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Psychological perspectives in the Acute Inpatient Setting

Two chapters including:

Trauma-informed Practice in the Acute Inpatient Setting:

An Interpretative Phenomenological Analysis involving Mental Health Nurses

&

**A Systematic Review of Group Based Psychological Interventions in the
Acute Inpatient Setting**

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Doctorate in Clinical Psychology

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Lay Summary

This research portfolio explored psychological perspectives in the acute inpatient setting. The acute setting is characterised by a high turnover of admissions, significant acuity of illness, and high levels of risk. The portfolio includes two chapters. The first chapter is a qualitative study looking at mental health nurses' experiences of trauma-informed practice in the acute setting. The second chapter is a systematic review that synthesises the evidence on group-based psychological interventions in the acute setting.

Chapter one: Trauma-informed Practice in the Acute Inpatient Setting

The Scottish government has committed to the development of trauma-informed public services as part of the National Trauma Transformation Programme. A trauma-informed organisation is one that adopts significant adaptations including those that promote trust and safety, and reduce the risk of retraumatisation.

Provisional findings suggest that trauma-informed practice can support positive outcomes in the acute inpatient setting. At the same time, several potential challenges face the development of trauma-informed acute services. These include navigating the use of restrictive practices and the associated risk of retraumatisation, and the degree of workplace trauma. Therefore, the development of trauma-informed acute services is both important, and potentially complex.

Eight mental-health nurses took part in a qualitative interview-based study to explore trauma-informed practice in the acute inpatient setting, using Interpretative Phenomenological Analysis (IPA). Themes were identified from interview data including '*A Welcome Shift: We are Trying*', and '*The Person Behind the Nurse*'. The study explored some of the inherent conflicts experienced between trauma-informed principles including safety and choice, in a setting that is dominated by a risk-management narrative. The impact of significant workplace trauma, moral distress, and the strength of internal team support were considered within the analysis. Recommendations were made on the development of context-specific training, staff wellbeing, and improved access to psychological perspectives.

Chapter 2: Group-Based Psychological Interventions in the Acute Inpatient Setting

Psychological interventions are a recommended treatment option in the acute inpatient setting, but remain widely unavailable. An improved understanding of the evidence supporting psychological interventions in the acute setting will help inform their wider provision. Group-based interventions may be an effective and efficient way to provide psychological therapy in the acute setting. However, to date, little is known about their effectiveness or feasibility in the acute context.

A systematic review of the literature was undertaken to establish what is known about the effectiveness and feasibility of group-based interventions in the acute inpatient setting. The review identified 18 published studies involving a range of quantitative designs, of which five were randomised controlled studies. Findings from the present review suggest slight but inconclusive evidence that supports the use of group-based psychological interventions in the acute inpatient setting. Findings were significantly limited by the overall low-quality of included studies. Group-based interventions were consistently seen as a feasible way to deliver psychological interventions. Additional controlled research is required to establish the causal link between group-based psychological interventions and improved outcomes, and to better understand the circumstances under which improved outcomes might be achieved.

Thesis Portfolio Abstract

Background: The acute inpatient setting provides short-term intensive care during times of mental health crisis. Psychological perspectives including trauma-informed practice, and the delivery of psychological interventions, are recommended in the acute setting. The effective integration of psychological perspectives may support improvements to the quality of acute inpatient care.

Aims: The current portfolio contributes to the growing evidence supporting the integration of psychological perspectives into the acute setting. The thesis is divided into two parts. The first section is a qualitative study of mental health nurses' experiences as they integrated trauma-informed practice into the acute setting. The second section is a systematic review of group-based psychological interventions in the acute setting.

Method: The qualitative study involved eight semi-structured interviews and used Interpretative Phenomenological Analysis (IPA). The systematic review involved a systematic search of databases Embase, MEDLINE, CINAHL Plus, and PsycINFO. Findings were reviewed using narrative synthesis, and comparison of effects for studies involving intent-to-treat analyses.

Results: The qualitative study identified two themes, '*A Welcome Shift: We are Trying*', and '*The Person Behind the Nurse*'. A tension was identified between trauma-informed principles, and the dominant risk-management paradigm. Accounts of work-based trauma, moral distress, and stigma were considered. The systematic review identified 18 quantitative studies of variable and predominantly low-quality designs. Consideration was given to adaptations, effectiveness, and feasibility. Moderate quality designs and controlled studies involving intent-to-treat analyses were prioritised.

Conclusion: The qualitative study suggested that trauma-informed practice has been well-received by nurses in the acute setting, but highlighted practical and conceptual challenges facing its uptake. Recommendations were made regarding the delivery of context-specific training, staff wellbeing, and improved access to psychological perspectives. Findings from the review pointed to tentative but inconclusive evidence in support of the use of group-based approaches in the acute inpatient setting. Groups were largely seen as a feasible way from which to deliver psychological interventions. Further controlled research involving treatment-as-usual controls and ITT analysis is needed to establish these preliminary findings, and better understand the circumstances under which improved outcomes might be achieved.

Keywords: *Acute, inpatient, trauma, trauma-informed practice, mental health nurse, psychological intervention, psychological therapy*

Chapter 1: Empirical Project

Trauma-informed Practice in the Acute Inpatient Setting: An Interpretative Phenomenological Analysis involving Mental Health Nurses

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Abstract

Background: Acute inpatient settings provide assessment and treatment during times of mental health crisis. Provisional findings suggest trauma-informed practice can support positive outcomes in the acute setting. At the same time, acute settings face potential challenges as they transition towards a trauma-informed approach, including the use of restrictive practices and the associated risks of retraumatisation.

Aim: To conduct an in-depth exploration and analysis of nurses' experiences of trauma-informed practice in the acute inpatient setting. Findings from the present study will help inform the development of trauma-informed acute inpatient services.

Method: Eight mental health nurses were recruited. Semi-structured interviews were conducted to explore participants' experiences of trauma-informed practice in the acute setting. An Interpretative Phenomenological Analysis (IPA) approach was used. Themes were identified for each participant, and across the data set.

Findings: Two Group Experiential Themes (GET's) were identified across the data. Firstly: *'A Welcome Shift: We are Trying'*. This first theme was divided into two subthemes; *'Seeing things differently, doing things differently'* and *'Navigating our reality: it's not easy'*. The second theme was titled: *'The Person Behind the Nurse'*. This theme was divided into three subthemes; *'Dilemmas we face'*, *'Nobody should have to see what we saw'*, and *'Support... we support each other'*.

Conclusion: Trauma-informed practice appeared to be conceptually well-received by nurses in the acute setting, but there was at times a disconnect with reality. Participants explored the tension between patient safety as the *'number one priority'*, and the genuine incorporation of trauma-informed principles of choice, empowerment, collaboration and trust. Nurses were exposed to significant workplace trauma, within a culture of *'just get on with it'*. The stigma in accessing external support was contrasted with a sense of strong internal support between colleagues. Recommendations were made regarding context-specific training, staff wellbeing, and improved access to psychological perspectives.

Keywords: *Acute, inpatient, trauma, trauma-informed practice, mental health nurse*

Introduction

Overview

Public services in Scotland are transitioning towards a trauma-informed model of practice. The present study aimed to develop an in-depth understanding of mental health nurses' experiences of trauma-informed practice in the acute inpatient setting.

The prevalence and impact of trauma

The Adverse Childhood Experiences study established the cumulative relationship between exposure to trauma and adversity during childhood, and a range of health-related risk factors (Felitti et al., 1998). Further research has consistently demonstrated the relationship between trauma and negative health and social outcomes. This includes the increased risk of physical and mental health conditions, addiction problems, lower educational attainment, and involvement with the criminal justice system (Beilharz et al., 2019; Cantürk et al., 2021; Cooke, 2016; Farris et al., 2014; Garami et al., 2018; Hardcastle et al., 2018; Hughes et al., 2017; Khoury et al., 2010; Liming & Grube, 2018; Maschi et al., 2013; Mauritz et al., 2013; Nelson et al., 2020; Offer et al., 2022; Public Health Wales, 2015). Circumstances involving multiple or sustained traumas are more likely to result in significant impairment (Brewin et al., 2017).

Traumatic experiences are not uncommon. An NSPCC survey found that 20% of children reported experiencing severe maltreatment (Radford et al., 2011). 85% of people facing severe and multiple disadvantages as adults have reported traumatic childhood experiences (Bramley et al., 2015). A high proportion of people with mental health difficulties have experienced trauma and adversity in their lives (Butler et al., 2011; Dillon et al., 2014; Edwards et al., 2003; Mauritz et al., 2013; Mueser et al., 1998; Porter et al., 2020; Posner et al., 2008; Dyakova et al., 2016; Read et al., 2001, 2005; Varese et al., 2012).

Trauma-informed practice

Trauma informed practice has been defined by the Scottish Government as “a model that is grounded in and directed by a complete understanding of how trauma exposure affects service user's neurological, biological, psychological and social development” (The Scottish Government et al., 2021, pg. 8). The concept of trauma-informed practice developed in response to growing awareness of the prevalence and adverse impact of trauma (Bloom, 2006; Harris & Fallot, 2001). Trauma-informed services aim to reduce barriers and support better outcomes for those impacted by trauma (Harris & Fallot, 2001; Sweeney et al., 2018). This is achieved through structuring and delivering services in a way that promotes the principles of choice, collaboration, empowerment, safety and trustworthiness, and helps prevent retraumatisation (Harris & Fallot, 2001; The Scottish Government et al., 2021).

As well as for those accessing services, staff may be affected by trauma (Esaki & Larkin, 2013; Menschner & Maul, 2016; Sweeney et al., 2018). Furthermore, staff may be exposed to workplace trauma that can impact on their wellbeing and the quality of care they provide (Berry et al., 2023; NCTSN, 2011; The Scottish Government et al., 2021). Supporting staff wellbeing is seen as an essential component of a trauma-informed system (NCTSN, 2011; NHS Education for Scotland, 2017; Sweeney et al., 2018).

A growing number of studies suggest trauma-informed approaches can result in better outcomes (Lovell et al., 2022; NHS Education for Scotland, 2017; Substance Abuse and Mental Health Services Administration, 2014; The Scottish Government et al., 2021). For example, trauma-informed interventions have been found to support reductions in restraint, and improved knowledge and attitudes among staff (Kelly et al., 2023; Purtle, 2018). In recognition of the prevalence and impact of trauma, and the growing evidence supporting trauma-informed practice, the Scottish Government set out its

aspiration for the development of trauma-informed public services (NTTP, 2024; NHS Education for Scotland, 2017).

As services adopt a trauma-informed approach, aspirational principles need to be translated into routine practice (Isobel, 2015; Isobel & Delgado, 2018; Muskett, 2014). Understanding the factors that potentially hinder trauma-informed practice can help inform their mitigation. Criticisms of trauma-informed practice have included the lack of conceptual clarity, as something potentially 'fuzzy', 'complex', 'something that service providers already do', or simply a call for practitioners to 'be nicer' (Sweeney & Taggart, 2018 p.383). Other potential challenges include the issue of general fatigue that surrounds the constant upheaval of UK public services, the established diagnostic understanding of distress, and the general lack of supervisory support (Sweeney et al., 2016). As well as these more generally relevant factors, settings may encounter more service-specific challenges as they transition toward trauma-informed practice. The present study is interested in the delivery of trauma-informed practice in the acute inpatient setting.

Trauma-informed practice in acute inpatient settings

The acute inpatient setting provides short-term intensive care during times of mental health crisis (Kings Fund, 2015). Admissions are often predicated by significant concerns around safety and have a clear risk management focus (Evlat et al., 2021; Kings Fund, 2015, Slemon et al., 2017). The acute setting is characterised by a high turnover of admissions, significant acuity of illness, and high levels of risk.

Effectively integrated trauma-informed practice is important in the acute inpatient setting, with a significant proportion of those accessing services likely affected by trauma (Mauritz et al., 2013; Asarnow et al., 2020). At the same time, the transition towards trauma-informed acute services may prove complex, recognising factors such as the restrictive nature of the acute setting, the risks of retraumatisation, and the issue of workplace trauma.

In the acute setting, trauma-informed principles, such as choice and empowerment, operate within limits. Admission itself can be involuntary (Mental Health (Scotland) Act, 2003). Acute inpatient wards have developed to be inherently restrictive environments, settings dominated by laws, acts, policies and rules (Isobel, 2015). Restrictions are used to manage significant risk concerns, such as violence or self-harm. Restrictive approaches can include the use of locked doors, limited access to personal items, body searches, forced medication, physical restraint or seclusion (Butler et al., 2011; O'Dwyer, Tarzia, Fernbacher, & Hegarty, 2020; Sweeney, Filson, Kennedy, Collinson, & Gillard, 2018, SAMHSA, 2014). At the same time, restrictive approaches such as physical restraint are recognised to potentially cause harm, having been reported as emotionally and physically unsafe, disempowering, and re-traumatising (Cusack et al., 2018; Douglas et al., 2021; Cohen, 1994; Frueh et al., 2005; Paksarian et al., 2014, Hennessy et al., 2023; Robins et al., 2005; Sugiura et al., 2020). Within a trauma-informed model of practice a reduction in restrictive practice is advocated (Muskett, 2014; Sweeney et al., 2018). Nurses must navigate complex risk-based decisions on how and when to use restriction, whilst incorporating trauma-informed principles and aiming to mitigate the risk of retraumatisation (Muir-Cochrane et al., 2018; Muskett, 2014; Sweeney et al., 2018).

A further potential challenge to the integration of trauma-informed practice is exposure to workplace trauma, and the impact this may have on staff and their relationships with patients. Acute care nurses work in a highly pressured environment, involving many competing demands on their time (Cleary, 2004; Cleary et al., 2012). Nurses are at risk of exposure to challenging and potentially traumatic situations through their work. Workplace trauma may involve exposure to violent assault, witnessing incidents of self-harm, participation in restraint, or vicarious exposure (Ayres et al., 2022; Groves et al., 2024; James et al., 2012; Liu et al., 2019 Baum, 2015; Ham et al., 2022; NCTSN, 2011; Weltens et al., 2021). Workplace

trauma can have a significant impact on staff's wellbeing and mental health (Kelly et al., 2016; Baum, 2015; Berry et al., 2023; Hilton et al., 2022; Mento et al., 2020; Seto et al., 2020). In turn, exposure to workplace trauma can contribute to the development of compassion fatigue and burnout, potentially impacting the quality of patient care (Batanda, 2024; Cusack et al., 2018; Jacobowitz et al., 2015; Kelly, 2020; Stevenson et al., 2015; Wolotira, 2023).

There remains a relative lack of research looking at trauma-informed practice in the acute setting. Provisional findings suggest trauma-informed practice can support encouraging outcomes. A review involving acute services found that trauma-informed practice was associated with an improved ward culture and more positive experiences of care, but emphasised the lack of available research on which these conclusions were based (Wilson et al., 2017). More recently, a scoping review assessed trauma-informed approaches across a range of acute and residential settings (Saunders 2023). The authors concluded trauma-informed practice appeared to support positive outcomes, including a reduction in seclusion and restraint, a greater degree of empathy among staff, and an increase in trust among patients, while acknowledging the low quality of included studies (Saunders 2023). This supported similar findings from an earlier review (Muskett, 2014). A recent UK-based service evaluation reported trauma-informed interventions in the acute setting appeared to be associated with reductions in self-harm and restrictive interventions (Nikopaschos et al., 2023).

On the available qualitative literature, a small number of studies have explored trauma-informed practice from the perspective of inpatient staff, predominantly from outside the UK context (Chandler, 2008; Copperman & Knowles, 2006; Isobel, 2015; Isobel & Edwards, 2017; O'Dwyer et al., 2019). A synthesis of qualitative literature highlighted that staff could experience fear and reluctance towards change, and suggested this impacted on the adoption of trauma-informed practice (O'Dwyer et al., 2020). A different qualitative review pointed to the challenging balance acute nurses face between managing safety and organisational demands, and the uptake of trauma-informed practice (Wilson et al., 2021). Both reviews recommended further in-depth research to better understand healthcare professionals' experiences surrounding the adoption of trauma-informed practice in the acute inpatient setting (O'Dwyer et al., 2020; Wilson et al., 2021).

The current study

Trauma-informed practice is highly relevant to the acute inpatient setting, with a high proportion of people accessing acute services likely affected by trauma (Asarnow et al., 2020; Mauritz et al., 2013). However, several factors may impact on its effective adoption. Aspirational principles need to be translated into routine practice (Isobel, 2015; Isobel & Delgado, 2018; Muskett, 2014). Nurses must navigate the use of restrictive practices and the risk of retraumatisation (Muir-Cochrane et al., 2018; Sweeney et al., 2016, 2018). Nurses themselves may be exposed to trauma through their work (Ayres et al., 2022; Bloom, 2006; Jacobowitz et al., 2015). At the same time, emerging evidence suggests that trauma-informed practice can support better outcomes in acute and inpatient settings (Muskett, 2014; Saunders et al., 2023; Wilson et al., 2017). An improved understanding of trauma-informed practice in the acute inpatient setting will help inform its effective adoption.

To date, little is known about nurses' perspectives of trauma-informed practice in the acute inpatient setting. To better understand mental health nurses' perspective of trauma-informed practice in the acute inpatient setting, an in-depth qualitative study is proposed. Within the wider context of the Scottish government's National Trauma Transformation Programme (NTTP, 2024), this study aims to help inform the development of trauma-informed acute inpatient settings.

Objectives

The aim of this study is to establish an in-depth understanding of mental health nurses' experiences of trauma-informed practice in the acute inpatient setting.

Method

Design

Interpretative Phenomenological Analysis (IPA) (Smith et al., 2022) was chosen as the most appropriate qualitative design method for this study. IPA has a particular interest in the human experience (Smith et al., 2022). The approach maintains an interest in both the individual and the group, in which convergent and divergent themes are identified across the data (Smith et al., 2022). By rigorously exploring the lived experience of participants, IPA aims to carefully consider what may be otherwise 'taken for granted' elements of understanding (Giorgi, 1995, pp. 33). Accounting for these factors, IPA was determined as a suitable approach from which to develop an in-depth understanding of mental health nurses' experiences of trauma-informed practice in the acute setting.

In advance of deciding on an IPA approach, alternative qualitative methods were first considered. These included Thematic Analysis (Braun & Clarke, 2006) and Grounded Theory (Glaser & Strauss, 1999). Whilst Thematic Analysis could have been used to identify shared themes across participants, IPA's emphasis on the lived experience, on both individual and group experiences, was felt to be more appropriately matched to the research's interests. Grounded Theory, an approach that aims to develop theory from analysis of qualitative data, was also considered (Glaser & Strauss, 1999). However, the current research's exploratory aims were felt to be more appropriately met through IPA.

Once the research's initial design was established, contributions from people who had experienced admission to the acute inpatient setting were sought, to help inform the research design and focus. Three individuals provided written feedback on the preliminary interview schedule. Their feedback was carefully incorporated into the final interview, based on collaboration between the first and second author.

Ethics

Ethical approval was obtained via the Integrated Research Application System (reference 303096). The study was submitted to the School of Health in Social Science Ethics Committee at the University of Edinburgh. The University of Edinburgh acted as sponsor to the study. Please see appendices seven and eight for ethical approval documents.

Participants

Participants were registered mental health nurses employed to work on an NHS acute inpatient ward. They had a minimum of one year's experience working in the acute inpatient setting. Participants were required to have completed trauma-informed training, with a minimum being relevant e-learning modules within the National Trauma Training Programme (NES, 2021). Eight participants were recruited for the study, within the recommended six–ten range appropriate for a professional doctorate-level study (Smith et al., 2022).

Procedure

Participants were recruited using a purposive sampling approach, to obtain a specific and homogeneous sample, as recommended for an IPA study (Smith et al., 2022). Acute wards within the Local NHS board were approached, and information about the study was distributed. A small incentive was included to

encourage participation, funded by the University of Edinburgh. Where participants expressed their interest, they were provided additional information (see appendix 2). Participants who agreed to take part provided their written consent, and completed a brief demographic information form (see appendix 3 and 5). No participants had a pre-existing relationship with the researcher.

Eight in-person recorded interviews were conducted between February and July 2022, lasting between 50 minutes and one hour and 15 minutes. Interviews took place on NHS property, in private rooms on the relevant acute ward. The semi-structured interview schedule was used to guide the interviews, using open-ended questions and prompts to encourage in-depth answers (see appendix 4). On completion, participants were verbally debriefed and provided with a debrief sheet (see appendix 6).

Recorded interviews were transcribed verbatim. Each participant was asked to review their transcribed interview, before confirming their agreement to be included in the study.

Analysis

Interview data was analysed according to guidelines set out by Smith et al (2022) (see table. 1) (see appendices 10 and 11).

Table 1. IPA analysis stages, adapted from Smith et al. (2022)

Stage of analysis	
1. Reading and re-reading each interview	This stage allowed the researcher to become immersed in each participant's data.
2. Exploratory noting	The researcher completed a comprehensive and detailed set of notes that were closely linked to the original data. Attention was given to elements that seemed most important to the participant.
3. Constructing experiential statements	The researcher constructed experiential statements that aimed to reduce the volume of noting, whilst capturing the important features of participants' experiences.
4. Searching for connections	Experiential statements were printed and individually cut out. The researcher identified interconnections by clustering connected groups of statements together.
5. Naming Personal Experiential Themes (PETs)	Each group of connected statements were given a name, called a Personal Experiential Theme (PET). Some PET's included subthemes.
6. Continuing the analysis of each case	After completing a PET's table for each participant, the researcher analysed the next interview transcript in the same way, following stages one to five.
7. Developing Group Experiential Themes (GETs)	On completion of this process for each interview, the researcher compared PET to look for patterns of similarity and difference across the dataset. This allowed for the identification of Group Experiential Themes (GETs) and subthemes.

Reflexivity

In IPA, the role of the researcher is explicitly acknowledged (Smith & Osborn, 2008). Reflexivity is a process that allows the researcher to consider their role in the research process (Shaw, 2010). Of relevance to the present study, the researcher had previously worked as a mental health nurse in an acute setting.

The personal experiences of the researcher will have influenced this study in many ways. Their interest in the topic developed from their own experiences, from which they recognised a potentially complex issue that would benefit from exploration. The choice of IPA was influenced by the researcher's interest in the lived experiences of nurses, as someone who had previously been employed as a nurse in this context. In IPA, it is important to consider the researcher's role when interpreting the interpretations of others (Smith & Osborn, 2008). In this case, the researcher's own experiences working as a mental health nurse will have influenced their interpretation of the experiences of other mental health nurses.

To enhance awareness of how their role as a researcher may have influenced the research process, the researcher completed a reflexive diary, as recommended by Smith (1999). The researcher used their diary to reflexively consider the decisions they made at different stages of the research process, and how their own role and context may have influenced that process. Additionally, the researcher sought out the contributions and perspectives of others. This included seeking input from people with lived experience. Also, the researcher engaged in regular discussions about research-based decisions with a number of professionals, including their clinical supervisor, a senior research nurse employed in the relevant NHS Board, and their academic supervisor. These discussions were used to consider alternative perspectives and to support a reflective stance. Through familiarity with the wider literature, the researcher further engaged with a breadth of views on the topic of interest. Collectively, these approaches helped the researcher to maintain a curious and reflexive approach, whilst recognising the inevitable influence of their own context on this research.

Validity and quality considerations

Qualitative research is often criticised as lacking in quality and rigour (Anderson, 2010). Smith et al., (2009) recommend Yardley (2000) as an appropriate model from which to assess the quality of an IPA study. The principles proposed by Yardley (2000) are considered below in relation to the present study.

Sensitivity to context

Sensitivity to context recognises the importance of the context of the research, those being researched, and the researcher (Yardley, 2000). This principle was adhered to in several ways. To establish the broader context of the current research, a review of the relevant literature was undertaken, and again in relation to the study's findings. The active inclusion of people with lived experience helped consider the wider context in which the research was conducted. The use of a reflexive diary allowed the researcher to reflect on the contextual nature of the research, including the potential impact of power-dynamics and their own role in the research process. The use of verbatim quotes supported the analysis by providing context to the themes, allowing the reader to make their own assessment of the author's interpretations.

Impact and importance

Impact and importance refer to the impact and utility of the research (Yardley, 2000). This study explored a highly relevant topic, within the broader context of Scotland's National Trauma Transformation Programme (NTTP, 2024; The Scottish Government et al., 2021). The adoption of trauma-informed practice in the acute inpatient setting can support positive outcomes (Muskett, 2014; Saunders et al., 2023; Sweeney et al., 2016; Wilson et al., 2017). In-depth qualitative research will likely improve our understanding of trauma-informed practice in the acute setting, which will help inform its effective integration. Dissemination of findings from this study are intended, through the NES Trauma Strategy Group, and publication in a peer-reviewed journal.

Commitment, rigour, transparency and coherence

The remaining principles proposed by Yardley refer to the thoroughness of the data collection, analysis and reporting (Yardley, 2000). First considering commitment and rigour, an appropriate sample was

recruited, in line with recommendations for a doctorate-level study (Smith et al., 2022). A thorough and systematic approach was carefully adhered to, in line with IPA guidelines (Smith et al., 2022). An 'independent mini-audit' was conducted involving the review of an example transcript by an independent contributor, to confirm that the analysis appeared appropriate and representative, in line with recommendations described by Smith et al. (2022). The breadth of included verbatim quotes showed a rigorous approach and illustrated how themes were developed. On coherence and transparency, the write-up aimed to communicate a clear and convincing narrative. The inclusion of a reflexive statement and full appendices demonstrated transparency regarding both the researcher's motivations and context, and the research process more generally. To ensure transparency, an invitation to access the final study will be provided to all research contributors.

Results

Contextualising the Sample

Participants were drawn from four acute wards. Participants included two male and six female mental health nurses. Six participants held roles that involved different levels of managerial responsibility. Participants' experience of working in the acute setting varied from between one and three years, to over nine years. All participants had completed trauma-informed practice e-learning modules, and three had completed additional in-person training. Pseudonyms have been utilised throughout this report for the purpose of confidentiality.

Key findings

Data analysis produced two general experiential themes (GET's) and five subthemes (see table 2). The first theme was titled '*A Welcome Shift - We Are Trying*' and was divided into two subthemes '*Seeing things differently, doing things differently*' and '*Navigating our reality: it's not easy*'. The second theme was titled '*The Person Behind the Nurse*' and was divided into three subthemes: '*Dilemmas we face*', '*Nobody should have to see what we saw*', and '*Support... we support each other*'. Overall, there was a high endorsement of each theme and subtheme identified. This endorsement was reflective of a high degree of convergent experiences explored by participants across the sample. A number of less prevalent sub-themes were identified during the analysis process, but were felt to be appropriately explored within the wider context of a broader relevant subtheme. The number of participants contributing to each component of a wider sub-theme was set out in the results.

Table 2: *Group Experiential Themes*

Group Experiential Themes	Subthemes	Prevalence
1. A Welcome Shift - We Are Trying	- <i>Seeing things differently, doing things differently</i>	8/8
	- <i>Navigating our reality: It's not easy</i>	8/8
2. The Person Behind the Nurse	- <i>Dilemmas we face</i>	8/8
	- <i>'Nobody should have to see what we saw'</i>	6/8
	- <i>Support... we support each other</i>	6/8

Theme 1: A Welcome Shift – We are Trying

This initial theme captured the significant contrast between a real sense of enthusiasm and interest in trauma-informed practice, in the context of a reality involving complex daily challenges that all nurses found hard to overcome. The theme is explored across two subthemes: *'Seeing things differently, doing things differently'*, and *'Navigating our reality - it's not easy'*

Subtheme 1: *'Seeing things differently, doing things differently'*

This subtheme illustrated the significance of the shift in understanding experienced by participants through trauma-informed practice, and the influence this had on them. Six participants spoke of seeing things really quite differently through a trauma-informed lens where *'once someone kind of opens your eyes to it'* (Jordan) there is *'a realisation that actually... there's reasons for this...'* (Rowan). There was a humanising effect, where *'you don't look at people as labels, you look at people as people'* (Morgan), becoming *'more mindful of peoples... lives.. before they got here.'* (Jamie). Participants spoke of developing a more nuanced and curious stance, becoming *'more interested'* (Frankie). *'Every time somebody says they're "badly behaved"... this per... or this person has "acted out"... it's made me ask ... "why?"'* (Alex).

All participants spoke about how they found systemic applications of trauma-informed practice helpful, bridging conceptual ideas into a tangible reality. Participants gave examples such as adaptations to care planning, bringing a *'real... person centered-ness... not... how they used to be... very generic'* (Ellis), and the debrief process *'that focus on really checking in'* (Alex). Participants use of the words *'real'* and *'really'* appeared to emphasise the degree of sincerity they saw as being involved in a trauma-informed approach, in contrast to a task that must be completed. A key application noted by all eight participants involved the real value of incorporating trauma-informed perspectives into the Prevention and Management of Violence and Aggression (PMVA), particularly in relation to restraint. Ashley considered *'when I look back to how PMVA used to be years ago, and how it is now... it's... it's much more informed'*, reducing the severity of impact on those involved *'that the therapeutic relationship then isn't... damaged'* (Jordan).

'You know, they've significantly improved... and they have... people have ad... just adapted really well to it. Um... and they can see the benefits to it... because it... they can... you can see that... having somebody in a seated position, being able to give them some medicine, and there are meds... you can continue your therapeutic... you know relationship with that person afterwards. [...] I think you can see that the trauma is less.' (Alex)

Alex alluded to a situation where before, the trauma caused by restraint was evident. Using different approaches, *'you can see that the trauma is less'*. By saying the shift in practice allowed for the preservation of the relationship (*'you can continue'*), Alex suggests this was not previously the case. Being able to *'see'* the impact of trauma-informed adaptations appeared to be an important reinforcement for Alex and their team, supporting a motivation to shift their working approach (*'can see the benefits'*).

Participants explored a shift in the emphasis placed on their interpersonal interactions and relationships. Trauma-informed practice was seen as helping *'build up relationships, it makes them be more... honest and open'* (Morgan). This sentiment was echoed by Jordan and Jamie; *'just to build those better*

relationships, 'you build better relationships with that patient'. Frankie reflected on this issue, highlighting the importance of the interpersonal ('connection'):

'I think it's more... meaningful... um... I think it's more meaningful connection between two people, rather than going in, saying there's some lorazepam... tell me how you feel in half an hour, you know like... what's... what you do see happening at times... but it's... I think it's... truly getting to those... truly getting to understand somebody, truly understanding... where they're coming from, where the pain's coming from... what's happened to them. Empathy... show them that... you care about them... it's as simple as that there, but I think the more you do that, the more... of a relationship you build, and there ... I think it does last longer... it... it really does. But... we don't do enough of it...' (Frankie)

Frankie contrasted having a more deeply connected approach, with seeing medication as the sole solution ('*there's some lorazepam*'), recognising the advantages of engaging therapeutically ('*I think it does last longer*'). They placed an emphasis on the word '*truly*', highlighting the need for sincerity to develop a meaningful connection. Frankie appeared to acknowledge the aspirational element of what they were saying, recognising that '*we don't do enough of it*'. Like Frankie, Alex considered the advantages of engaging differently:

'You realise that it's because that's what they've always experienced before from people, they've had to fight in that manner, to get what they need... and they've just learned that... people-people respond to the threats, more than they have responded to anything else. But it's... you can... you can change that, you know... you can change it, sometimes with just a sentence' (Alex).

Alex considered how deliberately choosing to interact with someone therapeutically in the face of a threatening situation could have a tangible therapeutic impact ('*you can change it, sometimes with just a sentence*'). They connected the shift in their interpersonal approach with their theoretical understanding of the impact of trauma, giving a sense that they feel empowered through this knowledge. Whilst participants predominantly emphasised the development of '*better relationships*', Frankie also explored how awareness of trauma could bring a degree of complexity and doubt to interpersonal dynamics:

'See it's hard, because you don't want to avoid the patient, you don't want to ... disengage with the patient, but you wonder to yourself... how do... how do I engage with this person, how do I ... make this person feel that... I'm not a threat or I'm not a worry, or... anything like that. So that's constantly going round and round in my head' (Frankie)

Frankie suggested their increased awareness had made them at times question how they could sensitively interact with somebody. They highlighted the significant degree of care and consideration in this situation, their desire not to risk causing this person distress ('*how do I ... make this person feel that... I'm not a threat*'). Their words suggested a lack of confidence around how to support this person in a trauma-informed way ('*going round and round in my head*'). This provided a useful illustration of the potential complexity that trauma-informed perspectives might bring.

Within this subtheme, participants appeared to welcome the concept of trauma-informed practice with interest and enthusiasm. They reflected on having a deeper level of curiosity in a person's story, and how trauma may have impacted on them. Participants valued the practical applications of trauma-informed practice, especially for elements of their role they knew to be potentially harmful, such as around the use of restraint. Trauma-informed practice was further considered in relation to a shift in

interpersonal dynamics, with participants describing greater emphasis on the need for connection, and awareness of the need to mitigate risks of potential inter-relational harm.

Subtheme 2: Navigating our reality- it's not easy

The second subtheme, *'Navigating our reality - it's not easy'* captured the sense of the dissonance experienced by participants, as they spoke of the significant challenges faced in adopting trauma-informed practice. The sheer pressure they were under, and hard-to-change factors in their work including the reliance on medication, non-therapeutic environments, and significantly contrasting perspectives within their team.

All eight participants spoke of the impact of a range of pressures they faced. Examples included the pressure on staffing and high clinical need *'short staffed [...] really high acuity'* (Jordan), the significant organisational and administrative burden *'consumed by sitting in front of the bloody computer'* (Alex), and the gap between expectations and reality, the *'magic wand that we don't have'* (Ashley); *'people think that they come into hospital, and they get lots of support and... that isn't the case, because... there's not time'* (Morgan). Rowan reflected how some of these pressures impacted on their ability to work in a trauma-informed way:

'You're working in a very busy acute ward, having that time to be able to change... change your working styles, you know... at times you - you have to spend alot of times changing [...] acuity has been through the roof... with very unwell patients that have come through... um with high levels of sort of aggression as well, so... yea it's just been trying to... manage all that...' (Rowan).

By listing off the pressures they face, Rowan communicated a sense of an at-times overwhelming role (*'trying to... manage all that'*). They alluded to a situation where they feel at emotional and physical capacity, without sufficient time or energy remaining for anything else. As well as the indirect effects of these kinds of cumulative demands, the direct impact of service pressures was considered:

'To put female patients in a male corridor, or male patients in a female... to me that is the least trauma-informed way we could... we could manage. But we have... we have to do it... all the time... because again the organisational pressure on beds is enormous... So we... sometimes we find that we're going in ever decreasing circles' (Ashley)

Ashley described how they must make decisions that feel contrary to trauma-informed practice, having no choice but to do so (*'we have to do it... all the time'*). They communicated their sense of frustration and pessimism in relation to *'enormous'* pressures, that are worsening over time (*'we're going in ever decreasing circles'*).

Participants spoke about hard-to-change circumstances that they felt limited their ability to incorporate trauma-informed practice. Three participants spoke about the lack of psychologists and a reliance on medication as issues of concern for them. Morgan reflected *'we don't have psychology. And I think that's the huge thing, it... I mean it's easy to throw pills at people... they don't work for... alot of people'* (Morgan). Ashley went further; *'the damage that we do, through... our inability... to manage them any other way'* (Ashley).

'19-year-old girls that are on more medication than people that have schizophre... you know, it's scary...' (Ellis).

Collectively, they expressed their discomfort with the primary use of medication in some instances, emphasised through the use of emotive language ('damage', 'scary'). Ellis reflected how on the one hand there was an expectation for services to become more trauma-informed, but on the other, there were a lack of options to support this shift.

'You know, we are trying to move away from such a medicalised model in nursing, an... and be more sort of psychology based, trauma-informed and stuff... but... just now, all it feels like sometimes is you have medica... that's all you have left, is medication...' (Ellis)

Ellis communicated their sense of helplessness in being asked to change, but feeling they had no options from which to do so ('that's all you have left, is medication'). Another example of hard-to-change factors in the acute setting was the perceived therapeutic inadequacy of the environment 'I walked in and I thought... oh my god, what a horrible place...' (Morgan). Three participants spoke about non-therapeutic ward environments, but felt that competing priorities took precedence. For example, Ellis reflected how 'we have that balance between... what's a ligature risk, and what's a therapeutic environment', and Rowan described being 'bound by infection control guidance'. By contrasting 'ligature risk' with 'therapeutic environment', Ellis appeared to suggest potential risks must take priority, and that this limited what was realistically possible in terms of the development of a therapeutic space. Rowan's use of the word 'bound' depicted a sense of the rigidity of this environment, recognising understandable but uncompromising factors. Morgan described the non-therapeutic nature of the ward environment at times where the alarms were used:

'The alarms are horrific, the alarms are so loud, if you heard it now, you would jump from your seat... it's not nice [...] it's that, seeing them sprinting along the corridor... adrenalines pumping... 'where am I going' and they're in that... they're in that heightened state [...] I might have pulled the alarm, I know it's coming but I still get a fright. But for the patient, holey moley, yea... and the... not even the patients in the incident, the patient having a cup of tea in the lounge...'

Morgan illustrated the sheer atmospheric intensity in these circumstances (*horrific, jump from your seat*), setting out the degree of fear and tension experienced by all patients and staff in the vicinity when exposed to the risk management driven alarm system.

A final example of such hard-to-change issues related to significantly differing views amongst colleagues, seen as a potential challenge trauma-informed practice in acute wards by four participants. Alex spoke about having had 'quite a few challenging conversations with people, wondering why I'm... bothering'. Rowan and Morgan reflected on examples of views they felt to be incongruent with trauma-informed perspectives 'back to the 'attention seeking' (Rowan), 'that idea of manipulation and all this sort of nonsense (Morgan). Jamie considered a reality where some colleagues would always be reluctant to adopt a change in perspective:

'You'll always have those kind of nurses.... 'yea they're still the same, they're just personality disordered', or 'they're just this or they're just that'... and... so some people you can't... you'll never ever change them, and you just have to accept that you'll never change them' (Jamie)

Jamie distanced themselves from colleagues who speak in this way ('those kind of nurses...') but communicated a sense of resigned acceptance of their views as a part of an inpatient team ('you'll never ever change them'). Alex highlighted how inconsistency between colleagues could undermine their own efforts:

'There's no point in me doing one thing, and somebody coming in and doing it the next day...it's just... That is a waste of time. You need everybody to be in... but you're never going to get that [...] you can only try and work with what you've got' (Alex)

On the one hand, Alex appeared quite despondent about differing approaches in the team (*that is a waste of time*). On the other, they took a pragmatic stance, acknowledging the need to '*work with what you've got*'.

Across the subtheme '*Navigating our reality: it's not easy*' participants illustrated the many challenges they faced as they endeavour to incorporate trauma-informed practice, and the dissonance this could bring. These included the significant pressures facing both the system and them personally, and several hard-to-change considerations that seemed significantly incongruent to a trauma-informed approach: the lack of psychology, the non-therapeutic environment, and significantly contrasting views amongst the team.

Overall, the first theme '*A Welcome Shift - We Are Trying*' captured participants' significantly contrasting experiences. One of interest and enthusiasm in a different conceptual framework, and that of resignation and frustration in the face of reality.

Theme 2. The Person Behind the Nurse

The second theme captured the human experience, behind the professional face. Participants reflected on what it feels like to work within an acute ward. They spoke about the tension they experienced between safety and other trauma-informed principles, the personal exposure to traumatic situations that they faced at work, and how they felt about support. This theme was divided into three subthemes, '*Dilemmas we face*', '*No-body should see what we saw*' and '*Support... we support each other*'.

Subtheme 1: Dilemmas we face

Participants felt a clear sense of responsibility to keep people safe. This priority at times raised a dichotomous tension with other trauma-informed principles including choice, collaboration, empowerment and trust. These tensions brought uncomfortable dilemmas for participants, usually resolved on the side of physical safety, in a setting where significant risk of harm was a daily reality.

All eight participants described variations of the view that '*safety needs to be our number one priority*' (Jordan). Participants illustrated a heightened vigilance whereby they were perpetually alert to danger '*that's [safety] always... it's always... more... most in your mind [...] we've all got... ligature cutters in our pockets*' (Jamie). Ensuring safety was described as '*a constant battle, and it's a constant worry*' (Jamie). Jordan reflected:

'It's a constant struggle, because... um... you know we're trying to take... positive risks with patients... um... to work with them ... um but at times, that can... that can be a challenge when... they... struggle to maintain their own safety' (Jordan)

This sense of conflict appeared to arise where nurses' safety concerns felt unaligned with patients' ability or wishes to keep themselves safe. All eight nurses spoke about a point at which they saw intervention as becoming necessary, where someone's choices might have to be overruled '*that is going to end up with massive injury [...] people don't want to be touched... um... but we have to do it*' (Rowan), '*there'll come a point, where safety above all will trump peoples... choices...*' (Ellis). Jamie considered:

'Every hourly check you... you go round and they've got another ligature around their neck, and another ligature around their neck... it gets to the point where you have to...' (Jamie).

Jamie pointed to the situation where choice or collaboration no longer appeared compatible with ensuring safety, that point at which intervention becomes necessary (*you have to*).

Whilst agreeing that intervention was at times needed, all eight participants explored the significant degree of complexity surrounding these decisions. Participants considered the subjectivity of risk related dilemmas. Alex reflected how *'... I sit quite... with quite a high level of risk... I'm quite comfortable with that, whereas others I know aren't...'*, suggesting that personal anxiety tolerance influenced their risk-based decisions, and that their experience differed to others. On the flip side, Rowan spoke of how fears of adverse consequences influenced a more cautious stance:

'We have to... we have to risk-manage on this ward. We've... obviously... you know there's-there's been deaths in the... in the service. Ummm so... everybody is kind of like... so we're probably being a bit over... how do I say this... you know we always want to be... you know... do 'positive risk taking', but I think a lot of staff now... on other wards... not so much this ward I don't think... but in other wards... a risk of... risk sort of... yea... they just don't want to do positive risk taking because they're scared... And it hits the papers.' (Rowan)

Rowan suggested that whilst they wanted to work with patients using a *'positive risk'* mindset, their fear of adverse consequences and the possible fallout (*'deaths', 'it hits the papers'*) impacted on their decisions (*'probably being a bit over...'*). Rowan spoke in a somewhat hesitant way, suggesting some discomfort in acknowledging the reality of these fears. By shifting to speak about *'other wards'*, Rowan hinted to a stigma surrounding risk aversion, which they wanted to perhaps distance themselves from. Rowan's reflections illustrated how clinicians felt pushed towards a more cautious, restrictive approach, as illustrated by Jamie *'you're not allowed to, you're not getting to do that... not on my watch...'* (Jamie). This statement pointed to the real sense of personal responsibility, and an underlying fear of blame should something go wrong.

Awareness of the detrimental emotional impact on patients contributed to the sense of dilemma around the use of restriction. Alex considered how *'it can't not... retraumatise'*. Frankie reflected on the emotional challenge they faced in knowing intervention could *'[make someone] more distressed, but then... you can't not intervene, cos they're self-harming as well... so it's quite difficult that...'* Jordan reflected:

'We can absolutely justify it... because it's the only way to safely manage a situation, but... that may then spark... further trauma for someone as well. And... and we don't want to do that... um... but unfortunately, we have to safely manage a situation. So it's a... it's a really like... ethically a very horrible situation to have to be in' (Jordan)

By describing an *'ethically horrible situation'* Jordan pointed to the moral discomfort that could arise for nurses (*'we don't want to do that'*) who were aware they were causing emotional distress for the person they were trying to help (*'spark... further trauma'*).

As well as considering the impact on patients, all participants described their own experience of restraint using versions of the words *'awful [...] horrible'* (Alex), *'something that's really horrible'* (Jordan), suggesting the significant personal discomfort felt around the use of restraint. Frankie considered a particularly distressing situation:

'The reason they fought, was because they thought they were getting attacked again, but we knew that every single time... [...] that went on for weeks and weeks and weeks. And we tried to do it... every time... every day [...] at last their mental health improved and they was alot better for it. It's kind of... on the ward it is like that, and it's not healthy... it's not... do you walk off the ward saying... oh am I a good person for doing that? But then you have to... weigh the good with the bad, and say... look well they needed it... they will get better, this way I think they will get better...' (Frankie)

Frankie considered how this situation had brought up questions for them around the morality of what they were doing ('*am I a good person for doing that?*'). At the same time, they illustrated some reconciliation in taking a longer-term perspective, focussing on the hoped-for outcome ('*this way I think they will get better*'). Similarly, Jamie seemed able to reconcile the use of restraint as something required, in some circumstances: '*I can... honestly say that I can... deal with that cos I ... I know that it's necessary at times*' (Jamie).

As well as the emotional impact surrounding the use of restrictions on patients and staff members, participants considered the enduring impact on relationships. '*When you're trying to build trust and relationships with people... can be... can be difficult...*' (Ellis); '*that kind of breaks that down... the trusts not there... er... the relationship breaks down*' (Frankie). Ellis considered how:

'I need to full-down body search you... the impact that has on our therapeutic relationship with patients, you know that is potentially re-traumatising somebody, that we then have to work with. And that's really difficult...' (Ellis).

The words '*difficult*' or '*hard*' were used to point to the strain and discomfort that could be placed on a relationship. Alex spoke of the need for a personal robustness to cope with the strain that restriction could place on relationships:

'You also have to not be afraid that the patient will be angry at you. Cos often they will be. And that's ok, they will be angry at you. They're not getting what they want. But you have to sometimes be that bad person, because you have to protect them. Because it's too risky. Yea... it's quite hard.' (Alex)

Whilst acknowledging the impact on the relationship when imposing restrictions ('*be that bad person*') Alex appeared to have a clear sense of personal resolve on this issue, driven by their unambiguous responsibility to protect ('*you have to protect them*').

The assumption that intervention was an effective response to manage risk was critiqued by four participants, further illustrating the complexity of risk-management driven decisions. Jamie considered the issue of physical safety and emotional safety:

'We don't want them to do that, when they might cut an artery and kill them-self by accident, you know. If they constantly cut at their throat and stuff... you know, that's about... there's a safety element in that, for us. Cos we want to make them safe. But that safety element for them's a completely different thing isn't it?... That's... maybe stopping them from... from... experiencing the most.. awful stress [...] that's how... that's what keeps them safe' (Jamie)

Jamie here recognised their own personal need to '*make them safe,*' with their own fears of adverse outcomes driving the need to intervene ('*they might cut an artery and kill them-self by accident*'). At the same time, they acknowledged their dilemma; if they intervene to keep someone safe, they might cause

someone to become less safe. Ellis alluded to a view that restrictions could feel somewhat futile; *'the more restrictive that we are, the more ingenuity people put into harming themselves'*. Morgan reflected on the unintended longer-term harms of intervention: *'taking things away doesn't help [...] people become more dependent [...] dependent on staff, um... and that's... yea that's not helpful'* (Morgan). Ashley echoed these concerns: *'do we empower? No. No we don't. We dis-empower'*, suggesting that short-term risk management efforts can incapacitate those they are trying to keep safe, leaving them less able to cope. The earlier sense of clarity that safety was the *'number one priority'* appeared to become somewhat more blurred when participants explored the potential impacts of risk-management-driven interventions.

Overall, the subtheme *'Dilemmas we face'* captured the complicated navigation acute inpatient nurses face as they attempt to keep people safe. Participants considered the real risk of harm encountered in the acute setting, and their personal sense of responsibility to mitigate this. At the same time, they reflected on the impact of a reactive risk management approach, including the emotional distress caused to patients and moral discomfort as staff, the lasting impact on the relationship, the loss of emotional safety, and the potential for longer-term unintended consequences.

Subtheme 2: *'Nobody should have to see what we saw'*

All participants spoke about being exposed to traumatic situations through their work. This subtheme looked at the, at times, shocking reality of participants' working lives, and the effect this could have on them. The inevitability of exposure to traumatic situations was conveyed as something *'part and parcel'* (Jamie) of the job.

'Nobody should have to see what we saw, but we did. And it can't be unseen' (Ashley)

In these few words, Ashley highlighted the at times harrowing nature of what they were exposed to through their work, suggesting there could be no expectation this be a part of someone's job, but it is. The statement *'it can't be unseen'* emphasised the enduring impact, imprinted to memory. Ashley reflected how *'we're not... we're not any different [...] we just put a uniform on. But we're still... um... we're still very human'* (Ashley), suggesting that whilst acute nurses may be perceived as robust, they are in fact vulnerable, just like everyone else. Ellis echoed this acknowledgment of vulnerability:

'Repeatedly cutting ligatures from people, which doesn't matter how many times you're doing that... it's a really scary situation to go into... 'specially depending on... how tight that ligatures been'n, potentially if the patient's airway's been compromised... I know [...] people have... have died... from ligatures, and... sometimes I think we're ... we're good at 'it's fine, this is what we do' but actually, sometimes, we forget about our own trauma in here' (Ellis)

Ellis pointed to a reality in which situations can feel *'really scary'*, and repeatedly so (*'doesn't matter how many times'*). They highlighted how their fears of the worst possible circumstance are based on reality (*'people have... have died...'*). At the same time as acknowledging their fear and vulnerability, Ellis alluded to a superficial coping culture often adopted in the acute setting (*'it's fine, this is what we do'*). In contrast to Ellis' illustration of fear, two participants reflected on their emotional detachment in the face of exposure to traumatic situations in work, becoming *'quite numb to it'* (Morgan):

'Nothing kind of phases me anymore... um... for instance we had a bad... [serious incident described] it was [time period] ago... and I was first to find [...] and [...] was actually blue in the face, and I cut it off... but I didn't think about doing the job, I just went in and did it... um... checked

that [...] was breathing and all that kind of stuff... and it wasn't 'til I actually got home where just suddenly, all this emotion kind of hit me... and I was scared...' (Frankie)

During this high-risk and traumatic situation, Frankie described a cognitive and emotional disconnection, going into an 'autopilot mode' (*'I just went in and did it'*). They considered how it was only much later that they experienced strong emotion in relation to the incident. There appeared to be a degree of incongruence to Frankie's narrative, from how *'nothing kind of phases me'*, to recognising the significant emotional impact, albeit later (*'I was scared'*). This perhaps provided a good example of Ellis' earlier reflection, recognising the culture of *'it's fine, this is what we do'*. Frankie went on to illustrate the severity of trauma exposure they have experienced through their work:

'I'm used to it... um... used to ligatures. I've cut somebody down from the roof hanging... umm... I've seen a [person] cut... all their arms and all their legs, and the whole room's covered in blood, the walls and everything... so... I don't know... like... I've seen that, that was ... traumatic at the time. But... I won't see worse; I don't think so. You know what I mean? So... I would say I'm numb-ish to it, if that makes sense' (Frankie)

In their matter-of-fact descriptions of what seem to be highly traumatic situations, Frankie appeared to minimise their severity. Frankie seemed to suggest there was a link between emotional detachment and repeat exposure (*'used to it'*) which they view as in some way protective (*I won't see worse*). This again appeared somewhat divergent from Ellis' thoughts, where they expressed how *'it doesn't matter how many times'*, they still experience fear at the time of the event. Whilst describing quite different responses in the face of workplace trauma, both Frankie and Ellis acknowledged taking an *'it's fine' 'I'm used to it'* approach, whilst recognising that, in reality, exposure to traumatic situations has a significant impact on them. As well as considering the impact of direct personal exposure to traumatic situations, participants spoke of the effects of secondary exposure to the trauma of others. Rowan considered how:

'I think sometimes we... like to be blinkered, so that... "this does not happen" and then when you're hearing it first-hand from somebody that has suffered... and you're just like, wow this is dreadful' (Rowan).

Rowan alluded to the potential comfort in not knowing about the trauma other people have faced (*'we like to be blinkered'*), but how when you are exposed firsthand to someone's experience, it is impactful (*'this is dreadful'*). Alex reflected on how this can feel:

'It's... I can feel myself... I can't... I can't have this in my head, and you know, you immediately need to get it out...' (Alex).

The intolerability of the information, the need to get rid of it, was emphasised (*'I can't have this in my head'*). This information of course cannot be removed, cannot be unknown. Jordan echoed this sense that once they have been exposed, the impact can be hard to mitigate, despite their efforts to protect themselves:

'As a professional, you need to have that ability to... be empathetic and show compassion... but also not... have it impact you... too emotionally. Um... but I suppose there's a really fine line between... showing compassion and empathy and... and your own emotion. So it's a difficult one to... to kind of balance. Cos you need to remain profession...' um... but... we're all human, and hearing something really horrible is... is difficult' (Jordan)

Jordan described how they attempt to maintain control by managing the degree to which they engage emotionally with someone's story, seeming to suggest that engaging too closely can increase personal vulnerability. At the same time, they acknowledged they had limited control over their emotional response ('we're all human'). Whilst not explicitly stated, Jordan alluded to a reality where reduced engagement may be personally protective, a point aligned with Rowan's: 'we like to be blinkered'. This highlights a potential for nurses to adopt a protective cautiousness from developing deeper relationships, to avoid the risk of secondary exposure to trauma. In a model that emphasises the role of the relationship as with trauma-informed practice, this is an interesting consideration. Jordan went on to further consider exposure to trauma and the impact on interpersonal relationships:

'I think that's the reality of acute care, is... you know we face... incredibly challenging situations with staff. And how can you build really positive relationships when... we... the patients traumatise the staff and... you know sometimes the staff can trigger that trauma in patients? Almost... that's a really difficult place to be. Um... but unfortunately sometimes... the reality of the job' (Jordan)

Jordan suggested that in the face of trauma, there becomes a two-way attribution of accountability that can impede staff and patients' ability to form 'really positive relationships'. They suggested this can be severe 'how can you [...]?', seeing damaged relationships as a 'reality' in the acute setting. Ellis reflected on an example that illustrated this point; 'we had somebody who had a [health emergency] because a patient, who has capacity, um... [assault detailed] and that caused alot... of ... anger towards the patient (Ellis). In different ways, Jordan and Ellis illustrated the complex inter-relational dynamics that may surround traumatic situations, impacting on the ability of staff and patients to form trusting, connected relationships.

Overall, the subtheme 'Nobody should have to see what we saw' explored the at times shocking life-and-death situations nurses face during their routine work in an acute ward, and how they navigate these situations. The theme highlights an 'it's fine, this is what we do' culture, as an established response among nurses working in the acute setting. At the same time, participants recognised the personal impact of trauma on their emotional wellbeing, instilling strong emotions ranging from fear and horror to anger, and considered the impact that trauma could have on relationships.

Subtheme 3: Support... we support each other

The third and final subtheme explored the somewhat ambivalent view participants held around the need for support, whilst recognising the vital importance of the mutual support provided from within the acute team. Participants appeared to see formal support as something of importance for others. Ashley had spoken of their own involvement in a highly traumatic incident. They later reflected:

'I think of some of the traumas that staff in here have been through. It worries me that they don't [access support] (Ashley).

Ashley expressed their clear concern for others. At the same time, they did not seem to consider their own potential needs. This perhaps further illustrated 'an ingrained culture in nursing to - just get on with it' (Ellis), echoed by Frankie: 'we're used to it, and we take it, and we just get on with it', a culture that was also acknowledged in subtheme 'Nobody should have to see what we saw'. Participants reflected how accessing support was not something they tended to consider for themselves 'no-one goes looking, I don't think for support...' (Morgan).

'I've never... I've never thought to myself I need support ummm... not necessarily... maybe other people have thought of it... ummm... I've never... thought about it... never had to look for it, ummm... probably never needed it. Don't know if I needed it? But... but you know, I've never needed it... so I've never... ummmm don't think anybody has... maybe suggested... you know or said...' (Frankie)

Frankie seemed somewhat perplexed by the idea they might have ever 'needed' support, suggesting they had not ever considered it an option (*'don't know if I needed it...?'*). They appeared to feel support might only be of relevance where it became sufficiently evident for someone to 'suggest...', that support may be helpful. Rowan considered some of the reasons for such hesitations, acknowledging they themselves had not accessed support:

'I don't k... I don't know if it's... they don't want to seem weak? They don't want to seem that they're struggling? They don't want to seem that... "there's something wrong with me...?"'

These considerations hinted to the stigma that may surround support services, a point explicitly recognised by others *'there is still a bit of a stigma about it, which is wrong...'* (Alex), *'it's like them failing if they need help'* (Rowan).

'If you say that to some people... you will... that's a really great service, that counselling... "I'm no' speaking to a stranger about how I feel, that's not going to happen"' (Jamie)

The irony of these reflections was of interest, considering clinicians' choice of work as mental health nurses, a role that routinely requires others to speak openly and transparently about their mental health. The hesitant response around accessing external support appeared to be a manifestation of the acknowledged coping culture *'it's fine' 'just get on with it'*. Whilst participants appeared quite open to the idea of support being acceptable for others, the more prevailing stigma seemed to be something internally applied, as individuals.

In contrast to the hesitancy surrounding more formal support options, the particular importance of peer support was emphasised, with participants describing versions of *'a really strong... strong support system... in the ward'* (Alex). *'I will say this teams very, very good at supporting each other'* (Ellis).

'It's funny... it's the funniest thing I think on mental health wards that... you could have disagreed about something 15 minutes beforehand, but if you need somebody, they'll be there for you... it doesn't matter that you've disagreed with them, they'll still be there. So I think there's a really strong... strong support system... in the ward' (Alex)

Alex and Ellis both pointed to a strength of trust between colleagues. Alex suggested this level of trust was somehow connected to the acute setting. They alluded to a situation where *'if you need somebody'* you really 'need' them, and *'they'll be there'*. The reliance on each other was described as one superseding minor frustrations *'you've disagreed with them, they'll still be there'*. The sense that exposure to traumatic situations could strengthen this mutual support was considered; *'we'll always pull together, if something's happened...'* (Ellis)

'I think we're a... we're acutely aware of it because we've had... [number] very traumatic events in the past couple of years. So... and the recent one... was... particularly... horrible. So... um... and it's had an... awful effect on nurses. So I think that... in itself... has made us all mindful of... being... of caring for each other and checking in and making sure we're... we're all ok. Is everybody ok...? How are you...? Even the way you speak.' (Jamie)

Jamie suggested that through witnessing the suffering of colleagues (*'awful effect on nurses'*) a more caring considerate approach had developed within the team. This suggested that shared traumatic experiences could enhance closeness within a team, as they became more astutely responsive to the needs of others. The sharing of mutually challenging experiences was considered as something that could be therapeutic, where *'you don't feel alone, like maybe it wasn't just me that went home and thought about that today ...'* (Ellis).

'It's quite good that... a-actually sometimes when you self... 'oh I... I really struggled with that', and somebody else will say 'oh I struggled with that too' and you're like... you know that you're not alone...' (Rowan).

Knowing that other people found something difficult too appeared to help Rowan in the face of challenging work situations, seeming to bolster their own confidence by knowing they were not alone. Ellis reflected on how the challenges of working in the acute setting was, for them, off-set by the people and relationships they had developed through their work:

'I've worked in... [different clinical areas listed] this... is the most draining area to work in because... it is... it's busy, it's stressful, you manage a high level of risk... you meet some really great people, I've met some really great staff, who really just... the compassion they have for coming in, doing their jobs... really just... enlightening sometimes' (Ellis)

The respect and appreciation of work colleagues came through from Ellis' words, as the factor that not only supported them through significant challenges, but something that made their role something quite special (*really just... enlightening sometimes*).

Overall, the sub-theme *'Support... we support each other'* highlighted a contrast between the hesitancy surrounding access to external support, and the strength of trust and support provided internally within the nursing team. Participants recognised the need for support in a challenging role, but explored some of the limits around what felt comfortable. Questions were raised about stigma and the personal barriers to support services that this might raise.

The theme *'The Person Behind the Nurse'* explored the reality of being a nurse in the acute inpatient setting from a trauma-informed lens, across three subthemes. The first subtheme, *'Dilemmas we face'*, explored the complex decisions nurses negotiate around risk, whilst attempting to incorporate trauma-informed principles into their practice. The second subtheme *'Nobody should have to see what we saw'* highlighted the at times shocking exposure to traumatic situations nurses encounter through their work, and the impact this can have. The final subtheme *'Support... we support each other'* explored the sense of hesitancy around access to more formal support, whilst recognising the internal strengths of the team who pull together at times of need.

Discussion

The Scottish government outlined its commitment to the development of trauma-informed public sector services as part of the National Trauma Transformation Programme (NTTP, 2024). Recognising both the importance and potential complexity surrounding the development of trauma-informed acute inpatient services, the current study aimed to develop an in-depth understanding of nurses' lived experiences as they integrate trauma-informed practice into their working lives.

An Interpretative Phenomenological Approach (IPA) was used to analyse eight participants' data. Two general experiential themes were identified. The first theme was titled '*A Welcome Shift - We Are Trying*' and included two subthemes, '*Seeing things differently, doing things differently*' and '*Navigating our reality: it's not easy*'. The second theme was titled '*The Person Behind the Nurse*' and included three subthemes, '*Dilemmas we face*', '*Nobody should have to see what we saw*' and, '*Support... we support each other*'. The findings are considered below with consideration to how they relate to the wider literature.

Evaluation of findings

Within the first theme, '*A Welcome Shift - We Are Trying*', the degree of enthusiasm and interest in the concept of trauma-informed practice was evident, illustrated within the subtheme '*Seeing things differently, doing things differently*'. Staff attitudes are known to influence the effective adoption of evidence-based practices (Aarons et al., 2012; Aarons & Sawitzky, 2006; Marshall & Olphert, 2008; Stokke et al., 2014). A key component of trauma-informed practice involves the relational approach adopted by service providers (NHS Education for Scotland, 2017; Sweeney et al., 2018). Recognising the personal nature of trauma-informed practice, the endorsement of service providers is likely to be of particular relevance for its effective adoption. It was therefore encouraging that the present study suggested a generally positive attitudinal response to trauma-informed practice in the acute inpatient setting.

It was of interest that participants highlighted the usefulness of several practical applications of trauma-informed practice, suggesting this helped provide a tangible framework from which to apply a change in approach. The translation of aspirational principles into clinical practice has been identified as a potential challenge in the adoption of trauma-informed practice (Isobel, 2015; Isobel & Delgado, 2018). This point appeared especially important in relation to practices known to be potentially retraumatising, where participants felt better able to mitigate harm through practical adaptations to approaches. This finding gave some illustration to the proposal that staff must be supported to have a clear understanding of their responsibilities in the mitigation of retraumatisation as a key factor in the successful development of trauma-informed inpatient settings (Muskett, 2014). The parallel introduction of evidence-based initiatives such as 'Safewards' and 'Restrain yourself' (Bowers, 2014; Duxbury et al., 2019) may further support this bridge between concept and reality, providing practical steps from which inpatient nurses can adopt changes to clinical practice that are aligned to trauma-informed practice.

Whilst expressing a generally positive attitude towards trauma-informed practice, the subtheme '*Navigating our reality - it's not easy*' highlighted the challenging reality of working within the modern NHS. This narrative can be seen within the wider public discourse. A recent report found public satisfaction with the NHS has fallen to its lowest since the 1980s, indicative of services under serious strain (Jefferies et al., 2024). The British Medical Association has highlighted the significant and growing problem of pressures facing services (BMA, 2024). Recognising these wider systemic issues and their inevitable impact on those working within the NHS is important to ensure there is not a significant disconnect between policy and reality. Whilst acknowledged as aspirational, trauma-informed publications place emphasis on the importance and value of staff wellbeing (NHS Education for Scotland, 2017; The Scottish Government, 2021). This theoretical prioritisation of staff wellbeing appeared somewhat incongruent with the lived experience of participants in the present study, who felt expected to work '*in ever decreasing circles*', struggled to access more intensive trauma-informed training, and felt they had limited access to psychologists to support them in implementing a shift in approach. The discrepancy between policy-level statements on staff wellbeing and insufficient commitment in practice has been identified as problematic considering policy more widely, with The Kings Fund highlighting a need for both action and words on this issue (The Kings Fund, 2020).

Moving to the second theme, *'The Person Behind the Nurse'*, one key finding within *'Dilemmas we face'* related to a dichotomous tension between safety and the other trauma-informed principles of choice, trust, collaboration, and empowerment. A similar sense of tension between safety and other trauma-informed principles has been described elsewhere, suggesting that these findings are not unique to the acute setting, but relevant to other contexts where an emphasis is placed on safety and risk management (The Scottish Government et al., 2021, Muir Cochrane 2018, Kinner et al, 2016). In the present study, this tension appeared to develop from nurses' sense of responsibility to ensure patient safety, which was seen as taking precedence over other trauma-informed principles. This prioritisation of safety as a predominant aim of inpatient mental health nurses, and psychiatry more widely, has been described elsewhere (Bowers et al., 2010; De Santis et al., 2015; Delaney & Johnson, 2008; Slemon et al., 2017).

Safety is undoubtedly an important component of acute inpatient care, acknowledging the real potential of severe harm, whether through violence, self-harm or suicide (Hunt et al., 2024; James et al., 2012; Langsrud et al., 2007). Patient safety initiatives can have a significant real-life impact, with notable reductions in inpatient suicides over the last decade potentially attributable to risk management efforts (Hunt et al., 2024). On the other hand, criticisms have been levelled where a risk management narrative becomes overly dominant, as legitimising harmful restrictive practices and overshadowing the therapeutic relationship (Paterson et al., 2013; Slemon et al., 2017). In the present study, participants illustrated both sides of this emotive debate. On the one hand, they felt clearly responsible for preventing severe harm, and saw restrictive practices as a means to keep people safe where other options were not available. On the other, restrictive risk-management practices were acknowledged as being at times unhelpful, ineffective, distressing, and retraumatising.

The literature exploring the complexity of this issue suggests a cultural shift is required for a reduction in restrictive practices to become possible (Bowers, 2014; Duxbury et al., 2019; Slemon et al., 2017; Sweeney et al., 2018; Sweeney & Taggart, 2018). Slemon et al., maintains the need for a fundamental re-evaluation of the risk-management culture in the acute setting, which they see as currently legitimising the use of harmful restrictive practices (Slemon et al., 2017). From a trauma-informed perspective, Sweeney et al., argue there needs to be a move away from a culture that aims to 'fix' or 'rescue' people within which 'power-over' relationships develop, in turn legitimising the use of restrictive practices (Sweeney et al., 2018 pp328). The need to consider physical and emotional safety on more equal terms has also been raised (Veale et al, 2023). The current study illustrated the reality of participants' experience, in which safety was accepted in almost orthodox terms as *'the number one priority'*. Participants saw this stance as helping prevent severe harm or even death. This highlighted the contrast between the deeply held need to prioritise safety amongst nurses working in the acute setting, and wider calls to move away from such an emphasis on safety and risk. This suggests that the established risk-management narrative needs to be thoughtfully considered during the transition towards trauma-informed acute inpatient services. Due consideration would help provide support and clarity to clinicians as they adopt trauma-informed practice into this traditionally risk-management-dominated setting.

Increasingly, nurses work within systems that emphasise the need to reduce restrictive practices (Bowers, 2014; Department of Health, 2014; RCN, 2023). In circumstances where restrictive practices are used, nurses have been documented to report experiencing fear, blame or moral distress concerning their involvement (Pérez-Toribio et al., 2022; Power et al., 2020; Vedana et al., 2018 Muir-Cochrane et al., 2018). Moral distress refers to the feeling of unease that can occur when clinicians are required to act in a way that does not align with their moral principles (BMA, 2021). The experience of moral distress has been associated with a series of negative outcomes, including higher stress levels, burnout, workplace fatigue, and impaired relationships (Alimoradi et al., 2023). In the present study, nurses identified experiencing a sense of moral discomfort in relation to the use of restrictive

approaches, particularly where they felt they resulted in distress to the patient involved. It is possible that as awareness grows, the experience of moral distress amongst staff who are involved in potentially retraumatising incidents may increase. Whilst the issue of moral distress was touched upon within the current study, further research would provide greater insight into this issue.

Within the subtheme '*Nobody should have to see what we saw*', explicit insight was given to the degree of traumatic exposure acute nurses encounter through their work. Their qualitative experiences gave some context to the reported incidence of posttraumatic stress disorder (PTSD) among inpatient psychiatric nurses, thought to be around 10% (Jacobowitz, 2013). A higher incidence of posttraumatic symptoms has been described among inpatient nurses than their community counterparts, with factors including high work stress and exposure to violence as potential explanations (Zerach & Shalev, 2015). Exposure to suicide and self-harm, as detailed in the current study, have been connected to significant distress among staff (Groves et al., 2024; Rytterström et al., 2020; Takahashi et al., 2011).

Posttraumatic stress has been associated with the experience of burnout (Jacobowitz et al., 2015; Mealer et al., 2009; Annaloro et al., 2023). Burnout has been related to a host of negative outcomes including high staff turnover and absenteeism, decreased job satisfaction, negative attitudes toward those accessing services, and a detrimental impact on patient care (Johnson et al., 2018; Morse et al., 2012; NCTSN, 2011). For both staff wellbeing and patient care, it is therefore important to minimise the impact of factors that contribute to staff burnout. Appropriate staff support has been found to mitigate the risks of exposure to workplace trauma and the development of burnout (NCTSN, 2011; The Scottish Government et al., 2021). Supporting staff wellbeing is an important component of a trauma-informed organisation (The Scottish Government et al., 2021). The present study pointed to a situation where nurses were exposed to significant trauma through their work, but gave limited consideration to the possible need for support. Nurses acknowledged an established coping culture, in which they tended to '*just get on with it*'. Furthermore, they described a prevailing stigma surrounding access to support services. This reported stigma appeared to be something individually imposed, rather than in relation to others. The combination of exposure to significant workplace trauma, an established coping culture, and an individual hesitancy around accessing support highlighted a need to improve available support structures for a potentially hard-to-reach staff group.

Whilst access to structured support was viewed with some hesitancy, internal team support was highly valued. Participants spoke of the responsive nature of team support, in which exposure to shared traumatic experiences was seen as supporting additional closeness between colleagues. This sense of closeness within an acute inpatient nursing team has been explored elsewhere (Deacon et al., 2006). In the present study, the closeness between colleagues was viewed as supportive, and responsive to need. However, sole reliance on informal within-team support might place nurses in a potentially vulnerable position, should support not prove forthcoming. Team cultures can develop that are unconstructive or at times harmful (Dyer, 2023). Furthermore, teams can collectively legitimise problematic approaches, a process that can influence significant variability in the care at times seen between settings (Larsen & Terkelsen, 2014; Bowers 2010, 2011). The integration of support mechanisms into daily routines have been connected to significant improvements in staff wellbeing (Bailey & West, 2020; The Scottish Government et al., 2021). This approach may be useful in the case of acute inpatient wards, enhancing the current internal support provided between colleagues, within a structure that ensures availability to the whole team.

Clinical implications

Findings from the present study will help inform the effective implementation of trauma-informed practice in the acute setting. Based on this research, the following recommendations are made:

Context specific training

1. To develop acute inpatient trauma-informed training designed to complement standard trauma-informed training. This will recognise and address the setting-specific challenges faced in the development of trauma-informed acute services. To ensure this training's relevance, resources should be designed with input from key stakeholders (NHS England, 2009). In this instance, stakeholders include acute inpatient nurses and other members of the multidisciplinary team, and those who have experienced admission to the acute inpatient setting. Training should:
 - Emphasise that proactive cultural change will reduce the need for restrictive interventions over time, ensuring a consistent message across relevant policies and initiatives, for example, Safewards (Bowers, 2014) & Observation to Practice (Healthcare Improvement Scotland, 2019)
 - Identify strategies that support staff to navigate the tensions between safety and other trauma-informed principles including choice, collaboration, empowerment and trust (e.g. advance statements, clear communication about the limitations of choice, debriefs following incidents (Azeem et al., 2011; Mangaoil et al., 2018; The Scottish Government et al., 2021).
 - Help clarify responsibilities surrounding risks of retraumatisation, a recommendation previously highlighted as important in the development of trauma-informed inpatient settings (Muskett, 2014).
 - Support staff to recognise the effects of workplace trauma, moral distress, and burnout.
 - Highlight the importance of accessing different forms of support, and when it may be appropriate to do so.

Staff wellbeing

1. Optimise or develop internal support systems in each acute inpatient setting, to ensure support is routinely available and normalised. To enhance the outcomes and sustainability of support initiatives, stakeholders should be actively involved in their development (NHS England, 2009). Routine support options might include:
 - Short daily reviews that provide regular support whilst aiming to facilitate learning, a process that has been demonstrated to improve staff wellbeing outcomes (Bailey & West, 2020; The Scottish Government et al., 2021).
 - Development of routinely available reflective practice groups, providing a normalised space to 'off-load' outside of the handover period. Reflective practice groups have been found to support positive outcomes in the acute care context, with benefits seen on compassion measures and on team cohesion (Davey et al., 2021; Thomas & Isobel, 2019).
 - Development of routinely available team formulation sessions, providing a space to reflect on individual patients. Team formulation sessions have been found to support improved outcomes on staff-patient relationships, teamwork and staff wellbeing (Berry et al., 2016; Kramarz et al., 2023; Nikopaschos et al., 2023).
2. The identified stigma surrounding access to wellbeing services to be countered through the provision of training and information, potentially facilitated by service providers.
3. Assessment of whether inpatient mental-health nurses are an under-represented staff group in accessing staff wellbeing services. This could be achieved through the completion of a service evaluation.

Increased access to psychological perspectives

1. Improved access to therapeutic intervention training such as Safety and Stabilisation (National Trauma Transformation Programme, 2024; NHS Education for Scotland, 2017) to increase nurses' competence and confidence in using psychological approaches during their routine clinical work.

2. For consistent access to psychology colleagues in line with recommendations for inpatient settings (RCPsych & CCQI, 2019). Psychologists to support nurses directly through supervision, and indirectly through formulation and case discussion.
3. For patients to be given access to psychological therapies, in line with government treatment targets (NHS Education for Scotland, 2014; NHS Education for Scotland), 2023).

Limitations

Whilst the present study provided insight into trauma-informed practice in the acute inpatient setting, findings should be considered within the context of several limitations.

In terms of the participants, all eight nurses were recruited from a single NHS health board. Nurses' experiences may differ between NHS boards, for example where there were differences in access to training, staff wellbeing services, or organisational cultures. Furthermore, participants were self-selected, with a significant proportion holding senior roles, and being of female gender. The contextual influence of such factors was difficult to consider within the analysis, due to their deliberate exclusion for the purpose of anonymity. Combined, it is possible that the experiences explored in the present study were not representative of acute inpatient nurses' perspectives more widely.

Recruitment to the study was driven by participants' expression of interest. The proportion of participants with managerial responsibility may have resulted in a sample with enhanced exposure to the wider integration of trauma-informed practice. This may have influenced the study's findings. For example, participants' apparent enthusiasm and awareness may have influenced what appeared to be a high level of endorsement in the concept of trauma informed practice.

The study's design was in some ways a strength, providing insight across several areas of interest encapsulated within trauma-informed practice. At the same time, the breadth of the study at times may have impacted the depth of exploration. Some areas of interest identified through the present study would benefit from additional in-depth exploration, noted below under the heading 'future research'.

A further limitation related to the role of researcher bias. IPA explicitly acknowledges the role of the researcher, as they make sense of participant experiences, who in turn try to make sense of their own experiences (Smith et al., 2009, 2022). Whilst the researcher's interpretative role is recognised, the primary researcher for the present study had lived experience of the phenomenon in question. Therefore, whilst efforts were made to ensure reflexivity, the researchers' perspectives on the issue under investigation will have had some influence on the findings in this study.

Future research

Several areas of interest emerged from the present research that would benefit from further qualitative exploration. Notably, the relationship between the use of restriction and experience of moral distress among nurses, the impact that exposure to workplace trauma can have on the therapeutic relationship, and the potential barriers nurses face in accessing support, including stigma. Better understanding of these areas would inform appropriate support systems for staff working in this highly pressured setting, which may in turn support improvements to acute inpatient care.

Considering the topic more widely, there remains a lack of qualitative research involving people who have experienced an admission to the acute inpatient setting (Hennessy et al., 2023). Further research involving this patient group will be vital to inform the development of genuinely trauma-informed acute inpatient settings.

There is emerging evidence to suggest psychological interventions in the acute inpatient context can support positive outcomes (Barnicot et al., 2020; Jacobsen et al., 2018; C. Paterson et al., 2018; Wood et al., 2020). However, the overall quality of evidence remains limited and additional randomised

controlled research is needed to better understand the effectiveness of psychological interventions in the acute setting. Whilst recognising the limitations of available published studies, systematic reviews can collate the evidence to date. In line with this recommendation, the second chapter of this portfolio involves a systematic review of group-based psychological interventions conducted in the acute inpatient setting.

Conclusion

The present study explored mental health nurses' experiences of trauma-informed practice in the acute setting. Findings suggested that trauma-informed practice has been met with interest and openness. At the same time, setting-specific challenges and complexities have placed limits on nurses' ability to adopt changes in practice. A disconnect was considered between a trauma-informed narrative, and the reality of employment in the modern NHS. Participants explored how tensions could arise between ensuring safety, and genuinely incorporating trauma-informed principles of choice, empowerment, collaboration and trust. The dominant risk management narrative will require thoughtful consideration within the transition toward trauma-informed acute services, to support a degree of clarity for nurses as they navigate these tensions. The study highlighted the potential for moral distress among staff involved in using restrictions to ensure safety, within a wider context that recognises the emotional harm that can be associated with these approaches. On the issue of staff wellbeing, experiences of significant workplace trauma were paired with a response to '*just get on with it*'. External support systems were viewed in hesitant terms, with issues of stigma and a wider coping culture seen as potential barriers. However, internal team support was highly valued and seen as responsive to need. The clinical implications of this study are described through recommendations on context-specific training, staff wellbeing, and improved access to psychological perspectives.

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Chapter 2: Systematic Review

A Systematic Review of Group Based Psychological Interventions in the Acute Inpatient Setting

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Abstract

Background: Psychological interventions are recommended as part of available treatment in the acute inpatient setting. To establish whether groups are an effective and feasible format from which to deliver psychological interventions in the acute setting, a review of the literature was proposed.

Aims: A systematic review was conducted to assess the effectiveness and feasibility of group-based interventions in the acute inpatient setting.

Method: A systematic search of Embase, MEDLINE, CINAHL Plus, and PsycINFO was conducted. Findings were reviewed using narrative synthesis, and comparison of effects for studies involving intent-to-treat (ITT) analyses.

Results: A total of 18 studies were identified, including five randomised controlled studies, four clinical control, four cohort, and five pre-post designs. Of the nine controlled designs, four reported some advantages of group-based interventions over controls, although there were a number of limitations, including the lack of ITT analysis or treatment as usual control. Of the controlled designs that applied ITT analysis, a slight but inconclusive advantage of group-based interventions was identified. Groups were consistently described as being a feasible approach to deliver psychological interventions in the acute care setting.

Conclusions: Findings from the review pointed to tentative but inconclusive evidence in support of the use of group-based approaches in the acute inpatient setting. Groups were largely seen as being a feasible way to deliver psychological interventions. The strength of findings taken from this review was limited by the overall low quality of the included studies, the lack of treatment-as-usual controls, and the number of studies that applies ITT analysis. Further controlled research is needed to further establish these tentative and preliminary findings.

Keywords: *Acute, inpatient, psychological intervention, psychological therapy, group*

Background

Psychological interventions in the acute inpatient setting

Acute inpatient settings provide intensive support for people experiencing a mental health crisis (Kings Fund, 2015). Admission occurs in circumstances where people are assessed to be at high risk of harm, either to themselves or others (Evlatt et al., 2021; Kings Fund, 2015). Circumstances of admission may be voluntary, or involuntary, under relevant mental health legislation (e.g. Acts of the Scottish Parliament, 2015). The acute setting aims to support the containment of crisis, reduce risk, and to prevent relapse (Bowers et al., 2015; Wood et al., 2019b, 2019a).

Traditionally, the medical model has dominated the acute inpatient setting, with an emphasis placed on medication-based treatments (Penfold et al., 2019; Raphael et al., 2021; Wood & Alsawy, 2016). However, the need for a holistic approach and a wider biopsychosocial understanding of difficulties has been increasingly recognised (Bowers, 2014; Evlatt et al., 2021; RCPsych, 2019; The Scottish Government et al., 2021). Within this context, psychological therapies have become recommended as an important component of inpatient care (Berry et al., 2016; BPS & ACP-UK, 2021; Evlatt et al., 2021; Penfold et al., 2019; RCPsych, 2019; Wood et al., 2019a, 2019b; Wood & Alsawy, 2016). Despite these recommendations, access to psychological therapies in the acute setting have remained limited and inconsistent (Evlatt et al., 2021).

We know that psychological interventions can be effective for the treatment of severe mental health difficulties (NES, 2014, 2023; 2023; NICE, 2014b, 2014a, 2015, 2022). However, the evidence base has been developed from predominantly longer-term and community-based samples (Paterson et al., 2018). Whilst the acute inpatient setting supports people experiencing severe mental illness, evidence-based interventions need to be adapted for this specific context. For example, interventions need to take into account the short and variable duration of admissions, the complexity and severity of symptoms, and risk related concerns (Berry et al., 2022; Wood et al., 2019).

Several systematic reviews and meta-analyses have been published assessing the effectiveness of psychological interventions delivered in the acute inpatient setting (Barnicot et al., 2020; Paterson et al., 2018; Wood et al., 2020). These reviews have included controlled designs, and predominantly reported findings from individually delivered psychological interventions. Whilst varying in their particular focus, each review found that the provision of psychological therapy supported some improvements in clinical outcomes in the acute context. Identified improvements included a reduction in depression, anxiety, readmission ratings, as well as improvements in psychosis-related symptoms (Barnicot et al., 2020; Paterson et al., 2018; Wood et al., 2020). At the same time, these reviews acknowledged included studies were of predominantly poor to moderate quality, and that their conclusions were limited by the overall lack of methodological rigour (Barnicot et al., 2020; Paterson et al., 2018; Wood et al., 2020). Overall, these findings point to what appears to be an emerging evidence base in support of psychological interventions in the acute inpatient setting, whilst identifying the need for further research in this area.

On this issue, The British Psychological Society and The Association of Clinical Psychologists collectively suggest there is sufficient and growing evidence to support the use of psychological interventions in the acute care system, and recommend that interventions are made available individually, through group format, or to the wider system (BPS & ACP-UK, 2021). Whilst the evidence supporting the use of psychological interventions in the acute setting has been reviewed more generally

(Barnicot et al., 2020; Paterson et al., 2018; Wood et al., 2020), little is known about the effectiveness of group-based interventions.

Group-based psychological interventions in the acute setting

To the best of my knowledge, a systematic evaluation of heterogeneous group-based psychological interventions in the acute setting has not been published. A scoping review including all formats of intervention found that groups were widely used as a mode of therapy delivery in the acute setting (Jacobsen et al., 2018). However, whilst groups were more frequently implemented than individual interventions, they were less likely to be evaluated using a randomised controlled design (Jacobsen et al., 2018). The authors considered the potential methodological challenges that may have contributed to this situation (Jacobsen et al., 2018). They suggested that group interventions may present ethical complexities such as where they are limited to certain patient groups, and highlighted the potential risk of cross-contamination effects between intervention and control groups when delivered within the same inpatient setting (Jacobsen et al., 2018). The overall lower quality of published group-based studies helps to explain their relative absence from systematic reviews that have employed more stringent inclusion criteria, being limited to controlled designs (Barnicot et al., 2020; Paterson et al., 2018; Wood et al., 2020).

The most recent review looking at group-based psychological interventions in the psychiatric inpatient setting was published in 2006 (Kösters et al., 2006). Based on a meta-analysis of outcomes taken from 108 studies, Kösters et al., concluded group-based psychotherapy provided a clear additive benefit to treatment as usual, with small-medium effect. Whilst these findings were encouraging, this review included studies from all psychiatric inpatient settings, and the average duration of interventions was not reported. The relevance of the conclusions taken from this review were therefore unclear in relation to short-term and high-turnover inpatient settings, noting that acute admissions in the UK average at around three weeks in duration (The Kings Fund, 2017; Wood et al., 2019a).

Considering the qualitative literature, psychologists have explored the importance and value of groups as a format of intervention in the acute inpatient setting (Wood et al., 2019a). The use of stand-alone group-based sessions has been set out as a recommendation, a potential solution to the provision of psychological therapy in the face of high patient turnover (Wood et al., 2019a).

It would seem group-format interventions are commonly used in the acute inpatient setting to deliver psychological therapy (Jacobsen et al., 2018). However, due to the lower quality of group-based studies, they have tended to be excluded from systematic reviews assessing the effectiveness of psychological interventions in the acute setting. Where group-based designs have been included in systematic reviews, their findings have been combined with the majority individual-based intervention designs, and analysed according to therapeutic modality (Barnicot et al., 2020; Paterson et al., 2018; Wood et al., 2020). Overall, there has been limited systematic assessment of group-based psychological interventions in the acute inpatient setting, and therefore little is known regarding their effectiveness or feasibility.

Group-based psychological interventions

Given the lack of group-based research conducted in the acute setting, it is useful to consider the evidence supporting the use of groups more widely. The Scottish Matrix provides a comprehensive overview of the evidence supporting different psychological interventions for different clinical presentations (NES, 2023). Across summarised findings, individually delivered interventions are widely recommended, with group-based interventions recommended in only a minority of circumstances (NES, 2014, 2023). A comparable picture can be observed across American Psychological Association (APA)

and National Institute for Health and Care Excellence (NICE) clinical guidelines (Rosendahl et al., 2021). This indicates there is an established evidence base supporting the use of individual-format interventions for the treatment of specific clinical presentations, according to sufficiently rigorous, high-quality research. The relative absence of group-format interventions across guidelines could suggest that groups are less effective than individual alternatives, or alternatively that they have been less rigorously or extensively researched.

Advocates of group-based interventions argue that groups provide an effective alternative to individual interventions for the treatment of a wide range of difficulties (Burlingame et al., 2016; Kealy & Kongerslev, 2022; Lo Coco et al., 2015; Rosendahl et al., 2021). Based on their meta-analysis, Burlingame et al., challenged the assumption that group interventions are inferior to an individual format, and reported that when identical treatments, patients, and doses were compared 'individual and group formats produced statistically indistinguishable outcomes' (2016, pg.457). Rosendahl et al. synthesised the findings of 11 meta-analytic reviews of group-based psychological interventions (2021). They surmised that group treatments achieved large effect sizes when compared to no-treatment and found a negligible difference between groups and alternative interventions, including individual therapy. Based on these findings, they suggested the relative absence of group-based interventions from clinical guidelines was surprising, and argued this circumstance demanded explanation (Rosendahl et al., 2021 pg. 56). As well as considerations in relation to the effectiveness of groups, their relative efficiency in terms of time and cost may support the argument for their wider application, amid significant pressures facing services (Burlingame et al., 2016; Cuijpers et al., 2014; Rosendahl et al., 2021; Yalom & Leszcz, 2020). A further value of group-based interventions has been argued to relate to the actual mechanisms of the group, whereby therapeutic benefit may be derived from the group, recognising the value of shared experience. For example, through the mutual provision of support, or where patients can witness the progression of others and envision similar progression for themselves (Malhotra & Baker, 2022; Yalom & Leszcz, 2020). On the other hand, several limitations have been associated with group-based psychological interventions. Fundamentally, running a group is a more complex undertaking than the provision of individual psychotherapy (Burlingame et al., 2016). The development and running of a group presents services with additional logistical challenges, such as the need for an appropriate environment and staff training. Furthermore, the group literature highlights that participants must be able to engage with the processes of the group (Yalom & Leszcz, 2020), conditions that may be challenging to achieve in circumstances involving a high-turnover of acutely unwell patients. Whilst groups may be comparably effective to individual interventions in some circumstances (Burlingame et al., 2016; Rosendahl et al., 2021), the parameters surrounding which group-based therapeutic modalities are most effective, and under what circumstances, remain unclear (Lo Coco et al., 2015). This wider lack of clarity on the evidence supporting group-based interventions perhaps explains their relative absence from clinical guidelines.

The current review: groups in the acute context

Psychological interventions have been recognised as an important component of acute inpatient care (BPS & ACP-UK, 2021; RCPsych, 2019). However, they have not been made consistently available (Evlat et al., 2021). Whilst the cumulative evidence supporting their use in the acute setting is undoubtedly growing (Barnicot et al., 2020; Paterson et al., 2018; Wood et al., 2020), the limited evidence-base supporting their use has been described as a barrier to their wider implementation (Evlat et al., 2021). Improved understanding of the available evidence will help inform the development of psychological interventions in the acute setting.

Group-based approaches have been recommended as a mode from which to deliver psychological therapy in the acute context (BPS & ACP-UK, 2021), and may already be a widely implemented approach (Jacobsen et al., 2018). Groups may prove to be an efficient and effective way deliver

psychological interventions in the acute setting, with evidence from other settings supporting their wider application (Burlingame et al., 2016; Rosendahl et al., 2021). To the best of the authors' knowledge, group-based interventions have not been systematically reviewed in the acute context to date, and therefore relatively little is known about their effectiveness or feasibility in this setting. To better understand the available evidence supporting the use of groups in the acute inpatient setting, a systematic review of the literature is proposed.

Objectives:

1. To collate the published quantitative literature assessing group-based psychological interventions conducted in the acute setting
2. To review how group-based interventions have been adapted to the acute setting
3. To assess the effectiveness of group-based interventions in the acute setting
4. To assess the feasibility of group-based interventions in the acute setting

Method

The systematic review was registered prospectively on Prospero (CRD42023467366). The design of this systematic review was informed by PRISMA 2020 guidelines (Page et al., 2021). Please see Appendix 13. for the protocol document.

Search strategy

A scoping review was initially conducted involving databases Prospero (registered Systematic Reviews), Embase, MEDLINE, CINAHL Plus, PsycINFO, and Google Scholar, to establish that no comparable systematic reviews had been conducted on this topic. Subsequently, scoping searches were used to establish appropriate search terms, aiming to balance breadth and specificity. Medical Subject headings (MeSH) were utilised to identify and refine keywords choices. Three sub-groups of terms were identified including: 1) Population (*inpatient admitted to acute inpatient setting*), 2) intervention type (*psychological intervention*), and 3) intervention format (*group*) (See table 1). The systematic search included databases Embase, MEDLINE, CINAHL Plus, and PsycINFO, using search terms as defined in table 1. Limitations were placed on the searches to exclude studies published in languages other than English. The review was not limited to controlled designs, as it was anticipated that this would have resulted in a small number of identified studies. Extracted studies were collated using Covidence systematic review software.

Table 1. Search terms

Population	<i>(inpatient* OR "in patient**" OR hospitali* OR admitted OR "acute phase") AND ("psychiatri* unit*" OR "psychiatr* ward*" OR "intensive unit*" OR "psychiatri* intensive" OR "mental health unit*" OR "institution* setting*" OR "inpatient unit*" OR "in patient unit*" OR "inpatient ward*" OR "in patient ward*" OR "inpatient setting*" OR "in patient setting*" OR "medical centre*" OR rehospitai*" OR "inpatient treatment" OR "in patient treatment" OR "acute phase" OR "psychiatric inpatient*" OR "psychiatric in patient*")</i>
	AND
Intervention type	<i>("cognitive behavio*" OR "cognitive therap*" OR "behavio* therap*" OR "cognitive analytic therap*" OR "acceptance and commitment" OR "compassion* focus*" OR mindfulness OR "treatment program*" OR "dialectic* behavio*" OR "schema focus*" OR "schema therap*" OR "interpersonal therap*" OR "interpersonal psychotherap*" OR "mentali* based therap*" OR "systemic therap*" OR "metacognitive" OR "meta cognitive" OR "psychological</i>

<i>intervention*</i> OR <i>psychological treatment*</i> OR <i>self help</i> OR <i>group* therap*</i>	
<i>OR group* psycho*</i> OR <i>group* treatment*</i> OR <i>psycho* therap*</i>)	
AND	
Intervention format	<i>group*</i>

*Asterix * indicates where truncation of terms was used*

Inclusion and exclusion criteria

The review identified studies involving group-based psychological interventions in the acute inpatient setting. Inclusion criteria: 1) Participants were working-age adults (18 - 65 years). 2) Participants attended a group-based psychological intervention whilst admitted to an acute inpatient setting. 3) Group-based interventions were based on an evidence-based psychological intervention. 4) Studies involved a quantitative design (including but not limited to: randomised and non-randomised studies, cohort studies, case control studies, pre/post, or case series designs). 5) Studies included an outcome measure. 6) Studies were published in a peer-reviewed journal. 7) Studies were published in English. 8) Studies were published at any date. Exclusion criteria: 1) Studies involved children (under 18), or older adults (over 65). 2) Studies were based in non-acute mental health settings (e.g. forensic, rehabilitation, residential, outpatient). 3) Studies where the diagnostic focus was a substance use disorder or non-psychiatric disorder. 4) Studies involved individual case study or qualitative designs. 5) Studies were unpublished.

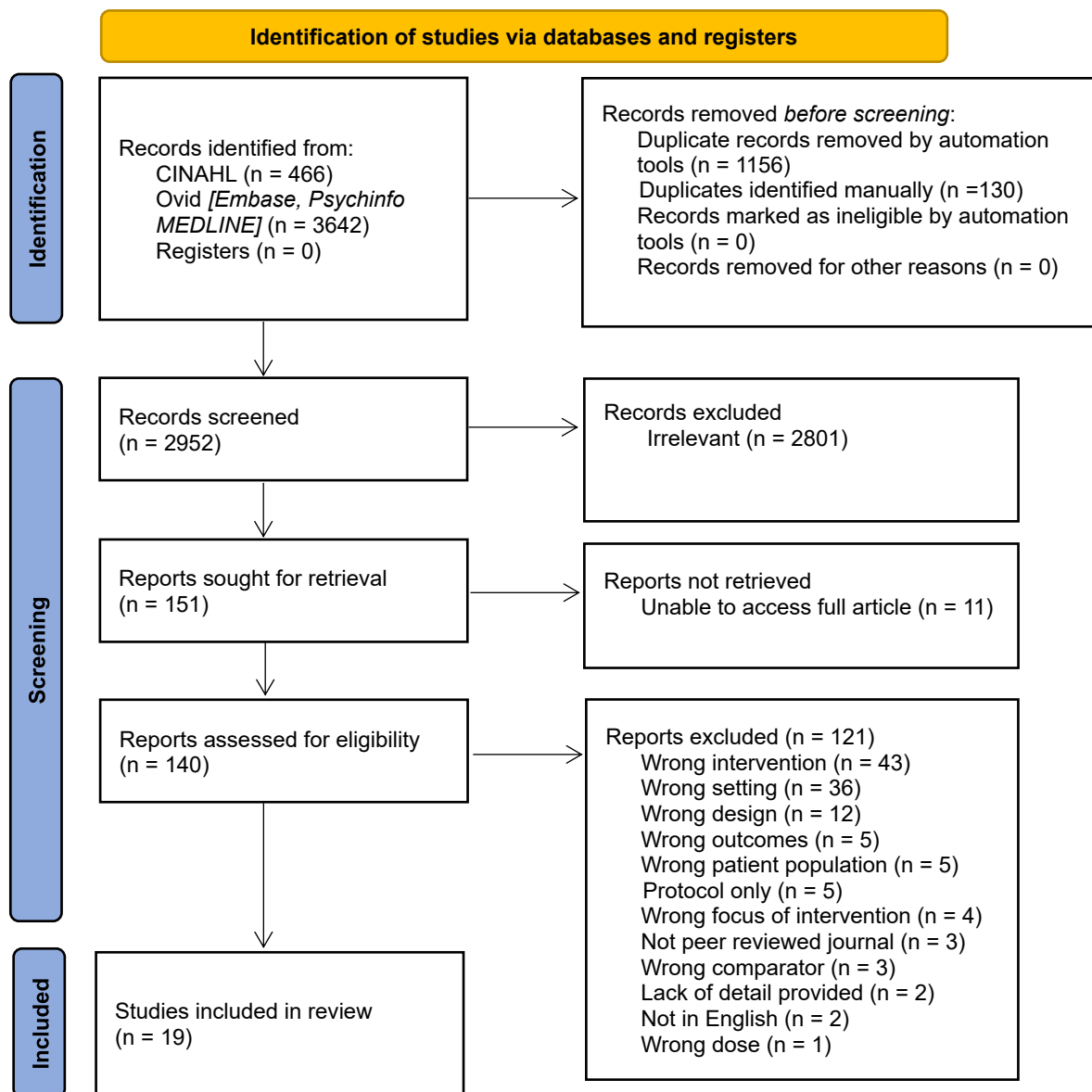
The main outcome of interest was the effect of group-based psychological interventions on clinical outcomes, for working-age adults admitted to the acute inpatient mental health setting. Comparison could include a separate intervention, treatment-as-usual, or pre and post data. Outcome measures could include any formal outcome measures (e.g. measures assessing symptoms or distress) and/or alternative measures of clinical outcomes (e.g. re-admission rates, admission length). Secondary outcome measures included outcomes that related to group feasibility and engagement.

Selection of studies

Searches were conducted on 8/11/2024 (see figure 1). Searches identified a total of 4108 articles. Duplicate records (n = 1156) were removed by automation tools End Note and Covidence. Of the remaining 2952 records, titles and abstracts were screened for eligibility, resulting in the identification of a further 130 duplicate records. 140 articles were extracted for a full article review. Of these, 19 met inclusion and exclusion criteria and were included in the analysis. Articles were excluded for several reasons, including the type of intervention (n=43), the setting (n=36), and the type of design (n=12).

Screening at both stages was completed by the first author and a co-reviewer. There was a 92% rate of agreement between reviewers. Cohens Kappa (*k*) statistic was used to assess inter-rater reliability (*k* = 0.3025) assessed as 'fair' (McHugh, 2012). At the full article screening stage, there was a 97% rate of agreement, and a high degree of inter-rater reliability was observed (*k* = 0.834) (McHugh, 2012). Any conflicts were resolved by discussion.

Figure 1. PRISMA flowchart



Data extraction

Following identification of relevant full text articles, data was extracted from each included study. Two articles reported on follow up data from the same original study, and were combined in the analysis (Veltro 2006, 2008). Extracted data and quality assessment findings were organised into tables, as below:

- a. Table 2. Study characteristics: Study context (*design, country, funding*), intervention (*modality, open/closed, number of sessions, delivered by, group size*), comparison, inclusion and exclusion criteria, integrity of intervention, sample size (*including attrition, power analysis*), outcome measures, time-points, and analyses (*strategy, intention to treat analysis*)
- b. Table 3. Participant characteristics: Gender, age and diagnoses
- c. Table 4. Quality assessment of studies
- d. Table 5. Study results: Main study findings and measures of effect

Data was organised by study design, including randomised controlled trials, clinical control designs, cohort, and pre-post designs. Effect sizes of interventions were reported using Cohens *d* or partial eta-squared (η^2), when available.

Quality assessment

The Quality Assessment Tool for Quantitative Studies EPHPP tool was used to assess the quality of included studies (Thomas et al., 2004). This tool was chosen due to its ability to assess the quality of a range of different quantitative designs. The tool utilises eight categories including selection bias, study design quality, confounders, blinding, data collection methods, withdrawals and dropout rates, intervention integrity and analyses. Ratings of weak, moderate and strong were allocated for each category, and for each study overall.

The main reviewer appraised all included studies, and the co-reviewer appraised a random selection of included studies ($n = 6$), to assess inter-rater reliability. There was an 85% chance of agreement. Inter-rater reliability was $k = 0.59$ using Cohen's Kappa (k) statistic, indicating a moderate level of inter-rater reliability (McHugh, 2012). Discrepancies within each category and overall ratings were discussed, to reach consensus.

Data synthesis

Following extraction of data, meta-analysis was excluded as an appropriate synthesis approach due to heterogeneity and low quality of included studies, factors that would have limited the credibility of findings (Boland et al., 2017; Higgins et al., 2019). Synthesis without meta-analysis guidelines were used to guide the data synthesis process (Campbell et al., 2020). During this process, a range of alternative synthesis methods were considered (see Higgins et al., 2019), with challenges identified relating to the variable clinical outcome measures, and limited number of studies providing intent-to-treat (ITT) analysis data. To assess the effect of group-based interventions on clinical outcomes, the minority of studies that had applied ITT analysis were assessed separately, involving the conversion of effect size data which was displayed in a tabulated format (table 6) and forest plot (figure 2). The significant limitations on the strength of conclusions based on this approach were acknowledged, notably in relation to the variability of outcome measures. A narrative synthesis was used to assess findings across all included studies, with findings from ITT based analyses given priority when considering the overall evidence in support of group-based interventions.

Results

Description of included studies

Of the 18 included studies, there were five randomised controlled trials (including two described as pilot and feasibility designs), four clinical control designs, four retrospective cohort designs, and five pre-post studies (see table 2). The largest proportion of studies were conducted in Germany ($n=6$), followed by the UK ($n=5$), and Canada ($n=2$). The remaining studies were conducted in Italy, the USA, France, Japan,

and the Republic of Ireland (n=1 respectively). The total sample of participants from across the studies was n=2319, ranging from n=8 (Nenadić et al., 2017) to n=427 (Veltro et al., 2006, 2008), with a median of n=57.5.

Outcome data predominantly involved the use of valid and reliable clinical outcome measures, although the choice and focus of measures varied significantly between studies (displayed in table 2 & 5). A minority of studies included alternative measures, such as readmission and treatment completion rates (Nikolitch et al., 2016; Veltro et al., 2006, 2008). Eight studies reported some secondary outcome measures on group feasibility or engagement, for example through the collection of feedback questionnaires or attendance measures.

All participants were patients recruited from the acute inpatient setting who had attended a group-based psychological intervention (see table 3). The mean age of participants was 38. Six of the 18 studies included a naturalistic transdiagnostic acute inpatient sample. The remaining 12 studies required specific diagnostic criteria to be met to merit inclusion. These diagnostic sub-groups included schizophrenia spectrum disorder (n = 5), borderline personality disorder (n = 2), depression or mood disorder (n = 2), deliberate self-harm (n = 2), and anxiety (n = 1). Whilst these studies placed some diagnostic limits on who could attend the group (n=12), comorbid difficulties were generally permitted. This was with the exception of two designs that excluded participants if psychotic symptoms were present (Bernard & Walburg, 2020; Nenadić et al., 2017).

Description of interventions

Across studies, group interventions varied significantly including in relation to group frequency, number of participants, duration of the group, duration of the group-programme, therapeutic modality, and facilitators.

The frequency of groups ranged from five per week to one per week. The largest proportion of groups operated biweekly (n=7), followed by five per week (n=5). The remaining studies ran groups three or four times per week (n=5), with a single study operating once weekly (Owen et al., 2015). Most studies involved groups lasting from between 45 minutes to an hour and a half (n=13). Outliers included a two-hour biweekly DBT group (Bernard & Walburg, 2020), and two 10-minute-long groups, both involving mindfulness-based interventions (Moussaoui et al., 2022; Nikolitch et al., 2016).

Group size was not consistently reported across studies, with several studies reporting maximum possible numbers, and others actual attendance. Group sizes ranged from as low as three (Moussaoui et al., 2022) to as high as 20 (Nikolitch et al., 2016), with a median of n=8.5.

There was almost equal division to 'open' or 'closed' designs. Within an 'open' design, participants could commence or leave the group programme at any time (n=8). Within a 'closed' design, a fixed number of participants attended for the duration of the programme (n=7). The three remaining studies operated a semi-closed/open design, where new participants could join within set parameters. Closed or semi-closed/open programmes generally offered a fixed total number of sessions. The longest programmes involved sixteen groups over eight-weeks (Bechdolf et al., 2004; Haga et al., 2022), with the shortest offering four groups over two (Bernard & Walburg, 2020; Fife et al., 2019). The most intensive programme involved 24 sessions over six weeks (Gibson et al., 2014). In contrast, the eight studies operating an 'open' design either operated a rotating series of groups (e.g. Hauschildt et al., 2022; Samaan et al., 2021; Stroud & Griffiths, 2021), or applied the same format each time (e.g. Forsyth et al., 2010; Nikolitch et al., 2016; Veltro et al., 2006, 2008), with either option allowing for groups to be attended as a stand-alone session.

Across the eighteen studies, groups were facilitated by a variety of different professionals, including psychologists, therapists, nurses, psychotherapists, and occupational therapists. One group involved a facilitator who had personal experience of inpatient care (Owen et al., 2015). Two studies reported student or trainee facilitation (Moussaoui et al., 2022; Owen et al., 2015). Groups were predominantly run by two or more facilitators, with a smaller proportion involving a single facilitator (n = 5).

Several therapeutic modalities were applied across the studies. Most frequently, cognitive-behavioural therapy groups were described (n=7), followed by mindfulness-oriented interventions (n=3), and metacognitive therapy (n=3). The remaining studies were based on dialectical-behavioural therapy (n=2), compassion-focused therapy, schema therapy and emotion-focused therapy (n=1 respectively). The most frequently applied comparison was treatment-as-usual (n=5), followed by acceptance and commitment therapy, occupational therapy, psychoeducation, euthymic therapy, and individual therapy (n=1 respectively). The remaining studies compared pre-post outcome data taken from the same cohort (n=8).

There were some patterns noted between therapeutic modality and design. Mindfulness-based interventions were more likely to report an unstructured design and a short group duration. Both metacognitive-based and dialectical-behavioural interventions described a more structured approach, targeting a specific diagnostic group. All three metacognitive studies involved biweekly groups, although differed in their use of semi-closed and open approaches. Both dialectical behavioural groups operated within a closed group design, but varied significantly in intensity, with one offering 24 sessions (Gibson et al., 2014) and the other just four (Fife et al., 2019). On the other hand, there were no apparent patterns amongst the seven cognitive behavioural designs which varied considerably in their application. Studies included examples of both closed (n=2) and open format (n=5). Frequency ranged from weekly (Lynch et al., 2011) to five times weekly (Forsyth et al., 2010; Veltro et al., 2006a, 2008). More than half of the cognitive behavioural groups targeted a transdiagnostic patient group (n=4), although this was not exclusively so (e.g. Bechdolf et al., 2004; Owen et al., 2015, Dodd & Wellman, 2000).

The characteristics for each study are set out in more detail below, displayed in table 2. Patient characteristics for each study are displayed in table 3.

Table 2. Study characteristics

Author, year	Study context	Intervention (I)	Comparison (C)	Integrity	Sample size	Outcome measure/s	Time points	Analyses
	Design, country, funding	Modality, open/closed, number of sessions, delivered by, group size			Attrition, Power analysis			Strategy Intention to treat (ITT)
Randomised control trial								
(Haga et al., 2022)	<u>Pilot RCT</u> Unblinded Stratified randomisation Japan Funding not reported	MCT + OT Semi-closed 45-60 minutes Biweekly 16 sessions By OT Group size:12	OT only Group and individual, variable	Manualised Integrity not reported	N = 24 MCT: n = 12 OT: n = 12 Attrition: MCT: n = 4 (16.6%) OT: n = 4 (16.6%) Power analysis: not reported	BACS BICS PANSS IMI CSQ Readmission rates	Pre, post Readmission at one year	Two way repeated ANOVA for analysis of assessment scores Chi-square test to compare readmission rates
(Moussaoui et al., 2022)	<u>Feasibility RCT</u> Assessor blinded Simple randomisation Canada Funding not reported	MOI + TAU Open 10-minute Five per week By research assistants Group size: three or four	TAU	No manual Facilitators trained and regular supervision Integrity not reported	N = 20 MOI: n = 11 TAU: n = 9 Attrition: MOI: n = 2 (10%) TAU: n = 1 (5%) Power analysis: not reported	Enrollment rate Retention rate Completion rate BPRS EQ-5D AIS CAMS-R	Pre, post	Descriptive statistics for feasibility outcomes Mann Whitney U tests for analysis of assessment scores
(Hauschildt et al., 2022)	RCT Partial blinding	D-MCT Open	ET 60 minutes	Manualised	N = 75 D-MCT: n = 38 ET: n = 30	HDRS BDI DAS	Pre, post, three months	ANCOVAs for analysis of assessment scores

	Simple randomisation	60 minutes	Biweekly	Therapists trained and supervised	Attrition: <u>D-MCT:</u> n = 10 (26 %) <u>ET:</u> n = 8 (21%)	MCQ-30 Questionnaire		ITT analysis & actual intervention analysis
	Germany	Biweekly		Integrity not reported				
	Funding - Universitätsklinikum Hamburg-Eppendorf	Eight sessions			Power analysis: 52 needed			
		By two therapists						
		Group size: not reported						
(Böge et al., 2021)	RCT	MOI and TAU	TAU	Manualised	N = 40 MOI: n = 21 TAU: n = 19	SMQ CHIME PANSS DASS PSP CFQ Quality of life	Pre, post, three months	Descriptive statistics for analysis of retention rate
	Rater blinded	Closed		Integrity not reported				
	Simple randomisation	60 minutes			Attrition: MOI: n = 8 (38%) TAU: n = 12 (63%)			Chi square and t- tests for analysis of assessment scores
	Germany	Three per week						
	Funding not reported	12 sessions			Power analysis: not reported			
		By psychotherapist & psychologist						
		Group size: five						
(Bechdolf et al., 2004)	RCT	CBT group	PE group	Protocol based	N = 88 CBT: n = 40 PE: n = 48	PANSS 4-point rating scale Relapse criteria Re-hospitalisation	Pre, post, six months	T-tests and two tailed t-tests to assess effect of treatment for dependent samples
	Unblinded	Closed	60-90 minutes	Integrity not reported				
	Simple randomisation	60-90 minutes	Weekly		Attrition: CBT: n = 9 (22.5%) PE: n = 8 (16.7%)			Two tailed ANCOVA to assess between intervention differences
	Germany	Biweekly						
	Funding not reported	16 sessions			Power analysis: not reported			Chi Squared tests to assess readmission effects
		By psychiatrist or cohort psychologist						
		Group size: eight						ITT analysis
Clinical control								

(Samaan et al., 2021)	Clinical effectiveness trial	CBT group	ACT group	Protocol based	N = 206 CBT: n = 106 ACT: n = 100 Attrition: CBT: n = 23 (22%) ACT: n = 31 (31%)	ADS-k MADRS ISR SWLS ZUF-8	Pre, post, six month	A Pillai's trace, two-way MANOVA was used to assess effect of time on scores
	Rater blinded	Open	50 minute sessions	Sessions were recorded and assessed for integrity				A two way ANOVA was used to assess the effect of time on SWLS
	Partial randomisation	50 minute sessions	Biweekly		Power analysis: 154			ITT analysis
	Germany	Biweekly						
	Funding - Humbolt University	By 1x therapist per group	Group size: not reported					
(Bernard & Walburg, 2020)	Non randomised trial	EFT group	Individual therapy	Protocol based	N = 24 EFT: n = 12 IT: n = 12	HADS DERS CERQ TAS UPPS-P	Pre, post, one month	Mann-Whitney U test and repeated measures Friedman ANOVA were used for the analysis of non-parametric assessment scores
	Non-blinded	Closed	60 minutes	Integrity of intervention not reported	Attrition: N = 0			
	France	120 mins sessions	Biweekly		Power analysis: not reported			
	Funding not reported	Biweekly						
		Four sessions						
		By MSc student						
		Group size: 12						
(Owen et al., 2015)	Non randomised trial	CBTp group	TAU	Manualised	N = 113 CBTp: n = 71 TAU: n = 42	CORE-10 MHCS PSYRATS Satisfaction questionnaire	Pre, post, one month	ANOVA's for analysis of assessment scores both between and within groups
	Non blinded	Closed		Facilitators received training and supervision	Attrition (by follow up) CBTp: n = 46 (65%) TAU: n = 29 (69%)			ITT analysis
	UK	90 minutes		Integrity of intervention not reported	Power analysis: not reported			
	Funding not reported	Weekly						
		Four sessions						
		By trainee clinical psychologist, service user, & ward staff						
		Group size: eight						

(Gibson et al., 2014)	Non randomised trial	DBT + TAU	TAU + waitlist	Manualised	N = 103 DBT: n = 82 TAU: n = 21	DSI DERS CERQ	Pre, Post, six weeks	Paired t-tests to measure change over time
	Non-blinded	Closed		Integrity of intervention not reported	Attrition: DBT: n = 62 (77.5%) TAU: not reported			One-way ANCOVA's to assess between group differences
	Republic of Ireland	60 minutes						MANCOVA for overall multivariate differences
	Funding not reported	Four per week			Power analysis: not reported			Pearson correlation to assess pre-post differences
		Three x two week cycles: 24 sessions						Repeated measure ANOVA to assess DSH score at follow up
		By clinical psychologists						ITT analysis
		Group size: not reported						
Cohort								
(Stroud & Griffiths, 2021)	Retrospective cohort	CFT group	TAU	Pre-designed programme	N = 197 CFT: n = 90 TAU: n = 107	CORE-OM Likert scales	Pre, post	Wilcoxon and Mann Whitney U tests were used to analyse data
	Self-allocation	Open		Integrity not reported	Attrition: CFT: n = 81 (90%) TAU: n = 94 (87%)			
	UK	60minute session						
	Funding - 'no information to disclose'	Five per week						
		Six sessions rotated						
		By facilitators unspecified						
		Group size: not reported						
(Nikolitch et al., 2016)	Retrospective cohort	MOI + TAU	N/A	Not manualised	N = 40 Attrition n = 3 (7.5%)	Likert scale mood Completion rate Adverse events	Pre, post	Chi squared analyses were used to analyse
		Open						

	Canada	10 minutes		Integrity of intervention not reported				dichotomous variables
	Funding: 'no specific sources'	Three per week						Mann-Whitney U tests were used to analyse continuous variables
		By OT						A Fishers exact test was used to analyse MOI variable
		Group size: 10-20						
(Forsyth et al., 2010)	Retrospective cohort	CBT group	N/A	Based on CBT book	N = 427	ATQ BDI-II	Pre, post	Paired t-tests were used to analyse pre/post results
	UK	Open group		Integrity of intervention not reported	Attrition: N/A			
	Funding not reported	60 minutes			Power not reported			
		Five per week			Groups attended: Mean 3.1 (2.4)			
		By psychiatric nurse specialist						
		Group size: variable						
(Veltro et al., 2006, 2008)	Retrospective case control	CBT group	N/A	Manualised	Year (Y)	Readmissions Ward atmosphere Satisfaction questionnaire Restraint Length of stay Cost / income	Pre intervention data (Y0) compared to post intervention data from Y1, Y2, Y3, Y4	ANOVA's were used to assess parametric variables
	Italy	Open group		Integrity of intervention not reported	Y0 n = 150 Y1 n = 171 Y2 n = 181 Y3 n = 129 Y4 n = 102 Total n = 733 90% admissions attended			Chi squared tests were used to assess non parametric variables
	Funding not disclosed	90 minutes						
		Five per week						
		By professionals, various						
		Group size: seven to 14						
Pre-post								

(Gussmann et al., 2023)	Pre-post single arm Germany Funded by the Max Planck Institute of Psychiatry and the Alfred Golombek Foundation.	MCT Semi-open 60 minutes Biweekly Three modules, nine sessions By facilitators unspecified Group size: seven	N/A	Predesigned programme Integrity not reported	N = 37 Attrition: n = 4 10.8% Recommended sample: 20	Likert scale PANSS PSYRATS GAF CGI WHODAS-2.0 BCIS CFQ Rehospitalisation	Baseline, pre, post each module, post intervention 1 year (rehospitalisation)	Descriptive analysis for feasibility and acceptability measures Intraclass correlation coefficients for pre-post comparisons, using linear mixed models AI analysis
(Fife et al., 2019)	Pre-post single arm feasibility trial UK Funding: University of Essex	DBT + TAU Closed 60 minutes Biweekly Four sessions By clinical psychologists Group size: not reported	N/A	Predesigned programme Integrity not reported	N = 24 Attrition: N = 15 (62%) Recommended sample: 24-50	Attendance ISAS DTS Feedback Adverse events	Pre, post	Descriptive statistics were used to analyse results
(Nenadić et al., 2017)	Pre-post single arm, pilot Germany Funding not reported	ST + TAU Closed 45-50min Biweekly Over six-seven weeks	N/A	Predesigned programme Integrity of intervention not reported	N = 8 Attrition N = 1 (12.1%)	SMI YSQ-3 BSCL-53-S ZUF-8 GCQ-S	Pre, post	A MANOVA with repeated measures was used to analyse changes over time Exploratory correlation analysis

		By psychiatrist, psychotherapist, and co-therapist						
		Group size: nine						
(Lynch et al., 2011)	Pre-post, with comparison USA Funding not reported	CBT group Every weekday Open group 60 minutes Five per week By ward staff and psychology intern Group size: variable	Did not attend CBT group	Pre-designed programme Staff training and supervision Integrity of intervention not reported	N = 137 CBT: n = 78 Attrition: n = 59 (43%) 87% attended n = 3 or above	OQ-45 Follow up questions	Pre, post, 1 month	Repeated measures ANOVAs were used to analyse pre and post scores
(Dodd & Wellman, 2000)	Pre-post, pilot study UK Funding not reported	CBT + TAU Semi-open 75 minutes Three per week By staff development nurse, + OT or PT Group size: unreported unclear	N/A	Manualised Integrity of intervention not reported	N = 23 Attrition by post measure n = 12 52%	BAI ADL Feedback questionnaire	Pre, post	A two tailed Wilcoxon Z was used to compare pre and post scores Descriptive statistics were used to describe satisfaction feedback

**Abbreviated terms*

Assessment measures: AIS: Athens Insomnia scale (Soldatos et al., 2000), ADS-k: Allgemeine Depressions-Skala, Kurzversion (Lehr et al., 2008), ATQ: Automatic thought questionnaire (Hollon & Kendall, 1980), BAI: Beck Anxiety Inventory (Beck et al., 1988), BACS: Brief assessment of cognition in Schizophrenia (Keefe et al., 2004), BCIS: Beck cognitive insight scale (Beck et al., n.d.), BDI-II: Beck depression inventory II (Beck, A.T., Steer, R.A., & Brown, 1996), BPRS: Brief psychiatric rating scale (Overall & Gorham, 1962), BSCL-53: Brief symptom checklist (Franke G, 2017), CAMS-R: Cognitive and Affective Mindfulness Scale- Revised (Feldman et al., 2022), CERQ: Cognitive Emotion Regulation Questionnaire (Garnefski & Kraaij, 2007), CFQ: Cognitive fusion questionnaire (Gillanders et al., 2014), CGI: Clinical Global Impression Scale (Busner & Targum, 2007), CORE-10: Clinical outcomes in routine evaluation (Barkham et al., 2012), CSQ: Client satisfaction questionnaire (Larsen et al., 1979), DAS: Dysfunctional attitudes scale (Weissman, 1979), DERS: Difficulties in Emotion Regulation Scale (Hallion et al., 2018), DSI: Deliberate Self Harm Inventory (Gratz, 2001), DTS: Distress tolerance scale (Simons & Gaher, 2005), EQ-5D: Euro-Quality of Life (Rabin & De Charro, 2001), GAF: Global assessment of functioning (Aas, 2010; McDowell & Newell, 1987), GCQ-S: Group Climate Questionnaire-Short (MacKenzie, 1983), HADS: Hospital Anxiety and Depression Scale (Zigmond & Snaith, 1983), HDRS-17: Hamilton depression rating scale (Williams et al., 2008), IMI: Intrinsic motivation inventory (Choi et al., 2010), ISR-ICD-10 Symptom rating (Tritt et al., 2008), ISAS: The Inventory of Statements About Self-Injury (Klonsky & Olino, 2008), MADRS: Montgomery-Asperg Depression Rating Scale (Montgomery & Asberg, 1979), MCQ-30: Metacognitive beliefs questionnaire (Clark et al., 2003), MHCS: Mental Health Confidence Scale (Carpinello et al., 2000), OQ-45: Outcome Questionnaire-45 (Lambert et al., 2004), PANSS: Positive and negative symptoms scale (Kay et al., 1987), PSYRATS: Psychotic symptoms rating scale (Haddock et al., 1999), SCL-90-R: Symptom checklist 90 Revised (Derogatis & Savitz, 2000), SMI: Schema mode inventory (Young et al., 2007), SMQ: Southampton Mindfulness Questionnaire (Feng et al., 2022), SWLS: Satisfaction with Life Scale – Adapted scale from Client Satisfaction Questionnaire (Larsen et al., 1979), TAS: Toronto Alexithymia Scale (Leising et al., 2009), UPPS-P: Impulsive Behaviour Scale – short version (Lynam et al., 2006), WHODAS-2.0: World Health Organization Disability Assessment Schedule 2.0 (WHO, 2012), YSQ: Young Schema Questionnaire (Young, 1999), ZUF-8: Questionnaire to evaluate patient satisfaction (Schmidt & Wittmann, 1989)

Interventions: AMG: Anxiety management group, CBTp: Cognitive behavioural therapy for psychosis, CFT: Compassion focused therapy, DBT: Dialectical behavioural therapy, D-MCT: Depression metacognitive training, EFT: Emotion focused therapy, ET: Euthymic therapy, ST: Schema therapy, MCT: Metacognitive training, MOI: Mindfulness oriented intervention, OT: Occupational therapy/ist, PE: Psychoeducation, PT: Physiotherapist, Closed group: same group of participants throughout intervention, Open group: new participants could join throughout intervention

Diagnoses / clinical abbreviation: BPD: borderline personality disorder, ER: Emotional regulation, MDD: Major depressive disorder, SSD: Schizophrenia spectrum disorders, DSM-IV/V: Diagnostic Statistical Manual, ICD-11: International Classification of Diseases

Table 3: Patient characteristics

Author, year	Gender	Age	Diagnostic inclusion criteria
	<i>[% male]</i>	<i>mean, (SD), or range if specified</i>	
Randomised controlled trial			
(Haga et al., 2022)	MCT: 73% OT: 27%	MCT: 44.3 (8.54) OT: 43.3 (7.98)	Schizophrenia spectrum disorder
(Moussaoui et al., 2022)	MOI: 56% TAU: 75%	MOI: 40.22 (17.33) TAU: 38.63 (14.71)	Transdiagnostic
(Hauschildt et al., 2022)	D-MCT: 29% ET: 37%	D-MCT: 41.5 (12.85) ET: 38.8 (12.73)	Major depressive disorder
(Böge et al., 2021)	MOI: 52% TAU: 68%	MOI: 37.1 (12.82) TAU: 42.7 (14.11)	Schizophrenia spectrum disorders
(Bechdolf et al., 2004)	CBT: 45.0% PE: 45.8%	CBT: 32.2 (9.9) PE: 31.4 (10.6)	Schizophrenia spectrum disorders
Clinical control			
(Samaan et al., 2021)	CBT: 39% ACT: 39%	CBT: 40.98 (13.41) ACT: 37.96 (12.57)	Transdiagnostic
(Bernard & Walburg, 2020)	41%	37 (8.36)	Borderline personality disorder
(Owen et al., 2015)	CBTp: 59.2% TAU: 90.5%	CBTp: 42.15 (12.43) TAU: 38.60 (11.65)	Psychotic illness
(Gibson et al., 2014)	DBT: 21.4% TAU: 42.9%	DBT: 38.07 (10.26) TAU: 31.52 (11.23)	Deliberate self-harm
Cohort			
(Stroud & Griffiths, 2021)	DBT: 40%	Range:18-60	Transdiagnostic
(Nikolitch et al., 2016)	47.5%	51.6 (16.6)	Transdiagnostic
(Forsyth et al., 2010)	33%	40.6 (13.2)	Mood disorder
(Veltro et al., 2006, 2008)	Not reported	Not reported	Transdiagnostic
Pre-post			
(Gussmann et al., 2023)	MCT: 43.24%	45.43 (15.09)	Psychotic illness
(Fife et al., 2019)	DBT: 70%	36.3 (8.8)	Deliberate self-harm
(Nenadić et al., 2017)	ST: 12.5%	23.9	Borderline personality disorder
(Lynch et al., 2011)	0% (Female only setting)	35.8 (11.5)	Transdiagnostic
(Dodd & Wellman, 2000)	43.48%	40.6 (1.6)	Anxiety

*See table 1 footnotes for abbreviations

Quality Assessment

The quality assessment ratings of studies are reported in table 4. Studies were predominantly rated as weak (n=14), with a minority meeting the criteria for a moderate rating (n=4). Of the five randomised-controlled trials, two were described as pilot or feasibility studies and involved low participant numbers (n<24).

Overall strengths were noted in the study design and data collection categories. In the design category, randomised-controlled trials and clinical control designs were assessed as strong (n=9), according to the tool guidelines. The remaining studies were assessed as moderate (n=5), or weak (n=4). Studies predominantly rated well on data collection methods, due to the implementation of reliable and valid measures (n=16). One study was rated as moderate, having reported assessment of reliability, but where measure validity was unclear (Veltro et al., 2006, 2008). One study was rated as weak on data collection, due to circumstances where the validity and reliability of data collection methods could not be verified (Nenadić et al., 2017) .

Overall, weaknesses were observed across the remaining categories, including selection bias, confounders, blinding, and withdrawal & dropouts. There was evidence of selection bias across studies, with an almost equal split between weak and moderate ratings. This rating was applied to the sub-group of participants targeted by an individual study, rather than the acute inpatient group overall. One large pre-post design was given a strong rating due to its involvement of a large transdiagnostic cohort with 90% participation rates (Veltro et al., 2006, 2008). On the confounders rating, studies were predominantly found to be weak (n=10), with a minority allocated a moderate rating (n=7). This was in part due to the context of the study, where there were many potential confounders in the form of inpatient treatment-as-usual, with parallel treatments including medication and occupational therapy. Where a moderate rating was allocated, retrospective assessment of potential confounders had occurred, such as comparing medication dosages between groups. One study attempted to minimise the impact of confounders by using a stratified randomisation approach (Haga et al., 2022). Blinding was rarely considered at either the allocation or analysis stage and the vast majority of studies rated poorly on this item (n=14). In circumstances where there was partial evidence of blinding (e.g. at analysis stage only), a moderate rating was allocated (n=3). The criteria for a strong rating were met in one study (Hauschildt et al., 2022). Finally, on the withdrawal and dropout item, most studies were rated as weak (n=12). The remaining six studies met criteria for moderate and strong ratings in equal measure. However, ratings on this item were not indicative of engagement, due to the significant heterogeneity of the studies' intensity, approach to selection, and follow-up.

Of the 18 studies, explicit assessment of intervention integrity was limited. Only one study reported formally assessing intervention integrity (Samaan et al., 2021). Four studies reported including training and supervision to encourage facilitator consistency, and a majority reported following a semi-structured or manualised format (n=16). Two studies, both involving mindfulness-oriented interventions, did not involve a structured approach (Moussaoui et al., 2022; Nikolitch et al., 2016). Across studies, the naturalistic context meant that attribution of change could often not confidently be attributed to the intervention alone, with studies including comparison to treatment-as-usual holding some advantage in this regard (Böge et al., 2021; Gibson et al., 2014; Moussaoui et al., 2022; Owen et al., 2015; Stroud & Griffiths, 2021). The comparison to treatment-as-usual was likely to be less relevant in circumstances where randomisation was not applied, recognising the influence of selection bias (e.g. Gibson et al., 2014; Owen et al., 2015; Stroud & Griffiths, 2021). The risk of attrition bias was present across the majority of included studies. A significant limitation overall related to the lack of intent-to-treat (ITT) analysis (n=5), with two of these five studies providing only partial ITT analysis data.

Table 4. Quality assessment

Author(s)	Selection Bias	Design	Confounders	Blinding	Data collection methods	Withdrawals/dropouts	Global rating
Randomised controlled trial							
(Haga et al., 2022)	Weak	Strong	Moderate	Weak	Strong	Moderate	Weak
(Moussaoui et al., 2022)	Weak	Strong	Moderate	Moderate	Strong	Weak	Weak
(Hauschildt et al., 2022)	Moderate	Strong	Weak	Strong	Strong	Moderate	Moderate
(Böge et al., 2021)	Moderate	Strong	Moderate	Moderate	Strong	Weak	Moderate
(Bechdorf et al., 2004)	Moderate	Strong	Weak	Weak	Strong	Weak	Weak
Clinical control							
(Samaan et al., 2021)	Moderate	Strong	Moderate	Moderate	Strong	Weak	Moderate
(Bernard & Walburg, 2020)	Weak	Strong	Moderate	Weak	Strong	Strong	Weak
(Owen et al., 2015)	Moderate	Strong	Moderate	Weak	Strong	Weak	Weak
(Gibson et al., 2014)	Moderate	Strong	Moderate	Weak	Strong	Weak	Weak
Cohort							
(Stroud & Griffiths, 2021)	Weak	Moderate	Weak	Weak	Strong	Weak	Weak
(Nikolitch et al., 2016)	Moderate	Moderate	Weak	Weak	Weak	Weak	Weak
(Forsyth et al., 2010)	Moderate	Weak	Weak	Weak	Strong	Weak	Weak
(Veltro et al., 2006, 2008)	Strong	Moderate	Moderate	Weak	Moderate	Moderate	Moderate
Pre-post							
(Gussmann et al., 2023)	Moderate	Moderate	Weak	Weak	Strong	Strong	Weak
(Fife et al., 2019)	Weak	Moderate	Weak	Weak	Strong	Weak	Weak
(Nenadić et al., 2017)	Weak	Weak	Weak	Weak	Strong	Strong	Weak
(Lynch et al., 2011)	Weak	Weak	Weak	Weak	Strong	Weak	Weak
(Dodd & Wellman, 2000)	Weak	Weak	Weak	Weak	Strong	Weak	Weak

Table 5. Study results

Author, year	Intervention/ comparison	Outcome measure(s)	Main findings	Effect size
			<i>Within and between group findings</i>	<i>Partial eta squared (η_p^2), Cohens d (d)</i>
Randomised control trial				
(Haga et al., 2022)	MCT+OT vs OT only	BACS BICS PANSS IMI CSQ Readmission rates	<p><u>BACS</u>: Statistically significant within group change pre-post intervention ((F [1, 14] = 7.68, $p = 0.02$), no between groups difference (F [1, 14] = 0.14, $p = 0.71$).</p> <p><u>BCIS</u>: Statistically significant within group change (F [1, 14] = 4.82, $p = 0.04$), no between groups difference ((F [1, 14] = 1.15, $p = 0.30$). Analysis of individual items of the BCIS tool, a significant difference was reported on the 'self-reflection' item with MCT superior ($p=0.03$).</p> <p><u>PANSS</u>: Both groups statistically significant change between pre-post scores ((F [1, 14] = 37.88, $p = 0.00$). No significant difference between groups (F [1, 14] = 0.00, $p = 0.97$). Greater alleviation of symptoms on the general psychopathology item in the MCT group were reported.</p> <p><u>IMI & CSQ</u>: There were no significant differences within or between groups.</p> <p><u>Readmission</u>: The MCT group reported significantly lower readmission rates than OT only ($p=0.046$)</p>	<p><u>BACS</u>: Within groups: $\eta_p^2 = 0.02$ Between groups: $\eta_p^2 = 0.01$</p> <p><u>BCIS</u>: Within groups $\eta_p^2 = 0.08$ (medium) Between groups: $\eta_p^2 = 0.05$</p> <p><u>PANSS</u>: Within groups: $\eta_p^2 = 0.38$ (large) Between groups: $\eta_p^2 = 0.00$</p> <p><u>Moderating effects</u>: At baseline the MCT group took more antipsychotics than the OT group</p>
(Moussaoui et al., 2022)	MOI vs TAU	Enrolment/ retention/ completion rate BPRS EQ-5D AIS CAMS-R	<p><u>Enrolment /retention /completion</u>: 39.22% enrolment rate, 15% attrition</p> <p><u>BPRS</u>: No clinically significant reduction in BPRS for either group. No significant differences between groups ($p=0.42$).</p> <p><u>AIS, EQ-5D, CAMS-R</u>: No significant differences between groups in relation to sleep, quality of life or mindfulness outcomes (AIS $p = 0.09$, EQ-5D $p = 0.27$, CAMS-R $p = 0.27$).</p>	<p><u>Measure of effect</u>: Not reported</p> <p><u>Moderating effects</u>: Some differences in gender and age between groups, significance not reported</p>
(Hauschildt et al., 2022)	D-MCT group vs ET	HDRS BDI DAS MCQ-30	<p><u>HDRS, BDI</u>: A significant reduction in scores for both groups between pre-post, and pre-three month follow up. No significant difference between groups at post (HDRS: (F(1,62) = 0.64, $p = 0.426$), BDI: (F(1,61) = 0.33, $p = 0.566$) or three month follow up (HDRS: (F(1,54) = 0.11, $p = 0.746$) BDI: (F(1,54) = 0.87, $p = 0.356$).</p>	<p><u>HDRS</u>: Between groups post: ($\eta_p^2 = 0.010$) and follow up: ($\eta_p^2 = 0.002$)</p>

	Approval questionnaire		<p><u>DAS</u>: A significantly higher reduction for D-MCT than the ET group at three month follow up ($F(1,54) = 5.70, p = 0.020$)</p> <p><u>MCQ-30</u>: A significant difference on subscale 'need for control' in favour of D-MCT at post treatment ($F(1,60) = 6.38, p = 0.014$) and three months follow up ($F(1,53) = 7.90, p = 0.007$)</p> <p><u>Approval questionnaire Likert scale</u>: D-MCT significantly superior on subitems 'improving understanding' ($p < 0.001$) and 'coping with depression' ($p < 0.001$)</p>	<p><u>BDI</u>: Between groups post: ($\eta p^2 = 0.005$) and follow up ($\eta p^2 = 0.016$)</p> <p>Effect size was described as 'significant' for MDD when no comorbidity</p> <p><u>DAS</u>: Between groups post: ($\eta p^2 = 0.095$) medium</p> <p><u>MCQ</u>: Between groups follow up: 'Need for control' item: ($\eta p^2 = 0.130$) large</p> <p><u>Moderating effects</u>: Comorbidity a moderator, with single MDD benefiting more from D-MCT</p>
(Böge et al., 2021)	MOI+TAU vs TAU	SMQ FMI CHIME PANSS DASS PSP CFQ WHO-Qol	<p><u>SMQ</u>: A significant difference in favour of the MOI group ($F(1,35) = 7.77, p < .05$)</p> <p><u>CHIME</u>: No significant differences between groups ($p = 0.52$)</p> <p><u>PANSS</u>: A significant reduction in positive symptoms for both groups, a large effect for MOI+TAU, medium effect in TAU.</p> <p><u>Other measures</u>: Significant within group improvements for MOI+TAU across remaining measures and sub-items of CFQ. Within group improvements for TAU only identified for positive PANSS, and social functioning</p>	<p><u>SMQ</u>: Between groups post: ($\eta p^2 = 0.18$) large. Effect not given at three month follow up.</p> <p><u>PANSS</u>: A significant reduction in positive symptoms for both groups, a large effect for MOI+TAU, medium effect in TAU.</p> <p><u>Moderating effects</u>: Significant differences between medication regimes, TAU on higher dosages</p>
(Bechdolf et al., 2004)	CBT vs PE	PANSS Compliance scale Relapse Re-hospitalisation	<p><u>Adherence to treatment</u>: CBT – mean attendance 74.37%. PE – mean attendance 80% (total of 8 possible sessions)</p> <p><u>Re-hospitalisation</u>: Re-admission rates lower at 24 months for CBT (37.5%) than PE (59.3) but not significant ($p = 0.114$). Length of stay lower for CBT group (mean = 94 days) than PE group (mean = 163 days) but not significant ($p = 0.224$).</p> <p><u>PANSS</u>: Significant within-group improvement at post and follow-up up (24 months) CBT ($p < 0.05$) and PE ($p < 0.05$). No significant improvement between pre and 24-month follow-up for either group. No significant between-group difference at 24-month follow-up ($p = 0.64$)</p>	<p><u>Measure of effect</u>: Not reported</p> <p><u>Moderating effects</u>: Non identified</p>

Clinical control

(Samaan et al., CBT vs ACT 2021)	ADS-k MADRS ISR SWLS ZUF-8	<p><u>ADS-k, MADRS & ISR:</u> Large within group reductions for both ACT and CBT groups depression and anxiety ratings between pre and post, remaining by follow up, across different measures: ($V = 0.70$, $F(6, 131) = 50.37$, $p < 0.001$). There were no significant between group differences ($p = 0.11$)</p> <p><u>ADS:</u></p> <p><u>SWLS, ZUF-8:</u> A small increase in life satisfaction within both groups at Post: ACT ($d = 1.46$), CBT ($d = 2.01$) and follow up: ACT ($d = 1.13$), pre-post and by follow up on the SWLS measure ($F(2, 135) = 12.89$, CBT ($d = 1.61$) $p < 0.001$). There was no significant difference between groups on the SWLS or ZUF-8 measures ($p = 0.92$)</p> <p><u>MADRS:</u></p> <p>Post: ACT $d = 1.70$, CBT $d = 2.01$ and follow up: ACT ($d = 1.42$), CBT ($d = 1.56$)</p> <p><u>ISR:</u></p> <p>Post: ACT $d = 0.83$, CBT $d = 1.03$ and follow up: ACT ($d = 0.68$) CBT ($d = 0.93$)</p> <p><u>Between group</u></p> <p>Effect sizes were $d > 0.2$ (<i>small effect</i>) at both time-points and across all measures</p> <p><u>ADS</u> ($d = 0.17$, $d = 0.17$)</p> <p><u>MADRS</u> ($d = 0.08$, $d = 0.05$)</p> <p><u>ISR</u> ($d = 0.0$, $d = 0.05$)</p> <p><u>Moderating effects:</u> Non identified</p>
(Bernard & Walburg, 2020)	EFT vs 1:1 CBT HADS DERS CERQ TAS UPPS-P	<p>Significant within group differences for EFT and 1:1 CBT groups across DERS, CERQ, TAS and UPPS measures ($p < 0.001$). No significant change in within group HADS scores.</p> <p><u>Measure of effect:</u> Not reported</p> <p><u>Moderating effects:</u> Non identified</p> <p><u>DERS:</u> At post, EFT had significantly lower emotional regulation difficulties than CBT (EFT $\bar{x} = 59.16$, CBT $\bar{x} = 106.33$, $p < 0.001$), and at follow up (EFT $\bar{x} = 54.33$, CBT $\bar{x} = 106.08$, $p < 0.001$).</p>

CERQ: At post, EFT had significantly lower 'non-adaptive regulation' scores (EFT \bar{x} =27.42, CBT \bar{x} =35.33, $p = 0.004$), and at follow up (EFT \bar{x} =25.92, CBT \bar{x} =36.58, $p = 0.001$). EFT had significantly higher 'adaptive regulation' at post (EFT \bar{x} =72.00, CBT \bar{x} =57.83, $p < 0.001$), and follow up (EFT \bar{x} =78.00, CBT \bar{x} =55.00, $p < 0.001$).

TAS: At post, EFT had significantly lower alexithymia scores than CBT (EFT \bar{x} =40.08, CBT \bar{x} =62.83, $p < 0.001$), and at follow up (EFT \bar{x} =30.50, CBT \bar{x} =57.25, $p = 0.003$).

HADS: No significant differences between groups

UPPS: Between group differences not reported

(Owen et al., 2015) CBTp group vs TAU CORE-10 MHCS PSYRATS	<p><u>CORE 10, MHCS combined</u>: No significant differences between groups ($p = 0.80$)</p> <p><u>CORE-10</u>: A significant within-group change on CBTp pre-post scores ($F(1, 29) = 13.94, p = 0.01$) but not by follow-up ($p = 0.39$). The CBTp had greater reduction than TAU.</p> <p><u>MHCS</u>: No significant within-group differences in CBTp</p> <p><u>PSYRATS</u>: No significant between or within group differences</p>	<p><u>Measure of effect (partial eta squared)</u>:</p> <p><u>CORE 10</u>: CBTp within group post ($\eta p^2 = 0.33$) <i>medium</i>, and follow up ($\eta p^2 = 0.03$)</p> <p><u>MHCS</u>: CBTp within group post ($\eta p^2 = 0.07$) and follow up ($\eta p^2 = 0.00$).</p> <p><u>Moderating effects</u>: Significant differences between groups including gender, socio-economic, and size of groups.</p>
(Gibson et al., 2014) DBT LTD group vs waitlist DSI SCL-90-R DERS CERQ-S	<p><u>DSI</u>: Significant between group difference in deliberate self-harm in pre-post ($F(1, 89) = 4.53, p = 0.04$) in favour of DBT</p> <p><u>SCL-90-R</u>: No significant between group difference</p> <p><u>DERS, CERQ</u>: Significant between group difference on 'emotion regulation' in DBT at post: (Wilks' $\lambda = .686, F(15, 70) = 2.14, p = 0.02$)</p>	<p><u>DSI</u>: Between group post ($d = 0.27$) <i>small</i></p> <p><u>DERS, CERQ</u>: Between group post ($\eta p^2 = 0.31$) '<i>significant</i>'</p> <p><u>Moderating effects</u>: Difference between groups on age, but stated as not significantly associated with outcomes</p> <p>ITT data not provided*</p>

Cohort

(Stroud & Griffiths, 2021)	CFT group Vs TAU	CORE-OM Compassion scales	<p><u>CORE-OM</u>: Significant within group differences on CORE-OM scores for both groups. Smaller reduction in TAU (\bar{x} 21.41->18.55; $Z = -2.028, 0.35$) than CFT (\bar{x} 24.01->15.89; $Z = -3.702, p = .000$).</p> <p><u>Compassion Likert scales</u>: Scores improved across domains following group (D (249) = .001, $p > .05$).</p>	<p><u>CORE-OM</u>: Within groups post: CFT ($d = 0.90$) <i>large</i>, TAU ($d = -0.35$) <i>small</i>.</p> <p><u>Compassion Likert scales</u>: Effect size 'small' across all sessions and subdomains</p> <p><u>Moderating effects</u>: Data was not normally distributed Each session accompanied with breathing and relaxation</p>
(Nikolitch et al., 2016)	MOI group	Likert scale Completion of intervention	<p><u>Tolerability</u>: 92.5% tolerated intervention (remained for group)</p> <p><u>Suitability</u>: 50% reported reduced pre-post scores indicating benefit</p>	<u>Measure of effect</u> : Not reported
(Forsyth et al., 2010)	CBT group	ATQ BDI-II	<p><u>ATQ</u>: Significant reduction between admission and discharge ($p = 0.001$)</p> <p><u>BDI-II</u>: Significant reduction between admission and discharge ($n = 414, SD = 12.5; p < .0001$)</p>	<u>Measure of effect</u> : Not reported
(Veltro et al., 2006, 2008)	CBT group	Readmissions Ward atmosphere Patient satisfaction Restraint Length of stay	<p>Y = year</p> <p><u>Readmissions</u>: Readmissions significantly reduced between Y0 (38%) and next four years (+/-24%) ($\chi^2 = 11.8, df = 4, p < 0.02$). Compulsory admissions significantly decreased ($\chi^2 = 16.5; df = 4; p < 0.02$).</p> <p><u>Ward atmosphere</u>: Significant improvement in ward atmosphere ratings between Y0 and next four years ($F = 115.7; df = 4; p < 0.001$).</p> <p><u>Patient satisfaction</u>: Significant increase in satisfaction between Y0 and Y2 ($p < 0.001$). Continued in Y3 and Y4</p> <p><u>Restraint</u>: Physical restraint used five times in Y0, and once in Y1, 2, 3, and 4.</p> <p><u>Length of stay</u>: The mean stay reduced between Y0 (14 days) and Y1, 2, 3 and 4 (mean = 11.5 days) but not statistically significant.</p>	<u>Measure of effect</u> : Not reported
Pre-post				

(Gussmann et al., MCT group 2023)	Likert scale PANSS PSYRATS GAF CGI WHODAS-2.0, BCIS CFQ Rehospitalisation rate	<u>Feasibility and acceptability:</u> Eligibility rates (75.8%) and consent rates (78.7%). 89.2% retention rate. >80% participants rated intervention on highest feedback rating. <u>PANSS, PSYRATS, GAF</u> <u>CGI, BCIS, CFQ:</u> Significant reductions from pre-post scores were on all measures <u>WHODAS-2.0:</u> Non-significant change (p=0.279). <u>Readmission:</u> 16.2% readmitted within 12 months	<u>PANSS, PSYRATS, GAF</u> <u>WHODAS-2.0:</u> Post d = -0.20 <u>CGI, BCIS, CFQ:</u> 'Medium to large' effect sizes reported, where d = >0.5 across measures
(Fife et al., 2019) DBT CWC	Attendance ISAS DTS Feedback questionnaire	<u>Suitability:</u> Of the 63 people referred, 68% met researcher (n=43). Of those, 55% consented (n=24). <u>Engagement:</u> 74% (n=17) completed at least one group. 37.5% completed outcome measure (n=9). Discharge main reason for disengagement (45%) <u>IDAS, DTS:</u> 38% completed measures. Unable to access data in relation to outcome measures. <u>Feedback questionnaire:</u> Qualitative data	<u>Measure of effect:</u> Not reported <u>Moderating effects:</u> Impact of other elements of acute admission on symptoms
(Nenadić et al., ST group 2017)	BSCL-53-S YSQ-3 SMI ZUF-8 GCQ-S	<u>BSCL-53-S:</u> Significant improvement (p=0.029) <u>SMI:</u> 'Trend level' improvements on maladaptive schema modes (p=0.054)	<u>BSCL-53-S:</u> (d= -0.857) 'considerable' <u>SMI:</u> (d=0.693) 'considerable'
(Lynch et al., CBT group 2011)	Participation OQ-45	<u>Participation:</u> Sample attended average of 79.3% CBT groups. Patients with depression more likely to attend than those with SSD (82.5% compared to 59.5%; p= 0.01) <u>OQ-45:</u> Significant improvement between admission and discharge (F(2, 154) = 66.35, p < 0.001) with no significant differences between diagnostic groups.	<u>Measure of effect:</u> Not reported <u>Moderating effects:</u> Other groups running in tandem

(Dodd & Wellman, 2000)	CBT AM group	BAI ADL	<u>BAI</u> : A significant reduction between pre and post (Wilcoxon $Z = -2.823$, $P = 0.005$) <u>ADL</u> : A significant reduction in functional impairment (Wilcoxon $Z = -3.623$, $P = >0.001$)	<u>Measure of effect</u> : Not reported
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* see table 1 footnotes for abbreviations

Analysis of results

Primary outcomes - Effectiveness of interventions

A narrative synthesis was used to collate effectiveness-related outcomes. This involved the narrative assessment of statistically significant findings ($p < 0.05$) and reported effect sizes, by study category. Additionally, effect sizes were compared for studies applying an intent-to-treat (ITT) analysis, with these findings given priority when considering the overall evidence in support of group-based interventions.

Cohens-d effect sizes were interpreted according to parameters: small ($d = 0.2$), medium ($d = 0.5$), or large ($d \geq 0.8$) (Cohen, 1969). Partial eta-squared effect sizes were interpreted according to parameters: small ($\eta^2 = 0.01$), medium ($\eta^2 = 0.06$), or large ($\eta^2 = 0.14$) (Miles & Shevlin, 2001).

Control group designs

Randomised Controlled Studies

Of the five randomised controlled designs, two studies involved metacognitive-based interventions (Haga et al., 2022; Hauschildt et al., 2022), two mindfulness-oriented interventions (Böge et al., 2021; Moussaoui et al., 2022), and one, cognitive behavioural therapy (Bechdorf et al., 2004). Two studies were of higher overall quality (Böge et al., 2021; Hauschildt et al., 2022). Of the three 'weak' designs, two were described as pilot or feasibility trials (Haga et al., 2022; Moussaoui et al., 2022), and therefore findings were considered with additional caution (Abbott, 2014). Four studies included follow-up data, at three months (Böge et al., 2021; Hauschildt et al., 2022), six months (Bechdorf et al., 2004), or one year (Haga et al., 2022), respectively. Two reported ITT analysis data (Bechdorf et al., 2004, Hauschildt et al., 2022).

With the exception of one study (Moussaoui et al., 2022), all of the randomised controlled designs reported significant within-group pre-post improvements for both intervention and control groups. Of these, two studies found no significant differences between groups, suggesting a similar degree of improvement for both intervention and comparison (Haga et al., 2022; Bechdorf et al., 2004). These included comparisons between metacognitive therapy and occupational therapy, and occupational therapy alone (Haga et al., 2022), and cognitive-behavioural therapy, and psychoeducation (Bechdorf et al., 2004). Due to the absence of a treatment-as-usual comparison in both instances, within-group improvements could not be confidently attributed to either control or intervention group. The remaining study reported no significant improvements for either the intervention or treatment-as-usual control group (Moussaoui et al., 2022). This study involved a small sample size ($n=20$) and did not include follow-up data.

A difference in effect between intervention and comparison group was described by both moderate quality designs, in favour of group-based psychological therapy (Böge et al., 2021; Hauschildt et al., 2022). Hauschildt et al., (2022) reported a medium effect size (η^2) on one outcome measure, and a large effect size (η^2) on a single sub-item of another, at both timepoints [(DAS Weissman, 1979), (MCQ-30 Clark et al., 2003)]. Findings were not replicated across all outcome measures. Key limitations included the absence of a treatment-as-usual control, and the relatively short follow-up period (Hauschildt et al., 2022). Böge et al., reported a group-based intervention as superior to treatment-as-usual on two outcome measures, with a large effect size (η^2) [SMQ (Feng et al., 2022) and PANSS (Kay et al., 1987)]. However, these findings were not based on ITT analysis, there was high attrition by follow-up, and significant differences between the groups, considerably limiting their overall strength (Böge et al., 2021).

Clinical control designs

Of the four clinical control designs, two applied cognitive behavioural therapy (Owen et al., 2015; Samaan et al., 2021), one emotion-focussed therapy (Bernard & Walburg, 2020), and one dialectical behavioural therapy (Gibson et al., 2014). Three of the designs were assessed as weak quality overall, with one study meeting criteria for a moderate rating. All four studies provided follow up data, ranging from four weeks (Bernard & Walburg, 2020; Owen et al., 2015), six weeks (Gibson et al., 2014), to six months (Samaan et al., 2021).

Three of the four clinical control studies reported some within-group improvements. Samaan et al., (2021), the only moderate-quality clinical control design, compared two group-based therapy interventions: cognitive-behavioural therapy and acceptance and commitment therapy. Authors reported what appeared to be encouraging within-group improvements on all measures, with a large effect size (d). This improvement was consistent at both timepoints and for both groups. However, the absence of a treatment-as-usual control meant that the observed improvements could not be confidently attributed to either intervention. Bernard & Walburg, (2020) compared an emotion-focused group and individual therapy. They found significant within-group improvements across all measures, with small advantages in relation to the group-based intervention. The third study found within-group improvements relating to a cognitive-behavioural group for psychosis (Owen et al., 2015). At the post intervention timepoint, authors reported a significant within-group improvement on one outcome measure, with a medium effect size (η^2) [*CORE-10* (Barkham et al., 2012)]. However, improvements did not remain by one-month follow-up, and similar findings were not observed on other outcome measures [*MHCS* (Carpinello et al., 2000), *PSYRATS* (Haddock et al., 1999)].

Two of the clinical control designs identified some advantages of the group-based psychological intervention over a control group (Bernard & Walburg., 2020, Gibson et al., 2014). Of these, Bernard & Walburg, (2020) reported significant differences on some sub-items of measures, but findings did not involve ITT analysis [*DEERS* (Hallion et al., 2018), & *CERQ* (Garnefski & Kraaij, 2007)], *TAS* (Leising et al., 2009)], and were not replicated on other outcome measures, or measures overall [*UPPS-P* (Lynam et al., 2006) *HADS* (Zigmond & Snaith, 1983)]. Gibson et al., reported some between-group differences with a 'small-medium effect size' (η^2) in relation to one outcome measure [*DSI* (Gratz, 2001)], and sub-items of two others [*DEERS* (Hallion et al., 2018) and *CERQ* (Garnefski & Kraaij, 2007)]. These advantages were not observed across all measures [*SCL-90-R* (Derogatis & Savitz, 2000)].

In sum, across the four clinical control designs, two studies reported significant within-group improvements for both intervention and control groups. However, attribution of change was limited by a lack of a treatment-as-usual control. A further study that applied ITT analysis reported some within-group improvements, but involved a small sample size and improvements were not maintained by follow-up (Owen et al., 2015). Two studies reported some differences between the intervention and control groups, generally identified through sub-item analysis, suggesting modest advantages of group-based psychological interventions over controls (Bernard & Walburg, 2020; Gibson et al., 2014). Findings from this group of studies were collectively limited by the absence of randomisation, increasing the possible influence of selection bias on findings.

Controlled studies applying intent-to-treat analyses

Table 6. Effect size of intent to treat based analyses

Study	Intervention	Control	Effect (Cohens d - 95% CI)	Odds ratio (95% CI)
Moderate quality (some concerns)				
(Hauschildt et al., 2022) RCT	153.28 (SD 36.7) - 137.51 (SD 44.32)	150.87 (SD 39.34) - 139.01 (SD 34.04)	-0.103 (-0.562-0.357)	1.185 (0.555- 2.530)
DAS	N = 38	N = 37		
(Samaan et al., 2021) Clinical control	28.20 (SE 0.98) -1 4.83 (SE 1.03)	30.39 (SE 0.88) - 13.30 (SE 0.88)	0.171 (0.124-0.465)	1.324 (0.812-2.157)
ADS	N=83	N = 94		
Low quality (high risk of bias)				
Bechdolf et al., 2004) RCT	33.3 (SD 9.6) - 28.0 (SD 9.2)	31.6 (SD 8.5) - 25.0 (SD 6.2)	0.144 (-0.281 - 0.569)	1.268 (0.687- 2.558)
PANSS	N = 40	N = 48		
(Owen et al., 2015) Clinical control	23.05 (SD 9.38) - 18.30 (SD 9.18)	21.18 (SD 6.94) - 13.27 (SD 8.03)	0.353 (-0.337-1.044)	1.790 (0.573-5.599)
CORE 10	N = 20	N =11		

(Hauschildt et al., 2022) – Published data CC with authors stated results of ITT analyses did not differ with regard to status of significance. Data reported above CC. (Gibson et al., 2014) – Authors reported ITT analysis results relating to DSH ($F(1, 89) = 4.53, p = 0.04, \text{Cohen's } d = .27$) but detailed data set only available for CC. Therefore, Gibson excluded from ITT table. SD Standard deviation, SE Standard error

Figure 2. Odds-ratio forest plot for intent to treat analyses

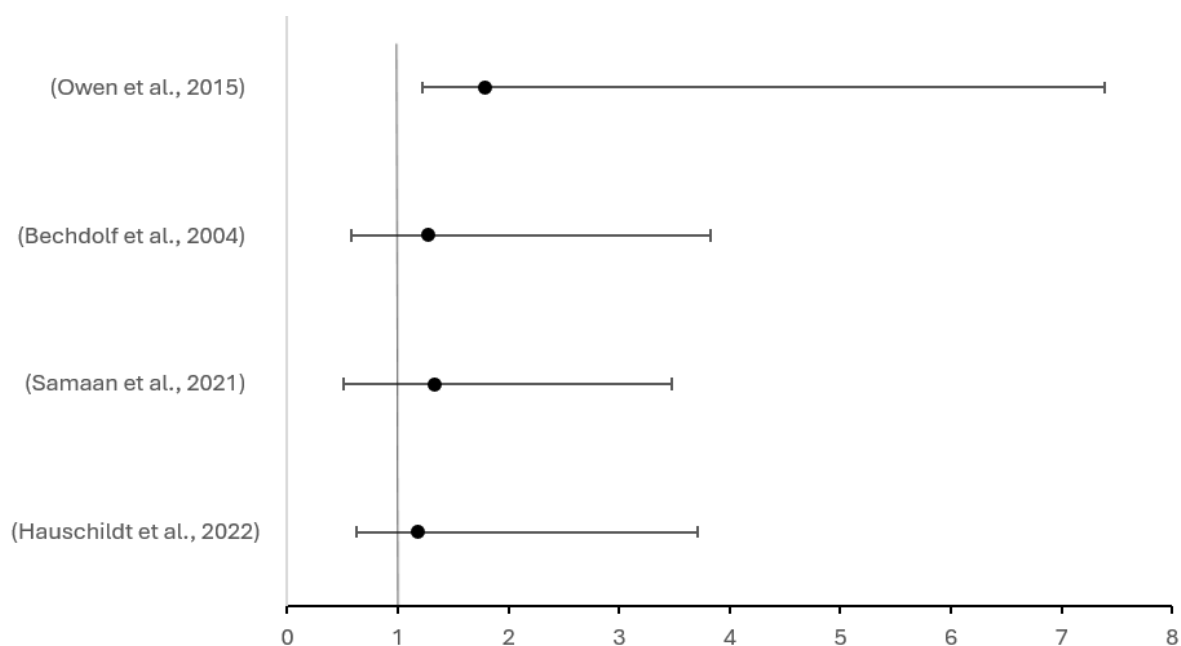


Table 6. and figure 2. display the relative effect estimates of the four control group studies applying ITT analysis, converted to show an odds-ratio measure. A single outcome measure was selected for each

study, as an appropriate measure of symptoms or distress relevant to that study's intervention and population.

Of the two moderate quality studies (Hauschildt et al., 2022; Samaan et al., 2021), a small advantage of the group-based interventions was identified, with confidence interval range suggestive of inconclusive findings. Of the low-quality studies, a similarly small advantage of a group-based intervention was identified by Bechdorf et al., (2004), with confidence interval range again indicative of inconclusive findings. The final study (Owen et al., 2015) identified a small advantage of a group-based intervention, with the large confidence interval highlighting a low degree of precision, noting the small sample on which their study was based (n=31).

Overall, relative effect sizes based on the four controlled studies providing ITT analysis data pointed to what could be described as slight but inconclusive evidence in support of group-based interventions conducted in the acute inpatient setting.

Non-controlled designs

Cohort designs

Four retrospective cohort designs were included in the review. Of these, one study included a treatment-as-usual comparison (Stroud & Griffiths, 2021). The remaining three compared pre-post data from an intervention group, including a mindfulness intervention (Nikolitch et al., 2016), and two cognitive-behavioural groups (Forsyth et al., 2010; Veltro et al., 2006, 2008).

One of the four cohort designs was assessed to be of a higher overall quality and given a 'moderate' rating (Veltro et al 2006, 2008). This study included a large number of participants (n=733) and involved a long follow-up period (four years). The authors reported statistically significant improvements on several indirect clinical outcomes including readmission rates, compulsory admissions, ward atmosphere and patient satisfaction. Significant improvements were observed every subsequent year following the introduction of a daily cognitive-behavioural therapy group. Outcomes were recognised as being correlational in nature, but the authors attributed improvements to the introduction of the daily group intervention.

The remaining three cohort designs were assessed as 'weak' quality. Two compared admission and discharge outcome scores, and identified significant improvements in scores (Forsyth et al., 2010; Stroud & Griffiths, 2021). In the case of Forsyth et al., findings involved no comparison, so it was not possible to distinguish observed improvements from treatment-as-usual. Stroud & Griffiths included both an intervention and treatment-as-usual group. They reported a large within-group effect for the intervention, a compassion-focused therapy group, in comparison to a small effect for the treatment-as-usual group (*d*). However, limitations included the correlational nature of the design. The final study retrospectively compared outcomes collected before and after standalone mindfulness groups (Nikolitch et al., 2016). They found that 50% of attendees reported a reduction in scores following their attendance, and suggested this indicated a beneficial effect associated with group attendance. However, the approach was limited by the lack of validity or reliability of included measures.

In sum, of the cohort designs, one was of notably higher quality, providing a large data set over a long duration (Veltro et al., 2006, 2008). A correlation was identified between the introduction of the group programme, and improvements on several indirect outcomes. Of the remaining three cohort designs, all reported improvements in relation to the group, but findings were limited by the 'weak' overall design. Conclusions drawn from all four cohort studies were limited by the correlational nature of findings.

Pre-post designs

The five remaining studies utilised a pre-post design. This included one metacognitive study (Gussmann et al., 2023), one dialectical-behavioural design (Fife et al., 2019), one schema therapy group (Nenadić et al., 2017) and two cognitive-behavioural therapy groups (Dodd & Wellman, 2000; Lynch et al., 2011). All pre-post designs were assessed as overall 'weak' quality and did not include follow up data.

Four of the five pre-post studies reported significant improvements on clinical outcome measures. Gussmann et al., found a significant reduction in pre-post scores across several measures with 'medium-large' effect size (d), but no significant changes were found on a further outcome measure [*WHODAS-2.0* (WHO, 2012)]. Nenadić et al., described significant improvements on two measures [*BACL-53-S* (Franke G, 2017), *SMI* (Young et al., 2007)] with 'medium-large' effect size (d). Both Dodd & Wellman, (2000) and Lynch et al., (2011) reported significant improvements on outcome measures [*OQ-45* (Lambert et al., 2004)], *Anxiety* [*BAI* (Beck et al., 1988)]. Fife et al., did not report any effectiveness related results, highlighting issues with high attrition.

In sum, four of the five pre-post studies reported improvements on some outcomes between pre and post scores, with a medium-large effect size in some instances. Overall, findings from these studies were significantly limited by the role of selection bias, and the lack of any control. Therefore, causal attribution was not possible to establish, as improvements could not be distinguished from treatment-as-usual.

Effectiveness of interventions- summary of findings

Across the nine controlled designs, four studies reported group-based interventions as holding some advantages over a control group (Böge et al., 2021; Hauschildt et al., 2022, Bernard & Walburg, 2020; Gibson et al., 2014). Two of these were RCT designs of moderate quality (Böge et al., 2021; Hauschildt et al., 2022), although only one involved an ITT based analysis (Hauschildt et al., 2022). Considering controlled studies involving ITT analysis (Bechdorf et al., 2004; Hauschildt et al., 2022; Owen et al., 2015; Samaan et al., 2021), advantages of group-based interventions were found to be slight and inconclusive. However, with the exception of Owen et al., (2015), these studies involved a comparison to an alternative therapeutic intervention, that may have independently supported improvements to clinical outcomes (Bechdorf et al., 2004; Hauschildt et al., 2022; Samaan et al., 2021). Further research involving a treatment-as-usual control would provide greater insight into the effect of group-based interventions on clinical outcomes.

The remainder of studies involving non-controlled designs pointed to a pattern of within-group improvements for those attending a group-based intervention. However, any conclusions based on this group of studies were significantly limited by the low quality of these designs, and the lack of controls on which to compare any improvements against, with reported improvements potentially a result of treatment-as-usual. One exception to this was the study conducted by Veltro et al., (2006, 2008), which reported a correlation between improved indirect outcomes (readmissions, ward atmosphere, patient satisfaction) and the introduction of a group-based programme, over a number of years. Whilst findings remained correlational in nature, the large sample and long follow-up period provided a greater degree of credibility on which the authors positive conclusions were based.

Finally, consideration was given to the possible influence of therapeutic modality on intervention effect. However, the small number of designs in each therapeutic category, and the significant differences between each design, limited the degree to which any effective comparison could be made. Whilst acknowledging the limitations surrounding any comparison, no clear advantages could be seen between therapeutic modalities. On the other hand, two of the three studies that reported non-significant findings involved a 10-minute mindfulness group (Nikolitch et al., 2016; Moussaoui et al., 2022). The low-quality

of these two designs, and the possibility that they catered to people experiencing particularly severe symptoms, might have influenced these non-significant outcomes.

Secondary outcomes: feasibility and engagement

Overall, secondary outcomes in relation to group feasibility and engagement were not rigorously or consistently reported, so a systematic assessment of relevant outcomes was not possible. Authors across all studies qualitatively reported that group-based interventions were feasible in the acute setting. Engagement was challenging to assess, due to variability across designs. Findings on feasibility and engagement outcomes are considered below.

Of the four design categories, the pre-post designs gave more emphasis to the issue of feasibility, considering participation and retention. Gussmann et al., reported a high eligibility, consent and retention rate, and suggested this was indicative of an acceptable intervention (2023). Lynch et al., reported a high level of group attendance, although noted those with schizophrenia spectrum diagnoses were less likely to do so (2011). In contrast, Fife et al., described difficulties with both recruitment and retention, but despite these challenges reported that the intervention was a feasible way to deliver psychological interventions in the acute setting (2019).

A small number of control and cohort designs included some assessment of feasibility and engagement. For example, Hauschildt et al., collected qualitative feedback that suggested metacognitive therapy was superior to individual euthymic therapy (2022). Samaan et al., reported comparable positive feedback for both cognitive-behavioural and acceptance and commitment therapy groups (2021). Veltro et al., described a very high rate of group attendance (90% of all inpatients), and reported a significant increase in treatment satisfaction when comparing pre-intervention data with all subsequent years ($p < 0.001$) (2006, 2008).

Attrition might have provided a useful metric from which to assess group feasibility and engagement. However, comparison between designs was challenging, due to significant variations in intervention intensity, inclusion criteria, drop-out criteria, and follow-up periods. In light of this, whilst attrition metrics were available in some form across most studies, they were not considered to be a viable source from which to assess engagement or feasibility.

Whilst groups were generally described in positive terms, some challenges were highlighted. The high rate of hospital discharge was a particular difficulty, resulting in treatment being cut short, an issue highlighted explicitly by Gibson et al., (2014); Haga et al., (2022); Owen et al., (2015) and Samaan et al., (2021). One study suggested that the presence of comorbidities had a negative influence on outcomes, with those without comorbidities appearing to benefit most from the group intervention (Hauschildt et al., 2022).

In sum, group-based interventions were viewed as a feasible way to deliver psychological interventions in the acute setting. Considering design categories, the randomised and clinical control designs qualitatively reported groups to be a feasible, acceptable and well-tolerated way from which to deliver therapy (Bechdorf et al., 2004; Böge et al., 2021; Hauschildt et al., 2022; Moussaoui et al., 2022; Owen et al., 2015). Echoing this, the cohort designs described group-based interventions as suitable and well-tolerated (Forsyth et al., 2010; Nikolitch et al., 2016; Stroud & Griffiths, 2021; Veltro et al., 2006, 2008). Finally, the pre-post designs described groups as a feasible and acceptable approach, with some challenges noted in relation to recruitment and retention (Dodd & Wellman, 2000; Fife et al., 2019; Gussmann et al., 2023; Lynch et al., 2011; Nenadić et al., 2017). No study reported that group-based interventions were unsuitable for the acute inpatient setting.

Discussion

Prior to the present review, no systematic assessment of a range of group-based psychological interventions conducted in the acute setting had been completed, to the best of the authors knowledge. This review aimed to; 1) Collate the published quantitative studies assessing group-based psychological interventions conducted in the acute setting. 2) Review how group-based interventions have been adapted to the acute setting. 3) Assess the effectiveness of group-based interventions in the acute setting. 4) Assess the feasibility of group-based interventions in the acute setting.

Main findings

The existing evidence-base

The review identified 18 studies in total, including four randomised controlled designs, five clinical control studies, four retrospective cohort studies, and five pre-post designs. This highlighted the overall limited number of published studies that have specifically evaluated group-based psychological interventions in the acute inpatient setting.

The majority of included studies were assessed as being 'weak' quality (78%), with four designs meeting criteria for a 'moderate' rating (Thomas et al., 2004). Moderate studies included two randomised controlled designs (Böge et al., 2021; Hauschildt et al., 2022), one clinical control (Samaan et al., 2021), and one retrospective cohort design (Veltro et al., 2006, 2008). Across studies, strengths were found in the study design and data collection categories, with most included studies using reliable and valid outcome measures. Overall weaknesses were noted on selection bias, confounders, blinding, and withdrawal & dropouts. A minority of studies used and intent to treat analysis, and only one assessed intervention fidelity. Any findings from this review are therefore limited by the overall quality of the published studies.

Adaptations made to groups

Group-based interventions varied considerably in terms of therapeutic modality and intensity. However, several adaptations were evident, to a degree, across included studies. A common adaptation involved the high frequency of available groups. The vast majority of interventions involved two or more groups per week, with five involving sessions every weekday.

A second adaptation appeared to relate to the frequent use of 'open' groups. Around half of the studies operated an open-group design, where people could join or leave the group at any time, either including regularly rotating sessions (e.g. Hauschildt et al., 2022; Samaan et al., 2021; Stroud & Griffiths, 2021), or standalone repeat-format groups (e.g. Forsyth et al., 2010; Nikolitch et al., 2016; Veltro et al., 2006, 2008). Open groups were seen as a useful way to manage the unpredictability and high turnover of admissions, typical to the acute setting. On the other hand, a comparable number of studies operated using a closed or semi-closed/open design, suggesting that despite a high turnover of admissions, limits on those who attending groups can function as a viable option. Interestingly, a higher percentage of closed group designs were seen across the controlled designs, suggesting that the choice of a closed group may have been influenced by research-driven decisions rather than clinical feasibility.

A final adaptation appeared to relate to the inclusive nature of groups, where around one third were made available to anyone admitted to the ward. The remaining two thirds of groups operated within some diagnostic parameters, but usually permitted comorbid difficulties, suggesting an inclusive approach. This relatively naturalistic sampling stance appeared to account for the diversity of difficulties experienced within the acute inpatient setting.

Effectiveness of group-based interventions

Findings from the current review suggest there is tentative but inconclusive evidence supporting the use of group-based interventions in the acute inpatient setting. Whilst the review identified several controlled designs that reported group-based interventions holding some advantages over a control (Böge et al., 2021; Hauschildt et al., 2022, Bernard & Walburg, 2020; Gibson et al., 2014), these studies were limited by overall quality (Bernard & Walburg, 2020; Gibson et al., 2014), and the lack of ITT analysis (Bernard & Walburg, 2020; Gibson et al., 2014; Böge et al., 2021). An additional non-controlled design supported the use of group-based interventions in relation to in-direct outcomes, but findings were correlational in nature (Veltro et al., 2006, 2008). Of the controlled studies that involved an ITT analysis (Bechdorf et al., 2004; Hauschildt et al., 2022; Owen et al., 2015; Samaan et al., 2021), a comparison of effects suggested group-based interventions may hold a slight advantage over controls, but overall findings were inconclusive (see figure 2). However, it should be noted that three of these studies compared group-based interventions to an alternative therapeutic intervention, not to treatment-as-usual (Bechdorf et al., 2004; Hauschildt et al., 2022; Samaan et al., 2021), a factor that may have influenced the strength of findings.

In sum, the evidence supporting the use of group interventions in the acute setting appears both tentative and inconclusive, with a clear need for higher quality research involving treatment as usual controls and ITT analyses to better establish the impact of group-based interventions on clinical outcomes.

Feasibility and engagement

Feasibility and engagement were not rigorously measured across studies. Therefore, a systematic comparison of outcome measures was not possible. A synthesis of authors' conclusions suggested that groups were widely viewed as an acceptable and feasible way to deliver psychological interventions in the acute inpatient setting, whilst noting some difficulties with recruitment and retention. A particular feasibility challenge related to the high rate of hospital discharge, with many studies losing group participants for this reason. Assessment of engagement was challenging, due to the significant variation between studies in how they recruited, the intensity of the intervention, and the duration of follow-up.

Strengths and limitations

A decision was made to include a range of quantitative designs, based on findings reported by a previous scoping review suggesting a lack of available group-based controlled research (Jacobsen et al., 2018). This resulted in a larger number of relevant studies, but lowered the overall quality of findings. To mitigate this, findings were considered by study category, with close consideration given to study quality. The international nature of studies increased the breadth of research included in this review, whilst at the same time pointed to potential limitations. It was of note that the highest proportion of studies were conducted in Germany (33%), perhaps indicative of international variation in treatment traditions. Similar findings have been reported in a previous review, one that incorporated German language publications, where 60% of papers were conducted in Germany (Kösters et al., 2006). It is therefore possible that the limits placed on the English language in the present review resulted in the omission of relevant papers. On the same issue of international differences, there appeared to be a number of variables surrounding the parameters of acute care between countries, that may influence the relevance of this review. For example, the average length of closed-group programmes was found to be around four and a half weeks, with some interventions lasting as long as eight weeks (Bechdorf et al., 2004; Haga et al., 2022). Longer programmes such as these were unlikely to be compatible with the UK acute system, with an average admission being around three weeks (The Kings Fund, 2017; Wood et al., 2019a). In contrast, the two UK-based closed-group designs opted for a shorter programme, at either two-weeks (Fife et al., 2019) or four-weeks (Owen et al., 2015), more aligned with UK timeframes. Encouragingly, those studies that

demonstrated the most significant effect on outcomes were both of four weeks in duration, suggesting that shorter duration group-based programmes can be effective (Böge et al., 2021; Hauschildt et al., 2022). Another example of apparent differences between healthcare systems related to the availability or absence of 1:1 therapy as a component of treatment-as-usual. For example, 1:1 therapy appeared to be the norm across a number of German-based studies, but was not mentioned in UK-based studies. These examples pointed to a situation where there may be considerable variation between acute inpatient systems internationally, although effective comparison between international health-care systems has been difficult to achieve (Moran & Jacobs, 2013). It is difficult to know how much variations to the wider acute care system might influence the viability, adoption or effectiveness of group-based interventions, between different health-care systems

Finally, the overall low quality of studies and significant heterogeneity of design, including on study type, inclusion criteria, intensity of intervention, outcome measures and reporting of effect, meant that the effective synthesis of evidence was considerably limited. Effect sizes were compared in relation to the minority of studies involving ITT analyses, with conclusions based on this approach limited by the heterogeneity of study outcomes being compared.

Clinical implications

Group-based interventions have been recommended as a mode from which to deliver psychological interventions in the acute setting (BPS & ACP-UK, 2021), but prior to the current review there was a lack of clarity in relation to their application, feasibility or effectiveness. The current review suggests there is only tentative empirical support for this recommendation, highlighting the considerable limitations to the available evidence, and the clear need for additional research to establish the causal effect of group-based interventions in the acute setting. On the other hand, the review appears to support the use of groups as a feasible way from which to deliver psychological therapy in the acute setting.

The summarised findings and synthesis of evidence set out within this review will help inform clinicians and service providers involved in the development of group-based interventions in the acute setting, who require access to the best available evidence. As well as setting out the limits of the available evidence, this review may help instil a degree of confidence in clinicians on the issue of group feasibility, highlighting the widely accepted view that groups are a feasible way from which to deliver psychological therapy in the acute context. Furthermore, summarised information on adaptations that have been made to group-based interventions may be of practical value to clinicians and service providers, helping inform the development of group-based programmes.

Finally, by highlighting group-based programmes that hold potential and identifying the considerable gaps within the current evidence-base, this review helps determine key focus areas that would benefit from further research.

Future research

When considering the UK context, additional research assessing the effectiveness of groups delivered within or under a three-week period would be of particular interest, recognising the short average admission duration (The Kings Fund, 2017; Wood et al., 2019a). On this point, it would be useful to establish the value and effectiveness of groups that can operate as a 'stand-alone' intervention, as a potential solution to the high rates of discharge in the acute setting, an issue explored as a key feasibility challenge by studies in this review (Gibson et al., 2014; Haga et al., 2022; Owen et al., 2015; Samaan et al., 2021). The potential value of groups conducted as a stand-alone session has been commented on elsewhere (Jacobsen et al., 2018; Wood et al., 2019). A qualitative assessment of patient experiences

of open, short-duration group-based programmes would help inform whether such interventions are perceived as holding therapeutic value.

The acute setting aims to support the containment of crisis, reduce risk, and to prevent relapse (Bowers et al., 2015; Wood et al., 2019b, 2019a). A better understanding of the effectiveness of groups that are closely aligned to these wider aims would be of interest, for example those that have a focus on emotional regulation or self-harm. A specific focus on emotion management and risk was observed in a small number of included studies in the present review (e.g. Bernard & Walburg, 2020, Fife et al., 2019, Gibson et al., 2014), with two reporting small positive effects (Bernard & Walburg., 2020, Gibson et al., 2014).

A small number of trials tentatively suggested that groups may have a positive effect on clinical outcomes (e.g. Böge et al., 2021; Hauschildt et al., 2022; Bernard & Walburg., 2020, Gibson et al., 2014). To establish the effectiveness of these interventions, it would be important to replicate these preliminary findings, including ITT analyses and treatment-as-usual controls. A number of included studies described interventions that may hold promise, but that were unable to demonstrate causation by way of their design. These interventions would benefit from further evaluation through randomised-controlled design research, including a treatment-as-usual control (e.g. Veltro et al., 2006, 2008). Collectively, this additional research would help to establish the causal effect of group-based interventions on clinical outcomes in the acute inpatient setting.

Conclusion

Findings from the present review suggest there is tentative but inconclusive evidence supporting the use of group-based approaches in the acute inpatient setting. Groups do appear to be a feasible means from which to deliver psychological interventions in this setting. Conclusions remain limited by the quality and small number of published studies on which they are based. Further controlled design research is required to establish a causal effect of group-based interventions in this setting. Further research is recommended looking at the effectiveness and the patient experience of short or stand-alone group programmes, on programmes focussed on the key aims of the acute inpatient setting including crisis management and risk, and to replicate the tentative findings identified through the present review.

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Appendices

Appendix 1. Empirical study protocol

Non-CTIMP Study Protocol

Trauma-informed practice in acute inpatient settings – an Interpretative Phenomenological Analysis involving mental health nurses

	The University of Edinburgh	
Protocol author	Miriam Zoeller	
Chief Investigator	Miriam Zoeller	
Sponsor number	CAHSS2108/03	
REC Number		
Version Number and Date	V2 03/12/2021	

LIST OF ABBREVIATIONS

ACCOR D	Academic and Clinical Central Office for Research & Development - Joint office for The University of Edinburgh and Lothian Health Board
CI	Chief Investigator
CRF	Case Report Form
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
PI	Principal Investigator
QA	Quality Assurance
REC	Research Ethics Committee
SOP	Standard Operating Procedure
ACE's	Adverse Childhood Experiences
RMN	Registered Mental Health Nurse

INTRODUCTION

BACKGROUND

In recent decades, interest in adverse childhood experiences (ACEs) and their association with negative outcomes, has highlighted the prevalence and impact of trauma (Ashton, Bellis, & Hughes, 2016; Felitti et al., 1998). A clear negative association between adverse and traumatic life experiences, mental health, physical health and social outcomes has been consistently demonstrated (Edwards, Holden, Felitti, & Anda, 2003; Felitti et al., 1998; Green et al., 2010; Kessler et al., 2010; Molnar, Buka, & Kessler, 2001; NHS Education for Scotland, 2017; Rees et al., 2011).

The concept of trauma-informed practice has developed in light of this increased awareness (Harris & Falloot, 2001). The approach recognises that trauma can have a complex and pervasive effect on an individual's worldview and relationships with others and that this may make accessing or engaging with services more difficult (NHS Education for Scotland, 2017; The Scottish Government, 2021). Trauma-informed practice advocates the adoption of certain principles, including safety, trustworthiness, choice, collaboration and empowerment, in an effort to optimise outcomes for trauma survivors, through increasing the accessibility of services and reducing additional harm caused by services (NHS Education for Scotland, 2017; The Scottish Government, 2021). There is an emerging evidence base that suggests trauma-informed systems can result in better outcomes, both for people affected by trauma, and for staff (NHS Education for Scotland, 2017; SAMHSA, 2014; The Scottish Government, 2021). Trauma-informed care is now a national priority for Scotland, and multi-level processes to integrate trauma-informed approaches across systems and services are underway (NHS Education for Scotland, 2017; The Scottish Government, 2021).

Considering possible barriers or challenges that may arise to the adoption of trauma-informed approaches may be helpful, so that they may be better understood and mitigated against. A particular barrier to the implementation of trauma-informed approaches has been identified as the translation of aspirational principles into clinical practice (Isobel, 2015; Isobel & Delgado, 2018; Muskett, 2014),

perhaps mitigated through guidelines e.g. (NHS Education for Scotland, 2017; The Scottish Government, 2021). Other barriers may relate to the perspectives of staff members involved in the delivery of trauma-informed care. Considering the UK mental health context, a number of challenges relating to this have been suggested, including; the continuous change and upheaval in UK public services (that has left many wary and weary of further initiatives), the focus on diagnostic categories and biological explanations for distress, and the lack of supervision available for staff delivering care, all suggested to negatively impact on the adoption of trauma-informed practice (Sweeney, Clement, Filson, & Kennedy, 2016). Other difficulties may relate to the misinterpretation of trauma-informed practice, as 'fuzzy', 'complex', 'something that service providers already do', or a theorised call for practitioners to "be nicer" (Sweeney & Taggart, 2018 p.383). It is known that stakeholder concerns can impede the implementation of evidence-based practice (Essock et al., 2003), therefore awareness of stakeholder perspectives are important if systematic changes are to be successfully integrated.

The proposed study is interested in trauma-informed approaches in the inpatient mental health setting. There is a strong link between childhood trauma and later mental health difficulties (Butler, Critelli, & Rinfrette, 2011; Mauritz, Goossens, Draijer, & van Achterberg, 2013; Mueser et al., 1998; Posner, Eilenberg, Friedman, & Fullilove, 2008; Sweeney et al., 2016). 50-60% of inpatients in a mental health setting report being sexually or physically abused in childhood (Read, Van Os, Morrison, & Ross, 2005), and levels of abuse may be underreported (Read, Hammersley, & Rudegeair, 2007). Additionally, this population are significantly more likely to have experienced a recent traumatic event, compared to the general population (Goodman et al., 2001). Survivors of childhood sexual or physical abuse are more likely to have longer and more frequent admissions, more likely to self-harm, and are more likely to attempt suicide, than those who have not experienced abuse (Read et al., 2007). Given the prevalence and impact of trauma on the acute inpatient population, it is of particular importance that trauma-informed practice is effectively integrated into routine care.

However, acute inpatient settings may face particular challenges in the integration of trauma-informed approaches. Potential barriers discussed above remain relevant to inpatient settings, but add to this, working within trauma-informed principles may present some particular dilemmas for staff working within a restrictive clinical setting e.g. (Regan, 2010). Inpatient mental health wards are set up to support patients who are acutely unwell and are likely to be busy environments characterised by unpredictability and competing priorities (Cleary, 2004; Cleary, Hunt, Horsfall, & Deacon, 2012). Management of risk is of particular importance, and restrictive risk management approaches may be used (Slemon, Jenkins, & Bungay, 2017). Practices such as seclusion or restraint (SAMHSA, 2014), body searches, forced or threatened medication, or compulsory treatment, are likely to cause distress (Butler et al., 2011; O'Dwyer, Tarzia, Fernbacher, & Hegarty, 2020; Sweeney, Filson, Kennedy, Collinson, & Gillard, 2018), and their negative impact is documented in the qualitative literature (Robins, Sauvageot, Cusack, Suffoletta-Maierle, & Frueh, 2005). Such strategies and procedures are experienced as emotionally unsafe, disempowering and can be re-traumatising for trauma survivors (Cohen, 1994; Frueh et al., 2005; Paksarian et al., 2014).

The extent and manner that restrictive approaches are relied upon will vary. Interactional loops between systems, staff and patients can develop, described as parallel processes (Bloom, 2006), which may result in an increased reliance on restrictive approaches. An illustration of this would be staff initially using a restrictive approach (e.g. enhanced observation levels), that may cause a trauma survivor to feel unsafe, increasing the risk that they behave in an aggressive way, resulting in staff using further restrictive approaches (Sweeney et al., 2016). In contrast, studies looking at the impact of staff training in trauma-informed approaches have demonstrated a reduction in restrictive practices can also be achieved e.g. (Azeem, Aujla, Rammerth, Binsfeld, & Jones, 2011; Hale & Wendler, 2020). The approach taken by staff members is known to be an important component of trauma-informed practice (NHS Education for Scotland, 2017; SAMHSA, 2014), and staff member perspectives may help to better understand how trauma-informed practice can be effectively integrated into the acute inpatient setting.

RATIONALE FOR STUDY

A systematic review of the literature looking at trauma-informed care in inpatient settings suggests that the majority of studies looking focus on strategies to reduce seclusion and restraint as an outcome of interventions (Ashcraft & Anthony, 2008; Azeem et al., 2011; Barton, Johnson, & Price, 2009; Borckardt et al., 2011; Muskett, 2014). The literature review proposed that a culture and belief in the value of trauma-informed care only appeared possible when staff felt confident and competent in their understanding about the prevalence and impact of trauma and understood their responsibilities around

mitigating re-traumatisation (Elliott, Bjelajac, Fallot, Markoff, & Reed, 2005; Gatz, Brounstein, & Noether, 2007; Muskett, 2014), highlighting the importance of staff perspectives in the delivery of trauma-informed care.

The published literature on trauma-informed practice in inpatient settings is predominantly based on research conducted outside of the UK context e.g. (Isobel, 2015; Isobel & Delgado, 2018; Isobel & Edwards, 2017; O'dwyer, Tarzia, Fernbacher, & Hegarty, 2019; Wilson, Hutchinson, & Hurley, 2017). To date, there is limited qualitative research looking at trauma-informed care in acute adult inpatient mental health settings from the perspective of healthcare professionals (O'Dwyer et al., 2020; Wilson et al., 2017), and of those, are not based in a UK context e.g. (Chandler, 2008), or do not have a specific focus on trauma-informed practice e.g. (Copperman & Knowles, 2006; O'dwyer et al., 2019). As such, there is a limited in-depth understanding of the experiences of mental health nurses working in an acute inpatient setting and aiming to deliver care within a trauma-informed approach.

In the review of the literature described above, possible challenges in the implementation of trauma-informed approaches in the acute inpatient setting have been explored, particularly relating to how principles of trauma-informed care may contrast with restrictive approaches used at times in this environment. The effective implementation of trauma-informed practice into an acute inpatient setting may be of particular importance, with consideration given to the high levels of trauma experienced within the population acute wards support e.g. (Read et al., 2005), and the identified risks of re-traumatisation in this setting (SAMHSA, 2014).

To better understand the translation of trauma-informed practice into a real-life acute inpatient context, a qualitative interview-based study involving NHS clinical staff is proposed. Inpatient mental health nurses' perspectives on the delivery of trauma-informed care will be explored, to identify, explore and better understand particular barriers and opportunities presented through trauma-informed care in this setting. It is hoped that findings from this study will help inform the continued effort to improve care delivery in this setting, in the wider context of the Scottish government's commitment to delivering better outcomes for people who have experienced trauma in their lives (NHS Education for Scotland, 2017; The Scottish Government, 2021).

POTENTIAL BENEFITS FOR PARTICIPANTS

Contribution to research

Participants will have the opportunity to express their perspective on a topic highly relevant to current clinical policy, and therefore contribute to the wider discourse around trauma-informed approaches. Through their contribution, they may help highlight areas where further research is needed, and influence decisions around the ongoing and active implementation of trauma-informed care into this clinical setting.

Recruitment incentive

Participants will be offered a £10 voucher as an incentive to participate. This is to try to expand the breadth of people who are interested to participate in the study, in the hope that a greater variety of perspectives may be obtained. Additionally, the incentive intends to recognise that the time that nurses take to participate in the study may mean that they are required to work late to finish any work that they would have been doing during that time. NB The voucher will be transferred via secure NHS email to the participant once they have completed the interview, and they will receive the voucher even if they later choose to withdraw from the study.

STUDY OBJECTIVES

OBJECTIVES

Primary Objective

To find out how nurses experience the impact of trauma informed training on their delivery of care, in an inpatient mental health setting

Secondary Objectives

To find out how nurses experience implementing the principles of trauma informed care, in an environment that requires a high level of risk management

ENDPOINTS

Primary Endpoint

- The completion of recording, transcription and analysis of eight to ten x 1:1 semi-structured interviews using Interpretative Phenomenological Analysis

Secondary Endpoints

- The dissemination of research findings to participants, contributors, NHS Tayside inpatient mental health settings, the NES Trauma Strategy group and through publication to a relevant journal

STUDY DESIGN

Design summary

The proposed study is a qualitative project. Semi-structured interviews will be used to explore mental health nurses experience and perspective of trauma-informed practice in an inpatient setting. Data will be analysed using Interpretative Phenomenological Analysis (IPA) (Smith, Flowers, & Larkin, 2009).

Ethical approval

Ethical approval will be sought as required for this study, in accordance with guidance provided by ACCORD, the University of Edinburgh.

Participants and recruitment

Suitable participants will be qualified mental health nurses, on the NHS Agenda for Change pay banding of five, six or seven, who work in one of the four acute mental health adult inpatient settings in NHS Tayside.

A purposive sampling approach will be used to recruit between 8 and 10 participants, to obtain a specific and homogenous sample, as recommended for an IPA study (Smith et al., 2009). In order to recruit suitable participants, the primary investigator will first approach the senior charge nurse on each of the four acute wards in NHS Tayside via email, to request a time to present the study. They will then discuss any logistical issues and how they can be appropriately managed in each setting. Following the presentation and discussion relating to the study, the primary investigator will distribute information leaflets and posters to each acute inpatient ward providing details about the study. The senior charge nurse or the administrative support staff on the ward will be asked to forward information about the study to potential participants via email, so the primary investigator has no contact potential participants directly. Participants will be offered a £10 voucher as an incentive to participate. Participants will then express interest by emailing the primary investigator.

According to Smith et al, a sample of between four and ten is an appropriate sample size for a professional doctorate level study conducting qualitative research using 1:1 interviews within an IPA framework (Smith et al., 2009). Based on this recommendation and considering the purposes of this study, it is hoped that between 8-10 individuals will participate in the study.

There are approximately 72 qualified RMN's working across the four NHS Tayside acute inpatient wards, and therefore it is anticipated that a sample size of 8-10 should be achievable. If there are difficulties obtaining this sample size, then a snowballing approach will be used during the interviews where participants will be invited to invite other colleagues to consider participating in the study.

Method

The researcher will send interested participants the consent form and the planned interview schedule via email. Interested participants will be invited to ask any further questions, before returning a signed written consent form (completed electronically) confirming that they agree to participate in the study. Participants will then be sent a demographic information form and asked to return it via email.

Participants will be invited to attend an audio-recorded 1:1 semi-structured interview. A suitable room will have been identified, for either a Microsoft Teams or face to face interview. The primary investigator will access Microsoft Teams either from their home address or a suitable room in NHS Tayside. NHS Tayside lone working policy will be followed. The primary investigator will access Microsoft Teams via their secure NHS login and will set the record function so only the primary investigator can access the recording after the interview is finished.

Interviews will be facilitated by the primary investigator using a pre-prepared interview schedule. They will take place either via Microsoft Teams or face to face, according to the preference of the participant and the COVID 19 guidance in NHS Tayside at the time the interview. The researcher will confirm with the person meets the study criteria and that they are happy with the informed consent process. They confirm that the demographic information has been provided.

* If Microsoft Teams is used, then the programme will be used to both record and transcribe the interview. A password protected Dictaphone will be used as a back-up to record the interviews. Audio files will then be saved in a password protected file on an NHS computer / laptop, and deleted from the Dictaphone. Once transcription is complete then all audio files will be deleted.

* If face to face interviews are used, then a password protected Dictaphone will be used to record the interviews. Audio files will be directly transferred to a password protected audio file on an NHS computer / laptop, and deleted from the Dictaphone. The interviews will be transcribed manually by the primary investigator. Once transcription is complete then all audio files will be deleted. If Face to face interviews are conducted, the researcher will also collect participants telephone number so that if required they can provide this to Test and Protect. This data will be stored separately to other information gathered during the study, in a password protected file on NHS computer / laptop, and will be deleted after 21 days.

Participant audio files will be saved using a personal code.

A maximum of 10 interviews will be conducted. If more than 10 people express interest then they will be advised that they are on a 'reserve list' and that the primary investigator will make contact if a space becomes available.

Once each interview has been conducted and transcribed, the transcribed interview will be sent by the primary investigator to the participant for them to review via secure NHS email, to confirm that the transcription is an accurate representation of their views.

All data gathered for the purposes of this study will be stored securely, in line with the University of Edinburgh and NHS Tayside data protection guidelines according to GDPR. All personal data will be stored on NHS computers in password protected and separate files, including consent forms, demographic data, participant contact information (email addresses), and audio files. All personal data will be deleted once no longer required.

Analysis

Data will be analysed utilising IPA, as described by Smith et al., (2009). IPA was felt to be an appropriate analysis approach for the current study, as it attempts to really understand the lived experience of participants, to gain a rich and in-depth understanding of the topic being explored (Callary, Rathwell, & Young, 2015; Smith et al., 2009). Additionally, the interpretative component of

IPA will allow the researcher to draw from the participant's collective perspectives a clinically useful interpretation of findings, potentially enhancing the usefulness of the study's findings when considering the implementation of trauma-informed practice in this particular setting.

Validity and quality

Smith et al (2009) suggest Yardley's approach (2000, 2008) is a useful model to assess the validity and quality of an IPA study. Each of the four broad principles proposed by Yardley are considered below (Yardley, 2000, 2008).

Sensitivity to context

- Through carefully designed 1:1 interviews, where expertise and service user feedback will be sought on the design and wording of included questions.
- Through carefully conducted 1:1 interviews, where the researcher will show empathy, and attempt to negotiate anticipated power dynamics, and will reflect on this process through supervision and a reflective diary.
- Through the use of verbatim excerpts used to support the argument being made based on the data provided.
- Through the comprehensive discussion of the wider literature, in order to show the context within which the study has been undertaken.
- Through the use of a reflective diary.
- Through the use of clinical and academic supervision throughout the research process.

Rigour

- Through the in-depth nature of the individual interviews.
- Through the reasonably homogenous sample from which the data will be gathered.
- Through the application of a thorough and systematic approach utilised in IPA studies, following the specific guidance set out by Smith et al., (2009).
- Through the inclusion of excerpts from each participant in the results of the study, to provide illustration of the rigorous approach used and to justify the themes identified.
- Through the interpretative level of analysis undertaken, and inclusion of the wider literature.
- Through a second independent researcher analysing the data set, to ensure identified themes are representative of the data set.
- Through the use of a reflective journal, clinical and academic supervision.

Coherence

- Through demonstration that the study has been conducted in line with the underlying theoretical assumptions described in IPA, drawing on academic supervisory expertise.
- Through the second independent researcher, who will compare and explore any identified discrepancies or lack of coherence in their identified themes with the original researcher.
- Through the presentation of an argument that is both logical and coherent, where discrepancies or contradictions are thoroughly explored by referencing the wider literature in the discussion of the data.

Impact and importance

- The current study explores a topic that is relevant to contemporary clinical directions (NHS Education for Scotland, 2017), and is therefore anticipated to be of relevance and interest.
- The study aims to explore a topic on which limited research has been carried out e.g. (O'Dwyer et al., 2020).
- Through the findings being appropriately disseminated on a local level, in order to inform the ongoing implementation of the trauma informed care agenda in NHS Tayside inpatient mental health settings
- Through the wider dissemination of findings, through the NES Trauma Strategy Group, and the publication of the findings in a relevant journal.

STUDY POPULATION

NUMBER OF PARTICIPANTS

Between eight and ten participants will be recruited. Suitable participants will be qualified mental health nurses, band five, six or seven, who work in one of the four acute mental health adult inpatient settings in NHS Tayside. It is anticipated that recruitment will last up to six months depending on the interest expressed in the study. A purposive sampling approach will be used to recruit participants, to obtain a specific and homogenous sample, as recommended for an IPA study (Smith et al., 2009).

INCLUSION CRITERIA

- Permanent or fixed contract staff member
- Employed to work on one of the four adult inpatient mental health wards by NHS Tayside
- Band 5, 6 or 7 qualified Registered Mental Health Nurse (RMN)
- Has worked on the acute inpatient ward for 6 months or more
- Has completed NHS Education for Scotland (NES) trauma informed e-learning, and/or additional trauma informed training
- Aged between 21 and 65 years of age

EXCLUSION CRITERIA

- Non-English speaking
- Bank or temporary staff

PARTICIPANT SELECTION AND ENROLMENT

IDENTIFYING PARTICIPANTS

The clinical supervisor or the senior practice development nurse in NHS Tayside will facilitate the introduction of the primary investigator and the four senior charge nurses who manage the four acute inpatient wards in NHS Tayside.

The primary investigator will approach the four senior charge nurses. They will request a time to present the study. This will be either via Microsoft Teams or face to face (according to NHS Tayside policy relating to COVID 19 restrictions at that time).

Following the presentation and discussion relating to the study, the primary investigator will distribute information leaflets and posters to each acute inpatient ward providing details about the study. At this point, they will request that the senior charge nurse (or administrative support for the ward) forwards a pre-prepared email with an attached participant information sheet to all the staff working on each ward thought to meet the criteria for the study. This email will provide additional information about the study. If there is been a lack of interest in the study then the primary investigator will also include a snowball sampling approach where they will request that those participants who have completed an interview ask their colleagues if they are interested.

The identification of senior charge nurses will be the only time that the primary investigator is aware of specific names. The primary investigator will not review any screening of identifiable personal information of patients, service users or any other person. Once participants have expressed interest in taking part in the study, then the primary investigator will become aware of their names.

CONSENTING PARTICIPANTS

Informed consent will be obtained from participants before they participate in the study.

Before contacting the primary investigator the interested participant will have been provided with a copy of the participant information sheet, which will have been previously circulated by their ward admin / senior charge nurse. If a participant then emails the primary investigator to express interest in participating, they will be sent an informed consent form detailing what they are agreeing to do. Participants will be invited to ask any questions about the study before they provide consent to participate over email. They will then return the digitally signed consent form prior to the study

commencing. The primary investigator will confirm with the participant prior to commencing the interview that they are happy with the consent form. No other person will be involved in the consent process.

Participants will have a minimum of one day and a maximum of four months to consider the participant information sheet and consent form before they agree to provide informed consent.

Withdrawal of Study Participants

Participants are free to withdraw from the study at any point or a participant can be withdrawn by the Investigator. If withdrawal occurs, the primary reason for withdrawal will be documented in the participant's case report form, if possible.

The participant will be able to withdraw from the study until the point that they agree to 'sign off' their transcribed interview.

STUDY ASSESSMENTS

STUDY ASSESSMENTS

	Providing consent Day 1	Research task 2 Week 1	Research task 1 Month 1	Research task 2 Month 4	Final contact How to access results Month 20
Written informed consent	X				
Demographic data		X			
Semi-structured Interviews			X		
Review transcript				X	
View results					X

LONG TERM FOLLOW UP ASSESSMENTS

Once each interview has been conducted and transcribed, the transcribed interview will be sent to the participant via NHS email for them to review, to confirm that the transcription is an accurate representation of their views. It is anticipated that this would occur within a three to four-month period of the interview.

DATA COLLECTION

Data collection will include collecting demographic information forms, conducting 1:1 interviews, and obtaining a confirmation that transcripts are acceptable to the participant. The primary investigator will be the only person involved in data collection.

Demographic data

Descriptive data will be collected from participants via a multiple-choice form in advance of the interview, via email.

Interview data

A pre-prepared interview schedule will be used to guide the 1:1 interviews (see supporting documents). It has been suggested that for an IPA study, between six to ten questions are appropriate when interviewing adult, articulate participants (Smith et al., 2009). Accordingly, the anticipated schedule will include around ten open questions, with additional prompts. The schedule will be designed with support from experienced researcher/s familiar with IPA, and with feedback from people who have lived experience of acute inpatient wards and from NHS staff. The interview will begin with broader more descriptive questions, and move towards more focussed and sensitive questions as the interview proceeds, as recommended by Smith et al., (2009).

On completion of the interview, participants will be debriefed and given time to provide feedback.

Review of transcription

After three to four months the participants will be contacted by secure NHS email and asked to review their transcripts for accuracy and to confirm that they are in agreement with the included content being included in the study.

Source Data Documentation

- Anonymised demographic questionnaire
- Audio recordings
- Transcribed data set

DATA MANAGEMENT

Personal Data

All data gathered for the purposes of this study will be stored securely, in line with the University of Edinburgh and NHS Tayside data protection guidelines according to GDPR.

The study will adhere to the principles of Good Clinical Practice.

All storage and use of **personal data** will be done on NHS computer / laptops using password protected files, storing different data in separate files. All files will be saved using a personal code. This will include audio recordings, consent forms, contact information (email addresses) and demographic data.

Audio recordings

Audio recordings will be made and saved onto a password-protected Dictaphone, and through Microsoft Teams record function when interviews are conducted over Microsoft Teams.

Recordings will be transferred to a password protected file on an NHS computer / laptop at the soonest opportunity. The original audio recordings will be deleted at this point. All audio recordings and transcribed interviews will be saved using a personal code.

The primary investigator will use an auto transcribe option on Microsoft Teams to transcribe the interviews if conducted over MS Teams, and they will transcribe face to face interviews manually. An external transcriber will not be used.

All password protected audio files will be deleted once the transcription has been completed.

The transcription of the interviews will be anonymised and pseudonymised. Anonymised transcribed interview data set will be saved onto the University of Edinburgh One Drive system. The primary investigator will then be able to continue to analyse the anonymised data set whilst at their home address.

Once the study is complete, the anonymised transcribed interviews will be stored on the University of Edinburgh's Data Store system for up to 10 years in a password protected file.

Participant contact information

Participant email addresses will be stored in a separate password protected file on NHS Tayside computer system. This file will provide the link between the participant and their personal code.

At the end of the study once participants have been emailed to find out how to access the results of the study, then their email addresses will be permanently deleted from the password protected file.

If Face to face interviews are conducted, the researcher will also collect participants telephone number so that if required they can provide this to Test and Protect. This data will be stored separately to other information gathered during the study, in a password protected file on NHS computer / laptop, and will be deleted after 21 days.

Consent forms

Consent forms will be returned digitally via secure NHS email. Once the consent form is received, they will be saved onto a password protected file on NHS Tayside computer system. If any forms are returned in paper format they will be scanned and uploaded to the password protected file, and the original paper copy will be safely destroyed.

Consent forms will be stored in a separate password protected file on NHS Tayside computer system.

Consent forms will be permanently deleted within 6 months of the study's completion.

Demographic Information

The following data will be collected as part of the research.

- *Age range*
- *Gender*
- *Employment period in current role*
- *Trauma training received and when*
- *NHS agenda for change banding*

The data that will be collected will not be specific, to minimise the risk that it could result in participant being identifiable from this information. Demographic data will be saved under the personal code provided to each participant. Anonymised demographic information will be stored in a password protected file on the NHS Tayside computer system for the duration of the study, and will be permanently deleted within 6 months of the study's completion.

Transfer of Data

Data collected or generated by the study (including personal data) will not be transferred to any external individuals or organisations outside of the Sponsoring organisation(s).

Data Controller

The University of Edinburgh and NHS Tayside are joint data controllers along with any other entities involved in delivering the study that may be a data controller in accordance with applicable laws (e.g. the site).

Data Breaches

Any data breaches will be reported to the University of Edinburgh and NHS Tayside Data Protection Officers who will onward report to the relevant authority according to the appropriate timelines if required.

STATISTICS AND DATA ANALYSIS

SAMPLE SIZE CALCULATION

According to Smith et al, a sample of between four and ten is an appropriate number for professional doctorates conducting qualitative research using 1:1 interviews in an IPA framework (Smith et al., 2009). Based on this recommendation and considering the purposes of this study, it is hoped that between 8-10 individuals will participate in the study.

PROPOSED ANALYSES

Once transcribed by the researcher, data will be analysed utilising IPA. Each interview will be analysed in turn, working through the steps described by Smith et al (2009), including:

- Reading and re-reading the transcript
- Conducting 'initial noting' in order to ensure increasing familiarity with the content
- Developing emergent themes
- Identifying connections between themes
- Repeating this process for each transcribed interview

A second researcher will review the anonymised transcribed interviews. This person will be a trainee clinical psychologist at the University of Edinburgh. Any discrepancies will be discussed between the two researchers, before identifying final overarching themes. The overarching themes will be used to guide the discussion, during which they will be explored in depth and with reference to the wider literature, including an interpretative component.

The clinical and academic researchers involved in this study may also provide input on the analysis phase, and will be provided secure access to the anonymised transcribed interviews if required.

RISKS

POSSIBLE DISTRESS TO PARTICIPANTS

It is not anticipated that distress will be caused to participants. However, the topics explored are sensitive in nature and it is possible that participants may experience distress during or after the interview. A number of steps will be taken to minimise this risk. Participants will be advised of the topics that will be explored and of their right to withdraw from the study at any time as part of the written consent process. The interview will explore more sensitive topics later on, so the participant has time to become comfortable with the process. Should a participant become distressed during the interview, the interview will be terminated and support will be offered. Once interviewing has ended, all participants will be debriefed and given the opportunity to provide feedback. A debrief and feedback form will be provided, including helpline numbers.

COVID-19

Depending on the situation with the ongoing COVID-19 pandemic, it would be unethical to create any additional risk of exposure participants working on acute inpatient wards for the purposes of this research. Therefore the research will be conducted according to local guidelines set out at the time of the research, and will only be conducted face to face if this is acceptable within NHS Tayside at that time. As such unless guidelines allow for face to face interviews at the time of the research, Microsoft Teams will be used to conduct the interviews to minimise the risk of COVID-19 exposure to participants or the primary investigator. Even if face to face interviews are permitted, participants will be offered the choice of face to face or Microsoft teams interviews.

PERSONAL DISCLOSURE

A disclosure relating to personal experience of trauma - It is possible that participants disclose their own experiences of trauma during the current study. If any disclosure is made and a participant becomes distressed, support will be offered (as above). Participants will be reminded that they can withdraw from the study at any stage if they wish to. Additionally, participants will be provided with a transcript of their interview to review at a later date and will be able to request the exclusion of any disclosures made in the data set if they wish to. Audio recordings will be destroyed once interviews have been transcribed, so personal data will not be stored. Transcribed interviews will be anonymised and stored according to data management requirements, in a password protected file. Lastly, the primary investigator will ensure a sensitive use of the included verbatim quotations and will obtain explicit consent from the participant if they are considering using any potentially identifiable information relating to a personal disclosure in the summarised findings.

WARD STAFFING LEVELS

Staff removing themselves from the ward - The current study will require a nurse to remove themselves from the clinical running of an acute inpatient ward in order to participate in the study. In order to avoid this impacting on the safe running of the ward, senior charge nurses will first be consulted on each ward to find out how to achieve this in a safe manner. Having consulted one senior charge nurse in NHS Tayside, it is likely that they will recommend interviews are arranged during the handover period, at which time there is an overlap between shifts and additional clinical staff. This will ensure that the research participants can safely withdraw from the ward for an allocated time period in order to participate in the study. Interviews will be kept within a 1 hour time period.

MAINTAINING ANONYMITY

It is of particular importance that participants feel able to express their views openly without concern about how they may be perceived by the management team, including any clinical leads or the clinical supervisor for the current project. In order to protect the anonymity of participants, no one employed by NHS Tayside will see the raw data. One Trainee Psychologist employed by NHS Tayside otherwise uninvolved in the study will review the data set once it has been anonymised, for the purposes of ensuring the validity and quality of the data.

PUBLICATION AND ANONYMITY

Any direct quotations taken from the interview data will be recorded under a pseudonym. However, due to the small number of participants and the small number of wards from which recruitment will occur, it is possible that the nature of the quotations might appear recognisable to those familiar with the person (e.g. if a particular opinion is voiced). To minimise this risk, the participating individuals in the study will be asked to review their transcripts to confirm that they are comfortable with what is potentially included. They will provide informed consent to allow verbatim quotes to be taken from their transcripts. The primary investigator will be sensitive to this possibility and careful when considering what verbatim quotes to include in the data analysis. And lastly, there will be a number of other participants (between 8-10) minimising the risk that one individual could be clearly identified.

LONE WORKING

Lone working policy will be closely followed in accordance with NHS Tayside guidelines to minimise any risks in relation to working alone.

DISCLOSURE RELATING TO UNSAFE OR UNETHICAL PRACTICE

It is possible a participant discloses either ongoing or previous unsafe or unethical practices that have placed either staff or patients at risk of harm, then the researcher will closely follow ACCORD and NHS Tayside guidance with regard to whether to maintain confidentiality or to take the concern further. Where possible and if there is any lack of clarity regarding appropriate action (whether or not to break confidentiality), the primary investigator will first obtain external advice from their research supervisor, before then taking appropriate action in line with ACCORD and NHS Tayside policy. If there is any urgency relating to the disclosure, then the researcher will immediately take action according to ACCORD and NHS Tayside policy. During the informed consent process, participants will be made aware that the researcher may have to break confidentiality if concerns have been raised regarding unsafe or unethical practices.

OVERSIGHT ARRANGEMENTS

INSPECTION OF RECORDS

Investigators and institutions involved in the study will permit trial related monitoring and audits on behalf of the sponsor, REC review, and regulatory inspection(s). In the event of audit or monitoring, the Investigator agrees to allow the representatives of the sponsor direct access to all study records and source documentation. In the event of regulatory inspection, the Investigator agrees to allow inspectors direct access to all study records and source documentation.

STUDY MONITORING AND AUDIT

The ACCORD Sponsor Representative will assess the study to determine if an independent risk assessment is required. If required, the independent risk assessment will be carried out by the ACCORD Quality Assurance Group to determine if an audit should be performed before/during/after the study and, if so, at what frequency.

Risk assessment, if required, will determine if audit by the ACCORD QA group is required. Should audit be required, details will be captured in an audit plan. Audit of Investigator sites, study management activities and study collaborative units, facilities and 3rd parties may be performed.

GOOD CLINICAL PRACTICE

ETHICAL CONDUCT

The study will be conducted in accordance with the principles of the International Conference on Harmonisation Tripartite Guideline for Good Clinical Practice (ICH GCP).

Before the study can commence, all required approvals will be obtained and any conditions of approvals will be met.

INVESTIGATOR RESPONSIBILITIES

The Investigator is responsible for the overall conduct of the study at the site and compliance with the protocol and any protocol amendments. In accordance with the principles of ICH GCP, the following areas listed in this section are also the responsibility of the Investigator. Responsibilities may be delegated to an appropriate member of study site staff.

Delegated tasks must be documented on a Delegation Log and signed by all those named on the list prior to undertaking applicable study-related procedures.

Informed Consent

The Investigator is responsible for ensuring informed consent is obtained before any protocol specific procedures are carried out. The decision of a participant to participate in clinical research is voluntary and should be based on a clear understanding of what is involved.

Participants must receive adequate oral and written information – appropriate Participant Information and Informed Consent Forms will be provided. The oral explanation to the participant will be performed by the Investigator or qualified delegated person, and must cover all the elements specified in the Participant Information Sheet and Consent Form.

The participant must be given every opportunity to clarify any points they do not understand and, if necessary, ask for more information. The participant must be given sufficient time to consider the information provided. It should be emphasised that the participant may withdraw their consent to participate at any time without loss of benefits to which they otherwise would be entitled.

The participant will be informed and agree to their medical records being inspected by regulatory authorities and representatives of the sponsor(s).

Inspection by regulatory authorities can be deleted for non-CTIMP studies. The Investigator or delegated member of the trial team and the participant will sign and date the Informed Consent Form(s) to confirm that consent has been obtained. The participant will receive a copy of this document and a copy filed in the Investigator Site File (ISF) and participant's medical notes (if applicable).

Study Site Staff

The Investigator must be familiar with the protocol and the study requirements. It is the Investigator's responsibility to ensure that all staff assisting with the study are adequately informed about the protocol and their trial related duties.

Data Recording

The Principal Investigator is responsible for the quality of the data recorded in the CRF at each Investigator Site.

Investigator Documentation

- The Principal Investigator will ensure that the required documentation is available in local Investigator Site files ISFs.

GCP Training

For non-CTIMP (i.e. non-drug) studies all researchers are encouraged to undertake GCP training in order to understand the principles of GCP. However, this is not a mandatory requirement unless deemed so by the sponsor. GCP training status for all investigators should be indicated in their respective CVs.

Confidentiality

All evaluation forms, reports, and other records must be identified in a manner designed to maintain participant confidentiality. All records must be kept in a secure storage area with limited access. Clinical information will not be released without the written permission of the participant. The Investigator and staff involved with this study may not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished information, which is confidential or identifiable, and has been disclosed to those individuals for the purpose of the study. Prior written agreement from the sponsor or its designee must be obtained for the disclosure of any said confidential information to other parties.

Data Protection

All Investigators and study site staff involved with this study must comply with the requirements of the appropriate data protection legislation (including the General Data Protection Regulation and Data Protection Act) with regard to the collection, storage, processing and disclosure of personal information.

Computers used to collate the data will have limited access measures via usernames and passwords.

Published results will not contain any personal data and be of a form where individuals are not identified and re-identification is not likely to take place

STUDY CONDUCT RESPONSIBILITIES

PROTOCOL AMENDMENTS

Any changes in research activity, except those necessary to remove an apparent, immediate hazard to the participant in the case of an urgent safety measure, must be reviewed and approved by the Chief Investigator.

Amendments will be submitted to a sponsor representative for review and authorisation before being submitted in writing to the appropriate REC, and local R&D for approval prior to participants being enrolled into an amended protocol.

MANAGEMENT OF PROTOCOL NON COMPLIANCE

Prospective protocol deviations, i.e. protocol waivers, will not be approved by the sponsors and therefore will not be implemented, except where necessary to eliminate an immediate hazard to study participants. If this necessitates a subsequent protocol amendment, this should be submitted to the REC, and local R&D for review and approval if appropriate.

Protocol deviations will be recorded in a protocol deviation log and logs will be submitted to the sponsors every 3 months. Each protocol violation will be reported to the sponsor within 3 days of becoming aware of the violation. All protocol deviation logs and violation forms should be emailed to QA@accord.scot

Deviations and violations are non-compliance events discovered after the event has occurred. Deviation logs will be maintained for each site in multi-centre studies. An alternative frequency of deviation log submission to the sponsors may be agreed in writing with the sponsors.

SERIOUS BREACH REQUIREMENTS

A serious breach is a breach which is likely to effect to a significant degree:

- (a) the safety or physical or mental integrity of the participants of the trial; or
- (b) the scientific value of the trial.

If a potential serious breach is identified by the Chief investigator, Principal Investigator or delegates, the sponsor (seriousbreach@accord.scot) must be notified within 24 hours. It is the responsibility of the sponsor to assess the impact of the breach on the scientific value of the trial, to determine whether the incident constitutes a serious breach and report to research ethics committees as necessary.

STUDY RECORD RETENTION

Audio recordings will not be kept longer than necessary and will be destroyed once transcription has taken place. Contact details of the participants will be destroyed once they have been contacted to provide advice on how to access the study's findings.

All other study documentation will be kept for a minimum of 3 years from the protocol defined end of study point. When the minimum retention period has elapsed, study documentation will not be destroyed without permission from the sponsor.

END OF STUDY

The end of study is defined as the last participant's last visit.

The Investigators or the sponsor have the right at any time to terminate the study for clinical or administrative reasons.

The end of the study will be reported to the REC, and R+D Office(s) and sponsor within 90 days, or 15 days if the study is terminated prematurely. The Investigators will inform participants of the premature study closure and ensure that the appropriate follow up is arranged for all participants involved. End of study notification will be reported to the co-sponsors via email to resgov@accord.scot

A summary report of the study will be provided to the REC within 1 year of the end of the study.

INSURANCE AND INDEMNITY

The sponsor is responsible for ensuring proper provision has been made for insurance or indemnity to cover their liability and the liability of the Chief Investigator and staff.

The following arrangements are in place to fulfil the co-sponsors' responsibilities:

- The Protocol has been designed by the Chief Investigator and researchers employed by the University and collaborators. The University has insurance in place (which includes no-fault compensation) for negligent harm caused by poor protocol design by the Chief Investigator and researchers employed by the University.
- Sites participating in the study will be liable for clinical negligence and other negligent harm to individuals taking part in the study and covered by the duty of care owed to them by the sites concerned. The co-sponsors require individual sites participating in the study to arrange for their own insurance or indemnity in respect of these liabilities.
- Sites which are part of the United Kingdom's National Health Service will have the benefit of NHS Indemnity.
- Sites out with the United Kingdom will be responsible for arranging their own indemnity or insurance for their participation in the study, as well as for compliance with local law applicable to their participation in the study.

REPORTING, PUBLICATIONS AND NOTIFICATION OF RESULTS

AUTHORSHIP POLICY

Suggested text only - amend as appropriate.

Ownership of the data arising from this study resides with the study team.

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Appendix 2: Participant information sheet

Trauma informed practice in inpatient settings
V2 03/12/2021

THE UNIVERSITY
of EDINBURGH

PARTICIPANT INFORMATION SHEET

Trauma Informed Practice in Acute Inpatient Settings

The perspective and experience of Mental Health Nurses – A Qualitative Study

You are being invited to take part in research looking at trauma informed practice in the acute inpatient setting, from your perspective as a mental health nurse.

Miriam Zoeller, (Trainee Clinical Psychologist at NHS Tayside, with the University of Edinburgh), is leading this research.

Before you decide whether to take part, it is important you understand why the research is being conducted and what it will involve. Please take time to read the following information carefully.

WHAT IS THE PURPOSE OF THE STUDY?

The Scottish government has committed to the Scottish workforce becoming trauma informed, and trauma informed training opportunities have been offered to staff members in NHS Tayside. Trauma informed practice highlights the importance of safety, trustworthiness, choice, collaboration and empowerment.

The current study is really interested in finding out more about how mental health nurses working in acute wards view this national shift towards utilising a trauma informed approach, and how this has been perceived and experienced within the acute inpatient setting. The study is interested in finding out more on questions like:

- What is your opinion on taking a trauma informed approach in an acute inpatient setting?
- What are your thoughts around the challenges to working in a trauma informed way in an acute inpatient setting?
- What are your thoughts around the benefits when taking a more trauma informed approach in an acute inpatient setting?

NB. The full interview schedule will also be sent to you in a separate document if you decide to express interest in the study.

WHY HAVE I BEEN INVITED TO TAKE PART?

You are invited to participate in this study because you are a mental health nurse working in an acute inpatient mental health ward in NHS Tayside for at least 6 months who has completed NES trauma informed care e-learning and/or additional trauma informed training.

DO I HAVE TO TAKE PART?

No – it is entirely up to you.

If you do decide to take part, you are free to withdraw at any time and without giving a reason, until after the point that you have reviewed your transcribed interview and confirmed that you are happy for your interview to be included in the analysis phase of the study. After the point that you confirm that you are happy for your interview to be

included in the analysis stage of the research, you will not be able to withdraw from the study, due to analysis being underway. Deciding not to take part or withdrawing from the study will not affect your employment in any way.

Please note that your anonymised data may be used in the production of formal research outputs (e.g. journal articles, conference papers, theses and reports) prior to your withdrawal and so you are advised to contact the research team at the earliest opportunity should you wish to withdraw your data from the study.

WHAT WILL HAPPEN IF I DECIDE TO TAKE PART?

If you do decide to take part, please keep this Information Sheet. You will be asked to complete an **Informed Consent Form** to show that you understand your rights in relation to the research, and that you are happy to participate. This will be emailed to you in advance of the interview.

You will be then be asked to complete a short multiple choice demographic information questionnaire, including gender, age range, time in job, agenda for change banding and the level of Trauma Informed Training you have obtained.

After that, you will be invited to take part in a 1-to-1 interview with the primary investigator. During the interview you will be asked a number of questions regarding your experiences and your perspective on trauma informed practice whilst working in the acute inpatient setting. The interview will take place during working hours, in a safe environment agreed with the senior charge nurse for your clinical setting, and arranged at a time that is convenient to you. This may be online (via Microsoft Teams) or face to face, depending on your preference, and in line with COVID-19 related guidelines. We would like to audio record your responses (and will require your consent for this), so the location should be in a fairly quiet area. The interview should take no longer than 1 hour to complete.

After the interview has been transcribed, you will be sent a written copy of your interview to review, via email. This will be within approximately three months of your initial interview. You will then be asked to review your transcribed interview and to confirm whether you are happy to 'sign off' your transcribed interview, or if you would like to make any amendments. After you agree that your interview can be included in the study, you will no longer be able to withdraw due to the study entering the analysis phase.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

The main benefit of this study is to have an opportunity to share the experience of working on the frontline of mental health care, so that the findings from this research can be shared and influence clinical leads in NHS Tayside, and those involved in developing and implementing the trauma informed agenda.

We appreciate that participating in this study requires you to take time away from your normal work, and that this may place some additional pressure on you. Therefore we would like to re-imburse you for your time by giving you a **£10 Just Eat voucher**, which will be sent to you via email, shortly after you complete the interview.

ARE THERE ANY RISKS OR DISADVANTAGES ASSOCIATED WITH TAKING PART?

There are **no significant risks** associated with participating in this study.

Interviews are anticipated to take up to 1 hour to complete, and to minimise the inconvenience of this the researcher will endeavour to arrange the interview at a time that suits you and the ward. This may be during a weekend shift or during the overlap time between shifts.

POSSIBLE RISKS THAT HAVE BEEN CONSIDERED:

Discussing topics relating to trauma could be upsetting

- A copy of the interview schedule will be provided to you in advance, so you are aware of the topics that will be covered before you consent to participate in the study.
- If you were to become distressed during the interview, the interview would stop and support would be offered.
- Once the interview ends, you will be given the opportunity to debrief and to provide feedback. A debrief and feedback form will be given to you to take away, including helpline numbers.

Possible personal disclosure

- Whilst this is **not** something that will be asked about, it is possible that you may choose to disclose personal experiences of trauma during the 1:1 audio recorded interview.
- To ensure that nothing is included in the analysis that you are not comfortable with, you will be emailed a copy of the written transcript of your interview to review, approximately three months after the interview. This will give you time to make any changes or exclude anything you do not want include in the analysis phase.
- You will be able to withdraw from the study at any time until you confirm you are happy with your interview transcript. After this point data analysis will commence and you will no longer be able to withdraw from the study.

Disclosure relating to unsafe or unethical practice

It is possible that you may disclose unsafe or unethical practices during an interview. If this were to occur, then the primary investigator may have to act on this information according to NHS Tayside policy. If this were to occur, then the primary investigator would first discuss this with you.

Management of the ward

By participating in this study, you will have to leave the ward environment. To minimise the impact of nurses leaving the ward, the study will be discussed with the senior charge nurse in advance, to plan for minimal disruption to the running of the ward. The primary investigator will be flexible to the needs of the nurses on duty, and will agree to completing the interview at a time suitable to the nurse participant e.g. if a weekend is the best time then this will be accommodated where possible. Additionally, if for unforeseen reasons the ward is not safe without the additional staff member, then the primary investigator will be flexible with re-scheduling interviews if required.

Lone working

You may be alone for the purpose of completing the interview. Lone working policy will be closely followed in accordance with NHS Tayside guidelines to minimise any risks in relation to working alone.

COVID-19 RELATED RISKS OF PARTICIPATION, IF FACE TO FACE INTERVIEW

We have taken specific steps to minimise the risk of exposure to the Coronavirus during the study by adhering to the Scottish Government [guidance \(https://www.gov.scot/coronavirus-covid-19/\)](https://www.gov.scot/coronavirus-covid-19/). These measures include good hand hygiene and surface cleaning, good ventilation, keeping a safe distance, and continued requirement for face coverings in indoor public places. Further, if you have arranged to participate in a face to face interview, the interview will only go ahead if the primary investigator has had negative lateral flow test within 24 hours of the interview, has not experienced COVID-19-related symptoms, and has not been required to self-isolate due to close contact with a COVID-19 positive individual.

However, even with these control measures, there remains some additional risk of exposure to COVID-19 from participating in this study, but we do not assess that this risk is higher than engaging in other day-to-day activities.

In recognition of risk in relation to COVID 19, you will be given the choice between attending an interview conducted over Microsoft Teams, or face to face, according to your preference and personal circumstances.

Understanding your risk from exposure to COVID-19

It is not possible to eliminate all risk of exposure to COVID-19, and so it is important for you to understand and consider your own personal risk in the unlikely event of exposure.

You may be more likely to be at high-risk from infection if you have previously been advised to shield from the virus, if you have certain health conditions (including heart disease, lung disease, kidney disease, diabetes, or neurological disease), or if you are taking immunosuppressant medication or steroids. The risks of serious consequences from COVID-19 are also known to increase on average with age. To understand more about potential risk factors, please visit [this NHS webpage](#).

Making an informed choice

It is important that you make an informed choice whether or not to take part in this research, either via Microsoft Teams or face to face, considering your potential risk from the virus, and the measures in place to reduce the risk of exposure. It is important that you feel that you have all of the information required regarding these risks, and can consider that in light of your personal circumstances (e.g. health, caring responsibilities). You should have had a chance to reflect on these risks, and discuss them with a researcher

(researchers to determine if required), prior to agreeing to participate in the study.

Storing contact details (off campus)

For the purpose of [NHS Test and Protect](#) we will request and store your name and contact details for 21 days after the research interaction, if you choose to participate in a face to face interview. If during this 21 day period, the primary investigator has a positive COVID-19 test then, if requested, your contact details will be shared with NHS contact tracers, who may then contact you directly. The period of 21 days will ensure full cover of the typical incubation period and additional time during which people may be infectious. This information relating to your name and contact details is in addition to the data collected as part of the research study, will be stored separately from the research data shared with NHS Test and Protect if requested, and the legal basis for collecting these data is substantial public interest.

What if I am unwell prior to the research interaction?

If you feel unwell, experience COVID-19 related symptoms, have a positive lateral flow or PCR test, or have been required to self-isolated due to contact with a COVID-19 positive individual, then please contact the researcher Miriam Zoeller, 07412995740 and we will postpone or cancel the research interaction.

What if I become unwell after the research interaction?

If you experience COVID-19 related symptoms, and/or have a positive COVID-19 test following the research interaction, please follow the Scottish Government guidance.

WILL MY TAKING PART BE KEPT CONFIDENTIAL?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage.

HOW WILL WE USE INFORMATION ABOUT YOU?

We will need to use information from you for this research project, including:

- Your name
- Your NHS email address (so we can contact you)
- Your age range
- Your gender
- Your employment period in current role
- What level of Trauma training received and approximately how long ago
- Your NHS agenda for change banding

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Unless they are anonymised in our records, your data will be referred to by a unique participant number rather than by name. If you consent to being audio recorded, all recordings will be destroyed once they have been transcribed and you have checked the transcription. Your identifiable data will only be viewed by the primary investigator. All electronic data will be stored in an encrypted computer file. No paper files are intended to be used in this study. Your consent information will be kept separately from your transcribed data in order to minimise any risk of data becoming identifiable.

Once we have finished the study, we will keep some anonymised data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, however it will not be possible to withdraw your data once data analysis has commenced. You will be asked to review your transcript and confirm you are happy with it before that stage.
- We need to manage your records in specific ways for the research to be reliable. This means that once you have verified you are happy with your transcribed interview, we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information at <https://www.ed.ac.uk/records-management/privacy-notice-research> or by asking one of the research team.

The University of Edinburgh is the sponsor for this study, based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Identifiable information about you will be kept for 6 months after the study has finished in a password protected file on an NHS computer, in order to allow the primary investigator time to contact you about the results of the study. After that, the primary investigator will delete all identifiable data about you, including all email correspondence made during the study. Your anonymised data, including your interview transcript, will be safely stored for a minimum of 10 years and may be used in future ethically approved research.

WHAT WILL HAPPEN WITH THE RESULTS OF THIS STUDY?

The results of this study may be summarised in published articles, reports and presentations. You will not be identifiable from any published results. Quotes or key findings will be made anonymous in any formal outputs unless we have your prior and explicit written permission to attribute them to you by name. A summary of the findings

will be sent to participants by email. After this contact, participants email addresses and all email correspondence between participants and the primary investigator will be deleted.

WHO IS ORGANISING AND FUNDING THE RESEARCH?

This study has been organised by Miriam Zoeller, a Trainee Clinical Psychologist in NHS Tayside, and is sponsored by the University of Edinburgh.

WHO HAS REVIEWED THE STUDY?

The study proposal has been reviewed by The School of Health in Social Science Ethics Committee. NHS Management approval has also been obtained.

WHO CAN I CONTACT?

If you have any further questions about the study, please contact the lead researcher, Miriam Zoeller,

If you would like to discuss this study with someone independent of the study please contact Helen Sharpe, Research Lead for Clinical and Health Psychology at the University of Edinburgh on:

If you wish to make a complaint about the study, please contact:

Professor Matthias Schwannauer (), Head of School, School of Health in Social Sciences, The University of Edinburgh.

Appendix 3. Consent form

Trauma informed practice in inpatient settings
V1 18/09/2021



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PARTICIPANT CONSENT FORM

Trauma Informed Practice in Acute Inpatient Settings

The perspective and experience of Mental Health Nurses – A Qualitative Study

Researcher's name and contact details:

Miriam Zoeller (Trainee Clinical Psychologist)

Participant ID: _____


Please Initial Box

1. I confirm that I have read and understood the Participant Information Sheet (Version 1 dated 18/09/2021) for the above study.
2. I have been given the opportunity to consider the information provided, ask questions and have had these questions answered to my satisfaction.
3. I understand that my participation is voluntary and that I can ask to withdraw at any time without giving a reason and without my employment rights being affected.
4. I understand that relevant sections of data collected during the study may be looked at by individuals from the regulatory authorities and from the Sponsor (the University of Edinburgh) or from the NHS Board where it is relevant to my taking part in this research. I give permission for those individuals to have access to my records
5. I understand that my anonymised data will be stored for a minimum of 10 years and may be used in future ethically approved research
6. ONLY APPLICABLE FOR Face to Face RESEARCH: I am aware that participating in this study at the current time may carry risks in relation to potential exposure to coronavirus, and I understand the steps that have been taken in relation to minimise the risks of exposure and transmission
7. I agree to my interview being audio recorded.
8. I agree to take part in the above study.


Name of person giving consent	Date	Signature
_____	_____	_____
Name of person taking consent	Date	Signature
_____	_____	_____

Appendix 4. Interview schedule

Trauma informed practice in inpatient settings
V2 17/01/2022



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Interview Schedule

Trauma Informed Practice in Acute Inpatient Settings

The perspective and experience of Mental Health Nurses – A Qualitative Study

Researcher’s name and contact details:

Miriam Zoeller (Trainee Clinical Psychologist)

Introduction

Thank you for expressing interest in participating in this research. We are interested in your experience of trauma informed practice in the acute inpatient setting, from your perspective as a mental health nurse.

We expect the interview to take up to 1 hour, but we can stop to take a break at any point, and you can finish the interview at any time without giving an explanation.

[If participant has consented to be recorded, switch on the recorder]

May I double-check that you are happy for this interview to be recorded?

[Continue recording, if participant has confirmed their consent.]

Outline questions

1. **Can you tell me about your role, working on ... ward?**
 - *Prompts – what might your typical day involve? What might the difference be between a good day or a bad day at work?*
2. **Can you tell me a bit about what you understand by the term trauma?**
 - *Prompts – Can you tell me a bit more? How do you think trauma might affect people?*
3. **Can you describe how completing some training on trauma informed practice has affected the way you approach your work, if at all?**
 - *Prompts – If not, why not? If yes, in what kind of ways? How do you think your colleagues might view the idea of trauma informed practice? Do you think there are particular advantages or any disadvantages of trying to work in a Trauma Informed way?*
4. Trauma informed principles according to NHS Education Scotland are: *(show and read words: Choice, Collaboration, Trust, Empowerment and Safety)*. **In your experience, how would you say these principles fit into your work environment?**
 - *Prompts – What might be some practical examples of applying some of these principles? What might be some of the challenges of bringing these principles into your working practice/or work environment?*
5. **How do you think knowing someone has experienced trauma might affect the way you work with them, if at all?**
 - *Prompts – Why is that? Might that knowledge change how your colleagues work with someone? Why? Why not?*
6. **Can you tell me about your role and managing risk?**
 - *Prompts – What kind of approaches might you use to manage risk? How do you find using those kinds of approaches? How do you think people admitted on the ward may experience restraint? How might past trauma impact on someone's experience of restraint?*
7. **How do you think it would be for you, if someone on the ward wanted to open up to you about their experience of trauma?**
 - *Prompts – How would you feel about that situation? How might your colleagues manage it? Would it feel different if someone wanted to speak about their experience of sexual abuse?*
8. **How do you think exposure to potentially traumatic experiences through your work might affect staff members?**

- *Prompts – So for example, directly being involved or observing distressing situations, or being told about others experiences of trauma. Why is that? How do you think staff manage the pressures of working in this setting?*

9. **What is your experience of the support available to staff in your setting?**

- *Prompts – What kind of support systems for staff are you aware of? Do you know what systems are made use of? What is your experience around the culture around supervision and self-care in your work? How might support be improved?*

Closing question - Is there anything else you would like to discuss that has not already been covered?

Appendix 5. Demographic questionnaire

Trauma informed practice in inpatient settings
V1 18/09/2021



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Demographic Information

Trauma Informed Practice in Acute Inpatient Settings

The perspective and experience of Mental Health Nurses – A Qualitative Study

Thank you very much for agreeing to participate in the study!

Please could you return this completed form to:

Participant ID: _____ (please leave blank - to be completed by researcher on return)

		Please put a X in the right box
Gender	Male	
	Female	
	Other	
Age	20-30	
	30-40	
	40-50	
	50-60	
	60+	

		Please put a X in the right box
Agenda for change banding	5	
	6	
	7	
Employment period in an acute ward	>1 year	
	1-3 years	
	3-6 years	
	6-9 years	
	9 years +	
Level of trauma informed care training received	e-learning only	
	Less than half a day of training	
	2 days training +	

Appendix 6. Debrief sheet

Trauma informed practice in inpatient settings
V2 03/12/2021



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Debrief Sheet

Trauma Informed Practice in Acute Inpatient Settings

The perspective and experience of Mental Health Nurses – A Qualitative Study

Thank you very much for participating in this study, your time and contribution is appreciated.

The interview has been exploring a topic that may have been difficult to talk about at times.

If anything that was discussed during the interview has been in any way distressing or difficult, then please do not hesitate to contact the researcher to discuss what support may be available to you.

Please be aware of the following possible sources of support:

1. **NHS Tayside's Employee Assistance Provider (EAP) - Care First**

Care First provides short-term counselling support and can be contacted 24/7 on (Freephone) 0808 168 2143 (Minicom: 0800 174 319).

Their website has a wealth of information / advice about a huge array of topics at www.carefirst-lifestyle.co.uk (Username: NHS Tayside password: employee).

2. **NHS Tayside Staff Wellbeing & Support Service**

Telephone: 01382 423110, extension 40806 Emergency out of hours:
07917183804 Email: tay.wellbeing@nhs.scot

3. **NHS Tayside's Community Listening Service**

This service is here for you throughout this difficult time, with appointments available Monday – Friday. They will listen and can help you rediscover your strength. Just call or text 07967771941.

4. **The Scottish Government's National Wellbeing Hub**

The resources on this site are based on the principles of psychological first aid. The hub provides advice and support for practical, everyday needs and relationships, as well as tips on self-care, to help you cope with the challenges you're facing during the pandemic. Visit www.promis.scot.

5. **Samaritans**

Whatever you're going through, you can call any time, from any phone for FREE.-
116 123

6. **Breathing space**

A free confidential listening service for Scotland – 0800 83 85 87

If you have any further questions about the study, please contact the [primary investigator](#), Miriam Zoeller, [or by phone on 07412995740](#), [or should you require them for the purposes of Test and Protect following your interview](#).

If you would like to discuss this study with someone independent of the study please contact Helen Sharpe, Research Lead for Clinical and Health Psychology at the University of Edinburgh on:

If you wish to make a complaint about the study, please contact:

Professor Matthias Schwannauer (), Head of School, School of Health in Social Sciences, The University of Edinburgh.

Appendix 7. Confirmation of ethical approval with HISS

School of Health in Social Science Research Ethics Application

The supervisor or primary investigator must complete and sign this form after checking that all relevant sections are completed, and relevant documents are attached. For all undergraduate (UG) and MSc student projects, it is the supervisor's responsibility to submit this form and all attachments. Please note that failure to do this will result in the application being returned (and not processed) causing your research to be delayed.



Supervisor (name and UUN: Dr Rachel Happer, Senior Clinical fellow in Clinical Psychology)

Primary Investigator (name and UUN): Miriam Zoeller s0784290	
List of all collaborators (with affiliated institutions in brackets): Dr Ailie Castle – Clinical Supervisor, (NHS Tayside)	
Student’s programme of study (if applicable): Doctorate in Clinical Psychology	
Project Title: Trauma-informed practice in acute inpatient settings – an Interpretative Phenomenological Analysis involving mental health nurses	
Case Number (if known – assigned by Administrator at time of 1st submission): Not known	
Proposed Project Start Date: 01/01/2022	Proposed Project End Date: 01/09/2024

Please indicate whether the primary investigator on this project is staff or student and select your subject area:

- Staff UG or MSc Student DClin Student PhD Student
 CPASS Clinical Psychology Nursing Studies

This is a:

- New application for ethical review – first submission
 Resubmission following reviewer comments
 Resubmission with requested amendments

Has been reviewed by an external ethical board, such as NHS IRAS or a UK HEI (multi-site studies only) with a favourable opinion? Level 1 *

This study is in the process of review by the NHS Tayside R&D dept, who have requested that I submit confirmation of the University of Edinburgh’s Approval of this project to them first, before they approve the study. A request has been sent to the HiSS Ethics Lead by Charlotte Smith (Research Governance Coordinator, The University of Edinburgh) on the 10/11/21 to see if this is possible and I have been advised by Charlotte Smith to submit my HiSS ethical approval form even though I have not yet received R&D approval.

- IRAS (NHS research ethics) Other: NHS Tayside R&D dept in the process of reviewing and have requested my University Ethics approval

Please tick one option that best describes your application:

- Collecting or generating new data involving other people: Level 2
 Extracting, re-coding and analysing existing data that contains sensitive information (i.e. identifiable information): Level 2
 Analysing secondary (archival) data that is routinely collected or is an existing anonymised dataset: Level 1
 Collecting new data BUT an external ethical review board (such as NHS IRAS; UK HEI – for multi-site studies; etc) has fully reviewed this project and generated a favourable opinion: Level 1

This application is complete with the following attachments (tick all that apply):

Advert/flyer <input checked="" type="checkbox"/>	Caldicott application stating what data was requested <input type="checkbox"/>	Caldicott signed approval <input type="checkbox"/>		Consent form/s <input checked="" type="checkbox"/>
Data collection tools (e.g. interview guides) <input checked="" type="checkbox"/>	Debrief with signposting <input checked="" type="checkbox"/>	IRAS application <input checked="" type="checkbox"/>	IRAS opinion letter <input type="checkbox"/>	NGO or local authority letters <input type="checkbox"/>
Participant Information Sheet/s <input checked="" type="checkbox"/>	Participant Information Sheet (young person version) <input checked="" type="checkbox"/>	R&D application <input checked="" type="checkbox"/>	R&D approval <input type="checkbox"/>	Researcher Checklist (C-19) <input type="checkbox"/>
Risk assessment <input type="checkbox"/>	Standardised recruitment email <input checked="" type="checkbox"/>	Sponsorship Letter OR Email to confirm no sponsorship needed / statement explaining why sponsorship is not needed. <input checked="" type="checkbox"/>		

Other attachments (please specify):

To be completed by primary investigator or project supervisor
<p>By signing this front sheet, I confirm that I have prepared and/or reviewed this ethics application and related documents in accordance with ethical guidelines. I also confirm I have checked that all relevant sections of the application form are completed and relevant documents are attached.</p> <p>Supervisor or/PI Signature: <i>Miriam Zoeller</i></p> <p>Student signature: <i>Miriam Zoeller</i></p> <p>Date: 12/11/2021</p>

On completion, this Word document along with the relevant attachments should be submitted to ethics.hiss@ed.ac.uk.

Note: Please note all undergraduate and MSc applications MUST been signed and submitted by the project supervisor.

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<i>This section is to be completed after review only</i>
ISSUES ARISING FROM THE PROPOSAL – to be completed by Ethics Reviewer
<p>Thank you for your application. The review process has generated the following queries regarding your application. Please address the following items, and provide a note underneath each comment letting us know how you have addressed them:</p> <p>Application form</p> <p>Q1. Project summary</p> <p>It is stated that consent forms will be collected electronically – some explanation needs to be provided as to how this will be carried out.</p> <p style="padding-left: 40px;"><i>Change to Application form (V2 03/12/2021), Method section : Participants will receive the consent form via email. They will be required to fill each box with their initials, and insert their typed name at the end of the document. They will then return the form to the primary investigator via email. The primary investigator will present the completed consent form on the day of the interview, either a paper copy or by sharing the document on MS Teams, and confirm that the participant is happy with the consent process and that they completed the form. The Primary investigator will then insert their name and the date.</i></p> <p>Demographic information will be collected via an online survey as well as interviews – how will these be linked; through what identifier – where will the file be kept with the key needs to be clarified.</p> <p style="padding-left: 40px;"><i>Addressed by: Demographic information will be collected via a form sent over email (not an online survey) and will not include a participants name. Once a form has been returned over email, it will be saved in a password protected file using a personal code allocated to that participant.</i></p> <p style="padding-left: 40px;"><i>Change to Application form (V2 03/12/2021), Data management section: All storage and use of <i>personal data</i> will be done on NHS computer / laptops using password protected files, storing different data sets (audio recordings, transcribed data, consent forms, demographic data, and contact information including a personal code) in separate password protected files. All files will be saved under a personal code. There will be one file linking the personal code (key) to the individual will be the contact information file, and this will be stored separately to the other files, saved in a NHS computer / laptop password protected file. To link the personal code (key) to the audio recordings, transcribed data, consent forms or demographic data files, the contact information file including the personal code (key) would first need to be accessed. The primary investigator will be the only person who knows the different passwords required to access all files including personal data.</i></p> <p>Consent form</p>

It is noted (as per above) that consent will be collected electronically – however, the form seems to require physical completion. Are the participants meant to be printing the forms, completing them and signing them then scan and return? This needs to be explained in the Information sheet as well as in the application.

Changes made to consent form (V2 03/12/2021): The form has been edited to allow for electronic completion, so somebody will not be required to scan it (to minimise effort to the participant). To ensure that the form has been understood and completed by the participant, the primary investigator will present the completed consent form on the day of the interview, either a paper copy or by sharing the document on MS Teams, and confirm that the participant is happy with the consent process and that they completed the form. The Primary investigator will then insert their name and the date. This change has been described in the Method section and edits have been made to the consent form to remove the space for a handwritten signature.

Alternatively, is there going to be an online version of the consent form – if so please provide this for review. N/A

Information Sheet

Withdrawal - if participants can withdraw at any time how will you manage a withdraw post-analysis? It would be standard to place a reasonable timeframe on withdrawal to deal with this. Later in the information sheet it says "however it will not be possible to withdraw your data once data analysis has commenced" - which is inconsistent, please clarify

Addressed by clarifying this in consent and information form: - to say that participants will not be able to withdraw after they read their transcribed interview and confirm they are happy for it to be included in the analysis via email. This has been clarified in the consent form and the information form.

Change made to consent form (V2 03/12/2021) point 3, to say: *I understand that my participation is voluntary and that I can ask to withdraw at any time, until after the point that I have reviewed my transcribed interview and confirmed that my interview can be included in the study. If I choose to withdraw I do not need to give a reason and my employment rights will not be affected.*

Change made to Information form (V2 03/12/2021) 'DO I HAVE TO TAKE PART' section to say: *If you do decide to take part, you are free to withdraw at any time and without giving a reason, until after the point that you have reviewed your transcribed interview and confirmed that you are happy for your interview to be included in the analysis phase of the study. After the point that you confirm that you are happy for your interview to be included in the analysis stage of the research, you will not be able to withdraw from the study, due to analysis being underway. Deciding not to take part or withdrawing from the study will not affect your employment in any way.*

Change made to Information form (V2 03/12/2021) Possible personal disclosure section to say:

- *You will be emailed a copy of the written transcript of the interview to review, approximately three months after the interview. This will give you time to make changes or exclude any thing you do not want to include for analysis, before confirming whether you are happy for your interview to be included in the study for analysis.*
- *You can withdraw from the study at any stage, until after the point that you have agreed over email that your interview can be included in the analysis phase, after reviewing the transcribed version of your interview. After this point data analysis will commence and you will no longer be able to withdraw from the study.*

Possible risks - this section switches between third person (the participants) and second person (you). I would be consistent with the second person.

Changes have been made to Information form (V2 03/12/2021) to ensure consistent use of second person

Data management - given that identifiable information will be sent over email, be clear on how long you will keep these emails.

Addressed by: Email correspondence will all be deleted at the point that email contact details are deleted, once the participants have been emailed to provide them with a summary of the study's findings. This has been clarified through two changes to the Information sheet

1. Change to Information form (V2 03/12/2021) Where can you find out more about how your information is used? – text changed to: *After that, the primary investigator will delete all identifiable data about you, including all email correspondence made during the study.*
2. Change to Information form (V2 03/12/2021) to say: WHAT WILL HAPPEN WITH THE RESULTS OF THIS STUDY? *A summary of the findings will be sent to participants by email. After this point, participants email addresses and all email correspondence between participants and the primary investigator will be deleted.*
3. Change to Protocol (V2 03/12/2021), Data management section (participant contact information) To say: *At the end of the study once participants have been emailed to find out how to access the results of the study, then their email addresses will be permanently deleted from the password protected file. Additionally, all email correspondence between participants and the primary investigator will be deleted at this time.*

Debrief and information sheet – complaints should go to the head of school

Changes have been made to both the Debrief and Information sheet to say:

If you wish to make a complaint about the study, please contact:

Professor Matthias Schwannauer (), Head of School, School of Health in Social Sciences, The University of Edinburgh.

Covid checklist is missing and needs to be completed/included with the application

This has now been completed. Based on this checklist, I have made these adaptations to the following documents:

1. Information form (V2 03/12/2021), to say: to include an additional section following the risks section titled: **COVID-19 RELATED RISKS OF PARTICIPATION, IF FACE TO FACE INTERVIEW**, including the suggested text from the Covid Checklist form
2. Consent form (V2 03/12/2021),, to say: *ONLY APPLICABLE FOR Face to Face RESEARCH: The primary investigator will store your name and contact details for 21 days after the research interaction so that they can provide this information to Test and Protect if required, e.g. should the primary investigator subsequently test positive for COVID-19*

Signature: *Ingrid Obsuth (sig)*

Position: Ethics & Integrity Lead

Date: 2 Dec 2021

APPLICANT'S SIGNATURE FOLLOWING REVISIONS – to be completed by applicant

I confirm that I have addressed all of the queries generated during the ethical review process of my application. I have outlined in the box above underneath each comment how each request was addressed and/or provided further clarification.

Supervisor/PI Signature: Miriam Zoeller

Student signature: Miriam Zoeller

Date: 03/12/2021

CONCLUSION TO ETHICAL REVIEW – to be completed by Ethics Lead

The applicant's response to our request for further clarification or changes has now satisfied the requirements for ethical practice and the application has therefore been given a favourable opinion.

Signature: *Ingrid Obsuth (sig)*

Position: Ethics & Integrity Lead

If you are applying for amendments to a previously reviewed and processed project, please use the below form to detail the amendments you wish to make:

This section is to be completed for amendments only

AMENDMENT/S: REQUEST FOR APPROVAL – to be completed by applicant

I would like to apply for the following amendments to this previously processed project which had generated a favourable opinion:

After receiving feedback from people who have lived experience, as well as from my clinical and academic supervisors, I have made some changes to my original interview schedule (V1 MS 18 Sept 2021), including changes to the wording of some questions, changes to some questions overall, and further elaboration on interview prompts. These changes do not impact on the design, methodology or analysis of the study, and do not impact on the resources required for this study.

The amended schedule is saved under: Interview Schedule - V2 MZ 17 Jan 2022 and has been submitted along with this amendment request.

The project pending R&D approval and the same amendment has been submitted to them via IRAS.

Supervisor/PI Signature: Miriam Zoeller

Student signature: Miriam Zoeller

Date: 17/01/2022

CONCLUSION TO ETHICAL REVIEW OF AMENDMENT – to be completed by Ethics Lead

The requested amendments satisfy the requirements for ethical practice and have therefore received a favourable opinion.

Signature: Ingrid Obsuth (sig)

Position: Ethics & Integrity Lead

Date: 20 Jan 2022

NOTE: Once reviewed please include the page on which this box appears as a formal document demonstrating that favourable opinion has been provided for this project (for example as an attachment to MSc dissertations).

Date: 6 Dec 2021

Appendix 8. IRAS R&D ethics approval



Ref:

03 February 2022

Miriam Zoeller
Trainee Clinical Psychologist
Older People Psychology Service
Susan Carnegie Centre
Stracathro Hospital
By Brechin
DD9 7QA

Dear Miriam,

R&D MANAGEMENT APPROVAL – TAYSIDE

Title: Trauma-informed practice in acute inpatient settings – an Interpretative Phenomenological Analysis involving mental health nurses

Chief Investigator: Miriam Zoeller

Principal Investigator: Miriam Zoeller

Tayside Ref: 2021PZ04 NRS Ref: N/A IRAS ID: 303096

UOD Ethics Review Date: Ingrid Obsuth, Ethics Integrity Lead, 2/12/2021

Sponsor: University of Edinburgh

Funder: N/A

Tayside Reviewer: Katherine Coll

Many thanks for your application to carry out the above project here in NHS Tayside. I am pleased to confirm that the project documentation (as outlined below) has been reviewed, registered and Management Approval has been granted for the study to proceed locally in Tayside.

Approval is granted on the following conditions:-

- ALL Research must be carried out in compliance with the UK Policy Framework for Health & Social Care Research, Health & Safety Regulations, GDPR & data protection principles, statutory legislation and in accordance with Good Clinical Practice (GCP).
- All amendments to be notified to TASC R&D Office via the correct amendment pathway. Either direct to the R&D Office or via the Lead Co-ordinating Centre depending on how the study is set up.
- All local researchers must hold either a Substantive Contract, Honorary Research Contract, Honorary Clinical Contract or Letter of Access with NHS Tayside where required (<https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx>).

- TASC R&D Office to be informed of change in Principal Investigator, Chief Investigator or any additional research personnel locally. Tav.tasc@nhs.scot
- Notification to TASC R&D Office of any change in funding or an extension to study timelines.
- As well as any obligations to your Sponsor, you are required to notify TASCGovernance@dundee.ac.uk of all serious breaches of GCP and Serious Unexpected Serious Adverse Reactions (SUSARs) for Hosted Clinical Trials of Investigational Medicinal Products (CTIMPs).
- As custodian of the information collated during this research project you are responsible for ensuring the security of all personal information collected in line with NHS Scotland IT Security Policies, until destruction of this data.
- All Eligible and Extended Review studies will be added to the Scottish Research Database (SReDA). Recruitment figures for Eligible and Extended Review studies must be recorded onto the Scottish Portfolio every month. It is the responsibility of Tayside Health board to ensure recruitment data is being routinely uploaded into SReDA by working closely with study teams across Tayside and gathering this information. For further information on how your study recruitment data will be captured and uploaded, please contact the local Portfolio team at tav.tascportfolio@nhs.scot
- Annual reports are required to be submitted to TASC R&D Office with the first report due 12 months from date of issue of this management approval letter and at yearly intervals until completion of the study.
- Notification of early termination within 15 days or End of Trial within 90 days followed by End of Trial Report within 1 year to TASC R&D Office.
- You may be required to assist with and provide information in regard to audit and monitoring of study.

Please note you are required to adhere to the conditions, if not, NHS management approval may be withdrawn for the study.

Approved Documents

Document	Version	Date
University of Edinburgh School of Health in Social Science Research Ethics Application		02/12/2021
Researcher Checklist		04/09/2021
Participant Consent Form	2	03/12/2021
Debrief Form	2	03/12/2021
Participant Information Sheet	2	03/12/2021
Protocol	2	03/12/2021
Participants Voucher Funding Approval		25/11/2021
Combined Insurance		31/12/2022
Leaflet	1	18/09/2021
Poster	1	18/09/2021
Email correspondence	1	18/09/2021

Trauma informed practice in in patient group	1	18/09/2021
Interview Schedule	2	17/01/2022

May I take this opportunity to wish you every success with your project.

Please do not hesitate to contact TASC R&D Office should you require further assistance.

Yours sincerely

Elizabeth Coote
Head of Non-Commercial Research Services

TAyside medical Science Centre (TASC)
Ninewells Hospital & Medical School
TASC Research & Development Office
Residency Block, Level 3
George Pirie Way
Dundee DD1 9SY
Email:

Tel: 01382 383876
Mobile: 07876 104800

C.c.

Appendix 9. Reflexive diary extract

Situation – following first interview

That was surprisingly anxiety provoking, I felt quite unsure of myself back in the wards. Waiting about making awkward conversation in the nurse's office - probably to be expected, it's always quite chaotic – but it made me remember what it feels like. So many pressing things to do, patients knocking on the door a lot, phones ringing, staff trying to eat and write notes. Also not being part of the team – there was that real sense of being an outsider, everyone kind of looks at you questioningly.

Anyhow, the participant was really friendly, which was good as it helped me feel more at ease. But I think she was apprehensive too as they had not done anything like it before and she seemed a bit nervous. I think at first they felt like it was a bit of a test to see if they could remember trauma-informed training but once I relaxed too I think that helped them relax too. It was actually good to notice that my own anxiety may have influenced them, and I will try to be careful of this next time, making sure I speak slowly and perhaps spend a bit more time having a brief chat at the start – if that's possible. Although hopefully as I practice it will feel easier. I was also conscious that I was meeting her in her break, and I did not want to run over. I am glad I organised the vouchers as I really do feel like participants are going out of their way.

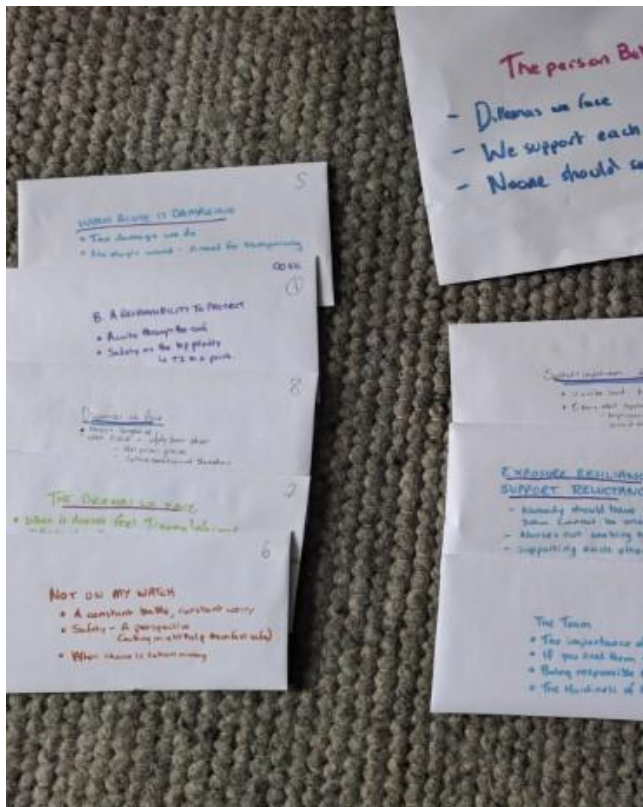
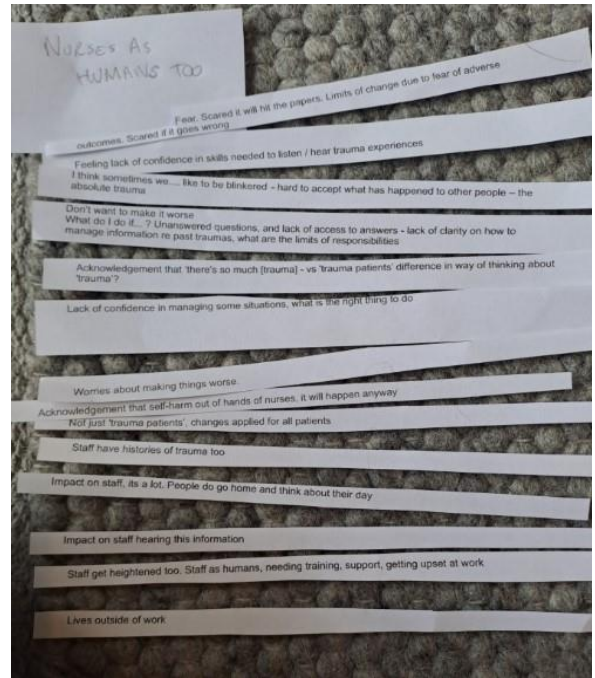
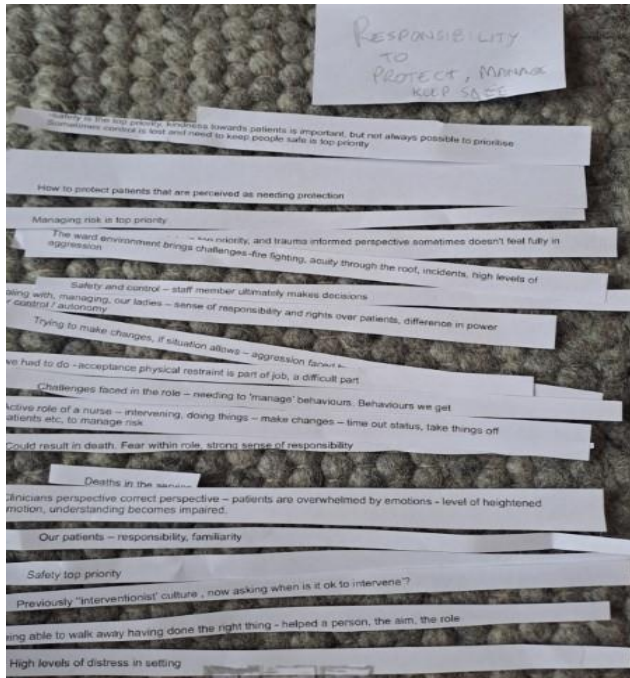
Once the interview got going it felt good, she started to answer with more depth. although I was also using the prompts more and that helped. My schedule felt a bit structured and I do think next time trying to be more flexible and not focused too much on the questions will help get deeper reflections. If I can memorise my questions so I don't need to look at them that will help.

I was pleasantly surprised how much she was interested and keen re trauma informed perspectives. I had anticipated more skepticism. Maybe times have changed a bit. Or maybe she was careful how she worded things as she knows I'm training as a psychologist. Though hopefully telling her I was a nurse will have minimised that feeling a bit. Hard to say. Really encouraging though. I explored what she thought about the perspectives of others to see whether others feel differently, although I'm thinking now that may not be IPA so much so need to not focus too much on that.

Key points:

- Next time slow down, try and be relaxed as this will help them relax
- Learn interview questions by heart so I can explore more and be less worried about reading the transcript

Appendix 10. Developing themes



Appendix 11. Sample of transcript analysis

<p>example, there's a [patient] that was sexually abused, and [...] didn't like anybody touching [...] and stuff like that, but we couldn't stop [...] from head banging as well, so we had to make a <u>choice</u>, <u>well</u> we <u>have to</u> restrain [...]... we <u>have to</u> give [...] medication. Yes, <u>its</u> going to cause [...] more distress, but we were fully aware of that, but you <u>have to</u>... let <u>um</u>... <u>out weigh</u> the risks <u>there</u>... um... [...] was starting to bleed from [...] head, head injury so... its stuff like that... <u>yea</u>... um... Never thought about it like until this <u>conversation</u>, <u>actually</u>, <u>but</u>... um... <u>its</u> difficult. It is <u>difficult</u>, <u>its</u> probably... really, <u>really</u> difficult because... if someone's tied a ligature or <u>self harmed</u>, you <u>can</u> remove them from that <u>area</u>, and you can probably do that here as well, but... they're exposed, they can keep banging on the floors, or on the chairs, you <u>know</u>... and where does trauma informed care come into there, because you're thinking about it, but you're not doing <u>it</u>, <u>but</u> you <u>have to</u> keep that person safe... yea...</p> <p>Interviewer – Sure... and you mentioned that when it comes to the point... of needing to intervene...and... from the kind of <u>safety</u>... then the <u>restraint</u>... can... you were saying can be... I think you said can be traumatising?</p> <p>Participant – Traumatising for the patient and for <u>staff</u>, <u>so it's</u>...the last resort, we don't like doing it, <u>its</u> horrible, especially if they have trauma in their past, where they've been <u>er</u>... sexually abused, raped or anything like that there... and they're going to have people, getting them from hurting themselves... and... are you really... being trauma ...<u>infor</u>... you've trauma informed, but are you providing it there? You're not... <u>but</u>... you're trying to keep that person safe as well. <u>So</u> you limit it as much as possible. But we've had an incidence in <u>here</u>... it might have been this room actually... um... and every <u>time</u>... [...] was relaxed, [...] would calm down, we would leave, [...]</p>	<p>in relation to <u>self harm</u> situations</p> <p>Having to weigh up distress caused and level of injury – weighing up risks, Thinking about historical sexual trauma and current distress and risk</p> <p><u>its</u> difficult, difficult decisions</p> <p>Can remove someone if they have tied a ligature or <u>self harmed</u> – as not fighting back?</p> <p>Someone head banging exposed as can keep head banging <u>where ever</u> they are. <u>Have to</u> keep someone safe but might not feel trauma informed</p> <p>Restraint as traumatising for the staff and patient – horrible. Especially if aware of trauma, particularly sexual trauma, in persons past</p> <p>Are you really being trauma <u>infor</u>... but are you providing it there</p> <p>And needing to keep that person safe</p> <p>Limiting need for restraint as much as possible</p> <p>Incident when can be repeated ongoing <u>self</u></p>	<p>Navigating the risk of current trauma and respect and care for past trauma</p> <p>Sense of incongruence between trauma informed care and safety</p> <p>Restraint as traumatising, for the staff and patient</p> <p>Is restraint ever trauma informed?</p> <p>No choice - restraint last resort but necessary to keep people safe</p>
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Appendix 12. Sample of PETS table

Personal Experiential Themes (PETS)

A. A FOCUS ON TRAUMA

- Seeing differently
- A meaningful connection, vs here's some lorazepam
- We're trying --> barriers we face

B. PART AND PARCEL – ACCEPTANCE OF WHAT WE SEE

- Exposure part and parcel of job – Risk every day, had to cut someone down hanging, feel numb-ish
- Impact on self – the emotion just hit me
- Needing support, but not needing 'support' - an unacknowledged stigma?

C. THINKING ABOUT GENDER

- I don't know what to say – the awkwardness of gender
 - Females would want to speak to females?
 - Do they feel safe? How can I show them I am not a threat
 - Othering of trauma - as a female experience?
-

D. THE DILEMMAS WE FACE

- When it doesn't feel trauma informed – restraint and trauma – they thought they were being attacked
 - When choice is taken away – the impact on relationships
-

E. WANTING TO KNOW MORE

- *Knowledge as a barrier to feeling confident and comfortable*
- *A lack of training or opportunity*

Appendix 13. Protocol for systematic review

PROSPERO

**International prospective register of
systematic reviews**



UNIVERSITY *of* York
Centre for Reviews and Dissemination

Systematic review

A list of fields that can be edited in an update can be found [here](#)

*** Review title.**

Give the title of the review in English

Group Based Psychological Interventions in the Acute Inpatient Mental Health Setting - A Systematic Review

Original language title.

For reviews in languages other than English, give the title in the original language. This will be displayed with the English language title.

*** Anticipated or actual start date.**

Give the date the systematic review started or is expected to start. 03/10/2023

*** Anticipated completion date.**

Give the date by which the review is expected to be completed. 30/09/2024

1. *Stage of review at time of this submission. [3 changes]

This field uses answers to initial screening questions. It cannot be edited until after registration.

Tick the boxes to show which review tasks have been started and which have been completed.

Update this field each time any amendments are made to a published record.

The review has not yet started: No

Review stage	Started	Completed
Preliminary searches	Yes	Yes
Piloting of the study selection process	Yes	Yes
Formal screening of search results against eligibility criteria	Yes	Yes
Data extraction	Yes	Yes
Risk of bias (quality) assessment	Yes	Yes
Data analysis	Yes	Yes
Provide any other relevant information about the stage of the review here.		

*** Named contact.**

The named contact is the guarantor for the accuracy of the information in the register record. This may be any member of the review team.

Miriam Zoeller

Email salutation (e.g. "Dr Smith" or "Joanne") for correspondence:

Miriam

* Named contact email.

Give the electronic email address of the named contact. s0784290@sms.ed.ac.uk

Named contact address

Give the full institutional/organisational postal address for the named contact.

School of Health in Social Science

8-9 Hope Park Square

University of Edinburgh

EH8 9NW

Named contact phone number.

Give the telephone number for the named contact, including international dialling code.

07412995740

* Organisational affiliation of the review.

Full title of the organisational affiliations for this review and website address if available. This field may be completed as 'None' if the review is not affiliated to any organisation.

The University of Edinburgh

Organisation web address:

<https://www.ed.ac.uk/>

* Review team members and their organisational affiliations.

Give the personal details and the organisational affiliations of each member of the review team. Affiliation refers to groups or organisations to which review team members belong. **NOTE: email and country now MUST be entered for each person, unless you are amending a published record. PLEASE USE AN INSTITUTIONAL EMAIL ADDRESS IF POSSIBLE.**

Ms Miriam Zoeller. The University of Edinburgh

Dr Rachel Happer. The University of Edinburgh

* Funding sources/sponsors.

Details of the individuals, organizations, groups, companies or other legal entities who have funded or sponsored the review.

There are no funders. This systematic review is being completed as part of the Doctorate training in Clinical Psychology at The University of Edinburgh

Grant number(s)

State the funder, grant or award number and the date of award

* Conflicts of interest.

List actual or perceived conflicts of interest (financial or academic). **None**

Collaborators.

Give the name and affiliation of any individuals or organisations who are working on the review but who are not listed as review team members. **NOTE: email and country must be completed for each person, unless you are amending a published record.**

Dr Andreas Paphiti. The University of Edinburgh

* Review question.

State the review question(s) clearly and precisely. It may be appropriate to break very broad questions down into a series of related more specific questions. Questions may be framed or refined using PI(E)COS or similar where relevant.

- In working age adults admitted to an acute inpatient mental health setting, what is the effect of a group- based psychological intervention, in comparison to an alternative intervention or no intervention, on outcomes?

Additional questions:

- How have group based psychological interventions been adapted to the acute inpatient setting?
- What factors influence the effectiveness of group-based psychological interventions in the acute inpatient setting?

* Searches.

State the sources that will be searched (e.g. Medline). Give the search dates, and any restrictions (e.g. language or publication date). Do NOT enter the full search strategy (it may be provided as a link or attachment below.)

MEDLINE, CLINAHL Plus, PsychINFO and Embase

Search dated - between October 2023 and August 2024

Restrictions - English language

URL to search strategy.

Upload a file with your search strategy, or an example of a search strategy for a specific database, (including the keywords) in pdf or word format. In doing so you are consenting to the file being made publicly accessible. Or provide a URL or link to the strategy. Do NOT provide links to your search **results**.

https://www.crd.york.ac.uk/PROSPEROFILES/467366_STRATEGY_20230926.pdf

Alternatively, upload your search strategy to CRD in pdf format. Please note that by doing so you are consenting to the file being made publicly accessible.

Do not make this file publicly available until the review is complete

* **Condition or domain being studied.**

Give a short description of the disease, condition or healthcare domain being studied in your systematic review.

Group-based psychological interventions conducted with working age adults admitted to an acute inpatient mental health setting

7. ***Participants/population.** [1 change]

Specify the participants or populations being studied in the review. The preferred format includes details of both inclusion and exclusion criteria.

Working age adults admitted to an acute inpatient mental health setting

Inclusion criteria

- Participants must attend a minimum of one group-based session whilst an inpatient
- Participants must be working age adults
- Participants can have any diagnosis or combination of diagnoses

Exclusion criteria

- Adolescents or children (under 18) or older adults (over 65)
- Main diagnostic focus relating to substance use disorder or non psychiatric diagnosis

***Intervention(s), exposure(s).** [1 change]

Give full and clear descriptions or definitions of the interventions or the exposures to be reviewed. The preferred format includes details of both inclusion and exclusion criteria.

A group-based psychological intervention conducted in an acute inpatient mental health setting

Inclusion criteria

- Group-based psychological intervention involving participants admitted to an acute inpatient mental health setting. *Interventions must be based on an evidence-based psychological intervention, which includes psychological interventions that have been proven effective (to some degree) through outcome evaluations

Exclusion criteria

- Group-based psychological interventions conducted in non-acute inpatient mental health

settings (e.g. forensic or rehabilitation), or fully in the outpatient setting

*** Comparator(s)/control.**

Where relevant, give details of the alternatives against which the intervention/exposure will be compared (e.g. another intervention or a non-exposed control group). The preferred format includes details of both inclusion and exclusion criteria.

Comparison to a separate intervention, treatment as usual, or pre/post data

*** Types of study to be included.**

Give details of the study designs (e.g. RCT) that are eligible for inclusion in the review. The preferred format includes both inclusion and exclusion criteria. If there are no restrictions on the types of study, this should be stated.

Inclusion criteria

- Any intervention-based studies using a quantitative study design, including but not limited to: randomised control trials, case control studies, case series designs, and cohort studies

Exclusion criteria

- Individual case study or qualitative study designs
- Studies which are unpublished

Context.

Give summary details of the setting or other relevant characteristics, which help define the inclusion or exclusion criteria.

Group-based interventions conducted in the acute inpatient mental health setting will include mental health settings designed for shorter term admissions, for example during times of crisis. This will include Triage and Psychiatric Intensive Care Unit (PICU) settings, or settings defined by shorter term, crisis intervention type admissions (which may be described differently in the international literature). In comparison, longer term rehabilitation, forensic or specialist services will be excluded.

*** Main outcome(s).**

Give the pre-specified main (most important) outcomes of the review, including details of how the outcome is defined and measured and when these measurement are made, if these are part of the review inclusion criteria.

The main outcome will be to determine the effect of group based psychological interventions on symptoms and/ or clinical outcomes, for working age adults admitted to the acute inpatient mental health setting.

Measures of effect

Please specify the effect measure(s) for you main outcome(s) e.g. relative risks, odds ratios, risk

difference, and/or 'number needed to treat.

Outcome measures can include formal outcome measures (e.g. measures assessing symptoms or distress) and/or measures of clinical outcomes (e.g. re-admission rates, admission length, or any other measurable change to clinical outcomes)

* Additional outcome(s).

List the pre-specified additional outcomes of the review, with a similar level of detail to that required for main outcomes. Where there are no additional outcomes please state 'None' or 'Not applicable' as appropriate to the review

A secondary outcome may include any measures relating to group engagement or satisfaction with the intervention

Measures of effect

Please specify the effect measure(s) for you additional outcome(s) e.g. relative risks, odds ratios, risk difference, and/or 'number needed to treat.

May include outcome measures such as attendance rate or rating of intervention by participants

* Data extraction (selection and coding).

Describe how studies will be selected for inclusion. State what data will be extracted or obtained. State how this will be done and recorded.

The searches will be undertaken according to the planned search strategy, and all retrieved study titles and/or abstracts will be then screened for relevance. Full texts of identified relevant articles will be retrieved and assessed for eligibility based on the specified inclusion criteria. A second reviewer will screen the full text articles deemed to meet inclusion criteria, and both reviewers will reach agreement on their eligibility for inclusion. Decisions regarding identified full text articles will be recorded in an excel spreadsheet.

The following data will then be extracted from included studies, where available:

- Author and year

- Country where data collection took place
- Study design
- Setting (acute, triage, PICU)
- Intervention design – therapy modality, open/ closed group, inclusion/exclusion criteria for group, number of participants, number of sessions

- Participants age, gender, diagnosis, inclusion criteria for group
- Facilitator profession, number of facilitators
- Intervention integrity
- Withdrawal / dropout rates
- Date / time-period of intervention
- Funding

- Outcomes related to intervention
- Key findings of authors
- Key limitations
- Any other relevant factors

Extracted data from included articles will be recorded using an excel spreadsheet, before data is collated.

*** Risk of bias (quality) assessment.**

State which characteristics of the studies will be assessed and/or any formal risk of bias/quality assessment tools that will be used.

The Quality Assessment Tool for Quantitative Studies (EPHPP tool) will be used to assess the quality of included studies, as it is intended to assess the quality of quantitative studies across a range of different quantitative designs. The tool assesses selection bias, study design quality, confounders, blinding, data collection methods, withdrawals and dropout rates, intervention integrity and analyses. The main reviewer will appraise all studies, and the second reviewer will co-review a random selection of included studies.

Discrepancies will be discussed to reach agreement.

***Strategy for data synthesis [2 changes]**

Describe the methods you plan to use to synthesise data. This **must not be generic text** but should be **specific to your review** and describe how the proposed approach will be applied to your data. If meta- analysis is planned, describe the models to be used, methods to explore statistical heterogeneity, and software package to be used.

Based on background reading of the available literature, it is expected that included studies will vary in design, intervention and outcome measures. Therefore, it is anticipated that synthesis will involve a narrative synthesis approach, accounting for the expected heterogeneity of studies.

Descriptive statistics will be used to summarise characteristics of population, interventions, attrition rates and outcome measures.

Synthesis without meta-analysis (SWiM) guidelines (Campbell et al. - BMJ, 2020) will then be followed to guide the data synthesis strategy, using their nine recommended best practice items.

- 1) It is anticipated that studies will be grouped according to study design (e.g. randomised trial, pre/post etc)
- 2) It is anticipated the majority of reported data will be continuous (e.g. clinical outcome measures). It is anticipated that, where possible, outcomes will be reported using a standardised mean difference
- 3) It is anticipated that published studies will not provide sufficient quantity or quality of data

to conduct a meta analysis. Depending on the quality of available data, a choice of synthesising methods including summarising effect estimates, combining P values, or vote counting based on direction of effects, will be utilised to synthesise data

4) If the data set includes randomised controlled trial design studies, then these studies would be prioritised in the analysis

5) Heterogeneity in reported effects will be assessed using informal methods, using tabular formats to compare factors between studies

6) A qualitative assessment of certainty will be made

7) Data will be presented in a tabular format, and discussed using descriptive text

8) For each comparison and outcome, synthesised findings will be described and the certainty of findings considered

9) Limitations of the approach to data synthesis will be described

Should any included studies not provide sufficient quality of data to fulfil the above synthesis process, an alternative approach to narrative synthesis will be undertaken whereby findings are summarised using descriptive text and tables, to set out study findings and give consideration to the study designs.

* Analysis of subgroups or subsets.

State any planned investigation of 'subgroups'. Be clear and specific about which type of study or participant will be included in each group or covariate investigated. State the planned analytic approach.

Possibility for subgroup analysis is not clear at this stage and will depend upon the range and quality of included studies, which is anticipated to be limited.

If possible, synthesised findings may be analysed according to subgroups - for example, analysis of the possible relationship between therapy modality, and the effectiveness of interventions.

* Type and method of review.

Select the type of review, review method and health area from the lists below.

Language.

Select each language individually to add it to the list below, use the bin icon to remove any added in error. English

There is an English language summary.

*** Country.**

Select the country in which the review is being carried out. For multi-national collaborations select all the countries involved.

Scotland

Other registration details.

Name any other organisation where the systematic review title or protocol is registered (e.g. Campbell, or The Joanna Briggs Institute) together with any unique identification number assigned by them. If extracted data will be stored and made available through a repository such as the Systematic Review Data Repository (SRDR), details and a link should be included here. If none, leave blank.

Reference and/or URL for published protocol.

If the protocol for this review is published provide details (authors, title and journal details, preferably in Vancouver format)

Add web link to the published protocol.

Or, upload your published protocol here in pdf format. Note that the upload will be publicly accessible. **No I do not make this file publicly available until the review is complete**

Please note that the information required in the PROSPERO registration form must be completed in full even if access to a protocol is given.

Dissemination plans.

Do you intend to publish the review on completion?

Yes

Give brief details of plans for communicating review findings.?

It is the intention that this review will be published in a peer reviewed journal on completion

Keywords.

Give words or phrases that best describe the review. Separate keywords with a semicolon or new line. Keywords help PROSPERO users find your review (keywords do not appear in the public record but are included in searches). Be as specific and precise as possible. Avoid acronyms and abbreviations unless these are in wide use.

Systematic review;

Acute inpatient;

Psychological intervention;

Group psychological intervention;

Details of any existing review of the same topic by the same authors.

If you are registering an update of an existing review give details of the earlier versions and include a full bibliographic reference, if available.

* Current review status.

Update review status when the review is completed and when it is published. New registrations must be ongoing so this field is not editable for initial submission.

Please provide anticipated
publication date **Review_Ongoing**

29. Any additional information

Provide any other information relevant to the registration of this review.

Update to initial submission following feedback - changes have been made to item 28 to provide additional detail regarding the planned data synthesis 03/10/2023

Update to original submission: Change to Participant/population section, exclusion criteria: 'Main diagnostic focus relating to substance use disorder or non psychiatric diagnosis'

Change to S28 strategy for data synthesis - changed from: The GRADE (Grading of Recommendations, Assessment, Development and Evaluations) framework will be utilised to assess certainty, dependant on the quality of data available to: 6) A qualitative assessment of certainty will be made

40. Details of final report/publication(s) or preprints if available.

Leave empty until publication details are available OR you have a link to a preprint (NOTE: this field is not editable for initial submission). List authors, title and journal details preferably in Vancouver format.

Give the link to the published review or preprint.

Appendix 14. EPHPP quality assessment tool

QUALITY ASSESSMENT TOOL FOR QUANTITATIVE STUDIES



COMPONENT RATINGS

A) SELECTION BIAS

(Q1) Are the individuals selected to participate in the study likely to be representative of the target population?

- 1 Very likely
- 2 Somewhat likely
- 3 Not likely
- 4 Can't tell

(Q2) What percentage of selected individuals agreed to participate?

- 1 80 - 100% agreement
- 2 60 - 79% agreement
- 3 less than 60% agreement
- 4 Not applicable
- 5 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

B) STUDY DESIGN

Indicate the study design

- 1 Randomized controlled trial
- 2 Controlled clinical trial
- 3 Cohort analytic (two group pre + post)
- 4 Case-control
- 5 Cohort (one group pre + post (before and after))
- 6 Interrupted time series
- 7 Other specify _____
- 8 Can't tell

Was the study described as randomized? If NO, go to Component C.

No Yes

If Yes, was the method of randomization described? (See dictionary)

No Yes

If Yes, was the method appropriate? (See dictionary)

No Yes

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

C) CONFOUNDERS

(Q1) Were there important differences between groups prior to the intervention?

- 1 Yes
- 2 No
- 3 Can't tell

The following are examples of confounders:

- 1 Race
- 2 Sex
- 3 Marital status/family
- 4 Age
- 5 SES (income or class)
- 6 Education
- 7 Health status
- 8 Pre-intervention score on outcome measure

(Q2) If yes, indicate the percentage of relevant confounders that were controlled (either in the design (e.g. stratification, matching) or analysis)?

- 1 80 – 100% (most)
- 2 60 – 79% (some)
- 3 Less than 60% (few or none)
- 4 Can't Tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

D) BLINDING

(Q1) Was (were) the outcome assessor(s) aware of the intervention or exposure status of participants?

- 1 Yes
- 2 No
- 3 Can't tell

(Q2) Were the study participants aware of the research question?

- 1 Yes
- 2 No
- 3 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

E) DATA COLLECTION METHODS

(Q1) Were data collection tools shown to be valid?

- 1 Yes
- 2 No
- 3 Can't tell

(Q2) Were data collection tools shown to be reliable?

- 1 Yes
- 2 No
- 3 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

C) CONFOUNDERS

(Q1) Were there important differences between groups prior to the intervention?

- 1 Yes
- 2 No
- 3 Can't tell

The following are examples of confounders:

- 1 Race
- 2 Sex
- 3 Marital status/family
- 4 Age
- 5 SES (income or class)
- 6 Education
- 7 Health status
- 8 Pre-intervention score on outcome measure

(Q2) If yes, indicate the percentage of relevant confounders that were controlled (either in the design (e.g. stratification, matching) or analysis)?

- 1 80 – 100% (most)
- 2 60 – 79% (some)
- 3 Less than 60% (few or none)
- 4 Can't Tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

D) BLINDING

(Q1) Was (were) the outcome assessor(s) aware of the intervention or exposure status of participants?

- 1 Yes
- 2 No
- 3 Can't tell

(Q2) Were the study participants aware of the research question?

- 1 Yes
- 2 No
- 3 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

E) DATA COLLECTION METHODS

(Q1) Were data collection tools shown to be valid?

- 1 Yes
- 2 No
- 3 Can't tell

(Q2) Were data collection tools shown to be reliable?

- 1 Yes
- 2 No
- 3 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

F) WITHDRAWALS AND DROP-OUTS

- (Q1) Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?**
 1 Yes
 2 No
 3 Can't tell
 4 Not Applicable (i.e. one time surveys or interviews)
- (Q2) Indicate the percentage of participants completing the study. (If the percentage differs by groups, record the lowest).**
 1 80 -100%
 2 60 -79%
 3 less than 60%
 4 Can't tell
 5 Not Applicable (i.e. Retrospective case-control)

RATE THIS SECTION	STRONG	MODERATE	WEAK	
See dictionary	1	2	3	Not Applicable

G) INTERVENTION INTEGRITY

- (Q1) What percentage of participants received the allocated intervention or exposure of interest?**
 1 80 -100%
 2 60 -79%
 3 less than 60%
 4 Can't tell
- (Q2) Was the consistency of the intervention measured?**
 1 Yes
 2 No
 3 Can't tell
- (Q3) Is it likely that subjects received an unintended intervention (contamination or co-intervention) that may influence the results?**
 4 Yes
 5 No
 6 Can't tell

H) ANALYSES

- (Q1) Indicate the unit of allocation (circle one)**
 community organization/institution practice/office individual
- (Q2) Indicate the unit of analysis (circle one)**
 community organization/institution practice/office individual
- (Q3) Are the statistical methods appropriate for the study design?**
 1 Yes
 2 No
 3 Can't tell
- (Q4) Is the analysis performed by intervention allocation status (i.e. intention to treat) rather than the actual intervention received?**
 1 Yes
 2 No
 3 Can't tell

GLOBAL RATING

COMPONENT RATINGS

Please transcribe the information from the gray boxes on pages 1-4 onto this page. See dictionary on how to rate this section.

A	SELECTION BIAS	STRONG	MODERATE	WEAK
		1	2	3
B	STUDY DESIGN	STRONG	MODERATE	WEAK
		1	2	3
C	CONFOUNDERS	STRONG	MODERATE	WEAK
		1	2	3
D	BLINDING	STRONG	MODERATE	WEAK
		1	2	3
E	DATA COLLECTION METHOD	STRONG	MODERATE	WEAK
		1	2	3
F	WITHDRAWALS AND DROPOUTS	STRONG	MODERATE	WEAK
		1	2	3
				Not Applicable

GLOBAL RATING FOR THIS PAPER (circle one):

- | | | |
|---|----------|----------------------------|
| 1 | STRONG | (no WEAK ratings) |
| 2 | MODERATE | (one WEAK rating) |
| 3 | WEAK | (two or more WEAK ratings) |

With both reviewers discussing the ratings:

Is there a discrepancy between the two reviewers with respect to the component (A-F) ratings?

- No Yes

If yes, indicate the reason for the discrepancy

- | | |
|---|---|
| 1 | Oversight |
| 2 | Differences in interpretation of criteria |
| 3 | Differences in interpretation of study |

Final decision of both reviewers (circle one):

- | | |
|----------|-----------------|
| 1 | STRONG |
| 2 | MODERATE |
| 3 | WEAK |