

Individual Case Formulation for Post-Traumatic Stress Disorder:

A Single Case Series.

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Abstract

Little is known about the usefulness of Case Formulation (CF) to Cognitive Behavioural Therapy (CBT) practice and outcome despite its highly held esteem within Clinical Psychology. The aim of this study was to explore the use of a new approach to formulating, Hallam's (2013) Individual Case Formulation (ICF), as a potential mechanism for contributing to change in PTSD treatment using a single case experimental design (SCED). The study had two components: firstly, training on ICF to shed light on how skills in formulation are developed and secondly, use of ICFs during PTSD treatment of eight individuals. It was hypothesised that ICF workshop training could increase therapist formulation skill. It was also tentatively hypothesised that quality and complexity of ICFs might relate to outcome for people with PTSD and that other specific elements captured within the ICF might link to outcome and rate of improvement for people with PTSD. A secondary hypothesis that sharing a formulation during treatment could be associated with reducing symptoms was also investigated. Formulation diagrams were coded using a newly devised rating scale in order to identify potential elements within ICFs. Coding results from diagrams and patterns of outcome measures from the eight participants were explored at group and individual levels. Due to the small sample size and the observational nature of many of the analyses, results were interpreted with caution. Findings from the training indicated increased formulation quality, suggesting that formulation skill can be enhanced in therapists. Group and individual analysis offered initial, preliminary support for the idea that higher quality CFs might be associated with reduction in symptoms. Other specific items within CFs appeared to show some association with change in symptoms. It was difficult to adequately address the hypothesis regarding

complexity, as very little complexity was shown across the sample of diagrams. Initial support was found for the secondary hypothesis, with visual analysis suggesting that some participants demonstrated symptom change following the shared formulation, suggesting that change in symptoms was linked to this process. Potential implications of the findings and suggestions for future research are discussed.

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Introduction

Case Formulation (CF) is a core clinical component widely advocated for use within Clinical Psychology as a way of synthesising theory, research and individual experience to assist in the collaborative understanding of a person's presenting difficulties. CF has been described as the heart of evidence-based practice (Hartley, Jovanoska, Roberts, Burden & Berry, 2015; Kuyken, Fothergill, Musa, & Chadwick, 2005) viewed as an essential skill taught to mental health professionals as a way of expressing, understanding and communicating a variety of psychological problems.

Despite its high regard, little systematic research exists on evaluation of the components or processes of CF. There is a particular lack of research investigating the link between formulation and treatment outcome. Therefore, although CF is viewed as a highly important element of Cognitive Behavioural Therapy (CBT), it is poorly understood at an empirical level (Zivor, Salkovskis, & Oldfield, 2013).

With the national roll-out of CBT across mental health services, there is a danger that formulation-based CBT may not survive in the current climate of the "mass-production of trained therapists" (Zivor et al., 2013, p.2). With psychology services increasingly treating more complex individuals with co-morbidities (Goddard, Wingrove, & Moran, 2015), it is more important than ever to scientifically evaluate components of CBT such as CF, to determine the worth it can provide for effective psychological therapy and maintain and enhance recovery rates.

There is a move towards theory-driven idiosyncratic models for evidence-based individualised treatment that focus on commonalities between disorders rather than viewing difficulties as single entities to be treated separately (Batten & Hayes, 2005). Due to increased interest in individualised approaches, CF is gaining more

attention. Hallam (2013) promotes training and use of an Individual Case Formulation (ICF) to assist in the full understanding and targeting of symptoms. However, there remains little research investigating the use, process and components of ICF (Macneil, Hasty, Conus, & Berk, 2012; Tarrier, 2006), including Hallam's (2013) approach.

Hallam (2013) proposes that an ICF system is a useful way to identify components that predict symptom trajectory and could be useful for difficult to treat disorders. Outcomes for Post-Traumatic Stress Disorder (PTSD) are poorer than for other disorders (Kar, 2011). This may be due to complexity of the presentation (Foa, Keane & Friedman, 2000) and a number of factors that potentially require formulation for fuller understanding. The ICF approach is intended to promote better formulations that enable therapists to better formulate complexity, which could help to enhance recovery rates of PTSD to the extent that they are able to better direct treatment. There also continues to be uncertainty around the process of completing formulations including whether sharing a formulation with a client could act as a mechanism of change in CBT (Gladwin & Evangelini, 2013). Again, there is a lack of systematic research investigating sharing CFs within services where CBT is rolled out on a large scale (Kuyken, 2006). Investigation into this process could highlight an important contribution to facilitating change within therapy (Hallam, 2013).

This preliminary and exploratory study of formulation for PTSD tested a newly proposed approach to operationalising formulation and a new scale for evaluating expertise in formulation. Using a small case series, the aim of the study was to (1) determine how therapist formulation skill develops following ICF training, (2) determine whether overall quality or complexity of case formulations are related to outcome and rate of improvement in PTSD symptoms, (3) evaluate whether specific components within an ICF appear to be associated with outcome and rate of

improvement for people with PTSD and (4) examine whether the process of sharing a CF with a client during PTSD treatment can produce change. By focusing on these aims, it was hoped that a clearer picture of what makes a “good” formulation that can improve treatment would emerge.

Case Formulation

Case Formulation (CF) represents idiographic theory of an individual and their current functioning detailing descriptions of the main difficulties being experienced, information on the development of the problem, current situational triggers and maintaining factors that describe how components relate to each other (Hallam, 2013). CFs often detail cognitions, beliefs and behaviours (Hartley et al., 2015), connecting assessment and treatment phases of psychological therapy, identifying variables that can be targeted within interventions (Jose & Goldfried, 2008). CFs have been created from multiple theoretical perspectives including cognitive, behavioural, systemic, psychodynamic and humanistic approaches (Sturmey, 2010) and used for understanding a multitude of psychological problems for children, adults and older adults across individuals, couples and within families. Use of CF enables effective selection and guiding of treatment using evidence-based interventions that aim to reduce psychological distress and improve well-being (Hartley et al., 2015; Kuyken, Padesky & Dudley, 2008). Flinn, Braham, and Nair (2015) suggest that CF corresponds with a scientist-practitioner view using “psychological science to help solve human problems” (DCP, 2010, p.3).

Case conceptualisation is a skill held in high regard within psychological treatment and reflects the contribution that a good formulation can make to the success of therapy (Hallam, 2013).

Formulation vs diagnosis

Psychiatric diagnosis has traditionally been emphasised within Psychiatry with the implied benefits that it reliably guides intervention (Kendell & Jablensky, 2003; Macneil et al., 2012). Within research, diagnosis enables categorisation of people by disorders for clinical and randomised controlled trials (RCTs) enabling empirically supported disorder-specific treatments to be developed (Shafran et al., 2009).

However, Hallam (2013) claims that used alone, psychiatric diagnosis is not sufficient for explaining the causes of a difficulty or for capturing the personal experience of that difficulty. Within current psychiatric diagnostic systems that use lists of possible criteria, the same diagnosis could be given to two people who have no symptoms in common (Tarrier & Calam, 2002) suggesting diagnosis could poorly inform clinicians about the intervention to use (Kuyken, 2006).

Although diagnostic categories suggest intervention based on clinical trials, they do not help clinicians to predict suitability to treatment, likelihood of outcome or offer explanation for non-responsiveness to interventions. Sim, Gwee, and Bateman (2005) argue that clinicians must determine suitability for psychological intervention and suggest that understanding of a person gained through CF facilitates this, connecting “aetiology, description, theory, practice and science” (Sim et al., 2005, p. 289).

Despite acknowledging that diagnoses may be useful working concepts, Kendell and Jablensky (2003) argue that many are not valid since they are not discretely separate from other disorders. Recognition of the limitations of psychiatric diagnosis has contributed to the increased interest that CF has started to receive (Macneil et al., 2012).

CF can be used as a Clinical Psychologist's alternative to diagnosis (Bucci, French & Berry, 2016), deemed a viable substitute by the Division of Clinical Psychology (DCP, 2013). CFs offer shared understanding of individual presentations linking current and past experiences within a person's context (DCP, 2011), help determine factors that have influenced experiences and assume that, "at some level it all makes sense" (Butler, 1998, p.2). Furthermore, they have the potential to help determine the problems to prioritise, anticipate challenges that might arise and identify criteria necessary for successful outcome (Butler, 1998; Johnstone & Dallos, 2006). Importantly, CF can promote collaborative therapy, providing a shared rationale and agenda for intervention (Macneil et al., 2012) and if completed thoughtfully involving clients, has the potential to "provide considerably better outcomes than diagnosis alone" (Macneil et al., 2012, p. 3).

Conversely, describing difficulties within an illness model can reduce agency and service user (SU) self-efficacy to work towards recovery (Boyle, 2013) leading to discrimination (Lasalvia et al., 2013), reducing self-esteem and collaborative decision-making (Pasman, 2011). Diagnosis might ignore contextual links between mental health and experiences, beliefs and behaviours including cultural and social contexts (DCP, 2013) whereas a CF can include these factors, detailing formation and maintenance of difficulties (Hallam, 2013). The DCP (2013) argues that approaches that contextualise distress and behaviour and recognise complexity of interactions between psychological, social, historical and biological factors are preferable and are in accordance with core principles of formulation in Clinical Psychology. Developing a CF enables negotiation of a shared psychological perspective between SUs and clinicians, normalising problems and enhancing containment for clients and therapists, aspects that can be lost in psychiatric diagnosis (DCP, 2011).

Summary. Various etiological factors may predispose people to psychological morbidity and will differ in how each factor affects an individual (Macneil et al. 2012). Integrating this information into a CF that enables individual treatment planning could enhance effective care. Macneil et al. (2012) warn that failure to do so may not only result in reduced outcomes but might exacerbate a person's symptoms. Advocates of CF claim that case conceptualisation allows synthesis of research and individual experience, combining rich information and enabling thorough understanding in ways that diagnosis alone does not (Hallam, 2013; Sim et al., 2005).

The reality of CF in clinical practice: concerns

Despite strong proponents for use of formulation, the reality is that little is known about how CF is implemented within clinical practice. This is in contrast to the scrutiny of investigation that CBT has undergone and suggests a need for detailed investigation into the use of CF (Zivor et al., 2013).

Poor agreement often exists between cognitive therapists when theory driven inferences are made about a person's difficulties (Dudley, Park, James, & Dodgson, 2010; Mumma & Smith, 2001; Persons, Mooney & Padesky, 1995). Some of the concerning inconsistencies associated with CF might be in relation to therapist skill and expertise as well as the lack of systematic research linking formulation to treatment outcome, the nomothetic components of current formulation systems and the unknown validity of CFs.

Skill and expertise. Level of skill and knowledge in CF have long been considered to be essential components that contribute to therapist competence in CBT highlighting formulation skills as fundamental for effective therapy (Dobson & Shaw, 1993). CBT is broadly disseminated as part of the Improving Access to Psychological Therapies (IAPT) programme (Zivor et al., 2013), a national government initiative aiming to improve access to psychological therapy within the NHS. A report detailing the necessary activities for high quality and effective CBT within IAPT found that developing a CF is a key competency in enabling development of a treatment plan (Roth & Pilling, 2007). The importance of CF is further recognised within the Cognitive Therapy Scale – Revised (CTS-R; Blackburn et al., 2001) that measures clinician CBT skills and promotes the use of individual conceptualisation.

However, there is concern about whether formulation based CBT will survive with the high volume of therapists trained with varying levels of formulation skill and expertise, with particular concern regarding the level of CF skill in novice therapists (Kendjelic & Eells, 2007; Misch, 2000). One study compared CFs between novice, experienced and expert clinicians (Eells, Lombart, Kendjelic, Carolyn, & Lucas, 2005) and found that CFs created by expert clinicians were more comprehensive, elaborate, explanatory and complex compared to the other two groups. The authors found that expert knowledge, that novices lacked, predicted best CFs rather than experience. Indeed, other research has suggested that experience alone is not sufficient to develop expertise and instead teaching and repetition of formulation skills, reflection on formulations and feedback from other therapists appears essential (Feltovich, Prietula, & Ericsson, 2006). Within Eells et al. (2005) “expertise” was defined as those who had published formulation systems or led formulation workshops. There is unlikely to be this level of expertise across all clinicians treating

psychological disorders. However, perhaps if these expert skills can be identified, they could be taught to novice therapists to increase formulation ability. Without this, the therapists “on the ground” are likely to be left in an unsatisfactory position whereby formulation based CBT is encouraged and shown to be effective in clinical trials involving practitioners trained very differently from themselves (Zivor et al., 2013).

Dudley et al. (2010) investigated level of agreement across mental health clinicians with varying levels of skill, qualification and training. Formulations were collected from 82 clinicians following a video of a person displaying delusional psychotic beliefs. Formulations were compared to a “benchmark” formulation of the same case that was created by three expert therapists. Increased clinical experience improved agreement with the benchmark formulation and theory-driven components of formulations were increased in those with more CBT experience. Interestingly, increased experience of working with psychosis reduced the rate of agreement with the benchmark formulation. This study suggested that experience in CBT predicts formulation skills rather than knowledge of a specific area and is therefore contradictory to the findings of Eels et al. (2005). Experience of trainees has also been shown to predict ability to integrate information in complex case conceptualisation (Ladany, Marotta, & Muse-Burke, 2001).

Kuyken et al. (2005) rated formulations on reliability and quality across mental health practitioners with different experience. Clinicians provided a CF based on a case description, and reliability (inter-rater agreement) and agreement with an expert formulation were measured. Results indicated that for quality of CFs, 22.1% of formulations were deemed “very poor”, 33.6% as “poor”, 34.5% as “good enough”, 9.7% as “good”. Therefore overall 44.2% were rated as “good enough”. Levels of

agreement between clinicians and with the expert formulation were reduced when greater levels of theory driven inferences were made. The differences in reliability and quality of formulations were associated with prior experience and training. Increased number of years post-qualification experience and professional qualification were positively associated with levels of theory driven inferences and higher quality formulations. This study suggests that increased qualification increases CF quality and highlights that CF is a complex skill that requires teaching to enhance CF reliability and quality within clinical practice.

Synthesis of this research suggests that there are differences between therapists in CF skill and indicates that CF is a skill requiring practice, time, resource and commitment to develop with experience and training appearing to be necessary in predicting quality of CF. Brosan, Reynolds, and Moore (2008) found that many clinicians rate their CF skills unrealistically highly, further suggesting that it is essential that these skills continue to be measured, developed, tested and fostered within practitioners, to promote good quality care.

Case Formulation and treatment outcome. CFs are linked to reducing emotional distress (Hartley et al., 2015), increasing meaning, agency and hope (DCP, 201) and ensuring that SU voices are heard, promoting a collaborative therapeutic style (Johnstone, 2011). However, as Kuyken (2006) asserts, the “primary criterion whereby CF stands or falls is whether it directly or indirectly improves the process or outcome of CBT” (Kuyken, 2006, p. 24). Interestingly, despite being defined as “the lynch pin that holds theory and practice together” (Butler 1998, p. 2) and an underpinning principle of cognitive therapy (Beck 1995), research on the impact of CF on outcome is scarce (Macneil et al., 2012). Tarrier (2006) suggests that it is

possible that CF has found a place in practice ahead of any evidence for its proposed advantages. Despite this, it is a widely used tool in CBT often viewed as the “first principle” when planning treatment (Freeston et al., 2001; Morrison, 2002). It is therefore concerning that the role of CF has not been linked to outcome.

Some preliminary research suggests that intervention guided by CF can improve outcome. Silberschatz, Fretter, and Curtis (1986) conducted one of the only studies investigating the effect of CF on outcome. They hypothesised that use of a “patient plan” (dynamic CF) that enhances therapist understanding and guides intervention would increase progress in therapy. Using brief psychotherapy, they found that “plan-compatible interpretations” utilised in treatment were related to better outcomes than those with lower proportions of interpretations. In other words, when therapists used CFs to guide interpretations, this led to better treatment outcomes. Crits-Christoph, Cooper, and Luborsky (1988) also investigated if accuracy of therapist interpretations within psychodynamic psychotherapy would predict treatment outcome. They measured the use of CF that included therapist interpretation and found that increased accuracy of clinician interpretation was strongly related to treatment outcome, suggesting a link between quality of CF and outcome. Although promising, these studies have mostly been conducted in psychodynamic psychotherapy and the research by Silberschatz et al. (1986) was conducted with only three individuals. The studies are also out-dated and are less likely to be applicable to services that routinely implement CBT. Kuyken et al. (2005) emphasise the need for CF studies to extend to investigation of the link to therapy outcome within CBT.

Worryingly, other interventions guided by formulation have not shown to enhance treatment (Macneil et al. 2012). Emmelkamp, Bouman, and Blaauw (1994) found that individualised behavioural treatment was no more effective than

standardised treatment for people with OCD, with both approaches leading to significant reductions in symptoms. Schulte, Kunzel, Pepping, and Shulte-Bahrenberg (1992) compared individual treatment planning, standardised exposure therapy and a control group in people with phobias. Contrary to expectations, the standardised group was found to produce the most successful outcomes in both experienced and inexperienced therapists. This suggests superiority of manualised approaches over formulation driven approaches in improving outcome regardless of therapist skill. However, these studies mainly focused on specific disorders with existing protocols as opposed to complex and comorbid cases, which CF could be most helpful for. Despite this limitation, the usefulness of CF to treatment outcome remains unclear, with a lack of empirical evidence from the literature for its proposed advantages. Indeed, Kuyken (2006) describes that the ‘idea’ of CF as a useful tool within CBT is not sufficient enough to advocate its use. A fuller understanding of its application and suitability to clinical practice and its explanatory and predictive power is fundamental as well as empirical research into how CF relates to treatment outcome. Measuring specific components and processes that occur within CFs whilst tracking outcomes will shed light onto the efficacy of CF. Without this, questions regarding usefulness of CF remain unanswered (Kuyken et al., 2005).

Existing representation schemes. Another problematic aspect of formulations may include the current representation schemes available to therapists. Many treatment protocols incorporate diagrammatic or written formulations that detail relationships and demonstrate how difficulties are maintained through cycles. A number of diagrammatic conceptualisations have been developed for specific disorders (Clark & Wells, 1995, Social Anxiety Disorder; Ehlers & Clark, 2000, Post-

Traumatic Stress Disorder; Salkovskis, 1985, Obsessive Compulsive Disorder). More general representations also exist including Padesky and Mooney's (1990) Hot Cross Bun that demonstrates how a trigger can lead to specific presenting problems, detailing the interaction between thoughts, emotions, physical sensations and behaviour. The Five Ps is another common formulation method used for describing presenting problems, predisposing factors, precipitating factors, perpetuating factors and protective factors (Johnstone & Dallos, 2006). These frameworks are often easy to measure within research, useful as supervision aids (Johnstone, 2011) and go beyond diagnosis to provide descriptions of individual experience and suggest targets for treatment (Macneil et al., 2012). However, they are often presented as one off "formulations-as-events" (Cole & Johnstone, in press) and suggest a clear start and end point to a difficulty (Johnstone, 2011). Moorey (2010) describes that these types of case conceptualisations are simple, quick and easy to use but generic and lack specificity and suggests that developing therapist and SU understanding through formulation takes time to effectively complete.

Regan (2013) interviewed CBT therapists within IAPT services on attitudes towards formulation and found that with increasing targets and time pressure, coupled with less space for reflection there is less opportunity for detailed, comprehensive and complex formulating. Therefore, disorder specific models and "formulations-as-events" might be the only option for therapists but may not fully reflect an individual's experience, especially in the current climate whereby services such as IAPT are having to meet the needs of more complex clients (Goddard et al., 2015).

Looming nomothetic principles. The presence of nomothetic elements within current representation systems might also hinder therapist choice to use CFs. Qualitative feedback from CBT therapists reported that “people don’t fit into boxes”, concerned that disorder specific CFs are like diagnostic and medical models, that can be detrimental to clients when symptoms are matched to a model (Regan, 2013). Disorder specific models, based on diagnosis, serve a different function to CF (Kuyken, Padesky, & Dudley, 2008) and Hallam (2013) suggests that despite specific CBT techniques such as Socratic questioning and identifying core beliefs to promote idiographic formulations, the “nomothetic element can loom very large when problems are matched to a psychiatric diagnosis” (Hallam, 2013, p.29). For example, although Persons (2008) suggests that her proposed formulation model is based on ICF, she includes a symptom and disorder level. Hallam (2013) asserts that formulation should not involve matching clients to models and that the therapist’s role is to tailor formulation and treatment according to a person’s presentation. In support, Moorey (2010) suggests that there is no “off-the-shelf” diagram to explain complex interactions that maintain difficulties.

Diagnosis appears to loom in other transtheoretical approaches to CF also. Nezu, Nezu, and Lombardo (2004) suggested a functional approach to CF using a problem-solving model focusing on working towards goals, rather than symptom reduction. However, this approach uses diagnostic categories and nomothetic principles to describe presenting problems. Hallam (2013) suggests that this is a “top down” approach to functional analysis and argues that the diagrams produced by Nezu et al. (2004) are not precise or succinct enough to use effectively. Macneil et al. (2012) argue that a key challenge is creating a formulation approach that integrates

clinical and theory-driven understanding from the evidence-base with a person's unique experience to move towards evidence-based individualised therapy.

Validity of CFs. Despite increased CF manuals being developed, there continues to be uncertainty around the validity of CFs (Kuyken et al., 2005). Validity should be evaluated to enhance CF accuracy and determine its usefulness in assisting with treatment (Mumma, 2011). However, CF validity has barely been addressed (Johnstone, 2011). This is surprising for a number of reasons: (i) validity has historically been a major factor considered when psychological constructs are being developed, (ii) CBT has been rigorously tested whereas consideration of CF validity has generally been ignored (Mumma, 2011) and, (iii) other therapies, including psychodynamic approaches, have developed methods to evaluate CF validity (Horowitz & Eells, 2007). Within CBT, theories and approaches are usually empirically tested to enhance validity (Shadish, Cook, & Campbell, 2002) and therefore it is concerning that little attention has been paid to CF validity on conceptual, methodological and empirical levels (Bieling & Kuyken, 2003; Mumma, 2011).

Validity of CFs also appears to be overlooked within formulation research. Within Emmelkamp et al. (1994) and Schulte et al. (1992), that concluded that manualised treatments were superior to formulation approaches, CF validity was not evaluated. Without measuring the quality of the CFs, it is difficult to accurately infer that formulation approaches lacked efficacy in these studies (Mumma, 2011). Secondly, these studies used standardised materials to measure symptom change, which does not reflect an idiographic approach to measuring subjective experience, suggesting that possible significant changes could have been missed.

Bucci et al. (2016) conducted a systemic review of available measures for assessing the quality of CFs, measuring ease of administration, generalisability, reliability, validity and psychometric properties. They found no single measure that has been validated for use across a range of settings. Although the researchers outlined measures that could be reliable and valid in particular settings, such as the Collaborative Case Conceptualisation Rating Scale (CCC-RS; Padesky, Kuyken, & Dudley, 2011) for evaluating CFs in live therapy, the review is limited by a number of issues. Firstly, only a small number of studies were included with different methods for validating the measures and were thus not easily comparable. Furthermore, many scales identified were not published and lacked items such as scoring manuals, suggesting a lack of rigorous and systematic methods used for evaluating CF scales. Additionally, the authors found that scales had been developed for different purposes, such as training or research, potentially accounting for the lack of clarity amongst clinicians with regards to measuring CFs. In agreement, Völlm (2014) found that within a Delphi survey of professionals, there was no consensus regarding the best way to evaluate a CF. Bucci et al. (2016) concluded that more robust and rigorous research is needed to develop and validate case conceptualisation scales by either modifying existing scales or creating new scales that assess all aspects of reliability and validity. Ridley, Jeffrey, and Roberson (2017) argue that it is unethical to have a lack of validity for such an integral part of treatment. Therefore, it is paramount to have a measure of the quality of CFs (Eels, 2010) for increased ethical and good practice of CF and enable more valid comparisons between formulation and manualised approaches in future research (Mumma, 2011).

Summary. CF is promoted for use within treatment for mental health problems. However, the reality in clinical practice suggests that for therapists using formulations, “on the ground”, there are worrying factors regarding use of CFs. Some of these include differing skills and expertise amongst therapists, concern from therapists around using disorder specific models that may include unhelpful nomothetic elements as well as practical considerations such as lack of time needed to complete comprehensive formulations. This is worsened by the little knowledge about the link of formulations to treatment outcome and the unknown validity of CFs. Further understanding of how CF can be measured and related to clinical change is vital. The variability amongst the quality and use of formulations is of concern and suggests a need for proposed solutions and scientific evaluation to improve and investigate formulation. Without this, a potential clinical tool that might activate a mechanism for clinical change may be lost.

Solutions for Case Formulation

A number of potential solutions may increase use and efficacy of CFs. These include training on CF to enhance skill, a move towards idiographic approaches to improve validity, sharing CFs with SUs and research investigating how these processes predict treatment outcome.

Training. For complex cases, training and expertise in creating formulations that better capture complexity are becoming increasingly recognised as essential for developing a systematic approach to CF (Bieling & Kuyken, 2003) that enables more coherent conceptualisations that identify specific targets for treatment (Kuyken et al.,

2005). Despite this, Kendjelic and Eells (2007) found no studies that evaluated a training manual specifically for CF. Holmes (2002) suggested that CBT is often viewed as a simple therapy and that practitioners could be underestimating the need for advanced CF training. However, training in CF seems to predict higher quality formulations.

Zivor et al. (2013) investigated knowledge, attitudes and use of formulation for obsessive compulsive disorder (OCD) between clinicians and highly specialist practitioners (HS) who had previous extensive training in CBT formulation. Zivor et al. (2013) found differences between the groups on what was deemed most important to include within an initial CBT formulation. Furthermore, the HS group tended to share formulations earlier on in treatment, share updated re-formulations more frequently and were less likely to adhere to a prescriptive CBT model than the clinician group, producing more non-standardised models, suggesting more idiosyncratic approaches to formulation. Interestingly, less specialist clinicians rated themselves as lower on perceived competency in formulation skills, although higher on general CBT skill, suggesting that formulation is recognised as a stand-alone skill that potentially requires extra training. This study also indicates that more extensive training can enhance formulation skill and increase confidence to use non-standardised approaches. This finding could be helpful to address clinicians concerns that (i) they lack training in formulation (Fleming & Patterson, 1993; Kelsey, 2014; Perry, Cooper, & Michels, 1987) and (ii) they do not wish to solely prescribe to disorder-specific models (Regan, 2013). It seems reasonable to assume that higher training through qualification leads to increased formulation skill, demonstrated by research showing that PhD level training predicts formulation ability (Persons, Mooney, & Padesky, 1995). However, this level of qualification is not always present

within all mental health workers and it is therefore necessary to determine if formulation skill can be taught without need for further qualification and determine if skills in increasing CF quality, especially the ability to adequately address the complexity of a case can be enhanced. Kendjelic and Eells (2007) compared psychotherapy CFs between 20 clinicians receiving 2-hour formulation training and 23 controls who received no training. Trained clinicians produced higher quality, more complex, comprehensive, elaborate and precise formulations compared to the control group. More higher-level inferences were also made in the training group, compared to simpler descriptions found in control group formulations. However, this study has limitations, as the authors could not ensure that the groups did not differ on skill level prior to the training. Comparing pre and post training formulations could have been a useful way to measure how skill level changed and to determine whether higher quality and more complex formulations were found as a result of the training. The authors also suggest that a two-hour training session may not be enough to significantly propel clinicians to an “expert” status and more intensive training may be necessary for this. Despite limitations, the results are promising and suggest that even a two-hour training session can improve quality and ability to formulate case complexity. Further research is required to replicate these findings. Increasing availability of formulation workshops could be important in order to provide therapists that implement CBT with increased and more adequate training.

Kendjelic and Eells (2007) outline a number of benefits that can be gained through training in CF, including increasing the number of inferences made, increasing communication and treatment planning, and enhancing SU and clinician confidence in the therapy. In addition, with comprehensive and integrative formulations, briefer, more targeted treatments might be facilitated that can also

predict when longer treatment may be required (Kendjelic & Eells, 2007). Hallam (2013) suggests one of the main contributions to outcome is CF skill. There is promising research showing that formulation skill can be taught. Shafran et al. (2009) suggests that outcomes can increase with clinician training and therefore training on CF could have implications for increasing recovery rates.

A move towards idiographic approaches. Another potential solution to difficulties encountered with current CBT formulation is a move towards use of idiosyncratic models that are tailored to an individual's experience (Kuyken, Padesky, & Dudley, 2009) and guide individualised treatment (Dudley, Kuyken, & Padesky, 2011) more than disorder-specific models. Popularity for interventions targeting common processes between disorders, rather than focusing on one disorder is increasing. Accordingly, "formulations-as-processes" have no start or end point and no clear guidelines on what to include (Johnstone, 2011). Bieling and Kuyken (2003) suggest that in the transfer from nomothetic to idiographic CFs, formulations should be evolving processes that move away from diagnostic labels.

Nezu, Nezu, and Cos (2007) suggest a bottom-up idiographic approach that excludes diagnosis. After identifying ultimate outcomes, instrumental outcomes and treatment targets, a clinical pathogenesis map is created, depicting idiographic variables hypothesised to be development and maintenance factors of an individual's presentation. Nezu et al. (2007) suggest that depicting variables in visual format enables SUs to feedback more easily once the CF is shared with them. Diagrams can be modified if an intervention suggested by the model does not produce an expected outcome.

Haynes and O'Brien (1990, 2000) focus on idiographic functional analytic clinical case models that encompass important causal variables associated with a person's difficulties and behaviours and the strength of hypothesised relationships. Functional equations are used to express parts of the model, generate alternative hypotheses and describe complex functional relationships between variables (Haynes & O'Brien, 2000). However, equations are often applied for nomothetic causal models and assume more predictive accuracy than is achievable (Haynes & O'Brien, 1990). Functional analytic causal models change over the course of assessment and intervention phases once new information arises or when treatment outcomes are not met post intervention. Haynes and O'Brien (2000) describe that the models increase understanding of difficulties and clinical decisions and enable communication of these processes between SUs and healthcare professionals.

Jose and Goldfried (2008) proposed the use of a Causal Analysis and Synthesis of Events (CASE) system. The CF details intrapersonal and interpersonal elements and identifies repeating patterns that are functionally linked and could be contributing to a person's difficulties. The authors suggest that CASE increases communication between clients and therapists during CF development, directly informs targets for intervention and can be implemented alongside validated treatment methods and other models.

Hallam (2013) suggests that in the move towards idiographic approaches, his proposed system extends other methodologies, allowing information to be drawn from the evidence-base in conjunction with an individualised approach.

Hallam's (2013) ICF. Hallam's (2013) ICF is a pragmatic synthesis of well-recognised therapy principles, compatible with treatment protocols and existing

theories and models to assist in the choice of intervention. Similarly to other idiographic approaches, Hallam's ICF is built around functional analysis principles, although he argues that he makes more explicit functional links than other authors. Hallam (2015) describes a preference for bottom-up processes, allowing for scepticism that individual problems fall into distinct categories explained by a specific theoretical model. Instead, an ICF allows for intervention grounded in theory applied to an individual case rather than driven by a diagnostic label or the interventions available. For ICF construction, a number of different theoretical perspectives should be drawn upon, meaning that a final CF "may not resemble anything that has been produced in any previous case analysis" (Hallam, 2015, p.54).

Hallam (2013) stipulates ways of arranging the information within the diagram. Figure 1 details a formulation diagram of an anxiety case depicted in an ICF. Observations (placed in circles) refer to the basic circumstances observed, including behaviour, thoughts, feelings, and emotions. The diagram shows the behavioural observations of avoiding eye contact and situating oneself at the periphery and speaking only when spoken to. Other observations are also detailed in circles. Some observations might also lead to, and affect, other observations. For example, a person anticipating humiliation might anticipate this more when they attend to body sensations or have the thought that they are turning red or that they are being judged by people. These reciprocal relationships are represented by a double-headed arrow.

Explanations are provided in order to suggest ways to make sense of the information represented by the observations. Explanations can take any number of forms: hypotheses, theories, diagnoses, inferred aetiology, inferred historical processes or developmental events. They are placed in rectangles and connected to the element they explain by a dashed, un-headed line. Behavioural avoidance has been

inferred to be an explanation for the observations of socially withdrawing oneself. The figure also demonstrates that sensitivity to judgment might explain why some of the observations occur at specific events.

Observations that serve the same function are said to be functionally equivalent. In the diagram, functionally equivalent observations are connected with non-headed double lines. In the case example, three functionally equivalent consequences of anxiety all permit a person to avoid social interaction. Other important elements included are contextual antecedents to make clear when the problem is more likely to occur. The antecedents include being at a charity event, a crowded shopping centre and at an exercise class. These are also functionally equivalent, demonstrated by the double lines, meaning that these triggering events all function to elicit a similar response in the person.

The central purpose of a formulation is to help guide where and how to intervene to ameliorate the circumstances being addressed. Within the formulation, there should be adequate information conveyed regarding how the circumstances in question arise and how they are maintained to enhance the ability to anticipate how they might change under different conditions and in response to different therapeutic strategies. Figure 1 demonstrates some of the situations and behaviours that could be potentially targeted in order to consider how to help with the thoughts and behaviours associated with this anxiety presentation. The process involves a SU and clinician collaboratively constructing an ICF, and unlike similar previous efforts (Haynes & O'Brien, 2000), avoids use of medical or technical behavioural analysis terminology that can be difficult for novices to understand and explain. It is considerably more flexible than the formulation templates typically employed in CBT such as the Hot Cross Bun and Five Ps. Resulting diagrams include client and therapist perspectives,

allowing for detailed behavioural descriptions, causal connections and higher levels of inferences from observations and interpretations, allowing complexity and comorbidity to be represented.

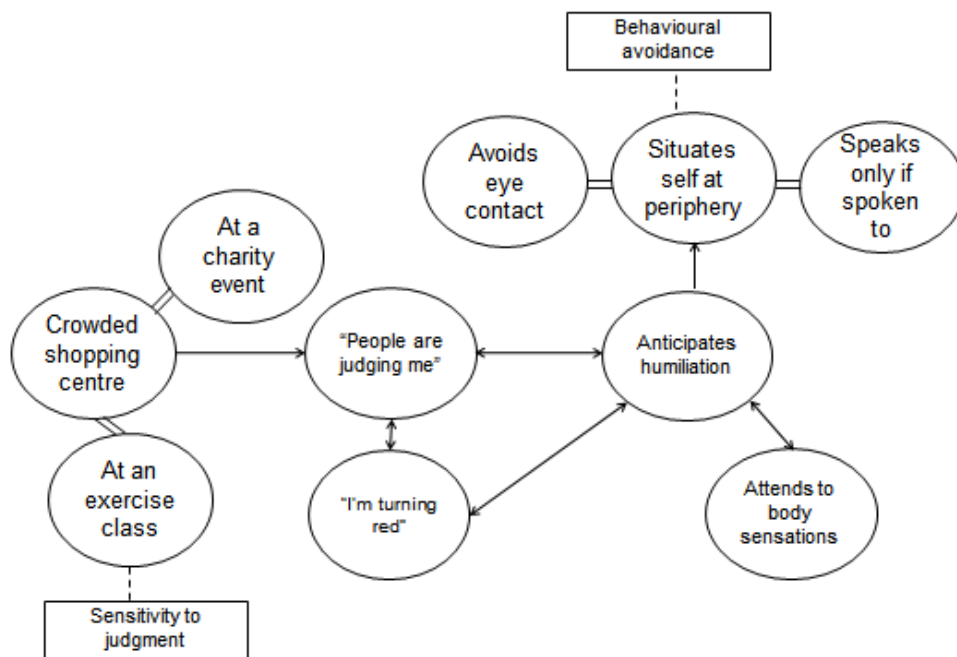


Figure 1: Example of a constructed ICF as according to Hallam (2013).

O'Connor (2014) argues that Hallam's approach demonstrates flexibility of theoretical, scientific yet impartial and empathic approaches to suit individual experiences and highlights the benefits of the open-mindedness and vigilance to SU cues, promoting client-centred ICFs.

Increasing validity. Use of idiographic approaches could also increase CF validity. CFs based on nomothetic theory contain a number of different validity issues

at both individual and aggregate levels (Mumma, 2011). Conversely, idiographic assessment should increase relevance and specificity to individuals as “fine-grained, highly individualised” (Mumma 2011, p.34) CFs can be developed which sensitively detect relationships between variables within a person’s current situation, increasing content validity of CFs. Mumma (2011) suggests that developing more individualised CFs allow clinicians to make relevant and person-specific predictions that can increase CF validity.

Testing hypotheses and processes to evaluate the predictive validity of a CF “is a critical step that has all but been ignored” (Mumma, 2011, p.46). Johnstone (2011) and Messer (1996) argue that formulations can only be assessed in terms of usefulness to the individual. By developing a CF based on idiographic principles whilst completing idiographic outcome measurement, clinicians can tailor treatment to specific issues and life circumstances, testing specific hypotheses detailed within the formulation, relevant to the SU (Mumma, 2011). A more idiographic functionally based approach to formulation diagramming, such as use of Hallam’s (2013) ICF could address validity and reliability issues that are a central weakness of existing literature on CF (Kuyken et al., 2005).

Sharing formulations. A final factor that could enhance use of CFs is sharing formulations, a process promoted by the DCP (2011). Sharing formulations within staff teams has been shown to reduce blame, increase optimism and increase understanding of SU difficulties, promoting positive feelings towards SUs (Berry, Barrowclough, & Wearden, 2009; Summers, 2006).

Sharing CFs with SUs in diagrammatic, written or verbal format differs between therapists, therapeutic models and presenting problems. It is an active part of

treatment within some modalities including Cognitive Analytic Therapy (CAT), but not always deemed an essential part of CBT. CAT involves sharing written reformulation letters and diagrammatic formulations with SUs that describe presenting problems within the context of an individual's developmental and social history (Ryle, 1990). SUs are given the opportunity to change and update formulations, aimed at increasing their understanding of difficulties and instilling hope (Ryle & Kerr, 2003). Research has indicated that developing and sharing formulations can reduce SU distress and increase coping (Horowitz, 1997) and might further therapist understanding (Kinderman & Lobban, 2000).

Evans and Parry (1996) shared formulations within CAT, aiming to enhance therapeutic relationships, focus the intervention and increase SU understanding. Results showed no association between sharing written CFs and improving outcome for people with borderline personality disorder. Gladwin and Evangelini (2013) explored the association between sharing CFs and the quality of written CFs and weight in women receiving CAT for anorexia nervosa (AN). They found evidence supporting an association between sharing written CFs and weight change (weight gain and loss). Higher quality CF was not associated with weight change. Therefore, it was suggested that sharing CFs can significantly impact therapeutic change but higher quality CFs do not necessarily benefit therapy. The authors also suggested that clinicians should not assume that sharing formulations is therapeutic in itself.

Chadwick, Williams, and Mackenzie (2003) and Pain, Chadwick, and Abba (2008) investigated the impact of sharing CFs on clients receiving CBT for psychosis. Chadwick et al. (2003) found that therapists reported enhanced optimism and understanding of presenting problems and theory-practice links. Some clients also reported increased hope, reassurance, encouragement and optimism, demonstrating

that there appears to be some therapeutic gains from shared formulations. However, with regards to outcome, there was no significant impact of the CF reducing conviction in core beliefs, easing distress or for improving therapeutic alliance. However, this study has a number of limitations and therefore needs replicating. Dependent variables were predetermined and were not idiographic measures, suggesting that individual benefits of sharing CFs may not have been captured. Furthermore, the effectiveness of CFs was only assessed once and thus there was no assessment of delayed benefits of the CF that may have occurred. Furthermore, data analysis lacked robust qualitative methodology and consequently, the results should be interpreted with caution. The authors also suggested that CF could provide other benefits not tested within this research, although they concluded that it appears that CF does not demonstrate short-term impact on clients. Within Pain et al. (2008), clients were encouraged to review their CF diagram and accompanying formulation letter. The CF impacted some clients positively, increasing hopefulness and enhancing the therapeutic relationship. Others responded negatively although Pain et al. (2008) suggest that this is normal in response to difficulties being recognised. The authors found that sharing the CF was “emotionally and cognitively powerful” (Pain et al., 2008, p.136) with some clients reporting that written formulations acted as a coping tool, allowing them to measure progress.

Treasure and Schmidt (2013) reviewed their Cognitive-Interpersonal Maintenance Model (2006) for AN which uses three sub-diagrammatic formulations detailing complex interactions including cognitive, social and emotional traits as well as carer vulnerabilities that can affect coping and maintenance of AN. The authors concluded that the model enhanced individual and family understanding of mechanisms underpinning and maintaining AN. The Maudsley Model of Anorexia

Nervosa, (Schmidt, Wade, & Treasure, 2014) was developed based on this model involving a “formulation phase” of treatment (Schmidt et al., 2012) where a collaborative CF is developed with SUs (Schmidt et al., 2013) and presented to the SU in diagrammatic form and a letter.

Overall, sharing CFs does not seem to be explicitly linked to improving treatment outcome. Kuyken (2006) argues that these studies raise questions about whether the idea that sharing CFs could be beneficial, holds any weight. However, small samples used within these studies and the limitations in methodology and analysis do not provide sufficient or robust evidence to rule out the efficacy of sharing CFs in assisting with therapy.

Hallam (2013) suggests that the therapeutic alliance “cannot be viewed as independent of the skills of formulation” (Hallam, 2013, p.121) and is premised on the agreement of a shared formulation between the therapist and client (Mumma & Mooney, 2007). Therefore, it follows that the juncture at which the formulation is shared could itself mark a point of change. Further research appears necessary to determine if sharing CFs with SUs could contribute to facilitating change. Despite being methodologically challenging, investigating causality of the process of sharing CFs by isolating this specific procedure appears necessary to test the impact on outcome.

Summary. There may be a number of possible solutions to assist with the problems associated with current CF in clinical practice. Training could be an important component to increase therapist formulation skill and confidence. Secondly, a move towards ICFs for clients could assist in more specific targets for treatment, as well as increasing validity of CFs and helping to identify components that maintain difficult to treat mental health problems by going beyond current existing models.

Sharing formulations within CBT requires further research to determine its usefulness to clinical practice. Indeed, CF in CBT appears to be in need of urgent research to investigate these ideas and thus shed light onto its potential for assisting treatment.

Implications for research

Despite lack of sufficient and robust evidence for use of CF in CBT, researchers continue to advocate its use in treatment planning (Grey, 2007). A more detailed investigation into CF is essential to focus on what form CF routinely takes, how CF is developed, whether it can assist with treatment outcome and whether CFs should be shared with SUs (Kuyken, 2006). This can potentially provide insight into how best to carry out effective techniques in CBT. The first step of research is to explore the usefulness of CF to treatment outcome. Focusing on a disorder with poorer outcomes would be a useful starting point to determine whether CF can assist in enhancing treatment.

Outcomes are particularly low for Post-Traumatic Stress Disorder (PTSD, Kar, 2011), commonly attributed to greater complexity that leads to challenges in treatment (Foa et al., 2000). Training has been shown to increase formulation quality and complexity (Kenjelic & Eells, 2007). The next step in formulation treatment is to link whether a better formulation might assist treatment. If an ICF can represent sufficient expertise in formulating increasingly complex cases (Hallam, 2013), difficult to treat disorders such as PTSD could potentially be better understood and potentially more effectively treated. This is a tentative idea but important to test with regards to the efficacy of a formulation in guiding treatment. If ICFs can provide additional individualised formulation alongside existing models this could enable increased relationships between variables and complexity to be captured to

demonstrate potential factors contributing to more chronic disorders. An ICF would also allow for an idiographic approach to CF and treatment detailing individual mediators and processes between factors.

Using formulations to increase treatment effects is suggested within the literature. Tarrrier (2006) proposes that a high quality CF is essential for effective therapy. Evaluation of ICFs during PTSD treatment would enable an idiographic approach to measuring treatment effects in more difficult to treat disorders, as recommended by Kaczurkin et al. (2016).

Post-traumatic Stress Disorder

Post-traumatic Stress Disorder (PTSD) arises from exposure to actual or threatened death, serious injury or sexual violence (*The Diagnostic Statistical Manual of mental disorders 5th ed*, DSM-V, 2013). Symptoms include re-experiencing intrusive memories, distressing dreams, flashbacks or dissociative reactions. Other symptoms include negative alterations in cognitions and mood as well as changes in arousal that can lead to difficulty sleeping, poor concentration and jumpiness. Avoidance of trauma related stimuli such as thoughts, memories, emotions and other reminders are common consequences. Re-experiencing symptoms are considered to be the hallmark of PTSD and involve fragmented, sensory representations of a past trauma (Ehlers & Clark, 2000). They can include images, sounds, smells, tastes and bodily sensations (Hackmann, Ehlers, Speckens, & Clark, 2004) and often involve the worst parts of the trauma known as hot spots (Holmes, Grey & Young, 2005). Sensory impressions are experienced as if they are happening in the present moment, often accompanied by original emotions and physiological reactions (Ehlers & Clark, 2000). These are triggered by trauma related external or internal cues such as a pattern

of light, tone of voice or body shape (Ehlers & Clark, 2000). The distressing nature of intrusions that lead to strong physiological reactions and emotions mean that avoidance of trauma related stimuli is common and can severely impact functioning.

Development and Maintenance of Intrusive Images. The main models that describe the development and maintenance of PTSD include the Cognitive model (Ehlers & Clark, 2000), Emotional Processing Theory (Foa & Rothbaum, 1998; Foa, Steketee, & Rothbaum, 1989) and Dual-Representation Theory (Brewin, Dalgleish, & Joseph, 1996; Brewin, Gregory, Lipton & Burgess, 2010). The Cognitive model is described below due to its application in CBT for PTSD (CBT-PTSD).

Cognitive Model. The Cognitive model (Ehlers & Clark, 2000) describes formation and maintenance of PTSD using a formulation diagram to depict how symptoms arise and are maintained (see Figure 2). As the formulation indicates, the way a traumatic event and/or its sequelae is processed can lead to a sense of current threat via two processes: (1) negative appraisals of the trauma and/or its sequelae and (2) the nature of the trauma memory. Negative appraisals of the trauma and the aftermath might include external appraisals (“The world is dangerous”), internal appraisals (“I attract disaster”), appraisal of behaviour (“Arousal during rape means that I am disgusting”), responsibility (“It was my fault”), coping (“I am going mad”) the consequences of the trauma (“I am permanently damaged”) and regarding violation of personal rules. Appraisals often have catastrophic implications for people and can lead to overgeneralisation about the danger of normal activities or exaggerate the probability of further traumatic events, leading to a sense of current threat that is

likely to result in avoidance, dysfunctional coping strategies and maintain fear (Ehlers & Clark, 2000).

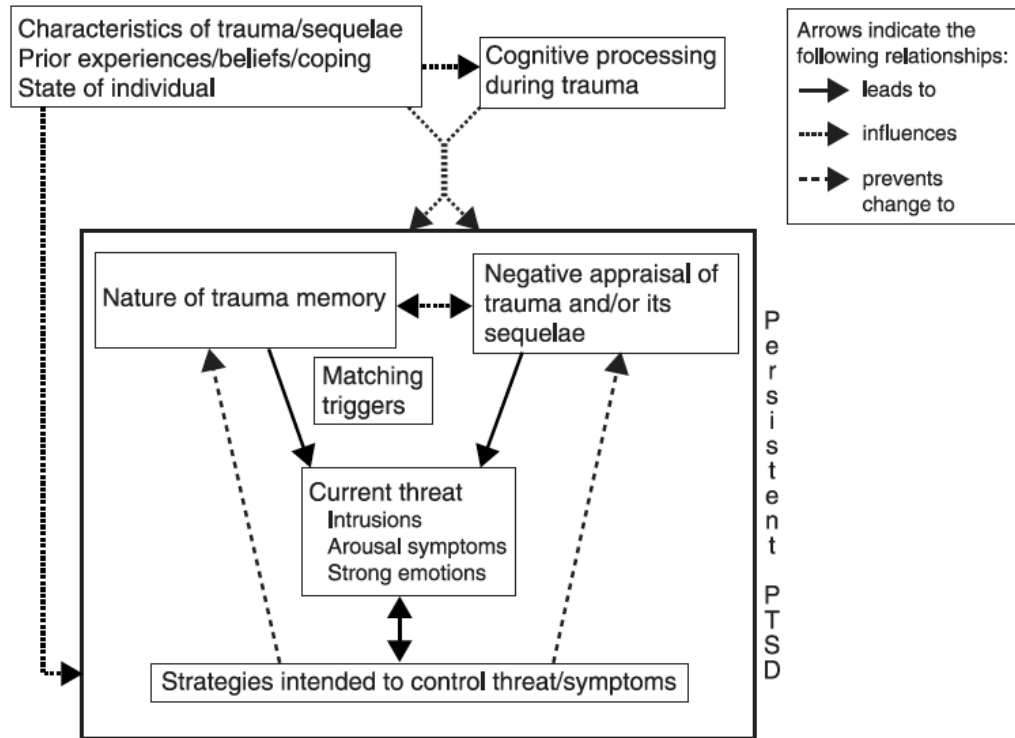


Figure 2. Ehlers & Clark (2000) Cognitive Model of PTSD (from Grey, 2007).

The nature of the trauma memory is also involved in maintaining PTSD. Ehlers and Clark (2000) suggest that unlike normal autobiographical memories that are stored in an ordered, time-stamped way that allow for intentional retrieval, high levels of physiological arousal during a traumatic event means that trauma memories are poorly elaborated and inadequately integrated into current autobiographical memory in context or time with subsequent and previous information. Retrieval of triggered memories from environmental cues occurs via an involuntary route that does not allow for the integration of trauma memories with other information. This

explains the nature of intrusions as being uncontrollable, easily triggered and the sense of them happening in the here and now. Strategies intended to help with PTSD symptoms such as avoidance can maintain symptoms, as there is no opportunity to update negative appraisals or the trauma memory.

Treatment implications. Exposure-based therapies are most effective for treating PTSD (Foa et al., 2000; NICE, 2005), involving reliving trauma details in the mind's eye as if it is happening in the present, describing images, sounds, smells, body reactions, thoughts and emotions as vividly as possible (Ehlers & Clark, 2000). Exposure can also involve writing a detailed narrative of experiences (Resick & Schnicke, 1993) or listening back to audio recordings of re-living (Grey, 2007). Eye movement desensitisation and reprocessing (EMDR, Shapiro, 1996) also has high effect sizes (National Centre for PTSD, 2011) and involves clients making saccadic eye movements whilst holding trauma images and content in mind (Grey, 2007). Cognitive restructuring alongside exposure that restructures the meaning of hot spots and creates alternative perspectives that are incorporated into reliving is often an essential part of treatment (Bryant, Moulds, Guthrie, Dang, & Nixon 2003; Ehlers & Clark, 2000).

Reducing symptoms. Ehlers and Clark (2000) suggest that trauma treatment should aim to: (i) reduce re-experiencing symptoms through elaborating on trauma memories to integrate them within autobiographical memory storage, (ii) address negative appraisals of the trauma and its sequelae and (iii) change avoidant strategies that prevent processing of memories and maintain appraisals. The main theories agree on the aims of treatment and all endorse reliving as essential in enabling elaboration

and contextualisation of memories. However, the mechanisms behind how reliving works are unclear, with theories offering different explanations (Brewin & Holmes, 2003).

Ehlers and Clark (2000) focus on the importance of reliving as a way of integrating memories into the context of the person's existing autobiographical memory store to give the memory context and a time-stamp. As treatment progresses, the nature of the trauma memory changes with added verbal descriptions and the narrative becomes more coherent, losing its here and now quality (Ehlers & Clark, 2000). This inhibits retrieval of sensory and physiological responses to trauma triggers. Reliving can also immediately update appraisals as new information is retrieved that was previously inaccessible and discriminates between the past and present (Ehlers & Clark, 2000).

In the emotional processing theory, Foa and Rothbaum (1998) suggest that reliving activates a fear network alongside corrective information and enables the memory to reintegrate with the existing memory network with disconfirmatory information incorporated, reducing fear associated with the trauma memory.

Brewin et al. (1996) describe that elaborating on trauma memories enables new and detailed verbal accessible memories to be created that reduce amygdala responses to trauma cues. In imagery rescripting, Brewin et al. (2010) suggested the retrieval competition hypothesis whereby new and less dangerous representations of the event are created that includes positive material. This memory competes with original representations to be retrieved following a trauma trigger and therefore the new competing representation is created to block the original memory (Brewin & Holmes, 2003). With retrieval practice, the new memory will be preferentially retrieved (Brewin, 2006).

As described, theories differ to whether PTSD treatment alters or elaborates original memories or whether new information is created and retrieved alternatively to original memories. Although mechanisms for symptom change may not be fully agreed upon, all theories have the same expectation of treatment: to reduce re-living symptoms and update key meanings of images. These changes should also reduce avoidance and help an individual learn that trauma memories and associated triggers are not threatening.

Recovery rates for PTSD

Ehlers and Clark (2000) treatment approach displays the largest treatment effect sizes (Ehlers et al., 2003, 2005) demonstrating significant symptom improvements (Gillespie et al., 2002), suggesting why it is widely carried out and recommended in IAPT services (Roth & Pilling, 2007). Despite efficacy of PTSD treatment in clinical trials that demonstrate large effect sizes (Cloitre et al., 2012) and recovery rates of 73-77% (Ehlers et al., 2014) PTSD recovery rates in IAPT (from *Psychological Therapies: Annual report on the use of IAPT services, 2014-2016*), were 37.5% in 2014/2015 and 37.8% in 2015/2016, the second worst recovery rate out of nine specific disorders investigated. Kar (2011) conducted a literature review of CBT-PTSD and found that nonresponse was as high as 50%. This is a worrying finding since it is widely acknowledged that PTSD can have a devastating impact on a person's level of functioning and well-being and is associated with greater risk of suicide, including increased risk of completed suicide (Kang et al., 2015). A number of reasons could account for observed recovery rates.

Co-morbidity. Grinage (2003) found that 80% of people with PTSD had at least one co-morbid psychiatric disorder, suggesting that PTSD treatment could be complicated by added complexity of co-morbidities. PTSD and substance use disorder (SUD) are highly co-morbid (Debell et al., 2014), with occurrence of one of these disorders significantly increasing risk of the other (Breslau, Davis & Schultz, 2003). PTSD is also comorbid with anxiety and depression (D'Ardenne & Hecke, 2014), chronic pain (Roth, Geisser & Bates, 2008) and suicidality (Marshall et al., 2001).

Multiple diagnoses may also result in ineffective directing of treatment, contributing to poor outcomes (Kar, 2011). According to NICE guidelines (CG26), a diagnosis of PTSD and SUD should result in initial treatment for SUD to prevent interference with PTSD treatment. However, PTSD and substance misuse are often viewed as functionally related (Brown, Stout, & Gannon-Rowley, 1998) with substances used to regulate negative emotions ('self-medication hypothesis', Khantzian, 1997) yet are treated using different models and treatment providers. Consequently, treatment does not always fully meet the needs of those with dual diagnoses and engagement in treatment may be poor if clients view co-morbidities as secondary to PTSD (Batten & Hayes, 2005). Outcomes for individuals with co-morbidities plus PTSD are poorer than those without PTSD (Berenz & Coffey, 2012; Resko & Mendoza, 2012). Due to the high prevalence of co-morbidities, interventions are being developed combining treatments (Kaczurkin, Asnaani, Alpert, & Foa, 2016).

Research suggests that if therapists use CBT interventions flexibly during PTSD treatment, the presence of co-morbidity does not predict poor outcome (Shafran et al., 2009) or reduce outcomes (Gillepsie, Duffy, Hackmann, & Clark, 2002). Duffy et al. (2007) found that presence of another psychiatric disorder or physical disability

did not impact PTSD treatment. Therapists within these studies used sessions flexibly to target co-morbidities allowing treatment for PTSD with and without co-morbidity to show similar, good outcomes. Transdiagnostic protocols to help with co-morbidities are emerging (McHugh, Murray, & Barlow, 2009); however, existing protocols typically lack guidance in relation to co-morbidity and thus, treatment may be ineffectively directed or delayed and clinicians continue to be left with an unsatisfactory understanding of where to focus treatment. This needs to be addressed as research suggests that the majority of clients seeking treatment for mental health problems display co-morbidities (Kessler, Chiu, Demler, & Walters, 2005). However, PTSD studies mainly exclude individuals with co-morbidities (Zandberg, Rosenfield, Aplert, McLean, & Foa, 2016) and thus the current research on PTSD may not be fully representative.

The nature of PTSD. The IAPT recovery workshop (2016) suggested that CBT-PTSD is a challenging treatment to deliver, possibly due to the nature of the disorder. Firstly, imagery can maintain PTSD, with images often characterised as distressing, consuming, full of sensory information, vivid and associated with extreme negative emotions (Brewin et al., 2009), impacting emotion more than thoughts (Holmes & Matthews, 2005). Wheatley and Hackmann (2011) found that presence of intrusive images predicts depression at follow-up, suggesting the role of imagery in maintaining difficult to treat psychological disorders (Brewin, Reynolds, & Tata, 1999). The strong role of images in maintaining PTSD suggests why targeting and modifying images in imagery rescripting is powerful in reducing PTSD symptoms (Smucker, 1997).

Furthermore, clients displaying sadness, fear, anger or disgust have reduced outcomes using exposure than those reporting anxiety as the main emotion (Power & Fyvie, 2013) with shame and guilt also found to be more treatment resistant than other emotions (Lee, Scragg, & Turner, 2001). These emotions are highly prevalent in PTSD (Lee et al., 2001) which could influence recovery rates. Steil and Ehlers (2000) suggested that dysfunctional appraisals are important maintenance factors in PTSD that often require extensive verbal and imagery cognitive restructuring (Foa & Meadows, 1997) with mental defeat also requiring more intense treatment (Ehlers et al., 1998) before reliving can be beneficial.

Lastly, people with PTSD often display a multitude of systemic difficulties including social and legal problems (d'Ardenne & Heke, 2014) following violence or trauma. A lack of awareness from clinicians of these contributing factors could lead to higher drop-out rates in assessment and treatment stages (D'Ardenne & Heke, 2014), found to be as high as 41.4% for CBT-PTSD (McDonagh et al., 2005). Therefore, it is essential that these factors are identified.

Knowledge of PTSD. The IAPT review suggested that staff might require extra training in trauma focused CBT or EMDR and highlighted that there is a need for CPD in this area to increase PTSD recovery rates. Shafran et al. (2009) argued that an obstacle to effective CBT is gaps in knowledge about delivery of treatments and suggested that for complex interventions such as trauma-focused CBT, further training is required. By filling gaps with training, an increased understanding of how to apply research findings to routine clinical practice could be obtained.

Lack of evidence-based working. Lastly, the IAPT review found that around 20% of sessions were not recommended by NICE guidelines. Indeed, research has indicated that despite clinicians reporting having used CBT, often sessions do not reflect evidence-based treatment (Carroll & Rounsaville 2007; Stobie et al., 2007). This means that therapists are deviating from current treatment protocols, suggesting protocols are not fully meeting the needs of clients. Research by Taylor and Chang (2008) suggested that clinicians select parts from various treatment protocols based on preference. Clinicians sometimes have concerns regarding the safety of exposure-based treatment when clients report fear of re-traumatisation from exposure (Young, 2009), acting as a barrier to treatment and reducing the likelihood of carrying out this technique (Becker, Zayfert, & Anderson, 2004). Waller (2009) argues that these preferences combined with clinician beliefs are likely to contribute to therapist drift and lead to ineffective treatment or even harm to the client. A way of expressing and capturing therapist assumptions could increase awareness of these.

Summary. There appears to be a number of potential factors that could account for low recovery rates for people with PTSD. These include co-morbidity and complexity of PTSD, including potentially difficult to shift images, appraisals or emotions, reduced knowledge about treating PTSD and lack of evidence-based practice that suggests that therapist factors also play a role in the maintenance of PTSD. PTSD appears to be a complex disorder to treat and there is a need to identify and formulate factors that could be contributing to poorer outcome. This is especially important since recovery rates observed within clinical trials are not being met in routine clinical practice. Identifying factors to help determine predictors of outcome could help inform effective treatment and increase recovery rates of PTSD.

Enhancing recovery rates of PTSD using ICF

Overview of the research literature has indicated that a growing number of studies are highlighting the utility of developing treatment protocols that go beyond disorder-specific models, in light of low recovery rates and increased complexity of clients (Goddard et al., 2015). Further formulation appears necessary in PTSD as a way of identifying components maintaining difficulties that are currently not captured within standardised models. An ICF could be a helpful tool to capture factors that extend current disorder specific models and influence change in PTSD symptoms such as contextual information, current social stressors, difficult to shift emotions, co-morbidities, observations and therapist interpretations that could be contributing to symptoms. Individualised formulation appears useful for understanding complex presentations (Bucci et al., 2016; Lee, 2006), for assisting with treatment of co-morbid problems (Drake & Ward, 2003; Eells, Kendjelic, & Lucas, 1998) and particularly important for non-responders to traditional interventions (Davidson, 2006). Grey and Young (2008) argue that individual factors are strong predictors of psychological problems and that individual variables and the links between them need to be identified within an ICF, drawing on systemic and identity theories alongside existing models. Use of an ICF might be helpful in demonstrating when to deviate from a routine protocol (Malatesta, 1995a, 1995b) and could potentially illustrate components that predict change in PTSD symptoms.

To fully test the efficacy of ICFs and the contribution to outcome in PTSD, therapists would require ICF training. Training appears to enhance formulation skill and can improve SU outcome (Shafran et al., 2009). It is important to determine if increased quality and increased ability of CFs to capture complexity of cases could be gained following ICF training and then if quality or ability to capture complexity of

ICFs can predict symptom trajectory. Training on completing an ICF is also necessary so that detailed idiographic analysis can be carried out on formulation diagrams that accurately indicate specific factors that could be predictors of change in PTSD and thus assist with increasing effective ways of carrying out CBT, an area in need of research (Shafran et al., 2009). Modifications to increase protocol flexibility to counter some of the difficulties associated with treating the PTSD population may be required to assist with poor recovery rates and therapist lack of evidence-based working. Research has highlighted a gap whereby inclusion of typical PTSD cases is required and use of a structured design to isolate and test specific treatment interventions idiographically and subsequently link these factors to treatment outcome.

Single Case Experimental Designs (SCEDs)

SCEDs allow for a rigorous evaluation of an intervention under different conditions within an individual, requiring a stable baseline that should reflect patient variables prior to implementation of an intervention. Following this, there is systematic introduction of an intervention allowing data to be compared between baseline and intervention phases. SCEDs use repeated measurement of a dependent variable before (baseline phase) and during an intervention (intervention phase) (Kratochwill et al., 2010). With an acquired stable baseline, SCEDs can attribute observed changes to the onset of an intervention. This enables causal inferences to be made that describe whether a functional relationship exists (Smith, 2012) between an intervention and change in participant variables. Therefore, within SCED, individuals act as their own controls to enable comparison of their data across different phases

(Kratzschwil et al., 2010) increasing internal validity (Horner et al., 2005). Replication across a number of cases enables patterns to be identified across a series of individuals, enhancing external validity (Horner et al., 2005). SCEDs are useful in testing conceptual theories and for isolating and detecting effective interventions in clinical practice (Horner et al., 2005) and therefore an appropriate design for a study investigating processes of CF.

The current study

This exploratory study used SCED to evaluate Hallam's (2013) system for developing ICFs and aimed to investigate how components within ICFs might contribute to clinical change in PTSD symptoms. Two phases were conducted. Phase 1 investigated changes between CFs before and after workshop training on creating ICFs. Four pre-/post- workshop formulations were analysed and rated to compare changes, thus also testing a rating scale of formulations for use in Phase 2. Phase 2 prospectively examined treatment for PTSD across eight participants using SCED. The main aim of this phase was to explore whether a relationship could be established between the presence or absence of components within ICFs and change in outcome. Furthermore, this phase aimed to provide evidence for whether sharing formulations with participants during treatment could be associated with change. Measures of image intrusiveness were completed by participants that explored frequency, distress, interference, controllability and sense ofnowness, key meanings of images and degree of belief in the meanings. Thus, the study explored change at an image symptom level and at a global level (meaning of the image), variables targeted in PTSD treatment. Participant data was examined at an individual level to inspect small

changes following shared formulations to investigate whether this impacted on image intrusiveness and the believability in the meaning of images. Participants were also divided into high and low treatment responders based on reductions in symptom severity (combined frequency and distress of image intrusiveness), enabling comparison of participants at a group level.

A number of preliminary and exploratory hypotheses were made. Firstly, that ICF workshop training would increase therapist formulation skill, potentially demonstrated through increased quality of ICFs. Secondly, that increased quality and ability to capture complexity within formulations might relate to outcome and rate of improvement for people with PTSD at a group and individual level. Next, that specific elements captured within ICFs might relate to outcome and rate of improvement for people with PTSD at a group and individual level. The final hypothesis was that sharing a formulation diagram would be associated with change in PTSD symptoms.

If specific aspects of the ICF are able to predict some contributors to change in PTSD, there are implications for use of ICFs across psychology services and for informing psychological treatment interventions. Furthermore, results will inform the evidence-base about the clinical usefulness of CFs, for training formulation skills and measuring CFs, aiming to enhance reliability and quality of CFs (Flinn et al., 2015). It will also add to existing understanding of theories for PTSD, potentially providing evidence for salient factors that could facilitate change in PTSD.

Method

Two Phases were involved. Phase 1 was carried out with therapists to investigate the changes between formulations following workshop teaching on ICF. This phase explored elements that contribute to expertise in formulation and the effect of training on therapist skill and quality of formulations. Phase 2 prospectively examined treatment for PTSD to investigate if elements included within ICFs related to therapeutic change and if sharing formulations related to change in symptoms of PTSD.

Phase 1

Sample. Four Therapists who attended ICF workshop training completed pre and post formulation diagrams. They were all high intensity therapists trained in treating a range of psychological difficulties, including CBT Therapists (n=3) and a Clinical Psychologist (n=1). The mean number of years of working in treating psychological problems was 5.4 years (SD=6, range=7 months-14 years).

Recruitment and setting. Therapists were invited to attend a training workshop on ICF as part of continuing professional development. They were invited from three NHS Improving Access to Psychological Therapy (IAPT) out-patient services, where Phase 2 of the study would be carried out. At the first service, therapists were invited to attend two half-day training workshops and the other two services were invited to attend a one full day workshop on ICF run by Dr Gary Brown (GB), the project supervisor and Professor Richard Hallam (RH), the author of ICF diagramming. Preference for a half or full day training session was decided by the head of the respective services. Figure 3 demonstrates the flow of therapists into the

training and those who completed pre and post formulation diagrams.

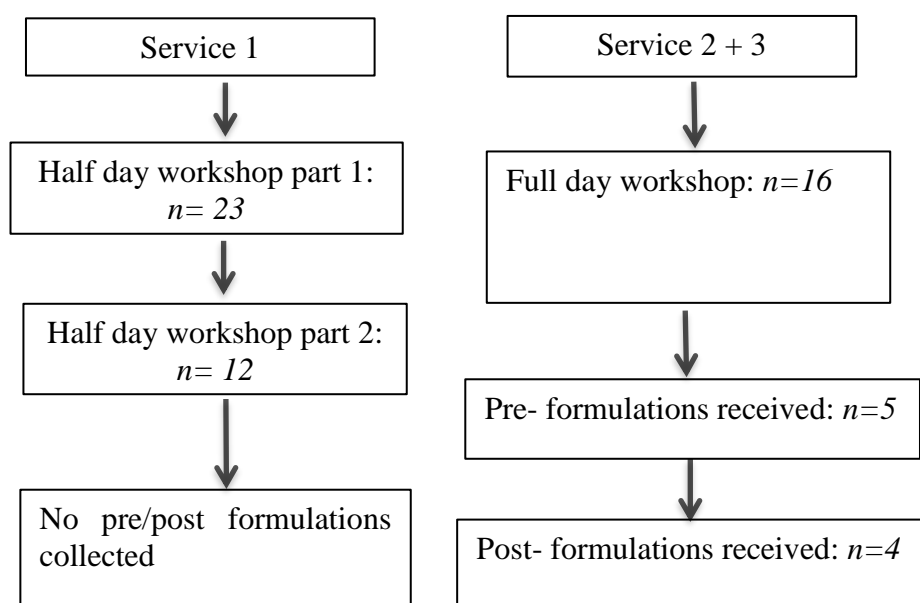


Figure 3. Flow of therapists into the workshop and Phase 1.

Measures.

Individual Case Formulation - Rating Scale (ICF-RS). The ICF-RS was used to analyse pre-/post- individual case formulations. The ICF-RS is a 9-item rating scale for measuring the elements that exist within an ICF diagram. The ICF-RS consists of two clusters: the definition of the problem (A) and validity and explanatory sufficiency (B). Raters record each of the 9 defined items indicating the extent to which a specific criterion is present within a diagram. Pre-workshop diagrams were rated dichotomously, indicating whether an item was absent or present (0=absent, 1=present). Post-workshop diagrams were rated using the full scale, whereby each item is rated on a four-point scale (0= not present, 1= partially present, 2=moderately present, 3= definitely present). Total scores range from 0-27, with the

maximum score being 27. A higher score indicates that an increased number of criteria were met within the ICF, suggesting that the formulation is of higher quality and detailed, indicating a high level of ICF skill. This tool was created by GB and RH as no such measure currently exists for identifying elements contained within an ICF diagram. Therefore, this tool has not been validated for use. However, it has been used within a research study conducted by Pettman (2017) who found that the measure displayed good internal consistency ($\alpha=.91$) and inter-item correlation ($r=.71$). Table 1 provides a brief summary of each of the 9 items. A full description of the items and criteria required for accurate scoring of the ICF-RS can be found in Appendix 1.

Table 1.

Summary of ICF-RS items.

A. The problem is clearly defined.	<p>The nature and source of observations are clear and explicit.</p> <p>The nature and basis for how observations relate to each other is clear.</p> <p>Explanations are included that are distinct from observations, used to help synthesise and make sense of the information included in the diagram.</p> <p>Key contextual elements are included.</p> <p>Functional equivalence between elements (triggers or responses) is denoted where this has implications for understanding the problem.</p> <p>Significant mediators are identified and their roles are made clear.</p>
B. Validity and Explanatory sufficiency	<hr/> <p>The formulation is a coherent and comprehensive account of the available information.</p> <p>The formulation delineates mechanisms of change and provides a basis for understanding where and how to intervene and what to prioritise.</p> <p>The formulation manages complexity successfully.</p>

Design. Phase 1 used a single group repeated measures design. Pre-formulation diagrams were completed before the workshop and were rated and compared to post-formulation diagrams by the same therapist. This enabled the changes in formulation skill post ICF workshop to be identified.

Table 2.

Summary of the content of the ICF workshop.

Topic 1	Policy context: five year forward view for mental health.
Topic 2	What is formulation? Working through 3 vignettes illustrating pitfalls of incorrect formulations.
Topic 3	The individual case formulation (ICF) approach as a means for depicting formulations and identifying problems.
Topic 4	Review of single disorder models.
Topic 5	Importance of Functional Analysis.
Topic 6	Review of the concepts so far.
Topic 7	Understanding formulation in Clinical Practice as a response to the challenges of improving efficacy in applied settings and the relationship to evidence based practice.
Topic 8	Description of formulation models (theoretical, conceptual, didactic).
Topic 9	ICF diagrams as a means of balancing fidelity and flexibility.
Topic 10	Application to PTSD (review of Ehlers & Clark, 2000, group ICF of PTSD vignette and independent ICF of a second PTSD vignette).

Procedure. The workshop took place over two half days (for service one) and one full day (for services two and three). The workshop slides were put together and facilitated by GB and RH. Table 2 briefly describes the content of the workshop. The half-day workshop covered topics 1-5 in Session one and topics 5-10 in Session two. Following the training at service one, feedback suggested it would have been useful to measure if therapist skill had increased following the workshop. Therefore, prior to the workshop with the second and third services, therapists were given a set of instructions asking them to complete a pre-workshop formulation based on a clinical vignette. Therapists were asked to draw a non-structured diagram that would be more

similar to an ICF rather than a structured one such as a single disorder model. An example of a non-structured diagram was provided for therapist guidance. Therapists were also asked to explain the symbols they used in their diagrams, for example: boxes= behaviours to ensure that the researchers could fully understand the components of the diagrams. Therapists were assigned an ID number so that their diagrams would remain anonymous to the researchers. Therapists gave in their formulation diagrams at the beginning of the workshop training.

Following the workshop, therapists were asked to complete a post-workshop formulation diagram based on the training, using the same vignette as previously and provided with instructions on how to create an ICF based on Hallam (2013). Following completion, therapists gave their post-workshop formulations to an admin member of staff, with their ID number to ensure anonymity and to enable comparison of pre-/post- workshop formulations. Appendix 2 shows instructions given to therapists for completing pre-/post- workshop diagrams.

The ICF-RS was used to measure pre-/post- workshop formulations. Pre-workshop diagrams were rated dichotomously and post-diagrams were rated using the full scale. To increase accuracy of ratings and increase inter-rater reliability, two researchers (AG & DP for pre-diagrams and GB & RH for post-diagrams) used the tool to rate the diagrams. The researchers discussed the items on the scale to ensure a similar understanding. Diagrams were rated independently and then compared. Discrepancies were minimal but when identified, researchers discussed their decision process and a consensus was agreed and any alterations made to the ICF-RS. The rating scale was also used within Phase 2 and therefore Phase 1 provided practice and familiarity of using the tool for the prospective phase.

Phase 2

Sample. Eight participants (6 female, 2 male) meeting criteria for PTSD took part in the study. The sample was highly heterogeneous, an important recommendation within SCED research to ensure intervention effects are tested across a diverse group of individuals (Kazdin, 1981). Participants had experienced a range of traumatic events including single instances of trauma and others with repeated or multiple traumas. The mean age was 33 years (SD= 10; range=19-48 years). Participants came from a range of ethnic backgrounds including White British (n=4), White other (n=1) Black African (n=1), Black Caribbean (n=1) and Portuguese (n=1). One person required an interpreter. Participants also had a range of co-morbidities including low self-esteem (n=1), depression (n=2), panic disorder (n=1), complicated grief (n=1), specific phobia (n=1) and health anxiety (n=1). See Table 3 for individual participant information. Some information has been altered to protect participant anonymity.

Table 3.

Individual participant information.

P	Gender	Age	Ethnicity	Medication	Co-morbidities	Years since Trauma
A	F	24	Portuguese	None	Low self-esteem	0.5
B	F	28	White-British	Sertraline	None	5
C	M	34	White-Other	None	Depression	0.5
D	F	39	White-British	None	Specific phobia Depression	4
E	F	41	Black-African	Propranolol Fluoxetine	Health anxiety Panic disorder	15
F	M	48	Black-Caribbean	None	Grief disorder	0.5
G	F	28	White-British	None	None	1
H	F	19	White-British	None	None	1-2.5

Inclusion criteria. Participants who were suitable for treatment for PTSD and experienced intrusive images as part of their PTSD were included in the study. PTSD diagnosis was determined by the treating clinician through use of PTSD measures such as the PTSD Checklist for DSM-5 (PCL-5, Weathers et al., 2013) and Impact of Events Scale-Revised (IES-R; Weiss, 2007) and/or clinical interview. A diagnostic tool was not used as part of the study for a number of reasons: (i) to enable an increased number of potential participants into the study, (ii) to capture a variety of individuals with ranging PTSD symptoms, which more accurately reflects those seeking treatment for PTSD and (iii) to reduce time pressure on

participants/clinicians. Completion of the IES-R (Weiss, 2007) as part of the study within Session 1 also indicated that all participants met criteria for PTSD according to this measure. The authors describe that a cut off point of 33 is a reasonable value to propose. All participants scored over the value of 33 at Session 1, indicating PTSD.

Exclusion criteria included presence of a psychotic disorder, borderline personality disorder, high and dangerous levels of substance abuse or those at high risk of self-harm or suicide, or if presence of any Axis I or II disorder may have interfered with PTSD treatment. This is similar to normal exclusion criteria for treatment within IAPT services.

There was not a standardised approach to inclusion/ exclusion criteria and the criteria is similar to normal exclusion criteria for treatment within IAPT services. The non-standardised approached meant that the sample gained was more likely to reflect people routinely seeking help for PTSD.

Sample size. For single case designs, number of observations rather than number of participants is most clinically significant (Allison, Silverstein, & Gorman, 1996). However, it is agreed that increased number of cases increases power (Shadish, Hedges, & Pustejovsky, 2014). What Works Clearinghouse (WWC) standards for single-case designs (Kratochwill et al., 2010) provide little guidance on the adequate number of cases to include for SCED. Therefore, sample size for this study was guided by suggestions from existing SCED literature (Shadish & Sullivan, 2011; Shadish et al., 2014). The median number of cases used within SCED is three (Shadish & Sullivan, 2011) and the WWC standards (Kratochwill et al., 2010) suggest a minimum of three data points per phase. However, according to Shadish et al. (2014), power of .80 will only be obtained with three cases when there is at least 6

observations in each phase and an anticipated effect size of $d = 0.8$. Shadish et al. (2014) suggest that when $d = 0.5$, power is adequate with 7 cases with 3 observations per phase or 5 cases and 9 observations per phase. Arntz, Sofi, and van Breukelen (2013) suggest that 80% power will be obtained with ten cases and enable a change of $d = .1$ to be detected.

With consideration of SCED literature, the study aimed to recruit ten participants. Ten participants were approached by treating clinicians with two declining to take part. The remaining eight participants took part. No participants dropped out of the study. The current study aimed to use phase lengths that enabled a minimum of 3 data points per phase. Phase lengths met this standard for almost all participants in Phase A and often consisted of more than 3 data points within Phase B meaning that observed effect sizes were likely to be moderate.

Recruitment and setting. Participants were recruited from three NHS Improving Access to Psychological Therapy (IAPT) out-patient services. IAPT treats people for a range of mental health problems, including PTSD. Treatment was carried out by CBT therapists ($n = 3$) and Clinical Psychologists ($n = 2$). The mean number of years of working in treating psychological problems was 4.8 years ($SD = 3$, range = 8 months - 8.5 years). All therapists had been trained in treatment for PTSD and received regular supervision. Eight services were contacted to take part. Three IAPT services and one specialist trauma service agreed to take part. The specialist trauma centre withdrew from participation, leaving three recruitment sites in total. Figure 4 depicts service involvement and final number of participants recruited from each site.

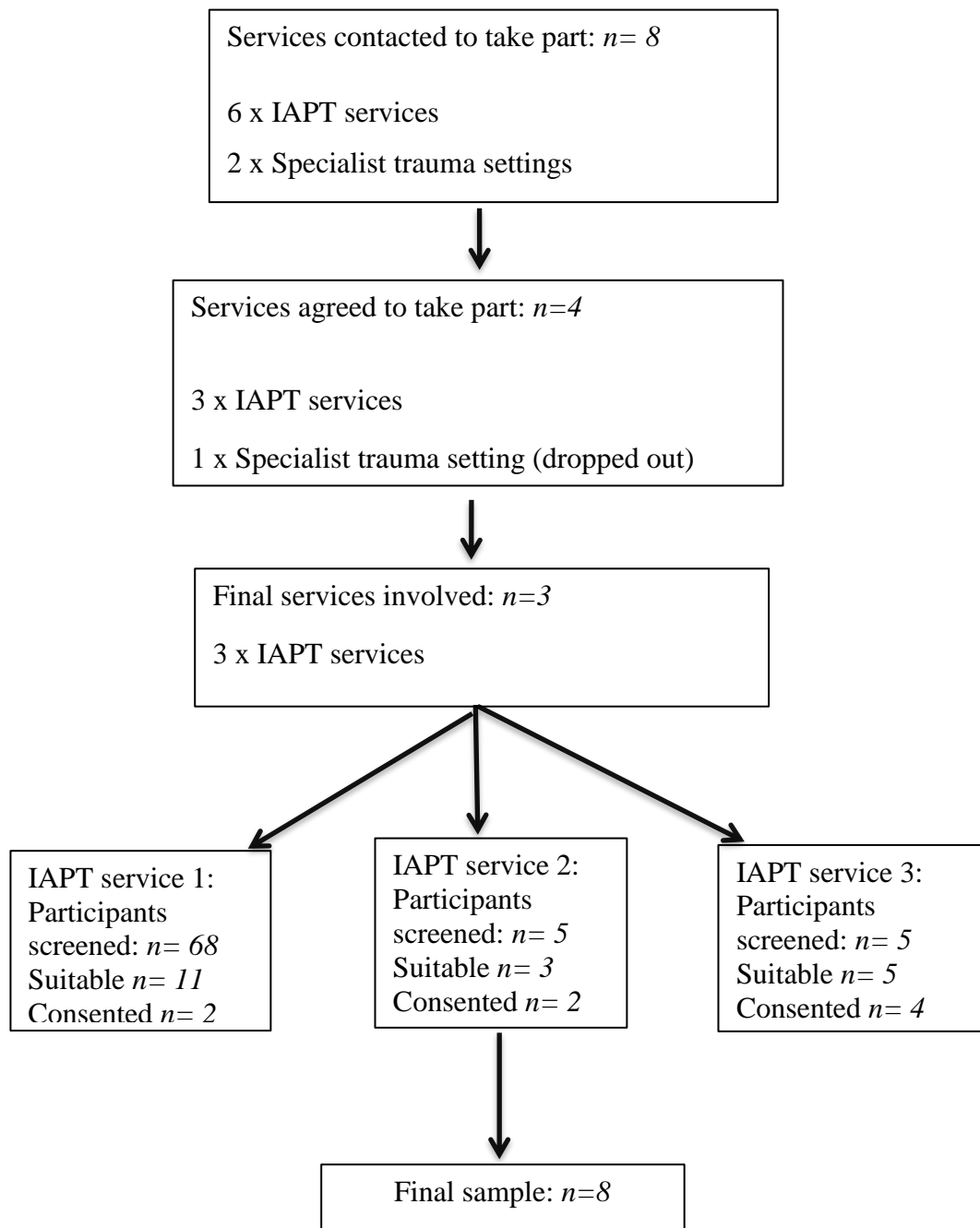


Figure 4. Final service and participant involvement.

Ethical approval. Ethical approval for the study was granted through the South East Scotland Research Ethics Committee 02 on 11 April 2016. Approval from the Health Research Authority (HRA) was granted 25 May 2016. A substantial amendment was made to include other co-morbidities, amend measures and add a new recruitment site. Approval for this amendment was granted on 19 October 2016 by the South East Scotland Research Ethics Committee (with added title change 27 October 2016), with HRA approving these amendments on 26 October 2016. Subsequent approval was granted by Royal Holloway University Departmental Ethics Committee and local Research and Development (R&D) departments. Non-substantial amendments to the study were made including adding a measure and adding new recruitment sites and approved by HRA and local sites for implementation. See Appendices 3-9 for ethical approval letters.

Measures. A fundamental part of SCED is the repeated measurement of participant variables across different phases over time (Hayes, 1981). The measures were used in order to test the research hypotheses and thus for pragmatic reasons as opposed to a priori theorising. Two types of measures were administered as part of the study including weekly measures and pre-/post- measures. Weekly measures consisted of Visual Analogue Scales (VASs) and were used because they are quick, easy to complete and easy to score (Briggs & Closs, 1999). Importantly, they are also sensitive to small changes across short periods of time. Pre-/Post- measures were used at the start of the baseline phase and during the intervention phase and were used as a way of measuring reliable and significant change following the intervention (Morley, 2015b).

Weekly measures.

Image Intrusiveness Visual Analogue Scales (IVAS). Image intrusiveness was measured using Brewin et al.'s (2009) self-report visual analogue scales (VASs). Participants rated intrusive images on a scale of 0-100 for frequency, distress, level of interference and uncontrollability. A fifth scale measuring sense of “nowness” was added as intrusive symptoms often have a here and now quality to them, with past traumatic events re-experienced as if they are happening in the present moment (Ehlers, Hackmann, & Michael, 2004).

Encapsulated Belief Scale (EBVAS). This scale identified the key meaning of intrusive images and measured the extent to which participants believed this meaning to be true on a scale of 0-100. The scale was adapted from previous studies (Hackmann, Clark, & McManus, 2000; Wild & Clark, 2011).

Although these VASs have not been validated, VASs are considered to be easy to administer (de Boer et al., 2004) and a simple way to measure subjective experience (McCormack, Horne, & Sheather, 1988). They are sensitive to measuring small changes within individuals (Maxwell, 1978) and for measuring therapy processes over time (Morley, 2015a). They are therefore extremely useful within SCEDs to enable multiple measures across a baseline phase and continuous measures across intervention phases. They are also suitable for use across different ethnic backgrounds (Gaston-Johansson, Albert, Fagan, & Zimmerman, 1990) and have been shown to have high reliability and validity (Ahearn, 1997). The IVAS and EBVAS were also used as part of a previous doctoral research project conducted by Looney (2016) and this study indicated that both of these VASs were sensitive to small

changes across therapeutic interventions.

Pre-/post- measures.

Impact of Events Scale-Revised (IES-R; Weiss, 2007). The IES-R is a 22 item self-report questionnaire measuring subjective distress in relation to a traumatic event. It is a widely used tool for assessing PTSD (Joseph, 2000), adapted from the original Impact of Events Scale (IES; Horowitz, Wilner, & Alvarez, 1979), which is a reliable, stable and valid measure of distress (Sundin & Horowitz, 2002). Beck et al. (2008) described that despite not being a diagnostic tool, the IES-R can discriminate between those with and without PTSD and enhances clinical and research assessment of PTSD. The IES-R consists of three subscales: intrusion, avoidance and hyperarousal. Respondents rate each of the 22 items on a 5-point scale (0=not at all, 1= a little bit, 2=moderately, 3= quite a bit, 4= extremely) rating how distressing each item has been over the past week. The total score ranges from 0-88 with IAPT suggesting a clinical cut-off of 33 for PTSD. Creamer, Bell, and Failla (2003) found that the IES-R has good psychometric properties with high levels of internal consistency ($\alpha=.96$) and subscales demonstrating adequate to good concurrent validity ($r=.66-.84$) with subscales of the PCL (Weathers et al., 1993) and good test-retest reliability ($r=.89-.94$, Weiss & Marmar, 1997).

PTSD checklist for DSM- 5 (PCL-5, Weathers et al., 2013). The PCL-5 is a 20 item self-report measure for assessing DSM-V symptoms of PTSD. It is used to screen for PTSD and monitor symptom change across treatment (Weathers et al., 2013). The PCL-5 consists of four clusters: intrusion, avoidance, negative alterations in cognitions and mood and alteration in arousal. Respondents rate each of the 20

items on a 5-point scale (0=not at all, 1= a little bit, 2=moderately, 3= quite a bit, 4= extremely). Total scores range from 0-80 with a clinical cut off suggested as 38 (Weathers et al., 2013). The PCL-5 has been found to have strong internal consistency ($\alpha=.94$) as well as test-retest reliability ($r=.82$) and convergent ($r_s=.75-.85$) and discriminant validity ($r_s=.31-.60$, Blevins, Weathers, Davis, Witte, & Domino, 2015).

Life Events Checklist (LEC, Blake et al., 1995). The LEC is a 17 item self-report measure for assessing exposure to 16 events known to result in PTSD with one extra item to include a traumatic event not captured within the 16 items. It is a tool that can identify how many traumas an individual may have experienced or been exposed to over their lifetime, a factor that might be important to consider in therapy. Respondents tick each of the 16 events on a 5-item scale (Happened to me, Witnessed it, Learned about it, Not Sure, Doesn't Apply). The LEC displays good test-rest reliability ($r=.82$) and good convergence ($r=-.55$) with an established measure of trauma history and measures of trauma specific psychopathology (Gray, Litz, Hsu, & Lombardo, 2004).

Mood and functioning. The following measures are used routinely within IAPT services.

The Patient Health Questionnaire (PHQ-9, Kroenke, Spitzer, & Williams, 2001). The PHQ-9 is a brief 9 item self-report questionnaire measuring symptoms of low mood over the previous 2 weeks. It has been shown to discriminate between those with and without major depression (Kroneke et al., 2001). Respondents rate each of the items measuring symptoms of depression on a 4-point scale (0= not at all, 1= several days, 2= more than half the days, 3= nearly every day) to reflect symptoms

over the past week. There is a total score from 0-27 with scores of 5-9, 10-14, 15-19 and 20-27 indicating mild, moderate, moderately severe and severe depression respectively. The PHQ-9 has good psychometric properties (Cameron et al., 2008) with excellent internal reliability ($\alpha=.89$) and test-retest reliability ($r=.84$, Kroenke et al., 2001). It can be used to measure symptoms over time and has been shown to have superior criterion validity compared with other depression measures (Lowe et al., 2004).

The Generalised Anxiety Disorder Scale (GAD7; Spitzer, Kroenke, Williams, & Lowe, 2006). The GAD-7 is a brief, 7 item self-report questionnaire used to measure symptoms of anxiety over the previous 2 weeks. Respondents rate each of the items that measure symptoms of anxiety on a 4-point scale (0= not at all, 1= several days, 2= more than half the days, 3= nearly every day). A total score of 21 is obtained with scores of 5-9, 10-14 and 15+ indicating mild anxiety, moderate anxiety and severe anxiety respectively. The GAD-7 has excellent internal consistency ($\alpha=.92$), good convergent validity ($r=.74$) (Mills et al., 2014; Spitzer et al., 2006), test-retest reliability ($r=.83$), construct validity, criterion validity and good procedural validity ($r=.83$) (Spitzer et al., 2006).

The Work and Social Adjustment Scale (W&SAS, Mundt, Marks, Shear, & Greist, 2002). The W&SAS is a measure of the extent to which a difficulty interferes with a person's ability to carry out every day tasks. It measures how much a person is impaired in five areas: work, home management, social leisure activities, private leisure activities and family and relationships on a scale of 0-8 (0= not at all, 2= slightly, 4= definitely, 6= markedly, 8= very severely). A total score of 40 is obtained and a score of 1-10 11-20, 21+ suggests mild, moderate and severe functional

impairment respectively. The W&SAS has good internal consistency ($\alpha=.70-.94$), test-retest reliability ($r=.73$) and is a useful tool within clinical research (Mundt et al., 2002). See Appendices 10-17 for measures.

Reliable change: severity of symptoms. In order to form another pre-/post-measure to distinguish high from low responders, two of the IVAS subscales were combined: frequency and distress. This is because VASs are more sensitive to change than the other pre-/post- measures and thus were likely to provide increased information about the changes in symptoms across therapy that might be lost with use of other measures. The reason for choosing the subscales of frequency and distress is because of the recognised importance of these two items. The Clinician-Administered PTSD Scale (CAPS; Blake et al., 1995), a well-validated measure of PTSD (National Centre for PTSD, 2016) uses frequency and distress to measure severity of PTSD symptoms and the latest version, the CAPS for DSM-5 (CAPS-5; Weathers, Blake, Schnurr, Kaloupek, Marx, & Keane, 2013) combines these items to give a single rating that reflects severity of PTSD symptoms. Therefore, within this study, frequency and distress subscales were combined to provide a pre/post outcome measure named “severity of symptoms” to discriminate between high- and low-responders. This score was then divided by 2 to give a total score between 0-100. The IES-R will also be used to measure reliable and clinically significant change.

Design. Phase 2 used a SCED approach with an AB design and aimed to follow participants before (Phase A) and after (Phase B) implementation of a formulation. Replication across eight participants with varying cultural backgrounds, trauma histories and demographics was used to enhance generalisability of findings.

To associate changes with sharing a formulation it was necessary to demonstrate symptom stability before the introduction of a formulation. SCED requires a minimum of three data points under each phase and to avoid interrupting routine treatment, baseline data was collected at the start of the first 3 sessions of PTSD treatment. This was Phase A.

Ideally, participants would not have commenced any type of treatment within the baseline period. This would increase the chance of obtaining a stable baseline, which becomes increasingly difficult when participants are already receiving treatment. Isolating treatment components and acquiring a stable baseline for participants already in therapy within naturalistic treatment and without disrupting SU care is a challenge for SCED. By collecting baseline data within the first 3 sessions, it ensured that participants were not having to wait unduly for treatment and still enabled repeated measures to be collected weekly, at 3 time points to investigate baseline stability. Despite treatment having commenced, it was still hoped that a stable baseline would be achieved to allow assessment of further changes brought about specifically through sharing a formulation.

Due to the limited time to recruit and to increase the power of the study, criteria for inclusion was broadened to include participants who had already commenced treatment and therefore for one participant it was not possible to acquire 3 baseline data points.

Treatment for PTSD within IAPT services begins with assessment of difficulties, typically followed by creation of a formulation. This may or may not be shared with clients and is not a requirement of CBT-PTSD. For this study, therapists were required to create an ICF prior to Session 3 and then share any type of formulation with participants in Session 3. Therapists were explicitly asked not to

begin formulating with the client before Session 3. This ensured the start of Phase B to help associate any symptom change with sharing a formulation. SCED requires at least three data points within each Phase and therefore measures were collected from Session 4-6 as a minimum. Following the formulation, routine treatment for PTSD usually moves onto processing of the trauma memories, which might involve reliving traumatic events, imagery rescripting or EMDR. Treatment for PTSD was treatment as usual that was required for the specific client. Participants completed extra measures more frequently than usual as this is an important component of SCED. Other than asking therapists to explicitly formulate in Session 3, treatment procedures themselves remained unaltered.

Procedure. The study was described to potential participants by treating clinicians and/or the principal investigator after they were assessed and deemed appropriate for PTSD treatment. If they were interested in taking part, they were given an information sheet (Appendix 18) and asked to sign a consent form (Appendix 19). Potential participants were told that if they did not wish to take part, it would have no impact on their treatment. Once a participant had consented, they completed Session 1 measures before their first treatment session.

Specifications about the particular trauma treatment to use were not imposed on therapists to ensure participants received the most useful treatment for them. Treatment included CBT-PTSD involving reliving (n=8).

Anonymity. To ensure clinician anonymity, all therapists that could potentially be involved in the study were assigned a unique ID number by an admin member of staff. When clinicians had a potential participant, they emailed the admin member who contacted the principal investigator. Anonymity for clinicians was maintained as

it is acknowledged that it can be exposing for clinicians to have formulations examined, rated and linked to SU outcome. Therefore, the principal investigator was not able to link ID numbers to specific clinicians. Once a participant was identified, the principal investigator dropped off a study folder for therapists to use labeled with the therapist ID number. This ensured anonymity of therapists and also helped the study implementation to be as simple and easy for therapists as possible and maintained a standardised procedure across participants. The research pack included session-by-session measures, check boxes and reminders for clinicians about which measures to administer and when to complete formulation processes. Two example pages from the study folder are shown in Appendix 20.

For participants, all data was anonymised and stored on an encrypted memory stick. As described, some demographic information and details of specific traumas has been altered or omitted to protect client identity.

Session 1. Clinicians completed the demographic details sheet giving information on participant age, gender, ethnicity, trauma type, co-morbidities, current medication and previous treatment. Participants were asked to complete the PCL-5, IES-R, LEC, VAS's and the IAPT minimum data set (PHQ-9, GAD-7, W&SAS) before the start of the session.

Image intrusiveness was measured using the IVAS, measuring frequency, interference, distress, uncontrollability and sense of 'nowness' of intrusive images over the past week. To identify the key meaning of the intrusive images, therapists were encouraged to use Socratic questioning and downward arrow techniques to determine the key meaning of the images. Examples of questions that could be used to identify the encapsulated belief include, "*What is the worst thing about this image?*",

“What does the image mean about you as a person?”, *“What does the image mean about other people?”*, *“What does the image mean about the world?”*, *“What is it about this image that makes it so distressing for you?”*. Once a key meaning was identified, it was recorded and then rated on the EBVAS to measure how much the participant believed the meaning to be true over the past week. Completion of these measures represents the first baseline point. One participant (C) completed Session 1 baseline measures in his second treatment session.

Session 2. Participants were asked to complete the VAS’s and the IAPT minimum data set before their session. This represents the second baseline point.

Between Session 2 and 3. Prior to Session 3, therapists were asked to create an ICF diagram based on the workshop training that they had received. The principal investigator sent follow up information on how to conduct an ICF via admin to the therapist to remind them how to do this. They were asked to include all information relevant to the client’s presentation to ensure detailed formulations.

Session 3. Participants were asked to complete the VAS’s and the IAPT minimum data set before their session. This represents the third and final baseline point. Once measures were completed, this marked the end of Phase A. Within Session 3, therapists were required to share any type of formulation with participants. Due to the naturalistic design, no specifications about the particular formulation to be shared with the participant were imposed. They were told that they could share a verbal, diagrammatic or written formulation depending on what the therapist felt to be most helpful for the client. Originally it was hoped that therapists would share the completed ICF diagram, however to ensure more naturalistic treatment and to reduce imposing any particular formulations on clients, it was decided that therapists could share a formulation that they deemed to be most useful for the participant. Therapists

were asked to record the type of formulation they shared with the participant. A range of formulations were shared including a vicious flower (n=1), Ehlers and Clark (2000) cognitive model of PTSD (n=4) and the individual case formulation (n=3). Session 3 represented the start of Phase B.

Session 4 onwards. At the start of Session 4, following sharing of the formulation from the previous week, the IVAS and EBVAS were re-administered as well as the IAPT minimum data set (PHQ-9, GAD-7, W&SAS). These measures were also collected in the proceeding sessions as repeated measurements across Phase B. Within Session 6, participants also completed the IES-R and PCL-5 again, as this marks the sixth data point and also reflects approximate half way of PTSD treatment within IAPT services. The IES-R and PCL-5 were also taken at the last possible treatment session.

The procedure of completing measures was continued across PTSD treatment. Participants were followed for a maximum number of sessions that study data collection allowed. Therefore there is some inconsistency across cases in terms of how many data points were obtained in Phase B, however all participants, apart from one, had a minimum number of 3 data points in Phase B. Participation ended in the study when recruitment ended in May 2017. Study involvement was terminated at this point and participants continued with treatment as usual. Due to limited time to collect data, no follow up data was collected. Table 4 details the measures taken within each session.

Table 4.

Summary of measures taken within each session.

Measure	Session 1	Session 2	Session 3	Session 4	Session 5	Session 6	Session 6 onwards
PCL-5	✓					✓	
IES-R	✓					✓	
IVAS	✓	✓	✓	✓	✓	✓	✓
EBVAS	✓	✓	✓	✓	✓	✓	✓
LEC	✓						
PHQ-9, GAD-7, W&SAS	✓	✓	✓	✓	✓	✓	✓

Coding. All formulation diagrams were rated using the ICF-RS. Similarly to the post-diagrams in Phase 1, two researchers (GB & RH) rated diagrams on each of the 9 items. This ensured rating accuracy to the scale and increased inter-rater reliability. A final score out of 27 was given for each ICF created by clinicians.

Service user perspective. In order to gain valuable insights from people with PTSD to determine the acceptability of study materials, SUs were approached in individual sessions by treating clinicians. SUs were given questionnaire measures including VASs and the participant information sheet and consent form and asked to comment on the ease of understanding the materials and how well the measures reflected PTSD symptoms. This was carried out in order to capture any concerns with the materials and to highlight potential changes that could be made to the study.

SU feedback yielded a number of useful comments and suggestions. Firstly, SUs felt that there were a lot of measures to complete that could be burdensome for people who are in distress. One SU involved in the study described the measures as tiring and taking a long time to complete. However, mostly SUs agreed that the routine, weekly measures looked quick and easy to complete so it would not be too onerous for participants and it was only the weeks requiring increased measures that might be more time-consuming. Furthermore, one SU described that it would be useful to track symptoms weekly using the VAS scales and also that the measures mapped well onto the symptoms they were experiencing. Another SU in the study also described that because the measures were relevant and often discussed in the session, completing them did not feel burdensome.

One therapist involved in the study described that the EBVAS had been a little confusing to complete and that they and the SU had found it difficult to fully understand what was being asked because of the way the scale was written. This was useful feedback to take forward to future research using this scale.

One SU described that the idea of having difficulties shared with them in a formulation, especially in a diagram sounded potentially daunting but also helpful to increase understanding of symptoms. Other feedback included that the consent form was easy to understand but that the participant information sheet could be shortened.

Unfortunately, by the time service user feedback had been collected, most participants had started in the research with baseline data already collected and thus there was insufficient time to make any changes to the measures. However, if the research protocol is continued to be utilised within the services it would be important to take the SU perspective forward and make necessary amendments for participants and therapists involved.

Results

Phase 1

Coding. Phase 1 analysis involved rating pre-/post- workshop formulations. Four pre-workshop formulations were rated dichotomously by two researchers (AG & DP), indicating whether an item was present or absent. Inter-rater reliability was assessed using Cohen's Kappa that expresses the level of agreement after chance agreement has been taken into account. The inter-rater agreement in Phase 1 was $\kappa=0.68$, indicating a good level of agreement between the raters.

The ICF-RS was used to rate four post-formulations by two researchers (GB & RH). Table 5 demonstrates the dichotomous comparisons of scores for the pre-/post-formulations. Due to the small sample size, statistical comparison was deemed inappropriate and thus tentative qualitative observational differences are discussed.

As Table 5 indicates, all post-workshop formulations contained an increased number of elements compared to pre-workshop formulations, demonstrating that a higher number of ICF criteria were met following training. Therapist 2 (T2) showed the most changes, with five extra items detailed in their post-workshop diagram and four additional items for T1 and T3 compared to pre-workshop diagrams. T4 only included one extra item however had already scored 8/9 for the pre-workshop diagram. Importantly, no items that were present in the pre-workshop formulations were absent in the post-workshop diagrams, suggesting that the only difference between the diagrams were additions made and that no skills were "lost" following training.

Table 5.

Comparison of scores for pre-/post- workshop formulation diagrams.

Therapist	Item 1		Item 2		Item 3		Item 4		Item 5		Item 6		Item 7		Item 8		Item 9		Change pre/post
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Post	Post	Pre	Post	Pre	Post	Pre	Post	
1	0	1	1	1	0	1	1	1	0	1	0	1	1	1	1	1	1	1	+4
2	0	1	1	1	1	1	0	1	0	1	1	1	0	1	0	1	0	1	+5
3	0	0	0	1	1	1	0	1	0	1	1	1	0	1	0	0	0	0	+4
4	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	+1

Note: A score of 1 means an item was present, 0 means an item was absent. Changes in scores between pre-/post- formulations are in bold.

As the table illustrates, when an item was not present in pre-workshop diagrams, it was either present in post-workshop diagrams or continued to be absent, supporting the inference that changes between pre- and post-workshop reflected skills gained.

Inspection of the differences reveal that there were some patterns across therapists with regards to item criteria being increasingly met in post-workshop diagrams compared to before the training. Item 4 was an additional item in post-workshop diagrams for T2, T3 and T4. This means that following workshop training, key contextual elements were more likely to be included that were not included in pre-workshop diagrams. Therefore, post-workshop diagrams contained increased moderators relevant to the exacerbation or improvement of an aspect of a difficulty, providing a useful context for understanding triggers and the circumstances under which it presents itself. Since the case vignette was the same for pre/post-workshop formulations, this suggests that the workshop assisted clinicians in adding contextual information that they did not include in their first attempt. Other patterns demonstrate that Item 1 was included in post-formulation diagrams compared to pre-workshop diagrams by T1 and T2 suggesting that the workshop assisted with representing increased nature and sources of observations that were separated successfully from explanations. Item 5 was also added in T1 and T3's diagrams compared to pre-workshop diagrams, suggesting that the workshop helped with representing functional equivalence between elements that demonstrate understanding of the problem. Lastly, Item 7 was an addition for T2 and T3, suggesting that increased comprehensive accounts of the available information were included post-training, with the diagrams structuring information in a way that more comprehensively drew factors together that were influencing the problem, portraying patterns of interaction.

Closer analysis of the individual differences between therapists also indicates that therapists individually met increased criteria for items in post-diagrams. T1 seemed to enhance skills mostly in defining the problem. T3 demonstrated some increases also with these items but also provided a more coherent and comprehensive account post-training. Despite an additional four items within their post-workshop diagram, T3 did not improve on Item 1, 8 or 9 with these items absent in both pre- and post-workshop diagrams suggesting that some skills and knowledge were not gained from the workshop for this individual. For T2, some skills appeared to be picked up across the scale including defining the problem in more detail but mostly in adding explanatory and validity sufficiency. These findings provide further indication that knowledge was gained as a result of the workshop.

Phase 2

Findings across the whole sample are presented followed by individual analysis to provide detailed examination between formulations and outcomes.

Overview. Table 6 and 7 provide a summary of pre-/post- outcome measures across participants for PTSD measures and IAPT measures. Since most participants were still in treatment, the post score indicates the most recent data point available. Further analyses were carried out to determine those who met reliable and clinically significant change.

Table 6.

Summary of pre-/post- scores for PTSD measures.

Participant	SS pre	SS post	PCL-5 Pre	PCL-5 Post	IES-R Pre	IES-R Post
A	65	10	38	14	46	9
B	61.3	15	57	9	62	13
C	95	0	36	4	46	7
D	25	3.5	39	3	35	7
E	38.3	5	47	2	45	16
F	42	10	55	7	64	3
G	52	20	54	32	40	29
H	85	85	66	-	67	-

Note. SS - Symptom Severity, PCL-5 - PTSD Checklist for DSM-5, IES-R - Impact of Events Scale- Revised.

Table 7.

Summary of pre-/post- scores and interpretations for PHQ-9, GAD-7 and W&SAS.

Participant	PHQ-9 pre	PHQ-9 post	Interpretation	GAD-7 pre	GAD-7 post	Interpretation	W&SAS pre	W&SAS post	Interpretation
A	11	2	Moderate- None	7	3	Mild- None	19	8	Moderate- Mild
B	17	4	Moderately severe - None	14	4	Moderate- None	27	6	Severe- Mild
C	17	3	Moderately severe - None	21	1	Severe- None	30	4	Severe-Mild
D	7	2	Mild- None	9	2	Mild- None	10	0	Mild- None
E	14	5	Moderate- Mild	15	3	Severe- None	16	10	Moderate- Mild
F	12	3	Mild-None	20	3	Severe- None	8	0	Mild-None
G	11	7	Moderate- Mild	14	8	Moderate- Mild	21	9	Severe-Mild
H	24	25	Severe- Severe	20	20	Severe- Severe	26	35	Severe- Severe

Note: PHQ-9 - measure of depression, GAD-7 - measure of anxiety and W&SAS – Work & Social Adjustment Scale.

Changes in Symptomology

Symptom severity. The Symptom Severity measure (SS; combination of Frequency & Distress on the IVASs) was used to identify those who met statistically reliable and clinically significant changes following the shared formulation in Phase B. Figure 5 depicts changes on symptom severity scores between baseline Phase A

and the last data point available in intervention Phase B and indicates those that met reliable and clinically significant change.

To calculate reliable change, the standard error of the mean (SE_m) and the standard error of the difference (SE_{diff}) need to be computed (Morley, 1994). To calculate the standard error of mean, $SE_m = SD \times \sqrt{(1-r)}$ with r = test-retest reliability of the measure. Using each participant's first two baseline data points, test-retest reliability was calculated using Kendall's r and found to be .74. The Standard Error of Difference is calculated as $SE_{diff} = (\sqrt{2 \times SE_m^2})$. SE_m was calculated as 10.25 and the SE_{diff} calculated as 14.50.

Reliable change was calculated using Jacobson and Traux (1991) reliable change index (RCI), calculated as $RCI = M_1 - M_2 / SE_{diff}$. Each participant's last available data point for SS was subtracted from their average baseline SS score and divided by SE_{diff} . If the RCI is greater than 1.96, this is indicative of statistically reliable change (Jacobson & Traux, 1991; Morley, 1994).

Clinically significant change was also calculated using two standard deviations above/below the mean of the pre-formulation scores (Veale, Page, Woodward & Salkovskis, 2015). A cut off point of 14 was produced. As displayed in Figure 5, three participants (PA, PB, and PC) met criteria for reliable change. Of these, two (PA and PC) also met criteria for clinically significant change.

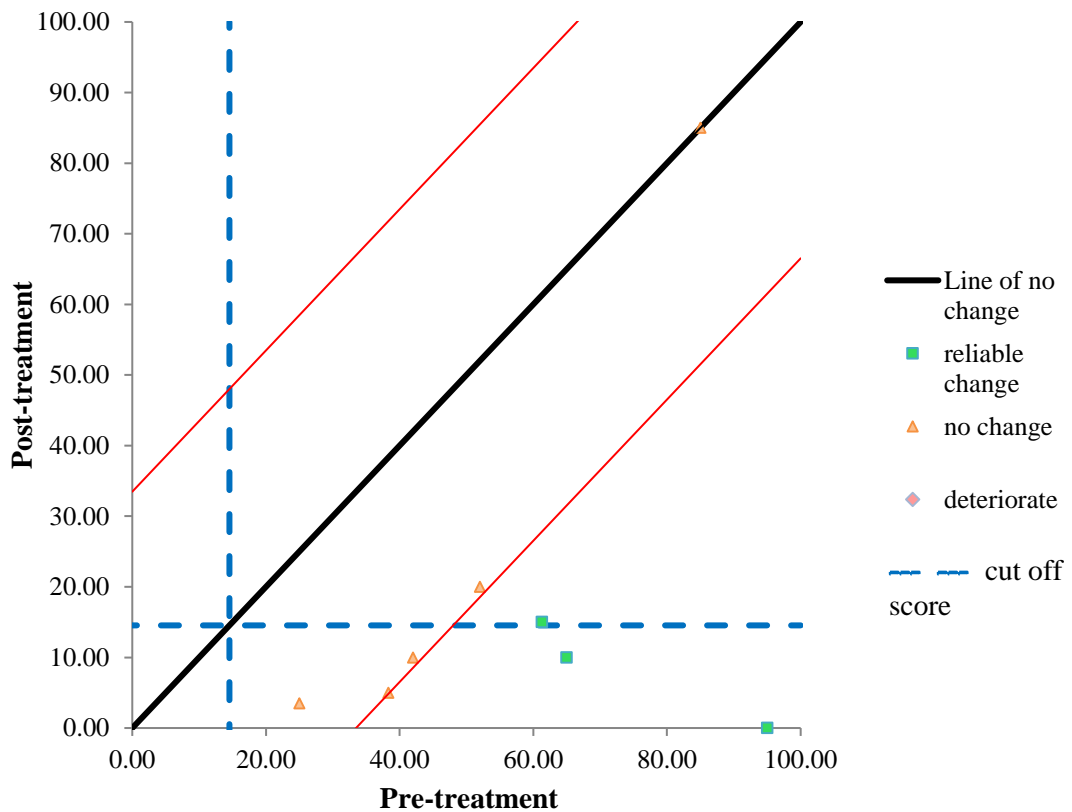


Figure 5. Scatter plot of pre- and post- Symptom Severity scores.

Impact of Events Scale-Revised. Reliable and clinically significant change was also calculated for the Impact of Events Scale-Revised (IES-R), as this is a standardised and routine measure of PTSD symptoms. Figure 6 depicts changes on IES-R between scores from Session 1 and the last data point available in intervention Phase B and indicates those that showed reliable and clinically significant change. Reliable and clinically significant change were calculated in the same way as the SS as guided by Jacobson and Traux (1991), but with use of the IES-R clinical cut-off score for PTSD of 33 as recommended across PTSD literature (Creamer et al., 2003; Haagsma, van Beeck, Toet, & Polinder, 2013; Morina, Ehring, & Priebe, 2013) and using reliability, $r=.89-.94$ from the literature (Weiss & Marmar, 1997). Participant H

(PH) was excluded from the analysis since they did not have an available data point to compare to Session 1. As the plot demonstrates, all seven participants included in the analysis (PA-PF) met criteria for reliable and clinically significant change, demonstrating that symptoms of PTSD improved for all participants over the course of the study.

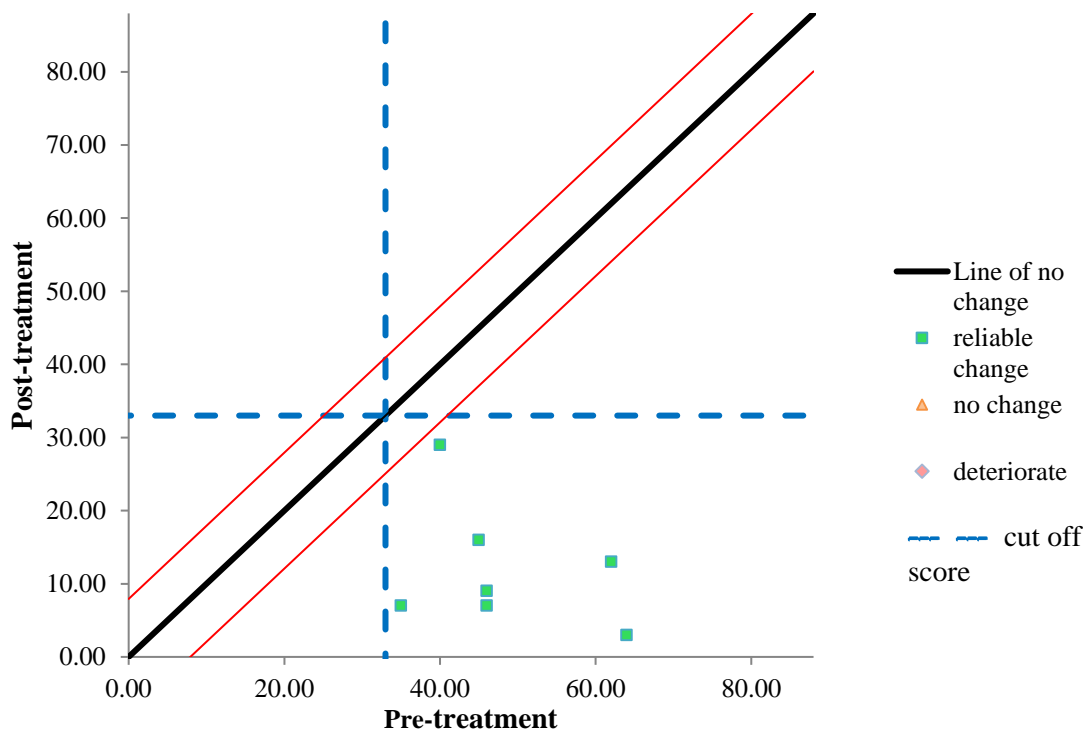


Figure 6. Scatter plot of pre- and post- IES-R scores.

Coding. The ICF-RS was used to rate ICFs within Phase 2. Eight ICFs were rated by two researchers (GB & RH). The raters agreed on almost 70% of the ratings exactly and 98% of ratings were within one rating point. The small sample precluded

use of intra-class correlation to evaluate reliability more formally. Average ratings were calculated between raters where there was a one-point difference. Where there was disagreement >1 point between the raters, the middle rating was agreed on.

Table 8 details the scores given to each item on the ICF including the total score for each participant's diagram. As described, all participants met reliable and clinically significant change on the IES-R but not the SS measure. The SS measure permitted a detailed analysis of the changes and thus, the results are discussed in relation to those deemed as "high responders" indicating participants who met reliable change on the SS (PA, PB, PC). Table 8 depicts differences between the eight participants ICF's alongside associated changes in SS across the intervention. Generally, scores on the ICF's were rather low compared to the possible maximum score of 27, with many items averaging a score of 1, suggesting low quality of formulations across the sample. Due to the small sample size, statistical comparison was deemed inappropriate and thus observational differences between high and low responders are described instead. Results are discussed tentatively in light of the low quality of formulations observed, the small sample size and the reliance on visual analysis.

Overall, changes in SS scores across treatment were moderate-good with all participants demonstrating change, except for PH. Higher quality formulation diagrams are indicated by a higher total score on the ICF-RS, suggesting that diagrams created for PA, PC, PE, PF and PG met more criteria compared with other participants. Of those with the highest scores, PA and PC also showed reliable and clinically significant change. The diagram with the least criteria met was created for PB, however PB still met criteria for reliable change. PE and PF also showed similar ICF ratings to high responders but did not demonstrate comparable change. PG had

the diagram with the most criteria met and this was therefore rated as the highest quality. However, it is worth noting that for PF and PG, they had only had six sessions at this point, compared to PA and PC who had finished treatment (receiving 10 and 13 sessions respectively). Therefore, it is likely that PF and PG would have shown improved scores as treatment progressed. Therefore, with the exception of PB, a slight trend could be observed whereby increased ICF ratings and increased SS changes are linked. This is backed up by the finding that other than PB, the lowest responders (PD and PH) also displayed the lowest scores on the ICF-RS. However, overall, ICF scores are quite similar across participants and mostly rated as low in quality.

Some preliminary observations are potentially worth noting. With regards to formulation content, an observed difference was found for Items 7, 8 and 9 that rate the extent to which the formulation provides a coherent and comprehensive account of the available information and has a relationship to intervention, providing detail on mechanisms of change for guiding treatment. While the scores are quite low, it does appear that scores were slightly higher on these items for individuals who improved most, with PA and PC who met clinically significant change scoring mostly the highest on these items. This suggests that these participants' formulations met criteria for increased integration and structure of information to convey factors influencing the presentation of the problem, compared to other diagrams of lower responders.

Table 8.

Scores on each item of the ICF-RS for Participants A-H.

Participant	SS Change	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9	Total
A*	-55	1.5	0.5	0.5	1.5	1	1	1.5	1.5	1	10
B	-46	0	0.5	0.5	1	0.5	0.5	1	1	0.5	5.5
C*	-95	1.5	0.5	1	1.5	1.5	1.5	1.5	1	0.5	10.5
D	-22	1.5	0.5	0.5	1	0.5	0.5	0.5	1	0.5	6.5
E	-33	1	0.5	1.5	1.5	2	1	1	1	0.5	10
F	-32	2	0.5	0.5	2	1.5	0	1	1	1	9.5
G	-32	1.5	1	1	2	1.5	1.5	1	1	0.5	11
H	-0	1	0.5	1	1	1.5	1	1	1	0.5	8.5

Note. High-responders are shown in bold with an asterisk for those meeting clinically significant change. Coding of each item Ranges from 0-3. Darker shading represents higher scores.

Interestingly, diagrams of lower responders generally scored higher on Item 5 than diagrams of high responders, suggesting that lower responders' diagrams displayed increased functional equivalence between elements. This suggests that observations noted are more functionally equivalent, in that they function to produce similar consequences (for example, avoidance) or that comparably more cues are present that function equivalently to provoke a similar response. The degree of functional equivalence might be an indirect marker of a more chronic difficulty, which would suggest that the individual could have developed increased ways of coping maladaptively for the same purpose or had an increased number of cues triggering a difficulty in a similar way.

A similar pattern that is likely to be linked to the foregoing observation regarding functional analysis can be noted for Item 4, with lower responders generally scoring for having a greater number of moderators within the diagrams, such as immediate and historical information that could be impacting a problem, than high responders who tended to score slightly lower on this item. Moderators and functional equivalence are likely to be linked (for example, triggering cues serving as moderators that are functionally equivalent), which could account for the observed patterns of these items.

Less clear differences were found for Item 1: the nature and source of observations are clear and explicit and not confused with explanations. Most diagrams scored moderately for this item, apart from PB's. For high responders, 2/3 mostly met this criteria within formulation diagrams and for low responders, this criteria was met in 3/5 diagrams.

All participants apart from PG scored 0.5 on Item 2, indicating that detailing contingencies between observations and how they increase each other's occurrence

could be a skill that was not as developed as some of the others might have been. This is one of the key items of the ICF model as it demonstrates that arrows represent meaningful contingent relationships as opposed to indicating vague connections. This suggests a common default to represent ambiguous links between items in a diagram. This finding is the same for Item 9, with only PA and PF scoring above 0.5, suggesting that for most cases, managing complexity in the diagrams was often not rated as successful. For the remaining items including diagrams containing mediators displaying meaningful links between factors (Item 6) and diagrams displaying clear distinctions between observations and explanations (Item 3), no discernible patterns were observed.

Overall, use of an ICF to capture elements was applied with low quality across the sample. However, there appears to be some suggestion that participants whose diagrams reflected some increased synthesis of elements showed signs of improvement.

Individual analysis.

For SCEDs, visual analysis of data is typically employed in order to judge if a relation between an independent variable and outcome appears to exist as well as inferring the strength of that relation (Kennedy, 2005; Kratochwill et al., 2010). If changes in the outcome variable following systematic introduction of an independent variable are observed between baseline and intervention phases with at least three demonstrations of the effect (Kratochwill et al., 2010) and differ more than would be expected (Horner et al., 2005), causal relations can more readily be inferred (Kratochwill et al., 2010).

Kratochwill et al. (2010) described the necessary steps for completing visual analysis. Firstly, baseline stability needs to be established to determine if the baseline is stable enough to assess and demonstrate intervention effects. The second step involves examining the data and documenting the level, trend and variability within each phase (Kratochwill et al., 2010). Gast (2005) describes level as the magnitude/strength of the data, trend as the progress of the data over time and variability as the stability of the data. Next steps include comparing the data between phases to investigate patterns across phases and to determine if an effect exists.

Gast and Spriggs (2010) provide guidance on baseline stability. Ideally, baseline data would be collected until clear stability is observed (Kennedy, 2005). To ensure participants did not wait unduly for treatment, this study required three baseline data points. Gast and Spriggs (2010) suggest that for cases like this, baseline stability can be assumed when 80% of the baseline data falls within a 20% range of the median. For this study, it was decided that baseline stability would be assumed when all of the data points fell within 20% range of the median, due to the small amount of data.

When baseline data is not deemed to be stable, it is recommended that statistical analysis of data is carried out (Morley, 2015a; Parker, Vannest, David, & Sauber, 2011). Tau-U analysis can be used which combines nonoverlap between phases with trend from the intervention Phase controlling for trend in the baseline Phase (Parker et al., 2011). Therefore, when there were three data points in both baseline and intervention phases, Tau-U analyses were carried out. Where there were less than three data points in either phase, variability is discussed without the use of statistical analysis, as suggested by Kratochwill et al., (2010). In these cases, observations are interpreted with caution.

Morley and Adams (1991) and Morley (2015a) describe useful tools for documenting the level, trend and variability and provide guidance depending on phase lengths. Morley and Adams (1991) suggest using central tendency, recommending use of the median. Rosenberger and Gasko (1983) suggest that when there are over five data points, the broadened median (BMED) is calculated, because the median may not fully reflect the magnitude of the sample. For fewer than five data points, the median is calculated. For investigating non-linear trends, Morley and Adams (1991) suggest use of the running median (RM) that plots central tendency over time, calculated by segmenting data into successive sets and calculating the average for each set. For this study, a RM of two was used. To demonstrate variability across time, Morley and Adams (1991) suggest plotting the trended range (TR) using a split middle technique of dividing the data into two halves and identifying the maximum and minimum values. For the repeated VASs, central tendency, trend and variability were calculated for each participant. Definitions of the terms used and how they are represented graphically are displayed in Table 9.

Table 9.

Definitions of visual analysis terms.

Term	Definition	Represented graphically
Raw data	Data points.	Round Dots
Median (M)	The middle value when the data is rank ordered. Used when there were 1-5 data points in the Phase.	Dashed line
Broadened Median (BMED)	The average of the three middle values when the data is rank ordered. Used when there were 5+ data points in the Phase.	Dashed line
Running Median (RM)	Average of consecutive sets of 2 data points throughout the Phase.	Dotted line Connected with Crosses
Trended Range (TR)	Lines connecting maximum and minimum data points in each half of the Phase.	Solid lines connected with Diamonds

For each participant, increased information regarding trauma details and the treatment type each person received is presented. Some information has been changed in order to protect participant anonymity. Graphical analysis depicting central tendency and trend of repeated outcome measures are displayed for each participant. Baseline and intervention phases are separated by solid vertical lines. Graphs showing TR are displayed in Appendices 21-28. A summary of the ICF content is also presented for each participant.

Participant A. Table PA1 details trauma information, specific images and the key meaning of the images, treatment type and the formulation shared. PA spoke Portuguese as her first language and had experienced a single instance of trauma 2 months prior to receiving treatment. In the past she had also witnessed other traumatic incidents. She also had some features of low self-esteem.

Table PA1.

Trauma type, specific images, encapsulated beliefs, formulation shared, treatment type for PA.

Trauma type	Specific images	Encapsulated beliefs	Formulation shared	Treatment type
Sexual Harassment– fear of sexual assault.	Perpetrator becoming angry. Perpetrators face. Being sexually assaulted.	He is going to rape me. I can’t trust anybody. There is no justice in the world. He is capable of killing me.	Individual Case Formulation	Trauma Focused CBT.

PA had three baseline data points followed by seven data points captured following sharing of the formulation, reflecting the full course of treatment she received. Baseline data across measures with the exception of frequency was either increasing or within a 20% range of the median and was therefore deemed to be stable. Further statistical analyses were carried out for the VASs, controlling for baseline instability for frequency, summarised in table PA2. Image intrusiveness and encapsulated belief VASs are graphically displayed in Figures PA1-5 and PA6 respectively. Summary of the ICF content is shown in Table PA3.

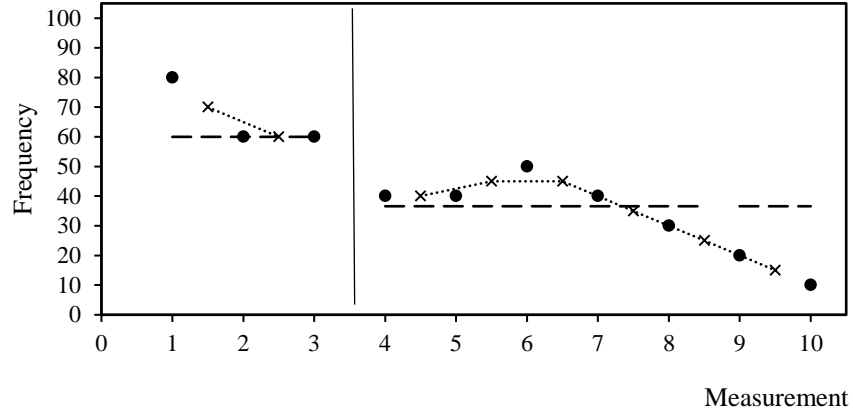


Figure PA1. Frequency VAS: raw data, central tendency and trend.

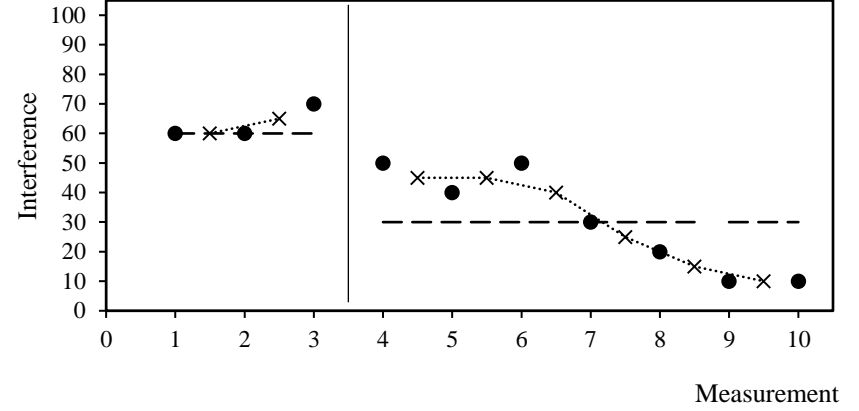


Figure PA2. Interference VAS: raw data, central tendency and trend.

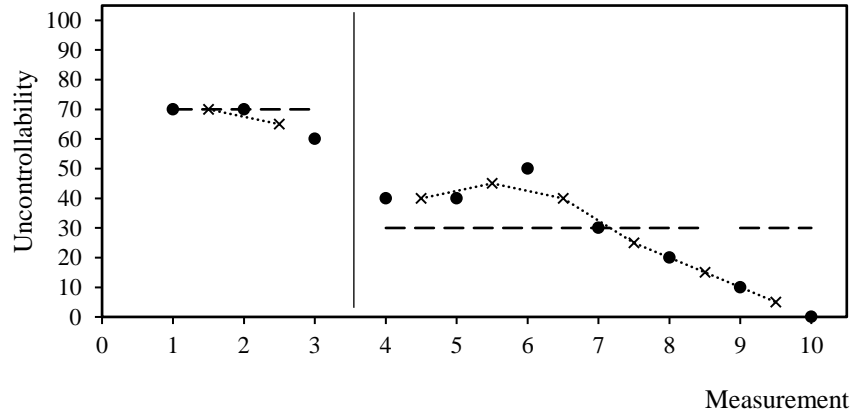


Figure PA3. Uncontrollability VAS: raw data, central tendency and trend.

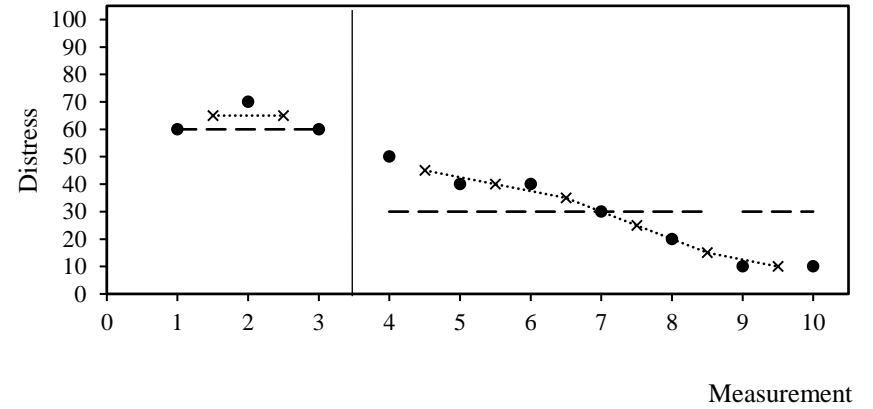


Figure PA4. Distress VAS: raw data, central tendency and trend.

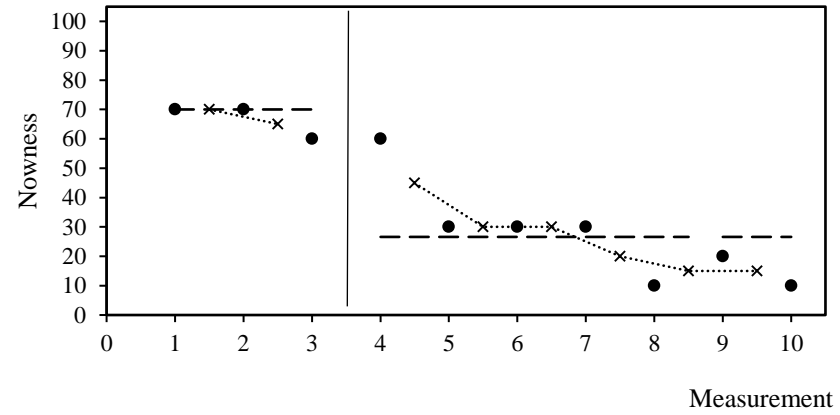


Figure PA5. Nowness VAS: raw data, central tendency and trend.

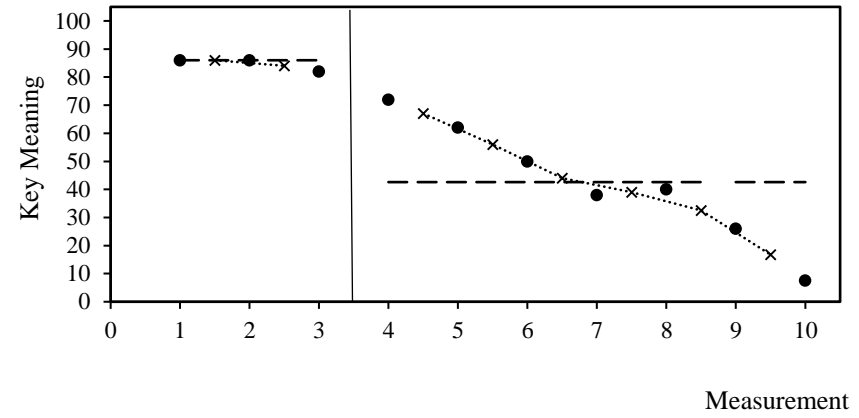


Figure PA6. Key Meaning VAS: raw data, central tendency and trend.

Table PA2.

Tau-U analysis for Frequency, Interference, Uncontrollability, Distress, Nowness and Key Meaning for PA.

	TAU _b	p value	CI 90%
Frequency	-.90	.03	-1 <> -.22
Interference	-1	.02	-1 <> -.31
Uncontrollability	-1	.02	-1 <> -.31
Distress	-1	.02	-1 <> -.31
Nowness	-.98	.02	-1 <> -.27
Key Meaning	-1	.02	-1 <> -.31

Sharing the formulation. For image intrusiveness, there is a general downward trend, suggesting improvement across treatment. This trend was also observed on the EBVAS for the key meaning of the images. Promisingly, the gains observed were maintained over the course of treatment. There are clear, observable differences in scores at Session 4 for all of the image intrusiveness items apart from nowness. Reductions in scores are observable at Session 4 for frequency, interference, uncontrollability and distress. This is also apparent for the EBVAS, suggesting that sharing the formulation could have contributed to reducing image intrusiveness and belief in the meaning of images. A change in nowness was observed but not until Session 5.

For frequency, baseline was deemed unstable. However, non-overlap analysis was carried out for all VASs, to determine if any significant differences between phases existed. These revealed that for all IVASs and the EBVAS, scores in baseline

Phase A were significantly different from scores in Phase B, indicating a significant change in image intrusiveness and key meaning of images between Phases.

Table PA3.

ICF-RS content code.

ICF-RS total	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9
10	1.5	0.5	0.5	1.5	1	1	1.5	1.5	1

Linking ICF to outcome. The coding summary shows that PA's diagram scored 10/27 in total, scoring within all domains, suggesting it captured an element of each item, albeit very little for some items and scoring low for overall quality. Highest ratings were given for Items 1, 4, 7 and 8, although still moderate. This included meeting criteria for containing the nature and source of observations clearly and explicitly, with observations not confused with explanations, containing key contextual elements and providing a fairly coherent account of the information available which allows some basis for identifying where and how to intervene. Items 5, 6 and 9 were deemed to be partially present in the diagram suggesting functional equivalence between elements, mediators between factors and complexity are all partially present but mainly did not display main links or add explanatory value. Items 2 and 3 were less apparent in the ICF, demonstrating that there was a high degree of ambiguity in the diagram with regards to observations and explanations and how they linked to each other.

In terms of outcome, PA’s scores showed a general downward trend across all items including the IVASs and EBVAS over the course of treatment with a significant difference between phases obtained. For all items apart from nowness, this occurred at the start of Phase B. These scores continued to decrease in a stable manner as treatment progressed. This finding occurred for all pre-/post- measures including on the PHQ-9, GAD-7 and W&SAS and standardised PTSD measures with PA no longer meeting caseness for PTSD by the end of treatment. Thus, observed gains from baseline to end of treatment across all measures were large.

Participant B. Table PB1 details trauma information, specific images, the key meaning of the images, formulation shared and treatment information. PB spoke English as her first language and had experienced a single instance of trauma 5 years prior to receiving current treatment. She also had low mood.

Table PB1.

Trauma type, specific images, encapsulated Beliefs, formulation shared, treatment type for PB.

Trauma type	Specific images	Encapsulated beliefs	Formulation Shared	Treatment type
Attempted sexual assault at knifepoint.	Being pushed onto the floor. Her and perpetrator trying to grasp the knife. Hooded heads.	I am guilty. I should have fought him off.	Ehlers & Clark.	Trauma Focused CBT.

PB had three baseline data points followed by seven data points captured following sharing of the formulation. This captured all of her treatment sessions. VASs are graphically displayed in Figures PB1-5 and PB6. Baseline data did not meet stability criteria for uncontrollability or nowness. See table PB2 for Tau-U analyses. Summary of the ICF content is shown in Table PB3.

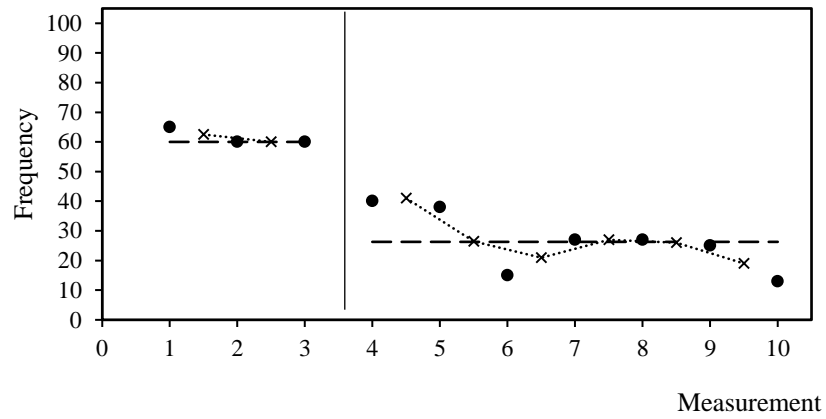


Figure PB1. Frequency VAS: raw data, central tendency and trend.

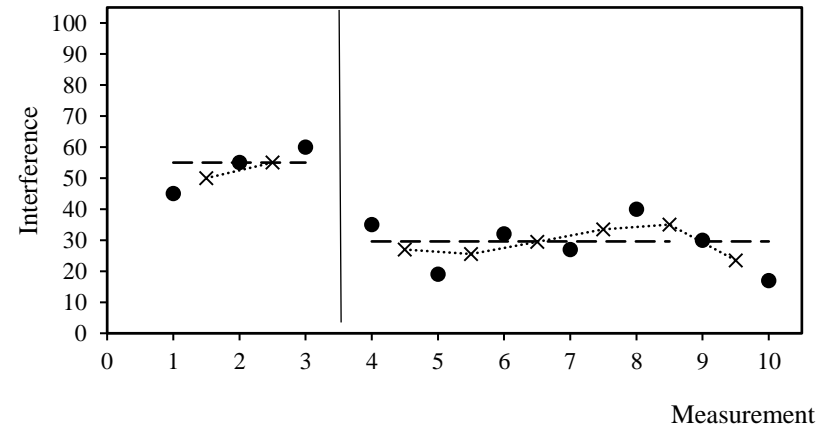


Figure PB2. Interference VAS: raw data, central tendency and trend.

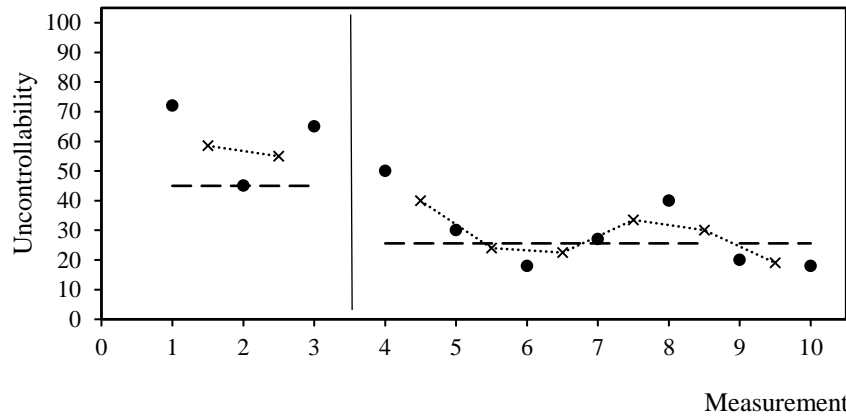


Figure PB3. Uncontrollability VAS: raw data, central tendency and trend.

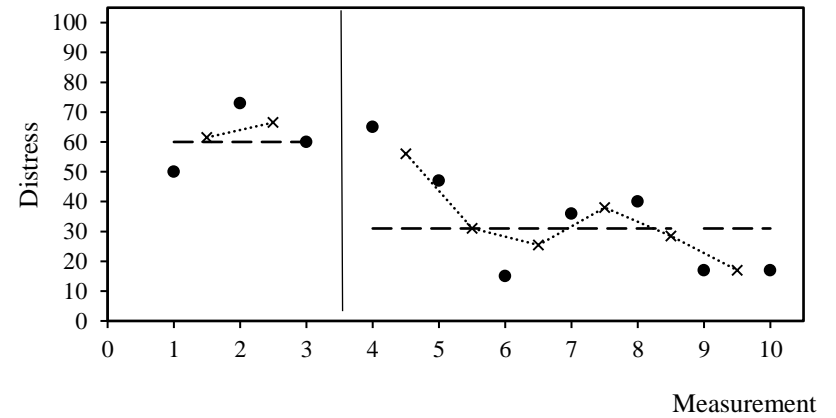


Figure PB4. Distress VAS: raw data, central tendency and trend.

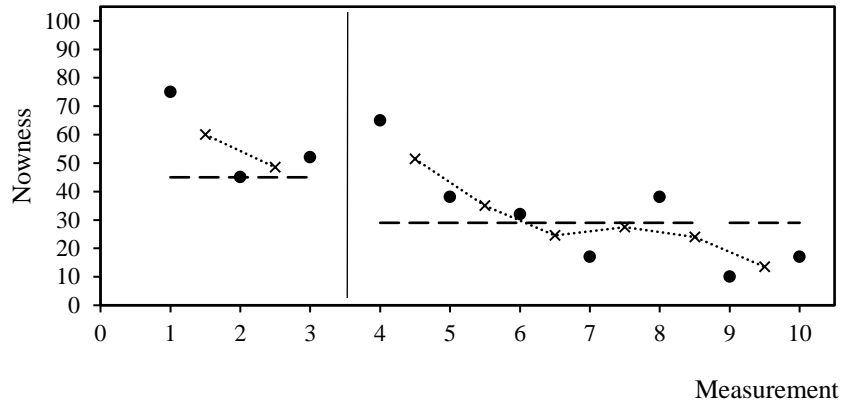


Figure PB5. Nowness VAS: raw data, central tendency and trend.

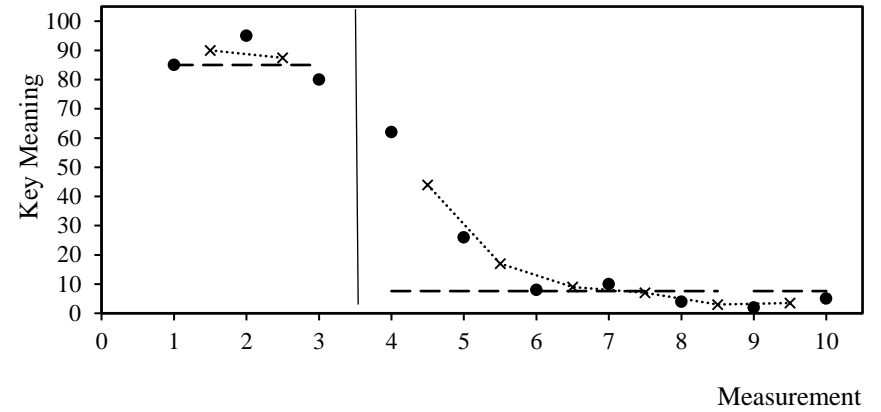


Figure PB6. Key Meaning VAS: raw data, central tendency and trend.

Table PB2.

Tau-U analysis for Frequency, Interference, Uncontrollability, Distress, Nowness and Key Meaning for PB.

	TAUb	p value	CI 90%
Frequency	-1	.02	-1<>-.31
Interference	-1	.02	-1<>-.31
Uncontrollability	-.86	.04	-1<>-.17
Distress	-.81	.05	-1<>-.12
Nowness	-.76	.07	-1<>-.08
Key Meaning	-1	.02	-1<>-.31

Sharing the formulation. In general, there is a downward trend from Phase A to Phase B, suggesting improvement in image intrusiveness and encapsulated belief scores across treatment. At session 4, scores reduce for frequency, interference and key meaning with a downward trend generally continued for these items across treatment. With baseline data meeting stability criteria including increasing for interference, this suggests that sharing the formulation could potentially have contributed to reducing image intrusiveness in these domains and for reducing believability of images. Furthermore, nonoverlap analyses revealed that there was a significant difference in these VASs between Phase A and Phase B.

For uncontrollability and nowness, significant baseline trend also resulted in further statistical analyses being carried out. Nonoverlap analyses revealed that for uncontrollability, there was a significant difference between scores in Phase A and B. For distress and nowness, scores increased at Session 4, suggesting that sharing the formulation was not helpful for assisting with these domains. However, at Session 5,

scores had reduced again followed by a downward trend mostly continuing for the remainder of treatment. Nonoverlap analysis indicated that for nowness and distress, scores were not significantly different between phases.

Despite general downward trends, raw data points reveal variability of the data whereby scores increased at Sessions 7 and 8 in almost all image intrusiveness measures. The EBVAS did not show this trend and scores continued to reduce across treatment from Session 4.

Information from the treating therapist revealed that PB had been experiencing stressors in other areas of her life including work and home issues that had also affected her sleep. One of these stressors had involved another potentially traumatic incident. The therapist felt that an increase in PTSD symptoms towards the end of therapy was due to these factors and that scores were relatively low considering this.

Finally, despite not being required to provide qualitative feedback, PB described having a “180 degree turn around” after sharing of the formulation diagram with regards to beliefs about coping with reliving or elaborating on memories. She described thinking that it would be “overwhelming and frightening”, but that the formulation made “absolute sense” and that she found the diagram “extremely valuable” and kept a copy of the diagram to reference.

Table PB3.

ICF-RS content code.

ICF-RS total	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9
5.5	0	0.5	0.5	1	0.5	0.5	1	1	0.5

Linking ICF to outcome. The coding summary reveals that PB's diagram scored low for overall quality with a total score of 5.5/27. The formulation was rated as not meeting criteria for Item 1 suggesting that observations were not sufficiently described with regards to their origin, which could have created ambiguity in terms of what was reported by the participant or actually observed. The diagram also only very marginally met criteria for Items 2, 3, 5, 6 and 9. This means that the diagram was mostly ambiguous with regards to how observations were thought to be linked and follow on from each other, required explanations were lacking, very little functional equivalence between items existed that did not add explanatory value and mediators that were included failed to demonstrate their linking function. Complexity was also not often successfully captured within the diagrams.

The diagram scored 1 for Item 4, 7 and 8 indicating that it met criteria for containing some moderators that contributed to a difficulty although they provided limited information about how they operate. The formulation also partially accounted for information gained about the problem however some important observations were deemed to not have been included. Next, the formulation did not satisfactorily provide an account for how the difficulty arose or how it was maintained and thus it would be difficult to fully determine where and how to intervene. Therefore, overall the ICF

produced for PB lacked many factors deemed to increase quality to a formulation diagram.

In terms of overall outcome, PTSD and IAPT measures showed symptom reduction across therapy with PB not meeting caseness for PTSD by the end of treatment. Qualitative feedback gained from PB suggested helpfulness of the shared formulation. Further discussion with the therapist revealed that the ICF diagram was drawn out and rated prior to Session 3, as per the instructions of the research design. However, over the course of treatment, the diagram was added to and revised. Therefore, the diagram that was completed by the end of therapy, which was subject to changes and revisions, would have looked quite different and possibly more complex to the formulation diagram that was rated at Session 3. This suggests that the diagram could have been higher in quality and better represented the complexity of the case by the end of treatment and that the rated diagram does not account for all the factors that could have been included by the end.

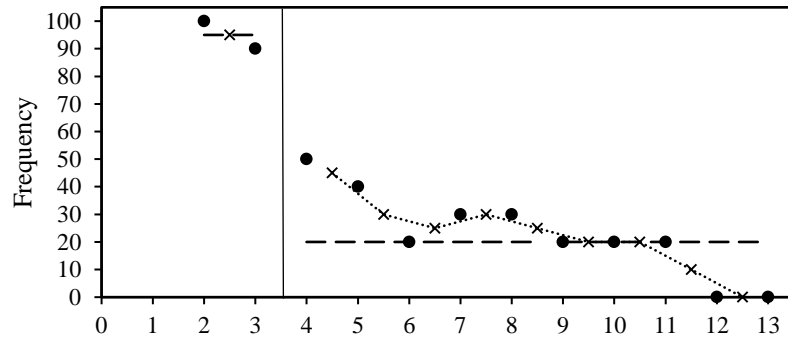
Participant C. Table PC1 details trauma information, specific images, the key meaning of the images, treatment received and the formulation shared. PC was Ukrainian and therefore English was not his first language. He had experienced multiple traumas in his life but was receiving treatment for a single incident that occurred 6 months prior to treatment. He also suffered with low mood.

Table PC1.

Trauma type, specific images, encapsulated Beliefs, formulation shared, treatment type for PC.

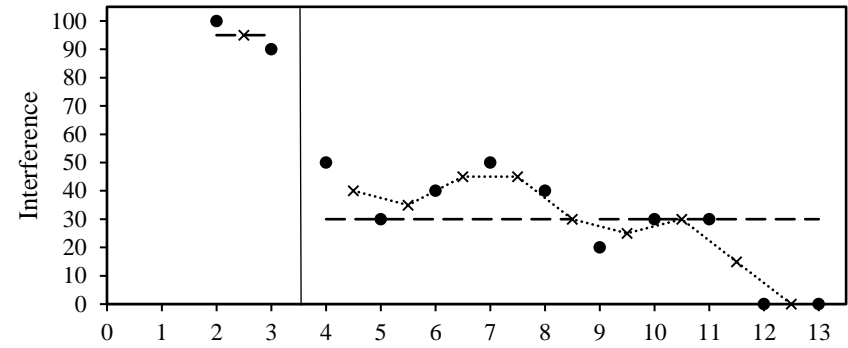
Trauma type	Specific images	Encapsulated beliefs	Formulation shared	Treatment type
Machinery accident at work.	Being put in jail. Images of the accident.	The world is a bad place. I am powerless. I am vulnerable. The government has created all these problems.	Ehlers & Clark.	Trauma Focused CBT.

For PC, only two baseline data points were available followed by ten data points in Phase B. Baseline data therefore falls short of what is necessary to make clear inferences in SCED and thus no statistical analyses were carried out on the data. PC continued to receive treatment following data collection. VASs are graphically displayed in Figures PC1-5 and PC6. Summary of ICF content is shown in Table PC2.



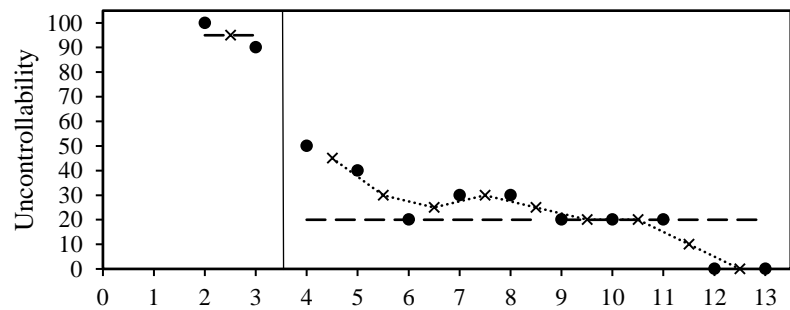
Measurement

Figure PC1. Frequency VAS: raw data, central tendency and trend.



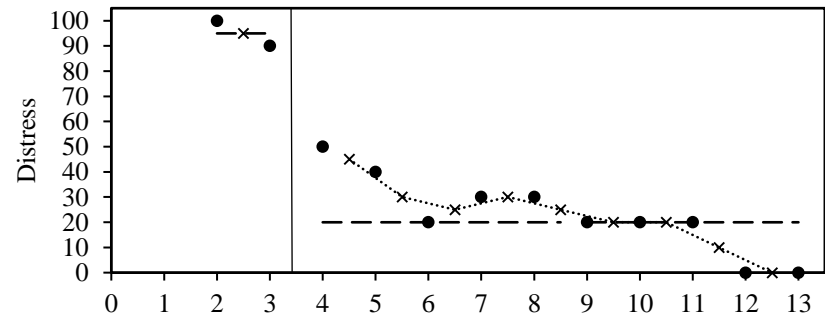
Measurement

Figure PC2. Interference VAS: raw data, central tendency and trend.



Measurement

Figure PC3. Uncontrollability VAS: raw data, central tendency and trend.



Measurement

Figure PC4. Distress VAS: raw data, central tendency and trend.

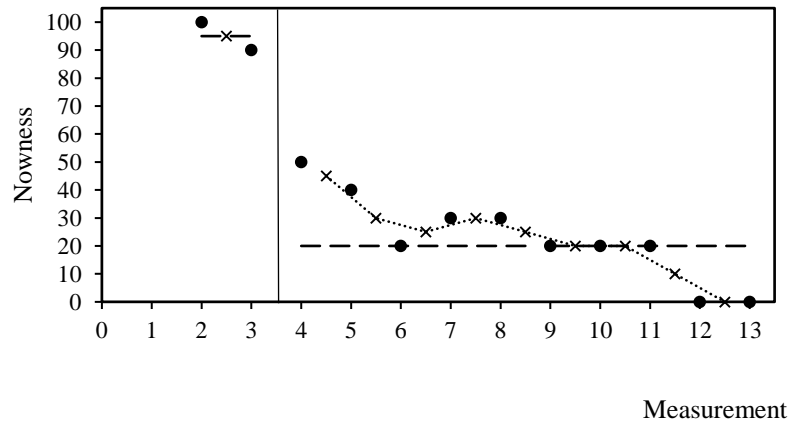


Figure PC5. Nowness VAS: raw data, central tendency and trend.

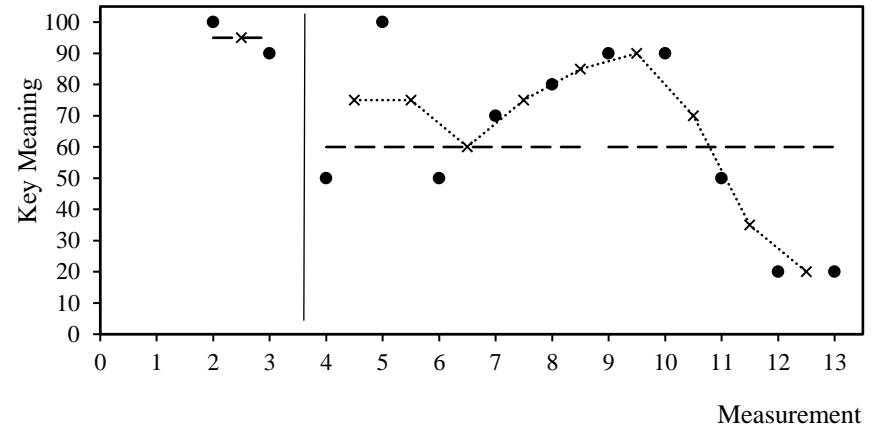


Figure PC6. Key Meaning VAS: raw data, central tendency and trend.

Sharing the formulation. Despite lack of complete baseline data, visual analysis demonstrates a downward trend following the shared formulation for all items on the IVAS. Although the scores had begun to reduce in the baseline phase between Session 2 and 3, the reduction from Session 3 to 4 across all items on the IVAS is the largest across all sessions. This suggests that sharing the formulation with PC impacted on these scores. Although there are some patterns of variability in the data, especially for interference and across other items with scores increasing at Session 7 and 8, this is mostly followed by a continued and stable decrease across treatment with scores of 0 by Session 12 and 13. Conversely, the EBVAS displays high levels of variability, with scores declining at Session 4, followed by a large increase at Session 5, reduction in Session 6 and gradually increasing again until scores begin to reduce from Session 11. Thus, the gains made at Session 4 for the belief in the meaning of the images were not maintained. However, by the end of data collection, the score on the EBVAS had reduced considerably in comparison to baseline data.

Table PC2.

ICF-RS content code.

ICF-RS total	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9
10.5	1.5	0.5	1	1.5	1.5	1.5	1.5	1	0.5

Linking ICF to outcome. PC's diagram scored 10.5/27, the second highest score of all participants, scoring within each item, albeit still low for overall quality. Highest ratings were given for Items 1, 4, 5, 6 and 7. This suggests that the diagram

moderately met criteria for observations being described with some precision with regards to their nature and source, although some ambiguity remained regarding whether they were based on inference or supposition. Next, some moderators were included that helped to build a picture of the problem, as well inclusion of some mediators linking observations together. Detail regarding how they operate is somewhat lacking although there is some functional equivalence between items represented. Scores demonstrated that the formulation accounts for the information gained to a degree but that some information is not completely integrated to reflect a comprehensive account.

Items 3 and 8 were deemed to be partially present in the diagram suggesting that some explanations were present in the diagram, although they did not always relate to or distinguish from specific observations. The formulation fails to provide a readily apparent account of how the problem has arisen and how it is being sustained. Therefore, it is less useful for anticipating how the problem could change under different circumstances and for choosing where and how to intervene and what to prioritise. Furthermore, Items 2 and 9 were less apparent in the ICF, suggesting that the formulation contained ambiguity about how processes link to each other and that it did not fully capture the complexity of the person's presentation.

In terms of outcome, PC's scores showed a reduced trend across all items including the IVASs and EBVAS despite patterns of variability over the course of treatment. The scores mostly continued to decrease in a stable manner as treatment progressed, suggesting that although baseline data was not complete and thus stability was not fulfilled, it seems that the graphs are suggestive of a reduction in symptoms across treatment. This finding occurred for all pre-/post- measures with PC no longer

meeting caseness for PTSD, depression or anxiety by the end of data collection. Thus, observed gains from baseline to end of treatment across items were large.

Participant D. Table PD1 details trauma information, specific images, key meaning of images as well as the formulation shared and the treatment received. PD spoke English as her first language. She had experienced a single incident of trauma around 4 years prior to receiving treatment. She also had a long-term health difficulty.

Table PD1.

Trauma type, specific images, encapsulated beliefs, formulation shared, treatment type for PD.

Trauma type	Specific images	Encapsulated beliefs	Formulation shared	Treatment type
Medical procedure involving going into hospital theatre for an operation.	Lying in hospital bed in hospital room with medical procedures about to happen.	I am going to die. I will not wake up. I am not in control.	Vicious flower	Trauma focused CBT.

PD had three baseline data points followed by five data points following sharing of the formulation. PD continued to receive treatment following involvement in the study. Baseline data did not meet stability criteria for any items of the IVAS and thus further statistical analyses were carried out for frequency, interference, uncontrollability distress andnowness and key meaning. See table PD2 for Tau-U analyses. Image intrusiveness and encapsulated belief VASs are graphically displayed in Figures PD1-5 and PD6. Summary of the formulation content is shown in Table PD3.

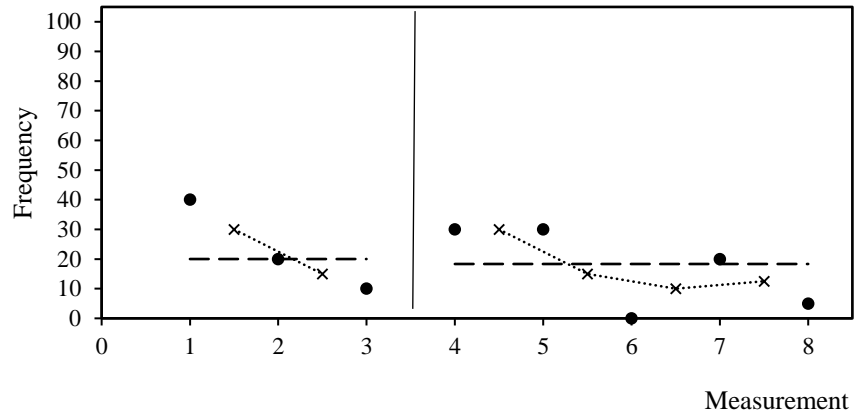


Figure PD1. Frequency VAS: raw data, central tendency and trend.

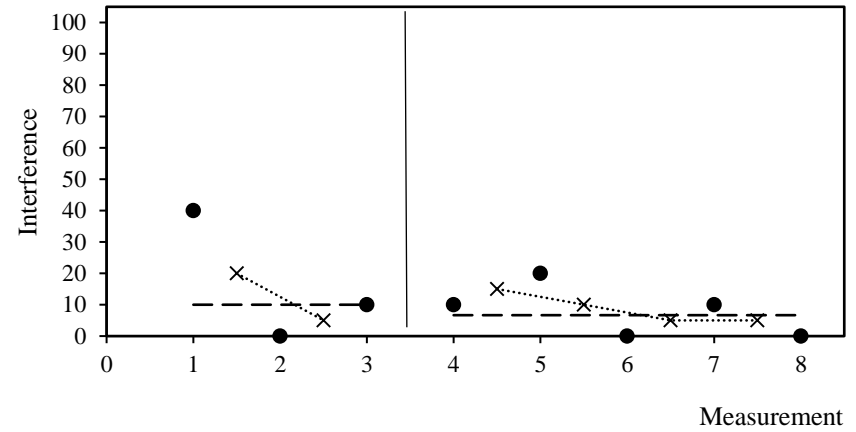


Figure PD2. Interference VAS: raw data, central tendency and trend.

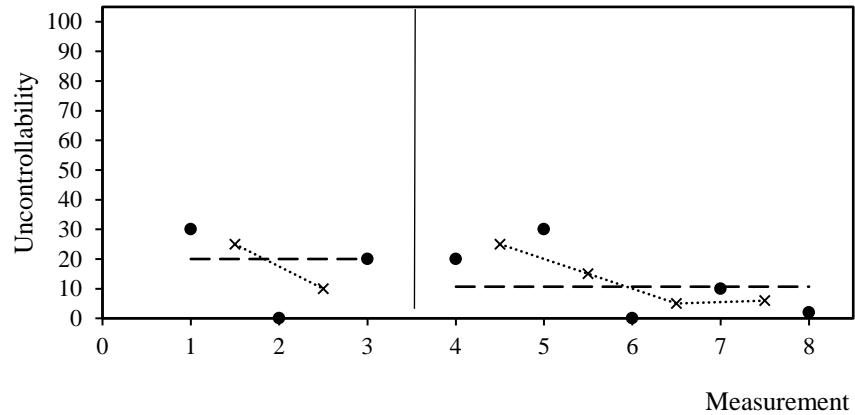


Figure PD3. Uncontrollability VAS: raw data, central tendency and trend.

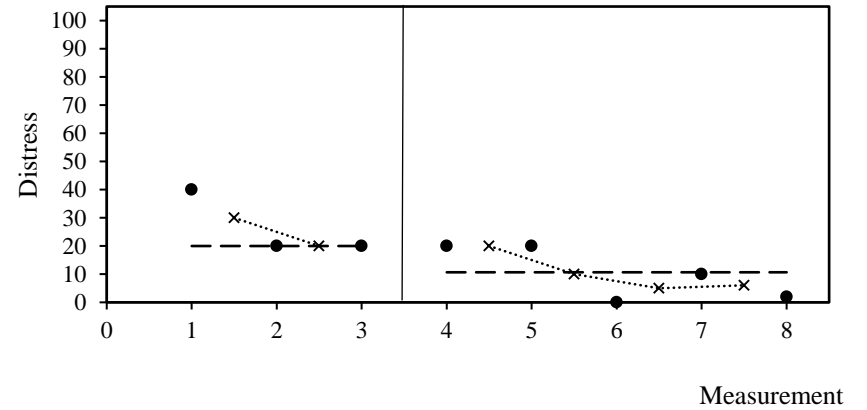


Figure PD4. Distress VAS: raw data, central tendency and trend.

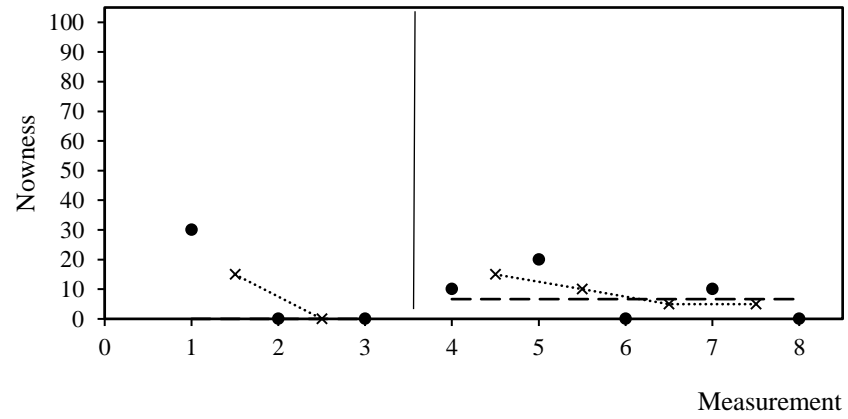


Figure PD5. Nowness VAS: raw data, central tendency and trend.

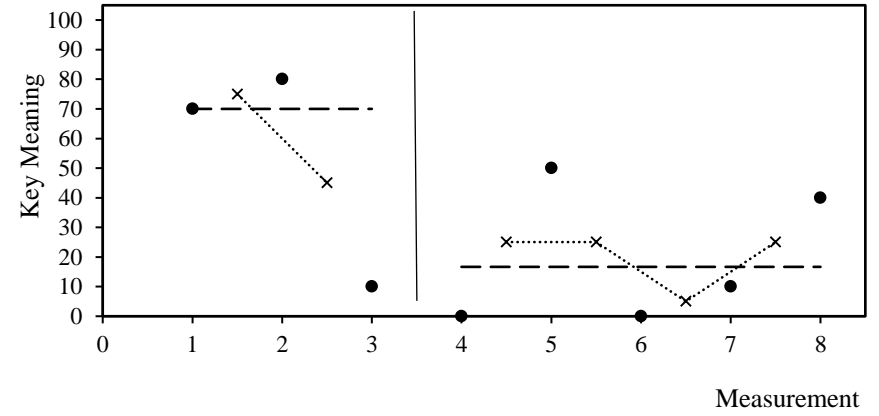


Figure PD6. Key Meaning VAS: raw data, central tendency and trend.

Table PD2.

Tau-U analysis for Frequency, Interference, Uncontrollability, Distress, Nowness and Key Meaning for PD.

	TAUb	p value	CI 90%
Frequency	-.07	.88	.80<>0.67
Interference	.15	.77	-.87<>.60
Uncontrollability	-.07	.88	.80<>0.67
Distress	-.70	.18	-1<>.14
Nowness	.23	.65	-.54<>.94
Meaning	-.62	.18	-1<>.14

Sharing the formulation. As the graphs display, PD's scores generally show lower levels of image intrusiveness symptoms in the baseline Phase compared to some other participants. The data shows a pattern of variability whereby scores decreased at Baseline point 2. This was followed by a further decrease in scores (frequency and nowness), a slight increase (interference and uncontrollability) or the same score (distress) at Session 3. The variability of the data and unstable baseline of all items could have been due to a positive life event that happened to PD between Sessions 2 and 3 and therefore results need to be interpreted with caution. The data also continues to show a pattern of variability over the course of therapy. For frequency, scores increase at Session 4 and begin to reduce at Session 6. Nowness also slightly increases at Session 4 also, with other image intrusiveness scores remaining the same. Belief in the key meaning of images reduces slightly at Session 4. The EBVAS demonstrates a pattern of variability whereby scores decrease in

Session 3 and 4, increase at Session 5, decrease at Session 6 and rise again in Session 7 and 8.

Tau-U analyses revealed no significant differences between scores in Phase A and Phase B for any of the Items. Towards the end of data collection, scores across all IVAS items reduced. However, with the patterns of variability in the data, it is difficult to be confident that this finding would remain stable.

Table PD3.

ICF-RS content code.

ICF-RS total	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9
6.5	1.5	0.5	0.5	1	0.5	0.5	0.5	1	0.5

Liking ICF to outcome. Overall, PD’s diagram scored low for quality with a total score of 6.5/27 scoring 0.5 on most items. The diagram scored highest on Item 1. This suggests that the diagram moderately met criteria for demonstrating the nature and source of observations and these were moderately separated from explanations. Items 4 and 8 were marginally represented suggesting that there was some evidence of contextual elements included in the diagram and also some ability to provide a basis of understanding of how to intervene, although this was deemed as too basic to enable precise guiding of treatment.

Other item criteria very slightly met in the diagram included some linking of observations and explanations, some functional equivalence highlighted between factors and some identification of mediators, although the score suggests that mostly

these were not coherently organised as complex pieces of information into a comprehensive understanding.

With regards to outcome, PD showed a reduction in PTSD symptoms on pre/post measures including the IES-R and PCL-5 whereby she no longer met caseness for PTSD. She also improved on IAPT measures of depression and anxiety. However, due to the weekly variability of scores observable it is not clear if these findings would remain stable over the course of therapy. Furthermore, the gains made from the beginning of treatment to when the last data point was collected are moderate. However, as PTSD scores were fairly low at the start of treatment and she had not yet completed treatment, this is more likely to be expected.

Participant E. Table PE1 details trauma information, specific images, key meaning of the images, the formulation shared as well as treatment received. PE spoke English as her first language. She had experienced a number of traumatic events over her lifetime but was receiving treatment for a specific trauma that occurred 15 years ago that had recently been triggered. PE was also experiencing symptoms of depression, health anxiety and panic disorder.

Table PE1.

Trauma type, specific images, encapsulated beliefs, formulation shared, treatment type for PE.

Trauma type	Specific images	Encapsulated beliefs	Formulation shared	Treatment type
Armed robbery in which family members were shot and assaulted.	Being attacked. Family being hurt and she not being able to help. Dying of an unknown illness.	My family is going to die. I will be attacked. I am vulnerable. The world is dangerous.	Individual Case Formulation	Trauma focused CBT.

PE had three baseline data points followed by five data points captured following sharing of the formulation. She continued to receive trauma focused CBT following the study involvement. Baseline data for measures of frequency,nowness and key meaning failed to meet stability criteria. VASs are graphically displayed in Figures PE1-5 and PE6. See Table PE2 for Tau-U analyses. Summary of the ICF content is shown in Table PE3.

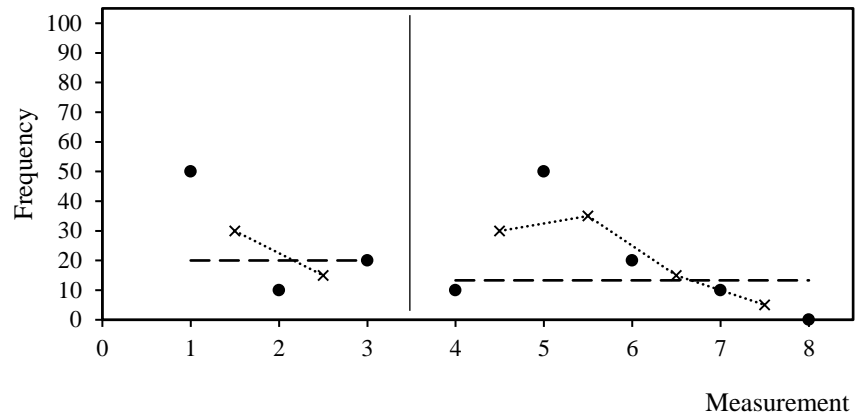


Figure PE1. Frequency VAS: raw data, central tendency and trend.

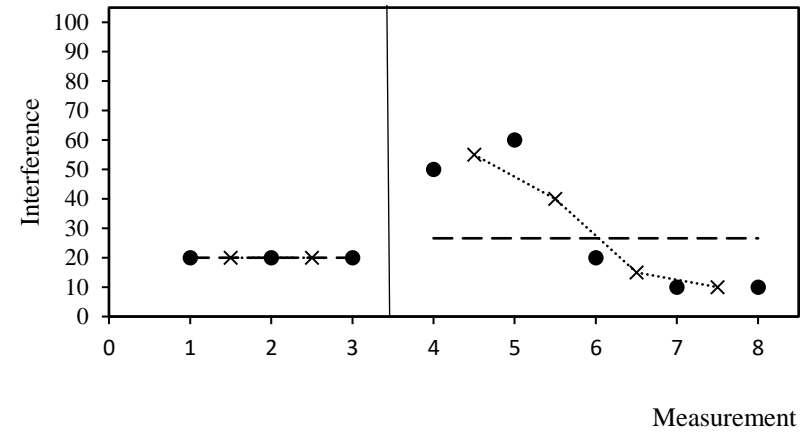


Figure PE2. Interference VAS: raw data, central tendency and trend.

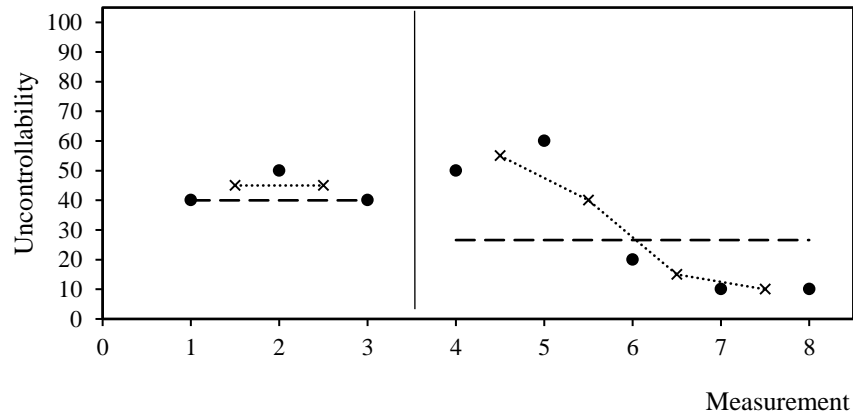


Figure PE3. Uncontrollability VAS: raw data, central tendency and trend.

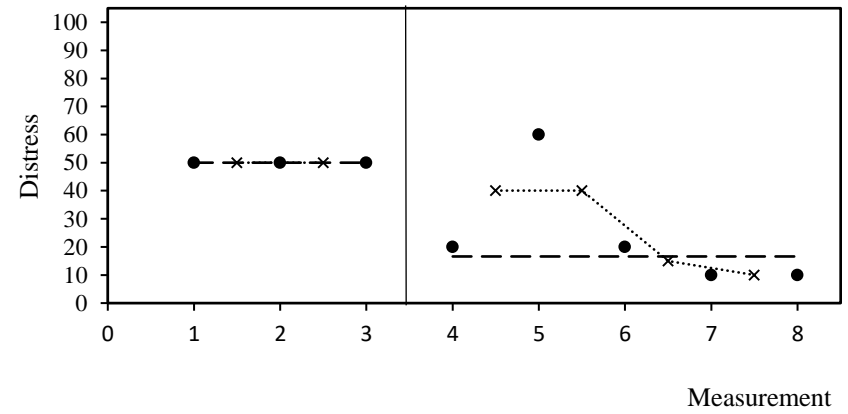


Figure PE4. Distress VAS: raw data, central tendency and trend.

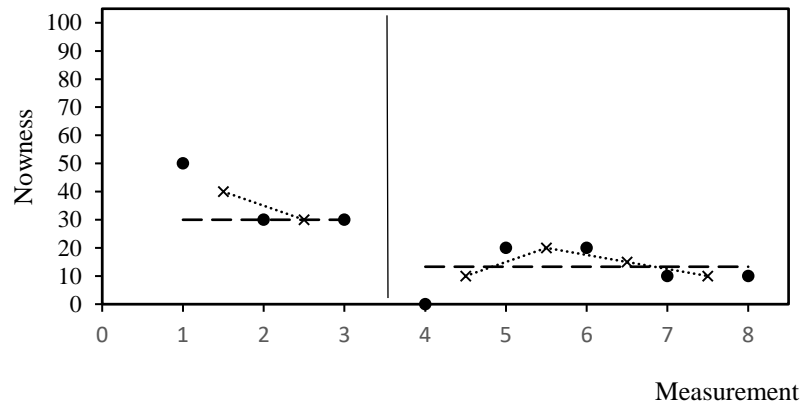


Figure PE5. Nowness VAS: raw data, central tendency and trend.

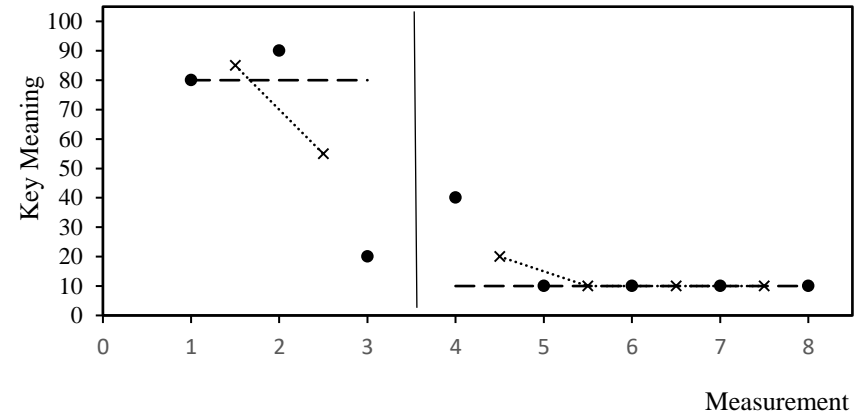


Figure PE6. Key Meaning VAS: raw data, central tendency and trend.

Table PE2.

Tau-U analysis for Frequency, Interference, Uncontrollability, Distress, Nowness and Key Meaning for PE.

	TAUb	p value	CI 90%
Frequency	-.31	.55	-1<>-.47
Interference	0	1	-.73<>.73
Uncontrollability	-.28	.55	-1<>.47
Distress	-.60	.17	-1<>.17
Nowness	-.87	.05	-1<>.13
Key Meaning	-.80	.07	-1<>-.06

Sharing the formulation. PE's scores are generally low for image intrusiveness compared to other participants in the baseline phase, but high for key meaning of the image. Scores have mostly reduced by Session 8 on image intrusiveness and encapsulated belief. However, visual analysis reveals considerable variability of the scores. The baseline is stable for interference, uncontrollability and distress. Interference and uncontrollability show a similar pattern of variability whereby scores increase at Session 4 and 5 followed by a decrease in scores from Session 6. Distress shows a pattern whereby scores decrease at Session 4 but increase considerably at Session 5, followed by a decrease from Session 6. Scores for belief in the meaning of the images also increase at Session 4. Therefore Session 4 appears to be a point of change for PE, with scores either increasing considerably or decreasing. Tau-U analyses reveal that there was no significant differences between Phase A and B for any of the IVASs. Overall there is a reduction of symptoms across treatment, with

greatest gains on the EBVAS. However, Tau-U analyses revealed that differences on the key meaning of images between Phase A and B were not significant.

Table PE3.

ICF content code.

ICF-RS total	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9
10	1	0.5	1.5	1.5	2	1	1	1	0.5

Linking ICF to outcome. Overall, PE's diagram scored 10/27 on the ICF-RS scoring low for over quality. Scores reveal that PE's diagram showed a high level of functional equivalence (Item 5) between elements that allows some understanding for how elements contributed to the delineation of the patterns of circumstances. Linked to this, there is also presence of explanations used to make sense of the information included as well as contextual elements (moderators) that give some understanding about the conditions under which the problem presents and is maintained. The diagram also somewhat met criteria for containing mediators, although their linking function to other observations is not convincingly established and the nature and source of the observations are not completely clear. These scores demonstrate that the diagram met some criteria for level of detail available in the diagram that allows for some information regarding how factors relate to each other. However, the diagram does not provide a readily apparent account of how the problem has arisen and how it is being sustained. Therefore, it is of limited use for anticipating how the problem could change under different circumstances and for choosing where and how to

intervene. Therefore, although some level of detail is present, especially with regards to the functional equivalence of items, the diagram does not manage complexity as successfully as required to adequately guide intervention.

Overall outcome revealed that by the end of data collection, PE no longer met criteria for PTSD, displaying asymptomatic scores on the PCL-5 and IES-R. Scores on IAPT measures also reduced including depression. Gains from Session 1 to Session 8 appear moderate.

Participant F. Table PF1 details trauma information, specific images, key meaning of images, the formulation shared and the treatment received. PF spoke English as his first language. He had experienced a number of traumatic events over his lifetime but was receiving treatment for a specific trauma that occurred within the last year. As well as symptoms of PTSD, PF had symptoms of complicated grief disorder and was finding the death of a family member very difficult to cope with.

Table PF1.

Trauma type, specific images, encapsulated beliefs, formulation shared, treatment type for PF.

Trauma type	Specific images	Encapsulated beliefs	Formulation shared	Treatment type
Physically assaulted whilst caring for dying relative.	Perpetrator attacking him. Hands of perpetrator around neck.	He is going to kill me. People are unpredictable. The world can be horrible.	Individual Case Formulation.	Trauma focused CBT.

PF had three baseline data points followed by three data points following sharing of the formulation. PF continued to receive therapy following involvement in the study. Image intrusiveness and encapsulated belief VASs are graphically displayed in Figures PF1-5 and PF6. PF showed significant baseline trend on all Items of the IVAS requiring further statistical analyses that are summarised in Table PF2. Summary of formulation content is shown in Table PF3.

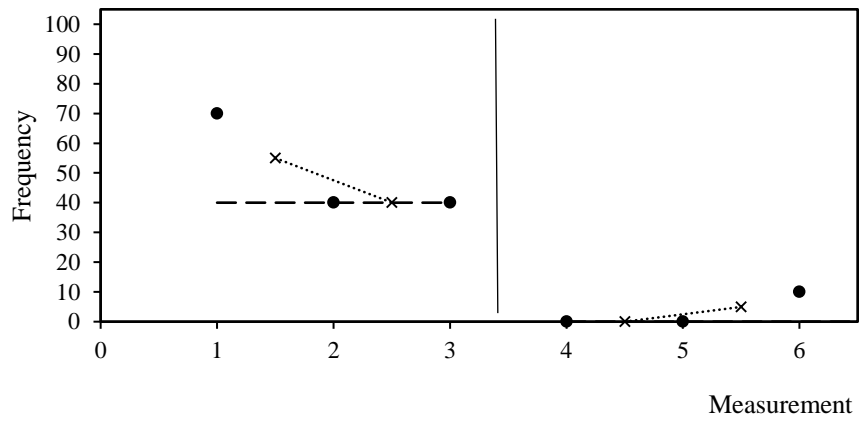


Figure PF1. Frequency VAS: raw data, central tendency and trend.

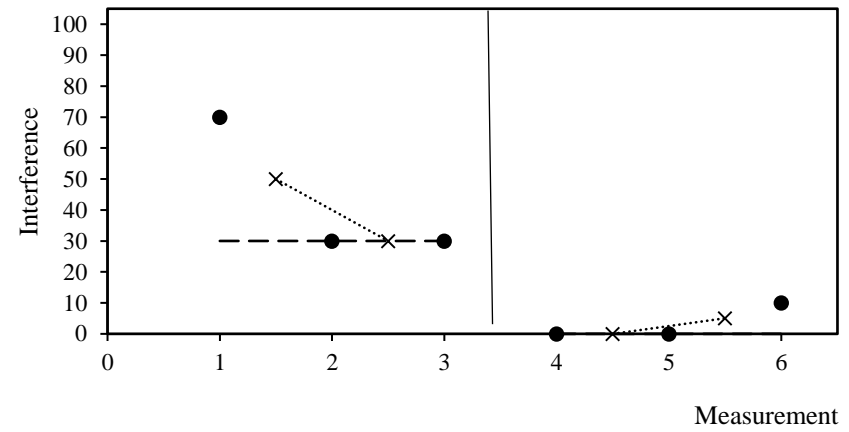


Figure PF2. Interference VAS: raw data, central tendency and trend.

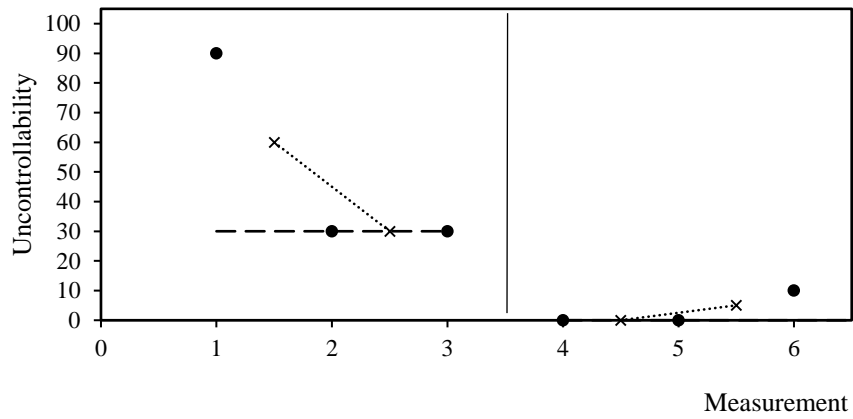


Figure PF3. Uncontrollability VAS: raw data, central tendency and trend.

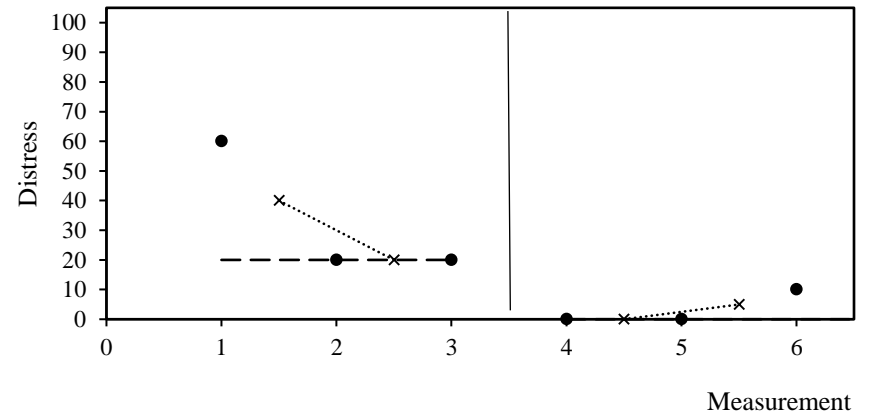


Figure PF4. Distress VAS: raw data, central tendency and trend.

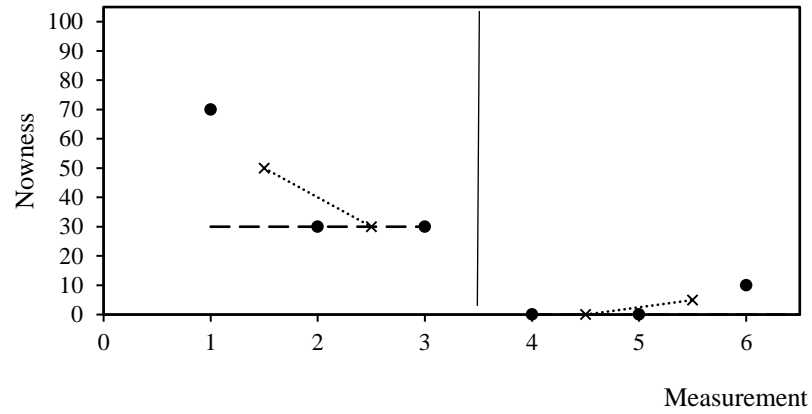


Figure PF5. Nowness VAS: raw data, central tendency and trend.

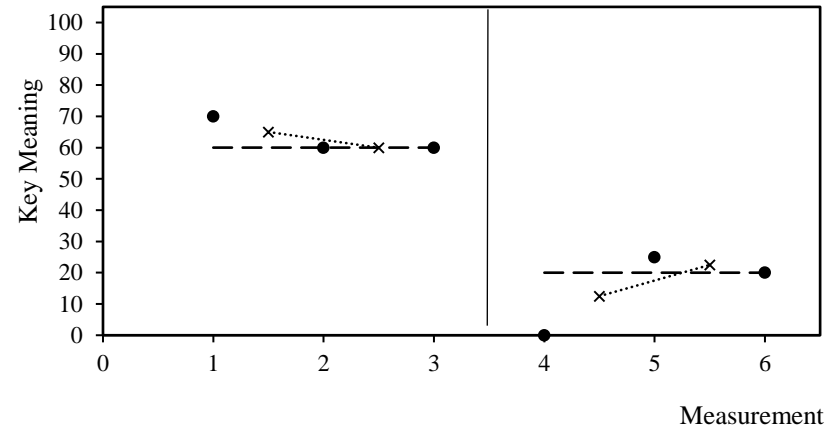


Figure PF6. Key Meaning VAS: raw data, central tendency and trend.

Table PF2.

Tau-U analysis for Frequency, Interference, Uncontrollability, Distress, Nowness and Key Meaning for PF.

	TAUb	p value	CI 90%
Frequency	-.78	.13	-1<>.06
Interference	-.78	.13	-1<>.06
Uncontrollability	-.78	.13	-1<>.06
Distress	-.78	.13	-1<>.06
Nowness	-.78	.13	-1<>.06
Key Meaning	-1	.05	-1<>-.16

Sharing the formulation. Visual analysis reveals that there is a pattern of variability in the data whereby scores reduce at Baseline point 2, followed by the same score at Session 3. Scores reduce again at Session 4 and remain reduced until Session 6 where there was a slight increase in scores. This occurred across all image intrusiveness items. There is a clear reduction in scores at Session 4 for PF, suggesting that sharing the formulation diagram may have contributed to reduction of image intrusiveness scores. However, as described there was also a reduction at Session 2 suggesting that these findings need to be interpreted with caution. Furthermore, Tau-U analyses revealed no significant differences between Phase A and Phase B in any of the items, suggesting that any observed differences were not significant. For key meaning of images, visual analysis shows that following the stable baseline, there was a reduction at Session 4, followed by an increase in Session 5 and a reduction at Session 6. Tau-U analyses revealed that the differences just failed

to meet significance. Although scores generally appear to reduce over treatment, the differences between phases are not significant and with the patterns of variability in the data, it is difficult to be confident that scores would remain stable.

Table PF3.

ICF content code.

ICF-RS total	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9
9.5	2	0.5	0.5	2	1.5	0	1	1	1

Linking ICF to outcome. The coding summary shows that PF's diagram scored 9.5/27 in total, scoring within all domains except Item 6. Highest ratings were given for Items 1 and 4. This suggests that items regarding the nature and source of observations were clear and explicit, and not confused with explanations. Furthermore, the diagram contained key contextual elements that provided a useful context for understanding triggers of the problem and where it presents itself. Functional equivalence between items, contributing to the difficulty, was also moderately captured.

Item 7, 8 and 9 were scored as partially meeting criteria suggesting that the diagram moderately accounts for information gained about the client's problem, but that some important observations were not satisfactorily integrated, suggesting that it is difficult to adequately direct treatment from this information. Regarding complexity, the formulation included some higher-level detail but the overall organisation appeared somewhat problematic. The formulation also fails to identify or

include mediators that maintain difficulties leaving ambiguity with regards to explanations and observations and the links between them.

With regards to overall outcome, PF demonstrated a good level of symptom reduction across all measures, no longer meeting caseness on PTSD measures. IAPT measure scores also reduced considerably for depression and anxiety. Considering that PF was only half way through treatment at this stage, gains made this far were promising.

Participant G. Table PG1 details trauma information, specific images, key meaning of images, the formulation shared as well as the treatment received. PG spoke English as her first language and had experienced a single instance of trauma one year prior to receiving treatment.

Table PG1.

Trauma type, specific images, encapsulated beliefs, formulation shared, treatment type for PG.

Trauma type	Specific images	Encapsulated beliefs	Formulation shared	Treatment type
Road Traffic Accident.	Person's leg being hit People kicking the car.	I am a bad person. I can't deal with responsibility. I can't be trusted. I am not good enough.	Ehlers & Clark.	Trauma Focused CBT.

PG had three baseline data points followed by three data points following sharing of the formulation. PG continued to receive therapy following involvement in the study. Image intrusiveness and encapsulated belief VASs are graphically displayed in Figures PG1-5 and PG6. Baseline data was stable, either within a 20% range of the median or increasing. However, further Tau-U analyses were carried out to statistically investigate the differences between phases, detailed in Table PG2. Summary of formulation content is shown in Table PG3.

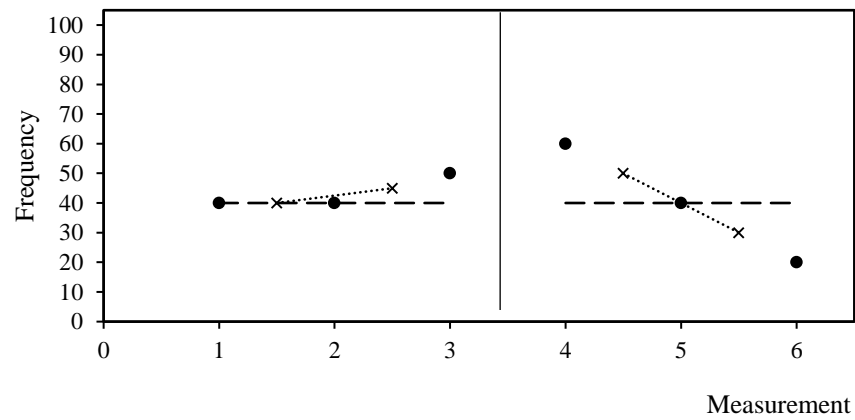


Figure PG1. Frequency VAS: raw data, central tendency and trend.

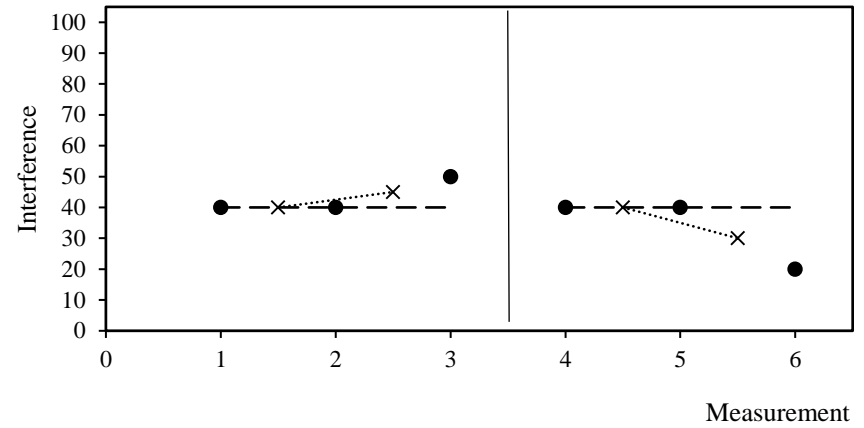


Figure PG2. Interference VAS: raw data, central tendency and trend.

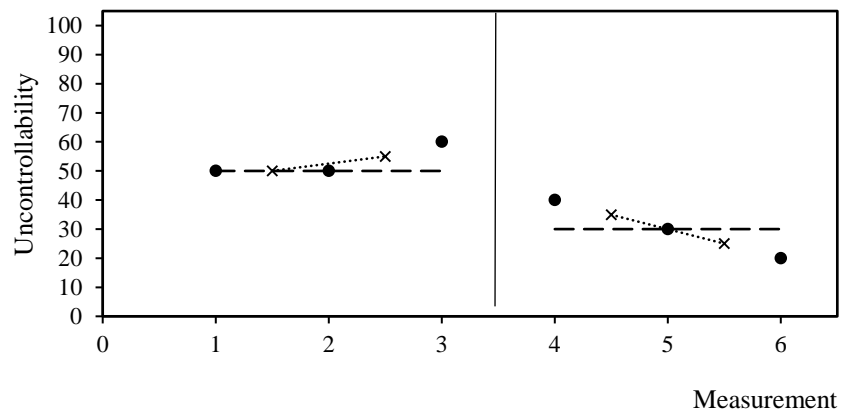


Figure PG3. Uncontrollability VAS: raw data, central tendency and trend.

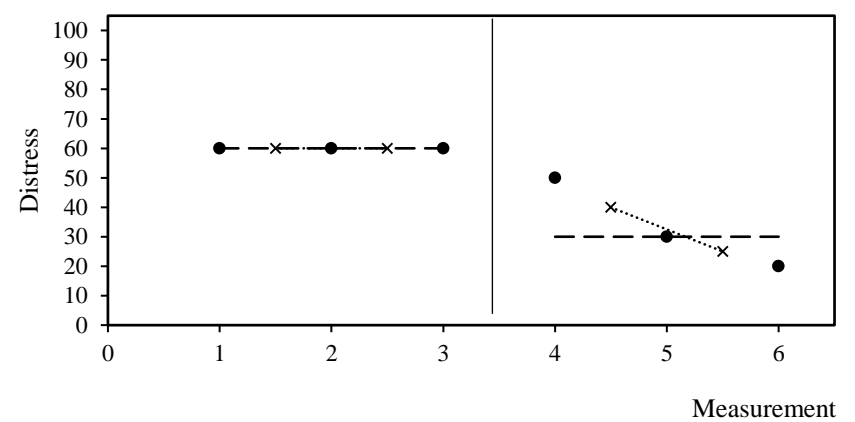


Figure PG4. Distress VAS: raw data, central tendency and trend.

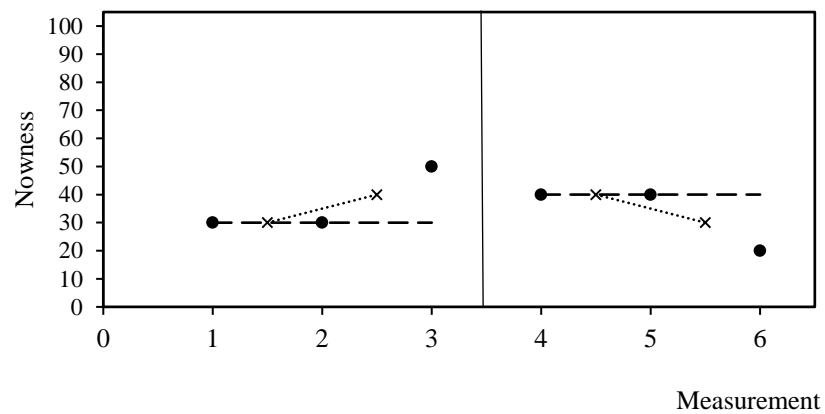


Figure PG5. Nowness VAS: raw data, central tendency and trend.

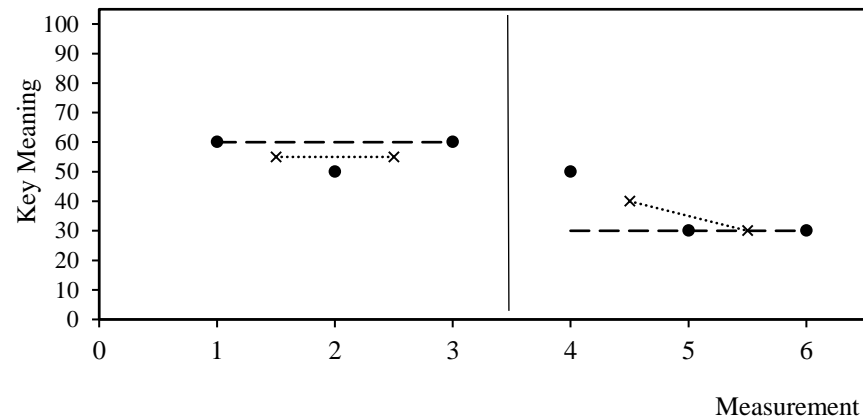


Figure PG6. Key Meaning VAS: raw data, central tendency and trend.

Table PG2.

Tau-U analysis for Frequency, Interference, Uncontrollability, Distress, Nowness and Key Meaning for PG.

	TAUb	p value	CI 90%
Frequency	.13	.82	-.95<>.73
Interference	-.71	.28	-1<>.28
Uncontrollability	-1	.04	-1<>-.16
Distress	-1	.04	-1<>-.16
Nowness	-.11	.83	-.95<>.73
Key Meaning	.94	.08	-1<>.05

There is variability in the data for image intrusiveness across treatment. At Session 4, for frequency, there is a pattern of variability whereby scores increase followed by a decrease in Session 5 and 6. Scores had already begun to increase at Session 3. For the other items, variability is generally lower with a stable and continued decrease for scores for interference, uncontrollability and distress from Session 4, an important observation because baseline data for these was either stable or increasing. Further visual analysis through investigation of the central tendency for frequency and interference reveal no changes across Phase A and B. For nowness, central tendency increased in Phase B. For distress and uncontrollability central tendency is lower in Phase B. Tau-U analyses reveal that there was a significant difference for scores for uncontrollability and distress between Phases. None of the other analyses revealed a significant difference between Phase A and B. For the key meaning of the image, baseline is stable with a reduction in scores at Session 4

followed by a decrease in scores.

Table PG3.

ICF content code.

ICF-RS total	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9
11	1.5	1	1	2	1.5	1.5	1	1	0.5

Linking ICF to outcome. The coding summary demonstrates that PG's diagram scored 11/27 in total, making it the highest scoring formulation across all participants and scoring within all domains, capturing an element of each item. Despite this, it still scores low for overall quality. The highest rating was given to Item 4 indicating that the diagram successfully met criteria for inclusion of key contextual moderators that provided a useful context of the circumstances in which the problem could be expected to occur and the form it takes. The diagram also partially met criteria for Items 1, 5 and 6, suggesting that some descriptions of observations were present as well as functional equivalence between elements and that mediators between factors were partially present.

Items 2 and 3 scored moderately illustrating that although explanations and observations were mostly present, there was some ambiguity in terms of how these differed and were related to each other. Scores on Items 7 and 8 suggest that the diagram partially met criteria for including relevant information about the presentation of the problem but that this was not sufficiently detailed to adequately

direct intervention and was also limited with regards to anticipating how the problem could change under different circumstances. Overall, the diagram appears to not capture complexity as successfully as it could have.

In terms of overall outcome, at Session 6, PG showed reductions in scores on PTSD measures of IES-R and PCL-5 and was just under caseness on these measures. However, scores were still relatively high for PTSD, although this is expected since PG was only half way through treatment. Reductions were observed across IAPT measures also. Thus, observed gains from baseline to Session 6 appear to be moderate with further improvements hoped for as treatment progressed.

Participant H. Table PH1 details trauma information, specific images, key meaning of the images, formulation shared and treatment received. PH spoke English as her first language. She had experienced two traumatic incidents over her lifetime of a similar nature with similar themes and beliefs attached to them. PH had other systemic difficulties at the time of treatment.

Table PH1.

Trauma type, specific images, encapsulated beliefs, formulation shared, treatment type for PH.

Trauma type	Specific images	Encapsulated beliefs	Formulation shared	Treatment type
Sexual and physical assault.	Images relating to sexual and physical assault.	People cannot be trusted. The world is unfair. I will not survive this.	Ehlers & Clark.	Trauma Focused CBT.

Due to data collection time restrictions, PH had three baseline data points followed by one data point in Phase B. PH continued to receive therapy following involvement in the study however since dropped out of therapy. Due to the limited data in Phase B, results are interpreted with caution. Image intrusiveness and encapsulated belief VASs are graphically displayed in Figures PH1-5 and PH6. Baseline trend was significant for interference and uncontrollability, but was increasing or met stability criteria for remaining items. Tau-U analyses were deemed inappropriate due to the limited data available. Summary of formulation content is shown in Table PH2.

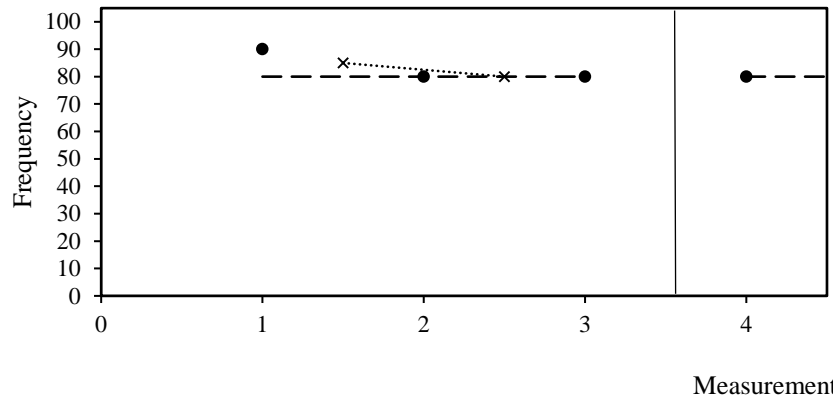


Figure PH1. Frequency VAS: raw data, central tendency and trend.

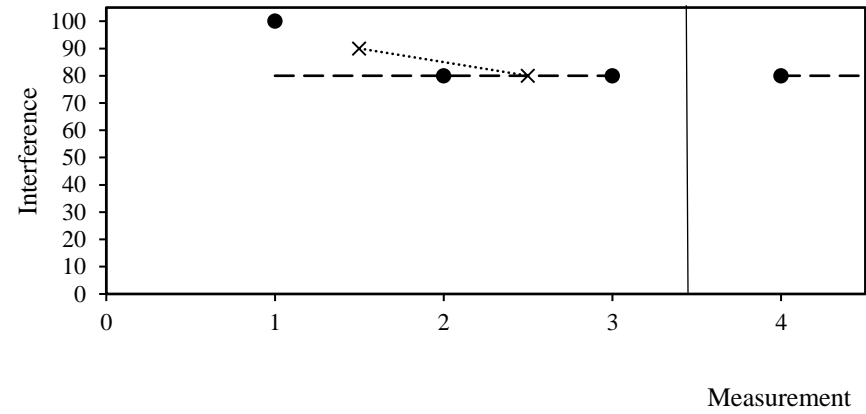


Figure PH2. Interference VAS: raw data, central tendency and trend.

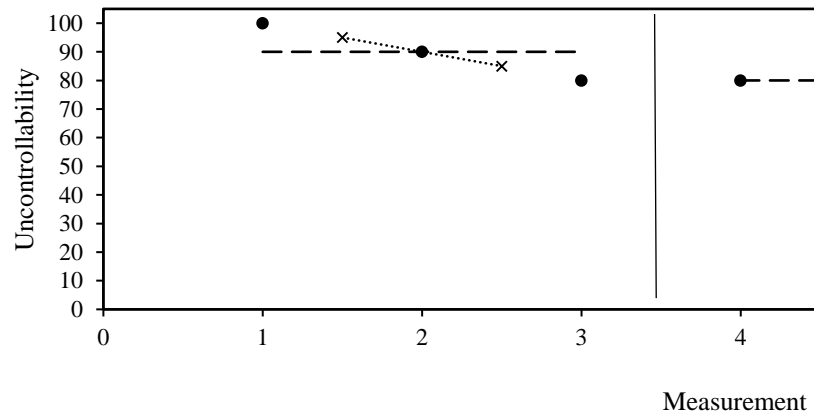


Figure PH3. Uncontrollability VAS: raw data, central tendency and trend.

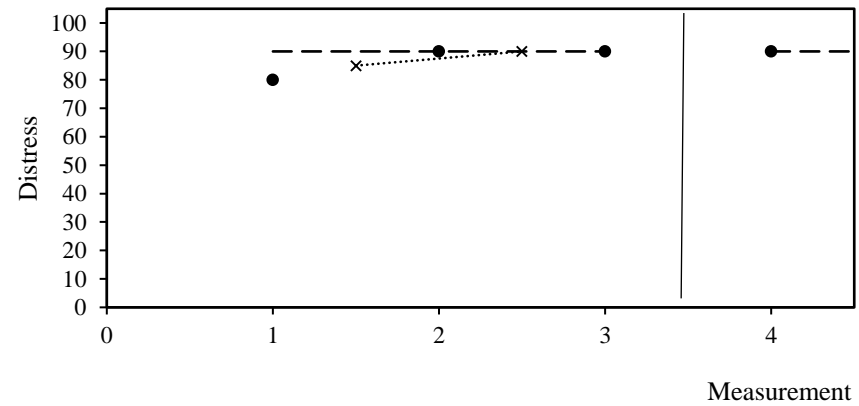


Figure PH4. Distress VAS: raw data, central tendency and trend.

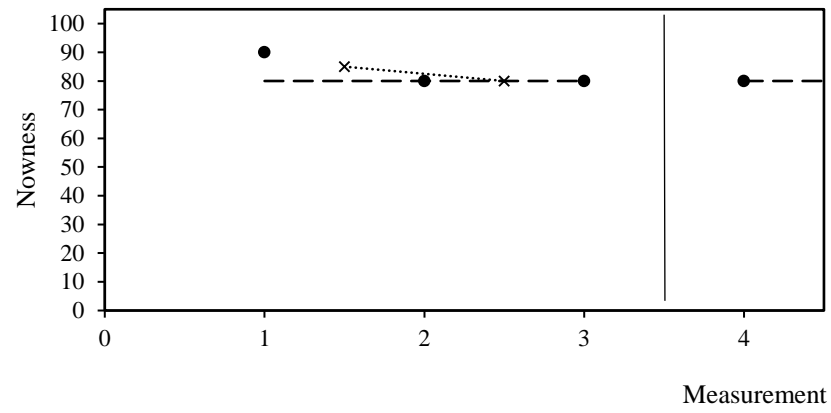


Figure PH5. Nowness VAS: raw data, central tendency and trend.

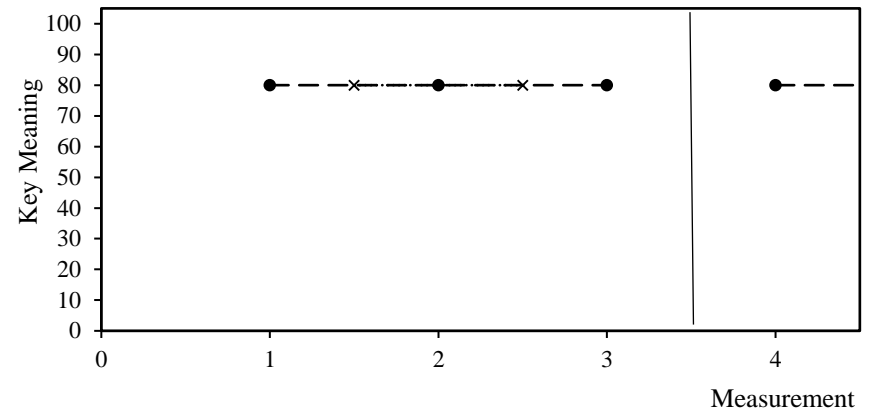


Figure PH6. Key Meaning VAS: raw data, central tendency and trend

Sharing the formulation. Visual analysis reveals that following sharing of the formulation, there was no change in scores. For frequency, interference, uncontrollability and nowness, there was a pattern whereby scores decreased at Session 2, with this reduction maintained across the following two sessions. Distress increased at Session 2 and remained at this score in the following sessions. There was no difference for key meaning of images over the course of the sessions. Discussion with the therapist revealed that this individual since dropped out of treatment, suggesting that they found the treatment difficult or that there were other difficulties that made committing to therapy hard. With this information and due to the lack of treatment phase data, caution is required when interpreting the data.

Table PH2.

ICF content code.

ICF-RS total	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9
8.5	1	0.5	1	1	1.5	1	1	1	0.5

Linking ICF to outcome. Overall, PH’s diagram scored 8.5/27. All item criteria were met to an extent, but scores were generally low. Item 5 was rated highest, suggesting that the formulation diagram contained elements with functional equivalence that moderately explained how elements contributed to the pattern of circumstances observed.

Items 1, 3, 4 and 6 were also partially present, suggesting that some explanations and observations were included, although explanations were not completely related to a particular observation. Furthermore, observations were not

described with sufficient precision. Some moderators and mediators were included in the diagram to demonstrate elements that contribute to the difficulty, however they provided somewhat limited information about how the problem operates under certain circumstances.

Scores for Items 7 and 8 indicate that the formulation partially accounted for information gained about the problem, but that it does not allow a complete understanding for how the problem arose or is maintained. Therefore it is of less use for anticipating how the problem could change under different circumstances, for guiding intervention or choosing what to prioritise than perhaps if it was increased in quality. Indeed, overall quality for this diagram was low.

Due to limited data in Phase 2, little information is obtained regarding outcome. However, scores on the SS measure reveal no change in symptoms between Phase A and Phase B and IAPT measures on depression, anxiety and W&SAS demonstrate that PH's symptoms worsened over the captured treatment.

Summary across participants. Patterns across participants are discussed tentatively in light of baseline instability, high levels of variability and small sample size. Findings reveal differential responses of eight participants undergoing similar treatment. Most participants showed improvement over the course of treatment with PH as the only non-responder according to measures. All other participants met reliable and clinically significant change on a standardised measure of PTSD, despite some participants only being half way through treatment. Again it is worth noting that for PH, there were systemic issues and other difficulties that likely contributed to symptoms and could have resulted in her dropping out of treatment.

Overall, formulation diagrams were rated as low for quality and the change in scores across participants was quite similar. However, there seems to be some evidence that participants whose diagrams yielded higher ratings tended to experience greatest decreases across most image intrusiveness items and encapsulated belief scores. Those with increased quality of formulations mostly displayed a downward trend across image intrusiveness scores and key meaning. However, one participant (PB), whose formulation diagram was rated the lowest met reliable change and showed significant reductions on scores across treatment.

Whilst the scores were quite low, image intrusiveness and key meaning of images was reduced most in those with a higher score on Items 7 and 8. This suggests that those who displayed downward trends in scores had formulations that mostly provided slightly more coherent and comprehensive accounts of the available information, integrating some of the information necessary to draw together the factors influencing the problem. This then potentially displayed some of the patterns of interaction between factors, which may have assisted with some understanding of how to intervene. Those who responded lower tended to have a lower score on these items, suggesting a less coherent account of information displayed in the diagram that did not assist with as clear and precise targets for treatment.

Those who displayed increased variability in scores over therapy and responded less to treatment appeared to have increased scores for Items 4 and 5. This suggests that those whose scores reduced less had increased moderators included in diagrams that demonstrated exacerbation or improvement of symptoms as well as demonstration of functional equivalence between elements (either triggers or responses) that described the overall pattern of circumstances that made aspects of the problem more likely to occur.

Session 4 appeared to be a marker of change for most participants, either displaying decreases (PA, PB, PC, PF, PG) or increases (PE, PD, PG) in scores in some image intrusiveness measures. In most cases, frequency, interference, uncontrollability, distress and key meaning reduced at Session 4, although for some participants, frequency (PD, PG) andnowness (PD) increased. Nowness was also slower to change in some participants (PA, PB), compared to other image intrusiveness items. Most changes that occurred during treatment tended to appear stable, however with high variability across participants (PC, PD, PE, PF), it is difficult to assert that these changes would be sustained.

Those with increased variability tended to score more highly for Item 1 but less highly for Item 9. This suggests that although the nature and source of observations could have been made fairly clear and explicit in some cases, overall, the formulations did not address issues of complexity, and there were some questionable decisions about what was included, the level of detail or organisation of elements.

With regards to image intrusiveness, decreases ranged from small-large and stable-variable. Mostly, participants displayed a downward trend in image intrusiveness even when they had not completed treatment. Significant differences between phases tended to mostly be observed in treatment completers, although PG showed a significant difference between phases in two IVASs after only six sessions. In general, key meaning was more variable than image intrusiveness. Some participants showed a stable and decreased decline (PA, PB, PE, PG), whereas others showed variable data that changed considerably, in some participants, across weeks (PC, PG, PF).

A pattern did not appear to exist between the types of formulation diagram shared with participants, with gains found for all participants with varying diagrams

shared. Sharing of the Individual Case Formulation and Ehlers and Clark (2000) model was associated with similar results in terms of responsiveness to treatment. Interestingly, the less complex diagram, the vicious flower, was shared with the lowest responder to treatment between Phase A and B (PD).

Idiographic and group analysis revealed that participants experienced differential changes in symptoms in differing phases of treatment. Overall, the use of an ICF was applied with low quality across the sample. Promisingly, all participants except one demonstrated a reduction in PTSD symptoms during study involvement. However, it is important to note that scores might reflect changes from therapy in general and the natural course of treatment for PTSD, as opposed to being linked to formulation processes.

Discussion

This study employed a SCED design with a newly proposed individual approach to formulation with use of a rating scale to investigate factors potentially contributing to change in PTSD symptoms. The study also sought to evaluate whether sharing a formulation diagram could relate to treatment outcome especially in relation to reducing frequency, distress and the meaning of intrusive images. This study hoped that therapists would use the ICF to inform their treatment and that they might use the ICF in other ways that Hallam (2013) suggests in order to supplement the means they chose for communicating a formulation diagram. In this way, the hope was to predict outcome using the rating scale and demonstrate a relationship that would support the interpretation that the ICF approach impacted treatment. Bieling and Kuyken (2003) set out a research agenda for CF: (i) more in depth analysis with regards to how practicing clinicians formulate in reality, (ii) investigation of the link of formulation and treatment outcome (iii) investigation of reliability and validity of CFs and (iv) begin the process of moving towards an evidence base for individual CFs. Therefore, the current research provided a starting point in investigating these factors using an exploratory design with a small sample of people with PTSD.

Inherent difficulties that arise during formulation research due to the nature of formulations including variation across therapists with regard to formulation style and form, the naturalistic approach with which CF is carried out in therapy and the often idiographic nature of CFs, mean that investigation and measurement of this core process of CBT is methodologically challenging. As in this study, introducing a new and untested CF to clinicians can be difficult during formulation research and might suggest that the efficacy of ICF might not have been measured or used in the way it

was originally hoped and proposed by Hallam. In this study, the extent to which the newly proposed system of an ICF was drawn upon in order to guide treatment is unknown, although a rating scale was used to attempt to demonstrate a relationship between ICF and outcome. However, as little differences between ICFs were observed, it is difficult to attribute changes in symptomatology to ICF specifically as opposed to formulation in general (or in fact to normal PTSD treatment). The fact that treatment commenced in the baseline phase is also problematic for making strong inferences about the specific implications of the ICF, as again, treatment gains may have occurred even before ICF construction. These are the main limitations and difficulties encountered in this study and mean that making strong, confident inferences regarding the usefulness of ICF to PTSD outcome is challenging.

Phase 1 of the study aimed to evaluate if training on a new approach to formulation, Hallam's (2013) ICF, can contribute to higher quality formulations, to provide insight into how expertise and skill are developed in formulation. This phase also used a new rating scale to measure components within the formulations. Phase 2 prospectively investigated changes in symptoms of PTSD after a formulation was shared with participants. Close attention was paid to quality and ability to capture complexity within formulations and also whether components within diagrams appeared to contribute to treatment outcome. In general, diagrams were found to be lower in quality than expected including scoring very low for managing overall complexity. Furthermore, a central confound to the study is that the observations could be a result of on-going PTSD treatment. Given these factors, findings are discussed with caution. Overall effectiveness of the treatment will be discussed followed by Phase 1 and 2 findings in relation to the hypotheses and existing theory

and literature. Following this, strengths and limitations of the current study will be discussed as well as future research and clinical implications.

Effectiveness of the Treatment: Interpretation of results

Case series analysis provided detailed data for eight participants from assessment, baseline and intervention using measures of PTSD symptoms. All participants presented with PTSD at the start of the study, all above proposed clinical ranges on standardised measures of PTSD. By the end of data collection, only one was still within clinical range, despite the fact that most participants were still receiving therapy. The participant still within clinical range since dropped out of treatment. Of those below clinical range, all met criteria for reliable and clinically significant change on the IES-R.

This suggests that treatment was effective in reducing PTSD symptoms in seven of eight participants. For many cases, the latest data point available was used for pre-/post- analyses suggesting that if analysis had occurred with data collected further into treatment, further symptom reduction would have been observed. Despite promising results, graphical analysis revealed heterogeneity between participants in the patterns of changes observed, as well as between measures. Therefore, results are discussed tentatively.

Training on ICF. The first hypothesis was that therapist formulation skill would increase following workshop training on ICFs, potentially demonstrating increased quality of formulations, as shown by comparing pre-/post- workshop formulation diagrams. Comparison of diagrams was conducted via visual inspection only and therefore preliminary findings are discussed with caution. Visual inspection suggested that there was a difference between pre and post diagrams, with post-

diagrams meeting a higher number of ICF criteria than pre-workshop diagrams. All therapists' post-formulation diagrams contained more elements than pre-diagrams and thus were rated as being higher in quality than pre-diagrams. This is consistent with the expectation that workshop training assisted with enhancing knowledge and skills of formulation in therapists.

A recent study conducted by Pettman (2017) also found that following ICF workshop training of 47 trainee psychological well-being practitioners, ICF diagrams were rated as significantly higher in quality following training, as measured through differences in pre-/post- diagrams using the same rating scale used within this study. Since the same pattern was found in the small current sample, this provides a basis for greater confidence in the interpretation of the present results as showing a gain in skills following training.

In the current study, additional elements were enhanced most in post-formulation diagrams including, (i) additional key contextual elements (moderators), (ii) increased representation of the nature and sources of observations, (iii) increased representation of functional equivalence between elements and, (iv) increased comprehensive accounts of the available information that more comprehensively draw factors together that influence a problem and display patterns of interaction. This suggests that the workshop could have assisted with increasing formulation skills within these areas and therapists could potentially enhance skills in these areas with formulation training. Therapists also demonstrated individual differences in post-diagrams also, suggesting training could improve therapist formulation skills in varying ways.

These observations are consistent with the findings of Kendjelic and Eells (2007) who found that a short amount of training can increase formulation skill and

assist clinicians in producing higher quality and more comprehensive formulations. In accordance with their recommendations, it might not be that clinicians are now at an “expert” status, but certainly results are promising and suggest that even a short workshop could be helpful in improving formulation skill. Findings suggest that formulation is indeed a skill that clinicians need extra training in to fully understand, use and develop (Dudley et al., 2010). This research has highlighted that formulation skills can be taught and potentially enhanced through formulation training.

Quality and complexity of ICFs. Results offer tentative and initial support to the idea that quality of formulations could be related, in part, to outcome and rate of improvement for people with PTSD. Overall, diagrams displayed a low level of quality across participants. However, findings appear to suggest that participants whose diagrams reflected increased synthesis of elements, indicated by a higher overall score showed signs of improvement. At a group level, higher responsiveness to treatment appeared to show some links to having some increased quality of formulation diagrams. At an individual level, some higher formulation scores observed were also linked to larger and more stable reductions in image intrusiveness measures and key meaning of images. This finding suggests that when clinicians created higher quality formulations that reflected and included comprehensive and coherent linking of elements, this was linked to improvement. This idea is supported by the finding that lower responders in the study were clients of therapists who produced diagrams that scored some of the lowest overall ratings. Perhaps higher quality formulations display organisation and structure of materials that better provides guidance for where and what to prioritise during intervention. This supports some psychodynamic literature from Silberschatz et al. (1986) and Crits-Christoph et

al. (1988) who found that increased accuracy and quality of interpretations were associated with enhanced therapy gains.

It cannot be ignored that formulations were mostly rated as low in quality across the sample, a finding replicated within Kuyken et al. (2005) who found that overall quality of formulations produced by mental health practitioners were low, with over a third of therapists rated as producing “very poor” CFs. Furthermore, most participants in the current study demonstrated a moderate amount of change, with all participants apart from one demonstrating reliable and clinically significant change on a standardised measure of PTSD. The study conducted by Gladwin and Evangeli (2013) also found that quality of CF was not associated with change. Therefore, these findings do not support the claim made by Tarrier (2006) that high quality CF is essential for effective treatment as most participants in the current study demonstrated symptomatic reduction with low quality formulation diagrams. Indeed, a central confound to the study is that the observations of reductions in symptoms could be a result of normal PTSD treatment and reflect typical symptom trajectory of the disorder whilst undergoing treatment in primary care.

Furthermore, one could propose that increased scores on items actually suggest that a case is increasingly more difficult to treat rather than that the diagram is of higher quality. Increased scores on items could suggest that an element was increasingly captured or that there are increased factors that trigger a similar response. Therefore, a higher score overall could potentially indicate that treatment might be less likely to be successful if there are increased elements to target. This idea is reflected in the findings from one participant who scored highest on the ICF-RS but did not meet clinical or reliable change on the SS measure.

Therapists had limited success in representing complexity in their diagrams and no clear patterns of differences were observed between diagrams. Therefore, at a group level, it was not possible to satisfactorily address the idea that well formulated complexity within CFs might be linked to treatment outcome within this study. One participant who met reliable and clinically significant change scored highest for representing complexity in the diagram produced. However this finding alone is clearly not adequate to make inferences about the link of CF ability to capture complexity to outcome and more research is needed to investigate this.

In summary, the findings offer tentative and preliminary support to the idea that quality of formulations might potentially be linked to outcome. It is worth noting that participants did demonstrate enhanced recovery compared to typical recovery rates observed across IAPT services for PTSD treatment. If there is a link between case formulation and outcome, the direction of the outcome might be variable. For some therapists, development of higher quality and detailed formulations might enhance understanding of the presentation, providing helpful targets for treatment. For other therapists, a higher “quality” formulation that actually demonstrates increased processes, links and maintaining factors might suggest that treatment will be more difficult. With very little complexity successfully captured within formulation diagrams, it was difficult to adequately address the hypothesis regarding complexity and make inferences about the link of complexity to treatment outcome. There are potential reasons for why case complexity may have been more difficult to capture within the diagrams. Firstly, the ICF was a new formulation system for therapists and therefore, linking all the information together, using a new system to represent the full extent of a client’s problem may have been challenging for therapists. Increased practice using an ICF might help to enhance this skill. It might also be that therapists

did not gather as much information about the client as is necessary to understand and represent clear links and that the organisation of the information might not have been represented as successfully as hoped. Therapists might also have preferred to rely on other, more frequently used formulation models. This also means that the ICF may have only been completed as part of study involvement, rather than something to draw upon and fully utilise. A formulation capturing increased case complexity might have been less appealing to some clinicians who prefer to use simpler looking diagrams, rather than capture the full complexity of a case. It is worth noting that this was a tentative hypothesis and more research appears to be required to determine if there is any link between ability to formulate case complexity and outcome. It might be that complexity in formulations is in no way linked to outcome. This information is likely to be useful for any training on formulation skill.

Predictors of outcome. The third hypothesis was that components found within ICFs could potentially help to predict outcome at a group and individual level. As described, at a group and individual level, patterns across results tentatively indicated that there appeared to be some suggestion that overall higher scores on the ICF-RS, suggesting higher quality CFs with regards to ICF principles, was associated with participants showing most signs of improvement. However, there was variability within the findings, with some participants demonstrating similar ratings in ICFs to high responders but showing less probable change indicators.

Results suggest that there might be some preliminary evidence to indicate that there could be a link between other specific items within the ICF and outcome. Despite scores being quite low, participants generally showing increased symptom

improvements had diagrams that increasingly met criteria for including increased coherence and comprehensiveness of available information that in turn, suggested links to intervention. Increased structuring of information could have contributed to increased understanding of where and how to intervene and what to prioritise in intervention. Hallam (2013) suggests that a feature of the ICF is that it assists with choosing an intervention guided by the mechanisms assumed to be maintaining the problem. Findings from Silberschatz et al. (1986) and Crits-Christoph et al. (1988) support this; they found that when more accurate interpretations were made and used to direct and guide treatment, enhanced therapy gains were produced. Therefore, this suggests that increased information in formulations that then guides intervention can assist with outcomes. Accordingly, CF has been described as a “therapist’s compass”, (Persons, 1989, p.37), used to steer treatment in the correct direction.

Item scores for lower responders were relatively higher on items measuring the extent to which the diagram captured functional equivalence between elements and contained moderators that could impact a problem, compared to other items in the diagram. Firstly, it is unsurprising that these items might show similar scores and be linked, for example if there are triggering cues serving as moderators that are functionally equivalent and set a difficulty in motion. Hallam (2013) describes the importance of identifying contextual moderators to demonstrate when the problem is more or less likely to occur and what is maintaining it, especially when there is a common theme underlying difficulties during different time periods from a person’s history. Hayes and O’Brien (2000) discuss the role of causal mechanisms at length, noting that a number of functional relationships could be equivalent that maintain a difficulty. For lower responders, increased observations of these items suggest that there might be increased triggers to a difficulty that function equivalently to produce a

response or that particular observations lead to similar consequences occurring (for example, avoidance). The degree of functional equivalence might be an indirect marker of a more chronic difficulty which would suggest that the individual could have developed increased ways of coping maladaptively for the same purpose or have an increased number of cues triggering a difficulty in a similar way. This might suggest why these individuals scored higher on these items but demonstrated less change in symptoms. Indeed, Hallam (2013) suggests that functional relationships can be interpreted as representing key arrangements that provide conditions for learning and intervention and could be a central hypothesis within a formulation for understanding a presentation.

Sharing formulations. Results offer tentative, initial support to the hypothesis that sharing formulations may, in part, contribute in some way to change in symptoms. Change was observed to occur at the session subsequent to sharing the formulation, supporting the inference that this process was associated, to an extent, with the resulting change. Therefore unlike previous studies that found no link between outcome and sharing formulations (Chadwick et al., 2003; Evans & Parry, 1996), this study suggested that change in symptoms might be associated with the shared formulation.

CAT (Ryle, Leighton & Pollock, 1997) involves diagrammatic formulation development and modification between clients and therapists (Denman, 2001). Formulation sharing in CAT is carried out on the premise that it can serve a number of functions. For individuals experiencing the world in a threatening and fragmentary way as in PTSD, diagrammatically formulating these processes could help an individual make sense of their internal world in the context of life experiences and

highlight patterns of entrenched maladaptive behaviours to both the client and therapists (Mitzman, 2010). However, despite serving as an active part of the intervention (Gladwin & Evangeli, 2012), research has found no support that joint formulation letter writing improves treatment outcome (Evans & Perry, 1996).

Bieling and Kuyken (2003) argued that there was no evidence to link CF to treatment outcome and that the only benefit that they had identified in sharing CFs is in Chadwick et al. (2003) study, where therapists reported increased therapeutic alliance. Bieling and Kuyken (2003) suggest that it may have been wrongly assumed that CF can directly impact outcome and instead, it might be that CF can indirectly assist with treatment, for example through aiding selection of an appropriate intervention (Jacobson et al., 1989). Findings from one of the only studies linking CF to outcome (Crits-Christoph et al., 1988) also support this finding.

Within the current study, graphical analysis revealed heterogeneity between participants in the patterns of change observed, suggesting that clients might be influenced differently by a shared formulation perhaps due to individual differences. This is supported by the Gladwin and Evangeli (2013) study, which found that seven participants had improved outcomes following sharing CF but six did not. However, the current study revealed that at Session 4, a change in scores was often observed within most participants. Typically, there was a downward trend in scores following sharing of the formulation with five participants demonstrating reductions in scores at Session 4 for some image intrusiveness measures. Image intrusiveness increased at Session 4 for three participants, suggesting that sharing the formulation was associated with change in symptoms in some way. It is important to consider what it is about sharing formulations that might have directly or indirectly contributed to therapist or participant behaviour that was associated with a change in symptoms.

Therapists. Gladwin and Evangeli (2012) suggested that it has been assumed that sharing a CF is therapeutic in itself and that the mechanism between CF and outcome might be direct. However, this relationship might instead be mediated by separate variables that are reflective of the therapeutic relationship during sharing a CF including enhancing therapeutic alliance and therapist motivation, increasing engagement or self-esteem of the client (Gladwin & Evangeli, 2012). Further research has also suggested that developing shared CFs could have indirect effects on outcome through increasing clinician understanding (Kinderman & Lobban, 2000) and confidence (Chadwick et al., 2003), selecting of intervention by therapists (Johnstone & Dallos, 2013), predicting difficulties in treatment (Butler, 1998), increasing empathy (Horowitz et al., 1989) assisting with supervision guidance (Bieling & Kuyken, 2003) or as Kuyken (2006) suggests, it might be a combination of these factors that influence therapist behaviour. Therefore, reduction in symptoms at Session 4 observed in the current study could be due to effects on therapists that sharing the formulation had, that in some way enhanced treatment. This idea however does not account for some increases displayed in symptoms at Session 4.

Service-Users. It is possible that CF could provide insight to service users that contributes to behavioural change. One study examined the experiences of completing CF in young people with PTSD and first episode psychosis (Halpin, Kugathasan, Hulbert, Alvarez-Jimenez, & Bendall, 2016). Clients reported increased insight into predisposing, precipitating and perpetuating factors, benefits also highlighted by other CF manuals (Smith et al., 2007). Halpin et al. (2016) found that increased insight

facilitated awareness to past experiences and their relationship to current symptoms, encouraging relevant behavioural changes to reduce the maintenance of symptoms. This suggests that by using CF and highlighting to clients unhelpful coping strategies such as avoidance that are linked to past experiences, insight is gained that leads to actions to change these behaviours. This suggests indirect assistance of CF to support behaviour change.

Similarly, Stiles (1999) suggests an assimilation process that occurs in therapy whereby a problem (for example a trauma memory) is assimilated into a schema (a way of living or narrative of a problem). According to Stiles and Morrison (1991), stages occur during assimilation including “understanding/insight” whereby the problem is formulated and understood. Stiles (1999) warns that there might be unpleasant recognition during this process, but that it offers strong insight. The next stage involves “application/working through” whereby the gained understanding from formulation is used to address the difficulty, leading to optimism in the client. This suggests that sharing a formulation may start this assimilation process, whereby clients gain insight and understanding that in turn encourages a person to begin to address problems and update their behaviour.

Smith et al. (2007) also detail case studies whereby developmental CFs enabled clients with PTSD and psychosis to reappraise traumatic events without use of reliving. This suggests further indirect assistance of a shared CF, through facilitating a different way of perceiving an event. This research also suggests the usefulness of CF for those where there is not an evidence-based protocol, for example in co-morbid cases. In the current study, it might be that the formulation sharing provided new insights that helped to begin to challenge appraisals. Increased compassion could be gained whereby clients understand that their response is normal

and expected given the circumstances. Indeed, in Compassion-Focused Therapy, the role of the formulation is to validate fears, make sense of safety strategies and highlight the role of compassion for assisting with PTSD symptoms and remove blame (Gilbert, 2010). Therefore, Halpin et al. (2016) and Smith et al. (2007) studies suggest that for clients, developing insight could be a helpful, indirect route to assisting with alleviating symptoms through affecting behaviour change or updating appraisals. This could potentially assist in explaining the reduction of symptoms at Session 4.

Another factor that could explain the reduction in image intrusiveness is that, whilst CF is not specifically intended to figure into exposure treatment, it could serve to function as part of exposure to trauma memory processing. In support of this, Van Dan Berg et al. (2015) found that extensive trauma interview and assessment can lead to covert exposure in people with PTSD. Halpin et al. (2016) also found that one client reprocessed memories whilst undertaking the CF. PTSD theories (Brewin et al., 1996, 2010; Ehlers & Clark, 2000, Foa et al., 1989) also suggest this idea to an extent, describing that exposure to original trauma imagery might facilitate processing of material and reduce intrusive symptoms. This could tentatively suggest that the formulation process could potentially serve a function to expose people to trauma memories. Indeed, when trauma experiences are put into words, as they typically are during CF sharing, this acts as a part of reliving (Foa & Rothbaum, 1998). Therefore, CF sharing could possibly start the elaboration and contextualisation of memories into autobiographical memory store, helping the memory to become a more normal recollection, increasing coherence of the narrative and reducing reliving symptoms (Ehlers & Clark, 2000). Indeed, one would expect lower scores on image intrusiveness and belief in appraisals once trauma memories begin to be processed as

endorsed by the theories of PTSD treatment (Brewin et al., 1996; 2010; Ehlers & Clark, 2000; Foa & Rothbaum, 1998). This idea was not specifically tested and is therefore offered as a preliminary explanation to account for some of the findings. However, this idea is consistent with the observation of initial symptom increases in some participants, as research indicates that when trauma memories are triggered and begin to be processed, exacerbation of symptoms can occur in the short term (Van Minnen, Harned, Zoellner, & Mills, 2012). Halpin et al. (2016) suggest that the idiosyncratic nature of CFs increases distress because individualised information collected resonates with the individual. This could also suggest why participants in other studies have found sharing of the formulation difficult (Chadwick et al., 2003; Deman, 2001; Halpin et al., 2016) if past memories are being triggered and relived.

This study provides a potential basis for the interpretation of the current findings and might offer preliminary and tentative explanations as to reasons for improvements being observed following sharing of the formulation: (i) via an indirect route whereby therapist factors are influenced, which in turn leads to better understanding and thus more suitable therapy, (ii) via an indirect route that highlights to the client dysfunctional behaviours, negative appraisals or patterns of avoidance or (iii) directly contributing to assisting with processing memories, beginning to bring parts of the memory “online”.

Study Strengths

Firstly, this study is believed to be the first to investigate the use of an individual case formulation for assisting with predicting treatment outcome of PTSD. This included investigating the association between sharing a formulation and

symptoms of PTSD as well as examining the components of an ICF that could predict treatment outcome. Some research suggested that CF might have found a place in practice ahead of any evidence for its proposed advantages (Tarrrier, 2006). Thus, this research was important for a number of reasons: (i) to generally determine the clinical usefulness of CF to outcome, (ii) to determine the impact that CF can have on outcome for PTSD (iii) to offer insight and recommendations to assist with poor recovery rates for PTSD.

Design. The use of SCED was a strength of this study. A SCED design meant that detailed case-by-case analysis examining change processes within individuals (Elliott, 2002) was possible. Each participant demonstrated different patterns of change and these differences would not have been identifiable without use of idiographic analysis. Findings suggest that participant characteristics are important in predicting change (Kazdin, 1981). Using an idiographic approach to analysis through SCED enabled enhanced clinical depth and understanding that would not be gained if experimental approaches had been employed (Grey & Holmes, 2008). With a large sample, this level of detailed analysis would also not be feasible.

The use of repeated continuous measurement is a further strength of this study. Firstly, research has indicated that regular symptom monitoring and eliciting feedback from SUs is likely to reduce dropout rates in PTSD treatment (Zandberg et al., 2016). Standardised measures also enabled pre-/post- clinical and reliable changes over time to be detected. However the strength of the measures lie in the VASs that enabled a high level of specificity relating to specific images. The EBVAS also provided a specific idiographic measure in relation to the key meaning of the images. Other formulation studies have not used idiographic outcome measures (Chadwick et al.,

2003; Emmelkamp et al., 1994; Schulte et al., 1992) meaning that important, small changes might have been missed. Idiographic measures are recommended within SCED (Morley, 2015b) as they capture small changes over short time periods that standardised measures may not. Repeated measurement occurred across Phase A and B, allowing for clear, in-depth examination into the change to PTSD symptoms following sharing a formulation. Often, more than three data points were collected during Phase B, over the course of full treatment in two cases, allowing change in participant variables to be measured for longer, providing more detailed information than would be the case if fewer data points had been collected.

Furthermore, isolating the treatment component was also relatively straightforward within this study without significantly interrupting routine treatment. This increased the ability to make inferences about how sharing the formulation impacted on treatment outcome. Use of a baseline phase and investigating and controlling for baseline instability using statistical analysis also assisted in interpreting the data.

Coding formulations. Coding of formulations using the ICF-RS was another strength of this study. It is widely agreed within CF literature that there is a need to develop ways of measuring CFs (Bucci et al., 2016; Eels, 2010). This study utilised a new measurement of CFs in an attempt to begin to address the lack of reliability that is a central weakness of the existing literature on formulation (Kuyken et al., 2005). Furthermore, using the ICF-RS allowed for in-depth analysis of the components that made up formulations. Coding on the ICF-RS highlighted components within a formulation that might not have been so easily observable or understood in the first instance, assisting with detailed analysis into the processes within ICFs, allowing a

wider range of potentially important factors that may have contributed to treatment outcome to be identified. Furthermore, reliability was also established by two researchers coding the formulations.

External validity. Due to the naturalistic design, this study did not substantially impact routine treatment for PTSD. Kazdin (2007) highlights the importance of understanding the mechanisms that occur within therapy that might affect outcome. Therefore, this study focused on the process of formulation and no specific treatment was imposed on participants with therapists using their own clinical judgment to decide the most appropriate treatment to use, unrelated to study involvement. Although therapists were required to share formulations within Session 3, the style and form with which formulations were shared was based on therapist judgment. Therefore, as far as possible, this study reflects routine treatment for PTSD. Differences in formulations used enabled comparison between these methods and allows consideration of refinement to future studies. Anonymity of therapists also means that hopefully formulation procedures and routine therapy was not impacted by the possibility of being recognised and was reflective of routine practice.

An additional strength of the study was the heterogeneous sample used, a recommendation for SCEDs (Kazdin, 1981). Participants were from a range of different cultures, of different ages, including both male and female participants with varying trauma histories in terms of trauma type and length of time since the trauma. Also, although not a requirement, no participants had received prior treatment before involvement in the study. Therefore, this reduces the chance that previous knowledge of CBT or other psychological therapy techniques or prior processing may have impacted on symptom changes.

PTSD clients with co-morbidities are also often excluded from research studies (Zandberg et al., 2016), whereas the inclusion criteria of this study enabled participants with co-morbidity to be included and thus, the sample gained is likely to reflect people who routinely seek help for PTSD. The heterogeneous sample combined with the specificity of measures and the routine nature of the PTSD treatment enhances external validity of this study.

Study Limitations

Sample. Despite some strengths, the sample was limited by a number of factors. Firstly, the final sample did not reach the intended recruitment target. The aim of the study was to recruit ten participants. The final recruitment fell short of this by two participants. Therefore, the study may lack sufficient power to make strong inferences. Recruitment was made difficult for a number of reasons. Firstly, the site that was meant to recruit the majority of participants pulled out of study involvement in Summer 2016. This meant that amendments to the study had to be made that required further ethical approval as well as identifying new recruitment sites. This had a significant impact on the time available to recruit participants. Given that it can be challenging to engage clients in treatment for PTSD (Courtois, 2004) and with limited recruitment time for the study, a sample of eight is satisfactory. In addition, participants with mental health difficulties can be difficult to recruit into studies (Hughes-Morley, Young, Waheed, Small, & Bower, 2015). Woodall, Morgan, Sloan, and Howard (2010) found that barriers to study recruitment included distrust and suspicion of researchers as well as stigma of mental health. PTSD is associated with strong emotions including guilt, shame and mistrust (Lee, Scragg, & Turner, 2001). These difficult emotions may prevent clients from taking part in a research study if

they feel ashamed or are concerned about not being able to trust a research team with sensitive and difficult information. This suggests that there is a possibility that sampling is selective. Perhaps those who agreed to take part were more trusting of therapists, meaning that changes in symptom scores could have been influenced by individual or therapist factors.

Furthermore, this study did not use a control group and therefore there was no comparison to clients who did not have a formulation shared with them during their treatment. Although formulation sharing is not always a necessary part of CBT, it would have been unethical to explicitly withdraw case conceptualisation from a person's therapy or curtail it in some way to permit an empirical comparison. However, lack of a control group makes it difficult to infer if scores relate to sharing the formulation or whether they reflect the natural course of the disorder or treatment.

Lastly, one participant required the use of an interpreter. Although this therapy was carried out in the individuals own language, hopefully increasing accurate descriptions of experiences and enabling the participant to communicate more fluently (Costa, 2010), some of the measures may have been invalid for use. Adapting measures for use in different languages is a complex task requiring careful consideration of factors for validity for the intended population (Cassepp-Borges, Balbinotti, & Teodoro, 2010). Another participant in the current study also had an alternative first language to English, meaning they may have struggled with accurate communication and fully understanding the measures. Therefore, this may have impacted the data with regards to how much they could understand and accurately complete measures.

Finally, because there was no standardised inclusion / exclusion criteria for the study, it might be that this study is more difficult to replicate especially as individual

factors appear to affect the formulation process.

Training. Although changes were observed in post-formulation diagrams in this study and Pettman's (2017) study, it is unclear how useful the training on formulation was from therapists' perspectives. This study did not collect or evaluate therapist feedback on the training. This would be important for future implementation of ICF training. Furthermore, diagrams were mostly rated as low in quality in Phase 2, suggesting that the training might not have improved skills as much as it was first hoped. However, it might be that this study had too high expectation of therapists to produce higher quality diagrams following workshop training. With all diagrams demonstrating some elements of the ICF approach, credit should be given to therapists for capturing some of the elements.

However, despite this, it is difficult to completely attribute changes in post-formulations to the training. Increased quality in formulations observed in the post-formulations could have been due to a variety of factors including increased time to complete post-formulations, discussion with other therapists about the vignette that highlighted items missed out in the pre-formulations or perhaps motivation to score more highly on post-formulations, knowing that these would be rated and compared to pre-formulations. Furthermore, no information was collected on how much training therapists had previously received on formulation prior to the workshop.

Design. SCED strictly adheres to repeated measurements over time and a stable baseline. This ensures that change can be attributed to a specific intervention (Turpin, 2001). In this study, one participant did not have all the baseline data points and only one participant displayed a completely stable baseline. Turpin (2001)

suggested that data should be collected until a stable baseline is produced, although acknowledges that in therapeutic research, this can be difficult. Indeed, it would have been unethical to ask participants to wait for treatment for this extended period. However, without a stable baseline, there is increased risk that interpretations are wrongly attributed to sharing the formulation, rather than natural variation of PTSD or maturation effects.

Next, it is problematic that treatment commenced during the baseline period. This means that obtaining a stable baseline was more difficult because treatment effects might have already commenced. This also means that something other than sharing the formulation might have impacted changes in symptom scores, as it would be expected to observe change as the therapy progresses. Research carried out by Ilardi and Craighead (1994) indicated that 60-70% of symptom improvement for people with depression occurred in the first four weeks of treatment, suggesting that most improvement is seen in the first four sessions. This is problematic for the current research because changes observed in Session 4 might wrongly be inferred to being linked to sharing the formulation, whereas these changes may have occurred nonetheless. However Tang and DeRubeis (1999) criticised Ilardi and Craighead's (1994) study as their account suggests that only four therapy sessions occurred in the first four weeks in the study. However, they found that, in fact, two sessions were typically carried out per week, suggesting that changes observed were not actually observed until session eight. Therefore, this in turn strengthens the inferences observed in the current study because changes were observed in some participants by Session 4, following sharing of the formulation, further strengthening the conclusion that sharing a formulation can impact treatment outcome.

Another limitation of the design is the lack of follow-up data for participants.

Due to time constraints, it was not possible to collect follow-up data, meaning it is unknown whether effects were maintained and extended past treatment. This is an important consideration for future research investigating formulation and outcome.

Furthermore, the number of sessions could explain the results. Higher responders typically had an increased number of sessions or had completed treatment compared to low responders. Therefore, duration of treatment is likely to have been a contributing factor to outcome.

Lastly, as in the study conducted by Chadwick et al. (2003), this study did not include a second rating of formulation diagrams in Phase 2. Any additional elements incorporated into the formulation following the initial creation of the diagram would have been lost if the diagrams were rated too early, missing potentially important information. Furthermore, formulation diagrams created by therapists might have contained other specific items not measured by the ICF-RS, suggesting that other factors contributing to PTSD might not have been captured. If this is the case then the ICF-RS might lack content validity.

Lastly, the extent to which ICFs were used and referred to by therapists to assist treatment was not measured and therefore it is unclear how much ICFs might have been used to support treatment or completed simply as part of study involvement.

Therapist factors. Silberschatz and Curtis (1986) suggest that many other factors are likely to contribute to therapy outcome including therapist skill (Schaffer, 1983), a good therapeutic relationship (Luborsky, 1984) and even fostering hope in treatment (Frank, 1982), suggesting the importance of therapist factors in outcome. Factors including warmth and empathy have been found to be related to treatment

outcome, rather than the therapeutic approach used (Lambert & Barley, 2001). This suggests that observed effects could be dependent on therapist variables or factors within the therapeutic alliance rather than sharing the formulation or items within the ICF. However, Hallam (2013) would argue that some of these additional factors could be aspects that arise during the formulation process or that these factors might even rely on the formulation, suggesting that the shared understanding of the intervention could provide a basis for the therapeutic alliance.

In addition, this study may have been exposing for therapists. Despite anonymity procedures, therapists may still have felt that their work was being assessed as the study linked formulation diagrams to treatment outcome. Fear of judgement may have prevented some therapists from taking part. This may explain why, despite some SUs expressing interest in taking part, some therapists declined to be involved in the study. This is a factor to consider in future research investigating treatment outcome.

Other. For some participants, extra formulations were completed as part of homework. Completion of an extra formulation as part of homework was not measured or controlled for as part of this study. Cully and Teten (2008) found that homework can facilitate skill and acquisition in CBT and even reduce symptoms by integrating concepts from sessions into daily routines. Therefore, homework can be a mechanism for facilitating progress. Completing formulation homework and drawing on the concepts of the formulation between sessions may have impacted symptom scores. An additional measure of homework would have been useful.

Lastly, the extent to which ICFs were used and referred to by therapists to

assist treatment was not measured and therefore it is unclear how much ICFs might have been used to support treatment or completed simply as part of study involvement. Therefore, the nature or complexity of ICFs that were produced might not fully measure the efficacy of ICFs.

Future Research

Given that the findings provide some evidence that components of formulations could link to treatment outcome, there is a strong case to continue research in this area and to replicate findings. A first step would be to continue to measure and follow-up with participants to investigate if gains observed remained.

It is necessary to further determine if sharing a formulation can impact on outcome. To broaden this investigation, the next step would be to vary when therapists share formulations with participants and therefore vary the length of the baseline phase. This could be done naturally in therapy as in Pain et al. (2008) and increase external validity, maintaining clinically valid conditions or manipulated in an experimental design. Either way, varying when the formulation was shared would increase the ability to make inferences about how this process can impact outcome and relate to change in symptoms.

The mechanisms of formulation also need to be investigated in detail. It would be important to further determine why sharing a formulation might predict symptom change. This could be collected by qualitative feedback from clinicians or participants to gain information on how they were influenced by the CF, if at all. The present study did not collect qualitative feedback from clinicians or participants; however, this would have been useful to help to shed light on whether CF can directly or indirectly contribute to outcome, by collecting participant verbal responses to sharing

the CF.

This study was one of the first to investigate the predictive validity of CFs. Some links were identified that might predict outcome in treatment. Further research into this is necessary to investigate if CF can predict expected outcomes and difficulties in therapy. If it can, it could be an extremely powerful tool (Bieling & Kuyken, 2003). Further research could also help to identify whether formulation factors can independently impact on outcome or whether they rely on each other to contribute to outcome. Studies also comparing outcomes between clinicians using CBT, based on a working CF, compared to those not drawing on a formulation, with related investigation of adherence to high-quality CF, would provide further insight into the role of CF to outcome.

Lastly, this study used a new scale to measure formulations. More frequent ratings of formulation diagrams as a process over the course of treatment would be important for future research, in case added complexities have been included later in therapy, which would be lost if rated too early. This would also give an indication into how formulations evolve as treatment progresses. Furthermore, increased research is required to develop and test the rating scale to work towards creating a standardised measure of CFs with strong validity and reliability, which is lacking in the CF literature (Bucci et al., 2016). Systematic measurement of CFs using a valid measure would improve the quality of formulation research allowing clearer inferences to be made about the usefulness of CF. Bieling and Kuyken (2003) argue that CFs could be valid and reliable and have no impact on outcome, or be unreliable and invalid and enhance outcomes through alternative mechanisms. Further research will shed light onto this and determine the most useful criteria for “good” formulation practice. By doing so, training programs can incorporate teaching on evidence-based CF.

Larger scale studies, with increased recruitment time, are required to demonstrate effects across more participants and to assist with sample limitations and reduce selection bias, allowing more detailed analysis of how CF components contribute to treatment outcome.

Clinical implications

Clinical implications are provided tentatively in light of limitations. However, the findings offer some suggestions for clinical practice. Although this study specifically investigated PTSD, some findings could extend across other disorders treated with CBT. Firstly, teaching on formulation appeared to enable increased elements to be captured in formulation diagrams, suggesting that formulation skill may have been improved following training. Therefore, this research highlights the importance of further training in CF for clinicians, in order to develop formulation skills. Indeed, increased literature is highlighting the importance of identifying existing gaps in expertise by commissioning services advocating a roll out of CBT and suggests that these gaps should be filled with specific skills training (Zivor et al., 2013).

Secondly, results from this study and from other studies indicate that sharing formulations impacts people differently. Therefore, it appears necessary that clinicians use clinical judgement in deciding when and how and which parts of a CF to share with clients, based on understanding of the individual in order to reduce disengagement from treatment. Linked to this, as Stewart (2014) argues, this finding also suggests that CF is not a 'one size fits all' approach and emphasises the importance of considering individual processes when formulating in order to develop

idiosyncratic links. Dallos, Wright, Stedmon, and Johnstone (2006) also suggest that CFs are interpersonal processes. This study found features within ICF diagrams that would not have been included in the standardised model of PTSD. This study therefore promotes use of an idiographic approach to CF, formulating in a bottom-up way using theory to enhance individual understanding (Bieling & Kuyken, 2006) and assist in identifying any off model elements that might be contributing and maintaining factors. Despite this, this research also suggests that clinicians should not become so focused on idiosyncrasies that factors important for assisting with effective treatment are ignored (Zivov et al., 2013). Overall, even though sharing formulations is not a routine part of CBT treatment, this study has provided preliminary evidence that it could contribute to change in symptoms.

Another finding related to use of ICF suggests that if the produced formulation can provide a coherent account of the available information, portraying patterns defining mechanisms of change, it might be important for assisting with treatment outcomes by providing a basis for understanding where and how to intervene. Furthermore, identification of increased contextual elements contributing to the problem that demonstrate functional equivalence (triggers or responses) could be an indication that a person demonstrates increased chronicity or enduring symptoms that may require longer or more extensive treatment. Therefore, gathering increased information to add to a diagram followed by scrutiny of formulation diagrams might provide better guidance to assist with treatment or predict when a person might respond less to therapy. Furthermore, when an intervention is unsuccessful, therapists are encouraged to re-formulate and reflect on the reasons that a person's symptoms may not be improving (Hallam, 2013). There is currently little guidance on this process. An ICF could be helpful during these conditions, when empirically supported

treatment protocols are not sufficient in treating a difficulty (Halpin et al., 2016) or when no evidence-based treatments are available (Persons, 2012) or difficulties are more complex (Van Dan Berg, 2015) than for use of single-disorder models.

Furthermore, this study found that for one participant, reliving enabled activation and elaboration of another memory, which was then added to the formulation. This highlights the importance of viewing formulations as an ongoing, collaborative and dynamic process (Dallos et al., 2006), rather than a one-off event. Indeed, Kindermann and Lobban (2000) argue that formulations should be an evolving process that enables development of complex, idiographic understanding. If appropriate, the evolving nature of formulations should be reflected in clinical practice and thus be regularly reviewed, reshaped and re-shared in supervision and in therapy.

For PTSD specifically, in light of the tentative idea suggesting that processing may potentially occur during CF it is important to ensure that clients have adequate coping skills and feel in a safe environment to complete the CF to prevent re-traumatisation from elaborating on the memory. Teaching grounding techniques is usually an important first part of PTSD treatment (Coleman, 2015), but it might be that these skills need to be taught earlier in therapy if memories are triggered through formulation. It also suggests that if CF can act as a facilitator or mechanism of change, through beginning to activate past trauma memories, a clear rationale for completion should be discussed, to potentially reduce therapy drop out in clients. Psycho-education of finding the CF process difficult could be carried out in order to normalise and validate this reaction. This also suggests that CFs need to be completed tentatively and sensitively.

Lastly, this research provides some evidence that PTSD treatment that does not exclude people due to co-morbidities can decrease other symptoms, including symptoms of depression and anxiety. This supports other trans-diagnostic treatment approaches that are emerging that detail similar cognitive and behavioural processes across disorders (Barlow, Allen, & Choate, 2004; Mansell, Harvey, Watkins, & Shafran, 2008, 2009). Some changes to current protocols might be required in order to account for co-morbidity in psychological treatment to improve therapist confidence to treat people presenting with co-morbidities.

Conclusions

This preliminary and exploratory study aimed to assist with answering some of the questions that remain regarding usefulness of CF in clinical practice, including the efficacy of training to increase formulation skill and specifically the link of CF to treatment outcome.

The first phase of this study found some evidence that training can improve skills in formulating, increasing the overall number of elements captured following training and increasing the overall quality of formulation diagrams. This suggests that formulation is a skill that can be taught and further developed and specific training on formulation can increase formulation skills and quality of formulation diagrams.

The second phase of this study offers initial support that overall quality of diagrams might be linked to improving treatment outcome, with increased elements synthesised within diagrams demonstrating a potential link to increased symptom reduction. No compelling evidence was found suggesting that better diagrams made

for more complex cases is linked to overall outcome, although future research is required to investigate this further.

Some evidence was found suggesting specific items within formulation diagrams might predict symptom trajectory. Formulations containing increased organisation and structure of coherent information that provides a basis for directing treatment might be associated with increased change in symptoms if the information is used to guide treatment. Formulations that suggest long-term chronicity of difficulties through increased moderators and functional equivalence between items might suggest lower responsiveness to treatment.

Sharing formulations with clients appeared to act as a marker of change across many participants mostly followed by a reduction in symptoms. This suggests that sharing a formulation might be useful for contributing to change in PTSD symptoms. Significant differences between phases observed within some participants strengthen this inference. Hypothetical reasons for why formulations might influence change have been suggested, but further research is required to investigate these in more detail. Furthermore, it cannot be ruled out that these findings simply reflect typical symptom trajectory during treatment for PTSD.

Results offer some useful insights into case formulation factors that may contribute to clinical change in symptoms of PTSD. Interpretation of the results remains tentative due to the small sample size, the observational nature of analysis and the variability across some of the data. Future research will be necessary in order to support some of the findings within this study and to further investigate the mechanisms of case formulation in clinical practice.

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Appendices

Appendix 1. Individual case formulation rating scale

Individual case formulation rating scale

A. The problem is clearly defined in terms of how observations inter-relate.

1. The nature and source of observations are made clear and explicit, and observations are not confused with explanations.

0 – The diagram mainly consists of observations that are not described with sufficient precision. Sources of information are not made clear, which may create ambiguity about whether information provided is based on supposition or speculation rather than reflecting what has been reported or directly observed.

1 – A substantial proportion of observations in the diagram are not described with sufficient precision, or sources of information are unclear. There may be some instances of observations appearing to be based at least in part on inference or supposition.

2 - Descriptions of observations are sometimes ambiguous or insufficiently precise, or sources of information are sometimes not clear, or there is minor or infrequent ambiguity regarding whether observations are based on inference or supposition.

3 - Sufficiently detailed and precise descriptions of observations are provided and sources of information are made clear if they are not self-evident. These are based on what is directly observable and/or what can be determined with minimal inference or speculation.

2. The nature and basis for how observations relate to each other is made clear

0 – For the most part, it is not possible to readily discern how observations are thought to be linked and to follow from each other. The positioning of observations in relation to each other and the links portrayed between them seem arbitrary or loosely based on a common theme rather than representing sensible contingent relationships. What is provided bears little resemblance to how events inter-relate in real-life, and the diagram does not appear to depict a plausible configuration of circumstances.

1 – There is considerable ambiguity in the diagram regarding the positioning of observations in relation to each other and the use of linking symbols to convey the nature of their contingent relationships, leaving the intention of what is being depicted difficult to fully understand and to infer the set of real-life circumstances to which the diagram corresponds.

2 – There is minor ambiguity in the diagram regarding the positioning of observations in relation to each other and the use of linking symbols to convey the nature of contingent relationships. However, where this occurs, what is intended can be readily inferred, and it is possible to imagine a set of real-life circumstances to which the diagram corresponds.

3 – For the most part, the basis for how observations are linked to each other is made clear through their relative positioning within the diagram and through clear use of linking symbols (e.g., specifying if causally related or correlated and direction of causality). The nature of contingencies between observations and how they are thought to increase the likelihood of each other's occurrence is readily understood and corresponds sensibly to a potential real-life situation.

3. Explanations (hypotheses, theories, membership in a diagnostic group or other typology, inferred aetiology, inferred historical processes or developmental events) are included that are distinct from observations. These are used to help synthesise and make sense of the information included in the diagram.

0 – Needed explanations are lacking and little is provided by way of conceptual synthesis.

1 – Insufficient explanations are provided to complement what can be portrayed by the observations alone. Provided explanations are unclear or it is not immediately apparent what the basis is for relating the explanation to the particular observations.

2 – Sufficient explanations are provided that are clearly linked to relevant observations, but there is some lack of clarity about the conceptual basis for explanations or their relevance to the observations.

3 – Provided explanations are clearly and sensibly linked to observations, and they complement what can be addressed by observations alone. The explanations contribute to an integrated conceptual basis for what is represented in the formulation.

4. Key contextual elements are included. The formulation incorporates contextual elements (moderators) such as time, place, others present or absent, emotional state, and other factors relevant to exacerbation or amelioration of an aspect of the problem in terms of its form and frequency of occurrence. Taken together, they provide a useful context for understanding the antecedents (both immediate and historical) of the problem and the circumstances under which it presents itself.

0 – Moderators are not included or their presence does not add explanatory value

1 – Some moderators are included but these are isolated or otherwise provide limited information about how they operate and the circumstances in which the problem can be expected to occur.

2 – Moderators are included that help build a contextual picture of the circumstances in which the problem can be expected to occur and the form it takes, but how they operate is incomplete or unclear in some way.

3 – Moderators are included that play a clear role in the formulation and together help build a comprehensive contextual picture of the circumstances in which the significant aspects of the problem can be expected to occur and what form this takes.

5. Functional equivalence between superficially dissimilar elements (either triggers or responses) is denoted where this has implications for understanding the problem. The common function underlying the elements contributes to the delineation of the overall pattern of circumstances that make aspects of the problem more likely to occur.

NA- Not applicable

0 - Functional equivalence is overlooked or not represented when appropriate

1 – Functional equivalence is represented but equivalence is not convincing or doesn't add explanatory value.

2 – Functional equivalence is represented but equivalence is not fully convincing or adds little explanatory value

3 - Functional equivalence is represented convincingly and in a way that contributes to understanding of the patterns of circumstances within which the problem is likely to occur.

6. Significant mediators are identified and their roles are made clear. Potential psychological (e.g., client self-talk and content of beliefs) or other mediators (e.g., mood) are identified through the client's report or, where clearly justified by the evidence, through inference. These are meaningfully situated within the diagram in a manner that makes their role clear.

0 – Mediators are not included where they would be expected to play a role or their presence or how they are described is confusing or otherwise does not add explanatory value

1 – Mediators are included but their linking function between the other observations to which they are related is not convincingly established or made clear.

2 – Mediators are included that meaningfully link indirectly related observations but there is some lack of clarity about the nature of its mediation role or its necessity in the causal sequence in which it plays a part.

3 – Mediators are included that meaningfully link indirectly related observations in a way that sheds light on their necessity in the causal sequence in which they play a part.

B. Validity and Explanatory sufficiency

7. The formulation is a coherent and comprehensive account of the available information. The diagram integrates and structures the information to draw together all the factors comprising and influencing the problem and portrays their patterns of interaction.

0 – The formulation lacks coherence and does not satisfactorily account for information that has been gained.

1 – The formulation partially accounts for the information gained about the client's problem, but there are important observations that are not satisfactorily integrated or accounted for and an overall lack of explanatory coherence.

2 – The formulation accounts for most of the information gained about the client's problem, but there are some observations that are not satisfactorily integrated or accounted for or comparable minor issues related to explanatory coherence.

3 – Overall, the formulation provides a coherent account of the client's problem that incorporates the relevant information and leaves comparatively little unexplained, integrating and structuring the factors contributing to the problem and delineating their patterns of interaction.

8. The formulation delineates mechanisms of change in terms of the elements (observations and explanations) depicted in the diagram and their connections, and provides a basis for understanding where and how to intervene and what to prioritise.

0 – The formulation does not appear to be suitable for establishing how the problem has arisen and how it is being sustained and so does not provide any apparent basis for choosing where and how to intervene and what to prioritise.

1 – The formulation does not provide a readily apparent account of how the problem has arisen and how it is being sustained and so is of limited use for anticipating how the problem could change under different circumstances and for choosing where and how to intervene and what to prioritise.

2 – The formulation accounts for how the problem has arisen and how it is being sustained, which provides a basis for identifying where and how to intervene. However, this basis may not be immediately apparent or it may be incomplete or unclear in some respect. There may also be uncertainty about

how the problem could change under different circumstances or what to prioritise.

3 – The formulation incorporates key causal patterns that account for how the problem has arisen and how it is being sustained. It supports inferences about how the problem could change under different circumstances that provide a sufficient basis for choosing where and how to intervene, including what to prioritise.

9. The formulation manages complexity successfully.

NA- Not applicable

0 – The formulation fails to address the issue of complexity in terms of the overall organisation of information into separate or non-separate sets of problems.

1 – Regarding complexity, the formulation reflects questionable decisions about what to include or the level of detail. There may be problems with the overall organisation of the information into separate or non-separate sets of problems or arbitrary lumping together of observations with minimal conceptual basis.

2 –Complexity is adequately addressed, but minor shortcomings are evident with regard to level of detail, what is included, how information is combined or kept separate, or ambiguity regarding how separate problems are defined.

3 – The formulation achieves a successful balance between choice of what information to include, the level of detail, and whether multiple problems should be combined or addressed separately. Where multiple problems exist, these are clearly defined and are discernible from each other.

Appendix 2. Pre and post formulation instructions

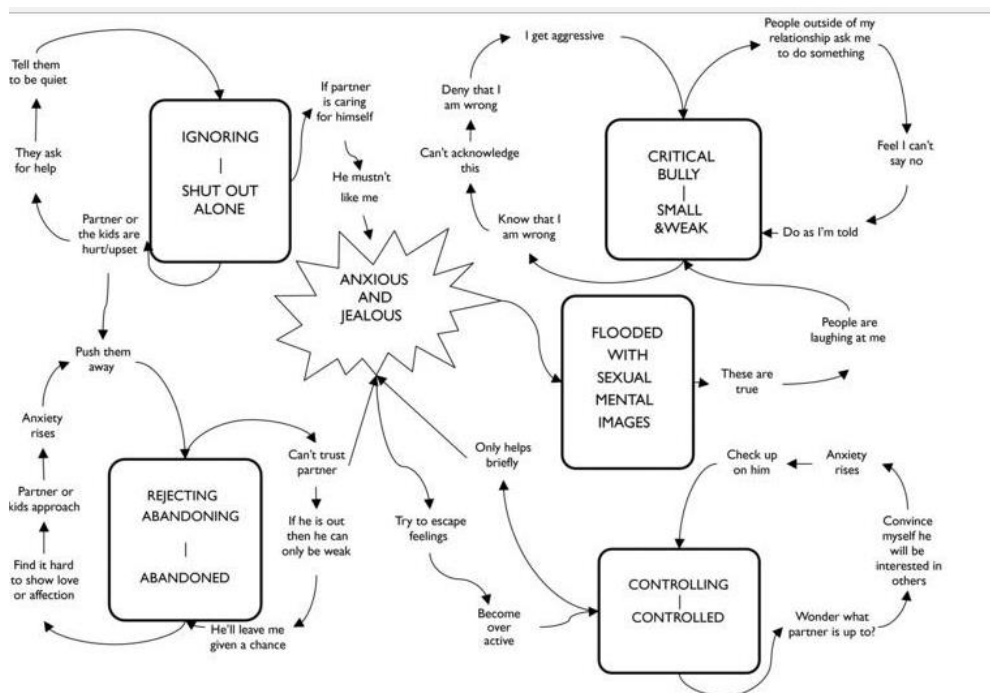
Pre- Formulation training diagram form

INSTRUCTIONS:

Thank you for helping our research by completing a formulation diagram—we are very grateful for your assistance. Please follow these steps:

1. Please look at the next page for an idea of the sort of diagram we are interested in. We are asking you to provide an ad hoc, non-structured diagram, rather than a structured diagram such as a hot-cross bun, vicious flower, etc.
2. Please read the vignette, identifying the information that appears to be relevant to addressing the person's concerns.
3. On Page 4, please provide a formulation diagram of the client's situation that conveys how you have drawn on the information provided in the vignette to formulate their problem in order to guide a potential intervention.
4. Please explain the symbols you used in your diagram, below.

Example: Boxes = behaviours; Single headed arrows = shows one thing causing another



Therapist number:

Your formulation diagram:

Post- Formulation training diagram form

INSTRUCTIONS:

Thank you for helping our research by completing a post workshop formulation diagram—we are very grateful for your assistance. Please follow these steps:

1. Based on the workshop you attended, please complete an **individual case formulation** in line with the system presented in the workshop, etc.
2. Please re-read the vignette (the same vignette as for the pre-workshop diagram), identifying the information that appears to be relevant to addressing the person's concerns.
3. On Page 3, please provide a formulation diagram of the client's situation that conveys how you have drawn on the information provided in the vignette to formulate their problem in order to guide a potential intervention.

Suggested strategy for creating an ICF diagram

1. Run through the text, identifying potential elements that need to go into the diagram. Elements requiring little or no inference are represented in circles or ovals.
2. Identify elements that are functionally equivalent—e.g., elements that are either (a) all capable of evoking the main problem or (b) how the person responds/tries to cope when the problem arises. Group functionally equivalent elements together, linked by double non-headed lines.
3. Consider what the antecedents are of observed elements (behaviours, unpleasant emotions, thoughts, etc.) or groups of elements (where these are functionally equivalent). Link antecedents to corresponding behaviours with a single headed arrow where the direction of causality is one-way or with a two-headed arrow where the causality is reciprocal.
4. For reciprocal relationships, indicate whether it is a positive loop or a negative one, if clarity is needed.
5. Consider what the consequences are of observed elements or groups of elements (where functionally equivalent). Link triggering elements to their consequences.
6. Consider what could possibly explain the relationships among the observed elements. Place possible explanations in squares/rectangles and link these to the relevant observed elements with dashed un-headed lines.

Therapist number:

Your formulation diagram post workshop:

Appendix 3. Ethical Approval: South East Scotland Research Ethics Committee 02

Lothian NHS Board

**South East Scotland Research
Ethics Committee 02**



Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Telephone 0131 536 9000

www.nhslothian.scot.nhs.uk

Date 11 April 2016
Your Ref
Our Ref

Enquiries to: Joyce Clearie
Extension: 35674
Direct Line: 0131 465 5674
Email: Joyce.Clearie@nhslothian.scot.nhs.uk

11 April 2016

Miss Alicia Griffiths
Trainee Clinical Psychology
Camden and Islington NHS Foundation Trust
2nd Floor, West Wing, St Pancras Hospital 4 St Pancras Way,
London
NW1 0PE

Dear Miss Griffiths

Study title: A single case study exploring the use of an individual case formulation for assisting treatment of PTSD in the context of comorbid cannabis and alcohol use.
REC reference: 16/SS/0078
IRAS project ID: 201009

Thank you for your letter of 11th April 2016, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Ms Joyce Clearie, joyce.clearie@nhslothian.scot.nhs.uk. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

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

Conditions of the favourable opinion

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



Headquarters
Waverley Gate, 2-4 Waterloo Place, Edinburgh EH1 3EG

Chair Mr Brian Houston
Chief Executive Tim Davison
Lothian NHS Board is the common name of Lothian Health Board

study.

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

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise). Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at <http://www.rdforum.nhs.uk>.

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

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

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

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant. There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

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

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

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

Ethical review of research sites

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

Approved documents

The documents reviewed and approved by the Committee are:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering PO response letter to REC		11 April 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		
GP/consultant information sheets or letters	1.0	
Participant consent form	2	08 April 2016
Participant information sheet (PIS)	2	08 April 2016
REC Application Form [REC_Form_22032016]		22 March 2016
Research protocol or project proposal		11 February 2016
Summary CV for Chief Investigator (CI)		10 March 2016
Summary CV for supervisor (student research)		
Validated questionnaire [IES-R, PCL 5, LEC, PHQ 9, W&SAS]		

Statement of compliance

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

After ethical review

Reporting requirements

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

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

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

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: <http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance>

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

16/SS/0078	Please quote this number on all correspondence
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With the Committee's best wishes for the success of this project.

Yours sincerely



Mr Lindsay Murray
Chair

Email: joyce.clearie@nhslothian.scot.nhs.uk

Enclosures: *"After ethical review – guidance for researchers" [\[SL-AR2\]](#)*

Copy to: *Miss Lucy Caton*

Noclor, Camden and Islington NHS Foundation Trust

Appendix 4: Health Research Authority (HRA) approval



Health Research Authority

Miss Alicia Griffiths
Trainee Clinical Psychologist
Camden and Islington NHS Foundation Trust
2nd Floor, West Wing, St Pancras Hospital
4 St Pancras Way
London
NW1 0PE

Email: hra.approval@nhs.net

25 May 2016

Dear Miss Griffiths,

Letter of HRA Approval for a study processed under pre-HRA Approval systems

Study title: A single case study exploring the use of an individual case formulation for assisting treatment of PTSD in the context of comorbid cannabis and alcohol use.

IRAS project ID: 201009

REC reference: 16/SS/0078

Sponsor: Royal Holloway, University of London

Thank you for your request to bring the above referenced study under HRA Approval.

I am pleased to confirm that the study has been given **HRA Approval**, on the basis of the document set provided, any clarifications noted in this letter and taking account of reviews and approvals previously conducted and issued.

The extension of HRA Approval to this study on this basis allows the sponsor and NHS organisations to set-up the study in accordance with HRA Approval processes, with decisions on study set-up being taken on the basis of capacity and capability alone.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to participating NHS organisations in England which are being set up in accordance with HRA Approval Processes.

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

IRAS project ID	201009
-----------------	--------

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.

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

Appendices

The HRA Approval letter contains the following appendices:

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

After HRA Approval

In addition to the document, “*After Ethical Review – guidance for sponsors and investigators*”, issued with your REC Favourable Opinion, please note the following:

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

Scope

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

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at <http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/>.

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

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please email the HRA at hra.approval@nhs.net. Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at <http://www.hra.nhs.uk/hra-training/>.

Your IRAS project ID is **201009**. Please quote this on all correspondence.

Yours sincerely

Simon Connolly
Senior Assessor

Email: hra.approval@nhs.net

Copy to: *Miss Lucy Caton, Royal Holloway (Sponsor contact)*
Noclor Research Support (Lead NHS R&D contact)

Appendix A - List of Documents

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

<i>Document</i>	<i>Version</i>	<i>Date</i>
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		03 August 2015
GP/consultant information sheets or letters	1.0	
Other [Statement of activities]		
Other [Schedule of events]		
Participant consent form	2	08 April 2016
Participant information sheet (PIS)	2	08 April 2016
REC Application Form [REC_Form_22032016]		22 March 2016
Research protocol or project proposal		11 February 2016
Summary CV for Chief Investigator (CI)		10 March 2016
Summary CV for supervisor (student research)		
Validated questionnaire [IES-R, PCL 5, LEC, PHQ 9, W&SAS]		

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as assessed for HRA Approval, meets the relevant standards for a study processed through pre-HRA Approval systems, taking account of existing reviews and approvals. Any queries about the assessment from NHS organisations should be escalated to hra.approval@nhs.net in the first instance.

The appendix also provides useful information to sponsors and participating NHS organisations in England to assist in assessing and arranging capacity and capability under HRA Approval processes.

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

Andrew Macleod, Royal Holloway, A.Macleod@rhul.ac.uk

HRA assessment

<i>This provides detail confirmation that the study meets the relevant HRA standards for studies which were processed through pre-HRA Approval systems. It also provides clarifications where useful.</i>
Following assessment, the HRA confirms that the study meets the relevant standards for studies that were processed under pre-HRA Approval systems.
The statement of activities will form the agreement between sponsor and NHS organisation for this student study. The schedule of events has been completed.

Participating NHS Organisations in England

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

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.

Participating NHS organisations in England **will be expected to formally confirm their capacity and capability to host this research.**

- Following issue of this letter, participating NHS organisations in England may now confirm to the sponsor their capacity and capability to host this research, when ready to do so. How capacity and capability will be confirmed is detailed in the *HRA Assessment* section of this appendix.
- The [Assessing, Arranging, and Confirming](#) document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).

A principal investigator has been named at the participating organisation. The student with their academic supervisors and the principal investigator will be responsible for the conduct of research activities at the participating NHS organisation.

GCP training is not a generic training expectation, in line with the [HRA statement on training expectations](#).

Appendix 5. A substantial amendment Approval by the HRA

Dear Alicia Griffiths,

Further to the below, I am pleased to confirm that HRA Approval has been issued for the referenced amendment, following assessment against the HRA criteria and standards.

The sponsor should now work collaboratively with participating NHS organisations in England to implement the amendment as per the below categorisation information. This email may be provided by the sponsor to participating organisations in England to evidence that the amendment has HRA Approval.

Please contact hra.amendments@nhs.net for any queries relating to the assessment of this amendment.

Yours sincerely,

Rekha

Rekha Keshvara | Assessor

Health Research Authority

Nottingham HRA Centre, The Old Chapel,

Royal Standard Court, Nottingham NG1 6FS

E: Rekha.Keshvara@nhs.net | T: 0207 104 8191

Appendix 6: A substantial amendment Approval by South East Scotland Research Ethics Committee 02

Lothian NHS Board

**South East Scotland
Research
Ethics Committee 02**



Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Telephone 0131 536 9000

www.nhsllothian.scot.nhs.uk

Direct Line: 0131 465 5674
Email: Joyce.Clearie@nhsllothian.scot.nhs.uk
Enquiries to: Joyce Clearie
Extension: 35674

27 October 2016

Miss Alicia Griffiths
Trainee Clinical Psychologist
Camden and Islington NHS Foundation Trust
2nd Floor, West Wing, St Pancras Hospital 4 St Pancras Way,
London, NW1 0PE

Dear Miss Griffiths,

Study title: A single case study exploring the use of an individual case formulation in assisting treatment of PTSD
REC reference: 16/SS/0078
Amendment number: AM01 (REC Ref 16/SS/0078/AM01)
Amendment date: 30 September 2016
IRAS project ID: 201009

The above amendment was reviewed on 14 October 2016 by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

The Committee raised no ethical concerns regarding this amendment.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
GP/consultant information sheets or letters	2.0	26 September 2016
Notice of Substantial Amendment (non-CTIMP)		30 September 2016
Other [VAS PTSD Weekly Rating of Intrusive Memories]	N/A	
Participant consent form	3.0	26 September 2016
Participant information sheet (PIS)	3.0	26 September 2016



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Waverley Gate, 2-4 Waterloo Place, Edinburgh EH1 3EG

Chair Mr Brian Houston
Chief Executive Tim Davison

Lothian NHS Board is the common name of Lothian Health Board

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.


Statement of compliance

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

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

16/SS/0078:	Please quote this number on all correspondence
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Yours sincerely,



Ms Joanne Mair
Chair

E-mail: joyce.clearie@nhslothian.scot.nhs.uk

Enclosures: List of names and professions of members who took part in the review

*Copy to: Noclor, Camden and Islington NHS Foundation Trust
Miss Lucy Caton, Royal Holloway, University of London
Prof Andrew MacLeod, Royal Holloway, University of London*

Appendix 7. Local Research and Development (R&D) department ethical approval: Homerton University

Homerton University Hospital 
NHS Foundation Trust

Research & Development
Chair: Dr Claire Gorman

Christine Mitchell-Inwang
Research & Development Manager
Christine.Inwang@homerton.nhs.uk

Homerton University Hospital
Research and Development
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Amendment of Approval Letter

Mr John Wheatley
Homerton University Hospital NHS Foundation Trust
Homerton Row
London E9 6SR

30th May 2017

Dear Jon Wheatley,

Re: A single case study exploring the use of an individual case formulation in assisting treatment of PTSD.

REC: 16/SS/0078
R&D No: 1680
Chief Investigator: Alicia Griffiths

Thank you for sending all the relevant documents for Homerton University Hospital Trust Research and Development Approval of the above research study. As part of the Research and Development approval process we have conducted a site specific assessment for this study. I am happy to inform you that the Trust has approved the conduct of the study and that the Trust will indemnify against negligent harm that might occur during the course of this project.

The following main document/s has been received by R&D department as part of the approval process;

Protocol Version 1	Dated: 11/02/2016
Participant Information Sheet Version 3	Dated: 26/09/2016
Participant Consent Form Version 3	Dated: 26/09/2016
GP Letter Version 2	Dated: 26/09/2016

All other document/s you have sent in as part of the process has also been received.

I would like to draw your attention to the following conditions of the approval of this research project with which you must comply. **Failure to do so may result in the Trust withdrawing R&D approval which allows you to conduct this research project at Homerton University Hospital NHS Foundation Trust.**

Untoward events - Should any untoward event occur it is **essential** that you complete a clinical incident form and write on the form 'R&D'. Contact the R&D Office immediately and if patients or staff are involved in an incident you must also contact the Risk Manager on 020 8510 7649.

Incorporating hospital and community health services, teaching and research

Status of Research - Inform us if your project is amended or if your project terminates early/requires an extension as well as informing the Research Ethics Committee. This is necessary to ensure that your indemnity cover is valid and also helps the office to maintain up-to-date records. A copy of any publications arising from the research should be sent to the R&D Office for use in the R&D Annual Report. Please be reminded that this hospital should be acknowledged in any publication.

Research Information - You will be required to complete a project update as required by the R&D Office to ensure that we have up to date information so that we can send accurate reports to the DoH and research networks. The project update form will be emailed or sent to you by the R&D Office.

Research Governance - As part of research governance, all investigators accessing identifiable personal information are required to comply with current data protection requirements.

Intellectual Property - If you believe that protectable intellectual property may arise from your research, please contact the Christine Mitchell-Inwang, R&D Manager on ext 5134 who will advise you on the proper course of action.

Monitoring of Studies - You must comply with the Trust's legal responsibility as host of this research project to monitor and audit the research to ensure that the Research Governance Framework and Good Clinical Practice (GCP) if applicable is being adhered to. Monitoring questionnaires will be sent to you and random audit visits will also take place across the trust and will be conducted following at least a seven day notice period. **Failure to respond to any of these monitoring or auditing requests may result in the Trust withdrawing your R&D approval to conduct this research at Homerton University Hospital NHS Foundation Trust.**

Please note that all NHS and social care research is subject to the DoH *Research Governance Framework*. If you are unfamiliar with the standards contained in this document, you may obtain details from the Trust R&D Office or from the DoH website (www.dh.gov.uk).

Please do not hesitate to contact Christine Mitchell-Inwang, Research and Development Manager or me if you have any further questions.

Yours sincerely,



WILLIAM NMAJU

on behalf of

Dr Claire Gorman
Director Research & Development

Appendix 8. Local Research and Development (R&D) department ethical approval: Barnet, Enfield & Haringey

Dear Alicia,

RE: IRAS 201009. Confirmation of Capacity and Capability at Barnet Enfield & Haringey NHS Mental Health Trust

Full Study Title: A single case study exploring the use of an individual case formulation for assisting treatment of PTSD.

Latest HRA Approval Date: HRA Approval – Dated 25.05.2016

This email confirms that Barnet Enfield & Haringey NHS Mental Health Trust has the capacity and capability to deliver the above referenced study. Please find attached the signed agreement as confirmation.

Barnet Enfield & Haringey NHS Mental Health Trust agrees to start this study on a date to be agreed when you as sponsor give the green light to begin. Please ensure the R&D office and local CRN contacts are provided with this date.

If you wish to discuss further, please do not hesitate to contact us.

As specified in the HRA Approval, Letters of Access for members of the external research team maybe required and should be arranged prior to the relevant team members conducting any study interventions.

Please note, in line with national HRA approvals process, you will no longer receive an NHS R&D Approval/Permission letter.

Kind regards,

Atote On behalf of Barnet Enfield & Haringey NHS Mental Health Trust

Noclor Research Support Service

Appendix 9. Local Research and Development (R&D) department ethical approval: The Whittington Hospital

Dear Alicia,

RE: IRAS 201009. Confirmation of Capacity and Capability at The Whittington Hospital NHS Trust

Full Study Title: A single case study exploring the use of an individual case formulation for assisting treatment of PTSD.

Latest HRA Approval Date: HRA Approval – Dated 25.05.2016

This email confirms that The Whittington Hospital NHS Trust has the capacity and capability to deliver the above referenced study. Please find attached the signed agreement as confirmation.

The Whittington Hospital NHS Trust agrees to start this study on a date to be agreed when you as sponsor give the green light to begin. Please ensure the R&D office and local CRN contacts are provided with this date.

If you wish to discuss further, please do not hesitate to contact us.

As specified in the HRA Approval, Letters of Access for members of the external research team maybe required and should be arranged prior to the relevant team members conducting any study interventions.

Please note, in line with national HRA approvals process, you will no longer receive an NHS R&D Approval/Permission letter.

Kind regards,

Atote On behalf of The Whittington Hospital NHS Trust

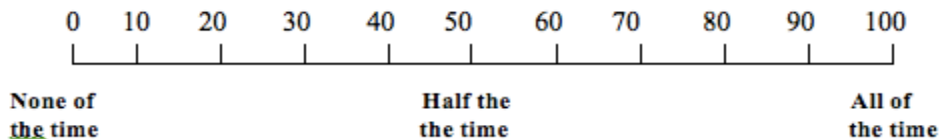
Research Support Service

Appendix 10: Image Intrusiveness Visual Analogue Scales (IVAS)

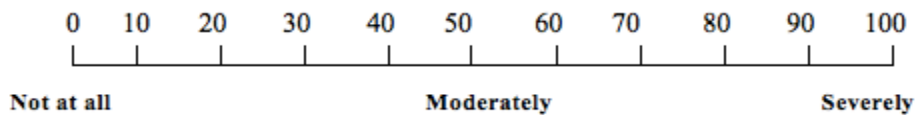
When people experience traumatic events they often have distressing intrusive images or memories from the past.

Please circle a number from the scales below which best describes your experience of distressing intrusive images or memories you have had over the past week.

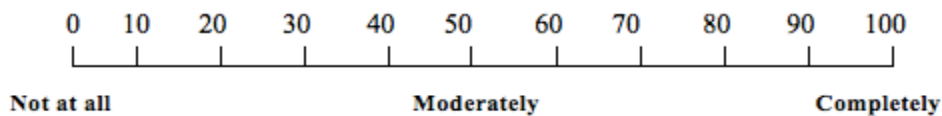
1. Over the past week how frequently did you experience intrusive images or memories?



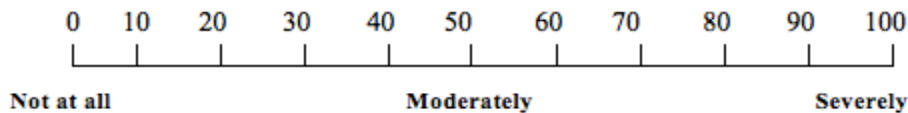
2. How much did intrusive images or memories interfere with your daily life?



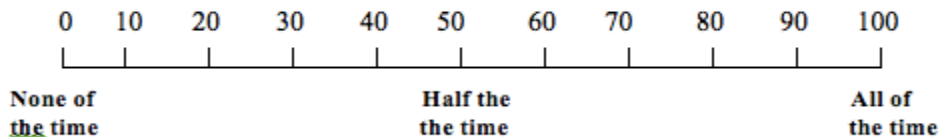
3. How uncontrollable were your intrusive images or memories?



4. Over the past week, how distressing were your intrusive images or memories?



5. Over the past week, how much did you feel like you were experiencing intrusive images/memories in the moment i.e. right here and now?



Appendix 11: Encapsulated Belief Visual Analogue Scale (EBVAS)

Participant ID:

Week:

Date:

Weekly Rating of Encapsulated belief

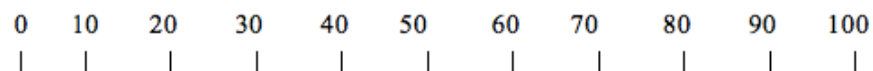
Distressing and intrusive images or memories from the past often have a key meaning for people. The key meaning is a statement of what the image means to you. This might be a statement about you, about the memory or about the world. It is often what upsets you most about the image and what the implication of the intrusive image is.

You identified what the key meaning of the image(s) is with your therapist in a previous session.

Please circle a number from the scales below which best describes your experience of believing the meaning of this image to be true over the past week.

Key Meaning of image(s):

1. Over the past week, how much have you believed this statement to be true?



**Do not believe
it at all**

Half believe it

**Completely
believe it**

Appendix 12: Impact of Events Scale-Revised

IMPACT OF EVENTS SCALE-Revised (IES-R)

INSTRUCTIONS: Below is a list of difficulties people sometimes have after stressful life events. Please read each item, and then indicate how distressing each difficulty has been for you DURING THE PAST SEVEN DAYS with respect to _____ (event) that occurred on _____ (date). How much have you been distressed or bothered by these difficulties?

	Not at all	A little bit	Moderately	Quite a bit	Extremely
1. Any reminder brought back feelings about it	0	1	2	3	4
2. I had trouble staying asleep	0	1	2	3	4
3. Other things kept making me think about it.	0	1	2	3	4
4. I felt irritable and angry	0	1	2	3	4
5. I avoided letting myself get upset when I thought about it or was reminded of it	0	1	2	3	4
6. I thought about it when I didn't mean to	0	1	2	3	4
7. I felt as if it hadn't happened or wasn't real.	0	1	2	3	4
8. I stayed away from reminders of it.	0	1	2	3	4
9. Pictures about it popped into my mind.	0	1	2	3	4
10. I was jumpy and easily startled.	0	1	2	3	4
11. I tried not to think about it.	0	1	2	3	4
12. I was aware that I still had a lot of feelings about it, but I didn't deal with them.	0	1	2	3	4
13. My feelings about it were kind of numb.	0	1	2	3	4
14. I found myself acting or feeling like I was back at that time.	0	1	2	3	4
15. I had trouble falling asleep.	0	1	2	3	4
16. I had waves of strong feelings about it.	0	1	2	3	4
17. I tried to remove it from my memory.	0	1	2	3	4
18. I had trouble concentrating.	0	1	2	3	4
19. Reminders of it caused me to have physical reactions, such as sweating, trouble breathing, nausea, or a pounding heart.	0	1	2	3	4
20. I had dreams about it.	0	1	2	3	4
21. I felt watchful and on-guard.	0	1	2	3	4
22. I tried not to talk about it.	0	1	2	3	4

Total IES-R Score: _____

INT: 1, 2, 3, 6, 9, 14, 16, 20
 AVD: 5, 7, 8, 11, 12, 13, 17, 22
 HYP: 4, 10, 15, 18, 19, 21

Weiss, D.S. (2007). The Impact of Event Scale-Revised. In J.P. Wilson, & T.M. Keane (Eds.) *Assessing psychological trauma and PTSD: a practitioner's handbook* (2nd ed., pp. 168-189). New York: Guilford Press.

AETR2N

22

1/13/2012

Appendix 13: PTSD checklist for DSM- 5

PCL-5

Instructions: This questionnaire asks about problems you may have had after a very stressful experience involving *actual or threatened death, serious injury, or sexual violence*. It could be something that happened to you directly, something you witnessed, or something you learned happened to a close family member or close friend. Some examples are a *serious accident; fire; disaster such as a hurricane, tornado, or earthquake; physical or sexual attack or abuse; war; homicide; or suicide*.

First, please answer a few questions about your *worst event*, which for this questionnaire means the event that currently bothers you the most. This could be one of the examples above or some other very stressful experience. Also, it could be a single event (for example, a car crash) or multiple similar events (for example, multiple stressful events in a war-zone or repeated sexual abuse).

Briefly identify the worst event (if you feel comfortable doing so):

How long ago did it happen? _____ *(please estimate if you are not sure)*

Did it involve actual or threatened death, serious injury, or sexual violence?

_____ Yes

_____ No

How did you experience it?

_____ It happened to me directly

_____ I witnessed it

_____ I learned about it happening to a close family member or close friend

_____ I was repeatedly exposed to details about it as part of my job (for example, paramedic, police, military, or other first responder)

_____ Other, please describe _____

If the event involved the death of a close family member or close friend, was it due to some kind of accident or violence, or was it due to natural causes?

_____ Accident or violence

_____ Natural causes

_____ Not applicable (the event did not involve the death of a close family member or close friend)

<i>In the past month, how much were you bothered by:</i>	<i>Not at all</i>	<i>A little bit</i>	<i>Moderately</i>	<i>Quite a bit</i>	<i>Extremely</i>
1. Repeated, disturbing, and unwanted memories of the stressful experience?	0	1	2	3	4
2. Repeated, disturbing dreams of the stressful experience?	0	1	2	3	4
3. Suddenly feeling or acting as if the stressful experience were actually happening again (as if you were actually back there reliving it)?	0	1	2	3	4
4. Feeling very upset when something reminded you of the stressful experience?	0	1	2	3	4
5. Having strong physical reactions when something reminded you of the stressful experience (for example, heart pounding, trouble breathing, sweating)?	0	1	2	3	4
6. Avoiding memories, thoughts, or feelings related to the stressful experience?	0	1	2	3	4
7. Avoiding external reminders of the stressful experience (for example, people, places, conversations, activities, objects, or situations)?	0	1	2	3	4
8. Trouble remembering important parts of the stressful experience?	0	1	2	3	4
9. Having strong negative beliefs about yourself, other people, or the world (for example, having thoughts such as: <i>I am bad, there is something seriously wrong with me, no one can be trusted, the world is completely dangerous</i>)?	0	1	2	3	4
10. Blaming yourself or someone else for the stressful experience or what happened after it?	0	1	2	3	4
11. Having strong negative feelings such as fear, horror, anger, guilt, or shame?	0	1	2	3	4
12. Loss of interest in activities that you used to enjoy?	0	1	2	3	4
13. Feeling distant or cut off from other people?	0	1	2	3	4
14. Trouble experiencing positive feelings (for example, being unable to feel happiness or have loving feelings for people close to you)?	0	1	2	3	4
15. Irritable behavior, angry outbursts, or acting aggressively?	0	1	2	3	4
16. Taking too many risks or doing things that could cause you harm?	0	1	2	3	4
17. Being "superalert" or watchful or on guard?	0	1	2	3	4
18. Feeling jumpy or easily startled?	0	1	2	3	4
19. Having difficulty concentrating?	0	1	2	3	4
20. Trouble falling or staying asleep?	0	1	2	3	4

PCL-5 (8/14/2013) Weathers, Litz, Keane, Palmieri, Marx, & Schnurr – National Center for PTSD

Appendix 14. Life Events Checklist

LIFE EVENTS CHECKLIST (LEC)

Listed below are a number of difficult or stressful things that sometimes happen to people. For each event check one or more of the boxes to the right to indicate that: (a) it *happened to you* personally, (b) you *witnessed it* happen to someone else, (c) you *learned about it* happening to someone close to you, (d) you're *not sure* if it fits, or (e) it *doesn't apply* to you.

Be sure to consider your *entire life* (growing up as well as adulthood) as you go through the list of events.

Event	Happened to me	Witnessed it	Learned about it	Not Sure	Doesn't apply
1. Natural disaster (for example, flood, hurricane, tornado, earthquake)					
2. Fire or explosion					
3. Transportation accident (for example, car accident, boat accident, train wreck, plane crash)					
4. Serious accident at work, home, or during recreational activity					
5. Exposure to toxic substance (for example, dangerous chemicals, radiation)					
6. Physical assault (for example, being attacked, hit, slapped, kicked, beaten up)					
7. Assault with a weapon (for example, being shot, stabbed, threatened with a knife, gun, bomb)					
8. Sexual assault (rape, attempted rape, made to perform any type of sexual act through force or threat of harm)					
9. Other unwanted or uncomfortable sexual experience					
10. Combat or exposure to a war-zone (in the military or as a civilian)					
11. Captivity (for example, being kidnapped, abducted, held hostage, prisoner of war)					
12. Life-threatening illness or injury					
13. Severe human suffering					
14. Sudden, violent death (for example, homicide, suicide)					
15. Sudden, unexpected death of someone close to you					
16. Serious injury, harm, or death you caused to someone else					
17. Any other very stressful event or experience					

Appendix 15. The Patient Health Questionnaire-9 (PHQ-9)

PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

Over the **last 2 weeks**, how often have you been bothered by any of the following problems?
(Use "✓" to indicate your answer)

	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

FOR OFFICE CODING 0 + + +
=Total Score:

If you checked off **any** problems, how **difficult** have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult
at all

Somewhat
difficult

Very
difficult

Extremely
difficult

Appendix 16: The Generalised Anxiety Disorder Scale (GAD-7)

GAD-7 Anxiety

Over the <u>last 2 weeks</u> , how often have you been bothered by the following problems? <i>(Use “✓” to indicate your answer”</i>	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

Column totals: ___ + ___ + ___ + ___
 = **Total Score** ____

Appendix 17. The Work and Social Adjustment Scale (W&SAS)

Work & Social Adjustment Scale

People's problems sometimes affect their ability to do certain day-to-day tasks in their lives. To rate your problems, look at each section and determine on the scale provided how much your problem impairs your ability to carry out the activity. 0 indicates no impairment at all and 8 indicates very severe impairment.

	0	1	2	3	4	5	6	7	8	N/A
	<i>Not at all</i>		<i>Slightly</i>		<i>Definitely</i>		<i>Markedly</i>		<i>Very severely</i>	
1. WORK (If you are retired or choose not to have a job for reasons unrelated to your problem, please tick N/A - not applicable)	0	1	2	3	4	5	6	7	8	N/A
2.HOME MANAGEMENT – Cleaning, tidying, shopping, cooking, looking after home/children, paying bills etc.	0	1	2	3	4	5	6	7	8	
3.SOCIAL LEISURE ACTIVITIES - With other people, e.g. parties, pubs, outings, entertaining etc.	0	1	2	3	4	5	6	7	8	
4.PRIVATE LEISURE ACTIVITIES – Done alone, e.g. reading, gardening, sewing, hobbies, walking etc.	0	1	2	3	4	5	6	7	8	
5.FAMILY AND RELATIONSHIPS – Form and maintain close relationships with others including the people that I live with.	0	1	2	3	4	5	6	7	8	

Appendix 18. Participant Information sheet

Participant Information Sheet (version 3, 26/09/2016)



(Headed paper of NHS foundation Trust)

Study title: A single case study exploring the use of an individual case formulation in assisting treatment of PTSD.

Invitation

We would like to invite you to take part in our research study. Joining the study is entirely up to you and before you decide we would like you to understand why the research is being conducted and what it would involve for you. One of our team will go through this information sheet with you to help you to decide whether or not you would like to take part and answer any questions you may have. Please take time to read the following information carefully and feel free to ask any questions as you go through the information sheet.

Summary

This study is part of a Clinical Psychology Doctoral research project investigating how **clinicians make sense of individual cases in treating Post-Traumatic Stress Disorder (PTSD), a process called “formulation”**. **We are interested in finding out more about treating PTSD that co-occurs with other disorders** and this study will examine which aspects of a formulation relate to treating PTSD, particularly in the context of co-existing problems.

This research will potentially have implications for psychology services and treatment of psychological disorders that co-occur with other disorders.

Why have I been invited?

You have been invited to take part because you have symptoms of PTSD **and are awaiting treatment for PTSD at xxxxxxxx**, where this research is being carried out.

What would taking part involve?

By taking part, the treatment that you receive for PTSD will not differ from treatment as usual. You will be asked to complete questionnaire measures at 3 time points before you start treatment and also at the end of each treatment session. The questionnaires should take around 10 minutes to complete after each session. For PTSD treatment, people usually attend sessions weekly, but this will be decided between you and your treating Clinician. The study will last around 10 months in total. You will be involved in the study for as long as your treatment lasts. Data collection for this study will end in spring 2017 and therefore if your treatment has not finished at this point, we will use the data that we have collected already and your treatment will continue as normal.

If you would like to know the results of this study, please inform your Clinician as a report will be generated at the end of the study for all research participants to learn about the results. By taking part, you will be adding to existing knowledge about formulations and also about treatment of PTSD alongside co-morbidities.

Are there any risks of taking part in the study?

There are no additional risks of taking part in the study than there are for routine treatment for PTSD.

Confidentiality

Confidentiality will be maintained during the study. All data that is collected will remain confidential to the researchers. You will be given a unique identification number and no one other than the research team will be able to identify you from this number. Data collected will be anonymised, stored securely and evaluated only at **xxxxxxxxxx**. Your data will be kept for the purposes of this research only and will be destroyed once the study has finished. We would like to let your GP know that you are involved in the study. The findings of this study will hopefully be published. Your anonymity will be maintained during publication.

Risk to confidentiality

Consistent with treatment as usual, if you disclose risk of harm to yourself or another individual, we might need to inform your GP. Any risk issues that are disclosed will be managed and monitored by your Clinician and **the team at xxxxxxxxxxxx**.

Onward referral

As with normal treatment, onward referral to another service may be required part way through the study (or at the end of the study). Onward referral to a crisis team might be required if you disclose risk of harm to yourself during treatment sessions.

What happens if I decide not to take part?

There is no obligation to take part in this study. If after reading this information sheet you decide that you do not wish to participate in the study, your treatment will not be affected in any way.

Can I leave the study part way through?

If you decide to take part in the study, you have the right to withdraw at any time during the study without giving a reason. Your access to treatment will not be affected.

What happens next if I decide to take part?

If after reading this information sheet you are happy to be involved in the study, please sign the consent form. You will be asked to complete some questionnaires prior to your treatment sessions.

Thank you for reading this participant information sheet. If you have any questions now or at any time, please do not hesitate to contact a Clinician at **xxxxxxx** or contact **xxxxxxx, Consultant Psychologist and Clinical Lead** who is the field supervisor for this project.

Appendix 19. Consent form



(Headed paper of NHS Foundation Trust)

Participant Identification Number:

Consent form (version 3, 26/09/2016)

Title of Project: **A single case study exploring the use of an individual case formulation in assisting treatment of PTSD.**

Name of Researcher: Alicia Griffiths

Please initial box

1. I confirm that I have read the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the research team, or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
4. I agree to my General Practitioner being informed of my participation in the study.
5. I agree to take part in the above study.

Name of Participant Date Signature

Name of Person taking consent Date Signature

Appendix 20: Example pages from the therapist research pack

THESIS PROJECT: A single case study exploring the use of an individual case formulation in assisting treatment of PTSD.

Dear therapist,

Thank you for supporting this research project. This folder was created in order to clarify and simplify administration of measures and to increase consistency across participants.

Project information

This study is using a single case experimental design (SCED). This means that the study requires 3 baseline data points per participant before implementation of the intervention. Data will then be collected after the intervention for a minimum of 3 weeks.

This folder contains an index detailing where you can find the materials including all the measures necessary on a week-by-week basis.

Procedure

- **Measures are to be collected at each Session.**
- **This pack will provide a step-by-step guide as to which measures to collect at each Session (they are all in plastic wallets provided labeled by Session number).**

	Index page
Demographic information	Page 3
Session 1 + 2	Page 4
After Session 2	Page 5
Session 3	Page 7
Session 4 onwards	Page 8

Demographic information

Participant ID _____

Age _____

Gender _____

Ethnicity _____

Current employment _____

Trauma Type _____

Trauma Duration _____

Time since Trauma _____

Previous trauma treatment _____

Co-morbid disorders _____

Current medication _____

Sessions 1 + 2 - measures only

Measures are provided in the plastic wallets labeled Session 1 and Session 2. Please ask Clients to complete all of these before the start of each session and put them back in the wallets afterwards. I will collect these and remove them afterwards.

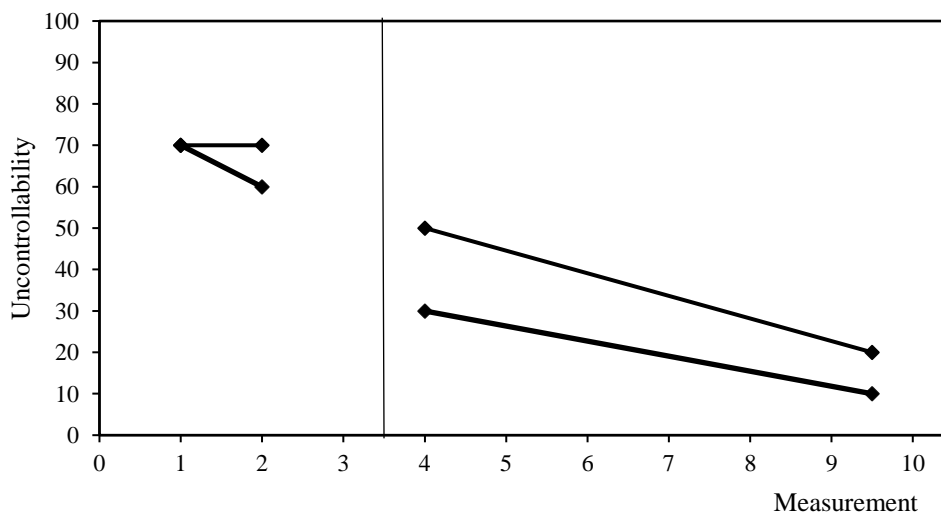
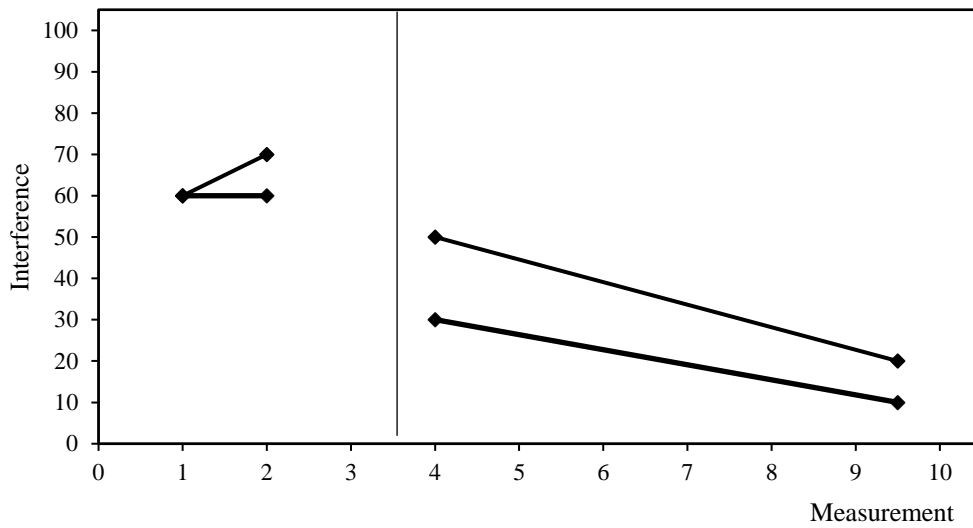
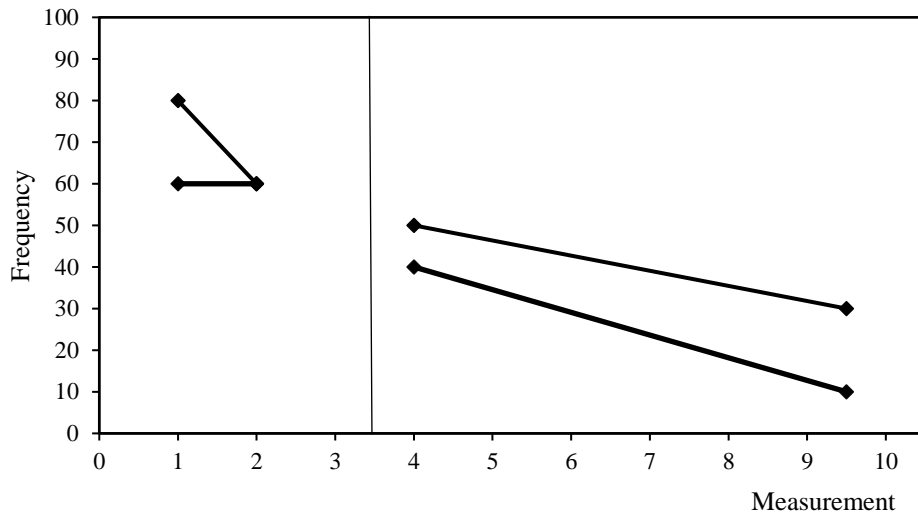
Measure	(Session 1)	(Session 2)
	PLEASE TICK WHEN COMPLETE	PLEASE TICK WHEN COMPLETE
Intrusive images visual analogue scales (VASs)		
Encapsulated belief scale (EVAS)		
Impact of Events Scale Revised (IES-R)		
PTSD checklist for DSM-5 (PCL-5)		
Life Events Checklist (LEC) – only at Session 1		

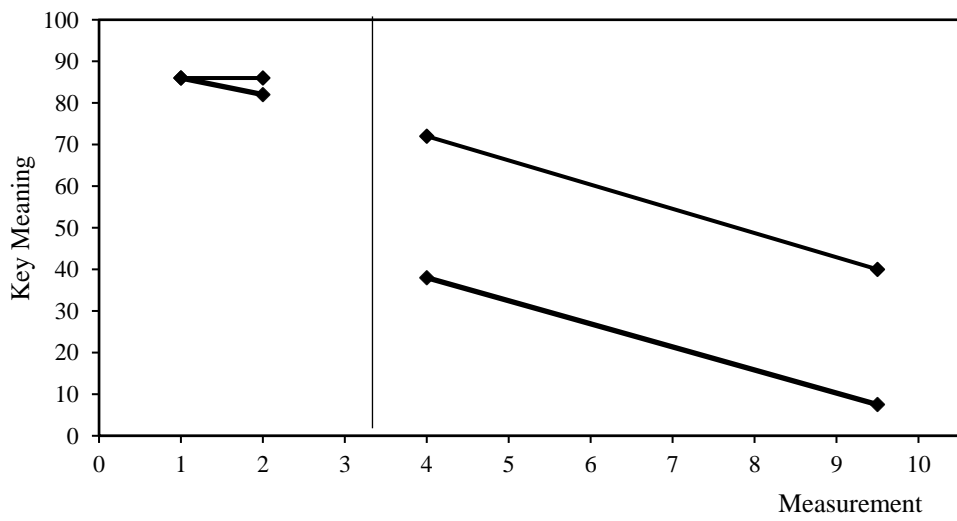
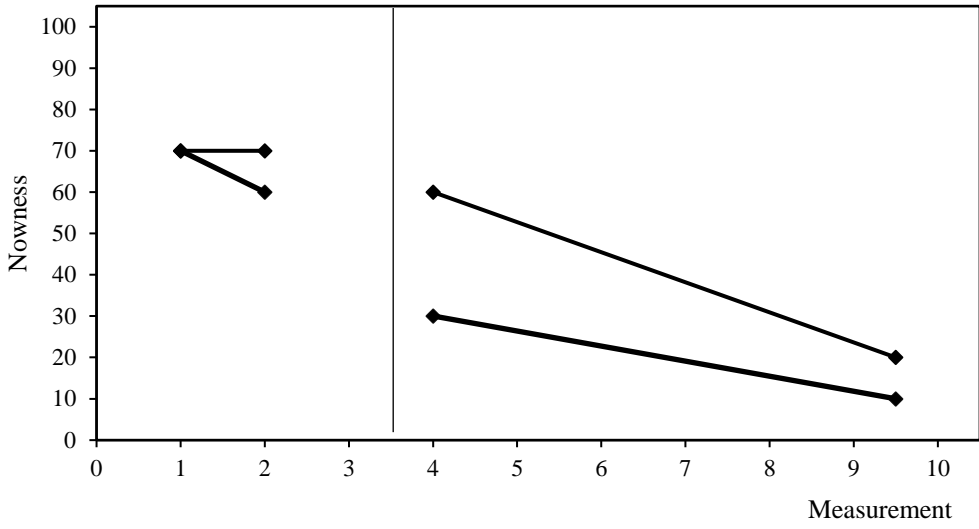
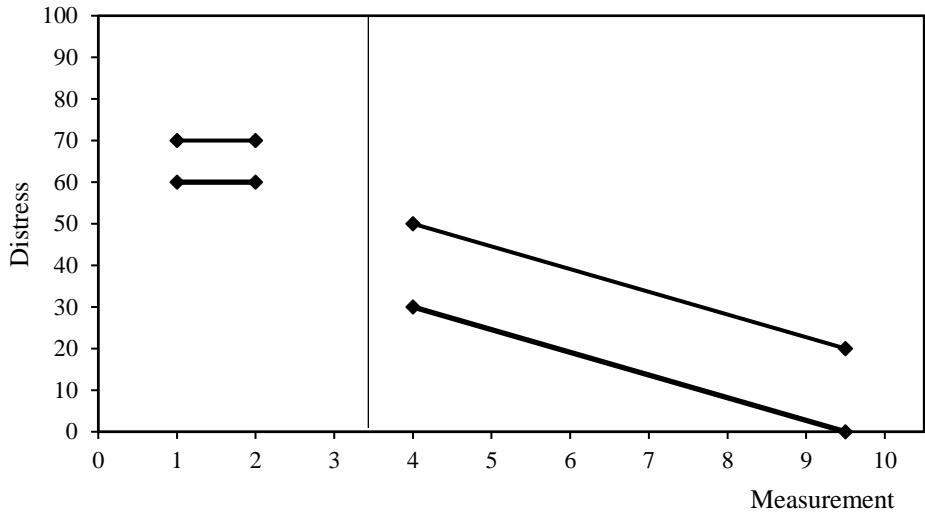
After session 2 - Creating the formulation

After Session 2, we will ask you to complete an Individual Case Formulation for your client based on the training you had. There is a step-by-step guide on the next page to help you to do this. Please use this check box to help you to remember the stages.

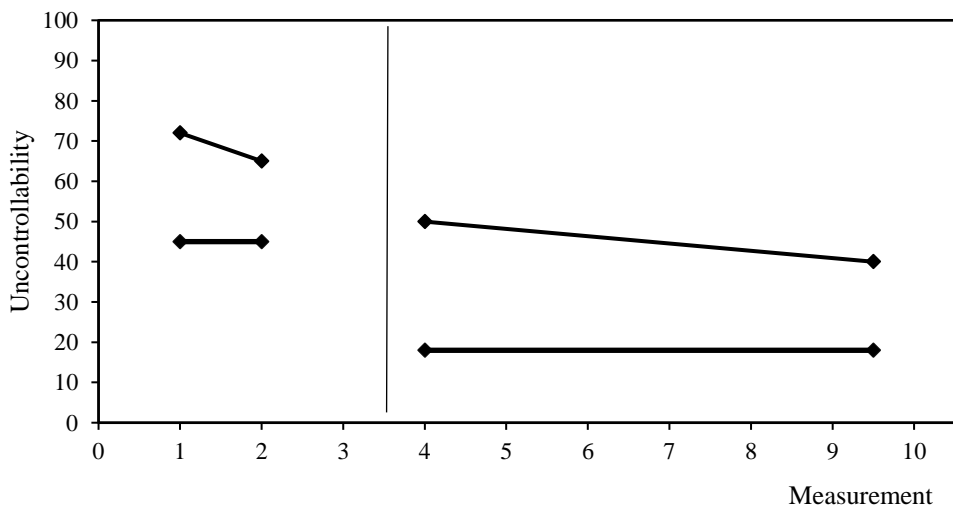
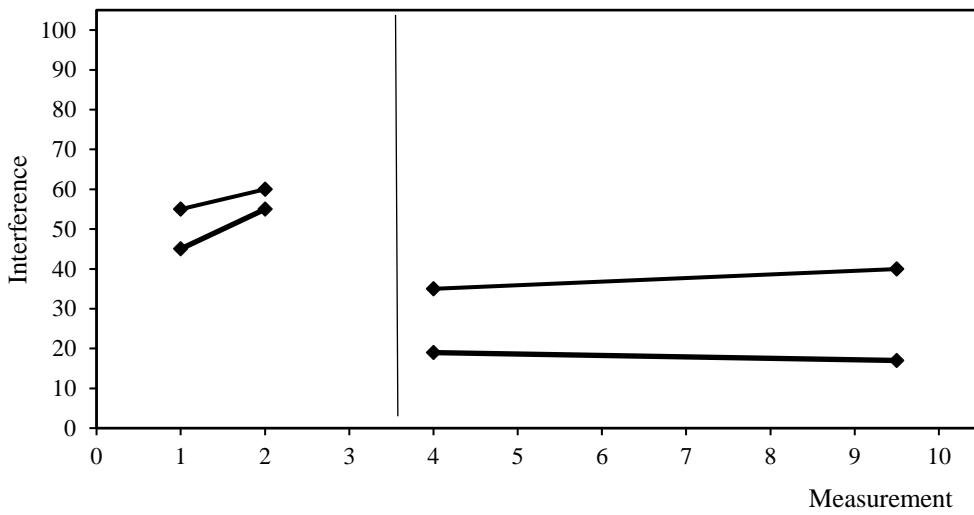
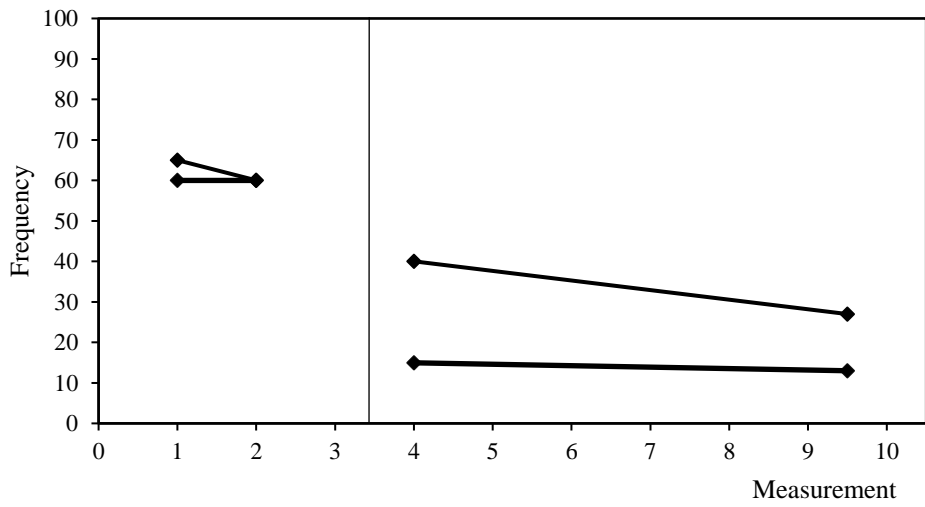
	YES/NO
Have you drawn out an ICF for this participant prior to session 3?	

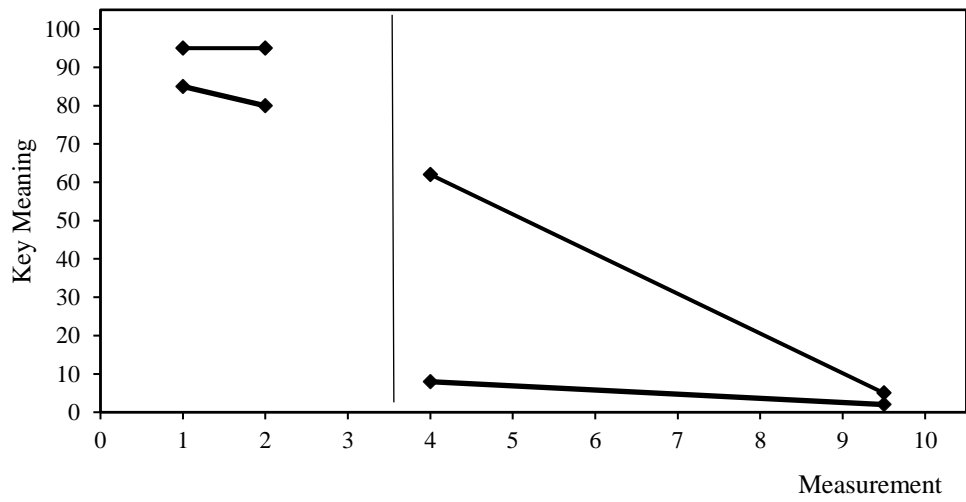
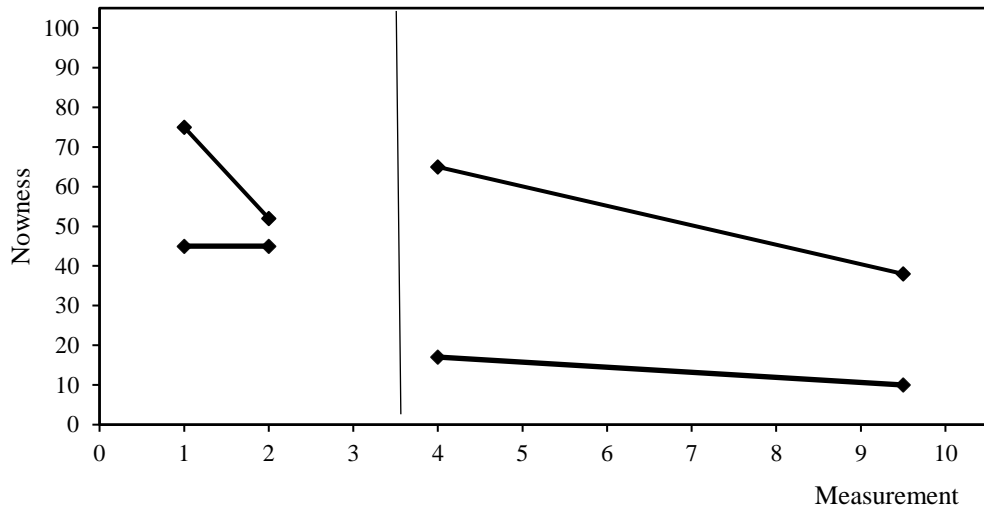
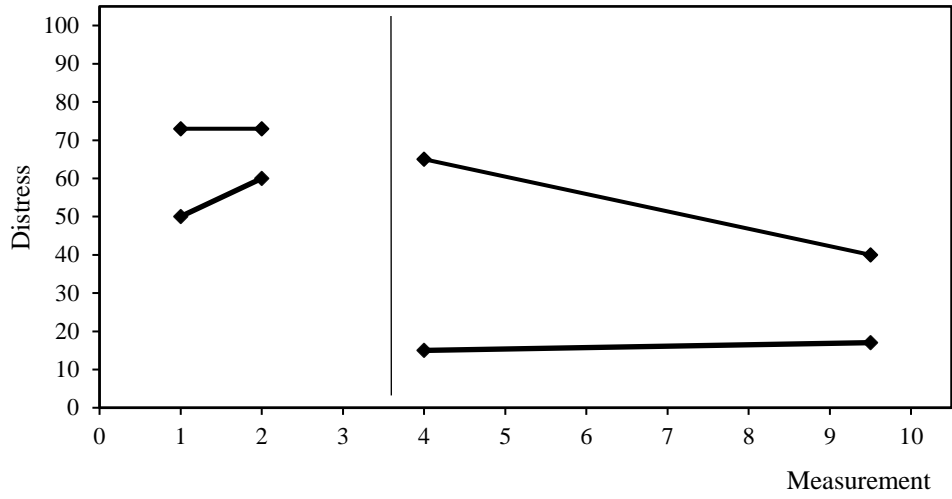
Appendix 21. PA: Variability Analysis (Trended Range) IVAS and EBVAS



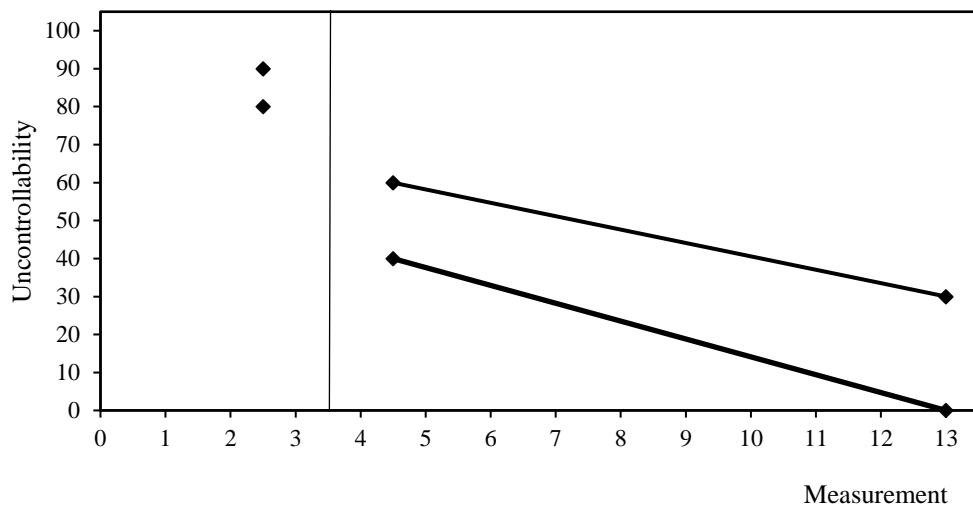
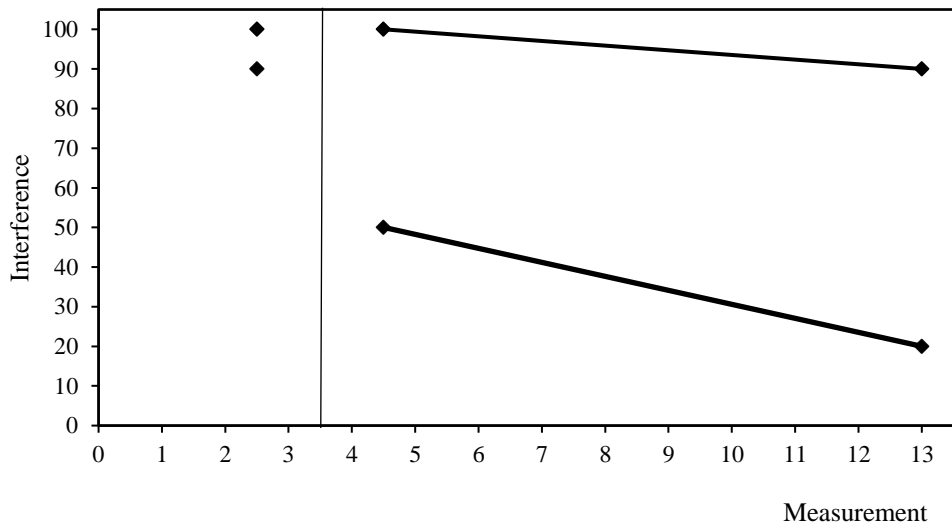
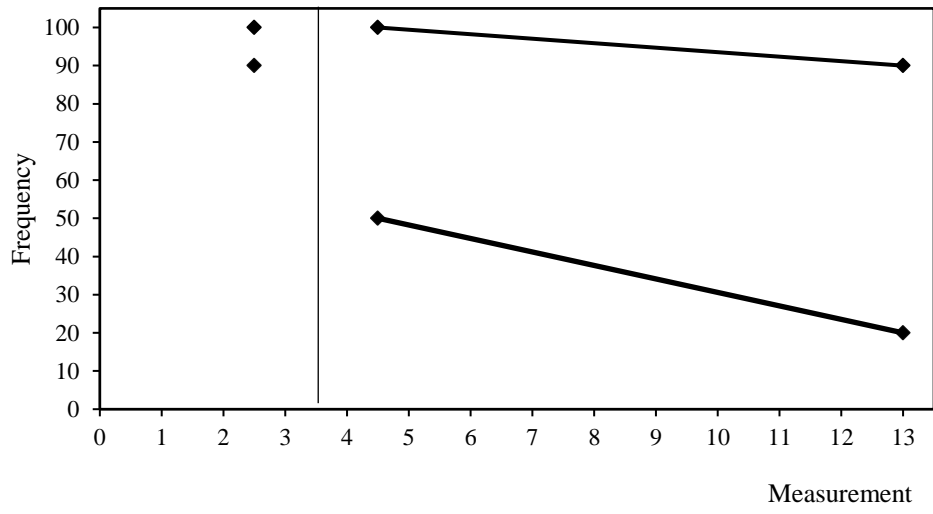


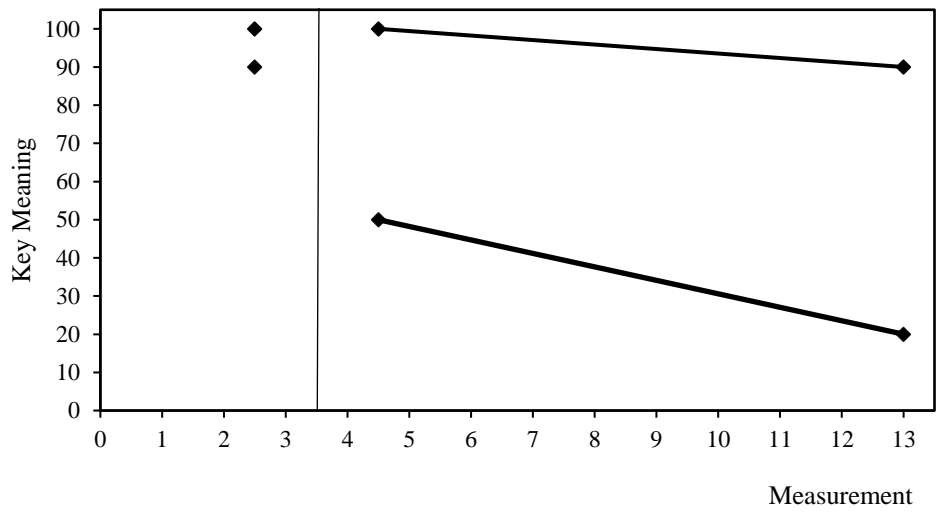
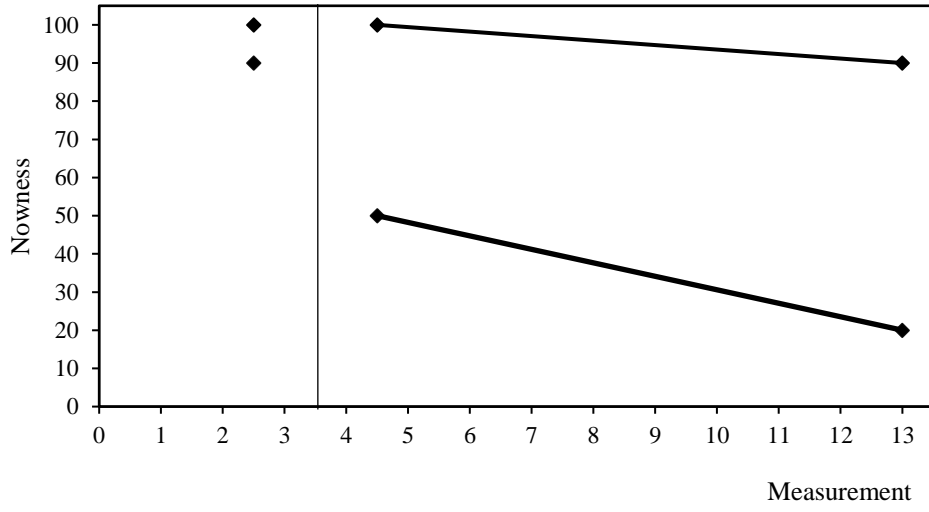
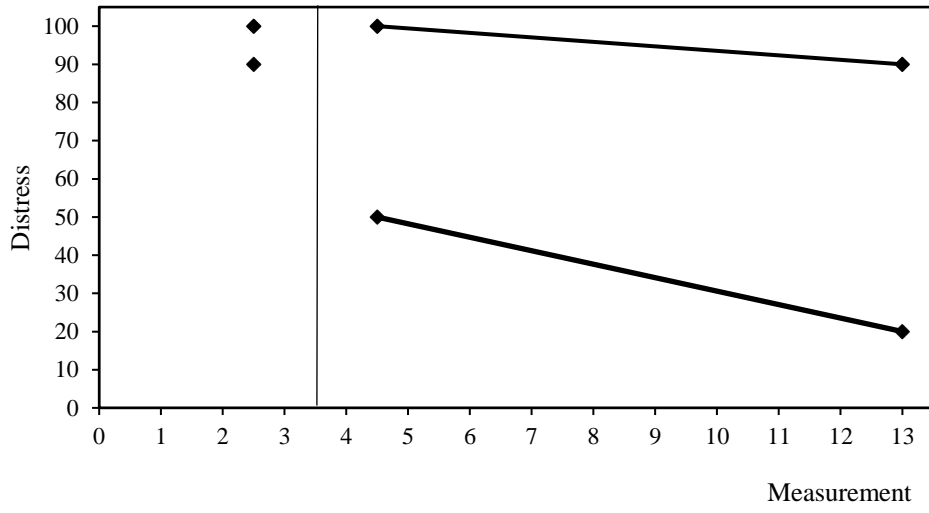
Appendix 22. PB: Variability Analysis (Trended Range) IVAS and EBVAS



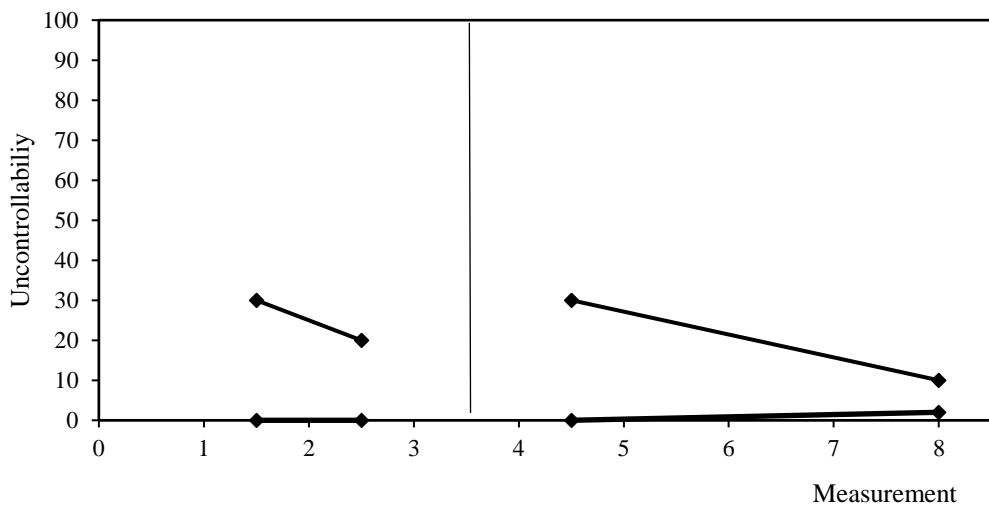
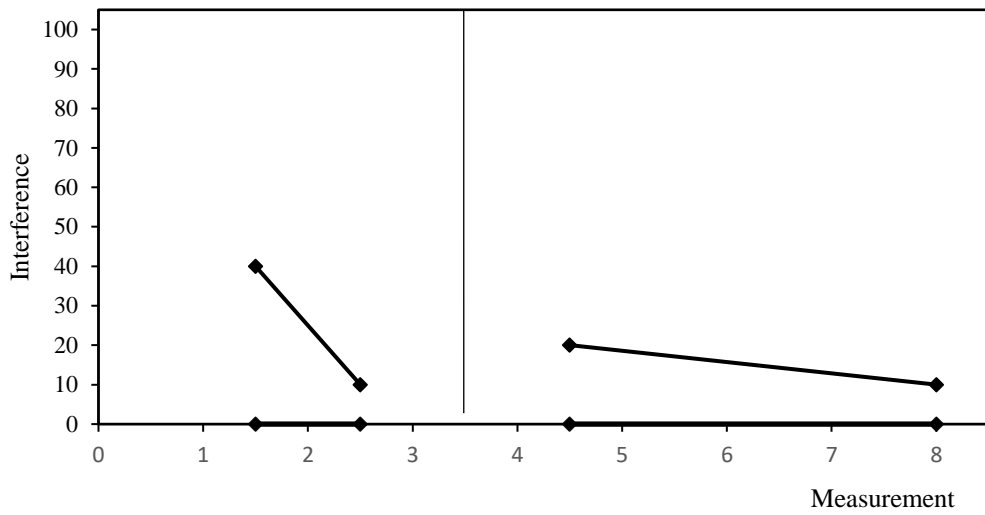
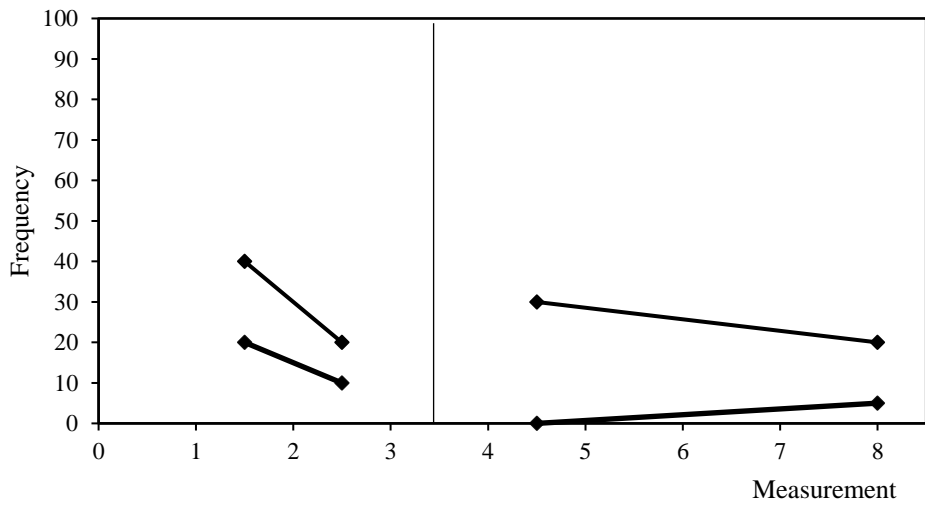


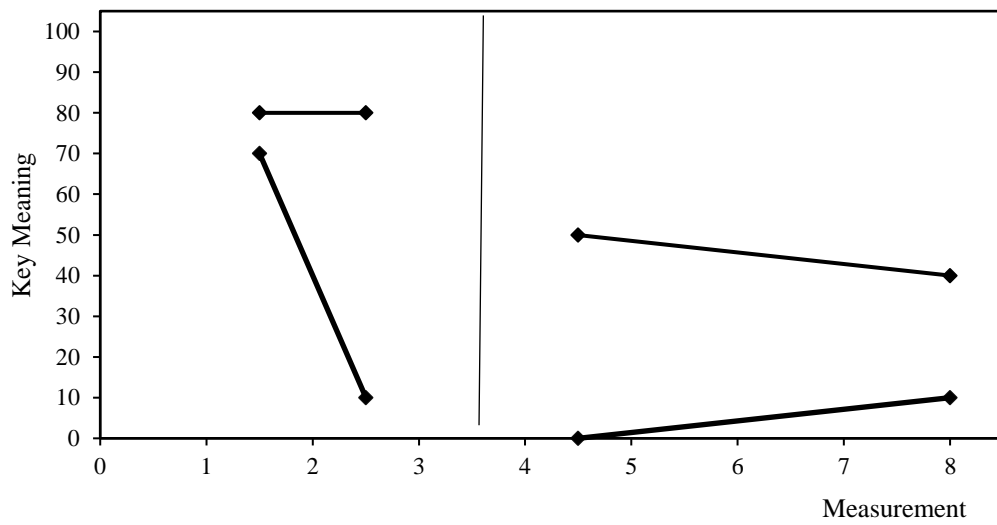
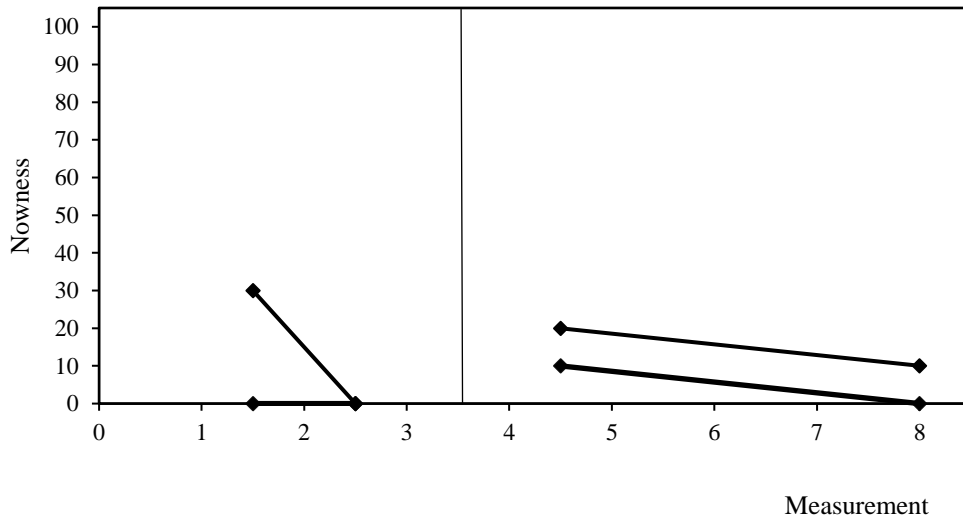
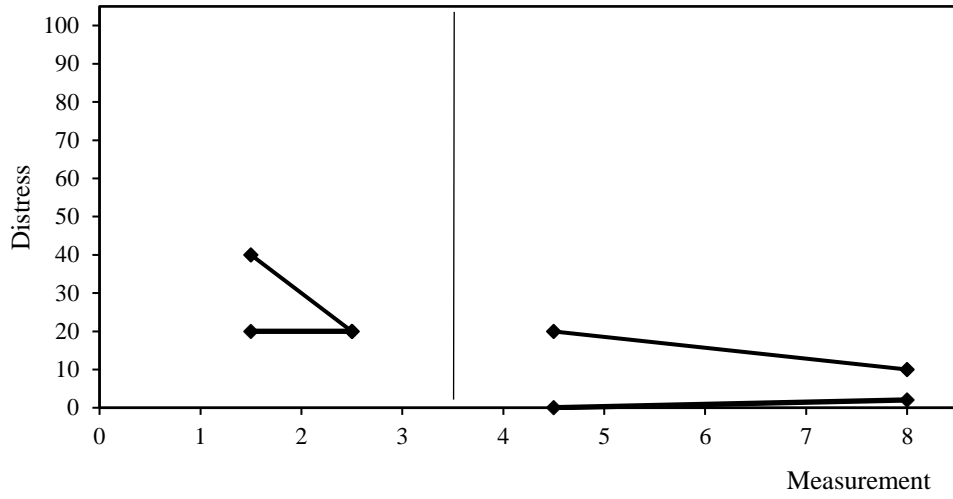
Appendix 23. PC: Variability Analysis (Trended Range) IVAS and EBVAS



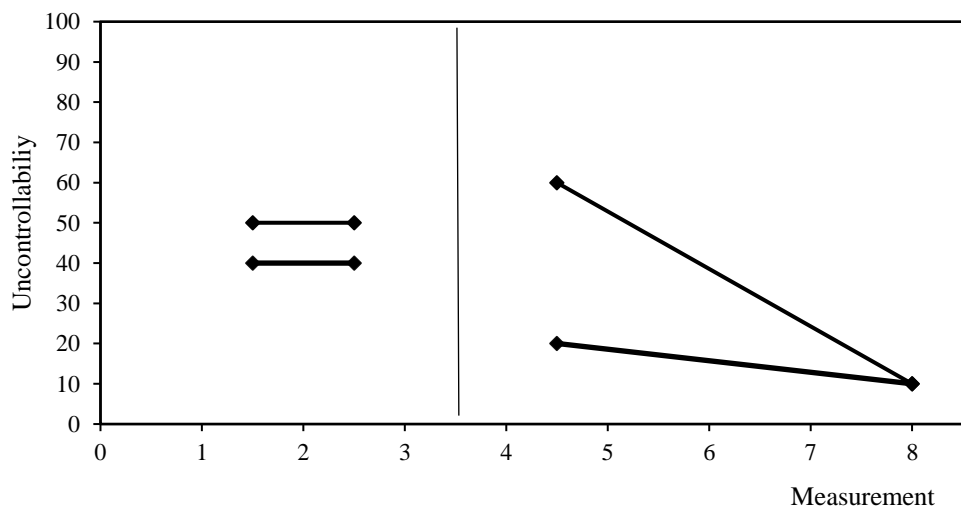
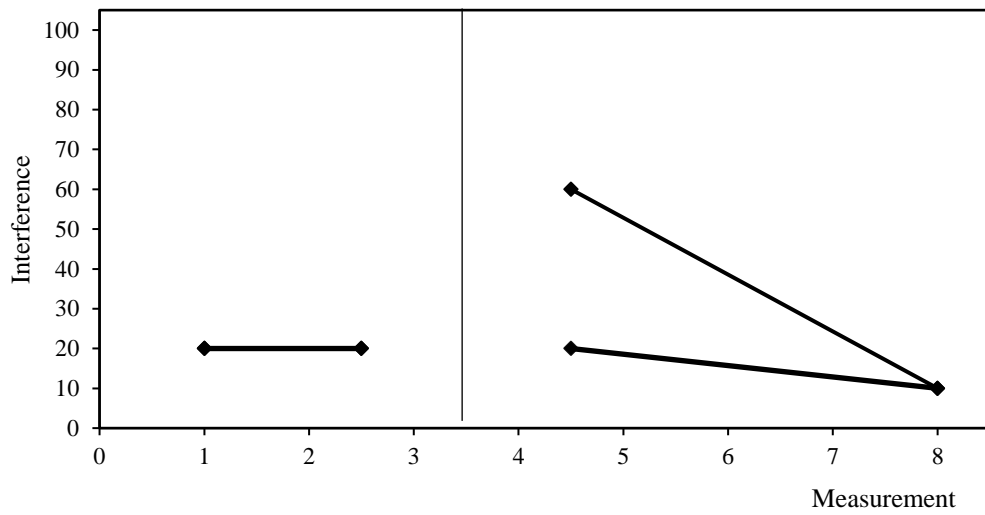
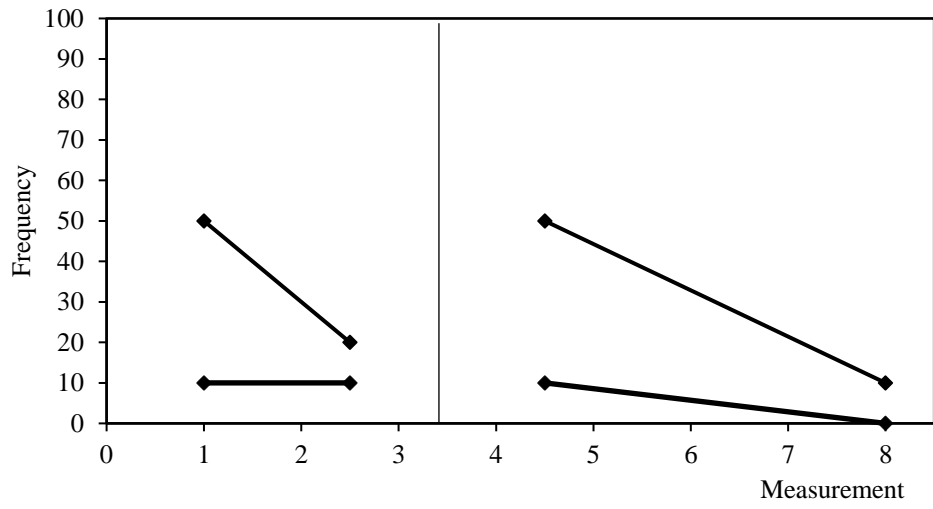


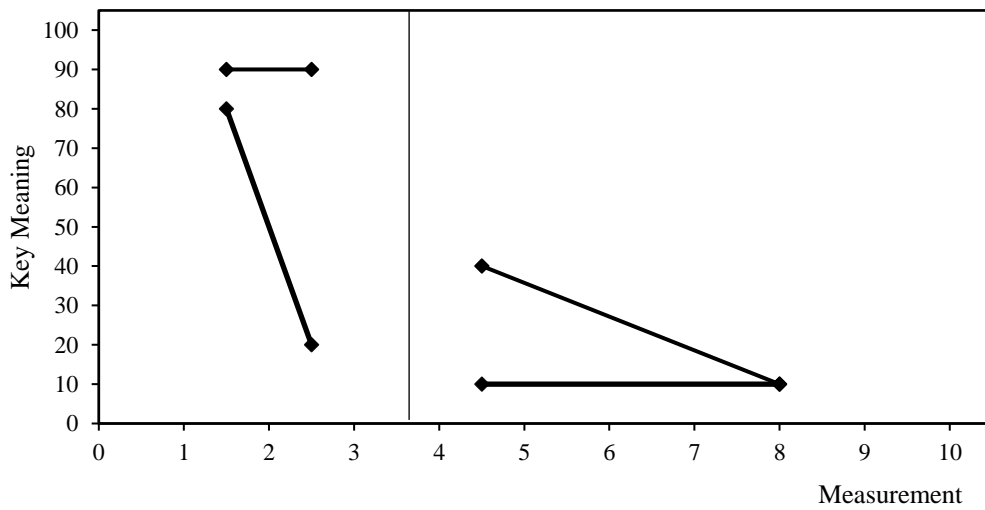
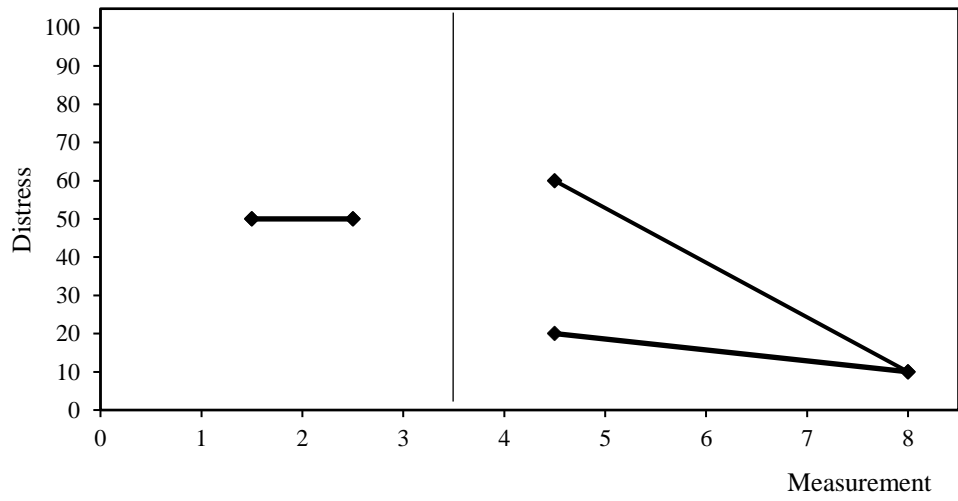
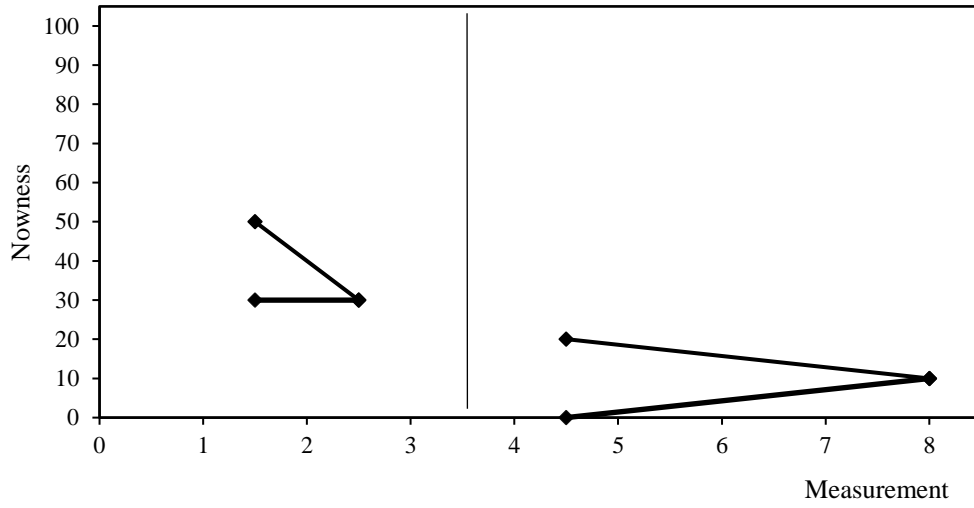
Appendix 24. PD: Variability Analysis (Trended Range) IVAS and EBVAS



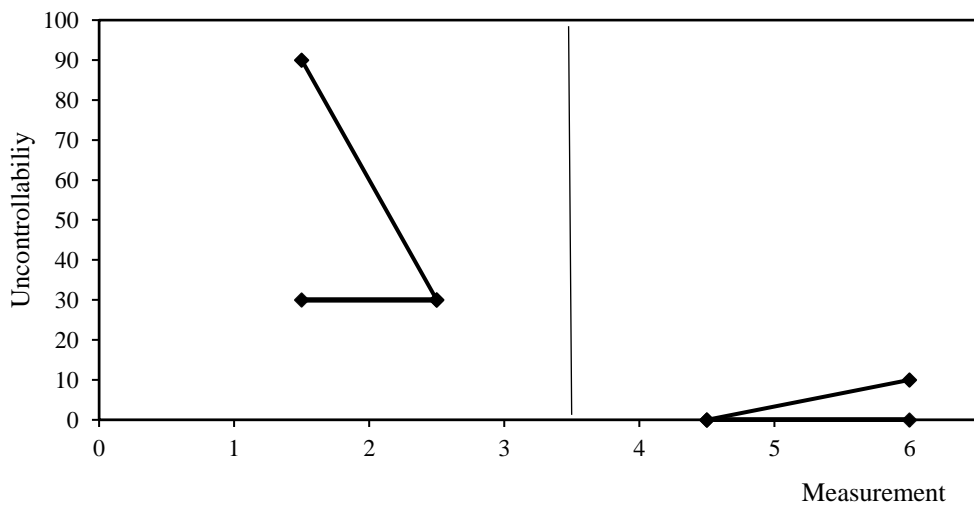
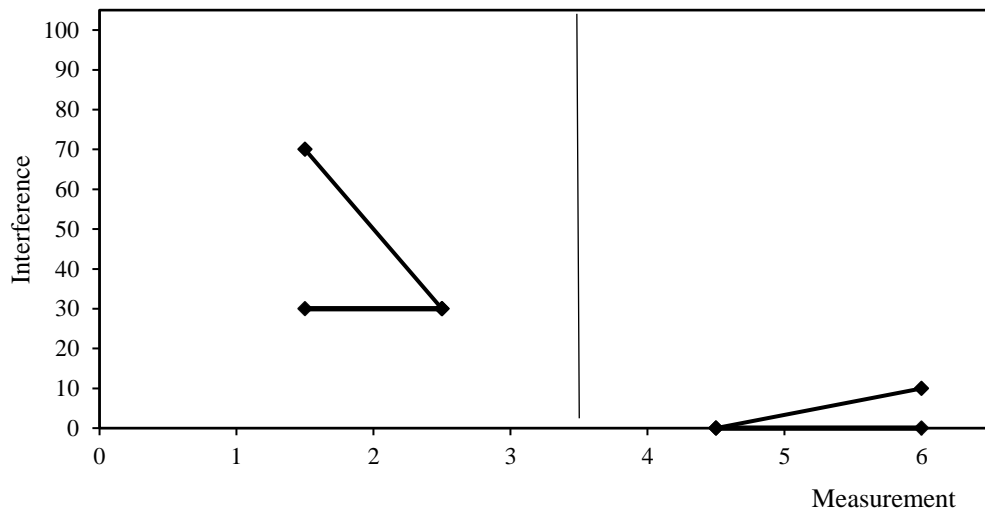
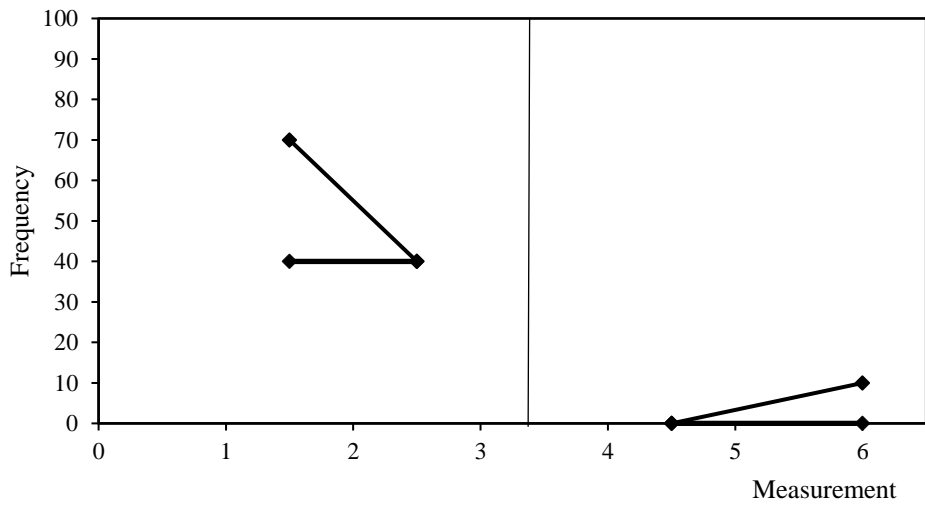


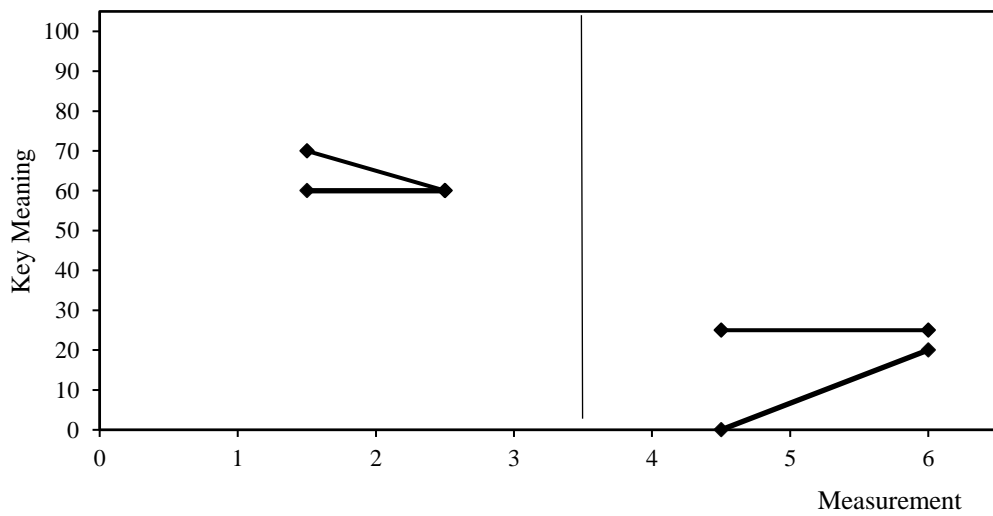
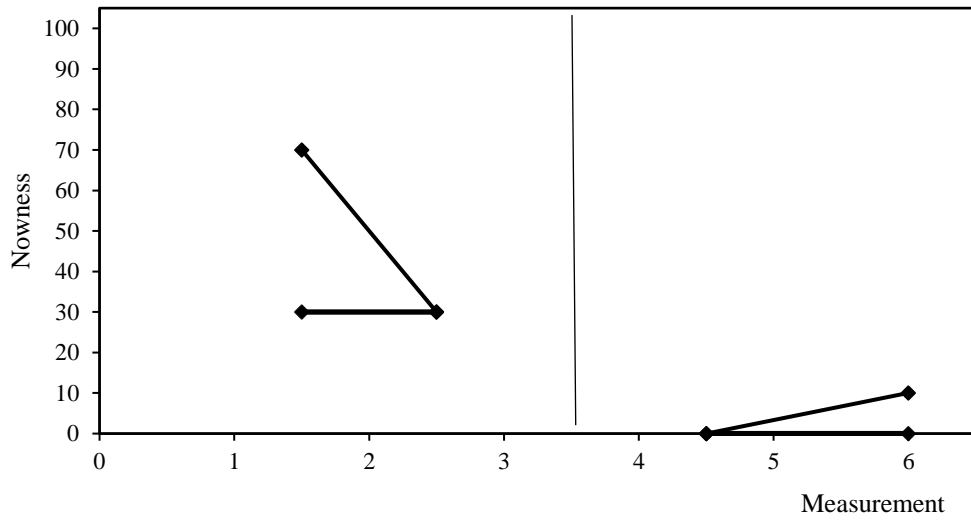
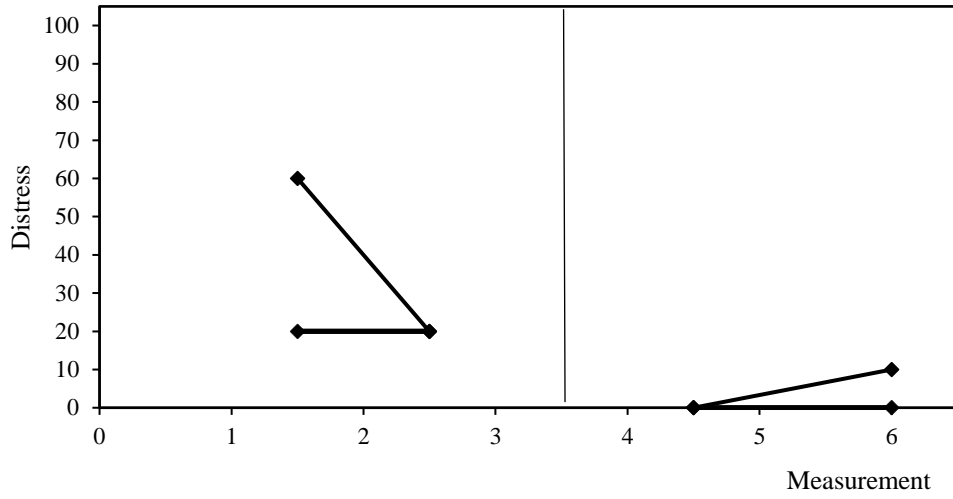
Appendix 25. PE: Variability Analysis (Trended Range) IVAS and EBVAS



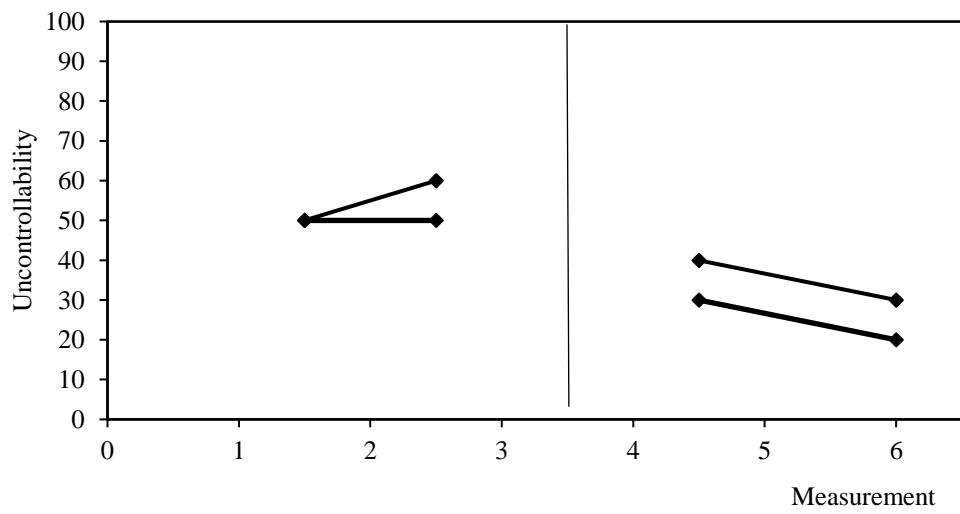
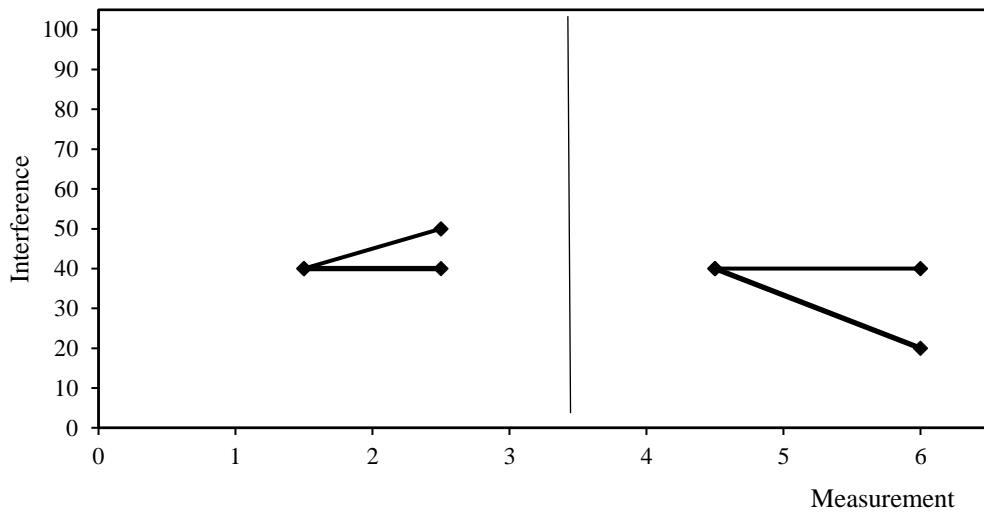
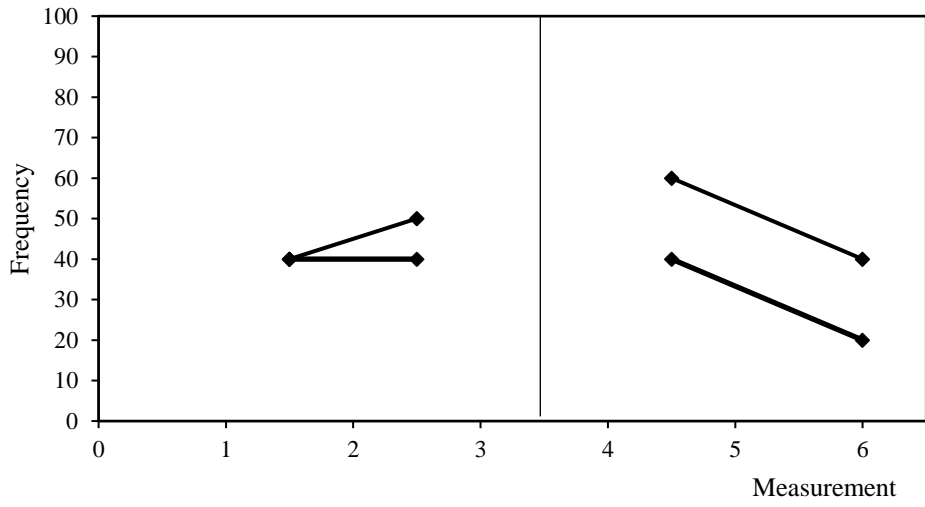


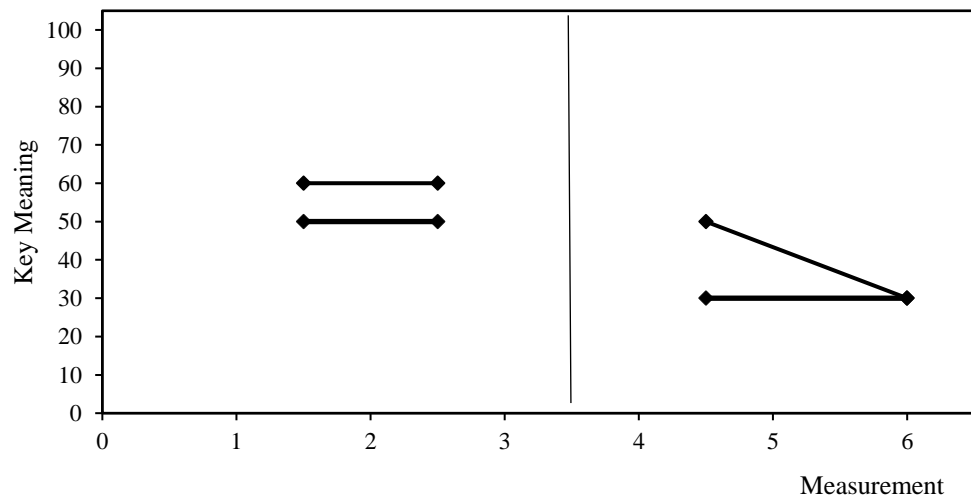
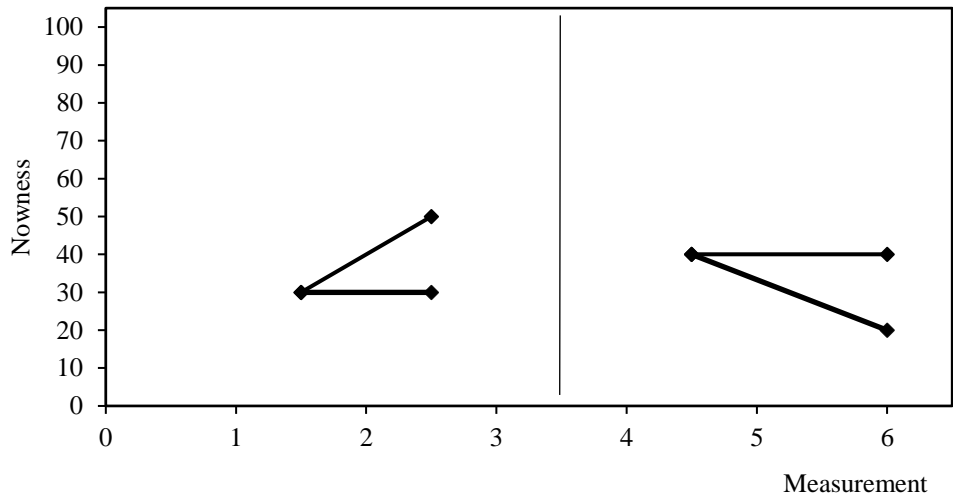
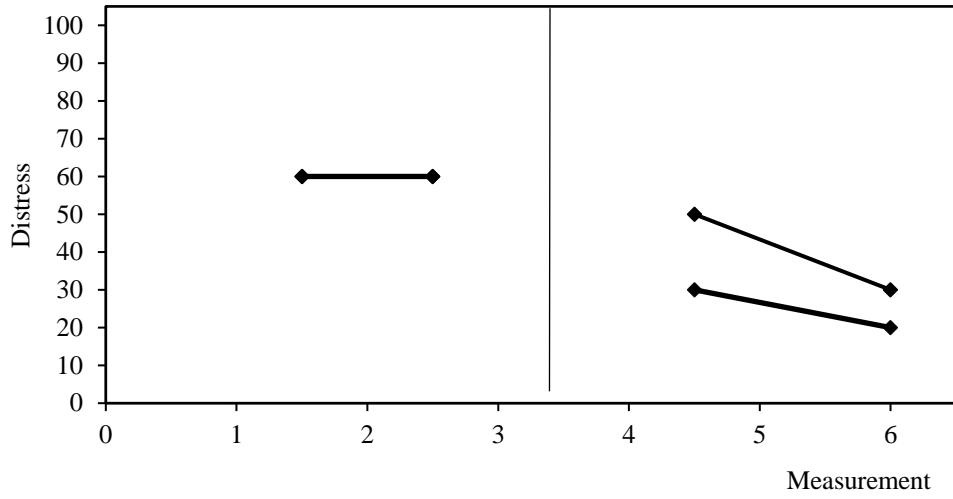
Appendix 26. PF: Variability Analysis (Trended Range) IVAS and EBVAS





Appendix 27. PG: Variability Analysis (Trended Range) IVAS and EBVAS





Appendix 28. PH: Variability Analysis (Trended Range) IVAS and EBVAS

