The Acceptability of a Guided Self-Help, Internet-based Trauma-Focused Cognitive Behavioural Therapy, for Adults with Mild to Moderate Post-Traumatic Stress Disorder (PTSD)

Natalie Simon

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School of Medicine, Cardiff University

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Supervised by

Professor Jonathan I. Bisson

Dr Catrin E. Lewis

To my children, Gwendolyn, and William, and in loving memory of my mother, Eleanor Jones.

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Summary

Guided Self-Help (GSH) internet-based Cognitive Behavioural Therapy (i-CBT) is an effective treatment for people with PTSD, recommended in treatment guidelines. Less is known about the acceptability of this relatively novel approach to PTSD treatment. There is some resistance towards the adoption of i-CBT, with some concerns about establishing therapeutic alliance.

There is a drive towards improving access to psychological therapies, not least given the need for 'pandemic-proof' remote therapies. It may be timely to implement i-CBT approaches at scale within the NHS. Knowledge of the acceptability of GSH i-CBT for PTSD is required, alongside efficacy, for implementation and treatment decision making.

A systematic review of the acceptability of i-CBT for PTSD was conducted. A Randomised Controlled Trial (RCT) compared the acceptability of GSH i-CBT with face-to-face Trauma-Focused CBT (TF-CBT), for adults with mild to moderate PTSD. Interviews were conducted with participants and therapists, and NHS commissioners and managers. GSH was found to be acceptable, comparable to face-to-face TF-CBT, across various facets of acceptability, including measures of adherence, satisfaction, therapeutic alliance, and qualitative interviews. RCT participant and therapist interviewees corroborated ratings and highlighted the importance of adapting GSH i-CBT to suit an individual's needs and preferences. Interviews with NHS commissioners and managers revealed an openness to internet-based approaches and recommendations were offered to address implementation challenges.

Further research is required, including examining the potential for GSH i-CBT for people with severe PTSD, and more complex presentations. Improved, robust methodology and dissemination of the multi-faceted construct of acceptability is needed. Shared decision making will help ensure GSH i-CBT is a treatment of choice, and encouragingly GSH i-CBT offers potential to be adaptable to meet the needs and preferences of different people. Practice-based evidence is required to continuously monitor the acceptability of GSH i-CBT for PTSD as it is delivered in routine care.

Publications

The work in this thesis is reproduced in part or whole in the following publications:

Simon, N., Ploszajski, M., Lewis, C., Smallman, K., Roberts, N. P., Kitchiner, N. J., Brookes-Howell, L., Bisson, J. I. 2021. Internet-based psychological therapies: A qualitative study of National Health Service commissioners and managers views. *Psychology and Psychotherapy: Theory, Research and Practice*, 2021-03-31.

Simon, N., McGillivray, L., Roberts, N. P., Barawi, K., Lewis, C. E., Bisson, J. I. 2019. Acceptability of internet-based cognitive behavioural therapy (i-CBT) for post-traumatic stress disorder (PTSD): a systematic review. *European Journal of Psychotraumatology,* 10**,** 1646092.

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My contributions to the work described in this thesis.

Systematic review and meta-analyses of the available evidence for the acceptability of internet-based Cognitive Behaviour Therapy (i-CBT) for PTSD. The methodology is presented in part one of chapter four, and the results are presented in chapter five. I prepared the protocol and conducted all parts of the review and its dissemination, apart from the review search, which was conducted by Cochrane.

Mixed methods Randomised Controlled Trial (RCT) to determine the acceptability of Guided Self-Help (GSH) i-CBT with a trauma focus. The methodology is presented in part two of chapter four, and the results are presented in chapter six. I contributed to the RCT protocol and study design. I obtained my research passport and contributed to the procedures involved in obtaining ethical approval and ethical amendments and assisted with RCT site set up. I helped develop the RCT data collection database, including writing metadata and database testing, in line with Standard Operating Procedures. I helped develop all trial documents, including recruitment information for participants. I played a key role in the recruitment of participants, through regular contact with, and presentations at, primary and secondary mental health teams, with GPs across South Wales, and with Cardiff University, and NHS employee wellbeing services. I screened potential participants and conducted baseline assessments, including obtaining informed consent, and follow-up assessments with eligible individuals across the sites in South Wales, and with a portion of participants in NHS Lothian. I coordinated PTSD Public Advisory Group meetings and activities to ensure PTSD lived-experience contributions to the Trial design, conduct and dissemination. I contributed to the development of topic guides for qualitative interviews with participants and therapists, but I did not conduct these interviews. I designed and conducted all acceptability analyses and interpreted the results.

Qualitative interviews with National Health Service (NHS) commissioners and managers to determine the acceptability of internet-based psychological therapies. The methodology is presented in part two of chapter four, and the results are

presented in chapter seven. I contributed to the design of this RCT sub-study, including obtaining my research passport and contributing to the procedures involved in obtaining ethical approval. I worked with the PTSD Public Advisory Group and other stakeholders to co-produce study materials, including interview topic guides. I recruited and interviewed all NHS commissioners and managers, obtaining informed consent, and I analysed and disseminated the results.

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1. Chapter One: An Introduction to Post-Traumatic Stress Disorder (PTSD)

1.1 Psychotraumatology: an historical perspective

The term trauma originates from the Greek word *'τραύμα'* or *'τραυματίζω'*, meaning "*to wound*" (Trauma, 2021). The use of the term trauma has diverged, and these days is as likely to be used with respect to *psychological* wounds as with physical wounds, including the impact realised by people with post-traumatic stress disorder (PTSD)[1].

Psychotraumatology is the study of the psychological impact of trauma, and for hundreds of years conditions presenting in individuals exposed to trauma have been described, and a great variety of names ascribed. Such 'illnesses' presenting in individuals, where symptoms ranged from nightmares to uncontrollable twitching, have been noted in the literature, across both military and civilian accounts, with recognisable names such as 'neurosis', 'psychoneurosis', 'shell shock', 'railway spine', 'nervous shock', 'hysteria', 'rape trauma syndrome', 'soldier's heart', and 'post-Vietnam syndrome'.

1.1.1 The Great Fire of London, 1666

One of the best-known historical accounts of psychological response to trauma was provided by Samuel Pepys, administrator of the navy of England and Member of Parliament. Having lived through the Great Fire of London in 1666, Pepys's sleep was affected by thoughts and dreams of fire and falling houses. His diary entry of 15th September stated:

> *"terrified in the nights nowadays, with dreams of fire and falling down of houses" (Daly, 1983) (p.66).*

[1] Individuals with PTSD, or people suffering with PTSD, will be termed 'people with PTSD' throughout the thesis, informed by lived-experience perspectives of the Cardiff University Traumatic Stress Research Group, 'PTSD Public Advisory Group'.

Six months after the Great Fire, Pepys diary accounted *"I did within these six days see smoke still remaining of the late fire in the City"*, perhaps resembling what we now know as 're-experiencing' symptoms (p.66).

1.1.2 Nineteenth century: 'railway shaking', and 'railway spine'

Another well-known historical account of a psychological response to trauma is described by Trimble (1985). English writer and social critic, Charles Dickens, had been a passenger on a train involved in a railway accident, at Staplehurst, Kent, on 9th June 1865. In a letter to a friend, Dickens wrote of distress being trapped for several hours surrounded by dead and dying passengers. Trimble reported Dickens's writings, years later, of being "*not quite right within*", and believing it to be "*an effect of the railway shaking*" (p.7).

The emotional response to railway trauma, or 'railway spine' as it was commonly termed, was the subject of a book published by Page, a surgeon to the London and North West Railway, in 1885, entitled ***'injuries of the spine and spinal cord without apparent mechanical lesion'*** (Trimble, 1985). Page's view of a psychological response to trauma was in contrast with the general view across medicine at that time, with most physicians believing trauma response to be due to organic damage to the nervous system (Ray, 2008). Page had rejected the phrases 'concussion of the spine', and 'railway spine', being unable to find any evidence that 'railway spine' in the majority of cases, was associated with organic disease, reporting symptoms to be essentially psychological in origin, contributed by fright, alarm and fear.

1.1.3 Early-twentieth century: 'shell shock'

The term 'shell shock' was used by many to describe problems seen in soldiers sent home and returning home from the traumas of the First World War. Macleod (2004) referred to accounts of the aftermath of the Battle of the Somme, which took place in July 1916, and the psychiatric casualties, with 40% being 'shell shocked'. Famously, Myers, a Royal Army Medical Corps doctor authored a publication in The Lancet (Myers, 1915), relating to 'shell shock' in the First World War. It was argued whether soldiers suffering from the stressors of combat war were 'moral invalids', or if indeed such problems could occur for any man subject to the horrors of war.

A re-examination of 'shell shock' case records was recently undertaken (Linden and Jones, 2014), revisiting 462 case referrals made to the National Hospital for the Paralysed and Epileptic, during the First World War. The Hospital, in Queen Square, London, played a significant part at that time in the understanding and treatment of 'shell shock'. The authors reported on the records of diverse symptoms of traumatised soldiers, including involuntary movements, speech disturbances, and commonly found psychological symptoms of irritability, difficulty sleeping and increased sensitivity to noise. Interestingly, they found little agreement by the doctors treating patients at the time, on the fundamental nature, or organic pathology of the disorder, which was commonly categorised as 'hysteria'.

There was a growing acknowledgement for the psychological origin of post-traumatic symptoms, dating back to 1885 in the case of 'railway spine', if not earlier. Nonetheless, the view that post-traumatic symptoms could be due to anything, but a physical health phenomenon, persisted. Several physicians who were presented with First World War battle casualties, without externally inflicted injuries, hypothesised the cause to be the 'wind of a ball', the 'ball' concerned being a cannon ball. In a paper which aimed to confront the issue of the 'mind-body dichotomy' in medical theory (McMahon, 1975), some of the hypotheses put forward were quoted, including:

> *"substances… such as grass, shrubs, mud … canvas, rope-yarns, part of the bedding, etc., which, when carried along with the velocity of the ball, or even driven but a short way with the force, are to do considerable injury and, … may not produce external mark of injury"* (McMahon, 1975) (p.125).

1.1.4 Mid-twentieth century

Terms ascribed to 'illnesses', argued in the literature to be resembling post-traumatic stress symptoms, continued to evolve and expand in the mid-twentieth century. During the Second World War, 1939 to 1945, terms included 'battle fatigue', and 'combat exhaustion'. In 1952, coinciding with the Korean War, a unique syndrome, 'Stress Response Syndrome', was included in the first edition of the Diagnostic and Statistical Manual of Mental Disorders (DSMI) (APA, 1952). The realisation that some reactions could occur in people at times of extreme emotional and physical stress was formally acknowledged by this inclusion.

'Post-Vietnam syndrome' was a term in use following the Vietnam war years of 1955 to 1975, (Trimble, 1985), and the term 'Rape Trauma Syndrome' was another term in use in the 1970s, with therapists Burgess and Holstrom acknowledging the nightmares and flashbacks resembling the traumatic neuroses of war (Ray, 2008).

1.1.5 Late-Twentieth century

By the latter part of the twentieth century, there existed a range of accounts of variable symptoms occurring in people exposed to trauma, and as noted a move over time towards a psychological presentation of symptoms. The accuracy of these accounts was questionable, with limited medical records and most accounts being historical and anecdotal in nature. There was a clear need, and clinical demand, across many generations, for the formal acknowledgement of a set of symptoms presenting in individuals exposed to traumatic event(s). By the turn of the century PTSD was formally acknowledged as a disorder occurring following a stressful event, within the two major classification systems: the DSM; and the International Classification of Diseases (ICD).

1.1.5.1 DSM PTSD classification

Published by the American Psychiatric Association (APA), for mental health professionals, the DSM is a comprehensive classification of officially recognised mental disorders. In 1980 authors of the DSM, third edition (DSM-III) (APA, 1980), included for the first time, formal acknowledgement of a set of symptoms presenting in people exposed to traumatic stress: PTSD. This first formal conceptualisation of PTSD viewed the trauma agent as a traumatic 'event' that occurred outside of the individual and was a formal requirement for a diagnosis of PTSD. The traumatic event became known as Criterion A and was defined then as a horrific event that is beyond the scope of the normal human experience. Figure 1 presents Criterion A and the additional criteria: at least one symptom of re-experiencing of the trauma; at least one symptom of numbing of responsiveness to, or reduced involvement with the external world; at least two of a range of other symptoms that were not present before the trauma, for example sleep disturbance and guilt.

DSM-III

A	Existence of a recognisable stressor that would evoke significant symptoms of distress in almost everyone.
B	Re-experiencing of the trauma as evidenced by at least one of the following: (1) Recurrent and intrusive recollections of the event (2) Recurrent dreams of the event (3) Sudden acting or feeling as if the event were recurring, because of an association with an environmental or ideational stimulus
C	Numbing of responsiveness to, or reduced involvement with, the external world, beginning some time after the trauma, as shown by at least one of the following: (1) Markedly diminished interest in one or more significant activities (2) Feeling of detachment or estrangement from others (3) Constricted affect
D	At least two of the following symptoms that were not present before the trauma: (1) Hyperalertness or exaggerated startle response (2) Sleep disturbance (3) Guilt about surviving while other have not, or about behaviour required for survival (4) Memory impairment or trouble concentrating (5) Avoidance of activities that arouse recollection of the traumatic event (6) Intensification of symptoms by exposure to events that symbolize or resemble the traumatic event

APA (1980)

Figure 1: Diagnostic and Statistical Manual of Mental Disorders, Third edition (DSM III) Post Traumatic Stress Disorder (PTSD) Criteria.

Revisions to the DSM-III were made in 1987 (APA, 1987), including re-classification of symptoms in to three new groups: re-experiencing of the traumatic event through phenomena such as dreams; avoidance and numbing, characterised by avoidance of trauma reminders, and numbing of emotions; and increased arousal symptoms, such as difficulty sleeping and concentrating. Diagnosis was possible when the stressor, Criterion A, was met along with a specific number of symptoms in each of the clusters.

DSM-IV (APA, 1994), and its text revision, DSM-IV TR (APA, 2000), included further modifications to the criteria for PTSD diagnosis, and full DSM-IV TR Criteria are included in Table 1. Importantly, the Criterion A definition was tightened, recognising the problematic definition within DSM-III. Defining the trauma as an event 'outside the normal range of events', as per DSM-III's definition, was cumbersome. As outlined by Spritzer et al., (2007), the fact that it did not specify adequately the classes of stressors was problematic given that several stressors, besides traumatic ones, but 'outside the normal range of events', may cause distress for almost everyone. Criterion A therefore required an individual to have experienced, witnessed, or be confronted with an event that involved actual or threatened death or serious injury, or a threat to the physical integrity of the person or others. This revision allowed for diagnosis not only for direct victims themselves but also others who might be affected, and for diagnosis where no threat to life had occurred but physical integrity to self or others was compromised. This version also required a fear, horror, or helplessness response to the event to reach Criterion A.

DSM-IV recognised the long-term psychological responses of some individuals exposed to prolonged trauma, including childhood physical and sexual abuse, and prolonged periods of captivity, and included a set of symptoms frequently presenting in some people with PTSD, for 'disorders of extreme stress not otherwise specified' (DESNOS) (Herman, 1992).

PTSD treatment guidelines are discussed later in this chapter, and it is important to note that it is the DSM-IV PTSD criteria that predominantly informs current treatment guidelines, with research findings contributing to the evidence base being based, in most cases, on DSM-IIR and DSM-IV criteria.

1.1.5.2 ICD PTSD classification

Maintained by the World Health Organisation (WHO), the ICD is a healthcare classification system, a global health information standard. PTSD first appeared in the ICD, in 1992, in its 10th edition (ICD-10) (WHO, 1992). It was included within its category 'Reaction to Severe Stress, and Adjustment Disorders', as a disorder that arises following exposure to a stressful event or situation of exceptionally threatening or catastrophic nature. The full ICD-10 PTSD Criteria are listed in Table 1.

Diagnostic and Statistical Manual of Mental Disorders, 4th edition text revision (DSM-IV TR), Post-Traumatic Stress Disorder (PTSD) criteria	**International Classification of Diseases, 10th edition (ICD-10), Post-Traumatic Stress Disorder (PTSD) criteria**
Trauma exposure and emotional reaction to stressor (required)	Trauma exposure (required)
Re-experiencing (one or more required): 1) Recurrent distressing recollections of event 2) Recurrent distressing dreams of event 3) Flashbacks 4) Psychological distress to trauma-associated reminders 5) Physiological reactivity to trauma-associated reminders	Persistent remembering or reliving of trauma (one or more required): 1) Flashbacks 2) Vivid memories or dreams 3) Experiencing distress when reminded of trauma
Persistent avoidance of trauma-associated stimuli and numbing of general responsiveness (three or more required): 1) Avoidance of thoughts /feelings 2) Avoidance of places/ people/ situations 3) Inability to recall important aspects of trauma 4) Markedly reduced interest in activities 5) Feeling distant or cut-off from others 6) Restricted range of affect 7) Sense of foreshortened future	Avoidance or preferred avoidance of trauma-associated stimuli (required)

Diagnostic and Statistical Manual of Mental Disorders, 4th edition text revision (DSM-IV TR), Post-Traumatic Stress Disorder (PTSD) criteria	**International Classification of Diseases, 10th edition (ICD-10), Post-Traumatic Stress Disorder (PTSD) criteria**
Persistent increased arousal (two or more of the following): 1) Sleep difficulty 2) Irritability or aggression 3) Difficulty with concentration 4) Hypervigilance 5) Exaggerated startle response	Inability to recall aspects of trauma OR two of more of the following: 1) Difficulty sleeping 2) Irritability 3) Problems with concentration 4) Hypervigilance 5) Exaggerated startle response
Duration of disturbance of at least one month (required)	Onset of symptoms within 6 months of trauma (required)
Distress and impairment associated (required)	

Table 1: Diagnostic and Statistical Manual of Mental Disorders, 4th edition text revision (DSM-IV TR), and International Classification of Diseases, 10th edition (ICD-10), Post-Traumatic Stress Disorder (PTSD) Criteria

1.2 PTSD in the present day: current classification

1.2.1 DSM-5

Following publication of DSM-IV in 1994 (APA, 1994), PTSD criteria were debated by experts in the field, with individuals holding different opinions on trauma definition, symptoms and grouping of symptoms, resulting in several proposals for its amendment (McNally, 2009). Following an extensive review of the literature, vigorous debates, and public and professional review (Pai et al., 2017), the fifth revision of DSM was published, in 2013 (DSM-5) (APA, 2013). The changes were substantial. DSM-5 reclassified PTSD from the anxiety disorders category to a new 'Trauma and Stressor-related Disorders' category. The subjective response to a trauma of fear, horror or helplessness was removed from Criterion A, which both limited the types of qualifying events that could lead to PTSD, and at the same time carefully defined how the qualifying traumas needed to be experienced. In response to research positing concerns about the three-factor structure of PTSD symptomatology according to DSM-IV and DSM-IV TR, confirmatory factor analysis was applied to test the fit of competing models, and based on this work, DSM-5

applied a fourth symptom cluster to PTSD (Yufik and Simms, 2010, Pai et al., 2017). The fourth cluster was defined as "*negative alterations in cognitions and mood associated with the traumatic event(s), beginning or worsening after the traumatic event(s) occurred*" (APA, 2013) (p.271). It was developed by separating out the avoidance criteria and expanding the numbing symptoms group, including the introduction of the role of negative emotions such as guilt and shame. These symptoms are associated with more complex presentations of PTSD, such as distorted cognitions manifesting in self-blame, and feelings of detachment or estrangement from others (Karatzias et al., 2016, Friedman, 2013). With this reorganisation at least one avoidance symptom is required, which was not previously the case, with DSM-IV (APA, 1994), and DSM-IV TR (APA, 2000).

DSM-5 PTSD Criteria requires the presence of symptoms for a duration of more than one month, from each of the four symptom clusters: at least one intrusion symptom; at least one avoidance symptom; at least two symptoms of negative alterations in mood and cognition; and at least two hyperarousal symptoms. Additionally, DSM-5 stipulates that to qualify, symptoms must begin (for Criteria B and C), or worsen (for Criteria D and E), after the traumatic event. The DSM-5 PTSD Criteria are shown in Table 2.

Dissociative PTSD subtype

DSM-5 (APA, 2013) included a new dissociative subtype of PTSD, where individuals meet diagnostic criteria for PTSD as well as experiencing additional high levels of depersonalisation or derealisation, and emotional detachment, where dissociative symptoms are not related to another medical condition, nor to substance use.

Delayed expression PTSD subtype

Since the formal acknowledgement of the 'delayed-onset' PTSD subtype in DSM-III (APA, 1980), it has remained a consistent DSM concept, though was replaced in DSM-5 with 'delayed expression' and defined as *"the full diagnostic criteria are not met until at least 6 months after the event (although the onset and expression of some symptoms may be immediate)"* (APA, 2013) (p.272).

1.2.2 ICD-11

The eleventh edition of the ICD (WHO, 2018) classified PTSD according to a reduced set of symptoms, acknowledging six qualifying symptoms: two re-experiencing symptoms; two avoidance symptoms; and two threat symptoms. Factors setting ICD-11 apart from ICD-10 included the requirement for impairment in at least one area of functioning (impairment in social, occupational, or parenting/other important activities), requirement for symptom duration of at least one month (Maercker et al., 2013), and its acknowledgement of a delayed symptom onset of more than six months (Andrews et al., 2007).

Importantly the publication of ICD-11 formally acknowledged complex PTSD (CPTSD), a new sibling condition to PTSD. The full Criteria for ICD-11 PTSD and ICD-11 CPTSD are shown in Table 2. Proposed as a new category of trauma related disorders in 2013 (Maercker et al., 2013), the construct of CPTSD was drawn from symptom presentations reflecting sustained, pervasive emotion regulation disturbances, diminished sense of self, and difficulties maintaining relationships (Cloitre et al., 2009, Morina and Ford, 2008), first articulated in 1992 (Herman, 1992). Complex presentations of PTSD are acknowledged in DSM-5 criteria, albeit not allowing for a separate diagnosis. Contrastingly, ICD-11 allows for a diagnosis of PTSD or a diagnosis of CPTSD, with the latter requiring the presence of complex features, known as 'disturbances in self-organisation' (DSO) symptoms (Cloitre et al., 2013), in addition to the core symptoms of PTSD. Support for this factor structure is demonstrated in factor analytic studies and latent class analyses demonstrating two overarching factors of PTSD symptoms and DSO symptoms, with a class of people with high PTSD and high DSO symptoms, and another class with high PTSD and low DSO symptoms (Karatzias et al., 2017, Shevlin et al., 2017). Both PTSD and DSO symptoms have been found to be stable over time (Hyland et al., 2020). In a study with 165 Danish psychiatric outpatients, albeit relying on self-report measures, one quarter of patients with ICD-10 PTSD did not meet criteria for ICD-11 PTSD, nor ICD-11 CPTSD, suggesting tighter clinical utility of ICD-11 diagnostic criteria (Møller et al., 2020).

DSM-5 PTSD criteria	**ICD-11 PTSD criteria**	**ICD-11 CPTSD criteria** **(*All ICD-11 PTSD diagnostic requirements necessary plus disturbances in self-organisation*)**
Trauma exposure required	Trauma exposure required	Affective dysregulation (one of two required): 1) Emotional reactivity 2) Emotional numbing
Intrusion (one or more required): 1) Involuntary distressing memories 2) Distressing dreams 3) Flashbacks 4) Psychological distress to trauma-reminders 5) Physiological reactions to trauma-reminders	In the here and now (one of two required): 1) Upsetting dreams 2) Flashbacks	Negative self-concept (one of two required): 1) Feelings of being a failure 2) Feelings of worthlessness
Avoidance of traumatic reminders (one or more required): 1) Avoidance of internal trauma-associated reminders, such as thoughts/ memories/ feelings 2) Avoidance of external trauma-associated reminders, such as people, places, situations	Avoidance of traumatic reminders (one of two required): 1) Internal reminders 2) External reminders	Disturbances in relationships (one of two required): 1) Cut off from other people 2) Hard to stay close to others
Negative alterations in cognition or mood (two or more required): 1) Inability to recall key features of the trauma 2) Strong negative thoughts about self, other people, or the world	Sense of Threat (one of two required): 1) Vigilance 2) Hyperarousal	

3) Exaggerated blame of self or others for the cause of the trauma 4) Negative affect 5) Decreased interest in usual activities 6) Detachment from others 7) Difficulty experiencing positive affect		
Alterations in arousal and activity (two or more required): 1) Irritability or aggression 2) Risky or destructive behaviour 3) Hypervigilance 4) Heightened startle reaction 5) Difficulty concentrating 6) Difficulty sleeping		
Functional impairment associated with symptoms required	Functional impairment associated with symptoms required	Functional impairment associated with symptoms required

Table 2: Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5) Post-Traumatic Stress Disorder (PTSD) Criteria, and International Classification of Diseases, 11th edition (ICD-11) Post-Traumatic Stress Disorder (PTSD) and Complex Post-Trauma (CPTSD) Criteria.

1.2.3 Current classifications: clinical utility

A strong rationale is evident for the use of either of the current classification systems of DSM-5 and ICD-11, when working in PTSD clinical and research contexts, with the development of each based on robust empirical evidence. There are, however, substantial differences between the current systems of DSM-5 and ICD-11, and it is important to understand these differences, with respect to clinical utility.

The parsimonious conceptualisation of ICD-11 PTSD, with its tightened focus on the core PTSD symptoms, and distinction between basic and complex forms of the disorder, is considered an attempt at addressing clinical utility, the usefulness of diagnosis in leading to better intervention and health outcomes. ICD-11's simplified conceptualisation of PTSD is in contrast with DSM-5's broader symptomatology, which aims to capture the full phenomenology of PTSD. DSM-5's broad criteria

consequentially allow for diagnosis of PTSD based on over half a million different combinations of symptoms (Galatzer-Levy and Bryant, 2013), producing wide heterogeneity in presentations (Maercker et al., 2013). In particular, the ICD-11 requires that re-experiencing be not just remembering the traumatic event involuntarily, but that it is experienced as occurring in the here and now, whereas more general intrusive memories can qualify as a DSM-5 symptom of re-experiencing. Indeed, diagnostic rates under combined ICD-11 PTSD and CPTSD have been demonstrated as significantly lower than those under DSM-5 (64.5% vs 76.1%, z=2.30, SE=.05, p=.01) (Hyland et al., 2017b). Furthermore, general intrusive memories are found across several psychiatric disorders (Brewin et al., 2010), therefore the tighter focus of ICD-11 on re-experiencing in the here and now may be particularly helpful.

ICD-11 and DSM-5 both agree on the requirement for impairment in at least one area of functioning, and each system uses the same functional impairment items. However, the ICD-11 diagnosis is suggested to be the more sensitive of the two in identifying individuals with clinically significant levels of disability (Shevlin et al., 2018). Additionally, DSM-5 criteria allow for dissociation subtypes of PTSD, in contrast with ICD-11 criteria, though can be identified with respect to emotional deactivation, within the ICD-11 emotion dysregulation symptomatology.

Commonly used PTSD assessment tools that align with the DSM-5 framework include the Clinician Administered PTSD Scale for DSM-5 (CAPS-5) (Weathers, 2013a), an interview considered the 'gold standard' for PTSD assessment with strong psychometric properties (Weathers et al., 2018); and the PTSD Checklist for DSM-5 (PCL-5), self-report measure (Weathers, 2013b). Tools aligning with ICD-11 diagnostic criteria for PTSD/CPTSD are the International Trauma Interview (ITI) (Roberts, 2019, Bondjers et al., 2019) , and the International Trauma Questionnaire (ITQ) (Cloitre et al., 2018), each with emerging evidence of strong psychometric properties (Murphy et al., 2020, Bondjers et al., 2019) .

1.3 Epidemiology of PTSD

1.3.1 Prevalence

PTSD has been shown to be a common global mental health condition. Widely cited, epidemiological data reported from the USA, using the 5,877-strong

subsample of the National Comorbidity Survey (NCS) (Kessler et al., 1995), estimated lifetime prevalence of PTSD to be 7.88%, with most people experiencing at least one traumatic event in their lifetime. A replication of the study conducted between 2001 and 2003, with 9,282 American adults, using DSM-IV criteria, estimated the lifetime prevalence to be 6.8% (Kessler et al., 2005). Consistent findings were reported in a more recent epidemiological survey in the USA (Pietrzak et al., 2011), reporting a lifetime prevalence of PTSD of 6.4%.

Lifetime prevalence of PTSD has been examined using data from the WHO World Mental Health (WMH) survey initiative. This is a project coordinating the implementation and analysis of general population epidemiological surveys of mental, substance use, and behavioural disorders in countries in all WHO regions. Atwoli et al., utilised the surveys (2015) and reported findings that included the following country prevalence rates: 1.3% in Japan (Kawakami et al., 2014); 2.2% in Spain (Olaya et al., 2015); 2.3% in South Africa (Atwoli et al., 2013); and 8.8% in Northern Ireland (Ferry et al., 2014).

Studies of the prevalence rates for PTSD/CPTSD according to the new ICD-11 criteria are growing, and estimates exist. Within a nationally representative sample in Israel, estimates are available for PTSD and CPTSD of 9.0% and 2.6% respectively (Ben-Ezra et al., 2018). Cloitre and colleagues (2019) found prevalence rates of 3.4% for PTSD and 3.8% for CPTSD in a USA population-based study. With respect to UK-based treatment-seeking samples, larger groups of people meet diagnostic criteria for ICD-11 CPTSD, compared with ICD-11 PTSD (Karatzias et al., 2017, Hyland et al., 2017b). In an overview of ICD-11 PTSD and CPTSD concept and measurement, Karatzias et al., (2018a) included studies from the UK, USA, Germany, and Lithuania and demonstrated lifetime prevalence of combined PTSD and CPTSD of 7.3%, comparable with the NCS findings reported earlier, with 4% PTSD and 3.3% CPTSD.

Caution must be exercised when considering PTSD prevalence reporting, across the literature. For example, variable methodological approaches in the field mean that it is difficult to compare prevalence findings, including diagnostic criteria and assessment tools (Kessler et al., 2017). Emerging evidence suggests prevalence rates are significantly lower when based on ICD-11 criteria for PTSD, when compared with DSM-IV and DSM-5 PTSD criteria (Brewin et al., 2017, Hyland et al., 2017b). Furthermore, there may be difficulty interpreting research conducted with trauma-exposed populations, given that research commonly considers symptoms

to an 'index' trauma, rather than to an array of traumas that individuals are likely to have experienced (Priebe et al., 2018), and methodological approaches to overcome this conundrum remain contested. This might explain why Karam et al., (2014) reported considerably lower lifetime prevalence rates, compared to those noted above by Atwoli et al., (2015). Karam et al's findings were based on the index or 'worst' trauma, and were 0.1% in Japan, 0.4% in Spain, 0.4% in South Africa, and 3.8% in Northern Ireland. Atwoli et al., took a more atypical approach of prevalence based on a randomly selected trauma, rather than on the index trauma. This approach was taken to avoid an overestimation of the probability of PTSD in a community sample, previously demonstrated when using the index trauma method (Breslau et al., 2004).

Variable estimates exist for trauma exposure during the lifetime, including 70.4% across WHO WMH surveys in 24 countries (Kessler et al., 2017), between 37% and 92% in a US sample (Breslau et al., 1998), 54% in Spain (Olaya et al., 2015), and 73.8% in South Africa (Atwoli et al., 2013). Prevalence has been shown to double in populations affected by conflict (Steel et al., 2009); indeed, risk of PTSD in terms of traumatic event exposure is variable across countries, often due to political, cultural, and historical factors. Refugees and asylum seekers are often exposed to traumatic events during their escape or resettlement process (Lee et al., 2017). Higher prevalence is apparent in high-risk professional groups, such as military service members and first responders (Sareen et al., 2013, Wilson, 2015). Repeated exposure to traumatic events in healthcare workers can lead to PTSD (Sage et al., 2018). For example, a systematic review of studies conducted in the context of the Severe Acute Respiratory Syndrome (SARS) 2003 and the Middle East Respiratory Syndrome (MERS) 2012 outbreaks, and the ongoing Coronavirus Disease 2019 (COVID-19) pandemic, found healthcare workers to be at high risk of PTSD during pandemics (Carmassi et al., 2020). Whilst the long-term health effects of working as a healthcare worker during the COVID-19 pandemic are not yet known (Mehta et al., 2021), high symptom levels of PTSD, anxiety and depression were demonstrated in frontline UK healthcare workers during the first wave of the pandemic (Greene et al., 2021).

PTSD risk varies depending on trauma type, for example intentional acts of interpersonal violence, particularly sexual assault and combat have been shown to be more likely to lead to PTSD than accidents and disasters (Kessler et al., 2017, Kessler et al., 1995, Stein et al., 1997).

Whilst the Criterion A requirement does not differ for a PTSD and CPTSD diagnosis, there is evidence for an association between repeated interpersonal trauma, including sexual and domestic violence, and childhood trauma and complex presentations of PTSD (Hyland et al., 2021, Brewin et al., 2017, Powers et al., 2017, Karatzias et al., 2017).

1.3.1.1 Demographics and pre-trauma factors

Numerous risk factors for PTSD are proposed in the literature. Widely cited meta-analyses (Brewin et al., 2000), found evidence for pre-trauma PTSD risk factors including: prior mental health disorder; family history of psychopathology; childhood trauma; lower socio-demographic background; and female gender. Brewin et al., also found, however, evidence for non-uniformity of risk factors across studies, for example the effects of gender, age at trauma, and race, which were shown to disappear in certain subsets of studies. Brewin's work highlighted the differing methodological approaches across studies and therefore the need for caution when considering the PTSD risk factor literature. Similar caution is expressed by Ozer et al., with respect to their meta-analyses of predictors of PTSD (2003), yielding significant effect sizes for the pre-trauma characteristics of family history and prior trauma. For example, the authors note that with respect to prior trauma, they make an assumption in the analyses that all prior traumas are equal in their effects, for example that a single exposure is not dissimilar to multiple traumas.

Gender and PTSD

A higher prevalence of PTSD is reported in women than in men, with women having a two- to three-times higher risk of developing PTSD (Stein et al., 1997, Pietrzak et al., 2011, Ditlevsen and Elklit, 2012, Kessler et al., 1995, Olff, 2017), and CPTSD (Hyland et al., 2017a). This is incongruent to the finding that there are gender differences in trauma exposure, with female sex associated with reduced risk of traumatic event exposure, overall (Carmassi et al., 2014, Ferry et al., 2014), though may be explained by the finding that women disproportionately experience the trauma types associated with higher PTSD risk. Kessler et al., (1995), found that rates of PTSD vary according to trauma stressors, the traumas most commonly associated with PTSD among women being rape and molestation, and among men being combat exposure and witnessing someone being badly injured or killed.

Consistent findings were reported in a more recent epidemiological survey in the US, demonstrating a higher prevalence of PTSD in women, higher rates of sexual abuse trauma among women with PTSD and substantially higher rates of military combat trauma among men (Pietrzak et al., 2011).

1.3.1.2 Peri- and post-trauma factors

An individual's subjective response to a trauma has been demonstrated to be associated with PTSD. One example is peritraumatic dissociation, which is understood as a subjective change in cognitive perception and functioning, feelings of emotional numbness, reduced awareness of surroundings, and derealisation around the time of the traumatic event (APA, 1994). In Ozer et al's (2003) meta-analyses of predictors of PTSD, peritraumatic dissociation was demonstrated as the predictor with the largest effect size (weighted r=.35). More recently, peritraumatic dissociation has been demonstrated to be a moderate risk factor for PTSD (Breh and Seidler, 2007).

Cognitive processing style during an event, and negative appraisals of the event and its sequalae have been demonstrated to be associated with PTSD in a prospective study of individuals exposed to physical or sexual assault (Dunmore et al., 2001). Similarly, cognitive styles, coping styles, and psychological traits have been identified as pre-trauma predictors of PTSD (Wild et al., 2016a). An individual's locus of control, the extent to which an individual believes they can control events that affect them, has also been suggested to be associated with PTSD. An internal locus of control, where an individual believes they have control over their life, is demonstrated as a protective factor of resilience against PTSD symptoms (Zhang et al., 2014, Karstoft et al., 2015) .

Poor perceived social support is widely accepted as one of the most important risk factors for the onset and maintenance of PTSD symptoms (Ozer et al., 2003, Brewin et al., 2000, Holeva et al., 2001, Robinaugh et al., 2011, Ehlers and Clark, 2000). Indeed, in support of this are theories that posit the hinderance of negative post-trauma cognitions through greater social support (Ehlers and Clark, 2000). Brewin et al's meta-analyses (2000) found a modest effect size for low social support during/after trauma exposure as a risk factor, and that this peri-trauma risk factor, along with others, such as trauma severity and additional life stresses, had a somewhat stronger effect than pre-trauma factors such as demographics, a finding also demonstrated in Ozer et al's meta-analyses (2003).

1.4 Comorbidity

PTSD commonly occurs with other conditions (Bisson et al., 2015). Comorbidity presents a challenge for clinicians with respect to prioritising treatment options. A further clinical challenge is that PTSD comorbid with other conditions has been associated with poor PTSD symptom trajectories and poor health-related quality of life (Li et al., 2018). Two commonly cited epidemiological studies, conducted in Australia and the USA, demonstrated high levels of PTSD comorbidity, up to 88% in men and 80% in women (Kessler et al., 1995, Creamer et al., 2001), with around 50% experiencing three or more comorbidities, and PTSD often found to be primary to substance use and affective disorders and in half of cases to be primary to anxiety disorders.

The relationship between PTSD and other conditions appears to be multifaceted and there may be several underlying common factors that are implicated in the relationship, for example overlapping symptoms such as negative affectivity, or perhaps more genetic environmental vulnerabilities predisposing an individual to various disorders (Lockwood and Forbes, 2014). Common comorbidities include depression, panic disorder, borderline personality disorder, substance use disorders, and chronic pain, which are now discussed.

1.4.1 PTSD and Depression

Research has demonstrated co-occurrence of major depressive disorder in around a half of people diagnosed with PTSD (Rytwinski et al., 2013), though CPTSD has been found to be more strongly associated with symptoms of depression than PTSD (Hyland et al., 2018a). In a systematic review of factors associated with outcome of psychological treatments for PTSD, Barawi et al., (2020) found smaller reductions in PTSD symptom severity post-treatment for PTSD that was comorbid with depression.

Negative cognitions, affect, and avoidant behaviours are common components in both PTSD and depression (Horesh et al., 2017), and explanations for comorbidity include possible symptom overlap, including dysphoria, for example loss of interest, negative appraisals about the self and world (Lockwood and Forbes, 2014). Researchers have also proposed the presence of a distinct trauma-related phenotype, potentially a subtype of PTSD (Flory and Yehuda, 2015). Some have argued that each disorder is independently a consequence of trauma (Horesh et al., 2017). However, longitudinal work with war veterans has shown PTSD to predict

depression, but not vice versa (Ginzburg et al., 2010), therefore, further work is required to understand the development and maintenance of PTSD-depression comorbidity.

1.4.2 PTSD and Panic Disorder (PD)

A lifetime prevalence of comorbid PTSD-PD has been estimated at around 11% (Kessler et al., 1995). 'Anxiety sensitivity' is considered a contributory factor in each disorder, with disorders sharing overlapping features including hypervigilance and heightened perception of danger (Teng et al., 2013). Further research in this comorbidity is required, however evidence to date suggests panic may develop following the onset of PTSD, rather than panic preceding PTSD (Brown et al., 2001).

1.4.3 PTSD and Borderline Personality Disorder (BPD)

The literature points to overlaps between PTSD and BPD, with BPD found to be particularly associated with childhood abuse and neglect (Cattane et al., 2017), and recent evidence suggests a stronger association with CPTSD than with PTSD (Hyland et al., 2018b).

Not surprisingly the dissociative subtype of PTSD has been found to be associated with high levels of dissociative symptoms overall, and interestingly with other psychopathology, for example borderline and schizophrenia spectrum disorders (Blevins et al., 2014). Research suggests that the subtype is associated with complex presentations, severity of PTSD symptoms, and comorbid psychiatric disorders (Schiavone, 2018).

1.4.4 PTSD and Substance Use Disorder (SUD)

PTSD and SUD have been demonstrated as highly comorbid conditions (Pietrzak et al., 2012). The self-medication explanation for this comorbidity, whereby an individual uses alcohol or drugs to alleviate distressing PTSD symptoms, is supported by research that shows that individuals consume more alcohol on days on which they experience more PTSD symptoms (Dvorak et al., 2014). Furthermore, research has demonstrated PTSD onset preceding the development of SUD (Mills et al., 2006). That said, it is also proposed that people with SUD may be at increased risk of trauma exposure, which may lead to PTSD (Testa and Livingston, 2009), further contributing to the association between PTSD and SUD.

1.4.5 PTSD and chronic pain

The literature reports PTSD commonly co-occurring with chronic pain (Sharp and Harvey, 2001, Siqveland et al., 2017), and with opioid use (Morasco et al., 2013). Clinical and research practice indicate the two disorders may interact in a way that could negatively impact the course and outcome of treatment of either (Otis et al., 2003, Asmundson and Hadjistavropolous, 2006). Longitudinal research suggests PTSD symptomatology and pain develop in parallel following an injuring traumatic event, with simultaneous trajectories suggesting there may be shared factors contributing to each (Beck and Clapp, 2011). Another associated factor is post-trauma cognition. Negative cognitions regarding the self have been found to be associated with pain, and to partially mediate the relationship between PTSD and pain-related interference/disability in veterans seeking treatment for PTSD (Porter et al., 2013).

Chronic pain syndrome has been traditionally considered to be within a cluster of physical symptoms that cannot be fully medically explained, along with other conditions such as irritable bowel syndrome, and chronic fatigue syndrome (Afari et al., 2014). DSM-5 conceptualises medically unexplained symptoms (MUS), as 'somatic symptom disorders' (SDD) and requires the presence of distressing physical health complaints in association with excessive concern or preoccupation with somatic symptoms (Afari et al., 2014). Network analysis has found that PTSD and somatisation symptoms form distinct clusters, with sleep difficulty playing a potential role in bridging these domains (Astill Wright et al., 2021b).

1.5 PTSD burden

PTSD symptoms, and comorbidity aside, there are many additional negative potential consequences of PTSD. These include a range of physical health problems, impaired functioning, including social functioning, and maladaptive coping mechanisms (Rauch et al., 2009, Roberts et al., 2016). Not to mention the significant economic burden of PTSD on society. Research has found it to be the highest of the anxiety disorders with respect to costs of hospitilisation, health visits and work impairment (Greenberg et al., 1999). More recently this cost was reported to be £172,756,062 in Northern Ireland, for reasons that include high rates of unemployment due to symptomatology impacting job loss (Ferry et al., 2015).

Although research on death from suicide as an outcome of trauma is limited (Gradus, 2017), it was considered in a study accessing the Danish national

healthcare and social registries (Gradus et al., 2015). Sadly, it was found that people with PTSD had 13-times the rate of suicide death than those without PTSD (95% CI=4.3, 42), following adjustment for depression, anxiety, and SUD. More recently, CPTSD has been found to be more strongly associated with suicidality than PTSD (Hyland et al., 2018b).

1.6 Aetiology of PTSD

Many people will be exposed to trauma at some point in their lives, yet only a small proportion will develop PTSD, and for many people difficulties are sub-clinical, and most will recover to pre-trauma levels of psychological functioning (Bonanno et al., 2015, Giummarra et al., 2018). Indeed, research supporting this demonstrates trajectories of the course of PTSD, including findings for a resilient class of people presenting with few PTSD symptoms, as well as a recovery class of people presenting with initial distress followed by gradual remission, amongst other classes with higher PTSD levels (Bryant et al., 2015). Approximately one third of people with PTSD at four to six weeks post-trauma exposure are found to remit naturally by three months (Santiago et al., 2013). Other biopsychosocial factors, in addition to trauma exposure, are at play in determining an individual's likelihood of being at risk, or being resilient to, the development of PTSD.

1.6.1 Biological theories

Most theories of PTSD are concerned with fear conditioning processes as a direct result of an external event, and neural alterations in people with PTSD provide evidence of this. Indeed, Hypothalamic-Pituitary-Adrenal (HPA) axis abnormalities and hippocampal volume, have been proposed as biological markers of PTSD (Radant et al., 2001). HPA activity is a normal reaction to stress, and overactivity would naturally be expected in models of stress. PTSD has often associated with lower levels of the stress hormone, cortisol (Yehuda et al., 1990, Olff et al., 2006), and proposals have been made that lower cortisol levels in PTSD may result in elevated ongoing activity of the HPA axis, resulting in over-consolidation of traumatic memories (Bryant, 2019). There is, however, evidence also for decreased HPA-axis activity in people with PTSD (Radant et al., 2001), and a possible explanation for this is the potential impact of variables suggested to be confounders in the effect of HPA functioning on the development and maintenance of PTSD, including early life stress, gender, and glucocorticoid use (Dunlop and

Wong, 2019). PTSD has been associated with reduced hippocampal volumes (Schuff et al., 1997, Smith, 2005), though evidence is mixed for whether hippocampal volume is a risk factor for, or consequence of, PTSD.

A review of the evidence of twin studies of PTSD concluded there is genetic variation underlying individual differences in risk and resilience to PTSD (Duncan et al., 2018a), with studies suggesting these genetic influences account for around one third of the variance in risk of developing PTSD (Stein et al., 2002). Broekman et al., (2007), noted inconsistent findings across association studies investigating eight major genotypes in connection with PTSD, including candidate genes in the serotonin, dopamine, and glucocorticoid systems. They concluded the complex aetiology of PTSD, where trauma exposure is a requirement, making specific gene identification problematic. More recent research examining genetic influences on the development of PTSD (Duncan et al., 2018b, Nievergelt et al., 2019), using genome-wide case-control data, has found a polygenic risk profile for PTSD overlapping with other psychiatric disorders, interestingly in particular with schizophrenia.

1.6.2 Psychosocial theories

Many psychosocial theories have been proposed in the aetiology of PTSD, predominantly focusing on conditioned reactions to trauma-related stimuli, and the maintenance of these reactions through avoidant coping behaviours. Earlier and more recent theories draw on classical conditioning, learning, and psychodynamic theory. Classic cognitive theory is particularly influential in current models, with attachment theory and factors of social support also bearing weight (Bisson, 2009).

1.6.2.1 Conditioning theory

Classical conditioning[2] theories propose intense fear and anxiety as an unconditioned response to trauma, which becomes paired with objectively safe trauma-related stimuli that were present during the event (Keane, 2002). For example, an individual might become acutely distressed every time they hear any

[2] Classical conditioning was first described by Pavlov as the transfer of a physiological response to a stimuli previously considered neutral. PAVLOV, I. P. 1941. *Lectures on conditioned reflexes. Vol. II. Conditioned reflexes and psychiatry,* New York, NY, US, International Publishers.

siren, following their experience of being rushed by ambulance to hospital in a life-threatening state of health. The theory alone cannot however account for PTSD maintenance, since the conditioned fear and anxiety response would gradually extinguish through repeated presentation of objectively safe trauma-related stimuli, as is the case in symptom remission for most trauma survivors. Nonetheless, several later theories of PTSD build on classic conditioning.

Mowrer et al., advanced the classical conditioning model, applying a model like that used in the treatment of phobias and anxiety: an early two-factor learning and conditioning theory of PTSD (Mowrer, 1960). This model proposed the trauma as an unconditioned stimulus, with the initial reaction of fear/distress as the unconditioned response. It posited a marked response leading to trauma memory over-consolidation, with reminders becoming conditioned stimuli that evoke a conditioned fear response. The second factor, drawing on operant principles, proposed that the usual extinction of the conditioned response, which would occur through repeated exposure of objectively safe trauma-related stimuli, is prevented in individuals who typically avoid trauma-related cues to reduce the elicited emotional arousal. More recent PTSD theories incorporate cognitive components focusing on memory and information processing in addition to learning and conditioning elements.

1.6.2.2 Stress response theory

Horrowitz described the 'Stress Response Theory' (Horowitz and Becker, 1971), considered to be a social-cognitive theory (Brewin et al., 1996), rooted in psychodynamics[3] (Holmes, 1987). In this theory an individual's views of self and others spurred by the trauma are thought to conflict with their pre-trauma views of self and others, and this overloading leads to the mobilisation of defence mechanisms, including denial and dissociation. The goal of these defence mechanisms is numbing, to allow trauma information to be gradually processed and assimilated. Re-experiencing, including flashbacks and nightmares, is thought to occur due to a need to process new information, despite the inhibitory control. The result is an alternating state of avoidance and intrusion, which gradually allows

[3] Attributed to Freudian psychoanalytics, placing emphasis on the unconscious mind, where feelings and thoughts are affected by unconscious motives. GULLESTAD, S. E. 2005. Who is 'who' in dissociation?: A plea for psychodynamics in a time of trauma. *The International Journal of Psychoanalysis,* 86**,** 639-656.

for assimilation of trauma information. Where this system fails, and an individual does not fully process trauma information, PTSD may develop.

Despite the influence of Horowitz's work in the field, the proposed theory does not fully account for several factors, including the difference between flashbacks and ordinary trauma memories, individual variations in trauma response, nor environmental factors such as social support (Brewin et al., 2000).

1.6.2.3 Social support theory

Earlier in this chapter poor perceived social support was introduced as one of the most important risk factors for the onset and maintenance of PTSD symptoms (Brewin et al., 2000, Ehlers and Clark, 2000, Holeva et al., 2001, Ozer et al., 2003, Robinaugh et al., 2011). Social support is multi-dimensional, with a distinction made in the literature between the actual support an individual receives, and their perceived availability of support, with perceived social support shown to be more closely related to an individual's ability to adjust and cope with stress, compared with ratings of actual social support (Norris and Kaniasty, 1996). Explanatory models for the widely recognised association between social support and PTSD symptoms include: 'social causation' models, such as the stress-buffering hypothesis (Cohen and Wills, 1985), based on the assumption that lack of social support may precede and contribute to increases in psychological distress following trauma; 'social erosion' models, where an individual's social support resource is thought to decline due to psychological distress following trauma (Kaniasty and Norris, 2008); and attachment theory, elaborated below, whereby social cognition, developed in infancy, mediates the relationship between trauma and PTSD symptoms (Bryant, 2016, Woodhouse et al., 2015). Whilst there is debate regarding the direction of causality, perceived social support has been linked to psychological distress and PTSD/CPTSD symptomatology (Simon et al., 2019b).

1.6.2.4 Attachment theory

Arguably a psychodynamic theory, attachment theory, places emphasis on early attachment relationships and their impact on the development of an individual's working models of self and others (Bowlby, 1984). In this theory, an individual's sense of self, developed through their attachment experiences, is considered to influence how that individual appraises a traumatic event and its aftermath. For example, an individual's attachment style might impact their ability to manage their

emotions, and to form and maintain interpersonal relationship, and indeed insecure attachment style, has been found to be associated with CPTSD (Karatzias et al., 2018b).

1.6.2.5 Theory of shattered assumptions

A widely cited social-cognitive model concerns trauma information processing (Janoff-Bulman, 1992), this theory proposes that the development and maintenance of PTSD is underpinned by the shattering of previously held assumptions, because of trauma exposure. This theory necessitates that individuals generally feel invulnerable, that they can comprehend the world, and that following trauma these assumptions may no longer hold up, leaving residual feelings of helplessness and fear, perhaps a prolonged sense of threat caused by shattered assumptions of a predictable world. Feelings of self-blame may manifest in an attempt to restore control, for example. Whilst the theory helps explain a range of PTSD symptoms, it is not alone sufficient. It assumes that individuals with the most positive experiences in life, holding the most positive assumptions, would be those most at risk of PTSD, and evidence shows us that this is not the case, with people with previous trauma exposure at higher risk of developing PTSD (Brewin et al., 2000).

1.6.2.6 Emotional processing theory

Emotional processing theory argues for the existence of complex fear structures in the memory, which upon activation produce cognitive, behavioural and physiological reactions, for example excessive physiological arousal and avoidance (Foa and Kozak, 1986). It theorises the trauma is considered as vastly significant, threatening formerly held concepts, or schemas, of safety in the world and self-competency, at the same time as leading to a trauma representation in memory that is different to memories of an everyday experience (Foa et al., 1989). It suggests that *benign* stimuli may become associated with fear and danger and excessive, pathological, physiological, and behavioural response. The supposed fragmented traumatic memory is thought to interfere with information processing, until new information that challenges these new assumptions can be used to update the trauma memory. If this updating does not happen naturally, for example through disconfirming activities, an individual may develop PTSD.

Emotional processing theory has been greatly influential since it was first described with respect to anxiety disorders and has led to the development of exposure-based treatments, also known as trauma-focused treatments for PTSD, which are introduced later in this chapter. Nonetheless it has been argued that the single level of memory representation offered in the theory is not able to account for instances of numbing and amnesia, which suggest information to be stored at a higher level of representation (Brewin et al., 1996).

1.6.2.7 Dual representation theory

Contrary to the fear structure of memory purported in emotional processing theory, dual representation theory supposes pathological responses, including re-experiencing, occur due to the existence of *dual* memory systems (Brewin et al., 1996). These systems are thought to occur simultaneously, resulting in differing outcomes of emotional processing, including pathological chronic emotional processing and premature inhibition of processing. The theory describes trauma memories as being represented as everyday memories in the Verbally Accessible Memory (VAM), as well as by image-based memories in the Situationally Accessible Memory (SAM). The theory implicates the SAM system in the experience of flashbacks and intrusive thoughts, with this system remaining unconscious until triggered, including low-level processed information of trauma details that received relatively little conscious attention at the time of the trauma, and hence were not processed in the VAM system. To allow for successful emotional processing, conscious processing of the SAM is required, to bring to cognition the sensory and physiological information experienced at the time of the trauma. This outcome can be achieved naturally, for example processing might be assisted through social support, however where it is not achieved, pathological chronic emotional processing, or premature inhibition of processing, can occur, as is the case with PTSD.

1.6.2.8 Ehlers and Clark's cognitive model

A commonly cited model of PTSD, Ehlers and Clark's cognitive model (2000) highlights a core role for cognitions and the meaning attributed to the trauma experience. It proposes that the perception of threat, characteristic of PTSD, arises from negative trauma appraisals, and disturbed autobiographical trauma memory, where perceptual memory of images and emotions are disconnected from trauma

context and understanding. It helpfully highlights the paradox in PTSD whereby individuals express anxiety about the future, despite the trauma occurring in the past. The memory of the trauma is thought to be poorly processed, contextually incomplete, and therefore not embedded within the autobiographical memory. Subsequently, intentional retrieval is thought to be problematic, though retrieval in a cue-driven, unintentional way, is much easier, resulting in frequent re-experiencing. This unintentional retrieval is often triggered by stimuli, with individuals sometimes unaware of the triggers, and evokes specific sensory information about the event and a particularly strong response. It is theorised the nature of the trauma memory, along with negative appraisals, results in processing of trauma information in a way that elicits a sense of current threat.

The negative appraisals aspect that is emphasised in this model helps to explain the variety of emotions reported by people with PTSD. Negative appraisals might include appraisals concerned with an individual's own actions, for example feeling they deserved the trauma to have happened to them, or with other people's reactions. This offers explanation for the finding that previous trauma exposure increases likelihood of developing PTSD (Brewin et al., 2000). Prior beliefs and experiences, including previous experience of trauma, are believed to further increase the likelihood of negative appraisals, for example perceiving the self as being vulnerable to danger.

Ehlers and Clark also consider the maladaptive behavioural and cognitive styles that help to maintain the disorder, including avoidance of trauma reminders, abandonment of usual activities, thought suppression, and rumination.

1.7 PTSD Treatment

Various aetiology theories have been proposed for PTSD, as described, with biological, social, and psychological underpinnings. A range of treatments are available, which attempt to address the numerous presentations of PTSD symptomatology, in this heterogeneous disorder (Dimauro et al., 2014, Bisson and Olff, 2021). The two key groups of interventions are pharmacological, and psychological.

This PhD concerns the treatment of PTSD rather than its prevention, specifically treatments using CBT with a trauma-focus (TF-CBT). This section, therefore, provides a brief overview of a selection of key treatment interventions, with a more

detailed consideration given to TF-CBT interventions. Evidence-based treatment guidelines are then outlined.

1.7.1 Pharmacological

Selective Serotonin Reuptake Inhibitors (SSRIs), including sertraline, paroxetine, fluoxetine, and Selective Serotonin Norepinephrine Reuptake Inhibitors (SSNRIs) such as venlafaxine, are efficacious treatments for PTSD (Huang et al., 2020). Sub-optimal prescribing has however been demonstrated (Bisson et al., 2020).

1.7.2 Psychological therapies without a trauma focus

There are several psychological therapies without a trauma focus for PTSD, including CBT without a trauma-focus.

1.7.2.1 The development of CBT

CBT utilises a range of therapeutic techniques to address emotions through thoughts, behaviours, and beliefs, and has been described as behavioural experiments to give rise to cognitive change (Bennett-Levy, 2004). In traditional individual CBT it is an individual's belief which is the theory being tested in behavioural experiments, during and between treatment sessions.

A large and growing number of CBT interventions exist to treat a range of conditions, with wide variability in their empirical evidence base and a wide range of components, though goal processes, therapeutic processes and change principles are common characteristics of CBT (Mennin et al., 2013). The clinical value of CBT is particularly apparent in the rapid growth in membership of the British Association of Behavioural and Cognitive Psychotherapies (BABCP, 2020), and national CBT organisations and training programmes (Bennett-Levy, 2004), since the 1990s and the birth of evidence-based medicine.

Early CBT interventions were predominantly behaviour-focused, drawing on exposure. Behavioural exposure approaches derive from classical conditioning principles, for example Wolpe (Wolpe, 1968), and inhibitory learning models (Bouton, 1993), though their role in promoting habituation to a feared or avoided stimulus is however more commonly cited (Foa et al., 1989). The 1970s saw an increase in the popularity of cognitive frameworks so that the initial emphasis of

CBT on behaviour change expanded to allow cognition to become a central characteristic of CBT. Beck (1979), was one of a few pioneers of cognitive therapy, and clearly stated that a behavioural experiment can only be developed after a patient and therapist have identified a particular belief or assumption to be investigated. Beck also stated a requirement for a discussion of the patient's doubts and review of the results of the experiment, to fine tune experiments for cognitive change. Beck's landmark treatment manual ***'Cognitive Therapy of Depression'*** (Beck, 1979), preceded the development of many cognitive models for a range of disorders, including PTSD, bipolar disorder, eating disorders, and personality disorders.

1.7.2.2 CBT without a trauma focus

CBT for PTSD without a trauma-focus normally includes psychoeducation, stress/relaxation management, and non-trauma-focused cognitive restructuring, and these components are described in Table 3. Without focusing on the trauma, such interventions may target specific PTSD symptoms, for example sleep disturbance, and these interventions are therefore considered suitable options for adults who are unwilling or unable to engage in trauma-focused interventions (NICE, 2018c).

Psychoeducation	Usually delivered early on in treatment, psychoeducation is the provision of information on the disorder, symptoms, and treatment.
Stress relaxation management	Stress/relaxation management to enable increased wellbeing and to teach individuals breathing, mindfulness, and relaxation techniques; helpful coping skills for traumatic memories and the therapeutic process. For example, progressive muscle relaxation (Sermsak et al., 2008), whereby an individual tenses and relaxes groups of muscles, systematically.
Cognitive restructuring	Cognitive work aims to modify unhelpful thought patterns, by challenging self-held beliefs. For example, overgeneralisation, where an individual might tend to make broad generalisations based on isolated case experiences.

Table 3: Typical components of Cognitive Behavioural Therapy without a trauma focus.

Interventions are offered in a variety of forms, on a one-to-one basis, referred to as individual CBT, and as couples-, families-, group-based therapy. They are also available in the form of internet-based CBT (i-CBT).

Evidence for CBT for PTSD without a trauma-focus has been demonstrated in a meta-analysis of seven studies of 318 individuals comparing CBT without a trauma focus with waitlist or treatment as usual (TAU) (Lewis et al., 2020a). The quality of evidence was however low, when judged according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system (Andrews et al., 2013). No effect has been shown however for non-trauma-focused CBT when compared with Present Centred Therapy (PCT), albeit with a very low quality of evidence judged according to GRADE (Lewis et al., 2020a).

1.7.2.3 Present Centred Therapy (PCT)

PCT was designed as a strong comparator treatment for Trials examining the potential superiority of TF-CBT over nonspecific psychotherapeutic benefits (Schnurr et al., 2007). Its components include establishing positive interpersonal connections through the therapeutic relationship, symptom normalisation, emotional support, and increasing self-confidence in dealing with problems. Treatment aims to provide individuals with insight into PTSD and how it might influence their behaviours and how they might implement solutions to problem behaviours. Homework is typically set as noting problems in a weekly diary. PCT is non-trauma-focused, nor does it include behavioural activation and cognitive restructuring. PCT may be modified in length and may be delivered to individuals and groups (Belsher et al., 2019).

In a meta-analysis of PCT versus waitlist or TAU, in two studies with 138 individuals, a positive effect was found for PCT, albeit with a very low quality of evidence judged according to GRADE (Lewis et al., 2020a).

1.7.3 Trauma-focused psychological therapies

Trauma-focused psychological therapies include Eye Movement Desensitisation Reprocessing, Reconsolidation of Traumatic Memories, and TF-CBT.

1.7.3.1 Eye Movement Desensitisation and Reprocessing (EMDR)

EMDR treatment is based on the hypothesis that eye movements facilitate the desensitisation of trauma memories (Shapiro, 1989), and more recently with respect to hypotheses that eye movements facilitate memory reprocessing effects. Typically, EMDR is a structured, eight-phase approach (Shapiro, 2001), commencing with an assessment of the individual and the provision of coping skills, to ensure the individual has resources to manage treatment. The core component of treatment, the desensitisation and reprocessing, takes place between sessions three to six, where an individual keeps in mind the most problematic visual image relating to their trauma, a negative belief of the self, and their bodily sensations. This occurs while the individual focuses on a dual attention stimulus, whilst also considering a preferred positive belief about the self. This phase may be repeated several times, as required, thus the protocol facilitates comprehensive evaluation of the trauma memory, preparing an individual for, and undertaking processing of the event(s), current disturbed situations, and future challenges (Shapiro, 2014). A positive clinically important effect has been demonstrated for EMDR when compared with waitlist or TAU, in a meta-analysis of 11 studies with 415 participants, albeit with a low quality of evidence judged according to GRADE (Lewis et al., 2020a). In the same review, when EMDR was compared with therapies broadly defined as TF-CBT, in ten studies of 387 participants, no difference was found. Despite its popularity and efficacy, the underlying mechanisms for EMDR have been debated since its inception in the 1990s and remain elusive (Landin-Romero et al., 2018).

1.7.3.2 TF-CBT

> *"The conflict between the will to deny horrible events and the will to proclaim them aloud is the central dialectic of psychological trauma" (Herman, 2015) (p.1)*

TF-CBT interventions are typically delivered to individuals, with some couples- and group-based interventions. There are an increasing number of internet-based interventions, which is the focus of this PhD and is therefore expanded in chapter two.

Therapies typically include psychoeducation and cognitive restructuring, as described in Table 3, and exposure, with the latter being the component that sets TF-CBT apart from CBT without a trauma focus. Exposure includes behavioural

experiments concerned with the trauma, visiting the scene of the traumatic event, or imagining and expressing the trauma as it occurred, with a view to updating the individual's traumatic memory and their thoughts and beliefs, in a helpful way. Exposure has been demonstrated to be effective in the treatment of patients with a range of conditions, for example social phobia (Blanco et al., 2010).

Interventions of CBT with a trauma-focus are a heterogeneous group and robust evidence is available for its efficacy in the treatment of PTSD. When compared with waitlist or TAU, therapies broadly defined as TF-CBT were found to have a clinically important effect in a meta-analyses including 51 Randomised Controlled Trials (RCTs), with 1380 participants (Lewis et al., 2020a), with the evidence judged as moderate quality according to GRADE . Clinically important effects, albeit with a low quality of evidence judged according to GRADE, were shown for the following specific TF-CBT protocols in the same systematic review: Resick and Schnicke's Cognitive Processing Therapy (CPT) (Resick and Schnicke, 1996); Foa's Prolonged Exposure Therapy (PE) (Foa and Rothbaum, 1998); and Ehlers and Clark's Cognitive Therapy (CT) (2000), and these are now described. These therapies share similarities however the weight of behavioural and/or cognitive elements within each do vary, for example PE being largely behavioural in its approach, and cognitive elements dominating in CPT and CT.

Foa and colleagues' Prolonged Exposure (PE) protocol

Drawing on Emotional Processing Theory, Foa and colleagues' protocol for Prolonged Exposure (PE) treatment (Foa and Rothbaum, 1998) stipulates that an individual's fear structure be activated in a vivid sense, through exposure behavioural approaches, for successful treatment, usually over nine to 12 sessions. Behavioural experiments of real-life repeated exposure are undertaken, with respect to avoided and fear-evoking situations, that are now safe but associated with the trauma. Activation through exposure is expected to allow for habituation of the fear stimulus and at the same time allows for processing of the fragmented trauma memory and new information, thereby evaluating old and new information. Treatment therefore focuses on helping people with PTSD to gradually confront their traumatic memories and to learn that these memories and cues are not dangerous and do not need to be avoided. The approach is a verbal narrative exposure technique where an individual recounts in detail their traumatic

experience, recording and listening to the account on a repeated basis, with the goal of habituation.

Resick and Schnicke's CPT protocol

CPT for PTSD (Resick and Schnicke, 1996), is a CBT treatment typically lasting 12 sessions, with an optional trauma-focused component in which an individual provides a detailed written account of the trauma. CPT focusses on three phases, including education, processing, and challenging. Cognitive techniques are used by the therapist and individual to challenge unhelpful or unrealistic thoughts that have developed following the traumatic experience, and how these thoughts and beliefs have impacted their beliefs about their pre-existing schemas, including themselves, other people, and the world, for example feelings of intense self-blame. The aim is to change these unhelpful thoughts and beliefs, to allow an individual to return to a normal life.

Ehlers and Clark's Cognitive Therapy (CT) protocol

Drawing on a widely cited cognitive model within the field of PTSD, Ehlers and Clark's treatment protocol (2000), aims to help individuals to lose unhelpful coping strategies, and to identify and update unhelpful negative appraisals of the trauma, and to correct the disturbed autobiographical memory of the trauma. Behavioural experiments within the therapy might include: testing unhelpful appraisals of symptoms, for example an individual's fear of loss of control; re-evaluating altered appraisals of the self and the world, for example an individual's altered perception of appearance; re-evaluating distorted appraisals at the time of the trauma, for example returning to the trauma site; and examining the helpfulness of safety behaviours, for example an individual's overgeneralisation of danger following a road traffic accident (Mueller, 2004). The therapy typically lasts over 12 weekly sessions, though an intensive version of CT for PTSD, where individuals received up to 18 hours of therapy over a period of five to seven working days, with up to four follow-up sessions, has been demonstrated to be a feasible alternative (Ehlers et al., 2010).

Clark (2004), describes the flexibility of behavioural experiments in PTSD, and that they offer an opportunity to break a link between a trauma trigger and the trauma memory. Clark uses the example of the terror experienced in a road traffic accident at night, which might be triggered by a visual resembling a headlight, for example

a shaft of sunlight. Through behavioural exposure experiments, this link can be used intentionally to elicit the trauma memory, which can be accompanied by asking the individual to focus on the differences between the trauma and now, to appreciate the trauma being in the past, thus contextualising the trauma memory.

1.7.3.3 Reconsolidation of Traumatic Memories (RTM)

RTM is a non-pharmacological approach aiming to treat PTSD through memory reconsolidation (Muss, 1991). Memory reconsolidation is the process by which longer term memories are reactivated, or mobilised, changed and updated, to prevent intrusive memories. In RTM a traumatic memory is activated, and a procedure undertaken whereby an individual imagines the trauma as a black and white film, dissociated from its content, and then re-winding it whilst fully associated with the content over two seconds.

The mechanism of RTM remains unclear, though in a meta-analyses comparing RTM with waitlist or TAU, in two studies with 96 individuals, RTM showed a positive effect, though the quality of evidence was judged very low, according to GRADE (Lewis et al., 2020a). A Phase II RCT of RTM is currently underway (Astill Wright et al., 2021a).

1.7.4 CPTSD treatment

Whilst not the focus of this PhD, it is worthwhile noting that further research is needed to understand the appropriateness of existing psychological interventions aimed at PTSD, for the treatment of CPTSD. It is not yet known whether people with CPTSD would benefit from current PTSD treatments that are tailored for complex factors (Cloitre, 2015, Cloitre et al., 2012, Van Minnen et al., 2012, Cloitre et al., 2013, ISTSS, 2018a). Given the pervasive nature of some of the complex symptoms, including negative self-concept (Karatzias et al., 2018b), such symptoms may require alternative or adapted approaches to treatment. Whilst there is no current consensus regarding the need to apply different treatment for PTSD and CPTSD, since ICD-11 PTSD and CPTSD diagnoses are new, a recent meta-analysis suggests CBT and EMDR to be superior to waitlist or treatment as usual (Karatzias et al., 2019).

Strategies for stepped-care or phase-based treatment for CPTSD are gaining popularity, for example where complex factors such as affect regulation and

interpersonal skills are targeted before trauma-focused therapy, thereby focusing first on improving an individual's functioning and their subsequent ability to engage in trauma-focused work. For instance, treatments such as Skills Training in Affective and Interpersonal Regulation plus Modified Prolonged Exposure (STAIR/MPE), an evidence-based two-phase cognitive behavioural treatment (Cloitre et al., 2002).

1.7.5 PTSD prevention and treatment guidelines

PTSD treatment guidelines have been developed with the intention of synthesising research data to help individuals navigate evidence-based treatment options. Evidence-based treatment guidelines are available globally, though pertinent to this PhD are the guidelines of the National Institute for Health and Care Excellence (NICE, 2018a), a non-departmental public body developing national guidance on physical and mental health and social care in the UK. NICE guidelines are developed using the best available evidence, with recommendations put together by service users, carers and the public, and experts. Also of importance are the guidelines developed by the International Society for Traumatic Stress Studies (ISTSS, 2018b), since these are most recently developed and based on the most recent empirical evidence, rigorous methodology with 361 included RCTs reviewed systematically, and 208 meta-analyses conducted (Bisson et al., 2019). Three further major guidelines for PTSD treatment include: the American Psychological Association (APA) (2017); the Pheonix Australia Centre for Posttraumatic Mental Health (Phoenix Australia) (2013); and the US Departments of Veterans Affairs and Defence VA/DoD (2017).

All five major guidelines strongly support the use of trauma-focused psychological treatment, most prominently TF-CBT, either as a category in itself, or the specific interventions of CPT, CT for PTSD, and PE. EMDR (Shapiro, 1989), is also strongly recommended in NICE, ISTSS, APA, and the Pheonix Australia guidelines (2018c, 2018, 2017, 2013), and given a moderate recommendation in APA guidelines (2017). NICE, VA/DoD, and Pheonix Australia treatment guidelines recommend trauma-focused psychotherapies over pharmacotherapies (2018c, 2017, 2013), and they are given stronger ratings than pharmacotherapies in APA and ISTSS guidelines (2017, 2018b) .

1.7.5.1 NICE PTSD guidelines

NICE's PTSD recommendations (2018c), are based on the best available evidence of what works and what it costs. Guideline development committees include at least two lay members, or people with lived-experience, or from a community affected by the guideline (2018c), where individuals provide feedback on the recommendations, and each guideline is allowed opportunity for external peer review. RCTs are most often used to assess efficacy, including cost-effectiveness, in addition to other non-randomised evidence (NICE, 2018a). A summary of NICE recommendations for the prevention and treatment of PTSD in adults is provided in Table 4, below.

Prevention / Treatment	Pharmacological / Psychological	Strength of recommendation	Intervention	Trauma Focus
Prevention (within a month of the traumatic event)	Psychological	Strong recommendation	Individual, manualised Trauma Focused Cognitive Behavioural Therapy (TF-CBT)	Yes
Treatment (more than a month after a traumatic event)	Psychological	Strong recommendation	Individual, manualised Trauma Focused Cognitive Behavioural Therapy (TF-CBT), including: Cognitive Processing Therapy (CPT) Cognitive Therapy for PTSD (CT) Narrative Exposure Therapy (NET) Prolonged Exposure (PE) Or eye movement desensitisation and reprocessing (EMDR) (consider EMDR for adults after a non-combat-related trauma, if EMDR preferred).	Yes
		Moderate recommendation	Guided internet-based trauma-focused Cognitive Behavioural Therapy (TF-CBT), if preferred to face-to-face TF-CBT and EMDR (where symptoms are not severe, in particular dissociative symptoms, and the individual is not at risk of harm to themselves or others)	Yes
	Pharmacological	Moderate recommendation	Consider medications if the person has a preference for drug treatment. Venlafaxine or selective serotonin reuptake inhibitors, such as Sertraline. Antipsychotics such as Risperidone, in addition to psychological therapies, if individual has disabling symptoms and behaviours, including psychotic symptoms, and symptoms have not responded to other drug or psychological treatments.	No

Table 4: National Institute for Health and Care Excellence (NICE) recommendations for psychological and pharmacological PTSD prevention and treatment (NICE, 2018c).

1.7.5.2 ISTSS PTSD guidelines

The ISTSS is an international interdisciplinary organisation promoting advancement and exchange of knowledge about traumatic stress. Recommendations set out in the ISTSS guidelines for PTSD prevention and treatment (Bisson et al., 2019), are based on extensive recent review of the evidence, relative efficacies of different interventions, as well as the strength and quality of the evidence, and other factors such as adverse effects. The ISTSS treatment guidelines make recommendations at the following levels: strong (at least reasonable quality of evidence and the highest certainty of effect); standard (at least reasonable quality of evidence and lower certainty of effect); low effect (at least reasonable quality of evidence and high certainty of a low level of effect); emerging evidence (lower quality of evidence and/or certainty of effect); and insufficient evidence to recommend.

ISTSS recommendations for PTSD prevention and early treatment interventions, *post-trauma*, within the first three months of a traumatic event, include: single session brief EMDR; multiple session self-guided internet-based interventions; multiple session guided self-help internet-based CBT, with TF-CBT approaches; and hydrocortisone. These are recommended at an emerging evidence level, which effectively means that more research is required. It should be noted that there are a limited, albeit growing number of internet-based preventative interventions to date (Olff 2015), some of which are prevention interventions intended for delivery *pre-trauma*, for populations at higher risk of trauma exposure and development of PTSD, including emergency workers. There is limited evidence to date for the efficacy of such interventions (Wild et al., 2020a), however a trial is currently underway examining a pre-incident internet-delivered cognitive training for resilience (i-CT-R) intervention (Wild et al., 2018). Findings of a systematic review suggest that pre-incident interventions targeting modifiable predictors of trauma-related psychiatric disorders hold potential (Wild et al., 2020b).

Recommended at a standard level of evidence are the following early treatment interventions: multiple session TF-CBT; multiple session Cognitive Therapy (CT) without a trauma focus; or multiple session EMDR.

ISTSS recommends at a strong level of evidence the following multiple session treatments: TF-CBT; PE; CPT; CT; EMDR. Recommended at a standard evidence level are the following interventions: multiple session CBT without a trauma-focus; Narrative Exposure Therapy (NET); PCT; multiple session internet-based TF-CBT

Guided Self-Help (GSH). Pharmacological treatments, for example fluoxetine and paroxetine, are recommended to a low effect level of evidence.

1.7.5.3 Comparing treatment guidelines

Methodologies and recommendations of the five major treatment guidelines of NICE, VA/DoD, Phoenix Australia, ISTSS, and APA (2018c, 2017, 2013, 2018b, 2017) were contrasted in 2010 (Forbes et al., 2010), and this work was updated in 2019 (Hamblen et al., 2019), following dissemination of criteria[4] developed by the Institute of Medicine (2011). The authors noted an overall rigorous and consistent approach to guideline development. The use of Cochrane criteria (Higgins et al., 2019) and the GRADE system (Andrews et al., 2013), for evaluation of the evidence was noted in the development of NICE and ISTSS guidelines. Despite consistency across the PTSD guidelines, the authors highlight some variation in methodological decisions and interpretation of the evidence that results in some differences in recommendations, as well as pointing out the limitations of treatment guidelines in general, for example the limited availability of RCTs comparing treatments against each other.

1.7.6 Accessing PTSD treatment

There are a variety of factors that affect access to mental health treatment in general, with estimates of around 70-75% of young people and adults not receiving treatment (Thornicroft, 2007, Davies, 2014). Analyses of WHO Mental Health Surveys across 24 countries found that of the respondents who were exposed to trauma with 12-month prevalence of PTSD, according to DSM-IV criteria (including therefore both new cases and cases where symptoms were persisting), fewer than half of individuals reported seeking any PTSD treatment at all. Treatment seeking in high-income countries (53.5%), was found to be roughly double that in low- to lower-middle income countries (22.8%), and upper-middle income countries (28.7%) (Koenen et al., 2017).

[4] Criteria stipulates guidelines be: based on systematic review of the evidence; developed by experts from multiple disciplines, with stakeholder input; account for patient sub-groups and preferences; based on transparent process, minimising bias and conflict of interest; provide ratings of the quality of evidence, and strength of outcomes; and be reviewed and revised continuously to reflect new evidence.

The availability of CBT falls short across mental healthcare (Bennett-Levy, 2004). Indeed, TF-CBT is not covered by national health services or health insurances in *all* countries (Kazlauskas et al., 2016), thereby excluding individuals who cannot afford such treatment in those countries. The UKs National Health Service (NHS) does offer TF-CBT, yet despite its evidence, challenges exist in accessing timely TF-CBT for people with PTSD. Clinicians have reported a lack of time to commit to providing treatment due to a high case load, as a barrier to using evidence-informed interventions for PTSD (Finch et al., 2020).

1.7.6.1 PTSD treatment and comorbidity

A systematic review of 34 studies of barriers and facilitators to the use of evidence-based interventions for PTSD found that the most reported client-level barriers influencing clinicians' use included client comorbidities (Finch et al., 2020). Whether or not PTSD is the primary problem for an individual should be assessed and should influence whether PTSD should be the focus of treatment (Bisson et al., 2005). Clinicians may be reluctant to use PTSD disorder-specific treatments for individuals with comorbid disorders, for fear of the treatment exacerbating comorbid symptoms (Minnen et al., 2015), and they may choose to attend to an individual's problems with substance misuse, for example, by referring to addiction treatment, before attempting to treat PTSD (Adams et al., 2016). Indeed, research leading to evidence-based treatments, including PTSD treatment, is tightly controlled, and often excludes individuals with clinically challenging comorbidities, for example substance use disorders, due to these individuals tending to present with more severe clinical profiles (Roberts et al., 2016). Trauma-focused therapies can however be effective for PTSD with comorbidities. For example, in the case of comorbid PTSD and depression, treatment studies of PTSD have demonstrated that with the successful treatment of PTSD, secondary comorbid problems of depression are greatly reduced (Blanchard et al., 2003).

1.8 Chapter summary

This introductory chapter commenced with a brief history of Psychotraumatology, offering accounts through the ages of conditions resulting from trauma exposure, likely resembling what we now know to be PTSD. The chapter described the move over time towards a formal conceptualisation of PTSD, as a set of symptoms presenting in individuals exposed to traumatic event(s). Refinement of the

diagnosis of PTSD according to DSM and ICD PTSD classification systems was explored, including the divergence of the current DSM-5 and ICD-11 systems, reflecting disagreements in the field regarding the construct of PTSD.

The variable prevalence rates of PTSD, and the myriad of risk factors, were examined, noting the heterogeneity apparent in the field, due in part to differing methodological approaches. Whilst a large proportion of people exposed to trauma may not go on to develop PTSD, pre-trauma and particularly peri-trauma factors put certain individuals at risk, and high prevalence rates for PTSD are reported overall, with a high prevalence of PTSD co-occurring with other conditions.

Various biological and salient psychosocial models of PTSD were outlined, and it appears that theories are overlapping and can help to explain PTSD development and maintenance to varying degrees. Psychosocial theories of PTSD, including emotional processing theory, dual representation theory, Ehlers and Clark's cognitive model, and attachment theory, appear to draw on the importance of trauma memory and information processing, as well as social-cognition, including assumptions, appraisals, and beliefs, about the self and one's place in the world.

PTSD treatment was introduced, and there is robust evidence for EMDR and for various cognitive-behavioural therapies for PTSD, particularly those with a trauma-focus in clinical treatment guidelines, including NICE and ISTSS. Consideration of i-CBT, in particular internet-based TF-CBT (i-TF-CBT), will be expanded within the next chapter.

2. Chapter Two: Introducing i-CBT for PTSD and its acceptability.

We have witnessed an explosion in computerised and internet-based interventions, otherwise known as digital therapy, or e-health, over the last twenty years, enabled by the advent of the mobile phone and evolution of Web 2.0 applications (Andersson, 2018, Gibbons et al., 2011). In the UK, 88% of adults have internet access at home and 75% own a smartphone (Ofcom, 2017). Internet-based psychological interventions were recommended for anxiety and depression in 2006 in their first nationwide health recommendation by NICE in England and Wales (2006), and digital mental health services have risen globally. For example, the MindSpot Clinic, offering digital assessment, referral, and treatment services, for adults with anxiety and depressive disorder symptoms, throughout Australia (Titov et al., 2020). In 2020 National Safety and Quality Digital Mental Health Standards were produced for Australia, the first worldwide Standards developed amidst this rapidly changing environment requiring changes in policy and practice.

Internet-based treatment options may however potentially exclude some people who are not engaged with technology, for example for self-exclusion reasons, or due to digital literacy (Ennis et al., 2012). Whilst not a panacea, internet-based approaches offer an option for some to be used as an adjunct to usual care and as a cost-effective alternative to in-person face-to-face treatment (Lewis et al., 2012, Titov et al., 2009), and a 'pandemic-proof' option.

2.1 Defining internet-based psychological therapies

It is important to acknowledge the wide heterogeneity of internet-based psychological therapies and the wide terminology that is used in the literature (Barak et al., 2009). There are a great number of terms used to label the interventions, including e-health; digital health; computer-based interventions; online therapy; guided self-help (GSH); and teletherapy. A recent Delphi exercise was conducted with 23 experts in the field, finding overwhelming agreement that there are terminological challenges, with significant consequences for clinical practice and treatment, and that a common glossary would be beneficial (Smoktunowicz et al., 2020).

Internet-based interventions differ from each other with respect to their content, the technologies they employ and the extent of human and/or automated contact. For example, they may be delivered on internet-linked computers and laptops, or smartphone Applications (Apps). Barak et al., (2009) helpfully categorised internet-based interventions into the following: web-based interventions; online counselling and therapy; internet-operated therapeutic software, such as artificial intelligence and virtual reality applications; and other online activities, for example blogs, social medias and other supplements to in-person face-to-face therapy. The authors described a web-based intervention as:

> *"a primarily self-guided intervention program that is executed by means of a prescriptive online program operated through a website and used by consumers seeking health- and mental-health related assistance. The intervention program itself attempts to create positive change and improve/enhance knowledge, awareness, and understanding via the provision of sound health-related material and use of interactive web-based components." (Barak et al., 2009) (p.5).*

The authors described there being four key components to web-based interventions, which are not mutually exclusive: program content, multimedia choices, interactive online activities, and guidance and supportive feedback. A distinction is drawn between interventions with an *education* content that provide access to information in a particular area and are relatively inactive, and self-guided, and human-supported interventions with a *therapeutic* content, which are designed to create positive cognitive, behavioural, and emotional change and include more active/interactive multimedia components. This PhD concerns i-CBT that is guided by a clinician, and thus falls quite neatly within Barak and colleagues' category of human-supported therapeutic web-based interventions. For the purposes of this PhD, where I refer to GSH, this can be assumed to be i-CBT that is guided by a clinician.

2.2 The evolution of internet-based psychological therapies

Several factors have led to the rapid expansion of internet-based interventions. A key factor is the growing need to diversify treatment options and improve access to psychological therapies, impacted also by COVID-19 and the need for 'pandemic-proof' interventions.

2.2.1 Improving access to psychological therapies

Internet-based psychological therapies may be accessed flexibly at a convenient time, and in a range of places, whilst also avoiding travel costs to regular in-person appointments (Romijn et al., 2015). This may be advantageous for individuals who may have limited ability to access outpatient health services due to difficulty getting time off work to attend appointments, reduced mobility, financial, geographical restraints (Knaevelsrud and Maercker, 2007, Lovell and Richards, 2000, Taylor and Luce, 2003). Some internet-based therapies offer anonymity, being 'stand-alone' programmes with no guidance, which may appeal to individuals who fear mental health treatment-seeking stigma (Gega et al., 2004, Kitchiner et al., 2012, Kantor et al., 2017). Programmes may include helpful features such as reporting back to the user their progress and self-ratings and allowing users to choose the gender of voice-overs (Peck, 2008). The programme and its content of treatment may be available for some time after the end of therapy, which may be useful in terms of consolidation. Furthermore, internet-based interventions facilitate working across language barriers, for example the i-TF-CBT intervention, 'Interapy' (Lange et al., 2003), which is available in several languages.

Internet-based approaches typically demand far less support time than in-person face-to-face approaches, and may be delivered by non-specialist clinicians, thereby potentially improving access to psychological therapies, and saving costs (Lindsäter et al., 2019). The ability to offer internet-based interventions to a greater number of individuals seeking treatment would help towards addressing the long waiting lists for in-person face-to-face TF-CBT in the UK. It is not surprising therefore that international research, policy, and commissioning has prioritised the opportunity for digital therapies to widen access to evidence-based psychological care (Torous et al., 2019). In the UK there has been a shift in paradigm in clinical practice towards the introduction of Low Intensity (LI) forms of treatment (Bennett-Levy, 2010), including internet-based therapies, in an attempt to address the shortfall in patient access to psychological treatments. Since 2008, NHS Health Boards across the UK are expected to deliver NICE-recommended LI interventions for people with depression and anxiety disorders, and the British Psychological Society (BPS n.d.), accredit training for Psychological Wellbeing Practitioners (PWPs) to deliver LI CBT-based interventions within the NHS. Improving Access to Psychological Therapies (IAPT) services have developed in England, with the aim of expanding services so

that by 2024, 1.9m adults can access evidence-based psychological therapies each year (Wakefield et al., 2021).

2.2.1.1 COVID-19

Access to psychological therapies was tested significantly during the writing of this PhD, with the outbreak of the COVID-19 pandemic (Békés and Aafjes-van Doorn, 2020, Shore et al., 2020). Since the pandemic took hold, remote and 'pandemic-proof' interventions, with a reduction or lack of face-to-face therapist contact, have become increasingly important, given lockdown measures across the globe (Békés and Aafjes-van Doorn, 2020, Shore et al., 2020). For example, the WHO Europe Regional Director suggested internet and mobile interventions in the delivery of psychological first aid to individuals in need (Van Daele et al., 2020). Recent literature has considered COVID-19 as the 'black swan' and a turning point for mental health care and increased e-Health (Wind et al., 2020).

2.2.2 Empowering treatment options

Another key factor in the rise of internet-based psychological therapies is their promotion as empowering treatment options (NHS, 2019). Internet-based interventions are largely self-help interventions, enabling people to engage in technologies to help monitor and manage their mental health problems, thereby empowering them with greater choice and control regarding their health needs (Hollis et al., 2018a).

2.2.2.1 A brief history of Self-Help and Guided Self-Help (GSH)

> *"Men [sic] must necessarily be the active agents of their own well-being and well- doing; and that, however much the wise and the good may owe to others, they themselves must in the very nature of things be their own best helpers." Samuel Smiles 1859 (Smiles, 2009)*

Self-Help

The existence of self-help materials dates from as early as the 19th century, with written material aimed at personal improvement. For example, Scottish Author and Government reformer, Samuel Smiles' 1859 book, ***'Self Help'*** (Smiles, 2009).

Self-help has been defined as *"an individualised voluntary enterprise, an undertaking to alter, reform or transform the self"* (Rimke, 2000) (p.62). A multitude of self-help materials exist for consumers, providing techniques to enable individuals to engage in personal improvement in their own time and at their own pace, increasingly with respect to understanding and managing mental and physical health.

Self-help books, also known as bibliotherapy, have been developed for a range of mental health disorders, including PTSD. For example, ***'Overcoming Traumatic Stress'*** (Herbert, 1999), which discusses the 'grip' of trauma and how working through trauma can take many forms, with the grip of trauma gradually loosening as one starts to gain control. Further research is required, however evidence from one RCT comparing a self-help book for PTSD with CT and repeated assessments, found fewer individuals (3 [11%]) receiving CT had PTSD at follow-up, compared with individuals receiving the self-help book (17 [61%]; odds ratio, 12.9; 95% CI, 3.1-53.1), and the self-help book was not superior to repeated assessments (Ehlers et al., 2003).

Computer-based self-help interventions have developed alongside bibliotherapy (Osgood-Hynes et al., 1998), and in more recent years so have internet-based, including mobile App-based, self-help interventions. Alongside the opportunities afforded by technological innovations, there is however also an inherent risk of commercial exploitation and the availability of open access interventions that are not rigorously designed, nor tested (Hill et al., 2017). The evidence base for the growing number of open access Apps is limited (Lewis, 2020). A systematic review (Sander et al., 2020), found 69 Apps targeting PTSD in the British Google Play and Apple iTunes stores. A large proportion of the Apps (41 Apps) reviewed were self-help Apps, most being based on CBT and established PTSD psychological treatment methods, such as processing trauma-related emotions and beliefs. The overall App quality, as measured by the Mobile App Rating Scale (MARS), was medium (M=3.36, SD=0.65). The researchers reported however that only one App (1.4%) had an evidence base. These findings should be treated with some caution given that evidence base was defined as been examined in an RCT according to Google Scholar. Nonetheless, concern is raised across the literature given the absence or limitations of quality standards in the development of publicly-available Apps for mental health, including PTSD (Bakker et al., 2016, Olff, 2015), and the limited evidence for their efficacy (Donker et al., 2013). Encouragingly, a recent validation

of the MARS, which considers App quality according to four dimensions of engagement, functionality, aesthetics and information quality, has demonstrated its suitability for quality assessment (Terhorst et al., 2020).

Guided Self Help (GSH)

Increasingly, therapist and clinician guidance has been provided alongside self-help materials, and this is referred to as GSH. The type and extent of guidance can vary widely between interventions (Ebert et al., 2018), though typically the purpose of guidance is in providing support, including recognising, and reinforcing an individual's engagement with the self-help materials, for example through weekly feedback (Berger, 2017). Qualitative interviews with patients accessing i-CBT for depression have demonstrated that therapist support provided motivation, as well as personal contact and feedback (Gerhards et al., 2011). Feedback may be either in the form of email, text, telephone, video meetings, or in-person face-to-face sessions. Interventions offering a blend of internet-based therapy and in-person face-to-face sessions, are sometimes referred to as 'blended treatment'.

GSH may be offered as a treatment step within a 'stepped care' model, a model which is being increasingly adopted in psychological services (Bower and Gilbody, 2005, van Straten et al., 2015). In this model an individual's progress through treatment is monitored, with an individual 'stepping up' to a higher intensity treatment if applicable, following current treatment. Bower and Gilbody described four qualitatively different steps, with pure, or stand-alone self-help being the lowest intensity step, and GSH and group therapy as the next step up.

2.3 I-CBT

Individual-based treatment protocols have been adapted into internet-based materials, for use as self-help or GSH interventions, for several mental health disorders (Andersson, 2016). I-CBT is more commonly developed and offered in the context of mild to moderate severity disorders but may be delivered at both LI and high intensity (HI) within stepped-care models (Bower and Gilbody, 2005).

The translation of CBT interventions to digital form is aided by the fact that CBT is often manualised, with techniques clearly described (Richardson and Richards, 2006). Content commonly includes a series of modules, often interactive audio, and video materials, with agreed homework tasks. For instance, 'Beating the Blues'

(BtB), an early example of a computerised CBT intervention for depression, includes interactive, multimedia techniques including video vignettes of case study patients, and homework exercises (Proudfoot et al., 2003). More recently in the case of i-CBT, modules are typically delivered via website browser or mobile App (Ebert et al., 2018), for example internet-based interventions such as 'SilverCloud' for depression and anxiety (Silvercloud, 2020), and 'deprexis' (Meyer et al., 2009).

2.3.1 I-CBT efficacy

There is a growing evidence base for i-CBT approaches in the treatment of a range of mental health conditions, including depression, anxiety and PTSD (Karyotaki et al., 2021, Simon et al., 2021a, Van Daele et al., 2020, Lewis et al., 2018, Ebert et al., 2018, Karyotaki et al., 2018, Karyotaki et al., 2017, Carlbring et al., 2017). I-CBT has been demonstrated as effective for patients with anxiety disorders (mean effect size 1.08, CI 95%: 0.84–1.32; k=23), with no suggestion that face-to-face treatment was less effective than i-CBT (13 comparisons, d=-0.06) (Cuijpers et al., 2009). The effect sizes were smaller for studies where the i-CBT interventions included less therapist time, however the researchers noted that more research is needed. For example, research to determine the modality of human support: phone, email, or face-to-face. The researchers pointed out the limitations of their meta-analyses, limitations that exist across the literature, including the small number of studies available, mostly of small sample sizes, and varying quality.

A Cochrane review (Olthuis, 2016), found low quality evidence from 11 studies (N=866) contributed to a pooled risk ratio (RR) of 3.75 (95% CI, 2.51 to 5.60 I^2=50%), for clinically important improvement in anxiety post-treatment, favouring therapist-supported i-CBT over a waitlist, attention, information, or online discussion group only. Results found that i-CBT with therapist support may not differ in effectiveness as compared to face-to-face CBT, for people with anxiety disorders (k=4, N=365; RR 1.09, 95% CI, 0.89 to 1.34; I^2=0%; low quality evidence). At post-treatment there were no clear differences between unguided i-CBT and therapist-supported i-CBT for disorder-specific anxiety symptoms (k=5, N=312; SMD -0.22, 95% CI, -0.56 to 0.13; I^2=58%; very low quality evidence) or general anxiety symptoms (k=2, N=138; SMD 0.28, 95% CI, -2.21 to 2.78; I^2=0%; very low quality evidence).

Karyotaki et al., (2021) conducted a systematic review and meta-analysis of i-CBT for depression. Their review of 39 studies comprising 9751 participants

demonstrated superiority of both guided and unguided i-CBT interventions in treating depression symptoms compared to TAU. In contrast to Olthuis's findings of no difference between guided and unguided i-CBT interventions in reducing anxiety symptoms, guided i-CBT was associated with more effectiveness than unguided i-CBT (MD=-.8, 95% CI, -1.4 to -.2), though this difference was not maintained at six- or twelve-months post-randomisation. Interestingly, the most important modifier of the efficacy for guided versus unguided i-CBT was baseline depression score, with guided i-CBT benefits found to be more substantial for individuals with moderate to severe depression, compared to those with mild to subthreshold depression.

Comparing i-CBT with face-to-face CBT for psychiatric and somatic disorders, in an updated review and meta-analysis, Carlbring et al., (2017), found a pooled effect size post-treatment of Hedges g=0.05 (95% CI, -0.09 to 0.20), indicating that these treatment modes produced equivalent overall effects. The researchers noted a lack of research comparing guided i-CBT with face-to-face treatment, with 20 studies included in the review, and that more research is needed, with larger samples. No studies comparing i-CBT with CBT were identified for PTSD.

In a narrative Umbrella review of recent meta-analyses of i-CBT for adults with anxiety and mood disorders, i-CBT was concluded as an effective treatment, as effective as face-to-face therapy (Andersson et al., 2019a).

It is important to note that most studies of i-CBT have a follow-up period of a year or shorter, however one study of i-CBT for social anxiety disorder has demonstrated large and enduring effects, with treatment gains at one year follow-up sustained five years after the completed treatment (Hedman et al., 2011). This study did not however randomise to a control condition with which treatment results at five years could be compared.

2.4 I-CBT for PTSD

An increasing number of i-CBT programmes exist to treat PTSD. The common components do not deviate from those of traditional CBT and TF-CBT that were discussed previously. These include psychoeducation, distress management techniques, cognitive restructuring, and relapse prevention, with or without trauma processing/exposure, and the extent of guidance across i-CBT programmes appears to vary quite considerably (Simon et al., 2019a).

2.4.1 I-CBT without a trauma focus for PTSD

Several programmes exist, and these are often designed for use with no contact, or limited contact with therapists. These include 'PTSD Coach' (Kuhn et al., 2014), and 'DESTRESS' (Engel et al., 2015), which are now described.

2.4.1.1 'PTSD Coach'

The 'PTSD Coach' App was developed by the US Veterans Affairs (VA) National Centre for PTSD, designed as an adjunct to face-to-face in-person treatment, to provide individuals with psychoeducation about PTSD and symptom monitoring and assessment (Kuhn et al., 2014). Its scope, features and functions were developed via a series of focus groups with veteran PTSD patients and VA healthcare providers. It is delivered via an App intended for use across a broad range of trauma types, not limited to veterans, providing tools, assessments, and psychoeducation about PTSD. It is flexible in its structure to allow individuals to determine how they use the App. The App can be personalised, for example individuals can select their own photos or music. There are four main sections, which are described in Table 5, below:

Learn	Psychoeducational information about trauma, PTSD, and professional treatment options
Manage Symptoms	CBT-based self-management tools, stress inoculation training, and grounding.
Self-Assessment	Self-assessment of PTSD, using the PTSD Checklist Civilian Version (PCL-C) (Weathers, 1993)
Find Support	Provision of contacts, for example crisis contacts, or emergency services

Table 5: Four major sections of 'PTSD Coach' App.

As of March 2018, 'PTSD Coach' had been downloaded over 350,000 times in 106 countries. Globally, individuals from academic and governmental sectors have sought its use and have tailored its content to the needs of specific populations.

For example, revising the language, tone, and detail for an Australian audience in 'PTSD Coach Australia' (Kuhn et al., 2018), and modifications to the look and feel, using simple icons for navigation, in the Dutch 'SUPPORT Coach' (van der Meer et al., 2020).

2.4.1.2 'DESTRESS'

The Delivery of Self Training and Education for Stressful Situations, 'DESTRESS' programme uses CBT and stress inoculation training approaches and is designed to be nurse-guided (Engel et al., 2015). Avoiding exposure, it includes PTSD, stress and trauma psychoeducation, sleep and anger management techniques, and the stress management techniques of deep, slow diaphragmatic breathing and simple progressive muscle relaxation. The intervention also includes cognitive reframing techniques to challenge unhelpful thought patterns. The programme is broken down into five units with assignments, or homework, and the programme also allows users to record PTSD symptoms and levels of depression. Users are encouraged to contact the 'DESTRESS' Nurse for assistance if required, and a portion of the programme is accessible to the Nurse to monitor adherence and symptom levels.

2.4.2 I-TF-CBT

I-TF-CBT interventions for PTSD are designed to be accompanied by therapist involvement, feedback, and encouragement. The GSH internet-delivered TF-CBT (i-TF-CBT) interventions, 'Spring' (Lewis et al., 2013), and 'Interapy' (Lange et al., 2003), are examples that are now described. Other examples include an internet-based version of CT for PTSD (Wild et al., 2016b). Given that it is the acceptability of 'Spring', an example of an i-TF-CBT intervention, that is examined within this PhD, a focus is given to describing this intervention.

2.4.2.1 'Interapy'

The 'Interapy' online platform has been running for two decades, and was developed at Linkoping University, Sweden, for the purposes of running research studies for the treatment of psychological and behavioural health problems including depression, anxiety, phobia, hearing loss and tinnitus, as well as psychological trauma (Vlaescu et al., 2016). The platform supports multiple

languages including English, Lithuanian, Portuguese, Swedish, Polish, and the interface, including an internal messaging system, are available in English, Swedish, German, Romanian and Hebrew. The platform utilises Ecological Momentary Assessment (ECA), to allow users to be asked questions, daily, to allow improved assessment of behaviour and mood in the real-world.

Developed from studies investigating structured writing assessments, the 'Interapy' intervention for PTSD has evolved in to a GSH i-TF-CBT intervention consisting of self-confrontation, cognitive reappraisal, and social sharing (Knaevelsrud et al., 2015). The five-week structured writing programme aims for the individual to engage in ten, 45-minute writing sessions, therefore two writing sessions per week.

The protocol consists of three phases, which are outlined in Table 6, and through the internet-based client-server (interfaces of participant and therapist), a therapist provides the individual with feedback on their writing exercises in the middle of each of these phases, with instructions on how to proceed.

Phase I	Self-confrontation. The individual is provided with on-screen psychoeducation about the rationale of self-confrontation, or exposure. The individual writes an account of their trauma in the first person and present tense, including as much detail as possible and noting their fears and thoughts around the trauma.
Phase II	Cognitive-reappraisal. The goal is helping the individual to regain a sense of control. Individuals are given a writing exercise to provide encouraging advice for a hypothetical friend who has experienced a similar trauma.
Phase III	Individuals receive psychoeducation about the benefits of sharing, and are instructed to write a letter to themselves, or others who were involved in the trauma, about the trauma and how the trauma has changed them and how they are going to cope in the future.

Table 6: 'Interapy' intervention phases.

2.4.2.2 'Spring'

'Spring' (Lewis et al., 2013), is internet- and App-based and was developed by Cardiff University and Healthcare Learning Company, in line with Medical Research

(MRC) guidance for the development of a complex intervention (Craig et al., 2008). Informed by systematic reviews of the literature, 'Spring' was co-produced with people with mild to moderate PTSD, at a time when GSH interventions had not been sufficiently explored in the context of PTSD. Iterations of its development occurred through qualitative analysis of a series of focus groups and interviews with stakeholders, resulting in a prototype that was tested in a RCT (Lewis et al., 2013).

'Spring' is an eight-step GSH i-TF-CBT-based intervention. 'Spring' steps are described in Table 7 and a screen shot image of a webpage of the 'Spring' programme is included as Figure 2. The 'Spring' intervention includes a therapist manual (Appendix A), instructing on guidance to support users through steps and homework. Helpful tools and techniques are unlocked as the programme progresses, to assist with symptom management, and an individual's exit point is bookmarked so that they can restart at the point at which the left. Sessions commence with an initial hour-long session with a therapist, to introduce the programme, with further guidance scheduled fortnightly in 30-minute sessions, in person or on the telephone. A five-minute demonstration of the 'Spring' intervention is available via the following weblink: Spring - Guided self-help for PTSD - YouTube

Step 1	**Learning About My PTSD** – Psychoeducation about PTSD, illustrated by four actors describing their experience of PTSD to four different types of traumatic event.
Step 2	**Grounding Myself** – Explanation of grounding and its uses along with descriptions and demonstrations of grounding exercises.
Step 3	**Managing My Anxiety** – Explores the link between PTSD and anxiety and includes education around the benefits of relaxation with learning through videos of a controlled breathing technique, deep muscular relaxation, and relaxation through imagery.
Step 4	**Reclaiming My Life** – Explores why it is common for people with PTSD to stop doing some of the activities they used to enjoy and includes behavioural re-activation approaches to help individuals return to previously undertaken/new activities, for example setting weekly goals using a tool in the programme's toolkit. The user is encouraged to

	congratulate themselves on the goals they have managed to achieve, and to share their success with family and friends.
Step 5	**Coming to Terms with My Trauma** – This step allows the user to come to terms with their traumatic event, gradually and safely. It provides rationale for the imaginal exposure exercise to come, and narratives of the four video characters are provided. The therapist helps the participant to begin writing a narrative, which they complete remotely and read every day for at least 30 minutes. By the end of this step, it is hoped the user will find it less distressing to think about what happened and will also see some gradual improvement in traumatic stress symptoms, such as nightmares and flashbacks. The written account of the trauma becomes an active part of the toolkit, available to be edited.
Step 6	**Changing My Thoughts** – This step explores the link between PTSD and unhelpful thoughts and encourages the use to look at ways of changing the way they think. Cognitive techniques are used to address PTSD symptoms, for example a pie chart of responsibility, to allow the user to type in all of the factors and people that contributed to what happened during the trauma and the percentage of responsibility that applies to each.
Step 7	**Overcoming My Avoidance** – This step helps the user to gradually face their fears and overcome their avoidance of situations that remind them of the trauma. Through graded real life exposure work, for example developing a fear ladder, an individual can think about the things they've been avoiding, and can enter these in to a tool in the toolkit and can see the progress they are making.
Step 8	**Keeping Myself Well** – This session reinforces what has been learnt during the programme, provides relapse prevention measures and guidance on what to do if symptoms return.

Table 7: Steps covered in 'Spring' GSH intervention.

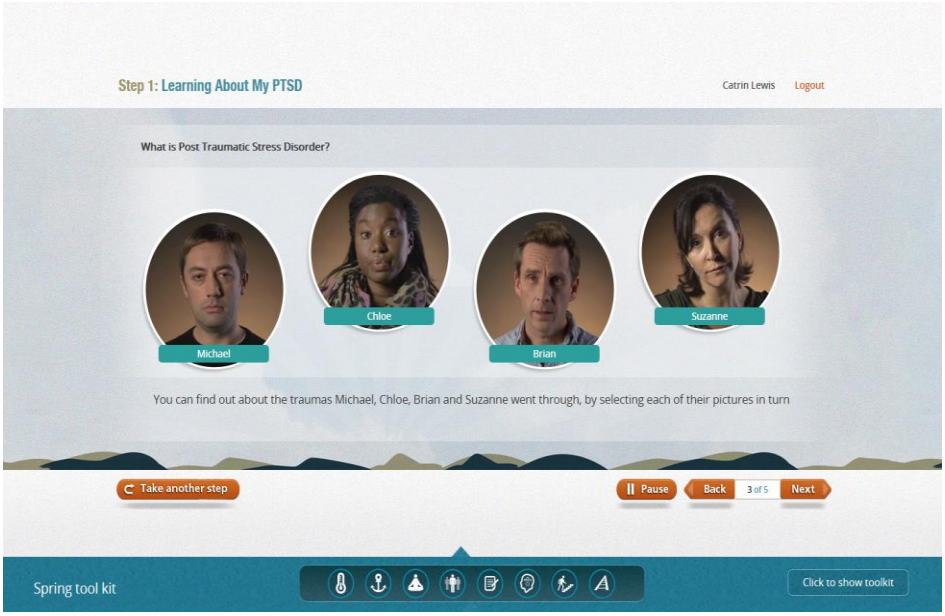

Figure 2: Screenshot of 'Spring', Step 1: Learning About My PTSD. Showing actors whose PTSD case histories are followed through the intervention. Also showing at the bottom of the webpage, the interactive 'toolkit'.

2.4.3 Evidence base for i-CBT for PTSD

Given the focus of this PhD, it is important to note the efficacy of the 'Spring' intervention, which has been demonstrated in a Phase II RCT design with 42 adults with DSM-5 PTSD of mild to moderate severity (Lewis et al., 2017a). Participants with PTSD to a single traumatic event were randomised to receive 'Spring' treatment either immediately or after a short waiting time. In an intention to treat (ITT) analysis, PTSD sufferers' symptoms improved by over 40% with an average of 149 minutes of therapist input; the authors noting this as around a fifth of that of the first line face-to-face therapies that were recommended by NICE (NCCMH 2005). At post-treatment and one-month follow-up, significantly lower levels of traumatic stress symptoms, depression, anxiety, and functional impairment were found for participants in the immediate treatment group, compared with the delayed treatment group, who improved to the same extent following receipt of the 'Spring' intervention. It should be noted that the participants in the study were highly educated, and the majority were employed, which limits the generalisability of the findings to people with PTSD more widely.

A Cochrane review of the evidence for i-CBT for PTSD was recently conducted (Simon et al., 2021a), which updated an original review by Lewis et al., (2018). The review included 13 studies with 808 participants. Ten of the studies compared i-CBT delivered with therapist guidance to a waitlist control. Two studies compared

guided i-CBT with i-non-CBT. One study compared guided i-CBT with face-to-face non-CBT. There was substantial heterogeneity among the included studies.

Very low-certainty evidence showed that i-CBT for PTSD was associated with a clinically important reduction in post-treatment PTSD symptoms, when compared with waitlist (SMD -0.61, 95% CI, -0.93 to -0.29; k=10, N=608). However, there was no evidence of a difference in PTSD symptoms when follow-up was less than six months (SMD -0.45, 95% CI, -1.29 to 0.39; k=4, N=154). Sensitivity analysis showed that, with very low-certainty quality of evidence, compared with waitlist, guided i-CBT may be associated with a clinically important reduction in PTSD post-treatment (SMD -0.78, 95% CI, -1.09 to 0.47; k=8, N=439). However, there was no evidence of a difference in PTSD symptoms post-treatment when comparing non-guided i-CBT with waitlist (SMD -0.09, 95% CI, -0.39 to 0.22; k=2; N=169). Sensitivity analysis also showed that, with low-certainty quality of evidence, compared with waitlist, i-TF-CBT may be associated with a clinically important reduction in PTSD post-treatment (SMD -0.94, 95% CI, -1.24 to -0.65; k=6, N=342). However, there was no evidence of a difference in PTSD symptoms post-treatment when comparing non-trauma-focused i-CBT with waitlist (SMD -0.16, 95% CI, -0.41 to 0.22; k=4; N=266).

Two studies found no difference in PTSD symptoms between the i-CBT and i-non-CBT groups when measured post-treatment (SMD –0.08, 95% CI, –0.52 to 0.35; k=2, N=82; very low-certainty evidence), or when follow-up was less than six months (SMD 0.08, 95% CI, –0.41 to 0.57; k=2, N=65; very low-certainty evidence).

Very low-certainty evidence based on one small study, suggested face-to-face non-CBT was more effective than i-CBT at reducing PTSD symptoms post-treatment (MD 10.90, 95% CI, 6.57 to 15.23; k=1, N=40).

In line with these findings are those of a previous systematic review of digital mental health interventions for PTSD, which found significant improvements in PTSD symptoms, in favour of the active intervention group (SMD=-.35, 95% CI, -.45 to -.25, $p<0.01$, $I^2=81\%$) in comparison with waitlist (Simblett et al., 2017). Though most interventions in Simblett et al's review were i-CBT for PTSD, with or without a trauma-focus, their review also included other interventions, for example mindfulness-based stress reduction.

In line with the findings from the Cochrane review (Simon et al., 2021b), greater effects have been shown for guided i-CBT elsewhere in the literature (Lewis et al., 2019, Cuijpers et al., 2015, Andersson et al., 2016, Andersson et al., 2019b,

Carlbring et al., 2017), and GSH is advocated within NICE guidelines for depression, general anxiety disorder, and panic disorder, and PTSD (NICE, 2009, NICE, 2011, NICE, 2018c). Importantly, the results of meta-analyses from the Lewis et al., review were taken forward as evidence in the generation of the ISTSS guidelines (ISTSSb, 2018).

There is however a dearth of evidence for the maintenance of symptom improvement at follow-up. For example, Lewis et al's Phase II RCT (Lewis et al., 2017a) did not assess participants beyond three months after treatment, limiting conclusions regarding longer term intervention effectiveness. This is a limitation across the literature in general. Simon et al's (2021a) systematic review found that only three of the included studies reported follow-up data and the maintenance of symptom improvement at follow-up of 3-6 months was not evident (Lewis et al., 2018). Sustained reductions in PTSD symptoms have been shown at 18-month follow-up (Knaevelsrud and Maercker, 2010), though the authors themselves acknowledge the limitations of their naturalistic follow-up study. Further RCTs with long-term follow-up are clearly required.

2.5 I-CBT acceptability

The growing evidence base for the efficacy of i-CBT was discussed in the previous section and is undoubtably of key importance. The evidence base for i-CBT falls short, however, with respect to another key factor; acceptability.

A scarcity of evidence for acceptability appears to be applicable across the healthcare literature, not unique to studies of i-CBT. To illustrate, treatment guideline developers place far less weight on a treatment's acceptability than its efficacy, when determining the strength of the evidence and putting forward recommendations (Hamblen et al., 2019). The limited understanding of treatment acceptability across the healthcare literature is of concern given that the extent to which an individual finds a treatment acceptable, or not, has been demonstrated to be associated with treatment outcome (Swift and Callahan, 2009), is also likely to affect treatment implementation (Wallin et al., 2016), and is widely recognised as vital in the roll-out of healthcare interventions (Craig and Petticrew, 2012, Craig et al., 2008). In other words, the extent to which a treatment is understood to be acceptable to patients and treatment providers, may influence its availability, adherence, and effectiveness. Treatment acceptability is thus crucial in the

treatment decision making process, which is now briefly covered, drawing broadly on the healthcare literature.

2.5.1 Treatment decision making: patient-centred care and shared decision making

'No decision about me without me' (DoH, 2012) (p.1)

Shared decision making is a process whereby clinicians and patients make treatment and care decisions together, as per evidence-based practice, and is informed by: the scientific evidence; a clinician's experience and training; and a patient's preferences and values (APA, 2006). Godolphin (2009) describes shared decision making as a process of open and honest communication between patients and healthcare providers, in which patients' treatment goals and preferences are considered and barriers to treatment engagement are addressed, in the context of the evidence-base.

Shared decision making is believed to be an integral part of person- or patient-centred care, a concept that has evolved since its first depiction in 1969 by Edith Balint as "*understanding the patient as a unique human being" (Balint, 1969) (p.271)*. A variety of terms and conceptualisations have been offered since then, for example McWhinny (1989) described a patient-centred approach as one where "*the physician tries to enter the patient's world, to see the illness through the patient's eyes"*. Broadly, descriptions acknowledge that symptoms that are important to one individual with a condition are not necessarily important for another individual with that condition.

Shared decision making is evidenced as leading to improved patient experiences and treatment outcomes and health-care provider satisfaction (McMillan et al., 2013, Swift and Callahan, 2009). Though previously not integrated into health care quality improvement, more recently principles of patient-centred care and shared decision making have been placed high on international and UK healthcare policy agendas (DoH, 2012, WHO, 2007, WG, 2015), and shared decision making is recommended alongside all NICE guidance (NICE, 2018b).

2.5.1.1 Decision aids to support patient-centred care

There are an increasing number of decision aids available to support shared decision making for people facing decisions about treatment or screening (BMJ, 2013). Decision aids typically outline treatment options and aim to help individuals consider the aspects of treatment that matter most to them and to raise these matters when making choices with their healthcare provider. Benefits and harms and scientific uncertainties are usually outlined, and individuals are encouraged to consider these things in relation to their values. Decision aids are thus different to common health education materials, which are not focused on decision points, but rather point to broad diagnostic, treatment, and management information (Stacey et al., 2017).

A decision aid and a process of shared decision making might draw an individual's attention to factors that matter to them when it comes to choosing the most suitable treatment, for example, culturally sensitive factors. In a RCT of web-based psychotherapy for PTSD in war-traumatised Arab patients, Knaevelsrud et al., (2015), discuss the development of their i-CBT programme, a cultural adaptation of the 'Interapy' programme. The authors note the cultural shaping of patients' expectations of healthcare professionals and that in Muslim countries healthcare professionals are authoritative and *"straight instructions and responsibility for therapeutic choices are expected"*, therefore shared decision making, and treatment acceptability may be culturally sensitive. Furthermore, the effective use of decision aids might assist an individual to engage with their chosen treatment, for example Stecker and colleagues (2013) note veterans with PTSD struggling with treatment engagement due to concerns about providers not understanding them or their unique situation, and not taking their treatment preferences into consideration.

Improved PTSD treatment initiation, retention and outcomes have been shown for individuals using patient decision aids in a limited number of studies (Mott et al., 2014, Watts et al., 2015, Schottenbauer et al., 2008). A Cochrane review of decision aids for health treatment or screening decisions, included 105 RCTs (Stacey et al., 2017), and concluded their use to be positive, overall. The review found that 12 of the 105 RCTs were at high risk of bias, and that further research is required. Overall, the aids were shown to improve patients' knowledge of options, to assist individuals in feeling clearer about what matters most to them and resulted in individuals participating more in decision making and achieving decisions

consistent with their values. No adverse effects on health outcomes nor satisfaction were found.

There is an increasing recognition for the utility of decision aids in promoting patient choice within healthcare policy, for example UK healthcare policy (NICE, 2018b). Measures have been taken to quality control their production and availability, including the use of the International Patient Decision Aid Standards instrument (IPDASi), which assesses the quality of decision support technologies (Elwyn et al., 2009).

Effective treatment decision making therefore relies not just on an understanding of a treatment's efficacy but also on a treatment's acceptability. Understanding and measuring treatment acceptability is however not straightforward and its operationalisation is now discussed in detail, again drawing broadly across the healthcare literature.

2.5.2 Defining and measuring treatment acceptability

Acceptability has been described as a facet of healthcare quality (Maxwell, 1992), and a wide variety of measurements are reported in the healthcare literature, though explicit theories and definitions are lacking.

Literature attempting to define, and measure treatment acceptability is mainly found within childhood behavioural work, with an emphasis on 'social perception', including:

> *"the judgements about the treatment procedures by nonprofessionals, lay persons, clients and other potential consumers of treatment" (Kazdin, 1980) (p.259).*

A smaller literature base exists for the acceptability of behavioural interventions in adults. A definition by Hunsley (1992), includes judgements of the therapists who suggest and implement treatments, in addition to the judgements made by non-professionals, lay persons, clients and other potential consumers of treatment. Hunsley reports that this definition acknowledges counselling and psychotherapy literature, and that patient perceptions of therapists as trustworthy and knowledgeable are strongly linked to therapeutic intervention effectiveness.

There exist various widely used and cited acceptability measures in the field of behavioural psychology, for example the Treatment Evaluation Inventory (Kelley et al., 1989), and the Treatment Acceptability Questionnaire (Hunsley, 1992), however there appear to be fewer standardised measures of acceptability in other areas of healthcare. In an overview of 43 reviews and studies across healthcare interventions, measurements varied widely and no explicit theory or definition for acceptability was found (Sekhon et al., 2017). The reviewers reported that acceptability was assessed according to self-report measures in 12 of the included studies, including satisfaction measures (k=6), attitudinal measures, perceptions of, and experience with interventions, and reported side effects. Over half (k=23), of the included studies that were accessed via the Cochrane Database of Systematic Reviews assessed acceptability according to objective measures of behaviour, with dropout rates commonly adopted. This work attempted to address a lack of instruction by the UK's MRC in defining and operationalising acceptability, despite referring to acceptability within their documents, for example guidance on developing and evaluating complex interventions (Craig et al., 2006). The authors concluded that a combination of self-report measures of acceptability, which might include standardised acceptability measures, and/or treatment satisfaction measures, in addition to observed behaviour measures, for example uptake and dropout, may provide a clearer picture of an intervention's acceptability.

2.5.2.1 Treatment acceptability measures

Treatment acceptability measures do exist, though there is no gold standard measure. Whilst much of the literature points to actual or experienced acceptability, some suggests acceptability depends on a person's views about treatment options and their judgement of acceptability *prior to* participating in an intervention. Sidani et al., (2009) developed the Treatment And Preference (TAP) measure of perceived acceptability, with items relating to perceptions about the intervention's convenience and effectiveness in managing the clinical problem, and its suitability to an individual's lifestyle. Another example of an *anticipated acceptability* measure is the Treatment Acceptability/Adherence Scale (TAAS) (Milosevic et al., 2015).

I-CBT treatment acceptability measures

Measures exist in the literature, though are often developed specifically for a study. For example, the Internet-based Interventions Acceptability Questionnaire - Indonesia (IIAQ-ID) (Arjadi et al., 2018). There is no gold standard measure for i-CBT acceptability.

2.5.2.2 Proxy indicators of acceptability

Informed by a non-systematic review of the general healthcare literature, the following proxy indicators of acceptability are now considered: treatment engagement/adherence; treatment satisfaction; and therapeutic alliance.

Treatment engagement / adherence

The literature includes various definitions for treatment engagement, including the terms adherence, and compliance. The WHO uses the term adherence and suggest it to be the extent to which one's behaviour corresponds with agreed treatment recommendations (WHO, 2003). Engagement in PTSD treatment, for example, is discussed by Kehle-Forbes and Kimerling (2017), who suggest it to be the behaviours required to achieve optimal benefit from health care. The authors propose treatment initiation, retention and adherence being the aspects of engagement most often examined in the literature, stating these aspects are useful indicators, reflecting more broadly the domains of behaviour that constitute engagement. Indeed, theories of patient adherence, or engagement, tend to draw on behavioural constructs, such as the theory of planned behaviour, and self-efficacy models (Brawley and Culos-Reed, 2000).

Adherence is operationalised in various ways in the literature, including through treatment uptake and dropout, or the percentage of participants randomised who finished a course of treatment (Andrews et al., 2018), or the total number of sessions completed shared by the total number of treatment sessions (Karyotaki et al., 2017). As noted previously, Sekhon et al's review (2017) found that more than half of the included studies assessed acceptability by objective measures of uptake/adherence, most commonly reporting dropout rates.

Pharmacological treatment adherence is more commonly and consistently reported in the literature, compared with adherence to, or engagement with, psychological treatment, and is measured in terms of compliance, or the extent to

which an individual follows a recommended medication dosage. It is of concern that adherence to non-pharmacological psychological/psychosocial treatment is reported far less frequently. Whilst it could be argued that psychological/psychosocial treatments may be more flexible and tailored to the patient, perhaps resulting in less straightforward adherence measurement, this is not a reason adherence should not be routinely collected and reported. Models have been developed to assess psychotherapy treatment adherence, specifying psychotherapies in terms of 'dosage' (frequency and number of sessions), the therapy 'ingredients', condition of administration/assessment and whether the treatment was adequately delivered to all patients (Carroll et al., 2000).

Importantly, adverse effects are likely to impact on treatment engagement, in particular attrition. Adverse effects therefore ought to be considered with respect to treatment acceptability, however they are often not considered or reported. For example, in a Cochrane review of 70 psychological therapies for PTSD in adults, no adverse side effects were considered or reported, a matter of concern pointed out by the review authors, particularly given the potential for re-experiencing following exposure treatment (Pitman et al., 1991).

I-CBT adherence

Though there is no common or widely accepted definition or understanding of adherence in internet-based interventions (Sieverink et al., 2017), i-CBT engagement has been proposed as the degree to which an individual engages with online intervention content (Christensen et al., 2009). This is of vital importance in the case of i-CBT, given that it is a relatively novel mode of treatment delivery where there is an emphasis on self-help and homework. Online intervention reporting guidelines are available, addressing adherence, or engagement (Eysenbach, 2011), and call for reporting of usage in primary publications, discouraging the commonly practised splitting of outcome and adherence, and other findings, into several publications. There is an increasing focus on treatment adherence in the literature in general, including i-CBT, yet standards for measuring and reporting are still variable.

Beintner et al., (2019), performed a systematic review of RCTs of internet-based interventions for the prevention and treatment of common mental disorders, to examine adherence reporting. The reviewers found substantial variety in the metrics used. Adherence had been addressed in 85% of full-text manuscripts, but

only in 13% of abstracts. The most frequently reported usage metric was completion of an intervention, which had been reported in 61% of the manuscripts. The reviewers offered suggestions for the number and type of appropriate metrics, depending on the design and delivery mode of an intervention. For example, for the guided interaction in a GSH intervention, such as the number of messages sent, may be a metric of importance, and completion of exercises might be a metric that is considered if authors wish to capture 'deeper content-focused engagement'. The authors also noted that developers of internet-based interventions may incorrectly assume their intervention works optimally if "*all users expose themselves to all parts of the content, and other patterns of use are rarely considered*". The authors suggested that adherence should be addressed from the following perspectives: progress through the intervention; and level of active engagement with the intervention's content, though the difficulty in measuring the latter had been acknowledged. Interestingly, whilst the review did not evaluate the relationship between adherence and outcome, it was found that adherence and its relation to outcomes was more frequently included in manuscripts published in specialised eHealth journals, compared with non-specialised journals, which suggests more importance is placed on adherence in the field of eHealth than in general medicine. Though the review did not allow for the inclusion of RCTs for PTSD, the findings may be applicable to the PTSD literature, and it is clear from this study that the general variability in measurement and reporting of adherence limits the comparability of trial results, which is of great concern.

Therapeutic alliance

Therapeutic alliance is the relationship between therapist and client and is often considered a cornerstone in psychological treatment, an essential ingredient in psychotherapy (Bordin, 1979), and important for supporting individuals to feel safe for trauma treatment engagement (Wild et al., 2020c). Hunsley's expansion of Bordin's definition of acceptability, to include not just judgements about treatment procedures but also judgements about the therapist, highlights the importance of the therapeutic alliance in psychological treatment acceptability (Hunsley, 1992). The adaptation was made to acknowledge the evidence base suggesting patient perceptions of therapists as trustworthy and knowledgeable are strongly linked to therapeutic intervention effectiveness. Indeed, a robust yet modest association has been demonstrated between therapeutic alliance and treatment outcome

across psychological treatments (Horvath et al., 2011), including PTSD treatment outcome (Capaldi et al., 2016, Knaevelsrud and Maercker, 2006).

There are several standardised measures in existence, for example the Working Alliance Inventory (WAI) (Horvath and Greenberg, 1989), the Therapeutic Alliance Questionnaire (TAQ) (Luborsky, 1996), and the Agnew Relationship Measure (ARM), which comprises parallel patient and therapist versions asking about the same person's experiences viewed from two perspectives (Agnew-Davies et al., 1998).

I-CBT therapeutic alliance

There is a limited literature concerning therapeutic alliance in the specific i-CBT context (Berger, 2017). I-CBT studies have however utilised standardised measures of therapeutic alliance, for example one study used the WAI to examine therapeutic alliance in the i-CBT programme 'Interapy' (Knaevelsrud and Maercker, 2007), demonstrating a strong alliance. Another study used the TAQ in an open trial evaluation of the i-CBT intervention 'PTSD Online' (Klein et al., 2010).

Treatment satisfaction

Treatment satisfaction is another proxy indicator and facet of acceptability in the literature. Sekhon et al's review (2017), found satisfaction measures were used to infer acceptability in six healthcare intervention studies. The authors highlighted that whilst treatment satisfaction may be used as a proxy indicator of acceptability, it is limited given that it can only relate to *experienced* acceptability and not to *anticipated* acceptability. In a systematic review of studies comparing virtual-reality exposure-based therapy for PTSD to another treatment or waitlist (2015), very few of the 48 included studies evaluated or reported acceptability, but for those that did, satisfaction was measured, as well as expectations prior to treatment, with some studies including qualitative data.

I-CBT treatment satisfaction

Satisfaction was used, along with measures of adherence, to indicate acceptability in a meta-analysis of 22 studies of i-CBT for people meeting diagnostic criteria for depression, panic disorder, social phobia or generalised anxiety disorder (Andrews et al., 2010). Kaltenthaler et al., (2008) reviewed acceptability of i-CBT for

depression, considering acceptability as any of the following information sources: take-up rates; drop-out rates and reasons; questionnaires or surveys of acceptability or satisfaction. They found 12 of the 16 included trials reported largely positive acceptability and satisfaction information from treatment completers. Unfortunately, none provided information for the large percentage of participants who had dropped out. Satisfaction, and intervention usability were measured and reported in a study that examined the acceptability of an exposure-based internet-based intervention for flying phobia (Campos et al., 2018).

2.5.3 I-CBT acceptability evidence base

2.5.3.1 Systematic reviews

As noted previously, the evidence base for i-CBT falls short with respect to acceptability. Encouragingly however, in 2006 the UK Health Technology Appraisal commissioned a systematic review of i-CBT for depression and anxiety which did consider treatment acceptability when evaluating treatment effectiveness (Kaltenthaler et al., 2006). This review found overall acceptability for i-CBT, for the five of the 20 included studies that reported on it, however the authors note that other treatment options would need to be available for NHS patients who do not have internet access or do not wish to use i-CBT and that careful monitoring of suicide risk would be required.

More recently, a systematic review of 49 included studies examined the acceptability of online and App interventions for individuals with severe mental health problems (Berry et al., 2016). Hypothetical, or anticipated acceptability was measured as individuals reporting an interest in receiving the online intervention, which was reported in seven of the included studies, and actual acceptability was measured in terms of satisfaction ratings and intervention use and module completion rates and was reported in 42 of the studies. Hypothetical acceptability was found to be relatively low, however actual acceptability was higher, in particular for interventions where there was provision of remote online support. The authors noted that some studies reported qualitative information regarding participant views, and themes that emerged included concerns about technical issues, online intervention privacy, and the importance of an engaging delivery format and of the inclusion of peer support. The reviewers concluded that the disjunct between hypothetical and actual acceptability is a reason for future

research to continue to examine both constructs to monitor whether perceptions change after intervention use.

Kantor et al., conducted a systematic review of barriers and facilitators to mental health service utilisation in adult trauma survivors (2017). The review examined treatment utilisation in general, though the findings might be applicable to attitudes towards i-CBT for PTSD. Key barrier themes were identified and ordered as follows: 1) low mental health literacy, described as a disbelief that symptoms are an aspect of mental ill health; 2) availability/resources, that is access problems or language barriers; 3) concerns about stigma, shame, and rejection, including embarrassment or fear of being labelled; 4) having no time; 5) lack of knowledge about treatment and what services are about; 6) not wanting to talk about the trauma; 7) expenses; 8) mistrust about confidentiality; 9) alternative ways of coping, for example alcohol and drug use; 10) fearing negative social consequences, such as treatment seeking impacting on one's career; 11) lack of encouragement to seek professional help; 12) negative experiences with professional help; and 13) prioritising needs of others, for example feeling others need more help.

2.5.3.2 Perspectives of healthcare providers

A survey of mental health services use of internet-based therapies for stress, anxiety and depression in England found inconsistency in their use and their recommendation across the country (Bennion et al., 2017), and LI treatment adoption in clinical practice, remains limited (Mohr et al., 2017). The gap between promising research findings and low uptake has been reported elsewhere (Andersson et al., 2019b), including findings from eight European countries (Topooco et al., 2017). The European MasterMind project has been designed to address this gap, to increase and evaluate uptake and implementation (Vis et al., 2015).

Possible explanations for the low adoption of i-CBT in the UK include negative attitudes towards internet-based interventions amongst staff responsible for their implementation, and NHS system-wide implementation barriers. Indeed, the literature reports therapists' perceptions that the therapeutic alliance, considered by many to be the cornerstone of therapy, may be threatened in i-CBT interventions (Thew, 2020). These views are not, however, supported by the available evidence. For example, equality of alliance in online and face-to-face therapy is suggested (Andersson et al., 2012a, Hadjistavropoulos et al., 2017, Berger, 2017). Research

concerning panic disorder and agoraphobia has found no difference in therapeutic alliance between i-CBT and in-person face-to-face CBT (Kiropoulos et al., 2008). Most studies to date have examined alliance measures only at post-treatment and have considered only ratings of therapeutic alliance from the perspective of patients and not from their therapists.

Other therapists' perceptions reported in the literature include views that such interventions are lacking in evidence, that they will not be as effective as face-to-face approaches, that they are only suitable for less severe problems, and that they will fail to meet patient expectations (Thew, 2020).

European studies have examined psychotherapists' perspectives of internet-based therapies (Topooco et al., 2017, Schuster et al., 2020, Mol et al., 2020, Dijksman et al., 2017), and qualitative interviews have been conducted with UK PWPs (Gellatly et al., 2017, Lovell et al., 2017). Topooco et al., (2017) explored views on implementing internet-based interventions into regular care services, from a range of stakeholders consisting of individuals in organisations representing government bodies, care providers, service users, funding/insurance bodies, technical developers, and researchers. The findings revealed that perceived barriers included concerns about the therapeutic process and that perceived advantages included flexibility and cost-efficiency. Low feasibility or non-readiness within present care systems to implement and integrate internet-based and blended treatments was also considered a barrier. There was higher overall acceptance for blended-treatment and GSH over non-guided approaches and for interventions intended to treat mild forms of disorders. As noted by the authors themselves, the stakeholders were convenience sampled and the sample varied in its representation across countries. Also, some of the barriers proposed seemed to be based on assumptions about other stakeholder groups, for example negative attitudes from patients and professionals as a barrier to implementation, which was put forward by government bodies. Similar findings were reported in the Schuster et al., (2020) and Gellatly et al., studies (2017).

The perceived advantages of flexibility and cost-efficiency, concerns about therapeutic processes and implementation non-readiness, and higher acceptance for GSH over non-guided approaches were also identified in a recent systematic review of health professionals' perspectives on implementing internet-based therapies in routine mental health care (Davies et al., 2020).

Research conducted in the UK to date has focused on the views of PWPs and of healthcare professionals more generally (Gellatly et al., 2017, Lovell et al., 2017, Davies et al., 2020). Broader implementation of internet-based therapies across the NHS requires knowledge of the views of NHS employees involved in intervention commissioning and implementation, given their unique position in understanding additional factors that are likely to impact this process.

2.5.4 I-CBT for PTSD acceptability evidence base

The evidence base for the acceptability of i-CBT for PTSD is scarce. Understanding the acceptability of i-CBT for PTSD is vital given that it is a relatively new treatment mode in the unique PTSD population.

Lewis et al., (2012), conducted a systematic review of the efficacy, cost-effectiveness and acceptability of multimedia self-help interventions for individuals diagnosed with an anxiety disorder, including PTSD. The authors considered acceptability in terms of any formalised measure of satisfaction and of the 31 RCTs included in their review, none assessed the acceptability of self-help approaches. The authors concluded the need for further research.

I-CBT interventions for PTSD have considered acceptability in their development, however this has often been hampered by limitations in the subsequent measurement of acceptability. To illustrate, the 'Spring' intervention was developed with the intention of maximising not just on efficacy but also on acceptability, systematically developed following MRC guidelines and with a high degree of service user input (Lewis et al., 2013). Its measurement at Phase II RCT (Lewis et al., 2017a) was inferred through the number of participants dropping out of treatment post-randomisation. There are however limitations of using the typical indicators of adherence, that is dropout and non-uptake, to interpret acceptability, and this is apparent across the healthcare literature. To illustrate, according to a review of barriers to the uptake of i-CBT (Waller and Gilbody, 2009), high acceptability was found among individuals participating in studies, despite low uptake rates, with several possible explanations for this, including potential research participation burden, completing lengthy questionnaires (Sanders et al., 2012), and level of perseverance in contacting hard to reach participants.

2.5.4.1 Therapeutic alliance and the importance of guidance

Clinicians frequently report concern about using trauma interventions in general with exposure (Schumacher et al., 2018), for fear of tolerability and re-traumatisation (Cook et al., 2004). For example, a systematic review of 34 studies found that one of the most influential client-level barriers to a clinicians' utilisation of PTSD evidence-based treatment was a clinician concerns about re-traumatising the client, or making their symptoms worse (Finch et al., 2020). A survey of psychologists' attitudes towards trauma-focused work found concerns about tolerability and dropout to be amongst the main reasons for its limited utilisation, despite its evidence-base (Becker et al., 2004).

Therapeutic alliance may impact the extent to which an individual engages with or tolerates a treatment (Imel et al., 2013). Kehle-Forbes and Kimerling (2017), discuss the importance of therapeutic alliance in PTSD psychological work. They discuss the importance of patient and clinician communication and feedback, given the suggestions that early and strong therapeutic alliance may mediate some of the difficulties that might arise during trauma intervention work, including exposure content. Indeed, research has demonstrated the maintenance of alliance throughout trauma-focused therapies (Capaldi et al., 2016).

The potential for therapeutic alliance to assist during trauma-focused work may extend also to i-TF-CBT, though the literature is very limited. Knaevelsrud and Maercker's (2007), study of the GSH i-TF-CBT 'Interapy' measured ratings from both patients and therapists, both during and post-treatment. They found high ratings of the seven-point scale of alliance at both timepoints, for both patients and therapists, using the short 12-item version of the Working Alliance Inventory (WAI-SR) (Busseri and Tyler, 2003). During treatment, the mean score for the patients' view of therapeutic alliance was 5.8 (SD=0.64), and the therapists mean score was 6.3 (SD=0.54). At post-treatment, the mean score for patients was 5.6 (SD=0.72), and for therapists was 5.8 (SD=0.98). Furthermore, ratings increased from the two-week timepoint during treatment to the five-week time-point post-treatment, though not to a statistically significant level in the case of therapist ratings. Patient ratings post-treatment were found to be significantly associated with the primary self-reported outcome, but not to a significant level for therapist ratings. The authors acknowledge as a limitation of this study the fact that the intervention was examined against a waitlist, therefore there was no control group against which the outcomes at follow-up could be compared. This limited evidence does suggest a positive therapeutic alliance can be formed in GSH i-CBT for PTSD, even for trauma-

focused interventions, at least from the patient perspective, and to a similar extent to that found for face-to-face therapies (Berger, 2017), however further research is required.

It is important to note that dropout is frequently used to indicate treatment tolerability. A systematic review of dropout from RCTs of psychological therapies for PTSD (Lewis et al., 2020a), found typically high dropout with a pooled rate of treatment dropout of 16% (95% CI, 14 to 18%), with evidence that trauma-focused psychological therapies were significantly associated with greater dropout. As noted previously however, interpreting treatment tolerability through dropout may be problematic. This was acknowledged by authors of the review themselves who highlighted that few studies provided explanations for dropouts. Dropout is inconsistently operationalised though mostly defined as those individuals who dropout prior to the end of treatment. Whilst dropout might in some cases indicate intolerability, and non-improvement of symptoms, research has also shown that some individuals who have dropped out of treatment have also displayed significant gains in symptomatology and might be better defined as early treatment responders (Szafranski et al., 2017). This suggests a need for consistent implementation and operationalisation of dropout and regular symptom checking throughout treatment to better acknowledge any sudden therapeutic gains and better understand any dose-response effect.

2.6 Chapter summary

This chapter explored the development of i-CBT, and i-CBT for PTSD, with specific interventions outlined. There is a growing evidence base for the efficacy of i-CBT for PTSD, presently allowing for a moderate recommendation to be given to GSH i-CBT with a trauma focus (NICE, ISTSS, VA/DoD).

Much less is known with respect to i-CBT acceptability, not least i-CBT approaches for people with PTSD. The limited research and knowledge are due in part to the wide variability in acceptability operationalisation and reporting and arguably because it is not fully acknowledged as a key treatment factor. The available findings suggest i-CBT for PTSD to be an acceptable psychological treatment, however, there appears to be some resistance towards its adoption, particularly with respect to concerns around whether a therapeutic alliance can be established and maintained in GSH i-CBT.

Despite the challenges with its operationalisation, treatment acceptability should be measured. Careful consideration of its measurement is required. It appears to be a multifaceted and complex construct, incorporating measures of intervention usage and adherence, along with measures of satisfaction, therapeutic alliance, and qualitative views from the perspectives of patients and treatment providers.

With the planned expansion of Improving Access to Psychological Therapies (IAPT) services, and the increasing evidence for the effectiveness of i-CBT, it may be timely to implement LI i-CBT approaches at scale within NHS and other services. Whilst the efficacy of a treatment is indeed important, it is not sufficient in terms of treatment decision making, and the extent to which i-CBT for PTSD is perceived as acceptable, or not, to patients, healthcare providers, and commissioners, will be a crucial consideration.

3. Chapter Three: Aims

The aims of this PhD were:

1) To systematically review and analyse the available evidence for the acceptability of i-CBT interventions for adults with PTSD.

2) To determine through a mixed methods approach, including RCT design and qualitative interviewing: a) the acceptability of a GSH i-TF-CBT intervention, 'Spring', for adults with mild to moderate PTSD, and how this compares with the acceptability of an individual face-to-face TF-CBT intervention, and b) whether treatment outcome is influenced by treatment acceptability.

3) To evaluate the acceptability of internet-based psychological therapies from the perspective of NHS commissioners and managers implementing and facilitating access to mental health interventions.

4. Chapter Four: Methods

Part One of this chapter describes a systematic review and meta-analyses of the available evidence, undertaken in pursuit of the first aim of this PhD, to synthesise the available evidence for the acceptability of i-CBT for PTSD (Simon et al., 2019a). The methods and analyses employed in pursuit of aims two, three and four of the PhD are described in part two.

4.1 Part One. Methodology for the systematic review and meta-analyses of the available evidence for the acceptability of i-CBT for PTSD

A protocol of the mixed-methods approach, examining RCTs of i-CBT for PTSD, was published (Simon, 2017), by PROSPERO, an international prospective register of systematic reviews (Booth et al., 2011). Acknowledging acceptability as multi-faceted, Sekhon et al's (2017) definition of acceptability was adopted as a working definition for the review:

> *"a multi-faceted construct that reflects the extent to which people delivering or receiving a healthcare intervention consider it to be appropriate, based on anticipated or experienced cognitive and emotional responses to the intervention." (Sekhon et al., 2017) (p.14)*

The outcomes of interest were standardised measures of acceptability, either self-reported, or clinician-administered, and proxy indicators of acceptability, which included treatment non-uptake and dropout, adverse effects, and standardised measures of satisfaction.

4.1.1 Selection criteria

Selection criteria are displayed in Table 8.

Criteria for considering studies
Randomised cross-over trials, and cluster-randomised trials evaluating the efficacy of internet/App based cognitive/behavioural therapies aimed at reducing symptoms of PTSD in individuals aged 16 and over.
At least 70% of participants were required to be diagnosed with PTSD according to DSM/ICD criteria, consistent with other reviews of psychological therapies for PTSD (Lewis et al., 2018).
Co-morbidity was allowed if PTSD was the primary diagnosis and a reduction in PTSD symptoms was the primary aim of the intervention.
Studies were eligible if they included therapies delivered with or without guidance from a therapist, and if they provided up to a maximum of five-hours of therapist guidance, delivered face-to-face or remotely.
No restrictions were placed on number of interactions with a therapist or length of the online programme.
No restrictions were placed on the basis of duration or severity of PTSD symptoms or the type of traumatic event, or time since trauma.
Eligible comparator interventions were face-to-face psychological therapy; waitlist/minimal attention/repeated assessment/usual care; and non-CBT internet-delivered psychological therapy.
Only studies published in English
No minimum sample size
Unpublished studies were eligible

Table 8: Study inclusion criteria

Randomised cross-over trials, and cluster-randomised trials of i-CBT for PTSD, were eligible, for optimal confidence interpreting findings, given the rigorous methodology/reporting expected of these designs.

4.1.2 Search strategy

A search strategy used for a review of the efficacy of i-CBT for PTSD was adopted (Lewis et al., 2018). Search terms were identified and these are displayed in Table 9. The Cochrane Common Mental Disorder's Group's Information Specialist ran initial searches of the Cochrane Common Mental Disorders Group (CCMDG) clinical trials registers databases, for studies published up to 2nd March 2018 (see Appendix B for information on this specialised register). These databases are updated weekly from searches of OVID MEDLINE (from 1950), Embase (from 1974), and PsycINFO (from 1967), quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL), and review-specific searches of additional databases. Reference lists of studies and reviews were checked, and the WHO's International Clinical Trials Registry Platform was searched, to identify additional unpublished/ongoing studies. Authors of included studies were contacted, to identify unpublished/submitted studies and a search of the Published International Literature on Traumatic Stress (PILOTS) database was conducted. Abstracts of studies identified in the search and full-text publications of potentially eligible studies were screened independently by myself and another author, Leah McGillivray (LM), and whilst we had put in place a procedure to resolve any disagreements with the input of a third reviewer, Catrin Lewis (CL), full inter-rater agreement meant that this was not required.

Search terms used for the CCMDCTR-Studies Register electronic search:	
Condition = (PTSD or *trauma* or "acute stress" or "stress reaction") AND Intervention = (computer* or internet or web* or online or self-help or self-manage* or self-change)	
Sensitive search terms used for the CCMDCTR-References Register electronic search (to identify additional untagged or uncoded reports of RCTs):	
#1.	(PTSD or *trauma* or "combat disorder*" or "stress reaction" or "acute stress" or "stress disorder" or "war neurosis"):ab,ti,kw,ky,emt,mh,mc
#2.	(self near3 (care or change or guide* or help or intervention or manag* or support* or train*)):ab,ti,kw,ky,emt,mh,mc
#3.	(android or app or apps or audio* or blog or iCBT or cCBT or i-CBT or c-CBT or CD-ROM or "cell phone" or cellphone or chat or computer* or cyber* or distance* or DVD or eHealth or e-health or "electronic health*" or e-Portal or ePortal or eTherap* or e-therap* or forum* or gaming or "information technolog*" or "instant messag*" or internet* or interapy or ipad or i-pad or iphone or i-phone or ipod or i-pod or web* or WWW or "smart phone" or smartphone or "mobile phone" or e-mail* or email* or mHealth or m-health or mobile or multi-media or multimedia or online* or on-line or

	“personal digital assistant” or PDA or SMS or "social medi*" or Facebook or software or telecomm* or telehealth* or telemed* or telemonitor* or telepsych*or teletherap* or "text messag*" or texting or tape or taped or video* or YouTube or podcast or virtual* or remote):ab,ti,kw,ky,emt,mh,mc
#4.	(#1 and (#2 or #3))
Complementary search on PILOTS (Published International Literature on Traumatic Stress) database	
Relevant subject headings and search syntax (1990 to 2 March 2018)	
To identify unpublished or ongoing studies:	
1.	Search on the World Health Organization International Clinical Trials Registry Platform (ICTRP) and ClinicialTrials.gov to 2 March 2018
2.	ProQuest Dissertations and Theses Database
3.	National Guideline Clearing House (guideline.gov/)
4.	Worldwide Regulation Agencies (www.globepharm.org/links/resource_agencies.html)
5.	Open Grey (www.opengrey.eu/)
To check for studies we may have missed	
1.	Scrutinised reference lists of included studies
2.	Cited reference search on Web of Science
3.	Contact made with trialists and subject matter experts for information on unpublished or ongoing studies.

Table 9: Systematic search strategy including electronic search terms

[Key to CRS field tags: ab:abstract; ti:title; kw:CRG keywords; ky:other keywords; emt:EMTREE headings; mh:MeSH headings; mc:MeSH checkwords]

4.1.3 Data extraction

Systematic extraction of study methodology, participant characteristics, interventions, outcomes, treatment uptake and dropout, was conducted by LM and I, separately, using a pre-designed data extraction form. The primary measures of interest are listed in Table 10, and measures of acceptability, including proxy indicators were the main outcomes of interest, rather than the primary outcomes of the included studies themselves, which was a reduction in PTSD symptoms in every case.

Primary outcome measure	*Definition*
Standardised acceptability measure	Any standardised measure of acceptability, at any time point, self-reported or clinician-administered
Non-uptake rate	Percentage of individuals offered but not taking treatment
Dropout or lost to follow-up rate	Dropout or lost to follow-up rate from baseline and prior to treatment completion, as a percentage
Adverse effects	Indicated by increased PTSD symptoms from baseline to last available follow-up, measured using a standardised scale, for example the Clinician Administered Scale for PTSD (CAPS-5) (Weathers, 2013a), or any other adverse effect reported from baseline including increased self-harm and suicide
Satisfaction measure	Any standardised measure of satisfaction administered from baseline
Internet-based Cognitive Behavioural Therapy programme usage	Module completion / logons / self-reported usage / homework completion

Table 10: Systematic review primary outcome measures

4.1.4 Data synthesis plan

Meta-analyses for dropout was planned, as a proxy of acceptability, if sufficient quantitative data were available across all studies. I planned to enter data into the Cochrane Collaboration's Review Manager (RevMan) software (2014), and categorical outcomes would be analysed as risk ratios (RRs), using 95% confidence intervals. I planned to assess clinical heterogeneity by looking at variability in the experimental and control interventions, participants, settings, and outcomes, and to further assess heterogeneity through the I^2 statistic and the chi-squared test of heterogeneity, as well as a visual inspection of the forest plots. I intended to pool data using a fixed-effect meta-analysis where homogeneity was present, and with

random-effects meta-analysis where heterogeneity was present, and planned to generate funnel plots to assess reporting bias if a meta-analysis included more than ten studies (Higgins et al., 2019).

I also planned to adopt a narrative synthesis methodology to bring together evidence, given the likely limited number of included studies with insufficiently similar acceptability measures. Narrative synthesis is an approach described as a form of *"trustworthy story-telling"*, and *"taking a textual approach to the process of synthesis"* (Popay, 2006). This would allow for the organisation and description of extracted data which would be interpreted and refined by myself and two of the co-authors, CL, and LM, written up in a story-telling narrative.

Each study was assessed for risk of bias using Cochrane Criteria (Higgins et al., 2019), and another author, LM, also did so, independent of my assessment. This examines for sequence allocation for randomisation, to ensure there is a specified rule for allocating interventions to participants, based on a chance (random) process. Allocation concealment is assessed, to ensure strict implementation of the allocation process by preventing foreknowledge of forthcoming allocations. Blinding of assessors is assessed, to ensure protection of bias after assignment (which cannot always be implemented). The criteria also assess for incomplete outcome data, and selective outcome reporting, for example failures to report, as well as any other notable threats to validity such as premature termination of the study, or non-manualised intervention. LM and I set out to discuss any discrepancies with a third researcher, CL, to reach a unanimous decision.

Data extraction and synthesis was planned and conducted in line with Cochrane Collaboration Guidelines (Higgins et al., 2019), and Preferred Reporting Items for systematic reviews and meta-analyses (PRISMA) (Moher et al., 2009).

4.2 Part Two. Methods and analyses of a mixed methods RCT to determine the acceptability of GSH i-TF-CBT.

Mixed methods data collection and analyses were employed to achieve aims two and three of this PhD, as outlined in Table 11. Integrating quantitative and qualitative data collection and analysis allowed for a richer, more comprehensive dataset, generating deeper insight than when either method is used alone (Alan, 2003).

PhD Aim	Description of Aim	Analyses
Aim 2	To determine through a mixed methods approach, including a RCT design and qualitative interviewing: a) the acceptability of a GSH i-TF-CBT intervention, 'Spring', for adults with mild to moderate PTSD, and how this compares with the acceptability of an individual, face-to-face TF-CBT intervention, and b) whether treatment outcome is influenced by treatment acceptability.	Analysis of Covariance (ANCOVA) using version 23.0 of the Statistical Package for Social Science, SPSS (IBM 2019). Multiple regression using the Statistical Package for Social Science, SPSS (IBM 2019). Thematic framework analysis of participant and therapist interviews, organised through QSR NVivo 12 qualitative data analysis software (QSR, 2020).
Aim 3	To evaluate the acceptability of internet-based psychological therapies from the perspective of NHS commissioners and managers implementing and facilitating access to mental health interventions.	Thematic framework analysis of interviews with NHS commissioners and managers, organised through QSR NVivo 12 qualitative data analysis software (QSR, 2020).

Table 11: PhD aims and planned analyses

This work formed a sub-study of a multi-centre Phase III single blind RCT, with nested process evaluation: a Pragmatic RAndomised controlled trial of a trauma-focused guided self-help Programme versus InDividual TF-CBT for PTSD (RAPID), led by Chief Investigator Professor Jonathan Bisson, at Cardiff University (Nollett et al., 2018).

4.2.1 Registration and approvals

Funded by the National Institute for Health Research (NIHR), the trial was registered at ClinicalTrials.Gov, and ethical approval was granted by the South East Wales Local Research Ethics Committee, in February 2017. To obtain broad rural and urban and economic representation across England, Scotland, and Wales, Research and Development approvals were sought across the following research sites: Aneurin Bevan University Health Board (UHB); Cardiff and Vale UHB; Coventry and Warwickshire Partnership NHS Trust; Cwm Taf Bro Morganwg UHB; NHS Lothian; East London NHS Foundation Trust; Pennine Care NHS Foundation Trust; and South West Yorkshire Partnership NHS Foundation Trust.

4.2.2 Design

The RCT design employed is the 'gold standard' methodology, being the most rigorous to determine cause and effect between a specific treatment and an outcome and to determine proof of efficacy (Sibbald and Roland, 1998). The *pragmatic* nature of the RAPID Trial allowed the methodology to go one step further, with the design mimicking NHS routine practice, thereby allowing efficacy, cost-effectiveness, and acceptability to be evaluated in a broad clinical context, albeit with the exception that participants are randomly allocated to treatment (Schwartz and Lellouch, 2009). The *process evaluation* incorporated, in line with MRC guidance, explored contextual factors and mechanisms of change that may impact on the effectiveness and successful rollout of the intervention, post-trial. This included assessing fidelity to treatment delivery, adherence to treatment and factors that influence outcomes.

Participants were randomly allocated to receive the 'Spring' GSH i-TF-CBT intervention, with up to five sessions with a therapist, and up to eight steps of the online programme over an eight-week period, or face-to-face TF-CBT, consisting of up to twelve weekly hour-long sessions with a therapist.

The target sample size was 192 individuals, determined according to a power calculation which considered a non-inferiority margin, as opposed to effect size, to demonstrate that the GSH i-TF-CBT intervention was not worse than the comparator face-to-face TF-CBT by more than a pre-specified amount, which was agreed as five points on the 80 points CAPS-5 scale, and allowed for a 20% rate of attrition. A meta-analysis indicated that the standardised mean difference between face-to-face TF-CBT and waitlist/usual care for the treatment of PTSD is

1.62 (Bisson et al., 2013). This corresponds to 16.6 points on the CAPS-5 with a common standard deviation of 10.3. This meant that if non-inferiority was demonstrated to within five points of the gold standard, it would also demonstrate superiority over waitlist/usual care in line with ICHE9 guidance for non-inferiority studies (Chow and Shao, 2006). This was based on the Trial's primary outcome, being a reduction from post-traumatic stress symptoms, measured using the Clinician Administered PTSD Scale for DSM-5 (CAPS-5) (Weathers et al., 2017).

A proportion of participants and therapists were invited to take part in semi-structured interviews, post-treatment, with the aim of describing the experience of receiving the interventions from the patients' perspective, and the delivery from the therapists' perspective. To evaluate factors relevant to the successful future roll-out of the intervention, across the NHS, and beyond, additional stakeholders, NHS managers and commissioners, were invited to take part in a semi-structured interview. The intended sample sizes were around ten participants, and around eight therapists. We aimed to recruit ten NHS commissioners and managers for sufficient information power, based on several considerations, including the specific study aim and sample specificity (Malterud et al., 2016). The qualitative components were designed using the principles of the Critical Appraisal Skills Programme (CASP) qualitative checklist (2019).

4.2.3 Identification of participants

Participants were identified predominantly through clinical referrals from NHS primary mental health services. Referrals were also received from General Practitioners, secondary mental health services, and other non-NHS mental health services such as University Student Wellbeing Services. Non-systematic recruitment occurred in the form of self-referrals from individuals made aware of the Trial via posters, leaflets, and the media (internet, press).

All referrals were received by secure phone call method, ensuring permission had been given by potential participants for their information to be passed on, and were stored securely in a locked facility. Individuals were contacted as soon as possible afterwards, usually via telephone, to discuss the research, and to ensure they received a summary patient information sheet with information, its inclusion and exclusion criteria and methodology (see Appendix C). Individuals were contacted five times before being noted as unable to contact.

A proportion of participants and therapists were purposively sampled between February 2018 and November 2019 for qualitative interviews. Qualitative researcher Kim Smallman (KS), received notification whenever a participant was randomised to the trial. Participants were identified according to their intervention allocation, gender, age, ethnicity, education level, nature of trauma, and therapists were sampled according to their gender. Sampling also took into account geographic research sites. Contact attempts and outcome were recorded for each individual and involvement required the availability of both KS and the participant to complete the telephone interview.

Sampling of NHS commissioners and managers took place between January and June 2020. Potential participants were identified by clinical members of the RAPID Trial Management Group, and through discussions with interviewees. Purposive sampling ensured participants with a range of familiarity with internet-based interventions, with representation across genders, RAPID recruitment sites, and NHS roles. Twelve eligible individuals from England, Scotland, and Wales, were invited and provided written informed consent to participate, although two were unable to progress due to unforeseen shifts in their role due to COVID-19.

4.2.4 Eligibility

Participants were consenting adults with mild to moderate PTSD to a single traumatic event, where PTSD was the only, or primary diagnosis. Individuals were recruited according to the eligibility criteria shown in Figure 3.

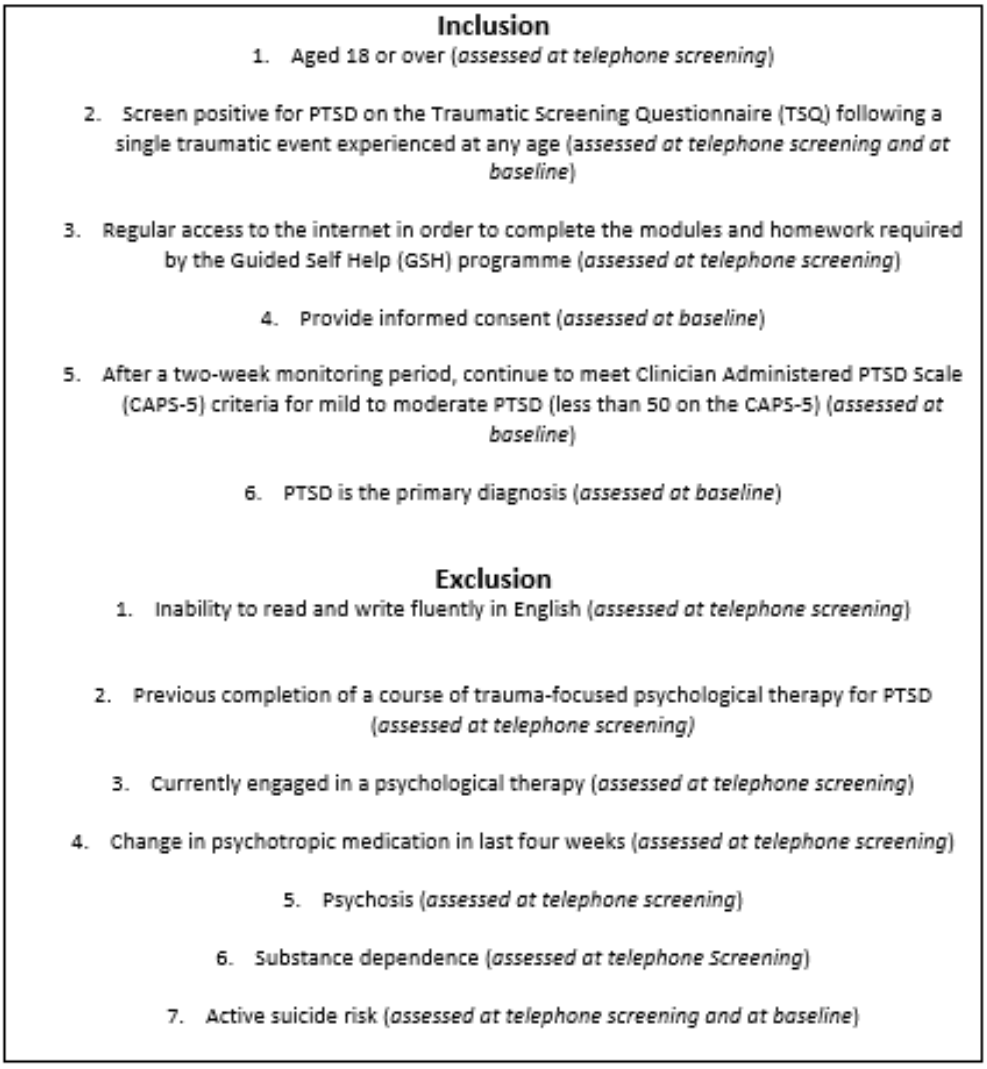

Figure 3: RAPID eligibility criteria

With their permission, individuals found to be ineligible at the point of referral, as well as throughout the recruitment screening process, were referred back to the referring clinician, or to their GP if they had self-referred, for clinical input. Individuals were provided with an information sheet signposting to relevant support organisations, for example the Samaritans helpline (see Appendix D).

Individuals were eligible for the additional stakeholder qualitative interviews if they were in roles likely to fund, commission, signpost-to, or implement an i-CBT intervention for NHS patients. Exclusion criteria were: individuals with involvement in the RAPID Trial, or in the development of the 'Spring' intervention.

4.2.5 Procedure

4.2.5.1 Recruitment: telephone screening

An initial telephone screening assessment considered the suitability of participants according to the following criteria: aged 18 or over; having regular access to the internet, and screening positive for probable PTSD following a single traumatic event experienced at any age, using the Trauma Screening Questionnaire (TSQ), indicated with a cut-off score of six (Brewin et al., 2002). A copy of the telephone screening case report form is available as Appendix E.

Individuals found temporarily ineligible due to a change in the type/dose of their psychotropic medication in the last four weeks, or those currently receiving psychological therapy, were invited to take part in a telephone re-screening in four weeks, or after psychological therapy completion, respectively.

Eligible individuals were booked in for face-to-face baseline assessment roughly two and a half weeks later, which allowed time to post a patient information booklet (PIB), and to ensure that the individual's symptoms were enduring beyond one month, as required for the DSM-5 diagnosis. The PIB (see Appendix F), provided further information about the study, in lay terms, including assurances regarding data protection. Additionally, symptom monitoring diaries (see Appendix G) were posted for individuals to monitor their traumatic stress symptoms for two weeks prior to attending the baseline appointment. Measuring the symptoms by diary monitoring is a normalising process that can alleviate symptoms in itself (Ehlers et al., 2003).

4.2.5.2 Recruitment: consent

Written, informed consent was taken at the baseline assessment (see Appendix H for a copy of the consent form). Lasting around two hours, the face-to-face appointment with individuals found to be eligible at telephone screening assessed for eligibility criteria four, five and six, rechecked inclusion criterion two (single traumatic event), and rechecked exclusion criterion seven (active suicide risk) (see Figure 3). The assessment took place within a clinical setting and occasionally at an individual's home.

Consent to be contacted and invited to undertake qualitative interviews was included in the RAPID participant consent forms (Appendix H). Potential RAPID

therapist interviewees were provided with an information sheet with details of the interview study, including rights to withdraw (Appendix I), and written, informed consent was taken (Appendix J). Potential candidates for the stakeholder NHS commissioners and managers interviews were provided with an information sheet (Appendix K), and written, informed consent was taken (Appendix L). Recruitment screening logs were maintained recording approaches and outcomes, including the sampling characteristics, to ensure representative sampling.

In all cases individuals were provided with time to reflect on and discuss the study with myself and other researchers, and individuals were reminded of their right to withdraw at any time and without giving a reason.

4.2.5.3 Randomisation and allocation concealment

Eligible participants were randomly assigned by computer using an online minimisation algorithm to either GSH i-TF-CBT, or individual face-to-face TF-CBT, and this was communicated to participants via the therapist assigned to that individual. Minimisation ensured balance between treatment arms on age, gender, and whether trauma type involved bereavement, stratified by research centre. Randomisation did not consider baseline depression scores, though these were found to be very similar across treatment groups. A letter was sent to the participant's GP to inform them of their involvement in the Trial, though the treatment type was not specified, since assessors were blind to treatment arm allocation.

4.2.6 Intervention and comparator

Therapists were trained to deliver the GSH intervention and its comparator, both of which were manualised. Training, supervision, and fidelity checks ensured treatment arms were delivered consistently, and therapists completed therapist record sheets at every contact with a participant.

4.2.6.1 'Spring' GSH i-TF-CBT

Individuals randomly assigned to this intervention met with a therapist initially for one hour to develop rapport and to introduce the programme, 'Spring', which was described in chapter two. There were four subsequent fortnightly meetings of 30 minutes, undertaken face-to-face, or by telephone, according to participant

preference. The programme modules, which were available via web browser or mobile phone App, were accompanied by homework, and at each session the therapist reviewed progress and guided the participant through the programme. The steps of 'Spring', described previously, were completed in turn, with tools activated in the Toolkit area. Everything that the participant had entered into the toolkit was visible, with the participant's knowledge, for the therapist to facilitate input.

4.2.6.2 Individual face-to-face TF-CBT

Individuals randomly assigned to individual face-to-face TF-CBT met with a therapist for up to twelve sessions, each lasting 60-90 minutes. One of the standard treatments adopted by IAPT services in England, and described previously in chapter two, this treatment involves identifying the relevant appraisals, memory characteristics and triggers, and behavioural and cognitive strategies that maintain PTSD symptoms (Ehlers and Clark, 2000). In-session treatment was augmented by homework assignments which participants were required to complete between sessions.

4.2.7 Retention: follow-up assessments

Various attempts were made to reach participants for two follow-up assessments, at 16-weeks and 52-weeks. Contact was attempted via the available communication channels, including telephone and email, for six weeks, then letters or emails were sent monthly for three further months. Participants were offered a £20 high street shopping for each assessment.

4.2.8 Study withdrawal

Participants who were entered into the Trial were able to refuse participation at any time without giving reasons. Whilst it was not required, the Chief Investigator was free to offer alternative treatment to that specified in the Trial's protocol, at any stage, if it was felt it to be in the interest of the individual. Withdrawal of individuals was dealt with using a withdrawal case report form (see appendix M), which logged withdrawal level (see Table 12) and invited individuals or their therapist/trial team to report the reason. Level of withdrawal impacted whether an individual was contacted for follow-up assessments.

Qualitative interviewees could withdraw participation at any time, and reasons were invited.

Level	Type of Withdrawal
1	Withdrawal from the trial intervention
2	Withdrawal from follow-up interviews/questionnaires
3	Withdrawal from both the trial intervention and follow-up interviews/questionnaires
4	Withdrawal as for point 3, plus withdrawal to use previously collected data. Unless specifically stated otherwise however, consent to use existing data will be assumed

Table 12: RAPID withdrawal levels

4.2.9 Safety reporting

Any Adverse Event (AE), or Serious Adverse Event (SAE), concerning a participant, was reported by the Principal Investigator immediately, and within 24 hours of knowledge of the event, and where applicable the individual concerned was withdrawn, and the event dealt with appropriately.

4.2.10 Measures

Data collection took place between September 2017 and January 2021, with assessments and interviews taking place in confidential settings predominantly in-person, within an NHS setting, or at an individual's home, or on the telephone. From March 2020 onwards, data collection was conducted only via the telephone or via Zoom video calls, to ensure adherence to social distance measures that were put in place because of the COVID-19 pandemic. Table 13 summarises all measures and data collection, and timepoints.

Outcome Measure / Qualitative Information	Collection Time Points	Explanation of Measure / Qualitative Interview
Life Events Checklist for DSM-5 (LEC-5)	Baseline	A modified version of the LEC-5 was used (Weathers FWB, 2013). The modification was the addition of two items assessing exposure to childhood physical abuse and childhood sexual abuse or molestation (See Appendix N). Eligible individuals were participants experiencing PTSD symptoms to a single traumatic event, the 'worst' traumatic event, and it was this single event that was addressed within the CAPS-5 interview that followed.
The Clinician Administered PTSD Scale for DSM-5 (CAPS-5)	Baseline / 16 weeks	The CAPS-5 (Weathers, 2013a), is widely used in clinical and research settings and is recognised as a benchmark criterion measure of PTSD, with strong test-retest reliability (κ=.83), high internal consistency (α=.88), and good convergent validity with other measures (Weathers et al., 2018). Twenty of the 29 items in the interview are used to create a score, which can range from 0 to 80. The standardised symptom severity scoring system combines frequency and intensity information in to a single 5-point (0-4), severity scale, with anchor points: 0 (absent); 1 (mild/subthreshold); 2 (moderate/threshold); 3 (severe/markedly elevated); and 4 (extreme/incapacitating). Symptom cluster severity scores are sums of the individual item severity scores per cluster, with Criterion B (re-experiencing) being a sum of the severity scores for five items, Criterion C (avoidance) being a sum of two items, Criterion D (negative alterations in cognitions and mood) being a sum of seven items, and Criterion E (hyperarousal) being a sum of six items. A symptom is considered present if the corresponding item severity score is rated ≥2, with additional items requiring a trauma-relatedness rating of 'definite' or 'probable'. DSM-5 requires the presence of at least one Criterion B symptom, one Criterion C symptom, two Criterion D symptoms, and two Criterion E symptoms. With the additional requirement of presence of Criterion F and G, disturbance of at least one month, and disturbance causing significant distress or functional impairment, respectively. The *past month* version of the CAPS-5 was used at baseline assessment, assessing symptomatology anchored to the previous month. A copy of the past month interview is available as Appendix O.

The Patient Health Questionnaire (PHQ-9)	Baseline	The PHQ-9 (Kroenke et al., 2001), was used at baseline to capture depression symptoms, for their use as a covariate in the analyses, given our hypothesis that depression would act as a confounding variable. The PHQ-9 is a widely used reliable and well validated brief self-report measure of depression. It is the outcome measure of choice for evaluating improvement in depressive symptoms in IAPT services (IAPT, 2011). Individuals are asked how often they have been bothered by problems over the last two weeks, with four possible responses for each of the nine items: 0 (not at all); 1 (several days); 2 (more than half the days); 3 (nearly every day). Scores are summed to produce an overall score (0-27), with a higher score indicating greater levels of depression.
The Client Satisfaction Questionnaire (CSQ-8)	16 weeks	The CSQ-8 (Larsen, 1979) is a widely used 8-item, Likert Scale which was developed through literature review and expert ranking, pretested on 248 individuals in five settings. It is a self-report statement of satisfaction with a high degree of internal consistency, good concurrent validity and reliability (Nguyen et al., 1983) and is brief and easy to complete. All items are based on a four-point scale, and the numerical anchors for items is reversed in a random manner throughout the scale, to minimise stereotypic response. There are no subscales, the scale producing a single score of overall satisfaction, ranging from 8 to 32, with higher values indicating higher satisfaction. For the scale to fit our use, we had purchased and signed a contractual license agreement to amend the word 'service' with 'treatment' consistently throughout the measure. We purchased this alongside the normal purchase cost of administration of the scale and added a preamble to the case report form to ensure its administration was contextually meaningful (see Appendix P). We chose to remove the 'comments' section normally included in the CSQ-8, to reduce the risk of unblinding, should an individual disclose views about their allocated treatment arm.

The Agnew Relationship Measure short 5 item version (ARM-5)	Three weeks mid-treatment / 16 weeks	The ARM-5 is a validated version of the 28-item ARM, comprising patient and therapist versions containing parallel items (Cahill et al., 2012). The full ARM has reported sound consistencies, strong convergent validity with the widely used alliance measure, the Working Alliance Inventory, and correlations with gains in therapy, and the shortened version has demonstrated acceptable psychometric properties and convergence with the full ARM (Cahill et al., 2012). See Appendix Q for a copy of the ARM-5 case report form for participants, and Appendix R for a therapist version. Items ask the individual to indicate the extent to which they agree or disagree with five statements, with items 1, 2, 4 and 5 producing scores of 1 to 7, from 'strongly disagree' to 'strongly agree', and item 3 reversed so that 'strongly disagree' produces a score of 7, and 'strongly disagree' produces a score of 1. The scores for each item are summed, with a higher score indicating a greater level of alliance.
Therapy adherence (Therapist Record Sheet)	Every therapy session	In line with recommendations proposing the use of intervention-appropriate metrics (Beintner et al., 2019), therapy adherence was measured via therapy record sheets, completed by therapists at therapy contacts with their participants, thereby recording therapy adherence for both TF-CBT and for GSH. See Appendix S for a copy of the therapy record sheet. A percentage therapy adherence was computed per individual for statistical analyses, based on the number of therapy sessions attended, as a percentage of the expected number of therapy sessions, which was five for GSH and twelve for TF-CBT. Where individuals had attended more than the expected number of sessions, this was assumed to be 100% adherence. For descriptive statistics, individuals were also categorised into two groups: partial adherence, where individuals had completed less than three GSH sessions, or less than eight TF-CBT sessions; and full adherence, where individuals had completed three or more GSH sessions, or eight or more TF-CBT sessions.

'Spring' steps completed	At any point a participant completed a step on 'Spring'	In line with recommendations to report 'universal' usage metrics (Beintner et al., 2019), data from the 'Spring' GSH i-CBT programme was accessed. Individuals were categorised into the following groups: not-started, where no steps had been started; partial completers, where any number of steps could be started or completed, but not all steps were complete; or full completers, where all steps were complete. This information was used for descriptive statistics.
Qualitative interviews with GSH participants	Post-treatment	Interviews explored acceptability. A topic guide (see Appendix T) included questions addressing thoughts on the GSH treatment received; and whether general impressions about PTSD treatment had changed since taking part in the trial.
Qualitative interviews with therapists	Post-trial treatment delivery	Interviews explored acceptability. A topic guide (see Appendix U) included questions to allow individuals to reflect on their experience of delivering the GSH treatment and its acceptability and sustainability.
Qualitative interviews with NHS commissioners and managers	One interview per individual, timing not dependent on trial procedure	Interviews explored acceptability with respect to the roll-out of internet-based healthcare intervention, from the perspective of individuals likely to be involved in such roll-out in the NHS. A topic guide (see Appendix V) broadly invited discussion of the following topics: the participant's role, organisation and interventions they were involved with; their reflections on internet-based interventions; and their understanding of the barriers and facilitators to implementing mental health treatment, including internet-based interventions.

Table 13: Data collection and time points

4.2.10.1 Quantitative measures at baseline assessment

The pre-treatment, baseline assessment consisted of collecting demographic information and self-report outcome measures, the LEC-5, and PHQ-9, and administering the CAPS-5 interview.

4.2.10.2 Quantitative measures during treatment

Therapy adherence was collected during treatment, within therapist record sheets, completed at every therapy session (see Appendix S). To avoid assessor 'unblinding', staff at CTR emailed the ARM-5 measure to participants three weeks following their date of randomisation, and weekly reminders were sent by email.

4.2.10.3 Quantitative measures post-treatment

At the 16-week post-randomisation follow-up, the *past week*[5] CAPS-5 interview was administered and participants completed the self-report ARM-5, CSQ-8 and PHQ-9 measures. Participants were asked not to disclose details of treatment allocation to reduce the chance of assessor unblinding. Occasionally individuals were offered to undertake the CAPS-5 interview only, if there were difficulties with the individual's engagement. Therapists completed the ARM-5 therapist version via the final therapy record sheet.

4.2.10.4 Qualitative interviews

Participants and therapists were invited to complete the qualitative interviews with researcher KS, who was not 'blind' to treatment allocation, nor was required to remain free from any potentially unblinding information that could become apparent during interviews with therapists. This PhD utilised interviews conducted with participants allocated to GSH, post-treatment, and at the end of treatment delivery, for therapists. Interviews were audio-recorded.

NHS managers and commissioners were invited to complete a single semi-structured interview with myself. Interviews were conducted with participants in confidential NHS settings, in person (n=3), on the telephone (n=6), and via videoconference (n=1), at a date and time convenient for the participants. All work

[5] In order for the CAPS-5 interview to most accurately reflect an individual's experience of symptoms at *post-treatment,* the *past-week* CAPS-5 was administered at the 16-week assessment, as it was felt that the past-week version, as opposed to the past-month version, would be less likely to overlap with treatment.

was undertaken in full compliance with the General Data Protection Regulation (GDPR). Demographic information was collected at interview.

Interview topic guides

Topic guides (see Appendices T-V) were developed with input from researchers and clinicians of the RAPID Trial Management Group, co-produced with individuals with lived-experience of PTSD from Cardiff University's Traumatic Stress Research Public Advisory Group. With respect to the NHS commissioners and managers interview topic guide (Appendix V), additional input was sought from an NHS Consultant Clinical Psychologist, with responsibility for determining types of service provision, including internet-based service provision. Semi-structured interviews were conducted to ensure consistency in questioning across participants, whilst also allowing for exploration of topics that were important to the interviewee, to gather in-depth experiences and views. The interviews included prompts, to probe for further views and information and detail and to maintain the conversation flow. The tone of the interview was informal to allow individuals to feel welcome to introduce new topics.

Recordings

With each participant's agreement, interviews were recorded on an encrypted Olympus digital voice recorder, and field notes were written immediately after each interview to aid the preliminary analysis. Interviews were transcribed to produce orthographic verbal verbatim and audio recordings and transcripts were uploaded and saved in a folder with restricted access permissions. The original raw copies of field notes were stored securely within a locked facility. The described process of recording, storing and transcribing was undertaken by KS for participant and therapist interviews and by myself for the additional stakeholder interviews.

4.2.11 Analysis

Quantitative analyses were conducted in May 2021, when all RAPID participants had completed their involvement in the Trial. Statistical analysis advice was taken from Dr Philip Hyland, Senior Lecturer in Psychology, Maynooth University. In this section I outline the mixed methods analyses applied.

4.2.11.1 Descriptive analysis

The sample was described and summarised in tables, including the descriptive analysis of data collected at baseline which was conducted using SPSS (IBM, 2019). Means and standard deviations were calculated for continuous variables and frequencies (%) for categorical variables. I did not plan to conduct tests of statistical significance for baseline characteristics; I planned to consider the clinical importance of any potential imbalance.

Therapy session uptake and adherence was described with percentages across the GSH and TFCBT groups. Non-uptake was defined as being offered, but not starting therapy sessions, and therapy adherence was described in terms of partial adherence, and full adherence, and mean total adherence, as described in Table 13.

'Spring' programme usage was described for the GSH group, with percentages displayed for individuals who had either not started the programme, had partially completed the programme steps, or had completed all programme steps, as described in Table 13.

4.2.11.2 ANCOVA

To assess whether the independent variable, treatment type, influenced acceptability, one-way ANCOVA was applied, for several facets of acceptability that were identified in the systematic review (Simon et al., 2019a), as listed in Table 14:

Facet of acceptability	**Defined as**
Therapy Adherence	The number of therapy sessions attended as a % of planned sessions, as recorded in therapist record sheets.
Participant-reported Therapeutic Alliance mid-treatment	The mean total patient-reported ARM-5 score mid-treatment (three weeks post-randomisation).
Therapist-reported Therapeutic Alliance mid-treatment	The mean total therapist-reported ARM-5 score at mid-treatment (three weeks post-randomisation).
Participant-reported Therapeutic Alliance post-treatment	The mean total patient-reported ARM-5 score at post-treatment (16 weeks follow-up).
Therapist-reported Therapeutic Alliance at post-treatment	The mean total therapist-reported ARM-5 score at post-treatment (final therapy contact).

Treatment Satisfaction	The mean total CSQ-8 score at post-treatment (16 weeks follow-up).

Table 14: Facets of acceptability and definitions

ANCOVA assumptions were checked and ANCOVA were conducted per facet of acceptability, controlling for gender, site, baseline CAPS-5, baseline PHQ-9, and time since trauma.

4.2.11.3 Multiple regression

Multiple regression was performed to assess whether PTSD symptoms at 16-week follow-up was predicted by acceptability, and to understand the relative contribution of the predictor variables to the total variance explained. The following facets of acceptability were used: therapy adherence, treatment satisfaction, and the four domains of therapeutic alliance. Analyses also considered the important covariate of PTSD symptoms at baseline. An illustration of the analyses is included in Figure 4.

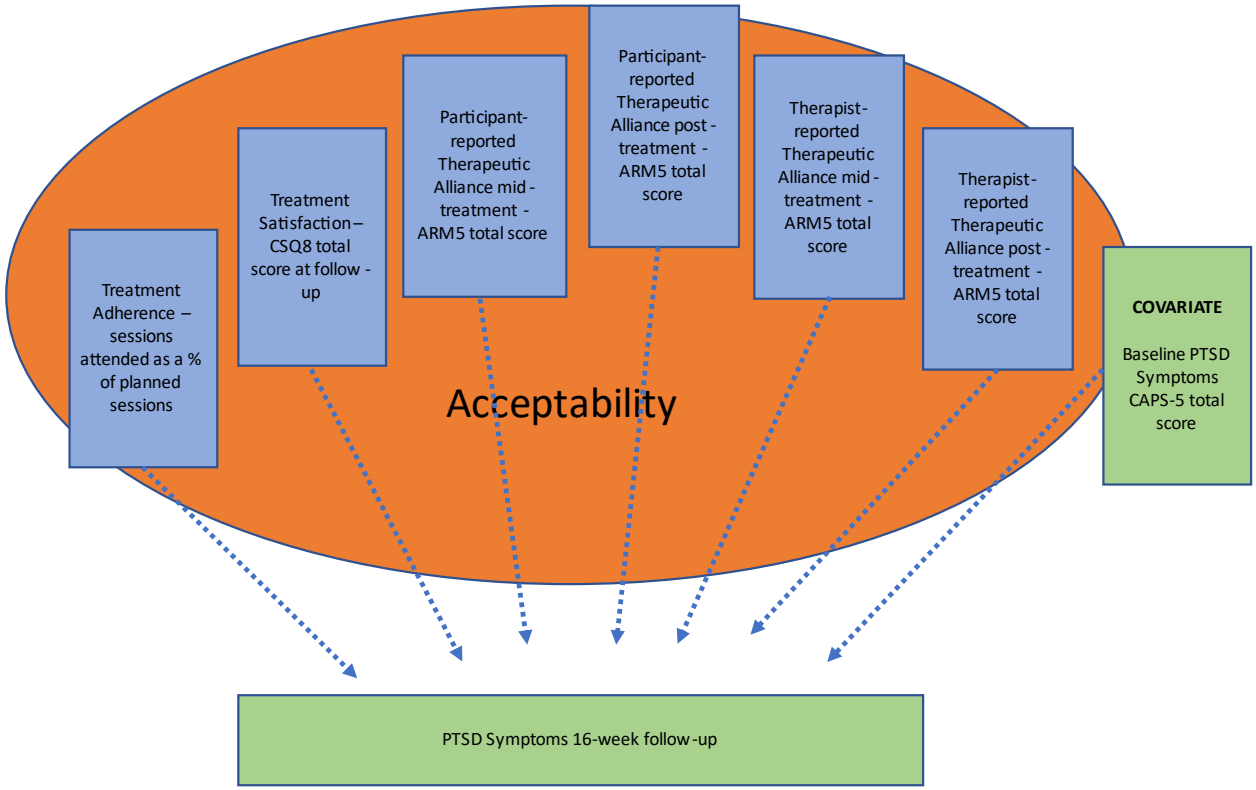

Figure 4: Illustration of multiple regression to assess whether PTSD symptoms at 16-week post-treatment follow-up was predicted by facets of acceptability, and baseline PTSD symptoms.

4.2.11.4 Thematic analysis

The analysis of data from qualitative interviews with participants, therapists and NHS commissioners and managers occurred concurrently with its collection. This allowed for a constant comparison approach to explore themes, to ensure sufficient data saturation (Saunders et al., 2018), in addition to our aim for sufficient information power via the recruitment of ten participants (Malterud et al., 2016). Saturation was monitored through a double-coding process and discussed between researchers Jonathan Bisson (JB), Lucy Brookes-Howell (LBH), CL, and KS, in the case of participant and therapist interviews, and between JB, CL, Matt Ploszajski (MP), and I, in the case of NHS commissioners and managers interviews. Transcripts were prepared for analysis, assigning pseudonyms for interviewees and removing the names of spoken others and their roles and institutions, to help preserve anonymity. Cleaned transcripts were imported into QSR NVivo 12 qualitative data analysis software (QSR, 2020).

Queries raised by the transcriber over accuracy, and missing segments, were checked against the original audio-recordings and corrected where possible. The codes that were generated were discussed with JB at regular intervals and we sought to discuss and reconcile any discrepancies, to ensure clear understanding and interpretation of themes. Final interpretations were made with oversight from JB and CL, and with input and support from Cardiff University's Traumatic Stress Research Public Advisory Group.

The Framework Method was used to support the thematic analysis of the interviews with participants, therapists, and NHS commissioners and managers. This method allows for an inductive approach and provides a systematic model for managing and mapping data (Gale et al., 2013). The principles of the CASP qualitative checklist were adhered to (CASP, 2019). An inductive approach was taken due to the theoretical flexibility, as well as the 'thick descriptions' afforded by the method (Braun and Clarke, 2006). Codes were generated by NS for 100% of the interviews with therapists; participants; and NHS commissioners and managers, identifying interview segments that were analytically intriguing. KS double-coded 20% of the transcripts of RAPID participant and therapist interviews and MP double-coded 100% of the interviews with NHS commissioners and managers. NS and KS met regularly while coding participant and therapist interviews, and NS and MP met regularly while coding NHS commissioners and managers interviews. Meetings initially involved developing analytic frameworks from the coding conducted with the first few interview transcripts, and thereafter to develop the

analytic frameworks, for example as new codes were generated from further interviews. The analytic frameworks were applied when coding the remainder of the transcripts and to finally populate the codes into framework matrices. The matrices comprised rows based on interviewees and columns based on codes, with each cell therefore including verbatim quotes for the corresponding interviewee and code. See Tables 16, 17, and 18 for extracts of the matrices of interviews with RAPID participants, RAPID therapists, and NHS commissioners and managers, respectively. Coders met with JB at regular intervals to discuss generated codes and themes and to be able to reconcile any interrater reliability discrepancies, and to ensure clear understanding and interpretation of themes. Final interpretations were made with oversight from JB and CL, and with input and support from Cardiff University's Traumatic Stress Research Public Advisory Group.

Pseudonym	Theme – Barriers/Challenges to engagement with 'Spring' GSH i-TF-CBT		
	Concentration difficulties.	**Difficulties fitting in homework.**	**Treatment was too short and slow paced.**
Mike	*"the iPad work, well it was alright I done it all no problem at all but it's hard for people that can't concentrate, I think."*	*"could be a bit less, the homework side of it….I understand going up through the course why it is because there's obviously different scenarios and different people and like tending on different, erm things to help you out to understand that. But I think it could be a bit less on the iPad end."*	*"I think it was eight weeks for the course, yeah….And then all of a sudden bang….Yeah, because like the course finished at the start of May...And there's been nothing since" And "I honestly don't think that eight weeks, in my situation, I can't speak for anybody else, it's not long enough."*
Becky		*"I didn't realise that it would be so intensive.., when it got to the point of writing down what you erm, your erm trauma and then having to go over it for an extra forty minutes or whatever it was a day, that was you know, that was an hour and ten minutes a day I was supposed to be spending on it and I didn't have an hour and ten minutes."*	*"I think that it probably could've done with being over a longer period of time and not half an hour every day"*
Emma		*"factoring in something that was self-driven myself, at home when I had a new born and when I suffering from trauma was very difficult to do... at one point what it did do was apply a very unintended and probably undesirable additional pressure on me...I was particularly concerned at one point was I going to be able to stick this through… was sort of carrying some guilt each day, oh I haven't done that, I haven't done it…"*	

Pseudonym	Theme – Barriers/Challenges to engagement with 'Spring' GSH i-TF-CBT		
	Concentration difficulties.	**Difficulties fitting in homework.**	**Treatment was too short and slow paced.**
		"it took me roughly the same amount of time to build up to doing it, to doing the time and then the same amount of time to wind down...And so that, that is a huge, then it becomes a huge chunk of, of a day..it was, it was just inevitable that it became sort of an onerous task to do, sort of building up in my mind...switching off from doing that hour of therapy, erm, I found very difficult."	
Stewart			*"it was too short...For my problems it, it…I would imagine if, if it could have been better a bit longer... I think the eight weeks is, is just, you know, just touching the nub of the problem...I think to be honest it wasn't long enough, 'cause I still needed her [therapist] and, and she thought that as well…"*

Table 15: Participant (pseudonym) qualitative interviews matrix extract

Pseudonym	Theme – Barriers/Challenges to engagement with 'Spring' GSH i-TF-CBT		
	Participant preference for face-to-face therapy	**Therapist unfamiliarity with intervention and modality**	**Technology challenges**
Christian	*"if they were, if they were happy to do and pleased to have the online, no, no problem at all really, um people that were disappointed, that wanted the face to face, you know, an hour to ninety minute, twelve week therapy...you know, I think people vote with their feet...In these instances, and you cancel appointments or, or drop out early."*	*"there are a lot of Therapists who are a bit can't undertake it themselves, who don't like using computers and they're not very confident with computers and websites...So you know, that they start from a, an anxious position and then...You know, it, it's out of their comfort zone isn't it to, to do that, when they'd prefer to have someone in, in a room, face to face..."*	*"great when it worked, you know, so there were a few teething problems with it at times, which was frustrating...Yeah so for instance, being able to access the Dashboard towards the end of my time, was difficult, I couldn't get my patients up err on the Dashboard to see how they were doing, there was some techy issues which was frustrating me...then your participant would read, you know, report an issue accessing or um, particularly in step five where they write their narrative account of their trauma....and then it wasn't saved, and that was very distressing for the participant....I would say to patients, you know, write, write it in a Word document, or, or in Notes, and then cut and paste it into the website, just in case, so you've always got a copy....I think some of the, the daily ratings of trauma symptoms, wasn't adhered to, err or, or if it was adhered to by a participant, it didn't [ph] show up nicely in the Dashboard, so you couldn't really log and see how their daily symptoms were going, in fact I don't think many people used it if I'm honest....some patients would use the App rather than the website, and so there were, there were problems at times with the two syncing between, between platforms."*
	"So they would say oh you know, I wanted to come every week, I wanted to have, you know, longer with you to talk more, it felt a bit pressured and felt like it was all my responsibility to do most of the work and I didn't feel I was getting much from you...so yeah I think it, it comes down to patients preference at the beginning um, and yeah and some people like to talk and they like to talk a lot and but those people that don't..."		

Pseudonym	Theme – Barriers/Challenges to engagement with 'Spring' GSH i-TF-CBT		
	Participant preference for face-to-face therapy	**Therapist unfamiliarity with intervention and modality**	**Technology challenges**
Laura	*"I think there's a bit of a societal expectation in certain thoughts of trauma a that you'll get more than, er, that your, you know, there's something about being attended to by a human being…… in a compassionate way, when you've experienced sort of, the sort of trauma that society finds abhorrent...So, like a bombing or something like that...And it feels a bit flippant to just give them four face to face sessions with a computer, you know, I think that's just really difficult...so I just think that's really quite hard, so, so some clients, you know, just giving them, some people welcomed it but other people it didn't feel right...I think it's partly about asking someone what they feel comfortable with."*	*"It felt strange at the first, at the beginning and I think the time, shortening the time was very challenges, cause, erm, you know, we're not used to working in a brief kind of way with people ...Er, er, and I think it was very difficult offering them a package when they were bringing a horrible trauma...And we want to offer them a human being, like, contact....I think it felt bad from the therapist position that you weren't giving the client as much as you felt they needed...."* *"the challenge of using a new product where you might not have made the leap of faith that it's as good for them as an old method."*	*"one of my clients had an iPhone I think and it didn't work...So that was a real problem because they didn't have a laptop so I don't think they could continue...maybe it just affected them so they lost interest or something."*

Pseudonym	Theme – Barriers/Challenges to engagement with 'Spring' GSH i-TF-CBT		
	Participant preference for face-to-face therapy	**Therapist unfamiliarity with intervention and modality**	**Technology challenges**
Jenny	*"sometimes people were less optimistic about the guided self-help and, and mostly perhaps it, yeah, I mean, it wasn't too bad. One or two that, erm, had the cognitive therapy said you know, if they'd have had the guided self-help, erm, they probably wouldn't have taken up the option....Actually, but, erm, all the ones that did get sort of randomised to the guided self-help seemed okay about being on the guided self-help and it might have been a bit more about my anxiety of telling them…… what arm they were on."*	*"initially it was quite, erm, different I suppose it, it's different than sort of face to face therapy and it felt a lot more sort of, erm, directive I suppose"*	*"I got used to delivering it, erm, it was, it was absolutely fine and I think initially there were a few teething problems with the package. Erm, you know, people weren't seeming to be able to download it so, so those were a bit stressful at the, at the start of the, erm, trial but, but those kind of ironed out."*
	"I think, erm, there were one or two that, that were on the CT part of the, er, programme that said they wouldn't have gone ahead if they had have been on the guided self-help…… but all the ones that did it seemed to find it helpful…. … and they, they liked the programme."	*"I think at the beginning it felt a bit challenging because it was, you know, it felt a very different way of working...I think as, as you got used to delivering it then, then [coughs] you know, it started, you kind of adapt-adapted your way of working, erm, with that, that modality I guess"*	*"and then I suppose sometimes when they would go, go from the appointment and then they'd go home and try to do it themselves, there just seemed to be a lot of hitches in those, in those first few, er…… partly, you know, I think sometimes, you know, people gave up if it didn't sort of happen quite easily or, you know…"*

Pseudonym	Theme – Barriers/Challenges to engagement with 'Spring' GSH i-TF-CBT		
	Participant preference for face-to-face therapy	**Therapist unfamiliarity with intervention and modality**	**Technology challenges**
		"I suppose as a, as a therapist it's not as fulfilling as, erm, you know, as when you're having one to one therapy."	

Table 16: Therapist (pseudonym) qualitative interviews matrix extract

Pseudonym	Theme - Service capacity issues		
	Unmet governmental targets.	**High demand.**	**Staffing issues.**
Phil	*"it's a complicated setup… It's quite easy for people perhaps to end up in the wrong bits of it or waiting too long for bits of it."*	*"But you know, I think we've got to be realistic it might be that what will happen is as this becomes widely available and people know about it, erm we'll find that perhaps the threshold for referring into the system does gradually creep downwards a little bit and people who previously might not have been put forward for treatment, actually are now put forward for treatment…So that a previously unmet need might become a bit more apparent because we now have a service to provide"*	*when talking about why services are oversubscribed: "there's a little bit of an issue with striking the balance between generic community mental health team psychology… which is actually very difficult to attract people into these days and the more specialist areas which tend to be much more popular, for example eating disorders and indeed, post-traumatic stress."*
	"…the only measures we would have of whether we're providing access would be the waiting lists, cos as I've said already, these are not in any sense useful or reliable measures. They will simply show if there's a tail of people waiting a long time to access a particular therapy but they may simply be the tip of an iceberg of people who could theoretically benefit from that		

Pseudonym	Theme - Service capacity issues		
	Unmet governmental targets.	**High demand.**	**Staffing issues.**
	therapy and we don't know how big the iceberg below the water is… all we see is the tip of it which sometimes is quite substantial and sometimes is almost non-existent… It's an iceberg that floats up and down a bit."		
Tim	*"anyone that is referred into, er, psychological therapies should be seen within 18 weeks, erm, but I think it's interesting that some of my understanding is that there's no board in [country] that's currently meeting that target… and that's across both adult services and CAMHS… for face to face therapy, erm, for the digital services we have a much, er, we don't have waiting list for the digital therapy, so the computerised CBT patients will tend to get access to the programme within five working days of being referred."*	*"there's the demand [for therapy], so and as we're, and digital technologies are becoming much more prevalent… they now recognise that the traditional models of service are not really going to meet that demand if the rates continue."*	*"…even in those areas where they do have a full, er complement of staff that you tend to find that there's high demand of services…. as investment has been put in, you know, increasing the workforce but the demand is still going up… and digital technologies are becoming much more prevalent… Because they now recognise that the traditional models of service are not really going to meet that demand if the rates continue."*

Table 17: NHS commissioners and managers (pseudonym) qualitative interviews matrix extract

4.2.12 Missing data

An online database was developed to minimise the risk of missing data, by enforcing entry of a response to all items of all measures, and where missing was the only option for the respondent, this was dealt with by setting the value at -9. Regarding missing qualitative data, this can take the form of: missing dialogue from an interview, missing text from a transcript; and missing demographic and sampling characteristics. For missing dialogue and text, we considered processes on intercoder reliability to seek clarification; and for missing demographic and sampling characteristics, where possible we considered obtaining this information and noted what was missing, if anything, within the project memos.

5. Chapter Five: Results of a systematic review and meta-analyses of the available evidence for the acceptability of i-CBT for PTSD

This chapter reports the findings of a systematic review and meta-analyses of the available evidence for the acceptability of i-CBT for PTSD (Simon et al., 2019a), which was the first aim of this PhD.

5.1 Included studies

As presented in Figure 5, at the initial search 983 studies were identified as potentially eligible. Abstracts were considered, and we obtained full text copies for 66 studies deemed as potentially relevant (Appendix W lists references to excluded studies). Ten RCTs of 720 participants met the review inclusion criteria for the review.

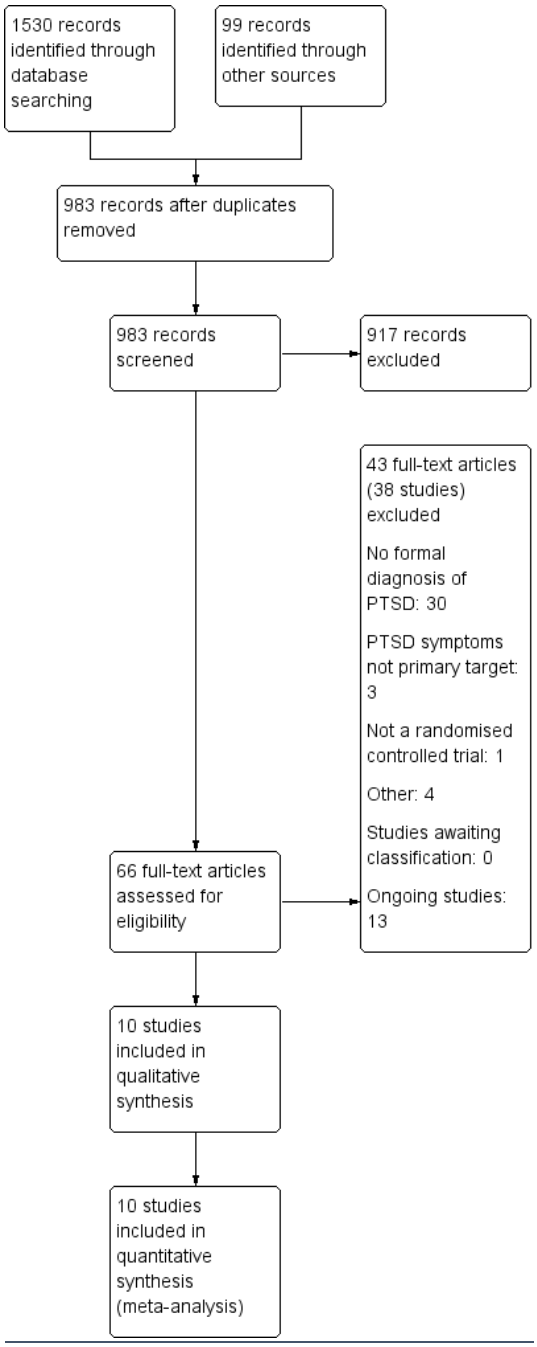

Figure 5: Flow diagram for study selection

5.1.1 Characteristics of included studies

A summary of the included studies is presented in Table 18.

The majority of the included studies had excluded individuals on the basis of: receiving treatment elsewhere; with current psychosis; substance dependence; active suicidal ideation; and individuals who had recently changed type/dosage of their mental health medication. Three studies excluded individuals with comorbid depression where depression presented immediately prior to the traumatic event (Litz, 2007), and where symptoms of severe depression presented at assessment

(Lewis et al., 2017a, Spence et al., 2011), and another excluded individuals with gross cognitive impairment (Krupnick et al., 2017). Two studies did not exclude based on comorbidity, nor suicidal ideation (Kuhn et al., 2017, Miner et al., 2016).

5.1.2 Interventions of included studies

Included studies examined the following i-CBT programmes: 'DESTRESS' (k=2); 'Interapy' (k=1); PTSD Coach (k=2); 'From Survivor to Thriver' (k=1); 'Spring' (k=1); 'Warriors Internet Recovery & Education' (WIRED) (k=1); a non-specified i-CBT (k=2). 'PTSD Coach', was the only stand-alone programme, with no guidance, examined by two included studies. The extent/nature of guidance for the guided programmes examined by the remaining studies was widely variable. Only one study reported face-to-face guidance, comprising an hour-long introductory session and fortnightly 30-minute appointments thereafter, face-to-face or by phone, according to patient preference, with a trauma therapist, amounting to a mean therapist input per participant of 147.53 minutes (SD=57.01) (Lewis et al., 2017a). The remainder of studies reported limited email/telephone check-in contact, for example one study reported 'brief check-ins' by Clinical Psychology students, approximately once fortnightly (Littleton et al., 2016). Of the eight studies of guided i-CBT, six reported guiding clinician qualifications, and three reported their training on the i-CBT programme. Three studies evaluated the following i-CBT interventions without a trauma focus: 'DESTRESS' (primary care version) and 'PTSD Coach'. The programmes were i-TF-CBT in the other studies, and the common components were: psychoeducation; distress management techniques; cognitive restructuring/trauma processing; and relapse prevention. Duration of treatment ranged from four weeks, to fourteen weeks, averaging 8.3 weeks (SD=2.65), across studies.

	Engel et al., 2015	Ivarsson et al., 2014	Knaevelsrud et al., 2015	Krupnick et al., 2017	Kuhn et al., 2017	Lewis et al., 2017	Littleton et al., 2016	Litz et al., 2007	Miner et al., 2016	Spence et al., 2011
Country	USA	Sweden	Iraq	USA	USA	UK	USA	USA	USA	Australia
N	80	62	159	34	120	42	87	45	49	42
Mean age (SD)	Exp - 36.2 (7.75) Con – 36.7 (9.75)	Imm – 44.8 (11.2) Del – 47.2 (12.2)	Exp – 29.11 (8.20) Con – 27.15 (6.48)	Exp – 35.44 Con – 44.75 (SDs nr)	Exp – 39.43 (15.16) Con – 39.12 (14.08)	Exp – 38.86 (11.91) Con – 37.71 (13.8)	22 years (range 18-42) across sample	Exp – 38.63 (9.41) Con – 39.86 (7.72)	45.7 (13.9) across sample	Exp – 43.0 (15.2) Con – 42.0 (10.4)
Gender	18.75% women 81.25% men	82.3% women 17.7% men	Exp – 60 women (79%) Wait – 55 women (69%)	8.8% women 91.2% men	69.2% women 30.8% men	59.5% women 40.5% men	100% women	Exp – 25% women Con – 19% women	81.6 % women 18.4% men	81% women 19% men
Unemployment and education	Unemp – nr Uni – 62.8%	Unemp – 8.1% Uni – 56.5%	Unemp – Exp, 26 (33%), Con, 29 (36%) Uni – Exp, 56 (71%), Con, 38 (48%)	Unemp – nr Uni – nr	Unemp – nr Uni – 14.2%	Unemp – 16.6% Uni – 42.8%	Unemp – nr Uni – all in sample were students	Unclear	nr	Unemp – 40% Uni – unclear
Method of recruitment	Adverts	Adverts	Adverts	Clinician referral	Adverts	Clinician referral / Adverts	Adverts	Adverts	Adverts	Adverts

	Engel et al., 2015	Ivarsson et al., 2014	Knaevelsrud et al., 2015	Krupnick et al., 2017	Kuhn et al., 2017	Lewis et al., 2017	Littleton et al., 2016	Litz et al., 2007	Miner et al., 2016	Spence et al., 2011
Method of diagnosis	Clin, CAPS-5	Clin, CAPS-5	Self, PDS	Self, PCL-M	Self, PCL-C	Clin, CAPS-5	Clin, PSS-I	Clin, CAPS-5	Self, PCL-C	Clin, MINI
Trauma Type	Military	Various	War- related	Military	Various	Various	Rape	Military	Various	Various
Intervention length	6 weeks	8 weeks	5 weeks	10 weeks	12 weeks	8 weeks	14 weeks	8 weeks	4 weeks	8 weeks
Intervention name	DESTRESS	Unnamed i-CBT	Interapy, translated into Arabic and culturally adapted	WIRED	PTSD Coach	Spring	From Survivor to Thriver	DESTRESS	PTSD Coach	Unnamed i-CBT
Intervention access	devices on which this could be accessed were not specified	devices on which this could be accessed were not specified	devices on which this could be accessed were not specified	devices on which this could be accessed were not specified	App	devices on which this could be accessed were not specified	Computer-based	devices on which this could be accessed were not specified	App	devices on which this could be accessed were not specified

	Engel et al., 2015	Ivarsson et al., 2014	Knaevelsrud et al., 2015	Krupnick et al., 2017	Kuhn et al., 2017	Lewis et al., 2017	Littleton et al., 2016	Litz et al., 2007	Miner et al., 2016	Spence et al., 2011
Intervention description	Program introduced by a Nurse, which included psychoeducation, anger, stress management strategies, sleep hygiene, cognitive reframing.	Guided. Text-based modules, of psychoeducation, anxiety coping skills, in-vivo and imaginal exposure (writing and reading trauma narratives), and cognitive restructuring.	Guided. Structured writing activities, with the following treatment phases: self-confrontation with the trauma; cognitive restructuring; and social sharing.	Guided. Adapted from 'Interapy'. Writing intervention, using principles of prolonged exposure and cognitive therapy.	Not guided. Instructions to download the App, or lent an iPad. Four components: Learn; Self Assessment; Manage Symptoms; Find Support.	Guided, 8 steps: Learning about my PTSD; Grounding myself; Managing my anxiety; Reclaiming my life; Coming to terms with my trauma; Changing my thoughts; Overcoming my avoidance; Keeping myself well.	Guided, programme, designed to be completed sequentially, consisting of three phases: psychoeducation including distress management and healthy coping; challenging unhelpful thoughts; and behavioural experiments addressing specific concerns.	Guided, promoting stress and negative affect management strategies applied to trauma triggers.	Not guided. App, skills-based, intervention of four components: Learn; Self Assessment; Manage Symptoms; Find Support.	Guided. Including lessons and homework, concerning: assertiveness skills; anger management; panic; sleep; diet and exercise; exposure and behavioural activity session.

	Engel et al., 2015	Ivarsson et al., 2014	Knaevelsrud et al., 2015	Krupnick et al., 2017	Kuhn et al., 2017	Lewis et al., 2017	Littleton et al., 2016	Litz et al., 2007	Miner et al., 2016	Spence et al., 2011
Trauma-focused?	No	Yes	Yes	Yes	No	Yes	Yes	No	No	Yes
Therapist time	Nurse guidance, monitoring as necessary, via website	Clinical psychology students, guidance once a week and occasional reminders via website	Psychotherapists weekly reminder emails and phone contact if no response	Short response after each writing exercise and as required	None	Trauma therapists, hour long introductory session and fortnightly appointments face-to-face or by phone	Brief check-ins by clinical psychology students, approximately once every two weeks	Two hour long introductory session (including basis assessment), phone and email guidance as required	None	Clinical psychologist via telephone, email, and forum
Control	Optimised usual care - primary care augmented with low intensity care management (15 minute telephone check-ins with	Minimal attention - answering weekly questions on wellbeing, stress, and sleep	Waitlist	Treatment as usual, an average of 2.44 psychosocial treatment sessions, such as cognitive processing	Waitlist	Waitlist	Non-CBT website including psychoeducation as well as relaxation, grounding and coping strategies	Non-CBT based internet intervention (monitoring non-trauma related concerns, psychoeducation, stress	Waitlist	Waitlist

	Engel et al., 2015	Ivarsson et al., 2014	Knaevelsrud et al., 2015	Krupnick et al., 2017	Kuhn et al., 2017	Lewis et al., 2017	Littleton et al., 2016	Litz et al., 2007	Miner et al., 2016	Spence et al., 2011
	DESTRESS nurse, including risk assessment), and feedback to the primary care provider.			therapy, antidepressant medication, and acupuncture.				management. Therapist contact as required, focused on non-trauma related concerns.		
Acceptability outcome measures and proxy indicators	Treatment non-uptake and dropout, and treatment engagement (% of participants completing all modules)	Treatment dropout and engagement (% of participants completing all modules)	DEVS and treatment dropout with reasons.	Acceptability measure developed for the study, and treatment dropout.	None	Treatment non-uptake and dropout, with reasons, treatment engagement (% of individuals completing all modules, and	STTS-R, WAI-S, non-uptake of treatment, treatment dropout, and adverse effects.	Treatment non-uptake and dropout.	Acceptability measure developed for the study, reporting typical time of the day the App was used. Treatment dropout, and engagem	Acceptability measure developed for the study. Measure of satisfaction based on the standardised Credibility/Expectancy questionnaire. Non-uptake of treatment, dropout, treatment engagement

	Engel et al., 2015	Ivarsson et al., 2014	Knaevelsrud et al., 2015	Krupnick et al., 2017	Kuhn et al., 2017	Lewis et al., 2017	Littleton et al., 2016	Litz et al., 2007	Miner et al., 2016	Spence et al., 2011
						adverse effects).			ent (mean weekly programme usage).	(mean number of lessons completed).

Table 18: Summary of systematic review included studies

Key: nr=nor reported; Exp=Experimental; Con=Control/Comparator; Imm=Immediate treatment; Del=Delayed treatment; Unemp=Unemployed; Uni=University education; Clin=Clinician-reported; Self=Self-reported; CAPS-5=Clinician-Administered PTSD Scale for DSM-5; PDS=Post-Traumatic Diagnostic Scale; PCL-M=PTSD Checklist for DMS-5 (military); PCL-C=PTSD Checklist for DSM-5 (civilian); PSS-I=PTSD Symptom Scale – Interview for DSM-5; MINI=Mini International Neuropsychiatric Interview; i-CBT=internet-based Cognitive Behavioural Therapy; DEVS=Distress/Endorsement Validation Scale; STTS-R= Satisfaction with Therapy and Therapist Scale-Revised; WAI-S= the Working Alliance Inventory-Short form.

5.1.3 Methodological quality of studies

Figure 6 presents the findings of the risk of bias assessments that were undertaken. Method of sequence allocation was judged to pose 'low' risk of bias for seven studies, the remainder rated 'unclear' due to insufficient details. Allocation concealment was judged 'low' risk for three studies, the remainder rated 'unclear'. The outcome assessor was aware of the participant's allocation in two of the studies, with the remaining studies using blinded-raters or self-report questionnaires delivered in a way that could not be influenced by members of the research team. Incomplete outcome data was judged to be 'high' risk for four studies, and the remainder were felt to have dealt with dropouts appropriately. Selective reporting was judged 'low' risk across studies. We could not rule out potential researcher allegiance since treatment originators evaluated i-CBT interventions in all but one of the studies. Sample sizes were often small, however, all studies presented objectives.

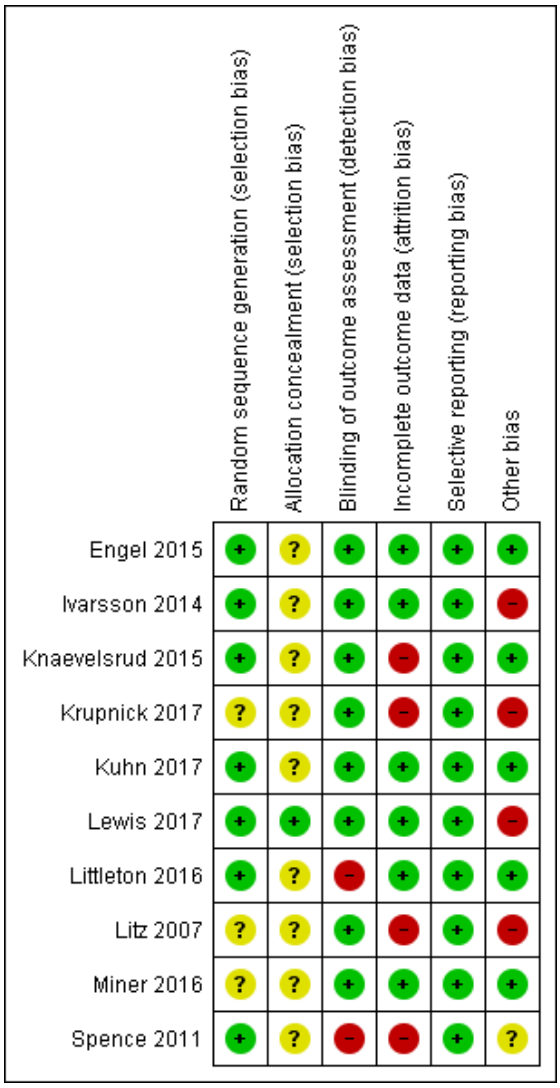

Figure 6: Methodological quality of systematic review included studies

Risk of bias judgments for each study (in seven domains: A=random sequence generation; B=allocation concealment;l; C=blinding of assessors; D=incomplete data; E=selective reporting; F=other bias) (green / +=low risk; yellow / ?=unclear risk; red / -=high risk).

5.2 Measures of acceptability

None of the studies used a standardised/validated acceptability measure; however, three used measures developed specifically for their studies (see Table 18) (Krupnick et al., 2017, Spence et al., 2011, Miner et al., 2016). Questions addressed whether individuals had learned new tools/skills/techniques to manage symptoms, whether they would recommend the programme to a friend with PTSD, and opinions/experience using the programme. Qualitative data was collected from participants randomised to the experimental treatment arms in three studies, that compared to waitlist, and responses were noted as 'extremely enthusiastic' in one of these studies (Krupnick et al., 2017), with moderate to high acceptability

responses also reported in the other studies (Miner et al., 2016, Spence et al., 2011). For example in one study, nearly 83% of participants in the i-CBT arm reported they had learned new tools to cope with their symptoms (Miner et al., 2016). Acceptability was also found in another study, assessed in the experimental treatment group using the Distress/Endorsement Validation Scale (DEVS) (Devilly, 2004), with 76% of individuals reporting they would recommend the treatment to others (Knaevelsrud et al., 2015).

5.2.1 Treatment satisfaction

Two studies that measured post-treatment satisfaction in the experimental treatment arms, found high levels of satisfaction (Littleton et al., 2016, Spence et al., 2011): one used the Satisfaction with Therapy and Therapist Scale-Revised (STTS-R), measuring satisfaction with one's therapist and with treatment received (Oei and Green, 2008); the other used a measure of satisfaction, based on a standardised Credibility/Expectancy questionnaire, measuring satisfaction with the programme, and quality of correspondence with therapist, and treatment modules.

5.2.2 Therapeutic alliance

Eight of the studies examined i-CBT programmes guided by a therapist, the other two being stand-alone programmes (Miner et al., 2016, Kuhn et al., 2017). I did not set out to consider therapeutic alliance, given the limited, albeit growing research on therapeutic alliance in i-CBT (Knaevelsrud and Maercker, 2007), however it is widely considered an essential ingredient in psychotherapy (Bordin, 1979), and was measured post-treatment in the experimental treatment arm in one guided i-CBT study (Littleton et al., 2016). Using the Working Alliance Inventory-Short form (WAI-S) (Horvath and Greenberg, 1989), strong alliance was reported across three areas of measurement: agreement of therapeutic tasks; bond between therapist and client; and mutual endorsement of therapeutic goals.

5.2.3 Treatment non-uptake

Five studies reported non-uptake, defined as the number of individuals offered but not taking up treatment (Engel et al., 2015, Litz, 2007, Spence et al., 2011, Littleton et al., 2016, Lewis et al., 2017a). Non-uptake for two studies comparing i-CBT with active treatment comparators, reported 18.60% for i-CBT, and 0% for optimised

care (Engel et al., 2015), and 15.22% for i-CBT, and 14.63% for psycho-education website comparison (Littleton et al., 2016). It was not possible to conduct meaningful non-uptake meta-analyses since non-uptake rates in the remaining studies that reported this information did not differentiate between experimental arms.

5.2.4 Treatment dropout

Dropout ranged from 8.69-62.5% and was higher in the i-CBT intervention across all but two of the studies, both studies of guided, i-TF-CBT interventions compared to waitlist (Knaevelsrud et al., 2015, Spence et al., 2011). There was statistically significant evidence for greater dropout from i-CBT compared with waitlist/TAU/minimal attention (k=8; N=585; RR 1.39; CI, 1.03 to 1.88), as shown in Figure 7. As can be seen in Figure 8, there was no evidence of greater dropout from i-CBT than i-non-CBT (k=2; N=132; RR 2.14; CI, 0.97 to 4.73). Interestingly, dropout was higher for i-CBT, compared with waitlist/usual care/minimal attention for two of the three included studies that concerned i-CBT programmes without a trauma focus (Kuhn et al., 2017, Miner et al., 2016), as can be seen in Figure 7.

Two studies attempted to record dropout reasons with rates. Knaevelsrud et al., (2015) reported few responses with some individuals noting technical problems, lack of privacy to use the programme undisturbed. Lewis et al., (2017a) reported eight participants dropped out (19.05%), with two individuals reporting a lack of time to dedicate to the programme, two finding the programme difficult, one feeling symptoms had improved, and three individuals did not provide a reason.

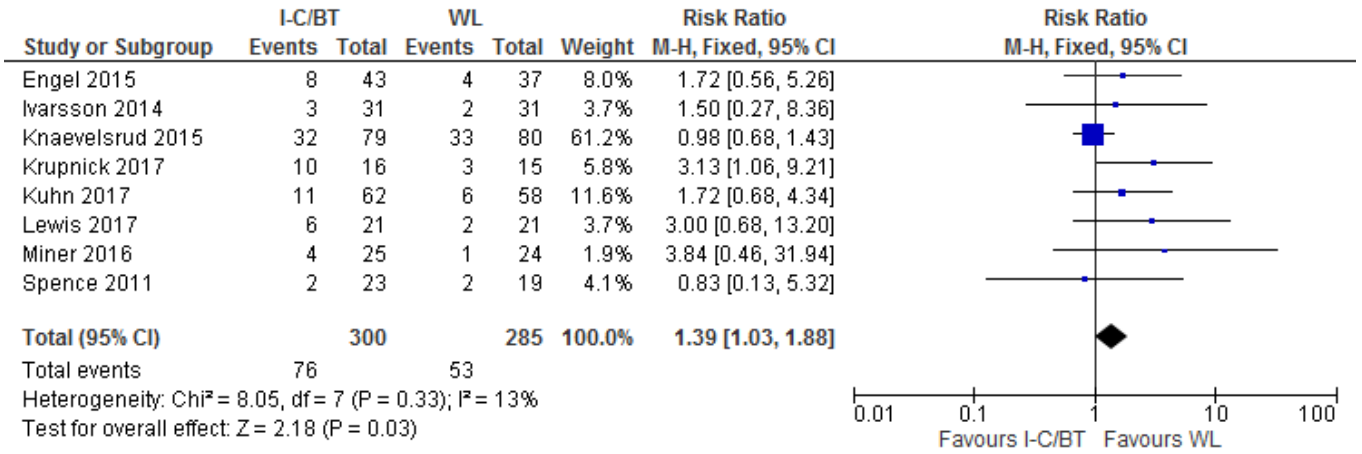

Figure 7: Dropout forest plots for i-CBT versus waitlist/usual care/minimal attention

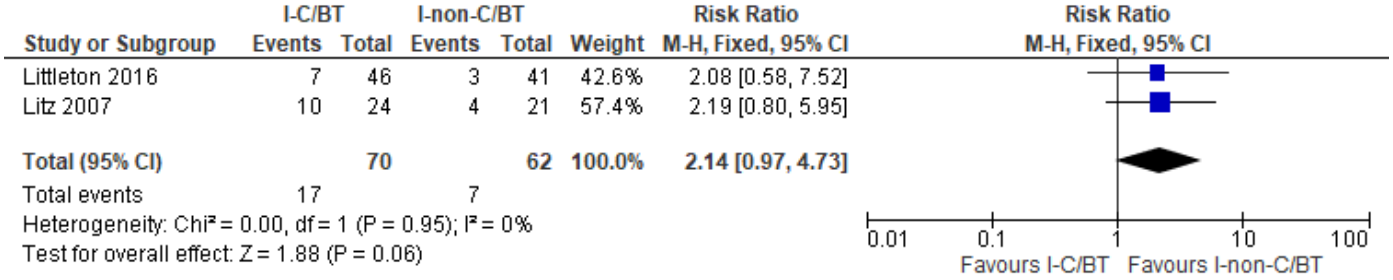

Figure 8: Dropout forest plots for i-CBT versus i-non-CBT

5.2.5 I-CBT programme usage: therapy and homework adherence

Most studies reported programme usage, albeit in a range of formats, including information on module/homework completion, logons, and self-reported usage. Three studies reported the percentage of individuals completing all programme modules, from 35-38.71% (Engel et al., 2015, Lewis et al., 2017b, Ivarsson et al., 2014). Two studies examining 'PTSD Coach' found mean, self-reported weekly usages of 2.65 times per week (SD=1.03) and 2.27 days per week (SD=1.76), in the treatment groups (Kuhn et al., 2017, Miner et al., 2016). Engel et al., (2015) reported 65% of participants completed at least 6 of the 18 expected logins, with 35% completing all logins. Spence et al., (2011), reported the highest level of engagement, with a mean of 6.74 'lessons' completed (SD=0.54), the total number of lessons being seven, strong homework compliance, with 81% reporting 20 minutes or more daily homework practice, and participants downloaded the majority (85%) of the additional resources available.

5.2.6 Adverse effects

The presence/absence of adverse effects was reported in only two studies. Littleton et al., (2016) noted a clinically significant increase in depression symptoms post-treatment for two individuals in the intervention condition, with one of these individuals also reporting a clinically significant increase in anxiety symptoms. However, it is difficult to attribute this to i-CBT as, sadly, these individuals had also both experienced the death of an immediate family member during treatment. Post-treatment clinically significant increases in anxiety were reported for three individuals, and one individual in the control condition experienced a clinically significant increase in depression symptoms between post-treatment and follow-up. An increase in PTSD symptoms was not reported in any study, from baseline to last available follow-up.

5.3 Chapter summary

A systematic review of ten included studies found i-CBT acceptability according to measures of acceptability, satisfaction, therapeutic alliance, and i-CBT programme usage. Lower levels of acceptability were suggested through non-uptake and dropout rates.

6. Chapter Six: Results of an RCT to determine the acceptability of GSH i-TF-CBT

This chapter presents quantitative analyses of a sub-study of the RAPID RCT, to determine the acceptability of 'Spring' GSH i-TF-CBT, for adults with mild to moderate PTSD, and how this compared with the acceptability of individual face-to-face TF-CBT. Results of analyses determining whether treatment outcome is influenced by treatment acceptability are also presented. Qualitative findings from interviews with RAPID participants and therapists are reported in chapter seven.

6.1 Recruitment and retention of RAPID participants

RAPID participant recruitment and retention is shown in Figure 9. Between August 2017 and December 2019, 726 referrals of individuals with probable PTSD were received; telephone screening was conducted with 420 individuals (57.85%), and of these, 302 individuals (71.90%) were found to be eligible at the screening stage. Of those who were telephone screened, 106 individuals were excluded at baseline assessment: 58 (54.72%) refused to continue to baseline; PTSD was not the primary diagnosis for 11 (10.38%); 23 (21.70%) were experiencing PTSD due to more than one event; seven (6.60%) scored more than 49 on the CAPS-5; three (2.83%) refused to consent at baseline; three (2.83%) had expressed a preference for one study arm and it was therefore agreed they would not proceed; and a medication change occurred a day prior to baseline for one individual (0.94%). Of the 420 screened, 196 (46.67%) individuals met inclusion criteria and were randomised to receive treatment in the RAPID Trial. Ninety-seven participants (49.49%) were randomised to GSH i-TF-CBT and 99 (50.51%) were randomised to TF-CBT.

The 16-week assessment was completed by 160 individuals (81.63%): 77 (79.38%) GSH participants, and 83 (83.84%) TF-CBT participants. The 52-week assessment was completed by 139 individuals (70.92%): 69 (71.13%) GSH participants, and 70 (70.71%) TF-CBT participants.

Withdrawal from the trial and/or intervention, post-randomisation, was reported for 16 individuals (8.16%). None of these participants withdrew due to adverse events, nor did they request that their data be removed, and reasons for withdrawal were reported in every case. Eleven individuals withdrew from GSH, providing the following reasons: not ready to engage in therapy (n=1), unable to commit to therapy (n=3), physical health reasons (n=1), wanted more than

GSH/preferred alternative (n=3), feeling better due to a medication change (n=1), , finding it difficult to engage with 'Spring' (n=1), and 'no longer interested' (n=1). Five individuals withdrew from TF-CBT, reporting the following reasons: not feeling solutions were offered (n=1), difficulty getting time off work for sessions (n=1), serious illness in the family (n=3).

Difficulties engaging with the allocated treatment, or a preference for an alternative treatment, were the reported reasons for seven of the 16 participants, five of whom were GSH participants. However, we acknowledge that the other participants might also have withdrawn due to treatment specific reasons, though may have preferred to report other reasons that may have been more palatable for the research team. We can therefore be reasonably confident in inferring treatment non-acceptability as a reason for withdrawal in at least seven of the sixteen cases (43.75%).

Of the 97 participants randomised to GSH, eight (8.25%) participated in post-treatment qualitative interviews. Of the 23 RAPID therapists delivering treatment, seven (30.44%) participated in post-treatment qualitative interviews.

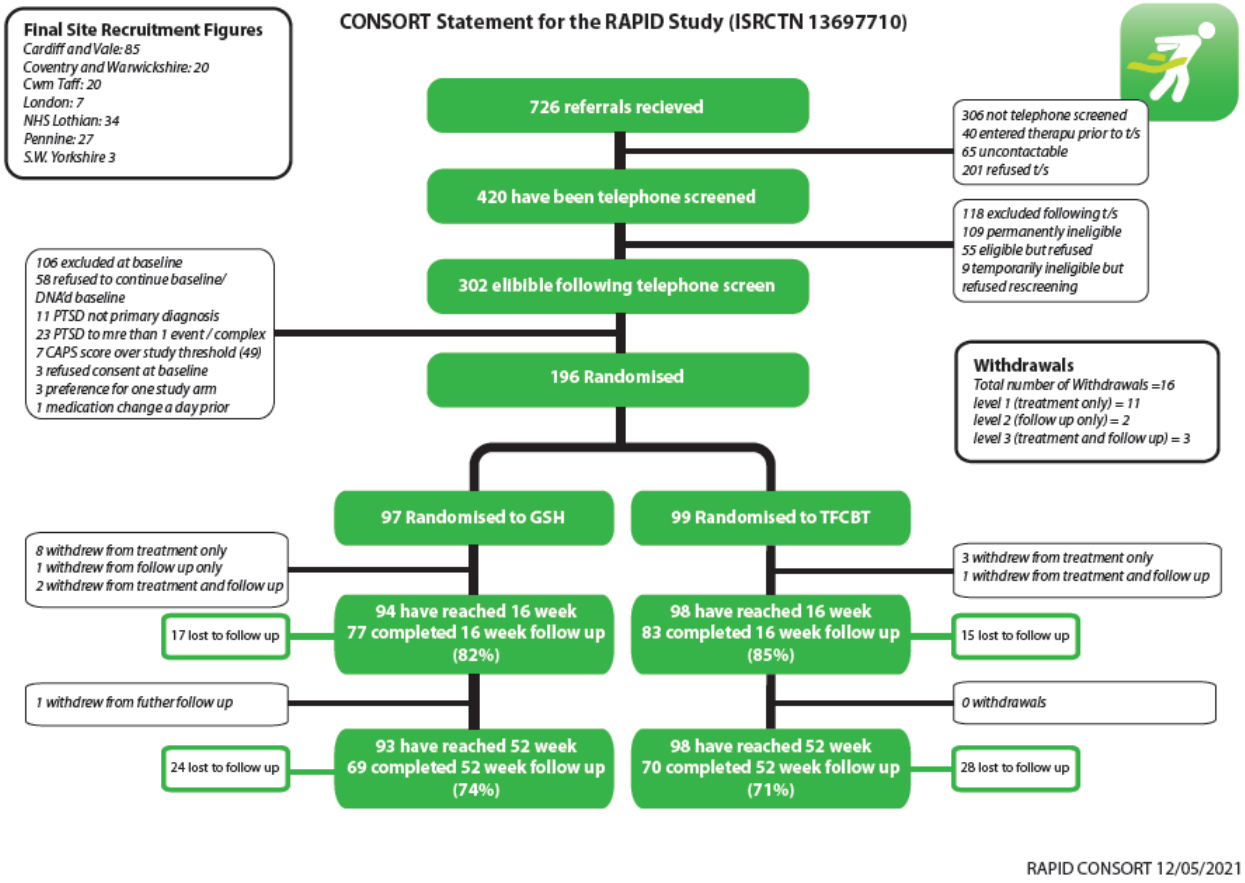

Figure 9: RAPID consort

6.2 Participant characteristics

Participant demographic and clinical characteristics across treatment allocations are shown in Table 19. Roughly two-thirds of participants were female, though this proportion was reflected consistently across groups. Total mean age was 36.54 (SD=13.44), time since trauma was 37.42 months (SD=77.15), CAPS-5 baseline score was 35.10 (SD=6.72) and mean total PHQ-9 baseline score was 16.62 (SD=6.69) and means across groups were consistent for all these characteristics. Participant ethnicity and recruitment site was also roughly equivalent across groups, though 'White: Welsh/English/Scottish/Northern Irish/British' was the predominant ethnic group, making up 172 (87.76%) of the participants. The Cardiff & Vale UHB site was the largest site, recruiting, 77 participants (39.29%). One hundred and twenty-four (63.27%) participants had a level of education of '2+ A levels or equivalent', and level of education was roughly equivalent across groups, apart from 'degree level or above', and '1-4 GCSEs or equivalent', where there was less equivalence.

	Total (n=196)	**GSH (n=97)**	**TF-CBT (n=99)**
Female Gender (%)			
	125 (63.78%)	62 (63.92%)	63 (63.64%)
Age at assessment			
	36.54 (13.44)	35.42 (13.46)	37.63 (13.40)
Time since trauma (in months)			
	37.42 (77.15)	36.31 (80.94)	38.53 (73.62)
Mean Total Baseline PTSD Symptoms Clinician Administered PTSD Scale for the Diagnostic and Statistical Manual of Mental Disorders Version 5 (SD)			
	35.10 (6.72)	34.63 (6.80)	35.57 (6.65)
Mean Total Baseline Depression Patient Health Questionnaire Version 9 (SD)			
	16.62 (6.69)	16.54 (7.15)	16.71 (6.24)
Ethnicity			
White: Welsh/English/Scottish/Northern Irish/British	172 (87.76%)	86 (88.66%)	86 (86.87%)
White: Irish	2 (1.02%)	1 (1.03%)	1 (1.01%)

	Total (n=196)	**GSH (n=97)**	**TF-CBT (n=99)**
White: Any other White background	6 (3.06%)	3 (3.09%)	3 (3.03%)
Mixed/Multiple ethnic groups: White and Black Caribbean	1 (.51%)	_	1 (1.01%)
Mixed/Multiple ethnic groups: White and Black African	1 (.51%)	1 (1.03%)	_
Mixed/Multiple ethnic groups: Any other Mixed / Multiple ethnic background	1 (.51%)	1 (1.03%)	_
Asian/Asian British: Indian	3 (1.53%)	2 (2.06%)	1 (1.01%)
Asian/Asian British: Pakistani	1 (.51%)	1 (1.03%)	_
Asian/Asian British: Bangladeshi	1 (.51%)	_	1 (1.01%)
Asian/Asian British: Chinese	2 (1.02%)	1 (1.03%)	1 (1.01%)
Black / African / Caribbean / Black British: African	3 (1.53%)	1 (1.03%)	2 (2.02%)
Black / African / Caribbean / Black British: Caribbean	1 (.51%)	_	1 (1.01%)
Black / African / Caribbean / Black British: Any other Black / African / Caribbean background	1 (.51%)	_	1 (1.01%)
Any other ethnic group	1 (.51%)	_	1 (1.01%)
Highest level of qualification			
'No qualifications'	8 (4.08%)	7 (7.22%)	1 (1.01%)
'1-4 GCSEs or equivalent'	24 (12.25%)	12 (12.37%)	12 (12.12%)
'5+ GCSEs or equivalent'	36 (18.37%)	17 (17.53%)	19 (19.19%)
'Apprenticeship'	4 (2.04%)	1 (1.03%)	3 (3.03%)
'2+ A Levels or equivalent'	46 (23.47%)	24 (24.74%)	22 (22.22%)
'Degree level or above'	64 (32.65%)	27 (27.84%)	37 (37.37%)
'Other qualifications' (level unknown)	14 (7.14%)	9 (9.27%)	5 (5.05%)

	Total (n=196)	GSH (n=97)	TF-CBT (n=99)
Recruitment Site			
Aneurin Bevan UHB	9 (4.59%)	5 (5.15%)	4 (4.04%)
Cardiff & Vale UHB	77 (39.29%)	40 (41.24%)	37 (37.37%)
Coventry and Warwickshire Partnership NHS Trust	20 (10.20%)	9 (9.28%)	11 (11.11%)
Cwm Taf Morgannwg UHB	19 (9.69%)	8 (8.25%)	11 (11.11%)
East London NHS Foundation Trust	7 (3.57%)	3 (3.09%)	4 (4.04%)
NHS Lothian	34 (17.35%)	17 (17.53%)	17 (17.17%)
Pennine Care NHS Foundation Trust	27 (13.78%)	13 (13.40%)	14 (14.14%)
South West Yorkshire Partnership NHS Foundation Trust	3 (1.53%)	2 (2.06%)	1 (1.01%)

Table 19: Demographic and clinical characteristics of RAPID participants at baseline

Demographic and clinical characteristics of individuals who participated in qualitative interviews are described in chapter seven.

6.3 Therapy adherence

Acceptability was suggested by therapy uptake, with only five (5.15%) GSH participants, and only three (3.03%) TF-CBT participants being offered, but not attending any therapy sessions. Acceptability was also indicated through full therapy adherence, with 77 (79.38%) GSH participants fully adhering to therapy, completing three or more therapy sessions, and 55 (55.55%) TF-CBT participants fully adhering to therapy sessions, completing eight or more sessions. Twelve (12.37%) GSH participants partially adhered to therapy sessions, or dropped out, completing less than three sessions, compared with 37 (37.37%) TF-CBT participants, dropping out, or completing less than eight therapy sessions. This is shown in Table 20.

	GSH (n=97)	TF-CBT (n=99)
Missing data	3 (3.09%)	4 (4.04%)
Non-uptake (no sessions attended)	5 (5.15%)	3 (3.03%)
Partial adherence (<3 GSH sessions, <8 TF-CBT sessions)	12 (12.37%)	37 (37.37%)
Full adherence (≥ 3 GSH sessions, ≥8 TF-CBT sessions)	77 (79.38%)	55 (55.55%)
Mean Total Adherence per group (%)	79.57 (SD=36.47)	72.40 (28.94)
Mean Total Adherence (pooled) (%)	75.98 (33.03)	

Table 20: Therapy session non-uptake, partial adherence, and full adherence

A one-way ANCOVA, controlling for gender, site, time since trauma, baseline CAPS-5 score, and baseline PHQ-9 score, did not find a statistically significant difference between therapy adherence for GSH and TF-CBT [$F(1,179)=2.747$, $p=0.099$, $\eta^2=.015$].

6.4 'Spring' usage

Of the 97 participants randomised to GSH, ten (10.31%) did not log in to the 'Spring' programme. As 'Spring' log-in details were provided at the first therapy session, we know that four of these participants did not have the means to log in, due to not attending any therapy sessions. Forty-eight (49.48%) participants partially completed 'Spring' steps, which was defined as starting any number of steps, and/or completing up to seven steps. Thirty-nine (40.21%) participants completed all eight steps. This is shown in Table 21.

'Spring' Steps Completed		
Not Started	**Partially Completed**	**Completed**
10 (10.31%)	48 (49.48%)	39 (40.21%)

Table 21: 'Spring' steps completion

6.5 Therapeutic alliance

Therapeutic alliance scores using the ARM-5 were available mid-treatment for 99 participants and 106 therapists, and post-treatment for 125 participants and 106 therapists (see Table 22). ARM-5 total scores can range from 5 to 35, with higher scores indicating higher acceptability. Acceptability was indicated by the high mean scores found for participant- and therapist-reported alliance, at both treatment timepoints, across both GSH and TF-CBT groups.

	Mean Total Therapeutic Alliance (Agnew Relationship Measure Version 5) (SD)			
	Participant Mid-Treatment	**Therapist Mid-Treatment**	**Participant Post-Treatment**	**Therapist Post-Treatment**
GSH	26.91 (2.98) (n=44)	25.52 (2.54) (n=52)	26.90 (3.55) (n=58)	23.27 (14.14) (n=52)
TF-CBT	27.38 (3.09) (n=52)	26.08 (1.95) (n=51)	28.06 (1.81) (n=65)	25.73 (6.20) (n=51)
Total	27.17 (3.03) (n=96)	25.80 (2.27) (n=103)	27.51 (2.82) (n=123)	24.49 (10.97) (n=103)

Table 22: Therapeutic alliance scores reported by participants and therapists at mid- and post-treatment, across groups

Participant-reported mid-treatment therapeutic alliance

A one-way ANCOVA, controlling for gender, site, time since trauma, baseline CAPS-5 score, and baseline PHQ-9 score, found that participant-reported therapeutic alliance scores at mid-treatment did not differ significantly [$F(1,89)=0.134$, $p=.715$, $\eta^2=.002$]. This suggests acceptability, equal across groups.

Therapist-reported mid-treatment therapeutic alliance

A one-way ANCOVA, controlling for gender, site, time since trauma, baseline CAPS-5 score, and baseline PHQ-9 score, found that therapist-reported therapeutic alliance scores at mid-treatment did not differ significantly, suggesting acceptability, equal across groups [$F(1,96)=1.639$, $p=.514$, $\eta^2=.017$].

Participant-reported post-treatment therapeutic alliance

A one-way ANCOVA, controlling for gender, site, time since trauma, baseline CAPS5 score, and baseline PHQ-9 score, found a statistically significant difference between groups for participant-reported post-treatment therapeutic alliance for GSH and TF-CBT participants [$F(1,116)=4.850$, $p=.030$, $\eta^2=.040$]. Therefore, whilst high levels of therapeutic alliance were found across groups, indicating acceptability, TF-CBT was the superior.

Therapist-reported post-treatment therapeutic alliance

A one-way ANCOVA, controlling for gender, site, time since trauma, baseline CAPS5 score, and baseline PHQ-9 score, found that therapist-reported therapeutic alliance scores at post-treatment did not differ significantly across GSH and TF-CBT groups [$F(1,96)=1.488$, $p=.225$, $\eta^2=.015$]. This suggests acceptability, equal across groups.

6.6 Treatment satisfaction

CSQ-8 data was available for 70 of the 97 participants randomised to GSH, and for 75 of the 99 participants randomised to TF-CBT. CSQ-8 scores can range from 8 to 32, with higher scores indicating higher satisfaction. Acceptability was suggested by the mean total satisfaction scores for participants across groups. Means and standard deviations (SD) are presented in Table 23.

	Mean	**SD**	**N**
GSH Treatment Satisfaction	26.43	6.543	69
TFCBT Treatment Satisfaction	29.74	3.307	74
Total Treatment Satisfaction	28.15	5.37	143

Table 23: Means and standard deviations of treatment satisfaction scores across groups

A one-way ANCOVA, controlling for gender, site, time since trauma, baseline CAPS5 score, and baseline PHQ-9 score, comparing treatment satisfaction across GSH and TF-CBT participants found a statistically significant difference between groups [$F(1,136)=15.17$, $p=.000$, $\eta^2=.10$]. This suggests that whilst high levels of satisfaction were found across groups, indicating acceptability, TF-CBT was the superior.

6.7 Adverse events

Adverse and Serious Adverse Events were recorded but none were found to be related to an individual's involvement in the RCT / treatment.

6.8 Treatment acceptability and treatment outcome

A multiple regression was conducted to test if the following variables were associated with treatment outcome, or PTSD symptoms at 16-weeks follow-up, pooled across groups: therapy adherence, treatment satisfaction, participant- and therapist-reported therapeutic alliance, mid- and post-treatment.

Missing data were excluded pairwise, with 65 cases included. The results indicated that the overall regression model was a good fit for the data. The model of acceptability (therapy adherence, satisfaction, therapeutic alliance, controlling for baseline PTSD symptoms) explained 45.0% of the variance in treatment outcome across treatment groups (R^2=.450, F(7, 57)=6.675, p=0.000). As shown in Table 24, treatment satisfaction significantly predicted PTSD symptoms at 16-week follow-up, with greater treatment satisfaction associated with lower PTSD symptoms at follow-up (standardised Beta=-.482, p=.002). Baseline PTSD symptoms also significantly predicted PTSD symptoms at 16-week follow-up, with lower baseline PTSD symptoms associated with lower PTSD symptoms at follow-up (standardised Beta=.355, p=.001).

Predictor	**Beta**	**p-value**
Therapy adherence	.021	.850
Satisfaction	-.482	.002
Therapeutic Alliance Participant Mid-treatment	.235	.058
Therapeutic Alliance Participant Post-treatment	-.140	.399
Therapeutic Alliance Therapist Mid-treatment	.051	.667
Therapeutic Alliance Therapist Post-treatment	-.168	.156
Baseline PTSD Symptoms	.355	.001

Table 24: Summary of multiple linear regression analyses for therapy adherence, treatment satisfaction, and therapeutic alliance, as correlates of treatment outcome

6.9 Chapter summary

GSH acceptability was indicated by therapy adherence, which did not differ across treatment groups. A considerable number of participants took up therapy sessions, and fully completed all planned sessions, and only a small number of participants did not attend all planned therapy sessions or chose to withdraw from a trial intervention. 'Spring' programme usage was also indicative of GSH acceptability, with only ten (10.31%) participants not logging in to the programme, and the remainder partially or fully completing steps.

GSH acceptability was indicated through ratings of therapeutic alliance reported by participants and therapists mid- and post-treatment. Scores did not differ across treatment groups, apart from participant-reported post-treatment therapeutic alliance, which was slightly in favour of the TF-CBT group. Satisfaction ratings were also indicative of acceptability, though slightly in favour of TF-CBT.

A good fit multiple regression model confirmed that the model of acceptability predicted treatment outcome, also controlling for baseline PTSD symptoms. Therapy adherence, satisfaction, therapeutic alliance, and baseline PTSD symptoms explained 45.0% of the variance in treatment outcome, and treatment satisfaction and baseline PTSD symptoms were significant predictors in the model.

7. Chapter Seven: Results of qualitative interviews with RCT participants and therapists to determine the acceptability of GSH i-TF-CBT

This chapter describes the findings of qualitative interviews with RAPID RCT participants and therapists to determine the acceptability of a GSH i-TF-CBT intervention, 'Spring', for adults with mild to moderate PTSD to a single traumatic event.

7.1 Participant interviews

7.1.1 Participant characteristics

As shown in Table 25, five female, and three male RAPID participants randomised to 'Spring' GSH i-TF-CBT were interviewed, following treatment. All were white, with a mean age of 39.25. Interview lengths ranged from 20 to 60 minutes, with a mean of 40.25. Six participants were interviewed prior to the COVID-19 national lockdown commencing 23rd March 2020, and two were conducted after, having received their treatment just prior to national lockdown.

Pseudonym	Gender	Age	Ethnicity	Education level	Trauma type	CAPS-5 Baseline Total score	CAPS-5 16week Total score	'Spring' completion	Pre/Post COVID-19 UK national lockdown	Interview length (minutes)
Mike	Male	51	White Irish	Other vocational/work-related qualifications (level unknown)	Serious accident at work, home, or during recreational activity	39	36	Full completion	No	46
Kay	Female	69	White British	Other vocational/work-related qualifications (level unknown)	Life threatening illness or injury	33	3	Full completion	No	46
Ellen	Female	25	White	5+GCSEs	Sudden violent death	32	9	Partial completion	No	38
Stewart	Male	53	White	Other vocational/work-related qualifications (level unknown)	Transportation accident	39	24	Full completion	No	43
Becky	Female	27	White	2+ A levels	Transportation accident)	40	16	Full completion	No	28
Clare	Female	24	White	Degree level or above	Other unwanted or uncomfortable sexual experience	49	40	Full completion	No	20
Emma	Female	34	White	Degree level or above	Any other stressful event or experience	27	11	Partial completion	Yes	60
Luke	Male	31	White	5+ GCSEs	Transportation accident	39	7	Full completion	Yes	41

Table 25: Participant (pseudonym) characteristics, 'Spring' GSH i-TF-CBT steps completed, and interview length.

7.1.2 Participant interview themes

Participants talked about their experience of GSH treatment and analyses revealed three overarching themes related to acceptability: 1) barriers/challenges to engagement with 'Spring' GSH i-TF-CBT; 2) facilitators/opportunities for engagement with 'Spring' GSH i-TF-CBT; and 3) outcomes. These themes are illustrated in Figures 10, 11, and 12. The views of participants were contradictory at times; therefore, some sub-themes were described by some participants as barriers and by some participants as facilitators.

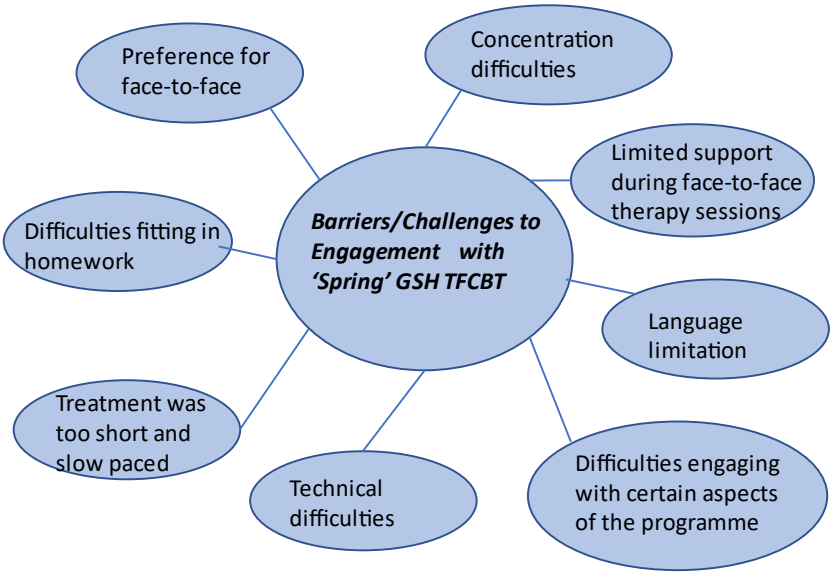

Figure 10: RAPID participant interviews theme 1: barriers/challenges to engagement with 'Spring' GSH i-TF-CBT

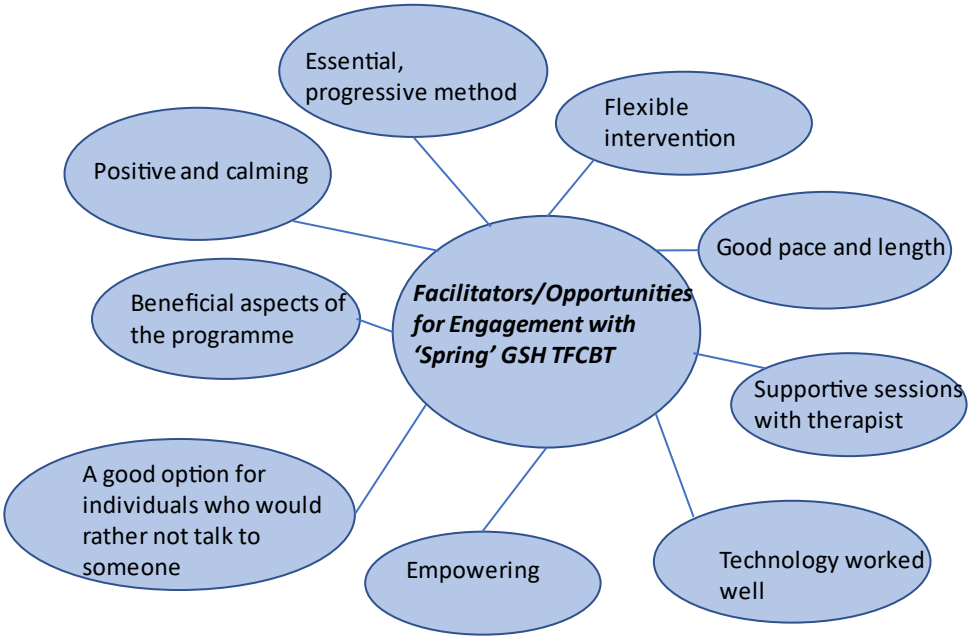

Figure 11: RAPID participant interviews theme 2: facilitators/opportunities for engagement with 'Spring' GSH i-TFCBT

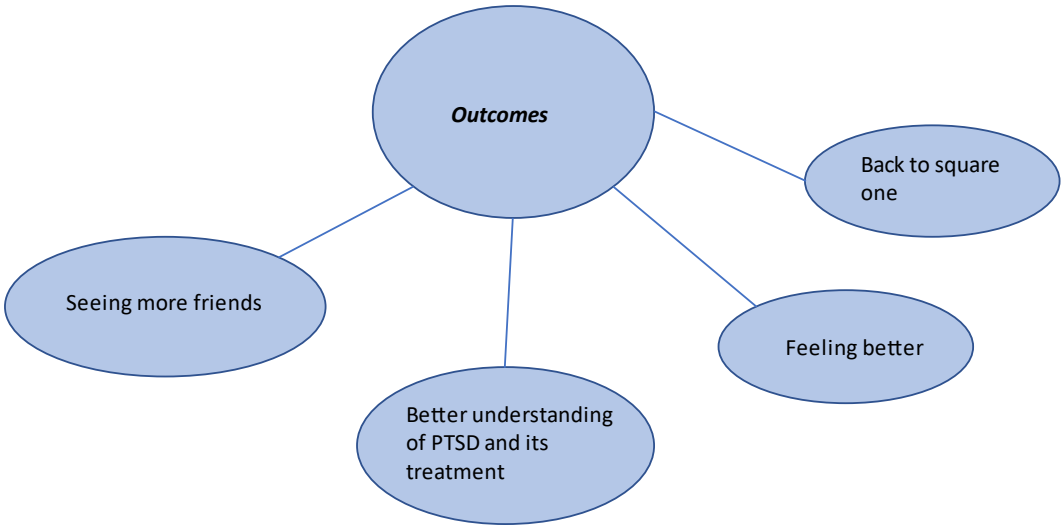

Figure 12: RAPID participant interviews theme 3: outcomes

7.1.2.1 Barriers/challenges to engagement with 'Spring' GSH i-TF-CBT

Concentration difficulties

Difficulties with concentration, impacting engagement, were highlighted. For example, Mike said, *"the iPad work, well it was alright I done it all no problem at all but it's hard for people that can't concentrate, I think... I was struggling with my concentration."*

Difficulties fitting in homework

Some participants highlighted difficulties fitting in the required 'Spring' programme homework. Becky said, *"I didn't realise that it would be so intensive.., when it got to the point of writing down… your erm trauma and then having to go over it for an extra forty minutes or whatever it was a day… that was an hour and ten minutes a day… I didn't have an hour and ten minutes."*

Emma struggled to fit in the homework around other demands, *"factoring in something that was self-driven myself, at home when I had a new born and when I suffering from trauma was very difficult to do... at one point what it did do was apply a very unintended and probably undesirable additional pressure on me... I was particularly concerned at one point was I going to be able to stick this through… was sort of carrying some guilt each day, oh I haven't done that …"*

Emma highlighted difficulties finding time for the required 'down time', *"it took me roughly the same amount of time to build up to doing it… and then the same amount of time to wind down... And so that… becomes a huge chunk of, of a day."*

Treatment was too short and slow paced

Participants commented on the appropriateness of the length of the treatment, and some found it too short. Stewart talked about this, *"it was too short... For my problems… I think the eight weeks is, is just, you know, just touching the nub of the problem... I think to be honest it wasn't long enough, 'cause I still needed her [therapist] and, and she thought that as well…"*

Mike shared similar views, *"I think it was eight weeks for the course, yeah… And then all of a sudden bang… I honestly don't think that eight weeks, in my situation, I can't speak for anybody else, it's not long enough."*

Clare felt the programme was paced too slow, *"when I was going through the programme, it was a little like err, it felt very slow going, especially in the beginning where it was very like educational."*

Technical difficulties

Technical difficulties caused frustration for some individuals. For example, Kay, experienced difficulties with the 'Spring' website being down: *"I gained a lot from it and possibly lost a little from it because of the teething problems of the, er the web-site... you know so there was a little bit of frustration… So I'd go to it when I was at a particularly low ebb… and I couldn't access it... Which put me back a little…"*

Clare described frustrations with the toolbox, *"so a couple of times um, when I would like load the programme, the tool err box at the bottom… wouldn't load... but yeah that wasn't, that wasn't too major."*

Luke spoke of difficulties with the App, *"Um I had a few occasions where it was down... I could have really been having a bad day and I, and I really tried to get on... But just, for, for it to go down... Err was not a good thing really... I was almost, almost using the, the App as a bit of a safe haven you know."*

Difficulties engaging with certain aspects of the programme

Participants talked about the intervention components, some expressing the difficulty they had found engaging with particular components. For example, Ellen found it difficult to relate to the character/case studies, *"what I found with the, with the case studies… I just found that none of them related to what I went through... And I couldn't really relate with them or empathise because... I didn't understand... like I know it's a bad thing they went through but I think there was no link I found...*

it's like my [traumatic event]... there was no story... Not even close to it... there was nothing like for like a sudden death."

Emma felt she would have benefited from hearing a real account, rather than accounts read by actors*, "my feeling was that the four different accounts were real and truthful accounts but read by actors... And the effect that it had on me, and the reason I'm flagging it is because it was quite, erm, quite a strong response that listening to those accounts took me out of that immersive experience… I can't really maybe articulate the feeling but it was almost like bursting a bubble when I was very immersed in it, thinking, you know, I, I'm really dealing with my, my feelings here and then I sort of was brought out of that... I just feel that as a participant I would have greatly benefitted from hearing a real account... somebody reading from the heart would have made a huge difference."*

Ellen talked about treatment being a difficult process that gets worse before it gets better, *"mentally you need to be ready for it because it's not an easy process, any therapy would not be an easy process… on the guided self-help it says on there that it does get worse before it gets better, and to just expect to get better would be wrong. And [therapist] went through it with me as well, saying… during the course of the treatment it could get worse before it will get better... I probably would have questioned is this working otherwise."*

Becky highlighted the challenge of the trauma narrative writing exercise, within step five, *"going over the, the story thing over and over again… that wasn't particularly nice you know, I got… kind of very down after doing that quite a lot and a bit stressed out and headaches and stuff after doing that... But then that got easier the more I did it and the more I went through it."*

Becky suggested improvements to the pie chart of responsibility exercise, within step six of the programme, *"I think there were a few erm, things that probably could've been improved… there was a, like a pie chart thing that said how much of the responsibility over the incident erm, do you attribute to yourself... and there wasn't an option saying I don't attribute any of it to myself... because you know, I*

couldn't have helped what happened to me... I know it wasn't my fault and I kind of felt that I had to put that it was partially my fault … I think that needs to be changed."

Emma highlighted the juxtaposition faced by some of coming to terms with their trauma, whilst also not wishing to forget the event. Emma felt that the programme was encouraging her to move away from her trauma, however her trauma was an event that she also didn't wish to forget, *"I was being encouraged and I can see why to move away from, from the trauma. Now in my mind, moving away and not thinking about my trauma meant moving away and not thinking about the birth of my first baby and, I wanted, and I still want to remember the birth of my first baby"*

Clare expressed frustrations with the 'challenging your thoughts' exercise, *"the activity where you had to challenge… your thoughts… like both were generalisations or catastrophizing... And it felt a little bit like, it didn't apply to… sexual assault or I don't know how to explain it, like, like um sexual assault is very common and, and one of the things that he kept saying, like it's not likely to happen, like you don't have to worry about it anymore, and that was a little bit frustrating I guess, but that might have just been me reading too much into it…."*

Limited support during face-to-face therapy sessions

The majority of interviewees commented on strong and supportive relationships with their guiding therapists, suggesting acceptability for several individuals. Not all participants felt this way though. For example, Becky felt the therapy sessions were, *"very administrative, it was you know, I didn't really feel that there was any point of travelling to go to them… it wasn't very personal… I thought it would be good to you know be able to actually speak to somebody and I dunno, I kind of just felt very shutdown every time I tried to kinda expand on you know a question... the lady I saw I didn't have that connection so yeah, you know… the majority of it being at home you know on your own sorta thing but I thought there would be a bit more of an element of support there off somebody…"*

Language limitations

Interviewees received the programme through the medium of English. Whilst receiving the intervention in English had not been a barrier to Emma's engagement, she did acknowledge that it would have helped her if the programme were available in her mother tongue, the Welsh language: *"the one thing… that I think would have helped the, the process for me was had I been able to express entirely through my mother tongue which is Welsh… erm, and the reason I say that is because when I think about the trauma, the, you know, the raw emotion that comes out... It comes out first in Welsh [laughs] and, and there is a degree, I know it sounds ridiculous 'cause I'm obviously bilingual but there is a degree that I'm translating a way from what I felt most comfortable in… I really believe that I would have got to the end result quicker… this is not a, this is not a Welsh only thing… there's a number of language in, in [town … if there can be an element of encouraging that individual to write it in their native language."*

Preference for face-to-face

Of those who indicated a treatment preference, following receipt of the GSH intervention, face-to-face was considered to be preferable. For example, Kay stated *"I think I was the type of person that was better off with a one-to-one that needed to do that eye contact with me and bring me back into the, the real world."*

7.1.2.2 Facilitators/opportunities for engagement with 'Spring' GSH i-TF-CBT

Participants highlighted many facilitators and opportunities for engagement with, and acceptability of the 'Spring' GSH intervention.

Positive and calming

Some participants commented that the GSH intervention was positive and calming, suggesting acceptability for some. Kay commented, *"I didn't know what to expect erm but it was, it was all done very calmly..."*

When asked how he would describe GSH to another person, Stewart remarked positively, *"if they genuinely think they've got PTSD, you know, if it's been some trauma that's caused this... Then go for it... there's a lot of self-searching that goes on… even though you don't know you're doing it."*

Essential and progressive method

Some participants described the intervention method as progressive, and essential in the context of COVID-19. For example, Emma expressed her passion for the benefit she received, *"I think it was… a very great and, and progressive method of doing this and ironically as the year's gone on with COVID I think you know, something like that is more and more essential… I feel so passionate about the benefit that I received."*

Flexible intervention

As noted previously, GSH non-acceptability was suggested by some individuals, through difficulties fitting in the homework. In contrast, interviewees overwhelmingly spoke positively about the flexibility of the intervention, fitting it around other life commitments. Ellen talked about this, *"because I've got a little one, erm I... it was nice to be able to just sit down and make new things and do it instead of having to go to treatments all the time which with work and life commitments is ... can be quite stressful… I think it was the perfect balance to be honest. It was a weekly check in essentially, erm on one week I didn't have to go out of my way or leave the house. Whereas it's not far but when you go to an appointment you usually have to put aside like two/three hours... But it was with a phone call, you can do the phone call and then carry on with your day... I think with a lot of people they struggle with work commitments."*

Stewart also talked about the flexibility of the intervention, *"luckily it fit in around work as well, so I'd gone back to work at the time... it didn't impede on my work."*

Good pace and length

Some interviewees had felt that the treatment was too short, though some found the pace and length to be just right. For example, Luke said, *"you have to use it every day, it was nice to just do half an hour every day… Um I think it was just, just perfect for me."*

Supportive sessions with therapist

Some participants talked about limited support with their therapist. However, some participants frequently reported feeling supported by their therapist, and

described a positive therapeutic connection, indicating acceptability for some. Mike talked about this, *"I've got a lot of time for [therapist] because she could see that I needed help and she tried... Err, she was really good, [therapist] was, I've got to be honest.... when I was there with her it helped for me to talk about things... And give me a bit of motivation… my concentration sort of thing."*

Kay expressed positivity around her therapeutic relationship with her therapist, commenting *"the therapist that was dealing with me was absolutely perfect, I couldn't fault her… "I couldn't make eye contact and one thing I did notice about the therapist and it's obviously part of the training, her head would come down with mine and she'd bring my eyes back up without me realising she was doing it... And I got this eye contact with her, so she was superb... Even birds in the garden frightened the living daylights out of me. And bit by bit and then suddenly, I'd sit, sit out in the garden, there's birds fluttering around me, I live on a farm and, and I didn't care. I, I was happy and, and I put that down actually down to her."*

Stewart also talked positively about his therapist, *"and she [therapist] could point out things to me that I, I wasn't in any fit state to even, to even contemplate."*

Ellen found the sessions with her guiding therapist to be helpful, particularly with respect to the trauma narrative writing exercise, part of step five, which Ellen was initially avoiding. Ellen said, *"because she [therapist] was reassuring and showing where I should be... every time I'd go in to see if my, erm, erm symptoms were improving. Or if I was suffering badly we'd talk... Because I had a little bit of a dip where I was in the middle and it sort of gets worse before it gets better when you're confronting it... there's a bit of a mental fight going on... So it's nice to be able to go through it with [therapist] if I was having any problems... So she like sort of sat down and made me do it [trauma narrative exercise] there with her... that was the most difficult part of it... I felt that I needed a bit of a push to do... That was, erm sort of where I went over the hill and it got it a lot easier... Someone's sort of picking you up as you're going along."*

Luke felt comfortable with, and supported by his therapist, *"he was brilliant, err he made me feel comfortable... he really made me you know, open up and really get into, err the accident you know... something that I'd never really, done, that I'd done with anybody before... So, I felt comfortable enough to, to feel and even when I was holding back you know, I still, I still felt comfortable, to tell him, you know..."*

Technology worked well

Some interviewees encountered technology difficulties, impacting on acceptability, though not all had issues with technology. For example, Becky said, *"it worked really well... I think it was all quite, quite user friendly… It seemed very well structured."*

Empowering

Some interviewees remarked on the empowering self-help learning gained through the GSH approach, indicating acceptability. Becky talked about this, *"the whole like self you know learning thing, self-therapy I thought it was really good and you know, quite a lot of the time going through it I thought oh okay, yeah that makes sense…."*

A good option for individuals who would rather not talk to someone

A preference for face-to-face was indicated by some interviewees, though some acknowledged that an alternative to face-to-face may be more acceptable for individuals who would prefer not to talk to a therapist in the traditional face-to-face therapy approach. For example, Becky said, *"I thought it [GSH] was such a good idea and I think it's great you know that people can do it in their own homes if they felt a bit nervous about talking to somebody."*

Beneficial aspects of the programme

Some interviewees found aspects of the programme to be challenging, including the trauma narrative exercise. However, acceptability was also inferred for some participants who expressed positivity around the App and its tools, and of the treatment benefit of certain components of the intervention, including the trauma narrative exercise. Some interviewees talked about the handiness of the App, something that they continue to use. For example, Stewart said, *"I used the app a lot... I still am using it... Just for the relax, er, techniques... it's got some very good*

grounding stuff on there… I used it at work when I found myself getting a bit wound up… it helped, I know how to calm down now... It helped me deal with managing the problem shall we say."

Ellen spoke of the benefit of the programme in helping her to confront her problems, *"it made me confront my problems instead of trying to push it to the back of my head which I was obviously doing. I was subconsciously doing... I was trying to hold the door shut on something that wanted to be let out... through the treatment I've sort of accepted this has happened to me but I can't let it define me."*

Ellen described the trauma narrative writing exercise as a turning point: *"erm sort of where I went over the hill and it got it a lot easier...I think it's acceptance of what has happened...And essentially getting it out."*

Becky described the benefits of the exposure narrative writing exercise, *"I appreciated although it was difficult, to do the erm writing down and reading like exposure therapy… I think that really helped because after that, because before when I was talking about it I would get myself really like anxious and talk really quite quick and get really tense and then afterwards, it became just like I would just tell it like it hadn't happened to me because… it was just, it was just a story that I'd read to myself over and over and over again... So it became less of an upset when talking about it... So I think that definitely helped."*

Luke also talked about the benefits of the narrative writing exercise, *"I'd say that the, the most useful was the actual err, reading back of the event... the explanation of what happened that day... My thoughts, what I saw that day err and really brought everything back... Just reading over it every time... I kept adding and adding, and eventually I had quite a long paragraph, well a long story of what had happened that day... But now it's just, do you know, I openly talk about the accident to anybody now, you know... it sank, it was fitting, it was fitting a piece into my mind... It really put things into perspective, that part of it... Um it really, it, it changed my thoughts on, on a lot of things, you know... To, to not blame myself for*

things that out of your control...So, err, and it just made me, it made me happy, I guess...I felt happy again."

Luke also found benefit in the grounding tools, *"I would just log on um and… did err breathing exercises and stuff like that, so if I ever felt anxious about it, I would log on... it was a comfort for me... just really brought me back down to, to a level that was, right, you know… I wouldn't say, I felt happy, but I felt grounded."*

7.1.2.3 Outcomes

Interviewees shared a mixture of outcomes following receipt of the 'Spring' GSH i-TF-CBT intervention.

Feeling better

Many interviewees shared that they were feeling much better since the treatment, suggesting treatment satisfaction and acceptability. For example, Stewart commented, *"If it wasn't for the trial I wouldn't be where I am now."*

Ellen reflected, *"now I'm out of the other side of it my quality of life is definitely better….Erm, a lot less symptomatic. Erm, even to concentrate better… Looking forward… as long as I don't have like a relapse I think I'm okay."*

Luke described a reduction in symptoms, *"I was sleeping better... I was, I was having less and less flashbacks so... massively in a better place yeah, massively... on that last time that I went to see my Counsellor, he said "This is the last session", and I... I walked into err, it was just before COVID actually, before, we, we, we went into lockdown and everything you know... That was my last session you know… it was perfect timing for me, I felt, I felt great. ..Even through lockdown and through, I still, I've still not had any anxieties or anything, you know...everything's positive now."*

Back to square one

Contrastingly, some participants did not feel better, suggesting treatment dissatisfaction and non-acceptability in some cases. Mike shared, *"to be honest I feel like it's gone back to square one to be honest with you."*

Better understanding of PTSD and its treatment

Some interviewees had gained an increased understanding of PTSD and its treatment, suggesting treatment satisfaction and acceptability. For example, Mike said, *"When I first had my accident which was obviously six and half years now... I didn't understand it... And why I was feeling like I was... But I've got a better understanding why I feel like I do now...."*

Kay talked about a broadened awareness of how trauma can affect anybody, *"you tend to, to think of PTSD with serving erm soldiers and… And of course it, it, it affects every one of us er in life that goes through a trauma. So yes it did make me sit up and, and think about that and recognising it in people... But when traumas do come along in all shapes and sizes then erm the way it affects the brain is, is actually quite a shock and having experienced it… it was quite a shock to, to realise just how, what trauma does do to the brain."*

Ellen talked about how treatment helped her to understand how the mind can be impacted following trauma exposure, *"it was basically my mind, erm reacting to what happened and not being able to process it essentially… so it [the psychoeducation] sort of normalises it."*

Emma felt that her increased understanding of PTSD had validated the way she had been feeling: *"my understanding of it has certainly, you know broadened and deepened because I now understand, you know, what I was experiencing was, was in that group of, of mental health conditions as well... that it was actually, er, erm, a, a medical, clinical, physiological change in, in my brain... That, erm, that explained the change in how I was feeling and so, yeah, there was a degree of validation, definitely."*

Seeing more friends

Some interviewees shared their experiences of re-engaging with activities, including seeing friends, following treatment. Becky talked about this, *"I just didn't wanna be around anyone cos I just felt angry all the time for no reason and I didn't wanna put that on anybody else but it kinda helped me realise that it's normal and I can stop being angry. I can realise that I'm being angry but other than just sitting there feeling it, I can tell myself you're being angry, there's no need to be and you know, and then I can be around people more and I did then start making more of an effort to see my friends again."*

7.2 Therapist interviews

7.2.1 Therapist characteristics

As shown in Table 26, three male, and four female therapists were interviewed following their delivery of the 'Spring' GSH i-TFCBT intervention in the RAPID Trial. Most interviewees were therapists working in Cardiff & Vale UHB, the majority with low familiarity with 'Spring' prior to their involvement in the RCT. Interview lengths ranged from 28 to 78 minutes, with a mean of 59.29. All interviews were conducted post-COVID-19 UK national lockdown.

Pseudonym	***Research Site***	***Gender***	***Familiarity with 'Spring' (prior to RAPID RCT)***	***Interview Length (minutes)***
Christian	Cardiff & Vale UHB	Male	Very high	46
Laura	Cardiff & Vale UHB	Female	Low	62
Jenny	Cardiff & Vale UHB	Female	Low	78
William	Cardiff & Vale UHB	Male	Low	28
Annabel	Coventry and Warwickshire Partnership NHS Trust	Female	Low	78
Meg	NHS Lothian	Female	Low	57
Gavin	NHS Lothian	Male	Low	66

Table 26: Therapist (pseudonym) characteristics, familiarity with 'Spring' (prior to RAPID RCT), and interview length

7.2.2 Therapist interview themes

Therapists reflected on GSH intervention delivery and analyses revealed three overarching themes concerning GSH acceptability: 1) barriers / challenges to GSH engagement; 2) facilitators / opportunities for GSH engagement; and 3) considerations for the future of GSH. These are summarised in Figures 13, 14, and 15, respectively. Views of therapists were contradictory at times; therefore, some sub-themes were described by some therapists as barriers and by some therapists as facilitators.

Figure 13: RAPID therapist interviews theme 1: Barriers / challenges to engagement with 'Spring' GSH i-TF-CBT

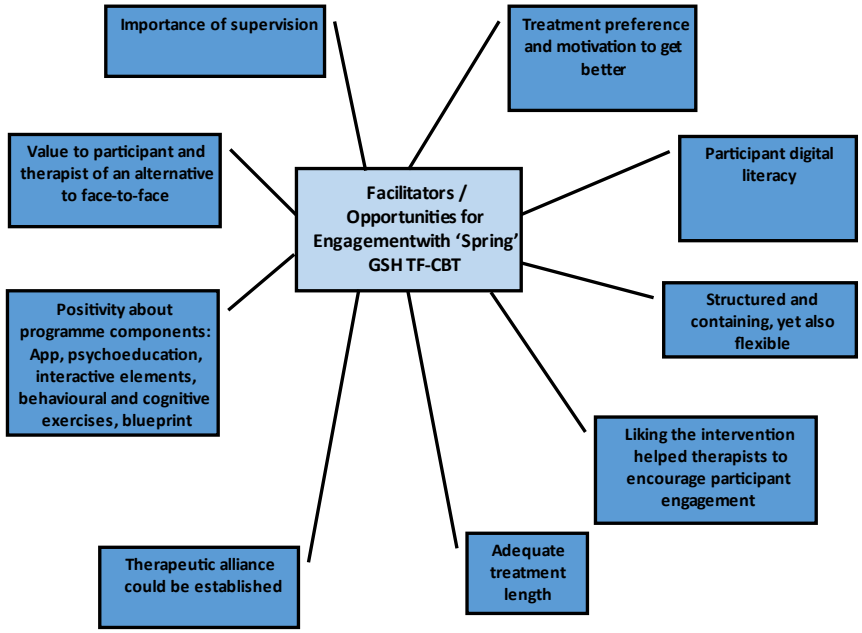

Figure 14: RAPID therapist interviews theme 2: Facilitators / opportunities for engagement with 'Spring' GSH i-TF-CBT

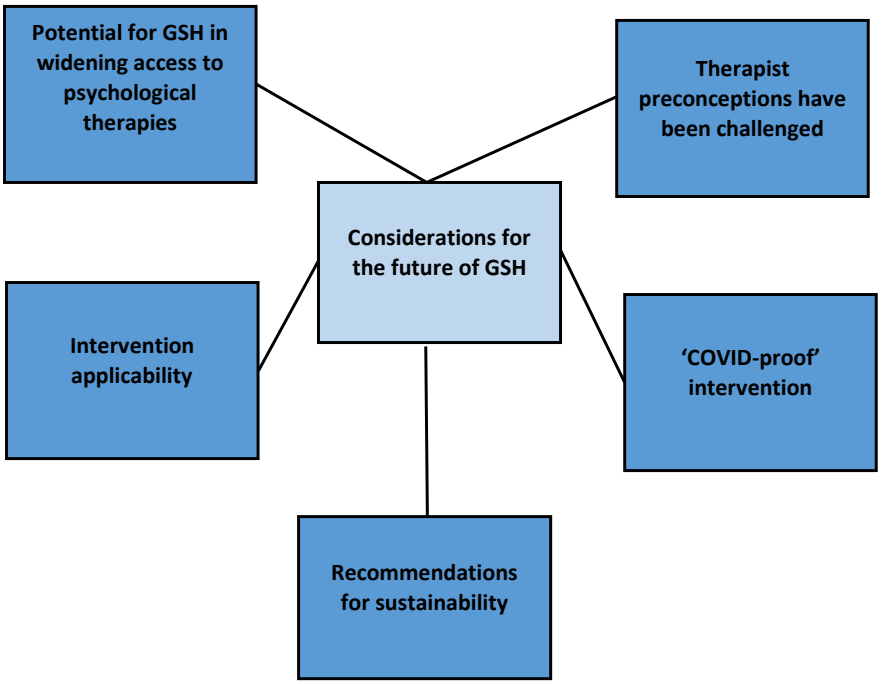

Figure 15: RAPID therapist interviews theme 3: considerations for the future of GSH

7.2.2.1 Barriers/challenges to engagement with 'Spring' GSH i-TF-CBT

Therapists highlighted several barriers and challenges to engagement and acceptability.

Participant preference for face-to-face therapy

Some participants had revealed a preference for face-to-face therapy, and likewise some therapists perceived a participant preference for face-to-face, which was considered a barrier to GSH engagement, and non-acceptability in some instances. For example, Christian said, *"if they were happy… to have the online, no, no problem at all really, um people that were disappointed, that wanted the face to face... you know, I think people vote with their feet... In these instances, and you cancel appointments or, or drop out early… I think it, it comes down to patients preference at the beginning."*

Laura proposed some participants might have considered the GSH offering to be 'flippant', expecting more human support, *"I think there's a bit of a societal expectation in certain thoughts of trauma… something about being attended to by a human being… in a compassionate way, when you've experienced sort of, the sort*

of trauma that society finds abhorrent... it feels a bit flippant to just give them four face to face sessions with a computer… some people welcomed it but other people it didn't feel right."

Therapist unfamiliarity with intervention and modality

Some interviewees felt challenged initially by the unfamiliarity of the product and the new modality, suggesting non-acceptability for some, at least initially. Laura talked about, *"the challenge of using a new product where you might not have made the leap of faith that it's as good for them as an old method."*

Laura also found that shortening the time was challenging, saying, *"we're not used to working in a brief kind of way with people... I think it was very difficult offering them a package when they were bringing a horrible trauma"*

Jenny felt challenged, initially, by the new way of working, but adapted to the new modality, *"at the beginning it felt a bit challenging because… it felt a very different way of working... I think as, as you got used to delivering it then… you kind of adapt-adapted your way of working, erm, with that, that modality I guess."* Jenny also reflected, *"I suppose as a, as a therapist it's not as fulfilling as, erm, you know, as when you're having one to one therapy…"*

Christian perceived some therapist anxieties around using computers, *"there are a lot of therapists who are a bit can't undertake it themselves, who don't like using computers and they're not very confident with computers and websites... So you know, that they start from a, an anxious position and then... You know, it, it's out of their comfort zone isn't it to, to do that, when they'd prefer to have someone in, in a room, face to face..."*

Technology challenges

Some therapists talked about the technology challenges that came up, suggesting non-acceptability in some cases, but also a sense of adaptation to new ways of working. Gavin highlighted technology issues, *"some things were logging on, some were just connective issues… or put something in, and hadn't saved.."*

Annabel adapted her way of working to ensure she was at a venue with computer and internet access for her GSH sessions, *"some of my clinics, erm, I don't have internet access or a computer in the room… so it was just like logistically making sure that we were going to be at a venue that had the access…"*

Participant literacy levels

Participant language abilities were raised as a challenge to engagement, and some therapists also talked about literacy levels being a barrier, impacting on acceptability. For example, Meg said, *"one person that I worked with, um, found it very difficult just from… from the literacy point of view... And I just kept saying, it doesn't matter, I'm not there checking your spelling, I don't care, just write whatever, but I still think that was difficult for them."*

Sessions felt too short

Participants had expressed a mixture of views about treatment length. Similarly, some therapists felt the eight-week GSH intervention length to be adequate, though some felt the in-person face-to-face sessions were too short; that there was a lot of content to cover. For example, therapist Christian said, *"you had to, as a therapist work pretty hard at times to contain everything within thirty minutes and get the steps reviewed and the next steps on the table, um... So you know, you need to be organised, you need to be pretty structured and good at containing patients... and also to socialise the patient to that, you know, that we've only got thirty minutes."*

Jenny also felt the sessions were too short, particularly when she needed to engage participants in the reliving elements of the intervention, *"the sessions were very short… I would have liked a little bit more time for the face-to-face meetings... with the reliving element of it… there were one or two that just couldn't do that and so that was something that we had to do together in the session."*

Some interviewees felt therapy session time was lacking to adequately cover the cognitive elements of the intervention. For example, Laura said, *"the avoidance*

and cognitive part came at the end and they came after… writing the trauma account… I think it was quite hard, the engagement to keep people engaged at that stage… when they came to the trauma account, they needed more therapy time to keep them engaged and safe to continue working."

Gavin also felt more time could be allocated to key steps: *"it could make more sense to be longer, and with more steps, within the key steps, rather than steps as I said, at the end, even though it's equally as important, but er, they um, you know, the steps four and five and six probably."*

William felt the length of the intervention was adequate but suggested a bit more face-to-face in the introductory phase would have been helpful: *"it was probably adequate for the guided self-help, but, erm, if it could be tweaked in any way I would say a bit more face-to-face contact before jumping into it, perhaps."*

Not knowing how long individuals were spending on the programme

Some therapists talked about participants moving through the programme steps at different paces, and that it would have been more acceptable to know how long everyone was spending on each step. Annabel talked about one participant, *" especially the person that was zooming through because I think in that sense you get the feeling of, you know, had they just literally skim read it and then moved on because they don't want to do that bit... [Laughs] or, or was it something they'd spent some time really sort of trying or thinking about or, yeah…The time, if, if it did log the time, that might be useful."*

Limited therapeutic alliance

Some therapists felt a therapeutic alliance could be established with GSH, suggesting acceptability, though they talked about it being inferior to the alliance established in face-to-face therapy. For example, Meg said, *"there is a very strong collective belief that, actually, that [therapeutic relationship] is what matters, above all; you know, beyond the… model that you're delivering… Guided Self Help will always be a second best to the real gold standard treatment, which would be me sitting with you…"*

Meg did however emphasise the importance of the Guided element, *"I think the… point… is that it's Guided Self Help; it's not just, you know, we're just going to stick you with… an email address... So, I think it's the Guided element that's the most important."*

William expressed views that the therapeutic alliance did not feel the same, compared with face-to-face, *"I noticed that I had, erm, obviously a much stronger therapeutic alliance with the patients I was doing the face-to-face sessions with as compared to the guided self-help... yeah it is tricky to, erm, you know build a rapport in a very limited timeframe... I'm mindful that, you know, the quality of the therapeutic relationship often predicts the direction of the therapeutic outcome."*

Jenny felt the approach was directive rather than collaborative, *"I suppose it, it's different than sort of face-to-face therapy and it felt a lot more sort of, erm, directive I suppose, you know… it felt a little bit that, that I'm leading it rather than it feeling a bit more collaborative I guess."*

Participant finding programme components to be challenging

Some participant interviewees had spoken of challenging programme components, as did some therapist interviewees. Some individuals highlighted a lack of patient awareness of the efforts involved in undertaking trauma-focused psychological work, and avoidance in terms of confronting the trauma memory and related cognitions. Gavin talked about a lack of awareness of the efforts involved, *"there are certain people that… they must have been blinded by the desperation of… they wanted something rather than waiting the two years or whatever, when the reality sunk in… they had to go and… do something themselves… when it comes down to putting the effort into it… it's not always there... I think people will sign up for psychological therapy, when in fact they don't actually know what it entails."*

The trauma narrative exercise was considered by some therapists and participants to be one of the most impactful elements of the intervention, though some therapists highlighted resistance and avoidance from some participants in engaging

in this work. Jenny said, *"they didn't particularly like… writing their trauma narrative... that kind of goes without saying if you like [laughs], 'cause it is, it probably is the most difficult part of the programme."*

Annabel also talked about avoidance as a barrier to engagement, *"there was one, one patient I remember on the guided self-help who there was a little bit of avoidance at one stage… she'd, you know, named the avoidance herself and was very aware of it… and it sort of took a couple of sessions where she kind of came back the next week and… she'd avoided again but after that she got on with it, so it was a little bit of like working around perhaps some of her thoughts and feelings… she was kind of avoiding the things that perhaps were most important … so skimming over the things that she felt less comfortable with."*

Therapist concerns about exposure work in GSH

Some therapists raised concern about exposure work within the GSH modality, including directing participants to undertake exposure exercises alone, and concerns that exposure work was less powerful through GSH. Therapist, Jenny, talked about her concerns for participants doing exposure work alone and how she would offer to do these exercises with an individual during sessions, if needed: *"it's kind of thinking about them having to go through that [exposure/reliving] on their own... which is why I was kind of quite, you know, happy to do that in the session, together if we needed to, or even if they'd made a start and we kind of elaborated on it… in the session... you're kind of there to really sort of help that process… and you really feel kind of attuned… I guess with the guided self-help it's a little bit more like, okay you're going to go off and do this thing on your own."*

William talked about the 'eureka' moments that can be gained when working with patients outside of the office, in vivo exposure, which weren't possible with GSH: *"working through someone's narrative… working through it in real time and, erm, doing some of th… trigger discrimination work, and some of the… kind of in the field, out of office stuff was incredibly useful and, you know, obviously we couldn't do anything with that with the guided self-help package... some of the bigger kind of eureka moments when we'd done that work and then went out into the field and did out of office work."*

Challenge of complexities, including grief

Some therapists expressed opinions that GSH had been suitable for participants with more complex presentations, though some raised concern about its acceptability for use with such individuals. Some therapists pondered on the potential limitations of GSH for individuals where their trauma had included grief and loss. For example, Jenny expressed concerns, *"delivering the programme when somebody had, er, lost a loved one I found that a little bit challenging... I think it does get a bit more difficult perhaps when there are like, the grieving is going on as well. I think, you know, people probably benefit more from one to one…"*

Laura wondered if GSH was less suited where the trauma had impacted on an individual's feelings of shame and guilt, suggesting *"they [shame or guilt element] could be addressed through guided self-help but I just felt that it needed more of a personal component to it from the therapist."*

Participant lack of time and competing demands

Some participants had perceived a lack of time and other competing demands to be a barrier to engagement and acceptability, and some therapists expressed similar views. For example, Jenny said, *"it felt sometimes… a bit of effort, you know trying to keep people really engaged with the programme... I think it was people, erm, having that sort of space at home to do it, so, erm, you know, if they had children or, you know, they were kind of waiting for a space when… perhaps their husband would come home from work and have the children for a period of time… if, if people were working, you know, when they kind of said they could come home sometimes they didn't feel like then going onto the computer and doing that, so, erm… maybe being able to kind of organise a particular time when they could fully engage with it."*

Less flexibility in intervention content

Some therapists perceived flexibility in treatment content to be afforded by the GSH programme, indicating acceptability, though some did not. Meg talked about face-to-face therapy being more adaptable, being heavily informed by formulation, *"you sit there with the formulation, you draw it out, you make sense of it together. And from there you… you then think about what your intervention is. I think that's*

done much more detailed than it is in the Guided Self Help... I think you've got ways to respond in CT [Cognitive Therapy] that would be informed by the formulation, and you can… you can use or not use those… ways of dealing with it. Whereas, in the Guided Self Help, you just have to go through the steps, regardless."

7.2.2.2 Facilitators/opportunities for engagement with 'Spring' GSH i-TF-CBT

Interviewees spoke of several facilitators and opportunities of the 'Spring' GSH i-TF-CBT intervention, indicating acceptability.

Treatment preference and motivation to get better

Some therapists perceived participants preferring face-to-face TF-CBT, and some perceived that participants were accepting of GSH and engaged well with it, particularly if it was their preferred treatment, and if they were motivated to get better. Christian talked about this, *"I think it's true for, for all patients, who receive psychological therapies… those patients that are very keen to access treatment and you know, want to do anything that can, that hopefully will get them better and, and do homework, as directed... Usually do well... so I don't think there's any difference between Guided Self Help and face to face in that, in that way… so yeah I think it, it comes down to patients preference at the beginning um, and yeah and some people like to talk and they like to talk a lot and but those people that don't..."*

Some therapists talked about the value of GSH being an alternative to face-to-face therapy. Laura talked about the relief some participants had expressed when informed of their allocation to the GSH treatment: *"some people really welcomed it because… they were quite avoidant anyway of their trauma... So, you know, they thought it was a relief [laughs]... They quite liked doing the guided self-help because they didn't have to engage, it was more, there was quite a lot of psycho-education in it, and they didn't have to engage that much in the trauma memory… In the same way that in cognitive therapy people really have to be in it, and you're activating the memory all the time and if they come to a session, they know they're going to have their memory activated at some point..."*

Liking the intervention helped therapists to encourage participant engagement

Some therapists reported feeling challenged initially by the unfamiliarity of the product and the new modality. However, most therapists liked the programme, and the GSH approach and talked about how liking the programme helped them to encourage participant engagement. *For example,* Jenny said, *"I think it helped that I really liked the programme and, you know, I did kind of believe it would be a good programme… with important elements in, so I think that helped in kind of encouraging others to use it."*

Meg talked about the ease and enjoyment of delivering the GSH, *"I really enjoyed it. And, actually, in the end, it became… it was an easier thing to deliver… than the full model… And it put the, I guess, the responsibility, much more on the patient to be doing things in between sessions… it took some negotiating to begin with, to learn how to use it… But, once you'd got it, it was fine."*

Positivity about programme components

Like some participants, some therapists highlighted the value of various 'Spring' programme components including: the App, psychoeducation, interactive elements, behavioural and cognitive exercises, and the final blueprint. William said, *"the programme itself was so well designed… you know, it didn't really require much heavy lifting from me."*

William also reflected, "I think the ones who did the guided self-help all had a positive experience with it."

Interviewees felt the programme worked best when participants utilised the desktop version and the App version. For example, Jenny said *"…a lot of people were kind of doing it on their phone which, although it's handy having it on the phone, you know, I think maybe it was more helpful if they had it on the computer and the phone…"*

The accessibility and usefulness of the App was highlighted by some therapists. For example, Meg said, *"I think most of the people that I worked with got the App… that was very easy for them to carry around."*

Meg also highlighted the helpful consistent messages and psychoeducation that is delivered by the programme, *"the message was so consistent… I then remember thinking, gosh… work with people will never be as consistent as… I think that probably surprised me… I think having that basic education at the start is really important... And you have it from somebody, very calmly delivered… And I think that's what I was meaning is that, you know, that story can change by patient... But when you have it delivered… by a recording… that's a much more consistent story… than if you deliver the story yourself… I loved the voice of the narrator… to be able to, um, make sure that the patient has that basic education… that's very significant."*

Gavin talked about the benefits of the psychoeducation component, including the 'lightbulb' moment that an individual might experience when understanding that they are affected by PTSD: *"There was, other than the classic oh, I thought that this only happened to soldiers… I can't remember if it's four or five, examples of people's stories, I think it's four isn't it?... then understanding… it's actually PTSD they had… that's a little … little light bulb, um, moment for them… I imagine."*

Annabel reflected on how well participants had engaged with the grounding techniques, *"the anxiety and the grounding stuff… they're really kind of well explained and people sort of tended to, when you rang them, they were like, oh yeah, it all made sense and yeah no problems with it and they've been practising and had been using it".*

Some therapists reflected on the helpfulness of the interactive elements and tools. Key steps in the programme were frequently highlighted, particularly the behavioural components of treatment, including the trauma narrative exercise of step five, and the cognitive elements that followed. For example, William talked about the importance of the trauma narrative exercise, *"they needed to have done*

that and really, erm, you know emotionally engaged with their story to have the best kind of outcome. It was all useful but I think that's really the most important part... the participant would have spent more time on that than any other step."

Similarly, Annabel perceived participants took a lot away from the trauma narrative exercise, *"being able to, er, sort of break the whole situation down and I think facing it, facing the actual memory in itself, because often people are avoided it and staying away from it... So I think the feedback usually from those sessions is that at, that the time of doing it, it's extremely difficult, erm, but then they've, they take a lot from that part."*

Laura remarked on the helpfulness of the blueprint exercise at the end of the programme, *"I think what was really good was the blue print at the end, it was really helpful 'cause again they had something to take away and it was a really good summary and frame for the therapy and a really helpful way of ending…"*

Participant digital literacy

Digital literacy was not raised by participants to be a facilitator for engagement, though it was raised by some therapists. Jenny said, *"if they were kind of… accessing their computer more regularly anyway... perhaps that made it a little bit easier than, erm, perhaps for people who don't often use the computer in their lives… so perhaps if they're on it regularly they might think, oh, I'm on the computer I've got 10 minutes… maybe I'll dip into the programme…"*

Gavin reflected on digital familiarity and youth, *"I had one person actually, the guided self help, which worked... He was actually a student, because they were… young as well, and they… they were used to using electronics… they just said it was just a part of their life, so it was just what they would expect, having a phone in their hand… in my [employment], when I have an 18 year old, um, young adults, you know, anything with a phone, and that's how they want their therapy, via the phone."*

Laura talked about how younger people may more regularly emotionally engage with IT, *"I've had really good experiences with people who are younger and they just ran with it, and they loved it... I think it's generational, I think they're used to properly engaging with IT material … They're used to emotionally engaging with IT material... Whereas older people aren't used to thatI think older people could be offended when you offer them a package, whereas younger people they wouldn't be offended, er, because you know, their whole virtual world is behind a screen..."*

Meg also pondered on younger people engaging well with GSH, given their familiarity with digital devices, though Meg also highlighted that more and more people may be digitally familiar since COVID-19, *"The younger patients were much able to say, you know, almost … oh yeah, that's fine... But I also want to know if that's changed because of Covid, you know?.. With us all turning to technology, I imagine suddenly everyone can use Zoom, you know? It's a very different world that we're in now. So, I imagine us introducing this at… right now… it would be seen as being now almost past the norm, whereas we did it, it wasn't part of the norm... I would have thought youth would have a… bigger impact… they might prefer… to communicate through that medium."*

Laura talked about the benefit of participants bringing their devices with them to the therapy sessions, *"so then you're helping them do it rather than working through the content as if you're a therapist... I just found that it wasn't very helpful if you just talked about engaging with the package rather than doing it live... also it enabled me to understand what device they were using and what they were actually seeing."*

Structured and containing, yet also flexible

Some interviewees felt the in-person face-to-face sessions were too short, given all the content to be covered. On the other hand, some t*herapists spoke positively about* the acceptability of the structured and containing nature of the GSH approach. Gavin talked about how this could be beneficial when working with some people*, "you're limited anyway with the guided self help… in the back of my head, having my supervisor [name] saying no, it's got to be half an hour, no more... because I also felt it was so structured, it also helped me to try and also maintain a*

structure, and the other people as well. Especially if they've had previous therapy, that hasn't been as structured, um, they're prone to going off at a tangent, then they you know, it helped them as well."

The importance of sticking to the manual and providing a structured GSH intervention was highlighted by some therapists, though some talked about the flexibility afforded by the GSH approach. For example, Christian talked about flexibility with respect to the content delivery, *"so if I thought that they needed to spend a bit more time on a particular step, then I'd perhaps roll it over to a, to another week as well... and the cognitive therapy element, if I didn't think that was that important for that patient, I would you know, spend less time on that, and, and major on step five probably... I'm kind of flexible in the delivery but um, but was true to the manual."*

Some therapists also talked about flexibility for the participant, with engagement possible in their own time and at their own pace. Meg remarked on the potential difference made to the participant by the intervention's flexibility, *"the fact that people could do this in their own time, um, and in their own way, I think that probably made a difference… I do remember one guy who went on holiday who appreciated that he could carry on whilst he was on holiday."*

Adequate treatment length

Therapists generally felt the length was acceptable. Meg said, *"it's not too long, it's not too onerous... although we were very clear, if you're going to benefit from this… you need to spend half an hour a day …and you need to commit to that."*

Annabel described one participant moving very quickly through the programme, suggesting completion might be possible for some individuals in less than eight weeks, *"I think generally everybody used the appointments and we always stayed in the time frame, so… it didn't feel restrictive, it didn't feel like we weren't spending enough time... so it probably was on point really... the client that I mentioned before that was like zooming through... So, as I said there was a little bit of avoidance and*

once we'd done the work on that and overcome that… it felt like probably we could have finished about two sessions earlier potentially..."

Therapeutic alliance could be established

Some therapists felt the alliance in GSH to be inferior to that established in face-to-face therapy. Some therapists however talked about connection, facilitated particularly by the first hour-long face-to-face session, indicating acceptability in some cases. For example, Annabel said, *"Obviously there were parts that kind of felt more, erm, therapeutic… especially about the, the thoughts work and the updates to the memory, that sort of stuff felt a lot more therapeutic... And I think rapport was built quite well and I think that first face to face appointment makes a big difference… it's a really good starting point, you've met them in person… you get a sense of what's going on and I think, yeah, people engaged really well… I think the patients kind of liked that set up, it was kind of like that just su-supported the programme… so it was their journey, their working through that and this is their opportunity to check in, as you said, and review... they seemed fine with it."*

Meg felt able to connect with participants through the GSH intervention, *"you can build that rapport… I think the reason why it worked was because we did have that contact... there was no issue for me with rapport for the Guided Self Help… It really does matter to me…. it felt, from my point of view, that I was connected with that patient... It felt a very engaged process; it didn't feel a distant process."*

Value to therapist of an alternative to face-to-face

Annabel spoke of the value for the therapist of having a variety of treatment approaches, including less intensive options, *"so I think just having, obviously choices for patients, but also having that variation for the therapist helps, like I did feel like the ones that I did guided self-help, obviously it took… a lot less time for treatment… and it puts a lot less time on the therapist… it felt more like… guiding them along their journey... Obviously there were parts that kind of felt more, erm, therapeutic and kind of more specific parts… but the other aspects felt… yeah, it's a lot less intensive for the therapists."*

Importance of supervision

Therapists perceived supervision to be extremely beneficial for their engagement with 'Spring' and its acceptability. William talked about this, *"So I had regular supervision… it was really useful listening to whether therapists' experiences… you know taking part in those discussions."*

Meg perceived supervision as crucial, and it had been particularly helpful to be supervised by the developers themselves, *"the supervision… which was crucial, and very supportive… I'm a trainer too, so I'm effectively putting myself down as I say this… but there's nothing better than being trained by the person that actually came up with it, wrote it… that's a luxury, and I get that that's a luxury. And that… that can't always be replicated and won't be replicated... and it is probably not a necessity, to be honest."*

7.2.2.3 Considerations for the future of GSH i-CBT for PTSD

Some interviewees pondered on the future of GSH for PTSD and considered it to be an acceptable, 'COVID-proof' therapy that could widen and diversify treatment access. Recommendations for its roll-out and sustainability were offered.

Therapist preconceptions have been challenged

Therapists shared that their preconceptions that individuals would prefer face-to-face had been challenged, suggesting that their views around its acceptability had altered through experience. This finding chimes with the earlier reported finding that whilst some participants had expressed a preference for face-to-face therapy, some acknowledged people may prefer an alternative to traditional face-to-face therapy approaches. Therapist, Meg, reflected, *"… the bias I entered into was that the full, you know, cognitive therapy for PTSD… the Anke Ehlers model… was going to be superior over the online version… But very quickly that's challenged."*

Laura's initial assumptions and bias towards face-to-face therapies were also challenged, *"For the guided self-help, I think it's slightly surprising because people weren't as shocked as you think about only offering them that, you know... the guided self-help, so that's sort of a positive thing."*

Annabel talked about her initial impressions that the GSH intervention would be similar to other computerised CBT packages, but how this had been challenged by the realisation that more input from a therapist is required: *"I used to do CCBT with people, so computerised CBT, so that was a lot more, it looks on the surface it looks similar, oh it's a CCBT for PTSD but it's, I think the actual, it feels different, it feels like, erm, I don't know it was just the nature of the presentation of PTSD possible... But it just feels like there needs to be more input from a thera-, even though it's a lot less time heavy."*

Interviewees reflected that they have felt more relaxed with online and GSH approaches since COVID-19, suggesting increased acceptability for GSH since COVID-19. Gavin expressed this, *"I've become more um, relaxed about using online patients, and you know, using all the um… Microsoft Teams and all these sort of things."*

William talked about remote delivery being part of the future, *"if anything it was a good, erm, kind of testing for how everything is now for Covid because everyone does everything on the phone, erm, nowadays. So, erm, yeah I think it's probably going to be a part of our future."*

Potential for GSH in widening access to psychological therapies

Some interviewees talked about GSH offering potential considerable benefits to the accessibility and availability of psychological therapies. Christian talked about the growing evidence base for GSH, *"the systematic reviews on different types of Guided Self Help for different disorders is you know, increasingly err increasingly saying that it works, for particular disorders."*

William talked about diversifying services, and said, "*I think the potential benefits, erm, would probably be huge, erm, in you know a neglected health services where access to psychological therapies is, erm, limited... I think the ability for… clinicians, therapists, to deliver something hopefully as effective as what I imagine guided self help to be to a larger number of people, erm, because of the limited therapist*

contact is going to be of huge benefit... I think a lot of therapists would probably appreciate having another tool like this in their armoury."

Similarly, Laura talked about widening accessibility, *"the benefit is getting it much wider accessibility and availability of therapeutic intervention than is already in existence, so those people who have… a simple PTSD as in they have one trauma… And they're probably getting nothing, or they've got to wait a very long time by which time other things have come into play like depression... And so, it's a lovely thing to think that people can access it..."*

Annabel reflected on clinical practice and how GSH could be perfect for individuals who need flexible treatment options, *"some people… they might have contacted us for an assessment and they might be suited for PTSD treatment but they're, they're saying actually I work 9 to 5 and I wouldn't be able to attend and I haven't got like an hour and a half every week… to come to the sessions, so for the people, again like for people who might need something that's more convenient or more flexible I feel like it's perfect."*

Gavin expressed his views on the potential for GSH and services having a variety of interventions to be able to offer patients, *"I know the evidence for telephone CBT is up there… comparable to face to face, so… and I know this has also got that face to face as well. So it's getting the best of both worlds, but er, um, with a few tweaks, I think it… it could be a goer... if it works for some and it doesn't work for others, it's like maybe other interventions… see it's nice to have er, a range of things rather than sort of restricted… and I can imagine newly qualified therapists, so people in the NHS, could er, you know, they could, you know, do something, and they could pick up sort of supervision, you know, fairly easily."*

Some interviewees suggested that staff delivering the intervention need not be specialist clinicians. Christian talked about this, *"You know, we, in [country], we're a bit behind, because we don't have IAPT... So I think the [country] Therapists you know, it's not new to them... They'll adapt to it very easily... it probably doesn't need a, a highly skilled, high intensity psychological Therapist to deliver it, I think*

someone… can be trained to deliver it very easily... I think it's um, if people are interested and then putting themselves forward for training, that's probably the best way to go, rather than force it onto people."

'COVID-proof' intervention

Although some therapists felt the face-to-face GSH sessions were important for therapeutic alliance, some therapists suggested the entire intervention could be conducted online, replacing face-to-face sessions with videocalls, and thereby 'COVID-proofing' the intervention. Christian talked about this, *"we've learnt from COVID is that um, you know, one of, I think one of the options should be video conference call err, and you know, for some people that could be never meeting face to face. You could have, have your hour session where the Therapist gives you the log in details and shows you the website err by sharing their screen with you."*

Intervention applicability

When talking about the future of GSH, interviewees reflected that the GSH may be better suited and more acceptable for individuals with mild to moderate PTSD. Christian talked about this, *"my hunch is that um, yeah it works well for mild to moderate, single, single-ish trauma... if it works for that population, then they don't need to get referred to [service], at [geographical area], you know, for the high intensity work, and hopefully reduce waiting lists and only those people then go for high intensity therapy... I think, as long as they engaged in it, and came to the sessions and did the homework, they've probably done okay with it...Um it probably hasn't worked as well for those people with more complex PTSD... because they perhaps needed something else, that wasn't in one of the eight steps..."*

Similarly, William reflected, *"patients with, you know, symptom severity on the kind of lower end. Erm I think that's where this would be targeted... I think, erm, primary care it would probably be ideally suited to. So probably mental health support services, erm, err, erm, possibly liaison services."*

Some therapists suggested the acceptability of the use of GSH in a stepped care model. Laura suggested, *"I think it's a step, you know, a match step, so it could be offered… as a first, er, intervention....I think it's great as a stepped intervention."*

Jenny suggested GSH could be an acceptable and useful adjunct to therapy for more complex presentations, *"in the [name] service here I guess our, erm, patients are complex... Erm, they have complex PTSD, erm, but it could still be used as a helpful adjunct to therapy, you know, I still think, you know, even in sort of secondary or, erm, you know, in a clinic like ours, you know, there are some really useful resources within it that could kind of add to therapy."*

Recommendations for sustainability

Interviewees made recommendations for the roll-out and sustainability of GSH within the NHS. Christian talked about the importance of IT, equipment, and data accessibility for both patients and therapists, *"NHS IT, can be a little bit backward… if NHS Trusts are gonna adopt it across the U.K., and elsewhere in the world... Then computer systems need to be of a certain standard, that will run, you know, something like this, without it glitching and dropping off or freezing... You need a good level of spec and so does the participant, if they're gonna run it off their mobile phone, tablet or at home... So I think, I think future iterations on it, need to make sure it's mobile, very mobile friendly um... and testing should be you know, rigorous to make sure it does work on mobile phones."*

Annabel expressed concern that not everyone would have access to the internet, *"I work in [area] and some of those areas are quite deprived and they might not have the means to have access to internet and stuff like that, so, I think, yeah, the majority of people do… but not everybody."*

Some therapists recommended the intervention would be more acceptable to staff if it was championed amongst therapists, for example, Christian said, *"I think you need people that champion it and want to use it verses being mandated and they have to do it, I think that would be a more helpful way, initially anyway um... Um*

champions that just roll with it and build some expertise and sell it to other people..."

Interviewees suggested the intervention be placed on the clinical pathway. For example, Jenny said, *"so it's about it having it, its place on the pathway, erm… and having a… particular criteria so that… people can kind of clearly know where it's going to sit… what it's hoped to achieve and, erm, yeah, everyone…… knows what they're doing in, erm, providing it."*

Some interviewees also expressed the importance of policy influence to commission it, and funding. For example, William talked about funding for nationwide provision, *"it's got to be… fairly funded across different regions. So if we were looking at [country]… you know, if it's available in one part of [country] it should be available in all parts of [country]."*

Christian talked about the importance of having people with the power to commission GSH interventions, *"you need the influencers don't you, people with the power to commission and you know, people that can see the value in it, so you know, the, the senior people, in psychotherapies and mental health and, and um policy makers and Government."*

Christian suggested supervision should be local, *"I think it would be good to have someone in the same Trust... You can either be with face to face, or via Zoom... Um someone that's local, that, someone that knows the system that you're working within... it might be for an hour with three or four people on a, on a telephone conference call... maybe in the early, early stages, fortnightly might be helpful, until people find their feet and feel more confident."*

Jenny talked about the importance of having a supervisor with knowledge of PTSD, *"it would be important for the supervisor to have knowledge about PTSD and maybe some, some of the presentations that, you know, may come up, you know, that are unanticipated if you like… so, you know, if somebody's become quite dissociative*

and, erm, you know… during the programme so I guess it would be important to have supervision that, you know, can help inform the practitioner in that way. And I guess it would be important for them to, erm, you know, be comfortable with delivering the intervention themselves, so again kind of really believing in it....”

7.3 Comparison of participant and therapist interview themes

Analysis revealed several common themes across interviews with participants and therapists, as well as contrasting views, as shown in Table 27.

	Participant Theme	Therapist Theme
Common Theme one	Barrier: Difficulties fitting in homework	Barrier: Participant lack of time and competing demands
Contrasting with common theme one, some participants talked about the flexibility of the intervention		
Common Theme two	Barrier: Treatment was too short and slow paced	Barrier: Sessions felt too short
Contrasting with common theme two, some participants and therapists felt the treatment pace and length to be suitable		
Common Theme three	Barrier: Technical difficulties	Barrier: Technology challenges
Contrasting with common theme three, some participants remarked on technology working well		
Common Theme four	Barrier: Difficulties engaging with certain aspects of the programme	Barrier: Participant finding programme components to be challenging AND Barrier: Therapist concerns about exposure work in GSH
Contrasting with common theme four, some participants and therapists talked with positivity about beneficial aspects of the programme		
Common Theme five	Barrier: Limited support during face-to-face therapy sessions	Barrier: Limited therapeutic alliance
Contrasting with common theme five, some participants and therapists talked about a supportive alliance		
Common Theme six	Barrier: Language limitation	Barrier: Participant literacy levels
Common Theme seven	Facilitator: Essential and progressive method	Facilitator: COVID-proof intervention
Common Theme eight	Barrier: Preference for face-to-face	Barrier: Participant preference for face-to-face therapy
Contrasting with common theme eight, some participants and therapists spoke of GSH being a good option for individuals who would rather not talk to someone, and that preconceptions about treatment preference have been challenged		

Table 27: Table of common themes across participant and therapist interviews

7.4 Chapter summary

RAPID participants and therapists held a mixture of views relating to the acceptability of the 'Spring' GSH i-TF-CBT intervention, and spoke of several facilitators and barriers to engagement with this type of approach. The array of views, sometimes opposing, around the GSH intervention and its delivery suggests a 'one size fits all' model adoption would not be suitable. Rather, the findings suggest an overall acceptability of GSH for PTSD, with an appreciation for the importance of adapting interventions to suit an individual's needs and preferences, therefore offering flexible, personalised GSH approaches.

8. Chapter Eight: Results of qualitative interviews with NHS commissioners and managers to determine the acceptability of internet-based psychological therapies

This chapter describes the findings of a sub-study of the RAPID Trial, qualitative interviews with NHS commissioners and managers. This was to address aim three of this PhD, to understand the factors that may impact on the successful roll-out of internet-based therapies across the NHS.

8.1 Participant characteristics

As shown in Table 28, five males and five females participated, were mostly white British with a mean age of 50.7, and with a degree level of education or over. Interview lengths ranged from 27 to 62 minutes, with a mean of 48.9. Six interviews were conducted prior to the COVID-19 UK National Lockdown commencing 23rd March 2020, and four were conducted after.

Pseudonym	***Gender***	***Age***	***Ethnic origin***	***Type of NHS Role***	***Length of interview (mins)***	***Interview conducted Pre/Post 23rd March COVID-19 UK Lockdown***
Phil	Male	59	White British	Clinician Clinical service management	50	Pre
Tim	Male	44	White British	Clinical service management	57	Pre
Sue	Female	59	White British	Clinical service(s) strategic lead	56	Pre
Patrick	Male	51	White British	Clinical service management	57	Pre

Pseudonym	***Gender***	***Age***	***Ethnic origin***	***Type of NHS Role***	***Length of interview (mins)***	***Interview conducted Pre/Post 23rd March COVID-19 UK Lockdown***
Isla	Female	55	White British	Clinical service(s) strategic lead	43	Pre
Geoff	Male	53	White British	Clinical service management	47	Pre
Sarah	Female	49	White British	Clinician Clinical service(s) strategic lead	40	Post
Robert	Male	34	White Irish	Clinical service management	62	Post
Gwendolyn	Female	52	White British	Clinical service(s) strategic lead	27	Post
Rose	Female	51	White and Black African	Clinician Clinical service management	50	Post

Table 28: Participant (pseudonym) characteristics and interview length

8.2 Themes

Analysis revealed codes with three overarching themes, and these are summarised in Table 29.

Theme 1 ***Service capacity issues***
Unmet governmental targets
High demand
Staffing and deployment issues

Theme 2 ***A movement towards the acceptance of internet-based psychological therapies.***	
Reservations	Participant preference for face-to-face
	An 'add-on'
	Using internet-based interventions in the proximity of others
	Exclusion in terms of literacy and digital literacy and access
	Lack of awareness of intervention applicability
	Resistance to change in practice and a threat to the therapeutic alliance relationship
Acceptance	Some patients may prefer remote therapy
	Flexibility and convenience
	Value of accessing the online intervention and its tools after the treatment period had ended
	Different ways of connecting with patients are required, CBT lends itself to be delivered in a variety of formats
	Accessible quickly after screening and assessment
	Empowering
	Suitable as first stage interventions for people with more complex or severe conditions
	Advantages to offering internet-based interventions in primary mental health services, rather than referring to other services
	Preference for guided interventions
	Guidance could be with low intensity therapy contact
	Internet-based interventions can include built-in outcome measures and risk assessment
Theme 3 ***Considerations for the successful implementation of internet-based interventions.***	
The evidence base is an important but not a sufficient factor	
Challenges of NHS Information Governance procedures	
Challenges of NHS funding	
The importance of a culture promoting digital health	

A coordinated nationwide approach to implementation, including commissioning services at scale, can be a facilitator.
A clear understanding of implementation requirements, with no hidden surprises, can be a facilitator.
External opportunities, including external directed funding and changing circumstances such as during the COVID-19 pandemic, can be facilitatory.
The availability of timely training and supervision can be a facilitator.

Table 29: Summary of NHS commissioners and managers interview themes

8.2.1 Service capacity issues

Interviewees were invited to talk about interventions they were involved with and their understanding of the barriers and facilitators to accessing mental health treatment in general, including face-to-face, in-person therapies. Interviewees described capacity issues, stretched services, and the impact of this on patient access to treatment, evidenced by unmet governmental targets. The reliability of waiting times as a measure of treatment access was debated, although long waiting times were identified as being of concern. Tim described difficulties meeting targets for face-to-face therapy: *"anyone that is referred into, er, psychological therapies should be seen within 18 weeks, erm, but I think it's interesting that some of my understanding is that there's no board in [country] that's currently meeting that target… for face to face therapy"*

Explanations for service capacity issues were offered, including a high and increasing number of referrals, complicated referral pathways, and issues around funding, staffing, deployment, and supervision. Rose talked about limited resources: "*people come and they want to be treated straight away don't they and to keep them waiting is, is a challenge when you know, actually a lot of that is about resources when you've just got one therapist and one team… What can you do?"*

Patrick also noted staffing as a barrier to treatment access, *"there's a national shortage of err particularly step 2 [low intensity] but also step 3 [high intensity] people [staff] who have undertaken an a accredited err recognised HIT [High Intensity Training] training course at step 3, so CBT therapists, or and the PWPs in terms of there just aren't enough of them… the demand outstrips the supply of trained therapists."*

Interviewees suggested staffing and deployment solutions alone would not be sufficient in increasing patient access to therapies. Tim stated *"…even in those areas where they do have a full, er complement of staff that you tend to find that there's high demand of services…. as investment has been put in, you know, increasing the workforce but the demand is still going up… and digital technologies are becoming much more prevalent… Because they now recognise that the traditional models of service are not really going to meet that demand if the rates continue."*

8.2.2 A movement towards the acceptance of internet-based psychological therapies.

Various attitudes towards internet-based therapies were expressed, including interviewees own views and perceived views of patients and colleagues. A movement towards digital proficiency and acceptance of internet-based therapies was described, for example when reflecting on a digital intervention for depression, Sarah remarked *"It wasn't very, wasn't successful, um, the uptake of licences was very low, but I think people's digital… capability was lower back then."* Reservations were also raised, and these are presented first.

8.2.2.1 Reservations about internet-based psychological therapies

Interviewees perceived that internet-based approaches were an 'add-on' and that patients might expect face-to-face therapy. Patrick suggested *"often patients don't want group offer or e-therapy, they want to see somebody".*

Concerns were raised over patients' use of internet-based interventions in the proximity of others, for example those with whom they live. Rose was interviewed post-COVID-19 UK lockdown and talked about this: *"So one of the things we've learnt with, with this…pandemic is there's a challenge around people doing therapy in their own home you know… particularly in trauma when you may have you know, perpetrator or something like that in the next room… about safety and boundaries."*

The potential for internet-based treatments to exclude some people due to literacy, computer literacy, and access issues, was raised as a concern. Gwendolyn talked

about this: "*there are individuals who don't have access to phones that are able to use that kind of... this kind of technology. Nor do they have access to, you know laptops and other ways of working. So, I think there is a concern about if we have a more blended approach... perhaps some of the individuals who are hardest to reach, who most need psychological interventions, aren't going to be able to access it easily with that approach."*

Interviewees perceived limited staff knowledge of internet-based interventions and who they are aimed at helping. Tim remarked, *"there's still quite a lot of, er, misconceptions about what computerised therapies are or internet interventions are."*

Interviewees perceived staff resistance to change. Sue suggested, *"people often don't like changing what they're already doing…sometimes, um, you almost have to get to the point where people understand they can't carry on delivering things a certain way, before you all realise other opportunities."*

Rose reflected on resistance to telephone-based assessments prior to the COVID-19 pandemic and how, *"the staff didn't want it to succeed and it didn't succeed. Now, we're talking about you know, telephone assessments are fantastic, we've been able to keep the service going, we must do more of these".*

Reservations also included perceptions of internet-based interventions being a threat in terms of how staff interact with and work with people, for example, Tim talked about 'pushback' due to clinicians'…*"strong belief on the kind of therapeutic relationships that occurs between the clinician and patient."*

8.2.2.2 Acceptance of internet-based psychological therapies

Whilst interviewees perceived patients expecting face-to-face approaches, interviewees also perceived that some patients may prefer therapy that is more remote, and that internet-based interventions may facilitate openness. Isla suggested *"I think some people would want to see somebody face-to-face initially*

and actually might be more comfortable doing something through the internet or through, a bit more remote…"

Robert, who was interviewed post-COVID-19 UK lockdown, reflected on his experience of people entering information into a website "*more openly than they would face-to-face."*

Interviewees preferred guided internet-based therapies over self-directed therapies, with guidance viewed as important for treatment uptake, engagement, and enrichment. Phil said *"it would probably be a good idea for somebody using this method-based therapy to actually come into some centre and… sit down with a person who's very familiar with the material… that person would meet them again and ask how things are going… it might be some little areas that aren't quite covered perhaps they're a bit tangential and the individual therapist then might be able to just enrich the process further by adding some… localised idiosyncratic examples or ways of expressing certain concepts."*

Geoff weighed up the costs and benefits of clinician guidance in GSH: *"adding a lot of layer and more money because you've got a one to one session with a clinician, but if it gets them in and using it then that's probably going to be quite useful."*

Interviewees expressed the opinion that guidance need not necessarily be provided by a clinician, but it would depend on skills required. Rose suggested, *"so is it something that could be done by somebody with level one skills or do you need to have somebody who's got a therapy training, who erm, who knows [pause] erm, who knows more than that that is provided in the actual treatment."*

Interviewees highlighted the advantages of internet-based interventions with in-built outcome measurement and risk assessment. Intervention usability, treatment satisfaction, and goal attainment questions were provided as examples of built-in measures. Interviewees discussed the importance of service user involvement and co-production, in particular with the development of outcome measures, for

example Sue said, "*the outcome for me is what the service user thinks is the outcome*".

Sarah talked about the importance of an intervention linking outcome data with NHS patient record systems and key performance indicators: *"otherwise we've got an administrator going into the programme, getting the data off, taking that data to another programme… it creates the potential for an Information Governance risk."*

Interviewees perceived patients would value the convenience of accessing treatments at their own pace, in their own time. Gwendolyn, interviewed post-COVID-19 UK lockdown, suggested internet-based interventions were, *"a really important part of the suite of offers that we have for patients…. there are also real benefits in terms of being able to provide that kind of input for people at a time and place that most suits them, as opposed to needing to make appointments with an individual during the day which may not be convenient for the patients."*

The potential for continued access to the internet-based intervention after the treatment period had ended was also considered a positive, for example Isla said, *"it may be something you would then want to go back to the beginning and do again."*

Geoff acknowledged that different ways of connecting with patients are required: *"I think that's come through in our staff group here is that we've got to think of different ways of connecting with our patients".*

Interviewees remarked upon the structured format of CBT, which lends itself to be delivered in a variety of formats. Phil suggested, *"it [CBT] is very much an educational approach… And there's no earthly reason why it shouldn't be delivered in a structured classroom format or indeed, lends itself perfectly to deliver on the internet…"*

The potential for quick access to internet-based interventions was viewed positively. Patrick suggested, *"there is some evidence I think that err people who wait longer have poorer outcomes, so the quicker you can start treatment the better, for me that's a plus, it helps the patient err and it also helps towards our waiting times, achieving our waiting time targets, so it's a win-win."*

Interviewees suggested internet-based interventions were empowering treatment approaches for people with mild to moderate severity conditions. Gwendolyn said, *"if, for instance, somebody has milder levels of, erm, psychological morbidity or mental illness and they are able to engage in those kind of [internet-based] interventions then they are going to find it empowering."*

Sue expressed this further, with respect to general healthcare movements encouraging people to take responsibility for their health, stating, *"unless we find a way of helping people be more open and take responsibility for their own health, and access stuff that's really good for them on the internet and things like that, we will never manage to reach them all".*

Interviewees were positive about offering internet-based interventions within primary mental health services, for example Geoff said, *"we are very keen to be offering interventions for that [primary care] cohort rather than referring on… If we can be offering interventions at the right level… we want to be doing that."*

Sarah remarked upon the advantages of internet-based interventions as first stage interventions for people with complex or severe conditions: *"I think we have to have a digital, a digital first mentality… the least intensive intervention first, see how somebody responds to that… if somebody does need a kind of one to one situation, that's gonna cost a lot of money, that we haven't got a lot of people delivering, at least it's reserved for the people who really, really need it…"*

8.2.3 Considerations for the successful implementation of internet-based interventions.

NICE and other country-specific guidelines and practice-based evidence were considered an important but interestingly, not a sufficient factor for intervention implementation and acceptance amongst staff. Sue noted NICE guidelines, *"should be part of the conversation and evidence is really important, but it's not you know, sometimes we don't have the evidence and we just have to try things."*

Rose expressed her interest in practice-based evidence, *"randomised control trials are great but what they miss is most people that come to our door are not, you know, a neat little box or they're not going to fit into a neat little box… so I suppose it's, I'm very much in favour of practise-based evidence".*

NHS inflexibility was considered a barrier. Sarah stated, *"we have been a bit slow on the uptake, it, it's really about the way I think the NHS bureaucracy works, a lot of the time, it doesn't allow itself to have the agility to implement…"*

Tim expressed problematic implementation delays due to information governance and procurement processes: "*within digital what you're trying to do is streamline the processes as quickly as possible because the technologies always evolving and changing and if it takes you two years to get past information governance and procurement then actually you're already two years behind where the technology is."*

Interviewees highlighted NHS funding barriers. Phil explained, *"there isn't one overarching form of budgetary control… So you could argue there isn't a great deal of central coordination because of that."*

Tim reflected on an experience of potentially prohibitive intervention set-up costs: *"one of the biggest barriers, er, when we initially tried to bring CCBT [computerised CBT] into [country] was the cost of the product… the actual ability for them [smaller health boards] to, erm, purchase the product in addition to then the service*

infrastructure means that many, many areas, particularly smaller board are prohibitive to the set up."

Sarah suggested internet-based interventions would start to happen with a, *"change in culture from commissioners and that comes from the top… If it was expected that you know, um, seventy five percent of your workforce were bums on seats and twenty five percent was digital... cos it would hold that accountability in the system."*

Tim reflected on a positive experience of a coordinated national approach and commissioning services at scale: *"We have one implementation approach which we did across [country] but… we built into the implementation programme ability to then allow people to go different speeds… with a national deployment… you're able to then look at the costs and identify what the big costs are, and then extract them…. within [country] we fund the national CCBT licence for the whole of the country…. for every single person."*

Knowledge of set-up and ongoing requirements was recommended. Isla said, *"setting up a service you would have sort of initial costs… And then the ongoing costs… So it could be that every year they [staff] go on a refresher training or, so you… just build that in really so you haven't got any surprises really."*

Rose reflected on her experience regarding timely training and supervision as a facilitator: *"So a therapist came to me saying, look there's this training and at the end of it I get a, erm a treatment manual that's tailored to our service and I'll be up and running and ready to run this group immediately after I've finished this course... that's quite a big selling point… something that is erm, accessible and useful straight away so that after a training in it, people could, could run with it very quickly… maybe after training thinking about some supervision… to enable implementation and to pick upon any problems."*

Interviewees reflected on implementation facilitated through opportunistic ventures. Isla talked about external directed funding: *"a lot of investment for new service tends to come from directed investments... [country] Government may decide they want to invest in that area …"*

Sarah, interviewed prior to the COVID-19 UK lockdown, reflected, *"I think COVID's helped… We've just managed to get Silver Cloud [internet-based intervention for stress, anxiety and depression] in, um I've been struggling for two years… and suddenly we've got it within three weeks…"*

8.3 Chapter summary

Interviews with NHS commissioners and managers revealed three main themes relating to the implementation of internet-based psychological therapies: 1) an acknowledgement for service capacity issues; 2) a movement towards the acceptance of internet-based psychological therapies, indicating their acceptability, with reservations; 3) considerations for their successful implementation. The findings suggest an openness to internet-based approaches, particularly GSH interventions, so long as they do not compromise on therapy quality. Interviewees acknowledged implementation may be challenging, and recommendations were offered.

9. Chapter Nine: Discussion

The findings demonstrate that GSH i-TF-CBT is an acceptable treatment for adults with mild to moderate PTSD. This was demonstrated through a systematic review of ten included studies (N=720) (Simon et al., 2019a), and through a pragmatic Phase III RCT across England, Scotland, and Wales, where 'Spring' GSH i-TF-CBT was found to be acceptable and comparable to face-to-face individual TF-CBT. GSH implementation recommendations have been made.

This chapter summarises how the main findings address each of the PhD aims. The fit of the findings to the existing literature is discussed and the strengths and weaknesses of the work are outlined. Research and clinical implications of the results as a whole are then explored.

9.1 Findings of PhD Aim One

> *To systematically review and analyse the available evidence for the acceptability of i-CBT interventions for adults with PTSD.*

This aim was addressed in chapters four and five; part one of chapter four outlined the methodology, and the results were reported in chapter five.

9.1.1 Summary of the findings

I-CBT is an acceptable treatment for people with PTSD, inferred through study-specific acceptability measures, measures of satisfaction and therapeutic alliance, usage of the i-CBT programmes, and qualitative information. However, greater dropout rates were found for i-CBT than for waitlist/TAU/minimal attention and i-non-CBT.

9.1.1.1 Findings in the context of the existing literature

The certainty of the evidence in the review was very low, not least due to the small number of included trials, limiting our ability to comprehensively determine whether i-CBT is an acceptable treatment for people with PTSD. This is reflected in

the evidence base for acceptability across the healthcare literature in general. Encouragingly however, research examining i-CBT, including its acceptability, is growing. A Cochrane systematic review found that measurements of acceptability were included in several planned and ongoing studies examining i-CBT for PTSD (Simon et al., 2021b). One example is an ongoing RCT, comparing therapist-assisted online psychological therapies for PTSD (STOP-PTSD) (Ehlers et al., n.d.), considering patient experience through interview and questionnaire.

The generalisability of the findings to people across other PTSD populations was limited. Participants included in the ten studies were predominantly white, employed, and had relatively high levels of education. This is inconsistent with reports about service user ethnicity across mental health care settings. For example, in an NHS report on Adult psychiatric morbidity in England, 2007, black men were found to be more likely than men in other groups to screen positive for current PTSD (NHS, 2007). However, it should be noted that underuse of, and lack of awareness of mental health services, has been evidenced for service users of black and minority ethnicity populations (Doyle et al., 2012, Memon et al., 2016). The predominant method of recruitment across studies was media/website advertising, therefore not all participants were necessarily treatment-seeking. Furthermore, people who have volunteered to be part of a trial arguably may engage more with treatment *per se*, than the general population of people with PTSD. The included studies were conducted in Australia, Iraq, Sweden, the UK, and the USA, limiting the generalisability of the results globally, especially to low- and middle-income countries.

The finding that i-CBT is an acceptable treatment aligns with some of the literature. Acceptability for GSH i-CBT and i-TF-CBT for PTSD was suggested by Berger et al., (2017) who reported therapeutic alliance of a similar extent to that found for face-to-face therapies. Berry et al., (2016) demonstrated acceptability through ratings of satisfaction and intervention usage for online and App interventions for individuals with severe mental health problems, particularly where there was provision of support. Kaltenthaler et al., (2008) reviewed acceptability of i-CBT for depression and found 12 of the 16 included trials reported largely positive acceptability and satisfaction information from treatment completers through questionnaires or surveys of acceptability or satisfaction measures.

Combined dropout across all ten studies was greater for i-CBT than for the comparator groups of waitlist/TAU/minimal attention, and i-non-CBT, though

comparable with dropout rates demonstrated for i-CBT for PTSD elsewhere in the literature (Klein et al., 2009). The included studies showing lower attrition in the i-CBT group, compared to waitlist/TAU/minimal attention, were studies of guided i-CBT interventions (Knaevelsrud et al., 2015, Spence et al., 2011). It is possible that the lower rates of attrition demonstrated in these two studies may be a result of the guidance and therapeutic alliance, which may have assisted with engagement. In line with this are findings from a study of the guided i-CBT 'PTSD Online' (Klein et al., 2009), which demonstrated high ratings of therapeutic alliance, despite low/moderate levels of programme satisfaction. The authors suggested:

> *"participants may have found some of the program content difficult; however communication with their therapist was strong and may have mediated these effects" (Klein et al., 2009) (p.129).*

The incongruency of i-CBT acceptability according to measures of satisfaction, alliance, and programme usage, and non-acceptability according to non-uptake and dropout, was surprising. It is not however atypical of some of the PTSD literature. A study of barriers to the uptake of computerised-CBT (Waller and Gilbody, 2009), reported high acceptability among individuals participating in studies, yet low uptake rates, with explanations suggested, including perceived barriers around research participation. Potential or actual research burden may explain the high non-uptake and dropout in the included studies of the systematic review, including the burden of completing lengthy questionnaires (Sanders et al., 2012). Another possible explanation is a perceived or actual intolerability for trauma-focused PTSD treatment. It is possible that participants randomised to i-TF-CBT in the included studies may have anticipated the treatment to be intolerable, therefore choosing not to take it up, or may have experienced the trauma-focused work as intolerable, albeit temporarily, resulting in some dropout. However, not all the i-CBT interventions were trauma-focused and higher dropout was found for i-CBT without a trauma focus, compared with waitlist/TAU/minimal attention, in two of three studies examining such interventions (Miner et al., 2016, Kuhn et al., 2017).

Therapeutic alliance was measured in one of the included studies of an i-TF-CBT intervention, and was found to be strong (Littleton et al., 2016), though as acknowledged by the authors themselves, alliance data was not obtained from individuals who did not complete the post-treatment assessment. Whilst it is largely unavoidable that participants dropping out will not complete follow-up

measures, and a common methodological limitation across the literature, it should be borne in mind that acceptability information may be largely reflecting the views of participants who have remained in treatment.

Methodological challenges highlighted in the review

Several methodological challenges that exist across the literature were highlighted in the review, hampering our ability to meaningfully interpret and synthesise information. These are now explored.

I-CBT acceptability was evident from acceptability measures developed specifically for three of the included studies. It was disappointing that none of the included studies used standardised measures of acceptability, yet not surprising given the evidence for the limited use of standardised measures of acceptability across the literature in general (Sekhon et al., 2017).

All included programmes were based on cognitive-behavioural approaches, with common components of psychoeducation, distress management techniques, cognitive restructuring/trauma processing, and relapse prevention. There was however heterogeneity across the interventions, and whilst we did consider this clinical heterogeneity alongside the statistical homogeneity of dropout data, pooling data using fixed-effect meta-analyses (Higgins et al., 2019), this is a challenge across the literature, and one that must be highlighted.

Acceptability was suggested by i-CBT programme usage, however there was wide variability in its measurement and reporting, from self-report questions to direct login information. This reflects findings in the literature pointing towards substantial variety in the metrics used in the measurement of internet-based interventions examining adherence, including programme usage (Beintner et al., 2019). There was also wide variability in the nature/extent/quality of therapist guidance, and the guiding-clinician's training in the programmes.

Despite dropout being the most frequently reported indicator in the review, and indeed elsewhere in the literature (Sekhon et al., 2017), interpreting acceptability according to dropout rates, with a lack of reported reasons, may be of limited value (Szafranski et al., 2017). Reasons for dropout, not to mention non-uptake, were poorly described in the included studies. Only four studies in the review reported reasons or provided reference to their attempted collection (Knaevelsrud et al., 2015, Krupnick et al., 2017, Lewis et al., 2017a, Spence et al., 2011), and the picture

was similar for non-uptake. This precluded in-depth consideration related to the anticipated or actual tolerability or acceptability of the interventions. Arguably an individual might dropout of treatment due to a perceived sense of feeling better, or conversely might engage with a treatment despite perceiving it to be unacceptable. Of course, dropout must indicate treatment unacceptability, and non-improvement of symptoms, in some cases, however research has shown improvement in symptomatology for a considerable proportion (35.85-55.56%) of individual(s) who discontinued psychotherapy for PTSD and depression (Szafranski et al., 2017).

Dropout findings: a systematic review update

Bearing in mind the potential limitations of dropout, it is a commonly reported measure of adherence and updated dropout analyses may offer new knowledge. We may therefore consider findings from a recent Cochrane systematic review of i-CBT for PTSD (Simon et al., 2021b), which considered the same ten included studies of the acceptability systematic review plus a further three studies.

Dropout data was available for one new study which compared i-CBT with waitlist/TAU/minimal attention, and when this was added, dropout rates were no longer statistically different across groups (RR 1.25, 95% CI, 0.97 to 1.60; k=9, N=634; low-certainty evidence). This suggests that according to dropout, i-CBT may be no less acceptable than waitlist/TAU/minimal attention.

A sub-group meta-analysis was conducted comparing dropout for interventions with and without a trauma focus found no difference [i-TF-CBT compared with waitlist/TAU/minimal attention (RR 1.22, 95% CI, 0.75 to 1.98; k=5, N=343); i-CBT without a trauma focus (RR 1.78, 95% CI 0.94 to 3.37; k=4, N=301); (test for subgroup difference: P=0.89)]. This suggests i-TF-CBT may be no less tolerable and acceptable than i-CBT without a trauma focus.

The update included a new study which compared i-TF-CBT with face-to-face trauma-focused non-CBT and no difference was found with respect to dropout rates between groups, albeit in a study judged as very low certainty evidence (RR 2.49, 95% CI, 0.91 to 6.77; k=1, N=40).

Rather surprisingly the results from another sub-group meta-analysis which assessed dropout for guided i-CBT compared with non-guided i-CBT, found no difference between groups [guided i-CBT compared with waitlist/TAU/minimal

attention (RR 1.22, 95% CI, 0.82 to 1.81; k=7, N=475); non-guided i-CBT compared with waitlist/TAU/minimal attention (RR 1.95, 95% CI, 0.83 to 4.57; k=2, N=169); (test for subgroup differences: P=0.32)]. However, it is important to note the stronger treatment effect found for guided i-CBT compared to non-guided i-CBT (P=0.002), and the heterogeneity of the guided interventions must be noted (I^2=52%).

9.1.2 Strengths and limitations

Strengths

This was the first systematic review dedicated to understanding the acceptability of i-CBT for PTSD. Eligible RCTs included adults who had been exposed to a variety of traumatic events and studies were included where at least 70% of participants had been diagnosed with PTSD. Studies were excluded if they evaluated i-CBT in participants with subthreshold PTSD symptoms, or traumatised people who were not formally diagnosed as having PTSD. This approach is in keeping with the Cochrane review of therapist-administered psychological therapies for PTSD, with the aim of ensuring empirical validity of the review (Bisson et al., 2013). The review did not restrict based on sample size, index trauma, time since trauma, severity/duration of symptoms, and allowed for comorbidity, so there is good reason to believe the findings could be cautiously generalised to clinical populations.

The review was conducted according to rigorous Cochrane Collaboration guidelines (Higgins et al., 2019), with myself and another author independently screening abstracts/relevant papers, against inclusion criteria, extracting data and rating risk of bias. A procedure was in place to resolve any disagreements with the input of a third reviewer, though full-inter-rater agreement meant this was not required. Databases were systematically searched for potentially relevant studies, and researchers in the field were contacted to help to identify missed studies or ongoing work.

Limitations

Several limitations must be considered when examining the review findings, and these are listed in Table 30. For empirical validity, eligibility was limited to RCTs,

given the rigorous methodology/reporting expected of this design. The inclusion of other designs may however have provided additional acceptability information. For example, qualitative studies may have provided more in-depth information. Experimental interventions were heterogeneous, though all were based on cognitive-behavioural approaches. Comparators were also heterogeneous, including face-to-face and non-CBT internet-delivered psychological therapy, and waitlist/minimal attention/repeated assessment/usual care. Whilst there were enough studies to undertake meta-analysis of dropout (Valentine et al., 2010), it may be argued that the meta-analyses comparisons lack statistical power, given that power was not calculated *a priori* (Hedges and Pigott, 2001), and it was not appropriate to conduct post-hoc power analysis (Hoenig and Heisey, 2001). Potential publication bias must be acknowledged, given that only published papers were included. The generalisability of the findings was limited by the exclusion of studies not published in English. However, since the meta-analyses included fewer than ten studies, it would not have been appropriate to use funnel plots to visually explore this possibility (Higgins et al., 2019).

Eligibility was limited to RCTs.
Heterogeneity of experimental and comparison groups.
Power analysis.
Potential publication bias.
Exclusion of studies not published in English. Limiting generalisability.

Table 30: Acceptability systematic review limitations

9.2 Findings of PhD Aim Two

To determine through a mixed methods approach, including a RCT design and qualitative interviewing: a) the acceptability of a GSH i-TF-CBT intervention, 'Spring', for adults with mild to moderate PTSD, and how this compares with the acceptability of an individual TF-CBT intervention, and b) whether treatment outcome is influenced by treatment acceptability.

The second aim of this PhD was addressed in chapters four and six; part two of chapter four outlined the methodology, and the results were outlined in chapter six.

9.2.1 Summary of the findings

The RCT demonstrated acceptability for 'Spring' GSH and its comparator, individual face-to-face TF-CBT. Therapy session adherence and therapeutic alliance did not differ across treatment groups, apart from post-treatment participant-reported alliance, which was slightly in favour of TF-CBT. A large proportion of GSH participants either partially or fully completed 'Spring' programme steps. Treatment satisfaction was high in both groups, and slightly in favour of TF-CBT. In-depth interviews with RCT participants and therapists corroborated ratings, with an appreciation for the importance of adapting GSH to suit an individual's needs and preferences. A multi-faceted model of acceptability was demonstrated as sound and influential in the reduction of PTSD symptoms across treatment groups.

9.2.1.1 Findings in the context of the existing literature

The work importantly goes some way towards addressing priority questions that were raised by over 600 people with mental health lived-experience, their carers, and health and social care practitioners, when considering digital technology in mental health care (Hollis et al., 2018b). These included questions such as the advantages and drawbacks of digital health care, and how Apps for mental health should be evaluated.

Roughly two-thirds of participants were female, reflected equally across treatment groups, consistent with the literature reporting a higher prevalence of PTSD in women than in men, with women having a two to three times higher risk of developing PTSD (Stein et al., 1997, Olff, 2017, Kessler et al., 1995, Pietrzak et al., 2011, Ditlevsen and Elklit, 2012). The total mean age at assessment was 36.54 (SD=13.44), roughly in line with the literature, for example a review examining the average age of onset for PTSD reported it to be 26.6 years (95% CI; 22.13 to 31.06), across 12 studies with 1459 participants (Lijster et al., 2016). However, age of onset for some RAPID participants may have been some time before the baseline assessment.

Roughly two thirds of participants were educated at '2+ A levels or equivalent', in line with reports that around 64% of people aged 19 to 64 years, in the UK, have an education level of NQF level 3, or above, which is equivalent to '2+ A levels or equivalent' (Statistics, 2020). This is important given that education level has been found to be a predictor of increased engagement with internet-based psychological interventions, which may impact on acceptability (Karyotaki et al., 2021, Beatty and Binnion, 2016, Castro et al., 2018).

I-CBT acceptability methodological challenges were discussed with respect to the acceptability systematic review. The validity of the RCT findings are also somewhat hampered given various methodological challenges, which are now discussed.

Methodological challenges highlighted in the RCT

One challenge was missing data. As is common across the literature, we did not have data from participants who had officially withdrawn or had become lost to follow-up. Several therapist record sheets, including final therapist record sheets, were outstanding at the time of this PhD analysis, the latter which included the post-treatment therapeutic alliance measure (ARM-5). This meant that full data sets were only available for 65 individuals, for the multiple regression conducted to understand the model of acceptability and its association with treatment. Whilst I am aware that attempts are being made to identify missing data, this has been challenging given the restrictions imposed by the pandemic, such as locating therapist records that were posted to unoccupied University buildings during lockdown.

We must again acknowledge the difficulties operationalising i-CBT adherence, given the lack of its standardised measurement. For descriptive purposes, therapy session adherence was categorised *a priori* as non-adherence, partial adherence, and full adherence. However, the cut-offs used for the partial adherence and full adherence groups may be too arbitrary and both groups were very broad category. Partial adherence was defined *a priori* as attending less than three GSH sessions (<60%), and less than eight TF-CBT sessions (<66.67%). Full therapy adherence was defined as attending three or more of five expected GSH sessions (>60%), and eight or more of twelve expected TF-CBT sessions (>66.67%). Perhaps more meaningful was the continuous scale of therapy session adherence, which was utilised for the statistical analyses, defined *a priori* as the number of sessions attended, as a percentage of the expected number of sessions. The continuum was however capped at 100% so that all individuals who attended the expected number of sessions *or more*, that is five or more GSH, or twelve or more TF-CBT, were interpreted as adhering at 100%. This is a potential limitation given that some individuals did receive more than five or twelve sessions, and the findings are not therefore reflective of this, given the metrics adopted.

The challenge operationalising 'Spring' programme adherence must also be acknowledged. Indeed, the difficulty in measuring progress through an internet-based intervention, particularly active engagement with the intervention's content, has been acknowledged in the literature (Beintner et al., 2019). Information available via the 'Spring' programme clinician dashboard meant that it was straightforward categorising GSH participants who had not started any steps; however, the range of 'Spring' usage in the category of partial completers was very large. For example, ranging from an individual starting just step one, to an individual completing steps one to seven but only starting step eight. Furthermore, some individuals shown to have completed some steps, may not have meaningfully engaged with these steps. To illustrate, the programme indicated that steps had only been started, and were not complete, when the individual had chosen not to take the non-mandatory quiz at the end of the step, even where the individual had entered information into this step. Alternatively, the programme might indicate a step as complete when the quiz had been taken, even if an individual had not entered in any other information into that step. To develop further categories within the category of partial completion was therefore deemed as not suitable.

Considering adherence according to therapy session attendance, alongside 'Spring' usage helped to address the methodological challenge of GSH adherence. This was facilitated by the multi-faceted model or construct of acceptability, considering various pieces of information as a collective, which is a strength of the research that is discussed later in this section. The findings of each of the facets of acceptability are now discussed in the context of the existing literature, as is the association between acceptability and treatment outcome.

Adherence

The very low non-uptake of therapy sessions for GSH (5.15%), and TF-CBT (3.03%), and the low number of GSH participants not starting any 'Spring' steps (10.31%), contrasts with findings in the literature. The acceptability systematic review (Simon et al., 2019a), found considerably higher i-CBT non-uptake rates in two studies reporting this information in both the i-CBT and active treatment comparison groups: 18.60% (Engel et al., 2015), and 15.22% (Littleton et al., 2016). However, the recruitment of participants in these included studies was through advert, whereas RAPID participants were a treatment seeking population recruited through the NHS. It is possible that all RAPID participants were very keen to commence treatment, though we must also acknowledge another possible explanation. Individuals were informed of their treatment allocation at their first therapy session, and some participants randomised to GSH may have logged in to the 'Spring' programme in the session. The very low non-uptake may therefore be reflective of this procedure.

The high rate of partial therapy adherence, or dropout, for TF-CBT participants (37.37%) is reflected in findings elsewhere, for example high dropout rates found across psychological interventions for PTSD (Lewis et al., 2020b). The partial therapy adherence, or dropout rate for GSH (12.37%) was slightly lower than GSH dropout rates of 14-62% found in a systematic review of eMental health interventions for PTSD (Gaebel et al., 2017), and at the lower end of rates found in the acceptability systematic review, of 8.69-62.5% (Simon et al., 2019a).

The finding that roughly three times as many TF-CBT participants (37.37%) dropped out, or partially completed therapy sessions, compared with GSH participants (12.37%), was surprising. It is possible that participants may have benefitted from the sessions they had received and did not feel it necessary to complete the full set of expected sessions. The finding of a discrepancy between GSH therapy session

adherence and 'Spring' usage was also surprising. Whilst 12 GSH participants (12.37%) partially adhered to therapy sessions, 48 GSH participants (49.48%) partially completed the 'Spring' steps. Similarly, 77 GSH participants (79.38%) fully adhered to therapy sessions, whereas only 39 participants (40.21%) fully completed all eight 'Spring' steps. There are several potential explanations. One might be a wish by some participants to attend therapy sessions, over and above completion of the online 'Spring' programme. Another possibility is that some participants might have attended therapy sessions despite struggling with the 'Spring' programme, for example due to technical difficulties. Indeed, some RAPID participant interviewees spoke of enjoying their supportive sessions with their therapist, and some spoke of frustrations due to programme technical difficulties. Another explanation, which was discussed previously as a methodological challenge that exists across the literature, is that the *a priori* definitions for therapy adherence and 'Spring' usage may not be as useful as we might have expected.

Adherence qualitative findings

Adherence to GSH therapy sessions and 'Spring' steps attunes with some views expressed by RAPID participant and therapist interviewees, such as views that GSH intervention offered flexibility, a facilitator for engagement. This is in line with the literature that internet-based psychological therapies may be accessed flexibly at a convenient time, and in a range of places, whilst also avoiding travel costs to regular in-person appointments (Romijn et al., 2015). The flexibility of internet-based therapies has been identified as an advantage in a recent systematic review of health professionals' perspectives of implementing internet-based therapies in routine mental health care (Davies et al., 2020).

Interviewees spoke about good engagement with GSH, particularly where individuals were motivated to get better, or where GSH was the preferred treatment. This aligns with a review of factors affecting therapeutic compliance, based on patient perspectives, which found that the patient-centred factor, motivation to change, was strongly related to compliance (Jin et al., 2008). A systematic review and meta-analysis of 29 RCTs with 5294 participants with a mental health condition found lower dropout for people who received their preferred psychosocial treatment, and there was also a positive association between preferred treatment and therapeutic alliance (Windle et al., 2020). Improved retention has been shown for individuals using patient decision aids,

which incorporate participant treatment preference (Mott et al., 2014, Watts et al., 2015, Schottenbauer et al., 2008).

Therapeutic alliance

Strong alliance was reported by participants and therapists, mid- and post-treatment, across GSH and face-to-face TF-CBT; mean total alliance scores ranged from 23.27 to 28.06, out of a possible total of 35. This is reflective of findings in the literature. A Royal College of Psychiatrists national audit of psychological therapies for anxiety and depression, including PTSD, utilised the ARM-5 as a measure of therapeutic alliance (RCP, 2011). The measure was distributed to 52,582 individuals and 10,176 responses were received (19%). The mean ARM-5 score was 30.6 (SD=7.0). The response rate of 19% should however be noted, and the authors themselves acknowledge the possibility that responses might be biased in favour of those who were more satisfied.

The findings also add to the limited, albeit growing literature concerning therapeutic alliance in the specific i-CBT context, including a growing literature supporting equality of alliance in online and face-to-face therapy (Andersson et al., 2012a, Berger, 2017, Hadjistavropoulos et al., 2017, Knaevelsrud and Maercker, 2007, Klein et al., 2010, Pihlaja et al., 2018). The acceptability systematic review demonstrated strong GSH alliance in a study of i-CBT for PTSD, post-treatment (Littleton et al., 2016). Research concerning panic disorder and agoraphobia has found no difference in therapeutic alliance between i-CBT and in-person face-to-face CBT (Kiropoulos et al., 2008).

Alliance was equivalent across groups, apart from for post-treatment alliance reported by participants, which was in favour of TF-CBT. It is possible that the slightly higher alliance for TF-CBT reported by participants post-treatment may be reflecting views from individuals who perceived a relationship strengthening over several sessions, sometimes as many as twelve, building trust and enabling them to disclose information that they may have previously avoided.

The finding of strong alliance across both trauma-focused treatments is in line with research evidencing that alliance can be maintained throughout trauma-focused treatment (Capaldi et al., 2016). Therapeutic alliance may impact on the tolerability of trauma-focused treatment (Imel et al., 2013), thus it is not surprising that high levels of therapy session adherence were found alongside high levels of therapeutic

alliance. Since alliance was high, and roughly equal across treatment groups, we might infer that the level of guidance provided in the 'Spring' GSH may be suitable, or potentially optimal, in fostering an alliance that is comparable with TF-CBT alliance. However, the alliance findings from qualitative interviews were somewhat mixed, which is now discussed.

Therapeutic alliance qualitative findings

Some of the views expressed in qualitative interviews chimed with the ratings of strong alliance. Several participants described a positive therapeutic connection, with therapists viewed as motivating them towards engagement and recovery, and some therapists spoke of therapeutic alliance being established in GSH, facilitated particularly by the first hour-long face-to-face session. Similar views have been expressed in other studies, for example a qualitative study of i-CBT for depression, where patients described their therapists providing them with motivation, as well as personal contact and feedback (Gerhards et al., 2011).

Not all views expressed by interviewees were concordant with strong alliance. Unfortunately, some participants described limited connection with, and support from their therapist. It is possible that the restricted face-to-face therapy sessions impacted on therapeutic connection, which might explain an interviewee's comment that the sessions were *"very administrative"*. Some therapists raised concern about exposure work conducted through the GSH approach, specifically about an individual conducting behavioural work alone. Similar views are expressed elsewhere in the literature (Thew, 2020, Stawarz K, 2018, Topooco et al., 2017).

Satisfaction

The high mean satisfaction scores of 26.43 (SD=6.54) for GSH participants, and 29.74 (SD=3.31) for TF-CBT participants, out of a possible total of 32, are comparable with findings elsewhere. For example, a pilot study of a group GSH intervention for low mood and depression, found a similar mean CSQ-8 satisfaction rating of 28 (SD=4.8) (McClay et al., 2015). In the acceptability systematic review, satisfaction was high for i-CBT in the included studies that measured it (Littleton et al., 2016, Spence et al., 2011). However, the literature is limited, with only a few studies that have directly measured acceptability of internet-based treatments for psychological disorders, in terms of satisfaction (Campos et al., 2018).

Satisfaction qualitative findings

The picture according to qualitative interviews with RAPID participants and therapists was mixed. Some corroborated the strong ratings of GSH treatment satisfaction, describing 'Spring' as positive and calming, and describing GSH as a progressive, structured, and containing method. In a study assessing uptake of blended internet-based therapies for depression in the Netherlands (Mol et al., 2020), 77% of therapists stated that blended i-CBT for depression met all or almost all their needs. Ninety-four per cent were overall very or mostly satisfied with it, and 97% said they would recommend it in the future to their patients, providing a few preconditions were met, including programme usability, current work routine, and more guidelines on the use of blended interventions. Interestingly, despite the high satisfaction indicated across ratings, qualitative interviews revealed that therapists perceived other therapists to be dissatisfied with blended internet-based approaches.

Some RAPID therapists acknowledged GSH as a good option for people who would prefer not to talk to someone in the traditional approach over several weeks. It is possible that a GSH option may feel safer than a purely face-to-face alternative for some individuals who may wish to minimise intimacy to protect themselves from potential shame or rejection. For example, the Online Disinhibition Effect (Suler, 2005), may be facilitated in GSH approaches, whereby individuals express themselves more openly online than in the face-to-face world. Individuals may feel more able to express themselves through the online 'Spring' programme, potentially promoting increased honesty and disclosure. Literature exists demonstrating that internet-based therapies offer anonymity and may appeal to individuals who fear mental health treatment-seeking stigma (Gega et al., 2004, Kantor et al., 2017, Olff et al., 2015, Kitchiner et al., 2012), therefore an alternative to pure face-to-face therapies may be more appealing for some. In line with this are findings from Kantor et al's (2017) systematic review of barriers and facilitators to mental health utilisation in adult trauma survivors. Amongst other barriers, the authors report the trauma-specific barrier of not wanting to talk about the trauma.

Satisfaction ratings were in favour of TF-CBT, and this was reflected in qualitative interviews, with some participants stating they would have preferred TF-CBT. Similar views have been expressed elsewhere in the literature, for example therapists' beliefs that internet-based approaches will not be as effective as face-to-face approaches, and that they will fail to meet patient expectations (Thew, 2020).

Interestingly, some therapists had reflected that their preconceptions that individuals would prefer face-to-face had been challenged, suggesting that their views around its acceptability had altered through experience. This casts doubt regarding treatment allocation equipoise, at least for the initial period for some therapists, which must be held in mind. Clinical equipoise is a methodological challenge of the RCT design, a potential bias that is perhaps more likely in cases where a therapist is more experienced in the delivery of one intervention, over the comparator and therefore one that exists across the literature, arguably largely unavoidable in trials of manualised interventions (Cook and Sheets, 2011).

Importantly, some RAPID participants considered GSH to be an empowering treatment option. This is encouraging, since, as noted in chapter two, a key factor in the rise of internet-based psychological therapies is their promotion as empowering treatment options (NHS, 2019). GSH interventions are considered empowering in terms of enabling greater choice and control regarding health needs (Hollis et al., 2018a). Some therapists remarked on GSH being less flexible in terms of delivery of its content, though it is possible this may be due to the necessary rigorous RCT design, including strict protocol and intervention delivery fidelity checks.

There were however several alternative views, including mixed views about the length of the GSH treatment, and time allocated to certain intervention components. Some participants felt the treatment was too short for their difficulties, whilst others wishing for an accessible treatment that could fit around other commitments felt it was perfect. The mixture of views suggests a wish to receive and deliver GSH in a flexible manner. This highlights the importance of patient-centred care and shared decision making, adapting, and personalising interventions, and at the same time assessing this approach in clinical practice to build practice-based evidence. This is discussed later in the clinical implications section.

Acceptability and treatment outcome

Encouragingly, the multi-faceted model of acceptability, incorporating therapy session adherence, satisfaction, participant- and therapist-reported therapeutic alliance, and the important covariate of baseline PTSD symptoms, explained 45.0% of the variance in treatment outcome across groups. This builds on previous work proposing acceptability as a multi-faceted construct, reflecting the views of

patients and providers (Sekhon et al., 2017). It demonstrates the importance and relevance of these facets of acceptability in studies of i-CBT for PTSD. Indeed, some RAPID participant interviewees talked about feeling better after treatment, having a better understanding of PTSD and its treatment, and seeing more friends, which are positive PTSD-related outcomes.

It is not surprising that treatment satisfaction, as well as baseline PTSD symptoms, were significantly associated with treatment outcome. Arguably, satisfaction may be assumed to be associated with treatment outcome, since presumably most people who see an improvement in their symptoms will also be satisfied with the treatment. However, as discussed previously with respect to dropout, the picture is not always straightforward. To illustrate, an individual might preconceive a treatment to be unacceptable, though may stick with it regardless, and might see an improvement in symptoms and therefore feel satisfied overall.

Equipoise was discussed previously, with respect to therapists delivering treatment, and participants may also hold their own preconceptions around treatments, which may be impacting on acceptability. It is therefore reassuring that the findings demonstrated treatment satisfaction to be significantly associated with outcome, suggesting that many individuals who felt better also felt satisfied with the treatment and its approach. Satisfaction appears to be an important part of the picture, particularly with respect to treatment outcome, and satisfaction is considered a key impact area by IAPT, considered essential in determining quality, efficiencies, and effectiveness of services provided (DoH n.d.). IAPT utilises a patient experience questionnaire, incorporating satisfaction, as well as treatment choice and access, with some localities using the CSQ-8 to capture satisfaction. In line with Prudent Healthcare, NHS Wales' Health Boards and Trusts have co-produced Patient Reported Experience Measures (PREMs) for members of the public accessing health care services, which includes a measure of satisfaction (Withers, 2018). It is encouraging that high ratings of satisfaction were reported by individuals utilising 'Spring' GSH i-TF-CBT, though we must bear in mind that satisfaction ratings were slightly in favour of face-to-face TF-CBT.

The i-CBT literature regarding alliance, adherence and treatment outcome is scant, and a systematic review of therapeutic alliance in guided internet-based therapies for depression and anxiety disorders found that none of the included studies reported alliance-adherence associations (Pihlaja et al., 2018). Drawing on the wider alliance literature, a robust yet modest association has been demonstrated

between therapeutic alliance and treatment outcome across psychological treatments (Horvath et al., 2011), including PTSD treatment outcome (Capaldi et al., 2016, Knaevelsrud and Maercker, 2006), and therapeutic alliance established during face-to-face therapy has been demonstrated as a predictor of positive treatment outcomes (Ardito and Rebellino, 2011). A study comparing the i-TF-CBT 'Interapy' with waitlist found that whilst a high alliance was established, it was found to be a less relevant predictor of the therapy outcome than that that found for face-to-face approaches (Knaevelsrud and Maercker, 2006).

9.2.2 Strengths and limitations

9.2.2.1 Strengths

Guided i-CBT has featured amongst treatment recommendations in recent treatment guidelines for PTSD (ISTSS, 2018b), though its acceptability has certainly not received the same attention. This is the first study to determine the acceptability of GSH TF-CBT in a rigorous mixed methods RCT design examining the efficacy and acceptability of GSH TF-CBT, head-to-head with face-to-face individual TF-CBT. The strengths of the study design are now described.

Trial management, conduct and fidelity

The RCT was a multicentre trial across England, Scotland, and Wales, pragmatic and applicable to real life, being delivered in the NHS services it would be adopted in. Therapists received thorough training and supervision in both treatments, and adherence to the protocol manual was fidelity checked. This means that we can be confident about a reasonable homogeneity of therapy delivery, including guidance in the case of GSH, across sites and participants. Similarly, the Raters, including myself, were trained to administer the CAPS-5 interview, the 'gold standard' clinician interview for PTSD. Regular inter-rater reliability assessments allow for confidence in the reliability of PTSD symptom measurement. All measures used were psychometrically sound and data collection at baseline and follow-up assessments was rigorous, for example the use of an electronic database designed to minimise missing or inaccurate data. The semi-structured interview method facilitated the collection of a rich set of data, with openness for individuals to present new topics, and at least 20% of interview transcripts were double coded.

The invaluable contributions from the PTSD Public Advisory Group must be acknowledged. One member was a co-applicant on the RAPID grant application and was also a member of the Trial Management Group, and all members contributed to the development of information for participants, interpretation of qualitative information, and plans for dissemination. Co-production is advocated within UK Research Governance Frameworks (HRA, 2020) and is considered the cornerstone of the 'patient-led' NHS (Newton et al., 2013, Hogg, 2007). Co-production thereby enhances the applicability of the findings (INVOLVE, 2021). The RAPID Team also included professional experts in the field, with coordination from an experienced Clinical Trials Unit (Centre for Trials Research, Cardiff University), thorough Standard Operating Procedures.

'Spring' intervention and comparator

A key strength was the 'Spring' GSH intervention. A unique selling point of 'Spring' is that it was co-produced with people with lived-experience of PTSD, therefore grounding its content and applicability. It was rigorously co-produced in line with MRC guidelines, and demonstrated as effective in pilot work (Lewis et al., 2012), and in a feasibility RCT, compared to waitlist (Lewis et al., 2017a). The comparator intervention, TF-CBT was based on Ehlers and Clark's widely cited CT for PTSD (Ehlers and Clark, 2000), which is recommended in PTSD treatment guidelines (ISTSS, 2018b, NICE, 2018c).

Recruitment and randomisation

RAPID participants were not excluded based on time elapsed since the trauma, providing the individual had been experiencing symptoms for one month, as required by DSM-5 PTSD diagnostic criteria. Participants were not excluded based on comorbidity, apart from substance dependence and current psychosis, providing PTSD was the primary condition. Recruitment was predominantly through local primary and secondary mental health services and participants are therefore likely to be representative of a PTSD treatment-seeking population. Furthermore, the findings can be applied to PTSD treatment-seeking populations across geographically and socioeconomically diverse areas, given that participants were recruited in a range of sites across Wales, England, and Scotland, albeit with a large proportion (39.29%) recruited from the Cardiff & Vale UHB Site. Participant demographics and characteristics at baseline were equal across treatment groups,

suggesting that the randomisation stratification process worked well. Mean baseline CAPS-5 and PHQ-9 scores were roughly equivalent across treatment groups.

The sample of GSH participant interviewees was roughly representative of the overall RAPID and GSH sample, and the range of ages of interviewees very closely resembled those of participants in the overall RAPID sample, and GSH group. Interviewees had experienced a range of traumatic events and were from a range of geographic research sites, which adds confidence in terms of the generalisability of the findings across trauma types and geographically and socioeconomically diverse areas.

Female and male gender was represented with rough equivalence in the RAPID therapist interviewee sample, and a good range of research sites were represented. Only one interviewee had a very high familiarity of 'Spring', prior to the RCT, which would be expected, given that it was a new intervention that had not been rolled-out across the NHS. This was enabled by purposive sampling.

The RCT sample size was large and robust, determined by a power calculation, and an excellent recruitment and retention rate was achieved. This is certainly a strength given that pragmatic trials, conducted in real-world NHS settings, often pose a challenge in terms of recruitment and retention. For example, the participants in South Wales were recruited from three different University Health Board sites and were required to travel to Cardiff for treatment, even though they may be living a considerable distance away. The therapists delivering the interventions were all NHS employees with high caseloads, posing potential issues in attending supervision sessions, and replacement of therapists was not a quick process. Strategies were in place to minimise these risks, for example ensuring travel cost claiming procedures were clearly outlined to participants, and a surplus of therapists were trained up.

Multi-faceted approach to acceptability measurement

"The whole is other than the sum of its parts" (Aristotle)

Conceptualising acceptability as a multi-faceted construct provided a broader and deeper understanding of acceptability. Findings from various facets were

combined, providing a picture of acceptability as a whole, that was greater than the sum of its parts. Furthermore, considering several facets alongside each other helped to address some methodological challenges that have been discussed. Measuring several aspects of GSH adherence, including therapy session adherence, and 'Spring' usage, helped build a clearer picture. The collection of reasons for withdrawal enabled increased confidence when interpreting dropout, at least with respect to withdrawal rates. Interpretation was further enabled with the collection of qualitative interview information, and from measures of alliance and satisfaction.

COVID-19 context

All RAPID therapist interviews, and two GSH participant interviews were conducted after the onset of the COVID-19 pandemic. It is therefore important to acknowledge the views expressed by some of the interviewees in the context of the rapidly changing circumstances due to COVID-19. The pandemic accelerated the provision and use of remote therapies, and it is important to consider that the views expressed represented the picture for the individual at the time of the interview. This may be considered an unintended strength of the study.

9.2.2.2 Limitations

Some caution must be exercised when interpreting the RCT findings. These are now discussed.

Participant characteristics

Though some strengths of the representation of the RAPID sample have been noted, there are limitations that impact on the generalisability of the findings to other PTSD populations. Most participants were white, and all GSH participant interviewees were white, reported previously as being inconsistent with reports that black men have been found to be more likely than men in other ethnicity groups to screen positive for current PTSD (NHS 2007). Most participants were educated with '2+ A levels or equivalent', and whilst this was noted earlier as being roughly reflective of education levels across the UK, a large proportion of these individuals had a level of education of 'degree or above'. Furthermore, all GSH

participant interviewees had an education level of 'at least 5+GCSEs', which was not representative of the overall RAPID and GSH sample.

All GSH participant interviewees had at least partially completed 'Spring' steps, with none being non-starters. The findings of the interviews do not therefore reflect views from the 10.31% of participants, albeit a small proportion, who did not take up the GSH intervention and its programme.

Reflexivity

It is important to note my changing experience as PhD researcher. I commenced a new role as an Assistant Psychologist in the Cardiff & Vale UHB Perinatal Community Mental Health Team, whilst I was analysing and writing up the RCT acceptability results. Whilst in this role I commenced training in the 'Spring' intervention and guided two patients through the intervention to complete my training. Whilst I always aim to work with an objective lens, this experience may have influenced my interpretation of the qualitative interviews with RAPID participants and therapists, and indeed my development of the Discussion overall. This is therefore an important consideration.

Additional limitations

Additional limitations are listed in Table 32.

Potential conflict of interest	A potential conflict of interest must be declared given that some members of the RCT management group were also developers of the 'Spring' intervention.
Therapist experience	RAPID therapists were very experienced therapists, limiting our ability to generalise the outcomes that might be achievable if less experienced therapists were delivering GSH in the future.
Long-term follow-up	Acceptability was measured post-treatment, at 16-weeks follow-up, with qualitative interviews happening at a similar time. Acceptability was not measured at the 52-week follow-up timepoint, therefore our understanding of the acceptability of GSH according to the views of participants,

	and indeed therapists, are limited to immediately post-treatment.
Length of treatment different across treatment arms	Whilst the strength of comparing the acceptability of GSH with the first line treatment of face-to-face TF-CBT must be acknowledged, the length of treatment across treatment groups was quite different and arguably it may have been advantageous to compare the acceptability of GSH with a face-to-face treatment of a similar length, delivered over eight weeks.
Views of significant others	We know that PTSD impacts interpersonal relationships, and indeed, several interviewees spoke about this. It might therefore have been beneficial to invite interviews with the carers or significant others of participants allocated to GSH, to draw on their invaluable perspectives.

Table 31: RCT additional limitations

9.3 Findings of PhD Aim Three

To evaluate the acceptability of internet-based psychological interventions from the perspective of stakeholders implementing and facilitating access to mental health interventions.

This aim was addressed in chapters four and seven; the methodology was outlined in chapter four, and the results were reported in chapter seven.

9.3.1 Summary of the findings

Ten NHS commissioners and managers took part in qualitative interviews and provided their opinions about the opportunities and challenges of providing internet-based therapies. Interviewees identified service capacity issues; a movement towards the acceptance of internet-based psychological therapies, indicating their acceptability, with reservations; and acknowledged considerations in their successful implementation.

9.3.1.1 Findings in the context of the existing literature

Interviewees remarked on GSH being flexible, empowering, and an alternative therapy option for people who would prefer not to talk to someone in the traditional face-to-face approach over several weeks. These views therefore resonated with views held by some RAPID participants and therapists. Guided internet-based therapies were preferred to non-guided options, which was encouraging given GSH i-CBT is recommended in NICE guidance, for example for depression and PTSD (NICE, 2009, NICE, 2018c), with guided interventions demonstrating greater effect compared with self-help in a recent Cochrane systematic review (Simon et al., 2021b).

Some NHS commissioners and managers perceived that staff held reservations around internet-based approaches; particularly that the therapeutic alliance, the cornerstone, and key component of traditional psychotherapy, might be compromised. Similar views have been reported by therapists elsewhere in the literature (Thew, 2020). These views are not however supported by findings of equality of alliance in online and face-to-face therapy (Andersson et al., 2012b, Berger, 2017, Hadjistavropoulos et al., 2017, Knaevelsrud and Maercker, 2007, Klein et al., 2010, Pihlaja et al., 2018), including the alliance findings of the RCT within this PhD.

Encouragingly, and in line with evidence-based medicine approaches, NHS commissioners and managers considered a strong evidence base for an intervention to be a facilitator in its implementation and acceptance amongst staff. Of concern was the finding that the evidence base was viewed as an important but not always a sufficient factor in its implementation. This may be in keeping with the literature, suggesting clinicians may value personal clinical experience over research evidence, particularly when the available evidence fails to address some real-world clinical contexts (Timothy et al., 2008). Indeed, in a study of mental health service utilisation of internet-based therapies in England, online interventions were recommended in service provision by 169 of 191 (88.5%) IAPT services providing this information, though only 24.3% of the i-CBT interventions were NICE-recommended (Bennion et al., 2017). We also know there is limited adoption of LI treatment in clinical practice (Mohr et al., 2017, Vis et al., 2015). It is possible that the views reflect the speed at which digital interventions are developed, surpassing the rate at which the evidence base can establish, given the lengthy, albeit necessary, traditional evaluation methods, including RCTs (Andersson, 2014, Torous and Roberts, 2017).

NHS commissioners and managers acknowledged several challenges to intervention implementation, including prohibitive intervention set-up costs, and delays due to NHS inflexibility. Somewhat similar are views expressed in previous surveys (Schuster et al., 2020, Topooco et al., 2017), however they reported *non-readiness* as the barrier, rather than inflexibility.

Interviewees perceived therapists to be resistant to changing practices in general, which reflects findings noted previously, that internet-based therapies have been inconsistently used and recommended in England (Bennion et al., 2017). It was clear, however, particularly from the four NHS commissioner and manager interviews that were conducted post-COVID-19 UK National lockdown, that there is a shift in practice and increasingly positive views from staff around remote therapies and different ways of connecting with patients. Interviewees felt reassured by digital 'COVID-proof' therapies that could widen and diversify treatment access, and some RAPID therapists expressed similar views. This is supported by recent literature which considers COVID-19 as the 'black swan' and a turning point for mental health care and increased e-Health (Wind et al., 2020).

Recommendations for implementation were revealed in interviews with NHS commissioners and managers and RAPID therapists. These included coordinated nationwide approaches and timely training and supervision, which will be discussed within clinical implications.

9.3.1 Strengths and limitations

9.3.1.1 Strengths

As far as I am aware, this was the first in-depth exploration of the views of NHS commissioners and managers of internet-based therapies and their implementation. Until now, limited attention has been given to the implementation of internet-based psychological therapies in practice, at least in terms of leadership factors (Palmili, 2013). As noted in chapter two, previous research conducted in the UK focused on the views of PWPs and of healthcare professionals more generally (Gellatly et al., 2017, Lovell et al., 2017, Davies et al., 2020). This work considered the views of NHS employees directly involved in intervention commissioning and implementation, allowing insight into factors that are likely to impact this process. Furthermore, since interviews were conducted

both pre- and post- lockdown restrictions, the information provides a unique insight in to shifting practices and views because of the pandemic.

The recruitment of ten interviewees was estimated for sufficient information power, based on the specific aim of the study, the specificity of the sample, being individuals working in specific NHS roles with specific knowledge and experiences, and the strength of the in-depth interview dialogue (Malterud et al., 2016). The data was analysed concurrently with its collection, adopting a constant comparison approach to explore themes, to ensure sufficient data saturation (Saunders et al., 2018). Purposive sampling supported this approach and ensured representation across genders, and across NHS clinical leadership and management roles. Representation was sought across England, Scotland, and Wales, which is a strength given that mental health services are commissioned and managed quite differently across the UK.

The semi-structured interview method provided a rich set of data, with openness for individuals to present new topics. The topic guide was developed with support from a Consultant Clinical Psychologist, and individuals with lived-experience of PTSD, grounding its applicability, and double coding of 100% of interview transcripts is another study strength.

9.3.1.2 Limitations

Most individuals were white British, and all but one of the individuals were over the age of 44, all with a degree level of education, or higher, limiting the generalisability of the findings. Arguably the age and education level demographics may reflect a fairly accurate representation of individuals in senior roles responsible for implementing NHS mental health interventions, though it is disappointing that the findings may not be representative of a broader ethnic diversity. As with all qualitative interviews, we must note that some of the views expressed may be based on assumptions rather than knowledge. For example, commissioners and managers perceived that staff may be resistant to changing practices. It is therefore advantageous that this PhD considers the view of NHS commissioners and managers alongside perspectives and measurements of acceptability from therapists delivering the treatment, and participants receiving it. Nonetheless, interviewee assumptions or perceptions about others should be considered cautiously.

Whilst the focus of this work was to examine the implementation of internet-based psychological therapies across the NHS, it may have been beneficial to invite additional stakeholders who might provide or signpost to internet-based therapies, such as individuals working in third sector and social services. Gathering perspectives from a wider group of stakeholders may provide further knowledge to indicate the potential for GSH across a wider public sector.

9.4 Research implications

There is a need for further research on the acceptability of i-CBT for PTSD as the field grows and as new interventions are developed. Indeed, interviews with NHS commissioners and managers highlighted a need for further research and emphasised the importance of both empirical and practice-based evidence.

Research should be co-produced, in line with UK Standards for Public Involvement (Involvement, 2021). This includes considering the views of stakeholders when prioritising research questions through inclusive methods, such as methods employed by the James Lind Alliance (JLA, 2021). A Delphi process is another example of a methodology ensuring stakeholder consensus (Kearney et al., 2017).

GSH for PTSD is a growing field, and as new study findings are disseminated, review updates will be required. Meta-analyses of individual patient data would also be beneficial, to examine the moderators and mediators of i-CBT efficacy and acceptability. This knowledge could build our understanding of for whom such interventions are most appropriate, as well as for whom non-response and non-acceptability may be likely (Rozental et al., 2019, Karyotaki et al., 2018). As discussed by Drozd et al., (2016), future studies should systematically describe the implementation of interventions, and wide and open access dissemination of research is important (Olff, 2020). Indeed, increasing digital health implementation and dissemination activities was proposed within a special issue of the European Journal of Psychotraumatology examining digital health applications in the field of traumatic stress (Bakker et al., 2020). Dissemination should be lay-friendly and open access, so that decision makers, including patients, can make informed choices.

The work of this PhD has highlighted methodological challenges that exist across the i-CBT acceptability literature. Research would be improved through the valid measurement of acceptability as a multi-faceted construct, which is now discussed.

9.4.1 Improved acceptability measurement and reporting

As new GSH i-CBT interventions are developed, their acceptability must be robustly measured. As introduced in chapter two, Apps and programmes should be quality-checked, utilising a validated measure, such as the MARS (Terhorst et al., 2020), and GSH interventions must continue to be rigorously tested through traditional evaluation methods, including RCTs.

The findings of this PhD promote the use of a combination of indicators, including standardised acceptability measures, validated measures of treatment satisfaction and therapeutic alliance, various measures of adherence, and qualitative information. Furthermore, a multi-faceted construct of acceptability was found to be influential in treatment outcome across the RCT treatment groups. Further research is required to understand the extent to which the acceptability of other GSH interventions for PTSD influence treatment outcome. If acceptability holds up as an important influencer of treatment outcome, across additional studies of GSH for PTSD, it may be important to consider acceptability as a primary outcome. As Eysenbach et al., (2011) suggest acceptability should be reported in primary publications, discouraging the commonly practised splitting of outcome and adherence, and other findings, into several publications. Furthermore, it will be important to consider potential moderators in the multi-faceted model of acceptability.

This PhD has highlighted common methodological challenges when measuring acceptability. Standardised acceptability methodology is required to interpret findings and to compare studies, to enable a clearer understanding. Online intervention reporting guidelines are available (Eysenbach, 2011).

The challenges operationalising adherence have been discussed, and further research is required to consider the usefulness of various measures of adherence, including the proxy indicator of dropout when reported without reasons. Findings of this PhD suggest an increased understanding when considering adherence information in a variety of forms: engagement with the GSH programme, including steps and exercises completed; therapy session adherence; non-uptake and dropout, including reason; and in-depth qualitative information.

The ‘Spring’ GSH intervention appeared to provide an acceptable level of guidance, fostering an alliance comparable with face-to-face TF-CBT, though it must be noted that the ARM-5 used in the RCT was intended for use with traditional face-to-face therapies. Future research should consider the development and use of alliance

measures in the context of GSH and internet-based approaches. Indeed, in a national study involving 600 mental health stakeholders in the UK, digital therapeutic alliance was voted as a top ten research priority (Hollis et al., 2018b). Encouragingly, Berry et al (2016) have developed a version of the ARM for digital health interventions.

9.4.2 Research questions

The findings of this PhD point towards several patient-specific factors that appear to be important for engagement and acceptability, including baseline levels of PTSD symptoms, depression, treatment preference and psychological readiness, and further research is required to determine patient-specific factors that may be associated with acceptability and treatment outcome. This PhD has also raised several specific questions about the potential reach of GSH for PTSD, questions that warrant empirical research. These are now discussed.

9.4.2.1 The acceptability of GSH across PTSD populations

'Spring' GSH i-TF-CBT is an acceptable treatment for people with mild to moderate PTSD to a single traumatic event, across the UK, and perhaps wider. Some NHS commissioners and managers expressed their views that internet-based therapies were generally suitable for mild to moderate disorders. This is in keeping with some of the literature (Davis et al., 2008, Gellatly et al., 2017, Schuster et al., 2020, Topooco et al., 2017, Stephen et al., 2011). However, further empirical research is needed to understand the extent to which GSH may be able to play a part in the treatment of people with severe PTSD, people with PTSD to multiple traumas, and people with the most complex needs (Ashwick et al., 2019, Olff et al., 2019). Research would be required to develop suitable GSH interventions, testing the acceptability of GSH approaches for people with specific symptom profiles, including dissociative symptoms.

The RAPID Trial did not exclude participants based on trauma type, suggesting that 'Spring' is an acceptable GSH intervention for people with PTSD following various trauma(s). However, an interviewee had suggested GSH may be a 'flippant' treatment offering for people with PTSD following particular types of trauma. It would be interesting to consider whether acceptability is influenced by trauma type, for example where trauma has involved traumatic grief.

9.4.2.2 GSH inclusivity

Some RAPID therapists and NHS commissioners and managers suggested that some people may not engage with internet-based approaches, or worse be excluded because of language and literacy issues, and online access issues. This is in line with some of the literature highlighting that access problems, including language may be a barrier to mental health utilisation in adult trauma survivors (Kantor et al., 2017), and the finding that there is a tendency for digital technologies to increase inequalities (Azzopardi-Muscat and Sørensen, 2019, Ennis et al., 2012). In contrast is literature supporting the value of internet-based interventions in offering opportunities to increase availability and equitable resources for mental health care globally, potentially addressing unmet needs (Olff 2015). Research is required to understand the extent to which internet-based interventions may increase access and reach, or if individuals are excluded from internet-based treatments, for example due to language, literacy and/or computer literacy issues. Where there is evidence for exclusion, this would allow for any inequity to be addressed, for example through developing and testing interventions to be more engaging and accessible for people with low levels of literacy, or digital literacy, including easy-read options. Research could include surveys or qualitative interviews.

The work of this PhD was undertaken prior to, and during the onset of the COVID-19 pandemic, and interviewees reflected on potential changes in digital literacy because of the COVID-19 pandemic. For example, interviewees suggested an increasing number of people engaging with technologies. A drive towards improving access to psychological therapies, including remote options, was evident before COVID-19, though the pandemic has certainly accelerated this movement, and research is required to keep up to date with attitudes and practices that may be rapidly changing. It would be interesting to conduct interviews with public and healthcare providers to assess attitudes towards GSH, and to consider if and how views develop over time.

9.4.2.3 The impact of decision aids on GSH acceptability

There is an increasing recognition for the utility of decision aids in promoting patient choice (BMJ, 2013, NICE, 2018a), therefore research is required to explore the impact of decision aids with respect to GSH for PTSD. Empirical research would offer insight into the impact of using a decision aid on treatment acceptability and

outcome, and shared decision making strategies are also discussed within the clinical implications section, which now follows.

9.5 Clinical implications

GSH may be an acceptable alternative to face-to-face therapy, which has great clinical implications for NHS services, clinicians, and service users. Nonetheless, GSH is not a 'one size fits all' solution, and shared decision making is necessary to consider its acceptability on a case-by-case basis, perhaps personalising GSH approaches, to ensure GSH is the most appropriate treatment of choice. Practice-based evidence is required to evaluate GSH for PTSD in routine clinical practice, and clinicians may wish to consider the recommendations that have been offered for its sustainable roll-out across the NHS.

9.5.1 GSH: a treatment of choice?

The finding that GSH may be an acceptable alternative to face-to-face therapy is important given the drive towards widening access to evidence-based psychological care (Torous et al., 2019), including the expansion of IAPT and other services across the NHS (Wakefield et al., 2021). Some individuals might have difficulty committing to, or not wish to engage in standard weekly treatment of weekly face-to-face appointments (Knaevelsrud and Maercker, 2007), and GSH may be an empowering alternative offering greater choice in PTSD treatment (Tarrier et al., 2006). There are cost-efficiency advantages to GSH, particularly if GSH can be delivered by non-specialist clinicians (Lindsäter et al., 2019).

9.5.1.1 Considerations for shared decision making

Careful assessment, formulation, and a shared decision making process would be required by clinicians and service users to ensure GSH is the most appropriate treatment option. Shared decision making was introduced in chapter two and is impacted largely through patient preference and evidenced as leading to improved patient experiences and treatment outcomes and health-care provider satisfaction (McMillan et al., 2013, Swift and Callahan, 2009) . It is recommended alongside all NICE guidance (NICE, 2018b), and the use of decision aids and other strategies should be adopted in routine care by patients and clinicians when considering GSH. Shared decision making should consider a service user's readiness to engage with

trauma-focused psychological therapies, including GSH. Indeed, RAPID participants talked about needing to be ready for the difficult therapy process. Shared decision making might consider the advantage of the flexibility and empowering nature of GSH, as was identified in interviews with RAPID participants and therapists. Some service users may prefer a GSH intervention which is entirely remote, including remote therapy sessions, which is discussed later. Clinicians should however hold in mind that some individuals may not be able to engage with internet-based approaches, for several reasons, including simply not wishing to do so (Ennis et al., 2012).

Digital literacy and language and literacy abilities are other important shared decision making considerations that were highlighted in interviews with RAPID participants and therapists and NHS commissioners and managers. It might be necessary to provide equipment or mobile network data, for inclusivity, and to consider whether a GSH programme may be available in different languages, or in an easy-read version. There are examples of i-CBT facilitating working across language barriers, for example the i-TF-CBT intervention, 'Interapy' (Lange et al., 2003), which is available in several languages. Whilst not identified within interviews, other important considerations might include sensory impairments, highlighting the importance of interventions that include a mixture of audio and visual communications.

Programme features that foster engagement may be important for some people. The ability to choose the gender of the programme voice-over or a character within a programme may help an individual to identify with the narrator or character, and may become extremely important where a trauma involved a perpetrator of a certain gender (Peck, 2008).

Feeding back progress to the end user may be important for engagement. NHS commissioner and managers had suggested GSH programmes could include co-produced built-in outcome measures. Indeed, the interests of people with PTSD might differ from the interests of those commissioning and providing the interventions. The ability to add goals to a goal attainment measure, for example, could assist with engagement and could allow service users and clinicians to monitor progress towards goals that are important to the service user. Furthermore, in-built outcome measures may be welcomed by services given that clinical practices might ordinarily administer outcome measures through a separate process, perhaps posting outcome measures for completion.

RAPID therapist interviewees highlighted their wish to know how long participants were spending on the 'Spring' programme, in addition to knowing the steps and exercises that they had completed. Clinicians should consider the information that will be made available to them via the GSH programme, when considering the suitability of GSH intervention for the service user they will be working with.

A wish to flex and personalise GSH treatment was clear given the contrasting mixture of views held by participants and therapists about the length and pace of the GSH intervention and the time allocated to certain components. It might therefore be important for a clinician and service user to consider whether the pace of the treatment could be adapted to suit the service user's needs and preferences, perhaps allocating additional time to certain components. Practice-based evidence would however be required to consider the impact of such adaptations on the efficacy and acceptability of GSH for PTSD. The limitation of the standard RCT design can be the lack of flexibility to personalise interventions, therefore practice-based evidence strategies offer an opportunity to examine the opportunities and drawbacks of personalised GSH.

9.5.2 The importance of practice-based evidence

The goal of researching an intervention should go beyond its efficacy, to its sustainable implementation into routine care. The GSH adaptations that have been described above, including personalising approaches to suit an individual's needs and preferences, may certainly help increasing the acceptability of GSH approaches, which would help facilitate their uptake and implementation routine clinical practice. The importance of practice-based evidence, of continuous evaluation and improvement, must not be underestimated.

One practice-based evidence strategy is a quality improvement (QI) initiative called the 'Plan-Do-Study-Act' (PDSA), whereby quality of care, or an intervention, is improved through iterative cycles, with each cycle informing the subsequent cycle (Knudsen et al., 2019). Knowledge is considered to expand with the continuous collection of data and accumulation of experience. A QI project examining 'Spring' in the context of routine NHS practice is currently underway, and it will be helpful to draw on the findings of this work and to consider the perspectives of staff delivering the intervention, staff supervising others in its delivery, and patients in receipt of the treatment, in the context of routine NHS practice. QI work may offer

further insight into the skill base required by clinicians guiding service users through GSH, and optimal training and supervision models, which are now explored.

9.5.2.1 Guiding clinician

The motivation and support provided through therapist guidance was highlighted by RAPID participant and therapist interviewees as being an important aspect of the GSH intervention, in fostering engagement and alliance. Clinicians guiding patients through a GSH intervention should adopt strategies influential in alliance and engagement, throughout the treatment, to allow an individual to engage with the programme and to feel safe to be able to disclose trauma information (Kehle-Forbes and Kimerling, 2017, Christensen et al., 2009, Capaldi et al., 2016, Maercker and Knaevelsrud, 2007). Practice-based evidence such as quality improvement work, would offer insight into the specific skill set and competencies required by a guiding clinician to foster effective alliance and engagement. Indeed, NHS commissioners and managers expressed views that guidance need not be provided by a specialist clinician, but it would depend on skills required.

9.5.2.2 Provision of training and supervision

RAPID therapists and NHS commissioners and managers highlighted the importance of timely training and supervision, including local supervision to enable implementation and to pick up on any problems. We know however that access to NHS training and supervision may be hampered by several factors including lack of time. Indeed, lack of supervision and training were identified as barriers to the use of evidence-based interventions in a survey of evidence-based practice, training, supervision, and clinician confidence relating to PTSD therapies (Finch J, 2020). Emphasis must therefore be placed on organisational policy that promotes and protects training and supervision (Sarre et al., 2018). Given that GSH interventions are still relatively novel, it will be important to understand, through QI work, the optimal level of training and supervision required for the provision of GSH that is acceptable to service users and clinicians, across the NHS. For example, a 'train the trainer' model may be a cost-effective opportunity to facilitate wide and timely implementation, which might be evaluated.

9.5.3 GSH i-CBT implementation and roll-out across the NHS

The importance of practice-based evidence has been discussed, to offer insight into the acceptability of GSH for PTSD when delivered in routine clinical practice. This requires the successful implementation of GSH in the NHS, which is now discussed.

Challenges to the timely and successful implementation of internet-based therapies were highlighted in interviews with NHS commissioners and managers and RAPID therapists. NHS providers must consider challenging their current practices and staff perspectives to ensure services are fit for purpose and can provide novel treatment choices, including GSH, as the evidence base is established. This includes raising staff awareness of the multitude of potential benefits of GSH for service users and services alike, including its place as an empowering and flexible treatment option. National, coordinated efforts for roll-out will be required, and policy makers and commissioners have an important role to play in ensuring timely implementation. Recommendations to address implementation challenges are listed in Table 32 and are followed by a discussion of a select few.

Challenge and increase NHS agility.
Implement at scale, including coordinated planning and collaboration with policy to access funding.
Challenge misconceptions.
Champion GSH and include it in the clinical pathway.
Provide timely training and local supervision.
Provide reliable IT, equipment, and data across services and for service users, where required.
'Pandemic-proof' GSH interventions.

Table 32: Recommendations for the successful roll-out of GSH across the NHS

9.5.3.1 Challenge and increase NHS agility

The NHS should be fit for purpose, to offer evidence-based interventions, in a timely manner, for the communities it serves, therefore the finding that NHS inflexibility was perceived by NHS commissioners and managers to be a barrier to implementation is concerning and warrants review. Interviewees spoke of implementation difficulties due to information governance and procurement

processes. Albeit a somewhat complex matter, NHS organisations might consider examining their policies and processes to understand how their services might be more agile and fit for purpose.

9.5.3.2 Implementation at scale

NHS commissioners and managers also recommended national and coordinated implementation roll-out efforts, not least to overcome the potentially prohibitive internet-based intervention set-up costs. This is perhaps another complex matter that would rely on several factors. For example, effective leadership and co-production, promoting a vision and a culture that is comfortable with change and is committed to the value of improving access to psychological therapies. It would also require coordinated planning and collaboration to seek out and access funding and consider commissioning interventions at scale. An NHS commissioner and manager interviewee shared their own experiences of a c-CBT nationwide implementation strategy, and another example of an intervention that has been rolled out at scale is the 'Silvercloud' i-CBT for depression and anxiety (Silvercloud, 2020). In September 2020, partly in response to the COVID-19 pandemic, Welsh Government committed £1.3m of funding to roll-out 'Silvercloud' and other online and phone support services, across Wales (WG, 2020).

9.5.3.3 Challenge misconceptions

Misconceptions that exist amongst NHS commissioners and staff should be addressed, which might include surveying attitudes and raising awareness of the GSH approach and its evidence base to dispel any mistruths. The finding that the evidence base is considered an important but perhaps not an essential factor in an intervention's uptake is a matter that should be explored and challenged within NHS mental health care services. Staff must be pointed to the latest treatment guidelines, for example UK and international treatment guidelines recommend i-TF-CBT that includes therapist support (ISTSS, 2018b, NICE, 2018c). These guidelines currently give only a moderate recommendation to GSH i-TF-CT, given that evidence is emerging, however the results of the RAPID efficacy Trial, and other efficacy trials will offer a significant contribution, and may affect treatment guidelines going forward. There are plans for the wide dissemination of the RAPID Trial in summer 2021 (Nollett et al., 2018).

It has been suggested that the policy perspective of digital interventions purports the main benefits of internet-based approaches to be their role in improving access to psychological therapies, rather than their effectiveness (Hollis et al., 2018b). This emphasis on widening access, instead of efficacy, may be impacting on public and provider trust and confidence, which is concerning, and the findings of the interviews with NHS commissioners and managers reflect these perspectives somewhat. Some interviewees viewed internet-based approaches having great value in widening access to therapies, and at the same time perceived them as an 'add on', and 'flippant' treatment offerings for people with a particular type of trauma.

In addition to pointing to the growing evidence base for GSH, staff should be made aware of the following: 1) the guided element of GSH, which sets it apart from pure self-help computerised CBT programmes; 2) the evidence base for the equity of therapeutic alliance across i-CBT and face-to-face therapies, including the findings of this PhD and findings elsewhere; 3) the empowering nature of GSH, given that empowering treatment options are encouraged across the NHS (NHS 2019), and evident from interviews with RAPID participants and NHS commissioners and managers; 4) that GSH programmes may be accessed beyond the end of the treatment period, which may further assist in consolidation and relapse prevention. Staff should be made aware of the potential for GSH to be integrated within stepped-care models (Ebert et al., 2018), appreciating the value of GSH as an intervention, whilst also emphasising the ongoing role of individual therapy for more complex presentations (Waller and Gilbody, 2009).

9.5.3.4 'Pandemic-proofing' GSH

We must acknowledge the unprecedented influence of the COVID-19 pandemic pushing forward remote working practices. For example, guidelines are now available for psychological assessment undertaken remotely (BPS, 2020). Clinicians will certainly wish to ensure that pandemic-proof interventions are available presently and into the future, and that these are acceptable to providers and recipients via remote delivery. Indeed, some RAPID therapists had considered whether 'Spring' could be delivered entirely remotely, joining patients for therapy sessions via videoconferencing and 'sharing screens', rather than meeting face-to-face in-person. Lockdown restrictions aside, a proportion of individuals who are accessing services may wish for an entirely remote intervention, for reasons

mentioned previously, including difficulties traveling to appointments and stigma of attending services in person. The 'Spring' QI work will offer insight, given that the intervention has been delivered entirely remotely, through the sharing of screens using NHS Wales 'Attend Anywhere' platforms.

Wild et al., (2020c) discuss how CT for PTSD can be delivered remotely over videoconference or telephone, utilising the treatment components of face-to-face, but with adjustments. The authors discuss the lack of hand gestures and other non-verbal cues during remote working, necessitating verbal statements and the use of warm voice tones to encourage alliance and engagement. In line with this are findings that treatment via videoconferencing has been demonstrated as acceptable to patients (Ashwick et al., 2019). Wild et al., (2020c) also suggest an in-vivo trauma site visit could be possible and acceptable through remote delivery. The client could attend the site alone or with a supportive other, and the therapist would be available via voice or videocall, to guide the client in reflecting how things have changed since the time of the trauma. A RAPID therapist had spoken about the 'eureka' moment achieved through trauma site visits in TF-CBT, which were lacking in GSH. If the GSH intervention could be flexed to allow for a site visit, the remote site visit option might be more suitable to ensure the therapy component to GSH treatment remains brief, as intended.

Where remote GSH therapy sessions are required or preferred, clinicians may need to check several things out, including the availability of equipment and data; that the cues that are necessary for collaborative working, and engagement are not compromised, for example due to poor audio or visuals, and privacy during online appointments. Indeed, interviews with NHS commissioners and managers revealed concern over patients' use of internet-based interventions in the proximity of others, for example those with whom they live.

9.6 Conclusions

GSH i-TF-CBT is an acceptable, timely, and accessible treatment choice for adults with mild to moderate PTSD to a single traumatic event. Recommendations for its roll-out have been made.

Further research is required, including considering the potential of GSH for people with severe PTSD, with PTSD to multiple traumas, and people with more complex presentations. There is a need for improved, robust measurement and dissemination of the acceptability of i-CBT GSH, acknowledging it as a multi-faceted construct. Research must be timely, not least to keep up with the speed at which digital health interventions are developing.

Clinicians must utilise shared decision making strategies to consider GSH interventions with service users, and encouragingly GSH offers potential to be adaptable to meet the needs and preferences of different individuals. Consideration must be given to the quality of, and access to, digital programmes and platforms, as well as the level of clinician guidance and the provision of training and supervision. Recommendations are made to facilitate the sustainability of GSH into the future, including 'pandemic-proofing' interventions.

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Appendices

Therapist Manual

Role of the Therapist

- The programme will be initiated with a **one hour-long face-to-face appointment**, followed by **4 fortnightly thirty minute sessions** and ***brief*** telephone or e-mail contact during the intervening four weeks. The aim of guidance is to offer:
  - Continued support
  - Monitoring
  - Motivation
  - Problem solving

The Programme

- The programme consists of an introduction, followed by **8 online steps** via the Spring website or App.
- The online programme and App are linked for each individual user account so that information entered online will be accessible through the App and vice versa.
- The **8 steps** will usually be completed in turn. Later steps rely on mastery of techniques taught in earlier steps.
- Each of the **8 steps** provides psycho-education and the rationale for specific components of treatment.
- Each step will activate a tool derived from CBT, which will aim to reduce traumatic stress symptoms.
- These tools will become live in the **Toolkit area** of the Spring website and App. The toolkit can be accessed from the homepage.
- The overall aim will be:
  - To work through the **8 steps** in turn
  - To activate each of the **9 tools** (step 6 has two tools).
  - To concurrently practice the tools over the course of the **8 weeks** to bring about symptom improvement

The programme can be accessed at: https://springptsd.cardiff.ac.uk

The clinician site is at: https://springptsdadmin.cardiff.ac.uk/

When you use either site for the first time open your browser and press the F5 command before logging in to clear your cache and ensure that you will be able to access the latest version of the programme.

To download the App follow the guidance on the "Spring App Access" document. The App and the log-in have the same username and password.

Programme Outline

Face-to-face guidance	Steps to be introduced	Tools/ techniques
Guidance session 1: Approximately 60 minutes	Step1: Learning About My PTSD	My symptoms
	Step 2: Managing My Anxiety	My Relaxation
	Step 3: Grounding Myself	My Grounding
Guidance session 2: approximately 30 minutes	Step 4: Reclaiming My Life	My Life
	Step 5: Coming to Terms With My Trauma	My Trauma
Guidance session 3: approximately 30 minutes	Step 6: Changing My Thoughts	My Thoughts
		Letter to a Friend
	Step 7: Overcoming My Avoidance	My Fears

<u>Before the first guidance session, the client's user name will be linked to your therapist account.</u>

Make sure that you are thoroughly familiar with the programme prior to beginning treatment on the Spring website and App. The foregoing guidance provides an outline of how the programme should ideally run across the course of treatment. Try to stick to this schedule as far as possible. However, bear in mind that clients are likely to differ in their degree of engagement with the programme and with the pace of work. *Some flexibility may therefore be required in negotiating homework goals so that the client doesn't feel overwhelmed by the tasks and remains engaged.*

Guidance

Week 0: Introductory Session (1 Hour)

- Review the client's clinical measures or help her/him to use the *surveygizmo* link to complete them.

- Make introductions, summarise and clarify your understanding of the client's trauma history and identify what they perceive as their key difficulties.

- Provide a hand-out with log-in instructions and an overview of how to use the programme on both website and App (please download to your mobile if possible). Make the client aware that the programme can be used on a range of devices, including tablets and phones and that information entered on one device will be available via their log in on other devices as well. If you have wifi availability you may wish to consider asking the client to download the App during the session.

- Provide the information sheet for family and friends.

- Talk a little about PTSD, using the programme as an aid.

- Provide the rationale for trauma-focused psychological treatment.

- Describe "Spring – a step by step treatment for PTSD". Emphasise that it is drawn from evidence-based protocols, containing the same active ingredients as therapist-administered treatment. Explain that it requires extensive commitment to working at home and outside with face to face contacts. Point out the evidence that work between sessions produces the largest gains, but that more traditional therapies also involve homework.

- Encourage use of the programme for an **hour or more every day** (30 minutes at the very minimum).

- Explain that it is an **8 step** programme. Each step activates a tool, which becomes active in the **Toolkit**. Each activated tool should be used every-day after activation to practise the new skill.

- Explain that the clinician can monitor progress remotely. The clinician will be able to see which modules have been started and which have been completed. (S)he will use this to maximise effectiveness.

- Explain that EVERYTHING ENTERED INTO THE TOOLKIT AND APP WILL BE VISIBLE TO THE CLINICIAN. This will allow the client's

clinician to prepare for the brief phone or email contact every 2 weeks. No other data will be visible.

- Demo the site by allowing the individual to have a go for themselves. Help them log-in and navigate through the menu. Spend time to give a brief introduction to PTSD. Show examples of information screens, multiple choice question screens, branching screens and videos. Emphasise the importance of completing each of the steps in order.

- Make sure that you are familiar with the story and process of recovery for the four characters who feature in the programme. Provide a bit of information about each of the characters. Suggest that one or more of the characters can be followed through the programme.

- Suggest completion of **Steps 1, 2 and 3** over the **first two weeks**. Introduce these as follows:

    - **Step 1 (Learning About My PTSD):** Demo use of the symptom monitoring tool.

    - **Step 2 (Grounding Myself):** Give a brief explanation of grounding and its uses. Demo a couple of grounding exercises.

    - **Step 3 (Managing My Anxiety):** Emphasise the importance of learning to relax, and how useful it will be through the programme. Demonstrate the controlled breathing technique with the video.

- Arrange next appointment (**2 weeks' time**), and arrange a time to make a brief telephone check-in the following week. It is possible to set additional goals during check-in. Suggest that if they have done well with **Steps 1 – 3**, they may want to move on to **Step 4 (Reclaiming My Life)** at that point.

- Record the time spent with client to the nearest **minute** and complete the contact sheet.

Week 1: Brief Phone Check In

- Review progress on the clinician site prior to the call.

- Discuss how the client is getting on with the tools (**My Symptoms, My Grounding, My Relaxation**) using data you have accessed and tackle any problems.

- If good progress has been made, suggest moving on to **Step 4 (Reclaiming My Life)**. The client should also continue to make use of Steps 1-3.

- Confirm the time of next appointment.

- Record the time spent with client to the nearest **minute** and complete the contact sheet.

Week 2: 30 Minute Guidance Session

- Review the client's clinical measures or help her/him to use the *surveygizmo* link to complete them.

- Review progress on the clinician site.

- Discuss how the client is getting on with the tools, and tackle any problems. Give praise for progress made. If progress has not been made, identify barriers and encourage better engagement moving forward.

- If **Step 4 (Reclaiming My Life)** has been completed, review the list of weekly goals. If it has not been started, give a brief introduction to the Step.

- If client has made sufficient progress, **Introduce Step 5 (Coming to Terms with My Trauma)**, and give the rationale for imaginal exposure. Demonstrate the narrative of one of the video characters.

- Be careful when considering which character's narrative to show. It may be best to show the narrative of a character whose trauma is different to that of the client in order to reduce the risk of re-traumatisation. In such cases, it may be helpful for the client to view similar narratives later in therapy, once some successful narrative processing has been undertaken.

- Begin writing a narrative with the client (first 2-3 sentences). Explain that it will be accessible in the toolkit, and the necessity of reading it every day several times (usually for at least 30 minutes) until their anxiety starts to reduce. Some clients prefer to write their narrative in a Word document and then cut and paste it into the programme. Be flexible about what works best for the client.

- Discuss the unhelpful role of avoidance bringing short term relief only.

- Arrange next appointment **(2 weeks' time)**, and arrange a time to make a brief telephone check-in the following week.
- Record the time spent with client in minutes in the case file.

Week 3: Brief Phone Check In

- Review progress on the clinician site prior to the call.
- Discuss how the client is getting on with **Step 4 (Reclaiming My Life)** and **Step 5 (Coming to Terms with My Trauma)** as applicable. Briefly review **Tool 5 (My Trauma)** to ensure client is on the right tracks with their narrative.
- Confirm the time of next appointment.
- Record the time spent with client to the nearest **minute** and complete the contact sheet.

Week 4: 30 Minute Guidance Session

- Review the client's clinical measures or help her/him to use the *surveygizmo* link to complete them.
- Review progress on the clinician site.
- Discuss how the client is getting on with **Step 4 (Reclaiming My Life)** and **Step 5 (Coming to Terms with My Trauma)** as applicable. Encourage the individual to continue using tools 1-5 daily.
- Give positive feedback for any efforts made on **Step 5**. Encourage the client to describe their trauma as fully as possible, including their emotional responses and sense of meaning of what was happening at the time, if they have not done so already. Encourage the client to update their trauma narrative with new information as this emerges. For hot spots, ask them to consider what they know now that is different to what they knew at the time and to include this information in the narrative as well. If progress has not been made, identify barriers and encourage better engagement moving forward.
- Introduce **Step 6 (Changing My Thoughts)** by giving an example of a thought challenge using the tool. It can be helpful to identify examples of negative cognitions from within the client's narrative

account and / or from self-report. Encourage the client to consider these ideas using the **Step 6 tools**.

- Briefly show the Pie Chart example and encourage the client to consider using it if they have feelings of guilt and responsibility.

- Briefly show the Supportive Letter screen (page 15). Introduce **Step 7 (Overcoming My Avoidance)** by showing an example fear ladder from the programme.

- Arrange next appointment (two weeks' time), and a time to make a brief telephone check-in the following week.

- Record the time spent with client to the nearest **minute** and complete the contact sheet.

Week 5: Brief Phone Check In

- Review progress on the clinician site prior to the call.

- Discuss how the client is getting on with **tools 1-5**. Briefly review **Tool 6 (My Thoughts)** and **Tool 7 (My Fears)**. Advise continuing use of all of the tools. Direct client to spend more time on the areas you think will result in greatest benefit.

- Encourage the client to add any new learning or understanding that they have made of the trauma experiences in **Step 6** to their trauma narrative. They might do this by adding new information in parentheses by writing "I now know …. ", (e.g. I now know that my reactions at this time were entirely understandable. This was a very frightening event. I was in shock and many other people would have reacted in a similar way).

- Confirm the time of next appointment.

- Record the time spent with client to the nearest **minute** and complete the contact sheet.

Week 6: 30 Minute Guidance Session

- Review the client's clinical measures or help her/him to use the *surveygizmo* link to complete them.

- Review progress on the clinician site.

- Discuss how the client is getting on with the tools, and tackle any problems.

- Introduce any Steps that have not been started to date. If all tools are activated, encourage continued use, and completion of **Step 8 (Keeping Myself Well)** before the final appointment.
- Arrange next appointment (two weeks' time), and a time to make a brief telephone check-in the following week.
- Record the time spent with client to the nearest **minute** and complete the contact sheet.

Week 7: Brief Phone Check In

- Review progress on the clinician site prior to the call.
- Discuss how the client is getting on with **tools 1-7**. Advise continuing use of all of the tools. Direct client to spend more time on the areas you think will result in greatest benefit.
- Remind client to complete **Step 8 (Keeping Myself Well)** before the final session.
- Confirm the time of next appointment.
- Record the time spent with client to the nearest **minute** and complete the contact sheet.

Week 8: 30 Minute Guidance Session

- Review the client's clinical measures or help her/him to use the *surveygizmo* link to complete them.
- Review progress on the clinician site.
- Discuss how the client is getting on with the tools.
- Discuss **Step 8 (Keeping Myself Well)**.
- Record the time spent with client to the nearest **minute** and complete the contact sheet.

Appendix B – Acceptability systematic review supplementary material

Specialised Register of the Cochrane Common Mental Disorders Group (CCMDCTR)

The Cochrane Common Mental Disorders Group maintains a specialised register of randomised controlled trials, the CCMDCTR. This register contains over 40,000 reference records (reports of RCTs) for anxiety disorders, depression, bipolar disorder, eating disorders, self-harm, and other mental disorders within the scope of this Group. The CCMDCTR is a partially studies-based register with more than 50% of reference records tagged to about 12,500 individually population, intervention, comparison, outcome (PICO)-coded study records. Reports of trials for inclusion in the register are collated from (weekly) generic searches of OVID MEDLINE (from 1950), Embase (from 1974), and PsycINFO (from 1967), quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL), and review-specific searches of additional databases. Reports of trials are also sourced from international trial registries, drug companies, the handsearching of key journals, conference proceedings, and other (non-Cochrane) systematic reviews and meta-analyses. Details of CCMD's core search strategies (used to identify RCTs) can be found on the Group's website, with an example of the core Medline search displayed.

Electronic searches

The Cochrane Common Mental Disorders Group's Information Specialist ran searches on their specialised register using the following search terms (to 2 March 2018).

1. The CCMDCTR-Studies Register:
Condition = (PTSD or *trauma* or “acute stress” or “stress reaction”) AND
Intervention = (computer* or internet or web* or online or self-help or self-manage* or self-change)

2. The CCMDCTR-References Register was searched using a more sensitive set of terms to identify additional untagged or uncoded reports of RCTs:
#1. (PTSD or *trauma* or “combat disorder*” or “stress reaction” or “acute stress” or "stress disorder" or "war neurosis"):ab,ti,kw,ky,emt,mh,mc
#2. (self near3 (care or change or guide* or help or intervention or manag* or support* or train*)):ab,ti,kw,ky,emt,mh,mc
#3. (android or app or apps or audio* or blog or iCBT or cCBT or i-CBT or c-CBT or CD-ROM or “cell phone” or cellphone or chat or computer* or cyber* or distance* or DVD or eHealth or e-health or "electronic health*" or e-Portal or ePortal or eTherap* or e-therap* or forum* or gaming or “information technolog*” or "instant messag*" or internet* or interapy or ipad or i-pad or iphone or i-phone or ipod or i-pod or web* or WWW or "smart phone" or smartphone or “mobile phone” or e-mail* or email* or mHealth or m-health or mobile or multi-media or multimedia or online* or on-line or “personal digital assistant” or PDA or SMS or "social medi*" or Facebook or software or telecomm* or telehealth* or telemed* or telemonitor* or telepsych*or teletherap* or "text messag*" or texting or tape or taped or video* or YouTube or podcast or virtual* or remote):ab,ti,kw,ky,emt,mh,mc
#4. (and (#2 or #3))
[Key to CRS field tags: ab:abstract; ti:title; kw:CRG keywords; ky:other keywords; emt:EMTREE headings; mh:MeSH headings; mc:MeSH checkwords]

3.The Information Specialist also ran a complementary search on PILOTS (Published International Literature on Traumatic Stress, US Department of Veterans Affairs), using relevant subject headings and search syntax appropriate to this resource (1990 to 2 March 2018)

4. We searched international trial registries via the WHO International Clinical Trials Registry Platform (ICTRP) and ClinicalTrials.gov to identify unpublished or ongoing studies (to 2 March 2018).

We did not restrict any of the searches by date, language, or publication status.

Searching other resources

Grey literature

We searched sources of grey literature including dissertations and theses, clinical guidelines, and reports from regulatory agencies (when appropriate).

- ProQuest Dissertations and Theses Database.
- National Guideline Clearing House (guideline.gov/).
- Worlwide Regulatory Agencies (www.globepharm.org/links/resource_agencies.html).
- Open Grey (www.opengrey.eu/).

Reference lists

We scrutinised the reference lists of all included studies and relevant systematic reviews to identify additional missed studies. We also conducted a cited reference search on the Web of Science.

Correspondence

We identified from included studies, authors working in the field of i-CBT and the study team agreed on subject matter experts and trialists that were then contacted for information on unpublished or ongoing studies, and to request additional trial data. Additionally, since the studies were included on the International Society for Traumatic Stress Studies (ISTSS), website for comment by the ISTSS membership, additional studies could be brought to our attention in this way, also.

Appendix C – RAPID summary patient information sheet

The RAPID Research Study

Summary Patient Information Sheet

We would like to inform you about a research study we are carrying out alongside Cardiff University which is funded by the National Institute for Health Research's HTA programme. The study is called RAPID and is comparing two treatments for Post-traumatic Stress Disorder (PTSD). You have been given this information because you have a diagnosis of PTSD and may wish to join the study.

What are the treatments?

Trauma-Focused Cognitive Behaviour Therapy (TFCBT) is a one-to-one talking therapy. At the moment, it is one of the recommended treatments for people with PTSD. Unfortunately, there are not enough trained NHS therapists to deliver this treatment and waiting times are often long.

To make access to treatment quicker and easier, we have developed an online Guided Self Help (GSH) programme. The programme is based on trauma focused therapy and combines some online sessions at home with regular guidance meetings with a therapist. A number of people with PTSD have completed the programme and have found it to be an acceptable and useful alternative to face-to– face therapy.

We now need to compare the online programme with regular face-to-face therapy in a large study to determine whether it is equally effective at helping people with PTSD. Similar treatments seem to be effective for depression and other anxiety disorders. If it proves to be an effective treatment, it could significantly shorten waiting times for PTSD treatment in the NHS.

Can I take part?

Your health care worker has given you this information because they believe you are eligible to take part and may benefit from the treatments on offer. To be able to take part you need to be over 18 years of age and have access to the internet. This can be through a computer, laptop, tablet or mobile phone. Please let your therapist know if this is not the case.

What should I do next?

We would like the opportunity to tell you more about the study and answer your questions. If you are happy for a researcher to contact you, please complete the contact details slip below with the details you are happy for us to have. There is no commitment at this stage.

In the meantime, if you have any questions about the study you can contact Katy Addison, the RAPID Trial Manager on 02920 687522 during office hours or email rapid@cardiff.ac.uk. Many thanks for your interest in the study.

---------- I am happy for a researcher to contact me to discuss the RAPID study

Full Name:

Mobile number:	Ok to leave a message	☐ Yes ☐ No

Alternative number:	Ok to leave a message	☐ Yes ☐ No

Email address:

Information Leaflet

Thank you for taking part in the research interview today. We hope that you found it interesting and really appreciate your time and commitment. The interviews cover some emotional topics and we understand that they can sometimes bring up difficult memories or feelings such as anger or sadness. We do our best in the interviews to discuss this with you and ensure that you do not leave feeling distressed. However, sometimes these feelings might resurface when you are on your own. The information below tells you what you can do if this happens and you feel the need for additional support.

- If you are about to start or are in therapy, you could discuss the feelings with your therapist, who will be able to help you manage them.

- If you have finished therapy, OR if you feel you would like to talk to somebody the same day, we recommend that you get in touch with your GP surgery. They will be available both during office hours and evenings and weekends through the out-of-hours service, and will be able to help.

- You can also call the Samaritans helpline 24 hours a day, 7 days a week on 116 123. This is a free number and they can provide a listening ear.

  Thank you once again for taking part in the research, your contribution is invaluable.
  If you have any questions, please do let us know using the contact details in the Participant Information Booklet.

Please keep this leaflet in a safe place for future use

Telephone Screening Questionnaire **Continue through the questionnaire in a sequential order unless instructed to go to another section.** **Text in italics are instructions for the rater.**	**YES**	**NO**
Part 1: Inclusion Criteria		
1. Are you aged 18 or over? (*if yes enter patient date of birth above*)		
2a. What was the traumatic event that caused the symptoms you are experiencing? Has the participant experienced a trauma that meets DSM5 criteria for an event that can lead to PTSD? *Additional questions about the nature of the trauma may be necessary to determine whether criteria are met– please refer to DSM5 Event Criteria.*		
2b. Have any other traumatic events contributed to your symptoms? *If YES explore further.*		
2c. Does the participant have PTSD symptoms following a SINGLE traumatic event?		
TRAUMA SCREENING QUESTIONNAIRE Please consider the following reactions which sometimes occur after a traumatic event. This questionnaire is concerned with your personal reactions to the traumatic event which happened to you. Please indicate (YES/NO) whether you have experienced any of the following at least twice in the last week. 1. Upsetting thoughts or memories about the event that come into your mind against your will		
2. Upsetting dreams about the event		
3. Acting or feeling as though the event were happening again		
4. Feeling upset by reminders of the event		
5. Bodily reactions (such as fast heartbeat, stomach churning, sweatiness, dizziness) when reminded of the event		
6. Difficulty falling of staying asleep		
7. Irritability or outbursts of anger		

8. Difficulty concentrating
9. Heightened awareness of potential dangers to yourself and others
10. Being jumpy or being scared at something unexpected
Total score (score 1 for YES, 0 for NO)

	YES	NO
2d. Does the patient answer YES to 6 or more questions on the Trauma Screening Questionnaire (TSQ)?		
3. Do you have regular access to the internet in order to complete the modules and homework required by the Guided Self Help (GSH) programme?		
Part 2: Exclusion Criteria		
1. Inability to read and write fluently in English?		
2. Have you previously completed a course of trauma-focused psychological therapy for PTSD *(Explore with the patient if they are unsure).*		
3. Are you currently receiving any kind of psychological therapy? (*Explore if the patient is unsure).* *If YES, currently ineligible—Date to be contacted in 6 weeks*		
4. If you are taking any medication for a mental health condition such as anti-depressants, anti-anxiety or anti-psychotic medication, have you had a change to the type or dose in the last 4 weeks? *If YES, currently ineligible—Date to be contacted in 4 weeks*		
5. Are you currently suffering from psychosis, for example, hearing voices or seeing things?		
6. Are you currently dependent on alcohol or drugs?		
7. Have you been having thoughts of ending your life? *(If YES, explore with the patient.*		
7a. Do you feel suicidal? *If YES, refer to suicidal ideation protocol*		

Is the patient eligible to take part?

Part 3: Patient details (Only if eligible)

Arrange baseline interview for 2.5 weeks time

Date of baseline visit agreed: ☐☐/☐☐/☐☐ (*dd/mm/yy)*

Go to CRF2a to check the contact details we already hold for the participant.

Part 4: Referral (Only if ineligible)

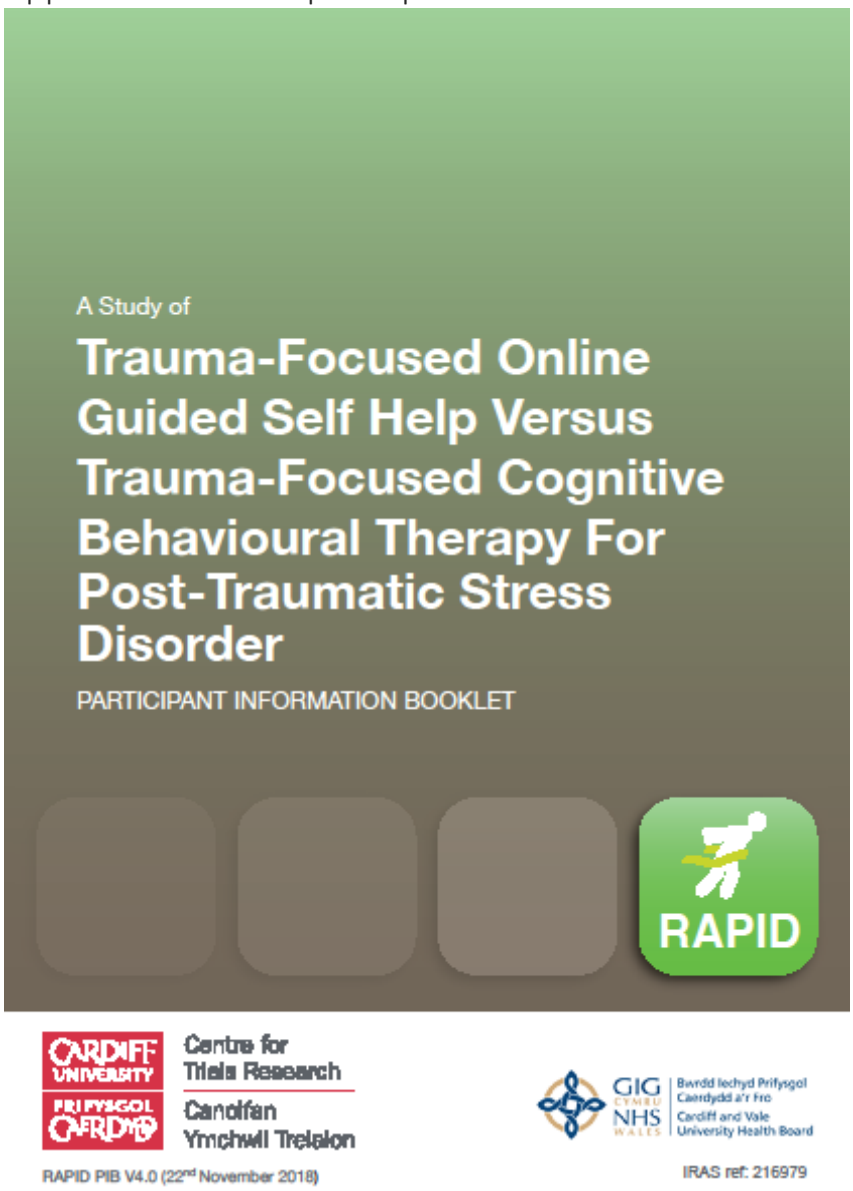
Thank the patient for their time, and explain that they are not eligible for the study.

Check you have the referrer's detail or the GP details if patient self-referred/NCMH referred—if not, collect now—and explain that you will refer them.

Make referral within <u>one week</u> and complete CRF3 when done.

Referral to be completed by : ☐☐/☐☐/☐☐ (*dd/mm/yy*).

Appendix F – RAPID participant information booklet



Pragmatic RAndomised Controlled Trial of a Trauma-Focused Guided Self Help Programme versus InDividual Trauma-Focused Cognitive Behavioural Therapy for Post-Traumatic Stress Disorder (RAPID)

We would like to invite you to join the RAPID research study set up by Cardiff University. We are carrying out a study comparing two treatments for Post-Traumatic Stress Disorder (PTSD). One is conducted face-to-face with a therapist and the other is conducted online with some support from a therapist. Our goal is to find out if they are equally effective at helping people with PTSD. Our results will inform the NHS about which treatments to recommend.

Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

If anything is not clear, or if you would like more information, please contact the study team using the details below.

You will also have an opportunity to ask questions at your first assessment with our researcher.

Thank you for taking the time to consider taking part in the RAPID study.

Contact Details—RAPID Trial Manager

02920 687 522

rapid@cardiff.ac.uk

Why is this study needed?

Trauma-focused talking therapies such as Trauma-Focused Cognitive Behavioural Therapy have been shown to be effective for helping people with PTSD. Unfortunately, there are not enough trained NHS therapists to deliver this treatment and waiting times are often long.

To make access to treatment quicker and easier, we have developed an online guided self help programme. The programme is based on trauma-focused therapy and combines some online sessions at home with regular guidance meetings with a therapist. A number of people with PTSD have completed the programme and have found it to be an acceptable and useful alternative to face-to-face therapy.

We now need to compare the online programme with regular face-to-face therapy in a large study to determine whether it is equally effective at helping people with PTSD. Similar treatments seem to be effective for depression and other anxiety disorders. If it proves to be an effective treatment, it could significantly shorten waiting times for PTSD treatment in the NHS.

Why have I been asked to take part?

The RAPID study aims to recruit nearly 200 people with PTSD following a single traumatic event, across England, Wales and Scotland. You have been invited to take part because you have PTSD following a single traumatic event and are attending one of the clinics taking part. The rest of the booklet details what taking part would involve, if you chose to join the study.

What therapy will I receive?

You will be allocated to receive either Individual Trauma-Focused Cognitive Behavioural Therapy OR Trauma-Focused Online Guided Self Help.

You will be allocated by a process called **'randomisation'**. This means a computer programme will be used to decide which therapy you will receive and you will have an equal 50:50 chance of being allocated to either group. You or your clinician will not be able to choose, therefore if you agree to take part, it is important that you would be happy with either treatment. This is because at the moment, we do not know which treatment would suit you best.

Trauma-Focused Cognitive Behavioural Therapy (TFCBT)

TFCBT is one of the current recommended talking therapies for PTSD. It involves meeting with a trained therapist once a week for up to 12 weeks. The meetings will last for about 60-90 minutes and you will work with the therapist to identify how the traumatic event has affected your thinking. You will be helped to develop skills to deal with negative thoughts and triggers that now cause you difficulty and make you feel anxious. Your therapist will ask you to complete some tasks between sessions.

Trauma-Focused Online Guided Self Help (GSH)

The GSH programme is based on TFCBT. Before you start the programme, you will meet with a trained therapist who will talk to you about your symptoms and show you the programme. This will last about 1 hour. You can then follow the programme online in your own time on your computer, laptop, tablet or mobile phone. There are 8 steps based on trauma focused cognitive behavioural therapy which will teach you more about PTSD and interactive activities to complete. The programme will last 8 weeks, and during that time you will have fortnightly contact (either face-to-face or on the telephone) with your therapist. This is to discuss your progress and tackle any problems and will last about 30 minutes. It is up to you how much time you dedicate to the programme.

What does taking part in the study involve?

Taking part in the RAPID study will involve:

- Completing a **short telephone assessment** with a researcher to check that you are suitable for the study. This will include some questions about your symptoms, at a time to suit you and will last around 20 minutes.
- If you are suitable, you would be asked to **monitor** your own symptoms for 2 weeks using a simple diary. If after 2 weeks, you still have significant symptoms, you will be asked to continue with the next steps of the study.
- Completing a **face-to-face assessment** with a researcher. This could be conducted in the research clinic or in your own home, at a time to suit you and will take around 60-90 minutes.
- Taking part in **treatment**; either the 8 week online Guided Self Help or the 12 week face-to-face therapy.
- Completing **follow-up assessments** at 16 weeks after you first started treatment and again at 52 weeks. These can be conducted in the clinic or in your own home, at a time to suit you and will last around 1 hour.
- A proportion of people taking part will also be asked to complete an **interview** with a researcher before they start treatment and after they have finished treatment. This is to help us understand people's views of the two treatments. With your permission these will be audio recorded to help the interviewer remember what you say. We may use direct quotes from the interviews but these will be anonymous.
- The meetings with your therapist may also be audio recorded. This is so we can supervise the therapist and check the therapy is being delivered as planned. The recordings will be kept confidential and what you say will not be shared. The only time we will share what you tell us is if you advise us of a possible risk of harm to yourself or others, in which case we would need to inform your GP or other qualified person.

What are the possible benefits of taking part?

TFCBT is a standard treatment for people with PTSD and can improve symptoms. GSH has also been shown to be useful for people in previous studies and may help you.

You will also be helping to find out if GSH is a suitable and accessible treatment for people in the future, which may help to reduce waiting times for treatment.

Are there side effects or risks to taking part?

There are no known side effects or risks to either the TFCBT or GSH, although some people may find that addressing their experiences can be upsetting. You will be monitored throughout your treatment by your therapist who will provide support as required if you do experience upset. You are also free to leave the study at any time if you would like to do so.

Do I have to take part?

No, it is completely up to you. If you decide to take part you will be asked to sign a consent form to say that you have read this information and are happy to join the study.

What will happen if I do not want to carry on with the study?

The study will be most helpful if people who join are able to continue their treatment and assessments through to the end. Therefore it is important to discuss any concerns you have with a member of the research team before you agree to join. But of course, once you have joined, you are free to leave at any time without giving a reason. This will not affect your usual NHS/clinical care.

How will information about me be kept confidential?

If you decide to join the study you will be given a unique number to identify you. All of your assessment and treatment data will use this number and will not include any personal identifiable data. All data will be stored on a restricted access database and in accordance with the Data Protection Act 1998. No individual will be able to be identified in any publications that result from the study.

Will my General Practitioner (GP) be told that I am taking part?

With your permission, we will let your GP know that you are taking part.

What will happen to the results of the research study?

We hope that the results of the study will help to inform the future care of people with PTSD. We will present the findings at conferences and in academic journals and will discuss them with voluntary organisations and NHS commissioners. We will send you a copy of the findings. We would also like to store your details on the National Centre for Mental Health PTSD register, so that we can contact you about future research. There is further information on this at the end of the booklet.

What if I have concerns or something goes wrong?

If you have a concern about any aspect of the study, you should speak to the researchers who will do their best to answer your questions (see inside front cover). If you remain unhappy and wish to complain formally about the research, you can do this by contacting James Walters at Cardiff University on 02920 688434 or waltersjt@cardiff.ac.uk.

The risk of anything going wrong or of you experiencing any harm as a result of taking part is minimal. In the very unlikely event this occurs and this is due to someone's negligence, then you may have grounds for legal action for compensation, but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you.

Will I receive travel expenses?

You will receive travel expenses to attend the research (but not therapy) appointments. You will also receive a £20 shopping voucher at the 16 week and 52 week assessments as a thank you for your time.

Who is organising and funding the study?

The RAPID project is funded by the National Institute for Health Research's (NIHR) HTA Programme. They have awarded the money to Cardiff University, who are sponsors for the study.

Who has approved the study?

All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee. They are there to protect your safety, rights, wellbeing and dignity. This project has been reviewed and given a favourable opinion by Wales REC 3.

What Next?

It is likely that you will have made an appointment with one of our researchers to complete the first assessment. They will ask you some questions about your symptoms. If you are suitable for the study, they will explain the next steps. If you do not yet have an appointment and would like to take part, please contact the research team to express your interest (see inside front cover).

Additional Information

Joining the National Centre for Mental Health (NCMH) Cohort

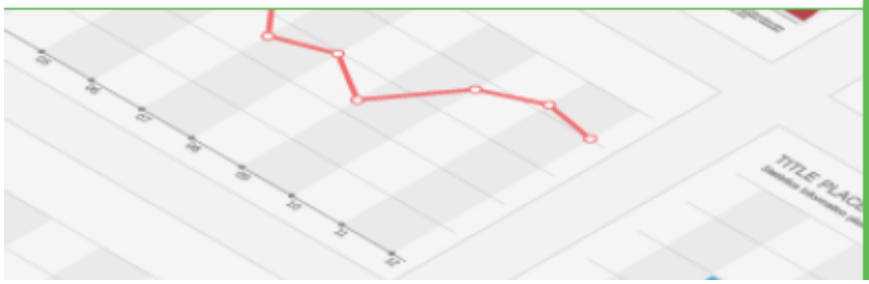
In addition to the main study, we would like to tell you about the National Centre for Mental Health (NCMH) to see if you would like to join their cohort. The NCMH is made up of researchers from Cardiff, Swansea and Bangor Universities. They are working to find out more about what causes mental health problems such as depression, bipolar disorder, schizophrenia, ADHD and PTSD.

What is the NCMH Cohort?

Researchers at the NCMH are trying to understand why some people experience problems with their mental health in order to improve understanding of conditions such as PTSD and help find better treatments in the future. The researchers aim to invite several thousand people to join the NCMH cohort and we would be grateful if you would like to help.

What would it involve for me?

Joining the NCMH cohort will not require you to do anything in addition to the main study. We will simply share the information collected through the main study with researchers at the NCMH. They will keep this information strictly confidential. They may contact you in the future with updates about the research and may invite you to complete some further questionnaires or give you information about other studies that you may want to take part in, but there will be **no obligation** for you to get involved with these future opportunities.



What data will NCMH use?

They may look at your medical records in strict confidence to gain further details about the kind of symptoms and treatments you have had. The information you provide in the main study may be linked anonymously to routinely collected data, for example, general practice records or hospital records. This is called data linkage.

All data linkage is undertaken in line with the Data Protection Act (1998) and University Governance. The information collected through this study may also be shared anonymously with other researchers, but the NCMH will never pass on personal/ identifying information (for example, your name, address, date of birth).

Do I have to join the cohort?

No, you do not have to join the cohort to take part in the main study. However, if you do join, we are able to get more from the data you share with us in the main study.

Can I withdraw form the cohort?

If you choose to join the NCMH cohort and change your mind in the future, you can withdraw by contacting the RAPID research team.

What Next?

When you attend your first appointment for the main study, the researcher will ask you if you would also like to be added to the NCMH cohort. You can opt in or out at this time and it will not affect your ability to take part in the main study or your usual clinical care.

If you would like to find out more you can contact the RAPID team (details on the front cover).

My Questions

You can use this space to note down any questions you have about the study and use them as a prompt at your first appointment.

RAPID

RAPID DIARY FOR RECORDING SYMPTOMS

Day 1 2 3 4 5 6 7 8 9 10 11 12 13 14 __ *(please circle one or enter a number)*

How much have you experienced the following over the past 24 hours?
Please indicate with a cross on the scales below.

BAD DREAMS

0	10	20	30	40	50	60	70	80	90	100
Not at All					Half of the time					All the time

UNWANTED THOUGHTS

0	10	20	30	40	50	60	70	80	90	100
Not at All					Half of the time					All the time

FLASHBACKS

0	10	20	30	40	50	60	70	80	90	100
Not at All					Half of the time					All the time

UNWANTED IMAGES

0	10	20	30	40	50	60	70	80	90	100
Not at All					Half of the time					All the time

When did these occur?
_____

_____
_____

What were they about?_____
__

_____
_____

How distressing were they?

0	10	20	30	40	50	60	70	80	90	100
Not at All										Extremely distressing

How did you cope with these symptoms?

_____

_____

Appendix H – RAPID consent form

Screening ID number:
PID:

PARTICIPANT CONSENT FORM

A Study of Trauma-Focused Guided Self Help versus Trauma Focused Cognitive Behavioural Therapy for Post-Traumatic Stress Disorder

Chief Investigator: Professor Jonathan Bisson

	Please initial boxes
1. I confirm that I have read and understood the information sheet (V4.0 dated 22nd November 2018) for the above study. I have had the opportunity to consider the information and to 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. If I withdraw from the study, I understand that any data which has already been collected may be retained and used for research purposes unless I inform the study team that I do not wish the information to be used.	
4. I understand that data collected during the study may be looked at by individuals from the Cardiff University study team, from the NHS Trust or from regulatory authorities.	
5. I understand that I may be contacted by text, telephone, e-mail or letter where this is necessary for the conduct of the study, and I may be offered an interview.	
6. I understand that my GP will be informed that I am taking part in this research study.	
7. I understand that my meetings with the therapist and/or interviewer will be audio recorded.	
8. If I take part in an interview, I agree for the researchers to use direct quotes from the interviews. These will be anonymous and I will not be identifiable from the quotes.	
9. I agree to being approached with information inviting me to take part in future research and understand that any such research would be voluntary.	
10. I understand that information collected about me may be used to support other research in the future, and may be shared anonymously with other researchers.	
11. I agree to take part in the above study.	

Name of participant	*Date*	*Signature*
Name of person taking consent	*Date*	*Signature*

When completed: original for site file, copy for participant, copy for CTR

THERAPIST INFORMATION SHEET

A Study of Trauma Focused Guided Self Help versus Trauma-Focused Cognitive Behavioural Therapy for Post-traumatic Stress Disorder

Chief Investigator: Prof. Jonathan Bisson

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you.

What is the purpose of this study?
The current recommended treatments for Post-Traumatic Stress Disorder (PTSD) are individual talking therapies, including trauma-focused cognitive behavioural therapy (TFCBT), delivered by a therapist. Unfortunately, the limited number of therapists available and length of treatment means that there are long NHS waiting lists. To address this issue, we are testing internet delivered TFCBT based Guided Self Help (GSH) to investigate whether it is equally effective, and cost-effective, compared to the usual treatment of TFCBT. If so, it has the potential to improve accessibility and reduce waiting times.

Why have I been asked to take part?
We understand that you are one of the therapists involved in delivering both the TFCBT and the GSH. We would like you to take part in interviews to get your views on the two treatments. This will help us to improve roll out of the intervention in the NHS, should this be appropriate.

What will happen to me if I take part in the study?
If you decide to take part we will ask you to attend up to two interviews. This may be in person or by internet/telephone and will last for 60-90 minutes.

The interview will be audio recorded for transcription and analysis. We may want to publish direct quotations from these discussions, but if we do, all quotations will be published anonymously.

Do I have to take part in this study?
Taking part in this study is voluntary and entirely up to you. Please take your time to think about whether or not you would like to take part. If you would like to talk more about the study, please contact the research team using the contact details given at the end of this leaflet. A decision not to take part will not affect your employment or future involvement in any research studies.

Are there any risks involved in taking part?
We do not think that taking part in this study will pose any risk to you.

Will I benefit from taking part?
It is unlikely you will benefit directly from taking part in this study, but you may help inform new practices for improving outcomes for PTSD sufferers.

Will I be paid to take part?

You will not be paid for taking part in the study.

What if I change my mind about taking part?
Taking part in this study is entirely up to you. If at any point during the study you decide that you no longer want to take part, you are free to withdraw without giving a reason why. If you decide to withdraw, your employment or future involvement in any research studies will not be affected.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions (contact details are at the end of this information sheet). If you remain unhappy and wish to complain formally, you can contact James Walters at Cardiff University on 02920688 434 or waltersjt@cardiff.ac.uk

Will my taking part in this study be kept confidential?
Yes, we will take steps to ensure your confidentiality at all times. Only people working on the study or working to ensure the study is run correctly will have access to the data. When you are enrolled in the study, you will be given a unique, anonymous study number that will be used to label any data associated with you. All information collected about you during this study will be kept confidential and will be handled, stored and destroyed in accordance with the Data Protection Act 1998.

What will happen to the results?
We will publish the results of this study in the medical and scientific literature. A summary of the results will also be made available on the Cardiff University website and forwarded to you on request.

Will I be able to be identified from the results?
No, we take your confidentiality very seriously and all results will be published anonymously, including any quotations taken from the interview.

Who is organising the research?
This study is being organised by Cardiff University and the Chief Investigator is Professor Jonathan Bisson, Professor in Psychiatry. The study is funded by the National Institute for Health Research's HTA Programme.

Who has approved the research?
This study has been approved by Wales REC 3.

What do I do now?
Please take time to consider whether you are willing to take part in this study. Discuss it with others if you wish, and please contact us for additional information or explanation of the information in this document. If you would like to take part in the study, please contact the study team.

For further Information please contact;
If you would like to know more about the study, please contact the Trial Manager using the details below.

Claire Bartlett
Centre for Trials Research, Cardiff University
Tel: 02920 687187 E-mail: rapid@cardiff.ac.uk

Appendix J – RAPID therapist interview study consent form

Participant ID number: ☐- ☐☐

THERAPIST CONSENT FORM

A Study of Trauma-Focused Guided Self Help versus Trauma-Focused Cognitive Behavioural Therapy for Post-Traumatic Stress Disorder

Chief Investigator: Professor Jonathan Bisson

	Please initial boxes
1. I confirm that I have read and understood the information sheet (V1 dated xx xxx 2016) for the above study. I have had the opportunity to consider the information and to 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. If I withdraw from the study, I understand that any data which has already been collected may be retained and used for research purposes unless I inform the study team that I do not wish the information to be used.	☐
4. I understand that data collected during the study may be looked at by individuals from the study team, from the NHS Trust or from regulatory authorities.	☐
5. I understand that I may be contacted by text, telephone, e-mail or letter where this is necessary for the conduct of the study.	☐
6. I give permission for my interviews to be audio recorded.	☐
7. I agree to being approached with information inviting me to take part in future research and understand that any such research would be voluntary.	☐
8. I agree to take part in the above study.	☐

_____	_____	_____
Name of participant	*Date*	*Signature*
_____	_____	_____
Name of person taking consent	*Date*	*Signature*

When completed: original for site file, copy for participant, copy for CTR

Appendix K – NHS commissioners and managers interview study information sheet

Stakeholder Interview Information Sheet

A Study of Trauma-Focused Guided Self Help versus Trauma-Focused Cognitive Behavioural Therapy for Post-Traumatic Stress Disorder.
Chief Investigator: Professor Jonathan Bisson

You are invited to take part in our research study. Before you decide we would like you to understand why the research is being conducted and what it would involve for you.

What is the purpose of this study?
The current recommended treatments for Post-Traumatic Stress Disorder (PTSD) are individual talking therapies, including trauma-focused cognitive behavioural therapy (TFCBT), delivered by a therapist. Unfortunately, the limited number of therapists available, and the typical length of treatment, mean that there are often long waiting lists in NHS services. To address this issue, we are testing an **internet-based, guided self-help version of TFCBT** in order to investigate whether it is equally effective, and cost-effective, compared with the usual face-to-faced delivery of TFCBT. If so, it has the potential to improve accessibility to therapy, and to reduce waiting times.

Why have I been asked to take part?
We understand that you are a person who may be involved in funding, commissioning, implementing, or signposting to, internet-based treatment programmes for individuals with PTSD. We would like you to take part in an interview to ask you about your role, and the role of your organization, in providing patient access to mental health treatment. We hope to gather your views on internet-based healthcare interventions, including your thoughts on factors that might facilitate, or be a barrier to, commissioning such interventions within your organisation, and requirements for successful intervention roll-out. This will help us with the successful roll-out of an internet-based guided intervention for individuals with PTSD, in the NHS, and more widely, should this be appropriate. We are looking particularly at contextual factors relevant to different areas and service provisions.

What will happen if I take part in the study?
If you decide to take part we will ask you to attend one interview with a Researcher. This may be in person or by telephone and will last approximately 60-90 minutes.

The interview will be audio recorded for transcription and analysis. We may want to publish direct quotations from these discussions, but, if we do, all quotations will be published anonymously.

Do I have to take part in this study?
Taking part in this study is voluntary and entirely up to you. Please take your time to think about whether or not you would like to take part. If you would like to talk more about the study, please contact the research team using the contact details given at the end of this leaflet.

Are there any risks involved in taking part?
We do not think that taking part in this study will pose any risk to you.

Will I benefit from taking part?
It is unlikely that you will benefit directly from taking part in this study, but you may help inform new practices for improving outcomes for PTSD sufferers.

Will I be paid to take part?
You will not be paid for taking part in the study.

What if I change my mind about taking part?
Taking part in this study is entirely up to you. If at any point during the study you decide that you no longer want to take part, you are free to withdraw without giving a reason.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions (contact details are at the end of this information sheet). If you remain unhappy and wish to complain formally, you can contact James Walters at Cardiff University on 02920688 434 or waltersjt@cardiff.ac.uk

Will my taking part in this study be kept confidential?
Yes, we will take steps to ensure your confidentiality at all times. Only people working on the study, or working to ensure that the study is run correctly, will have access to the data. When you are enrolled in the study, you will be given a unique, anonymous study number that will be used to label any data associated with you. All information collected about you during this study will be kept confidential and will be handled, stored and destroyed in accordance with the General Data Protection Regulation (GDPR) 2016.

What will happen to the results?
We will publish the results of this study in the medical/scientific literature. A summary of the results will also be made available on the Cardiff University website and forwarded to you on request.

Will I be able to be identified from the results?
No, we take your confidentiality very seriously and all results will be published anonymously, including any quotations taken from the interview.

Who is organizing the research?
This study is being organized by Cardiff University and the Chief Investigator is Professor Jonathan Bisson, Professor in Psychiatry. The study is funded by the National Institute for Health Research's HTA Programme.

Who has approved the research?
This study has been approved by Wales Research Ethics Committee (REC) 3.

What do I do now?
Please take time to consider whether you are willing to take part in this study. Discuss it with others if you wish, and please contact us for additional information or

explanation of the information in this document. If you would like to take part in the study, please contact the study team.

If you would like to know more about the study, please contact Natalie Simon, using the details below:

Natalie Simon
Division of Psychological Medicine and Clinical Neurosciences, Cardiff University.
Tel: 02920 688331; Email: SimonN2@cardiff.ac.uk.

Appendix L – NHS commissioners and managers interview study consent form

Participant ID number: _ _

STAKEHOLDER INTERVIEWS CONSENT FORM

A study of Trauma-Focused Guided Self Help versus Trauma-Focused Cognitive Behavioural Therapy for Post-Traumatic Stress Disorder

Chief Investigator: Professor Jonathan Bisson

	Please Initial Boxes
1. I confirm I have read and understood the information sheet (v1.0 dated 23/04/2019), for the above study. I have had the opportunity to consider the information and to 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.	☐
3. If I withdraw from the study, I understand that any data which have already been collected may be retained and used for research purposes unless I inform the study team that I do not wish the information to be used.	☐
4. I understand that data collected during the study may be looked at by individuals from the study team, or from regulatory authorities.	☐
5. I understand that I may be contacted by text, telephone, e-mail or letter where this is necessary for the conduct of the study.	☐
6. I give permission for my interviews to be audio recorded.	☐
7. I agree for the researchers to use direct quotes from the interviews. These will be anonymous and I will not be identifiable from the quotes.	☐
8. I agree to being approached with information inviting me to take part in any future research and understand that any such research would be voluntary.	☐
9. I agree to take part in the study.	☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

Appendix M - RAPID study withdrawal form

RAPID TRIAL

WITHDRAWAL CONFIRMATION LETTER

This form should be completed in the event that a participant withdraws from the trial.

Please ensure that the levels of withdrawal are altered to appropriate withdrawals for your trial

Site ID:_____ Screening ID: _____ Participant Initials: _____ Participant DOB:_____

Thank you for submitting a withdrawal CRF for the above participant at level (delete as appropriate):

- *Withdrawal from intervention*
- *Partial withdrawal from further data collection (e.g. follow up assessments)*
- *Complete withdrawal from further data collection*
- *Withdrawal of permission to use data already collected*

Withdrawal Date: *Add date as per CRF*

Please reconfirm the level of withdrawal or select a level of Withdrawal from the list below if original level was submitted incorrectly. I confirm that the above participant was withdrawn at level:

(Please tick)

Level of withdrawal	Tick
Withdrawal from intervention	
Partial withdrawal from further data collection at follow up assessments,	
**Complete withdrawal from further data collection For a participant who wishes to completely withdraw from the trial it needs to be noted in the participant's notes that they remove their consent for their data to be collected. If the participant has not expressed this then they will be considered as partial withdrawal. Please can you confirm the complete withdrawal request from the participant is clearly documented in the participant notes?	
**Withdrawal of permission to use data already collected	

**All subsequent CRFs received after the complete withdrawal or withdrawal of permission to use data will be destroyed by the CTR without notification.

I confirm that the above withdrawal level is correct.

Signed: _____
Position: _____
Dated:_____

Appendix N – Modified Life Events Checklist case report form

CRF ☐☐-☐☐ **CRF10: LEC-5**

Site ID ☐☐ **Screening ID** ☐☐/☐☐☐☐ **Patient Initials** ☐☐☐ **Patient DOB** ☐☐/☐☐/☐☐☐☐ **Date** ☐☐/☐☐/☐☐☐☐

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 a close family member or close friend; (d) you were exposed to it as part of your job (for example, paramedic, police, military, or other first responder); (e) you're not sure if it fits; or (f) 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.

	Happened to me	Witnessed it	Learned about it	Part of my job	Not sure	Doesn't apply
1. Natural disaster (e.g. flood, hurricane, tornado, earthquake)	☐	☐	☐	☐	☐	☐
2. Fire or explosion	☐	☐	☐	☐	☐	☐
3. Transportation accident (e.g. car accident, boat accident, train wreck, plane crash)	☐	☐	☐	☐	☐	☐
4. Serious accident at work, home, or during recreational activity	☐	☐	☐	☐	☐	☐
5. Exposure to toxic substance (e.g. dangerous chemicals, radiation)	☐	☐	☐	☐	☐	☐
6. Physical assault (e.g. being attacked, hit, slapped, kicked, beaten up)	☐	☐	☐	☐	☐	☐
7. Assault with a weapon (e.g. 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)	☐	☐	☐	☐	☐	☐

CRF10—Life Events Checklist V4.0 Final 25/05/17 Page completed by (initials) ☐☐ 1

CRF ☐☐-☐☐ **CRF10: LEC-5**

Site ID ☐☐☐ **Screening ID** ☐☐/☐☐☐☐ **Patient Initials** ☐☐☐ **Patient DOB** ☐☐/☐☐/☐☐☐☐ **Date** ☐☐/☐☐/☐☐☐☐

	Happened to me	Witnessed it	Learned about it	Part of my job	Not sure	Doesn't apply
11. Captivity (e.g. being kidnapped, abducted, held hostage, prisoner of war)	☐	☐	☐	☐	☐	☐
12. Life-threatening illness or injury	☐	☐	☐	☐	☐	☐
13. Severe human suffering	☐	☐	☐	☐	☐	☐
14. Sudden, violent death (e.g. homicide, suicide)	☐	☐	☐	☐	☐	☐
15. Sudden, unexpected death of someone close to you	☐	☐	☐	☐	☐	☐
16. Serious injury, harm, or death you caused to someone (if directly involved, mark as happened to me)	☐	☐	☐	☐	☐	☐
17. Any other stressful event or experience	☐	☐	☐	☐	☐	☐

CRF ☐☐-☐☐ **CRF10: LEC-5**

Site ID ☐☐☐ **Screening ID** ☐☐/☐☐☐☐ **Patient Initials** ☐☐☐ **Patient DOB** ☐☐/☐☐/☐☐☐☐ **Date** ☐☐/☐☐/☐☐☐☐

	Happened to me	Witnessed it	Learned about it	Part of my job	Not sure	Doesn't apply
18. Childhood physical abuse?	☐	☐	☐	☐	☐	☐
19. Childhood sexual abuse or molestation?	☐	☐	☐	☐	☐	☐

20. Which one of these was the worst event that has happened to you? ☐☐ *(enter 1 to 19 from above)*

21. How old were you when the event started/happened? ☐☐ *(age in years)*

22. How long did the event last? ☐☐☐ *(time in minutes)*

23. How long ago did the event end? ☐☐☐ *(time in months)*

Please hand the questionnaire back to the interviewer

24.Does the participant have PTSD symptoms to a single event only? Yes ☐ No ☐ *(go to CRF22)*

National Center for PTSD

CLINICIAN-ADMINISTERED PTSD SCALE FOR DSM-5

PAST MONTH VERSION

BASELINE

Version date: May 2015

Reference: Weathers, F.W., Blake, D. D., Schnurr, P. P., Kaloupek, D. G., Marx, B. P., & Keane, T. M. (2015). The Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) – Past Month [Measurement instrument]. Available from http://www.ptsd.va.gov/

URL: http://www.ptsd.va.gov/professional/assessment/adult-int/caps.asp

Study: ***Pragmatic RAndomised controlled trial of a Trauma-Focused Guided Self Help Programme versus InDividual Trauma-Focused Cognitive Behavioural Therapy for Post-Traumatic Stress Disorder (RAPID)***

ScID: _____

Interviewer: _____

Date: _____

Instructions

Standard administration and scoring of the CAPS-5 are essential for producing reliable and valid scores and diagnostic decisions. The CAPS-5 should be administered only by qualified interviewers who have formal training in structured clinical interviewing and differential diagnosis, a thorough understanding of the conceptual basis of PTSD and its various symptoms, and detailed knowledge of the features and conventions of the CAPS-5 itself.

Administration

1. Identify an index traumatic event to serve as the basis for symptom inquiry. Administer the Life Events Checklist and Criterion A inquiry provided on p. 5, or use some other structured, evidence-based method. The index event may involve either a single incident (e.g., "the accident") or multiple, closely related incidents (e.g., "the worst parts of your combat experiences"). However please note that for the RAPID study we are interested in PTSD relating to a single event or single incident.

2. Read prompts verbatim, one at a time, and in the order presented, EXCEPT:

    a. Use the respondent's own words for labeling the index event or describing specific symptoms.

    b. Rephrase standard prompts to acknowledge previously reported information, but return to verbatim phrasing as soon as possible. For example, inquiry for item 20 might begin: "You already mentioned having problems sleeping. What kinds of problems?"

    c. If you don't have sufficient information after exhausting all standard prompts, follow up ad lib. In this situation, repeating the initial prompt often helps refocus the respondent.

    d. As needed, ask for specific examples or direct the respondent to elaborate even when such prompts are not provided explicitly.

3. In general, DO NOT suggest responses. If a respondent has pronounced difficulty understanding a prompt it may be necessary to offer a brief example to clarify and illustrate. However, this should be done rarely and only after the respondent has been given ample opportunity to answer spontaneously.

4. DO NOT read rating scale anchors to the respondent. They are intended only for you, the interviewer, because appropriate use requires clinical judgment and a thorough understanding of CAPS-5 scoring conventions.

5. Move through the interview as efficiently as possible to minimize respondent burden. Some useful strategies:

    a. Be thoroughly familiar with the CAPS-5 so that prompts flow smoothly.

    b. Ask the fewest number of prompts needed to obtain sufficient information to support a valid rating.

    c. Minimize note-taking and write while the respondent is talking to avoid long pauses.

    d. Take charge of the interview. Be respectful but firm in keeping the respondent on task, transitioning between questions, pressing for examples, or pointing out contradictions.

Scoring

1. As with previous versions of the CAPS, CAPS-5 symptom severity ratings are based on symptom frequency and intensity, except for items 8 (amnesia) and 12 (diminished interest), which are based on amount and intensity. However, CAPS-5 items are rated with a single severity score, in contrast to previous versions of the CAPS which required separate frequency and intensity scores for each item that were either summed to create a symptom severity score or combined in various scoring rules to create a dichotomous (present/absent) symptom score. Thus, on the CAPS-5 the clinician combines information about frequency and intensity before making a single severity rating. Depending on the item, frequency is rated as either the number of occurrences (how often in the past month) or percent of time (how much of the time in the past month). Intensity is rated on a four-point ordinal scale with ratings of *Minimal*, *Clearly Present*, *Pronounced*, and *Extreme*. Intensity and severity are related but distinct. Intensity refers to the strength of a typical occurrence of a symptom. Severity refers to the total symptom load over a given time period, and is a combination of intensity and frequency. This is similar to the quantity/frequency assessment approach to alcohol consumption. In general, intensity rating anchors correspond to severity scale anchors described below and should be interpreted and used in the same way, except that severity ratings require joint consideration of intensity and frequency. Thus, before taking frequency into account, an intensity rating of *Minimal* corresponds to a severity rating of *Mild / subthreshold*, *Clearly Present* corresponds with *Moderate / threshold*, *Pronounced* corresponds with *Severe / markedly elevated*, and *Extreme* corresponds with *Extreme / incapacitating*.

2. The five-point CAPS-5 symptom severity rating scale is used for all symptoms. Rating scale anchors should be interpreted and used as follows:

   0 ***Absent*** The respondent denied the problem or the respondent's report doesn't fit the DSM-5 symptom criterion.

   1 ***Mild / subthreshold*** The respondent described a problem that is consistent with the symptom criterion but isn't severe enough to be considered clinically significant. The problem doesn't satisfy the DSM-5 symptom criterion and thus doesn't count toward a PTSD diagnosis.

   2 ***Moderate / threshold*** The respondent described a clinically significant problem. The problem satisfies the DSM-5 symptom criterion and thus counts toward a PTSD diagnosis. The problem would be a target for intervention. This rating requires a minimum frequency of *2 X month* or *some of the time (20-30%)* PLUS a minimum intensity of *Clearly Present*.

   3 ***Severe / markedly elevated*** The respondent described a problem that is well above threshold. The problem is difficult to manage and at times overwhelming, and would be a prominent target for intervention. This rating requires a minimum frequency of *2 X week* or *much of the time (50-60%)* PLUS a minimum intensity of *Pronounced*.

   4 ***Extreme / incapacitating*** The respondent described a dramatic symptom, far above threshold. The problem is pervasive, unmanageable, and overwhelming, and would be a high-priority target for intervention.

3. In general, make a given severity rating only if the minimum frequency and intensity for that rating are both met. However, you may exercise clinical

judgment in making a given severity rating if the reported frequency is somewhat lower than required, but the intensity is higher. For example, you may make a severity rating of *Moderate / threshold* if a symptom occurs *1 X month* (instead of the required *2 X month*) as long as intensity is rated *Pronounced* or *Extreme* (instead of the required *Clearly Present*). Similarly, you may make a severity rating of *Severe / markedly elevated* if a symptom occurs *1 X week* (instead of the required *2 X week*) as long as the intensity is rated *Extreme* (instead of the required *Pronounced*). If you are unable to decide between two severity ratings, make the lower rating.

4. You need to establish that a symptom not only meets the DSM-5 criterion phenomenologically, but is also functionally related to the index traumatic event, i.e., started or got worse as a result of the event. CAPS-5 items 1-8 and 10 (reexperiencing, effortful avoidance, amnesia, and blame) are inherently linked to the event. Evaluate the remaining items for trauma-relatedness (TR) using the TR inquiry and rating scale. The three TR ratings are:

    a. ***Definite*** = the symptom can clearly be attributed to the index trauma, because (1) there is an obvious change from the pre-trauma level of functioning and/or (2) the respondent makes the attribution to the index trauma with confidence.

    b. ***Probable*** = the symptom is likely related to the index trauma, but an unequivocal connection can't be made. Situations in which this rating would be given include the following: (1) there seems to be a change from the pre-trauma level of functioning, but it isn't as clear and explicit as it would be for a "definite;" (2) the respondent attributes a causal link between the symptom and the index trauma, but with less confidence than for a rating of *Definite*; (3) there appears to be a functional relationship between the symptom and inherently trauma-linked symptoms such as reexperiencing symptoms (e.g., numbing or withdrawal increases when reexperiencing increases).

    c. ***Unlikely*** = the symptom can be attributed to a cause other than the index trauma because (1) there is an obvious functional link with this other cause and/or (2) the respondent makes a confident attribution to this other cause and denies a link to the index trauma. Because it can be difficult to rule out a functional link between a symptom and the index trauma, a rating of *Unlikely* should be used only when the available evidence strongly points to a cause other than the index trauma. NOTE: <u>Symptoms with a TR rating of *Unlikely* should not be counted toward a PTSD diagnosis or included in the total CAPS-5 symptom severity score.</u>

5. **CAPS-5 total symptom severity score** is calculated by summing severity scores for items 1-20.

6. **CAPS-5 symptom cluster severity scores** are calculated by summing the individual item severity scores for symptoms contained in a given DSM-5 cluster. Thus, the Criterion B (reexperiencing) severity score is the sum of the individual severity scores for items 1-5; the Criterion C (avoidance) severity score is the sum of items 6 and 7; the Criterion D (negative alterations in cognitions and mood) severity score is the sum of items 8-14; and the Criterion E (hyperarousal) severity score is the sum of items 15-20.

7. **PTSD diagnostic status** is determined by first dichotomizing individual symptoms as "present" or "absent," then following the DSM-5 diagnostic rule. A

symptom is considered present only if the corresponding item severity score is rated *2=Moderate/threshold* or higher. Items 9 and 11-20 have the additional requirement of a trauma-relatedness rating of *Definite* or *Probable*. Otherwise a symptom is considered absent. The DSM-5 diagnostic rule requires the presence of least one Criterion B symptom, one Criterion C symptom, two Criterion D symptoms, and two Criterion E symptoms. In addition, Criteria F and G must be met. Criterion F requires that the disturbance has lasted at least one month. Criterion G requires that the disturbance cause either clinically significant distress or functional impairment, as indicated by a rating of *2=moderate* or higher on items 23-25.

Criterion A: Exposure to actual or threatened death, serious injury, or sexual violence in one (or more) of the following ways:

1. **Directly experiencing the traumatic event(s).**
2. **Witnessing, in person, the event(s) as it occurred to others.**
3. **Learning that the traumatic event(s) occurred to a close family member or close friend. In cases of actual or threatened death of a family member or friend, the event(s) must have been violent or accidental.**
4. **Experiencing repeated or extreme exposure to aversive details of the traumatic event(s) (e.g., first responders collecting human remains; police officers repeatedly exposed to details of child abuse). Note: Criterion A4 does not apply to exposure through electronic media, television, movies, or pictures, unless this exposure is work related.**

[Administer Life Events Checklist or other structured trauma screen]

I'm going to ask you about the stressful experiences questionnaire you filled out. First I'll ask you to tell me a little bit about the event you said was the worst for you. Then I'll ask how that event may have affected you over the past month. In general I don't need a lot of information – just enough so I can understand any problems you may have had. Please let me know if you find yourself becoming upset as we go through the questions so we can slow down and talk about it. Also, let me know if you have any questions or don't understand something. Do you have any questions before we start?

The event you said was the worst was (EVENT). What I'd like for you to do is briefly describe what happened.

Index event (specify):

What happened? *(How old were you? How were you involved? Who else was involved? Was anyone seriously injured or killed? Was anyone's life in danger? How many times did this happen?)*	*Exposure type:* *Experienced ___* *Witnessed ___* *Learned about ___* *Exposed to aversive details___* *Life threat? NO YES [self ___ other ___]* *Serious injury? NO YES [self ___ other ___]* *Sexual violence? NO YES [self ___ other ___]* *Criterion A met? NO PROBABLE YES*

For the rest of the interview, I want you to keep (EVENT) in mind as I ask you about different problems it may have caused you. You may have had some of these problems before, but for this interview we're going to focus just on the past month. For each problem I'll ask if you've had it in the past month, and if so, how often and how much it bothered you.

Criterion B: Presence of one (or more) of the following intrusion symptoms associated with the traumatic event(s), beginning after the traumatic event(s) occurred:

1. (B1) Recurrent, involuntary, and intrusive distressing memories of the traumatic event(s). Note: In children older than 6 years, repetitive play may occur in which themes or aspects of the traumatic event(s) are expressed.

In the past month, have you had any <u>unwanted memories</u> of (EVENT) while you were awake, so not counting dreams? [Rate 0=Absent if only during dreams]

How does it happen that you start remembering (EVENT)?

[If not clear:] ***(Are these <u>unwanted</u> memories, or are you thinking about [EVENT] on purpose?)***
[Rate 0=Absent unless perceived as involuntary and intrusive]

How much do these memories bother you?

Are you able to put them out of your mind and think about something else?

[If not clear:] ***(Overall, how much of a problem is this for you? How so?)***

<u>Circle</u>: Distress = *Minimal* *Clearly Present* *Pronounced* *Extreme*

How often have you had these memories in the past month? *# of times* _____

0 *Absent*

1 *Mild / subthreshold*

2 *Moderate / threshold*

3 *Severe / markedly elevated*

4 *Extreme / incapacitating*

Key rating dimensions = frequency / intensity of distress

Moderate = at least 2 X month / distress clearly present, some difficulty dismissing memories

Severe = at least 2 X week / pronounced distress, considerable difficulty dismissing memories

2. (B2) Recurrent distressing dreams in which the content and/or affect of the dream are related to the event(s). Note: In children, there may be frightening dreams without recognizable content.

In the past month, have you had any <u>unpleasant dreams</u> about (EVENT)?

Describe a typical dream. *(What happens?)*

[If not clear:] ***(Do they wake you up?)***

[If yes:] ***(What do you experience when you wake up? How long does it take you to get back to sleep?)***

[If reports not returning to sleep:] ***(How much sleep do you lose?)***

How much do these dreams bother you?

<u>Circle</u>: Distress = *Minimal* *Clearly Present* *Pronounced* *Extreme*

How often have you had these dreams in the past month? *# of times* _____

Key rating dimensions = frequency / intensity of distress

Moderate = at least 2 X month / distress clearly present, less than 1 hour sleep loss

Severe = at least 2 X week / pronounced distress, more than 1 hour sleep loss

0 ***Absent***

1 ***Mild / subthreshold***

2 ***Moderate / threshold***

3 ***Severe / markedly elevated***

4 ***Extreme / incapacitating***

3. (B3) Dissociative reactions (e.g., flashbacks) in which the individual feels or acts as if the traumatic event(s) were recurring. (Such reactions may occur on a continuum, with the most extreme expression being a complete loss of awareness of present surroundings.) Note: In children, trauma-specific reenactment may occur in play.

In the past month, have there been times when you <u>suddenly</u> <u>acted</u> or <u>felt</u> as if (EVENT) were <u>actually happening</u> again?

[If not clear:] ***(This is different than thinking about it or dreaming about it – now I'm asking about flashbacks, when you feel like you're actually back at the time of [EVENT], actually reliving it.)***

How much does it seem as if (EVENT) were happening again? *(Are you confused about where you actually are?)*

What do you do while this is happening? *(Do other people notice your behavior? What do they say?)*

How long does it last?

<u>Circle</u>: Dissociation = *Minimal* *Clearly Present* *Pronounced* *Extreme*

How often has this happened in the past month? *# of times* _____

0 *Absent*

1 *Mild / subthreshold*

2 *Moderate / threshold*

3 *Severe / markedly elevated*

4 *Extreme / incapacitating*

Key rating dimensions = frequency / intensity of dissociation

Moderate = at least 2 X month / dissociative quality clearly present, may retain some awareness of surroundings but relives event in a manner clearly distinct from thoughts and memories

Severe = at least 2 X week / pronounced dissociative quality, reports vivid reliving, e.g., with images, sounds, smells

4. (B4) Intense or prolonged psychological distress at exposure to internal or external cues that symbolize or resemble an aspect of the traumatic event(s).

In the past month, have you gotten <u>emotionally</u> <u>upset</u> when <u>something</u> <u>reminded</u> <u>you</u> of (EVENT)?

What kinds of reminders make you upset?

How much do these reminders bother you?

0 *Absent*

1 *Mild / subthreshold*

2 *Moderate / threshold*

3 *Severe / markedly elevated*

4 ***Extreme / incapacitating***

Are you able to calm yourself down when this happens? *(How long does it take?)*

[If not clear:] ***(Overall, how much of a problem is this for you? How so?)***

Circle: Distress = *Minimal* *Clearly Present* *Pronounced* *Extreme*

How often has this happened in the past month? # *of times* _____

Key rating dimensions = frequency / intensity of distress

Moderate = at least 2 X month / distress clearly present, some difficulty recovering

Severe = at least 2 X week / pronounced distress, considerable difficulty recovering

5. (B5) Marked physiological reactions to internal or external cues that symbolize or resemble an aspect of the traumatic event(s).

In the past month, have you had any <u>physical</u> <u>reactions</u> when <u>something</u> <u>reminded</u> <u>you</u> of (EVENT)?

Can you give me some examples? *(Does your heart race or your breathing change? What about sweating or feeling really tense or shaky?)*

What kinds of reminders trigger these reactions?

How long does it take you to recover?

<u>Circle</u>: Physiological reactivity = *Minimal* *Clearly Present* *Pronounced* *Extreme*

How often has this happened in the past month? *# of times* _____

0 *Absent*

1 *Mild / subthreshold*

2 *Moderate / threshold*

3 *Severe / markedly elevated*

4 *Extreme / incapacitating*

Key rating dimensions = frequency / intensity of physiological arousal

Moderate = at least 2 X month / reactivity clearly present, some difficulty recovering

Severe = at least 2 X week / pronounced reactivity, sustained arousal, considerable difficulty recovering

Criterion C: Persistent avoidance of stimuli associated with the traumatic event(s), beginning after the traumatic event(s) occurred, as evidenced by one or both of the following:

6. (C1) Avoidance of or efforts to avoid distressing memories, thoughts, or feelings about or closely associated with the traumatic event(s).

In the past month, have you tried to <u>avoid</u> <u>thoughts</u> or <u>feelings</u> about (EVENT)?

What kinds of thoughts or feelings do you avoid?

How hard do you try to avoid these thoughts or feelings? *(What kinds of things do you do?)*

0 *Absent*

1 *Mild / subthreshold*

2 *Moderate / threshold*

3 *Severe / markedly elevated*

4 *Extreme / incapacitating*

[If not clear:] ***(Overall, how much of a problem is this for you? How would things be different if you didn't have to avoid these thoughts or feelings?)***

Circle: Avoidance = *Minimal* *Clearly Present* *Pronounced* *Extreme*

How often in the past month? *# of times* _____

Key rating dimensions = frequency / intensity of avoidance

Moderate = at least 2 X month / avoidance clearly present

Severe = at least 2 X week / pronounced avoidance

7. (C2) Avoidance of or efforts to avoid external reminders (people, places, conversations, activities, objects, situations) that arouse distressing memories, thoughts, or feelings about or closely associated with the traumatic event(s).

In the past month, have you tried to <u>avoid</u> <u>things</u> that <u>remind</u> <u>you</u> of (EVENT), like certain people, places, or situations?

What kinds of things do you avoid?

How much effort do you make to avoid these reminders? *(Do you have to make a plan or change your activities to avoid them?)*

[If not clear:] ***(Overall, how much of a problem is this for you? How would things be different if you didn't have to avoid these reminders?)***

0 ***Absent***

1 ***Mild / subthreshold***

2 ***Moderate / threshold***

3 ***Severe / markedly elevated***

4 ***Extreme / incapacitating***

<u>Circle</u>: Avoidance = *Minimal* *Clearly Present* *Pronounced* *Extreme*

How often in the past month? *# of times* _____

Key rating dimensions = frequency / intensity of avoidance

Moderate = at least 2 X month / avoidance clearly present

Severe = at least 2 X week / pronounced avoidance

Criterion D: Negative alterations in cognitions and mood associated with the traumatic event(s), beginning or worsening after the traumatic event(s) occurred, as evidenced by two (or more) of the following:

8. (D1) Inability to remember an important aspect of the traumatic event(s) (typically due to dissociative amnesia and not to other factors such as head injury, alcohol, or drugs).

In the past month, have you had <u>difficulty</u> <u>remembering</u> some <u>important</u> <u>parts</u> of (EVENT)? *(Do you feel there are gaps in your memory of [EVENT]?)*

What parts have you had difficulty remembering?

Do you feel you should be able to remember these things?

[If not clear:] ***(Why do you think you can't? Did you have a head injury during [EVENT]? Were you***

0 ***Absent***

1 ***Mild / subthreshold***

2 ***Moderate / threshold***

3 ***Severe / markedly elevated***

4 ***Extreme / incapacitating***

knocked unconscious? Were you intoxicated from alcohol or drugs?) [Rate 0=Absent if due to head injury or loss of consciousness or intoxication during event]

[If still not clear:] ***(Is this just normal forgetting? Or do you think you may have blocked it out because it would be too painful to remember?)*** [Rate 0=Absent if due only to normal forgetting]

Circle: Difficulty remembering = *Minimal* *Clearly Present* *Pronounced* *Extreme*

In the past month, how many of the important parts of (EVENT) have you had difficulty remembering? *(What parts do you still remember?)* *# of important aspects* _____

Would you be able to recall these things if you tried?

Key rating dimensions = amount of event not recalled / intensity of inability to recall

Moderate = at least one important aspect / difficulty remembering clearly present, some recall possible with effort

Severe = several important aspects / pronounced difficulty remembering, little recall even with effort

9. (D2) Persistent and exaggerated negative beliefs or expectations about oneself, others, or the world (e.g., "I am bad," "No one can be trusted," "The world is completely dangerous," "My whole nervous system is permanently ruined").

In the past month, have you had <u>strong</u> <u>negative</u> <u>beliefs</u> about yourself, other people, or the world?

Can you give me some examples? *(What about believing things like "I am bad," "there is something seriously wrong with me," "no one can be trusted," "the world is completely dangerous"?)*

How strong are these beliefs? *(How convinced are you that these beliefs are actually true? Can you see other ways of thinking about it?)*

<u>Circle</u>: Conviction = *Minimal* *Clearly Present* *Pronounced* *Extreme*

How much of the time in the past month have you felt that way, as a percentage? % *of time* _____

Did these beliefs start or get worse after (EVENT)? *(Do you think they're related to [EVENT]? How so?)* <u>Circle</u>: Trauma-relatedness = *Definite* *Probable* *Unlikely*

0 *Absent*

1 *Mild / subthreshold*

2 *Moderate / threshold*

3 *Severe / markedly elevated*

4 *Extreme / incapacitating*

Key rating dimensions = frequency / intensity of beliefs

Moderate = some of the time (20-30%) / exaggerated negative expectations clearly present, some difficulty considering more realistic beliefs

Severe = much of the time (50-60%) / pronounced exaggerated negative expectations, considerable difficulty considering more realistic beliefs

10. (D3) Persistent, distorted cognitions about the cause or consequences of the traumatic event(s) that lead the individual to blame himself/herself or others.

In the past month, have you <u>blamed</u> <u>yourself</u> for (EVENT) or what happened as a result of it? Tell me more about that. *(In what sense do you see yourself as having caused [EVENT]? Is it because of something you did? Or something you think you should have done but didn't? Is it because of something about you in general?)*

What about <u>blaming</u> <u>someone</u> <u>else</u> for (EVENT) or what happened as a result of it? Tell me more about that. *(In what sense do you see [OTHERS] as having caused [EVENT]? Is it because of something they did? Or something you think they should have done but didn't?)*

How much do you blame (YOURSELF OR OTHERS)?

0 *Absent*

1 *Mild / subthreshold*

2 *Moderate / threshold*

3 *Severe / markedly elevated*

4 *Extreme / incapacitating*

How convinced are you that [YOU OR OTHERS] are truly to blame for what happened? *(Do other people agree with you? Can you see other ways of thinking about it?)*

[Rate 0=Absent if only blames perpetrator, i.e., someone who deliberately caused the event and intended harm]

Circle: Conviction = *Minimal* *Clearly Present* *Pronounced* *Extreme*

How much of the time in the past month have you felt that way, as a percentage? % *of time* _____

Key rating dimensions = frequency / intensity of blame

Moderate = some of the time (20-30%) / distorted blame clearly present, some difficulty considering more realistic beliefs

Severe = much of the time (50-60%) / pronounced distorted blame, considerable difficulty considering more realistic beliefs

11. (D4) Persistent negative emotional state (e.g., fear, horror, anger, guilt, or shame).

In the past month, have you had any <u>strong</u> <u>negative feelings</u> such as fear, horror, anger, guilt, or shame?

Can you give me some examples? *(What negative feelings do you experience?)*

How strong are these negative feelings?

How well are you able to manage them?

[If not clear:] ***(Overall, how much of a problem is this for you? How so?)***

<u>Circle</u>: Negative emotions = *Minimal Clearly Present Pronounced Extreme*

How much of the time in the past month have you felt that way, as a percentage? *% of time* _____

Did these negative feelings start or get worse after (EVENT)? *(Do you think they're related to [EVENT]? How so?)* <u>Circle</u>: Trauma-relatedness = *Definite Probable Unlikely*

0 *Absent*

1 *Mild / subthreshold*

2 *Moderate / threshold*

3 *Severe / markedly elevated*

4 *Extreme / incapacitating*

Key rating dimensions = frequency / intensity of negative emotions

Moderate = some of the time (20-30%) / negative emotions clearly present, some difficulty managing

Severe = much of the time (50-60%) / pronounced negative emotions, considerable difficulty managing

12. (D5) Markedly diminished interest or participation in significant activities.

In the past month, have you been <u>less</u> <u>interested</u> in <u>activities</u> that you used to enjoy?

What kinds of things have you lost interest in or don't do as much as you used to? *(Anything else?)*

Why is that? [Rate 0=Absent if diminished participation is due to lack of opportunity, physical inability, or developmentally appropriate change in preferred activities]

0 *Absent*

1 *Mild / subthreshold*

2 *Moderate / threshold*

3 *Severe / markedly elevated*

4 *Extreme / incapacitating*

How strong is your loss of interest? *(Would you still enjoy [ACTIVITIES] once you got started?)*

Circle: Loss of interest= *Minimal* *Clearly Present* *Pronounced* *Extreme*

Overall, in the past month, how many of your usual activities have you been less interested in, as a percentage? % *of activities* _____

What kinds of things do you still enjoy doing?

Did this loss of interest start or get worse after (EVENT)? *(Do you think it's related to [EVENT]? How so?)*
Circle: Trauma-relatedness = *Definite* *Probable* *Unlikely*

Key rating dimensions = percent of activities affected / intensity of loss of interest

Moderate = some activities (20-30%) / loss of interest clearly present but still has some enjoyment of activities

Severe = many activities (50-60%) / pronounced loss of interest, little interest or participation in activities

13. (D6) Feelings of detachment or estrangement from others.

In the past month, have you felt distant or cut off from other people?

Tell me more about that.

How strong are your feelings of being distant or cut off from others? *(Who do you feel closest to? How many people do you feel comfortable talking with about personal things?)*

0 ***Absent***

1 ***Mild / subthreshold***

2 ***Moderate / threshold***

3 ***Severe / markedly elevated***

4 ***Extreme / incapacitating***

Circle: Detachment or estrangement = *Minimal* *Clearly Present* *Pronounced* *Extreme*

How much of the time in the past month have you felt that way, as a percentage? % *of time* _____

Did this feeling of being distant or cut off start or get worse after (EVENT)? *(Do you think it's related to*

[EVENT]? How so?) Circle: Trauma-relatedness = *Definite Probable Unlikely*

Key rating dimensions = frequency / intensity of detachment or estrangement

Moderate = some of the time (20-30%) / feelings of detachment clearly present but still feels some interpersonal connection

Severe = much of the time (50-60%) / pronounced feelings of detachment or estrangement from most people, may feel close to only one or two people

14. (D7) Persistent inability to experience positive emotions (e.g., inability to experience happiness, satisfaction, or loving feelings).

In the past month, have there been times when you had difficulty experiencing positive feelings like love or happiness?

Tell me more about that. *(What feelings are difficult to experience?)*

How much difficulty do you have experiencing positive feelings? *(Are you still able to experience any positive feelings?)*

0 ***Absent***

1 ***Mild / subthreshold***

2 ***Moderate / threshold***

3 ***Severe / markedly elevated***

4 ***Extreme / incapacitating***

Circle: Reduction of positive emotions = *Minimal Clearly Present Pronounced Extreme*

How much of the time in the past month have you felt that way, as a percentage? *% of time* _____

Did this trouble experiencing positive feelings start or get worse after (EVENT)? *(Do you think it's related to [EVENT]? How so?)* Circle: Trauma-relatedness = *Definite Probable Unlikely*

Key rating dimensions = frequency / intensity of reduction in positive emotions

Moderate = some of the time (20-30%) / reduction of positive emotional experience clearly present but still able to experience some positive emotions

Severe = much of the time (50-60%) / pronounced reduction of experience across range of positive emotions

Criterion E: Marked alterations in arousal and reactivity associated with the traumatic event(s), beginning or worsening after the traumatic event(s) occurred, as evidenced by two (or more) of the following:

15. (E1) Irritable behavior and angry outbursts (with little or no provocation) typically expressed as verbal or physical aggression toward people or objects.

In the past month, have there been times when you felt especially irritable or angry and showed it in your behavior?

Can you give me some examples? *(How do you show it? Do you raise your voice or yell? Throw or hit things? Push or hit other people?)*

Circle: Aggression = *Minimal* *Clearly Present* *Pronounced* *Extreme*

How often in the past month? *# of times* _____

Did this behavior start or get worse after (EVENT)? *(Do you think it's related to [EVENT]? How so?)* Circle: Trauma-relatedness = *Definite* *Probable* *Unlikely*

0 ***Absent***

1 ***Mild / subthreshold***

2 ***Moderate / threshold***

3 ***Severe / markedly elevated***

4 ***Extreme / incapacitating***

Key rating dimensions = frequency / intensity of aggressive behavior

Moderate = at least 2 X month / aggression clearly present, primarily verbal

Severe = at least 2 X week / pronounced aggression, at least some physical aggression

16. (E2) Reckless or self-destructive behavior.

In the past month, have there been times when you were taking more risks or doing things that might have caused you harm?

Can you give me some examples?

How much of a risk do you take? *(How dangerous are these behaviors? Were you injured or harmed in some way?)*

Circle: Risk = *Minimal* *Clearly Present* *Pronounced* *Extreme*

0 ***Absent***

1 ***Mild / subthreshold***

2 ***Moderate / threshold***

3 ***Severe / markedly elevated***

4 ***Extreme / incapacitating***

How often have you taken these kinds of risks in the past month? *# of times _____*

Did this behavior start or get worse after (EVENT)? *(Do you think it's related to [EVENT]? How so?)* Circle: Trauma-relatedness = *Definite Probable Unlikely*

Key rating dimensions = frequency / degree of risk

Moderate = at least 2 X month / risk clearly present, may have been harmed

Severe = at least 2 X week / pronounced risk, actual harm or high probability of harm

17. (E3) Hypervigilance.

In the past month, have you been especially <u>alert</u> or <u>watchful</u>, even when there was no specific threat or danger? *(Have you felt as if you had to be on guard?)*

Can you give me some examples? *(What kinds of things do you do when you're alert or watchful?)*

[If not clear:] ***(What causes you to react this way? Do you feel like you're in danger or threatened in some way? Do you feel that way more than most people would in the same situation?)***

0 *Absent*

1 *Mild / subthreshold*

2 *Moderate / threshold*

3 *Severe / markedly elevated*

4 *Extreme / incapacitating*

<u>Circle</u>: Hypervigilance = *Minimal* *Clearly Present* *Pronounced* *Extreme*

How much of the time in the past month have you felt that way, as a percentage? *% of time* _____

Did being especially alert or watchful start or get worse after (EVENT)? *(Do you think it's related to [EVENT]? How so?)* <u>Circle</u>: Trauma-relatedness = *Definite* *Probable* *Unlikely*

Key rating dimensions = frequency / intensity of hypervigilance

Moderate = some of the time (20-30%) / hypervigilance clearly present, e.g., watchful in public, heightened awareness of threat

Severe = much of the time (50-60%) / pronounced hypervigilance, e.g., scans environment for danger, may have safety rituals, exaggerated concern for safety of self/family/home

18. (E4) Exaggerated startle response.

In the past month, have you had any <u>strong</u> <u>startle</u> reactions?

What kinds of things made you startle?

How strong are these startle reactions? *(How strong are they compared to how most people would respond? Do you do anything other people would notice?)*

How long does it take you to recover?

0 *Absent*

1 *Mild / subthreshold*

2 *Moderate / threshold*

3 *Severe / markedly elevated*

4 *Extreme / incapacitating*

<u>Circle</u>: Startle = *Minimal* *Clearly Present* *Pronounced* *Extreme*

How often has this happened in the past month? *# of times* _____

Did these startle reactions start or get worse after (EVENT)? *(Do you think it's related to [EVENT]? How so?)*
Circle: Trauma-relatedness = *Definite Probable Unlikely*

Key rating dimensions = frequency / intensity of startle

Moderate = at least 2 X month / startle clearly present, some difficulty recovering

Severe = at least 2 X week / pronounced startle, sustained arousal, considerable difficulty recovering

19. (E5) Problems with concentration.

In the past month, have you had any <u>problems</u> with <u>concentration</u>?

Can you give me some examples?

Are you able to concentrate if you really try?

[If not clear:] ***(Overall, how much of a problem is this for you? How would things be different if you didn't have problems with concentration?)***

<u>Circle</u>: Problem concentrating = *Minimal Clearly Present Pronounced Extreme*

How much of the time in the past month have you had problems with concentration, as a percentage? % *of time* _____

Did these problems with concentration start or get worse after (EVENT)? *(Do you think they're related to [EVENT]? How so?)* <u>Circle</u>: Trauma-relatedness = *Definite Probable Unlikely*

0 *Absent*

1 *Mild / subthreshold*

2 *Moderate / threshold*

3 *Severe / markedly elevated*

4 *Extreme / incapacitating*

Key rating dimensions = frequency / intensity of concentration problems

Moderate = some of the time (20-30%) / problem concentrating clearly present, some difficulty but can concentrate with effort

Severe = much of the time (50-60%) / pronounced problem concentrating, considerable difficulty even with effort

20. (E6) Sleep disturbance (e.g., difficulty falling or staying asleep or restless sleep).

In the past month, have you had any problems <u>falling</u> or <u>staying</u> asleep?

What kinds of problems? *(How long does it take you to fall asleep? How often do you wake up in the night? Do you wake up earlier than you want to?)*

How many total hours do you sleep each night?

0 *Absent*

1 *Mild / subthreshold*

2 *Moderate / threshold*

3 *Severe / markedly elevated*

4 *Extreme / incapacitating*

How many hours do you think you should be sleeping?

Circle: Problem sleeping = *Minimal* *Clearly Present* *Pronounced* *Extreme*

How often in the past month have you had these sleep problems? *# of times* _____

Did these sleep problems start or get worse after (EVENT)? *(Do you think they're related to [EVENT]? How so?)* Circle: Trauma-relatedness = *Definite* *Probable* *Unlikely*

Key rating dimensions = frequency / intensity of sleep problems

Moderate = at least 2 X month / sleep disturbance clearly present, clearly longer latency or clear difficulty staying asleep, 30-90 minutes loss of sleep

Severe = at least 2 X week / pronounced sleep disturbance, considerably longer latency or marked difficulty staying asleep, 90 min to 3 hrs loss of sleep

Criterion F: Duration of the disturbance (Criteria B, C, D, and E) is more than 1 month.

21: Onset of symptoms.

[If not clear:] **When did you first start having (PTSD SYMPTOMS) you've told me about?** *(How long after the trauma did the start? More than six months?)*

Total # months delay in onset _____

With delayed onset (>6 months)?

NO YES

22: Duration of symptoms.

[If not clear:] **How long have these (PTSD SYMPTOMS) lasted altogether?**

Total # months duration _____

Duration more than 1 month?

NO YES

Criterion G: The disturbance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.

23: Subjective distress.

Overall, in the past month, how much have you been bothered by these (PTSD SYMPTOMS) you've told me about? [Consider distress reported on earlier items]

0 ***None***

1 ***Mild, minimal distress***

2 ***Moderate, distress clearly present but still manageable***

3 ***Severe, considerable distress***

4 ***Extreme, incapacitating distress***

24: Impairment in social functioning.

In the past month, have these (PTSD SYMPTOMS) affected your relationships with other people? How so? [Consider impairment in social functioning reported on earlier items]

0 ***No adverse impact***

1 ***Mild impact, minimal impairment in social functioning***

2 ***Moderate impact, definite impairment but many aspects of social functioning still intact***

3 ***Severe impact, marked impairment, few aspects of social functioning still intact***

4 ***Extreme impact, little or no social functioning***

25: Impairment in occupational or other important area of functioning.

[If not clear:] **Are you working now?**

[If yes:] **In the past month, have these (PTSD SYMPTOMS) affected your work or your ability to work? How so?**

[If no:] **Why is that?** (Do you feel that your (PTSD SYMPTOMS) are related to you not working now? How so?)

[If unable to work because of PTSD symptoms, rate at least 3=Severe. If unemployment is not due to PTSD symptoms, or if the link is not clear, base rating only on impairment in other important areas of functioning]

Have these (PTSD SYMPTOMS) affected any other important part of your life? [As appropriate, suggest examples such as parenting, housework, schoolwork, volunteer work, etc.] **How so?**

0 ***No adverse impact***

1 ***Mild impact, minimal impairment in occupational/other important functioning***

2 ***Moderate impact, definite impairment but many aspects of occupational/other important functioning still intact***

3 ***Severe impact, marked impairment, few aspects of occupational/other important functioning still intact***

4 ***Extreme impact, little or no occupational/other important functioning***

Global Ratings.

26: Global Validity.

Estimate the overall validity of responses. Consider factors such as compliance with the interview, mental status (e.g., problems with concentration, comprehension of items, dissociation), and evidence of efforts to exaggerate or minimize symptoms.

0 ***Excellent, no reason to suspect invalid responses***

1 ***Good, factors present that may adversely affect validity***

2 ***Fair, factors present that definitely reduce validity***

3 ***Poor, substantially reduced validity***

4 ***Invalid responses, severely impaired mental status or possible deliberate "faking bad" or "faking good"***

27: Global Severity.

Estimate the overall severity of PTSD symptoms. Consider degree of subjective distress, degree of functional impairment, observations of behaviors in interview, and judgement regarding reporting style.

0 ***No clinically significant symptoms, no distress and no functional impairment***

1 ***Mild, minimal distress or functional impairment***

2 ***Moderate, definite distress or functional impairment***

3 ***Severe, considerable distress or functional impairment, limited functioning even with effort***

4 ***Extreme, marked distress or marked impairment in two or more major areas of functioning***

CAPS-5 SUMMARY SHEET

Name:_____ ScreeningID:_____
Interviewer:_____ Study: RAPID Date:_____

A. Exposure to actual or threatened death, serious injury, or sexual violence		
Criterion A met?	**0 = NO**	**1 = YES**

B. Intrusion symptoms (need 1 for diagnosis)		***Past Month***	
Symptom	***Sev***	***Sx (Sev ≥ 2)?***	
(1) B1 – Intrusive memories		**0 = NO**	**1 = YES**
(2) B2 – Distressing dreams		**0 = NO**	**1 = YES**
(3) B3 – Dissociative reactions		**0 = NO**	**1 = YES**
(4) B4 – Cued psychological distress		**0 = NO**	**1 = YES**
(5) B5 – Cued physiological reactions		**0 = NO**	**1 = YES**
B subtotals	***B Sev =***	***# B Sx =***	

C. Avoidance symptoms (need 1 for diagnosis)		***Past Month***	
Symptom	***Sev***	***Sx (Sev ≥ 2)?***	
(6) C1 – Avoidance of memories, thoughts, feelings		**0 = NO**	**1 = YES**
(7) C2 – Avoidance of external reminders		**0 = NO**	**1 = YES**
C subtotals	***C Sev =***	***# C Sx =***	

D. Cognitions and mood symptoms (need 2 for diagnosis)		***Past Month***
Symptoms	***Sev***	***Sx (Sev ≥ 2)?***

(8) D1 – Inability to recall important aspect of event	**0 = NO 1 = YES**	
(9) D2 – Exaggerated negative beliefs or expectations	**0 = NO 1 = YES**	
(10) D3 – Distorted cognitions leading to blame	**0 = NO 1 = YES**	
(11) D4 – Persistent negative emotional state	**0 = NO 1 = YES**	
(12) D5 – Diminished interest or participation in activities	**0 = NO 1 = YES**	
(13) D6 – Detachment or estrangement from others	**0 = NO 1 = YES**	
(14) D7 – Persistent inability to experience positive emotions	**0 = NO 1 = YES**	
D subtotals	***D Sev =***	***# D Sx =***

E. Arousal and reactivity symptoms (need 2 for diagnosis)	***Past Month***	
Symptom	***Sev***	***Sx (Sev ≥ 2)?***
(15) E1 – Irritable behavior and angry outbursts	**0 = NO 1 = YES**	
(16) E2 – Reckless or self-destructive behavior	**0 = NO 1 = YES**	
(17) E3 – Hypervigilance	**0 = NO 1 = YES**	
(18) E4 – Exaggerated startle response	**0 = NO 1 = YES**	
(19) E5 – Problems with concentration	**0 = NO 1 = YES**	
(20) E6 – Sleep disturbance	**0 = NO 1 = YES**	
E subtotals	***E Sev =***	***# E Sx =***

PTSD totals	***Past Month***	
Totals	***Total Sev***	***Total # Sx***
Sum of subtotals (B+C+D+E)		

F. Duration of disturbance	***Current***	
(22) Duration of disturbance ≥ 1 month?	**0 = NO**	**1 = YES**

G. Distress or impairment (need 1 for diagnosis)	***Past Month***	
Criterion	***Sev***	***Cx (Sev ≥ 2)?***
(23) Subjective distress	**0 = NO 1 = YES**	
(24) Impairment in social functioning	**0 = NO 1 = YES**	

(25) Impairment in occupational functioning		**0 = NO**	**1 = YES**
G subtotals	***G Sev =***	***# G Cx =***	

Global ratings	***Past Month***
(26) Global validity	
(27) Global severity	

PTSD diagnosis	***Past Month***	
PTSD PRESENT – ALL CRITERIA (A-G) MET?	**0 = NO**	**1 = YES**

Appendix P – The Client Satisfaction Questionnaire (CSQ-8)

Centre for Trials Research
Canolfan Ymchwil Treialon

RAPID

NCMH
National Centre for Mental Health

UKCRC Registered Clinical Trials Units

CRF30i: CSQ-8 16wk

Site ID ☐☐☐ **PID** ☐☐☐☐ **Patient Initials** ☐☐☐ **Patient DOB** D D / M M / Y Y Y Y **Date of visit** D D / M M / Y Y Y Y

Please answer some questions about the help that you have received. We are interested in your honest opinions, whether they are positive or negative. *Please CIRCLE your answers and please answer all of the questions.*

1. How would you rate the quality of treatment you received?	4 Excellent	3 Good	2 Fair	1 Poor
2. Did you get the kind of treatment you wanted?	1 No, definitely not	2 No, not really	3 Yes, generally	4 Yes, definitely
3. To what extent has our treatment met your needs?	4 Almost all of my needs have been met	3 Most of my needs have been met	2 Only a few of my needs have been met	1 None of my needs have been met
4. If a friend were in need of similar help, would you recommend the treatment to him or her?	1 No, definitely not	2 No, I don't think so	3 Yes, I think so	4 Yes, definitely
5. How satisfied are you with the amount of help you received?	1 Quite dissatisfied	2 Indifferent or mildly dissatisfied	3 Mostly satisfied	4 Very satisfied
6. Has the treatment you received helped you to deal more effectively with your problems?	4 Yes, it helped a great deal	3 Yes, it helped somewhat	2 No, it really didn't help	1 No, it seemed to make things worse
7. In an overall, general sense, how satisfied are you with the treatment you received?	4 Very satisfied	3 Mostly satisfied	2 Indifferent or mildly satisfied	1 Quite dissatisfied
8. If you were to seek help again, would you come back to receive the treatment?	1 No, definitely not	2 No, I don't think so	3 Yes, I think so	4 Yes, definitely

Completed by: **Name:** ☐☐☐☐☐☐☐☐☐☐ **Signature:** ☐☐☐☐☐☐☐☐☐☐ **Date completed:** D D / M M / Y Y Y Y

CTR use only

Date received: D D / M M / Y Y Y Y **Received by (initials):** ☐☐☐ **Date entered** D D / M M / Y Y Y Y **Entered by (initials):** ☐☐☐

Once completed this form should be sent to: RAPID, Centre for Trials Research, 4th Floor Neuadd Meirionnydd, Cardiff University, Heath Park, Cardiff, CF14 4YS

Appendix Q – The Agnew Relationship Measure (ARM-5), client/patient version

CRF31: ARM-5 (current therapy)

Site ID | **PID** | **Patient Initials** | **Patient DOB** (D D / M M / Y Y Y Y) | **Date of visit** (D D / M M / Y Y Y Y)

Thinking about your sessions with your therapist, please indicate how strongly you agree or disagree with each statement:

	Strongly Disagree	Disagree	Some-what Disagree	Neither Agree nor Disagree	Some-what Agree	Agree	Strongly Agree
1. My therapist is supportive							
2. My therapist and I agree about how to work together							
3. My therapist and I have difficulty work-ing jointly as a partnership							
4. I have confidence in my therapist and his/her techniques							
5. My therapist is confident in him/herself and his/her techniques							

Completed by: **Name:** | **Signature:** | **Date completed:** (D D / M M / Y Y Y Y)

CTR use only

Date received: (D D / M M / Y Y Y Y) | **Received by (initials):** | **Date entered** (D D / M M / Y Y Y Y) | **Entered by (initials):**

Once completed this form should be sent to: RAPID, Centre for Trials Research, 4th Floor Neuadd Meirionnydd, Cardiff Uni-versity, Heath Park, Cardiff, CF14 4YS

Appendix R – The Agnew Relationship Measure (ARM-5), therapist version

CRF32: RAPID Therapist ARM-5 (current therapy)

Please complete this questionnaire three weeks after you commence therapy with the participant.

Site ID: ☐☐☐ Pt ID: ☐☐☐ Pt Initials: ☐☐☐ Today's Date: ☐☐/☐☐/☐☐☐☐ (d d / m m / y y y y)

Thinking about your sessions with your client, please indicate how strongly you agree or disagree with each statement:

Statement about session with your client	Strongly Disagree	Disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Agree	Strongly Agree
I feel I was supportive with my client							
My client and I agree about how to work together							
My client and I have difficulty working jointly as a partnership							
My client has confidence in me and my techniques							
I feel confident in myself and my techniques							

Name of therapist: ..... **Signature:** .....

For CTR staff only:

Received date:	*Received by (initials):*	*Entered date:*	*Entered by (initials):*
☐☐/☐☐/☐☐☐☐	☐☐☐	☐☐/☐☐/☐☐☐☐	☐☐☐

Appendix S – RAPID therapist record sheet

Centre for Trials Research
Canolfan Ymchwil Treialon

RAPID

NCMH

CRF29: RAPID Therapist Record Sheet

Please complete one of these sheets any time you conduct a therapy session, contact a patient, write notes or spend any other time in relation to a trial participant.

Site ID: ☐☐ Pt ID: ☐☐☐ Pt Initials: ☐☐☐ Today's Date: ☐☐/☐☐/☐☐☐☐ (d d m m y y y y)

Is this a therapy contact? Yes ☐ *(Complete 1a-1h & sign)* No ☐ *(Complete 2a – 2b & sign)*

1a. Session number ☐☐

1b. Contact type: Face to face ☐ Phone/web call ☐ Email ☐

1c. Length of the session *(excluding notes/prep work/clinical measures)* ☐☐ (min)

1d. Time spent on preparatory work/note writing for session *(enter 00 if N/A)* ☐☐ (min)

1e. What percentage of the session was trauma-focused (as opposed to discussing issues unrelated to the trauma)? ☐☐☐ (%)

1f. Interventions/Steps covered:

.....

.....

.....

1g. Homework completion *(select only 1)*: As agreed ☐ Partial ☐ Not completed ☐

1h. Comments:.....

.....

.....

.....

2a. If not a therapy contact, what was the nature of the activity? *(only 1 activity per sheet)*

Check-in ☐ Unplanned Contact ☐ Admin/notes unrelated to specific session ☐

Other (Specify _____)

2b. Time spent on activity in 2a. ☐☐☐ (min)

Name of therapist: ..... **Signature:** .....

For CTR staff only:			
Received date: ☐☐/☐☐/☐☐☐☐	*Received by (initials):* ☐☐☐	*Entered date:* ☐☐/☐☐/☐☐☐☐	*Entered by (initials):* ☐☐☐

Once completed this form should be sent to:
RAPID, Centre for Trials Research, 4th Floor Neuadd Meirionnydd, Cardiff University, Heath Park, Cardiff, CF14 4YS

Topic Guide

- **Before the interview**

INTRODUCTION: Thank you for agreeing to speak with me today. As we discussed when we booked this interview, I am interested in hearing about your experience and thoughts on the treatment you have received as a participant in the RAPID Trial. As before, I will record our conversation and it will be transcribed (typed out, like a script/written record) however only direct members of the team and myself will have access to it. Your recording and script will not be labelled with any information that directly identifies you; they will be labelled as participant 1, 2, 3 etc. We will anonymise these records as much as we can to protect your identity as far as possible. I'd like to check that you are still happy to talk with me today and have the conversation recorded. Do you have any questions for me before we get started? Thank you – I am really keen to hear your opinions in your own words, and although I will be asking you questions, there are no right or wrong answers, anything you can tell me will be really helpful. You do not have to answer anything you do not want to and if you are unsure of a question, just let me know. Also, if you start to feel uncomfortable or overwhelmed in any way, please let me know at any time during our chat, we can take a break or stop the conversation all together.	
Part 1. Trial Processes So these first questions are reflecting on your experience of taking part in the trial.	
Questions	**Probes**
Looking back, how has it been for you taking part in this trial? How well informed do you think you were before taking part?	What did you think of how you were informed about the trial and taking part? What did you think about the paperwork assessments completed before and after treatment? How relevant was the information you received?

Was taking part what you had expected? Can you think of anything that might help improve people's involvement in this type of study?	What about the time needed/commitment to treatment programme? What changes/improvement could we make?

Part 2. Patient context The next question is about your views about your diagnosis of PTSD.	
Question	**Probes**
When we last spoke you mentioned . . . about your diagnosis and experience; I'm wondering if your views about PTSD have changed since then?	Knowledge of symptoms Feelings about PTSD diagnosis now Term PTSD – helpful or not – syndrome/illness/psychological injury

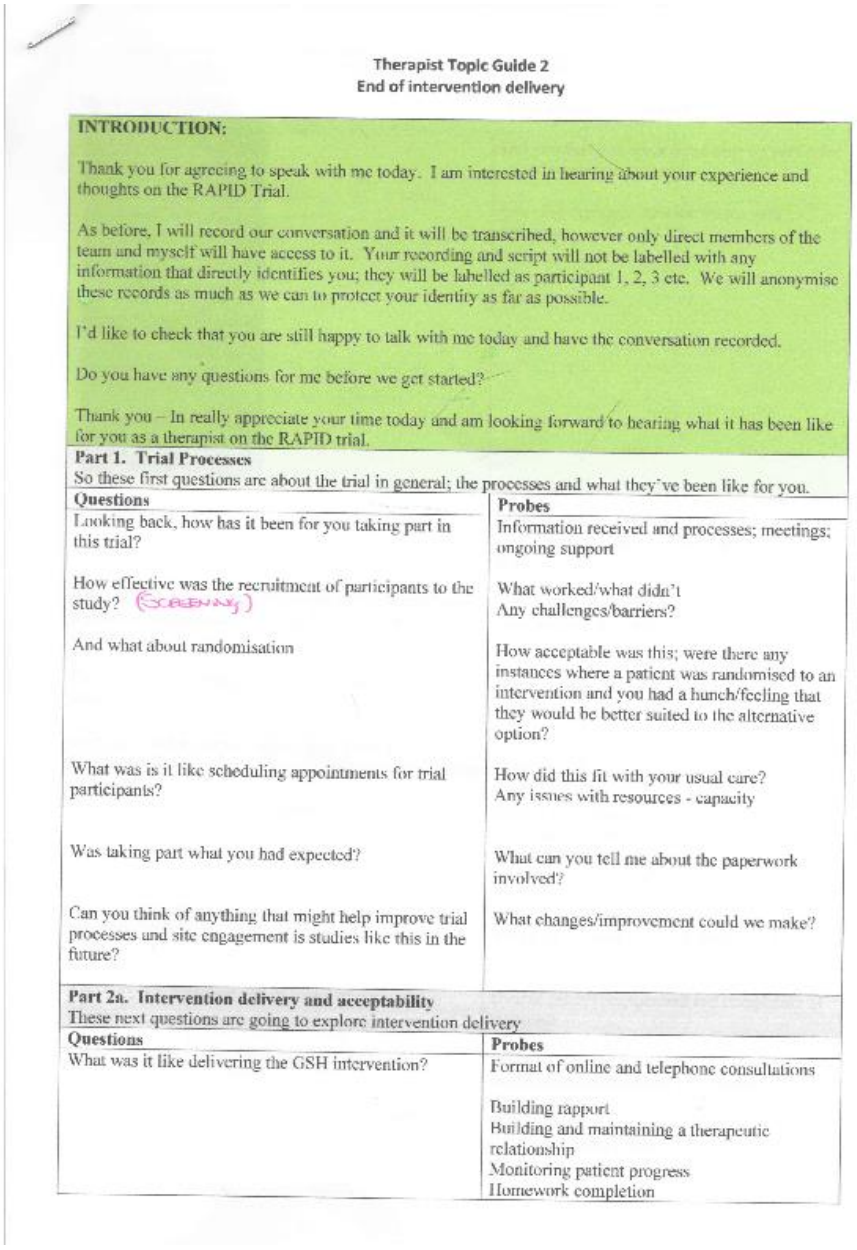
Part 3. Treatment – This is a key part of the process evaluation and therefore probes in detail essential! The next questions are concerned with your views of treatment.	
Questions	**Probes**
Can you tell me what you thought about the treatment you received in this trial; maybe describe to me what was involved? When you entered the trial, you said …….. about the treatment options and I'm wondering if	Did you face any challenges/barriers/motivation issues? Attending all appointments Length of treatment Working with therapist Use of technology / technology issues – GSH arm Homework completion Motivation Is there anything else you can think of that either made it more difficult or easier to take part in the treatment? How has the treatment you received compare to your thoughts before taking part? Were your expectations met?

your views about this have changed at all?	Think how you might explain your treatment to a friend?
What do you understand now about the treatment you received and how you think it might work?	How has it fitted with your lifestyle and day-to-day activities? Maybe use a scale with 0 being no effort at all
How would you describe the commitment and effort needed to take part in the treatment?	Think about appointments/tasks Input from the therapist What happened between meetings/contact with the therapist? Were they very hands-on/accessible or distant?
And what about the therapist, how would you describe their involvement?	Understanding, processes, homework What was easy/difficult about the treatment? Were there times when it was easier than others to do the treatment? Tell me more . . .
Did you feel able to follow and complete the treatment offered to you?	What makes you say that? Details and reasoning behind perceived side-effects and how these symptoms were perceived in relation to PTSD diagnosis.
Do you think you experienced any side effects from the treatment?	What do you think worked about the treatment? Any things that you think didn't work so well?
How well did the treatment you receive work for you?	And what about any additional benefits such as raised awareness of PTSD and symptoms, technology as an empowering treatment aid?
Can you tell me the best and worst aspects of the treatment you received?	Relationship with therapist Attending/completing sessions Completing homework – specific tasks? Anything else that made it easier/worse?
How likely are you to look for other treatment or help?	Why is that?
Overall, how do you feel about the treatment you received?	How much has it helped, if at all?

	The impact on your day-to-day activities; work and home?
And what about relationships with family and friends; has the treatment had any impact here?	What, if anything have you shared with them? Is it something that you would recommend; what would you say about it?
Have you undertaken any other treatments for your PTSD whilst taking part in the trial? And what about any medicines prescribed?	What do you plan to do next, if anything? What were they? Who provided them? How long did they last? What was involved?
What about other psychological help, such as counselling or other therapy? And what about taking part in any social, group or community activities for support?	What motivated you to do this; what did you do; what was it like; benefits/cons?
Have you looked for other help/information about your condition whilst taking part in the trial? In this study we are looking at two types of treatment for PTSD. This means that participants taking part experience either GSH or CBT. On reflection, what are your thoughts now about the treatment you did not receive? Have your impressions of counselling and talking therapies changed since participating in the Trial? Is there anything else about the trial or treatment you would like to tell me about that we haven't covered in the questions?	
Next steps:	

That is the end of my questions, thank you so much for taking the time to talk with me today.
It's been really useful to understand your personal experiences and your participation in the RAPID Trial

Appendix U – Therapist post-delivery qualitative interview topic guide



Therapist Topic Guide 2
End of intervention delivery

INTRODUCTION:

Thank you for agreeing to speak with me today. I am interested in hearing about your experience and thoughts on the RAPID Trial.

As before, I will record our conversation and it will be transcribed, however only direct members of the team and myself will have access to it. Your recording and script will not be labelled with any information that directly identifies you; they will be labelled as participant 1, 2, 3 etc. We will anonymise these records as much as we can to protect your identity as far as possible.

I'd like to check that you are still happy to talk with me today and have the conversation recorded.

Do you have any questions for me before we get started?

Thank you – In really appreciate your time today and am looking forward to hearing what it has been like for you as a therapist on the RAPID trial.

Part 1. Trial Processes
So these first questions are about the trial in general; the processes and what they've been like for you.

Questions	Probes
Looking back, how has it been for you taking part in this trial?	Information received and processes; meetings; ongoing support
How effective was the recruitment of participants to the study? (SCREENING)	What worked/what didn't Any challenges/barriers?
And what about randomisation	How acceptable was this; were there any instances where a patient was randomised to an intervention and you had a hunch/feeling that they would be better suited to the alternative option?
What was is it like scheduling appointments for trial participants?	How did this fit with your usual care? Any issues with resources - capacity
Was taking part what you had expected?	What can you tell me about the paperwork involved?
Can you think of anything that might help improve trial processes and site engagement is studies like this in the future?	What changes/improvement could we make?

Part 2a. Intervention delivery and acceptability
These next questions are going to explore intervention delivery

Questions	Probes
What was it like delivering the GSH intervention?	Format of online and telephone consultations Building rapport Building and maintaining a therapeutic relationship Monitoring patient progress Homework completion

The 8 steps of Spring: Step 1: Learning About My PTSD Step 2: Managing My Anxiety Step 3: Grounding Myself Step 4: Reclaiming My Life Step 5: Coming To Terms With My Trauma Step 6: Changing My Thoughts Step 7: Overcoming My Avoidance Step 8: Keeping Myself Well	Motivating patient What worked well and what didn't? Did you find you spent more time on particular steps/less time on others? Use of technology; specific issues with technology
What are your thoughts on the length of treatment?	Are you able to share any experience of when a participant may have needed shorter or longer treatment?
Any particular barriers to delivering the treatment' any aspects of the treatment that you found difficult or challenging?	Use of technology; in-between contact Own professionalism/experience
Did some people engage in GSH treatment more than others?	What can you tell me about their context, trauma and circumstances?

Part 2b. Intervention delivery and fidelity These next few questions focus on delivery and consistency of approach	
Questions	**Probes**
Was GSH delivered as you planned?	What do you think helped you facilitate the GSH intervention? Was there anything you did that made delivery easier in your practice?
What can you tell me about your experiences of delivering GSH at the start compared to the end of the trial?	Did you develop any particular techniques or strategies for working as the trial progressed?
Anything that surprised you or found of particular interest?	Overall patient engagement and completion of treatment
How comparable is the GSH intervention to TFCBT?	Building rapport Building and maintaining a therapeutic relationship Monitoring patient progress Homework completion Motivating patient

Part 3. Intervention sustainability These next couple of questions explore intervention sustainability	
Questions	**Probes**
What are your thoughts about future roll out of the GSH intervention?	What are the potential benefits? What are the potential barriers for therapists?
How does the GSII intervention fit within existing provision?	How does GSII align with service priorities? How does it align with local health agenda?
How well did the training equip you for delivery of GSH?	What was helpful/unhelpful Sufficient information/time/ Develop proficiency
What would supervision look like?	Similarities to existing supervision Any adaptions to existing supervision?
What recommendations would you suggest for successful rollout?	Any changes to the training/supervision?

Part 4. Mechanisms These final questions are interested in the mechanisms of the GSH intervention	
Questions	**Probes**
Do you think the GSII worked as hypothesised?	Any elements in particular that worked well? Any elements not needed?
What can you tell me about the active ingredients from TFCBT that were particularly pertinent to the delivery of GSII?	
What can you tell me about the feedback from patients about the GSII intervention?	What did they like? What didn't they like?
Is there anything else that you think would be useful for me to know about the trial and delivery of GSII?	

Thank you so much for taking the time to speak with me today.

Appendix V –NHS commissioners and managers qualitative interview topic guide

Semi-structured interview - *Open-ended questions with related prompts.*

1. <u>Describing their role</u>

1.1 Could you tell me about your post and your organisation?

Prompt: funder level / strategic / operational

1.2 What sort of impact might your role, and any decisions that you make, have on patient access to mental health treatment, including PTSD treatment?

Prompt: implementation opportunities / budget restrictions

2. <u>Current treatment for mental health, PTSD</u>

2.1 Can you tell me about the mental health psychological treatment services and interventions you are currently involved with, whether it be in terms of signposting, funding or implementing?

Prompt: group / individual therapy / internet-based programmes, scope, remit

2.2 Can you tell me about your understanding of timely access to current mental health psychological treatment and intervention, and about barriers and facilitators to these treatments and interventions?

Prompt: waiting lists / access to timely treatment / opportunities from minimal-contact therapies

2.3 Can you explain the process by which your organisation plans, and makes operational, access to mental health interventions, including PTSD treatment interventions?

Prompt: Matrics Cymru, service user involvement, Board and Committee decision, NICE recommendations, Governmental documents

2.4 And can you tell me how your organisation measures access to mental health treatment interventions?

Prompt: Matrics Cymru / Committee Review / Patient feedback / Patient-reported outcome measures/Waiting Lists

3. <u>Facilitating access to internet-based healthcare interventions</u>

3.1 Do you have any experience of facilitating access to internet-based healthcare interventions, in your current role, or in any previous role(s)? And if so, can you share your reflections on the positives and negatives of internet-based healthcare interventions?

Prompt: enabling any helpful aspects / constraining any less helpful aspects

3.2 [if no prior experience]: What is your impression of internet-based healthcare interventions, particularly of those guided by a therapist?

Prompt: potential benefits and opportunities / empowerment / treatment accessibility / potential concerns and less helpful aspects / internet and technology as a barrier

3.3 What factors might facilitate, or be a barrier to, deciding to commission or provide access to a guided internet-based healthcare intervention in your role / organisation?

Prompt: evidence base / budget / cost-effectiveness / investment / availability of guidance / would intervention be additional to, or would it need to replace access to, current interventions?

3.4 If a decision were made to implement a guided internet-based healthcare intervention what information, resources and training materials might you need from the intervention developers in order to facilitate access?

Prompt: technology and equipment / training and supervision / treatment manual with guidance specifications / information back-up / access to troubleshooting for software and technology queries?

At this point individuals will be shown a brief demonstration of the i-CBT 'Spring' intervention programme, and provided with information on the level of therapist guidance provided.

4. <u>Overall impression of the i-CBT programme, 'Spring'</u>

4.1 What is your overall impression of the i-CBT programme, 'Spring'? We are interested in, and value, all opinions, whether they are positive or negative.

Prompt: Helpful aspects / less helpful aspects / have you seen anything like this before?

4.2 What is your overall impression of this method of PTSD treatment delivery?

Prompt: Accessibility /unfamiliarity with technology / patient choice / necessity for therapist / limited human contact

5. Summary

5.1 Is there anything you'd like to add that you think is relevant or important that you have not had a chance to comment on yet?

Thank participant

Appendix W - References of systematic review excluded studies

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