children met the diagnostic threshold for PTSD following direct exposure to trauma. The empirical paper indicated a high prevalence of parents who were vulnerable to future psychological distress (PTSD and depression) following their child's PICU admission. Pre-trauma factors, including pre-existing mental health difficulties, and peri-trauma appraisals strongly predicted parent vulnerability to psychological distress. These factors predicted parental vulnerability over and above medical severity markers.

Conclusions: Children under six years old can develop PTSD, with similar prevalence trends to older children following different trauma types. It is therefore important for clinicians to be aware of symptoms in young children, and for appropriate interventions to be developed. A high proportion of parents of are at risk of developing longer-term psychological distress following their child's PICU

admission. Importantly, pre-trauma psychological factors, and peri-trauma appraisals, predict parental psychological vulnerability. The importance of applying appropriate diagnostic criteria, and using screening measures to identify individuals are discussed. Early identification can trigger support that will likely benefit both the individual and their family.

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None.

Chapter 7. Discussion and critical analysis

None.

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Chapter 1: Introduction to thesis portfolio

The aims of this thesis portfolio are to examine psychological responses to trauma in pre-schoolers and parents of severely unwell children. It also explores the factors that contribute to psychological distress and difficulties with adjustment following a traumatic event. A recent review indicated that many children are exposed to traumatic events in childhood (Lewis et al., 2019). Following exposure, some children recover naturally and show minimal signs of psychological distress (Meiser-Stedman, Smith, Yule, Glucksman, & Dalgleish, 2017). However, for a proportion of children, exposure to a traumatic event can result in longer-term psychological distress, such as post-traumatic stress disorder (PTSD; Alisic et al., 2014).

The impact of trauma exposure is less well-documented for preschool-aged children relative to older children and adults. Reasons for this include assumptions that pre-schoolers lack the cognitive ability to develop PTSD (Yule, 1994), and difficulties in the production and application of age-appropriate diagnostic tools and assessment measures for this population (Scheeringa, Zeanah, & Cohen, 2011). However, recent studies indicate that prevalence rates of PTSD may be equivalent, or even higher, in preschool-aged children than older children and adults (Scheeringa, Wright, Hunt, Zeanah, 2006).

The systematic review and meta-analysis presented in this thesis investigate the prevalence of PTSD in preschool-aged children following exposures to a range of traumatic events. The meta-analysis explores possible moderator variables, such as type of trauma, which may explain variations in PTSD prevalence rates across studies. The following types of trauma are compared: interpersonal, non-interpersonal, group, individual, single event, and repeated trauma. Although PTSD

has been present in diagnostic manuals since 1980 (Diagnostic and Statistical Manual of Mental Disorders, 3rd edition; DSM-III; American Psychiatric Association; APA, 1980), minimal adaptations have been made to improve the appropriateness of the diagnostic criteria for preschool-aged children. More recently, revised diagnostic criteria have been proposed to enable clinicians to diagnose PTSD in this young population, e.g. the alternative algorithm (PTSD-AA) and the DSM-5 preschool subtype (Scheeringa, Peebles, Cook, & Zeanah, 2001; APA, 2013). Following the introduction of these new criteria, the meta-analysis presented in this thesis reviews the impact of different diagnostic criteria on reported prevalence rates in this young population.

According to the DSM-5, observing a loved one in a perceived life-threatening condition can be deemed as a traumatic event (APA, 2013). Research has explored the psychological impact an admission to hospital, a medical procedure, or a medical diagnosis can have on children and their parents (Kazak, Boeving, Alderfer, Hwang, & Reilly, 2005; Muscara et al., 2015). Research has indicated that parental distress is higher following a child's admission to a Paediatric Intensive Care Unit (PICU) compared to an admission to a general hospital ward (Rees, Gledhill, Garralda, & Nadel, 2004). Parents typically show high levels of distress in the acute phase of the admission (Balluffi et al., 2004), and, for a subgroup, this acute stress response can develop into prolonged psychological difficulties (Bronner et al., 2009). The empirical paper reported in this thesis investigates the psychological impact of a child's admission to PICU on parents. It also examines the role of pre- and peri-trauma factors in determining parental psychological adjustment and sequalae following a child's admission. A screening tool, the Posttraumatic Adjustment Scale (PAS; O'Donnell et al., 2008), is used to identify parents at risk of

developing PTSD and Major Depressive Episode (MDE) as a result of their child's admission. The paper reflects on the importance of early screening of parents in PICU to offer early, focused, support to reduce long-term psychological distress.

In summary, this thesis aims to: i) raise awareness of the impact of different types of trauma on pre-schoolers and parents following a child's admission to PICU, and ii) explore factors that contribute to post-trauma adjustment difficulties and vulnerability of longer-term psychological distress. The outcomes of this work will help support clinicians by raising awareness of the possible prevalence and psychological vulnerability of these populations, and emphasise the importance of using age-appropriate diagnostic tools and screening measures in the acute phase.

Key terms:

Post-traumatic stress disorder (PTSD). PTSD, as defined by the ICD-10, is a response to a traumatic event that is threatening or catastrophic in nature (World Health Organisation, 1992). In the DSM-5, PTSD occurs following an exposure to an event that involved actual or threatened death, serious injury or sexual violation (APA, 2013). This exposure can be experienced directly, or indirectly by witnessing it occur to someone else. There are four main symptom clusters; 1) re-experiencing the event 2) avoiding reminders of the event, 3) negative changes in mood and 4) alterations in arousal (such as hyperarousal) (DSM-5;APA, 2013). The DSM-5 has produced a preschool subtype for children six years and younger. These diagnostic criteria consider the developmental stage of the child and focus more on behavioural symptoms, rather than symptoms based on verbal report or abstract cognition. The preschool subtype of PTSD has three symptom clusters 1) re-experiencing the event, 2) avoiding reminders of the event OR negative changes in mood, and 3) alterations

in arousal. Importantly, a diagnosis of PTSD can only be made at least one month after the traumatic event.

Paediatric Intensive Care Unit (PICU). PICUs are hospital wards for children aged 0-16years old with serious and life-threatening conditions. Approximately 55 children are admitted to PICU every day in the UK and Republic of Ireland (Paediatric Intensive Care Audit Network, 2017). Reasons for referrals can vary from long term physical health conditions to traumatic incidents such as motor vehicle collisions.

Preschool-aged children. There is some variation across the literature in what is considered "preschool-age". In this thesis, the age range is 0-6years, which is in-line with the DSM-5 preschool subtype of PTSD (APA, 2013). Throughout this thesis, the terms preschool-aged children and young children will be used interchangeably to refer to children under the age of six years old.

Outline of thesis:

This thesis portfolio starts with a meta-analysis of prevalence rates of PTSD in preschool-aged children. Following this, a bridging chapter summarises the results and considers how the findings relate to the wider research literature around child PTSD and considers the systemic impact of trauma exposure. This chapter also introduces the empirical paper that follows in the subsequent chapter. The empirical paper explores the psychological impact a child's admission to PICU can have on parents in the acute admission phase. This paper is followed by an additional methodology chapter and an additional results chapter. Finally, the thesis is concluded with a critical discussion and summary.

Chapter 2: Meta-analysis

Prevalence of Post-Traumatic Stress Disorder (PTSD) in preschool-aged children: A meta-analysis

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(Author Guidelines for manuscript preparation- Appendix A)

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Abstract

Exposure to a traumatic event can result in long term psychological difficulties such as Posttraumatic Stress Disorder (PTSD) in children and adults. This meta-analysis was conducted to determine the prevalence of PTSD in preschool-aged children (0-6years), who have directly experienced a traumatic event. Nineteen studies that used standardised interview measures were included, giving a total of 2016 children. Pooled prevalence estimates indicated an overall prevalence rate of 21.9% of young children meeting diagnostic criteria for PTSD. Young children showed similar trends in prevalence rates following different types of trauma, namely interpersonal and repeated trauma exposure, to older children and adolescents. Higher prevalence rates were found when age-appropriate diagnostic criteria were applied. These findings indicate that a significant minority of preschool children develop PTSD after direct trauma exposure, and underscore the importance of using age-appropriate diagnostic criteria.

Key words: preschool, posttraumatic stress disorder, prevalence, traumatic events

Introduction

It remains unclear how many preschool aged children, those aged up to six years, develop post-traumatic stress disorder (PTSD) after direct exposure to a traumatic event. Obtaining an accurate picture of the incidence of trauma exposure in this population (referred to as young children) is challenging. Certain types of traumatic experiences are known to occur more frequently in younger children. One survey reported that up to 44% of two to five year olds have been exposed to at least one physical assault (Finkelhor, Turner, Shattuck, & Hamby, 2013). However, this nationally representative survey only looked at exposures to interpersonal violence. It did not include other types of trauma such as accidental injury, illness, or natural disasters. The prevalence of exposure to trauma in the early years is therefore likely to be higher than this estimate. In fact, it has been suggested that following direct exposure to a traumatic event, young children develop PTSD at the same, or higher, rate than older children and adults (Scheeringa, Wright, Hunt, & Zeanah, 2006). Moreover, despite the fact that younger children have had relatively less time to experience traumatic events, these events may be appraised in a more life-threatening way than in older children (Scheeringa, 2019).

Limitations in the tools for diagnosing PTSD in young children complicates the estimation of prevalence rates in this age group (Scheeringa, Zeanah, & Cohen, 2011). Despite attempts to produce child-appropriate DSM-IV diagnostic criteria for PTSD (American Psychological Association, 1994), there are differences in symptom manifestation in young children compared to adults and older children (Scheeringa, Zeanah, Drell, & Larrieu, 1995). An alternative algorithm was subsequently produced to ensure diagnostic tools were age appropriate for younger children (PTSD-AA; Scheeringa, et al., 1995). This continued to be refined based on

empirical findings (Scheeringa, Peebles, Cook, & Zeanah, 2001; Scheeringa, Zeanah, Myers, & Putnam, 2003), and in 2013, a new subtype of PTSD was published in the DSM-5; Posttraumatic Stress Disorder for Children six years and younger (DSM-5 PTSD<6Y; APA, 2013). Now that the revised age-appropriate diagnostic criteria have been in use for a few years, it is timely to investigate the prevalence of PTSD in young children and to review the effect different diagnostic criteria have had on prevalence rates of PTSD in this population.

Estimates of PTSD vary widely. This is due in part to differences in the type of assessment used (Richardson, Frueh, & Acierno, 2010), the informant (Dyb, Holen, Braenne, Indredavik, & Aarseth, 2003), and the diagnostic criteria applied (De Young & Landolt, 2018). The type of trauma also has a large impact on estimated rates and trajectories of PTSD in children and adults (Alisic et al., 2014; Santiago et al., 2013). Rates of PTSD in children and adolescents are higher following interpersonal trauma compared to non-interpersonal trauma (Copeland, Keeler, Angold, & Costello, 2007; Nooner et al., 2012; Alisic et al., 2014), and exposure to intentional or assaultive injury is associated with higher rates of PTSD both in the acute phase and longer term (Zatzick, et al., 2008; Santiago, et al., 2013). PTSD is also typically reported as being more prevalent in females compared to males (Alisic et al., 2014; Olff, Langeland, Draijer, & Gersons, 2007; Dyregrov, & Yule, 2006; Tricky, Siddaway, Meiser-Stedman, Serpell, & Field, 2012), although this difference may be mediated by the different types of trauma commonly experienced by males and females (Olff et al., 2007; Tolin, & Foa, 2008).

Current meta-analysis

The aim of this meta-analysis is to understand the prevalence of PTSD in young children who have directly experienced a traumatic event. A meta-analysis is used to create a weighted pooled prevalence rate, which is more accurate than looking at individual studies, as it pulls together findings from multiple studies. Similar meta-analyses of children and adolescents report high levels of heterogeneity across samples. This variation is often due to the different types of trauma experienced by different samples, and variations in methodological design across studies (Engels, Schmid, Terrin, Olkin, &Lau, 2000; Higgins, 2008). Similar levels of heterogeneity are expected in the current analyses. For this reason, moderator analyses are conducted to explore the impact of different types of trauma on the prevalence of PTSD in young children. By understanding the prevalence of PTSD in young children, and gaining an insight into the possible factors that may impact this prevalence rate, professionals will be able to better identify and support young children who may be vulnerable following a trauma.

Method

The search was conducted between May and July 2019. The Cochrane database and Prospero were searched to ensure that no similar reviews were in progress, or had been published. This review was registered on Prospero (CRD41019133984).

Selection of studies

Relevant studies were identified through systematic searches in three electronic databases: PubMed(Medline), PsycINFO and the Published International Literature on Traumatic Stress (PILOTS). Relevant papers were also obtained from

the reference list of a recent review in the field (De Young & Landolt, 2018). Searches were restricted to empirical English language papers published in peer-reviewed journals between 1980 (when PTSD was first considered in DSM-III (APA, 1980)) and 10th July 2019. Doctoral and Masters theses/dissertations were also included. Poster-abstracts where the full paper was not available or had not been published were excluded. Human study filters were also applied.

MeSH terms were applied to the searches for two electronic databases; PsycINFO and PubMed (Medline). MeSH terms could not be applied to the searches on the PILOTS database. The following search terms and combinations were used for PsycINFO and Medline (PubMed). Non-MeSH terms were searched within the title or abstract: (((MeSH CHILD, PRESCHOOL) OR (MeSH Infant)) OR (Toddler* OR preschool* OR child*)) AND ((MeSH Stress Disorders, Post-traumatic) OR (PTSD OR "post-traumatic stress disorder" OR "posttraumatic stress disorder" OR "post traumatic stress disorder")). The following search terms were applied to the PILOTS database: (Toddler* OR preschool* OR child*) AND ("PTSD" OR "post-traumatic stress disorder" OR "posttraumatic stress disorder" OR "post traumatic stress disorder").

Inclusion and exclusion criteria

To ensure relevant papers were included in the meta-analysis, strict inclusion and exclusion criteria was set. All studies had to satisfy the following eligibility criteria:

1) Participants were all directly exposed to trauma as defined by the DSM-IV Criterion A for PTSD. Samples of children who only had indirect exposure were excluded.

2) Participants were from a community sample. Studies were excluded if the participants were recruited due to the presence of post-traumatic stress symptoms and/or they were seeking psychological treatment.
3) The study population needed to include preschool children under the age of six years old. If the age range exceeded the age of six, then studies were included if the mean sample age was under 6.5years. If the age range exceeded six, and the mean age was not provided, or could not be computed, the study was excluded.
4) The study measured PTSD diagnoses and symptoms at least one month after the trauma. (According to DSM-5, PTSD can only be diagnosed one month after the traumatic event (APA, 2013)).
5) The article provided enough information to derive the prevalence of PTSD in the sample.

Screening and selection of studies was conducted by the author (Figure 1). During the screening and selection process, the authors decided to add an additional inclusion criterion: papers were only selected if they included the use of a structured interview to diagnose PTSD. This decision was made in order to derive an estimate of the prevalence of diagnostic-level PTSD in young children, similar to the approach taken by Alisic and colleagues (2014). Studies that did not use a structured interview typically described only the number of symptoms of PTSD in their samples, and due to inconsistencies in the cut-offs applied across papers, it was not possible to extract the prevalence rates of PTSD.

An independent researcher (HG) conducted a review of 53% of studies (k=10) against the inclusion and exclusion criteria. All studies, except one (Ohmi et al., 2002) were deemed to meet the inclusion criteria by this independent researcher. The

study conducted by Ohmi and colleagues (2002) was further checked by another researcher (RMS) as it was unclear whether the measure used in the study was administered as an interview or questionnaire. It was finally agreed that this paper would be included in the meta-analysis. However, sensitivity analyses were conducted to observe the impact of including this paper on the overall pooled prevalence estimate.

Data extraction

Information on the sample characteristics, nature of trauma exposure, measurement of PTSD, diagnostic criteria applied, and outcomes of the PTSD assessment were extracted from the final set of relevant papers.

Sample characteristics. The lead author extracted the sample size, age-range, mean age and standard deviation (SD) and proportion of males from the trauma-exposed participants in each paper. Country of data collection and details of the inclusion and exclusion criteria for each study were also recorded.

Trauma exposure. The type of trauma was recorded and further categorized into "group" or "individual" trauma, "interpersonal" (war, terrorism, violence, abuse) or "non-interpersonal" trauma (natural disaster, injury due to accident, life threatening illness), and "single" or "repeated" exposure. One study looked at different types of traumas, and was therefore categorised as "mixed".

PTSD measurement. The type of standardised clinical interview, time post-trauma, and informant were recorded.

Outcomes. The number of young children who were given a PTSD diagnosis according to DSM-IV, DSM-5 (PTSD<6Y) or PTSD-AA was recorded. Some studies reported different prevalence rates according to different diagnostic criteria; these were all extracted.

Quality of studies

The quality of each study was analysed by two researchers (FW and HG) using an adapted version of a risk of bias tool used in a recent meta-analysis of PTSD prevalence (Burgess, 2019). This risk of bias tool includes common quality assessment questions that have been developed by Munn, Moola, Riitana and Lisy (2014). Due to the strict inclusion criteria, studies were only included if they used standardised interviews at least one-month post-trauma. Therefore, questions relating to potential bias in outcomes, such as the use of standardised assessment tools and use of measures at appropriate time intervals, were not included. As prevalence was the sole outcome extracted from each study, quality checks were not carried out in relation to the type of analyses used. The risk of bias assessment tool was comprised of six questions and assessed the quality and representativeness of the sample, non-response rates and reasons, recruitment procedures and inclusion and exclusion criteria. Each study was allocated a qualitative descriptor of risk of bias (Low, Medium, High) and the scoring was adapted to reflect the reduced number of items (9-12=low risk, 5-8= medium risk, 0-4=high risk). A total of 10 studies (53%) were randomly selected and inter-rated by the two researchers (FW and HG). Any discrepancies in ratings were discussed and resolved. Individual study ratings on each risk of bias criteria are detailed in Appendix C.

Statistical analysis

The analyses were performed using OpenMeta[Analyst], which utilises the metaphor package in R (Wallace et al., 2012). The prevalence of preschool-aged children who reached the threshold for PTSD was extracted from each paper. For those papers that included multiple prevalence data using different diagnostic criteria, the best available outcome data from the most developmentally appropriate

diagnostic criteria was used to calculate the main pooled prevalence estimate. Each study's most age-appropriate diagnostic criteria was referred to as the study's "optimal" criteria. Table 1 illustrates the difference between the three diagnostic criteria and reflects on their age appropriateness, therefore providing a hierarchy to establish each study's "optimal" criteria. As only two studies used the proposed DSM-5 PTSD<6Y criteria (prior to the DSM-5 being published and also reported PTSD-AA criteria), the "optimal" study criteria used in the pooled prevalence was either the PTSD-AA or the DSM-IV criteria. A random effects model was then used to compute a weighted estimate of prevalence of PTSD in young children who had been directly exposed to trauma. Due to the expected heterogeneity of studies, the arcsine transformation was used to account for issues with study weightings (e.g. 95% confidence intervals going below zero) when estimating prevalence (Barendregt, Doi, Lee, Norma, & Vos, 2013; Schwarzer, Chemaitelly, Raddad, and Rucker, 2019).

The heterogeneity of studies was assessed by visual inspection of the forest plots as well as the Cochran's Q test (Cochran, 1954) and the I^2 statistic (Higgins & Thompson, 2002). Cochran's Q test indicates whether heterogeneity within the studies included was significant. The I^2 provides a percentage of variation across studies due to heterogeneity as opposed to chance. I^2 between 30-60% can indicate moderate heterogeneity, 50-90% may represent substantial heterogeneity and 75% or more indicates considerable heterogeneity (Higgins & Green, 2011).

Sensitivity analyses were conducted using subgroup meta-analyses. Comparisons in prevalence rates were explored as a result of different diagnostic criteria being applied (DSM-IV and PTSD-AA). This was conducted on a subgroup of studies that used *both* the PTSD-AA and DSM-IV, as well as on studies that used

either diagnostic criteria. Further sensitivity analysis looked at the impact of including one study which included some young children who had not experienced the trauma directly (De Voe, Bannon, & Klein, 2006), and one study where it was unclear whether the authors had administered the assessment as a clinical interview or a questionnaire (Ohmi et al., 2002). Finally, sensitivity analysis was used to identify the impact of including studies whose age range exceeded the age of six years.

Moderator analyses using random effects models were run to identify differences in prevalence rates due to different types of trauma (interpersonal versus non-interpersonal trauma, group versus individual trauma, and single event versus repeated trauma) and best diagnostic criteria applied (PTSD-AA versus DSM-IV). In addition, moderator analyses were conducted to identify differences in prevalence rates due to study quality (high versus low quality studies). Holm-Bonferroni method (Holm, 1979) was used to correct for multiple comparisons.

Table 1
Hierarchy of “optimal” diagnostic criteria

Diagnosis	Notes	Criteria
DSM-5 PTSD<6Y (2013)	Incorporates changes in PTSD-AA. Takes into account developmental age. Increased focus on behavioural symptoms, rather than thoughts and feelings.	*Criterion A: 1)* Direct experience of trauma, 2)Witnessing person experience trauma, 3) Learning traumatic event occurred to parent or care-giver *Criterion B:* Intrusion Symptoms (One or more symptoms). *Criterion C:* Persistent Avoidance (One or more symptoms) *Criterion D:* Negative alterations in cognitions and mood (Two or more symptoms) *Criterion E:* Alterations in arousal and reactivity (Two or more symptoms) *Criterion F:* Persistence of symptoms for more than one month *Criterion G:* Significant symptom-related distress or functional impairment
PTSD-AA (1995)	Advance over DSM-IV, to make diagnostic criteria more age-appropriate. Takes into account developmental age. Focus on behavioural symptoms, rather than thoughts and feelings.	*Criterion A:* The person experienced, witnessed, or was confronted with an event or events that involved actual or threatened death or serious injury, or a threat to the physical integrity of self or others. N.B. Extreme reaction at time of the event is not required. *Criterion B:* Intrusion Symptoms (One or more symptoms) *Criterion C:* Persistent Avoidance (One or more symptoms) *Criterion D*: Increased Arousal (Two or more symptoms) *Criterion E:* Persistence of symptoms for more than one month *Criterion F:* Significant symptom-related distress or functional impairment

DSM-IV (1994)	Based on research of adults and older children. Symptoms are not appropriate for young children's developmental level e.g. verbal expression, memory and abstract thought.	*Criterion A:* The person experienced, witnessed, or was confronted with an event or events that involved actual or threatened death or serious injury, or a threat to the physical integrity of self or others (2) the person's response involved intense fear, helplessness, or horror. Note: In children, this may be expressed instead by disorganized or agitated behaviour. *Criterion B: Intrusion Symptoms* (One or more symptoms) *Criterion C: Persistent Avoidance* (Three or more symptoms) *Criterion D:* Increased Arousal (Two or more symptoms) *Criterion E:* Persistence of symptoms for more than one month *Criterion F:* Significant symptom-related distress or functional impairment.

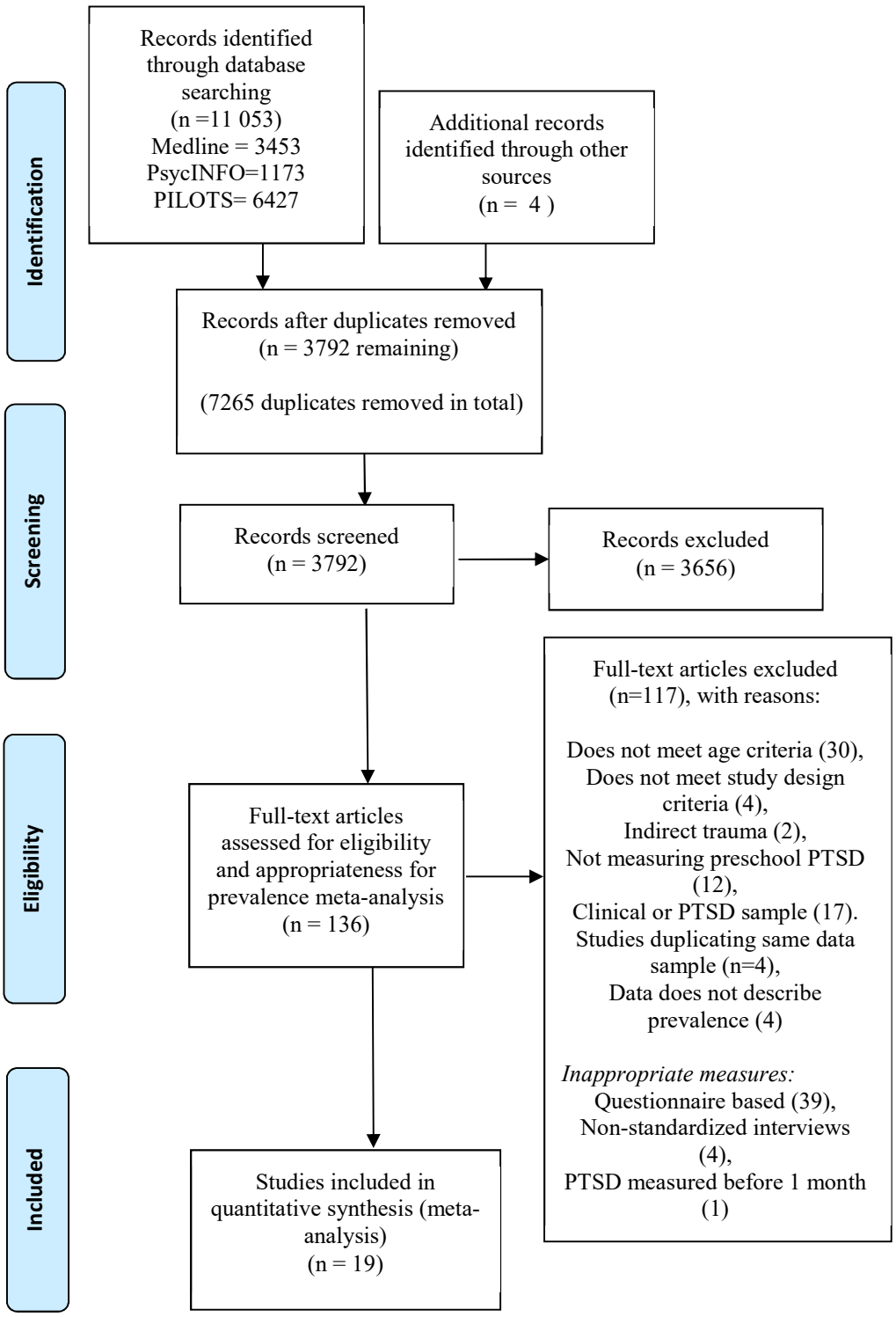

Figure 1. PRISMA diagram outlining the searching and exclusion process

Results

In total, 19 articles were included in the meta-analysis. Papers that reported the prevalence of PTSD on the same samples were removed. Consequently, the 19 articles included reported independent samples. Together, they reported the prevalence of PTSD in 2016 trauma-exposed young children (study samples ranged in size from 21 to 284).

Characteristics of studies

The characteristics of the studies included in the meta-analysis can be found in Table 2. Participants ranged in age from 0-16. Three studies included children over the age of six, but had a total mean age below 6.5years. The estimated mean age across all studies was 4.6years (four studies did not report mean age). Approximately 55% of participants were males (two studies did not report sex). Different types of trauma were reported by the different studies: interpersonal trauma (k=8), non-interpersonal trauma (k=10), single-event trauma (k=11), repeated trauma (k=7), group trauma (k=6) and individual trauma (k=12). One study collated prevalence for a mix of traumas (interpersonal, non-interpersonal, individual, group, repeated and single event). All studies were conducted in Organisation for Economic Co-operation and Development (OECD) countries: USA (k=8), Israel (k=3), UK (k=2), Switzerland (k=2), Australia (k=1), Canada (k=1), Japan (k=1) and the Netherlands (k=1). A range of inclusion and exclusion criteria were applied across studies. Participants were frequently excluded due to insufficient language abilities (k=5) or the child having a cognitive or neurological impairment (k=9). Thirteen studies used the Posttraumatic Stress Disorder Semi-Structured Interview (PTSDSSI; Scheeringa et al., 1995, 2003) to assess PTSD prevalence in their samples. Other studies used the Diagnostic Infant and Preschool Assessment (DIPA; Scheeringa, & Haslett,

2010; k= 2), the Development and Well-Being Assessment (DAWBA; Goodman, Ford, Richards, Gatward, & Meltzer, 2000; k=1), the Preschool Age Psychiatric Assessment (PAPA; Egger & Angold, 2004; k=2), or the Childhood PTSD Reaction Index (CPTSD-RI; Pynoos et al., 1987; k=1). Some studies utilised more than one diagnostic criteria. Thirteen studies used the PTSD-AA criteria to assess PTSD and 14 studies reported prevalence using the DSM-IV. Eight studies compared prevalence of PTSD when using the PTSD-AA and the DSM-IV. Two of these studies also compared prevalence rates when using the DSM-5 PTSD<6Y preschool criteria. To establish a pooled prevalence rate for all studies, the prevalence from the most age-appropriate diagnostic criteria, referred to as the study's "optimal" criteria, was used. Although two papers used the proposed DSM-5 PTSD<6Y preschool criteria, these studies gathered their data before the DSM5 PTSD<6Y was published, and due to the fact that they also reported on the PTSD-AA, the later prevalence estimates were used. Therefore, the "optimal" criteria in this meta-analysis were either PTSD-AA or DSM-IV. If a paper used the PTSD-AA, this was seen as the "optimal" criteria as it is more age-appropriate for the young population compared to the DSM-IV. However, on papers that only used the DSM-IV, this was their "optimal" criteria. One paper compared prevalence rates between therapists and parents as informants. The prevalence rate from the therapists was not included in this meta-analysis, due to all other studies only using caregivers as informants. The studies varied in time since trauma. One study reported prevalence at 2-4weeks and six months post-trauma. For the purpose of this meta-analysis, and in line with the exclusion criteria, only the six-month follow-up data on this paper was included in the meta-analysis. As such, time since trauma ranged from one month to three years across studies. Reported rates of PTSD ranged from 0-65%.

Pooled prevalence estimate

Prevalence rates from each study's "optimal" diagnostic criteria was used to calculate a pooled prevalence estimate. This estimate indicated that 21.9% (95% CI 13.1-32.1%) of the young children from the studies (k=19) who had been directly exposed to a traumatic event developed PTSD (Figure 2). The Q test was significant (Q=482.31, df =18; p<0.001), indicating a large degree of heterogeneity between studies (I^2=96.27) (Table 3).

Other prevalence rates reported, but not used in this meta-analysis were as follows: two studies using the DSM-5 criteria (in addition to DSM-IV and PTSD-AA) produced a combined prevalence of 15.2% (95% CI 2.2-36.9%; De Young, Kenardy, & Cobham, 2011; Gigengack, van Meijel, Alisic, & Lindauer, 2015); another used the DSM-IV with therapists as respondents and yielded a prevalence of 21.8% (Modrowski, Miller, Howell, & Graham-Bermann, 2013); and a final study using the PTSD-AA at a second time point (6months) reported PTSD prevalence rates as 10% (De Young & Kenardy, 2011).

Sensitivity analysis

Sensitivity analysis was used to explore differences in prevalence rates when studies applied the PTSD-AA criteria compared to the DSM-IV criteria. First, prevalence rates were compared using the eight studies that reported prevalence rates using *both* the DSM-IV and PTSD-AA (Table 3). Prevalence rates were higher when the PTSD-AA diagnostic criteria were applied (19.1%) compared to when the DSM-IV criteria were used (4.9%). Second, a sensitivity analysis was conducted on all studies that used *either* the DSM-IV (k=14) or the PTSD-AA (k=13). Subgroup analyses revealed that prevalence rates were higher when a study applied the PTSD-AA diagnostic criteria (25%) compared to the DSM-IV (9%; see Table 3).

One paper (De Voe et al., 2006) reported that some trauma exposed children did not directly witness the traumatic event. Unfortunately, prevalence rates were not reported for only directly-exposed children. Sensitivity analysis was used to investigate the difference in pooled prevalence estimates when this study was excluded. When the paper was excluded, the overall pooled prevalence increased marginally from 21.9% to 22.2% (Table 3). The heterogeneity across studies remained high. Given the small differences between including and excluding the study, it was included in further moderation analyses.

In a different paper (Ohmi et al., 2002), it was unclear whether the diagnostic measure (CPTSD-RI) was administered as a clinical interview or questionnaire. Sensitivity analysis was used to investigate the effect of excluding this paper. When it was excluded, the overall pooled prevalence reduced marginally from 21.9% to 21.7% (Table 3). The heterogeneity remained high. Due to this marginal change in prevalence, the paper was included in further moderation analyses.

Finally, despite all studies in this meta-analysis having a mean age of under 6.5years, the overall range of ages was between 0-16years. Three studies included children over the age of six years. A sensitivity analysis revealed a slightly higher prevalence rate in studies that only included children aged six and younger (25%) compared to the prevalence when all 19 studies were included (21.9%). However, due to all papers having a mean age under 6.5years, they were all included in further moderator analyses.

Moderator analysis

Prevalence rates were compared between studies that used the PTSD-AA and the DSM-IV as their optimal diagnostic criteria (most age-appropriate). Studies that used the PTSD-AA reported higher prevalence rates than those using the DSM-IV

criteria, but this difference was not significant (Table 3). Therefore, further moderator analyses were conducted on all samples and included those using either the PTSD-AA or DSM-IV diagnostic criteria.

Sub group analyses were conducted to look at the difference in prevalence rates following interpersonal or non-interpersonal trauma, group or individual trauma, and single or repeated trauma. One study (Scheeringa, 2015) was excluded from further moderator analysis, as the prevalence reported included a mix of these moderator variables. Moderator analysis was completed using 18 studies.

A moderator analysis suggested higher prevalence rates following exposure to interpersonal-trauma compared to non-interpersonal trauma. However, this trend was non-significant following a Holm-Bonferroni correction for multiple comparisons (p=.050). Similarly, prevalence rates were higher following repeated traumas compared to single traumas. However, this trend was non-significant following a Holm-Bonferroni correction for multiple comparisons (p=.033). No significant difference was found for group trauma compared to individual trauma (p=.672)

Finally, a sub-group analysis was conducted to look at the difference in prevalence rates reported in high quality studies (with a low risk of bias) compared to low quality studies (with a medium or high risk of bias). High quality studies were found to produce an overall lower prevalence rate compared to lower quality studies. However, a meta-regression indicated that this difference was non-significant (*p*=.328).

Table 2
Studies included in the meta-analysis

Author	Year	Type of trauma	Single/ Repeated	Interpersonal/ Non-interpersonal	Individual/ Group	Age range (years) (M, SD)	n	Proportion of males (%)	Time point (months)	Measure	Optimal Diagnostic Criteria	Risk of bias category (/12)
Cohen et al.	2009	Terrorism	Repeated	Interpersonal	Group	3.5-7.5 (5.47y, 1.34)	29	70.00%	6-18	SSIORIYC	PTSD-AA	High (4)
De Young et al.	2011	Accidental trauma	Single	Non-interpersonal	Individual	1-6 (2.7y, 1.54)	130	52.00%	1	DIPA	PTSD-AA	Low (12)
DeVoe et al.	2006	Terrorism	Single	Interpersonal	Group	0-5 (NR)	180	NR	9-12	PTSDSSI	DSM-IV	Medium (6)
Gigengack et al.	2015	Accidental trauma	Single	Non-interpersonal	Individual	0-7 (6.2y, 2.7)	98	68.00%	26[a]	DIPA	PTSD-AA	Low (10)
Graf et al.	2011	Accidental trauma	Single	Non-interpersonal	Individual	1-4 (32m, 9.5)	76	58.00%	15[a]	PTSDSSI	PTSD-AA	Low (11)
Graf et al.	2013	Medical illness	Single	Non-interpersonal	Individual	0-4 (34.8m, 11)	48	64.60%	15[a]	PTSDSSI	PTSD-AA	Low (9)
Graham-Bermann et al.	2012	IPV	Repeated	Interpersonal	Individual	4-6 (4.93y, 0.86)	85	53.00%	<24	PTSDSSI	DSM-IV	High (3)
Koolick et al.	2016	IPV	Repeated	Interpersonal	Individual	4-6 (4.96y, 0.815)	144	52.10%	<24	PTSDSSI	PTSD-AA	Medium (5)

Author	Year	Type of trauma	Single/ Repeated	Interpersonal/ Non-interpersonal	Individual/ Group	Age range (years) (M, SD)	n	Proportion of males (%)	Time point (months)	Measure	Optimal Diagnostic Criteria	Risk of bias category (/12)
Meiser-Stedman et al.	2008	Accidental trauma	Single	Non-interpersonal	Individual	2-6 (NR)	62	52.60%	6[b]	PTSDSSI	PTSD-AA	Low (11)
Modrowski et al.	2013	IPV	Repeated	Interpersonal	Individual	4-6 (5.0y, 0.93)	55	NR	<24	PTSDSSI	DSM-IV	Medium (5)
Ohmi et al.	2002	Accidental trauma	Single	Non-interpersonal	Group	1-3 (NR)	32	66.00%	6	CPTSD-RI	PTSD-AA	Low (11)
Pat-Horenczyk et al.	2013	War	Repeated	Interpersonal	Group	NR (Mixed[c])	262	61.20%	Mixed[d]	PTSDSSI	DSM-IV	High (4)
Scheeringa	2015	Mixed	Mixed	Mixed	Mixed	3- 6 (Mixed[e])	284	58.00%	NR	PAPA	PTSD-AA	Medium (6)
Scheeringa et al.	2006	Accidental trauma	Single	Non-interpersonal	Individual	0-6 (NR)	21	67.00%	2	PTSDSSI	PTSD-AA	Low (10)
Scheeringa et al.	2008	Natural Disaster	Single	Non-interpersonal	Group	3-6 (5.1y, NR)	70	57.10%	6-30	PAPA	PTSD-AA	Medium (6)
Stoddard et al.	2017	Accidental trauma	Single	Non-interpersonal	Individual	1-4 (1.93y, NR)	39	57.00%	1	PTSDSSI & DICA	PTSD-AA	Low (10)

Author	Year	Type of trauma	Single/ Repeated	Interpersonal/ Non-interpersonal	Individual/ Group	Age range (years) (M, SD)	n	Proportion of males (%)	Time point (months)	Measure	Optimal Diagnostic Criteria	Risk of bias category (/12)
Swartz et al.	2011	IPV	Repeated	Interpersonal	Individual	4-6 (63.8m, 11.2)	34	54.00%	<24	PTSDSSI	PTSD-AA	High (2)
Viner et al.	2012	Medical illness	Single	Non-interpersonal	Individual	3-16 (6.5y, 2.8)	245	42.00%	>36	DAWBA	DSM-IV	Medium (8)
Wolmer et al.	2015	War	Repeated	Interpersonal	Group	3-6 (64.12m, 8.48)	122	50.00%	>3	PTSDSSI	DSM-IV	High (4)

NR- not reported, IPV- interpersonal violence, [a]average time since trauma, [b]2-4 week data also reported, but not included in meta-analysis, [c]Continuous sample (M age=3.00y, SD=1.44), Past sample (M age=3.44y, SD=1.33) [d]Ongoing trauma or past trauma (time since trauma not recorded), [e]Single event (M age= 5.2y, SD=1.1), Hurricane Katrina (M age=5.1y, SD=1.0), Repeated trauma (M age=5.1y, SD=1.1)

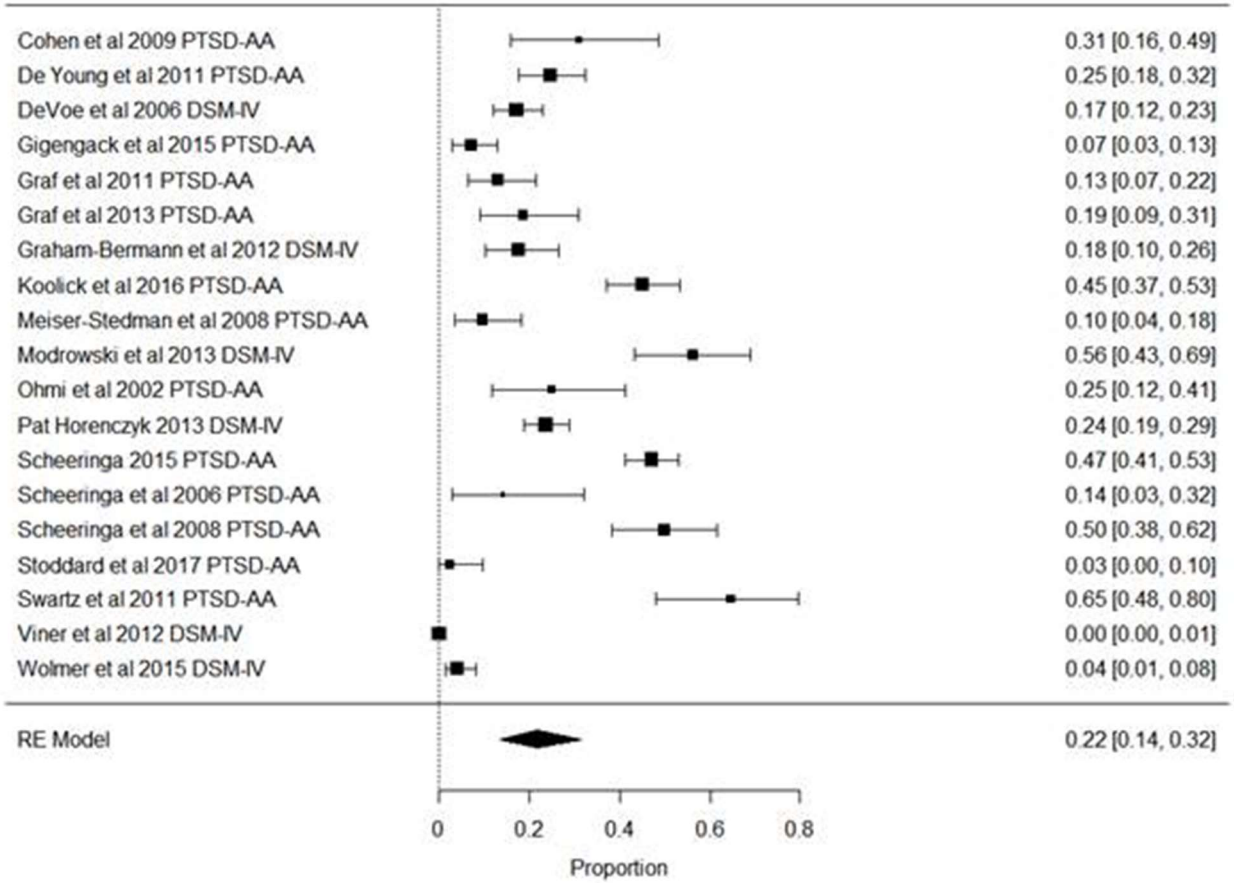

Figure 2. Forest plot for overall prevalence using optimal diagnostic criteria applied in each study
RE=Random Effects, Study-specific odds ratios (95% CIs) are denoted by black boxes (black lines) and presented in the right-hand column. The combined proportion estimate for all studies is represented by a black diamond, where diamond width corresponds to 95% CI bounds. Box and diamond heights are inversely proportional to precision of the proportion estimate.

Table 3. Meta-analysis outcomes for prevalence, including moderator and sensitivity analyses

	k	*n*	Prevalence	95% CI		Heterogeneity	
				Lower	Upper	Q test*	I^2
All studies using best available algorithm	19	2016	0.22	0.13	0.32	482.31	96.27
Moderator analysis:							
Moderator: PTSD-AA vs DSM-IV for optimal criteria applied							
PTSD-AA criteria	13	1152	0.25	0.15	0.36	182.99	93.44
DSM-IV criteria	6	864	0.16	0.04	0.33	189.61	97.36
Comparison	B=-0.118, 95% CI= -0.338 0.102, *p*=.293						
Moderator: Interpersonal vs non-interpersonal							
Interpersonal trauma	8	911	0.30	0.18	0.44	132.43	94.71
Non-interpersonal trauma	10	821	0.14	0.05	0.26	170.14	94.71
Comparison	B=-0.198, 95% CI=-0.396 0.00, *p*=.050						
Moderator: Group vs individual trauma							
Group trauma	6	695	0.23	0.12	0.37	67.23	92.56
Individual trauma	12	1037	0.21	0.12	0.34	298.12	96.31
Comparison	B=-0.049, 95% CI= -0.277 0.179, *p*=.672						
Moderator: Single vs repeated event							
Single event	11	1001	0.14	0.06	0.25	177.41	94.36
Repeated trauma	7	731	0.32	0.17	0.49	124.85	95.19
Comparison	B=-0.216, 95% CI=-0.415 -0.017, *p*=.033						
Moderator: High vs Low quality							
High quality	8	506	0.17	0.08	0.28	66.15	89.42
Low quality	11	1510	0.26	0.13	0.42	412.24	97.57
Comparison	B=-0.105, 95% CI=-0.317 0.106, *p*=.328						
Sensitivity analysis:							
PTSD-AA vs DSM-IV on same 8 studies							
PTSD-AA	8	495	0.19	0.09	0.31	64.80	89.20
DSM-IV	8	498	0.49	0.02	0.09	18.46	62.09
PTSD-AA vs DSM-IV, whole sample							
PTSD-AA	13	1152	0.25	0.15	0.36	182.99	93.44
DSM-IV	14	1447	0.09	0.04	0.17	229.68	94.34
Direct trauma only							
With DeVoe 2006	19	2016	0.22	0.13	0.32	482.31	96.27
Without DeVoe 2006	18	1836	0.22	0.13	0.33	480.87	96.47
Unclear measure							
With Ohmi 2002	19	2016	0.22	0.13	0.32	482.31	96.27
Without Ohmi 2002	18	1984	0.22	0.13	0.32	481.94	96.47
Age range							
Includes children >6years	19	2016	0.22	0.13	0.32	482.31	96.27
Excludes children >6years	16	1644	0.25	0.17	0.34	251.31	94.03

*****All Q tests were significant at p<.05. PTSD-AA= PTSD-Alternative Algorithm, DSM-IV=Diagnostic and Statistical Manual 4th edition.

Discussion

This meta-analysis investigated the prevalence of PTSD in preschool-aged children who had been directly exposed to a traumatic event. The overall prevalence rate was 21.9% across a total sample of 2016 children from 19 studies. This suggests that a significant minority of preschool children who experience a traumatic event develop PTSD. This prevalence rate is similar to, but greater than, rates reported for older children and adolescents (Alisic et al., 2014). There was significant heterogeneity across studies (I^2=96.27), which reflected variability in the demographics, trauma-related events, and methodological approaches across studies (Higgins, 2008).

The types of trauma for which prevalence rates of PTSD were reported varied across studies. The present data indicated a non-significant trend in prevalence rates following repeated trauma. Exposure to repeated traumatic events results in higher rates of PTSD than exposure to a single traumatic event (32% [95% CI 17-49%] versus 14% [95% CI 6-25%]). Although this finding was non-significant following a correction for multiple comparisons, this trend is consistent with the adult literature, which suggests that exposure to multiple traumatic events, even within the same type of event, is associated with higher levels of PTSD symptoms (McCauley et al., 1997; Follette, Polusny, Bechtle, & Naugle, 1996; Miranda, Green, & Krupnick, 1997). Little data is available on the impact of repeated trauma compared to single-event trauma in children. The number of available studies in this meta-analysis is limited, thereby reducing the available power for such analyses. Further studies investigating the impact of different types of trauma may in turn further highlight this effect of repeated trauma on PTSD prevalence rates in young children .

Further analysis suggested, albeit not conclusively, that exposure to an interpersonal trauma resulted in a doubling of the prevalence rates of PTSD relative to non-interpersonal trauma in preschool children (30% [95% CI 18-44%], versus 14% [95% CI 5-26%]). This trend is consistent with the finding that interpersonal trauma leads to greater psychological difficulties in children and adolescents aged 2-18years old (Alisic et al., 2014). Additional research with this young population, would enable such analyses to be further powered and would enable researchers to understand this trend and effect further.

Subgroup analyses were used to explore the impact of different types of traumas separately, however, the level of heterogeneity across studies remained significantly high. This suggests that the high variability across studies was not solely due to the different types of trauma being studied. Prevalence rates could not be compared across boys and girls because not all studies reported PTSD prevalence rates for boys and girls separately.

There were differences in the diagnostic criteria applied across samples, and in some cases multiple criteria were used. Where multiple criteria were used, the authors selected the study's "optimal" criteria; the most age-appropriate diagnostic criteria. The majority of studies applied an age-appropriate diagnostic criterion (PTSD-AA), but six studies only used the adult-derived DSM-IV criteria. Prevalence rates were higher when the PTSD-AA was the "optimal" criteria, compared to the DSM-IV. However, moderator analyses revealed that this difference in prevalence was not significant. Further sensitivity analyses indicated that prevalence rates were considerably lower when the DSM-IV criteria were applied compared to when studies used age-appropriate diagnostic criteria (PTSD-AA). This finding corroborates previous findings (Simonelli, 2013; Scheeringa, Myers, Putnam, &

Zeanah, 2012) suggesting that the DSM-IV criteria detect fewer cases of PTSD in this young population. Despite the fact that the PTSD-AA requires fewer endorsed symptoms compared to the DSM-IV, no difference in symptom counts have been found between children who meet the DSM-IV and the PTSD-AA diagnostic criteria for PTSD (Meiser-Stedman et al., 2008). This suggests that the higher prevalence rates of PTSD based on the PTSD-AA are not due to the lower number of required symptoms. One reason why the DSM-IV may be less sensitive in detecting PTSD in this young population might be due to the diagnostic criteria being adult-derived. As a result, the DSM-IV diagnostic criteria include symptoms which are not appropriate for the developmental level of young children, as they require skills that they have not yet developed e.g. verbal expression, memory and abstract thought (Scheeringa, Zeanah, Myers, & Putnam, 2003). Therefore, it is possible that young children may not meet the DSM-IV's PTSD threshold, as they do not show the adult-derived symptoms required to meet the diagnosis. The PTSD-AA was developed to focus on more developmentally appropriate symptoms of PTSD, particularly behavioural symptoms, which are easier for others to observe and therefore report on. Therefore, due to this adaption the PTSD-AA may be better suited to this population and therefore is more likely to identify young people with PTSD. This present finding therefore emphasizes the need for researchers and clinicians to apply age-appropriate diagnostic criteria to ensure that vulnerable children do not go un-diagnosed.

Additionally, moderator analyses indicated a non-significant trend in prevalence rates as a result of study quality. It was found that higher quality studies reported lower prevalence rates than those with medium to high risk of bias. One reason for this might be that the low quality studies had samples that were less representative. Therefore, their samples may have represented a sample of more

vulnerable individuals, thereby producing a higher prevalence rate than those with more representative samples. Importantly, however, the studies included in this meta-analysis had already undergone stringent inclusion and exclusion criteria, such as the time of assessment and type of assessment used. Therefore, the papers were rated on their risk of bias in addition to already being selected due to their strong methodological design. However, the impact of study quality on the reported prevalence is important to consider when interpreting the findings from this meta-analysis.

Limitations

There was a significantly high level of heterogeneity across studies included in the meta-analysis. This likely reflects the different types of trauma the samples were exposed to, as well as other methodological features of each study, such as different populations being assessed, in different countries and with different PTSD assessments. Heterogeneity remained significantly high when different types of traumas were compared in the moderator analyses.

Stringent exclusion criteria were applied to ensure that only studies using standardised interview measures were included. This was important to provide an accurate picture of the prevalence of PTSD in preschool aged children. Although this resulted in excluding some studies, it is very likely that including them would have further increased the heterogeneity across studies.

All studies included in this review used caregiver reports in interviews. This is unavoidable due to the age of the population, but it is important to consider caregiver's own psychological responses to their child's trauma, which may have impacted their reporting of their child's symptoms. Research has shown that caregivers often underestimate the level of trauma exposure a child has had, as well

as their PTSD symptoms (Ceballo, Dahl, Aretakis, & Ramirez, 2001; Richters & Martinez, 1993; Shemesh, et al., 2005; Meiser-Stedman, Smith, Glucksman, Yule, & Dalgleish, 2007, 2008; Egger & Angold, 2004). It is important to be aware of this limitation, as prevalence rates could be even higher. Future research could compare prevalence rates from different informants e.g. preschool classroom teachers and a range of caregivers.

This review indicates that few studies use age-appropriate diagnostic criteria for this age-group (PTSD-AA or DSM-5). As a result, the moderator analyses in this review were not very well powered. Conducting a similar meta-analysis in the future, when more studies have applied age-appropriate criteria, would be useful for further understanding the prevalence of PTSD in this young population following different types of trauma and to understand the impact of the utility of different diagnostic tools. All studies included in this meta-analysis were from OECD-countries. It remains unclear whether a similar prevalence rate would be found in preschool children exposed to traumatic events in non-OECD countries. In addition, the majority of the studies included in this meta-analysis were rated as being at moderate to high risk of bias. This field would therefore be improved by an increase in research into the prevalence of PTSD in this sample using age-appropriate diagnostic tools, in a variety of OECD and non-OECD countries and by ensuring that the research uses appropriate methodology and design to reduce the overall risk of bias.

Clinical implications

The current meta-analysis suggests that a significant minority of preschool aged children meet criteria for PTSD following direct exposure to a traumatic event. It was previously thought that young children did not have the cognitive capacity,

such as the memory or understanding of the inherent dangers in trauma, to develop PTSD (Yule, 1994). However, this meta-analysis indicates that preschool children are vulnerable of developing PTSD following direct trauma exposure. Clinicians and the system around young children therefore need to be aware of the potential psychological impacts of trauma exposure on young children. Relatedly, having an insight into the prevalence of PTSD in young children and the possible factors that influence a child's likelihood of developing PTSD, should assist clinicians in providing appropriate mental health support to those in need. Using a focused-approach to identify those most at risk aligns with the National Institute for Health and Care Excellence (NICE) guidance that psychological support for PTSD is best applied to those who are most vulnerable (2018), and it will enable services to provide a cost-effective and efficient support system. A key outcome, which is directly relevant to clinical practice, is the need to use age-appropriate diagnostic criteria when assessing young children for PTSD to ensure children are not missed or left undiagnosed and therefore unsupported.

Future research

Future research should focus on assessing pre-schoolers following direct-trauma using age-appropriate diagnostic tools to ensure accurate prevalence rates are being reported. An increase in studies in this area will enable researchers to look further into possible moderator variables that may contribute to different prevalence rates and help to identify those most at risk. Using data from different informants will also help provide a better picture of the prevalence of PTSD in this age-group.

Conclusion

A significant minority of preschool aged children meet diagnostic criteria for PTSD, which highlights the psychological impact exposure to a traumatic event can

have on young children. Young children show similar trends in prevalence rates following different types of trauma, namely interpersonal and repeated trauma exposure, to older children and adolescents, though this could not be confirmed conclusively based on the available research. The primary practical outcome of this meta-analysis is that age-appropriate diagnostic criteria should be used to ensure vulnerable individuals are identified and supported at an early stage.

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Chapter 3. Bridging chapter

Results from meta-analysis

The meta-analysis reported in Chapter Two identified that a significant minority of preschool-aged children met diagnostic criteria for Posttraumatic Stress Disorder (PTSD). This adds to the literature suggesting that despite their developmental age, young children have the cognitive abilities to develop psychological difficulties following direct exposure to a traumatic event (Scheeringa, Wright, Hunt, & Zeanah, 2006). The review also highlighted, albeit not conclusively, similar trends in prevalence rates following different types of trauma to older children and adolescents (Alisic et al., 2014). Repeated trauma exposure and interpersonal trauma exposure were associated with increased PTSD prevalences in this population that failed to be significant when adjustment for multiple comparisons was undertaken. This review discussed the impact different diagnostic criteria have on PTSD prevalence rates in young children, and highlighted the importance of using age-appropriate diagnostic tools in this population.

The systemic impact of trauma

It is important to consider the impact of the family system surrounding a young child who has been exposed to trauma. Due to the young age of the population in the meta-analysis, it is likely that caregivers were also present during the trauma (e.g. during an act of terrorism, political violence or domestic violence, or an accident). Similarly, parents who observe their child experience a medical trauma or accidental injury can also develop psychological adjustment difficulties and post-traumatic stress reactions (Farley et al., 2007; Hall et al., 2006). It is therefore crucial to consider the role of the caregiver and their relationship with their child, when they themselves may be struggling with post-trauma adjustment.

Parent and child distress scores and avoidant behaviours are significantly correlated following exposure to a traumatic event (Rees, Gledhill, Garralda, & Nadel, 2004; Colville & Pierce, 2012). Meiser-Stedman and colleagues (2017) found that parental stress responses in the acute phase of a trauma predicted child PTSD six months post-trauma (Meiser-Stedman, Smith, Yule, Glucksman, & Dalgleish, 2017). These findings are in line with Kazak and colleague's Paediatric Medical Traumatic Stress model (2006), which highlights that a trauma-exposed child is not separate from the family system. Instead the child sits within a family system, and as a result the entire family respond to the trauma, which may explain the development of PTSD in children and their caregivers following a trauma.

The relationship between post-traumatic distress in parents and their children could arise due to parents developing psychological symptoms in response to seeing their child's distress, or as a result of children picking up on their parent's distress (McFarlane, 1987). Due to their developmental age, and inability to regulate strong emotion, young children are reliant on their caregiver's reactions and behaviours to determine how to interpret or respond to an event (Carpenter, & Stacks, 2009; Nugent, Ostrowski, Christopher, & Delahanty, 2007). It is therefore important to identify caregivers who may be struggling with post-trauma adjustment because these difficulties may directly impact the psychological wellbeing of their child. Parental distress might also negatively impact the family's ability to function, which in turn could negatively impact a child's recovery following a traumatic event (Testa, Malec, Moessner, & Brown, 2006; Carpenter, & Stacks, 2009; Lieberman, 2004; Scheeringa, & Zeanah, 2001). By identifying caregivers who have psychological difficulties following a traumatic event, support can be offered to help

reduce the negative psychological impact on the caregiver and the whole family (De Young & Kenardy, 2013).

Empirical paper

An admission to a Paediatric Intensive Care Unit (PICU) can be a traumatic experience for both parents and their children (Colville, Kerry, & Pierce, 2008; Balluffi et al., 2004). For a proportion of parents, a child's admission to PICU can lead to longer-term psychological distress (Rees et al., 2004; Bronner et al., 2009). Therefore, an empirical research study was designed as part of this thesis portfolio to assess the prevalence of parents who were vulnerable, during the acute phase of a child's admission to PICU, to developing longer-term psychological difficulties. It also aimed to identify factors that might contribute to this psychological vulnerability and to difficulties with post-trauma adjustment in a subgroup of parents. By understanding the prevalence of at-risk parents, and the factors that contribute to this vulnerability, preventative support can be offered to reduce psychological difficulties in both the short and longer term for the parents and the family as a whole.

The empirical paper presented in this thesis portfolio describes data from the first wave of data-collection from a longitudinal prospective study looking at the psychological trajectory of parents of children admitted to PICU. Data and analyses from the subsequent time points of the larger study will be presented in future publications. The findings discussed in the present empirical paper illustrate the factors contributing to parental vulnerability in the acute phase of their child's admission to PICU. Further longitudinal data will endeavour to describe the role of these factors in a parent's psychological sequalae and longer-term post-trauma adjustment.

Chapter 4. Empirical paper

Factors influencing parental psychological vulnerability following their child's PICU admission

Written for publication to Journal of Paediatric Nursing

(Author guidelines for manuscript preparation- Appendix E)

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Abstract

Purpose: To identify the prevalence of parents who are at-risk of developing Posttraumatic Stress Disorder (PTSD) and Major Depressive Episode (MDE) following their child's Paediatric Intensive Care Unit (PICU) admission. In addition, this paper aims to understand the role of pre-trauma and peri-trauma factors in predicting parental difficulties with post-trauma adjustment and psychological distress.

Design and Methods: A total of 107 parents, of 75 children who were admitted to PICU, completed a demographic questionnaire and the post-traumatic adjustment scale (PAS) during admission. The PAS measured pre-trauma and peri-trauma factors as well as post-trauma adjustment difficulties.

Results: In the current sample, 59.8% of parents were at risk of developing PTSD and 74.7% were at risk of developing MDE following their child's admission. Pre-trauma stressors, such as mental health difficulties, and peri-trauma factors, such as negative parental appraisals, contributed significantly to parental difficulties with post-trauma adjustment and risk of psychological vulnerability. Medical severity markers such as length of admission or ventilation and reason for admission were not predictive of parental adjustment difficulties or psychological distress.

Conclusion: This study suggests that psychosocial pre-trauma and peri-trauma factors are strong predictors of post-trauma psychological adjustment difficulties and vulnerability of future distress.

Practice Implications: The importance of utilising psychological screening measures in PICU is discussed. Identification of vulnerable parents at admission, can enable a preventative approach to be taken to reduce long term psychological

distress for these families. Paediatric nurses have a central role in identifying and supporting vulnerable parents during admission.

Keywords: children, parents, PTSD, MDE, PICU, screening

Highlights

- A majority of parents were found to be at risk of developing PTSD or MDE following their child's admission to PICU
- The Posttraumatic Adjustment Scale (PAS) was introduced as a screening tool of psychological vulnerability in this population
- Pre- and peri-trauma factors were found to be significant predictors of psychological vulnerability and difficulties with post-trauma adjustment over and above medical and severity factors
- The importance of early detection of vulnerable individuals is highlighted

Introduction

An admission to a Paediatric Intensive Care Unit (PICU) can be a very stressful and traumatic event for children and their caregivers. Parents on PICU observe their children in life-critical conditions, and rely on medical professionals to help them. Parents often report significant levels of distress in relation to their child's admission, which is an understandable reaction in the acute phase of such a traumatic event (Balluffi et al., 2004; Board & Ryan-Wenger, 2003; Bronner, Knoester, Bos, Last, & Grootenhuis, 2008; Colville & Gracey, 2006; Colville et al., 2009; Rees, Gledhill, Garralda, & Nadel, 2004). For a subgroup of parents, acute stress reactions can become chronic and develop into longer-term mental health difficulties, such as post-traumatic stress disorder (PTSD) and depression. The primary aims of this study were to assess the proportion of parents at risk of developing PTSD and Major Depressive Episode (MDE) following a child's admission to PICU and to determine pre-, peri-, and post-traumatic factors that play a role in determining a parent's vulnerability of future psychological distress.

Paediatric research has highlighted the long-term psychological impact a hospital procedure, diagnosis, or admission can have on parents both in PICU and on other paediatric wards. For example, up to 68% of mothers and 57% of fathers were found to have Posttraumatic Stress Symptoms (PTSS) in the moderate to severe range one-month after their child's cancer diagnosis (Kazak, Boeving, Alderfer, Hwang, & Reilly, 2005). Crucially, parents of children admitted to PICU were nearly four times more likely to screen positive for PTSD compared to parents of children admitted to general wards, four-six months post-discharge (Rees et al., 2004). This suggests that parents of children admitted to PICU may be more

vulnerable to poorer psychological outcomes that can persist several months post admission (Bronner et al., 2009; Board & Ryan-Wenger, 2002).

Reports of parental distress following an admission to PICU vary widely. Between 18% and 45% of parents report clinically significant PTSS following their child's admission (Balluffi et al., 2004; Board & Ryan-Wenger, 2000; Bronner et al., 2008; Colville & Gracey, 2006; Rees et al., 2004), and a recent review indicated that nearly 84% of parents had subclinical symptoms of PTSD (Nelson & Gold, 2012). Parental acute distress is a strong predictor of later psychological outcomes for parents (Baluffi et al., 2004). It is therefore essential to understand how many parents in the acute phase are at risk of developing later mental health difficulties such as PTSD and depression.

Parent and child distress scores are significantly correlated after a traumatic event, such as an admission to PICU (Rees et al., 2004; Morris, Gabert-Quillen, & Delahanty, 2012). Although the direction of this relationship is not yet clear, it is evident that an admission to PICU can have a psychological impact on the wider family system (McFarlane, 1987). Family functioning is an important predictor of outcomes for children following a traumatic experience (Testa, Malec, Moessner, & Brown, 2006). Therefore, by identifying parents who are at risk of later psychological distress, preventative approaches could be implemented to help reduce psychological distress for the wider family.

Not all parents go on to develop mental health difficulties post-discharge (Colville et al., 2009). It is therefore important to evaluate the risk factors that may make parents particularly vulnerable to adverse outcomes following their child's admission to PICU. The adult PTSD literature defines a range of factors that are likely to contribute to an individual having poorer psychological outcomes following

a hospital admission, including gender, course of illness, duration of sedation, socio-economic circumstances, and the patient's acute stress reactions during intensive care (Madden, Barrett, & Pietromonaco, 2000; Faessler et al., 2016; Wade, 2011). Factors that may contribute to parents' likelihood of having poorer psychological outcomes following their child's PICU admission may therefore cluster into four groups: 1) child and parent demographics, 2) pre-trauma factors, 3) peri-trauma factors and 4) post-trauma adjustment. Demographic factors such as the child's age, parental gender and socio-economic status might interact with a parent's vulnerability for future psychological distress. For example, mothers may be more vulnerable than fathers (Riddle, Hennessey, Eberly, Carter, & Miles, 1989; Youngblut, Brooten, & Kuluz, 2005). Pre-trauma factors, including previous experiences and vulnerabilities may contribute to how well a parent can cope psychologically with their child's admission. Peri-trauma factors relate to factors at admission that could contribute to a parent's vulnerability. These include length of admission or medical severity of the child's illness. Interestingly, illness severity was found not to be linked to parental levels of Post-traumatic Stress (PTS; Colville & Gracey, 2006; Colville, Cream, & Kerry, 2010), whereas higher levels of PTS were found in parents following their child's emergency admission compared to an elective admission (Colville et al., 2010). Parental appraisal of the threat to their child's life was found to be related to later PTSS (Baluffi et al., 2004). For other factors, such as length of admission, the evidence is less clear (Rees et al., 2004; Colville et al., 2010). Post-trauma adjustment factors such as short-term emotional difficulties, acceptance, and psychological coping may contribute further to a parent's longer-term psychological outlook. Bronner and colleagues indicated that parental coping styles were associated with parental PTSD, and that peri-traumatic

dissociation was strongly associated with parental PTSD and depression (Bronner et al., 2009).

Together, these findings suggest parental outcomes following a child's admission to PICU can be influenced by a number of factors before, during and after admission. However, there are a number of factors not yet considered and few studies have combined the investigation of pre-, peri-, and post-trauma factors. The primary goal of the current study is to further investigate the influence these factors have on parental vulnerability and post-trauma adjustment in the acute phase.

Adult intensive care units have screening and follow-up protocols for their patients. However, in the UK, there is no standardised psychological screening or follow-up for patients nor their caregivers following a PICU admission. It is therefore highly likely that post-admission parental psychological distress goes undetected. Identifying parents in the acute phase of admission and investigating factors that might increase their vulnerability to later and prolonged distress provides the opportunity to establish support systems (i.e. follow-up clinics to reduce the psychological impact of a PICU admission on the family as a whole). Indeed, there is an unmet need for such services; in a survey, two thirds of parents reported that they would have appreciated a follow-up appointment to discuss their child's admission (Colville, Cream, & Gracey, 2003). Furthermore, Colville and Gracey (2006) showed that mothers who were able to talk about their distress at admission had fewer PTS symptoms eight months post-admission. National Institute of Health Care and Excellence (NICE) guidelines suggest that psychological interventions, such as PTSD treatments, should be offered in a targeted way to those most at risk or with symptoms (NICE, 2018). Such non-blanket follow-up approaches have been found to be the most effective in parents of children admitted to PICU (Colville et

al., 2010). This underscores the need to identify factors that increase parental vulnerability so those most at risk can be offered targeted psychological support in a cost-effective manner.

This study will use the Posttraumatic Adjustment Scale (PAS) to assess the prevalence of parents who present as "at risk" of later psychological distress in the acute admission stage. The PAS has been used primarily to assess adults who are at risk of developing PTSD or MDE following hospitalisation for a traumatic injury (O'Donnell et al., 2008). The PAS has recently been adapted and used successfully to screen a cohort of parents in PICU, to enable efficient targeting of follow-up parental support (Samuel, Colville, Goodwin, Ryninks, & Dean, 2015). The PAS provides insight into how parents are adjusting post-trauma, and identifies important pre- and peri- trauma factors that contribute to their psychological vulnerability. Furthermore, research has suggested that PAS scores of parent vulnerability predict symptoms of PTSD, anxiety and depression six months after discharge (Samuel et al., 2015). Therefore, this screening tool will provide a better understanding of the factors which may contribute to post-trauma adjustment difficulties and parental vulnerability of psychological distress in this sample.

Research Questions

1) In the acute stage, what proportion of parents screen as "at risk" of developing PTSD and MDE?
2) What factors play a role in determining a parent's post-trauma adjustment and vulnerability of future distress?

Materials and Method

Design:

This questionnaire-based study focuses on the psychological adjustment of parents following their child's admission to Paediatric Intensive Care Unit (PICU). This study investigates the psychological responses of parents in the acute phase; during admission.

This study is part of a wider prospective longitudinal cohort study. The larger longitudinal study is questionnaire based, and participants were contacted at three time points: 1) during admission; 2) 1-4months post-admission; and, 3) 12-18months post-admission. At each time point, parents were asked to complete a series of questionnaires about their own psychological adjustment to their child's admission. For children over the age of three years old, parents were asked to report on their child's psychological adjustment following admission.

Due to ongoing recruitment, only data from time point one (during admission) is included in this paper.

Participants:

The sample was recruited from a larger clinical population of families where a child had been admitted to PICU at Addenbrooke's Hospital, Cambridge University Hospitals NHS Foundation Trust, due to an acute trauma (e.g. a motor vehicle collision) or medical emergency (e.g. acute respiratory illness, meningitis). To get a representative sample of the population, the age-range of the sampled children matched those accepted into PICU more widely (0-16years old). Some children are admitted to PICU in order to receive specialist intensive support for longstanding and stable illnesses, while other children will be briefly admitted to PICU following a planned surgical procedure. In an attempt to make the sample

more homogeneous, and to only sample families of children who required an admission to PICU due to an acute trauma or medical emergency, only families of the most seriously unwell children were included. Therefore, only families of children who had been ventilated for a minimum of two days during their PICU admission were selected for inclusion. This sampling decision enabled the researchers to understand the psychological vulnerability and trajectories of families who are likely to have found the admission to PICU most distressing due to the seriousness of their child's medical condition. Families were excluded if: a) the child was not ventilated for the specified time; b) the child passed away during admission; c) there were any safeguarding concerns; and, d) there was a lack of fluency in English in the family.

Consecutive attendees at PICU were sampled to recruit eligible families. A total of 156 children who were admitted to PICU during the study period (April 2018- October 2019) met the eligibility criteria. These families were approached by research nurses. Twenty-one children were discharged before consent could be obtained, and a further 25 children were excluded after being approached by research nurses as they did not meet the full inclusion criteria due to the following reasons: safeguarding concerns (n=12), language barrier (n=8), withdrawal of care or death of a patient (n=5). Parents of a further 31 children did not consent to participate. In total, parents of 79 children consented to take part. Following consent, one child passed away during admission and two further parents, of one child, did not complete the questionnaires. One child's parent was recruited to the study twice, meaning one duplication was removed, and another child's parent did not complete the Posttraumatic Adjustment Scale (PAS) and was subsequently removed from the sample. In total 107 parents of 75 children completed all the questionnaires during

admission (see Table 2 and 4 for sample demographics). A chi square test showed that there was no significant association between type of admission (emergency or elective) and whether or not parents decided to consent to take part (p=.131).

Procedure:

Research nurses based at Addenbrooke's Hospital approached eligible families and provided them with a detailed information sheet about the longitudinal study (Appendix F). Families were given a minimum of 24hours to read through this information sheet, and were given the opportunity to ask the research nurses questions before consenting to take part. Parents were reminded that they could withdraw from the study at any time, and this would not affect their child's ongoing care. Once informed consent was gathered, parents were allocated a unique participant ID and were given the time-one questionnaires (detailed below). Due to the sensitive nature of one of the questionnaires (the Posttraumatic Adjustment Scale), parents were also given an envelope with their ID number, so that they could return the completed questionnaires without sharing their responses with the research nurses. The research nurses collated the questionnaires for collection by the research team.

Measures:

Demographic information

A questionnaire to obtain basic demographic information from families was created by the research team (Appendix H). This questionnaire asked about parent's age, ethnicity, marital status, level of education, employment status, whether they were home owners, and the number of children in the family. The questionnaire also asked about whether their child had previously been admitted to an intensive care unit (ICU). Parents were asked if they or their children had any mental health

difficulties prior to the admission, and current family stressors (e.g. financial, health, work for the family) were also assessed.

Posttraumatic Adjustment Scale (PAS; O'Donnell et al., 2008).

The Posttraumatic Adjustment Scale is a screening instrument that aims to identify adults at high risk of developing PTSD and/or Major Depressive Episode (MDE) following a traumatic event. The 10-item questionnaire assesses factors known to be strongly associated with the development of PTSD and MDE. With the authors permission, the phraseology of three questions was adapted for this study, for example "I can accept what happened to me", was changed to "I can accept what happened to my child". The questionnaire items cluster into three groups; pre-trauma factors, peri-trauma factors and post-trauma factors (Table 1). Parents were asked to rate how much they agreed with each statement from "Not at all" to "Totally". All responses contribute to an overall PAS-PTSD score which ranges from 0-40 and has a cut off of 16 indicating elevated risk of developing PTSD. Responses to five items are used to calculate a PAS-Depression score, scores range from 0-20 on this measure and scores of 4 or higher indicate elevated risk of developing MDE. A PAS-Post-adjustment score was calculated by summing scores on the four post-trauma items to indicate how well parents are adjusting psychologically following their child's admission. The PAS has a sensitivity of .82 and a specificity of .84 when predicting PTSD and a sensitivity of .72 and a specificity of .75 for predicting MDE (O'Donnell et al., 2008).

Table 1
Posttraumatic Adjustment Scale items

	Posttraumatic Adjustment Scale Items
Pre-trauma	
	I have needed professional help to deal with emotional problems in the past*
	Previous traumatic events have impacted negatively on my life in the past*
	In the past I was able to talk about my thoughts and feelings with my family members or friends
	In the past I was satisfied with the support that I had from my friends and family*
Peri-trauma	
	At the time of the event, I felt terrified, helpless or horrified
	During the event, I thought my child was about to die
Post-trauma	
	I have felt irritable or angry since the event*
	I have found it difficult to concentrate on what I was doing or things going on around me since the event*
	I am confident that I can deal with the financial stressors that may arise as a consequence of my child being on PICU
	I can accept what happened to my child

*Items are combined to calculate the PAS-Depression score.

Paediatric Infant Mortality-2 Scale (Slater, Shann & Pearson, 2003).

The Paediatric Infant Mortality-2 Scale is a routine measure used to assess mortality risk of patients admitted to intensive care. Using a logistic regression model, it uses an equation which describes the relationship between predictor variables measured at the time of admission and the probability of death. Such

predictor variables include physical observations which may illustrate the medical severity, such as blood pressure, need for ventilation, need for cardiac bypass and whether the admission was an emergency or elective admission. This assessment is completed by medical staff at admission, assigning each patient a mortality score.

Ethical considerations

This project was conducted following the British Psychological Society (BPS; 2010) guidelines for the conduct of psychological research and was granted ethical approval from East of England-Cambridge South Research Ethics Committee (reference: 18/EE/0035; Appendix I & J). All participants gave informed consent and were reminded of their right to withdraw from the study at any point (Appendix G) . All data was kept securely and participant confidentiality followed guidelines from the Data Protection Act (1998) and The General Data Protection Regulation (GDPR; 2016).

Data analyses

The data were analysed using the Statistical Package for Social Sciences (SPSS; version 25) and screened for errors and missing values. A mean substitution was used for one missing value. Assumption testing was conducted following Kim's (2013) guidance for medium sized samples. None of the dependent variables, PAS-PTSD, PAS-Depression and PAS-Post-trauma adjustment, were skewed or showed kurtosis. Descriptive statistics were used to summarise sample characteristics. Independent t-tests were conducted to test for group differences on PAS sores and Bivariate Pearson Correlations were conducted to identify relationships between the independent and dependent variables. Factors where significant group differences were found or variables that were significantly correlated with the outcome measures

were then entered into hierarchical linear regression models. Three regression models were used to investigate the impact of pre-traumatic and peritraumatic factors on PAS-PTSD, PAS-Depression and PAS-Post-traumatic adjustment scores. To control for multiple comparisons, a Bonferroni correction was applied meaning the threshold for significance was $p<.017$.

Results

Demographics:

Sample characteristics

Child demographics

Seventy-five children were recruited to the study and ranged in age from 0 years to 15years 3months (183 months), with a mean age of 50.40 months (SD=61.67). Fifty three percent of the children were male (mean age= 39.25 months). The mean age of the females was 63.14 months. For 31 children, both parents participated in the study. For these children there were two data points for each scale (one from each parent), so their information is repeated in further sample analyses.

The average length of ventilation was 140.88hours (*SD*=88.00) with a range of 54-424 hours. The mean PIM2 score was 4.77 (*SD*=6.28). Length of admission ranged from 2.82-115.58 days. Two children's admission lengths were outliers (more than three standard deviations above the mean). For these children, their length of admission value was replaced with the maximum value allowed; the sample mean plus three standard deviations. Following this adjustment, the length of admission ranged from 2.82- 59.10days, with a mean length of admission of 9.46days (*SD*=9.79). A high proportion of children had emergency admissions to

PICU (91%), which likely reflects the inclusion criteria of selecting parents of seriously unwell children. See Tables 2 and 4 for full sample demographics.

Children were admitted to PICU for a range of reasons; Respiratory Infections (n=38, 36%), Neurological (n=26, 24%), Surgical (n=19, 17%), Oncology (n=3, 3%), Sepsis (n=3, 3%) and Trauma (n=2, 2%). Parental outcomes were compared for the two main groups of children; Respiratory infections and Neurological reasons for admission. Additional analyses exploring the effect of reason for admission on parental outcomes is described in Chapter Six: Additional Results.

Parent demographics

Parents age brackets were as follows: 18-24 (n=3, 2.8%); 25-29 (n=16, 14.8%), 30-34 (n=37, 34.3%), 35-39 (n=23, 21%), 40-44 (n=13, 12%), 45-49 (n=14, 13%), 50+ (n=2, 1.9%). Further analysis investigating age effects on parental outcomes during the acute phase of a PICU admission are reported in Chapter Six: Additional Results. Further parent demographics are reported in Table 1. As a summary, the majority of parents were mothers, White British, and in a relationship. A high proportion of the sample had stayed in education over the age of 16, and over half of the sampled parents owned their own home.

Table 2
Parent PAS-PTSD, PAS-Depression and PAS-post-trauma adjustment scores by demographic, pre-trauma and peri-trauma variables.

	PAS-PTSD		PAS-Depression		PAS-post trauma adjustment	
	M	***SD***	***M***	***SD***	***M***	***SD***
Demographic variables						
Child gender						
Male (n=56;52%)	18.41	7.23	7.66	4.49	7.07	3.66
Female (n=51; 48%)	16.06	7.52	6.31	4.47	5.84	3.22
Comparison	*t*=-1.65, *p*=.10, *d*=0.32		*t*=-1.55, *p*=.12, *d*=0.30		*t*=-1.84, *p*=.07, *d*=0.36	
Parent gender						
Mother[a] (n=68; 64%)	17.96	8.23	7.78	5.00	6.76	3.54
Father (n=39; 36%)	16.13	5.69	5.69	3.13	6.00	3.40
Comparison	*t*=1.35, *p*=.22, *d*=0.26[b]		*t*=2.65, *p*=.02 , *d*=0.50[b]		*t*=1.09, *p*=.28, *d*=0.22	
Ethnicity						
White British (n=91; 85.%)	17.62	7.63	7.32	4.58	6.53	3.52
Other[c] (N=16; 15%)	15.44	5.99	5.31	3.77	6.25	3.44
Comparison	*t*=1.08, *p*=.28, *d*=0.32		*t*=1.57, *p*=.10,*d*=0.48		*t*=0.29, *p*=.77, *d*=0.08	
Relationship status						
Relationship (n=95; 91%)	16.99	7.03	6.73	4.25	6.46	3.38
Single/Divorced/Separated (n=9; 9%)	15.44	7.13	6.89	4.34	4.56	2.40
Comparison	*t*=-0.63, *p*=.53, d=0.22		*t*=0.11, *p*=.91, *d*=0.04		*t*=-1.65, *p*=.10, *d*=0.65	
Home owner						
Yes (n=63;59%)	16.05	6.97	6.22	3.88	6.03	3.53
No (n=44;41%)	19.07	7.78	8.16	5.12	7.14	3.37
Comparison	*t*=2.10, *p*=.04, *d*=0.41		*t*=2.12, *p*=.03, *d*=0.43[b]		*t*=1.62, *p*=.11, *d*=0.32	
Over 16 Education						
Yes (n=78;84%)	16.03	6.67	6.27	3.96	6.06	3.28
No (n=15;16%)	16.60	7.13	6.53	4.12	6.27	3.71
Comparison	*t*=0.30, *p*=.76, *d*=0.08		*t*=0.24, *p*=.82, *d*=0.06		*t*=0.22, *p*=.83, *d*=0.06	

	PAS-PTSD		PAS-Depression		PAS-post trauma adjustment	
	M	***SD***	***M***	***SD***	***M***	***SD***
Pre-trauma variables						
Previous parent MHPs						
Yes (n=54;51%)	20.98	6.71	9.37	4.31	7.89	2.98
No (n=51, 49%)	13.51	6.18	4.67	3.23	4.98	3.78
Comparison	t=-5.93, p<.001, d=1.16		t=-6.23, p<.001, d=1.23		t=-4.69, p<.001, d=0.85	
Parent pre-trauma life stressors						
Yes (n=56;52%)	19.50	7.12	8.55	4.56	7.39	3.37
No (n=51;48%)	14.86	7.04	5.33	3.85	5.49	3.38
Comparison	t=-3.38, p=.001, d=0.66		t=-3.93, p<.001, d=0.76		t=-2.91, p=.004, d=0.56	
Previous ICU experience						
Yes (n=34, 32%)	16.59	7.39	7.03	4.24	6.15	3.24
No (n=72; 68%)	17.72	7.47	7.08	4.66	6.68	3.63
Comparison	t=0.72, p=.47, d=0.15		t=0.06, p=.95, d=0.01		t=0.73, p=.47, d=0.15	
Peri-trauma variables						
Type of admission						
Elective (n=10;9.%)	15.20	5.18	7.10	3.48	5.70	2.63
Emergency (n=97; 91%)	17.51	7.61	7.01	4.62	6.57	3.57
Comparison	t=1.27, p=.35, d=0.35[b]		t=-0.06, p=.95, d=0.02		t=0.75, p=.46, d=0.28	
Reason for admission 1						
Neurological (n=26;24%)	18.19	7.72	7.42	5.00	6.92	2.92
Other (n=81;76%)	17.00	7.36	6.89	4.37	6.35	3.66
Comparison	t=-0.71, p=.48, d=0.16		t=-0.52, p=.60, d=0.07		t=-0.73, p=.47, d=0.17	
Reason for admission 2						
Respiratory Infection (n=38;36%)	16.08	7.19	6.32	4.23	5.79	3.43
Other (n=69;64%)	17.97	7.53	7.41	4.64	6.87	3.50
Comparison	t=1.26, p=.21, d=0.26		t=1.20, p=.23, d=0.25		t=1.54, p=.13, d=0.31	

[a] Number of mothers includes one foster mother. [b] Refers to equal variance not assumed as shown by Levene's test. [c] Refers to parents who described themselves as the following; African (n=1), American (n=2), Arab (n=1), Asian British (n=2), Australian (n=2), British Pakistani (n=1), Chinese (n=1), European (n=1), Filipino (n=2), Indian (n=2), Pakistani (n=1).

In the following sections, results are reported for each of the primary research questions.

Question 1: In the acute stage, what proportion of parents screen as "at risk" of developing PTSD and MDE?

PAS:

One-hundred-and-seven parents completed the PAS. Parents consented to the study and completed the PAS an average of 7.68 days into their child's admission (SD=5.37). A missing data point on the pre-trauma factor questions for one parent was replaced with the mean score for that parent's responses to the other pre-trauma questions. In total 64 of 107 (59.8%) parents scored at or above the cut-off for high risk of developing PTSD relating to their child's admission (PAS-PTSD). In addition, 80 of 107 (74.8%) scored at or above the cut-off on the depression items and were therefore at high risk of developing a Major Depressive Episode relating to their child's admission (PAS-Depression).

A measure of post-trauma adjustment was calculated from the PAS. Table 3 indicates that 56% of parents rated that they have felt angry or irritable since the event (moderate extent, large extent or totally), and 55% reported having difficulties concentrating since the event (moderate extent, large extent or totally). In contrast, 54% reported that they felt confident they could manage the financial stressors that may have arisen following their child's admission (moderate extent, large extent, totally), and 46% reported feeling able to accept what had happened to their child (moderate extent, large extent, totally).

Table 3
Frequency of responses to PAS items measuring post-trauma adjustment

	Not at all	**To a small extent**	**To a moderate extent**	**To a large extent**	**Totally**
Irritable or angry	23 (21%)	36 (34%)	19 (18%)	16 (15%)	13 (12%)
Difficulties with concentration	9 (8%)	39 (36%)	26 (24%)	16 (15%)	17 (16%)
Confidence in managing financial stressors	28 (26%)	30 (28%)	28 (26%)	14 (13%)	7 (7%)
Acceptance	27 (25%)	31 (29%)	25 (23%)	20 (19%)	4 (4%)

Question 2: What factors play a role in determining a parent's post-trauma adjustment and vulnerability of future distress?

An independent t-test, with unequal variances assumed, revealed that mothers scored higher on PAS-Depression compared to fathers. However, this finding was not significant following a Bonferroni correction for multiple comparisons. This indicates that there were no significant gender differences in terms of vulnerability to future distress (see Table 2).

Parents who self-disclosed having previous mental health problems scored significantly higher on PAS-PTSD, PAS-Depression and PAS post-trauma adjustment than those without self-disclosed mental health problems. Similarly, parents who disclosed having pre-trauma stressors scored significantly higher on PAS-PTSD, PAS-Depression and PAS post trauma adjustment compared to those who reported having no pre-trauma stressors (Table 2).

Parents who are home owners scored lower on PAS-PTSD and PAS-Depression than those parents who do not own their own home. Although this suggests a small protective effect of socioeconomic status, these comparisons were non-significant following a Bonferroni correction for multiple comparisons. No significant differences were found on PAS-Post adjustment scores between home owners and non-home owners (Table 2).

No significant differences were found on the outcome measures due to parent ethnicity, level of education, relationship status, type of admission (elective or emergency), previous child ICU experience or reason for admission (neurological vs other and respiratory infections vs other). All results are reported in Table 2.

Positive relationships were found between scores on the Post-trauma adjustment scale and PAS-pre-trauma and PAS-peri-trauma factors (see Table 4). This suggests that pre- and peri-trauma factors are related to parents' post-trauma adjustment difficulties. The following factors were not significantly rated to PAS-PTSD, PAS-Depression nor PAS-Post-trauma adjustment: child age, PIM2 score, length of admission, length of ventilation and time of completion of the PAS(see Table 4). These factors were not included in the subsequent hierarchical regression modelling.

Table 4
Pearson correlation matrices for continuous independent variables

	Mean (SD)	PAS-PTSD	PAS-Depression	PAS-Post adjustment
Demographic variables				
Parent Age	-	-.08	-.08	-.05
Child Age (months)	46.81 (59.50)	.06	.07	.03
Pre-trauma variables				
PAS-pre-trauma	5.06 (3.70)	-	-	.48**
Peri-trauma variables				
PAS-peri-trauma	5.67 (2.15)	-	-	.44**
PIM2 score	4.73 (6.26)	-.05	-.09	-.13
Length of admission (days)	9.48 (9.75)	-.04	.02	.11
Length of ventilation (hours)	141.30 (87.68)	.04	.02	.11
Time of participation (days into admission)	7.68 (5.37)	.08	.04	.06

**significant $p<.017$

Factors where significant group differences were identified, or those that were significantly related to the outcome measures were entered into a series of regression models. Pre-trauma and peri-trauma PAS scores were not entered into the PAS-PTSD and PAS-Depression model because they are summed to create the total PAS scores. All assumptions were met; regression residuals were normally

distributed and were homoscedastic. The predictor variables had a linear relationship with the outcome variables, and there was no multicollinearity.

A linear regression model was used to look at whether pre-trauma stressors and self-disclosed pre-trauma parental mental health problems predicted PAS-PTSD scores. Pre-trauma self-disclosed parental mental health problems significantly contributed to the model [β=.455, p<.001]). The presence of pre-trauma stressors did not quite reach significance [β=.169, p=.057]. These factors explained 26.7% of the variance in PAS-PTSD scores (R^2=.267, F(19.894), p<.001).

PAS-Depression scores were also significantly predicted by psychosocial variables (presence of pre-trauma stressors [β=.218, p=.012], and self-disclosed pre-trauma parental MHPs[β=.459, p<.001]. They explained 31.7% of the variance in PAS-Depression scores (R^2=.317, F(23.698), p<0.01).

A two-stage linear hierarchical regression was conducted with PAS-post trauma adjustment scores as the dependent variable. Pre-trauma factors (PAS pre-trauma score, presence of pre-trauma parental MHPs and presence of parental pre-trauma stressors) were entered at stage one, with peri-trauma factors (PAS-peri trauma score) added in to the second stage. Pre-trauma factors (PAS pre-trauma score [β=.387, p<.001] and presence of pre-trauma parental MHP [β=.210, p<.05], contributed significantly to the model. Presence of parental pre-trauma stressors did not significantly contribute to the model [β=.070. p=.431]. These factors explained 28.4% of the variance; (R^2=.284, F(14.736), p<.001). The PAS peri-trauma score [β=.297, p<.001] further significantly contributed to the model and explained a further 8% of variance. Therefore, the combined model explained 36% of variance; (Total R^2=.360, F(15.627), p<.001).

All regression R^2 scores detailed above are the adjusted R squared. β is the standardized coefficients Beta.

Discussion

This study investigated the impact of pre- and peri-trauma factors on parents' psychological outcomes and adjustment *during* their child's admission to PICU. The majority of previous studies have assessed levels of PTSS, PTSD and depression following discharge (Nelson & Gold, 2012; Colville, & Pierce, 2012). The current results provide a unique snapshot of parents' vulnerability during admission, providing scope to implement preventative measures to reduce longer-term psychological distress. Crucially, the data indicated a higher prevalence of parents at risk of developing MDE compared to PTSD. This is an important finding. Previous research has primarily focused on resulting posttraumatic stress reactions following PICU admissions because they are typically viewed as traumatic events. As a result, health care professionals, such as paediatric nurses, are more likely to look out for signs of PTSD following a traumatic admission, rather than more subtle signs of depression in parents. The current results emphasise the importance of looking for signs of depression in addition to PTSD to ensure vulnerable parents are not missed.

Overall a high proportion of parents were at risk of developing PTSD (59.8%) or MDE (74.7%) as a result of their child's admission to PICU. The prevalence of parents deemed to be at high risk of developing PTSD was higher than in a recent paper using the same screening tool (Samuel et al., 2015; 37%). This difference may be due to the use of a higher minimum length of ventilation in the current study (48hours compared to 12hours in Samuel et al., 2015). The present study may have therefore sampled more severely unwell children and their families.

Importantly, the PAS has high sensitivity and specificity for PTSD and depression. In the original sample (O'Donnell et al., 2008), the PAS correctly classified PTSD in 84% of participants at 12 months. Similarly, depression was correctly classified in 75% of the sample at the 12 month follow-up. Importantly, the PAS has a high negative predictive power. Suggesting that it can reliably screen out the majority of patients who are unlikely, due to their experienced trauma, to need mental health support in the future. Furthermore, Samuel and colleagues (2015) indicated that parents who were deemed at high risk at discharge were significantly more likely to score above the clinical cut-off for posttraumatic stress, anxiety and depression six months post-discharge. Therefore, due to the high predictive power of the measure, the proportion of parents deemed vulnerable to PTSD and depression in this current sample, would benefit from psychological support to minimise their experience of longer term psychological distress.

Key aims of the study were to further understand the demographic, pre- and peri-trauma factors that contribute to a parent's vulnerability of developing psychological difficulties in the acute adjustment phase following their child's admission. Importantly, no child or parent demographic factor predicted psychological adjustment or outcomes. These findings suggest that a parent or child's gender or socio-economic background alone does not predict their future risk of psychological distress. However, it is possible that demographic factors may interact together or with other pre-trauma and peri-trauma factors to predict vulnerability in this population. However, more power is required to investigate such factor interactions.

Peri-trauma factors including medical severity, and type and reason for admission were also assessed. The PIM2, a medical severity marker, did not predict

psychological vulnerability nor difficulties with post-trauma adjustment. This is consistent with previous studies (Balluffi et al., 2004; Bronner et al., 2010; Colville & Gracey, 2006). Similarly, length of admission and ventilation did not predict parent outcomes, and no differences were found in outcomes between parents of children who had emergency or elective admissions. Certain medical conditions, such as respiratory infections, may result in multiple admissions to PICU over a child's life. Therefore, for some parents the admission to PICU may not be a new experience. However, neither prior experience of an ICU, nor reason for admission (respiratory infections versus other) were found to be significant predictors of parent outcomes. Relatedly, there were no differences in outcomes for parents of children admitted due to neurological reasons compared to non-neurological reasons. Together, these findings suggest that, in this sample, severity of the child's condition does not influence parental vulnerability in the acute phase of a PICU admission.

Two peri-trauma factors; appraisal that their child might die, and feeling terrified, helpless or horrified, predicted parent's post-trauma adjustment. It therefore seems that parent appraisals and beliefs about being able to manage during the PICU admission are more influential than condition severity and medical measures when it comes to parental psychological outcomes. This is consistent with, and adds to, growing evidence that it is the subjective experience of a potentially traumatic event that determines whether it is traumatic for that individual (Balluffi et al., 2004; Stuber et al., 1997).

The important influence parental appraisals can have on determining their psychological adjustment following a traumatic event fits with the cognitive model of PTSD (Ehlers & Clark, 2000). This model proposes that appraisals of the traumatic event influence an individual's posttraumatic response, and therefore play

a crucial role in the development, maintenance and recovery of PTSD. Furthermore, a subjective trauma appraisal, such as a perceived threat to life, has been consistently found to predict PTSD, over and beyond any trauma severity measures (Blanchard et al., 1995; Ehlers, Mayou, & Bryant, 1998; Pynoos et al., 1987; March, 1993). This therefore suggests that assessing parental appraisals of the admission and their subjective appraisal of their child's severity and risk of death, is paramount in identifying parents at risk of developing PTSD.

Pre-trauma psychological variables contributed to vulnerability for PTSD, depression and post-trauma adjustment problems. Self-disclosed pre-existing parent mental health problems were strong predictors of parents' outcomes. However, it is important to note that items on the PAS, which contribute to both the PTSD and depression scores, also assess a parents' previous need for emotional support and experience of traumatic events. Therefore, it may not be surprising that parents who self-disclosed pre-trauma mental health difficulties and previous stressors, scored higher on the PAS for PTSD and depression. Despite this, self-disclosed mental health difficulties predicted parents' post-trauma adjustment difficulties, suggesting that pre-existing psychological factors are likely to be stronger predictors of a parent's adjustment following their child's admission.

In summary, this study found a high proportion of parents were at risk of developing PTSD and/or MDE following their child's PICU admission. Pre-trauma factors and peri-trauma appraisals contribute to a parent's difficulties with post-trauma adjustment and contribute to their vulnerability of longer-term psychological distress. The importance of pre-trauma and peri-trauma factors in the development of parental difficulties with adjustment and vulnerability for further psychological difficulties is in alignment with the model of paediatric medical traumatic stress

(Kazac et al., 2006). This model illustrates how pre-existing factors, such as ongoing stressors, can contribute to an individuals' subjective experience, perception and appraisals of the event. The model thereby suggests that it is the combination of the objective traumatic event and the subjective experience which contribute to an individual's psychological trajectory and adjustment post-trauma. Thereby highlighting that pre-trauma factors and peri-trauma appraisals are important areas on which to focus preventative therapeutic approaches for this population.

Implications for clinical practice

The current results highlight that an admission to PICU can be a traumatic experience for parents, and a subgroup of parents are subsequently at risk of later developing PTSD and MDE. Based on the current data, it is essential that paediatric nurses, and other health care professionals are aware of the high rates of vulnerability for not only PTSD, but also for depression in similar samples. Medical severity markers were not predictive of parents' abilities to manage their child's admission. Therefore, focusing follow-up support on families of the most severely unwell children is not guaranteed to target the most vulnerable parents. It may be more effective for paediatric nurses to understand the external pre-trauma and peri-trauma psychosocial variables that appear to intensify the distress of PICU admission for families and therefore increase their post-trauma adjustment difficulties. As the current study shows, these include pre-trauma factors, such as parental mental health problems and stressors and peri-trauma factors such as parental appraisals of the admission.

The use of screening tools for families in PICU could provide a system of early identification of families most at risk of current and future distress (Muscara et al., 2017). Early identification could promote targeted and effective support, and

may help to prevent long-term distress. A preventative approach would not only benefit the parent, but it would likely improve psychological functioning of the wider family due to close associations between parent and child distress (Rees et al., 2004; Morris et al., 2012). Screening tools such as the PICU Family Stress Screening Tool are being developed worldwide (Liaw et al., 2019). In order to successfully implement screening tools in a fast-paced PICU setting, tools need to be brief to enable paediatric nurses to screen all families before discharge. An adapted version of the PAS was used successfully in PICU in the current study, and as such it could be a useful short screening tool to use more widely. Adopting a universal screening approach will enable a systematic preventative approach to be used in PICUs to support families and their children both during and following admission.

Limitations and future research directions

This exploratory study reports data from the first time point in an ongoing longitudinal study. It is therefore limited in providing only a snapshot view of parental distress during their child's PICU admission. It is likely that parental distress and appraisals fluctuate during their child's admission. In this study, parents did not complete the questionnaires at the same time interval during their child's admission. Although the time of data collection varied between parents, this was not significantly related to distress levels. Future research may want to understand the fluctuations in distress levels during admission, by screening parents at different intervals such as at admission and at discharge. The analysis of the longitudinal study, of which this paper is time point one, will provide further insight into the long-term trajectory of parental vulnerability. In addition, it will investigate the factors that contribute to the longer term psychological sequalae of these parents.

This heterogeneous PICU sample was recruited from one hospital site, and due to the inclusion criteria and parental hesitation to participate in the research study, only a proportion of children admitted to PICU were included in this study. Therefore, the results may not generalise to wider PICU samples. That said, recruitment is typically difficult in PICU settings as it relies on approaching parents at a very stressful time. This clearly affects participant uptake. One benefit of the current study was that parents were approached by familiar paediatric research nurses, rather than independent researchers. This may have been a comfort to families as they were able to discuss the research with hospital staff, and they may have felt more able to turn down the request to participate. Unfortunately, 13% of children admitted to PICU were not able to be approached by research nurses before they were discharged. This reflects the fact that some admissions to PICU are very short, and therefore future research may want to consider approaching families at an earlier stage.

Due to the sample heterogeneity additional factors that may have predicted parental vulnerability may have been missed. Due to the high levels of variability between child admissions it is implausible for any single study to explore all potential factors. Focussing on a predefined set of demographics, and pre- and peri-trauma factors that may influence psychological distress in one hospital helped to control for factors such as the PICU environment, which is likely to have been consistent for all families. Further research into different psychosocial pre-trauma variables may provide a further understanding of the protective and predictive variables of parental psychological distress.

By sampling children who had been ventilated for a minimum of 48hours, the researchers were able to investigate the psychological reactions of a PICU admission

of parents of children admitted due to their medical severity. Although any admission to PICU is likely to be a distressing event for any child and family, the researchers sampled the most severely unwell children, in order to make the sample more homogeneous, and to only sample those children that were admitted due a critical medical emergency or trauma. It was predicted that these families would be most vulnerable to psychological distress and therefore important to follow-up through the three time points of the wider longitudinal study. However, through this sampling decision, limitations arose, as it did not allow for comparisons of parental appraisals or acute emotional responses between parents of severely unwell children and those who did not require ventilation. Therefore, the role of ventilation in parental peri-trauma appraisals and post-trauma adjustment difficulties cannot be explored. However, it is likely that by widening the sample to include families of children who were not ventilated for 48hours, the heterogeneity of the sample would significantly increase.

Two variables associated with parent outcomes were both self-disclosed by parents (presence of mental health problems and pre-trauma stressors). It is possible that parents who were in a state of acute stress were more likely to disclose having pre-trauma stressors and mental health difficulties, than those who were less stressed at admission. It is important to note that parental stress at the time of the study may have biased their reports on pre-trauma stressors.

There is currently no standardised procedure for screening parents of children admitted to PICU. Paediatric nurses' close contact with families means that they are in a prime position to screen families at an early stage during admission. Future feasibility studies could therefore assess the usefulness and practicalities surrounding the implementation of a screening tool. Research into preventative support systems

for these families will be invaluable to move towards a more standardised system of support for children and their families.

Conclusions

Overall, the current study found a high proportion of parents whose children were admitted to PICU were at or above the threshold for being at risk of developing PTSD and/or MDE. Pre-trauma and peri-trauma psychosocial variables predicted parents' difficulties with adjustment following their child's admission. Paediatric nurses should be aware of the importance of these pre- and peri- trauma factors, which may play a larger role than medical severity markers in predicting acute adjustment difficulties and vulnerability of later psychological distress. Future research is needed to understand how these factors contribute to parental psychological trajectories following discharge from PICU. Furthermore, by implementing a standard protocol of screening families in PICU, clinicians will be able to identify at risk individuals and provide preventative support to reduce long-term psychological distress.

Declaration of interests

None

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Chapter 5. Extended methodology

Ethical considerations:

Informed consent: Information sheets were given to participants when they were approached by research nurses (Appendix F). These provided information about the study and what would be involved at each of the three stages (at admission, three to four month follow-up and one year follow up). Participants were given time to think about whether they wanted to participate, and were able to ask the research nurses any questions in the hospital, or email the lead researcher. The consent form can be found in Appendix G.

Right to withdraw: The information sheet informed participants about their right to withdraw at any point, and stated that this decision would not affect their child's care. Participants were reminded of their right to withdraw at each stage of the longitudinal study, and were given contact details for the research team to do so.

Distress: The study was conducted at a time of heightened stress for families, but it was not anticipated that participating in the study would produce further distress for these individuals. Signposting to appropriate support networks (e.g. GP or Samaritans) was provided on the information sheet.

Confidentiality: The information sheet described for participants the ways in which their data would be kept anonymous and confidential. All anonymous data from the questionnaires was securely locked in a cabinet at UEA and were only accessible to the primary research team. For the purpose of follow-up, confidential information was shared between Addenbrooke's Hospital and UEA securely. All confidential information was saved electronically with a secure password on an encrypted memory stick. Participants were informed that all information collected in

relation to the study would be kept for 10 years at UEA in line with the UEA Research Data Management Policy.

Coercion: Participants were reminded that they were taking part in the research study voluntarily, and were under no obligation to take part. No financial incentive to take part was offered to participants. Participants were reminded that a decision to not participate would not affect their child's care or treatment.

Sample size calculations:

An a-priori power analysis was completed using G-power-3.1 (Faul, Erdfelder, Lang, & Buchner, 2007). To detect a large effect size with .9 power and an alpha of .05, it was calculated that a total of 68 participants would be required for the independent t-tests. To detect a large effect size with .9 power and an alpha of .05, a total of 73 participants would be required for the linear regression modelling (two-tailed). Therefore, with 107 participants, this study had sufficient power to detect large effect sizes.

Parametric assumption testing:

Assumption testing was conducted on the three dependent variables to ensure the data were appropriate for parametric tests following guidance from Kim (2013) for medium sized samples ($50<n<300$). A z test was used to test whether the data were normally distributed (skewness and kurtosis). The data breach normality if the z value is over 3.29, corresponding to an alpha level of .05. Outcomes are provided in the subsequent chapter.

Levene's test of equality of variances was carried out for the independent t-tests. Scatterplots were used to check for a monotonic relationship between variables for the Pearson correlations (Laerd Statistics, 2018). For the regression models, visual inspection of the Predicted Probability (P-P) plots and Scatter plots was used

to ensure the regression residuals were normally distributed and to assess homoscedasticity. Variance Inflation Factor (VIF) values were assessed to ensure the absence of multicollinearity. The outcomes of these assumption tests are provided in the following chapter.

Chapter 6. Additional Results

Parametric assumption testing:

Dependent variables

Assumption testing was carried out for the three dependent variables; PAS-PTSD, PAS-Depression and PAS-Post-trauma adjustment. Results from the parametric assumption tests can be seen in Table 1. Shapiro-Wilk tests indicated that PAS-Depression and PAS-post-adjustment scores were not normally distributed. However, visual inspection of the data, using box-plots and scatter quantile-quantile (Q-Q) plots suggested the data was normally distributed.

Following guidance by Kim (2013), Z_{Skew} and $Z_{Kurtosis}$ were calculated. Such z scores can be informative when the visual inspection of the data and Shapiro-Wilk test produce incompatible results. Z_{Skew} and $Z_{Kurtosis}$ are calculated by dividing the Skewness and Kurtosis score by their standard errors. For medium sized samples ($50<n<300$), a z test under 3.29 is indicative of normally distributed data. All z values were below this threshold (Table 1), therefore, parametric tests were conducted with these dependent variables. Using parametric tests enabled the author to maintain the power and sensitivity of using continuous rather than binary variables.

Table 1
Parametric assumption tests

	PAS-PTSD	PAS-Depression	PAS-Post trauma adjustment
Shapiro Wilk test (p)	.137	.001*	.025*
Z_{Skew}	1.65	2.88	1.43
$Z_{Kurtosis}$	-.310	.170	-.980

Regression residuals:

Assumption tests were also carried out for the three linear regression models following guidance by Field (2009). Predicted Probability (P-P) plots indicated that the regression residuals were normally distributed. Scatterplots were used to show that the data was homoscedastic. Finally, variance inflation factor (VIF) values were used to check the absence of multicollinearity. All scores were less than 10 indicating that this assumption was met.

One-way ANOVAs:

One-way ANOVAs were conducted to investigate differences on PAS-PTSD, PAS-Depression and PAS-Post adjustment scores by age. No significant difference was found on the outcome measures due to parent age (Table 2).

Table 2
Parent PAS-PTSD, PAS-Depression and PAS-post-trauma adjustment scores by parent age

		PAS-P		PAS-D		PAS-post trauma adjustment	
Parent age group	N (%)	M	SD	M	SD	M	SD
18-24	3 (2.8%)	20.67	4.73	11.00	2.65	7.00	2.00
25-29	16 (14.8%)	17.06	7.62	6.75	5.09	6.38	3.36
30-34	37 (34.3%)	17.75	6.25	7.14	4.20	6.61	3.33
35-39	23 (21.0%)	16.27	8.26	6.36	4.46	6.65	3.51
40-44	13 (12.0%)	17.46	7.60	7.00	4.42	6.46	3.64
45-49	14 (13.0%)	16.43	8.98	6.79	4.93	6.29	4.66
50+	2(1.9%)	13.50	2.12	5.00	1.41	4.00	0.00
Comparison		F=0.242, p=.96		F=0.468, p=.83		F=0.197, p=.98	

A series of one-way ANOVAs also revealed no significant differences in outcome scores due to reason for admission (Table 3).

Table 3
Parent PAS-PTSD, PAS-Depression and PAS-Post trauma adjustment scores by reason for admission.

		PAS-PTSD		PAS-Depression		PAS-post trauma adjustment	
Reason for admission	N (%)	M	SD	M	SD	M	SD
Neurological	26 (24%)	18.19	7.72	7.42	4.99	6.92	2.92
Sepsis	3(3%)	12.33	7.09	5.00	3.61	5.00	3.61
Respiratory Infections	38 (36%)	16.08	7.19	6.32	4.23	5.79	3.43
Respiratory Other	16 (15%)	16.81	7.94	6.63	4.94	6.44	3.92
Surgical	19 (17%)	19.11	7.68	8.47	4.21	7.32	4.14
Trauma	2(2%)	16.00	5.66	3.50	2.12	5.00	2.83
Oncology	3(3%)	21.67	3.79	9.67	4.04	9.00	2.00
Comparison		F=0.831, p=.55		F=1.014, p=.42		F=0.903, p=.50	

Correlations:

Pearson Bivariate correlations were performed and reported in the main paper. Non-parametric (Point-Biserial) correlations were conducted to explore the relationship between the outcome measures and the non-continuous independent variables. The results from the Point-Biserial correlations duplicated findings from previously reported independent t-tests (Table 4), so were not detailed in full in the main paper. Dichotomous coding is detailed in the table to illustrate the direction of correlation.

Table 4
Point-Biserial correlation matrix.

	PAS-pre-trauma	PAS-peri-trauma	PAS-PTSD	PAS-Depression	PAS-Post trauma adjustment
Demographic variables					
Parent Gender (mother =0 father=1)	-.19	.09	-.12	-.22*	-.11
Child Gender (female =0 male=1)	.06	.15	.16	.15	.18
Ethnicity (white=0, other=1)	-.13	-.10	-.11	-.16	-.03
Home owner (yes=1, no=0)	-.26**	.01	-.20*	-.21*	-.16
Education level over 16 (yes=1, no=0)	-.05	.02	-.03	-.03	-.02
Relationship status (relationship =1, no relationship =0)	-.06	.06	.06	-.01	.16
Pre-trauma variables					
Parental pre-trauma stressors (yes=1, no=0)	.32**	.08	.31**	.36**	.27**
Parental pre-trauma MHPs (yes=1, no=0)	.49**	.21*	.50**	.52**	.42**
Prior Child ICU experience (yes=1, no=0)	-.02	-.10	-.07	-.01	-.07
Peri-trauma variables					
Reason for admission (neurological= 1, other=0)	.05	.04	.07	.05	.07
Reason for admission (respiratory infection=1, other=0)	-.08	-.03	-.12	-.12	-.15
Type of admission (elective=1 or emergency=0)	.04	-.27**	-.09	.01	-.07

*significant $p<.05$, ** significant $p<.017$ (after Bonferroni corrections were applied)

Odds ratios:

Odds ratios were calculated to illustrate which independent variables predicted whether a parent would score above the cut-off for PAS-PTSD and/or PAS-Depression (Table 5). Three variables were found to significantly predict whether or not a parent scored above the threshold for PAS-Depression. Home owners were 68% less likely to score above the PAS-Depression threshold compared to those who did not own their own home. Parents with pre-trauma mental health problems were 23 times more likely to score above the PAS-Depression threshold than those without self-disclosed mental health problems (MHPs). Parents with pre-trauma stressors were 4.5 times more likely to score above the PAS-Depression threshold than those parents without pre-trauma stressors. Pre-trauma MHP and pre-trauma stressors also significantly predicted whether a parent would score above the PAS-PTSD threshold. Parents who self-disclosed pre-trauma MHPs were six times more likely to score above the PAS-PTSD threshold than parents without pre-trauma MHPs. Similarly, parents who reported having pre-trauma stressors were over three times more likely to score above the threshold for PAS-PTSD compared to parents without pre-trauma stressors. These findings are consistent with the results reported in the main empirical paper.

Table 5
Odds ratios

Predictor variable	PAS-PTSD status			PAS-Depression status		
	Odds ratio	95% CI		Odds ratio	95% CI	
		Lower	Upper		Lower	Upper
Demographic variables						
Parent gender (mother=0, father=1)	0.80	0.36	1.78	0.64	0.26	1.55
Child gender (female=0, male=1)	1.73	0.79	3.78	2.30	0.94	5.65
Ethnicity (white=0, other=1)	1.14	0.38	3.41	0.70	0.22	2.24
Relationship status (relationship=1, no relationship=0)	1.15	0.29	4.55	0.80	0.16	4.11
Home owner (yes=1, no=0)	0.55	0.25	1.22	0.32*	0.12	0.87
Over 16 education (yes=1, no=0)	1.02	0.34	3.09	0.87	0.25	3.02
Pre-trauma variables						
Previous MHP (yes=1, no=0)	6.06*	2.54	14.44	23.11*	5.08	105.20
Pre-trauma stressors (yes=1, no=0)	3.33*	1.48	7.47	4.52*	1.71	11.93
Previous ICU experience (yes=1, no=0)	1.09	0.47	2.52	1.38	0.52	3.69
Peri-trauma variables						
Type of admission (emergency=0, elective=1)	0.64	0.18	2.38	3.30	0.40	27.30
Reason for admission (neurological=1, other=0)	1.71	0.67	4.39	0.69	0.26	1.84

Reason for admission (respiratory infection=1, other=0)	0.45	0.20	1.01	0.92	0.37	2.27

*indicates significance

Chapter 7: Discussion and Critical Evaluation

Overview of chapter

This final chapter summarises the main findings from the meta-analysis and empirical paper. The research articles will be critically evaluated and the clinical implications will be considered. Ideas for future research will be suggested, and reflections on the thesis process will be discussed before a conclusion of the whole portfolio is provided.

Meta-analysis Findings

A meta-analysis was conducted to investigate the prevalence rate of PTSD in preschool-aged children who had directly experienced a traumatic event. Moderator analyses were conducted to explore prevalence rates of PTSD by type of trauma (interpersonal/non-interpersonal, individual/group, repeated/single event trauma). Comparisons were also made between studies that utilised age-appropriate diagnostic criteria, such as the alternative algorithm (PTSD-AA), compared to the DSM-IV.

The meta-analysis included only studies that utilised a standardised interview measure of PTSD. A total of nineteen studies were included, providing a total pooled sample of 2016 young children. The weighted pooled prevalence of preschool-aged children developing PTSD following direct exposure to a traumatic event was 21.9%. This indicates that a significant minority of preschool-aged children met the diagnostic threshold of PTSD when standardised interview measures were used.

Moderator analyses found a non-significant trend in prevalence rates following repeated trauma exposure. Higher prevalence rates of PTSD were found following repeated trauma exposure in this population compared to single-event trauma exposure. This finding is consistent with the adult literature investigating

moderators in PTSD prevalence rates (McCauley et al., 1997; Follette, Polusny, Bechtle, & Naugle., 1996; Miranda, Green, & Krupnick, 1997). A non-significant trend was also found for higher prevalence rates following interpersonal trauma compared to non-interpersonal trauma. For both of these non-significant trends, prevalence rates doubled when preschool children were exposed to interpersonal trauma or repeated trauma relative to non-interpersonal trauma or single-event trauma. Although these trends were non-significant, it is consistent with findings showing increased psychological difficulties in older children and adults following interpersonal and repeated trauma exposure (Alisic et al., 2014; Breslau., 2001).

Pooled estimates of prevalence were calculated and compared for all studies using the DSM-IV diagnostic criteria and those using the PTSD-AA. Prevalence rates were lower when the DSM-IV criteria were used. This underscores the importance of using age-appropriate diagnostic tools with young children, and suggests that a proportion of vulnerable children will not meet criteria and may be missed if non-age-appropriate tools and criteria are used. Age-appropriate diagnostic tools importantly consider the difference in PTSD symptoms typically found in this age group and predominately focus on behavioural symptoms, rather than complex cognitive symptomology criteria, which is more appropriate for young children whose cognitive capacities are still developing (Scheeringa, Peebles, Cook, & Zeanah, 2001). The findings reported in the meta-analysis reinforce the importance of using these age-appropriate tools in research and clinical settings.

A high level of heterogeneity was found across studies included in the meta-analysis, despite sub-group analyses looking at different types of traumas separately. This suggests that even studies investigating similar categories of trauma using standardised interview techniques still have significant variability. High levels of

heterogeneity are common in meta-analyses, but it is important to consider the implication of this when interpreting the results (Engels, Schmid, Terrin, Olkin, & Lau, 2000; Higgins, 2008).

Empirical Paper Findings

The empirical study aimed to identify the proportion of parents deemed to be "at risk" of developing longer-term psychological difficulties following their child's admission to Paediatric Intensive Care Unit (PICU). The Posttraumatic Adjustment Scale (PAS; O'Donnell et al., 2008) was used to screen parents who may be at risk of developing PTSD and/or a Major Depressive Episode (MDE) following their child's admission. This study also investigated the impact of pre- and peri- trauma factors on parental psychological outcomes and post-trauma adjustment during their child's PICU admission.

A total of 107 parents of 75 children from a single hospital PICU were recruited. A high proportion of parents scored at or above the cut-off for being at high-risk of developing PTSD (59.8%) or MDE (74.8%) following their child's admission. Crucially, more parents were vulnerable to developing depression than PTSD. This suggests clinicians should screen for depression as well as PTSD in parents following the traumatic event. Although we cannot say for certain how many parents will go on to develop PTSD and/or depression in the future, the psychometric properties of the PAS (e.g. sensitivity, specificity and high negative predictive power) suggest that parents who are deemed vulnerable in the acute phase would benefit from psychological support to minimise their longer term psychological distress.

The study looked at the impact of pre- and peri- trauma factors on parental vulnerability and difficulties with post-trauma adjustment. Demographic variables,

such as parent gender or socio-economic status, did not predict psychological vulnerability or difficulties with post-trauma adjustment. Neither did medical factors such as severity, reason for admission or type of admission. Psychological pre- and peri-trauma factors did predict parental psychological vulnerability and difficulties with post-trauma adjustment. This suggests that parental peri-trauma appraisals, acute emotions and pre-existing emotional difficulties are associated with parental psychological vulnerability and post-trauma adjustment difficulties over and above medical severity measures in the acute phase following their child's admission to PICU. These findings are consistent with the model of paediatric medical traumatic stress (Kazak et al., 2006), which highlights how pre-trauma factors can contribute to an individual's perception, experience and appraisals of an event. Relatedly, the importance of appraisals of the traumatic event are shown to be strongly linked with posttraumatic responses and PTSD in Ehlers and Clark's cognitive model of PTSD (2000).

Critical Evaluation

The studies included in the meta-analysis were highly heterogeneous, and the sample of parents included in the empirical paper were also heterogeneous. It is therefore possible that additional moderator factors were not assessed or examined. Although heterogeneity is common in PICU samples and meta-analyses, it is important to consider the implications of mixed samples when interpreting and generalising the results.

The meta-analysis estimated the pooled prevalence of PTSD in preschool age children. However, this meta-analysis only included 19 studies, with a total sample of 2016 young children. Although this meta-analysis provides an estimate of the prevalence of PTSD in this population, it is limited in the total number of studies and

therefore sample size. This may reflect the fact that research into PTSD in younger children is still relatively new, and therefore highlights the need for further high-quality research in this area.

Furthermore, only studies from Organisation for Economic Co-operation and Development (OECD) countries were included in the meta-analysis, and the parents included in the empirical study were sampled from one hospital site's PICU in the UK. This limits the generalisability of the results. It is possible that different trauma reactions and prevalence rates may have been found in preschool-aged children and parents of severely unwell children in non-OECD countries.

In addition, only parents of children who had been ventilated for a minimum of 48hours were included in the empirical study. This enabled the researchers to investigate the impact of a PICU admission on parents of the most severely unwell children, but it did not allow for comparisons of parental appraisals or acute emotional responses between parents of severely unwell children and those who did not require ventilation. Objective medical factors did not predict psychological distress and adjustment difficulties. However, parental peri-trauma appraisals, which did predict psychological vulnerability and adjustment, may have been focused on the ventilation alone. By including parents of non-ventilated children in future studies, the role of subjective factors, such as parental peri-trauma appraisals, can be further investigated.

It is important to note that the prevalence rates in the empirical paper and those papers included in the meta-analysis reflect the prevalence rate of PTSD at a single time point post-trauma. Although this provides insight into the overall prevalence, it only offers a single snap-shot. It is likely that rates of PTSD will

fluctuate over time following a traumatic event, and this should be considered when interpreting the data.

Furthermore, the empirical paper used a brief screening tool in the acute phase of a major trauma. Although the brief screening tool is likely to be useful in such a setting as PICU, it is limited in only containing a few items that measure pre-trauma and peri-trauma factors as well as post-trauma adjustment. Although a longer assessment may have provided a more detailed assessment of parental vulnerability and post-trauma adjustment difficulties, it is likely to be unfeasible to screen all parents on PICU with a comprehensive assessment in the acute post-trauma phase.

Finally, both the meta-analysis and empirical study used caregiver report. Parents who were in a higher state of acute stress following their child's PICU admission or trauma may have over-reported their child's trauma symptoms, or their own pre-trauma life stressors or mental health difficulties. It is important to consider the caregiver's emotional state when completing the questionnaire or interview, as this may have biased the results.

Clinical Implications

The findings from the meta-analysis and empirical paper have important clinical implications. Firstly, the meta-analysis highlights that a significant minority of children aged 0-6years old meet diagnostic criteria for PTSD after direct exposure to a traumatic event. This is an important finding for clinicians working with young children and their families, as this meta-analysis indicated that PTSD prevalence rates in this young population are similar to, if not higher, than the PTSD rates found in children and adolescents following exposure to trauma. Furthermore, the meta-analysis showed that younger children respond to different types of trauma exposure, such as repeated trauma and interpersonal trauma, in a similar way to older children

and adolescents. The meta-analysis also demonstrates the importance of using age-appropriate diagnostic tools when measuring the psychological impact of direct exposure to trauma in younger children. The empirical paper highlights the value of using screening tools with parents in the acute phase of their child's admission to PICU. Using such screening measures and age-appropriate diagnostic tools will enable clinicians to identify vulnerable individuals following a traumatic experience. Through early identification, targeted support could be offered in the acute phase in the hope of preventing longer-term distress. Due to the relationship between child and parent psychological responses and behaviours following a traumatic event, early identification and targeted support is likely to benefit not only the individual but the wider family system.

The meta-analysis and empirical paper investigated factors contributing to an individual's likelihood of developing psychological difficulties following exposure to a traumatic event. By highlighting the importance of pre-trauma factors, parental appraisals and acute emotional responses, clinicians may be able to screen and support individuals who may be more likely to struggle with post-trauma adjustment. The empirical paper highlighted that these psychological factors were more predictive than medical measures. This suggests that directing psychological support to families of the most severely unwell children, is likely to be an ineffective method for providing support to those most in need. The meta-analysis indicated that certain trauma characteristics, such as repeated or interpersonal trauma, may increase the likelihood of the development of PTSD in young children. This knowledge may enable clinicians to recognise and screen vulnerable individuals following certain types of trauma, to help support their long-term psychological well-being.

Future Research

The meta-analysis highlighted the need for more studies to investigate the impact of trauma exposure on young children using age-appropriate diagnostic criteria. It would be beneficial to repeat the meta-analysis when there are more papers using age-appropriate criteria. This will enable a fuller assessment of the impact of age-appropriate diagnostic criteria on pooled estimates of prevalence in this population and will enable further investigations into possible trauma moderator variables. All studies included in the meta-analysis relied on parent-report. It is likely that parental report is confounded by their own emotions following direct or indirect trauma. Therefore, future research, which does not solely rely on caregiver reports, may produce a more accurate picture of preschool PTSD prevalence. Furthermore, assessing prevalence of PTSD, using standardised interviews, in non-OECD countries would identify any similarities or differences in prevalence rates across OECD and non-OECD countries.

The empirical paper looked at the implementation of a screening tool to identify vulnerable parents on PICU. Future studies could look at producing reliable screening tools, and evaluate the feasibility of implementing such tools on PICU. For some patients, their admission to PICU is very short. Therefore, brief screening tools that assess pre- and peri-trauma factors may be beneficial in identifying vulnerable parents following their child's PICU admission. Following the implementation of a screening tool, future research could focus on designing and implementing preventative support systems for parents and the wider family system to offer support with post-trauma adjustment and to reduce the likelihood of longer-term psychological distress. Additionally, the empirical paper identified a high proportion of parents who were deemed to be "at risk" of developing depression following their

child's admission. Future research focusing on understanding the mechanisms between parental trauma and depression will further enable clinicians to identify and support vulnerable individuals.

Reflections

For my empirical paper, I had originally planned to present the full longitudinal study investigating parent responses to their child's PICU admission at three time points, rather than focusing on a single time point. Although screening parents in the acute phase and understanding the risk and protective factors for parents is important and informative, I had planned to take this further by investigating how these factors influence psychological trajectories post-discharge. However, due to the time-frame for producing the thesis portfolio and difficulties maintaining retention rates over the longitudinal time points, the empirical paper focused solely on the acute phase. I look forward to analysing and writing-up the longitudinal data in due course.

My placement work alongside the major trauma service over the last six months, has helped me contextualise the findings of both papers. In addition, this clinical experience has yielded new insights and possibilities for further directions of research. One area of interest is to understand the psychological reactions of parents, not only in the acute PICU admission stage and post-discharge, but also in response to a "step-down in care"; when children are moved to less intensive-care wards in the hospital. By ensuring that parental emotional responses are assessed at different stages of the treatment pathway, different clinical and non-clinical factors may be identified that may be predictive of longer-term psychological distress.

Overall conclusions

The aim of this thesis portfolio was to understand the psychological response to trauma in preschool aged children and parents of severely unwell children. The findings indicate that a significant minority of preschool children meet diagnostic criteria for PTSD following direct exposure to trauma. Furthermore, over half of parents, whose children are admitted to PICU, are vulnerable to developing PTSD and/or depression as a result of their child's admission. Factors that moderate and predict increased vulnerability to psychological distress in preschool children and parents of severely unwell children are presented and discussed. These factors can provide important clinical insights for targeted support. The importance of using age-appropriate diagnostic criteria, and the implementation of brief psychological screens in the acute post-trauma phase, are both demonstrated in the data presented in the thesis portfolio. Implementing these screening measures and utilising accurate diagnostic criteria would enable clinicians to identify and deliver psychological support to the most vulnerable individuals, which is likely to positively impact the wider family system. This research area would benefit from future studies utilising age-appropriate diagnostic tools, to ensure an accurate picture of prevalence is obtained. Furthermore, feasibility studies surrounding the design and implementation of psychological screening tools and early-psychological support systems would be beneficial.

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Appendices

Appendix A: Author guidelines for meta-analysis: Journal of Abnormal Child Psychology

Appendix B: Quality checklist for meta-analysis

Appendix C: Individual study outcome of risk of bias assessment

Appendix D: Reference list of excluded articles

Appendix E: Author guidelines for empirical paper: Journal of Paediatric Nursing

Appendix F: Parent Information Sheet (final version)

Appendix G: Parent Consent Form (final version)

Appendix H: Demographic questionnaire (final version)

Appendix I: Letter of HRA approval

Appendix J: Letter of REC approval

Appendix K: Minor amendment approval: Change of primary investigator (to Francesca Woolgar)

Appendix L: Letter of access for research

Appendix A :

Author Guidelines for Journal of Abnormal Child Psychology

Editorial procedure

Double-blind peer review

This journal follows a double-blind reviewing procedure. Authors are therefore requested to submit:

- A blinded manuscript without any author names and affiliations in the text or on the title page. Self-identifying citations and references in the article text should be avoided.
- A separate title page, containing title, all author names, affiliations, and the contact information of the corresponding author. Any acknowledgements, disclosures, or funding information should also be included on this page.

Manuscript Submission

Manuscript Submission

Submission of a manuscript implies: that the work described has not been published before; that it is not under consideration for publication anywhere else; that its publication has been approved by all co-authors, if any, as well as by the responsible authorities – tacitly or explicitly – at the institute where the work has been carried out. The publisher will not be held legally responsible should there be any claims for compensation.

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Please follow the hyperlink "Submit online" on the right and upload all of your manuscript files following the instructions given on the screen.

Please ensure you provide all relevant editable source files. Failing to submit these source files might cause unnecessary delays in the review and production process.

Cover Letter

Per APA guidelines, all submissions must include a cover letter that provides information about:

• Any previous presentation of the data.

• The existence of any closely related manuscripts that have been submitted for simultaneous consideration to the same or to another journal.

Of particular note, the cover letter must describe any previous publications or manuscripts being submitted for simultaneous consideration in which the main variables of interest overlap with the variables being examined in the current JACP submission. If the publication is using a publically available data set, authors must provide a link to a list of other publications using the data set and list previous publications using the same variables. Finally, the cover letter needs to include a statement describing how the current results add significantly to previous publications with the same sample to warrant publication as a separate paper.

Title Page

Please use this **template title page** for providing the following information.

The title page should include:

- The name(s) of the author(s)
- A concise and informative title
- The affiliation(s) of the author(s), i.e. institution, (department), city, (state), country
- A clear indication and an active e-mail address of the corresponding author
- If available, the 16-digit ORCID of the author(s)

If address information is provided with the affiliation(s) it will also be published. For authors that are (temporarily) unaffiliated we will only capture their city and country of residence, not their e-mail address unless specifically requested.

Abstract

Please provide an abstract of 150 to 250 words. The abstract should not contain any undefined abbreviations or unspecified references.

For life science journals only (when applicable)

Trial registration number and date of registration

Trial registration number, date of registration followed by "retrospectively registered"

Keywords

Please provide 4 to 6 keywords which can be used for indexing purposes.

Declarations

All manuscripts must contain the following sections under the heading 'Declarations'.

If any of the sections are not relevant to your manuscript, please include the heading and write 'Not applicable' for that section.

To be used for non-life science journals

Funding (information that explains whether and by whom the research was supported)

Conflicts of interest/Competing interests (include appropriate disclosures)

Availability of data and material (data transparency)

Code availability (software application or custom code)

Authors' contributions (optional: please review the submission guidelines from the journal whether statements are mandatory)

To be used for life science journals + articles with biological applications

Funding (information that explains whether and by whom the research was supported)

Conflicts of interest/Competing interests (include appropriate disclosures)

Ethics approval (include appropriate approvals or waivers)

Consent to participate (include appropriate statements)

Consent for publication (include appropriate statements)

Availability of data and material (data transparency)

Code availability (software application or custom code)

Authors' contributions (optional: please review the submission guidelines from the journal whether statements are mandatory)

Please see the relevant sections in the submission guidelines for further information as well as various examples of wording. Please revise/customize the sample statements according to your own needs.

Text

Text Formatting

Manuscripts should be submitted in Word.

- Use a normal, plain font (e.g., 10-point Times Roman) for text.
- Use italics for emphasis.

- Use the automatic page numbering function to number the pages.
- Do not use field functions.
- Use tab stops or other commands for indents, not the space bar.
- Use the table function, not spreadsheets, to make tables.
- Use the equation editor or MathType for equations.
- Save your file in docx format (Word 2007 or higher) or doc format (older Word versions).

Manuscripts with mathematical content can also be submitted in LaTeX.

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Please use no more than three levels of displayed headings.

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Abbreviations should be defined at first mention and used consistently thereafter.

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Appendix B:

Quality Checklist for Prevalence Meta-Analysis

Checklist to assess each study's quality.

Score 0, 1 or 2 for each question on each study.

Assessed by: _____

Population

Were participants and setting well described?

(2)Information regarding the characteristics (age, gender, ethnicity) of the sample and trauma variables (type, severity, duration) are well described with the setting well reported (health setting, country, geography)

(1)Some information regarding participants characteristics and trauma variables are reported, with limited information on the setting

(0)Sample characteristics, trauma variables and setting information are not reported in any detail

Was participation rate of those eligible at least 50%?

(2)More than 50% of those eligible to participate took part

(1)Less than 50% of those eligible to participate took part

(0)The number of eligible potential participants was not reported

Were reasons for non-response described?

(2)Reasons for non-response were described with the number of those participants not responding reported

(1)Reasons were described for non-responders but no numbers provided OR Numbers of non-responders are reported but with no reasons

(0)Non-response rates were not reported in the study

Was the sample representative – were there differences between those participants taking part and those not?

(2)There were no significant differences in demographics or trauma variables between those participating and those not

(1)Reported significant differences between those participating and those not

(0)Differences between participants and those not taking part were not reported

Were participants recruited in an appropriate way?

(2)Consecutive or random sampling was used to recruit potential participants in person by the research team

(1)Consecutive or random sampling was used to recruit potential participants via letter or phone call

(0)Recruitment procedures were not reported in the study

Were inclusion and exclusion criteria explicit and appropriate?

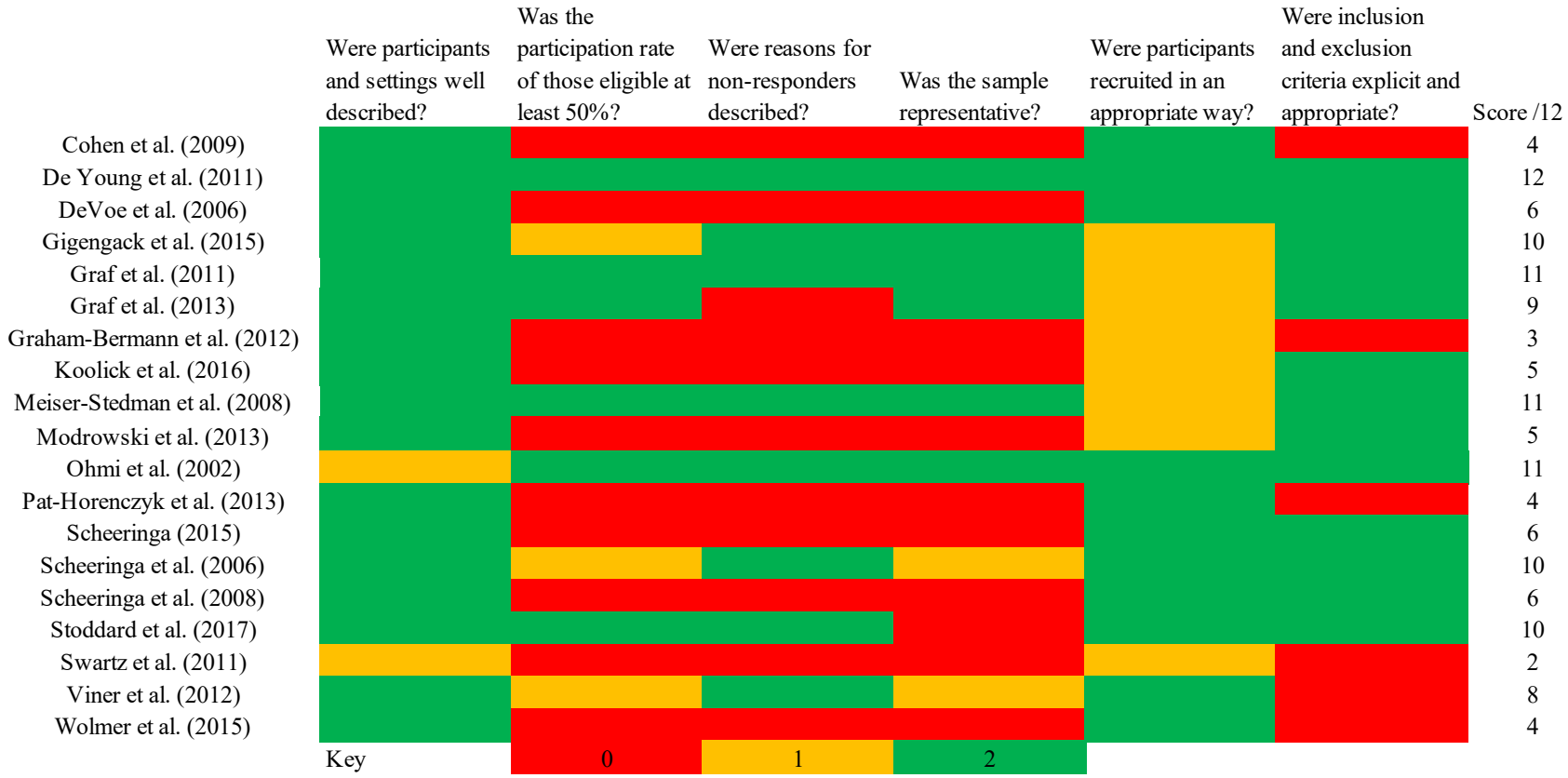
(2)Inclusion and exclusion criteria were reported in detail

(0)Inclusion and exclusion criteria were not reported

Appendix C

Individual study outcome of risk of bias assessment

Table 1: Risk of bias assessment outcomes by criteria



Appendix D

Reference list of excluded articles

Articles in which full texts were examined and then excluded from the meta-analysis (k=117)

Subheadings detailing the reason for exclusion are provided

Does not meet age criteria (*k*=30)

Almqvist, K., & Broberg, A. G. (1999). Mental health and social adjustment in young refugee children y 3½ years after their arrival in Sweden. *Journal of the American Academy of Child & Adolescent Psychiatry*, *38*(6), 723-730. https://doi.org/10.1097/00004583-199906000-00020

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Ellis, A., Stores, G., & Mayou, R. (1998). Psychological consequences of road traffic accidents in children. *European child & adolescent psychiatry*, *7*(2), 61-68. https://doi.org/10.1007/s007870050048

Endo, T., Shioiri, T., & Someya, T. (2009). Post-traumatic symptoms among the children and adolescents 2 years after the 2004 Niigata–Chuetsu earthquake in Japan. *Psychiatry and clinical neurosciences*, *63*(2), 253-253. https://doi.org/10.1111/j.1440-1819.2008.01914.x

Famularo, R., Kinscherff, R., & Fenton, T. (1992). Psychiatric diagnoses of maltreated children: preliminary findings. *Journal of the American Academy of Child & Adolescent Psychiatry*, *31*(5), 863-867. https://doi.org/10.1097/00004583-199209000-00013

Field, T., Seligman, S., Scafidi, F., & Schanberg, S. (1996). Alleviating posttraumatic stress in children following Hurricane Andrew. *Journal of applied developmental psychology*, *17*(1), 37-50. https://doi.org/10.1016/s0193-3973(96)90004-0

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Garfin, D. R., Silver, R. C., Gil-Rivas, V., Guzmán, J., Murphy, J. M., Cova, F., ... & Guzmán, M. P. (2014). Children's reactions to the 2010 Chilean earthquake: The role of trauma exposure, family context, and school-based mental health programming. *Psychological Trauma: Theory, Research, Practice, and Policy*, *6*(5), 563. https://doi.org/10.1037/a0036584

Grasso, D., Boonsiri, J., Lipschitz, D., Guyer, A., Houshyar, S., Douglas-Palumberi, H., ... & Kaufman, J. (2009). Posttraumatic stress disorder: The missed diagnosis. *Child Welfare*, *88*(4), 157.

Green, B.L., Korol. M., Grace, M.C., Vary, M.G., Leonard, A.C., Gleser, G.C., & Smitson-Cohen, S. (1991). Children and disaster: Age, gender, and parental effects on PTSD symptoms. *Journal of the American Academy of Child & Adolescent Psychiatry*, *30*(6), 945-951. https://doi.org/10.1097/00004583-199111000-00012

Husain, S. A., Allwood, M. A., & Bell, D. J. (2008). The relationship between PTSD symptoms and attention problems in children exposed to the Bosnian war. *Journal of Emotional and Behavioral Disorders*, *16*(1), 52-62. https://doi.org/10.1177/1063426607310847

Kessler, R. C., Duncan, G. J., Gennetian, L. A., Katz, L. F., Kling, J. R., Sampson, N. A., ... & Ludwig, J. (2014). Associations of housing mobility interventions for children in high-poverty neighborhoods with subsequent mental disorders during adolescence. *Jama*, *311*(9), 937-947. https://doi.org/10.1001/jama.2014.607

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Nader, K., Pynoos, R., Fairbanks, L., & Frederick, C. (1990). Children's PTSD reactions one year after a sniper attack at their school. *The American journal of psychiatry*. https://doi.org/10.1176/ajp.147.11.1526

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Santiago, C. D., Raviv, T., Ros, A. M., Brewer, S. K., Distel, L. M., Torres, S. A., ... & Langley, A. K. (2018). Implementing the Bounce Back trauma intervention in urban elementary schools: A real-world replication trial. *School Psychology Quarterly*, *33*(1), 1-9. https://doi.org/10.1037/spq0000229

Schilpzand, E. J., Sciberras, E., Alisic, E., Efron, D., Hazell, P., Jongeling, B., ... & Nicholson, J. M. (2018). Trauma exposure in children with and without ADHD: prevalence and functional impairment in a community-based study of 6–8-year-old Australian children. *European child & adolescent psychiatry*, *27*(6), 811-819. https://doi.org/10.1007/s00787-017-1067-y

Shears, D., Nadel, S., Gledhill, J., Gordon, F., & Garralda, M. E. (2007). Psychiatric adjustment in the year after meningococcal disease in childhood. Journal of the American Academy of Child & Adolescent Psychiatry, 46(1), 76-82. https://doi.org/10.1097/01.chi.0000242234.83140.56

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Wu, F., Meng, W. Y., Hao, C. Z., Zhu, L. L., Chen, D. Q., Lin, L. Y., & Wen, H. (2016). Analysis of posttraumatic stress disorder in children with road traffic injury in Wenzhou, China. *Traffic injury prevention*, *17*(2), 159-163. https://doi.org/10.1080/15389588.2015.1050719

Does not meet study design criteria (*k*=4)

Abd-Elshafy, S. K., Khalaf, G. S., Abo-Kerisha, M. Z., Ahmed, N. T., El-Aziz, M. A. A., & Mohamed, M. A. (2015). Not all sounds have negative effects on children undergoing cardiac surgery. *Journal of cardiothoracic and vascular anesthesia*, *29*(5), 1277-1284. https://doi.org/10.1053/j.jvca.2015.01.005

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Scheeringa, M. S. (2008). Developmental considerations for diagnosing PTSD and acute stress disorder in preschool and school-age children. *The American Journal of Psychiatry, 165 (10),* 1237-1239. https://doi.org/10.1176/appi.ajp.2008.08070974

Indirect trauma (k=2)

Abbo, C., Kinyanda, E., Kizza, R. B., Levin, J., Ndyanabangi, S., & Stein, D. J. (2013). Prevalence, comorbidity and predictors of anxiety disorders in children and adolescents in rural north-eastern Uganda. *Child and adolescent psychiatry and mental health*, *7*(1), 21. https://doi.org/10.1186/1753-2000-7-21

Saylor, C. F., Cowart, B. L., Lipovsky, J. A., Jackson, C., & Finch Jr, A. J. (2003). Media exposure to September 11: Elementary school students' experiences and posttraumatic symptoms. *American Behavioral Scientist*, *46*(12), 1622-1642. https://doi.org/10.1177/0002764203254619

Not measuring pre-school PTSD (*k*=12)

Al-Jawadi, A. A., & Abdul-Rhman, S. (2007). Prevalence of childhood and early adolescence mental disorders among children attending primary health care centers in Mosul, Iraq: a cross-sectional study. *BMC public health*, *7*(1), 274. https://doi.org/10.1186/1471-2458-7-274

Briere, J., Johnson, K., Bissada, A., Damon, L., Crouch, J., Gil, E., ... & Ernst, V. (2001). The Trauma Symptom Checklist for Young Children (TSCYC): Reliability and association with abuse exposure in a multi-site study. *Child abuse & neglect*, *25*(8), 1001-1014. https://doi.org/10.1016/s0145-2134(01)00253-8

De Young, A. C., Hendrikz, J., Kenardy, J. A., Cobham, V. E., & Kimble, R. M. (2014). Prospective evaluation of parent distress following pediatric burns and identification of risk factors for young child and parent posttraumatic stress disorder. *Journal of Child and Adolescent Psychopharmacology*, *24*(1), 9-17. https://doi.org/10.1089/cap.2013.0066

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McCrae, J. S. (2009). Emotional and behavioral problems reported in child welfare over 3 years. *Journal of Emotional and Behavioral Disorders*, *17*(1), 17-28. https://doi.org/10.1177/1063426608319141

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Sprang, G., Staton-Tindall, M., & Clark, J. (2008). Trauma exposure and the drug endangered child. *Journal of Traumatic Stress: Official Publication of The International Society for Traumatic Stress Studies*, *21*(3), 333-339. https://doi.org/10.1002/jts.20330

Stoddard, F. J., Saxe, G., Ronfeldt, H., Drake, J. E., Burns, J., Edgren, C., & Sheridan, R. (2006). Acute stress symptoms in young children with burns. *Journal of the American Academy of Child & Adolescent Psychiatry*, *45*(1), 87-93. https://doi.org/10.1097/01.chi.0000184934.71917.3a

Stoddard Jr, F. J., Sorrentino, E. A., Ceranoglu, T. A., Saxe, G., Murphy, J. M., Drake, J. E., ... & Sheridan, R. L. (2009). Preliminary evidence for the effects of morphine on posttraumatic stress disorder symptoms in one-to four-year-olds with burns. *Journal of Burn Care & Research*, *30*(5), 836-843. https://doi.org/10.1097/bcr.0b013e3181b48102

Clinical or PTSD sample (*k*=17)

Als, L. C., Nadel, S., Cooper, M., Vickers, B., & Garralda, M. E. (2015). A supported psychoeducational intervention to improve family mental health following discharge from paediatric intensive care: feasibility and pilot

randomised controlled trial. *BMJ open*, *5*(12), e009581. https://doi.org/10.1136/bmjopen-2015-009581

De Bellis, M. D., Hooper, S. R., Spratt, E. G., & Woolley, D. P. (2009). Neuropsychological findings in childhood neglect and their relationships to pediatric PTSD. *Journal of the International Neuropsychological Society*, *15*(6), 868-878. https://doi.org/10.1017/s1355617709990464

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Dehon, C., & Scheeringa, M. S. (2006). Screening for preschool posttraumatic stress disorder with the Child Behavior Checklist. *Journal of Pediatric Psychology*, *31*(4), 431-435. https://doi.org/10.1093/jpepsy/jsj006

Hulette, A. C., Freyd, J. J., Pears, K. C., Kim, H. K., Fisher, P. A., & Becker-Blease, K. A. (2008). Dissociation and posttraumatic symptoms in maltreated preschool children. *Journal of child & adolescent trauma*, *1*(2), 93-108. https://doi.org/10.1080/19361520802083980

Ippen, C. G., Harris, W. W., Van Horn, P., & Lieberman, A. F. (2011). Traumatic and stressful events in early childhood: Can treatment help those at highest risk?. *Child abuse & neglect*, *35*(7), 504-513. https://doi.org/10.1016/j.chiabu.2011.03.009

Karacetin, G., Demir, T., Baghaki, S., Cetinkale, O., & Elagoz Yuksel, M. (2014). Psychiatric disorders and their association with burn-related factors in children with burn injury. *Turkish Journal of Trauma and Emergency Surgery*, *20*(3), 176-180. https://doi.org/10.5505/tjtes.2014.49033

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Seng, J. S., Graham-Bermann, S. A., Clark, M. K., McCarthy, A. M., & Ronis, D. L. (2005). Posttraumatic stress disorder and physical comorbidity among female children and adolescents: results from service-use data. *Pediatrics*, *116*(6), e767-e776. https://doi.org/10.1542/peds.2005-0608

Smith, T. J., Lindsey, R. A., Bohora, S., & Silovsky, J. F. (2019). Predictors of intrusive sexual behaviors in preschool-aged children. *The Journal of Sex Research*, *56*(2), 229-238. https://doi.org/10.1080/00224499.2018.1447639

Studies duplicating same data sample (*k*=4)

Cohen, E., Chazan, S., Lerner, M., & Maimon, E. (2010). Posttraumatic play in young children exposed to terrorism: An empirical study. *Infant Mental Health Journal: Official Publication of the World Association for Infant Mental Health*, *31*(2), 159-181. https://doi.org/10.1002/imhj.20250

De Young, A. C., Kenardy, J. A., Cobham, V. E., & Kimble, R. (2012). Prevalence, comorbidity and course of trauma reactions in young burn-injured children. *Journal of Child Psychology and Psychiatry*, *53*(1), 56-63. https://doi.org/10.1111/j.1469-7610.2011.02431.x

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Data does not describe prevalence (*k*=4)

DeVoe, E. R., Klein, T. P., Bannon Jr, W., & Miranda-Julian, C. (2011). Young children in the aftermath of the World Trade Center attacks. *Psychological Trauma: Theory, Research, Practice, and Policy*, *3*(1), 1-11. https://doi.org/10.1037/a0020567

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Questionnaire based (*k*=39)

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Funding: This work was supported by the National Institutes of Health [grant numbers xxxx, yyyy]; the Bill & Melinda Gates Foundation, Seattle, WA [grant number zzzz]; and the United States Institutes of Peace [grant number aaaa].

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If no funding has been provided for the research, please include the following sentence:

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Units

Follow internationally accepted rules and conventions: use the international system of units (SI). If other units are mentioned, please give their equivalent in SI.

Math formulae

Please submit math equations as editable text and not as images. Present simple formulae in line with normal text where possible and use the solidus (/) instead of a horizontal line for small fractional terms, e.g., X/Y. In principle, variables are to be presented in italics. Powers of e are often more conveniently denoted by exp. Number consecutively any equations that have to be displayed separately from the text (if referred to explicitly in the text).

Table Footnotes

Indicate each footnote in a table with a superscript lowercase letter.

Figure captions

Ensure that each illustration has a caption. Supply captions separately, not attached to the figure. A caption should comprise a brief title (not on the figure itself) and a description of the illustration. Keep text in the illustrations themselves to a minimum but explain all symbols and abbreviations used.

Tables

Please submit tables as editable text and not as images. Tables can be placed either next to the relevant text in the article, or on separate page(s) at the end. Number tables consecutively in accordance with their appearance in the text and place any table notes below the table body. Be sparing in the use of tables and ensure that the data presented in them do not duplicate results described elsewhere in the article. Please avoid using vertical rules and shading in table cells.

References

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

Reference links

Increased discoverability of research and high quality peer review are ensured by online links to the sources cited. In order to allow us to create links to abstracting and indexing services, such as Scopus, CrossRef and PubMed, please ensure that data provided in the references are correct. Please note that incorrect surnames, journal/book titles, publication year and pagination may prevent link creation. When copying references, please be careful as they may already contain errors. Use of the DOI is highly encouraged. A DOI is guaranteed never to change, so you can use it as a permanent link to any electronic article. An example of a citation using DOI for an article not yet in an issue is: VanDecar J.C., Russo R.M., James D.E., Ambeh W.B., Franke M. (2003). Aseismic continuation of the Lesser Antilles slab beneath northeastern Venezuela. Journal of Geophysical Research, https://doi.org/10.1029/2001JB000884. Please note the format of such citations should be in the same style as all other references in the paper.

Web references

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

Data references

This journal encourages you to cite underlying or relevant datasets in your manuscript by citing them in your text and including a data reference in your Reference List. Data references should include the following elements: author name(s), dataset title, data repository, version (where available), year, and global persistent identifier. Add [dataset] immediately before the reference so we can properly identify it as a data reference. The [dataset] identifier will not appear in your published article.

References in a special issue

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

Reference management software

Most Elsevier journals have their reference template available in many of the most popular reference management software products. These include all products that support Citation Style Language styles, such as Mendeley. Using citation plug-ins from these products, authors only need to select the appropriate journal template when preparing their article, after which citations and bibliographies will be automatically formatted in the journal's style. If no template is yet available for this journal, please follow the format of the sample references and citations as shown in this Guide. If you use reference management software, please ensure that you remove all field codes before submitting the electronic manuscript. More information on how to remove field codes from different reference management software.

Users of Mendeley Desktop can easily install the reference style for this journal by clicking the following link: http://open.mendeley.com/use-citation-style/journal-of-pediatric-nursing When preparing your manuscript, you will then be able to select this style using the Mendeley plugins for Microsoft Word or LibreOffice.

Reference style

Text: Citations in the text should follow the referencing style used by the American Psychological Association. You are referred to the Publication Manual of the American Psychological Association, Sixth Edition, ISBN 978-1-4338-0561-5,

copies of which may be ordered online or APA Order Dept., P.O.B. 2710, Hyattsville, MD 20784, USA or APA, 3 Henrietta Street, London, WC3E 8LU, UK.
List: references should be arranged first alphabetically and then further sorted chronologically if necessary. More than one reference from the same author(s) in the same year must be identified by the letters 'a', 'b', 'c', etc., placed after the year of publication.
Examples:
Reference to a journal publication: Van der Geer, J., Hanraads, J. A. J., & Lupton, R. A. (2010). The art of writing a scientific article. *Journal of Scientific Communications, 163*, 51–59. https://doi.org/10.1016/j.Sc.2010.00372.
Reference to a journal publication with an article number: Van der Geer, J., Hanraads, J. A. J., & Lupton, R. A. (2018). The art of writing a scientific article. *Heliyon, 19*, e00205. https://doi.org/10.1016/j.heliyon.2018.e00205.
Reference to a book: Strunk, W., Jr., & White, E. B. (2000). *The elements of style. (*4th ed.). New York: Longman, (Chapter 4).
Reference to a chapter in an edited book: Mettam, G. R., & Adams, L. B. (2009). How to prepare an electronic version of your article. In B. S. Jones, & R. Z. Smith (Eds.), *Introduction to the electronic age* (pp. 281–304). New York: E-Publishing Inc.
Reference to a website: Cancer Research UK. Cancer statistics reports for the UK. (2003). http://www.cancerresearchuk.org/ aboutcancer/statistics/cancerstatsreport/ Accessed 13 March 2003.
Reference to a dataset: [dataset] Oguro, M., Imahiro, S., Saito, S., Nakashizuka, T. (2015). *Mortality data for Japanese oak wilt disease and surrounding forest compositions*. Mendeley Data, v1. https://doi.org/10.17632/ xwj98nb39r.1.
Reference to a conference paper or poster presentation: Engle, E.K., Cash, T.F., & Jarry, J.L. (2009, November). The Body Image Behaviours Inventory-3: Development and validation of the Body Image Compulsive Actions and Body Image Avoidance Scales. Poster session presentation at the meeting of the Association for Behavioural and Cognitive Therapies, New York, NY.
Journal abbreviations source
Journal names should be abbreviated according to the List of Title Word Abbreviations.

Supplementary material

Supplementary material such as applications, images and sound clips, can be published with your article to enhance it. Submitted supplementary items are published exactly as they are received (Excel or PowerPoint files will appear as such online). Please submit your material together with the article and supply a concise, descriptive caption for each supplementary file. If you wish to make changes to supplementary material during any stage of the process, please make sure to provide an updated file. Do not annotate any corrections on a previous version. Please switch off the 'Track Changes' option in Microsoft Office files as these will appear in the published version.

Research data

This journal encourages and enables you to share data that supports your research publication where appropriate, and enables you to interlink the data with your published articles. Research data refers to the results of observations or experimentation that validate research findings. To facilitate reproducibility and data reuse, this journal also encourages you to share your software, code, models, algorithms, protocols, methods and other useful materials related to the project.

Below are a number of ways in which you can associate data with your article or make a statement about the availability of your data when submitting your manuscript. If you are sharing data in one of these ways, you are encouraged to cite the data in your manuscript and reference list. Please refer to the "References" section for more information about data citation. For more information on depositing, sharing and using research data and other relevant research materials, visit the research data page.

Data linking

If you have made your research data available in a data repository, you can link your article directly to the dataset. Elsevier collaborates with a number of repositories to link articles on ScienceDirect with relevant repositories, giving readers access to underlying data that gives them a better understanding of the research described. There are different ways to link your datasets to your article. When available, you can directly link your dataset to your article by providing the relevant information in the submission system. For more information, visit the database linking page. For supported data repositories a repository banner will automatically appear next to your published article on ScienceDirect. In addition, you can link to relevant data or entities through identifiers within the text of your manuscript, using the following format: Database: xxxx (e.g., TAIR: AT1G01020; CCDC: 734053; PDB: 1XFN).

Mendeley Data

This journal supports Mendeley Data, enabling you to deposit any research data (including raw and processed data, video, code, software, algorithms, protocols, and methods) associated with your manuscript in a free-to-use, open access repository. During the submission process, after uploading your manuscript, you will have the opportunity to upload your relevant datasets directly to Mendeley Data. The datasets will be listed and directly accessible to readers next to your published article online. For more information, visit the Mendeley Data for journals page.

Data statement

To foster transparency, we encourage you to state the availability of your data in your submission. This may be a requirement of your funding body or institution. If your data is unavailable to access or unsuitable to post, you will have the opportunity to indicate why during the submission process, for example by stating that the research data is confidential. The statement will appear with your published article on ScienceDirect. For more information, visit the Data Statement page.

Appendix F:

Parent Information Sheet (final version)

Participant Information Sheet

Psychological impact of Paediatric Intensive Care on parents and children; how does this impact on Quality of Life?

You are being invited to take part in a research study about the psychological impact on children and their primary caregivers after being admitted to a Paediatric Intensive Care Unit (PICU). The study aims to consider how the psychological impact of admission affects family's quality of life after they have been discharged. Before you decide if you would like to take part we would like you to understand why the research is being done and what it would involve for you. Please take time to read the following information and take time to decide if you would like to take part.

What is the purpose of the study?
Being admitted to Paediatric Intensive Care can be a difficult time for children, and also for their parents and caregivers. As well as having a potentially physical impact, experiencing a traumatic event can also have a significant psychological impact. Research shows that people can experience higher levels of anxiety, lower mood and can sometimes develop Post Traumatic Stress Disorder (PTSD). PTSD is an anxiety disorder which is caused by very stressful, frightening or distressing events. It causes symptoms such as reliving the traumatic event through flashbacks or nightmares which often impacts on people's ability to sleep, and can therefore have a general impact on their day-to-day life.

We are investigating if there are ways in which we can identify factors that predict the development of PTSD in children and their caregivers, what role the potential PTSD plays in the parent and child's quality of life following discharge and what the relationship is between parent and child quality of life and PTSD. The findings of this study will help us to understand more about the psychological impact of admission to Paediatric Intensive Care Units and to therefore identify better ways of helping and supporting children and their families.

The study is being completed as part of the researcher's Doctorate in Clinical Psychology at the University of East Anglia (UEA) where the chief investigator is studying as a trainee clinical psychologist.

Why have I been invited to take part?
As you are a parent or caregiver of a child who has been admitted to Paediatric Intensive Care at Addenbrooke's Hospital.

What does the study involve?

The study involves 3 different parts;

- **Part 1:** After you have given consent to take part, a member of the research team will ask you to complete 2 brief questionnaires. One asks about your general information (your ethnicity, age, history of mental health) and the second ask about your experiences that occurred before, during and after your child's admission to PICU. These take around 5 minutes to complete.
- **Part 2**: A member of the research team will contact you, using your preferred method of contact (email, telephone, or post) around 1- 4 months after your child has been discharged from hospital. You will be asked to complete a further 7 questionnaires. The first 5 ask for information about your psychological well-being following your child's discharge from PICU. They ask about your current mood, anxiety levels, and quality of life. The following 2 questionnaires ask for information about your child's psychological well-being following their discharge from PICU. They ask about your child's mood, anxiety levels, their quality of life and their experience of being in a PICU. Both are completed by you. These questionnaires take around 25 minutes to complete in total.

- **Part 3:** This part is around 12 months after contact at stage 2. Your details will be passed to another member of the research team to contact you again in around 12 months. Contact will again be made on your preferred method of contact. At the 12 months follow up, you will be asked to complete the same questionnaires you completed during part 2.

Additionally, with your permission, relevant information regarding your child's health will be looked at in your child's medical notes. This will include the length of their admission, the type of traumatic event they experienced, and the severity of their physical illness.

What do I need to do to take part?
If you decide to take part in the study you will need to sign the enclosed consent form and give this back to a member of the research team. You will then be asked to complete the first set of questionnaires shortly after. The following questionnaires in part 2 and 3 will be completed either by telephone, email or post, depending on your preference. If you chose to complete the questionnaires by post then you will be asked to post them back to us using the pre-paid envelope provided. The questionnaires will be handled anonymously and the information will be analysed and then written about in an article without your name being mentioned.

Do I have to take part?
No. *It is up to you to decide whether or not to take part*. Your participation is optional. If you decide not to take part, that decision will not affect the care you or your child receive in any way.

If you do choose to take part, you are also free to withdraw your participation in the research at any point during the data collection period which is likely to be until January 2019. Any information you have provided up until this point will be confidentially destroyed, and your data will not be included in the analysis.

How will the information I provide be kept confidential?
All information you provide will be securely stored in a locked cabinet, in a locked office and kept anonymous and confidential. All information collected about you or your child as part of this study will be secured at Addenbrooke's Hospital, and transferred to the University of East Anglia. The reason for this transfer is so we can identify participants for the follow up part of the study, and we can provide feedback on the study results if this requested. Your own GP will not be notified of your participation in the study.

Any data collected in the study may be looked at by individuals from Addenbrooke's Hospital, the University of East Anglia, or from regulatory authorities or NHS Trusts for the purposes of auditing only. Otherwise, only those individuals involved in the research process will have access to the data.

What will happen to the results of the research study?
The results of this research will be written up as a thesis as part of the researcher's Doctorate in Clinical Psychology. All information will be reported as anonymous data. The results will also be written into articles and potentially published in academic journals so that others can learn from the findings. We will be pleased to send you a summary of the results in due course if you indicate this on the consent form.
The information collected in relation to the study will be kept for 10 years at the University of East Anglia in line with the UEA Research Data Management Policy.

Are there any benefits of taking part?
This study will improve our understanding of the long-term psychological impact of admission to paediatric intensive care on both children and their families. The study may identify specific groups of children or caregivers who need extra support and so may benefit the development of support services following discharge in the future.

Are there any disadvantages or risks of taking part?
It is possible that some of the questions may be difficult to answer. If this is the case you can stop completing the questionnaire at any point. If you experience any distress or concerns after completing the questionnaires you can access support and advice through contacting:

- Your GP
- Samaritans is a charity which provides confidential emotional support for people who are experiencing feelings of distress, despair or suicidal thoughts.
    - The support helpline is: 116 123 (UK)
    - Alternatively you can access further information via their website: www.samaritans.org/

If your responses on the questionnaires indicate high levels of stress or anxiety or significant low mood, we will contact you to let you know this and would advise you to consider seeking support from your GP.

Complaints
If you have any concerns about this study please feel free to contact Professor Niall Broomfield, Norwich Medical School, Room 0.22, University of East Anglia, Norwich NR4 7TJ. Telephone: 01603 591217 or the Patient Advice and Liaison

Service (PALS) at Addenbrooke's hospital, PALS and Complaints Department, Box 53, Cambridge University Hospitals NHS Foundation Trust, Hills Road, Cambridge, CB2 0QQ. Telephone: 01223 216756. Email: pals@adenbrookes.nhs.uk

Who is organising and funding the research?
This research is organised by Francesca Woolgar, Dr Richard Meiser-Stedman, and Dr Nazima Pathan and is funded by the University of East Anglia Doctoral Programme in Clinical Psychology.

Who has reviewed this study?
Before any research goes ahead in the NHS it needs to be checked by an independent group of people called a Research Ethics Committee. Their job is to ensure that any proposed research is ethical and to protect the safety, rights, well-being and dignity of participants. This study has been reviewed and approved by Cambridge South Research Ethics Committee.

Further information If you have any questions, or would like more information, please contact the chief investigator or primary supervisor:

Chief investigator: Francesca Woolgar
Trainee Clinical Psychologist
Department of Psychological Sciences, Norwich Medical School, University of East Anglia, Norwich, NR4 7TJ

Email: f.woolgar@uea.ac.uk
Phone: 07923407428

Primary supervisor: Dr Richard Meiser-Stedman
Reader in Clinical Psychology
Department of Clinical Psychology, Elizabeth Fry Building, University of East Anglia, Norwich, NR4 7TJ

Email: r.meiser-stedman@uea.ac.uk
Phone: 01603 593602

Thank you for taking time to read this information sheet, please keep this information for your records.

Appendix G:

Parent Consent Form (final version)

Participant Identification number:_____

CONSENT FORM

Title of Project: Post Traumatic Stress Disorder and Quality of Life in children and their caregivers following admission to Paediatric Intensive Care

Chief Investigator: Francesca Woolgar, Trainee Clinical Psychologist

Please initial **all** boxes:

1. I confirm that I have read and understood the information sheet dated **01.10.2018 (version 6) for** the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my, or my child's, medical care or legal rights being affected. ☐

3. I understand that relevant sections of my child's medical notes will be collected as part of the research. I give permission for these individuals to access my child records. ☐

4. I understand that relevant sections of my child's medical notes and data collected during the study may be looked at by individuals from Addenbrooke's Hospital, the University of East Anglia, or from regulatory authorities or NHS Trusts where it is relevant to my participation in this study. I give permission for these individuals to access my child's records. ☐

5. I agree to take part in the above study. ☐

6. I wish to be informed of the study findings in the future.
   Yes / No (please circle)

Name of Participant:	Date:	Signature:
_____	_____	_____
Chief Investigator:	Received on:	Signature:
_____	_____	_____

Appendix H:

Demographic questionnaire (final version)

Participant Information

For the purposes of this study, it is helpful if you are able to provide us with particular information about you, your child and your family. If you do not wish to answer a question you may leave it blank. If you have more than one child, please answer questions that refer to your child who was admitted to Paediatric Intensive Care.

Please tick the relevant boxes to indicate your responses.

1. What is your age?

☐ 18 – 24 ☐ 25 – 29 ☐ 30 – 34 ☐ 35 – 39 ☐ 40 – 44 ☐ 45 – 49 ☐ 50 +

2. How would you describe your ethnicity?

White

☐ White British (English/Welsh/Scottish/Northern Irish/British) ☐ Irish ☐ European
☐ Traveller ☐ Gypsy ☐ Other *(please specify)* _____

Black

☐ Black British ☐ African ☐ Caribbean
☐ Other *(please specify)* _____

Asian

☐ Asian British ☐ Indian ☐ Pakistani ☐ Bangladeshi
☐ Chinese ☐ Japanese ☐ Other *(please specify)*
_____

Other ethnic group

☐ Arab ☐ Any other ethnic group *(please specify)* _____

3. What is your marital status?

☐ Married ☐ Single ☐ Cohabiting ☐ Civil Partnership
☐ Divorced/Separated ☐ In a relationship but not living together

4. Prior to your child's admission to Paediatric Intensive Care have **they** ever suffered from any of the following?

☐ depression ☐ anxiety ☐ Post-traumatic Stress Disorder
☐ none of the above ☐ other *Please specify*_____

5. Prior to your child's admission to Paediatric Intensive Care have **you** suffered from any of the following?

☐ depression ☐ anxiety ☐ Post-traumatic Stress Disorder
☐ none of the above ☐ other *Please specify*_____

6. At the moment, do you have any other stressors in your life? *If yes, please specify…*
   (Please circle) *Yes/No*

☐ financial ☐ health ☐ work ☐ family
☐ none of the above ☐ other *Please specify*_____

7. Do you own your own home? *(please circle)* Yes/No

8. If you are currently working, what is your profession?
   _____

9. How many children do you have? _____

10. What is your level of education? _____

11. Prior to this admission, have you ever been in an intensive care setting before?
    (Please circle) *Yes/No*
12. Prior to this admission, has your child ever been in an intensive care setting before
    (Please circle) *Yes/No*
13. For the purpose of this study, I agree to be contacted by the main researcher (Francesca Woolgar) via:

☐ e-mail ☐ Post ☐ telephone ☐ any, I don't mind
☐ other *Please specify*_____

Please provide details of your preferred method of contact.

E-mail address: .....
.....
Postal address: .....
.....
.....
Telephone: .....

Caregiver's name: .....

Signature: .....

Appendix I:

Letter of HRA Approval

NHS
Health Research Authority

Miss Lucy Wilcoxon
Trainee Clinical Psychologist
University of East Anglia/Cambridgeshire and Peterborough
Foundation Trust
Norwich Medical school
University of East Anglia
Norwich
NR4 7TJ

Email: hra.approval@nhs.net

28 March 2018

Dear Miss Wilcoxon,

Letter of HRA Approval

Study title:	**Psychological Outcomes following Paediatric Intensive Care Admission for Children and their Families; Predictors, Interactions and Impact on Quality of Life**
IRAS project ID:	**230001**
REC reference:	**18/EE/0035**
Sponsor	**University of East Anglia**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from the HRA website.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document *"After Ethical Review – guidance for sponsors and investigators",* issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

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

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found through IRAS.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

IRAS project ID	230001

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details on the HRA website.

Your IRAS project ID is **230001**. Please quote this on all correspondence.

Yours sincerely

Maeve Ip Groot Bluemink, on behalf of
Thomas Fairman
HRA Assessor

Email: hra.approval@nhs.net

Copy to: *Ms Tracy Moulton, University of East Anglia, (Sponsor Contact)*
Ms Tracy Assari, Addenbrooke's University Hospital, (Lead NHS R&D Contact)

IRAS project ID	230001

Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [UEA Insurance & Indemnity Letter]		20 December 2017
HRA Schedule of Events	1.0	12 January 2018
HRA Statement of Activities	1.0	12 January 2018
IRAS Application Form [IRAS_Form_20122017]		20 December 2017
Letters of invitation to participant [Covering Letter for Participants]	v3	15 December 2017
Letters of invitation to participant [Covering Letter for Parents of children aged <7 years.]	v3	15 December 2017
Letters of invitation to participant [Covering Letter Parents of children for parents of children 7+years]	1	20 February 2018
Non-validated questionnaire [Demographics Questionnaire]	2	15 December 2017
Other [Condolences Letter to Participants]	3	15 December 2017
Other [Debrief Letter - after T2]	3	15 December 2017
Other [Distress Follow up Letter]	3	15 December 2017
Other [Follow-up Reminder Letter]	3	15 December 2017
Other [Feedback from Service Users on the Design/Materials]		15 December 2017
Other [Study Proposal Feedback from UEA Internal Review]		11 July 2017
Other [Letter in Response to REC Review]		06 March 2018
Participant consent form [Consent Form]	4	22 February 2018
Participant consent form [Child Assent Form - age 7-15 years]	1.0	22 February 2018
Participant consent form [Child Consent Form - age 16 years]	1.0	22 February 2018
Participant information sheet (PIS) [Participant Information Sheet]	5	20 February 2018
Participant information sheet (PIS) [Child Information Sheet - age 16+ years]	v1.0	22 February 2018
Participant information sheet (PIS) [Child Information Sheet - age 7-15years]	v1.0	22 February 2018
Research protocol or project proposal [Research Protocol]	3	15 December 2017
Summary CV for Chief Investigator (CI) [Chief Investigator CV]	1	15 December 2017
Summary CV for student [Francesca Woolgar - CV]		22 March 2018
Summary CV for supervisor (student research) [Primary Supervisor CV - R. Meiser-Stedman]		15 December 2017
Summary CV for supervisor (student research) [Secondary Supervisor - K. Mastroyannopoulou CV]		15 December 2017
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Study Flow Chart]	4	25 February 2018
Validated questionnaire [CATS - Child and Adolescent Trauma Screen Caregiver Response - age 3-6years]		27 February 2018
Validated questionnaire [CATS - Child and Adolescent Trauma Screen - Caregiver response - 7-17years]		27 February 2018
Validated questionnaire [Adjusted PAS]	1	15 December 2017
Validated questionnaire [GAD-7]	1	15 December 2017
Validated questionnaire [PHQ-9]	1	15 December 2017
Validated questionnaire [PTRQ]	1	15 December 2017

Validated questionnaire [QOLS]	1	15 December 2017
Validated questionnaire [R-IES]	1	15 December 2017
Validated questionnaire [PIM2]	1	15 December 2017
Validated questionnaire [PedsQL]	1	15 December 2017

IRAS project ID	230001

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the *participating NHS organisations, capacity and capability* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Name: Ms Tracy Moulton
Email: t.moulton@uea.ac.uk

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	No comment
3.1	Protocol assessment	Yes	No comment
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	The sponsor has submitted the HRA Statement of Activities and intends for this to form the agreement between the sponsor and study sites. The sponsor is not requesting, and does not require any additional contracts with study sites.
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional

Section	HRA Assessment Criteria	Compliant with Standards	Comments
			indemnity provided by their medical defence organisation covers the activities expected of them for this research study
4.3	Financial arrangements assessed	Yes	No application for external funding has been made. No study funding will be provided to sites, as detailed at Schedule 1 of the Statement of Activities.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comment
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	REC Favourable opinion was issued by the Cambridge South Research Ethics Committee on 14 March 2018.
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.
All participating NHS organisations will undertake the same study activities. There is therefore only one study site 'type' involved in the research. The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website. If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.
NHS organisations in England that are participating in the study **will be expected to formally confirm their capacity and capability** to host this research. • Following issue of this letter, participating NHS organisations in England may now confirm to the sponsor their capacity and capability to host this research, when ready to do so. How capacity and capacity will be confirmed is detailed in the Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria) section of this appendix. • The Assessing, Arranging, and Confirming document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).
A Principal Investigator should be appointed at study sites. GCP training is not a generic training expectation, in line with the HRA statement on training expectations.

IRAS project ID	230001

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken
As a non-commercial study undertaken by local staff, it is unlikely that letters of access or honorary research contracts will be applicable. Where arrangements are not already in place, researchers undertaking any of the research activities listed in A18 of the IRAS form would be expected to obtain a Letter of Access. This would be on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). These should confirm DBS checks and occupational health clearance.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.
The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.

Appendix J:

Letter of REC Approval

-

NHS
Health Research Authority
East of England - Cambridge South Research Ethics Committee
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

14 March 2018

Miss Lucy Wilcoxon
Trainee Clinical Psychologist
University of East Anglia/Cambridgeshire and Peterborough Foundation Trust
Norwich Medical school
University of East Anglia
Norwich
NR4 7TJ

Dear Miss Wilcoxon

Study title:	**Psychological Outcomes following Paediatric Intensive Care Admission for Children and their Families; Predictors, Interactions and Impact on Quality of Life**
REC reference:	**18/EE/0035**
IRAS project ID:	**230001**

Thank you for your letter of 06/03/2018, responding to the Committee's request for further information on the above research and submitting revised documentation.

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

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Confirmation of ethical opinion

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

Conditions of the favourable opinion

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

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

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

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

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

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

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

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

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

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

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will

be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

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

Ethical review of research sites

NHS sites

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

Non-NHS sites

Approved documents

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

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [UEA Insurance & Indemnity Letter]		20 December 2017
IRAS Application Form [IRAS_Form_20122017]		20 December 2017
Letters of invitation to participant [Covering Letter for Participants]	v3	15 December 2017
Letters of invitation to participant [Covering Letter for Parents of children aged <7 years.]	v3	15 December 2017
Letters of invitation to participant [Covering Letter Parents of children for parents of children 7+years]	1	20 February 2018
Non-validated questionnaire [Demographics Questionnaire]	2	15 December 2017
Other [Condolences Letter to Participants]	3	15 December 2017
Other [Debrief Letter - after T2]	3	15 December 2017
Other [Distress Follow up Letter]	3	15 December 2017
Other [Follow-up Reminder Letter]	3	15 December 2017
Other [Feedback from Service Users on the Design/Materials]		15 December 2017
Other [Study Proposal Feedback from UEA Internal Review]		11 July 2017
Other [Letter in Response to REC Review]		06 March 2018
Participant consent form [Consent Form]	4	22 February 2018
Participant consent form [Child Assent Form - age 7-15 years]	1.0	22 February 2018
Participant consent form [Child Consent Form - age 16 years]	1.0	22 February 2018
Participant information sheet (PIS) [Participant Information Sheet]	5	22 February 2018
Participant information sheet (PIS) [Child Information Sheet - age 16+ years]	v1.0	22 February 2018
Participant information sheet (PIS) [Child Information Sheet - age 7-15years]	v1.0	22 February 2018
Research protocol or project proposal [Research Protocol]	3	15 December 2017
Summary CV for Chief Investigator (CI) [Chief Investigator CV]	1	15 December 2017
Summary CV for student [Francesca Woolgar - CV]		22 March 2018

Summary CV for supervisor (student research) [Primary Supervisor CV - R. Meiser-Stedman]		15 December 2017
Summary CV for supervisor (student research) [Secondary Supervisor - K. Mastroyannopoulou CV]		15 December 2017
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Study Flow Chart]	4	25 February 2018
Validated questionnaire [Adjusted PAS]	1	15 December 2017
Validated questionnaire [GAD-7]	1	15 December 2017
Validated questionnaire [PHQ-9]	1	15 December 2017
Validated questionnaire [PTRQ]	1	15 December 2017
Validated questionnaire [QOLS]	1	15 December 2017
Validated questionnaire [R-IES]	1	15 December 2017
Validated questionnaire [PIM2]	1	15 December 2017
Validated questionnaire [PEDS]	1	15 December 2017
Validated questionnaire [PedsQL]	1	15 December 2017
Validated questionnaire [CATS - Child and Adolescent Trauma Screen Caregiver Response - age 3-6years]		27 February 2018
Validated questionnaire [CATS - Child and Adolescent Trauma Screen - Caregiver response - 7-17years]		27 February 2018

Statement of compliance

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

After ethical review

Reporting requirements

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

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

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

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form

available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

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

18/EE/0035	**Please quote this number on all correspondence**

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

Yours sincerely

pp. Gwelling

Dr Leslie Gelling
Chair

Email:nrescommittee.eastofengland-cambridgesouth@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Tracy Moulton*
Tracy Assari, Addenbrooke's University Hospital

Appendix K:

Minor amendment approval: Change of primary investigator (to F Woolgar)

Dear Francesca Woolgar

IRAS project ID:	230001
REC reference:	18/EE/0035
Short Study title:	PIPIC - version 0.001
Date complete amendment submission received:	17 October 2018
Amendment No./ Sponsor Ref:	Amendment number 1
Amendment Date:	02 October 2018
Amendment Type:	**Substantial**
Outcome of HRA Assessment	**This email also constitutes HRA and HCRW Approval for the amendment, and you should not expect anything further.**

I am pleased to confirm that this amendment has been reviewed by the Research Ethics Committee and has received a Favourable Opinion. Please find attached a copy of the Favourable Opinion letter.

HRA and HCRW Approval Status

As detailed above, **this email also constitutes HRA and HCRW Approval for the amendment**. No separate notice of HRA and HCRW Approval will be issued. You should implement this amendment at NHS organisations in England and/or Wales, in line with the conditions outlined in your categorisation email.

- If this study has HRA and HCRW Approval, this amendment may be implemented at participating NHS organisations in England and/or Wales once the conditions detailed in the categorisation section above have been met
- If this study is a pre-HRA Approval study, this amendment may be implemented at participating NHS organisations in England and/or Wales that have NHS Permission, once the conditions detailed in the categorisation section above have been met. For participating NHS organisations in England and/or Wales that do not have NHS Permission, these sites should be covered by HRA and HCRW Approval before the amendment is implemented at them, please see below;
- If this study is awaiting HRA and HCRW Approval, I have passed your amendment to my colleague and you should receive separate notification that the study has received HRA and HCRW Approval, incorporating approval for this amendment.

User Feedback

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

views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/.

If you require further information, please contact hra.amendments@nhs.net

18/EE/0035/AM01 Please quote this number on all correspondence

Kind regards

Katharine Loven

Health Research Authority

The Old Chapel | Royal Standard Place | | NG1 6FS

E. nrescommittee.eastofengland-cambridgesouth@nhs.net

W. www.hra.nhs.uk

Sign up to receive our newsletter HRA Latest.

Appendix L:

Letter of access for research

Cambridge University Hospitals NHS
NHS Foundation Trust

Francesca Woolgar
Trainee Clinical Psychologist
Dept of Clinical Psychology
Norwich Medical School
UEA
Norwich
NR4 7TJ

Research and Development Department
Box 277
Addenbrookes Hospital
Hills Road
Cambridge
CB2 0QQ

R&D Manager: Stephen Kelleher
stephen.kelleher@addenbrookes.nhs.uk
Interim HR Manager: Sarah Young
01223 274660
sarah.young@addenbrookes.nhs.uk
HR Advisor: Charlotte Wain
01223 348496
charlotte.wain@addenbrookes.nhs.uk

7th December 2018

Dear Francesca

Letter of access for research – A094772 – PIPIC

As an existing NHS employee you do not require an additional honorary research contract with this NHS organisation. We are satisfied that the research activities that you will undertake in this NHS organisation are commensurate with the activities you undertake for your employer. Your employer is fully responsible for ensuring such checks as are necessary have been carried out. Your employer has confirmed in writing to this NHS organisation that the necessary pre-engagement check are in place in accordance with the role you plan to carry out in this organisation. This letter confirms your right of access to conduct research through Cambridge University Hospitals NHS Foundation Trust for the purpose and on the terms and conditions set out below. This right of access commences on **7th December 2018** and ends on **30th September 2020** unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this NHS organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving permission to conduct the project and you have provided the Trust's R&D department with written evidence that you have completed GCP training from an EU institution before you start your research.

The information supplied about your role in research at Cambridge University Hospitals NHS Foundation Trust has been reviewed and you do not require an honorary research contract with this NHS organisation. We are satisfied that such pre-engagement checks as we consider necessary have been carried out.

You are considered to be a legal visitor to Cambridge University Hospitals NHS Foundation Trust premises. You are not entitled to any form of payment or access to other benefits provided by this NHS organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through Cambridge University Hospitals NHS Foundation Trust, you will remain accountable to your place of work, **UEA** but you are required to follow the reasonable instructions of **Dr Nazima Pathan and Dr Anna Maw** in this NHS organisation or those given on his behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with Cambridge University Hospitals NHS Foundation Trust policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with Cambridge University Hospitals NHS Foundation Trust in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on Cambridge University Hospitals NHS Foundation Trust premises. You must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other contract holder and you must act appropriately, responsibly and professionally at all times.

If you have a health condition or disability which may affect your research role and which might require reasonable special adjustments to your role, if you have not already done so, you must notify your employer and the Trust's R&D HR Office prior to commencing your research role at the Trust.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. Personal identifiable data must be carried securely at all times and mobile devices must be encrypted. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (https://www.gov.uk/government/publications/confidentiality-nhs-code-of-practice) and the Data Protection Act 2018 and General Data Protection Regulations 2016. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution. Data controllers could also be fined for a breach of the Data Protection Act 2018 and General Data Protection Regulations 2016. You must familiarise yourself with the Trust's Information Governance Code of Conduct.

You must keep confidential any information regarding the design, conduct or management or results of any research unless authorised in writing by the Trust to disclose it. You must acknowledge the Trust's contribution in any publication arising out of this Agreement.

Subject to any agreement with your employer to the contrary (e.g. as part of a multi-centre study), any Intellectual Property (IP) resulting from research carried out under this Agreement will be the property of the Trust and you will do all things necessary or desirable to give effect to the assignment of this IP.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that this NHS organisation accepts no responsibility for damage to or loss of personal property.

We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. You must not undertake regulated activity if you are barred from such work. If you are barred from working with adults or children this letter of access is immediately terminated. Your employer will immediately withdraw you from undertaking this or any other regulated activity and you MUST stop undertaking any regulated activity immediately.

Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

Cambridge University Hospitals NHS Foundation Trust will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 2018 and General Data Protection Regulations 2016. Any breach of the Data Protection Act 2018 and General Data Protection Regulations 2016 may result in legal action against you and/or your substantive employer.

INDUCTION AND MANDATORY TRAINING
You are responsible for familiarising yourself with the Trust's policies and mandatory training courses such as Moving and Handling, Health and Safety, Fire Training etc and be aware of the responsibility to maintain a safe environment for patients, staff and visitors

Your host Manager will ensure that you receive a comprehensive Departmental Induction. She/he will also provide you with details of Corporate Induction, research specific induction and annual Mandatory Refresher Training.

If your letter of access is for more than 3 months, you must attend Corporate Induction. Where your letter of access is for more that 12 months, you must attend annual Mandatory Refresher Training.

If your current role or involvement in research changes, or any of the information provided in your Research Passport changes, you must inform your employer through their normal procedures. You must also inform your nominated manager in this NHS organisation.

Yours sincerely

Stephen Kelleher
R&D Manager, Cambridge University Hospitals NHS Foundation Trust

cc: Dr Nazima Pathan, Consultant P.I.C.U,
nazima.pathan@addenbrookes.nhs.uk

Professor Richard Meiser-Stedman, Prof of Clinical Psychology, UEA,
r.meiser-stedman@uea.ac.uk