**Implementation of a case formulation to reduce restrictive interventions on a Psychiatric Intensive Care Unit: quasi experimental single case evaluation.**

**Abstract**

**Background.** Despite the use of case formulation being encouraged for inpatient psychiatric care, there have been no previous examples and evaluations of this type of work on a psychiatric intensive care unit (PICU). **Aims.** To evaluate whether a schema-informed formulation with a patient diagnosed with emotionally unstable personality disorder (EUPD), autism spectrum disorder (ASD) and mild learning difficulties was effective in reducing the use of restrictive interventions. **Method.** A biphasic N=1 quasi-experimental design with an 8-week baseline versus an 8-week intervention phase. The restrictive outcomes measured were use of physical restraint, seclusion, and intramuscular rapid tranquilisation. The formulation was developed through 8 one-to-one sessions during the baseline and was implemented via 6 one-to-one sessions during the intervention phase and discussion at the ward reflective practice group. The intervention encouraged better communication of schema modes from the patient and for staff to then respond with bespoke mode support. **Results.** Incidents involving need for seclusion, restraint and rapid tranquilisation extinguished. **Discussion.** The need for making access to psychological input a routine aspect of the care in PICUs and the necessity for developing a methodologically more robust evidence base for psychological interventions on these wards.

**Introduction**

Psychiatric intensive care units (PICUs) are highly specialist 24-hour inpatient wards providing intensive assessment and comprehensive treatment (Bowers et al., 2008). The typical PICU environment is that of a locked and secure ward with access to seclusion rooms, low patient capacity, high staff:patient ratios and PICUs are staffed by a multidisciplinary team (MDT). Studies have found patients on PICUs tend to be detained under the Mental Health Act, young, single and unemployed men typically from an ethnic minority (if in an inner city), presenting with psychosis, mania or a neurodevelopmental disorder, with a forensic history of violent behaviour and substance misuse (Brown & Bass; 2009; Bowers et al., 2008; Kasmi, 2007; Mele et al., 2022).  PICU staff see the core function of a PICU as ensuring the safety of patients (Berg et al., 2022). Admission is therefore often intended to be a short-term measure to manage various risks (i.e., including absconding) with patients likely ‘stepped-down’ to acute inpatient psychiatric wards, once the crisis period has passed or been managed (Brown & Bass, 2009; Kismi, 2007).

Treatments provided in PICUs tend to be mostly pharmacological (Winkler et al., 2019). Historically, restrictive management methods such as seclusion, restraint and rapid tranquilisation have also been widely used to contain incidents of aggression and manage ongoing risks to self and staff (Bowers et al., 2008). When seclusion facilities are available on wards, then staff rate seclusion use as more acceptable and use it more than those working in environments without seclusion facilities, so suggesting a continued preference for restrictive management methods in more restrictive environments such as PICUs (Pettit et al., 2017). The factors that increase the likelihood of seclusion are younger age, being legally detained and being female (Cullen et al., 2018). Physical aggression is the most common form of aggression on PICUs (Mele et al., 2022). Staff are often unfortunately physically injured during such acts of aggression (Yusaf et al., 2020), with qualified and unqualified nursing staff the most common victims of physical injury (Mele et al., 2022). For patients, use of restrictive practice increases risk of traumatisation or re-traumatisation as it invokes a sense of powerlessness (Sweeney et al., 2016).

Three studies have identified predictors of acts of violence and aggression on PICUs. Gumber et al., (2022) noted greater number of previous admissions, longer current non-voluntary admission and low permanent staffing levels in the MDT. Mele et al., (2022) noted the first five days of PICU admission as the period when acts of aggression were most likely. Lansgrud et al., (2018) found that poor duration of sleep and between-night sleep duration differences for patients admitted to a PICU, correlated with increases in aggression and violent incidents on the ward. The heightened challenges of working in a PICU can result in compassion fatigue amongst staff teams, where repeated exposure to elevated distress leads to reduced empathy (Peters, 2018) and the risk of iatrogenic and retraumatising care. Not surprisingly, the challenges of providing care in PICUs were particularly pronounced for MDTs during the COVID-19 pandemic (Skelten et al., 2021).

The national minimum standards for care in PICUs were updated in 2019 and recommended that psychological therapies were made available to patients, with both patients and their carers seeking to have psychological input as a routine aspect of inpatient care (RCP, 2019). Psychological provision as a routine aspect of inpatient psychiatric care has also been championed at a policy level (BPS, 2011, 2021). However, routine access to evidence-based psychological interventions has been described as ‘disappointingly low’ in PICUs (Garcia et al., 2005), with little identification as to what may be therapeutically beneficial for PICU patients (Archer et al., 2016). Various indirect psychological interventions in acute inpatient settings are identified as effective, including reflective practice, staff practice-based education sessions and most commonly, case formulation sessions (Man et al., 2022). Patients with lengthier admissions who staff find more challenging should be prioritised for psychological input, with reflective practice sessions forming a core component of staff wellbeing support (Raphael et al., 2020). MDTs want psychological input into wards to be a blend of direct and indirect case formulation work, one-to-one therapy with patients, supervision of nurse-led interventions and staff wellbeing interventions (Raphael et al., 2020).

 In terms of the evidence base for psychological interventions on inpatient psychiatric wards, Evlat, Wood and Glover’s (2021) narrative review found that most of the interventions delivered were based in cognitive-behavioural therapy. When the randomised clinical trials of inpatient interventions for psychosis are meta-analysed (Paterson et al., 2018), then the small-to-moderate improvements in psychotic symptoms at end of therapy degrade by follow-up, but psychological therapies reduce readmissions, depression and anxiety. Man, Wood and Glover’s (2023) systematic review of indirect work on inpatient units found that case formulation was the most common aspect of this work.

The aim of the current study was to provide an example of and evaluate the effectiveness of implementing a schema-informed formulation (Fassbinder, Brand-de Wilde, & Arntz, 2019) for a patient admitted to a PICU, as this has not been achieved before. Kennedy (2008) argued that inpatient formulations enable a more compassionate understanding of presenting and underlying issues beyond the medical model, map unhelpful patient/staff/context interactions, and notes that formulation development and sharing constituted an intervention in and of itself. Team formulations are where the MDT meet and discuss and formulate the patient without the patient being present with the aim of improving care and there are new guidelines available to guide this process and in particular how to gain patient consent (ACP, 2022). Formulations are useful in enabling the collaborative management of crises by the MDT and inpatients (Small et al., 2018) and have been encouraged particularly as a means of creating more consistent staff care and increasing the potential for patient self-management of their well-being (BPS, 2021). Berry et al.’s (2016) randomised clinical trial of implementing formulations on psychiatric inpatient wards found that patients in the intervention arm felt significantly less criticized by ward staff and that the overall ward atmosphere improved. Edwards (2022) highlighted the potential usefulness of schema formulations in inpatient settings, due to being able to capture and map the complexity and risk often present in this patient group. The current study evaluated the implementation of a schema-informed formulation on a PICU using a quasi-experimental N=1 methodology. The study hypothesis was that occurrence of incidents involving restraint, seclusion and/or intramuscular rapid tranquilisation would reduce after the formulation was introduced and supported by staff.

**Method**

**Design, context and ethical approval**

The study is reported according to the single-case reporting guidelines (SCRIBE; Tate *et al.*, [2016](https://bpspsychub.onlinelibrary.wiley.com/doi/full/10.1111/papt.12278#papt12278-bib-0069)). The participant gave their consent for the study to be reported and was shown a copy of the final report and agreed with the contents of anonymised publication version. Ethical approval for the study was granted (ref: 041077). Cooper, Turpin, Bucks and Kent ([2005](https://bpspsychub.onlinelibrary.wiley.com/doi/full/10.1111/papt.12278#papt12278-bib-0020)) provided guidance on the ethics of conducting quantitative single cases and these have been followed here. The study uses a bi-phasic quasi-experimental A/B design (Hersen, [1990](https://bpspsychub.onlinelibrary.wiley.com/doi/full/10.1111/papt.12278#papt12278-bib-0030)) that tracked three outcome measures. The study was conducted in routine practice in a 5-bedded mixed-sex PICU in a northern city in the United Kingdom. The formulation was developed and delivered by an assistant psychologist (AP) under the weekly clinical supervision of a consultant clinical psychologist (CCP). The baseline contained eight one-to-one sessions (i.e., total session time = 240 minutes, mean session duration = 30 minutes, session duration range 10-60 minutes). The intervention contained six one-to-one sessions (i.e., total session time = 208 minutes, mean session duration = 34.67 minutes, session duration range 3-60 minutes). The PICU had a weekly reflective practice group facilitated by the CCP in which the implementation of the changes by the staff group was discussed on six occasions. The piece of work was requested by the MDT because of the number of incidents of violence and aggression by the patient, and the associated stress levels this was creating in the MDT. Additionally, the MDT reported being confused by the changing nature of the patient’s presentation. It was thought that a schema-informed case formulation would enable the helpful mapping of the differing modes and the switches between them (Edwards, 2022), and this would then enable staff to better respond to and manage the patient. The patient had a positive behaviour support (PBS) plan already in place (Gore, 2013). The key differences between the schema-based formulation and the PBS plan, was that the PBS plan (a) did not recognise the differencing modes the patient could present in and (b) was focal to self-harm.

**Measures and administration**

The three outcome measures were a daily number count of all incidents involving (1) the use of seclusion, (2) restraint and/or (3) intramuscular rapid tranquilisation. The baseline (A) lasted 8-weeks, and the intervention (B) lasted 8-weeks. Therefore, the study had a 112 continuous day time-series dataset containing two phases (i.e., baseline and intervention). The intervention phase (B) was initiated by the sharing of the full case formulation with the staff team and the patient participant.

**The participant**

The inpatient participant was a female with a diagnosis of with a diagnosis of emotionally unstable personality disorder (EUPD), autism spectrum disorder (ASD) and mild learning difficulties. The participant was not actively psychotic at the time of the study. The EUPD diagnosis was characterised by marked emotional variability, including recurrent and high suicidal intent, impulsivity, self-harm and/or aggression towards others. The methods of self-harm were headbanging, cutting, burning and tying ligatures. The ASD diagnosis was characterised primarily by sensory difficulties, such as heightened sensitivity to loud noises. The participant had attended a specialist school for children with special educational needs/disabilities and the participant has been under learning disability services previously. The participant has experienced multiple traumas throughout childhood, including but not limited to sexual, emotional and physical abuse. The participant’s parents separated during her childhood, and she reported strong feelings of loss and abandonment, due to feeling ‘disowned’ by her parents due to her learning disability. The participant also lost a sibling to suicide. The participant stated that she had not grieved for this loss and the loss was profound as her sibling represented love and care to her.

The participant first had contact with services as a young child. Since an initial placement in a children’s unit, the participant had consistent contact with over twenty mental health and residential units/wards. A pattern of placements breaking down was apparent over time, involving a deterioration in mood, resulting in an escalation in risky behaviours and disengagement from treatment, leading to a transfer to often increasingly more restrictive or specialist environments. PICU admission was due to the breakdown of a residential placement, due to carrying weapons, threatening staff and declining medication. The participant was initially admitted informally but was then detained under the Mental Health Act. The section was due to acts of self-harm, frequent verbal abuse of staff, issuing physical threats to staff, extensive damage to the ward environment and inflicting injuries on staff. (e.g., during one incident of restraint, a staff member was briefly strangled). Escalating risks led to the regular use of physical restraint involving large numbers of the MDT, use of the seclusion room and increasing retort to use of intramuscular rapid tranquilisation. The MDT were finding the incidents difficult to manage, were burning out, and felt confused by the rapid mode shifting. The wellbeing and safety of both MDT and patient were, at times, compromised. The participant verbalised experiencing the restrictive practices as retraumatising.

**Developing the formulation**

A schema-informed formulation model (Fassbinder et al., 2019) was selected as this would enable the identification of differing schema modes to help both the patient and MDT to better recognise and then manage differing schema modes. Modes are identified as a constellation of predominant schemas and associated coping responses, with the patient shifting between modes due to stress, with fragmentation between modes being dictated by dissociation (Rafeali & Thoma, 2020). As the formulations used on the PICU with other patients tended to be cognitive-behavioural in orientation, other formulations based on other theories (e.g., a cognitive analytic formulation) were considered and rejected, because of the ease of staff implementation of a CBT-based formulation, due to prior learning. The formulation is presented in Figure 1 (see online supplementary materials) and identified four dysfunctional child modes (a) ‘fleeing’ as the desperate child mode, (b) ‘destructive of care’ as the humiliated child mode, (c) ‘sulking’ as the defiant child mode and (d) ‘rage’ as the impulsive/enraged child mode. The formulation contained one healthy adult mode (called the ‘happy’ mode) and an unmanageable feelings state (i.e., the maladaptive coping mode). Each mode was given an idiographic title to aid in patient recognition and contained the dominant feeling, physiology, thoughts and behaviours. The procedures linking modes were mapped and the MDT responses to each mode the participant experienced as ‘unhelpful’ were added. The formulation was built iteratively with the patient mode-by-mode. This involved the 1:1 conversations between the AP and the patient to identify the differing modes and what happens in and between each mode. This was achieved by naming the mode and then by asking questions to elaborate on the mode such as “when you or in X, what do you do, how do you feel, how does your body react and what are you expecting and experiencing from the staff team?” The procedures linking modes together were identified by questions such as “when you leave that mode, where do you do next?” Identifying the constituent parts of modes made development of the schema-informed formulation more accessible for the participant, as it made the work less abstract and in line with her neurodiverse needs. The participant was able to then talk about events that occurred on the ward, what led up to them and what made them better or worse in terms of the staff response and how she was left feeling, to help elucidate the formulation. The participant chose pictures to represent the different modes she presented in and the pictures enabled her to also describe the mode in greater detail. The language used on the formulation used the words used by the participant rather than language that would typically be used to describe each mode and enable better recognition. The MDT version and the patient versions of the formulation had the same content, but the patient version was more pictorial for ease of understanding due to their mild learning difficulties.

**Implementing the formulation**

The intervention intended to aid staff and the participant to work collaboratively to firstly stand back and recognise mode activation and then for the staff to intervene in ways that the patient defined would be helpful. A change-based formulation (see Figure 2) was therefore developed with the patient with a range of responses that staff could implement when differing modes were activated. Using her selected pictures as prompts, the participant was asked what was helpful and unhelpful when she was in that mode, and what would enable to move away from distressed modes and into or towards the ‘happy state.’ The happy mode may have appeared ‘elated’ or ‘manic’, but in context of the participant’s personality, is a desired and optimal state for her wellbeing. The means by which the MDT could help the participant move out of distressing modes were shared with the staff team during reflective practice sessions and discussed in detail there.

The participant’s role in the intervention phase was therefore to recognise and communicate to the MDT which mode she was in or about to enter. The staff’s role was to interpret or ascertain which mode the patient was occupying and then to offer support according to the change formulation guide. A set of flashcards was also developed at the participant’s request, consisting of individual picture summaries of the various modes to help the participant mode signal effectively and these also were again shared with the staff team and discussed at the reflective practice group. Staff were encouraged to prompt the participant to identify her current mode using flashcards. Implementation of the formulation was not intended to challenge the schemas, but to improve understanding of the various modes to better manage the participant’s presentation and reduce incidents on the ward. The one-to-one sessions during the intervention phase supported the patient using the formulation, but were in no way schema-therapy.

**Results**

Figure 3 displays the restraint incident rate over the two phases of the study. The total number of restraint incidents in the baseline (A) was 16, of which 10 required the additional use of intramuscular rapid tranquilisation and 4 the additional use of confinement in the seclusion room. The restraint incident rate during the intervention phase (B) was zero.

**Discussion**

This study was conducted because of the need to provide an example of the use of case formulation on a PICU and additionally to provide an empirical evaluation of outcome to contribute to the sparse PICU evidence base. Clinically, the aim was to help the patient and staff work more reciprocally to reduce the need for restraint, seclusion or intramuscular rapid tranquilisation, as this had been previously distressing and dangerous for both MDT and the patient. The single case methodology was quasi-experimental, as there was no experimental manipulation (Hersen, [1990](https://bpspsychub.onlinelibrary.wiley.com/doi/full/10.1111/papt.12278#papt12278-bib-0030)). The bi-phasic comparison showed that incidents of the use of restraint, seclusion or intramuscular rapid tranquilisation extinguished. There was no need for a statistical analysis of the outcome (e.g., non-overlap analyses; Manolov et al., 2016), because the three outcome variables all extinguished. Future research should implement a more robust experimental design (i.e., ideally with a neutral baseline) and take idiographic and nomothetic measures from both the patient and the MDT. This study provides encouraging, but only an initial, contribution to evidence base regarding the effectiveness of psychological interventions in PICUs (BPS, 2021; RCP, 2019).

This has been the first reported quantitative evaluation of a psychological intervention on a PICU and given the diversity and the levels of distress typically present in this context (Garcia, et al., 2015), then use of SCED as an outcome research methodology appears particularly useful in this clinical setting. As noted, further SCED studies need to implement methods that entail some form of experimental manipulation to increase internal validity, although the ethics of using withdrawal designs (e.g., ABAB) on PICUs is complicated. This would particularly be the case when the intervention appears to be effective in its first administration. It appears ethically more appropriate therefore to conduct cross-over SCEDs (e.g., ABCBC) in which phases of differing evidence-based psychological interventions can be compared against each other. The addition of follow-up phases is also hard to engineer during a PICU admission, but because patients are often ‘stepped down’ and discharged to acute wards (Brown & Bass, 2009; Kismi, 2007). Methodologically, then this could possibly constitute another phase to compare PICU progress against and also the baseline.

Psychological provision on PICUs entails the organisational work of supporting the MDT staff (BPS, 2021; RCP, 2019) and the current study made good use of the MDT reflective practice group to validate how hard it was to consistently and compassionately care for the patient, but also as a springboard for implementing the change methods of the formulation. Discussions with the MDT in the reflective practice group revealed a shift in staff attitude and approach during the intervention phase. Staff described a move toward a least restrictive approach when the participant was in the rage mode, whereby staff would give the participant space and strive to avoid use of restraint, seclusion or rapid tranquilisation, despite the risk behaviours. Staff found the participant would eventually self-soothe, and the participant found this approach helpful too. Staff were encouraged in the reflective practice group to trust that this settling would happen. This would be an example of more psychological thinking amongst the MDT, in line with previous suggestions as to the possible impact of psychology on inpatient wards by the BPS (2011). This is akin to evidence of the usefulness of staff support activities irrespective of the psychological model on PICUs (Foster, 2020). In terms of the skills and competencies required to deliver the intervention, then the work of the AP was closely supported and supervised by the CCP. There is pressure on PICU beds nationally and national guidance (NHS, 2002) suggest a maximum stay of 8 weeks, with an average length of admission of 26.5 days. Clearly, the patient in this study length of PICU stay was beyond national guidelines due to the severity of their presentation. Psychological input into the care of PICU patients offers the possibility of cost savings in the long-term due to shortening admissions, but economic evaluations are needed to support this. Any admission to a PICU needs to be purposeful admission and goal setting process.

The study clearly had limitations. The study could only explore the impact of a psychological intervention for a single patient (and one diagnosed with ASD, EUPD and mild learning difficulties). Generalisability to other patients may be poor. Future studies should evaluate outcomes with actively psychotic patients, who make up the majority of PICU populations (Bowers et al., 2008). The 16-week duration of the study enabled enough time to evaluate short-term effectiveness, but clearly failed to index long-term durability or generalisability. Assessment and development of the formulation cooccurred during the baseline period, which is a confounding factor. The case formulation was a schema-informed and so not a ‘pure’ schema case formulation. Indeed, this was not an evaluation of direct schema therapy and this was because of the risk of further destabilisation that schema therapy might have created. The AP was also not trained in implementing schema therapy. It is impossible to disassemble the therapeutic influence of the one-to-one sessions to support the formulation during the intervention phase and the changes to MDT responding. There were no formal adherence checks performed on the MDTs use of the formulation, or the competency of the AP’s input. There may have been variation in adoption of the methods in the staff in the MDT.

SCED methods rely on the use and integration of both idiographic and nomothetic outcome measures. A weakness of the current study is that the absence of any idiographic measures (e.g., a daily mood rating from the participant) or use of any service specific nomothetic outcome measures (e.g., Psychiatric Inpatient Patient Experience Questionnaire On-Site; PIPEQ-OS; Bjertnaes et al., 2015). The outcome measures used in the study were however sensitive to the PICU context, easy to collect and did enable the pattern of change to be elucidated. These more service-type indices of change appear to therefore have some virtue in a PICU context and particularly have traction in an MDT context. Future SCED research needs to also implement a broader blend of patient idiographic and nomothetic outcome measures and also include MDT outcome measurement (Berry et al., 2016).

To conclude, psychological change in PICU patients may well require bespoke blending of direct clinical work and indirect organisational work within the MDT. The clinical:organisational ratio will differ according to the needs of individual patients so that care is always personalised. It is acknowledged that due to the routine and acute levels of emotional distress, then psychological input may not be safe or effective in the early stages of some PICU admissions. This would signal the need for more organisational work in the clinical:organisational ratio. The study fits with the drive to make PICU environments and practices as least restrictive as possible, whilst retaining safety and efficacy (Hochstrasser et al., 2018; Moore et al., 2021). The study has been the first of its kind in evaluating a psychological intervention on a PICU ward, using a biphasic single-case experimental design. It demonstrates that this research design is practicable on PICUs, paving the way for future studies evaluating the effectiveness of psychological input on inpatient wards. There is a real need to systematise access to psychological input to inpatient psychiatric patients and simultaneously develop an evidence base for the efficacy and effectiveness of psychological interventions. Practice-based evidence and clinical trials therefore need to be considered in reciprocal equipoise in the development of a PICU specific evidence base.

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