Implicit Emotional Memory and Post Traumatic Stress in Adult ICU Patients

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Statement of Originality

I confirm that this is an original piece of work. The literature review and research reports contained within this thesis have not been submitted for any other degree, or to any other institution.

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PsyD Thesis Abstracts

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Part One: Literature Review

Purpose: Treatment in an ICU is a psychologically traumatic event yet it is unclear what factors independently or cumulatively lead to PTSD in some patients. *Method:* Electronic databases were searched for articles published between 1960 and 2013. 21 articles were reviewed. *Results*: The institution that is ICU and memories of the experience contributes to the development of PTSD; however, ecological validity was compromised in many studies. *Conclusion:* Memory of ICU in PTSD development warrants further exploration.

Part Two: Research Report

Introduction: ICU care can result in PTSD, with memories disrupted by sedative and/or analgesic drugs. We examine if a trigger for PTSD flashbacks is an emotionally salient sensory stimulus that occurred whilst sedated. *Method*: 24 general ICU patients were screened at 1-2 weeks and 4-5 weeks post ICU with commonly used screening tools (PTSS-14, HADS, ICUMT). Skin conductance responses to ICU and other sounds measured implicit memory. Patients' relatives (n=15) and a non-clinical sample (n=35) also participated. *Results*: A mixed ANOVA failed to find a significant difference within groups, but did find between group differences $F(2,69) = 6.82$, $p < .05$. Positive correlations approaching significance were found for sedation and analgesia with delusional and factual memories. A trend was found for ICU sounds and PTSS. Nine patients reached caseness on the HADS subscales and/or PTSS-14. *Conclusion:* Replication in a larger sample, ICU-specific screening tools, and intra-ICU and follow up psychological support is recommended.

Part Three: Critical Appraisal

Appraisal of the research process was undertaken. Reflections on conducting an independent research project are presented, and learning points highlighted.

Part Four: Service Evaluation

A community tenancy of an adult with extremely challenging behaviour was evaluated using a single case study design. The intervention was the package of care. Over time, the frequency and duration of challenging behaviour decreased, tactile and play behaviours increased, and antipsychotic medication significantly reduced. Suggestions for service improvement were made.

Acknowledgements

For my Dad

My greatest hero, critic, and friend.

You taught me courage, and gave me strength,

and will be with me always.

For my Mum

Who laboured, and won,

and is the most inspirational of women.

I love you both.

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Part One

Literature Review

Exploring the factors associated with the development of post-traumatic stress disorder (PTSD) in adults following Intensive Care treatment

Author: Elizabeth A. Trubshaw, CPsychol

Target Journal: British Journal of Clinical Psychology

Abstract

Purpose: Treatment in an ICU is a psychologically traumatic event yet it is unclear what factors independently or cumulatively lead to PTSD in some patients. *Method:* Electronic databases were searched for articles published between 1960 and 2013. 21 articles were reviewed. *Results*: The institution that is ICU and memories of the experience contributes to the development of PTSD; however, ecological validity was compromised in many studies. *Conclusion:* Memory of ICU in PTSD development warrants further exploration.

Key words: intensive care unit, memories, post-traumatic stress, distress.

Section 2: Introduction

2.1 *Background*

Treatment in an intensive care unit (ICU) is an increasingly acknowledged psychologically traumatic event for some, but not all, patients. It is acknowledged too, that relatives, as visitors, informal care givers, and decision-makers (at least in the critical phase of the admission), can also be traumatised by the experience (Jones et al., 2004). At its extreme, and since the refinement of diagnostic criteria for Post-Traumatic Stress Disorder (PTSD) in the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV, 1994, see Table 2.1 for criteria), a growing number of studies has found that a substantial proportion (ranging from 5% to 63%[1]) of patients develop PTSD post ICU discharge (e.g., Cuthberston, Hull, Strachan, & Scott, 2004; Griffiths, Fortune, Barber, & Young, 2007; Skirrow, Jones, Griffiths, & Kaney, 2001; Twigg, Humphris, Jones, Bramwell, & Griffiths, 2008), and many become chronic sufferers of the disorder (Kapfhammer, Rothenhausler, Krauseneck, Stoll, & Schelling, 2004). This finding is striking given that many patients spend only one or two days on the Unit (Sukantarat et al., 2007). Perhaps what is even more striking, is that patients with no explicit[2] (conscious) memory of ICU after one to two days can go on to develop PTSD.

[1] A reflection of the scale used to measure it, design, case mix, and timing of PTSD assessment.

[2] Explicit memory is the conscious, intentional recollection of previous experiences and information. Implicit memory refers to memories that we are unaware of, that we cannot consciously recall or recognise, yet which reveal themselves through changes in behaviour (Andrade & Deeprose, 2007).

Table 2.1
DSM-IV Diagnostic Criteria 309.81 Post-Traumatic Stress Disorder

A. The person has been exposed to a traumatic event in which both of the following were present:
   (1) The person experienced, witnessed, or was confronted with an event or events that involved actual or threatened death or serious injury, or a threat to the physical integrity of self or others.
   (2) The person's response involved intense fear, helplessness, or horror.

B. The traumatic event is persistently re-experienced in one or more of the following ways:
   (1) Recurrent and intrusive distressing recollections of the event, including images, thoughts, or perceptions.
   (2) Recurrent distressing dreams of the event.
   (3) Acting or feeling as if the traumatic event were recurring (includes a sense of reliving the experience illusions, hallucinations, and dissociative flashback episodes, including those that occur on awakening or when intoxicated).
   (4) Intense or psychological distress at exposure to internal or external cues that symbolize or resemble an aspect of the traumatic event.
   (5) Physiological reactivity on exposure to internal or external cues that symbolize or resemble an aspect of the traumatic event.

C. Persistent avoidance of stimuli associated with the trauma and numbing of general responsiveness (not present before the trauma), as indicated by three (or more) of the following:
   (1) Efforts to avoid thoughts, feelings, or conversations associated with the trauma.
   (2) Efforts to avoid activities, places, or people that arouse recollections of the trauma.
   (3) Inability to recall an important aspect of the trauma.
   (4) Markedly diminished interest or participation in significant activities.
   (5) Feeling of detachment or estrangement from others.
   (6) Restricted range of affect (e.g. unable to have loving feelings).
   (7) Sense of a foreshortened future (e.g. does not expect to have a career, marriage, children, or a normal life span).

D. Persistent symptoms of increased arousal (not present before the trauma), as indicated by two (or more) of the following:
   (1) Difficulty falling or staying asleep.
   (2) Irritability or outbursts of anger.
   (3) Difficulty concentrating.
   (4) Hypervigilance.
   (5) Exaggerated startle response.

E. Duration of the disturbance (symptoms in Criteria B, C, and D) is more than 1 month.

F. The disturbance causes clinically significant distress or impairment in social, occupation, or other important areas of functioning.

Specify if: **Acute**: If duration of symptoms is less than 3 months
Chronic: If duration of symptoms is 3 months or more

Specify if: **With Delayed Onset**: if the onset of symptoms is at least 6 months after the stressor

2.1.1 Definition of Post-Traumatic Stress Disorder

PTSD is a severe anxiety state, experienced as a result of a significant negative life event which threatened serious injury or death to the person concerned, witnessing death or serious injury to another person, or learning of such an event. Responses to the event involve total helplessness, intense fear, or extreme horror. The symptoms of PTSD comprise three symptom clusters[3]: persistent re-experiencing of the traumatic event; persistent avoidance of things associated with the event and a numbing of general responses to the trauma; and increased arousal levels (DSM IV, 1994). This seriously impacts upon social, occupational, psychological or other functioning. The full DSM IV diagnosis of PTSD is based upon the presence of three items out of the four domains and they should be present for more than one month.

A diagnosis of partial/subsyndromal PTSD is made if patients meet the symptomatic criteria for criterion B (re-experiencing cluster) plus either C (avoidance cluster) or D (hyperarousal cluster), but not C and D (Schnyder, Moergeli, Klaghofer, & Buddeberg, 2001)[4]. The associated level of distress can also be significant (Cukor, Wyka, Jayasinghe, & Difede, 2010).

It had previously been thought that such problems were fundamentally linked to the reason for admission, however more recent studies from various continents highlight the possibility that admission and treatment on an ICU can contribute to the later development of PTSD in adults (Capuzzo et al., 2005; Davydow, Gifford, Desai, Needham, & Bienvenu, 2008; Griffiths et al., 2007; O'Donnell et al., 2010). In fact, in the 2010 Annual Evidence update on Critical Illness Rehabilitation, Treacher and colleagues (Treacher et al., 2010) summarised the research and called for a 'disease specific' assessment tool, where ICU admission was the 'disease'.

Several systematic reviews of post-ICU morbidity have been conducted (e.g. Davydow, Desai, Needhamm, & Bienvenu, 2008; Dowdy et al., 2005; Griffiths et al., 2007; Jackson et al., 2007). The most prominent and recent was commissioned by the Department of Health (DoH), and undertaken by the National Institute of Clinical

[3] DSM V criteria differ from those in DSM IV. DSM V describes four instead of 3 diagnostic clusters of symptoms. Criterion A is more explicit in regard to how an individual experienced traumatic events. Criterion A2 (subjective reaction) has been eliminated.

[4] The DSM V does not specify formal diagnostic criteria for partial PTSD but indicates that it can be diagnosed as an "Other Specified Trauma-and Stressor-Related Disorder" (DSM V, APA, 2013).

Excellence (NICE). The results were published in 2009 (Clinical Guideline 83), and updated in 2010 as mentioned above.

The Guideline Development Group (GDG) of NICE used the QUADAS (Quality Assessment of Studies of Diagnostic Accuracy) checklist to critically review the research to date. They were not able to make recommendations on the use of specific screening or assessment tools for non-physical (psychological, emotional, and psychiatric) morbidity because of limited good-quality evidence specific to a UK general adult critical care population (NICE, 2009). However, they were able to develop short, medium, and long term rehabilitation care pathways that included physical morbidity problems (such as muscle loss, muscle weakness, swallowing, and communication problems), as well as non-physical morbidity.

The 2011 update reported Cuthbertson and colleagues' (Cuthbertson, Roughton, Jenkinson, Maclennan, & Vale, 2010) conclusion that "critical illness and ICU admission should be treated as a life time diagnosis with associated excess mortality, morbidity, and requirement for ongoing health care" (Treacher, Griffiths, & Parker, 2011). Greater understanding of the factors associated with a poor psychological recovery is needed.

2.2 *Aims of the Current Review*

This review aims to examine the literature of post ICU morbidity in an attempt to identify and understand the key factors of the ICU that are associated with the development of psychological disturbance in some patients that may lead to PTSD. The findings will be appraised, compared, and synthesized, in order to propose recommendations for future investigation.

Section 3: Method

3.1 *Search Strategy and Terms*

Using the search criteria detailed in Table 3.1, various databases and journals (listed below) were explored for relevant articles relating to PTSD in adult ICU, and a total of 279 abstracts were highlighted.

Table 3.1
Search Criteria for Initial Screen

Subject heading(s) /setting	Intensive care/posttraumatic stress/psychological distress/stress/memories/sedation (and variations)
Search within	Article headings and text
Search in	All Journals
Language	English Language only
Participants	Human/Adult/all
Date	1960-2012 (various)
Article type	Research articles only

Details of the databases searched, together with search terms and dates are as follows: Cochrane Reviews database, the NHS Evidence Health Information Resources Website and CINAHL databases, British Library Catalogue Integrated Database of Grey Literature 2003-2012, PsycINFO (1993-2012), Scopus (1992-2014), Web of Science and Ovid Medline (1982-2012), Embase (1960-2012). They were selected in order to facilitate comprehensive coverage of the topic and to minimise non-retrieval of relevant documents.

Search terms used were “intensive care” AND “posttraumatic stress” AND “psychological distress/disturbance” AND “memories” AND “sedation”/“posttraumatic stress” AND “sedation” and “intensive care” AND “psychological distress” AND “intensive care” AND “memories” (subject heading/title and then all text) “posttraumatic stress” AND “sedation” AND “intensive care” (subject heading/title, and then all text)/ and database-specific variations of spelling/nomenclature (for example, post* and “posttraumatic/post-traumatic”) “implicit memory” (subject/heading/title), all in English Language. These terms were

chosen in order to correspond to the coverage of the review in order to allow a reliable assessment of the data.

Figure 3.1 presents a detailed flow diagram illustrating the search and screen-out pathway, and is detailed below. Titles and abstracts were examined specifically for a focus on factors related to psychological distress and PTSD in adult ICU populations.

3.2 *Inclusion Criteria*

- Randomized Controlled Trials, and prospective, follow-up studies in adult ICU populations
- Medical and psychology studies focusing on potential causative factors, mechanisms, and prevention of PTSD in adult ICU populations
- Empirical studies using experimental methodologies in ICU
- Studies using ICU-validated measures of psychological distress
- Review articles containing information about empirical studies of psychological distress and disturbance, and post-traumatic stress following ICU.

3.3 *Exclusion Criteria*

- Paediatrics and children
- Case studies and single-case design studies
- Discussion articles and book chapters
- Articles not written in English.

The inclusion and exclusion criteria were specifically chosen to enable the researcher to capture and review the most relevant published empirical studies, focusing purely on factors relating to the development of psychological distress in adults following ICU treatment. The 21 relevant articles were assessed using Crombie's (1996) checklists, the first for appraising quantitative studies (see Appendix A), and the second for literature reviews (see Appendix B). The checklists were used as they provided a concise guide to the assessment of medical research and were simple to use.

3.4 *Synthesis of Data*

To facilitate comparison and synthesis of data across studies, information was gathered using a data extraction tool (Jones, 2007) as shown in Appendix C, before being tabulated and described within the results section of this review. They were then entered onto a spreadsheet and a quality rating score was allocated to each paper according to the Oxford Centre for Evidence Based Medicine guidelines (CEBM) (2009; see Appendix D). CEBM ratings range from 1a to 5, with lower numbers indicating higher quality. Letters used to designate level 1 to 5 studies indicate gradations of quality ranging from ‘a’ (higher) to ‘b’ (lower quality). Studies with ratings between 1 and 3 were included in this review.

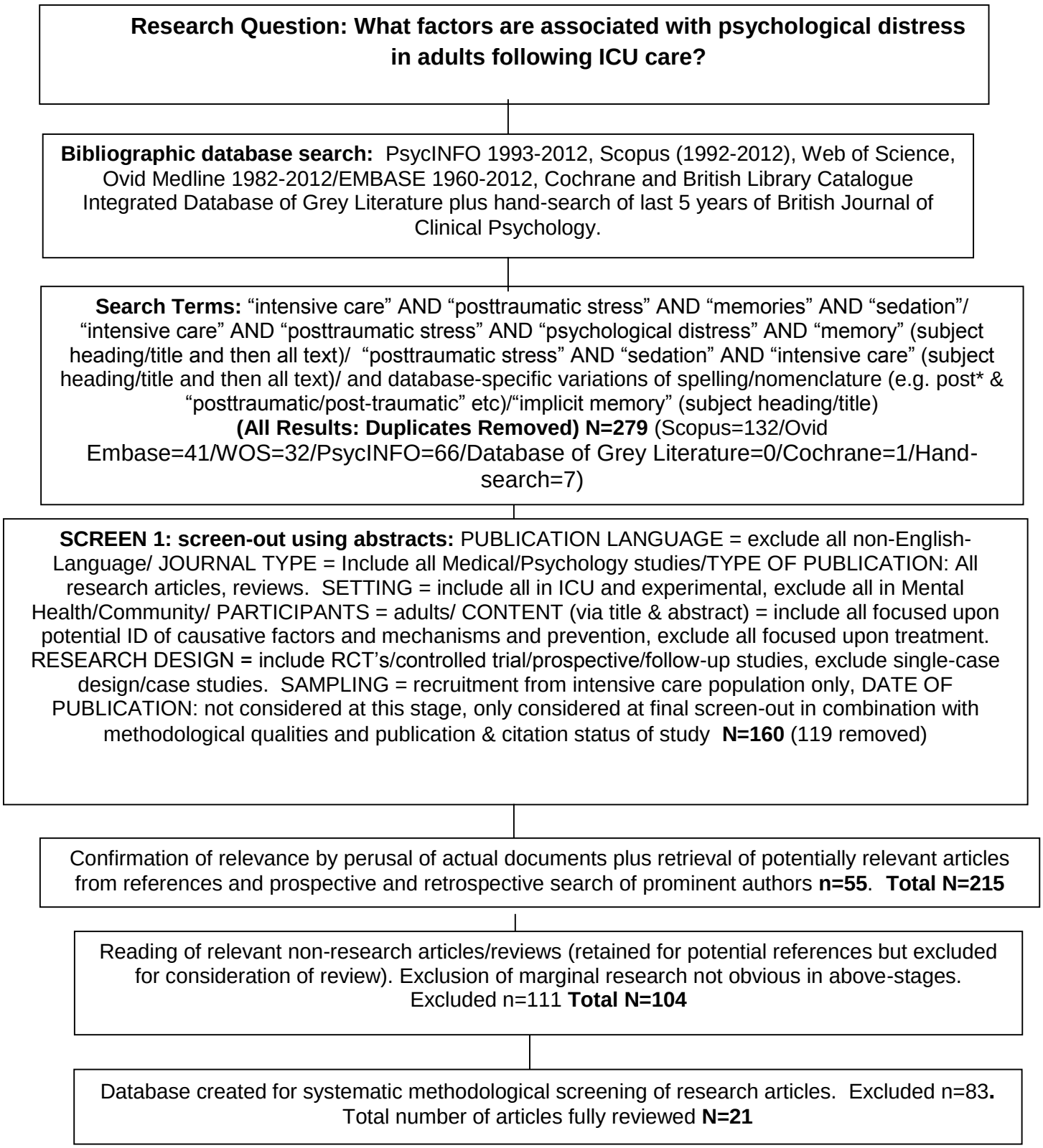

Figure 3.1. Diagram of search procedure (reproduced with permission from Tordoff, 2009)

Section 4: Results

4.1 *Overview*

Only one of the two major articles selected for inclusion in the current review utilised a randomised control trial. Both used large populations, and had the highest quality ranking (CEBM 1b). The rest of the articles were cross sectional prevalence, or prospective cohort studies (2b-3b). The total number of participants who were followed up and completed the research was 2586. Loss to follow up because of death, deterioration, change of location, or choice, was significant in all studies. Inclusion criteria varied across studies, some offering a representative picture of ICU populations by including those with premorbid psychiatric conditions and traumatic brain injuries, whereas others were more cautious so as to reduce potential bias.

Case-mix, length of ICU stay, and timing and mode of assessments varied. Screening tools were almost universally used, with the exception of O'Donnell and colleagues (O'Donnell, et al., 2010) who utilised a gold standard structured clinical interview to diagnose the presence or absence of PTSD. Cut-off scores for caseness[5] in measuring anxiety, depression, and trauma symptoms also varied, and resulted in inflation of prevalence rates in some cases. Notwithstanding, it is acknowledged that treatment in an ICU is a traumatic event. The need for intra-ICU and post-ICU psychological care is indicated, and standardized psychological assessment and intervention protocols are needed. In all studies reviewed, admission to the ICU was acknowledged as a significant factor in the development of PTSD symptomology, and PTSD symptoms were not significantly related to the severity of illness. Table 4.1 presents a summary grid and CEBM quality ranking (2009) of the studies included in the review.

[5] Caseness is the threshold at which it is appropriate to initiate treatment

Table 4.1
Summary Grid of Reviewed Studies

Study	Population and Country of origin	Sample and follow up	Design and CEBM Quality Ranking Score	Tools	Length of ICU stay	Rate of PTSD or PTSS, Anxiety or depression	Risk factors
O'Donnell et al 2010	5 trauma hospitals (admitted to ICU vs not admitted to ICU) Australia	3761 eligible 1598 randomised into study 1109 (70%) completed initial assessment 829 (75% of original sample) completed 280 lost to follow up. Structured clinical interview at 12-months. by phone	2-group Prospective Cohort. Longitudinal Multicentre, stratified by length of stay **1b**	CAPS-IV-gold standard CIDI (Composite International Diagnostic Interview)-PTSD MINI (Mini-International Neuropsychiatric Interview) Schuster Social Support Questions. Visual Analogue Scale (Pain) Acute Stress Disorder Interview	>24 hours to 44 days (median 8 days)	ICU patients were significantly more likely to have PTSD at 12 months than trauma controls (17% vs 7%) = 3.45 times more likely to have PTSD than non-ICU patients. 9% (n=73) who did not have PTSD at the time of injury did at 12 months	ICU admission. No differences in terms of age, gender, education, marital status, employment, psychiatric history, number of prior traumatic events, and preinjury social support.
Jones et al (2003)	General medical ICU 3 hospitals UK	126 eligible 114 at 8 weeks 102 completed study at 6 months follow up 24 (20%) lost to follow up. Questionnaires	RCT 2 group Routine ICU f/u 8wks & 6 months versus also had a 6-wk rehab package. **1b**	STAI Norbeck Social Support Questionnaire HADS IES ICUMT SF-36	3-114 days	51% probable PTSD at 6 month follow up (score of >19 on IES) >30% anxiety on HADS ≥ 11 8 (12%) intervention group vs 13 (25%) controls, depression on HADS ≥ 11	Presence of delusional memories increased risk of PTSD symptoms and had higher anxiety scores.
Jones et al (2001)	General ICU 1 site UK	45 patients at 2 weeks. (4% premorbid Ψ history) 30 completed. Standardized interviews at 2 & 8 weeks post ICU discharge face to face	Prospective Case series cohort. **2b**	ICUMT HADS ≥ 11 STAI IES at 8 weeks Fear Index	>24-hours & ventilated. Median 8 (range 1-60) days	73.3 % had delusional memories	Delusional but not factual memories had higher anxiety, & depression levels, higher scores of PTSD-related symptoms & panic attacks.
Boer et al (2007)	Surgical ICU Secondary peritonitis. 1 site Netherlands	278 eligible at time 1 131 still alive at 4years 118 alive at f/u 4-10years. 104 (88%) completed. Mortality 57.5% Mailed questionnaires (median receipt of them 7.3 years)	Retrospective cohort of consecutive patients **2b**	PTSS 10 ≥35 = PTSD symptomology, ≥27-35 = borderline PTSD Adverse Experiences Questionnaire	Median 16 (25^{th} – 75^{th}%ile = 5-30 days 89% ventilated (median 11 days)	24% =PTSD ICU group, 18% = non ICU group Symptomology- nightmares, panic attacks, pain, diffs breathing. No significant differences between groups	Older and male = protective. Higher APACHE scores = more PTSD symptoms = contrast to other studies. Ventilation associated with more PTSD symptoms. ICU stay Traumatic memories
Boer et al (2008)	Surgical ICU Abdominal sepsis. 9 sites Netherlands	132 eligible 108 completed (80%). Responses received on average 12.5-months post emergency laparotomy. Mailed questionnaires at 12 months	Prospective cohort **2b**	IES-R ≥24 & PTSS 10 ≥35 = PTSD symptomology, BDI II Life Stressor Checklist-Revised (questions 29 & 30)	Median stay 7 days. (IQR 19-55 days) Ventilated median 5 days	28% moderate PTSD symptoms 10% high PTSD symptoms. 5% severe depression symptoms on BDI-II. Confounder: 51% also had another trauma in the 3 years prior to questionnaires.	Not related to severity of illness. No sex differences. Younger age. Traumatic memories of the period of hospitalization and length of ICU stay.
Capuzzo et al (2005)	General medical ICU 1 site. Italy	100 eligible. 84 participated at 1 week, 60 completed at 3 months, 25% lost to follow up. Telephone interview at 1 & 3 months.	Prospective cohort. **2b**	ICUMT IES – medium = 9-19, high ≥20 Used ICUMT to screen the presence of PTSS	At least 3 days Sedation used only if absolutely necessary. Use of physical restraint.	5% PTSS	PTSD symptoms associated with fewer factual memories. Morphine related to PTSD symptoms.
Cuthbertson et al (2004)	General medical ICU 1 site UK	111 enrolled, 78 (70%) completed at 3 months, 30% lost to follow up. No exclusion criteria. Telephone assessment at 3 months	Prospective cohort **2b**	Davidson Trauma Scale screening tool	At least 24-hours to 51 days (median 5.6 days)	22% subsyndromal 14% PTSD	PTSD associated with younger age, length of ventilation, previous psychiatric history 11 (14%) had visited GP for psychological distress prior to their critical illness
Eddleston et al (2000)	General medical ICU UK	370 eligible. 227 alive at 3 months. 143 completed at 3 months. 39% died 37% lost to follow up Interviews	Prospective cohort **2b**	HADS ≥8 SF36	At least 24 hours Median 3.7	11.9% heightened anxiety 9.8% depressed 36% distressing flashbacks	Female gender related to increased risk of distressing flashbacks
Girard et al (2007)	Medical and Coronary ICU 1 site USA	555 admitted. 280 excluded. 275 enrolled. 96 died prior to discharge. 50 died in 6 months. 86 lost to follow up 43 completed (24%) at 6 months Interview	Prospective cohort **2b**	PTSS-10 CAM-ICU SF-12	Median – 10 days (range 5-13).	6 (14%) scored >35 on PTSS-10. Memoires of: panic (67%), nightmares (20%), Suffocation (50%) Severe pain (20%)	Total dose of Lorazepam was associated with increased PTSD symptoms. Women higher PTSS scores than men. Older patients less likely to have PTSD symptoms..

Study	Population and Country of origin	Sample	Design and CEBM Quality Ranking Score	Tool	Length of ICU stay	Rate of PTSD or PTSS, Anxiety or depression	Risk factors
Hepp et al (2008)	Surgical ICU 1 site Germany	121 recruited. 90 completed all 4 time points (within 1 month, 6, 12 and 36 months) German-speaking patients only Interviews	Prospective cohort **2b**	IES CAPS SCL-90-R HADS ≥7.	At least 24-hours To 26 days Mean 5.7 days (SD. 5.1)	At some point during 3 year f/u, 36% sub-threshold or full PTSD, dropping to 2-6% at 3 years.	Intrusions Biographical memory
Jones et al (2007)	Mixed general ICU. 5 sites UK, Norway, Italy, Sweden	304 recruited 238 (78%) completed at 3 months 26 lost to follow up. 38 died. Telephone	Prospective multicentre observational. **2b**	ICUMT PTSS-14.at 3 months repeated & PDS	Range 2-76 days Median 8	PTSD 9.2% range 3.2% to 14.8% across sites. 1 in 10 risk of developing PTSD	Independent of case mix & illness severity - recall of delusional memories, prolonged sedation & physical restraint with no sedation. Pre-existing PTSD
Kapfhammer et al (2004)	General ICU Austria	80 patients 46 completed. Median follow-up 8 years 42% lost to follow up	Retrospective cohort **2b**	PTSS-10 SCID, STAI Montgomery-Asberg Depression Rating Scale	Ventilated for 6-78 days	43% with PTSD at discharge 23.9% with PTSD at follow-up (av 8 yrs) 8.7% sub-PTSD on d/c & 17.4% on f/u	Greater length of ICU stay Those with PTSD, psychiatric comorbidity determined at follow-up, particularly somatization.
Kress et al (2003)	General medical ICU 1 site USA	105 eligible, Able to contact 35. 32 completed 70% lost to follow up Clinical interview at least 6mths<1year	Prospective Cohort **2b**	IES-R, STAI BDI-II PAIS (financial reimbursement)	At least 3 days	18.5% with PTSD, 54% from control group; 0 from intervention group.	Presence of delusional memories increased the risk of PTSD; Sedative interruption decreased the risk of PTSD
Myhren et al (2010)	Mixed ICU 1 site Norway	Questionnaires sent at 4-6 weeks, 3 & 12 months post discharge. 251 at Time 1 194 completed 61 lost to follow up	Prospective cohort **2b**	ICUMT LOT-R IES	At least 24 hours	27% (48/180) above Caseness on IES. Half had subthreshold levels (IES>20). 16% may have delayed onset of PTSD symptoms.	Adjusted for age and gender, low educational level, pessimism, memory of pain and recall were independent predictors of PTSS at 1 year. Optimism was a predictor for less anxiety & depression symptoms after one year.
Rattray et al 2005	General medical ICU 1 site Scotland	109 enrolled at discharge 87 at 6 months, 80 completed at 12 months. 27% lost to follow up. Structured interviews	Prospective cohort **2b**	IES ≥ 20 HADS ICEQ	At least 24-hours Median 4.9	20% with high avoidance scores 18% high intrusion scores	Avoidance and intrusive symptoms related to younger age. 'Frightening' ICU experience. APACHE II scores, ICU/hospital length of stay, recall of experiences.
Richter et al (2006).	Surgical ICU Germany.	101 patients Mortality 55%. 9 lost. 37 completed Time to follow up 7 months-58 months Interview. No exclusions	Retrospective cohort **2b**	SCL-90-R. AMDP	In ICU ≥ 30 days. 35 months post d/c 5 = DSM-IV PTSD	7 (19%) PTSD. 5 = subsyndromal. 24% PTSD in unconscious trauma group. 49% premorbid psych morbidity At follow up 22 patients (60%) had additional DSM-IV diagnoses.	ICU stay. Trauma patients more likely to have psychiatric diagnosis & to have additional psych disorders. Recall of factual events declined. Delusional memories retained
Schnyder et al (2001)	Major trauma ICU 1 site Germany	135 eligible homogenous sample. 121 (89.6%) seen at 1 month 106 completed 12mths Interview. Fluency in German	Prospective Cohort **2b**	IES CAPS Clinical interview Life events, social support	Mean 5.7 days	1.9% (2) PTSD at 1-year 12.3% (13) subsyndromal PTSD 17% possible/probable anxiety 8.5% possible/probable depression	Biological risk factors and a sense of death threat
Sukantarat et al (2007)	General ICU 1 site UK	518 eligible 51 enrolled 45 final at 9 months. Interviewed at 3 & 9 months	Prospective Cohort **2b**	SF-36 short form, EQ-5D VAS HADS ≥ 8 Anxiety=10 Depression ≥ 8 IES ≥21 probable PTSD, ≥18 = avoidance	3 - 78 days Median 9 days	35% Depression at 3/12, 21 (47%) at 9 months 24% anxiety at 3 & 9-months	Delayed physical recovery
Wade et al (2012)	General ICU 1 site UK	245 eligible 157 enrolled 100 completed at 3 months Postal questionnaires 3 months post ICU	Prospective Cohort **2b**	POMS, ICUSS, BIPQ at Time 1. 3 months: CES-D, STAI, SF-12	8 (85) median (range)	27% probable PTSD 46% probable depression 44% anxiety	Total mood disturbance, stress reactions, loss of memory in ICU, early intrusive memoires, illness perceptions. Psychological history & alcohol use. Stress in the ICU admission
Nickel et al (2004)	General medical ICU 1 site Germany	217 eligible 125 available 50 randomised to take part. 41 participated (82%). Interviewed 3-15 months post discharge	Cross-sectional. 1 site **3b**	PTSS-10 SCID I and II (DSM-IV)	≥ 24hrs (average 12.2 days)	PTSS 17% 9.76% PTSD	Half had a prior psychiatric disease. Depression, alcoholism, BPD. PTSD associated with previous psychiatric history.
Scragg et al (2001)	General ICU 1 site UK	142 mailed. 86 returned. 80 usable data. 44% lost to follow up. Discharged 12-24 months before Follow up >5years. Postal survey	Cross-sectional Postal **3b**	TSC-33, ETIC-7 HADS **≥8.** Full scale ≥12= clinical disorder IES .	≤ 48-hrs or less	30% PTSS 15% PTSD 43% =Anxiety 30% = Depression	Younger female Anxiety depression Chronic medical illness

Note: CEBM ratings range from 1b to 3b. Lower numbers indicate higher quality. Letters used to designate level 1 to 3 studies indicate gradations of quality ranging from 'a' (higher) to 'b' (lower quality).

4.2 *Acknowledgement of the Problem*

Perhaps the gold standard upon which to compare all other studies in this analysis is the Cochrane-reviewed two-group (those admitted to ICU versus those not admitted to ICU) prospective cohort study of 829 randomly selected injury patients from five major trauma hospitals across Australia. As the highest quality study that used a methodologically rigorous design, O'Donnell et al. (2010) found that after controlling for many risk variables, at 12-months post discharge, patients were three times more likely to develop PTSD if they had been admitted to an ICU than trauma patients who were not (based on a stepwise logistic regression where ICU admission was entered as the final variable). Telephone interviews were conducted twelve months after the injury by interviewers trained in CAPS administration (interrater reliability of 0.98, based on blind rescore of 5% of CAPS interviews). While there is an absence of visual cues and a loss of contextual and nonverbal information with telephone interviews, they are efficient and cost effective, and allow respondents to feel relaxed and able to disclose sensitive information.

The UK leaders in the field, Richard Griffiths and Christina Jones ("the Liverpool Group"), have contributed much to the body of evidence highlighting the consequences of ICU treatment. They have consistently demonstrated that the development of PTSD following critical illness is associated with a number of precipitating factors that are in part related to how patients are cared for within the ICU, adding weight to Parker and Griffiths' (2010) request for a 'disease specific' assessment tool, where ICU admission was the 'disease'. However, from a critical realist epistemological perspective this viewpoint is too narrow and reductionist. PTSD can be a side effect of ICU treatment but ICU admission is one of a combination of factors that elevates the risk of PTSD. The important words are 'how patients are cared for', with an emphasis on 'how', and 'cared for', psychologically, as well as physically.

Jones and colleagues conducted a European prospective follow-up study of 238 recovering, post-ventilated patients across five mixed-general ICUs. They found that recall of delusional memories, prolonged sedation, and physical restraint with no sedation, were related to the development of PTSD, independent of case mix and illness severity (Jones et al., 2007). One of the most significant findings of the

study has implications for best practice guidelines in some countries regarding the use of restraint without sedation. Opiate analgesia was used in the absence of sedation, but opiates may create and/or exacerbate hallucinatory and/or delusional experiences people may have of being restrained.

Notwithstanding the limitations and identified concern, the relatively large sample sizes included in the above studies allow more confident conclusions to be made. Other studies have contributed to the body of knowledge by replicating some of the findings. However, small sample sizes and methodological inconsistences weaken the validity of the conclusions. These studies will be summarised below under the identified precipitating factors.

4.3 *Causative Factors*

Until relatively recently, the event (e.g. assault, disaster, severe accident) that resulted in an ICU admission was considered responsible for the development of PTSD. Now research is consistently showing that this is not the case (Nickel et al., 2004). For example, in a retrospective study of long-term survivors of major surgery, Boer et al. (2007) conducted multivariate analyses controlling for age, sex, APACHE II (Acute Physiology and Chronic Health Evaluation II) score, number of repeat laparotomies, and length of hospital stay. They concluded that nearly a quarter of patients admitted to the ICU were at significantly greater risk for PTSD symptoms after adjusting for baseline differences, in particular, age, suggesting that ICU variables contributed to the distress, and possible delayed-onset of PTSD symptoms in this group. Limitations of the research are the acknowledged use of a screening questionnaire to assess symptomology, and the threat of maturation and history effects to the internal validity of the study. Similarly, although the study drew upon data over a long time span, data on post admission or post hospitalisation trauma was not recorded, which may have confounded the results.

4.3.1 *Pre-Trauma Factors*

In line with PTSD studies of populations other than ICU patients, pre-trauma variables such as younger age and being female have been identified in prospective cohort studies as risk factors for PTSD symptoms post ICU (Capuzzo et al., 2001; Cuthbertson et al., 2004; Schnyder et al., 2000; Scragg, Jones, & Fauvel, 2001). A

previous history of psychological problems increases the vulnerability to this disorder and has been an exclusion criterion in many studies, perhaps underestimating the prevalence rates overall. Several contributory factors have been identified: the need for extended sedation, and the experience of delusional memories (Jones et al., 2007; Nickel et al., 2004; Wade et al., 2012). At follow up, such patients were found to have additional DSM-IV diagnoses (Ritcher, Waydhas, & Pajonk, 2006).

4.3.2 *ICU Care Factors*

Most ICU patients are sedated and ventilated to ensure compliance with organ support during the acute phase of admission. Sedation is necessary because of the use of muscle relaxants: awake paralysis is extremely unpleasant and the cause of psychopathology (see the NAP5[6] report on anaesthetic awareness, Pandit & Cook, 2014). Unfortunately, sedatives, particularly benzodiazepines[7], can cause perceptual difficulties and confusional states due to altered visual and auditory processing. Delusional memories rather than factual, traumatic memories increase the risk of PTSD (Capuzzo et al., 2001; Girard et al., 2007; Jones et al., 2007; Jones & Griffiths, 2007). National guidelines on sedation practices have been introduced, and sedative interruption should occur at least once, daily (Schweickert & Kress, 2008). While not the explicit clinical rationale for sedation interruption, this also allows patients to wake and to assimilate factual memories, thereby reducing the risk of PTSD symptomology (Kress et al., 2003).

Length of ICU stay and time lag both in, and between, assessments can undermine results. An extended stay may allow a patient to become habituated and desensitized to the unit by the very nature of prolonged exposure, although admissions of one to two days can lead to PTSD symptoms (Boer et al., 2008; Sukantarat et al., 2007), with some authors reporting that distress increases with the length of stay (Richter et al., 2006). Equally, the psychological impact of the experience of chronic illness, in and of itself can be emotionally traumatic, making it

[6] NAP5 = 5th National Audit Project of the Royal College of Anaesthetists and the Association of Anaesthetists of Great Britain and Ireland.

[7] Benzodiazepines enhance the effect of the neurotransmitter gamma-aminobutyric acid (GABA), which results in anxiolysis, sedation, muscle relaxation, anterograde amnesia, respiratory depression, and anticonvulsant activity. *Source*: Medscape Today News: Sedation and Pain Management in Acute Neurological Disease: Classes of Sedative Agents.

difficult to distinguish between them. Patients may also be somewhat desensitized to the acute care environment due to frequent admissions.

4.3.3 *Memories Associated With ICU Care*

If ICU care is the stressor criterion for PTSD in a DSM-IV diagnosis, then memories associated with the time spent in ICU are instrumental in its development. Factual memories, even of unpleasant experiences, have been seen to be protective against the anxiety caused by retention of unreal memories (Boer et al., 2008; Jones, Griffiths, Humphris, & Skirrow, 2001). Unfortunately, consciousness is frequently altered by delirium (Griffiths & Jones, 2007), and recall of delusional memories is a major factor in PTSD development (Boer et al., 2007; Jones et al., 2010). Benzodiazepine use in particular, often results in hallucinations, delusions, and nightmares because they affect visual and auditory processing (Samuelson, Lundberg, & Fridlund, 2006). Sedation increases the risk of having no explicit recall of ICU, causing anterograde amnesia but with preserved implicit memory, and longer length of ICU stay increases the risk of delusional memories (Griffiths et al., 2007), and vice-versa. However, daily sedation interruption results in fewer symptoms (Kress et al., 2003). The findings are still ambiguous however, because length of stay is generally related to severity of illness and to ventilator support.

The literature has highlighted pre-trauma factors associated with post ICU PTSD: namely, being female and younger, and a previous psychiatric history associated with increased sedation requirements. ICU-specific variables can be attributed to sedative use and are summed as follows: traumatic delusional memories and reduced levels of consciousness, combined with a lack of explicit recall for events, but the presence of implicit emotional memory[8] for frightening experiences. Pain, delirium and agitation are contributory factors, however cause and effect are difficult to discern. Drugs are titrated in response to physiology, and length of ICU stay is dependent upon stabilisation of the patient's condition. Subjective accounts of the ICU experience reflect this (Jones et al., 2001; Rattray, Johnston, & Wildsmith, 2005). These factors can result in psychological dysfunction in the form of reduced concentration and memory recall abilities, anxiety, depression, nightmares, negative

[8] Explicit memory is the conscious, intentional recollection of previous experiences and information. Implicit memory refers to memories that we are unaware of, that we cannot consciously recall or recognise, yet which reveal themselves through changes in behaviour (Andrade & Deeprose, 2007).

feelings regarding the ICU stay, panic, and other PTSD-type problems. They are presented pictorially in Figure 4.1. Limitations of the reviewed studies are discussed next.

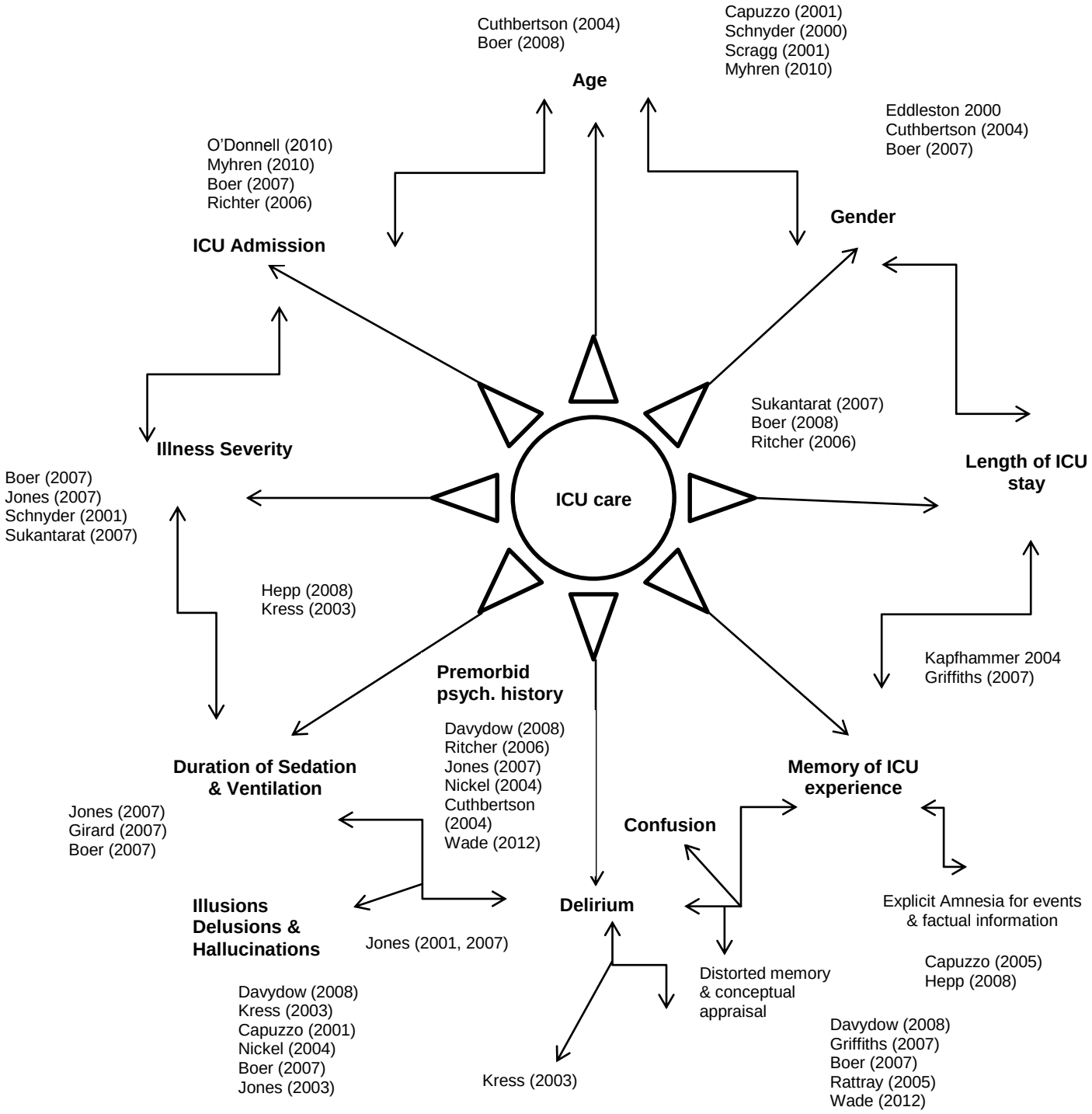

Figure 4.1. Factors contributing to PTSD development in relation to ICU care

Note: only the first author of each article is listed

Section 5: Discussion

The aim of the current review was to examine a selected sample of the literature, derived from a range of sources, in order to identify factors that independently or collectively contribute to the development of PTSD in some adult ICU patients. The most interesting finding was that logistic regression, conducted by O'Donnell and colleagues (2010), showed that ICU admission significantly contributed to the development of PTSD after controlling for demographic, pre-injury mental health status, and injury characteristic variables. At the same time, Myhren and colleagues found that the ICU admission diagnosis had no significant effect on the prevalence of PTSD in their cohort of mixed ICU patients (Myhren, Ekeberg, Toien, Karlsson, & Stokland, 2010).

Despite many methodological flaws that threaten internal and external validity, the remaining studies reviewed allowed the identification of several factors that are associated with the development of PTSD in adults following ICU treatment. It is recommended that more randomized controlled trials (RCT) are conducted, using standardized tools, and standardized timing and methodology, to ensure that assumptions based upon previous research (mostly at CEBM quality ranking 2b) are correct, and to provide more definitive answers regarding protective and causative factors. Whilst allowing the identification of subsets of post ICU patients at risk of developing PTSD, future studies need to do more than describe and confirm the phenomenon. This will help advocate for the development of psychological care both intra-ICU, and following ICU discharge.

A major limitation of the review was the very high attrition rates due to patient death, withdrawal, or loss to follow up - in one study by as much as 70% of participants (Kress et al., 2003), resulting in selection bias. Several explanations were offered by the researchers, including avoidance (a symptom of PTSD), or reported lack of mental health problems (Nickel et al., 2004; O'Donnell et al., 2010). This resulted in small sample sizes which inflate the chances of missing an effect, and also reduce the power of the study. This may, at least in part, explain the variation in prevalence rates across studies.

Many studies were cross-sectional and used brief screening tools with disparities in cut-off scores for caseness, resulting in inflation of prevalence, in some cases, and more importantly, a diagnosis of PTSD, when the tests themselves are not diagnostic (Boer et al., 2007; Scragg et al., 2001). Similarly, inclusion and exclusion criteria were inconsistent across studies, resulting in poor ecological validity (Hepp et al., 2008; Ritcher et al., 2006). Notwithstanding, each study included in the review supports earlier findings that admission and treatment on an ICU can have negative psychological consequences for some survivors.

Section 6: Conclusion

This review has highlighted, that despite inconsistent methodologies in assessment and lack of ICU-validated screening tools, treatment in an ICU is a traumatic event, and that intra-ICU as well as post ICU psychological care is needed to help patients (and relatives) to adjust to the experience. Several factors have been independently and cumulatively identified as contributing to the development of PTSD, however the most significant finding is that the ICU itself is a risk factor for PTSD symptomology. Despite this, efforts to minimise distress are, in the most part, physically/medically and environmentally orientated.

Most patients have their eyes closed, at least during the critical phase of admission, limiting the acquisition of explicit (factual) memories. Memory formation is also disrupted due to the effects of illness and/or the accumulation of sedative drugs, particularly benzodiazepines, as well as REM sleep deprivation. Sedation-hold protocols advocate daily interruption of sedation to reduce exposure to sedative agents, allow assessment of neurological status, assess readiness for extubation, and to reduce duration of mechanical ventilation. Daily interruption is also advocated to allow assimilation of factual memories, even unpleasant ones, to minimise side effects such as delusions, hallucinations, and delirium, but dysfunctional beliefs and appraisals may still occur. Factual memories of ICU are considered to be protective against the anxiety caused by retention of unreal memories and the disruption in visual and auditory processing by sedative drugs. Clearly, memory has a role. Patients may have little or no conscious recall of being in the ICU yet develop emotional reactions to innocuous cues post-operatively. This warrants further investigation.

The optimal timing of interventions to reduce such symptoms remains unclear (Hatch, McKechnie, & Griffiths, 2011), however a promising study by Peris and colleagues (2011) suggests that early intra-ICU psychological intervention promotes psychological recovery. Similarly, advances in psychopharmacology have led Gardner and Griffiths (2014) to postulate that the phenomenon of reconsolidation can be exploited therapeutically in extended psychological follow up of discharged ICU patients. Perhaps this should be implemented as standard care.

Section 7: References

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Part Two

Research Report

Implicit Emotional Memory and Post Traumatic Stress in Adult ICU Patients

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Target Journal: British Journal of Clinical Psychology

Section 1: Abstract

Introduction: ICU care can result in PTSD, with memories disrupted by sedative and/or analgesic drugs. We examine if a trigger for PTSD flashbacks is an emotionally salient sensory stimulus that occurred whilst sedated. *Method*: 24 general ICU patients were screened at 1-2 weeks and 4-5 weeks post ICU with commonly used screening tools (PTSS-14, HADS, ICUMT). Skin conductance responses to ICU and other sounds measured implicit memory. Patients' relatives (n=15) and a non-clinical sample (n=35) also participated. *Results*: A mixed ANOVA failed to find a significant difference within groups, but did find between group differences $F(2,69) = 6.82$, $p < .05$. Positive correlations approaching significance were found for sedation and analgesia with delusional and factual memories. A trend was found for ICU sounds and PTSS. Nine patients reached caseness on the HADS subscales and/or PTSS-14. *Conclusion:* Replication in a larger sample, ICU-specific screening tools, and intra-ICU and follow up psychological support is recommended.

Key words: ICU, PTSD, sedation, implicit memory, skin conductance

Section 2: Introduction

This study explores the psychological experience of seriously ill patients who have survived treatment in an adult intensive care unit (ICU). It argues that although treatment is aimed at saving life, the consequences or side effects of altered levels of consciousness that are controlled by sedative and analgesic medications, interfere with the encoding of the events, making accurate processing of the experience difficult for some people. In this way the ICU can be regarded as an environmental threat (van der Kolk, 1994).

The illness itself, and/or the medications used to treat it, can result in distorted memory formation, particularly as, in the critical phase of treatment, most patients are heavily sedated, thus making the encoding and assimilation of sensory information difficult (Capuzzo et al., 2001; Girard et al., 2007). As passive participants in this phase of care, patients may be aware that something is being done to them (e.g. suctioning), or be unable to move one or both arms due to intravenous lines giving fluids, sedation, and/or pain relief, yet experience perceptual distortions such as someone holding them down and preventing them from moving, and, in extreme cases, as trying to kill them. This can result in psychological problems post ICU treatment for some people. Although they occur in a minority, if severe enough, they can result in post-traumatic stress disorder (PTSD) (Griffiths, Fortune, Barber, & Young, 2007).

In what follows, aspects of the ICU environment and ICU intervention that have been identified in previous literature will be reviewed. Four cognitive models of PTSD will be presented to set the theoretical framework of the study. To set the scene, the institution that is intensive care will be described, followed by a discussion of the factors that contribute to psychological distress following ICU in some people.

2.1. *The Intensive Care Unit*

Although potentially life-saving, intensive care units are intimidating and disorientating environments to visit, both as a patient and as a relative. Even staff new to the specialty can be overwhelmed (Sabin-Farrell & Turpin, 2003). Patients, as passive participants in at least the critical phases of their admission, strive to

integrate their experiences into a coherent story (Williams, 2010). Many lack clear memories of what has happened (Backman & Walther, 2001), and often describe "odd perceptual experiences" that can influence their subsequent psychological adaptation (Rattray & Hull, 2008, p. 3). Relatives, restricted to minimal contact, stand by and watch the intimate contact of machines and specialist nurses employed to deliver life-sustaining therapies. It can be traumatic to watch (Jones et al., 2004). As a result, the entire family unit can become dysfunctional and in need of psychosocial support (Eddleston & Lupton, 2002; Rattray & Hull, 2008).

Many patients in intensive care will be emergency admissions, although some elective procedures require at least overnight observation on the Unit. All will be in a critical condition and may require artificial support of one or more major organ systems (Griffiths, 2001). Physical problems are generally anticipated and highlighted by alarms on the attached machines. Prompt action is taken to re-stabilise the patient until such time as s/he is stable enough for transfer from the unit, or, dies.

Current statistics indicate that there is a thirty percent mortality rate in an ICU setting (Sukantarat, Greer, Brett, & Williamson, 2007), with the five year mortality rate for survivors reported to be more than threefold higher than that of the general population (Scragg, Jones, & Fauvel, 2001; Wunsch & Angus, 2010). However, as Broomhead and Brett (2002) point out, survival is a poor metric for describing the impact of critical illness. Many survivors are slow to regain their previous physical health (Brooks, Kerridge, Hillman, Bauman, & Daffurn, 1997), and many have unrealistic expectations (Rattray & Hull, 2008). In fact, for some former ICU patients, returning home and convalescing can be the most psychologically stressful phase of critical illness (Prinjha, Field, & Rowan, 2009; Schelling et al., 2003). However this is not the experience of all.

The following discussion will explore the factors implicated in the development of psychological distress in ICU patients that leads to PTSD in some cases. It is important because as recently as 2007, Griffiths and Jones reported that "… as soon as awareness is achieved, the interest in cerebral function and psychological well-

being rapidly fades and rarely features in the recovery management of these patients" (p. 124).

2.2 *Psychological Distress Following ICU*

It is well known that some ICU survivors can experience psychological distress for some time after discharge from the Unit (see Davydow, Gifford, Desai, Needham, & Bienvenu, 2008, for a review), particularly if there is a premorbid history of anxiety and/or depression, and/or poor physical functioning (Weinert & Meller, 2007). The reported prevalence of anxiety ranges from 12% to 43% (Eddleston, White, & Guthrie, 2000; Scragg et al., 2001), and 10% to 30% for depression (Davydow, Gifford, Desai, Bienvenu, & Needham, 2009). Whilst this may reflect individual differences in vulnerability, risk, and resilience (Taylor, 2006; Voges & Romney, 2003) certain populations, for example younger females, appear to be more susceptible (Voges & Romney, 2003). However, methodological inconsistencies in assessment and diagnosis, as well as cultural differences in the expression of emotions, may contribute to the varied reported prevalence rates (Jobson & O'Kearney, 2009; Mesquita & Walker, 2003).

At its extreme, and since the refinement of diagnostic criteria for Post-Traumatic Stress Disorder (PTSD) in the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV, 1994, see Appendix A for criteria), a growing number of studies has found that a substantial proportion (ranging from 5% to 63%[9]) of ICU patients develop PTSD (e.g. Cuthberston, Hull, Strachan, & Scott, 2004; Griffiths, Fortune et al., 2007; Stoll, & Schelling, 2004; Skirrow, Jones, Griffiths, & Kaney, 2001; Twigg, Humphris, Jones, Bramwell, & Griffiths, 2008), and many become chronic sufferers of the disorder (Kapfhammer, Rothenhausler, Krauseneck; Stoll, & Schelling, 2004; Myhren, Ekeberg, Toien, Karlsson, & Stokland, 2010). This finding is striking given that many patients spend only one or two days on the Unit (Sukantarat et al., 2007). It is perhaps more striking that patients with no conscious (explicit) memory of ICU after one to two days can go on to develop significant psychological disturbance (Boer et al., 2008).

[9] A reflection of the scale used, case mix and timing of assessment

Equally important is the number of patients who show partial PTSD[10] (also known as subsyndromal or subthreshold) symptomology (Breslau, Lucia, & Davis, 2004; Carlier & Gersons, 1995; Cukor, Wyka, Jayasinghe, & Difede, 2010; Schnurr, 2014; Stein, Walker, Hazen, & Forde, 1997; Twigg et al., 2008). Their level of distress can be just as severe, and can also have far reaching effects on the quality of virtually all aspects of their life following treatment (Livingston, Tripp, Biggs, & Lavery, 2009; Warshaw et al., 1993). A paradox therefore exists whereby the potentially life-saving intensive treatment of ICU may result in disabling levels of psychological distress and PTSD post discharge for some patients, while others appear to be relatively unscathed by the experience.

2.3 *Factors Which May Generate ICU Psychological Disturbance*

2.3.1 *The ICU Environment*

The ICU is an abnormal, high-tech, and unique environment characterised by apparent sleep and sensory deprivation (Kornfeld, 1969). The Unit is popularly 'blamed' for the hallucinations and delusions experienced by many of its patients (Skirrow et al., 2001), and also for much of their distress (Jones, Hoggart, Withey, Donaghue, & Ellis, 1979). Passivity is enforced for at least some of the time as various professionals and machines monitor and control a patient's physiology, quality of sleep, and body position. For planned admissions, the need for passivity is explained pre-operatively, promoting a sense of security in the prescribed one-to-one relationship with nursing staff. For emergency admissions there is no time to prepare for the mechanics and processes of ICU, and both relatives and patients may feel themselves swept along in the process of seeking re-stabilisation. Such experiences may be frightening, thus contributing to distress (Rattray, Johnston, & Wildsmith, 2005).

2.3.2 *The Therapeutic Need for Sedation and Mechanical Ventilation*

Mechanical ventilation is the most common procedure in the management of critically ill patients (Frutos-Vivar, Ferguson, & Esteban, 2009) and can be regarded as a therapeutic intervention (Cheng, 1996). However, whilst enabling greater monitoring and control of a patient's condition, ventilation and accompanying paralysis has been cited as a significant risk factor for developing PTSD symptoms

[10] Diagnosed as "Other Specified Trauma-and Stressor-Related Disorder" in DSM V

following ICU discharge (Girard et al., 2007; Schelling et al., 1998). However, the largest ever audit of anaesthetic awareness published recently (see the NAP5[11] report on anaesthetic awareness, Pandit & Cook, 2014) has confirmed that it is experience of "awake paralysis" that is almost uniquely responsible for psychological trauma following awareness, not pain. Getting the balance right is difficult as well as idiosyncratic due to the sometimes unpredictable alterations in a patient's pharmacological profile (Kress, Pohlman, & Hall, 2002; Samuelson, Lundberg, & Fridlund, 2006), and the known side effects of some sedatives and analgesics such as hallucinations, delusions, awareness, and/or pain (Kress, Pohlman & Hall, 2002; Wang, 2000; Weissman, 2005).

It is important to note that sedation interferes with the encoding phase of memory, thereby affecting the transfer from short term to long term storage (see Richardson, 1989, for a review of this interaction). When used for minor procedures, sedation can often result in wakefulness without explicit recall (Wang, 2000), yet spontaneous flashbacks can sometimes occur, causing great distress (Weinert & Sprenkle, 2008). At the other extreme, sedation may result in limited conscious or fragmented memories of the time spent in ICU, or, indeed, none at all – a consequence that has been shown to be detrimental to psychological recovery (Ely et al., 2001; Page, 2010). When sedated, a patient cannot give sufficient attention to what is happening and fragmented sensory images of the event are stored. Information can be later accessed automatically by exposure to relevant cues and may be spontaneously re-experienced in the form of detailed visual images, affective responses, and emotion-laden flashbacks corresponding to moments of intense arousal during the trauma (Holmes, Brewin, & Hennessy, 2004). The theories behind intrusive memory development will be briefly presented following a discussion of further factors involved in interrupted memory formation.

Advances in ICU management now advocate the use of sedation protocols (Barr, Anderson, Owall, & Jakobsson, 2001; Waldmann, 2010) that are often nurse led and managed (Ely et al., 2001). Daily sedative interruption (DSI) is recommended (Schweickert & Kress, 2008) as it reduces the likelihood of peripheral build-up,

11 NAP5 = 5th National Audit Project of The Royal College of Anaesthetists and the Association of Anaesthetists of Great Britain and Ireland

reduces symptoms of withdrawal from drugs such as benzodiazepines (Jones, Griffiths, & Humphris, 2000), and allows some consolidation of factual memories (Kress et al., 2002; Page, 2010; Schweickert & Kress, 2008). However, the procedure has not met with universal approval (Heffner, 2000), and strong evidence that DSI alters the duration of mechanical ventilation, mortality, length of ICU or hospital stay, adverse event rates, drug consumption, or quality of life for critically ill adults receiving mechanical ventilation compared to sedation strategies that do not include DSI, has not been found (Burry et al., 2014).

2.3.3 *Delirium*

A further factor to be considered is the incidence of delirium, also known as ICU syndrome (McGuire, Basten, Ryan, & Gallagher, 2000). Delirium is not inevitable, although it may occur in up to 80% of ventilated patients across the UK (Griffiths & Jones, 2007; Page, 2010). As a neuropsychiatric condition (DSM-IV, 1994), it collectively describes a change in mental status that is acute or fluctuating (Ely et al., 2001; Griffiths & Jones, 2007). It is associated with a reduced clarity of awareness of the environment, and the ability to focus, sustain, or shift attention is impaired (DSM-IV, 1994).

Factors associated with delirium are severity of illness, sedatives and analgesics, use of psychoactive medications, particularly benzodiazepines, and poor quality and duration of sleep (Ely et al., 2001; Griffiths & Jones, 2007; Meyer & Hall, 2006). Delirium is accompanied by profound amnesia of events occurring during and preceding the confusional state (Broomhead & Brett, 2002). This results in patients' memories of their stay in the ICU being fragmented and frequently distorted.

2.3.4 *Delusions*

Of similar significance is the experience of delusions. The severity of illness (as measured by the Acute Physiology and Chronic Health Evaluation - APACHE II score), duration of mechanical ventilation, and length of ICU stay have been implicated in the experience of delusions, hallucinations and nightmares (Samuelson et al., 2006). Hopkins and Utah (2010) describe a delusional memory as a dream, nightmare or hallucination; or a belief or memory of the ICU that the patient later rejected as false; or a belief or memory of events in the ICU that is not

shared by medical staff or family members who were present during a patient's stay. Many survivors retrospectively report little conscious awareness of their critical illness, although delusional memories, often with violent and paranoid themes, are pervasive, and become integrated with benign actual events to form part of the patient's memories of their ICU experience (Hopkins & Utah, 2010; Jones et al., 2000). These are commonly the content of trauma memory for those experiencing post-ICU PTSD, although very little is known about why some people develop more images of a trauma than others (Holmes et al., 2004).

Delusional memories endure over time, and are significantly more persistent than factual memories (Hopkins & Utah, 2010). As such they may be important in the genesis of subsequent psychological problems, and worsen long-term quality of life (Granja et al., 2005; Jones et al., 2001; Weinert & Sprenkle, 2008).

2.3.5 *Pain*

Pain is an almost inevitable experience for most ICU patients (Kress et al., 2002) and is one of the most accessible memories of being on the unit (Capuzzo et al., 2001; Girard et al., 2007; Jones et al., 1979). It is estimated that as many as seventy percent of patients experience at least moderate-intensity procedure-related or postoperative pain during their ICU stay (Puntillo et al., 2009). Pain could manifest as agitation, sometimes beginning a cycle of increased sedative administration, muscle relaxants, and continued ventilation, resulting in reporting difficulty and a slower recovery. Uncontrolled pain increases anxiety (Puntillo, 1990). It may also be perceived as torture due to a lack of awareness regarding surroundings or the situation, and the benign intentions of ICU staff, especially if admission to the Unit was as a result of an emergency or an unforeseen medical complication.

2.3.6 *Sleep Disruption*

Another significant factor is the disruption of sleep. Sleep is important for healing and survival of critical illness, yet sleep, particularly slow-wave sleep, can be disrupted due to the twenty-four-hour care that is given, and the paradoxical effects of sedative and hypnotic medications on sleep quantity and quality (Bourne, Minelli, Mills, & Kandler, 2007; Cooper et al., 2000). Disruption in slow-wave sleep negatively impacts on the integration of factual memories (Broomhead & Brett,

2002). Patients may enter a hypnogogic state in which control of the boundary between internally generated fantasy, and the experience and recognition of external reality is impaired (Harvey, Jones, & Schmidt, 2003). This state predisposes the patient to hallucinations, and creates a mental environment favouring the development of paranoid delusions (Clifford & Buchman, 2002).

2.4 *The Nature of Post-Traumatic Stress Disorder (PTSD)*

PTSD is a severe anxiety state that can develop as the result of being exposed to a traumatic occurrence 'in which a person experienced, witnessed, or was confronted with an event or events that involved actual or threatened death or serious injury, or a threat to the physical integrity of self or others' and which generates 'intense feelings of fear, helplessness, or horror' in those exposed to the trauma (DSM-IV, 1994)[12]. PTSD is characterized by a constellation of symptoms in three domains: symptoms of re-experiencing the traumatic event, avoidance of things associated with the event resulting in emotional numbing, and increased arousal levels (DSM-IV, 1994). This seriously impacts upon social, occupational, psychological, and other functioning. The full DSM-IV diagnosis is based upon symptoms being present for at least one month. It is not uncommon for PTSD to occur with other mood disorders such as anxiety and depression (Rattray & Hull, 2008; Sukantarat et al., 2007).

2.4.1 *PTSD and Psychological Co-morbidity*

While the type and severity of event have been implicated as two of the most salient predictors of PTSD in some situations (Peterson, Prout, & Schwarz, 1991), individual differences in risk and resilience, personality traits such as 'conditionability' (Guthrie & Bryant, 2006), as well as gender, age, and demographic variables, predispose someone to develop the disorder (Lauterbach & Vrana, 2001; Voges & Romney, 2003), and, conversely, to protect them from it. However, many are unaware of their vulnerability to inaccurately remembered events and event sequences (Coursin & Coursin, 1998; Jones, 2010). Females are more vulnerable than males to PTSD following any kind of physical assault (Voges & Romney, 2003). The intentionality of the traumatic event, particularly if inflicted by other humans

[12] DSM-V criteria differ from those in DSM IV. DSM V describes four instead of 3 diagnostic clusters of symptoms. Criterion A is more explicit in regard to how an individual experienced traumatic events. Criterion A2 (subjective reaction) has been eliminated.

(Green, 1990), as well as the level and utilisation of social support (Griffiths, Jones, & Macmillan, 1996) leads to reappraisal-based emotional management that can reduce or increase psychological and behavioural consequences of stress (Voges & Romney, 2003). Memory of the event plays a vital role in psychological recovery, as well as in psychological ill-health. Anxiety and depression, and Axis II personality disorders (DSM-IV, 1994) often coexist with PTSD and interact to increase the level of distress (Samuelson, Lundberg, & Fridlund, 2007).

Not everyone exposed to traumatic events goes on to develop PTSD, and, of those, only some develop chronic PTSD (Taylor, 2006). As Taylor also points out, for people with few or no predisposing factors, extremely severe stress is needed to cause PTSD, whereas for people with a very strong vulnerability, milder stressors can be sufficient to give rise to the disorder. Psychological models of PTSD (as detailed in Taylor, 2006) are considered next.

2.5 *Psychological Models of PTSD*

2.5.1 *The Conditioning Model of PTSD*

The conditioning model of PTSD is based upon Mowrer's (1960, cited in Taylor, 2006) two-factor theory whereby fears are acquired by classical conditioning and maintained by operant conditioning. The model proposes that re-experiencing and hyperarousal symptoms occur because trauma exposure has resulted in an abundance of external (e.g., reminders of the trauma) and internal (recollections) fear-evoking associations which activate the cognitive representation (memory) of the unconditioned stimulus. As such, conditioning theories deal with learned associations and avoidance behaviours. What the model does not do however, is account for individual differences in conditionability, and also struggles to account for emotional numbing and for the role of dysfunctional beliefs in PTSD (Taylor, 2006).

2.5.2 *The Emotional Processing Model of PTSD*

The emotional processing model proposes that PTSD arises from a fear structure in long-term memory that contains representations of feared stimuli. It posits that there is a relationship between PTSD and knowledge available prior to the trauma, during the trauma, and after the trauma (Brewin & Holmes, 2003). These three

types of information – stimuli, responses, and meaning elements, are interlinked. Links can be innate, or acquired by processes such as conditioning. However, in PTSD many of the links are erroneous.

The model also holds that traumatic events are so intense that they cause fear conditioning to a wide range of stimuli (e.g. sights, sounds, odours, and bodily sensations associated with the trauma), and reminders activate the fear structure that then produces hyperarousal and intrusive recollections of the event. In this way, rigidity of beliefs can be problematic. The model emphasises the modification of memories by the incorporation of corrective information. However, not everyone wants to remember (Corrigan, Samuelson, Fridlund, & Thorne, 2007). Furthermore, research suggests that, generally, fears are overridden or inhibited by new memories.

2.5.3 *The Dual Representation Model of PTSD*

In the dual representation model of PTSD (Brewin, Dalgleish, & Joseph, 1996) two types of trauma memory can be detected in the same individual at the same time (see Figure 2.1). Traumas are encoded both in the form of verbal or narrative memories, and as lower level, image-based memories (Holmes et al., 2004). The focus of the theory is mainly on memory, emotion and appraisal, with little discussion of other features of PTSD (Taylor, 2006).

PTSD is maintained when individuals process the trauma in a way that leads to a sense of serious, current threat. Many features and details of a traumatic event such as the sounds, smells and sights, are initially retained in a 'situationally accessible memory' (SAM). When individuals reflect upon the information consciously, attempting to understand or to integrate the features and details, the consequent insights are then retained in another system called 'verbally accessible memory' (VAM). The VAM system corresponds to ordinary autobiographical memory and forms the basis of subsequent verbal accounts of the trauma (Holmes et al., 2004). However, when sedated or in a high state of arousal, information cannot receive a high level of conscious processing, therefore the information is stored in the situationally accessible memory that can be accessed automatically by exposure to relevant cues. Both systems interact with one another, and the system

that is most strongly activated will succeed in either activating or inhibiting fear through chronic processing, premature inhibition of processing, or, successful completion (Taylor, 2006).

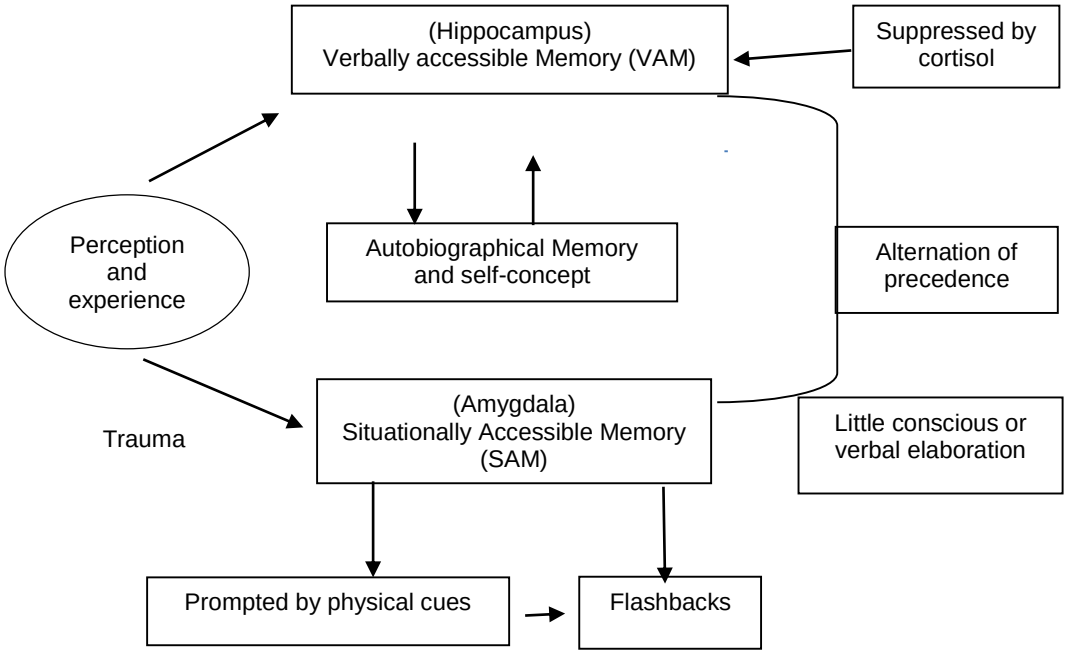

Figure 2.1. Dual representation model of PTSD[13].

2.5.4 *Ehlers and Clark's Cognitive Model of PTSD*

This model (Ehlers & Clark, 2000) draws attention to the paradox in PTSD whereby patients feel anxious about the future, even though the trauma lies in the past (Brewin & Holmes, 2003). PTSD persistence is the result of negative appraisals of the trauma or its sequelae, the nature of the trauma memory itself, and a frame of mind termed 'mental defeat' that may be predictive of later disorder. Sensory (data-driven) processing rather than processing the meaning and implications of the event lead to chronicity of the condition. Maladaptive coping strategies include avoidance of trauma stimuli, attempts to suppress unwanted, trauma-related thoughts, abuse of arousal-dampening drugs or alcohol, and other efforts to avoid distress and harm. This model, shown in Figure 2.2, emphasizes the role of negative appraisals in the

[13] Model schematic reproduced with permission from Professor M. Wang

maintenance of PTSD, but does not explain why some people are more affected than others.

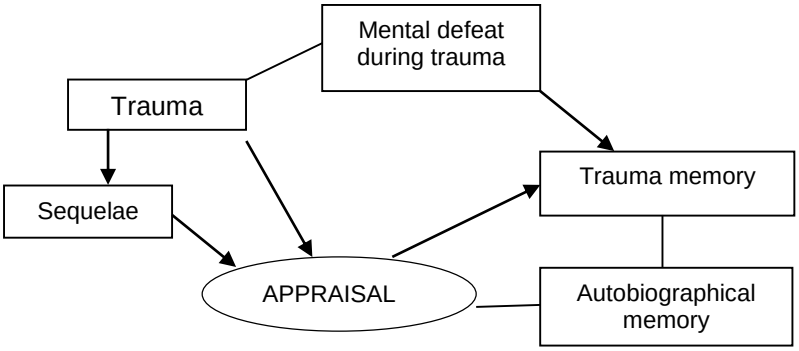

Figure 2.2. Cognitive model of PTSD[14]

Taylor (2006) concluded that none of the above models provides a comprehensive account of PTSD, as they generally focus on precipitating and perpetuating factors more than predisposing and protective factors. Each of the models discussed predicts that the effects of interpersonal factors are mediated by cognitions such as dysfunctional beliefs and appraisals, or exposure to danger or safety cues that may influence the activation of memories and fears. As such they are useful in trying to explain how some of the following factors may cause psychological distress for some patients.

Thus far the thesis has described the institution that is the intensive care unit. Psychological models and a definition of PTSD have been presented. Co-morbid disorders such as anxiety and/or depression have been discussed, and an explanation offered of how ICU treatments can lead to psychological distress in some people. With this in mind, the following sections will describe the formation of memory in order to demonstrate how memories can be disrupted by ICU treatment.

[14] Model schematic reproduced with permission from Professor M. Wang

2.6 *The Formation of Memory*

The formation of memories is complicated and still not fully understood. Fundamentally, as shown in Figure 2.3, remembering can be characterised by three consecutive processes: an original event is witnessed or experienced (acquisition); it is retained in memory over a period of time (retention); and finally the relevant information is retrieved or otherwise put to use (Richardson, 1989).

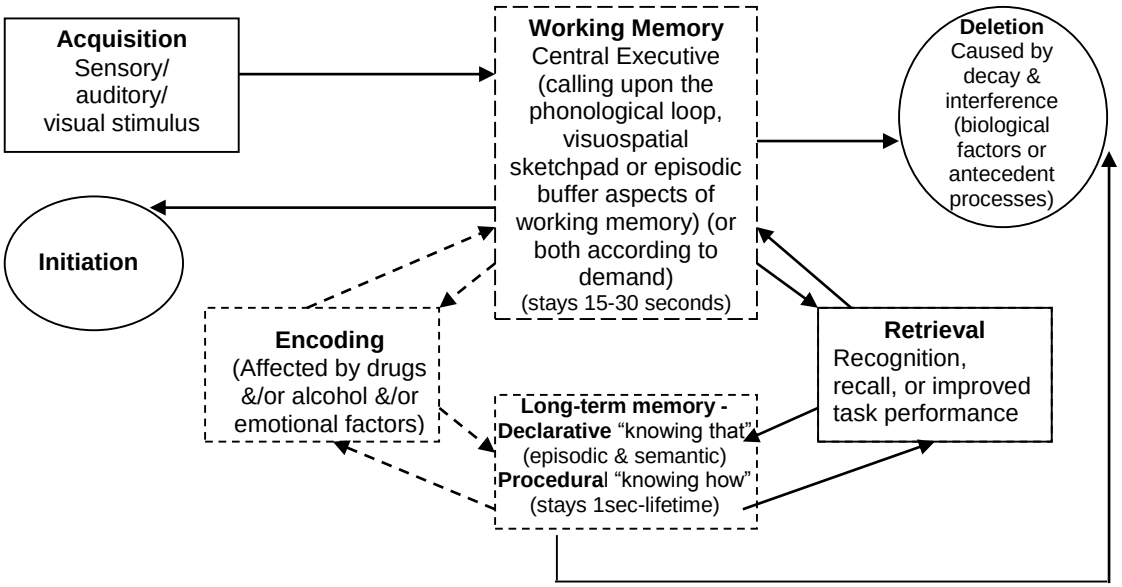

Figure 2.3. Cognitive model of memory [15]

Note: The dashed lines and boxes indicate processes involved in rehearsal

During acquisition, perceptual information is processed using a 'bottom-up' (received from the senses) and 'top-down' (previously acquired and assimilated knowledge) process to identify and encode the information acquired. Perhaps due to deficits in initial perception or in working memory (for example due to the effects of sedation and/or analgesia or emotional factors), the central executive may be prevented from calling upon the most appropriate part of working memory, and encoding may be disrupted. This, in turn, affects storage in long term memory, and may also impede the quality of its subsequent retrieval.

[15] Model schematic reproduced with permission from Professor M. Wang

For patients in the ICU, sedation, particularly with benzodiazepines and opioids, impairs the encoding phase of memory (Richardson, 1989) making it difficult to lay down accurate, new memories in long term storage. To illustrate, studies of anaesthetic awareness (Osborne, Bacon, Runciman, & Helps, 2005; Wang, 1998) and conscious sedation for endoscopy (Woodruff & Wang, 2004) indicate that sedated but conscious patients can assimilate emotional information but subsequently have no conscious contextual memory of such events. This corresponds with the dissociation in Brewin and colleagues' (1996) dual representation model of PTSD between situationally accessible memory (SAM) and verbally accessible memory (VAM).

2.7 *Conceptual and Theoretical Background to Methodology and Measures*

According to Clark, Voss, Barnard, and Sleigh (2003), both explicit and implicit memories may result when an individual knowingly attends to a particular stimulus. Explicit memory is the conscious, intentional recollection of previous experience and information. Implicit memory refers to memories that we are unaware of, that we cannot consciously recall or recognise, yet which reveal themselves through changes in behaviour (Andrade & Deeprose, 2007).

2.8 *Justification for Conducting the Current Study*

If ICU is regarded as an environmental threat, it is proposed that the triggering event for PTSD flashbacks and emotional distress (conditioned response) following ICU may be an emotionally salient sensory stimulus that took place when in the unit, whilst sedated (implicit memory acquisition). For many patients, this initial stressful situation (unconditioned stimulus) may not be immediately accessible to consciousness, but the spontaneous occurrence of the conditioned stimulus (such as the sound of the ICU as represented in, say, a hospital TV drama) in the patient's immediate environment will bring the conditioned traumatic emotional response into consciousness in an involuntary way. It is suggested that responses to such triggers are likely to occur at a behavioural/emotional level, occurring at a faster pace than that of intentional or declarative processing. The topic is worthy of investigation because, whilst implicit memory has been explored as a potential contributor to PTSD in ICU before (Clark et al., 2003), the emotional component of implicit memory and experimental implicit emotional memory measures has received minimal

attention. It is also important to identify the aspects of ICU that are appraised by patients as sources of distress.

2.9 *Classical Conditioning and Pairing*

Classical conditioning involves an initial response to an unconditioned stimulus. In the ICU setting and using prescribed sedation practices, patients fluctuate in their level of consciousness and ability to process sensorial information. They may experience anxiety and distress as a result of unconditioned stimuli such as care procedures (suctioning and position changes), - an unconditioned response. Delusions and/or hallucinations may occur at this time. While not accessible in verbally accessible memory, environmental cues such as sounds, sights and smells of ICU may act as cues to the unconditioned stimulus (situationally accessible memory), and implicit emotional memory may make a flashback more likely.

Experimental studies have traditionally employed tests of explicit memory using recall and recognition tasks. Cued recall and word completion tests in Vietnam veterans with and without PTSD suggested that only PTSD subjects showed any implicit memory bias for combat words, and that this bias may underlie the re-experiencing components which characterise part of PTSD (Zeitlin & McNally, 1991). McNally and Amir (1996) used trauma, positive, and neutral words to test a cohort of Vietnam veterans with and without PTSD. They were then shown a series of target and distractor words. More old words were identified than new words by both groups, but the priming effect was not enhanced for trauma words in the PTSD group. The authors concluded that tasks specifically aimed at capturing evidence of perceptual implicit memory may not provide enough sensitivity to detect further emotional variables concerned, adding weight to the dual representation theory of PTSD.

Perhaps unfortunately, very few ICU patients have clear memories of events since anxiety, benzodiazepines, opioids, and other drugs interfere with the encoding phase of memory formation (Clifford & Buchman, 2002; Jones et al., 2000; Page, 2010; Sackey, Martling, Carlsward, Sundin, & Radell, 2008; Schelling et al., 1998; Weinert & Sprenkle, 2008). Benzodiazepines, in particular, have been found to have a specific effect upon the transfer, encoding, or consolidation of new episodic

memories into long-term storage (Richardson, 1989; Wang, 1998), and may increase the incidence of hallucinations and delusions (Clifford & Buchman, 2002).

As previously stated, psychological studies of emotional trauma have found that implicit memory processes do play a part in the development of PTSD symptomology, in that a single traumatic episode can facilitate sensitisation and ensuing conditioned emotional responses in the absence of any factual (VAM) memory that can be consciously retrieved (Krikorian & Layton, 1998; Schwender et al., 1994). This in turn initiates physiological effects in the autonomic nervous system that lead to overt responses with or without any part of the data being represented in consciousness (Richardson, 1989). Such emotional arousal is often indexed in psychological research by measuring skin conductance responses (Bach, Daunizeau, Kuelzow, Friston, & Dolan, 2010; Lykken & Venables, 1971).

2.10 *Psychophysiological Measures of Stress*

Described as a robust tool by Lykken and Venables (1971), direct measurement of skin conductance is a non-invasive method of measuring the emotional state. As a person becomes more or less stressed, the skin's conductance increases or decreases proportionally (Bach, Friston, & Dolan, 2010). For this reason, changes in skin conductance are common indicators of sympathetic arousal caused by the changing activity of sweat glands innervated by the sympathetic branch of the autonomic nervous system (ANS). This method is specific for stimuli that induce the stress response (Storm et al., 2002), and can be an important measure of the nature of a patient's reaction to recalling their time in ICU.

2.11 *The Present Study*

2.11.1 *Aims of the Study*

The current study investigates whether classical conditioning of ICU environment sounds to a distressed emotional state occurs during ICU admission, and whether this can be detected by measuring skin conductance at 4-5 weeks post ICU.

2.11.2 *Hypotheses*

Hypothesis 1

Post ICU patients will demonstrate a stronger emotional reaction to ICU sounds than other sounds, as measured by skin conductance variables.

Hypothesis 2

Relatives of ICU patients will also show a stronger emotional reaction to ICU sounds in comparison with a control sample, but this will not be as great as that in the patient sample.

Section 3: Method

3.1 *Design*

The study included a single measurement point, group-comparison design for implicit memory. The groups included patients who were alive (and well enough) at four to five weeks post-ICU discharge; a 'significant-other' who had regularly visited the Unit, and a control sample (work colleagues of the researcher, with no prior exposure to an ICU). All were assessed using electrodermal activity to a range of pre-recorded (stimulus) sounds in order to measure emotional arousal. These two paradigms were intended to elucidate the presence and nature of implicit memory processes in ICU patients, and progress a model of the aetiology of psychological disturbance in post-ICU patients which will inform both intra and post-ICU psychological management. Figure 3.1 presents a schematic summary of the study design.

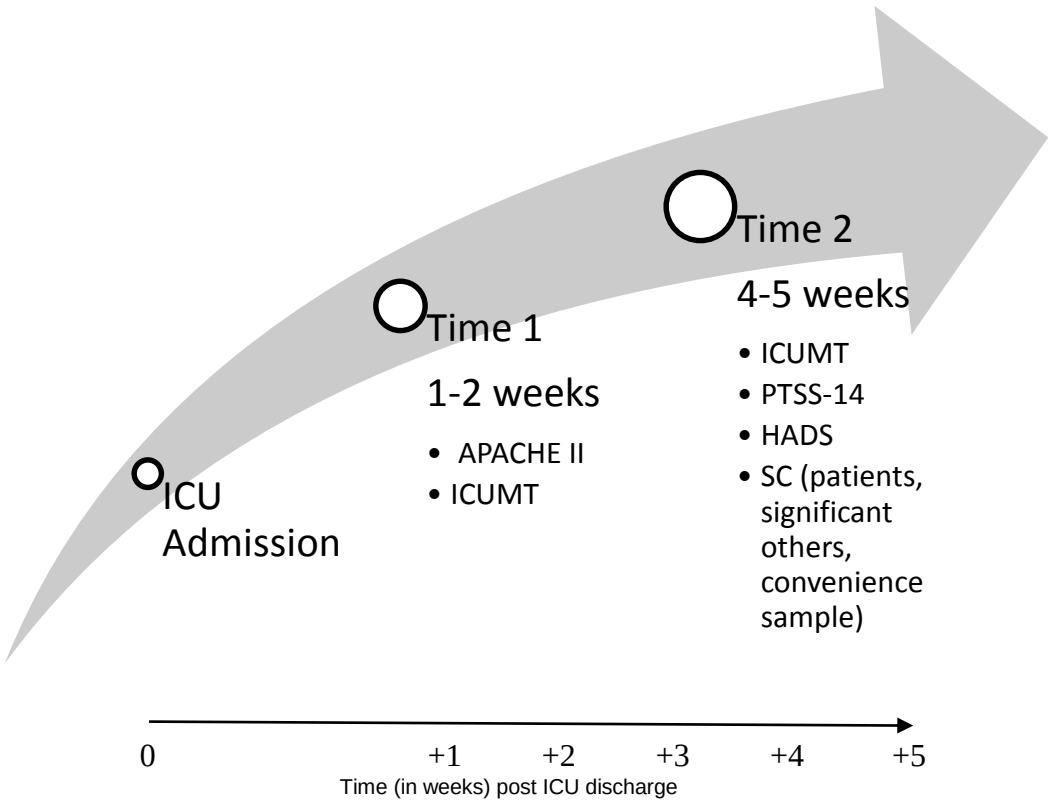

Figure 3.1. Schematic summary of study design

Legend:
APACHE II = Acute Physiology And Chronic Health Evaluation – 2nd edition
ICUMT = Intensive Care Unit Memory Tool;
PTSS-14=Post Traumatic Stress Symptom 14.;
HADS = Hospital Anxiety & Depression Scale,
SC=Skin Conductance in response to sound stimuli

3.2 *Inclusion Criteria*

All patients aged eighteen years and over, admitted to ICU for at least twenty four hours, expected to be alive at four weeks post ICU, and able to give informed consent, were eligible to participate.

3.3 *Exclusion Criteria*

Exclusion criteria included traumatic brain injury, active major mental illness (including admission following overdose or deliberate self-harm), significant hearing impairment, severe learning disability, those living with metastatic disease, and those with neurological disease (a confounding factor for psychological recovery). Any patients who had experienced unilateral hand or arm amputation were excluded as it was thought that the skin on the remaining hand and fingers would be harder and more calloused, thus reducing the achievement and reliability of their readings on skin conductance monitoring. Those enrolled in any other study were also excluded, to avoid placing unnecessary task demands upon them.

3.4. *Recruitment Process*

All patients admitted for at least twenty four hours to the ICU between 1st January 2010 and 31st May 2012 were screened for possible enrolment into the study. Two hundred and one patients were approached upon discharge to a ward and invited to participate. A Letter of Invitation (See Appendix B) and an Information Sheet (see Appendix C) were discussed with the patient and left for their consideration. The following day the author or a member of the research team approached the patient and obtained written consent if s/he was willing to participate (see Appendix D). The same process was applied to a patient's significant other who had visited ICU during their admission, and to a control group (work colleagues of the author) who had no direct experience of ICU. All groups consented (see Appendix E), listened to the sounds tape, and had electrodermal activity recorded.

3.5 *Apparatus*

3.5.1 *Sony Walkman B-Series MP3 USB 1 GB Digital Music Player (Model Number NWZ-B133) and Panasonic RP-HC150 Headphones*

A Sony MP3 B-Series Walkman (Model number NWZ-B133) was used to present the random one-minute blocks of sounds at the Time 2 data collection stage to

patients, significant others, and to the convenience sample. The sounds were delivered via a set of Panasonic RP-HC150 closed, 70% noise-cancelling headphones.

3.5.2 *BioBench Physiological Data Acquisition and Analysis, National Instruments Corporation (1997)*

The BioBench skin conductance machine is an electronic data-collection system designed to analyse physiological processes. The Datex 2000 skin conductance monitor, using silver-silver chloride electrodes attached to the palmar surface of the medial phalanx of the first and second fingers of the dominant hand, estimates physiological arousal levels by monitoring palmar sweat gland activity. The results are automatically recorded by the BioBench computer and the results are downloaded for analysis.

Electrodermal activity was recorded as skin resistance, therefore, in order to produce skin conductance readings the data needed to be calibrated and then transformed. Each data entry point for minimum, mean, and maximum skin resistance readings in response to the train, rain and ICU sounds was divided into 1.0 to convert to conductance values (Lyken & Venables, 1971). According to Lykken and Venables, the maximum and minimum SCL must be attributable to structural, physiological, and biochemical factors which are essentially unrelated to psychological processes.

In describing the above procedure, Lykken and Venables (1971) quote Rose's range correction (shown below) as a means of identifying the variation within the maximum and minimum Skin Conductance Level (SCL) for each participant to produce a variable determined mainly by psychological factors. It is achieved by expressing each participant's (*i*) tonic (average) SCL under each condition (*x*) (Train, Rain, ICU) and subtracting the overall minimum (SCL_{min}) of the 9 data points, and then dividing by the overall range of the 9 data points, as formulated below. All subsequent analysis of skin conductance used these final measures.

$$Øix = \frac{SCL_{ix} - SCL_{min}}{SCL_{max} - SCL_{min}}$$

The magnitude of the SCL provides a direct and objective measure of emotional reaction to each sound stimulus. It was reasoned that if a patient was in any way distressed by the ICU experience, this emotion might become associated with the single sound that was presented to him/her by a process of classical conditioning, and that this would subsequently enhance the amplitude of the SCL to that particular sound on testing four to five weeks post ICU discharge, in comparison with the other two sounds.

3.5.3 *Stimulus Sounds*

To test whether there was enhanced electrodermal activity to naturally occurring sounds, the ambient sound of the ICU was played back to patients at four to five week follow-up, alongside a series of other comparison sounds (i.e. a rainstorm and a steam train), whilst monitoring electrodermal activity. The rain and train sounds were sourced using the expertise of the University's Audio-Visual Department. The specific tracks were selected on the basis of their comparability in terms of sound density and dynamics from a range of available rain and train sounds. The ICU sound was commissioned by the Principal Investigator and recorded from the actual ICU where patients stayed by the Senior Audio-Visual Technician.

White noise was set as the first sound heard to habituate the participant. The remaining three sounds (train, rain, and ICU) were arranged together in six different orders (Tracks 1-6) for randomization purposes. Randomization tables[16] were used in order to randomly allocate participants to groups. Each group received a different order of sounds in a balanced latin square arrangement. A five-second delay was set between one sound and the next. The tracks were downloaded onto the MP3 player to present to all participants. Each sound lasted one minute. All participants were presented with only one track as shown in Table 3.1.

16 Available upon request

Table 3.1.
Track Number and Order of Sounds

Group Number	Order of Sounds*
1	123
2	132
3	213
4	231
5	312
6	321

Note: *= 1=Train; 2=Rain; 3=ICU

3.6 *Questionnaire and Rating Scale Measures*

3.6.1 *Acute Physiology And Chronic Health Evaluation – 2nd Edition (APACHE II) Severity of Illness Scale* (Knaus, Draper, Wagner, & Zimmerman, 1985)

The APACHE II (Appendix F) is a well-established severity-of-disease classification system using twelve basic physiological measurements combined with age and previous health status. It uses a fifteen-item, nine-point ordinal scale ranging from +4 (high abnormal) to -4 (low abnormal). It has been validated in ICU settings, is reliable across all disease categories, has good predictive validity, and has demonstrated clinical utility in the recruitment site.

The original reliability study demonstrated that an increased rating (range 0 - 71) was associated with an increased risk of death (5815 ICU patients recruited from thirteen different sites). The death rate (1.9%) for patients scoring 1 - 4 points was significantly lower (Chi-square = 5.28, p = .02) than the 3.9% death rate for patients rated 5 - 9 points. Similarly, the 73% death rate for patients scoring 30 - 34 points was significantly lower than the 84% death rate for patients scoring 35 or more points (Chi-square = 7.5, p = .01) (Knaus et al., 1985).

3.6.2 *ICU Memory Tool (ICUMT)* (Jones, Humphris, & Griffiths, 2000)

The ICU Memory Tool (ICUMT) (see Appendix G) consists of 14 items that assesses patients' memories of their intensive care experience. It contains a check list of 11

factual memories, 6 feeling, and 4 delusional memories, prompting a variety of 'yes/no', qualitative, and fixed choice answers. The numbers and type of memories can be summed. In order to test construct validity, twenty six of the 45 patients who had experienced severe infections and more likely to have been delirious at some point in their stay were interviewed at 2 weeks post ICU. Of these, 10 (38%) had no factual memories of ICU compared to two out of the 19 patients without severe infections (Fisher's exact Chi-square=4.38, *df* = 29, *p* = .04) (Jones et al., 2000). Test-retest reliability was high, using 8-week and 6-month data from 30 patients in factual (ICC = .81, *p* <0.0001) and delusional memory (ICC = .90, *p* <0.0001) subscales.

The ICUMT cannot be used to make a diagnosis of PTSD, but identifies patients with no factual recall of ICU, and/or delusional memories or memories of pain or discomfort, which are associated with a greater risk of developing PTSD. In the current study the Cronbach's alpha coefficient was .70.

3.6.3 *Hospital Anxiety & Depression Scale (HADS)* (Zigmond & Snaith, 1983)

The HADS (see Appendix H) is a self-rated questionnaire that measures levels of anxiety (7 items) and depression (7 items) over "the past week" using a four-point scale (0-3). The HADS is a widely used reliable and valid screening tool within ICUs, medical, surgical, psychiatry, and psychology settings. A score of 11-14 on either scale indicates moderate symptoms, and 15 and above, severe. A score of 11 for each subscale was chosen to indicate caseness[17] (Zigmond & Snaith, 1983).

Tests of the HADS in the general population revealed internal consistency alpha levels of .80 for anxiety and .82 for depression. Reliability statistics are .84 for anxiety, and .85 for depression at two weeks, .73 for anxiety and .76 for depression between two-six weeks, and .74 for anxiety and .63 for depression at two months (Zigmond & Snaith, 1983). Test-retest reliability at two months was .89 for anxiety and .92 for depression. In the current study Cronbach's alpha coefficient was .80 for Anxiety and .80 for Depression.

17 Caseness is the threshold at which it is appropriate to initiate treatment

3.6.4 *UK-Post Traumatic Stress Syndrome-14 Questions Inventory (UK-PTSS-14)* (Twigg, Humphris, Jones, Bramwell & Griffiths, 2008*).*

The UK-PTSS-14 (see Appendix I) is a 14-item self-report screening tool for acute stress symptoms. Each item is rated 0 (never) to 7 (always) with a total score ranging from 0 to 98. It incorporates all three DSM-IV elements of PTSD (re-experiencing, avoidance and hyperarousal). Griffiths et al (2007) proposed that self-report inventories can provide a cut-off score for screening use where a diagnosis of PTSD is likely. A score of at least 45 indicates that follow up is needed for formal assessment of PTSD.

The measure has achieved internal (.89 at four to fourteen days post-discharge, 0.86 two months post-discharge, and (.84 at three months post-discharge) and test-retest reliability (ICC = .90), and has good concurrent and predictive validity (Twigg et al., 2008). It showed a Pearson's *r* of .86 with the Post-Traumatic Diagnostic Scale (PDS) and .71 with the Impact of Event Scale (IES). The PTSS-14 has been validated against DSM-IV criteria, and was selected for its brevity, reliability and validity. It is commonly used in ICU research. Cronbach's alpha coefficient for the current study was .89.

3.7 *Procedure*

The current study is an extension to an existing and previously ethically approved study sponsored by the NHS Trust Research & Development Unit. It was approved following submission of a Substantial Amendment and Ethical Review by the Regional Ethics (Mental Capacity) Committee and University Hospitals Research & Development Committee (See Appendix J).

3.7.1 *Recruitment*

A3 posters were displayed in the ICU and Relative's Room advertising the study and inviting participation. Patients who had been admitted to Intensive Care for at least twenty four hours were potential participants. The nurse-to-patient ratio was 1:1-2, and nurses administered the amount of medication judged necessary to maintain the patient within the targeted sedation scores. Patients were not physically restrained, were never left alone by staff, and visitors were allowed at any

time. After the ICU stay, patients were discharged to different wards within the hospital. Critical care outreach nurses visited the patients on the discharge wards for several days in order to monitor their recovery.

All patients due to be discharged from the ICU were checked for eligibility every day by a member of the research team following review of daily ICU discharge lists. Eligible patients were visited on the ward two to four days after transfer and revisited one to two days later if unwell and/or unavailable. Patients who had not improved after a maximum of three visits were considered lost to follow-up. Informed consent was obtained from those patients willing to participate. A relative/significant other who had visited the patient in ICU and was willing to listen to the recorded sounds and have electrodermal activity recorded, was also invited to participate. At a later date, a convenience sample of people (work colleagues of the researcher, with no prior exposure to an ICU) listened to the sounds tapes as per a randomisation table, and had their skin conductance recorded. A CONSORT diagram of the study procedure is shown in Figure 3.2.

3.7.2 *Data Collection*

Data collection occurred over two time-points. The one to two week post-ICU discharge follow up (Time 1) was designed to minimise loss through decay, and to identify and facilitate treatment of any psychological distress. Time two (four to five weeks) was determined to be the most optimum time to capture PTSD symptomology, anxiety and depression, and to examine memory stability. It was thought that the patient would possess enough clarity of thought and good enough health in order to cope with the demands of the tasks at this time (Jones et al., 2000). All questionnaires were administered in interview format. A letter was sent to the GP informing them of involvement in the study.

Four to five weeks post discharge, participants were followed up at home to complete the full battery of questionnaires, including a repeat of the ICUMT, as well as the HADS and PTSS-14. At this time the recorded sounds were presented via headphones and MP3-player, and electrodermal activity was recorded (see Appendix K). This was repeated for a significant other, and at a later date, a convenience sample.

All participants were advised that if their scores on the questionnaires indicated the need for follow up, they would be contacted by the Consultant Clinical Psychologist (MW) for assessment, and offered therapy if appropriate. All participants were thanked for their time and effort and for allowing us in to their homes. They were advised that at the end of the study we would provide them with a summary of our findings.

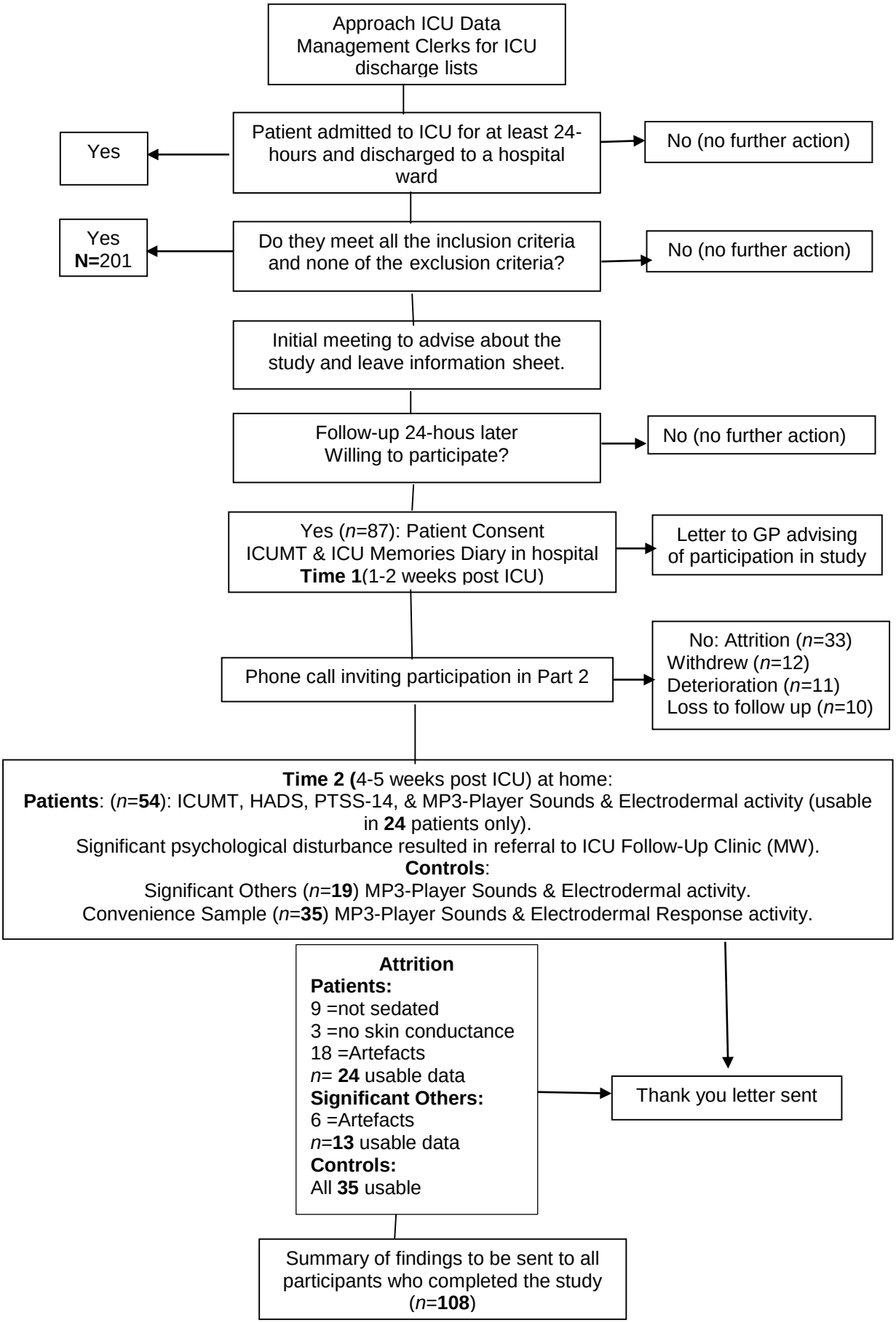

Figure 3.2. CONSORT diagram of study procedure

Section 4: Results

4.1 *Preliminary Analysis*

Prior to analysis, all data were examined through various Statistical Package for the Social Sciences (SPSS version 20) programs for missing values and fit between their distributions and the assumptions of parametric analysis. Given the small sample size, it was expected that the distribution of scores would not be normal, and, as suggested by Tabachnick and Fidell (1996, p. 73), a conventional but conservative (.01) alpha level was used to evaluate the significance of skewness and kurtosis. The inspection of z-scores of skew and kurtosis, and residual scatter and box plots revealed some outliers, however the issue of outliers is not overly critical when a variable has a finite and relatively limited possible scoring range (Tabachnick & Fidell, 1996). As extreme values represented caseness on the clinical scales, they were not removed.

In line with Tabachnick and Fidell's (1996) recommendation, extreme scores were changed so that the scores were one unit larger or smaller than the next most extreme score in the distribution to reduce their impact, and a square root (SQRT) transformation was then performed to give an improved distribution. Kolmogorov-Smirnov (*D*) tests of normality were not significant, and z-scores of skewness and kurtosis were less than the critical value of 2.58 (Field, 2009, p. 139), allowing parametric analysis. Internal consistency (α) was .7 or above for all scales used in the study. The electrodermal data was transformed from skin resistance to skin conductance levels (SCL) and square root transformations conducted to normalize it.

4.2 Quantitative Data

4.2.3 *Sample Demographics*

4.2.3.1 Response rate and representativeness

Two hundred and one patients were screened as eligible to participate in the study. A total of eighty seven (43.3%) patients consented into the study and completed Time 1 data collection measures. Eleven people became too unwell to continue, ten people were lost to follow up, and twelve decided to withdraw. Of those patients

who declined to participate, seven (6%) were invited for follow up by the Consultant Clinical Psychologist (MW) at the patient's next specialist outpatient follow-up clinic.

A total of fifty four (62%) patients aged between twenty and eighty eight completed both parts of the study. However, nine of the patients were not sedated and 3 competed Time 2 by mail. Twenty two relatives/significant others who were present on the day of Time 2 assessment were also invited to participate in the study, as they too had experienced the ICU environment. Three chose not to participate. Because of this and because of artefacts, only data from twenty four patients (44.4%), thirteen significant others (68.4%), and all of the convenience sample was used to test the hypotheses. Table 4.1 displays the descriptive data for the three groups.

Table 4.1
Descriptive Data of the 3 Groups of Participants

Participants	Mean Age	Standard Deviation
Patients (N=24: 9 females, 15 males)	60.79	13.72
Relative Controls (N=13: 10 females, 3 males)	56.73	14.44
Convenience Controls (N=35: 30 females, 5 males)	50.80	15.75

The following sections present the demographics and treatment variables of patients only, followed by analysis of the three participant groups in testing the hypotheses. Table 4.2 displays the admission type and diagnoses for the patient sample. The sample was representative with respect to gender and the general ICU population.

Table 4.2
ICU Admission Type and Diagnoses

Type	N	%
Emergency		
Road Traffic Accident	2	8.33
Ruptured AAA	4	16.66
Septic shock	2	8.33
Blocked airway/COPD	6	25.00
VF arrest	1	4.17
Gastric surgery	7	29.17
Sub total	22	91.66
Elective		
Cancer	1	4.17
AAA found = planned op	1	4.17
Sub total	2	8.34
Total	24	100.00

Note: AAA=Abdominal Aortic Aneurysm; COPD=Chronic Obstructive Pulmonary Disease

The patient treatment variables are listed in Table 4.3.

Table 4.3
Patient Treatment Variables

Variables	Mean	SD	Range
APACHE II Total Score	18.25	6.24	23
No. of hours ventilated	97.68	110.95	386.00
Morphine 1mg/ml (total dose)	580.10	1074.41	4813.00
Midazolam 1mg/ml (total dose)	436.04	670.28	2587.50
Propofol 10mgs/1ml (total dose)	122.00	243.06	1171.00
Length of sedation (hours)	130.70	131.26	549.00
Length of ICU stay (hours)	260.79	209.96	661.10
Length of Hospital Stay (days)	30.12	20.14	90

Measures of the possible impact of ICU treatment are presented in the following analyses of anxiety, depression, and posttraumatic stress symptoms.

4.3 *Anxiety, Depression, and Post Traumatic Stress Symptoms*

As Table 4.4 indicates, four patients reached caseness (a score of 11 or above) on anxiety symptoms, and four with depressive symptoms. Two people (8.4%) reached the threshold of 45 and above on the PTSS-14 symptom scale and were referred for follow-up with the Consultant Clinical Psychologist.

Table 4.4
Frequency (%) Distributions of HADS and PTSS scores

HADS	Anxiety		Depression	
	n	%	n	%
Normal (0-7)	17	70.8	18	75.0
Mild (8-10)	3	12.5	2	8.3
Moderate (11-14)	4	16.7	3	12.5
Severe (15-21)	0	0	1	4.2
Total	24	100	24	100

PTSS	n	%
Subthreshold (<45)	22	91.6
Above Threshold (45+)	2	8.4
Total	24	100

Table 4.5 provides the means and standard deviations for the measures used to measure psychological distress.

Table 4.5
Measures of Mental State

	Mean	SD	Range
HADS Anxiety	5.08	4.05	14
HADS Depression	5.58	3.82	15
PTSS-14	15.25	16.78	58

4.6 *Memories of ICU*

Memories of the time spent in ICU were recorded at two time points as shown in Table 4.6. Time 1 (one to two weeks post ICU discharge) was chosen by the ICUMT authors as it was thought that most patients had recovered from delirium by then. It was also an appropriate time to capture those memories most likely to arouse PTSD-related symptoms during recovery.

Table 4.6
Number of Memories

	Time 1 (*n*=24)			Time 2 (*n*=24)		
	Factual (0-11)	Feeling (0-6)	Delusional (0-4)	Factual (0-11)	Feeling (0-6)	Delusional (0-4)
Median	7	2.5	1.5	6	1	1
Range	11	6	4	11	5	4

Based on the literature and as a precursor to multivariate analysis, a (2-tailed) Pearson correlation analysis was conducted in order to observe the strength of relationships between the variables. The results of the analyses are presented in Table 4.7. Correlations of at least .3 are highlighted in bold.

Table 4.7
Pearson Correlations of Patient Variables

Demographics	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
1 Age																								
2 No. hours ventilated	-.18																							
3 ICU stay (hours)	-.12	**.64****																						
4 Hours sedated	**-.27**	**.50***	**.88****																					
5 Total Morphine	**-.45***	**.35**	**.73****	**.89****																				
6 Total Midazolam	**-.52****	**.55****	**.77****	**.87****	**.94****																			
7 Total Propofol	**-.28**	.03	**.58****	**.73****	**.81****	**.61****																		
8 Hospital stay (days)	**-.31**	**.29**	**.71****	**.73****	**.77****	**.69****	**.77****																	
9 APACHE II	-.12	**.35**	.09	-.01	-.14	-.01	**-.29**	-.16																
10 N. Factual Memories T1	-.03	-.10	.14	.13	.22	.20	.12	.16	**-.45***															
11 N. Feeling Memories T1	**-.45***	-.04	.00	.17	**.34**	**.33**	**.26**	**.34**	**-.34**	**.40**														
12 N Delusional Memories T1	-.12	-.15	.03	.14	.18	.11	.12	.10	**-.38**	**.52****	**.34**													
13 HADS Anxiety T2	-.18	-.23	**-.34**	-.11	.07	.03	.04	-.02	.24	**-.28**	.02	-.19												
14 HADS Depression T2	.12	**-.27**	**-.35**	-.23	-.14	-.24	-.07	-.15	.20	-.20	.13	-.09	**.61****											
15 PTSS-14 T2	-.22	-.15	-.12	.06	.23	.17	**.25**	**.27**	.08	.03	**.30**	-.11	**.80****	**.63****										
16 N. Factual Memories T2	-.16	-.06	**.25**	**.25**	**.41***	**.32**	**.35**	**.43***	**-.34**	**.87****	**.54****	**.52****	-.18	-.07	.20									
17 N. Feeling Memories T2	**-.45***	-.04	.04	.21	**.37**	**.32**	**.38**	**.38**	-.22	**.51***	**.82****	**.33**	.12	.22	**.49***	**.62****								
18 N. Delusional Mems. T2	**-.63****	.06	.06	.14	**.35**	**.32**	**.41***	**.39**	-.19	**.47***	**.58****	**.36**	.01	-.00	.23	**.56****	**.76****							
19. Rose Train T2	-.13	.02	-.08	.07	.03	.06	.03	-.16	-.04	.01	.16	**.27**	.03	**.28**	.03	-.07	.23	.18						
20. Rose Rain T2	.15	.03	**-.25**	-.21	**-.34**	**-.36**	-.13	**-.29**	-.03	**-.32**	-.14	-.15	**-.26**	-.22	**-.39**	**-.40**	-.20	-.09	.16					
21.Rose ICU T2	-.23	.03	-.07	.07	.22	.18	-.01	.02	.20	-.10	.14	.21	**.45***	.15	**.35**	.15	-.03	-.13	-.19	-.22				
22.Skin Fluctuations Train T2	-.04	-.07	.05	-.06	.12	.12	.14	.15	**-.26**	**.55****	.15	.16	.08	.08	**.33**	**.47***	**.42***	**.50***	.09	**-.26**	-.21			
23. Skin Fluctuations Rain T2	.05	-.09	-.05	-.18	-.12	-.12	-.09	-.15	-.00	.21	-.09	.03	.00	.11	.06	.07	.06	.14	.11	.12	-.10	**.55****		
24. Skin Fluctuations ICU T2	-.21	**-.25**	-.08	-.13	.15	.07	.16	.11	**-.26**	**.43***	**.25**	.17	.04	.03	.16	**.42***	**.42***	**.49***	-.00	-.11	-.04	**.67****	**.76****	

Note. **p*<.05. ***p*<.01 (2-tailed), *r* ≥.3 highlighted in bold. *N*=24. High scores indicate high levels on each variable: HADS, PTSS, Memories, and skin fluctuations. N=number of, T1=Time 1, T2=Time 2

There were several expected relationships between the variables. Importantly, there were significant correlations between Rose ICU readings and anxiety (HADS), $r = .45$, $p < .05$, and skin fluctuations and factual, feeling and delusional memories at Time 2. Correlations approached significance at Time 2 between factual memories and propofol ($p = .09$), and between feeling memories and morphine ($p = .08$), feeling memories and propofol ($p = .07$), and feeling memories and length of hospital stay ($p = .07$). Similarly, correlations approached significance for delusional memories and morphine ($p = .09$), and delusional memories and length of hospital stay ($p = .06$). A trend was seen in Rose ICU and PTSS, $r = .35$, $p = .10$.

Implicit memory for ICU sounds was measured by skin conductance levels and spontaneous fluctuation rates.

4.4 *Hypotheses Testing*

4.4.1 *Electrodermal Activity*

Table 4.8 presents the descriptive statistics for the Rose corrected skin conductance data for the three groups of participants. As can be seen, there is little difference between the means and standard deviations both within each participant group, and between them. However, the profile of group means is as predicted, with ICU sound associated with the highest arousal.

Table 4.8
Rose Corrected Skin Conductance (SC) Data

	Patients (n=24)			**Significant Others (n=13)**			**Convenience Sample (n=35)**		
				Mean SC					
Descriptive	**Train**	**Rain**	**ICU**	**Train**	**Rain**	**ICU**	**Train**	**Rain**	**ICU**
Mean	.5848	.5760	.6014	.4407	.4660	.4333	.5490	.6639	.6142
Std .Deviation	.1852	.2408	.2448	.2246	.2021	.2573	.1720	.1924	.1838
Minimum	.1873	.0000	.0000	.1775	.1580	.1361	.1960	.2356	.1745
Maximum	.8737	.9377	.9220	.8752	.7271	.8005	.8601	..8934	.9812

Tests of each hypothesis will now be presented. Both hypotheses were tested using a 3 x 3 mixed ANOVA to investigate individual and group differences in skin conductance level during sound presentations, using Rose calculations and spontaneous fluctuations in separate analyses.

4.4.2 *Hypothesis 1*

Post ICU patients will demonstrate a stronger emotional reaction to ICU sounds than other sounds, as measured by skin conductance variables.

Figure 4.1 displays the mean skin conductance level for each sound heard and Figure 4.2 displays the spontaneous fluctuation rates in reaction to the sounds. In both charts all error bars overlap, and are in fact, almost equal.

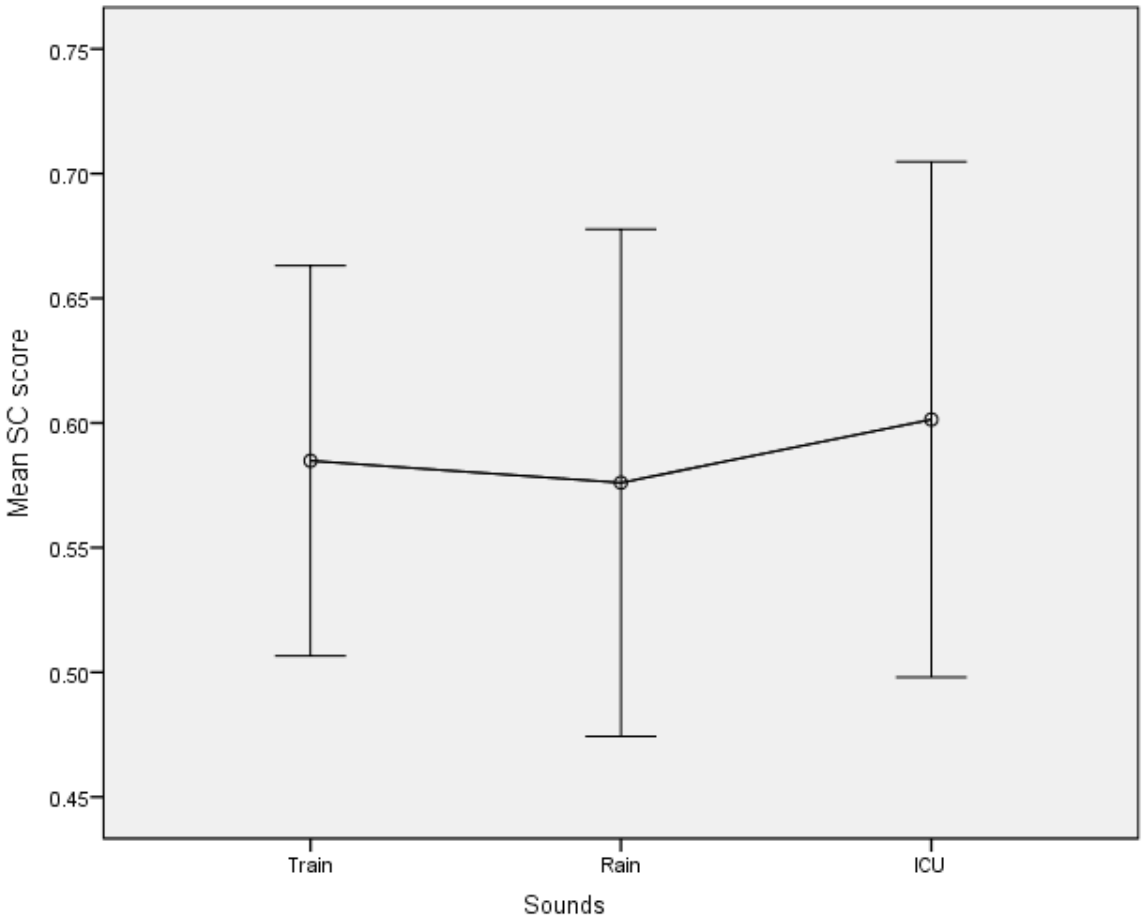

Figure 4.1. Skin conductance responses to sounds by patients

Legend
O = Mean
T Error Bar (±2 SD)

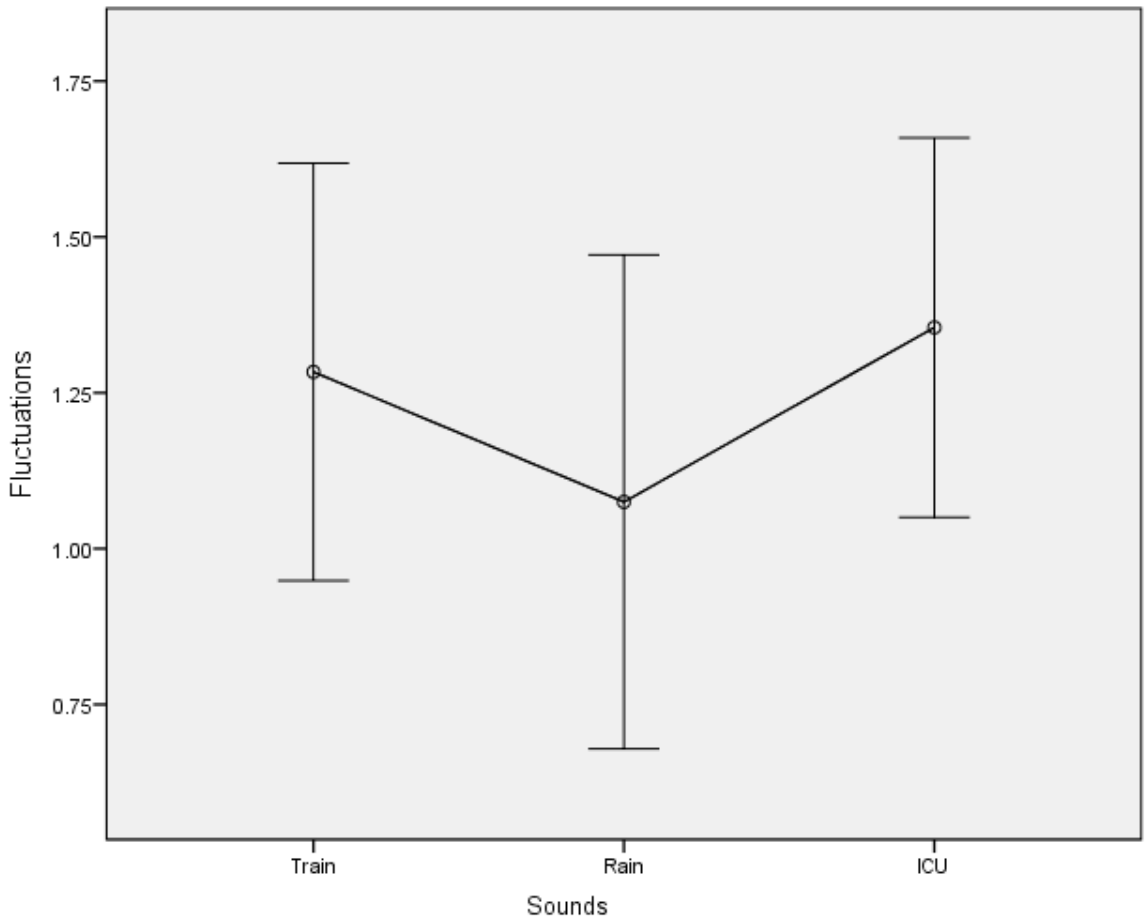

Figure 4.2. Fluctuation responses to sounds heard by patients

Legend
O = Mean
I Error Bar (±2 SD)

4.4.3 *Hypothesis 2*

Relatives (Significant Others) of ICU patients will show a stronger emotional reaction to ICU sounds in comparison with a control sample, but this will not be as great as that in the patient sample.

Figure 4.3 displays the mean skin conductance level for each sound heard. Figure 4.4 displays the spontaneous fluctuation rates in reaction to the sounds.

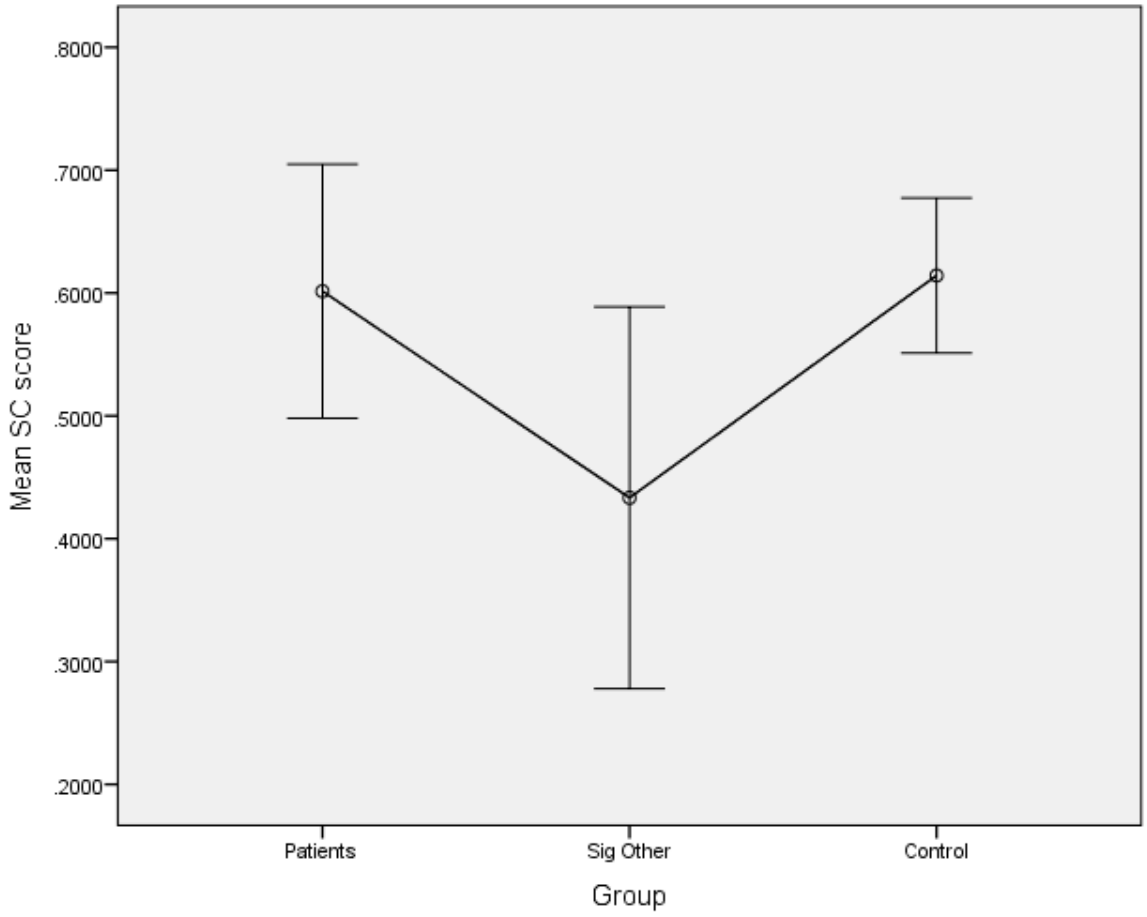

Figure 4.3. Skin conductance responses to ICU sounds for each group of participants.

Legend
O = Mean
T Error Bar (±2 SD)

The skin conductance chart suggests that relatives did not show a stronger reaction to the ICU sounds when compared to the control group. However, they had greater spontaneous skin fluctuations than both groups, as shown in Figure 4.4.

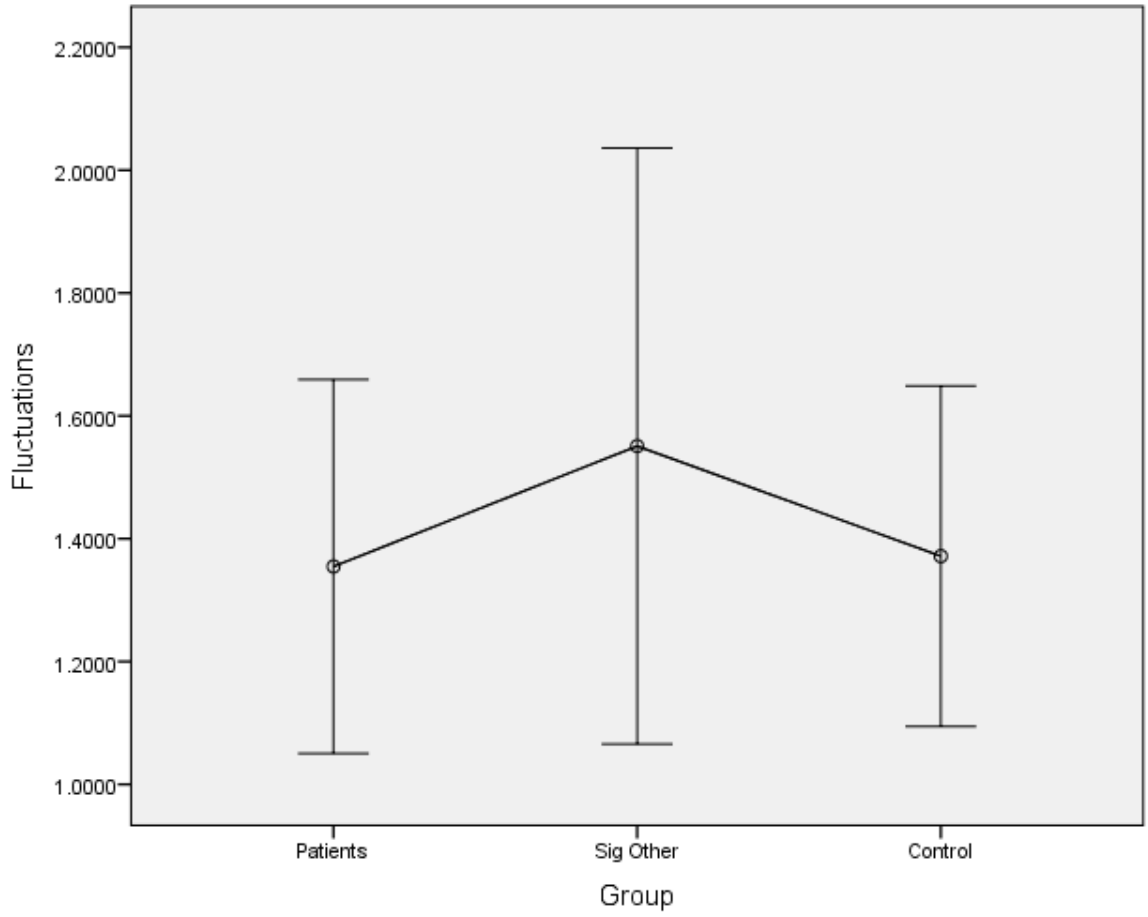

Figure 4.4. Skin Fluctuations to ICU sounds for each group of participants.

Legend
O = Mean
I Error Bar (±2 SD)

A 3 x 3 mixed ANOVA was performed to investigate individual and group differences in skin conductance level during sound presentations. The independent variables were group (Patient, Significant Other, Control) and sound (Train, Rain, ICU). The Sound factor was a repeated measure since the same participant heard each of the three sounds, hence the mixed ANOVA design. The dependent variable was skin conductance level.

Due to the small and uneven sample size, Pillai's Trace was used to measure the multivariate effects, as recommended by Field (2009). There were non-significant

effects for sounds $F(2,68) = 1.03$, $p = .36$, and no effect for sounds by group $F(4,138), = 1.02$, $p = .40$.

There was a non-significant within-subjects effect for sounds $F(2,138) = .83$, $p = .44$, supporting the null hypothesis that there is no difference in emotional reaction to the sounds. There were non-significant differences in responses to each of the sounds in each group $F(4,138) = .89$, $p = .47$. The interactions between conditions and change over sounds were significant for Group, $F(2,69) = 6.82$, $p < .05$, however Box's test was significant ($p = .03$). Therefore, although post hoc tests showed significance of $p < .05$ between patients and significant others, between significant others and controls $p < .01$, but not between patients and controls $p = .91$, the findings should be treated with caution, even though intuitively, it makes sense because patients and significant others were exposed to the stressors of ICU, whereas the control group were not.

Skin conductance spontaneous fluctuations were also measured during each of the sound presentation periods, and provided another measure of autonomic arousal (Table 4.9).

Table 4.9.
Descriptive Statistics For Spontaneous Fluctuations.

	Patients (n=24)			**Significant Others (n=13)**			**Convenience Sample (n=35)**		
	Median SC fluctuation rate								
Descriptive	**Train**	**Rain**	**ICU**	**Train**	**Rain**	**ICU**	**Train**	**Rain**	**ICU**
Median	2	1	2	2	4	3	2	3	2
Range	6	6	6	6	8	6	8	7	7

Non-parametric tests were used to compare the number of fluctuations to the different sounds by each group of people. The Kruskal-Wallis Test revealed that the distribution of responses was the same across each group, $p = .77$ (Train), $p = .27$ (Rain), and $p = .60$ (ICU). The null hypothesis that there is no difference, is retained.

Four patients (16.7%) demonstrated a stronger differential reaction to the ICU sounds than to the sounds of a Train and to Rain. Table 4.10 presents a description of their profiles.

Table 4.10

Profile of Patients with Differential Reactions to the ICU Sounds

Patient ID & Number of Skin Fluctuations	Age	Sex	Hours Sedated	Morphine Total 1mg/ml	Midaz Total 1mg/ml	Propfol Total 10mgs/ml	PTSS	HADS ANXIETY	HADS DEPRESSION	T1 ICUMT	T2 ICUMT
69 T 4 R 5 ICU 6	46	M	6	45	0	162	10	2	3	9 FACTUAL 4 FEELING 3 DELUSIONAL	8 FACTUAL 5 FEELING 4 DELUSIONAL
74 T 1 R 0 ICU 2	73	M	14	68	71	0	8	3	2	7 FACTUAL 3 FEELING 0 DELUSIONAL	6 FACTUAL 1 FEELING 0 DELUSIONAL
78 T 3 R 4 ICU 5	64	M	8	0	0	43	16	5	6	6 FACTUAL 5 FEELING 3 DELUSIONAL	6 FACTUAL 4 FEELING 1 DELUSIONAL
82 T 3 R 1 ICU 4	48	M	56	4813	2347	1171	40	8	7	8 FACTUAL 5 FEELING 3 DELUSIONAL	7 FACTUAL 1 FEELING 0 DELUSIONAL

Note: T=Train, R=Rain, Midaz = Midazolam, ICUMT = ICU Memory Tool, PTSS = Post Traumatic Symptom Scale

Section 5: Discussion

5.1 *Introduction*

The overall aim of the study was to investigate whether classical conditioning of ICU environment sounds to a distressed emotional state occurs during ICU admission, and whether this can be detected by measuring skin conductance at 4-5 weeks post ICU. Non-significant results were found. However, correlations approached significance between types of memory and type of sedative and analgesic medications, and with the arousal level whilst hearing the sound of the ICU and posttraumatic stress symptoms. These are noteworthy and warrant a more robust investigation.

5.2 *Discussion of Results*

Several explanations of the results are offered in the following paragraphs. Firstly, of the fifty one patients who listened to the sounds, not being sedated and/or because of artefacts, only twenty four patient's readings were able to be analysed. Artefacts also lowered the usable data from relatives to thirteen. This resulted in an underpowered study where the possibility of making a Type II error was increased. Also, this ICU admission may not have been the first for those with chronic illnesses such as cancer or COPD; they may have been desensitized to the acute treatment environment through exposure to repeated hospital admissions and procedures.

Almost half of those who completed Time 1 measures (*n*=87) did not complete Time 2 measures (*n*=33). Avoidance is another feature of PTSD (DSM-IV, 1994) and may have contributed to the attrition. Alternatively, these patients may not have been distressed. Secondly, ICUs and ICU sounds are commonly seen and heard on popular TV programs and patients and significant others may have become habituated to the sounds. Third, while the sounds of ICU machinery did not evoke strong emotional reactions, it is possible that the inclusion of voices of ICU staff would have had more resonance. During ward round for example, there is often at least eight people visiting each bed, talking about, and to, a patient. Life and (brain) death decisions are made quite openly. Everyday background ICU sounds such as voices, suctioning, and the sounds of various alarms (e.g. IV pumps, alarms on various machines that alert staff if oxygen saturation levels are too low, when BP is

too high or too low etc.), were also missing from the recordings. The sounds were of a ventilator and pulsometer and were presented in rhythmic isolation. They may have been experienced as soothing to some people, and as only part of the ICU picture. Perhaps most importantly, the amount of time spent in ICU may have resulted in habituation and extinction of the environmental sounds, resulting in a reduction in strength of an unconditioned response, and therefore, level of anxiety. Patients are fully awake before they are transferred off the Unit and will have formed explicit memories of the ICU environment.

It is possible that there were more marked implicit emotional memory effects earlier in each patient's course (e.g. within 24 hours of ICU discharge) as Daneman and Merikle (1996) found in their meta-analysis. However, we argue that any implicit effects that are not evident by one month are unlikely to be clinically significant, hence the design of this experiment.

Notwithstanding, the correlations between the skin conductance level during ICU sound presentation, HADS-A and PTSS, and between factual memoires and propofol, and feeling memories and morphine and propofol are important, and potentially tell us something about psychopathological processes underlying these symptoms. While it is possible to argue that implicit emotional memory may be a factor in causing symptoms in these patients, it is acknowledged that implicit emotional memory is one aspect of the constellations of symptoms that make up PTSD, since correlation cannot show cause and effect. Four patients did react more strongly to the sounds of ICU than to the other sounds, but did not reach caseness on any of the mental health screening tools. Three of them received propofol and they each reported delusional memories at Time1. This is interesting.

The prevalence rate for caseness on the HADS and PTSS-14 was low by comparison, though PTSD can have a delayed onset, developing only after the physical recovery period has passed (Cuthbertson, Hull, Strachan & Scott, 2004). Although not a diagnostic tool, some authors dispute the use of the PTSS-14 (Weinert & Meller, 2007), fuelling the argument that PTSD symptoms should exist

along a continuum[18] (Jones et al., 2007; Stein et al., 1997; Twigg et al., 2008), and that this should be assessed using standardized tools (Wade et al., 2014). It should be remembered that those who do not meet the full criteria for PTSD may still be distressed by their symptoms and require treatment (Creamer, McFarland, & Burgess, 2005; Carlier & Gersons, 1995).

An alternative explanation for the low levels of psychological distress may relate to several factors that suggest that for most people in the study, policy and clinical practice in this particular ICU were optimal. They include the careful management of sedation and delirium, with the aim of keeping the patient comfortable and pain-free. The nurse to patient ratio was 1:1-2, and nurses administered the amount of medication judged necessary to maintain the patient within the targeted sedation score. Sedation holds were a mandatory part of the ventilator care bundle. Periods of alertness, which allow for the consolidation of factual memories, may protect patients from developing PTSD-related symptoms after discharge.

Patients were not physically restrained, were never left alone by staff, and visitors were allowed at any time. After the ICU stay, patients were discharged to different wards within the hospital, and critical care outreach nurses visited them for several days in order to monitor their recovery. The research team were also in contact, firstly inviting participation into the study and subsequently following up for consent or refusal. The attendance of the research team may have biased the results. This, and other limitations of the study will be discussed next.

Although relatives' experienced the ICU environment when visiting, in contrast to the patients, they were not prone or semi-prone in bed, and were able to come and go. As such they may have been better able to contextualise what was happening, or to at least ask for clarification. Information booklets were routinely given to them upon admission to alert them to the process of ICU care, and for discussion with staff and the patient. Again, it is possible that the ICU sounds tape was not sensitive enough, nor as real-life and busy as the unit usually is. The relative's experience was not dissimilar to that of the patient or to the people who had never been to an ICU. They too may have become desensitized to the environmental sounds. Of

[18] DSM V does not reflect this

course, it is also possible that there may not have been a true difference in reaction to the sounds.

5.3 *Limitations of the Study*

The most obvious limitation of the study was the low number of participants with skin conductance data that could be used. This reduced the power of the study considerably. As there is no previous research of this kind, we consulted Cohen's (1988) tables to determine the number of participants needed to conduct a between subjects ANOVA, with power set at the conventional 0.80, and an assumed medium effect size (d = 0.5). Fifty two patients and 52 controls were needed. However, due to difficulty recruiting, as well as time constraints, recruitment stopped when 87 people entered into Time 1. Eligibility criteria included ICU admission for at least 24-hours without the need to be sedated. This meant fewer patients' data were available for some analyses. Therefore, firm conclusions cannot be made regarding the two hypotheses.

5.3.1 *Representativeness of the Sample*

As Tabachnick and Fidell (1996) point out, unequal *n* often results from the nature of the population, and differences in sample sizes reflect true differences in numbers of various types of subjects. The present sample was representative of the general ICU population at the hospital, but not of the cultural diversity of the city. Generalizability of the findings is therefore limited.

It is therefore probable that the study sampled the less critically ill patients, and/or those who did not have any mental health problems after the injury event, or that those with higher levels of distress may have avoided participation, resulting in a selection bias. Seven patients who declined to participate were offered follow-up at their next out-patient department follow up visit, however they declined assessment by the Consultant Clinical Psychologist.

Attrition is a challenge in this type of study. The most pertinent data are, therefore, potentially missed. Completion rates have been greater in studies where the researchers have been the clinicians involved in patient care (e.g. Hepp et al., 2008). Time 2 questionnaires were mailed out to several participants, however only

two were returned, resulting in several people being lost to follow up. This led to face-to-face administration of the questionnaires to all participants, which removed errors of misunderstanding, and prevented missing items. The sample consisted of predominantly older males, and this has been found to be a protective factor in some (Boer et al., 2007; Breslau et al., 1997), but not all (Schnyder, Moergeli, Trent, Klaghofer, & Buddeberg, 2001), PTSD studies.

A potential source of bias for the study is the influence the researcher had upon a patient's experience, firstly by inviting him/her in to the study, conducting part one within a very short time frame, and arranging to see the patient again in 4-5 weeks. By explaining the rationale of the study to patients, it is possible that they were then better able to process sensorial information, as also found by Rattray and colleagues (2005). This has important clinical implications.

5.4 Clinical Implications

These results add to the rapidly expanding field of study of psychological morbidity post ICU. The findings have implications for how ICU staff interact with paralysed patients, as they assume the patients are unconscious when, in fact, they may not be, and may add to the patient's paranoia concerning malign intent of ICU staff. It is important therefore, that staff do communicate with ICU patients, even though they look unconscious, and explain medical and nursing procedures so that the patients know what is happening to them.

Screening patients at one to two weeks following discharge could be conducted by the Outreach team, and if signs of psychological distress are identified, referral to the appropriate clinician could occur. Similarly, for planned admissions, meeting the team and visiting the ICU would help prepare patients and families for the process.

5.4.1 *Normalizing the experience of ICU*

Patients were relieved to hear that others had experienced strange memory phenomena whilst in the ICU. Specific questions regarding feeling safe and feeling unsafe would enable patients to talk about their experiences, and for staff to normalise them as a part of ICU care for some people.

It is therefore important that the Department of Critical Care leaflet "About the Critical Care Units" is discussed with the patient and relatives pre-admission, if possible, or as soon as practically possible following emergency admission. This could be built in to a patient's ICU diary – a concept that has been steadily introduced into ICU care in an effort to fill in the gaps and reduce the incidence of new PTSD (Jones et al., 2010).

5.4.2 *Psychological Involvement in ICU Care*

Currently, very few UK ICUs provide routine psychological follow-up of patients, although the practice is growing and was recommended in the 2010 update of the NICE critical care rehabilitation guidelines. A more pro-active approach has been taken by Peris and colleagues (2011) who recommend intra-ICU clinical psychology support. This is a very promising start and an important recommendation. There is a role for clinical and health psychologists in providing intra-intensive care education and support (Hatch, McKechnie & Griffiths, 2011). Further recommendations are made below.

5.5 *Future Research Recommendations*

5.5.1 *ICU Sounds*

A more representative sample of ICU sounds to facilitate access to sensorial information, and in a much larger sample is strongly recommended, although it is acknowledged that this may make comparison measurements more difficult. This would permit a more comprehensive exploration of any potential relationship between scores on psychological disturbance measures and PTSD mechanisms.

5.5.2 *Encouragement to Talk About Memories*

An intensified focus upon memory phenomena by staff and family is encouraged. Very little is known about why some people develop more unwanted images of a trauma than others, or why people develop images of particular moments (Holmes et al., 2004). What is known however, is that telling stories can help patients to recover psychologically after intensive care (Williams, 2010).

5.6 *Conclusion*

It is hard to identify with certainty which of the identified factors independently or collectively triggers psychological distress following ICU, for some patients. Some factors could be real, or imagined during delusional and hallucinogenic experiences. The interplay amongst them makes it very difficult to eradicate all the side effects of ICU treatment, however efforts to minimise them continue. Major improvements in the way ICU care is administered, and patient and relative involvement in decision making and debriefing has been increasingly implemented across some sites. However, significant numbers of patients continue to experience unacceptable levels of distress and are discharged home with no direct access to psychological support. This is alarming given the abundance of research into post-ICU psychological morbidity, and NICE guidelines (2009). In line with Weinert and Meller's (2007) assertion, there is recognition that ICU care may be an independent predictor of PTSD (O'Donnell et al., 2010), or in fact, the 'disease' (Parker & Griffiths, 2010). The role of implicit emotional memory in causing or exacerbating such symptoms warrants further investigation.

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Part Three

Critical Appraisal of the Research

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Part Three: Critical Appraisal

Section 1

The following paragraphs present my reflections of my experience of the process of planning, conducting and evaluating doctoral level research, and a narrative on myself throughout the process.

1.1 *Choice of research topic*

In my work as a clinical psychologist I have been involved in conducting many medico-legal assessments of PTSD in order to assess the level of psychological trauma experienced by victims of road traffic accidents (RTA). Many of these people had spent time in an ICU. I became curious - was it the event (e.g. RTA) or the experience of ICU – sometimes described to me as another trauma, that was the dependent variable in PTSD development? This laid the foundation of my interest in exploring the area.

My supervisor is a specialist in the area and I was invited to collaborate in a large and complex study looking at PTSD following ICU treatment with him. My research represented Stage 2 of a previously ethically approved study involving relatives assenting the patient to Stage 1. Stage 1 involved playing eligible patients' a story at sedation levels light enough for them to hear the story, but deep enough to maintain comfort. My study was also novel in that it evoked skin conductance changes in response to ICU sounds routinely heard whilst sedated, as well as to other sounds, in an effort to reach implicit emotional memory of the time spent in ICU. The literature has increasingly shown that it is more than the reason for admission that creates such disturbance.

1.2 Research design

Research in the area has grown significantly over the last forty years with psychological perspectives added to the literature base which challenge, yet complement, medical models of illness. The frustration with the literature is that firm conclusions cannot be made about prevalence rates due to inconsistent methodologies and lack of ICU-validated assessment tools of psychological morbidity. Many predictors have been confirmed in the literature, however more

recently the ICU itself has been identified as an independent contributor. This is very interesting.

As Arm 2 of an already approved major study occurring at the hospital, it necessitated submission of a substantial amendment for me and the study to be approved by ethics committees. The same measures and follow-up procedures were employed. The advantage I had over the Arm 1 protocol was that my participants were able to choose to participate or not. This enabled more of the team to recruit participants. In order to work in the acute setting in the hospital it was necessary to obtain an honorary research contract. This needed to be renewed due to the delay in starting data collection because of Stage 1 and other studies occurring simultaneously. Difficulties identified in Stage 1 of the study were somewhat resolved by Stage 2 in that patients were awake and able to consent or not to participate, themselves. However, the study and participants may have benefited from the utilisation of a longitudinal design to assess psychological morbidity. The memory diaries were very interesting but they were mostly retrospective accounts and it is possible that some valuable information has been lost or suppressed. The layout of the diary was not considered ideal, appearing more like a form to be completed rather than a safe place to be vulnerable. Unfortunately they were removed from the thesis but will be considered for future publications. All of these things will be considered in any other study that I propose of this nature.

1.3 *Timescale*

The substantial amendment took a long time to prepare, but it was quickly approved. Data collection was relatively straightforward once the procedure was learnt (albeit recruitment to Time 2 was sometimes difficult), but hindered by my living more than a hundred miles away, working 4 days a week, and needing to travel to, and all over the county to assess participants in their homes. Despite this, this was one part of the process I felt more in control of, and actually enjoyed the weekly visits to collect data and to touch base with the research team. Other members of the research team were involved in data collection. Helpfully, the nurses had direct, and at least daily contact with the ICU and were on-site. They were supervised by the

Consultant Clinical Psychologist in taking skin conductance recordings and in questionnaire administration. The study closed at the end of June 2012.

1.4 *Research setting and sample*

The study was conducted at two sites which were polar opposites. Part 1 was in hospital in the ward the patient was discharged to from ICU. The ICU can be an incredibly busy environment with many more staff than patients. At times being there felt like an intrusion into an already overcrowded space – the tension was sometimes very palpable.

Even as an ex-nurse it was still daunting to go on to the unit and witness the daily routines of staff and patients in life and sometimes death experiences. There was no acknowledgement or debrief of the impact of this on staff. While this enabled staff to continue to do their jobs I am very aware of the literature discussing staff burnout and staff PTSD symptomology in ICU. The proximity of other patients and relatives made it most likely that they overheard and understood what was said, potentially adding to their distress.

The ICU is a busy, fast paced environment with intense interventions by nursing and medical staff. Relatives observed not only their loved one, but the events of the people around them. Teams of doctors sometimes distanced themselves both physically (by standing at the bottom of the bed) and emotionally (talking to each other) from the person who was the patient to talk clinically about his/her physical state. It made me uncomfortable and I made a point of going to the patient and saying hello, while waiting for the team to acknowledge her/him. Younger doctors responded to this and I observed altered practice in some. Older doctors did not.

There was a stark contrast between the business of the ward, and the comfort of being home. Being invited into people's homes and meeting their significant other (often their animals), was a privilege. Ex-patients were much more relaxed in answering the questions posed to them, and were able to give richer and deeper accounts of their experiences. At this time, relatives, if present, contributed also. In this way, the research was less 'cold', and guaranteed no missing answers. Some patients particularly found retelling the memory stories useful and were relieved by

hearing that others had experienced strange dreams and memories. Of particular note was the individual differences in personality types and locus of control. I really did enjoy this aspect of the study.

1.5 Ethical considerations and role difficulties

I was very aware that in conducting the study – particularly the playing of ICU sounds and measuring skin conductance levels and spontaneous fluctuation rates that I was exposing patients to a potentially traumatic experience. It was important to consider the potential impact this could have on individuals and to ensure that their psychological safety was protected. Measures had to be put in place to offer support if needed at the time, and to refer on if necessary.

Of the participants I did visit at home, several caused me significant concern, not only because of their scores on the questionnaires, but because I was aware that none of them had psychological support in the community. One lady needed nursing support, and one gentleman had developed intractable hiccups that were so bad he was unable to eat as they made him vomit. I was able to use my clinical judgment to see beyond the cut-off scores of assessment tools (HADS, PTSS) and provide immediate support if needed, while being aware that this would change the dynamic of the relationship. At the time of the study there was no ICU follow up clinic. Fortunately no acute events occurred during my assessments. The NICE PTSD clinical guideline (number 26) stated that for initial screening and recognition of PTSD, healthcare practitioners should question patients in a sensitive manner and should consider asking specific questions about symptoms such as flashbacks, nightmares and hyperarousal. This was possible in the patient's home, incorporating the PTSS-14 screening tool in a semi-structured interview.

1.6 *Analysis and write-up*

I had mixed feelings about the process of data analysis. Before analysis could begin, the skin resistance data had to be transformed to skin conductance data. This took an inordinately long time to work out, and many discussions, manipulations, re-manipulations and eventually tears, before we agreed on how to convert the data to produce a variable determined mainly by psychological factors. This part of the process was one of the most frustrating.

Statistical analysis of the data was by far the most anxiety provoking aspect of the project. I began this journey with strong feelings of excitement, determination, and trepidation. I had not studied at university since 2004 so getting back into statistics was very difficult, not helped by the fact that SPSS has changed astronomically since then. I am also 11 years older and processing takes considerably longer. It took a while, and investment in Andy Field's (2009) textbook to get me through. My relationship with my computer has become almost symbiotic over the past year, at the expense of my family and my waistline.

The usable sample was dramatically reduced because more than half of the skin conductance readings were unreliable. This has been the most disappointing part of the research and one that could have been avoided. It resulted in a very underpowered study and increased the risk of Type II errors. There were insufficient numbers to justify multiple regression analyses. Frequent research supervision helped me to answer the hypotheses in the best way possible. The hypotheses were not supported, however trends approaching significance were found in correlations which, had there been a larger usable sample, may have been significant. This is very exciting because it hints towards something about psychopathological processes underlying these symptoms. The findings have raised more questions for investigation regarding the impact of sedative drugs on implicit and explicit memory.

Research supervision resulted in small changes that caused me to revisit many sections of the thesis. Too many words resulted in the painful decision to remove the qualitative component of a mainly quantitative dataset. Although rudimentary analysis was performed, the diaries provided rich and real experiences of participant's journey, and will be written up at some stage. Delay in write up has highlighted that some of my literature is old and that more studies of psychological morbidity have been produced with exciting developments in the field from a psychological perspective. Fortunately, the newer literature supports some of my own conclusions and it is unfortunate that at the current time my work is not available for others to read. I am also disappointed that the results are non-significant and that a wealth of data has not been used in the thesis.

1.7 *Conclusion*

Working full time and conducting this level of research has been phenomenally demanding and at times unforgiving. I have not always enjoyed the process but have learned a tremendous amount about the mechanics of intensive care, individual differences in risk and resilience, and the advantages and disadvantages of being an external member of an internal research team. There was a paradox where, as a nurse I understood the workings of ICU and the focus on keeping a body alive but as a psychologist I was acutely aware of the lack of a psychological context in which people were treated and cared for. The impact of such work on staff is phenomenal and burnout is quite common amongst this staff group. There is a role for psychologists in intra-ICU education and support, as well as in follow up assessments for people when back in the community. I found the study difficult, not because of the content, but because of the difficulties in accessing the university due to distance, and consequent lack of presence at important networking and educational events. Again, Blackboard has proved invaluable. Whilst not statistically significant my results contribute to the knowledge base of ICU care and to the unit where the study took place.

I have asked myself what I would do differently if I were to do this study all over again, and can say with sincerity, that I would do the study again, but I would do all of the data collection myself, and would move closer to the university and site of research. I would also attend lectures on advanced statistics as this would help with the efficiency of the analyses and write up. The skin conductance program was loaded onto a desktop computer that needed to be taken from house to house. It was old, heavy to carry, took time to set up, and invaded a person's home. Newer programs can be loaded onto laptops which are portable, less threatening, and potentially easier to use. Similarly, a more carefully thought out response to negative reactions to the sounds is required, so that people who need support receive it quickly. Ethically and morally I would have needed to swop hats had the need arisen.

On a personal level I have learned much about myself. I am capable of conducting and writing up research to doctoral level. I can commit and focus and get the job done. Supervision has helped enormously, particularly in these final weeks when

the end was in sight. In some respects the end is actually the beginning. I believe I have developed transferable skills that will be implemented in the future. I have been offered a place on a Masters in Clinical Neuropsychology degree to start later this year, and am already contemplating a thesis related to implicit memory. With that in mind, my experience of the research has been a memorable one.

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Part Four

Service Evaluation

Evaluation of a community tenancy based on a model of Emotional Development: A systematic case study

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Executive summary

The goal of learning disability services is to support an individual in achieving as good a quality of life as possible. Therefore, providing an individualised needs-based service within the context of an effective organisational infrastructure is vital. Interventions based on psychological principles have the strongest empirical support in understanding what challenging behaviour is communicating. Encompassing this, a Researcher developed a framework for the assessment of arrested emotional development to help contextualise challenging behaviour, and inform therapeutic interventions.

This study is an evaluation of a single person's community tenancy based on the Researcher's model. The intervention is the package of care, and the evaluation involved analysing staff ratings of a tenant's mood. Analysis of eight years of mood charts indicated an overall negative trend in the frequency and severity of challenging behaviour, and positive trends in play and tactile behaviours, suggesting some emotional development in the tenant's ability to tolerate distress. Review of medication records indicated significant reductions in prescribed antipsychotic medication, and elimination of all 'as required' drugs that were used to manage significant distress. It is difficult to distinguish between variables or to dismiss the influence of history and maturation effects, however the results are promising.

Recommendations

1. The approach should be continued in supporting the tenant.
2. The database is maintained with new observations added to the series to permit further analysis over time.
3. Descriptors used in mood charts should be operationally defined and extended to include self-injurious behaviours.
4. Goals and goal statements should be developed that describe the tenant's outcomes, rather than staff activity.
5. Application and evaluation of the model in other environments should be considered.

Introduction

Historically, people with intellectual disabilities and challenging behaviour[1] have been segregated from the community, and the focus of any intervention was on the elimination or physical containment of their behaviour, with minimal understanding of its cause and its meaning (Mansell, 2007). With a change in *zeitgeist*, people with such disabilities have been acknowledged as having the same rights and choices as people without them (Carnaby, Roberts, Lang, & Nielsen, 2010). Consequently, institutions have been closed in favour of care in the community, and there has been a greater focus on understanding the meaning and function of the behaviour, and in providing interventions to help manage it based on this understanding (Allen et al., 2005; Berry, 2003; British Psychological Society (BPS), 2004; Chung, 1997).

In preference to restrictive practices such as physical and chemical restraint (Bubb, 2014; Felce, Perry, Lowe, & Jones, 2011; McKenzie, 2011; Sturmey, 2009), positive behavioural support in the least restrictive setting, has taken the behavioural model forward to provide individualised and more comprehensive specialised packages of care for individuals displaying such difficulties (Felce, et al., 2011; McClean, Grey, & McCracken, 2007; NICE, 2014; Ravoux, Baker, & Brown, 2011). Integrating approaches provides a more sophisticated understanding of the behaviour, and allows the uniqueness and complexity of the individual to be captured (Rhodes et al., 2011; Sheehy & Nind, 2005; Whittington & Burns, 2005).

All staff working with this client group should be trained to deliver proactive strategies to reduce the risk of behaviour that challenges, and have access to professional advice to support the implementation of such interventions (Campbell, 2007; NICE, 2014; Perry, Felce, Allen, & Meek, 2011). It is important too, for services to attend to staffs' emotional reactions to the demands of this work, in order to reduce the risk of them burning out, and/or from working in ways

[1] Definition of challenging behaviour as being "of such intensity, frequency or duration as to threaten the quality of life and/or the physical safety of the individual or others, and likely to lead to responses that are restrictive, aversive or result in exclusion" Royal College of Psychiatrists (RCP), British Psychological Society (BPS), and Royal College of Speech and Language Therapists (RCSLT), 2007).

that could exacerbate their clients' challenging behaviour (Bubb, 2014; McKenzie et al., 2009; Whittington & Burns, 2005), and/or cause their clients physical and emotional harm (e.g. Winterbourne view, 2012). Assessment of need, as well as evaluation of interventions, is vital in keeping the individual in mind.

Direct observation is an essential component of challenging behaviour assessment (NICE, 2014), and currently provides the most accurate way of measuring the activity of service users who are unable to speak authoritatively for themselves (Hewson, 1991; Hewson & Walker, 1992). In applied behaviour analysis, repeated observations are used both to formulate and evaluate interventions. As such, they are a useful tool in service monitoring (Lawlor & York, 2007), and also allow for data to be explored using simple graphical techniques (Morley & Adams, 1989).

Observations can also be used to assess emotional development level. In her work with people with severe intellectual disabilities, the Researcher recognised the same type of behaviours previously described by Mahler and colleagues (Mahler, Bergman, & Pine, 1975), when referring to phases of emotional development in children (Differentiation, Practising, Early and Late Rapprochement). The Researcher concluded that the individuals in her client group were emotionally developmentally delayed. She asserted that emotional development happened within the context of attachment, and that it was important to provide a substitute emotionally nurturing environment to enable development to occur. Over time, the Researcher developed an observation tool that provided important information to assist in the planning of an intervention, in providing a therapeutic environment in which emotional development could occur, and in measuring change over time (Researcher, date). In order to facilitate and maintain it, support staff need introductory training in disability psychotherapy, and to be provided with regular psychology consultancy.

The following systematic case study evaluates one application of the Researcher's model in developing a package of care for an individual who, because of the complexity of his/her presentation, was very difficult to place during the local deinstitutionalisation process.

Method

As a means of judging her/his service, the evaluation involved an intervention which is the package of care. It involved the retrospective, visual analysis of the totality of his/her daily records since s/he was moved to the current residence in 2005, using a process recommended by Baer (1977, cited in Morley & Adams, 1991) to describe time series data. Archived monthly documentation spanning eight years of the tenancy served as the intervention data. As a purely paper review exercise, ethical approval was not required, however in the interest of protecting both the tenant's and stakeholder privacy, all identifying information has been removed.

Background

The tenant is a middle aged person with a severe learning disability, autism, and extremely challenging behaviour following an abusive early childhood. S/he was fostered and later transferred to a secure hospital where he/she lived for more than ten years. At times his/her behaviour was extreme, necessitating five people to physically restrain her/him. S/he was prescribed high doses of antipsychotic medication.

The tenancy was set up to reflect best practice in using ordinary housing to support people in the community. It involved a bungalow that was adapted to meet the tenant's specific needs in an environment that was less confrontational. There was room for other tenants if it became possible and acceptable to him/her. A 'safe room'[2] was provided as the least restrictive option to restraint for when the tension got too great. If levels of distress escalated s/he would be directed, first verbally, and then by escort if necessary, where he/she would be safe to de-escalate with visual and auditory contact with support staff. The room had a stable-style door, so that when closed s/he was still able to see out, participate, interact, and observe. CCTV was fitted in all rooms except the bedroom and bathroom.

[2] A time-out space where s/he could withdraw when the tension was too great. It was furnished only with padded benches and mats for him/her to sit or lie on, and had no stimulation provided.

To continue with the staff ratio of his/her previous address, the house was initially staffed by support workers on a ratio of 3:1, and a Registered Manager. This was able to be reduced to 1:1 with back up, and 1:1 at night, in 2012. Staff were responsible for supervising all the care, domestic and catering activities, and the general running of the house.

The staff team were provided with training and consultation sessions to assist them to provide care appropriate to the tenant's level of emotional development, which was assessed approximately yearly by the psychologist. They were also provided with a more general training about disability psychotherapy in order to give them a broader understanding of the model. This involved an introduction to psychoanalytical theories, emotional development, attachment theory, and psychodynamic perspectives. This enabled the team to provide a secure base for the tenant, with the knowledge of his/her particular emotional developmental needs, and of how best to support her/him with this understanding in mind. Staff support groups and individual psychotherapy for the tenant, occurred weekly.

Measures

Mood Charts

Support staff were required to rate the tenant's mood every ten minutes of every waking hour, every day. Table 1 lists the descriptors used to rate his/her mood.

Table 1
Description of Codes Recorded on Mood Chart

Code	Description	Example
AS	Assault Staff	Will lash out at staff with his/her hands or clothes. Incudes biting others, pulling hair, throwing objects.
TO	Time Out	Sits at the end of the corridor, with or without her/his toys
OS	Own Space	Takes self out of view either to her/his lounge or safe room, usually with toys. This use of the safe room is his/her choice and is not as a result of being unsettled and unable to calm.
T	Tactile	Will request tactile contact with staff by making eye contact and saying "Aww". Includes cuddles & massages.
C	Crying	Cries or attempts to cry. Puts fingers in ears & makes a mooing noise to make him/herself cry, but tears are not always visible.
SR	Safe Room	Monitored only when s/he accesses the safe room during an incident. Can be verbally prompted or escorted by staff. Sometimes takes him/herself distressed, before staff request her/him to go.
US	Unsettled	Grumbling at staff, snatching items from staff, lashing out over the door either with clothes or hands, banging him/herself against the door frame, screaming, kicking the door, pulling own hair or biting own hand, putting hand down throat and drawing blood. Flooding the bathroom. Throwing her/himself on to the floor. Biting own arms.
P	Play	Includes hand games with staff or others e.g. high/low fives, grabbing thumbs & touching thumbs. S/he will often laugh.
VI	Interaction	Initiates social interaction with others and responds to interaction by others. Can be by vocalizing as well as moving her/his head, making facial expressions and/or clapping that he/she wants the person to copy.
IF	Incident Free	Standing at the stable door to the kitchen or in the garden. Is usually playing with her/his toys or other items or using repetitive hand movements and is happy to entertain self. Does not want direct interaction at this time, but is calm.

Procedure

The evaluation measured the tenancy (the intervention), from 2005 when it began, to 2012. No comparable pre-intervention data were available, therefore the first year of the tenancy was used as a baseline for measurement of change over time. The intervention was measured by staff rating her/his mood using predefined codes and recording it on a mood chart every 10 minutes of every waking hour of every day of the tenancy.

The data from the mood charts were entered into an Excel database. The frequency of each mood was summed for each day, month, and year. Indices of challenging behaviour, such as staff assault and use of the safe room were examined, as well as more subtle measures of the tenant's mood, for example the frequency of play, crying, and tactile behaviours, to present a balanced view. Visual as well as numerical inspections were completed, using simple statistical tests for exploring single-case time series data as recommended by Morley and Adams (1989, 1991).

Data plots were calculated to aid in the description of the series. Investigation of a trend in median using the split middle method was drawn on to each plot. As there was substantial variability, the time series was then smoothed using running medians of 3 (RM3), and the plots recalculated. Finally, the Records Test was calculated as recommended by Foster and Stuart (1954, as cited in Morley & Adams, 1989), to test against trend, and change in variance. Plots were recalculated to show the results. The following pages present the findings.

Results

Moods

As a precursor to interpreting the results two things need to be borne in mind. In 2008 two new people moved in. This caused significant unrest for the tenant for many months as s/he adjusted to sharing his/her space. S/he was unhappy, and as a consequence the frequency of unsettled behaviour and assaults upon staff increased, and his/her willingness to play decreased. S/he became physically unwell during 2011, following self-injurious behaviour and needed to be admitted to hospital. Once home, district nurses visited every day for several weeks in order to redress his/her wounds. This too impacted upon her/his mood as reflected in the following charts.

Play

Figure 1 presents the total number of ten-minute intervals each year that the tenant engaged in play. A trend line was fitted using the split middle method. As

shown, her/his ability to engage in activity for enjoyment and recreation varied. The overall pattern has shown an increase, but this is not uniform, or unusual.

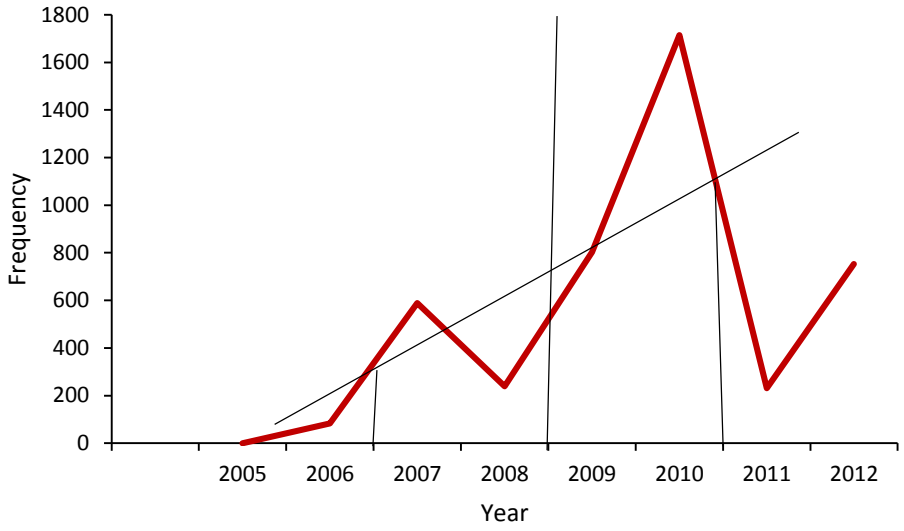

Figure 1. Frequency of play behaviour with split middle calculations added

A trend in median was calculated using running medians of 3 as shown in Table 2 and displayed in Figure 2.

Table 2
Frequency of Play 2005 to 2012 Calculated Using Running Medians of 3

	Time							
Year	1 (2005)	2 (2006)	3 (2007)	4 (2008)	5 (2009)	6 (2010)	7 (2011)	8 (2012)
Data	0	83	589	239	803	1714	231	753
R*M3*	*0*	83	239	589	803	803	753	*753*

Note: 1st and 8th figures in R*M3* are not a median

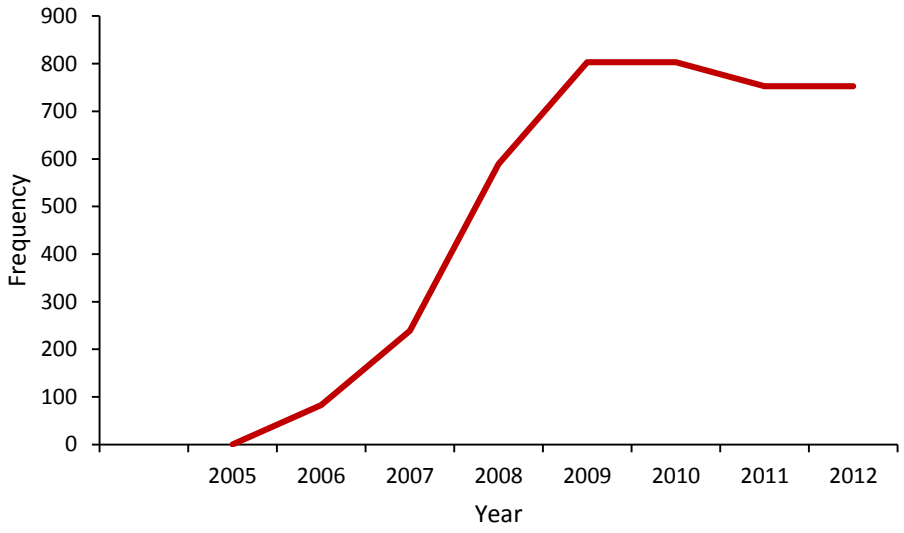

Figure 2. Frequency of play behaviour using RM3

Note: 1st and 8th figures in R*M3* are not a median

Smoothing the data revealed a continued rise in the tenant's level of engagement in activities for enjoyment and recreation. It also suggests a plateau. This is despite his/her obvious and continued distress when her/his neighbours moved in.

The records test (RT) was applied to test against trend and change in the variance, in order to extract any underlying pattern. The test is constructed to calculate the exact probability of a sequence of events occurring for a given set of data points. Beginning with the second point in the series, the upper and lower records are scored. For an upper record (Ur) to occur the point must be the largest so far in the series. For a lower record (Lr) the point must be the smallest. The total of upper records and lower records is summed to form the test statistic '*s*' (variance), and differenced to form '*d*' (trend). If the series has a positive trend there will be relatively more Ur than Lr and *d* will be positive. Likewise, *d* will be negative with a negative trend. The distribution therefore has two symmetrical halves and provides a test against trend in the mean. Table 3 presents the results.

Table 3
Records Test (RT) Against Trend and Change in the Variance in Play

Year	1 (2005)	2 (2006)	3 (2007)	4 (2008)	5 (2009)	6 (2010)	7 (2011)	8 (2012)
Data	0	83	589	239	803	1714	231	753
RT	0	83	589*	239	803*	1714*	231	753

Note: * = Upper record, _ = Lower record

Morley and Adams (1989) apply the formula $1 - (d/SE^d)$ to calculate trend. Using *z*-tables to calculate the area above the curve, a small, non-significant positive trend was found, $p = .14$. Thus, whilst there was an increase in frequency over the first four years, it plateaued over the remaining time of the study. Play could be a solitary activity or one that s/he engaged in with staff. Although play was measured as an independent descriptor, other recorded moods had elements of play within them (see Table 1), therefore the descriptor is not precise.

The exact probabilities of *s* for a series length of 8 is $p = .47$, indicating a non-significant change in the variance.

Differences in response to tactile stimuli are prevalent in people with autism. Figure 3 presents the frequency of tactile behaviour. Visual inspection of the chart shows a steady reduction from the baseline in 2005, to a significant increase over the year in 2010 followed by a significant decrease which then falls back to a position below that of the original measurements. The split middle method calculation suggests a positive linear trend, however, extreme scores were obvious.

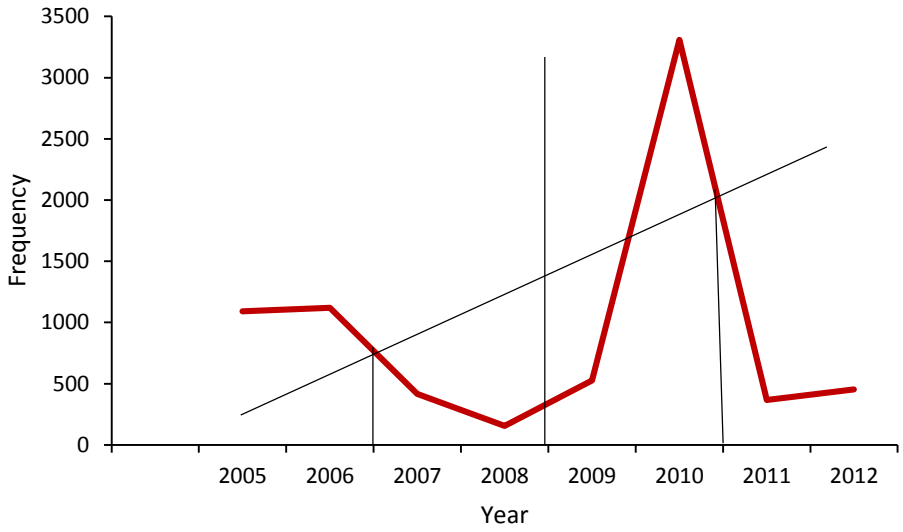

Figure 3. Frequency of tactile behaviour with split middle calculations added

Running medians of 3 were calculated to smooth the data as shown in Table 3 and presented in Figure 4.

Table 4
Frequency of Tactile Behaviours 2005 to 2012 Using Running Medians of 3

	Time							
Year	1 (2005)	2 (2006)	3 (2007)	4 (2008)	5 (2009)	6 (2010)	7 (2011)	8 (2012)
Data	1091	1121	416	156	526	3310	368	453
R*M3*	*1091*	1091	416	416	526	526	453	*453*

Note: 1st and 8th figures in R*M3* are not a median

Figure 4. Frequency of tactile behaviour using running medians of 3

Note: 1st and 8th figures in R*M3* are not a median

Figure 4 shows a sharp decrease in tactile behaviour over the year in 2007, with only a relatively slight increase in 2009 which was maintained for the rest of the evaluation period. The Records test was applied to measure trend and change in variance, as shown in Table 5.

Table 5
Records test (RT) Against Trend and Change in the Variance in Tactile Behaviour

Year	1 (2005)	2 (2006)	3 (2007)	4 (2008)	5 (2009)	6 (2010)	7 (2011)	8 (2012)
Data	1091	1121	416	156	526	3310	368	453
RT	1091	1121*	416	156	526	3310*	368	453

A positive, non-significant trend (p = .3) was found in the frequency of tactile behaviour. Similarly, a non-significant change in the variance was demonstrated, p = .79.

Crying behaviours showed a relatively similar pattern over the time period, as shown in Figure 5. As can be seen, the split middle calculation does not adequately describe the variability in frequency of crying and suggests an increase over time.

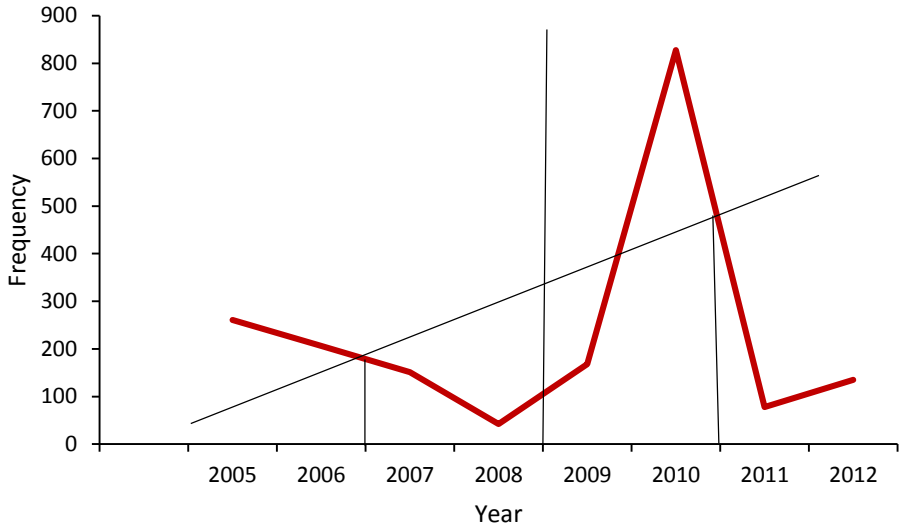

Figure 5. Frequency of crying with split middle calculations added

Running medians of 3 were calculated to smooth and data and reduce the influence of outliers as shown in Table 6.

Table 6
Frequency of Crying 2005 to 2012 Calculated Using Running Medians of 3

	Time							
Year	1 (2005)	2 (2006)	3 (2007)	4 (2008)	5 (2009)	6 (2010)	7 (2011)	8 (2012)
Data	261	206	151	42	168	828	78	135
R*M3*	*261*	206	151	151	168	168	135	*135*

Note: 1st and 8th figures in R*M3* are not a median

The results were then plotted on a chart as shown in Figure 6. This confirms an initial reduction in crying that stabilises over a five year period. It does not suggest an increase over time.

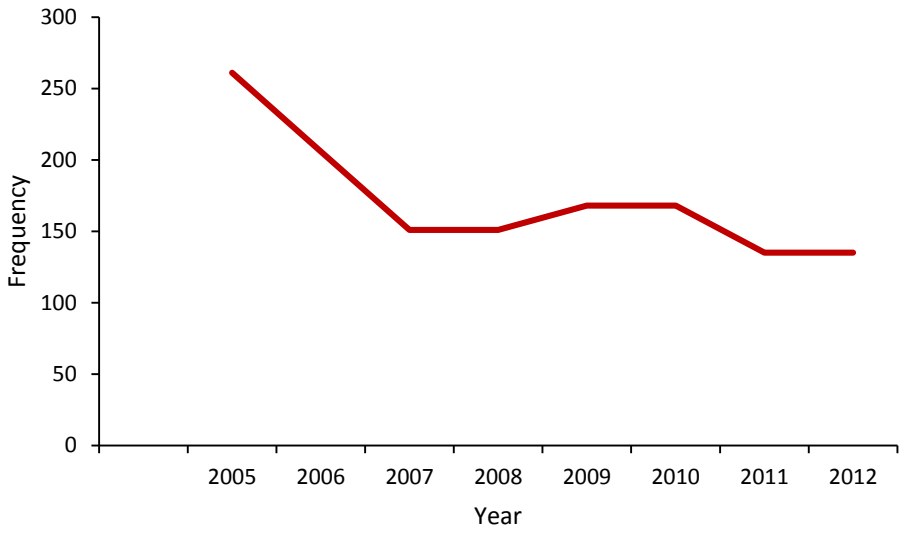

Figure 6. Frequency of crying using running medians of 3

Note: 1st and 8th figures in R*M3* are not a median

The records test was then applied as shown in Table 7.

Table 7
Records test (RT) Against Trend and Change in the Variance in Crying

Year	1 (2005)	2 (2006)	3 (2007)	4 (2008)	5 (2009)	6 (2010)	7 (2011)	8 (2012)
Data	261	206	151	42	168	828	78	135
RT	261	206	151	42	168	828*	78	135

Note: * = Upper record, _ = Lower record

In contrast to the split middle method, the records test showed a reduction in the frequency of crying behaviour. Although the trend was negative, it did not reach statistical significance $p = .71$. Similarly, the variance was not significant, $p = .79$.

Commissioners agreed the construction of a safe room as the least restrictive option to restraint. Visual inspection of the raw data shows significant increases in its use in 2009 and 2010, and then a dramatic reduction in 2011.

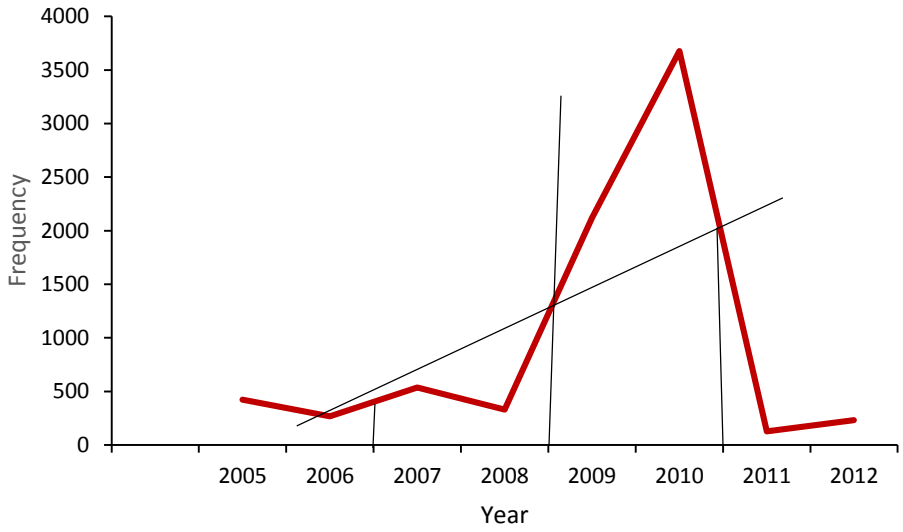

Figure 7. Frequency of safe room use with split middle calculations added

Split middle calculations suggest a positive trend in frequency of use of the safe room. However, the extremes in frequency distort the overall picture. Running medians of 3 were therefore calculated (see Table 8) to smooth the data, and plotted as shown in Figure 8.

Table 8.
Frequency of Use of the Safe Room 2005 to 2012 Using Running Medians of 3

	Time							
Year	1 (2005)	2 (2006)	3 (2007)	4 (2008)	5 (2009)	6 (2010)	7 (2011)	8 (2012)
Data	421	267	537	331	2121	3677	126	231
R*M3*	*421*	421	331	537	2121	2121	231	*231*

Note: 1st and 8th figures in R*M3* are not a median

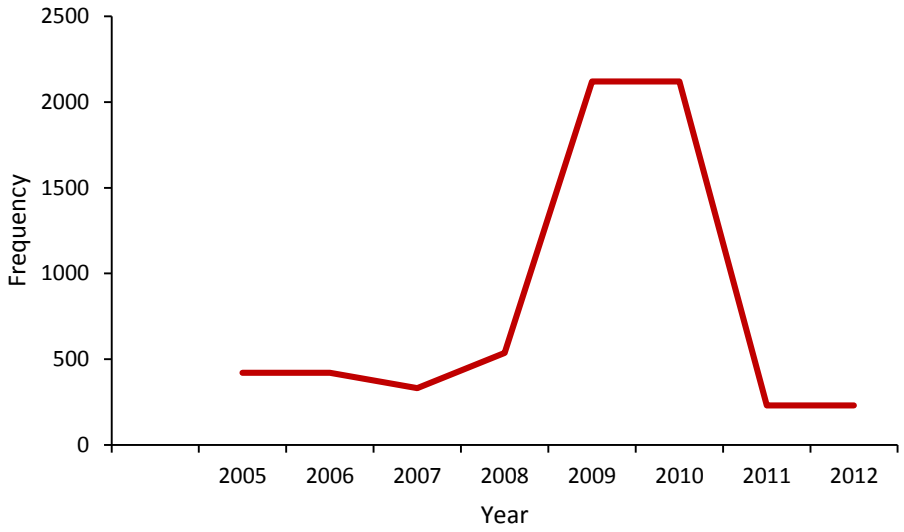

Figure 8. Frequency of safe room use using RM3

Note: 1st and 8th figures in R*M3* are not a median

Although the smoothed data suggests increased use between 2008 and 2010, its use actually decreased overall, over time (see Table 9).

Table 9
Records test (RT) Against Trend and Change in the Variance in Safe Room Use

Year	1 (2005)	2 (2006)	3 (2007)	4 (2008)	5 (2009)	6 (2010)	7 (2011)	8 (2012)
Data	421	267	537	331	2121	3677	126	231
RT	421	267	537*	331	2121*	3677*	126	231

Note: * = Upper record, _ = Lower record

There was a non-significant change in variance, p =.47, and a positive, non-significant trend in use of the safe room, p = .14. Following on from this, the frequency of assaults on staff were examined as displayed in Figure 9.

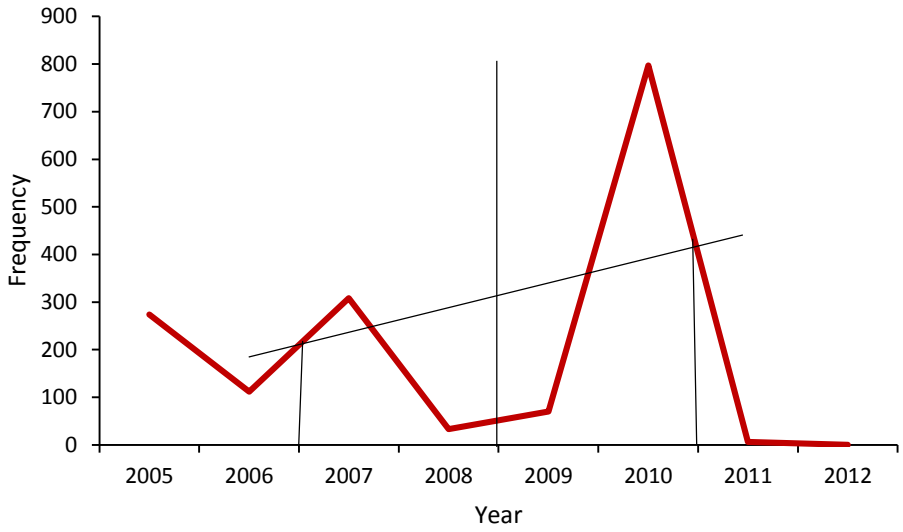

Figure 9. Frequency of staff assaults with split middle calculations added

Figure 9 indicates considerable variability in number of staff assaults over time. This is a volatile picture, where peaks and troughs disguise an overall downward movement. This was explained as his/her reaction to two new tenants moving in, and a trip to hospital. S/he returned to less than baseline once he/she had settled again.

Due to the variability in the data, running medians of three (RM3) were calculated, and used to smooth the data as shown in Table 10. The results were then re-graphed as shown in Figure 10.

Table 10
Yearly Totals of Assaults Using Running Medians of Three

	Time							
Year	1 (2005)	2 (2006)	3 (2007)	4 (2008)	5 (2009)	6 (2010)	7 (2011)	8 (2012)
Data	274	112	308	33	70	797	6	0
R*M3*	*274*	274	112	70	70	70	6	*0*

Note: 1st and 8th figures in R*M3* are not a median

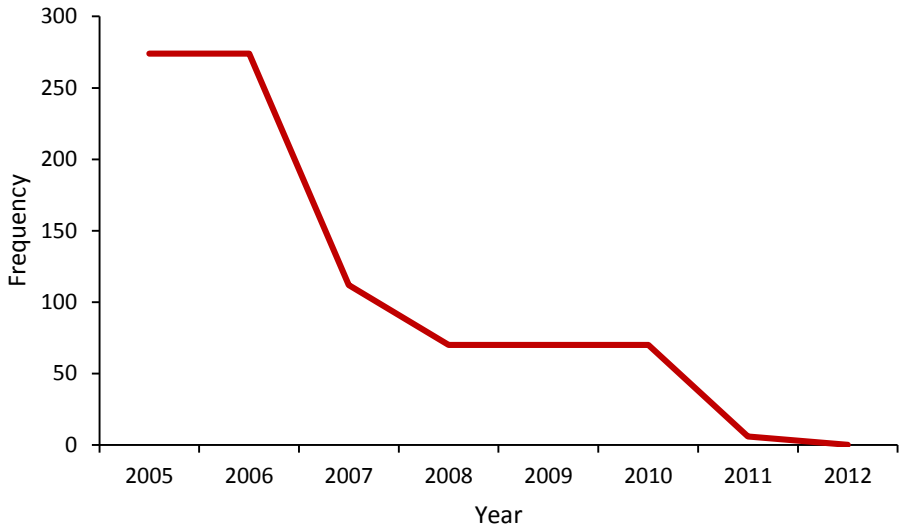

Figure 10. Number of assaults per year using a running median of 3 (RM3).

Note: 1st and 8th figures in R*M3* are not a median

Figure 10 indicates a steady decrease in number of assaults over time. The Records Test was then applied to measure variance and trend in the data as shown in Table 11.

Table 11
Records test (RT) Against Trend and Change in the Variance in Assaults to Staff

Year	1 (2005)	2 (2006)	3 (2007)	4 (2008)	5 (2009)	6 (2010)	7 (2011)	8 (2012)
Data	274	112	308	33	70	797	6	0
RT	274	112	308*	33	70	797*	6	0

Note: * = Upper record, _ = Lower record

A negative, non-significant trend was seen in the frequency of assaults on staff, p = .3. However, there was significant change in variance, p = .04.

A reliable indicator of a reduction in challenging behaviour is a reduction in anti-psychotic medication. Examination of medication charts indicated gradual changes and reductions in prescribed drugs over time.

Discussion

This service evaluation presents the graphical analysis and statistical exploration of single case, time-series data, of a community tenancy provided for a middle-aged person with autism, severe learning disabilities, and challenging behaviour. The intervention evaluated was the Researcher Model of Emotional Development, upon which the tenancy was developed. As such there is no comparable data. 2005, the year the tenancy began, served as the baseline. The evaluation ended at the end of 2012.

User activity patterns have been widely studied in research on British learning disability services, and in routine service monitoring. The data can be easily collated and updated as new observations are added to the series (Morley & Adams, 1989). In this way, reformulation of the needs of an individual and consequently the service, can be easily identified.

Analysis of mood charts completed every ten minutes of every waking hour of every day throughout the whole of the tenancy so far, showed trends in the decreasing frequency of staff assaults and increased frequency of play. The frequency of crying had also lessened. However, use of the safe room was not clearly defined, and the tenant began to voluntarily go there, often before requested to by staff, and sometimes even when not distressed.

A marker of a reduction in challenging behaviour is a reduction in antipsychotic medication (Ahmed et al., 2000). There had been reductions in regular doses of, and elimination of all, 'as required', antipsychotic medications. With the exception of two significant events, the number of assaults decreased over the time period. Similarly, although the staff team was constant, there were reductions in the number of staff on shift to support the tenant at any one time (McKenzie et al., 2009). These findings were supported by the observational assessment that he/she had emotionally developed.

It is difficult to describe eight years of data succinctly. People with autism spectrum disorders experience life-long difficulties with communication, social

interaction, and repetitive interests, and behaviours, and find change difficult. Emotional development happens within the context of attachment, and it is important to provide a substitute emotionally nurturing environment that is stable over time. In this case, the environment provided the secure base, and it is this that has been evaluated. Development has occurred. As yearly totals were presented, it is possible that random fluctuations within and over the months have not been reflected. It is unclear if the profiles presented represent an optimum, or if the tenant has yet reached her/his emotional developmental potential.

The coding sheets were completed every ten minutes of every waking hour. However, there was no measure of internal consistency in the descriptors of the tool, and it is possible that there was misallocation of codes to ambiguous descriptors some of the time. The reliability of the coding and code chosen, as well as in data entry, cannot be confirmed.

Some may argue that, at least on paper, there was a continuation of task-oriented institutionalised practices in the form of the documentation completed every day, without any justification for doing so. Staff contact and interaction were not recorded, only behaviour, and this was loosely defined as mood. This needs refinement, and descriptions of codes need to be operationally defined, to avoid ambiguity.

Conclusion

It is concluded that it was the environment that facilitated emotional development and ability to tolerate distress over time. However, the 'treatment' was the package of care that was delivered, and it is therefore difficult to attribute an effect to one intervention, at any one time, particularly as the change was gradual. It is also impossible to dismiss the possibility that the changes were due to normal developmental processes operating within the tenant as a function of time. Similarly, there were many extraneous variables occurring throughout the time of the evaluation that may have influenced the outcome. Notwithstanding, the results are promising, and represent a new and exciting proof-of-principle for future work. It is not clear if the tenant has reached his/her emotional

developmental potential, and only continued work with her/him, holding these ideas in mind, will substantiate this.

Recommendations

The approach should be continued in supporting this person. The database should be maintained, with new observations added to the series to permit further analysis over time. To avoid ambiguity, the mood codes need to be operationally defined, and extended to include self-injurious behaviours, and independent use of safe room when not distressed. Goals and goal statements should be developed that describe the tenant's outcomes, rather than staff activity. Staff contact and interaction with the tenant could be recorded alongside his/her behaviour. It may also be useful to measure the moods of the staff in conjunction with those of the tenant, to explore relationships and levels of staff stress. Review of the need for the medicalised and task-oriented paperwork completed on a daily basis is strongly recommended. Finally, larger scale studies of the model in practice are required to add to this and earlier research.

Critical Appraisal

The strengths of the study included the in-depth analysis of the package of care for an individual, holding the individual in mind. The process involved the creation of a database to add new data to. It took a considerable amount of time to find, read, and collate the information, and to establish the database. The findings were presented (see Appendix A) to the senior management team, who acknowledged, that at least on paper, there was a continuation of institutionalised practices. The findings were initially not well received, with the main stakeholders unable to tolerate what was intended to be a constructive piece of work. On a positive note, the tenancy continued, with the tenant at the centre, and reformulation of her/his needs and objectives was planned.

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Part Five

Appendices

Literature Review Appendices

Appendix A

The Standard Appraisal Questions (Crombie, 1996)

Are the aims clearly stated?

Was the sample size justified?

Are the measurements likely to be valid and reliable?

Are the statistical methods described?

Did untoward events occur during the study?

Were the basic data adequately described?

Do the numbers add up?

Was the statistical significance assessed?

What do the main findings mean?

Are important effects overlooked?

How do the results compare with previous reports?

Appendix B

Appraising Review Papers (Crombie, 1996**)**

How were the papers identified?

How was the quality of papers assessed?

Is the topic well defined?

Are the statistical methods described?

Were the detailed study designs reviewed?

Was missing information sought?

Were the basic data adequately described?

Was publication bias taken into account?

Was heterogeneity of effect investigated?

What do the main findings mean?

Are there other findings which merit attention?

Are the conclusions justified?

How do the findings compare with previous reports?

Appendix C

Data Extraction Form (Jones, 2007).

Article Number	Review Date	
Title:		
Author(s):	Publication Date:	
Journal:		
Volume:	Number:	Pages:
Keywords/definitions:		
Aims/design/method:		
Sampling/participants/analysis		
Controls/reliability/validity/conclusions:		
Notes:		

Appendix D

CEBM 2 pages

2nd page CEBM

Appendix E

Epistemological stance of the researcher in performing the review and empirical study

I entered the research process wanting to find out as much as I could about psychological distress following ICU treatment. I read extensively, focusing on prevalence rates, and the enormity of the problem. Arguably, it was reductionist in its approach. At first I was sceptical of the concept of post-ICU PTSD, questioning if the DSM-IV criteria were over inclusive. Then I questioned the validity of using cut-off scores to agree that a patient was or was not experiencing significant distress when, upon talking and interviewing them, a much richer and real description of their experience was shared. Discourse shapes reality and is shaped by it.

Experts in critical illness refer to ICU as the 'disease' responsible for the psychological distress that some patients feel, however from a critical realist epistemological stance, this viewpoint is too narrow and reductionist. It does not affect every patient who is admitted to ICU. Nor is it contagious. As representations of what is real, it is the mental processing as a result of altered perceptions, sensations and cognitions from illness and sedative medications, as well as individual differences in experiencing them that creates distress in some people. The ICU PTSD literature confirms that our senses deceive us. It is the meaning of the event that is important.

Research Report Appendices

Appendix A

DSM-IV Diagnostic Criteria 309.81 Posttraumatic Stress Disorder

A. The person has been exposed to a traumatic event in which both of the following were present:

(1) The person experienced, witnessed, or was confronted with an even or events that involved actual or threatened death or serious injury, or a threat to the physical integrity of self or others.
(2) The person's response involved intense fear, helplessness, or horror.

B. The traumatic event is persistently re-experienced in one or more of the following ways:

(1) Recurrent and intrusive distressing recollections of the event, including images, thoughts, or perceptions.
(2) Recurrent distressing dreams of the event.
(3) Acting or feeling as if the traumatic event were recurring (includes a sense of reliving the experience, illusions, hallucinations, and dissociative flashback episodes, including those that occur on awakening or when intoxicated).
(4) Intense or psychological distress at exposure to internal or external cues that symbolize or resemble an aspect of the traumatic event.
(5) Physiological reactivity on exposure to internal or external cues that symbolize or resemble an aspect of the traumatic event.

C. Persistent avoidance of stimuli associated with the trauma and numbing of general responsiveness (not present before the trauma), as indicated by three (or more) of the following:

(1) Efforts to avoid thoughts, feelings, or conversations associated with the trauma.
(2) Efforts to avoid activities, places, or people that arouse recollections of the trauma.
(3) Inability to recall an important aspect of the trauma.
(4) Markedly diminished interest or participation in significant activities.
(5) Feeling of detachment or estrangement from others.
(6) Restricted range of affect (e.g. unable to have loving feelings).
(7) Sense of a foreshortened future (e.g. does not expect to have a career, marriage, children, or a normal life span).

D. Persistent symptoms of increased arousal (not present before the trauma), as indicated by two (or more) of the following:

(1) Difficulty falling or staying asleep.
(2) Irritability or outbursts of anger.
(3) Difficulty concentrating.
(4) Hypervigilance.
(5) Exaggerated startle response.

E. Duration of the disturbance (symptoms in Criteria B, C, and D) is more than 1 month.

F. The disturbance causes clinically significant distress or impairment in social, occupation, or other important areas of functioning.

Specify if: **Acute**: if duration of symptoms is less than 3 months
Chronic: if duration of symptoms is 3 months or more

Specify if: **With Delayed Onset**: if the onset of symptoms is at least 6 months after the stressor.

Appendix B

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NHS Trust

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Senior Lecturer: Dr Jonathan Thompson

University of Leicester

LETTER OF INVITATION TO PARTICIPATE IN A RESEARCH PROJECT (PATIENTS)

Study Title: **Implicit Memory and Psychological Disturbance in ICU**

NHS REC Number…08/H0403/148. R&D Number ……..

Patient Identifier …… Study Number 10649…

Chief Investigator:	Jonathan Thompson 0116-2585291
Clinical Collaborating Investigator:	Ms Liz Trubshaw Tel: 0116-2231639
Clinical Collaborating Investigator:	Professor Michael Wang 0116-2231639
Research Nurse	Sarah Bowrey Tel: 0116-2585291

We are undertaking a study aimed at finding out more about the factors which we think may contribute to some patients developing psychological disturbance such as anxiety or stress reactions following a period in the Intensive Care Unit (ICU), and the role of different types of memory that may or may not contribute to the development of these. You may be able to help us by participating in a research study.

If you think that you would be interested in taking part, we will give you an information sheet to read and will be available to explain any details. If you indicate you are willing to participate, we will then ask you to sign a consent form. Thank you in advance for considering participation in this study. If you have any questions about this research, the investigators will be more than happy to answer them. Their contact details are given below:

Miss. Liz Trubshaw, Clinical Collaborating Researcher &
Professor Michael Wang, Honorary Consultant Clinical Psychologist
Doctorate in Clinical Psychology
School of Psychology
University of Leicester
104 Regent Road
Leicester
Tel: 0116-223 1639

Dr. Jonathan Thompson,
Senior Lecturer & Honorary Consultant in Anaesthesia & Critical Care
& Mrs. Sarah Bowrey, Research Nurse,
Department of Anaesthesia, Critical Care & Pain Management,
Victoria Building,
Leicester Royal Infirmary.
LE1 5WW
Tel: 0116 258 5291

Appendix C

University Hospitals of Leicester NHS
NHS Trust

Directorate of Anaesthesia, Critical Care & Pain Management,
Leicester Royal Infirmary,
Leicester,
LE1 5WW.
Tel 0116 258 5291
Fax 0116 247 0141

Senior Lecturer: Dr Jonathan Thompson

University of Leicester

PATIENT INFORMATION SHEET

Study Title: **Implicit Memory and Psychological Disturbance in ICU**

NHS REC Number…….	R&D Number
Patient Identifier…08/H0403/148……	Study Number …10649
Chief Investigator:	Dr. Jonathan Thompson 0116-2585291
Clinical/Collaborating Investigators:	Sherley Tordoff Tel: 0116-2231639
	Professor Michael Wang 0116-2231639
	Elizabeth Trubshaw 0116-2231639
Research Nurse	Sarah Bowrey Tel: 0116-2585291

1. Study background and purpose

We are undertaking a study aimed at finding out more about the factors which we think may contribute to some patients developing psychological disturbances such as anxiety or stress reactions following a period in the Intensive Care Unit (ICU), and the role of different types of memory that may or may not contribute to these.

2. Why have you been invited to take part?

You have been invited to take part in this research study because you have been admitted been a patient on the ICU. Before you decide whether you want to give your consent to be included in this study, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear to you, or if you would like further information before making any decision. Please take time to decide whether or not you wish the patient to take part. Thank you very much for taking the time to read about our study so far.

3. What will happen to you if you agree to participate in the study?

The research would involve you reading this leaflet, considering the information, and then if you still wish to proceed, to sign a consent form. Demographic information would also be collected at this stage.

One to two weeks following discharge from ICU you will be asked some questions about your memory of ICU using a structured questionnaire and ICU memories diary. Your memory will also be assessed at this stage to ensure that you are well enough to continue in the study. At four-five weeks after discharge from the ICU you will be sent an appointment to meet with us at the University or you will be followed up at home if this is more convenient. At this appointment you will then be asked to complete a number of short questionnaires looking memory, general physical and psychological well-being, anxiety, depression and post-traumatic stress. We will also play recording of some common sounds and record your responses to this using a monitor which measures sweating on your hand. You will also be asked about any unusual dreams, nightmares, flashbacks or daydreams you may have experienced during and following the period in ICU. We hope that you will find this an interesting experience.
We would expect that this final appointment would take no longer than an hour.
Travel expenses will be reimbursed for this return visit. If it is very difficult for you to attend at the University, it is possible that one of us could visit you at home.

5. What will you do with the results from the study?

We will anonymise all the data collected from the patient and then analyse this along with the rest of the study data. Whilst patients will not be provided with their individual study results, the final analysis of data will be written up and the patient will receive a summary of these results. If however, your results indicate anything of concern, we would report this initially to the ICU consultant and if appropriate, refer you to an ICU follow-up clinic.

6. What will you do with my data?

Any data that is collected (e.g. test forms etc) will be anonymised immediately and will be given an identifier so that the study researchers will know who the data belongs to. Once it has been collected, analysed and, if necessary, used clinically to help anyone experiencing post-traumatic stress symptoms, it will be stored safely in a locked cabinet, in a locked room for 5 years in accordance with EC directives and professional guidelines. At the end of five years it will be destroyed by incineration.

7. Are there any risks?

Occasionally it may be that patients find some of the sounds they hear or the questions asked lead them to become upset. If this does happen it is highly unlikely that hearing either the sounds or us asking you questions is going to be the only situation in which this occurs. Should this occur during our research, the patient will either be reassured that such an occurrence is a normal event or in the case of extreme distress they will be referred to an ICU follow-up clinic where these problems can be treated by qualified staff.

8. What are the benefits to the patient?

Although there will be no direct individual benefit to the patient (as with most other kinds of research), what we do learn from these tests may help us to better identify and treat patients who experience psychological disturbance following ICU stay in the future. The patient will not benefit financially from participation in the study. By agreeing to take part in this study you agree that the researchers, the Leicester Royal Infirmary and the University of Leicester may report on the results of the research and disseminate these by writing articles to submit to academic journals and by presentations and posters at meetings, conferences and symposiums. Your name or any other personal identifiers will not appear on this information.

9. Will personal information about the patient be kept confidential?

The study has been designed in such a way that personal details such as name and address will be kept separate from the patient's medical notes and the results of the tests and questionnaires. All data provided to us will be coded using a unique code number before they are analysed. Only the above-named investigators involved in the study will have access to these codes. The research results will not be recorded in the patient's medical records. All information collected during the process of the research will be kept strictly confidential. No information about the patient which leaves the hospital will contain any identifiers (for example, name, date of birth and address) so that they are not identifiable. Individuals will not be informed of their results, although a summary sheet highlighting the overall findings of all of the research will be sent out to the patient on completion of the study. As a safety precaution, the patient's general practitioner will be informed in writing that the patient is taking part in our study, although we will not pass on any information gathered from the study to the GP. If, however, it became obvious to any of the researchers that the patient was in urgent need of medical intervention or had symptoms causing concern, we would contact your consultant and GP, but we would always try to discuss this with you before we did this.

10. What if new information becomes available?

If new information becomes available which has significant implications for the continuation of the study, the investigators will seek advice from the Regional Ethics Committees and Trust R&D Departments regarding further action.

11. What happens when the research study stops?

When the research study stops all patients and nearest relative/friends who have contributed to the study will receive communication relating to the summarised results but there will be no further contact from the investigators after this point and the study will cease to function.

12. Can I refuse to participate?

Yes, absolutely, it is your fundamental right to do so. It is up to you to consider the information we have provided to you and then decide whether or not you wish to be included in the study. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you do decide to consent you are free to withdraw at any time and without providing us with a reason and this will not affect your subsequent treatment.

Whether you decide to be included, decide to consent and then withdraw, or decide you do not wish to consent from the outset, whatever decision you make will not affect the standard of care you receive.

13. What if something goes wrong?

Our study does not involve any drug or treatment and is therefore very low risk. You will continue to receive the required amounts of care you need whether or not you provide consent for inclusion in this study. If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, you may have grounds for a legal action but you may have to pay for it. If you are not happy with any aspect of the study or the way the study is being conducted then feel free to make a complaint.

14. Can I be excluded from the study?

The patient may be excluded from the study if their study doctor feels it would be in their best interests.

15. Who is organising and funding the research?

The research is being jointly funded by Leicester Partnership NHS Trust, University of Leicester and Leicester Royal Infirmary.

16. Who has reviewed the study?

The study has been reviewed by two peer review panels at the Clinical Psychology Unit, University of Leicester, and the Patient Reference Group. The study has been reviewed and

approved by the Local Research and Ethics Committee (LREC) and the R&D Department for Leicester Royal Infirmary.

17. Additional information

If you do decide to give consent to participating in the study, your GP will be informed of this in writing. Other than this, your participation in the study is kept confidential. The only time the investigators would break this confidentiality will be in the case where it is indicated to them that the patient is at risk from themselves or others, or that others are at risk from the patient. In cases such as this, we would be required to inform relevant authorities. The only circumstances where we might be forced to abandon participation in the research would be if you were to become seriously ill and/or the research was likely to seriously jeopardise treatment, or if the participant exhibited physical or verbal aggression within the sessions.

Results from the study will be written up in:

●Academic Report form
●Poster Presentation
●Conference Presentation
●Academic Journal Submission

Participants will not be identified from any of the data presented in any of the above. Some quotations may be extracted from the ICU Memories interview, but these will be presented in a way which does not identify anyone.

Thank you in advance for considering taking part in this study. If you have any questions about this research, the study staff will be more than happy to answer them. Their contact details are given below:

Dr Jonathan Thompson
Chief Investigator

Sherley Tordoff
Trainee Clinical Psychologist & Clinical Collaborating Investigator

Elizabeth Trubshaw
Clinical Collaborating Investigator

Prof Michael Wang
Professor of Clinical Psychology, Honorary Consultant Clinical Psychologist & Clinical Collaborating Investigator

Sarah Bowrey
Research Nurse

Appendix D

University Hospitals of Leicester NHS
NHS Trust

Directorate of Anaesthesia, Critical Care & Pain Management,
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Tel 0116 258 5291
Fax 0116 247 0141

Senior Lecturer: Dr Jonathan Thompson

University of Leicester

CONSENT FORM FOR PATIENT (Following ICU)

Study Title: **Implicit Memory and Psychological Disturbance in ICU**
NHS REC Number…08/0403/148. R&D Number 10649

Patient Identifier……	Study Number ……
Chief Investigator:	Dr. Jonathan Thompson 0116-2585291
Clinical/Collaborating Investigators:	Sherley Tordoff Tel: 0116-2231639
	Elizabeth Trubshaw 0116-2231639
	Professor Michael Wang 0116-2231639
Research Nurse	Sarah Bowrey Tel: 0116-2585291

Please initial box

1. I confirm that I have read and understood the information sheet dated 21st May 2010 (Version 2) for the above-mentioned study. ☐

2. I confirm that I have had the opportunity to ask questions about the study. ☐

3. I confirm that any questions that I might have in relation to the study have been answered to my satisfaction. ☐

4. I agree to the researchers holding the research data anonymised ☐

5. I understand that any records will be stored securely on NHS premises whilst in use and for 5years before being destroyed by incineration ☐

6. I understand that any data/quotes used will be anonymous and will not identify me. ☐

7. I understand that quotations from the thematic analysis of ICU memories diary and free recall of ICU memories will be analysed and used in the write up of the research but these will not identify me in any way. ☐

8. I give permission for my data to be used in relation to the following:

Sedation levels ☐

Levels of consciousness ☐

Demographic details
(eg. age, gender, type of illness/injury) ☐

☐

Memories of ICU

Anxiety & Depression ☐

PTSD ☐

Social Support ☐

ICU Memories since leaving hospital ☐

Responses to sounds ☐

Cognitive state ☐

General Health ☐

9. I understand that although I will not be given details of my individual results from the study, but that I will receive a summary of research results after the report has been written. ☐

10. I understand that my participation is voluntary, that I am free to refuse to answer any questions/participate in any tests/tasks I do not wish to and that I can withdraw my consent from the research at any time without having to state a reason, and without my current or future medical care and legal rights being affected. ☐

11. I understand that travel expenses for the 4/5 week return visit will be Reimbursed. ☐

12. I give permission for my data to be analysed in order to produce the final report from the study. ☐

| --- | --- | --- |
| Name of patient | Signature | Date |

Name of person taking consent (if different from investigator)	Signature	Date
Investigator	Signature	Date
Witness	Signature	Date

Appendix E

University Hospitals of Leicester NHS
NHS Trust

Directorate of Anaesthesia, Critical Care & Pain Management,
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Tel 0116 258 5291
Fax 0116 247 0141

Senior Lecturer: Dr Jonathan Thompson

University of Leicester

CONSENT FORM FOR CONTROL GROUP

Study Title: **Implicit Memory and Psychological Disturbance in ICU**
NHS REC Number…08/0403/148…. R&D Number 10649

Patient Identifier…… Study Number ……

Chief Investigator:	Dr. Jonathan Thompson 0116-2585291
Clinical/Collaborating Investigators:	Sherley Tordoff Tel: 0116-2231639
	Elizabeth Trubshaw Tel: 0116-2231639
	& Professor Michael Wang 0116-2231639
Research Nurse	Sarah Bowrey Tel: 0116-2585291

Please initial box

1.	I confirm that I have read and understood the information sheet dated 5th November,2008 (Version 2) for the above-mentioned study.	
2.	I confirm that I have had the opportunity to ask questions about the Study.	
3.	I confirm that any questions that I might have in relation to the study have been answered to my satisfaction.	
4.	I agree to the researchers holding the data, anonymised.	
5.	I understand that any records will be stored securely on NHS premises whilst in use and for 5 years before being destroyed by incineration.	
6.	I understand that any data/quotes used will be anonymous and will not identify me.	
7.	I understand that quotations from the thematic analysis of ICU memories diary and free recall of ICU memories will be analysed and used in the write up of the research but these will not identify me in any way	N/A
8.	I give permission for my data to be used in relation to the following:	
	Sedation levels	N/A
	Levels of consciousness	N/A

Demographic details (eg. age/gender)	N/A
Memories of ICU	N/A
Anxiety & Depression	N/A
PTSD	N/A
Social Support	N/A
ICU Memories since hospital	N/A
Responses to sounds	N/A
Cognitive state	N/A
General physical and emotional well Being	N/A

9. I understand that although I will not be given details of my individual results from the study, but that I will receive a summary of research results after the report has been written. ☐

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

11.	I understand that travel expenses for the 4/5 week return visit will be Reimbursed.	N/A
12.	I give permission for my data to be analysed in order to produce the final report from the study.	

---	---	---
Name	Signature	Date
---	---	---
Name of person taking consent (if different from investigator)	Signature	Date
---	---	---
Investigator	Signature	Date
---	---	---
Witness	Signature	Date

THE APACHE II SEVERITY OF DISEASE CLASSIFICATION SYSTEM

PHYSIOLOGIC VARIABLE	High Abnormal Range						Low Abnormal Range		
	+4	+3	+2	+1	0	+1	+2	+3	+4
TEMPERATURE – rectal (º c)	○ ≥41º	○ 39º-40.9 º		○ 38.5 º-38.9 º	○ 36º-38.4 º	○ 34º-35.9 º	○ 32º-33.9 º	○ 30º-31.9 º	○ ≤29.9
MEAN ARTERIAL PRESSURE – mm Hg	○ ≥160	○ 130-159	○ 110-129		○ 70-109		○ 50-69		○ ≤49
HEART RATE (ventricular response)	○ ≥180	○ 140-179	○ 110-139		○ 70-109		○ 55-69	○ 40-54	○ ≤39
RESPIRATORY RATE – (non-ventilated or ventilated)	○ ≥50	○ 35-49		○ 25-34	○ 12-24	○ 10-11	○ 6.9		○ ≤5
OXYGENATION:A-aDO$_2$ or Pa0$_2$ (mm Hg) a. F10$_{2\geq 0.5}$ record A-aDO$_2$	○ ≥500	○ 350-499	○ 200-349		○ <200				
b. FIO$_2$<0.5 record only PaO$_2$					○PO$_2$>70	○PO$_2$ 61-70		○ PO$_2$ 55-60	○ PO$_2$<55
ARTERIAL Ph	○ ≥7.7	○ 7.6-7.69		○ 7.5-7.59	○ 7.33-7.49		○ 7.25-7.32	○ 7.15-7.24	○ <7.15
SERUM SODIUM (Mmol/L)	○ ≥180	○ 160-179	○ 155-159	○ 150-154	○ 130-149		○ 120-129	111-119	○ ≤110
SERUM POTASSIUM (Mmol/L)	○ ≥7	○ 6-6.9		○ 5.5-5.9	○ 3.5-5.4	○ 3-3.4	○ 2.5-2.9		○ <2.5
SERUM CREATININE (mg/100ml) (Double-point score for acute renal failure)	○ ≥3.5	○ 2-3.4	○ 1.5-1.9		○ 0.6-1.4		○ <0.6		
HEMATOCRIT(%)	○ ≥60		○ 50-59.9	○ 46-49.9	○ 30-45.9		○ 20-29.9		○ <20
WHITE BLOOD COUNT (total/mm3)	○ ≥40		○ 20-39.9	○ 15-19.9	○ 3-14.9		○ 1-2.9		○ <1
GLASGOW COMA SCORE (GCS) Score = 15 minus actual GCS									
A Total ACUTE PHYSIOLOGY SCORE (APS): Sum of the 12 individual variable points									
Serum HCO$_2$ (venous-mMol/L) (Not preferred, use if no ABGs)	○ ≥52	○ 41-51.9		○ 32-40.9	○ 22-31.9		○ 18-21.9	○ 15-17.9	○ <15

B: AGE POINTS
Assign points to age as follows:

AGE(yrs)	POINTS
≤ 44	0
45-54	2
55-64	3
65-74	5
≥ 75	6

C: CHRONIC HEALTH POINTS
If the patient has a history of severe organ system insufficiency or is immuno-compromised assign points as follows:
a. for nonoperative or emergency postoperative patients – 5 points
OR
b. for elective postoperative patients – 2 points
DEFINITIONS
Organ insufficiency or immunoc-

compromised state must have been evident prior to this hospital admission and conform to the following criteria:-
LIVER: Biopsy proven cirrhosis and documented portal hyupertension; episodes of past upper GI bleeding attributed to portal hypertension; or prior episodes of hepatic failure/encephalopathy/coma.
CARDIOVASCULAR: New York Heart Association Class IV.

RESPIRATORY: Chronic restrictive, obstructive, or vascular disease resulting in severe exercise restriction i.e. unable to climb stairs or perform household duties; or documented chronic hypoxia, hypercapnia, secondary polycythemia, severa pulmonary hypertension (>40mmHg), or respiratory dependency.
RENAL: Receiving chronic dialysis
IMMUNOCOMPROMISED: The patient has received therapy that

Suppresses resistance to infection, e.g., immuno-suppression, chemotherapy, radiation, long term or recent high dose steroids, or has a disease that is sufficiently advanced to suppress resistance to infection, e.g. leukaemia, lymphoma, AIDS.

APACHE II SCORE
Sum of A + B + C
A APS points……
B Age points ……..
C Chronic health points …….
Total APACHE II ……

Appendix G

ICU Memory Tool (ICUMT)

(Please circle the appropriate answer)

1. Do you remember being admitted to hospital?
Clearly/Hazily/Not at all

2. Can you remember the time in hospital before you were admitted to Intensive care?
All of it/Some of it/Nothing

3. Do you remember being in intensive care?
Yes/No

4.a) Do you remember all the stay clearly?
Yes/No

4.b) What do you remember? *(circle those things you remember)*

*Family** *Alarms** *Voices** *Lights** *Faces** *Breathing Tube**

*Suctioning** *Being uncomfortable*† *Darkness** *Clock**

*Tube in your nose** *Ward round** *Feeling confused*† *Feeling down*†

Feeling anxious/frightened† *Feeling that people were trying to hurt you*‡

Hallucinations‡ *Nightmares*‡ *Dreams*‡ *Panic*† *Pain*†

4.c) If you had any feelings that someone was trying to hurt or harm you While you were in intensive care can you please describe these Feelings below:

……

……

……

Score for subscales:

*score of 0, 1 added to give number of factual memories

†score of 0,1 totalled to give number of memories of feelings

‡score of 0.1 totalled to give number of delusional memories + score of 1 for mention of nurse or doctor trying to kill the patient in description 4c.
(please circle the appropriate answer)

4d. If you had nightmares or hallucinations while you were in intensive care could you please describe these:

……

……

……

5. Do you remember being transferred from intensive care to the general wards?

Clearly/ Hazily/ Not at all

6. Have you had any unexplained feelings of panic or apprehension?

Yes/ No

6a. *If yes:* **What were you doing when these feelings happened?**

……..

7. Have you had any intrusive memories from your time in hospital or of the event that lead up to your admission?

Yes/ No

7a. *If yes:* **What were you doing when these intrusive memories happened?**

……..

7b. What did these memories consist of (e.g. tube in nose, or frightening Nightmares)?

……..

8. Have you talked about what happened to you in intensive care with:

A member of your family/ A nurse on the ward/ A friend/

A doctor on the ward/ Your family doctor

Appendix H

University Hospitals of Leicester NHS
NHS Trust

Directorate of Anaesthesia, Critical Care & Pain Management,
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Senior Lecturer: Dr Jonathan Thompson

University of Leicester

HAD Scale

ID Code: **Date:**

Doctors are aware that emotions play an important part in most illnesses. If your doctor knows about these feelings he will be able to help you more. This questionnaire is designed to help your doctor to know how you feel. Read each item and place a firm tick in the box opposite the reply which comes closest to how you have been feeling in the past week. Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought-out response.

Tick only one box in each section

I feel tense or "wound up":		**I feel as if I am slowed down:**	
Most of the time	☐	Nearly all of the time	☐
A lot of the time	☐	Very often	☐
Time to time, occasionally	☐	Sometimes	☐
Not at all	☐	Not at all	☐

I still enjoy the things I used to enjoy:		**I get a sort of frightened feeling like"butterflies"in the stomach:**	
Definitely as much	☐	Not at all	☐
Not quite as much	☐	Occasionally	☐
Only a little	☐	Quite often	☐
Hardly at all	☐	Very often	☐

I get a sort of frightened feeling as if something awful is about to happen:

Very definitely and quite badly ☐
Yes, but not too badly ☐
A little but it doesn't worry me ☐
Not at all ☐

I have lost interest in my appearance:

Definitely ☐
I don't take so much care as I should ☐
I may not take quite as Much care ☐
I take just as much care as ever ☐

I can laugh and see the funny side of things:

As much as I always could ☐
Not quite so much now ☐
Definitely not so much now ☐
Not at all ☐

I feel restless as if I have to be on the move:

Very much indeed ☐
Quite a lot ☐
Not very much ☐
Not at all ☐

Worrying thoughts go through my mind:

A great deal of the time ☐
A lot of the time ☐
From time to time but not too often ☐
Only occasionally ☐

I look forward with enjoyment to things:

As much as I ever did ☐
Rather less than I used to ☐
Definitely less than I used to ☐
Hardly at all ☐

I feel cheerful:

Not at all ☐
Not often ☐
Sometimes ☐
Most of the time ☐

I get sudden feelings of panic:

Very often indeed ☐
Quite often ☐
Not very often ☐
Not at all ☐

I can sit at ease and feel relaxed:

Definitely ☐
Usually ☐
Not often ☐
Not at all ☐

I can enjoy a good book or radio or TV programme:

Often ☐
Sometimes ☐
Not often ☐
Very seldom ☐

Appendix I

UK-PTSS-14

Presently (this means in the past few days) I suffer from:

		(never)							(always)
1.	Sleep problems	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**
2.	Nightmares	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**
3.	Depression, I feel dejected/downtrodden	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**
4.	Jumpiness, I am easily frightened by sudden sounds or sudden movements	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**
5.	The need to withdraw from others	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**
6.	Irritability, that is, I am easily agitated/annoyed and angry	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**
7.	Frequent mood swings	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**
8.	A bad conscience, blame myself, have guilt feelings	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**
9.	Fear of places and situations which remind me of the intensive care unit	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**
10.	Muscular tension	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**
11.	Upsetting, unwanted thoughts or images of my time on the intensive care unit	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**
12.	Feeling numb (e.g. cannot cry, unable to have loving feelings)	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**
13.	Avoid places, people, or situations that remind me of the intensive care unit	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**
14.	Feeling as if my plans or dreams for the future will not come true	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**

Appendix J

Substantial amendment 1

Appendix K

University Hospitals of Leicester NHS
NHS Trust

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Leicester,
LE1 5WW.
Tel 0116 258 5291
Fax 0116 247 0141

Senior Lecturer: Dr Jonathan Thompson

University of Leicester

Implicit Memory and Psychological Disturbance in ICU Study

Skin Conductance Responses Recording Form

Patient Identifier No: …… **Tape:**……

Sound Order	Skin Conductance Responses	Comments/Notes

Appendix L

British Journal of Clinical Psychology (BJCP)

Notes for contributors to Target Journal

Notes for Contributors
The **British Journal of Clinical Psychology** publishes original contributions to scientific knowledge in clinical psychology. This includes descriptive comparisons, as well as studies of the assessment, aetiology and treatment of people with a wide range of psychological problems in all age groups and settings. The level of analysis of studies ranges from biological influences on individual behaviour through to studies of psychological interventions and treatments on individuals, dyads, families and groups, to investigations of the relationships between explicitly social and psychological levels of analysis.

The following types of paper are invited:
Papers reporting original empirical investigations
Theoretical papers, provided that these are sufficiently related to the empirical data
Review articles which need not be exhaustive but which should give an interpretation of the state of the research in a given field and, where appropriate, identify its clinical implications
Brief reports and comments

1. Circulation
The circulation of the Journal is worldwide. Papers are invited and encouraged from authors throughout the world.

2. Length
Papers should normally be no more than 5000 words (excluding abstract, reference list, tables and figures), although the Editor retains discretion to publish papers beyond this length in cases where the clear and concise expression of the scientific content requires greater length.

3. Submission and reviewing
All manuscripts must be submitted via our online peer review system. The Journal operates a policy of anonymous peer review.

4. Manuscript requirements
Contributions must be typed in double spacing with wide margins. All sheets must be numbered.
Tables should be typed in double spacing, each on a separate page with a self-explanatory title. Tables should be comprehensible without reference to the text. They should be placed at the end of the manuscript with their approximate locations indicated in the text.
Figures can be included at the end of the document or attached as separate files, carefully labelled in initial capital/lower case lettering with symbols in a form consistent with text use. Unnecessary background patterns, lines and shading should be avoided.

Captions should be listed on a separate sheet. The resolution of digital images must be at least 300 dpi.

For articles containing original scientific research, a structured abstract of up to 250 words should be included with the headings: Objectives, Design, Methods, Results, Conclusions. Review articles should use these headings: Purpose, Methods, Results, Conclusions. Please see the document below for further details:

British Journal of Clinical Psychology - Structured Abstracts Information
For reference citations, please use APA style. Particular care should be taken to ensure that references are accurate and complete. Give all journal titles in full.
SI units must be used for all measurements, rounded off to practical values if appropriate, with the imperial equivalent in parentheses.
In normal circumstances, effect size should be incorporated.
Authors are requested to avoid the use of sexist language.
Authors are responsible for acquiring written permission to publish lengthy quotations, illustrations, etc. for which they do not own copyright.

For guidelines on editorial style, please consult the APA Publication Manual published by the American Psychological Association.

5. Brief reports and comments
These allow publication of research studies and theoretical, critical or review comments with an essential contribution to make. They should be limited to 2000 words, including references. The abstract should not exceed 120 words and should be structured under these headings: Objective, Method, Results, Conclusions. There should be no more than one table or figure, which should only be included if it conveys information more efficiently than the text. Title, author name and address are not included in the word limit.

6. Publication ethics
All submissions should follow the ethical submission guidelines outlined the the documents below:
Ethical Publishing Principles – A Guideline for Authors Code of Ethics and Conduct (2006)

7. Supplementary data
Supplementary data too extensive for publication may be deposited with the British Library Document Supply Centre. Such material includes numerical data, computer programs, fuller details of case studies and experimental techniques. The material should be submitted to the Editor together with the article, for simultaneous refereeing.

8. Copyright
On acceptance of a paper submitted to a journal, authors will be requested to sign an appropriate assignment of copyright form. To find out more, please see our Copyright Information for Authors.

Service Evaluation Appendix

CEBM
CENTRE FOR EVIDENCE BASED MEDICINE

UNIVERSITY OF OXFORD

Levels of Evidence (March 2009)

www.cebm.net

Level 1A	**Therapy/Prevention, Aetiology/Harm** **Prognosis** **Diagnosis** **Differential diag/symptom prevalence** **Economic and decision analyses**	1a SR (with homogeneity*)of RCTs SR (withhomogeneity*) of inception cohort studies; CDR† validated in different populations SR (with homogeneity*) of Level 1 diagnostic studies; CDR† with 1b studies from different clinical centres SR (with homogeneity*) of prospective cohort studies SR (with homogeneity*) of Level 1 economic studies
Level 1b	**Therapy/Prevention, Aetiology/Harm** **Prognosis** **Diagnosis** **Differential diag/symptom prevalence** **Economic and decision analyses**	Individual RCT (with narrow Confidence Interval‡) Individual inception cohort study with > 80% follow-up; CDR† validated in asingle population Validating** cohort study with good††† reference standards; or CDR† tested within one clinical centre Prospective cohort study with good follow-up**** Analysis based on clinically sensible costs or alternatives; systematic review(s) of the evidence; and including multi-way sensitivity analyses
Level 1c	**Therapy/Prevention, Aetiology/Harm** **Prognosis** **Diagnosis** **Differential diag/symptom prevalence** **Economic and decision analyses**	All or none§ All or none case series Absolute SpPins and SnNouts†† All or none case-series Absolute better-value or worse-value analyses ††††
Level 2a	**Therapy/Prevention, Aetiology/Harm** **Prognosis** **Diagnosis** **Differential diag/symptom prevalence** **Economic and decision analyses**	SR (with homogeneity*) of cohort studies SR (withhomogeneity*) of either retrospective cohort studies or untreated control groups in RCTs SR (with homogeneity*) of Level >2 diagnostic studies SR (with homogeneity*) of 2b and better studies SR (withhomogeneity*) of Level >2 economic studies
Level 2b	**Therapy/Prevention, Aetiology/Harm** **Prognosis** **Diagnosis** **Differential diag/symptom prevalence** **Economic and decision analyses**	Individual cohort study (including low quality RCT; e.g., <80% followup) Retrospective cohort study or follow-up of untreated control patients in an RCT; Derivation of CDR† or validated on split sample §§§ only Exploratory** cohort study with good††† reference standards; CDR† after derivation, or validated only on split-sample§§§ or databases Retrospective cohort study, or poor follow-up Analysis based on clinically sensible costs or alternatives; limited review(s) of the evidence, or single studies; and including multi-way sensitivity analyses
Level 2c	**Therapy/Prevention, Aetiology/Harm** **Prognosis** **Diagnosis** **Differential diag/symptom prevalence** **Economic and decision analyses**	"Outcomes" Research; Ecological studies "Outcomes" Research Ecological studies Audit or outcomes research
Level 3a	**Therapy/Prevention, Aetiology/Harm** **Prognosis** **Diagnosis** **Differential diag/symptom prevalence** **Economic and decision analyses**	SR (with homogeneity*) of case-control studies SR (with homogeneity*) of 3b and better studies SR (with homogeneity*) of 3b and better studies SR (with homogeneity*) of 3b And better studies
Level 3b	**Therapy/Prevention, Aetiology/Harm** **Prognosis** **Diagnosis** **Differential diag/symptom prevalence** **Economic and decision analyses**	Individual Case-Control Study Non-consecutive study; or without consistently applied reference standards Non-consecutive cohort study, or very limited population Analysis based on limited alternatives or costs, poor quality estimates of data, but including sensitivity analyses IIncorporatingclinically sensible variations.
Level 4	**Therapy/Prevention, Aetiology/Harm** **Prognosis** **Diagnosis** **Differential diag/symptom prevalence** **Economic and decision analyses**	Case-series (and poor quality cohort and casecontrol studies§§) Case-series (and poor quality prognostic cohort studies***) Case-control study, poor or nonindependent reference standard Case-series or superseded reference standards Analysis with no sensitivity analysis
Level 5	**Therapy/Prevention, Aetiology/Harm** **Prognosis** **Diagnosis** **Differential diag/symptom prevalence** **Economic and decision analyses**	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles" Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles" Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles" Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles" Expert opinion without explicit critical appraisal, or based on economic theory or "first principles"

Oxford Centre for Evidence-based Medicine Levels of Evidence (March 2009)
(for definitions of terms used see glossary at http://www.cebm.net/?o=1116)

Produced by Bob Phillips, Chris Ball, Dave Sackett, Doug Badenoch, Sharon Straus, Brian Haynes, Martin Dawes since November 1998. Updated by Jeremy Howick March 2009.

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NOTES

Users can add a minus-sign "-" to denote the level of that fails to provide a conclusive answer because:

EITHER a single result with a wide Confidence Interval

OR a Systematic Review with troublesome heterogeneity.

Such evidence is inconclusive, and therefore can only generate Grade D recommendations.

*	By homogeneity we mean a systematic review that is free of worrisome variations (heterogeneity) in the directions and degrees of results between individual studies. Not all systematic reviews with statistically significant heterogeneity need be worrisome, and not all worrisome heterogeneity need be statistically significant. As noted above, studies displaying worrisome heterogeneity should be tagged with a "-" at the end of their designated level.
†	Clinical Decision Rule. (These are algorithms or scoring systems that lead to a prognostic estimation or a diagnostic category.)
‡	See note above for advice on how to understand, rate and use trials or other studies with wide confidence intervals.
§	Met when all patients died before the Rx became available, but some now survive on it; or when some patients died before the Rx became available, but none now die on it.
§§	By poor quality cohort study we mean one that failed to clearly define comparison groups and/or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both exposed and nonexposed individuals and/or failed to identify or appropriately control known confounders and/or failed to carry out a sufficiently long and complete follow-up of patients. By poor quality case-control study we mean one that failed to clearly define comparison groups and/or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both cases and controls and/or failed to identify or appropriately control known confounders.
§§§	Split-sample validation is achieved by collecting all the information in a single tranche, then artificially dividing this into "derivation" and "validation" samples.
††	An "Absolute SpPin" is a diagnostic finding whose Specificity is so high that a Positive result rules-in the diagnosis. An "Absolute SnNout" is a diagnostic finding whose Sensitivity is so high that a Negative result rules out the diagnosis.
‡‡	Good, better, bad and worse refer to the comparisons between treatments in terms of their clinical risks and benefits.
†††	Good reference standards are independent of the test, and applied blindly or objectively to applied to all patients. Poor reference standards are haphazardly applied, but still independent of the test. Use of a non-independent reference standard (where the 'test' is included in the 'reference', or where the 'testing' affects the 'reference') implies a level 4 study.
††††	Better-value treatments are clearly as good but cheaper, or better at the same or reduced cost. Worse-value treatments are as good and more expensive, or worse and the equally or more expensive.
**	Validating studies test the quality of a specific diagnostic test, based on prior evidence. An exploratory study collects information and trawls the data (e.g. using a regression analysis) to find which factors are 'significant'.
***	By poor quality prognostic cohort study we mean one in which sampling was biased in favour of patients who already had the target outcome, or the measurement of outcomes was accomplished in <80% of study patients, or outcomes were determined in an unblinded, non-objective way, or there was no correction for confounding factors.
****	Good follow-up in a differential diagnosis study is >80%, with adequate time for alternative diagnoses to emerge (for example 1-6 months acute, 1 - 5 years chronic)

Grades of Recommendation

A	consistent level 1 studies
B	consistent level 2 or 3 studies or extrapolations from level 1 studies
C	level 4 studies or extrapolations from level 2 or 3 studies
D	level 5 evidence or troublingly inconsistent or inconclusive studies of any level

"Extrapolations" are where data is used in a situation that has potentially clinically important differences than the original study situation.

Oxford Centre for Evidence-based Medicine Levels of Evidence (March 2009)
(for definitions of terms used see glossary at http://www.cebm.net/?o=1116)

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12/06/2009

Dr Jonathan Thompson
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Leicester Royal Infirmary
LE1 5WW

Dear Dr Jonathan Thompson

Ref: UHL 10649
Title: Implicit memory and psychological disturbance in recovering intensive care unit patients
Project Status: Project Approved
End Date: 30/03/2010

Thank you for submitting documentation for Non-Substantial amendment for the above study.
I confirm that the amendment has the approval of the University Hospitals of Leicester NHS Trust R&D Department and may be implemented with immediate effect.

The documents received are as follows:

Document Name	Version Number	Date
CV, GCP & Consent Training for Liz Trubshaw		

Please be aware that any changes to these documents after approval may constitute an amendment. The process of approval for amendments should be followed. Failure to do so may invalidate the approval of the study at this trust.
Please ensure that all documentation and correspondence relating to this amendment are filed appropriately in the relevant site file.

Yours sincerely

Lisa Wann
R&D Team Leader

Slide 1

Psychological evaluation of the service provided to 'the tenant'
From March 2005 – end December 2012

Liz Trubshaw

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Slide 2

Scoping Preamble

- Service evaluation is undertaken to benefit those who use a particular service, and is designed and conducted solely to define or judge current service
- Participants are those who use the service or deliver it
- It involves an intervention where there is no change to the standard service being delivered
- Information gathered is constrained by the existing recording methods

2

Slide 3

Deinstitutionalisation & integration

What it is

- Living in an ordinary house in an ordinary street
- Being physically present in locations that are frequented by the general public
- Civil rights, independence, choice & inclusion

3

Slide 4

Deinstitutionalisation & integration

What it is not

- People who remain at home with their family
- Attend segregated schools or engage in sheltered employment
- Live in circumstances where they are mainly in the presence of other people with a similar disability
- Staff or family members are often the only non-disabled people in their proximity

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Slide 5

Background

Identifying information removed

5

Slide 6

XXXXX Care

- Statement of purpose: to provide a meaningful life
- Support provided since March 2005
- Single person's service. Staffed 24/7. Ratio 3:1
- Sensory room/quiet room/safe room/time-out space
  = least restrictive method
  – able to move freely around the house
- ½ stable door to kitchen
- CCTV except bedroom & bathroom
- Individual psychotherapy from clinical psychologist and disability psychotherapists
- Psychology consultancy to staff – support, debriefing, recommendations & training

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Slide 7

Daily paperwork

Identifying information removed

Slide 8

Psychology input

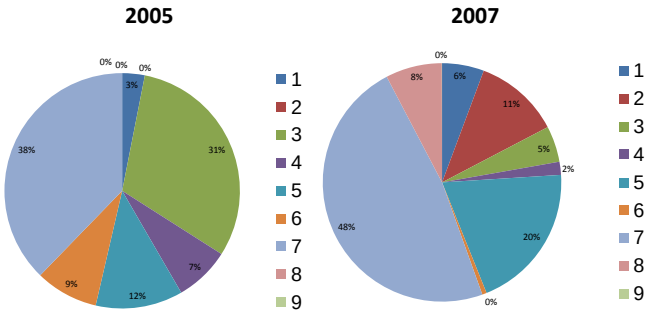
- Assessed as cognitive age of seven to eight
- Emotional level 1 year to 18 months
- Activities – 1 hour in the morning & 1 hour in the afternoon
- Selection of toys
- Transference discussed
- Having independence – more so at XXXXX
- Ability to tolerate

Slide 9

TO = Time Out
OS = Own Space
T = Tactile
C = Crying
SR = Safe Room
AS = Assault Staff
US = Unsettled Behaviour
P = Play
I = Interaction

Mood Charts

1 = TO, **2**=OS, **3**=T, **4**=C, **5**=SR, **6**=AS, **7**=US, **8**=P, **9**=I

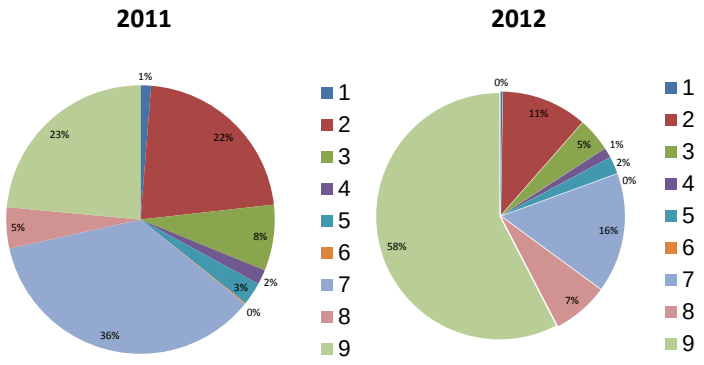


Slide 10

TO = Time Out
OS = Own Space
T = Tactile
C = Crying
SR = Safe Room
AS = Assault Staff
US = Unsettled Behaviour
P = Play
I = Interaction

Mood Charts continued

1 = TO, 2=OS, 3=T, 4=C, 5=SR, 6=AS, 7=US, 8=P, 9=I



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Slide 11

TO = Time Out
OS = Own Space
T = Tactile
C = Crying
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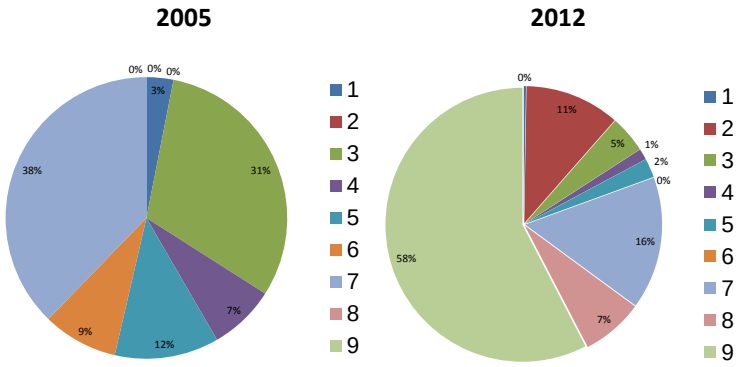
AS = Assault Staff
US = Unsettled Behaviour
P = Play
I = Interaction

Mood Charts continued

1=TO, **2**=OS, **3**=T, **4**=C, **5**=SR, **6**=AS, **7**=US, **8**=P, **9**=I



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Slide 12

Notes from Psychology reports

Identifying information removed

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Slide 13

Capable environment?

- A reduction in challenging behaviour constitutes only one aspect of a good quality service
- Staff must have the skills to help the individual to participate in enjoyable & meaningful activities within and outside the home (RCPsych, BPS, RCSLT, 2007)
- The capacity to promote meaningful activities is another

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Slide 14

Strong links & foundation for continuing

- Individual psychotherapy
- Staff support & education
- Building relationships of trust
- Emotional development over time – yearly assessment
  Tolerant of more people in her space
- Tolerated two other tenants moving in
- Able to be taken to hospital without the use of restraint (chemical and/or physical)
- Making choices – re safe room use, activities

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Slide 15

Staff training & support

Identifying information removed

15

Slide 16

Weak links - at least on paper……

- No written goals
- Not extending him/her
- Staff contact is not recorded (her/his behaviour is) – needs to be richer
- Incident Free implies negative behaviour (as recorded on mood chart)
- Physically integrated but not socially integrated in to the community (note s/he has not been out since 2001) – is this his/her choice?
- Staff are the only non-disabled people s/he sees
- Lives in circumstances where he/she is always in the presence of other people with a similar disability

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Slide 17

Ideas for strengthening the chain - Service improvement

- Is the staff skill mix suitable & the best it can be ?
- Assess levels of staff confidence, stress and turnover
- Conduct a functional analysis & follow up with staff positive behavioural support training
- Consider employing a psychology assistant on a long term basis to work with him/her & alongside support staff
- Rewording of Incident Free & re-look at mood chart categories
- Fill incident free time working towards goal attainment e.g. skills teaching & participation, as able
- Staff training Intensive Interaction
- Staff support to cover the emotional impact of working with people with challenging behaviour (e.g. self harm)

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Slide 18

Continued…

- Repeat Checklist of Challenging Behaviour
- Conduct a Periodic Service Review (PSR) (la Vigna et al. 1994)
- Expand to include other services within the organisation

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Slide 19

A mechanism for assessing & communicating the goal attainment of tenants from person centred planning can function as a link among organisational levels for evaluating performance. If used as one of several quality monitoring tools it can keep the tenant where s/he belongs – at the centre of the organisation processes, while supplying critical information to improve the health of organisations within the larger systems in which they reside.

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Slide 20

References

- Available upon request

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