Faculty of Health Sciences and Sport

A Process Evaluation to Determine the Barriers and Facilitators to Implementation of a Cognitive Behavioural Therapy for Psychosis Treatment Programme in a High Secure Setting

Thesis submitted for the degree of Doctor of Nursing.

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If men define situations as real, they are real in their consequences.

Thomas Theorem, (Thomas and Thomas, 1928).

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ABSTRACT

Aims

Up to 80% of patients in a high secure hospital in Scotland have a diagnosis of schizophrenia or other psychosis. However, despite limitations in delivering cognitive behavioural therapy for psychosis (CBTp) in forensic settings, clinical guidelines continue to recommend that all patients who experience persisting psychotic symptoms and /or depression, or who are in remission, should receive CBTp. A process evaluation was therefore conducted to understand the barriers and facilitators to delivering a bespoke forensic CBTp intervention in this setting.

Method

The study had three distinct phases. Phase 1 was a retrospective review of case notes (n=60); Phase 2 involved interviews with therapists (n=9) who were providing CBTp, and Phase 3 was a Delphi survey of experts informed by phases 1 and 2.

Results

There was poor adherence to the current psychological intervention. There were three main *barriers*: manual related factors (e.g. manual complexity); therapist related factors (e.g. preparedness of therapist to deliver CBTp); and environmental factors (e.g. negotiating security or risk issues). *Facilitators* also included factors related to the therapist (e.g. receipt of clinical supervision) and factors related to the manual (e.g. acceptability to patients). Expert consensus was much in keeping with the established evidence base and clinical guidelines for CBTp delivery in non-forensic settings.

Conclusion

To support consistent implementation of a manualised CBTp treatment intervention in a forensic setting: a clearly structured and accessible treatment manual for therapists is required; therapists' training requires to be updated and repeated on a regular basis; it is necessary to ensure governance and supervision structures are in place;

and it is advisable to utilise a CBTp adherence scale to support therapist development. Potentially it may also be appropriate for this type of intervention to be delivered by a small group of specialist practitioners, rather than a larger group of generalist practitioners.

Personal position, organisational role, and potential conflicts

I agree with Fowler et al's (1995) position that developing an understanding of the psychological processes that determine how an individual attempts to make sense of their experience of psychosis, and how they may then act in relation to this, is central to the practice of cognitive behavioural therapy for psychosis (CBTp) (Fowler et al. 1995). I also believe that developing this level of understanding becomes even more critical when implementing CBTp in a forensic setting. For example, where an individual may have made sense of a psychotic experience (perhaps a bullying and commanding 'voice'), by physically attacking someone to counter the perceived threat and associated distress they may have felt in response to this.

In 2001, I began working as a nurse psychotherapist within the newly established Psychosocial Interventions (PSI) Team at The State Hospital. It was at that time that my interest in CBTp was piqued; mainly due to the work of the hugely inspirational psychology colleagues I had just joined - Dr Karen Allan and Professor Andrew Gumley - who were developing a bespoke CBTp treatment programme ('CBTp (f)') for use in this high secure hospital (HSH) (Allan et al. 2002). In our team discussions about this emerging new treatment, I recognised the potential benefits to patients of engaging in CBTp (f) to support their recovery from mental illness and help reduce their risk. Whilst it was apparent that there was an established evidence base for CBTp (e.g. Kuipers et al. 1997; Tarrier et al. 1998), and it was one the primary treatments recommended in clinical guidelines (NICE 2002), it was also clear, from the small amount of literature available at the time, that there were limitations in delivering this complex intervention in HSH settings (e.g. Bentall and Haddock 2000; Benn 2002). I recognised this as an area of potential health inequality and became interested in trying to help address this.

My initial role and remit within the PSI team was to jointly lead the CBTp (f) programme, and act as a CBTp (f) implementer (a treating therapist) and intervention co-developer. In 2003, I also became an intervention evaluator when I conducted a

'within-subjects' single case series of the CBTp (f) programme (Cawthorne 2003). I recognised that this initial outcome evaluation was extremely limited. This was partly due to its small scale, but mainly because it focussed solely on the evaluation of outcomes. It did not help to explain what *processes* were required for successful implementation of CBTp (f), or why referrals for CBTp (f) began to steadily drop off in the ensuing 16-years since its inception (McLay 2017). Having noticed what was happening with ongoing attempts at implementation of CBTp (f) within this HSH, I contrasted this with what was happening with CBTp implementation nationally, and in non-forensic services. I discovered that many similar implementation difficulties were also being experienced and reported (e.g. Haddock et al. 2014; Ince et al. 2016). This further fuelled my interest in trying to help address this difficulty and acted as the catalyst for undertaking the research described in this thesis.

At present, I continue to have the same multiple roles and remit: *joint programme lead*, *intervention developer*, *implementer*, and *evaluator*. As a 'forensic' practitioner in the literal sense of the word, I also recognised that it was necessary for me to be transparent about these multiple roles, and to examine relationships between them; particularly those that could have led to potential conflicts of interest when undertaking this process evaluation (Audrey et al. 2006).

Critically observing the work of intervention developers and implementers is a key component of process evaluation. This presents a serious challenge to intervention evaluators who need to build and maintain good working relationships with these individuals, and yet remain sufficiently detached and independent for their evaluation to remain credible (Moore et al. 2015). Given that I fulfilled all three of these roles (and a fourth role as joint programme lead), this revealed a number of potential conflicts of interest. These were: i) the possibility that I could have evaluated and portrayed the CBTp (f) intervention too positively (mainly due to the potential conflict with my roles as programme lead, intervention developer and implementer); ii) the possibility that I could have been unduly critical of CBTp (f) implementers (the other therapists) (mainly due to the potential conflict with my roles as programme developer

and evaluator; particularly if it looked like there had been significant problems with implementation); and iii) the (perhaps less-likely) possibility that I could have evaluated and portrayed the CBTp (f) intervention too negatively, and implementation by the other therapists over-zealously (mainly due to the potential conflict with all my roles, including having a lack of an objective/external 'checking' mechanism, and/or a 'buck-stops-with-me' leadership style; especially if presented with an apparent programme 'failure', regardless of what process, or combination of processes, may actually have led to this.

To manage these potential conflicts of interest and reduce the possible influence of bias, I adopted the following strategies:

1. Research design. The types of method chosen across each phase of the process evaluation were applied, not only to achieve the research aim and objectives, but also to try to minimise the risk of bias as much as possible (Romain 2015). For the phase one study (case note review), the researcher used a specifically developed pro-forma that guided the retrospective examination of case notes and focussed on identifying whether expected components of the intervention were either present or absent. It did not focus on gathering my subjective views about the quality of previous programme implementation. For the phase two study (therapist interviews), an independent interviewer conducted these. This protected therapists' anonymity and helped to ensure that they felt free to discuss their experiences in a confidential manner. For phase three (Delphi survey), an independent panel of experts were asked to give their views on the results that had previously been synthesised by the researcher, following phases one and two. This also helped to reduce the potential for bias by giving an added independent oversight of these combined results.
2. Prior to starting the research, the researcher delivered a short presentation about it at a departmental meeting. This provided an opportunity to highlight to the therapists' group that process evaluation methodology had been specifically chosen to *help inform our combined efforts to improve the CBTp (f)*

intervention; not to assess outcomes, nor to assess whether individuals had passed or failed in terms of their CBTp (f) delivery. Ensuring that intervention staff have this understanding about process evaluation may help alleviate reservations or tensions they may have about engaging in it (Audrey et al. 2006).

3. Critical review. The researcher's doctoral supervisors were both independent of the HSH and had prior experience of the delivery of process evaluations. This meant that they were well placed to provide the researcher with occasional opportunities to critically reflect on her multiple roles and the potential for conflicts of interest to emerge from these. These occasional critical reflection meetings also helped to ensure that the researcher's interpretation of results remained grounded in the actual data generated throughout the study and did not e.g. veer off in a more subjective direction, which may have compromised the integrity of the research. This type of occasional critical peer/external review is recommended by Moore et al (2015) as a useful strategy for managing potential role conflicts when conducting a process evaluation.

Further detail regarding potential conflicts of interest and risks associated with the research are highlighted and discussed in Chapter 4, 'Method', of the ensuing thesis.

CHAPTER ONE: Introduction to thesis

This chapter introduces the reader to the specialist nature and context of the service - a HSH, where the research took place. It outlines the background and rationale for the study. In doing so, it emphasises the links between the research and the author's current area of practice. The overall aim of the study is described, together with the research objectives and method used. The potential significance and intended original contribution that this study will make to practice, and *why this was needed* is then explained, thereby creating the 'warrant' for the research (Thomson 2018). The chapter concludes with a description of the organisation of the remainder of the thesis

1.1 Overview of The State Hospital

This study was conducted at a single site; The State Hospital, located in central Scotland. The State Hospital is one of four National Health Service (NHS) HSHs in the UK (the other three being Ashworth, Broadmoor, and Rampton Hospitals, all located in England). The State Hospital is the only high secure treatment facility for all-male patients from Scotland and Northern Ireland. On the rare occasion that a female patient in Scotland requires care and treatment under conditions of high security, a cross-border transfer to Rampton Hospital occurs (Rampton Hospital and Forensic Network 2014).

Following a review of the forensic estate in Scotland, a 'new' State Hospital was commissioned and opened in 2011. This has 144 beds (four for emergency use), spread across four hub areas, each with three x 12-bedded wards. Twelve beds are specifically for patients with an intellectual disability. Bed occupancy figures tend to fluctuate but are generally in the region of 105 – 110 patients per day. All patients are compulsorily detained under the Mental Health (Care and Treatment) (Scotland) Act 2003 or other related legislation because of their dangerous, violent, or criminal tendencies. Patients detained without convictions have displayed seriously aggressive behaviour, usually including violence (The State Hospital 2020).

The hospital has two principal aims: 1) to rehabilitate patients using the best available evidence-based care and treatment to address their difficulties with mental illness and/or personality difficulties or other problematic behaviours, and 2) to reduce their associated level of risk such that they can be safely transferred to appropriate lower levels of security (The State Hospital 2020).

Approximately 80% (n=84/105) of the patients have a diagnosis of schizophrenia (Sz) or other psychosis, as identified in the *ICD-10* manual's diagnostic coding range F20 – F29 (World Health Organisation 2016). This diagnostic range also encompasses 'schizotypal', 'delusional' or other 'non-mood psychotic disorder'. This group of patients comprises of 75% (n=78/105) who have Sz or other psychosis as a primary diagnosis, and a further 5% (n=6/105) who have this as a secondary diagnosis (Mowbray 2019).

In addition, 62% (n=52/84) have convictions for violence-related offences, 17% (n=14/84) have no formal convictions, and a further 21% (n=18/84) were given specific legal disposals of either, "Not Guilty by Reason of Insanity" (1%, n= 1/84) or, "Acquitted by Reason of Insanity" (20%, n=17/84) (Mowbray 2019). In the case of the third group, this specifically indicates that, at the time of the offence or offences giving rise to their compulsory detention, the level of active symptoms of mental illness experienced by these patients was deemed so severe that it directly affected their risk of causing harm to others, and ultimately their culpability for having committed acts of violence.

It is estimated that 35% (n=29/84) of the above cohort of patients with primary or secondary Sz or psychosis also meet diagnostic criteria for comorbid personality disorder (PD), mainly Dissocial or Emotionally Unstable types (Mowbray 2019). Further, most patients have significant histories of adverse childhood experiences and trauma, and substance misuse and poor physical health are also common (Thomson, 2008). The average age of the current patient group is 42-years old.

Average length of stay is six years (range under one month to over 30 years) (The State Hospital 2020).

1.2 Schizophrenia and psychosis: definitions, prevalence and symptoms

Sz, as described in 1.1 is a significant illness among patients in this hospital. It is a type of major mental illness that affects more than 21 million people worldwide. It is characterized by distortions in thinking, perception, emotions, speech, sense of self and behaviour. It is slightly more common in men and typically manifests in young people in their twenties (World Health Organisation 2018). It is usually lifelong and presents as a form of 'psychosis' wherein the individual loses touch with reality (Royal College of Psychiatrists 2017). This loss of touch with reality may occur through the experiencing of 'positive symptoms' such as auditory hallucinations (hearing voices), delusions (holding unusual and/or seemingly bizarre beliefs) and thought disorder (experiencing disorganised thinking, often manifested in disrupted, incoherent or irrelevant speech), and by 'negative symptoms' such as social isolation and withdrawal, reduced self-care, and blunted emotions (Scottish Intercollegiate Guidelines Network) (SIGN 2013).

1.3. Schizophrenia and psychosis: impact and complications

This has also been independently associated with an increased risk of violence (Moran 2002; Moran et al. 2003), and violent offending; particularly homicide (Fazel and Grann 2004). However, most of this additional risk appears to be mediated by substance misuse comorbidity. The risk of violence in patients with schizophrenia or other psychoses, plus comorbid substance misuse, therefore, is similar to that for substance misuse without psychosis (Fazel et al. 2009).

From a symptom-specific perspective, Bjørkly (2002a) conducted a literature review that examined potential associations between delusions and violence, and found that persecutory delusions, particularly those co-occurring with emotional distress, may increase risk of violence. Within the same review, Bjørkly (2002a, p. 617) also found that "there is limited but tentative support to the existence of an association between

symptoms of perceived threat and internal control override (TCO) and violence". However, the number of studies indicating these possible associations were found to be low. Bjørkly (2002) therefore suggested that further empirical studies should be undertaken in this area to enable more decisive conclusions to be drawn.

In an associated study, Bjørkly (2002b) also found evidence that the experience of auditory hallucinations (voices) that 'command' acts of harm towards self or others ('command hallucinations'), may lead to violent behaviour by increasing the likelihood of compliance. Birchwood et al (2004) examined the relationship between command hallucinations and compliance [or appeasement] behaviours further. Birchwood et al (2004) found that where the voice hearer *appraised the voice as having malevolent intent*, and, more importantly, *the power to deliver on this*, this combined effect could lead to compliance or appeasement behaviours. These findings were independently replicated by Fox et al (2004) in a study that focussed on examining compliance with command hallucinations with specific violent content. Fox et al (2004) identified two groups of 'compliers' and 'noncompliers' and found that, compared to the noncomplier group, the complier group perceived the command hallucination to be much more powerful. In this same study, Fox et al (2004) also used social rank theory (SRT) (Gilbert 1992) to explore relationships between the voice hearers and their voices. SRT suggests that within different social hierarchies, individuals develop perceptions about their social rank and come to view themselves as either 'inferior' or 'superior' within social interactions. Fox et al (2004) subdivided the two (complier and noncomplier) groups into 'self-harm command hearers' and 'harm-other command hearers'. After applying SRT (Gilbert 1992), Fox et al (2004) identified that 'self-harm command compliers' had significantly higher ratings of perceived inferior social rank, whilst 'harm-other command compliers' had significantly higher ratings of perceived superior social rank. This additional finding appears to suggest that beliefs about social rank may also have an important mediating effect on voice compliance.

The final outcome from this study was that compliance with violent command hallucinations was found to be much more common than non-compliance in

psychiatric patients. However, all findings from this study must be viewed as tentative due to its small size (n=32) overall, particularly within the non-compliant arm (n=8) (Fox et al. 2004).

It is also known that treatment outcomes for individuals with a dual diagnosis of severe mental illness, such as Sz and co-occurring PD, tend to be less favourable than for those with a single mental disorder, with less symptom improvement, poorer quality of life, and higher treatment dissatisfaction rates (Tyrer and Simmonds 2003).

1.4 Management and treatment

The cohort of patients described in 1.1 spend lengthy periods in hospital and are all prescribed antipsychotic medication. In many cases, a limited response is observed; thus, a significant number of these patients continue to experience persisting symptoms, some of which may or may not have a direct bearing on their actual or perceived level of risk of violence to others (Cawthorne 2017a). A recent systematic review highlighted the dearth of knowledge on the effectiveness of pharmacological treatment in forensic settings and called for future high-quality studies to be conducted in this specific area (Howner et al. 2020).

There is some evidence, albeit limited, to suggest that response and outcomes in this population may be further improved by adding a CBTp intervention to pre-existing treatment regimes. Several meta-analyses have reported small effects of CBTp in the treatment of Sz in outpatient and other non-HSH populations when combined with antipsychotic medication (e.g. Wykes et al. 2008; Jauhar et al. 2014; Turner et al. 2014) and attempts were made to consider using this approach in HSHs and other forensic mental health settings. A number of authors (Bentall and Haddock 2000; Benn 2002) report findings from studies that tested and evaluated the effectiveness of non-adapted CBTp combined with antipsychotic medication in HSH settings. Other authors later report having made some adaptations to CBTp for use in a mixture of settings, including a HSH, integrating it with additional CBT strategies for dealing with concomitant problems with anger and violence (Haddock et al. 2009). However, their

failure to address some of the unique ‘forensic’ and/or other ‘contextual’ issues, such as the presence of co-occurring offending behaviours, or comorbid PD, either within the treatment protocols used, or in relation to the outcomes achieved following their delivery, were viewed as serious limitations. As a consequence, these authors recommended that the future use of CBTp interventions in HSH settings, and any subsequent evaluations that are undertaken in relation to these, should include specific adaptations that take cognisance of these types of additional forensic and contextual factors as they may, for example, [adversely] influence overall treatment response (Bentall and Haddock 2000), or the degree to which the individual actually engages in the intervention (Haddock et al. 2009).

Despite these limitations in implementing non-adapted CBTp in HSH settings, the current clinical guidance for the NHS in Scotland recommends that, “Individual CBTp should be offered to all individuals diagnosed with schizophrenia whose symptoms have not adequately responded to antipsychotic medication and where persisting symptoms and/or depression are being experienced” (SIGN 2013, p. 5). Guidance for health and care in England and Wales has gone a step further and extended the recommendation to include any individuals diagnosed with Sz who are in remission (National Institute for Health and Care Excellence) (NICE 2014).

SIGN and NICE guidelines also recommend that CBTp should be delivered:

- on a one-to-one basis
- over at least 16 planned sessions
- according to an established treatment manual (preferably one with trial-based evidence of efficacy)
- by appropriately trained and supervised therapists

1.5 Historical challenges implementing CBTp in The State Hospital

In 2002, based on the best available evidence at that time, the programme leads for the Psychosocial Interventions (PSI) Service at The State Hospital, developed a

bespoke ‘forensic CBTp’ intervention, known as the CBTp (f) programme (Allan et al. 2002).

Throughout the development of this new complex intervention, Allan et al. (2002), followed recommended clinical guidelines and the existing evidence base for CBTp, whilst also addressing the additional forensic and other context-specific factors that were likely to be necessary to successfully implement this CBTp (f) intervention within this setting. A provisional treatment manual was developed and used to help guide therapists in their delivery of the CBTp (f) programme. (See also Chapter 3, page 42 for a detailed description of the CBTp (f) intervention).

Despite the continuing high prevalence of patients with this identified treatment need (up to 80%), it was noted that referral to the CBTp (f) intervention was steadily dropping over the 16 years since its inception. Specifically, referrals peaked in 2005, 3 years after the launch of CBTp (f), with 26 referrals at that time (equivalent to n=26/178 eligible patients or 12.4%). However, these numbers reduced to zero by 2017. The overall mean annual referral rate for the 16-year period CBTp (f) was used was 10.3 referrals per year (McLay 2017). At the same time as noticing a drop off in referrals for CBTp (f), the researcher also became aware of a number of other difficulties with its ongoing implementation, particularly in relation to the context of the therapists’ role.

High reported variance in therapists’ adherence to the current treatment manual guidance, poor uptake of clinical supervision related to the intervention, high variability in the treatment ‘dose’ delivered to patients and high numbers of incomplete treatments were common issues. In addition, therapists reported difficulties in operationalizing the manual in treatment sessions due to its rather cumbersome and less than user-friendly nature.

1.6 Rationale for study – why it was needed

There were a number of reasons why this current study was required. Firstly, low uptake with the intervention indicated that the service needed to re-evaluate the intervention, the therapists' role, and the manual. Secondly, clinical guidelines clearly recommended that CBTp should be provided to The State Hospital patient population. It might therefore be argued that failure to provide sufficient access to this treatment potentially represented a health inequality issue, in so far as patients in HSHs are entitled to the same access to available treatments as other patients. This includes having the same access to available treatments for their mental health needs as they have for their physical health needs. Thirdly, one of the overall aims of the hospital is to provide the best available *evidence-based* care and treatment.

Also, both aforementioned second and third reasons directly align with several of the Millan Principles that underlie the Mental Health (Care and Treatment) (Scotland) Act 2003. In particular, the principles of a) *reciprocity*, which requires that, "where society imposes an obligation on an individual to comply with a programme of treatment and care, it should impose a parallel obligation on the health and social care authorities to provide safe and appropriate services, including ongoing care following discharge from compulsion", and b) *benefit,* which requires that, "any intervention under the 2003 Act should be likely to produce for the service user a benefit that cannot reasonably be achieved other than by the intervention " (Scottish Government 2005, p. 3). Therefore, it was incumbent on the service to ensure that any new treatment developments were appropriately tested and evaluated to establish evidence of their efficacy and/or effectiveness, or otherwise.

When the CBTp (f) was first launched in 2002, an initial within-subjects single case series (n=5) outcome evaluation was undertaken, the results of which appeared to suggest that the programme was fit for purpose (Cawthorne 2003). Following this, plans were proposed to undertake further, more outcome-focussed evaluation of the CBTp (f) programme. However, although many aspects of the original CBTp (f) programme appeared favourable, it was apparent that this had not yet sufficiently

evolved to the point where it could be tested in a randomised controlled trial (RCT) (Cawthorne 2017b). Thus, whilst future testing of the CBTp (f) intervention through such a trial remained the ultimate goal, it was also apparent that further significant preparatory work was required to achieve this. The first step, and the focus of this study, was to determine the *acceptability* of delivering this CBTp (f) intervention within this setting by conducting a mixed-methods process evaluation.

This was considered the best approach to determine the barriers and facilitators - specifically related to the therapists' role – in ensuring the intervention could eventually be tested within a trial setting. This approach aligns with the Medical Research Council's guidance on the [process] evaluation of complex interventions which suggests that the best, i.e. the most definitive, approach to the evaluation of such interventions is "to combine the evaluation of outcomes with that of process". Thus, the latest MRC guidance both recognises and emphasises the importance of not only determining whether these interventions 'work', but it also focuses on determining how they are implemented, their causal mechanisms and how effects may differ from one context to another (Moore et al. 2015, p. 6 of full guidance document. Available: www.populationhealth-sciences.org/Process-Evaluation-Guidance.html).

It was envisaged that this initial process evaluation would therefore help to explore and explain the apparent discrepancies that had been noted between the expected and observed programme referral and uptake rates, and outcomes attained in relation to this CBTp (f) intervention. It was anticipated that this information would then help to significantly inform the researcher's understanding of how the unique context and environment of care influences these factors, which could provide valuable insights to aid the future, more widespread, and increased implementation of this complex intervention. This may include, for example, informing the researcher about potential adaptations that may require to be made to the existing treatment manual, or possible changes that should be made to therapists' training in the use of the manual, or other,

as yet unidentified, 'process' factors that may need to be considered to aid the future successful implementation of the intervention (Craig et al. 2000, p. 4).

It was further envisaged that upon completion of this initial process evaluation, this complex intervention would have sufficiently evolved such that it would then be much more amenable to undertake a future, more *outcome-focussed evaluation* of its efficacy and effectiveness, i.e. within a more experimental design study format, ideally beginning with a Phase One randomised controlled trial.

1.7 Study aim

This study aimed to determine the barriers and facilitators to implementation of a specifically developed CBTp treatment programme, in a high-secure setting, using a mixed-methods design conducted over three phases.

1.8 Research objectives

The study sought:

- To explore and identify the processes that are required for successful implementation of this complex intervention within this specific setting.
- To explore whether there is any variance in compliance among the CBTp (f) therapists with the guidance contained in the current version of the treatment manual for the intervention.
- To elicit the views and experiences of the CBTp (f) therapists to establish what factors would enable them to successfully implement the intervention, within this HSH setting, with forensic patients, and
- To establish what elements of the treatment manual may potentially need changed to enable further, more robust, outcome evaluation of the intervention.

1.9 Original contribution to evidence-base for practice

As will be outlined at more length in the literature review in Chapter Two, to date no HSH or other forensic mental health service has developed a bespoke individual

CBTp (f) programme for use in a HSH, which is manualised, and otherwise in keeping with the core elements of CBTp as recommended in current clinical guidelines (SIGN 2013: NICE 2014). However, Haddock et al (2009) did conduct a trial of an integrated programme of CBTp for use in a mixture of settings, including a HSH. This intervention comprised CBTp with additional CBT strategies for dealing with concomitant problems with anger and violence (Haddock et al. 2009). One of the chief limitations of this approach, however, was that it did not address issues related to personality functioning, either in the intervention manual, or in relation to outcomes attained. Other authors, (e.g. Adshead et al. 2018) have highlighted the need to address personality-related risky psychological attitudes (such as lack of empathy, or cruel and derogatory attitudes toward others), as well as attitudes toward violence within treatment interventions in HSHs; as these are likely to have been implicated in the reason for the individual's admission to such environments in the first place.

Further, Slater (2011) completed an individual case study, defined by him as CBTp in a HSH. However, on closer inspection, this intervention did not reflect the core elements of CBTp as outlined in e.g. NICE (2014), but instead comprised of "transdiagnostic and symptom focused interventions", designed to address an individual's "chief complaint" (which was also transdiagnostic in nature) (Slater 2011, p. 161).

Other authors have reported on the use of non-adapted individual CBTp programmes for use in a HSH (e.g. Bentall and Haddock 2000; Benn 2002), and some have also delivered group-based CBTp using a non-forensic specific protocol (e.g. Williams 2014).

Some researchers have also looked at possible obstacles to the delivery of CBT in general in HSHs (e.g. Ferrito and Moore 2017); and CBTp more specifically, either in HSHs (e.g. Slater and Townend 2016), or other forensic mental health units (e.g. Haddock et al. 2004). However, these tended to be small and somewhat limited studies conducted at a brief qualitative, exploratory hermeneutic review, or case

series/case study level, i.e. there have been no in-depth multi-method evaluations; and no other process evaluations. These studies were also mainly outcome-focused, not process focused.

This intervention is ‘complex’ but not yet fully evolved – this study is intended to help incrementally develop it further, i.e. up to a point where it will be fit for a phase 1 RCT.

The issue of increasing access to, and wider implementation of CBTp, is a national one, not just specific to CBTp (f); it is therefore intended that this study will add to this wider/national evidence base.

Locally, this study is the first evaluation of processes required for successful implementation of a complex psychological protocol, of which there are a number currently in use. It is therefore envisaged that the use of the particular method in this study may help inform similar work within this service in the future.

This thesis is delivered over seven chapters. Chapter 2 provides a review of the literature, Chapter 3 provides a description of the complex intervention that is the focus of this study, Chapter 4 describes the method used to achieve the research aim and objectives, Chapter 5 presents the results from across all three phases of the study, Chapter 6 re-connects and re-acquaints the reader with the aim and objectives for the study and begins a commentary on whether these were met or not; and Chapter 7 completes the thesis by drawing together a number of conclusions and recommendations garnered from the results of the study, to be fed back to the service.

CHAPTER TWO: Literature review

This chapter reviews the key literature that reports the evidence base for CBTp, with particular emphasis on its delivery in HSH settings. Given the complex and highly specialist nature of the specific topic of this thesis, i.e. individual CBTp, as defined in clinical guidelines (SIGN 2013 and NICE 2014) and implemented in HSH settings; a paucity of available literature was noted. No meta-analyses or systematic reviews were available, and only one RCT was located. All other literature located consisted mainly of small case series or individual case studies and a theoretical review paper, as outlined in section 2.4 below. For this reason, it was not possible to conduct a systematic review. Instead, a scoping review of the current, much wider, body of literature related to CBTp implementation in general adult mental health services was performed (Mays et al. 2001). (This scoping review was first performed in mid-2018, updated in September 2020, and further updated in January 2021). An overview of the search strategy, selection of studies and findings will be presented, and the selected literature will then be discussed and critiqued.

2.1 Search strategy

The patient, intervention, comparison, outcome (PICO) framework (Richardson et al. 1995) is the most frequently used model for structuring clinical research questions (Eriksen and Frandsen 2018), particularly therapy questions (Huang et al. 2006). The researcher therefore considered this model to be highly suitable to help inform and guide the development of the search terms used in this scoping review. For the topic of interest, three broad concepts were identified: patients with schizophrenia or psychosis (the 'patient' component of the PICO model); CBTp or CBTp (f) (the 'intervention' component), and [barriers and facilitators to] implementation (the 'outcome' component). The comparison ('comparison' intervention or exposure component of the model) can be excluded if not relevant, as was the case with this search (Richardson et al. 1995). A search was conducted across five databases (EMBASE, MEDLINE, PsycINFO, CINAHL and the Cochrane Library). Full search details can be found in Appendix 1.

2.2 Inclusion and exclusion criteria

Studies were included in the review if they reported on: quantitative or qualitative analysis of CBTp implementation in high secure or other forensic mental health services (between 1990 to present date); quantitative analysis of CBTp implementation in general adult mental health services (between 2000 to present date); quantitative or qualitative analysis of suggested important/essential components of CBTp (between 2000 to the present date); and quantitative or qualitative analysis of barriers and facilitators to CBTp implementation (between 2000 to present date). The date ranges selected for each of these four inclusion criteria, reflect points where studies either begin to be listed (reflecting new, emerging themes or 'trends') in the literature; or they reflect pivotal points when the literature had become so saturated with e.g. meta-analyses or systematic reviews, that reviewing earlier studies would not have been useful.

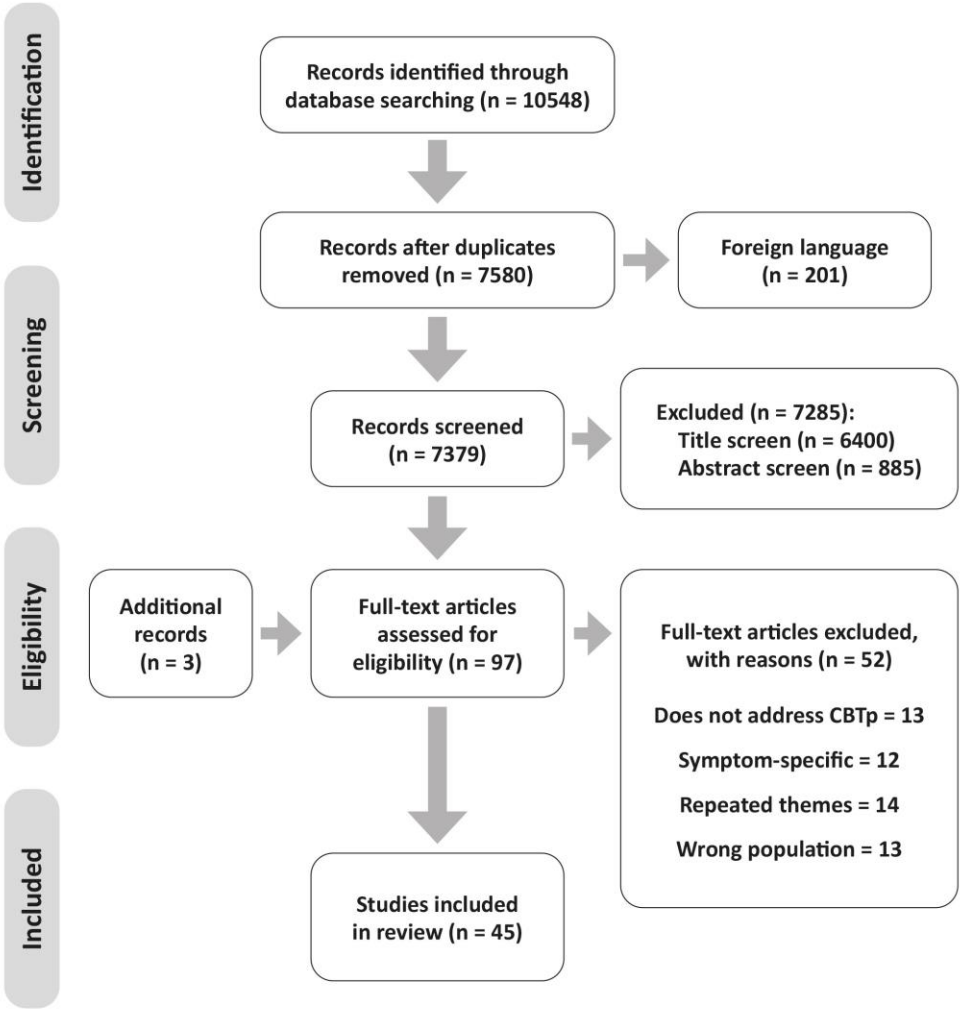
Studies were excluded if they were: not in English; related to non-adult populations; related to cognitive programmes that did not contain core CBTp elements (e.g. cognitive remediation or cognitive skills programmes); or related to other diagnoses outwith the ICD-10 manual coding range F20 - F29 (World Health Organisation 2016), e.g. F31.1 bipolar disorder.

2.3 Results

Forty-five studies were included in the review (Figure 1). Fifty-two studies were excluded at the final stage. These included 13 papers that described interventions that did not contain core elements of CBTp, but focussed instead on, e.g. therapeutic milieu initiatives or psychoeducation. Twelve studies were excluded on the basis that they focussed on symptom specific CBTp interventions. A further 14 studies were excluded either because they repeated themes that had already been mentioned in papers by the same authors, or they did not add any new information to themes that had already been identified (e.g. papers hypothesising about what may or may not constitute components of a CBTp intervention). A final 13 studies were excluded when they were found to relate to the wrong population. These involved studies that

reported either on psychosis prevention interventions (which focussed mainly on children and adolescents), or first episode interventions that related primarily to adolescent populations.

Fig 1. PRISMA flow diagram (Adapted from Moher et al. 2009)



2.4 CBTp in high secure and other forensic mental health settings

Twelve studies were located that relate specifically to the implementation of CBTp in HSHs and other forensic mental health services. (Although the study reported in this thesis relates specifically to a HSH population, the researcher considered it prudent to

extend the review to include studies from other forensic mental health services; particularly given the dearth of HSH-specific studies that were available). These 12 studies did not include any meta-analyses or systematic reviews; however, one study reporting on a RCT was located (Haddock et al. 2009). This was a single-blind trial that compared an integrated programme of CBTp and anger, with a social activity therapy programme. Goals of treatment were to investigate the effectiveness of CBT on anger, violence, psychosis and risk outcomes, with people who had a diagnosis of Sz or other psychosis and a history of violence. Participants were a mixed group of out-patients and in-patients, some of whom (n=48/77, 62%), were also residing in a HSH. This intervention met all clinical guideline recommendations for CBTp implementation (see pp.7 – 8 of this thesis) and included additional CBT components to address anger and motivational problems. It was also noteworthy for the "stringent procedures" employed by the trial team to ensure treatment fidelity (Haddock et al. 2009, p. 154). This consisted of the use of a clear therapy manual to guide treatment delivery, participation in at least fortnightly individual or group supervision, taping of therapy sessions and rating of these for fidelity to the treatment manual using the Cognitive Therapy Scale for Psychosis adherence scale (Haddock et al. 2001). A sample of these recordings (c.10%) were rated by internal supervisors and an external rater. Outcomes reported were, that whilst CBTp was not found to be superior on general symptom improvements, it was superior in reducing delusional severity and risk management, as measured on the 'clinical' and 'risk' items of the HCR-20 risk assessment tool (Webster et al. 1997). The intervention also had high acceptability to patients and a low drop-out rate. In terms of its limitations, the study was underpowered, and the trial team were unable to be clear about what the main mechanism of change was, particularly given the heterogeneous nature of the target population. This meant that the intervention may have had different impacts in each of the different environments it was trialled in. Haddock et al (2009) also noted that their failure to address personality-related issues in this trial was a particular limitation (as mentioned previously in p. 11 above).

An earlier pilot study, comprising a small case series (n=3), of this integrated CBTp intervention, was also conducted by the same lead author in a low secure service (Haddock et al. 2004) prior to advancing to the later RCT with mixed populations, including the HSH cohort (Haddock et al. 2009).

Two other studies reporting small case series in HSHs were located. Cawthorne (2003), the researcher, briefly described a small 'within-subjects' case series (n=5), conducted by her as an earlier pilot to this current study. This involved the implementation of 15-20 sessions of CBTp (f), as described by Allan et al. (2002) in their treatment manual. Interpretation of outcomes are extremely limited due to the highly subjective nature of the evaluation (once again the evaluator was also part intervention developer, as well as the primary treating therapist in all five cases). The study was also very small in scale. However, these limitations notwithstanding, there was some suggestion that statistically significant changes in level of delusional conviction (how much the delusion was believed), as measured by the Psychotic Symptom Rating Scale (PSYRATS) (Haddock et al. 1999), was achieved. Specifically, two patients achieved $\geq$ 25% improvement, and another two patients achieved $\geq$ 50% improvement in level of delusional conviction using this measure. More modest improvements in frequency of voice-hearing experiences were noted.

Garrett and Lerman (2007) published a brief 'frontline report' related to a CBTp intervention with a group of inpatients (n=8) in their HSH service in New York, USA. This consisted of an average of 20 sessions of CBTp. Unfortunately, due to the brevity of this report and the lack of empirical data provided in support of it, it was not possible to critically review this paper. However, in terms of outcomes, Garrett and Lerman (2007) reported that six of the eight patients who received this intervention appeared to benefit from it. They also highlight that, in one man in particular, "the improvement was dramatic" (Garrett and Lerman 2007, p. 712). This dramatic improvement related to a significant shift in this individual's level of conviction in a "cult delusion" that was deemed to have driven him to commit a double homicide 15-years earlier.

Bentall and Haddock (2000) described a case study that involved the delivery of CBTp for auditory hallucinations in a HSH. This study was included as part of a larger trial that was protocol-driven rather than formulation-driven. It therefore did not focus on the development of a shared understanding of the relationship between the individual's psychotic experiences and his offending behaviour. Small changes to perception of voices were noted during treatment, but these were not maintained at follow-up. The authors/therapists also drew attention to the 'tension' they felt in trying to maintain delivery of the CBTp treatment as per protocol (to ensure trial fidelity); with an individual who also wanted to talk, and develop an understanding about, how his psychosis may have been linked to his offending behaviour. Bentall and Haddock (2000) identified the failure to address this important area as being a particular obstacle to CBTp delivery with this man.

In contrast, Ewers et al (2002) described a case study that did involve formulation driven CBTp for delusions with an individual in a HSH. This intervention was based on Fowler et al's (1995) model. This was yet another study where a marked reduction in delusional belief conviction was reported, which was also maintained at 3-months follow up. Ewers et al (2002) also described the need for clinical supervision in this case, which was provided at a weekly rate. This frequency of supervision was largely due to the complexity of the case, which included an examination of the potential interface between this individual's psychosis and his offending behaviour. The supervision included 'close' supervision (which was facilitated by recording therapy sessions). This enabled the supervisor to not only independently evaluate the therapist's CBTp implementation, but it enabled both therapist and supervisor to work together on formulation development.

Benn (2002) explored the feasibility of applying CBTp in a HSH in two case studies where the management of mental health problems was considered integral to risk management. One individual was reportedly distressed by persisting symptoms of psychosis, whilst the other individual was not. The elements of the CBTp intervention implemented by Benn (2002), in both cases, appeared to be consistent with clinical

guidelines at the time (NICE 2002), which were also much in keeping with current clinical guidelines (e.g. NICE 2014). (Please cross-refer to p.6 of this thesis for further detail). However, it was not clear whether a particular CBTp treatment manual was used, and if so, which one. Outcomes attained were an improvement in level of delusional conviction in one case, and more indirect improvement in terms of being able to reduce disruption in daily life (due to some reduction in voice-hearing and level of conviction in a grandiose belief), in the other. In response to the specific question of whether CBTp could be feasible and/or useful in a HSH, Benn (2002, p. 178) suggested, "Clinical data from cognitive behaviour therapy case-work can provide compelling evidence supporting changes (or lack of change) in the level of risk that patients present".

Benn (2002), also described a series of common obstacles he encountered in engaging patients with psychosis in CBTp-based work within a HSH. These were: patients' responses to their perceptions of detention (e.g. feeling that they had been unfairly and involuntarily detained, often for very lengthy periods); poor insight into mental health problems (e.g. persecutory beliefs that they have somehow been 'set up' by others, which may also strengthen their sense of having been wrongfully detained); minimisation and poor insight into risk (e.g. oversimplified rationale, "I killed when I was ill, so I'm not really accountable"); and skill atrophy (e.g. basic relational or conflict resolution skills may be under-developed, but could be implicated in future risk management plans. It can sometimes therefore be helpful to engage the patient in hypothetical scenario-planning and role-plays to try and develop these skills, prior to transfer to conditions of lesser security).

Benn (2002) also concluded his studies by suggesting that future research into the use of CBTp, combined with antipsychotic medication, in HSHs, would be worthwhile. Adding, however, that "… the institutional context involving a wide range of treatment services, the coexistence of offending, substance abuse problems, and dual diagnoses would require a complicated research design" (Benn 2002, p. 179).

Rogers and Curran (2004) also report a case study, described by them as CBT for command hallucinations with a man in a HSH. However, the intervention described in this study appeared to be focussed around a rather 'idiosyncratic' formulation that was used to guide an eclectic mix of strategies to respond to the key problems identified within it. As a result, it was difficult to follow the authors'/therapists' intent with this case to enable a more critical review of it.

Slater's (2011) case study was briefly mentioned in Chapter One of this thesis (p. 11). The intervention described in this study did not reflect the core elements of CBTp as outlined in e.g. NICE (2014). Rather, both the formulation (which ran to over 13 pages of diagrams and narrative), and the strategies described as 'CBTp', appeared to involve a multiplicity of interwoven theories and approaches that were highly intricate and, as such, unlikely to be reproducible by others. Following this study, Slater and Townend (2016) went on to publish a theoretical paper. A brief critique of that subsequent paper is also given at the end of this section of the scoping review.

Williams et al (2014) conducted a controlled effectiveness trial of group based CBTp in a HSH with 27 male forensic patients. This intervention was delivered in accordance with a therapy manual written by Williams (2004), the first author of the trial. Treatment duration was 9-months and therapy 'dose' was 35 sessions. The intervention involved both group sessions (delivered at a rate of 90 minutes per week), and weekly one-to-one sessions (duration not stated). The authors reported that this intervention "adhered to NICE treatment for schizophrenia guidance" (Williams et al. 2014, p. 70), but this does not appear to borne out in its application (due to the fact that it was primarily delivered in a group format; also, no evidence of established efficacy for the treatment manual was given. See also p.6 in Chapter One for a full list of clinical guidance criteria). Other limitations to this study included its lack of randomisation. Outcomes reported included a rather difficult-to-fathom statement about "reductions in interpersonal problems and most notably in being socially inhibited and self-sacrificing" (Williams et al. 2014, p. 68). These findings appear rather spurious and consisted of two factors chosen from the Inventory of

Interpersonal Problems (IIP-64), which is a lengthy, 64-item, questionnaire (Horowitz et al. 2000). Another important finding from this study was that the 'treatment as usual' (TAU) group actually did better than the CBTp group for reductions in positive symptoms, as measured by the PSYRATS (Haddock et al. 1999); a reliable and validated CBTp measure. This finding was therefore difficult to reconcile with the authors' additional comment "that no iatrogenic effects of the treatment were found" (Williams et al. 2014, p. 68), as, based on their finding of symptom reduction within the TAU group, it would appear that, had the patients been left to TAU, their positive symptoms may well have slightly improved.

Slater and Townsend (2016) published a paper that reported on an 'exploratory hermeneutic review' of international literature regarding CBTp implementation in HSHs. This paper, which is largely theoretical in its content and based on both authors' subjective interpretations of the literature (which included three unpublished studies), is also particularly noteworthy, as among their conclusions is a proposed model of CBTp delivery for HSHs which deviates significantly from all other studies outlined above and in section 2.5. However, no clear rationale was offered for these deviations, most of which appear to have been based on conclusions drawn either from clinical impressions or subjective interpretations, or single case studies (e.g. Slater 2011). This paper is further commented on in section 2.6.

2.4.1 Summary

Very little published literature is available that specifically addresses implementation of individual CBTp, in accordance with clinical guidelines (e.g. SIGN 2013; NICE 2014), in HSHs. Most of the literature that was located was of extremely limited quality; the main exception being the one RCT of integrated CBTp and CBT for anger and violence (Haddock et al. 2009).

Despite current clinical guidelines continuing to recommend that all patients who experience persisting psychotic symptoms and/or depression, or who are in remission, should receive CBTp (SIGN, 2013; NICE 2014); and recognition by

experts in HSH services (e.g. Benn 2002; Garrett and Lerman 2007) of the additional significant role that CBTp can potentially play in helping to reduce risk; it seems remarkable that research into this area has advanced very little over the past 20 years. This appears even more remarkable when repeated studies also suggest that CBTp appears to show most benefit in helping to tackle the 'big delusions' that often drive some of the most serious violence (Ewers et al. 2002; Benn 2002; Cawthorne 2003; Haddock et al. 2004; Garrett and Lerman 2007; Haddock et al. 2009).

Several authors (Bentall and Haddock 2000; Benn 2002) have highlighted the complexity involved in delivering CBTp in HSHs and have recognised that future research in this area may require the use of more specifically designed 'forensic' CBTp protocols, and more complex research designs.

2.5 CBTp in general adult mental health services

In stark contrast to the paucity of evidence located for CBTp in HSHs and other forensic mental health services, the body of literature available that reviews CBTp in general adult mental health services is extensive. The researcher therefore applied a strict date parameter (2000 – present) to help manage this and focussed on reviewing studies that related to CBTp delivery as defined in current clinical guidelines (SIGN 2013; NICE 2014). All included studies/papers were additionally selected based on their ability to summarise and comment on the evidence for CBTp in this area, or if they drew attention to specific challenges to this.

Morrison et al (2004) produced an effectiveness study. This was designed to explore whether findings from previous efficacy studies for CBTp (e.g. Kuipers et al. 1997; Sensky et al. 2000), where treatment was delivered by unidisciplinary groups, under rigorous trial conditions, could be reproduced in a multidisciplinary group providing CBTp in a community mental health setting. A total of 87 participants took part; 30 were allocated to a waiting list control and 57 were allocated to the CBTp arm of the trial. Outcomes suggested that CBTp, delivered by trained practitioners within this setting, could produce improvements for positive symptoms, depression, and general

mental health problems at the end of treatment. This study also demonstrated that shorter length of [onset of] illness was associated with lower post-CBTp total Positive and Negative Syndrome Scale (PANSS) (Kay and Opler 1987) scores, which is consistent with the suggestion that there may be a 'critical period' in which to optimise symptom improvement (Birchwood et al. 1998). (The critical period hypothesis is discussed at more length in p. 128 of this thesis). Another key outcome from this study was that it highlighted that *higher symptom severity at the start of treatment is associated with good outcome* and should therefore not be used to contraindicate CBTp. Morrison et al (2004) also highlighted the importance of therapists receiving advanced training and supervision to competently deliver CBTp. The main limitations to this study were that it lacked a control group and relied on participants being 'naturalistically allocated' to CBT or the waiting list/TAU control, (with this decision being determined by the availability of a therapist).

Wykes et al (2008) conducted a meta-analysis and investigation of the effects of trial methodology across 34 CBTp studies, using the Clinical Trial Assessment Measure (CTAM) (Moher et al. 2001), and found that this had previously included many low-quality trials. Whilst Wykes et al (2008) found evidence of benefit for CBTp on positive symptoms of psychosis (at a 'small' effect size level), they also noted that more rigorous trials showed less effect than trials where the research team were aware of group allocation. They concluded their review by recommending that subsequent judgements of evidence should take this specific methodological detail into account.

A paper by Turkington et al (2013) described advances in CBTp. Turkington et al (2013) also highlighted the serious methodological issues associated with prior CBTp studies and noted how this created difficulty when trying to draw definitive conclusions about outcomes often associated with its implementation. They summarised these methodological issues as a series of challenges including, but not being limited to, the: heterogeneity of patients who present with Sz or psychosis; stage of illness (from 'ultra-high risk' through to chronic/treatment resistant); diversity

of CBTp interventions (ranging from basic social skills training or symptom-specific interventions, to formulation-based CBTp); high range of outcome measures used (e.g. symptom-focused or functional outcome measures); extent of therapist training; treatment delivery modality (e.g. individual or group); the number (i.e. 'dose') of sessions; length of sessions; length of follow-up; presence or absence of active control condition; inclusion and exclusion criteria for trial admission; and information related to comorbidity. Turkington et al (2013) also commented on how such methodological issues had influenced estimates of trial effect sizes in more recent meta-analyses of CBTp (e.g. Jones et al. 2012), leading to the evidence for CBTp being down-graded from a prior 'small-to-moderate' effect (e.g. Kuipers et al. 1997; Tarrier et al. 1998) to a 'small' effect size.

In their systematic review and meta-analysis, Jauhar et al (2014) also examined potential bias in the reporting of 34 previous CBTp trail effect sizes. They concluded that whilst effect sizes for CBTp (on Sz symptoms) were also seen within their meta-analysis, they were in the 'small' range. Also, similar to Wykes et al (2008), they reported that this effect was shown to reduce even further when sources of potential bias, especially masking, were controlled for. As a result of this finding, Jauhar et al (2014) also questioned whether CBTp had been over-sold, and, if so, whether it should still be recommended in clinical guidelines.

In a critique of the Jauhar et al (2014) paper, Birchwood et al (2014) suggested that, as Jauhar et al (2014) did not examine the clinical significance of dose or duration of CBTp in their review; both omissions should be viewed as considerable limitations; especially in view of Dunn et al's (2012) findings (discussed at more length in section 2.7 below), that whether an individual received a course of full or partial [CBTp] therapy, made both statistical and clinically significant differences to outcomes. Birchwood et al (2014) also highlighted that Jauhar et al (2014) did not include longer-term outcomes such as maintenance of symptom reduction at 9 or 18-months follow-up, as these also represent substantial benefit of effective CBTp. Birchwood et al (2014) further commented on specific measures of outcome, noting that whilst

symptom reduction is important, it is not the only focus of outcomes of effective CBTp. This can include other factors such as reduction in distress and improvement in coping ability. These latter factors in particular, challenge the more medical conceptualisation of 'recovery' (which is primarily concerned with absence of symptoms), as opposed to e.g. service-user/person-centred conceptualisations, that can include more functional outcomes measures such as improvement in self-management skills (Brown and Kandirikirira 2007). Birchwood et al (2014) ended their critique with a recommendation that future meta-analyses should also include examination of these wider, more functionally based, issues related to CBTp effectiveness.

Turner et al (2014) conducted a meta-analysis that looked at several psychological interventions for psychosis, including CBTp (and social skills training and cognitive remediation). Forty-eight outcome trials were examined. CBTp showed a small, yet robust effect in reducing positive symptoms, in accord with the Jauhar et al (2014) review. Turner et al (2014) were also able to identify specific components that were at least partially influential in determining treatment outcome with CBTp. These included: challenging positive symptoms, using a formulation-based approach, and cognitive restructuring, all of which are in keeping with key CBTp components recommended in current clinical guidelines (SIGN 2013; NICE 2014). This additional finding echoed earlier findings reported by Steel et al (2012), who reviewed specific variables within a series of earlier CBTp trials and found that best results for CBTp were found with individually tailored, formulation-based delivery, conducted by a skilled therapist.

van der Gaag et al (2014) conducted a meta-analysis of 18 trials of formulation-based CBTp: examining its effects for delusions and hallucinations separately. Effects, which varied between small and modest, were found for both hallucinations and delusions, with results for hallucinations showing some superiority. However, the authors reported that the slightly less effect for delusions may have been due to high levels of heterogeneity noted in the delusion-specific studies included in their review.

Morrison et al (2014) reported on a single-blind RCT that compared CBTp plus TAU, with TAU alone for a group of people with Sz spectrum disorders who were not taking antipsychotic drugs. There were 74 participants in this trial, divided equally across both groups. Morrison et al (2014) found that CBTp, delivered in accordance with clinical guidelines, significantly reduced symptoms and appeared to be a safe and acceptable alternative for people who chose not to take antipsychotic medication. However, a particular limitation of this trial was its small scale. Morrison et al (2014) acknowledged this limitation and suggested that a larger, more definitive trial was therefore needed.

In an opinion paper, Thomas (2015, p. 1) explored what he thought to be "wrong" with CBTp, referring to the current approach to CBTp research as a "battle fought with meta-analysis". Thomas (2015, p. 1) challenged researchers to look "beyond the effect size debate"; particularly as much of the difficulty in trying to reconcile this, is compounded by an additional debate about what the constituent components of CBTp actually are. Thomas (2015) argued that it is more important to pay closer attention, not to what outcomes can be achieved by highly specialist therapists implementing trial-standard CBTp (as there is also increasing evidence of this level of therapy failing to be delivered in the 'real world', e.g. van der Gaag et al. 2014); but to *what patients actually need*. Thomas (2015, p. 2) also refers to the Roth and Pilling (2013) competency framework for CBTp as having set a "high and exclusive bar for delivery" that not many services are able to achieve. He highlights that this often leaves services with two potential responses: 1) either disseminate simplified versions of CBTp to less intensively trained staff for them to deliver, or 2) increase the number of highly skilled therapists as an alternative approach to increasing service capacity. Thomas (2015) further reports that both these responses have been attempted, without much success. Initiatives like the 'Thorn Course' training (Gamble 1995), which sought to increase mental health nurses' skills and ability to deliver psychosocial interventions to patients and their carers in the community, had a negligible effect (Couldwell and Stickley 2007). And attempts by, e.g. Jolley et al (2015) to increase CBTp implementation by significantly increasing the number of

CBT therapists in their service, proved very costly and resulted in only a 3% increase in delivery for a caseload of almost 7000 patients.

Morrison et (2018) conducted a RCT pilot and feasibility study that made a head-to-head comparison of antipsychotic medication versus CBTp versus a combination of both in people with psychosis. Seventy-five participants were recruited and randomly assigned – 24 to antipsychotics, 26 to CBTp and 25 to the combination arm of the trial. Results from this trial suggested that a larger trial of the same configurations would be feasible. This was a particularly important paper as it shone a light on the possibility that future treatment options for patients with psychosis (particularly first-episode presentations), might not necessarily always need to include the use of antipsychotic medication, the negative effects of which are well-documented and include weight gain, sexual dysfunction, increased risk of developing Type-2 diabetes, long-term cardiovascular problems and premature death (Correll et al. 2017).

Kingdon and Turkington (2019) produced a paper that summarised key issues related to CBTp research and implementation. They highlighted that, at the time of their report, over 20 meta-analyses had been conducted on research trials of CBTp, using a range of inclusion criteria, and resulting in various findings. The main conclusion drawn from this considerable activity was that CBTp for Sz and other psychoses has shown consistent benefit, albeit small. They also point to the more recent 'controversy' stirred up by e.g. Morrison et al (2018) about whether patients should be offered a choice of antipsychotic medication or CBTp, particularly in view of medication side effects. They further discuss findings from symptom-specific studies of CBTp and highlight good outcomes achieved in relation to command hallucinations, i.e. reductions in distress and compliance (Birchwood et al. 2014), and in working with delusions, i.e. reductions in worry and persecutory delusions (Freeman et al. 2015).

Jones et al (2018a, p.1) produced a *Cochrane Database Systematic Review* of trial evidence for cognitive behavioural therapy plus standard care versus standard care

plus other psychosocial treatments for people with schizophrenia. They reported that, overall, the quality of evidence they found was of “mainly low or very low quality”, and that outcomes for CBTp did not show any clear advantage over other, often less intricate, and expensive, psychosocial treatment options.

Another *Cochrane Database Systematic Review* of cognitive behavioural therapy plus standard care versus standard care for people with schizophrenia, produced a month later, also concluded that the quality of evidence found was of “mainly low or very low quality” (Jones et al. 2018b, p.1). It also reported that whether CBTp leads to improvement in patients’ longer-term mental state, social functioning, or quality of life “remains unclear”.

Both above Cochrane reviews called for more high-quality trials to assist with future reviews and recommendations for CBTp. However, it is noted that, despite these findings, CBTp continues to be recommended in clinical guidelines for Sz and psychosis as a primary psychological intervention (SIGN 2013; NICE 2014). Further, a more recent NICE guideline, published in August 2020, that focuses on the rehabilitation needs of adults with complex psychosis (NICE 2020), also recommends that CBTp should be offered to this group of people, and that it should be delivered in accordance with criteria set out in its earlier guideline recommendations (NICE 2014).

Sitko et al (2020) produced a meta-analysis and meta-regression of CBTp across time. They reviewed 28 studies and concluded that CBTp had a small to medium effect on positive symptoms of psychosis, with increased effect for delusions across time. Interestingly this study made no mention of the above Cochrane reviews (Jones et al. 2018a and 2018b). It is unclear why this was the case, but it does seem likely that this may simply be due to the cut-off date for their included studies (mid-2018), as these two additional reviews were published in the final two months of that year.

Turner et al (2020) undertook a major review (via cumulative meta-analysis) of the evidence for case formulation-driven CBTp and its effect on hallucinations and

delusions. This review updated their previous review of 2014 (see Turner et al (2014), p. 25 above), involved 35 RCTs, and analysis of data on participants (n=2407) over 75 meta-analytic comparisons. They concluded that the evidence base for CBTp on delusions and hallucinations showed sufficiency and stability across time and comparisons, suggesting that there would be limited value in conducting further trials of generic CBTp. Turner et al (2020) also acknowledged both the 2018 Cochrane reviews (Jones et al. 2018a and 2018b) within their review, and argued that the apparent inconsistencies between their findings and Jones et al's (2018a and 2018b) was not due to lack of evidence, but rather due to methodological issues applied to the meta-analysis process, including issues concerning inclusion criteria, blinding, and pre-specification of methods.

2.5.1 Summary

Since the 1990s there has been excitement about CBTp as a treatment option as it appeared to show promise in helping to target symptoms of Sz and psychosis, which previously tended to be left to medication alone (Thomas 2015). There then followed an 'explosion' of RCTs, systematic reviews and meta-analyses to establish the evidence base for CBTp, as highlighted in the brief review above. However, whilst this evidence trajectory appeared to start off well, with 'small-to-moderate' effect sizes being reported (e.g. Kuipers et al. 1997; Tarrier et al. 1998), it has since been revised and reduced to more current reports of a 'small' but consistent effect. This appears to have arisen as more and better quality trials have been reported, and in response to changes in methodological approaches determining how meta-analyses are conducted (e.g. Wykes et al 2008; Turkington et al. 2013; Jauhar et al 2014; Birchwood et al 2014; Thomas 2015; Kingdon and Turkington 2019; and Turner et al 2020). This has led to the current situation where the evidence for CBTp is much contested.

However, despite this prevailing situation, CBTp continues to be recommended in SIGN (2013) and NICE clinical guidelines (2014) for schizophrenia; in the new clinical guideline related to the rehabilitation of adults with complex psychosis (NICE 2020),

and by the British Psychological Society (BPS) in their *Understanding Psychosis and Schizophrenia* (BPS 2017) report.

Whilst most of the above papers focused on examining outcome evaluations of CBTp, they also frequently reported on other issues that were emerging and being noted when conducting these trials, e.g. the high levels of heterogeneity in relation to patients who were in receipt of CBTp, the range and manner of delivery of interventions being offered (e.g. from individual to group formats; symptom-specific to formulation-drive interventions) and difficulties with CBTp implementation in many services. These additional emergent issues led to two further key themes being highlighted and briefly explored in this review. They are: what is CBTp? (i.e. what appear to be its important or essential components?), and what appear to be the barriers and facilitators to its implementation? These subsequent themes are discussed in sections 2.6 and 2.7 below.

2.6 Suggested important/essential components of CBTp

Several studies have explored the components that appear to be most important, if not essential, to the effective delivery of CBTp and have identified factors related to both the content and process of treatment.

Morrison and Barratt (2010) noted a lack of consensus regarding the essential components of CBTp and conducted a research study to identify the intrinsic components of treatment. This study required a group of experts in CBTp to identify what they regarded as the important elements of CBTp, through the process of a three-round Delphi study.

To produce an initial list of proposed essential CBT or CBTp items, Morrison and Barratt (2010) sifted through a number of existing treatment manuals, various adherence measures, e.g. the Cognitive Therapy for Psychosis Adherence Scale (CTPAS) (Rollinson et al. 2008), and competency scales (e.g. Roth and Pilling 2008). This enabled the development of 90 items for an initial round of Delphi. The 90 items

were sent to a panel of experts (predominantly authors of existing UK treatment manuals (n=12)), and participants who agreed to take part (n=7) were asked to add and respond to this initial list. At the end of stage one, one item was removed, and 45 items were added to the final questionnaire. At stage two a 134-item questionnaire was then sent to 60 participants (clinical psychologists, cognitive therapists, psychiatrists, and mental health professionals who work or have worked in a research capacity implementing CBTp). Participants were asked to rate the importance on a Likert scale of each item. 28 participants responded (47%). At the end of stage two, 69 items were endorsed as standard practice, and 41 items were excluded. 24 items were then re-rated by 23 of the 28 participants in stage three after which 10 additional items were added and 14 excluded.

Findings indicated that 77 items were endorsed as important or essential to CBTp with items being grouped as follows into factors related to:

- *engagement* (e.g. intervention informed by client feedback, consistent collaboration throughout sessions)
- *structures and principles* (e.g. aim to reduce distress and improve quality of life, accommodated to clients' needs and speed of learning). And within CBT sessions (e.g. client and therapist should agree problems list, and agreed short- and long-term goals should underpin intervention)
- *formulation* (e.g. good collaborative relationship formed to create comprehensive formulation, CBT should develop formulation of clients' difficulties and use psychological mechanisms to understand the processes that are controllable in relapse)
- *assessment and model* (e.g. CBT should explain the role behaviours have in triggering and maintaining the clients' difficulties, CBT must identify the needs of the clients and competency of the therapist before undertaking in-depth therapeutic work)
- *homework* (e.g. homework should be a standing item on agenda, practice assignments should be planned and reviewed)

- *change strategies* (e.g. therapists should use elements of self-disclosure to help normalise clients' psychotic symptoms, CBT should help a client modify core beliefs / schemas and associated behaviour)
- *therapists' assumptions* (e.g. therapists should believe that many people experience psychotic life symptoms without feeling distressed by them, therapists ought to believe that delusions can be quite understandable.

Importantly the outcome of this Morrison and Barratt (2010) study provides insight into expert views in informing the potential development of treatment manuals and the development of related competency frameworks. On the other hand, this study contains potential limitations. It is unclear within the paper what the rationale for the selection of experts was at each stage (i.e. the reason for selecting 12 developers of treatment manuals at Round One, but then not involving clinicians until Round Two). It might be argued that it is the day-to-day clinicians delivering CBTp who may actually have the higher level of expertise in its application. This was also recognised as a limitation by the authors themselves. At Round Two less than half of those approached participated in the study. It is unclear the reasons for such a high refusal rate and whether this may have in some way limited or biased the components regarded as essential. In addition, participants were individuals who tended to deliver therapy in a research context (e.g. as part of a RCT) and therefore participants' experience of ordinary clinical practice was unclear. Therefore, the factors identified may reflect therapy offered in a research context, but it is unclear whether this would also apply to treatment in a standard clinical setting.

Dunn et al (2012) conducted a planned analysis using a principal stratification technique, following a multicentre randomised controlled trial comparing protocolised CBT (CBT-P) with treatment as usual. The rationale for this approach was that Dunn et al (2012) wanted to investigate whether the degree of CBT-P treatment completion, impacted on outcome. The study compared three categories of CBT-P treatment; full, partial, and dropouts/no therapy, with a hypothesis that those who received full treatment would display better treatment outcome than those who received partial or

who dropped out. 'Full' treatment was defined as 12-20 months. This involved using the Fowler et al (1995) treatment manual (requiring evidence of active therapy techniques such as self-regulatory strategies, developing personal model of relapse, utilising relapse prevention strategies, developing model of psychosis, work on reinterpreting the meaning of delusional beliefs and hallucinations and schema work); and augmented with relapse prevention techniques; with therapist displaying sufficient competency and adherence to manual. 'Partial' treatment was defined as treatment that involved only engagement and assessment techniques. Drop-out/no therapy was regarded as less than five sessions.

Participants were inpatients and outpatients with non-affective psychosis. Therapists were lead trial therapists (n=5) trained to doctorial level who provided treatment to 96 patients. A further 37 patients were seen by additional trust therapists. When treatment was evaluated, 81 participants were deemed to have received either full (n=42) or partial (n=39) treatment.

Full CBT-P was associated with clinically and statistically significant differences in terms of months in remission and reduction in psychotic and affective symptoms. Those who received partial treatment or dropped out showed no benefit. Further, for those who received only partial treatment (treatment that never went beyond engagement and assessment techniques), an association was found between this configuration of CBT-P and a worsening of symptoms in some cases.

A strength of the above study related to the process of assessing the quality of treatment delivered; the process included the recording of treatment sessions, and evaluation by both trial therapists and external experts with random selection of recordings and rating of adherence. In addition, triangulation was achieved through also requesting therapists to self-rate. This process of assessing the quality of treatment provided, offers a more robust approach than review of case notes alone. It was also valuable to consider the potential iatrogenic effects of partial therapy. However, overall findings indicated that only 40% randomised to the CBT-P treatment

group in fact received full treatment. Limited explanation was given for this, but such a figure indicates potential barriers to the delivery of CBT-P (CBTp), even within a clinical trial setting.

Flach et al (2015) conducted a study that hypothesised that: the *development of a shared problems list*, *use of case formulation*, *use of homework tasks* and *use of active intervention strategies*, would act as process variables for mechanisms of change considered essential for successful CBTp treatment. This study followed on from an original multi centre RCT of psychotherapy for the prevention of psychosis and those at high risk of psychosis (Morrison et al. 2012). An analysis was conducted of 144 therapists' case notes to assess for presence or absence of the four components hypothesised as essential for CBTp treatment. Treatment outcome was assessed using the Comprehensive Assessment for At-Risk Mental State (CAARMS) (Yung et al. 2005) (to measure symptoms severity) which included semi structured interviews with patients and a questionnaire completed by therapists regarding symptoms. Following a series of ANOVAs, results indicated that there was a significant association between decrease in symptom severity and both the presence of case formulation and use of homework; and there was a "borderline significant" association between reduction in symptoms severity and the use of active change strategies. The study therefore concluded that there is a greater treatment effect if formulation and homework are involved as components of therapy.

This study offers a further step in identifying the mechanisms of change in therapy and offers not only the subjective view of clinicians, but instead explores the association between components of treatment and treatment outcome for patients. However, assessment about whether a component was delivered within treatment is based upon the review of case notes and consequently it is possible that in some instances a specific component was included but not recorded in case notes. In addition, it is unclear the extent to which results may be applicable in specialist services such as forensic settings.

Slater and Townend (2016) conducted an exploratory review of CBTp approaches within HSHs, including appraisal of the outcomes. The authors identified a range of relevant studies both published and unpublished, and applied hermeneutic analysis of the studies. A number of studies were identified that focused on individual CBTp, and through the hermeneutic approach, the authors drew inferences regarding the factors that appeared to impact upon treatment outcome. These included their assertions: that *protocols require the flexibility to incorporate the forensic context and index offence*; it is *important that interventions are individualised and collaborative*; and *identifying an individual problems list with a central complaint is important* (as opposed to simply addressing a list of symptoms). A number of limitations to this study was noted. First, the assertion that an individual's problem list should be based around a 'chief complaint' appears to have been made on the basis of a single case study conducted by the first author (Slater 2016, p. 669) which is offered as 'evidence' for this approach; this does not appear justified. Second, the authors highlight themselves that this approach is highly subjective and the reviewers "assumptions are embedded into the process". However, the paper does not make clear the assumptions on which various conclusions are drawn and so it is difficult for the reader to evaluate beyond this significant limitation.

2.6.1 Summary

Based upon literature to date, it would appear that with regard to factors that may be important to the delivery of CBTp, a number of components to treatment are potentially indicated. These include: assessment, use of problem list and goals, formulation, use of change strategies including modifying of beliefs, use of homework, and inclusion of relapse prevention. With regard to process factors, previous research suggests that the following may be important: a focus upon treatment engagement, collaborative approach, and ensuring the delivery of 'full dose' of treatment (16 sessions or more).

2. 7 Barriers and facilitators to CBTp implementation

A number of papers have reviewed in some way, the implementation of NICE guidelines (2002; 2009; 2014) which recommend that patients with schizophrenia should be offered CBTp. The following will therefore provide a brief overview of some of the studies that have contained a focus upon exploring potential barriers to implementation. NICE guidelines for psychosis were originally developed in 2002, updated in 2009 and updated again in 2014.

Berry and Haddock (2008) provided a review of the implementation of the NICE guideline for schizophrenia (2002), which also included a focus on the implementation of CBTp. They concluded that there was a paucity of studies reviewing the overall guideline implementation process, and a lack of evidence reviewing the barriers to CBTp implementation more specifically. They recommended that further studies should be undertaken to investigate this issue.

Williams (2008) conducted a qualitative peer audit with staff in assertive outreach teams, looking at barriers to implementation of CBTp based interventions. Staff across a range of services were invited as part of a focus group to explore this issue. Barriers identified were categorised into four areas: organisational, managerial, supervision, and locality specific barriers. Staff were asked to comment on these categories. Feedback included comments related to lack of organisational buy-in, caseload-related issues, and staff ambivalence. These confirmed the existence of significant barriers to CBTp implementation and recommendations were made to research this further.

Prytys et al (2011) investigated attitudinal factors in community mental health team staff affecting the implementation of NICE guidelines regarding psychological therapies for psychosis. This study also included an audit of service provision across four CMHTs. Across a two-year period, between 7–20% of patients with schizophrenia were offered CBTp. The study also included semi-structured interviews with staff members across the four teams, which aimed to identify the

factors affecting implementation particularly relating to staff attitudes and knowledge. Through thematic content analysis (Bauer 2000), common themes indicating potential barriers were found, including pessimism about outcomes, reference to chronicity of patients' illness, and ambivalence about recovery. One of the limitations of the research however related to a limited definition of the content of CBTp potentially ranging from a Thorn Course-type intervention (see also p.26 for further detail of this intervention) to full formulation-driven CBTp.

Haddock et al (2014) conducted an audit of the implementation of NICE guidelines for Sz over a 12-month period in mental health services in North West England. The audit involved a retrospective review of case notes of individuals with a diagnosis of schizophrenia under the care of community mental health teams. The outcome was that only 6.9% of service users were offered CBTp, and only 5.3% received it. The study identified three types of barriers: 1) organisational factors (e.g. how management services are set up to deliver interventions); 2) work force capability and expertise to deliver the interventions; and 3) service user factors (e.g. people's attitudes to receiving interventions). It concluded that any implementation package needed to address these factors.

Ince et al (2016) conducted a systematic review of selected research papers which focused upon primary research on the implementation of at least one of the NICE recommended psychological interventions for psychosis (i.e. either family interventions or CBTp) (NICE 2014). Findings were that rates of implementation ranged from 4% to 100% for CBTp across studies. The barriers to implementation identified from studies included organisational barriers (with lack of resource most common, followed by lack of dedicated therapy time, lack of specialist training, workload pressures, and time / caseload pressures). Additional barriers included barriers met by staff members (e.g. attitudes and beliefs of staff members, feelings that staff did not possess required skills, lack of clarity on who should be offered treatment, and the perceived value of psychological interventions) as well as barriers related to service users (e.g. poor engagement, and service users overly medicated).

Currell et al (2015) conducted a study exploring clinician views on client characteristics that impact on delivery and outcome of CBTp. Q methodology (Watts and Stenner 2005) was used to review the literature and gather views from clinicians experienced in CBT and/or psychosis. A Q-set of 61 client characteristics was developed, and 21 clinicians were asked to rate how significant the items were in affecting the outcome of CBTp (from most to least important). Items related to therapeutic alliance were consistently highly rated; and other important items also related to 1) clients being able to accept and apply the cognitive model; 2) the capacity / cognitive functioning to attend to therapy; 3) having a secure base that then enabled a therapeutic alliance to be built; and 4) the ability to collaborate and produce a formulation.

Ferrito and Moore (2017) provided a qualitative study involving six therapists as participants. In-depth qualitative interviews were used to explore these therapists' perspective regarding barriers to implementing CBT treatment (not specifically for psychosis) in a forensic setting. Challenges were grouped into four categories: patient characteristics (e.g. complex needs, severity of clinical problems), therapeutic context (seclusion or high dependency setting), ethical challenges (e.g. confidentiality, impact of detention on choice regarding treatment), and treatment challenges (e.g. difficulties engaging in homework in hospital setting, challenges engaging in behavioural experiments). Helpfully this study focused on barriers related specifically to a forensic setting. However, in terms of its limitations, the research related to a sample of only six therapists and so it is unclear how applicable results would be to other forensic settings or clinicians. The study also did not focus specifically on CBTp but rather on CBT treatment more generally. It is therefore unclear how generalisable or relevant these findings might be to the treatment of psychosis. Finally, the study focuses upon only barriers to treatment; no indication of potential facilitators were given.

Switzer and Harper (2019) provided a narrative review of the literature and focused further on barriers to CBTp implementation. Following identification of initial articles

via a search of relevant databases; an initial 430 papers were reduced to 18 based on specified inclusion and exclusions criteria. Analysis was conducted of 18 relevant articles and through the process of narrative synthesis, key barriers were identified and broken down into three broad themes: organisational barriers (e.g. underfunding, lack of supervision), staff views of barriers (e.g. patient symptoms too severe, lack of knowledge and confidence), and service user views of barriers (fear of disclosure due to prior negative experience, ability to form therapeutic relationship).

Switzer and Harper's (2019) findings appear to support the clinical observations within a high secure forensic setting on which this current study is based. It is a helpful study in terms of the attempt to draw out the potential challenges of implementing CBTp. The authors were also very clear about the process for selection of papers and so it would be possible to replicate as more research becomes available. There are however some limitations to the study; initially it focused only on barriers to delivery, although during the analysis it was possible to extrapolate factors what appeared to be facilitators, including ring fenced funding, high quality training, and protected time for staff. Further, given the current state of research, the study incorporated only one paper based on research conducted within a forensic setting. The authors state in their conclusion that it is their impression that CBTp is most effectively delivered in teams where training in both low and high intensity interventions is available to all staff. This study also reinforces the importance of training in high intensity interventions for delivery of CBTp. It is however unclear how the authors reach their additional conclusion regarding the need for low intensity training based on the information available.

2.7.1 Summary

Multiple authors have recognised problems with CBTp implementation. Several have explored this via audits, reviews, focus groups and other qualitative interview methods. Many overlapping themes relating to potential barriers to CBTp implementation were identified, including: organisational issues (e.g. lack of resources), workforce capacity issues (no dedicated time, lack of supervision and

training), service user issues (concerns re treatment duration) and staff attitude issues (e.g. concerns re complexity of client's presentation, lack of skills, chronicity of patient's illness).

2.8 Scoping review – overall summary

There is a vast body of literature on CBTp, particularly in relation to its application with non-forensic patients. However, many of the studies contained within this extensive literature are of limited quality. Many also reflect high levels of heterogeneity in terms of e.g. patients included, the dose and specific focus of the CBTp they receive (e.g. symptom-specific, protocol-driven, formulation-driven, etc), and outcomes attained, among many other factors. The co-existence of these multiple variables within this vast body of literature then becomes implicated in why the evidence base for CBTp is currently contested – i.e. because when attempts are made to pool, systematically review, or otherwise [meta]analyse configurations of these studies together, opinions appear to diverge considerably. The main areas of disagreement appear to focus on methodological issues related to how such meta-analyses are conducted and reported (e.g. inclusion and exclusion criteria).

Nonetheless, despite this prevailing situation, current clinical guidelines (SIGN 2013; NICE 2014; NICE 2020) continue to recommend that CBTp should be offered to all individuals diagnosed with schizophrenia or psychosis (including adults with complex psychosis), whose symptoms have not adequately responded to antipsychotic medication, where persisting symptoms and/or depression are being experienced, and to those who are in remission.

Whilst there may be an ongoing 'battle' about the evidence for CBTp in areas where it has been most researched, this is not the case within HSHs. Somewhat ironically, in the very area where CBTp may arguably have most effect, not just in helping to reduce or manage distressing psychotic symptoms, but in also helping to reduce levels of serious risk to others, it is significantly under-researched. Only one small RCT having been conducted of CBTp in a HSH, over the past 20 years. Several

factors that appear to be contributing to this are, the lack of forensic-specific CBTp protocols, and the need for such protocols to be evaluated using a complex research design that takes cognisance of the unique forensic context and environment.

In other, less contested, areas of the CBTp literature, work is also underway to try and develop more of an understanding about what the important/essential components of CBTp are and how they interact with each other, the environment, the patient, and the therapist, to bring about change. It is anticipated that by gaining this additional understanding of the mechanisms of change in CBTp, this may, in turn, facilitate its more consistent application and evaluation.

A final theme in the current literature is that as CBTp is a complex intervention, its implementation has not been easily generalised to services outwith trial sites. Some of the barriers and facilitators to this have been studied and some insights gained, but this area of the literature also needs to be developed further.

In 2002, the PSI Service Team in The State Hospital developed a bespoke CBTp (f) programme for use in this HSH. It was hoped that the existence of this programme would have kick-started its implementation in this service such that a phase 1 RCT could be undertaken to determine its efficacy. This has not yet been achievable due to myriad problems associated with the CBTp (f) programme's implementation, which are currently poorly understood. There is therefore a significant gap in the literature in this area, and in our knowledge about what the barriers and facilitators to CBTp (f) implementation are. A complex research design was therefore required to help answer this. This forms the rationale both for this present study, and for the choice of method that underpins it, i.e. a mixed-method process evaluation.

CHAPTER THREE: The CBTp (f) intervention

This chapter introduces the specific CBTp (f) intervention which is the basis for the mixed-methods process evaluation and the focus of this thesis. The conceptual framework and model underpinning the CBTp (f) intervention will be described and linked back to relevant parts of the literature outlined in Chapter Two. This chapter will then describe what the delivery of the CBTp (f) intervention entails, its causal assumptions, and information will be given about early pilot work that was undertaken. This chapter will end with a summary of the challenges surrounding the current use of the CBTp (f) intervention in this HSH.

3.1 Conceptual framework / model underpinning the CBTp (f) intervention

Excerpts from the CBTp (f) therapy manual (Allan et al. 2002), together with a brief case study, a diagrammatic formulation and a logic model, will all be used to help 'operationalise' the CBTp (f) intervention, in addition to the descriptions given about it below. (It was not possible to include the full CBTp (f) treatment manual as an appendix to this thesis due to its size, i.e. it is almost 10,000 words long). (The CBTp (f) intervention described in this is chapter is currently only delivered at The State Hospital in Scotland).

The conceptual framework for this intervention begins with the premise that psychosis is viewed as an interpersonal phenomenon, which evolves via interpersonal experiences (usually in early life), e.g. childhood adverse experiences or trauma. These experiences, in turn, then lead to the development of negative core beliefs (e.g. "I am bad", "other people are untrustworthy", "the world is dangerous"); and to the development of cognitive behavioural strategies which avoid, maintain or compensate for such beliefs. These cognitive behavioural strategies, which may have been helpful or functional in response to a difficult childhood experience, may, however, be carried into adulthood in the form of **overdeveloped** strategies (e.g. hostility, suspiciousness, social avoidance, distrust, exploitation, or aggression); whilst other potentially more functional/helpful strategies may, in contrast, be

underdeveloped (e.g. trust, intimacy, sharing, self-nurturance, empathy and care). It is then conceptualised that, later, onset of illness results in a range of negative outcomes (which are heightened if the individual becomes a forensic patient), such as: involuntary detainment, severe psychotic experiences, psychological and interpersonal distress, patient status, stigma and loss of social rank (Gilbert 1992). Such outcomes may then **confirm** already established core beliefs and associated behavioural strategies (e.g. "others are untrustworthy") or **undermine** existing beliefs and assumptions (e.g. "I am strong", "other people can't hurt me"). Psychotic experiences themselves relate **thematically** to the individual's core beliefs and assumptions and are **maintained** by the interplay between **overdeveloped and underdeveloped cognitive behavioural strategies.**

The key concepts within this framework are central to the Garety et al (2001) model of the positive symptoms of psychosis, which is why that model was chosen to underpin the CBTp (f) programme. The following excerpt from the CBTp (f) treatment manual (Allan et al. 2002, pp. 2 - 4)[1], describes this model in more detail.

CBTp (f) Treatment Manual (Allan et al. 2002, pp. 2 - 4)[1] *- Excerpt*

[1] *K Allan, A Gumley and P Cawthorne (2002) – Assessment and Treatment Protocol*
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Cognitive model of Psychosis

Garety, Kuipers, Fowler, Freeman and Bebbington (2001) have proposed a cognitive model of the positive symptoms of psychosis. They detail the cognitive processes that they propose lead to the formation and maintenance of the positive symptoms of psychosis. This model 'incorporates both disruptions in automatic cognitive processes and maladaptive conscious appraisals: it covers delusions and hallucinations in one framework; it posits a central role for emotion, and it considers how social factors may contribute to the origins, maintenance or recurrence of symptoms.'

They start with the point that most researchers agree that 'psychosis occurs in people with a vulnerable pre-disposition (of bio-psycho-social origin); that onset often follows life events, adverse environments, illicit drug use or periods of isolation; that there are emotional changes, and disruptions in cognitive processes of attention, perception or judgement; and that, at onset, it's most prominent symptoms are delusional beliefs and hallucinations'.

They postulate two routes to the development of positive symptoms of psychosis, one which proceeds through cognitive and affective changes: the other through affective disturbance alone. They believe the first to be the more common, whereby a triggering event gives rise in a pre-disposed person to a disruption in cognitive (information processing) processes which in turn leads to anomalous conscious experiences (i.e. heightened perception, actions experienced as unintended, racing thoughts). These experiences feel external and potentially threatening but are not psychotic symptoms at this stage. Emotional changes occur as a response to the triggering event and to the anomalous experiences. This arousal feeds into the moment by moment processing of anomalous experiences and influences their content. Furthermore, they postulate that because the anomalous experiences are puzzling and associated with emotional changes, they seem personally significant and the person will search for explanations about their cause. Garety et al (2001) propose that at this point 'biased conscious experiences' are critical and contribute to the thinking that the experiences are external in nature. These biased appraisal processes (jumping to conclusions, external attributional biases and deficits in understanding social situations and intention of others) are made worse by negative emotional states (anxiety, depression, anger).

These processes, they argue, work against a background of 'social adversity' where adverse experiences such as social marginalisation, childhood loss or severe childhood trauma may create an 'enduring cognitive vulnerability characterised by negative schematic models of the self and the world.' They maintain that these pre-existing negative schemas also provide content to the psychotic attribution; for example, an individual who has a strong religious upbringing and a belief that they have an innate wickedness may conclude that an external threat is caused by a punishing God.

At this point the authors argue that individuals who have anomalous experiences will not develop full blown psychotic symptoms if they are able to reject the idea that their experience is external to them and i.e. attribute their hallucinatory experiences to 'stress' (thus normalising the experience). They maintain that the 'externalising appraisal is thus a defining decision'.

The second route to psychosis postulated occurs in a small number of cases (i.e. delusional disorder) where the triggering event does not appear to cause a basic information processing disruption leading to anomalous experiences. Instead, life events trigger only disturbed affect which leads to the activation of biased appraisal processes and maladaptive self/other appraisals leading to an externalising appraisal (i.e. the delusion) for the life event or the disturbed affect. (Delusions occur independently of hallucinations and other psychotic disturbance).

Garety et al (2001) explain that a crucial aspect of their model relates to the question of which factors are responsible for the maintenance/recurrence of the psychotic appraisal – they hypothesise that a number of factors are involved in preventing the appraisal from correcting itself when the evidence for it is not forthcoming.

1. Reasoning processes

They argue that the biased cognitive processes that they think contribute to the formation of symptoms are also a factor in maintenance. (jumping to conclusions, data gathering bias, externalising attributional style and poor social understanding).

2. Dysfunctional schemas and adverse social environments

They point to the body of literature appearing which finds an association between self-esteem and psychosis and state that psychotic beliefs may be more firmly held if they are consistent with firmly-held distorted beliefs about the self (i.e. one is bad), others (others are hostile) and the world (the world is unsafe). Also, once formed, the delusion may act as further confirmation of the negative beliefs leading to further strengthening of the delusion. They link low self-esteem to aversive social environments and experience of traumatic events.

3. Emotion (i.e. anxiety, depression, anger, mania) and cognitive processes associated with emotion

Garety et al (2001) state that dysfunctional schemas will be closely associated with levels of emotional distress which will also contribute to the maintenance of the psychotic appraisal through other processes.

Birchwood and Iqbal (1998) found that residual symptoms of hallucinations and delusions are more common in people with co-morbid depression and psychosis and believe that feelings of hopelessness and uncontrollability factor in symptom maintenance.

Garety et al (2001) have studied anxiety and propose that there are three processes traditionally associated with anxiety disorders which may be particularly important –

i. information processing biases maintain psychotic beliefs by providing evidence for them, whilst safety behaviours will prevent someone obtaining evidence which will contradict the belief and therefor allow for change.
ii. Metacognitive beliefs, such as beliefs about the uncontrollability of one's thoughts will increase the distress caused by psychotic experiences.

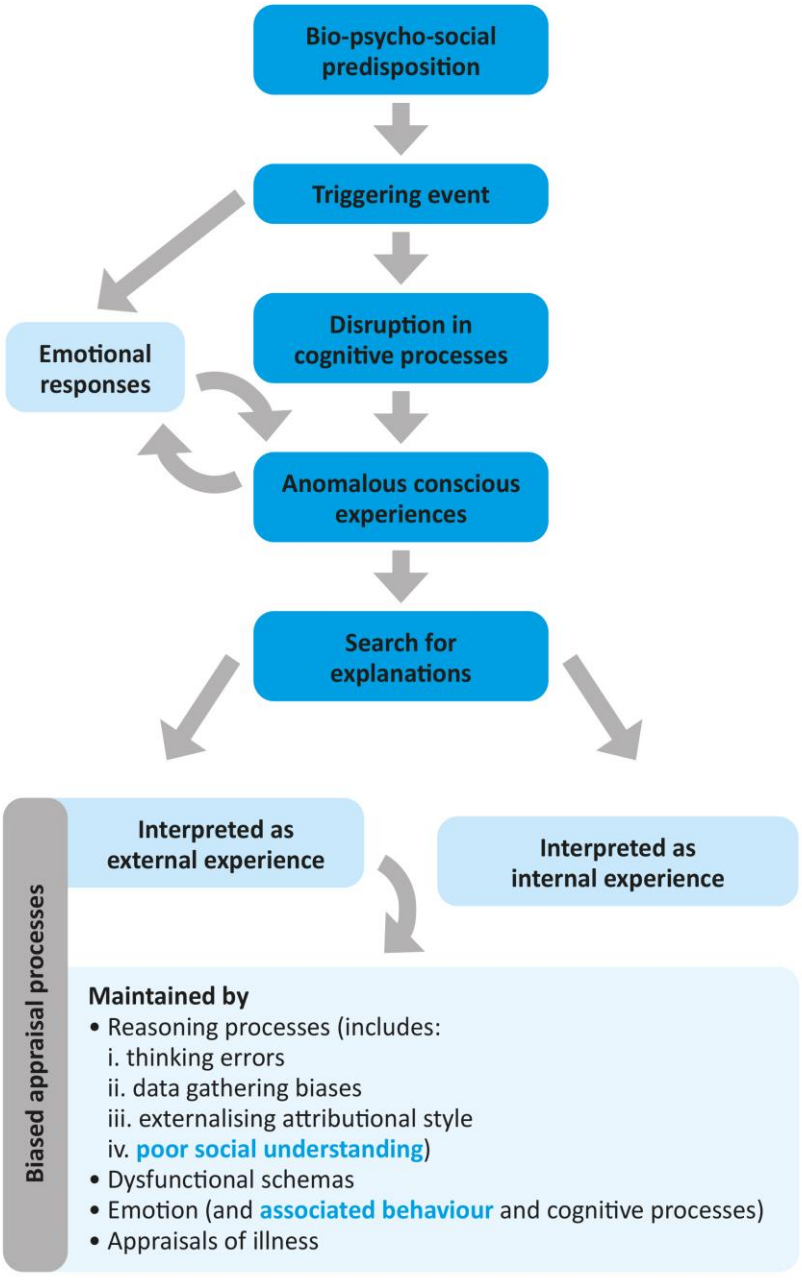
iii. the experience of emotion will drive a search for meaning and understanding that is consistent with affect-associated beliefs – i.e. anxiety will increase the probability that a threatening explanation is sought and accepted.

4. <u>The secondary appraisal of the experience of psychosis itself (illness perception or insight)</u>

Garety et al (2001) suggest that appraisals of illness influence engagement with treatment and adaptive behaviour. They maintain that appraisals of the experience of chronic mental illness as stigmatising and humiliating – may influence the development of depression.

A diagrammatic representation of this model is shown in Figure 2.[1]

Figure 2. A cognitive model of the positive symptoms of psychosis (after Garety et al., 2001)



To help describe and demonstrate this model further, a brief case study has been written. This is first described in narrative form below and is then subsumed within another diagrammatic representation of the model (Figure 2a) to help further demonstrate how this would be applied when working with a patient.

Case Study – James

James is a 25-years old single man, admitted to a HSH two years ago following a near fatal attack on his GP. James stabbed the GP as a result of a delusional belief that the GP was the driving force behind the multiple derogatory voices that James hears. These voices often comment on James in the second/third person, and say horrible things like, "You're useless", "Freak!", "Waster", "Look at the state of him!", "He's an embarrassment!" and they sometimes issue him with commands to kill himself as "Nobody likes you", "You're just a burden to everybody", "Nobody can stand you!". Occasionally one of the voices will also give James instructions to attack others he perceives might be conspiring against him with his GP, e.g. the practice receptionist or his community nurse or ward staff.

Biopsychosocial predisposition

James was born and brought up in the West of Scotland. He is the eldest child in a sibship of three (he has a younger brother and a younger sister). James was born via emergency C-section because his mother (who is asthmatic) had a severe asthma attack during labour and required emergency stabilisation of her breathing. James' mother suffered post-natal depression following this event. There is some family history of mental illness; one of James' aunts suffered from paranoid Sz, and his grandmother suffered from severe depression (sometimes with psychotic episodes). James' mother became pregnant with her second child, James' brother, within months of James' birth. There is also a very small age gap between James' brother and sister, meaning that his mother had her three children in fairly rapid succession.

James' father was "not a great coper", and as such, left much of James' care to his mother, despite her continued poor mental health at times. This (as well as other things) caused marital tensions. As these tensions grew and as other pressures arrived, James' father's drinking escalated, and he eventually became an alcoholic. There was often a lot of chaos and arguments at home, with both parents shouting and swearing at each other a lot of the time. This was mainly due to James' mum's ongoing distress, his father's poor coping, and the 'normal' stress of having 3 young children to care for with very little social or financial support. James' father also lost his job because of persistent late-coming or turning up for work smelling strongly of alcohol.

The family became quite isolated from others in their street and tended to be avoidant of others. James' father would often make comments about the need to stay private about their lives and to keep other nosey people out of their business. James was often too embarrassed to bring friends to the house as his father was always drunk and there were always ongoing tensions between him and James' mum. Also, when James' mum's mental health wasn't good, the house would often be dirty, smelly and very untidy. James learned to 'tune in' to his father's moods and try and stay away from him if he sensed danger. His father was sometimes violent towards him, his siblings and his mum. Sometimes James would step in if others were being attacked by his father, who would then turn on James even more because of this.

As a result of the interplay of all of the above, James felt very insecure, unsafe and worried a lot. James developed core beliefs about himself as someone who was ("flawed, yet someone who needs to be able to protect others"), and beliefs about the world as ("cruel, hostile and uncaring"). James' parents eventually divorced, and his mother appeared to recover her physical and mental health; she got a job and managed to stabilise things for herself and her children.

Triggering event

When James was 18-years old he was involved in some kind of accident with machinery at a local farm. This led to him having major bowel surgery, followed by a major bowel re-section, and a temporary colostomy, all of which has left him with persistent bowel difficulties now. James started using cannabis at this time as a means of self-medicating (managing pain from his abdomen/bowel and emotional pain and angst). James' father died suddenly following an alcohol-induced seizure. James was finding it increasingly difficult to cope and saw his GP for help but turned up 'stoned' and his GP commented on this. James sensed that his GP (and others in the surgery) were probably strongly disapproving of him.

Psychosis and index offence

Within weeks of seeing his GP, James started to hear voices. Nothing like this had ever happened to him before and he became 'lost' inside of himself trying to make sense of this for a while, whilst managing his ongoing difficulties with his health and drug use. James eventually reached an understanding about the voices. He attributed them to his (previously disapproving GP). When the voices escalated and started to "torture" him, James came to the conclusion that the only way to stop them, was to stop his GP from causing them. He took quite a lot of cannabis the following day and waited for his GP to finish surgery. When his GP locked up the building and went towards his car, James confronted him and stabbed him repeatedly.

Figure 2a shows how this case study would be formulated in accordance with the CBTp (f) model[1].

This figure can be found at the end of this document.

The Garety et al (2001) model does not, however, detail the **behavioural strategies** arising from negative core beliefs. This is important in terms of understanding processes associated with the **maintenance** of highly negative core beliefs (e.g. Davidson, 2000). Davidson (see Table 1 below) proposes that core beliefs are associated with a range of **overdeveloped and underdeveloped behavioural strategies**, which play a role in schema maintenance (Allan et al. 2002, pp. 4- 5).

Table 1 Core beliefs and Personality Disorder[1]

Typical core beliefs	**Behavioural strategies**	
	Overdeveloped	**Underdeveloped**
Borderline personality disorder		
I am bad	Self-punishment	Self-nurturance
No one will ever love me	Avoidance of closeness	Openness to relationships
I cannot cope on my own	Over-dependence	Independence
Antisocial personality disorder		
I can do what I want	Autonomous	Sharing
Other people will get in my way	Combative	Group identification
Don't get close to others	Self sufficiency	Intimacy

This CBTp (f) treatment model therefore further proposes that whilst core beliefs may be associated with the content of the delusion, or impact upon the appraisal or psychotic symptoms, it is also important to look at the **associated behavioural strategies** as they may well serve to help maintain the negative core beliefs. Indeed, the meaning of psychosis or the individual symptoms experienced may have strong links to pre-existing negative core beliefs (Allan et al. 2002, pp. 4 - 5). This is illustrated in Table 2 below.

Table 2 Core beliefs and Psychosis[1]

Typical core beliefs	Behavioural strategies	
	Overdeveloped	**Underdeveloped**
Punishment paranoia / Derogatory auditory hallucinations		
I am bad / vulnerable	Self-punishment	Self-nurturance
I am unlovable	Avoidance of closeness	Openness to relationships
People will harm me if I displease them	Pleasing others / compliance	Independence
Persecutory paranoia		
The world is unfair	Autonomous	Sharing
People are dangerous	Combative	Group identification
Don't get close to others	Self sufficiency	Intimacy

The addition of Davidson's (2000) conceptualisation framework to Garety et al's (2001) model, therefore, helps provide a more expansive formulation of the **complex and problematic relational and behavioural aspects of personality functioning**, **arising from core beliefs** that are often found in this specific population (e.g. Adshead et al. 2018). In addition, it helps to give an enhanced understanding of how these behavioural and relational patterns might also be implicated in the maintenance of psychotic symptoms (e.g. delusions) and/or their appraisals in this group. The finalised version of the 'CBTp (f)' model, therefore, represents an amalgamation of both Garety et al's (2001) model and Davidson's (2000) conceptual framework, as outlined above. (Davidson's (2000) '**associated behaviour**' (either overdeveloped or underdeveloped), has been added into the diagrammatic representation of Garety et al's (2001) model depicted in Figure 2 (page 47). It is shown under the list of

maintenance factors, within the 'Emotion' bullet point, and is highlighted in light blue font (in parenthesis).

To complete the process of formulation when using the CBTp (f) model, a number of other factors are highlighted within the treatment manual as requiring additional focus. These additional factors are detailed in the second excerpt from the CBTp (f) treatment manual, shown below (Allan et al. 2002)[1].

CBTp (f) Treatment Manual (Allan et al. 2002, pp. 7 - 8)[1] – Excerpt

Additional factors relevant to this population

There are a number of areas which in our opinion need further attention than the above model allows for when formulating cases in this type of population. (We have already discussed the relevance of negative core beliefs and behavioural strategies associated with Personality disorders in section above). The other three areas worthy of special attention are Alcohol and Drug misuse, Post Traumatic Stress Disorder and Offending Behaviour.

- Alcohol and Drug misuse

Haddock et al (2002) suggest that 'The following problems are common to most patients with psychosis and are likely to come up with most patients at some time: problems regarding hallucinations, delusions, negative symptoms, social functioning, self-esteem, depression, anxiety, familial difficulties, medication and side effects as well as financial and social problems. Although these areas are common for all psychotic patients, substance users may have pertinent problems relating to symptomatology that is masked or covered up by the substance use, financial problems relating to substance use, interpersonal and family difficulties related directly to disagreement regarding substance use, frequent and less predictable relapse, frequent hospitalisations, and problems relating to violence and aggression.'

- Post-Traumatic Stress Disorder

Meuser et al (2002) highlight the fact that there is a significant association between trauma exposure and symptom severity in people with serious mental illness (SMI) (particularly with reference to Schizophrenia). In order to explore the nature and type of relationship that exists, they present an integrated model which is an adaptation and extension of the stress-vulnerability model developed for schizophrenia and other serious mental illnesses. In the paper they limit their discussion to how they believe comorbid PTSD might interact with serious mental illness – particularly in terms of how PTSD symptoms may maintain or exacerbate symptoms of psychosis. They discuss the model in terms of direct and indirect effects of PTSD on SMI.

Direct effects of PTSD on SMI

Avoidance of trauma related stimuli - can lead to avoidance of social contacts and therefore reduced opportunity for reality testing, absence of meaningful stimulation and the buffering effects of the social network.

Distress due to re-experiencing the trauma – in the form of intrusive memories, nightmares, flashbacks resulting in the individual being at increased vulnerability to relapse due to the stressful nature to the symptoms. Might take on delusional intensity.

Over-arousal – increased physiological arousal linked with poor prognosis in patients with SMI. PTSD may further increase arousal in people with serious mental illness. Also overgeneralization of vigilance may be to the detriment of person's ability to assess actual probabilities of threat.

Indirect effects of PTSD on SMI

Substance abuse-is high in PTSD and associated with worse symptoms in SMI and is implicated in relapse.

Re-traumatisation – earlier victimisation (especially in case of child sexual abuse) is associated with an increased risk of later victimisation and PTSD over lifetime. Re-victimisation can have a negative effect on psychiatric disorder in the same way as other types of life stress has a negative impact.

Working alliance- problems related to hypervigilance, recurrent disturbing memories, efforts to avoid trauma related stimuli can have an impact of the ability of someone to form and maintain relationships (this could extend to the development of therapeutic relationship).

- Offending Behaviours

Finally, it would appear important to consider offending behaviour in this population– establishing through interview and file review any relationship between offending and mental health. In some cases, there appears to be a clear relationship – i.e. where an individual has committed an offence but has been found unfit to plead because of their mental health status or has been found guilty but with diminished responsibility. Less clear situations occur also, however. To illustrate this, I will refer to a case example from the hospital where a patient had disclosed being involved in anti-social/criminal practices since adolescence. He was also a very heavy user of cannabis. In his early twenties he developed symptoms of psychosis – in particular paranoid ideation. He was preoccupied by the thought that undercover police had put him under surveillance – to the extent that he was extremely anxious about the possibility of this and he altered his behaviour to avoid being seen. It can be seen that there is a relationship between offending and mental health in this case but not in the clear-cut way that someone who has carried out a crime whilst psychotic.

3.2 Process of CBTp (f) delivery – what does it entail?

To develop an understanding of how the various components of the CBTp (f) model [hypothetically] work in action, a specific logic model was developed. However, to help differentiate CBTp (f) from CBTp (as defined in clinical guidelines), two separate versions of this were developed. The first logic model (Figure 3) represents CBTp as defined in clinical guidelines, i.e. non-forensic CBTp.

The second logic model (Figure 3a) was specifically developed for the CBTp (f) intervention. To help further distinguish this logic model from CBTp, the additional 'forensic' components are highlighted in white shaded text boxes.

Figures 3 and 3a can be found at the end of this document.

The first and second stages in the process of CBTp (f) implementation are highlighted within the 'Target '(red) and 'Intervention' (amber) columns of Figure 3a. This complex intervention is designed to be delivered on an individual basis. Referral criteria to the intervention include, patients with schizophrenia or psychosis who are experiencing persisting symptoms and / or depression; [who are] currently distressed by these experiences; willing to engage in CBTp (f); and likely to remain in hospital for the next six to nine months. It is also recommended for use with patients who are in remission to assist with the process of recovery. (See also 'Target' section of the logic model. Figure 3a).

In accordance with the 'Intervention' section of the logic model, implementation of CBTp (f) should follow the theoretically informed treatment manual (Allan et al. 2002). The process of *assessment* (which includes assessment of specific co-morbidities), involves the patient and therapist working collaboratively towards developing a shared understanding (referred to as a psychological 'formulation') of the origins and nature of the individual's ongoing difficulties, particularly their sources of distress and associated level of risk of violence. This is achieved by helping the individual to firstly monitor and recognise current links between their thoughts, feelings and actions, and to begin to consider how these may be implicated in the development and maintenance of their problems.

Engagement with this group of patients can be complex, with patients often experiencing a lack of trust or suspiciousness of others, a high degree of co-occurring problems and a tendency to minimise the extent of illness symptoms or trauma. Nonetheless, the process of engaging with patients to develop a therapeutic alliance is central to the treatment intervention. *Socialisation* to the model of treatment (which involves familiarising the individual with the model) is central to CBTp (f) because it supports patients to set realistic expectations for treatment and assists them to understand what treatment will involve, to help them engage more fully in partnership working. Therapy will involve meeting once a week, will be problem focused, and will

involve the therapist and patient working collaboratively to develop a shared understanding of the patient's difficulties.

Use of *normalising rationale* is another important part of treatment. This is a process whereby patients are given information about situations in which phenomena such as voice-hearing may be construed as an understandable reaction to specific experiences (e.g. sleep deprivation, drug use, bereavement), because often voice hearers or sufferers think themselves "mad" and that they are suffering from something highly abnormal and/or incurable, Kingdon (1999).

Having built a good collaborative working relationship, the therapist and patient then develop their shared understanding of all information gathered during assessment; this results in the production of a *formulation*. This, in turn, helps the therapist and patient to establish a *problems and goals list* and to agree priorities for treatment.

(With a treatment that is problem-focused, a key priority is to identify areas that are most concerning to the patient to ensure their individual areas of distress are focused on). The identification of *treatment priorities* is also important and should have regard to four priorities in the treatment rationale; the first is identifying and targeting *behaviours that increase risk to self and others*; identifying and targeting *beliefs and behaviours that impact on therapeutic alliance*; targeting *beliefs and symptoms from the problem list*; and targeting *underlying beliefs via addressing overdeveloped and underdeveloped behavioural strategies*.

Once the formulation and treatment goals have been agreed, treatment progresses to the *use of specific cognitive and behavioural strategies*. These may include for example, strategies such as engaging in a search for alternative explanations for the experiencing of symptoms or reducing safety behaviours that may be maintaining symptoms (e.g. not sitting with back to the room in response to paranoia). It is not only important to discuss and apply these strategies within the one-hour CBTp (f) therapy session, but a further core component of this intervention, is that these

agreed strategies should also be used outwith the session. This additional work is usually completed in the form of (between-session) 'homework'.

If treatment is progressing well, and the identified problems are reduced, it would consequently be anticipated that the patient has also been developing an independent capacity and adeptness at using these treatment strategies outwith therapy sessions. For example, they will have learned how to make links between their thoughts, feelings and behaviours and can also re-evaluate them, where appropriate. Once treatment goals have been achieved, therapy then moves into the ending phase.

The ending phase of treatment includes *consolidation* of the knowledge and skills that have been learned, and a focus upon building a *relapse prevention* plan for future maintenance of their wellbeing. The expected outcomes at the end of this process would be, the reduction of distress, improvement in functioning and attainment of goals. In addition, within a forensic setting, and where relevant, the intervention should also have helped to inform risk assessment and management and helped to reduce risk of future violence.

The intervention also needs to be objectively measured through application of pre, mid and post treatment psychometrics and, where relevant, any impact the treatment may have had on their risk assessment and management should also be incorporated into the patient's risk assessment and management plan.

3.3 Causal assumptions

The hypothesised causal assumptions made in relation to the CBTp (f) intervention are detailed in the blue 'Change Mechanisms' column of Figure 3a. It is assumed that as/if these changes occur, the desired 'Outcomes' (shown in the green column of Figure 3a) will be achieved. From a risk assessment and management perspective, it is equally crucial to know whether these desired changes *do not occur*, as this would

generally be taken as evidence of continued risk, which, in turn, would indicate the need for further, perhaps alternative treatment in relation to this specific issue.

3.4 Early pilot study

Soon after its inception in 2002, an initial pilot study in the form of a small single case series (n=5) was conducted to explore the acceptability and potential utility of the intervention to patients (Cawthorne 2003). The sample included five males all of whom were single; with an average age of 37 years; mean duration of illness was 12.2 years (range 7-19 years); all had a primary diagnosis of Sz and a co-morbid diagnosis of dissocial personality disorder. Patients received between 15 and 20 sessions of the intervention. Outcome were measured using the (PSYRATS: Delusions and Hallucinations Scales) (Haddock et al. 1999) and the Calgary Depression Scale for Schizophrenia (CDSS) (Addington et al. 1990). Two patients improved more $\geq$25%; and two patients improved $\geq$ 50% on the PSYRATS (Delusions) Scale (Haddock et al. 1999); and the last patient did not show change in this score but had a very low pre-treatment score, which was maintained. Three participants made greater $\geq$ 25% improvement on the PSYRATS (Hallucinations) Scale (Haddock et al. 1999); and two did not show any change. All five patients reduced on the CDSS (Addington et al. 1990) (a mean score reduction from 10 to 6) across the course of treatment. Patient satisfaction questionnaires indicated that they found the intervention highly acceptable. Overall, results suggested that the intervention was fit for purpose and so delivery of this intervention continued to be supported within this environment. This study was the only previous research conducted to explore this CBTp (f) intervention, until the current study. The single case series also focused on outcome evaluation. In contrast, this current research utilises a process evaluation approach and is focused more upon evaluating the process of treatment delivery.

3.5 Current challenges to CBTp (f) delivery

These are identical to the historical challenges outline in section 1.5 of this thesis (please cross-refer to pp. 6-7).

CHAPTER FOUR: METHOD

This study was a mixed method process evaluation. In this chapter information about the design of the study and the influence of the Medical Research Council's (MRC) guidance on the evaluation of complex interventions (Craig et al. 2008) will be outlined. In addition, the three phases of this study are described in detail including the data collection and analysis: Phase One study, a review of case notes; Phase Two study, a series of interviews with current therapists, and Phase Three; the Delphi survey.

4.1 Conceptual framework

Based on Chapters Two and Three of this thesis, the main rationale for this programme of research was, therefore, that having recognised the difficulties that arose after the extremely limited outcome evaluation that was undertaken in relation to the CBTp (f) programme, the researcher also recognised the need to "take a step back" and return to the first and second steps in the 'development-evaluation-implementation' process for developing and evaluating complex interventions (Craig et al. 2008). As such, this current study was designed to considerably augment the earlier work done in that initial pilot, 'within-subjects', case series (n=5) (Cawthorne 2003).

In keeping with best practice, the ideal form of evaluation for any programme designed to effect behavioural change would involve some form of experimental design (Craig et al. 2008). However, due to the extent of 'known' difficulties with the implementation of this complex intervention (see also p. 7), and the acknowledgement that there were also likely to be a number of other 'unknown', or at least not fully understood, issues related to its ongoing implementation, the researcher concluded that the best/most helpful form of evaluation at this stage, would be to undertake an extensive process evaluation.

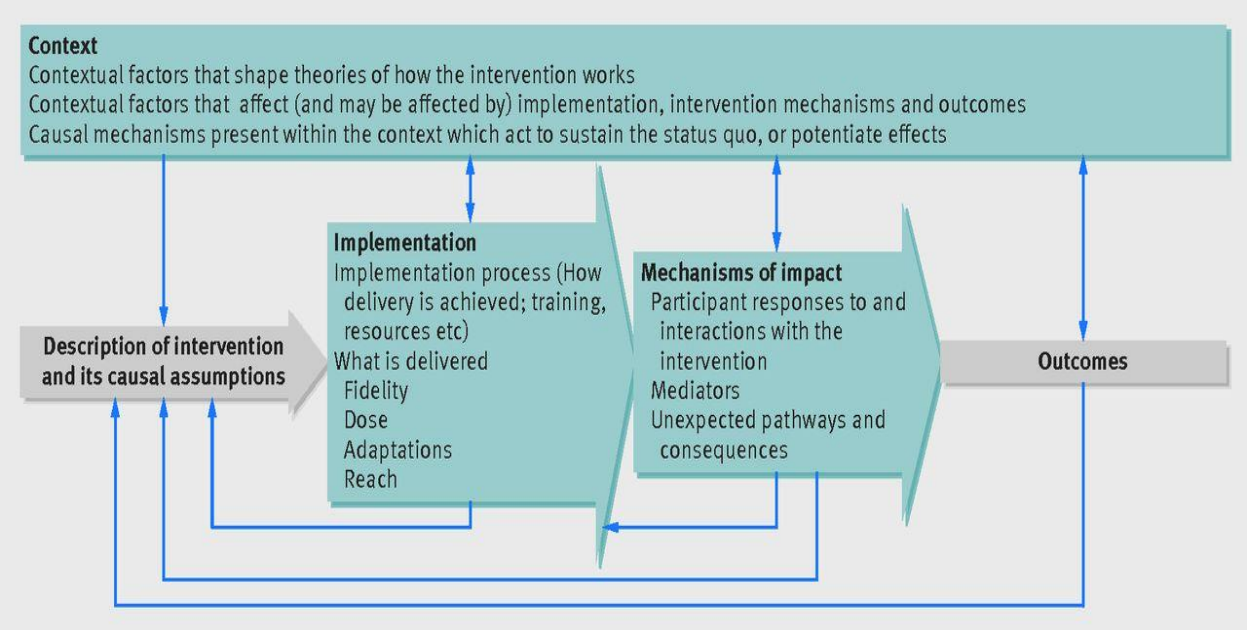
The research design is appropriate, with particular reference to one of the main recommendations contained in the current MRC guidance for the development and evaluation of complex interventions. That is, that after having conducted an extensive literature review and developed the theory for a proposed new complex intervention, this should then be followed up by some kind of modelling of the intervention and its intended processes and outcomes (usually in the form of a logic model). The conceptual framework, theoretical/clinical model, and logic model for the CBTp (f) intervention has been discussed at length in Chapter Three (please cross-refer to pp. 42 – 60 for more information). Two versions of the logic model were presented. An initial version (Figure 3, p. 56) that describes a logic model for CBTp (configured in accordance with current clinical guidelines), which is not forensic-specific; and a second logic model (Figure 3a, p. 56) which presents the logic model specifically developed for the CBTp (f) intervention.

The logic model (which should clearly define the intervention and its causal assumptions) should be used as the basis for any initial pilot/feasibility studies of the proposed new intervention. However, no such logic model was prepared in support of the earlier pilot evaluation of the CBTp (f) intervention. An important feature included in the overall conceptualisation of this latest research design, therefore, was to ensure that this crucial step was not overlooked on this occasion. The CBTp (f) logic model (Figure 3a) was built to ensure that it provided a clear description of the intervention and its causal assumptions, which in turn enabled the researcher to identify how these informed the overall research aim, research objectives and the choice of research methods used to explore these.

Another intended outcome of this process evaluation was that the CBTp (f) intervention and its associated treatment manual would be considerably remodelled and refined such that it would then be much more amenable to being subjected to more outcome-focussed evaluation following this study, ideally in the form of a phase one RCT.

In keeping with the underlying conceptual basis of the process evaluation method and structure (see Figure 4 below), the uncertainties about the implementation of CBTp (f) were deemed to exist in relation to: 1) the 'context' of the setting in which it was being used (how certain contextual factors influenced the delivery and working of the intervention), 2) the process of the actual 'implementation' itself (*how* delivery was achieved and *what* was delivered), and 3) the 'mechanisms of impact' (how the components of the intervention and participants' interactions with them, brought about change). At this stage, process evaluation can have a vital role in understanding the feasibility of the intervention and optimising its design and evaluation (Moore et al. 2015).

Figure 4. Key functions of process evaluation and relationships amongst them.[2]



It was therefore considered that this particular choice of method would enable the researcher to investigate the real-world difference, "…between the 'patient in the guideline' and the 'patient in the bed'." (Greenhalgh and Papousti 2019, p.1). It was further posited that this would be achieved, through the use of process evaluation, by directly 'attending to' rather than 'controlling for' the complexity, not just of the CBTp

[2] Moore et al (2015)

(f) intervention, but also of the system in which it was being delivered (Braithwaite et al. 2018 cited in Greenhalgh and Papoutsi 2019, p. 3).

The overall study aim and research objectives for this study were described earlier in Chapter 1 (please cross-refer to page 10.)

4.2 Study Design

In keeping with the composition of most process evaluations, a mixed-methods design was therefore developed.

Prior to settling on the final choice of methods for phases one – three, a number of other possible methods were considered and then rejected. First, experimental design methods, e.g. some kind of prospective controlled effectiveness study. This was not considered feasible for several reasons; mainly, due to the lack of patients (numbers in receipt of CBTp (f), ranged from zero to five at the start of the study), and an under-developed set of guidance for the intervention with no logic model or other clearly worked out framework that detailed the causal assumptions within it.

Second, the lack of patient numbers also meant that it was not possible to include a study that focused on the patient's perspective in any meaningful way. Either there were no referrals at all - the limitations of which are self-explanatory; or the numbers were too tiny to do anything other than single case study work again, which would not have moved the implementation of CBTp (f) on any further than the single case series previously undertaken (Cawthorne 2003).

Third, another possible way to include the patient perspective might have been to attempt some kind of survey of patients who had previously been in receipt of the CBTp (f) intervention. However, this too was unlikely to be very productive. It could also have placed a burden on patients by asking them to remember a therapeutic experience that they may have been involved with some time ago. Also, being asked to comment on a treatment they took part in a while ago, might have been

unnecessarily unsettling in other ways for some patients, particularly those who may be inclined towards suspiciousness/paranoia (e.g. wondering why the researcher would be going over a past event in this way). It was also possible that patients who had better experiences and/or better outcomes from CBTp (f) could have left the hospital already, leaving only those patients who did not benefit quite so much, thereby creating a potential for biased responding. However, the lack of opportunity to gather the patients' perspective at this stage was a clear limitation; chiefly because it meant that the overall evaluation lacked the voice of the [CBTp (f)] 'receivers' and prohibited exploration of e.g. their views on the acceptability of the intervention, or about any other factors that may have influenced their decision about whether to engage with it or not (Moore et al. 2015). Also, patient involvement in research more generally is thought to enhance its quality and relevance (Moore et al. 2015).

Fourth, the multiple roles already occupied by the researcher also ruled out any possibility of obtaining an independent evaluation via the programme manager, as both positions were occupied by the same person.

Fifth, some thought was also given to potentially conducting a straightforward audit of past case notes using a standard pro-forma. Whilst this may have given some information about what had previously been delivered, this method has well-documented limitations (e.g. difficulty making any causal inferences from an uncontrolled observation, as such observations may be mere coincidences; overinterpretation or misinterpretation of findings; and the process can be extremely time-consuming) (Nissen and Wynn 2014). Also, conducting an audit of an intervention without an underlying logic model was likely to be extremely unfocused, possibly even more time-consuming (due to lack of clarify about what it is that was actually being sought), and would have been limited in what it could confidently say; particularly if used as a unilateral approach to investigating implementation issues.

Last, focus groups (with therapists) was also considered but rejected on the basis that it may have felt too threatening to some people, particularly if they felt overwhelmed by aspects of this work, which subsequently transpired to be an actual finding.

Phase One – Review of case notes. This involved undertaking a retrospective quantitative review of a sample of case notes (n=60) of patients who had participated in CBTp (f) over the 16-year period since it was first delivered in this service (2002 to 2017). This part of the study addressed research objective one and part of objective two (please cross-refer to page 10). Quantitative data were generated using a specifically designed pro-forma, (see Appendix 2). Primarily, this part of the study helped the researcher to explore and build some empirical evidence about CBTp (f) implementation by enabling specific data to be generated about *how* delivery was achieved and *what* had actually been delivered. More specifically, it enabled the researcher to determine whether it had been possible to implement CBTp (f) in accordance with the underlying logic model (Figure 3a) and if so, to what extent? Were the causal assumptions borne out over the course of its delivery and were the desired outcomes attained? (However, there are clear limitations to using this method to make causal inferences as highlighted earlier. See page 65 above). Whilst this part of the study focused primarily on investigation of the 'implementation' component of the process evaluation structure, inevitably there was overlap with some of the 'contextual' and 'mechanisms of change' components also.

Phase Two – Interviews with current therapists. This qualitative part of the study was used to answer further aspects of research objective two and objective three (please cross-refer to page 10). A semi-structured interview schedule was designed to gather information for this purpose (see Appendix 3). Primarily this part of the study helped to build evidence around the '*mechanisms of impact'* component of the process evaluation. For example, it helped gather evidence about such factors as; how did the therapists describe their interactions with the treatment manual and to what extent did they consider that they could operationalise this and apply it with their patients? However, as before, due to the interrelatedness of all components in this

complex intervention and within this complex system, there was again some overlap with the 'implementation' and 'contextual' components.

Phase Three – **Delphi survey**. This (qualitative and quantitative) part of the study was designed to answer research objective four (see page 10) – to identify what elements of the treatment manual should be changed to allow for improved future implementation of CBTp (f). Further, once this improved manualised CBTp (f) was achieved, it was anticipated that this would enable more outcome-focussed evaluation of the intervention to be undertaken at a future point. The survey tool used for this was developed through a process of analysing the evidence gathered from phases one and two. The purpose of this phase was to gain a consensus from a panel of experts about the best way to systematically deliver a CBTp intervention in a HSH and to identify the changes to the treatment manual underpinning the current CBTp (f) programme that would be required to enable this to happen. Thus, primarily this part of the study focused more specifically on considering aspects of the *'context'* component of the process evaluation, although, as before, there was overlap with both the 'implementation' and 'mechanisms of change' components.

4.3 Key procedural considerations

This section focuses on the description of six key considerations that span across all three phases of the study: study approval, potential risks, informed consent, confidentiality and anonymity, data handling and main ethical issues. Additional procedural considerations for the individual phases are described later on in this chapter.

4.3.1 Study Approval

Prior to embarking on this process evaluation, study approval was sought and granted from both the Research Committee at The State Hospital (see Appendix 4) and the NHS, Invasive or Clinical Research (NICR) Committee at the University of Stirling (NICR 16/17 – Paper No17. See Appendix 5). Based on initial feedback, a submission to the Integrated Research Applications System (IRAS) was indicated. A

full research application was then uploaded onto IRAS. Following this, Dr Judith Godden, the Scientific Officer from the West of Scotland Research Ethics Service Office (WoSRES) contacted the researcher to advise that this study did not need NHS ethical review (see Appendix 6)

4.3.2 Potential risks

These can be categorised as patient, therapist and researcher-related risks

Potential risk to patients

No patients were directly approached in relation to this study and there were no risks to patient care. However, given that phase one involved a detailed review of 60 case notes, it was recognised that some patients could still have been in the hospital and therefore could be identified. To safeguard against this and protect the sensitivity of patient data, all information extrapolated from case notes was recorded on a pro-forma (Appendix 2) with no patient identifier on it. This protected and ensured the confidentiality and anonymity of these patients at all times. Further, to check that this procedure has been rigorously followed and equally applied to the researcher's own cases, a third party (the independent interviewer for the phase two part of the study) used the same pro-forma to independently extract information from [three] cases and compared this with the researcher's own findings. This verified that the same information had been correctly gathered by both raters (see Appendix 7).

Potential risk to therapists

During the phase two semi-structured interviews, therapists were asked to recall aspects of the care and treatment that they had delivered, or were currently delivering, to patients in the service. Whilst these therapists were all appropriately trained, experienced, highly-skilled and reflective practitioners who were used to working within robust governance structures, it was nonetheless recognised that they may still have experienced some degree of anxiety at this process.

Another potential risk was that by exposing their therapy practices to external scrutiny, this may have highlighted a particular knowledge or skill deficit for some therapist in relation to delivering CBTp (f).

To safeguard against these identified risks, all therapists entering into this study were provided with an information sheet about the study (Appendix 8a) and asked to provide written informed consent (Appendix 8b). This consent form highlighted that the purpose of this process evaluation was to help to develop a more detailed understanding about *what actually happens* in relation to the day-to-day delivery of CBTp (f). It emphasised that no specific patient outcomes would be reported and that all information that therapists had accrued through their implementation of this intervention to date, would be extremely helpful towards developing the service's understanding of the processes required for successful delivery.

To further safeguard against these risks all consenting therapists were given a guarantee that any information they supplied would be collated and coded in order to protect their anonymity. It would then be held in the strictest confidence in a locked cabinet by the researcher. The audio recordings used in individual interviews would be password-protected and stored in files on the University of Stirling 'Box' (computer) storage system. A final safeguard against risk to participating therapists, was the inclusion of an independent interviewer to conduct the phase two individual interviews with them. This strategy was designed to help protect the therapists from any actual or perceived potential 'power imbalance', embarrassment, or fear of being 'judged' by the intervention's researcher, who was also the programme developer and joint programme lead (see pages ix - xii). It was thought that this measure would also help free therapists up such that they could comfortably discuss and describe how they had specifically interpreted and implemented the intervention, including highlighting any potential deviations they may have made from the guidance in the current manual and their rationale for doing so.

Potential risk related to researcher

The researcher also had a key leadership role within this service (as joint programme lead), which could have given rise to an actual or perceived 'power imbalance' with the treating therapists. Moore et al. (2015, p.11) highlight the importance of paying attention to the potential for these types of relational challenges or tensions to emerge between researcher and complex intervention implementers and suggest that occasionally reflecting on these issues with a critical peer could be a useful means of dealing with this. Therefore, at the various points in the process of planning and conducting this study, whenever this risk was most prevalent, one of the researcher's former second supervisors (who had extensive prior experience of conducting process evaluations) specifically helped to facilitate such a process of reflection during occasional supervisory meetings and discussions with the researcher. Further measures taken to safeguard against risk related to a potential power imbalance are outlined in the 'potential risk to therapists' section above and in the introductory pages to this thesis (see pp. ix - xii).

Another potential risk (and ethical consideration) related to the review of past patient case notes by the researcher. This involved examining a high volume of patient case records which contained highly sensitive and confidential material. As a safeguard against this, it was noted that as the researcher was a joint programme lead within this service, they would have access to past patient records in fulfilment of other parts of their role such as for service audit purposes. In this regard, access to these records would not be deemed to be outwith the parameters of 'normal practice' for this service, as was recognised by the WoSRES in their exemption letter for the study referred to earlier (Appendix 6).

4.3.3 Informed consent

Due to the nature of the phase one study (case note review), informed consent was sought for participants in phase two (therapists) and phase three (Delphi experts) only. In the case of the individual therapists, participants who were willing to participate were asked by the researcher to provide written informed consent (see

Appendix 8b) prior to their inclusion in this study, in line with the Information Sheets and Consent Forms, Guidance for Researchers and Reviewers, Version 3.2 May 2007 (National Research Ethics Service: NRES). Further, as the researcher did not have a line management relationship with these therapists, it was anticipated that this separate relationship would help mitigate against the possibility of anyone feeling 'coerced' into participating in the study. For the Delphi study, participants (expert panel members) were asked to provide consent via electronic means (by clicking a radio button) to indicate their consent. This was accessible to them only after they had read the information page about the study (Appendix 9a). A copy of the corresponding informed consent information sheet is attached (see Appendix 9b). This was made available to Delphi participants via a hyperlink to it on the online survey website.

4.3.4 Confidentiality and anonymity

Confidentiality and anonymity were protected by ensuring that all information held in relation to individual patient case note files, therapist interviews, and Delphi study expert panel members, was coded such that no identifiers were used. Case note files were assigned a number from 1 – 60 and individual therapist interviews were assigned a number from 1 – 9 to reflect the number of cases and participants respectively. All participants were assigned a unique study identification number in accordance with this process. This number code was then used to identify the participant on all subsequent written forms, datasheets and databases. One hard copy record sheet linking patient case note identity, location and study identification number was kept in a locked filing cabinet, separate from datasheets.

At the Round One launch of the Delphi survey, the researcher emailed 20 prospective panel members using the nhs.net email system and invited them to participate. Those who consented were then asked to provide demographic information about their gender, professional background or clinical/non-clinical role only. No specific identifying information was gathered about them. This step was taken to protect their

anonymity and, in an attempt to optimise their continued participation in the survey. Responses to both rounds of survey questionnaires were sent to a central/ independent web-based host, the Bristol Online Survey platform (Online Surveys 2019), which was recommended by the University of Stirling for this purpose. This platform also meets requirements for General Data Protection Regulation (GDPR) compliance.

4.3.5 Data handling

All data gathered in this study, including files of audio digital recordings were kept secure at all times and maintained in accordance with the requirements of the Data Protection Act and local Caldicott Guidelines. At the end of the study it was then moved to the University of Stirling's secure 'Box' system, as per their policy, where it will be stored for a period of 10 years.

4.3.6 Main ethical issues

The main ethical issues identified over the course of the planning and execution of this research were: the researcher's pre-existing roles within the service in which this study took place; the review of case note information for research purposes; and the requirements to obtain both therapists' and Delphi study expert panel members' informed consent, to protect their confidentiality and anonymity, and to ensure that none of these professional participants would be subjected to any stress or anxiety beyond and above what they might reasonably expect in their everyday working lives. Each of these issues were identified and commented upon earlier in this chapter.

Having outlined above the key procedural considerations and steps that apply to all three phases of the study, this next section of the chapter goes on to describe the methods used in each separate phase of the study in more detail.

4.4 PHASE ONE STUDY – REVIEW OF CASE NOTES

Objectives

The specific objectives for this case note review were:

- To explore and identify the processes that are required for successful implementation of this complex intervention within this specific setting.
- To explore whether there is any variance in compliance among the CBTp (f) therapists with the guidance contained in the current version of the treatment manual for the intervention.

Method

A retrospective analysis of case note information was undertaken. This involved reviewing a sample of case notes selected from the PSI Service's database of patients recorded as having participated in the CBTp (f) intervention over the 16-years' period that it had been implemented.

Sample

A pragmatic decision was taken to sample one third (*n* = 60) of the total 174 sets of case notes that related to CBTp (f) delivery which had taken place between 2002–2017. The rationale for this decision was that this would likely yield a suitably representative, yet manageable sample. Cases were selected by stratifying them according to four different groups of therapists (given that the therapists' role was of primary interest in this study). Fifteen sets of case notes were randomly selected using an electronic randomization tool, *'Research Randomizer'* (Urbaniak and Plous 2013) from each of the following four distinct groups of therapists who had worked with this treatment intervention to date (thus 15 x 4 = 60).

1) Qualified clinical or forensic psychologist (therapist who had completed core component of training that included at least diploma-level equivalent training in CBT)

2) Trainee clinical or forensic psychologist (therapists who had completed core component of training included training in CBT up to at least postgraduate certificate level)
3) Nurse therapist (therapists with CBT Diploma level training) with two or more years post qualification experience
4) Nurse therapist (therapists with CBT Diploma or other level training) with less than two years post qualification experience

Design of pro-forma

The design of the 60-question pro-forma (Appendix 2) used to gather quantitative information from the sample of case notes (n=60) was based on the logic model for the CBTp (f) intervention (see Figure 3a). Fifty-eight of the questions on the pro-forma yielded quantitative data, whilst the final two questions yielded qualitative data. Specifically, these last questions asked whether there was any further information found in the case records that appeared to serve as either a 'barrier' or 'facilitator' to the implementation of the CBTp (f) intervention.

Procedure

Data collected from this phase of the study provided evidence of *how delivery of the intervention was achieved* and *what was actually delivered* in terms of pre-specified variables, including dose, reach, and the detailed components of the CBTp (f) intervention. (Please note, like the logic model, the design of the pro-forma also had some regard to the former *health improvement*, *efficiency*, *access to treatment* and *treatment* (collectively known as the 'HEAT') targets (Scottish Government 2006). These targets, now superseded by the Local Delivery Plan (LDP) Standards (ISD, NHS National Services Scotland 2010), were originally set out to ensure that standards of health care delivery services were constantly monitored and improved. The rationale for their inclusion in the organisation of the pro-forma design therefore was to remind the researcher to be attentive to the study site's requirement to also meet these nationally determined standards (in relation to psychological therapies waiting times).

A number of items on the pro-forma were coded as ‘yes’, ‘partial’, ‘no’ or ‘don’t know/or no information about this located in case note records’. These were rated as follows: ‘yes’ = clear evidence of presence of item; ‘partial’ = some evidence of presence of item, ‘no’ = within an otherwise clearly documented case, there was no mention of this particular item; and ‘don’t know’ = incoherent record, meaning that it was not possible to ascertain that this item was present. (This usually related to cases with absent or very minimal information).

It was estimated that the review of case notes would be completed at a rate of one-hour/set of case notes, which equated to a total of 60 hours, or just under nine days (based on a 7.5 hour working day). However, in practice this process took much longer. There were several reasons for this. First, the initial version of the pro-forma needed to be redesigned. This became apparent when piloting the questionnaire. Many of the questions in this first iteration were structured such that they were yielding qualitative, rather than quantitative information, or a mixture of both. It was therefore difficult to capture the required data using that version. Also, the overall structure of the pro-forma was not well enough aligned with the underlying logic model, such that there was a significant risk that it would not appropriately track the core components of the intervention and its causal assumptions.

Other pragmatic problems encountered at this stage in the data-gathering process included the volume and distribution of the sets of notes for each patient. For example, typically patients had on average two – three large sets of ‘main’ medical notes, a separate set of psychology files, a separate CBTp (f) file, several sets of nursing notes and, depending on when the patient was admitted and the duration of their stay, some files that were also located within the hospital’s RiO electronic record-keeping system (Servelec Ltd 2021) which went ‘live’ in 2012.

A significant amount of information was missing from each set of notes – in particular, information related to the multiple psychometric measures that applied to the programme. These omissions ranged from an absence of psychometric measures, to

partial completion of some at the start of CBTp (f), but not at the mid-point or post intervention; multiple blank sets of psychometrics located in files, differences in the actual measures used at different times points, and no apparent reference to or 'reconciliation' of information elicited from psychometric measurement when accounting for the overall process and outcome of the case, e.g. in either episodic treatment progress reports or in end of treatment reports. The extent of this missing information was so marked that it soon became obvious that trying to track any specific psychometric outcomes was a somewhat futile exercise.

As joint programme lead for the service this was a learning experience; from a research perspective, this added to the challenges of accurately capturing data on the intervention. It was clear from the condition of the case notes that work needs to be done to improve the quality of information held. Data-gathering using case note review was also extremely time-consuming and produced very little helpful data. For example, it did not directly address the second research objective (concerning degree of therapist compliance with the manual) and would therefore not be a helpful method to repeat in a future larger trial. Tests of treatment fidelity in larger trials are generally better answered by, e.g. use of recordings of sessions that are then rated for fidelity using specific therapy adherence scales.

Statistical Analysis

All data collected were labelled/coded and inputted into SPSS (IBM 2017) using a specifically developed coding framework. Analysis of this data was then undertaken using SPSS Version 25 (IBM 2017) in the form of frequencies and means. These were used to analyse demographic data and clinical characteristics of the sample, together with the various components of CBTp (f) that had been delivered.

It was originally planned that all scores from across the list of psychometric measures for the programme at baseline, mid-treatment and at the end of treatment points, and the total scores on each of these measures, would also be included in the data

analysis. However, as noted above, due to the extent of missing information, it was not possible to pursue or include this information in any meaningful way.

All results gathered for this phase of the study are reported in the Results section of this thesis.

4.5 PHASE TWO – THERAPIST INTERVIEWS

Objectives

The specific objectives for this series of interviews with therapists were:

- To explore whether there is any variance in compliance among the CBTp (f) therapists with the guidance contained in the current version of the treatment manual for the intervention.
- To elicit the views and experiences of the CBTp (f) therapists to establish what factors would enable them to successfully implement the intervention, within this HSH setting, with forensic patients.

Method

A qualitative analysis of individual interviews with therapists was undertaken. To help recruit support and to encourage participation in this part of the study, the researcher delivered a presentation about the study at a departmental meeting.

Sample

All trained therapists (n=9) who were delivering CBTp (f) and working in the department at the time (January 2018), consented to participate in the study.

Design of semi-structured interview schedule

This consisted of 22 questions that asked therapists about their training in CBTp, CBTp (f), the use of the CBTp (f) manual, their patients' characteristics; their views on the content and perceived utility of the CBTp (f) manual, their experiences of using it;

their perception of barriers and facilitators to CBTp (f) implementation and their experience of receiving clinical supervision for this work. This schedule was then piloted by the researcher with an appropriately trained colleague to gauge its acceptability and its estimated completion time. No changes were made to it at this stage as it appeared fit for purpose and took about 30 – 40 minutes to complete.

Procedure

Individual interviews with participants were conducted using the semi-structured interview schedule (Appendix 3). Interviews were conducted by an independent interviewer who had diploma-level training in CBT and prior knowledge of the CBTp (f) protocol. Completed interviews were transcribed verbatim by an independent transcriber who then sent them back to the independent interviewer for approval or to make any required amendments. At this point, the independent interviewer assigned the transcripts a number (from 1 – 9) and then sent copies of the transcript to the relevant participant for their final approval and to check whether any errors had been made. Once final versions of all the transcripts were returned to the independent interviewer, they then forwarded these to the researcher for analysis.

Unfortunately, this part of the overall evaluation did not produce as much 'rich' data as was hoped for, which was a point of frustration for the researcher. For example, had the potential power imbalance (due to the researcher also being programme lead and implementation developer), not given rise to such a clear conflict of interest, and had the researcher had the opportunity to ask questions directly; it might have been helpful to explore some of the *'why'* areas more thoroughly. In particular, the instances when therapists commented about using eclectic mixes of different therapeutic models, the 'stop, start' nature of some approaches described, and the rationale underpinning delivering CBTp using a non-CBT focussed formulation. Also, although piloted prior to its use, it was possible that the questionnaire was too long and/or the time allocated for each interview too short. The independent interviewer, however, did not comment on these issues in their feedback to the researcher.

Data Analysis

All information from transcripts was inputted into NVivo12 (QSR International 2018) and analysed using a thematic analysis approach (Braun and Clarke 2006). After familiarising themselves with the data by reading and re-reading transcripts, the researcher then coded the transcripts and began to build an initial coding framework. This emerging framework was then reviewed, and refined and discussed with the researcher's supervisors, and an independent reviewer, until a final set of main themes and sub-themes were agreed and identified. Table 3. Provides a diagrammatic representation of this process.

Final themes were then further organised according to their frequency of occurrence and whether they were considered to represent either a barrier or facilitator to CBTp (f) delivery, or both. Results for this phase of the study are reported in Chapter 5, page 105.

Table 3 can be found at the end of the document.

4.6 PHASE THREE – DELPHI SURVEY

Objective

The specific objective for this Delphi survey was:

- To establish what elements of the treatment manual may potentially need changed to enable further, more robust, outcome evaluation of the intervention.

Method

Results obtained from phases one and two of the study were first synthesised. Core elements and themes considered to be important to the delivery of CBTp (f) (based on information from clinical guidelines and evidence-based literature), were then extracted and used to help compile the 45-item questionnaire used in Round One of the Delphi survey (Appendix 10). (This included core elements of the underlying logic model. See Figure 3a). This questionnaire comprising, 24 quantitative and 21 qualitative questions, was then uploaded on to the Bristol Online Survey tool (Online Surveys 2019), to facilitate its dissemination as an eDelphi survey.

Sample

The researcher emailed a panel of 20 experts to invite them to participate.
This group consisted of males and females from different areas and backgrounds who were either authors of CBTp manuals, or clinicians from other HSHs in the UK involved in delivering and/or supervising CBTp in their services.

Procedure

The researcher e-mailed prospective panel members to give them information about the study and invite them to participate. This email included a link to the online survey tool. Participants were given one month to respond to the first round. (The researcher also followed-up on this by sending reminders to prospective participants about the closing deadline for completion of Round One, at two weeks, then one week, before the deadline).

Fourteen participants (70%, n=14/20) responded at the Round One stage. Analysis of the content of the Round One responses was then undertaken (as outlined below). At the end of Round One, 21 items were identified for inclusion in the final list of items for the revised manual; four items were identified to be re-rated; 13 new items were added; and 20 items were excluded. This then led to the development of a new 17-item questionnaire for surveying the expert panel again in Round Two. At the start of Round Two the researcher again sent notice about this new round of questions (via secure nhs.net e-mail) to the same participants who had been asked to participate in Round One. Participants who had not responded to Round One were asked not to respond at the Round Two stage either, as a means of ensuring that continuity of responses was maintained across the two rounds. The Round Two questionnaire included five repeated or re-framed questions (four to be re-rated from quantitative data, and one newly devised by counting the frequencies of responses to a qualitative question asked at the Round One stage). The panel were shown the percentage (%) response rate assigned to these questions in Round One. Experts were asked to reconsider their original response in light of this new information and invited to re-rate them. All 17 questions asked in Round Two were presented in the form of a five-point Likert scale with choices of responses ranging from 'Agree strongly' to 'disagree strongly'.

Eleven participants (79%, n=11/14) responded again at the end of Round Two. At this point the researcher, in discussion with their supervisor, decided to stop surveying due to high level of consensus already achieved in the survey process.

Analysis of Content

Items were included in the final list of results if there was clear consensus reached by >70% of the panel members and results were in keeping with the literature and evidence base for the delivery of manualised CBTp. Both the *definition* and *level* of consensus chosen for this study was set by the researcher with regard to the literature in this area (e.g. Jorm 2015; Keeney et al. 2011). For this study, the researcher based their decision-making on the following factors. First, the *diversity of*

expertise in the expert panel, their *independence* to each other, their high level of professional *autonomy,* and the use of the Delphi process to gather their *collective views*, was in keeping with Surowiecki's (2004) 'wisdom-of-crowds' construct. This suggests that the presence of these four factors in this group would have made them inherently 'wise', and therefore not requiring an exceptionally high level of consensus when expressing similar views. Second, in keeping with the overall rationale for this study, the delivery of CBTp (f) is an under-researched area; meaning that it was not possible for the expert group to form their views based on a large body of literature and evidence. If such a large body of evidence had been available, this may have led to a much greater range of opinions, which might then have justified setting the level of consensus higher (e.g. at >80% or 90%).

Items were also included if *qualitative* responses (e.g. comments relating to recommendations for training, delivery, or the manual) were made by more than one expert and were clearly aligned with clinical guidelines, recognised professional practice standards (e.g. for record-keeping), local governance structures and the current evidence-base. Further, if there was clear consensus (>70%) at the Round One stage, but the result was not in keeping with evidence-based literature, the item was reworded and included in Round Two. Similarly, if qualitative answers were minimal or suggested a lack of understanding of the intent of the original question in Round One; then these were reworded and included in Round Two.

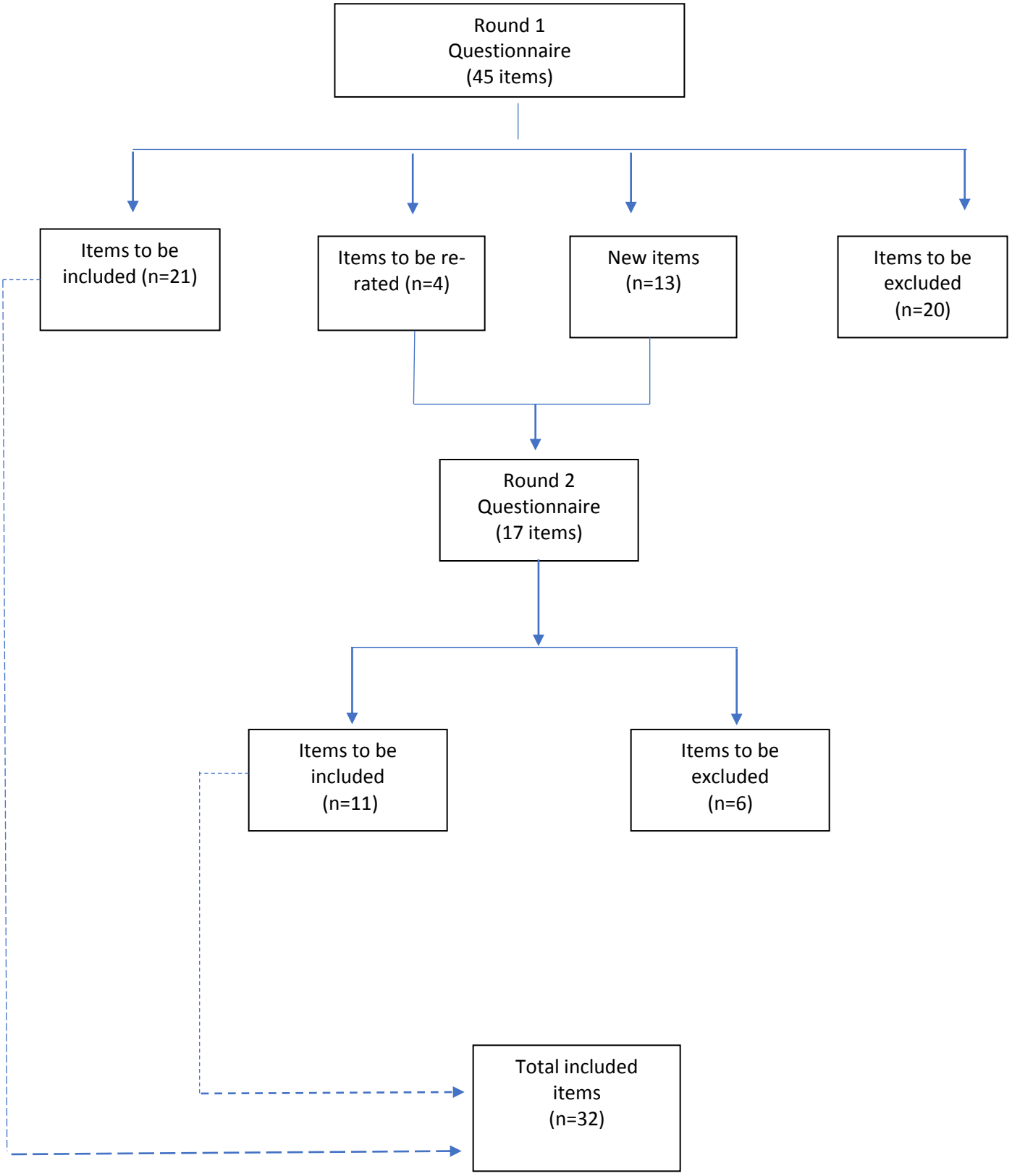
By the end of Round Two, a total 26 items were excluded (three did not achieve consensus; three achieved consensus >70% but were rated as too ambiguous and requiring revision; 16 were qualitative responses (comprising six questions that added no new information or duplicated information over several other responses, and ten that shaped new quantitative questions for Round Two) and four that achieved consensus >70%, one of which was not aligned with the current literature and evidence-base, one that conflicted with several other recommendations where consensus >70% was achieved, and two that did not relate directly to the delivery of

manualised CBTp). Thirty-two items were included in the list of items at the end of the Delphi survey.

Figure 5 presents a flowchart showing the number and outcomes of items in each Delphi round.

Results for the Delphi will also be presented in the next chapter, Chapter 5.

Figure 5. Flowchart showing number and outcomes of items in each Delphi round



CHAPTER FIVE: Results

This chapter presents the results of the mixed-methods process evaluation. The results are presented sequentially starting with phase one case note review, moving to phase two therapist interviews and finishing with phase three Delphi survey.

5.1 PHASE ONE – REVIEW OF CASE NOTES

The case note pro-forma was used on 60 sets of case notes. Of these, 12 (20%) were excluded from the analysis for the following reasons. One was selected where treatment was never started. Three were duplications of other cases. Eight had no discernible components of the specific CBTp (f) programme, or of CBTp in general. Examples of these included one case where at the outset of therapy, the course of treatment changed from intended CBTp (f), to CBT for sex offending, thus it involved offence-focused work only, and another case related to a distinct course of CBT for anxiety (where the therapeutic aims related only to anxiety and excluded any link with psychosis, such that no assessment of potential psychotic phenomena was mentioned or undertaken).

These excluded cases were not replaced for several reasons. First, the primary focus of this phase of the study was to determine what was actually delivered related to the CBTp (f) intervention under 'real world' conditions. This included gathering information about how the *context* in which the intervention was delivered influenced both what was implemented and how outcomes were achieved and reported. The information regarding excluded cases therefore was considered highly relevant and useful in helping to build an understanding of how such specific contextual factors, such as an apparent system-based propensity for case duplication and mislabelling, influenced the overall implementation of the CBTp (f) intervention. Second, the original sample of n=60 cases were randomly selected. Had the 12 excluded cases therefore been replaced, e.g. through a process of further randomisation, this would

have significantly interfered with the overall process of randomisation, thereby rendering any alterations to this questionable and possibly void. Third, as outlined previously in Chapter Four (page 61) a key feature of the choice of this particular research design was its use in helping to create a new understanding of these types of pre-existing issues. That is, there was already some degree of awareness of a number of pre-existing difficulties with both the quantity and quality of case note information held; issues similar to those experienced when the 60 cases were initially randomised and 12 excluded. It was therefore considered highly likely that any further or repeated random sampling would have continued to produce similar results, thereby necessitating similar repeated case exclusions.

However, by paying closer attention to the information gathered about the excluded cases, this helped to create the new and enhanced understanding that was being sought about what was causing some of the specific implementation difficulties in the day-to-day attempts at delivering the CBTp (f) intervention.

Further, the demographic information for the nine individuals who were excluded were reviewed. This showed that this group were very similar in terms of age, primary and secondary diagnoses, index offence and time in hospital at the start of CBTp (f). It therefore appears that no clear patient-related factor contributed to the non-provision of CBTp (f) to them.

In summary, the results presented relate to the total remaining 48 cases that were included in the overall analysis.

Demographic information on the patient case notes sample is presented in Table 4.

Table 4 Demographic data on patient case notes

Variable	Total Sample (*n* = 48)
Male gender, *n* (%)	48 (100%)
Age at start of CBTp (f)*:	
- 18 – 24 years, *n* (%)	3 (6%)
- 25 – 34 years, *n* (%)	11 (23%)
- 35 – 44 years, *n* (%)	18 (38%)
- 45 – 54 years, *n* (%)	8 (16%)
- 55 years and over, *n* (%)	3 (6%)
- Not recorded, *n* (%)	5 (11%)
Marital status:	
- Single, *n* (%)	39 (81%)
- Married/cohabiting, *n* (%)	3 (6%)
- Divorced/separated, *n* (%)	5 (11%)
- Widowed, *n* (%)	1 (2%)
Ethnicity:	
- White Scottish, *n* (%)	44 (92%)
- White Irish, *n* (%)	2 (4%)
- Other White Ethnic, *n* (%)	1 (2%)
- Multiple Ethnicity, *n* (%)	1 (2%)
Educational qualifications:	
- No qualifications, *n* (%)	25 (52%)
- School qualifications, *n* (%)	14 (29%)
- Degree level, *n* (%)	1 (2%)
- Not recorded, *n* (%)	8 (17%)
Socioeconomic status:	
- Skilled/professional, *n* (%)	7 (15%)
- Semi-skilled, *n* (%)	1 (2%)
- Unskilled, *n* (%)	34 (71%)
- Not recorded, *n* (%)	6 (12%)
Index offence:	
- Murder, *n* (%)	3 (6%)
- Culpable homicide, *n* (%)	7 (15%)
- Attempted murder, *n* (%)	7 (15%)
- Assault, *n* (%)	15 (31%)
- Sexual assault/rape, *n* (%)	8 (17%)
- Breach of the peace, *n* (%)	5 (10%)
- Fire-raising, *n* (%)	1 (2%)
- Other/no criminal charges, *n* (%)	2 (4%)

*CBTp (f), cognitive-behavioural therapy for psychosis (forensic)

The sample was mainly White Scottish, middle-aged men, who were predominantly single, had no educational qualifications and were mostly unskilled. Most patients had convictions for assault (31%, n=15), followed by sexual assault/rape (17%, n=8), attempted murder (15%, n=7) and culpable homicide (15%, n=7). Only 4% (n=2) of patients had either 'other' (i.e. road traffic offences) or 'no criminal charges'.

A summary of the diagnostic status, details of the CBTp (f) treatment, and concurrent psychological treatments of the study sample, is presented in Table 5.

Table 5 Diagnostic status, CBTp (f)* treatment and concurrent psychological treatment/s

	CBTp (f)* (*n* = 48) *n* (%)
Primary diagnosis:	
- Schizophrenia	40 (83%)
- Schizoaffective disorder	3 (6%)
- Other psychosis	5 (11%)
Secondary diagnosis:	
- Personality disorder - mixed/multiple	5 (11%)
- Personality disorder - single, antisocial	8 (17%)
- Personality disorder - single, schizotypal	1 (2%)
- Personality disorder - single, non-specified	1 (2%)
- Alcohol/substance misuse	14 (29%)
- Intellectual disability	2 (4%)
- Other, non-specified	1 (2%)
- Not recorded	16 (33%)
Time period start of CBTp (f):	
- 2002 – 2006	26 (54%)
- 2007 – 2011	17 (36%)
- 2012 – 2016	3 (6%)
- 2017 – present	1 (2%)
- Unknown	1 (2%)
Number of CBTp (f) sessions completed:	
- Confirmed < 16 sessions	12 (25%)
- Confirmed ≥ 16 sessions	9 (19%)
- Not confirmed < 16 sessions	6 (12%)
- Not confirmed > 16 sessions	21 (44%)
Therapist:	
- Qualified clinical or forensic psychologist**	8 (17%)
- Trainee clinical or forensic psychologist***	16 (33%)
- Experienced nurse therapist****	14 (29%)
- Trainee/novice nurse therapist*****	10 (21%)
Concurrent psychological treatment/s:	
- Low intensity	9 (19%)
- High intensity	3 (6%)
- Specialist/highly specialist	5 (10%)
- Other/unspecified	2 (4%)
- None	14 (29%)
- Not recorded	15 (32%)

*CBTp (f), cognitive-behavioural therapy for psychosis (forensic)
**, training was at least equivalent to diploma in CBT
***, training was at least postgraduate certificate level in CBT
****, CBT Diploma level training with ≥ 2 years post qualification experience
*****, CBT Diploma or other level training with < 2 years post qualification experience

In 100% of the cases (n=48/48) the primary diagnoses were schizophrenia or other psychosis as defined in Chapter One, section 1.1. (page 2). A high level of comorbidity with PD was also noted, with an overall 32% (n=15) of patients either having mixed/multiple PDs (11%, n=5), or a single PD (21%, n=10), mainly antisocial type (17%, n=8). However, the result for comorbid alcohol/substance misuse appeared much lower than anticipated (29%, n=14).

Most patients in the sample were treated in the early days of the intervention and whilst they were residing in the 'old', i.e. pre-2011, configuration of the hospital. Thus, 90% (n=43/48) of patients received CBTp (f) in the first ten years of its delivery.

In terms of an appropriate 'dose' of the CBTp (f) intervention, 63% (n=30/48) of patients received either a confirmed number (19%, n=9) or an unconfirmed number (44%, n=21) of $\geq$ 16 sessions, which is in keeping with current clinical guideline recommendations (SIGN 2013; NICE 2014). Both the trainee clinical or forensic psychologists 33% (n=16/48), and the more experienced CBT nurse therapists 29% (n=14/48) treated the majority of patients in the sample. Last, 61% (n=29/48) of the overall sample either received no concurrent psychological treatments (29%, n=14), or related information was not recorded (32%, n=15).

A summary of the *mean* values related to illness duration, time in hospital at start of CBTp (f), and total CBTp (f) treatment duration is presented in Table 6.

Table 6 Duration of illness, time in hospital at start of CBTp (f)* and total CBTp (f) duration (expressed as *mean* values)

Variable	*Mean* values
Duration of illness: - Recorded (n=33) - Not recorded (n=15)	13.85 (SD 12.026, range 1 – 50 years)
Time in hospital at start of CBTp (f): - Recorded (n=44) - Not recorded (n=4)	4.73 (SD 6.631, range 0.33 – 30 years)
Total CBTp (f) duration: - Recorded (n=40) - Not recorded (n=8)	1.40 (SD 1.105, range 0.08 – 4.5 years)

*CBTp (f), cognitive behavioural therapy for psychosis (forensic)

Information about illness duration was recorded for 69% (n=33/48) of the sample. Most patients had been in the hospital for > 4years (*mean*, 4.73 years, range 0.33 – 30 years) before receiving the CBTp (f) intervention.

Where recorded, the mean total duration of CBTp (f) treatment was 1.40 years (range 0.08 – 4.5 years).

The next series of tables relate directly to the underlying logic model (Figure 3a) and its four different colour-coded components. For ease of reading and to help visually align these tables with each relevant section on the logic model, the same colour codes are used in the corresponding heading section for each results table. Each table is then organised into three columns. The first column details the content of each specific component of the logic model. The second column identifies the series of corresponding questions used in the pro-forma (Appendix 2) to gather information from the case notes to check for the presence or absence of each aspect of these components. The third column presents the actual results gathered in respect of each sought-after item. Each table also displays results related to the 'moderators' section of the logic model. These appear in a small sub-section below each table and are all coloured grey.

The results related to the 'Target' component of the logic model (Figure 3a) are presented in Table 7.

Results here indicate that 100% (n=48/48) of the sample met diagnostic criteria for this CBTp (f) intervention. Results also indicate that 88% (n=42/48) had persisting positive symptoms, whilst 8% (n=4/48) were in remission. Results for sub-sections of question 24 indicated that 2% (n=1/48) of patients had active negative symptoms, and 19% (n=9/48) had depression. In relation to specific inclusion criteria for CBTp (f), 81% (n=39/48) were 'currently distressed', 92% (n=44/48) were 'willing to engage' and 94% (n=45/48) were 'likely to remain in hospital for the next 6 – 9 months'.

Table 7. Results related to 'Target' components of logic model

Component of 'Target' section of logic model	Corresponding questions from pro-forma for case note review	Results (*n* = 48)
Patients with schizophrenia or psychosis who are…	[q. 11]. Primary diagnosis? *n* (%)	Schizophrenia, 40 (83%) Schizoaffective Disorder, 3 (6%) Other psychosis, 5 (11%)
… experiencing persisting symptoms and/or depression….	[q. 24] Presenting difficulties/needs? *n* (%) [q. 25] [1] Presence active positive symptoms? *n* (%)	Active positive symptoms, 42 (88%) Not recorded, 1 (2%) No active symptoms/remission, 4 (8%) Other (anxiety), 1 (2%) (Presence of *active negative symptoms*, 1 (2%) and *depression*, 9 (19%) was noted in this question's subsections). Yes, 42 (88%) | No, 4 (8%) | Don't know, 4 (8%)
…currently distressed by experience of persisting symptoms and/or depression…	[q. 25] [3] Currently distressed…? *n* (%)	Yes, 39 (81%) | No, 5 (11%) | Don't know, 4 (8%)
…willing to engage in CBTp (f)*…	[q. 25] [2] Willing to engage…? *n* (%)	Yes, 44 (92%) | Don't know, 4 (8%)
…likely to remain in hospital for next 6 – 9 months.	[q. 25] [4] Remain for 6 – 9 months? *n* (%)	Yes, 45 (94%) | Don't know, 3 (6%)
Patients with schizophrenia or psychosis in remission**	[q. 24] In remission? *n* (%)	No active symptoms/remission, 4 (8%) Active positive symptoms, 42 (88%) Not recorded, 1 (2%) Other (anxiety), 1 (2%)
Can start during all phases including in inpatient setting.	All patients were inpatients.	Total = 48 (100%) inpatients

*CBTp (f), cognitive-behavioural therapy for psychosis (forensic) **(to assist promotion of recovery)

The results related to the 'Intervention' component of the logic model (Figure 3a) are presented in Table 8. These results are presented within clusters of the five pre-determined treatment phases of the CBTp (f) intervention (as detailed in the current version of the treatment manual).

Table 8. Results related to 'Intervention' components of logic model

Component of 'Intervention' section of logic model	Corresponding questions from pro-forma for case note review	Results (*n* = 48)
Manualised CBTp (f)*, comprising...	**See following sections. Treatment manual comprised of these various component parts.**	
...assessment	[q. 31] Did assessment include following key areas? *n* (%) [1] early experiences... [2] schema... [3] critical incidents... [4] problematic thoughts... [5] problematic emotions... [6] problematic behaviours...	 Yes (all), 30 (63%) | Yes (partial), 3 (6%) | No, 3 (6%) | Don't know, 12 (25%) Yes (all), 22 (46%) | No, 8 (17%) | Don't know, 12 (37%) Yes (all), 23 (48%) | Yes (partial), 3 (6%) | No, 3 (6%) | Don't know, 19 (40%) Yes (all), 22 (46%) | Yes (partial), 5 (11%) | No, 4 (8%) | Don't know, 17 (35%) Yes (all), 23 (48%) | Yes (partial), 7 (15%) | No, 3 (6%) | Don't know, 15 (31%) Yes (all), 20 (42%) | Yes (partial), 3 (6%) | No, 5 (10%) | Don't know, 20 (42%)
	[q. 32] Was a timeline completed? *n* (%)	Yes, 10 (21%) | No, 20 (42%) | Don't know, 18 (37%)
	[q. 33] Psychometric assessment? *n* (%)	Yes, all core measures completed, 1 (2%) | No (either partially present or missing), 47 (98%)
...engagement, socialisation to treatment and use of normalising rationale	[q. 25] [2] Did patient express willingness to engage?	Yes, 44 (92%) | Don't know, 4 (8%)
	[q. 27] Were patients interviewed by PSI** staff? *n* (%)	Yes, 41 (85%) | No, 1 (2%) | Don't know, 6 (13%)
	[q. 28] Were patients given a copy of the 'Patient Information Booklet'? *n* (%)	Yes, 22 (46%) | No, 3 (6%) | Don't know, 23 (48%)
	[q. 34] Did therapist record socialisation to CBTp (f)? *n* (%)	Yes, 23 (48%) | No, 6 (12%) | Don't know, 19 (40%)
	[q. 35] Did therapist record use of normalising rationale? *n* (%)	Yes, 9 (19%) | No, 6 (12%) | Don't know, 33 (69%)
	[q. 36] Was level of engagement recorded? *n* (%)	Yes, 42 (88%) | Don't know, 6 (12%)
	[q. 37] Extent of level of engagement. *n* (%)	None or very little, 9 (19%) Modest level, 8 (17%) Moderate level, 6 (12%) High level, 19 (40%) Don't know, 6 (12%)
	[q. 38] Frequency of sessions. *n* (%)	One per week, 37 (77%) | Once per fortnight, 2 (4%) | Other frequency, 2 (4%) | Don't know, 7 (15%)

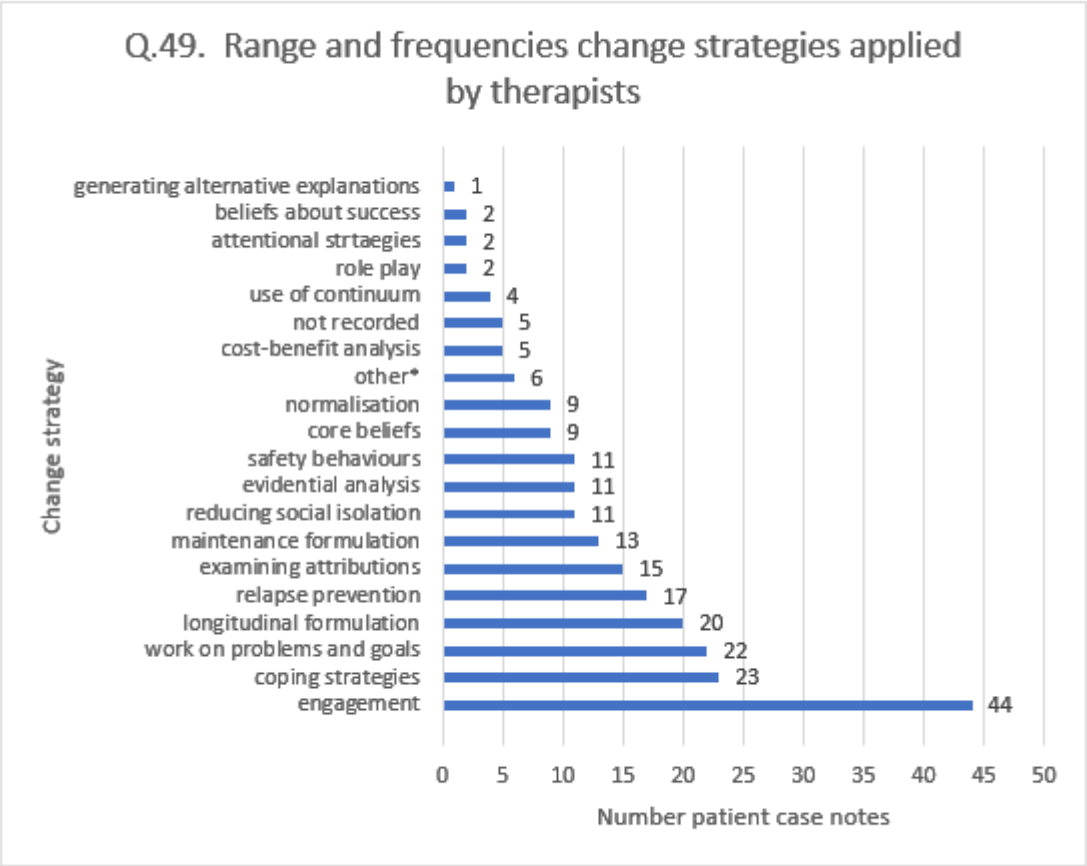
...engagement, socialisation to treatment and use of normalising rationale	[q. 49] [1] Was engagement used as change strategy? *n* (%)	Yes, 44 (92%) | Don't know, 4 (8%)
... formulation, establishment of patient problem list/goals and treatment priorities	[q. 39] Patient and therapist developed formulation? *n* (%)	Yes, 30 (63%) | No, 12 (25%) | Don't know, 6 (12%)
	[q. 40] Formulation underpinned by protocol? *n* (%)	No formulation achieved, 12 (25%) Yes, 5 (10%) No, but another model discernible, 18 (38%) No, and no other model discernible, 7 (15%) Don't know, 6 (12%)
	[q. 41] Formulation included information about: *n* (%) [1] early experiences... [2] schema... [3] critical incidents... [4] problematic thoughts... [5] problematic emotions... [6] problematic behaviours...	 Yes (all), 27 (56%) | Yes (partial), 3 (6%) | Don't know, 7 (15%) | N/A, 11 (23%) Yes (all), 23 (48%) | No, 5 (10%) | Don't know, 9 (19%) | N/A, 11 (23%) Yes (all), 24 (50%) | Yes (partial), 1 (2%) | No, 3 (6%) | Don't know, 9 (19%) | N/A, 11 (23%) Yes (all), 22 (46%) | Yes (partial), 4 (8%) | No, 2 (4%) | Don't know, 9 (19%) | N/A, 11 (23%) Yes (all), 24 (50%) | Yes (partial), 3 (6%) | No, 2 (4%) | Don't know, 8 (17%) | N/A, 11 (23%) Yes (all), 21 (44%) | Yes (partial), 2 (4%) | No, 5 (10%) | Don't know, 9 (19%) | N/A, 11 (23%)
	[q. 42] If non-formulation driven, are CBTp (f) strategies recorded? *n* (%)	N/A, 30 (63%) | Yes, 3 (6%) | Don't know, 15 (31%)
	[q. 43] Problem list agreed with patient? *n* (%)	Yes, 23 (48%) | No, 15 (31%) | Don't know, 10 (21%)
	[q. 44] Treatment priority order coverage. *n* (%), [1] Target - risk behaviours [2] Target - therapeutic alliance [3] Target - problem list [4] Target - o/u behaviours	 Yes (all), 16 (33%) |Yes (partial), 1 (2%) | No, 3 (6%) | Don't know, 18 (38%) | No p/list, 10 (21%) Yes (all), 24 (50%) | Don't know, 14 (29%) | No p/list, 10 (21%) Yes (all), 18 (37%) | Yes (partial), 1 (2%) | No, 8 (17%) | Don't know, 10 (21%) | No p/list, 11 (23%) Yes (all), 15 (31%) | Yes (partial), 1 (2%) | No, 8 (17%) | Don't know, 13 (27%) | No p/list, 11 (23%)
... use of cognitive and behavioural change strategies informed by collaboratively agreed formulation, patient goals and treatment priorities	[q. 47] Patient learned to identify links between thoughts, feelings and behaviour? *n* (%)	Yes, 16 (33%) | No, 16 (33%) | Don't know, 16 (34%)
	[q. 48] Patient learned to monitor links to risk? *n* (%)	Yes, 4 (8%) | No, 13 (27%) | Don't know, 31 (65%)
	[q. 49] Specific change strategies used? *n* (%)	(A varying range of strategies were found. Frequencies for each of these are provided according to highest prevalence. (Range of strategies and associated frequencies are shown below this table as a clustered bar chart. See Fig. 6)

… use of cognitive and behavioural change strategies informed by collaboratively agreed formulation, patient goals and treatment priorities	[q. 50] Information about patient shared with wider team? *n* (%)	N/A, no formulation, 5 (11%) | Yes completely, 4 (8%) | Yes partially, 2 (4%) | No, 3 (6%) | Don't know, 34 (71%)
	[q. 51] Patient completed homework tasks? *n* (%)	Yes always, 10 (21%) | Yes sometimes, 4 (8%) | Yes, but only rarely, 1 (2%) | No, 10 (21%) | Don't know, 23 (48%)
	[q. 55] End of treatment report completed? *n* (%)	Yes, 31 (64%) | No, 7 (15%) | Don't know, 10 (21%)
	[q. 56] Degree completion all phases of CBTp (f). *n* (%)	Not all phases completed and treatment ended after <16 sessions, 19 (40%) All phases completed and treatment ended after > 16 sessions, 11 (23%) Not all phases completed and treatment ended after > 16 sessions, 18 (37%)
… ending phase, including consolidation and relapse-prevention	[q. 57] End phase of CBTp (f) completed? *n* (%)	Yes, 13 (27%) | No, 13 (27%) | Don't know, 22 (46%)
	[q. 58] Staying well/relapse prevention plan completed? *n* (%)	Yes, 12 (25%) | No, 25 (52%) | Don't know, 11 (23%)

Delivered on a one-to-one basis, over at least 16 sessions	[q. 20] Number of CBTp (f) sessions completed? *n* (%)	Confirmed < 16 sessions, 12 (25%) Confirmed > 16 sessions, 9 (19%) Not confirmed < 16 sessions, 6 (12%) Not confirmed > 16 sessions, 21 (44%)
… by appropriately trained and supervised therapists	[q. 21] Allocated treating therapist? *n* (%)	Qualified clinical or forensic psychologist***, 8 (17%) Trainee clinical or forensic psychologist****, 16 (33%) Experienced nurse therapist*****, 14 (29%) Trainee/novice nurse therapist******, 10 (21%)

*CBTp (f),cognitive-behavioural therapy for psychosis (forensic)
**PSI, Psychosocial Interventions Service
***, (i.e. where training was at least equivalent to diploma in CBT)
****, (where training was at least postgraduate certificate level in CBT)
*****, (with CBT Diploma level training) and > 2 years post qualification experience
******, (with CBT Diploma or other level training) and < 2 years post qualification experience

Figure.6. Q.49. Range and frequencies of change strategies applied by therapists



*other, e.g. anxiety diaries, cognitive remediation therapy, fantasy modification strategies

(1) *Assessment.* Question 31 sought specific information about six key areas of assessment. Information was most frequently located for two of these areas, i.e. '*early experiences'* (69%, n=33/48) and '*problematic emotions'* (63%, n=29/48). For the remaining four areas, information was located with c. 50% frequency only, i.e. *'schema'* (46%, n=22/48), *'critical incidents'* (54%, n=26/48), *'problematic thoughts'* (57%, n=27/48), and *'problematic behaviours'* (48%, n=23/48). Use of a timeline was a recommended part of the assessment process. This was completed in 21% (n=10/48) of cases. All results for question 33, which was designed to gather detailed information related to the assessment phase, were excluded early in the data-gathering process. This arose because this information, which related to a large series of psychometric evaluation measures, and the manner in which it was

reported, was generally considered by the researcher to be unhelpful and ultimately unusable, mainly due to the fact that there was so much of it missing. For example, measures that were intended to be used at the pre, mid- and post- intervention points in all cases, were found to be either blank, or partially completed for one time point only, and mainly absent in relation to other time points. Overall, only one (n=1/48, 2%) fully completed set of pre-, mid- and post- measures was located.

(2) Engagement, s*ocialisation to treatment and use of normalising rationale*. '*Willingness to engage'* was recorded for the majority of the sample, as before (see Table 7). Level of *actual engagement achieved* was recorded by therapists in 88% (n=42/48) of cases, with 69% (n=33/48) reporting this as being at a 'modest', 'moderate' or 'high' level. 'None or very little' engagement or 'don't know' was noted in 31% (n=15/48) of cases. Qualitative information gathered in response to questions 45 ('patient-related barriers' – see Figure 7 below) and 59 ('additional barriers' – see Figure 8 below) also highlighted 'poor engagement' as a frequently reported *barrier* to CBTp (f) implementation. However, additional qualitative information gathered from two records noted that, in one case initial engagement improved significantly after a problem list was generated and agreed, and in the other case engagement was noted to improve after the socialisation phase of treatment and when the patient began to develop more of a sense of 'hope' that recovery was possible.

Figure 7. Q.45. Range and frequencies of patient-related barriers

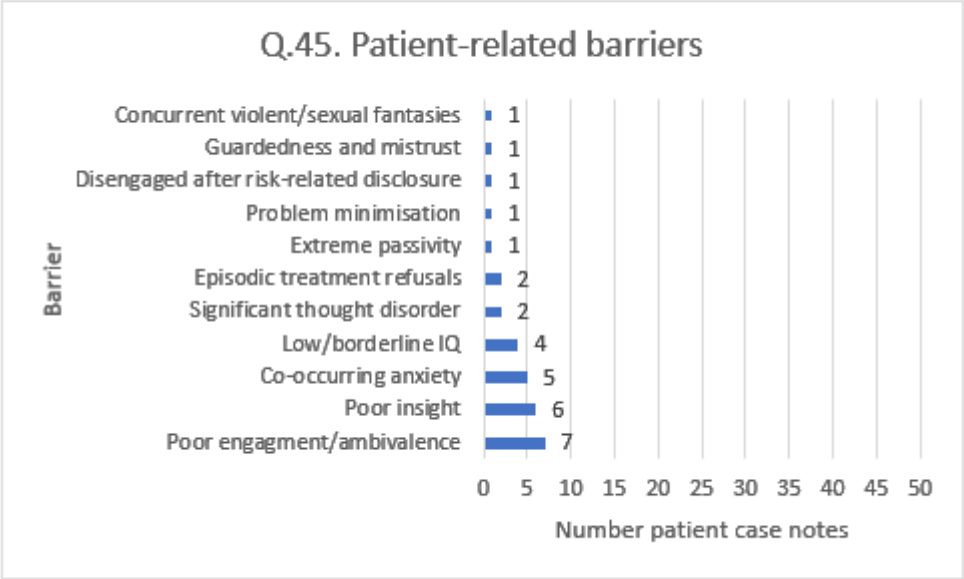
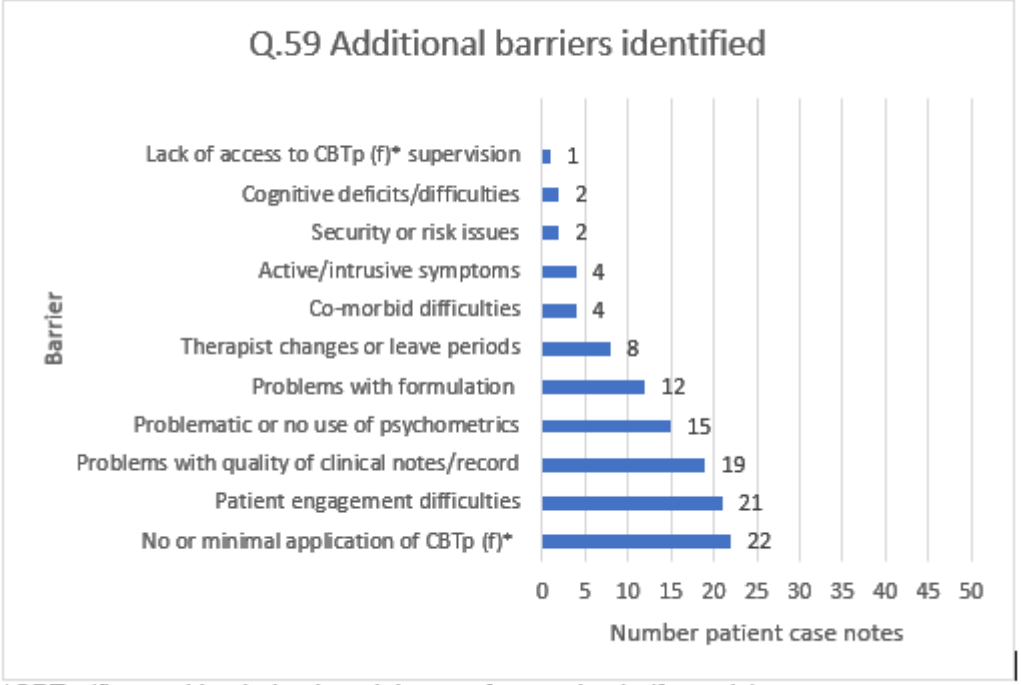


Figure 8. Q.59. Additional barriers identified during case note review

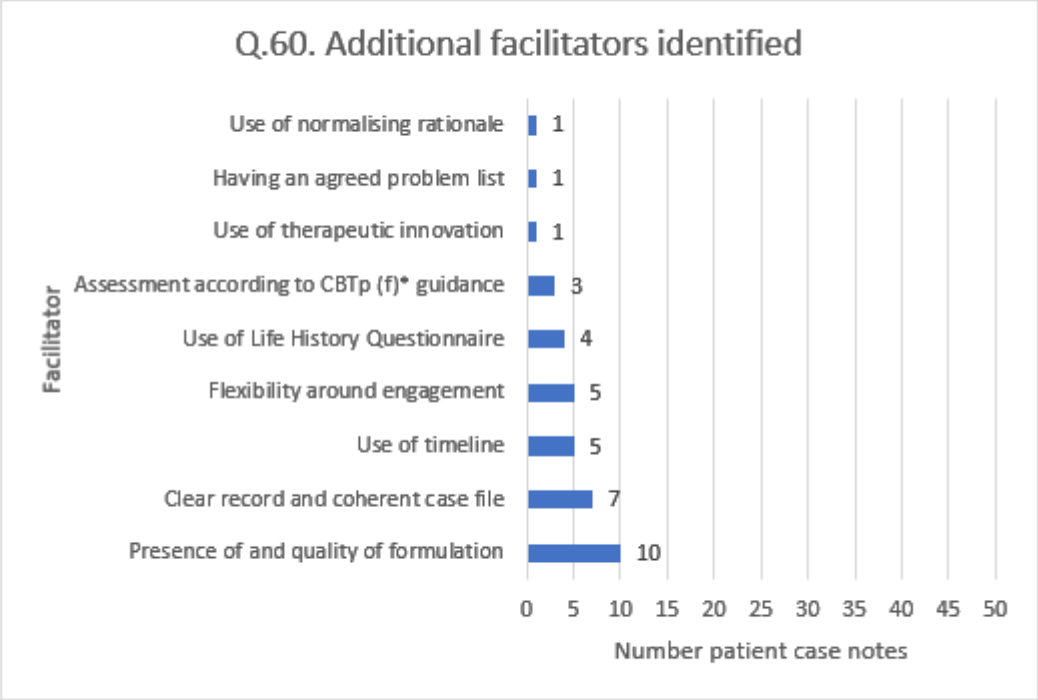


*CBTp (f), cognitive-behavioural therapy for psychosis (forensic)

Socialisation to CBTp (f), when delivered by members of the PSI Service, was undertaken in 85% (n= 41/48) of cases. Treating therapists recorded having completed this phase in only 48% (n=23/48) of cases. (It is however possible that therapists did not complete and/or record this information if they were under the impression that someone from the PSI Service had already done so). It was recorded that patients received a copy of the 'Patient Information Booklet' for this intervention (which also included information about potential iatrogenic effects) in 46% (n=22/48) of cases.

The use of normalising rationale, which is intended to be another key component of CBTp (f), was recorded in only 19% (n=9/48) of cases. One therapist noted as a qualitative response to Question 60 (see Figure 9 below) and thus as a potential *facilitator* to CBTp (f) implementation, how particularly helpful the inclusion of this component had been in relation to one patient's experience.

Figure 9. Q.60. Additional facilitators identified during case note review



*CBTp (f), cognitive-behavioural therapy for psychosis (forensic)

(3) *Formulation, establishment of patient problem list/goals and treatment priorities.* All three sub-components of this phase were also considered to be core elements of CBTp (f). Formulations were located for less than two-thirds of the sample, 63% (n=30/48). The majority of these, 38% (n=18/48) used non-CBTp (f) specific models of formulation (mainly the '5Ps model' or some form of narrative developmental formulation). 'Formulation' was also referred to and located in a further 15% (n= 7/48) of patients; however, in these cases no discernible underlying psychological model or formulation framework could be identified. Formulation in accordance with the specific CBTp (f) programme guidance was located in only 10% (n=5/48) of cases. Qualitative results noted in question 60 (see Figure 9 above) included reports in 21% (n=10/48) of cases to the effect that formulation had been a specific *facilitator* to CBTp (f) implementation.

An agreed problem list was noted in less than half the sample, 48% (n=23/48). Treatment priorities related to risk behaviours was noted as either 'present' or 'partially present' in about one-third, i.e. 35% (n= 17/48) of the sample. Presence/partial presence of treatment priorities related to therapeutic alliance was given the highest attention, at 79% (n=38/48) of cases. Presence/partial presence of treatment priorities related to problem lists was noted in 39% (n=18/48) of cases, which appeared to further dilute the attention given to this key factor. (As above, this was noted to be present in less than 50% of cases). Presence/partial presence of treatment priorities related to over- or under-developed behaviours, which are hypothesised to often play a key role in maintaining specific areas of difficulty, was noted to receive the least amount of attention in this section, with this being noted in only one-third, 33% (n=16/48) of cases.

(4) *Use of cognitive and behavioural change strategies informed by formulation*. Results here were elicited chiefly from question 49, which had a range of twenty-two possible strategies. These are outlined in Figure 6 (above). Strategies related to 'engagement' were noted to be most frequent, at 92% (n=44/48) of the sample, whilst

strategies related to ‘generating alternative explanations’ were noted to have the least frequency, at just 2% (n=1/48).

Question 50 related to whether information about the patient’s formulation was shared with other members of the clinical team. The rationale for this strategy was that additional support might be gained from other professionals to help re-enforce particular aspects of the CBTp (f) intervention with the patient, outwith formal therapy contact times. However, the frequencies for this were very low at just 12% (n=6/48) recorded as either having happened completely, or partially. Question 51 related to the use of homework, which is another means of applying specific CBT, CBTp, or CBTp (f) change strategies. This was recorded as used in about one-third of cases, with 31% (n=15/48) patients doing homework ‘only rarely’, ‘sometimes’ or ‘always’.

(5) *Ending phase, including consolidation and relapse-prevention.* Results for question 56 show that in less than one-quarter of cases, 23% (n=11/48) all phases of CBTp (f) were completed and treatment ended in $\geq$ 16 sessions. This left a reported 77% (n=37/48) of cases where treatment was deemed to have been incomplete. Other results of note here are that 64% (n=31/48) of cases had an ‘end of treatment’ report or summary, 27% (n=13/48) had a recorded ending phase, and 25% (n=12/48) completed a relapse-prevention plan.

Results also clarify that all treatment was delivered on a one-to-one basis. Patients receiving the recommended ‘dose’ of $\geq$16 sessions were confirmed in 19% (n=9/48) of cases. All therapists were trained as specified in Question 21, and they were supervised.

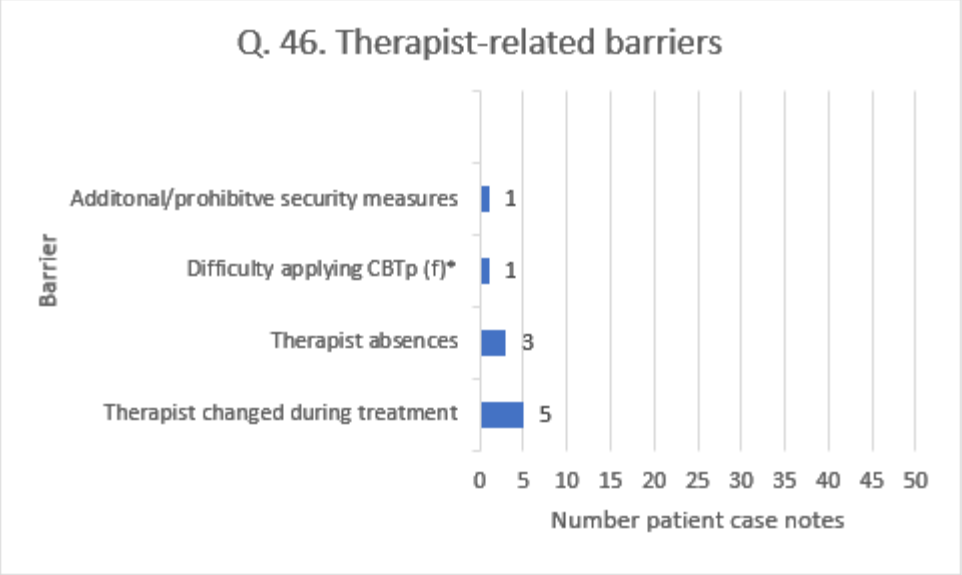
Results related to the ‘Change Mechanisms’ components of the logic model (Figure 3a) are presented next in Table 9.

Table 9. Results related to 'Change Mechanisms' components of logic model

Component of 'Change Mechanisms' section of logic model	Corresponding questions from pro-forma for case note review	Results (n = 48)
Patients engage with CBTp (f)* and can collaborate...	Cross-refer to [q. 25] [2]; [q. 36]; [q. 37] and [q. 49] [1] in Table 8 'Intervention' component for further details.	Cross-refer to results previously recorded for [q. 25] [2]; [q. 36]; [q. 37] and [q. 49] [1] in Table 8 for further details.
...in development of an agreed formulation...	Cross-refer to [q. 39] and [q. 42] in Table 8 'Intervention' component for further details.	Cross-refer to results previously recorded for [q. 39] and [q. 42] in Table 8 'Intervention' component for further details.
...and in establishment of a problem list/set of goals and treatment priorities.	Cross-refer to [q. 43] and [q. 44] in Table 8 'Intervention' component for further details.	Cross-refer to results previously recorded for [q. 43] and [q. 44] in Table 8 'Intervention' component for further details.
Patients learn to make links between their thoughts, feelings and behaviours...	Cross-refer to [q. 47], [q. 48] and [q. 49] in Table 8 'Intervention' component for further details. [q. 49] Specific change strategies used? n (%)	Cross-refer to results previously recorded for [q. 47], [q. 48] and [q. 49] in Table 8 and Fig. 6 clustered bar chart for 'Intervention' component for further details.
... and their current or past symptoms, treatment priorities and/or functioning.	Cross-refer to [q. 31], [q. 40], [q. 41], [q. 44]], [q. 48], and [q. 49] in Table 8 'Intervention' component for further details.	Cross-refer to results previously recorded for [q. 31], [q. 40], [q. 41], [q. 44], [q. 48], and [q. 49] in Table 8 and Fig. 6 clustered bar chart for 'Intervention' component for further details.
Patients can re-evaluate their thoughts, feelings and behaviours.	[q. 52] Patients engaged with re-evaluation? n (%)	Yes completely, 6 (12%) | Yes partially, 8 (17%) | No, 19 (40%) | Don't know, 15 (31%)
Patients complete homework.	Cross-refer to [q. 51] in Table 8 'Intervention' component for further details.	Cross-refer to results previously recorded for [q. 51] in Table 8 for further details.
Identification of barriers and facilitators to CBTp (f) implementation	[q. 45]. Were patient-related barriers identified? n (%)	Yes completely, 11 (23%) | Yes partially, 20 (42%) | No, 10 (21%) | Don't know, 7 (14%) (The specific range and frequency of patient-related barriers identified are shown in Fig. 7. (see below)
	[q. 46]. Were therapist-related barriers identified? n (%)	Yes completely, 3 (6%) | Yes partially, 7 (15%) | No, 21 (44%) | Don't know, 17 (35%) (The specific range and frequency of therapist-related barriers identified are shown in Fig. 10. (see below)
	[q. 59] Additional barriers identified? n (%)	Yes, 46 (96%) | No, 1 (2%) | Don't know 1 (2%) (The specific range and frequency of additional barriers identified are shown in Fig. 8. (see below)
	[q. 60] Additional facilitators identified? n (%)	Yes, 20 (42%) | No, 17 (35%) | Don't know, 11 (23%) (The specific range and frequency of additional facilitators identified are shown in Fig. 9. (see below)

*CBTp (f), cognitive-behavioural therapy for psychosis (forensic)

Figure 10. Q.46. Range and frequencies of therapist-related barriers



*CBTp (f), cognitive-behavioural therapy for psychosis (forensic)

Many of the results recorded in this section have already been commented on elsewhere. For example, results for question 47, which indicates that 33% (n=16/48) of patients learned to establish links between their thoughts, feelings and behaviour, were mainly based on subjective comments made by therapists in the case records. No independent or objective measures were found in support of these claims. For example, no potential shifts were recorded in dimensional measures such as the PSYRATS (Haddock et al. 1999) mentioned earlier. Outcomes for question 49 (Figure 6), which focused specifically on the application of change mechanisms, record that a wide variety of these strategies were apparently used, with from just under half of the sample, to less than one-fifth of the sample of cases. This information, when considered alongside the high number of incomplete treatments, would appear to suggest that many cases did not proceed to this phase of the intervention.

Results related to the 'Outcomes' components of the logic model (Figure 3a) are presented in Table 10.

Table 10. Results related to 'Outcomes' components of logic model

Component of 'Outcomes' section of logic model	Corresponding questions from pro-forma for case note review	Results (*n* = 48)
Individual/clinical: 1) Reduce distress	[q. 53] By end of CBTp (f)* did patient achieve.... [1] ...a reduction in level of distress? *n* (%)	N/A, 1 (2%) | Yes, 15 (31%) | No, 14 (29%) | Don't know, 18 (38%)
2) Improve functioning	[2] ...an increase in level of functioning? *n* (%)	Yes, 14 (29%) | No, 15 (31%) | Don't know, 19 (40%)
3) Goal attainment	[3] ...a reduction in experience of problematic symptoms? *n* (%)	N/A, 1 (2%) | Yes, 14 (29%) | No, 15 (31%) | Don't know, 18 (38%)
Risk: (where appropriate): 1) Help inform risk assessment/ management	[q. 48] Patients learned to monitor these links to risk? *n* (%)	Yes, 4 (8%) | No, 13 (27%) | Don't know, 31 (65%)
2) Help to reduce risk	[q. 54] Risk reduction or comments noted on HCR-20V3**? *n* (%)	No, 14 (29%) | Don't know, 34 (71%)
Organisational: 1) Meet national standard for psychological therapies access (i.e. 18 weeks from referral to treatment)	[q. 29] How soon after referral did CBTp (f) begin? *n* (%)	Within ≤ 18 weeks, 34 (71%) | Within > 18 weeks, 11 (23%) | Don't know, 3 (6%)
2) Demonstrate efficient use of resources	[q. 30] Where starting CBTp (f) took > 4 – 18 what was reason? *n* (%)	N/A, 33 (69%) | No therapist available, 1 (2%) | Security concerns, 1 (2%) | Patient in higher priority treatment, 3 (6%) | Don't know, 10 (21%)
	[q. 56] Degree of completion of CBTp (f). *n* (%). Cross-refer to Table 8 'Intervention' for further details.	Cross-refer to results previously recorded in Table 8.
Repeated psychometric measurement to track outcomes.	[q. 33] Psychometric assessment? *n* (%)	Yes, all core measures completed, 1 (2%) No (either partially present or missing), 47 (98%)
Clear and coherent case record	Cross-refer to [q. 59] and [q. 60] in Table 9 'Change Mechanisms' component for further details	Cross-refer to results previously recorded for [q. 59] in Table 9 and Figs 8 and 9.

*CBTp (f), cognitive-behavioural therapy for psychosis (forensic)
**HCR-20V3, Historical Clinical Risk Management-20, Version 3 (Douglas et al. 2013)

Results noted in the form of therapists' comments in case notes only, for all identified 'individual/clinical' outcomes, suggested that some degree of favourable response was achieved in all three areas. For example, a reduction in distress was reported in 31% (n=15/48) of the cases, improved functioning was reported in 29% (n=14/48) cases and goal attainment (specific to problematic symptom reduction) was reported in 29% (n=14/48) of the cases. However, as stated previously, no additional information was found in the records to help support these claims due to lack of any useable objective measurement of progress.

Other results of note recorded in this section related to the relative absence of any information about 'risk', which was also a core component of the CBTp (f) intervention. It was reported that 8% (n=4/48) of patients learned to monitor links between their risk and target symptoms, but none of these assertions by therapists were independently verifiable. The potential influence that patients' responses to the CBTp (f) intervention may or may not have had on their associated risk was not recorded in any of the notes viewed.

Specific data related to national waiting time standards showed that 71% (n=34/48) of patients entered into the CBTp (f) intervention within 18 weeks of being referred, with 23% (n=11/48) of patients waiting longer than 18 weeks for justifiable reasons. For example, the majority of these patients were in receipt of other, higher priority treatments at the time. Last, in relation to the issue of efficient use of resources, it was noted that of the overall 48 patients who entered this treatment, only 23% (n=11/48) completed all phases of the intervention after having received a recommended dose of $\geq$ 16 sessions. The implications of this overall finding are also discussed at more length in Chapter Six, and specific conclusions and recommendations are made in relation to this in Chapter Seven.

5.2 PHASE TWO – INTERVIEWS WITH THERAPISTS

Interviews were conducted with nine participants who were all therapists in the HSH. The demographic characteristics of the sample are presented in Table 11.

Table 11. Demographic data related to current therapists

Variable	Total Sample (*n* = 9)
Gender:	
- Male, *n* (%)	3 (33%)
- Female, *n* (%)	6 (67%)
Age (years):	
- 25 – 44 years, *n* (%)	4 (44%)
- 45 and over, *n* (%)	5 (56%)
Core profession:	
- Clinical psychologist, *n* (%)	5 (56%)
- Mental health nurse, *n* (%)	4 (44%)
Estimated number patients treated using CBTp (f)* protocol	10 (*mean*) (range 1 -30)**

*CBTp (f), cognitive-behavioural therapy for psychosis (forensic)
**calculated by dividing number patients treated by each therapist by x 9 therapists

To remove the risk of identification and protect therapists' anonymity some information presented in Table 11 was intentionally clustered, i.e. age, gender and core profession. The sample comprised mainly of older, female professionals and slightly more clinical psychologists than mental health nurses (56%, n=5). The mean estimated number of patients treated by each therapist was 10 (SD 9.72, range 1 - 30).

The qualitative data from the interviews were transcribed verbatim and coded using thematic analysis (as described in Chapter 4). A summary of the themes and sub-themes is presented in Table 12. It shows the frequency that themes and sub-themes were described by the participants across the nine interviews.

Table 12 Thematic analysis

Themes	Sub-themes	Therapist Interviews	
		Number interviews mapped to themes/sub-themes. (Total interviews = 9, 100%)	Frequency of references
Environment-related factors:			
• *Context-specific barriers*	• *Access to patients*	2, 4, 5, 7. (*n*=4, 44%)	11
	• *Fear of consequences of disclosures*	1, 4, 6. (*n*= 3, 33%)	3
	• *Limitations to clinical autonomy*	2, 4, 5, 6. (*n*=4, 44%)	9
	• *Security and/or risk issues*	1, 2, 4, 5, 6, 9. (*n*=6, 67%)	13
Manual-related factors:			
• *Challenges to adherence to manual*	• *Difficult to use and apply with patient*	1, 3, 4, 5, 6, 7, 8, 9. (n=9, 100%)	35
	• *Overwhelming for therapist*	2, 4, 6, 8, 9. (n=5, 56%)	15
	• *Presentation cumbersome and barrier to its use*	3, 4, 6, 7, 8, 9. (n=6, 67%)	20
	• *Working practices independent of manual*	1, 3, 4, 5, 6, 7, 8, 9. (n=9, 100%)	46
• *Perception of efficacy of manual*	• *Acceptability to patients*	1, 3, 4, 5, 6, 7, 8, 9. (n=9, 100%)	41
	• *Assisted clinical team working*	1, 3, 4, 5, 6, 7,8. (n=8, 89%)	12
	• *Changed symptoms or problems*	1, 3, 4, 5, 6, 7, 8, 9. (n=9, 100%)	30
Therapist-related factors:			
• *Determining patient readiness to engage with CBTp (f)*	• *Moving on to next stage*	2, 4, 7, 8. (*n*=4, 44%)	7
	• *Preparedness of therapist to deliver CBTp (f)**	1, 2, 3, 5, 6, 8, 9. (n=7, 78%)	19
	• *Therapist assessment of readiness*	1, 2, 4, 5, 7, 8, 9. (n=7, 78%)	20
• *Therapists' clinical supervision*	• *Delivery format*	2, 4, 8. (*n*= 3, 33%)	3
	• *Structure and content*	2, 3, 4, 5, 6, 7, 8, 9. (n=8, 89%)	17
	• *Value and importance*	1, 2, 3, 4, 5, 6, 7, 8, 9. (n=9, 100%)	21
• *Therapist training*	• *Gaps in knowledge*	1, 2, 4, 5, 6, 7, 8, 9. (n=8, 89%)	34
	• *Timing of training*	1, 2, 3, 6, 8, 9. (n=6, 67%)	8
			TOTAL= 364

*CBTp (f), cognitive-behavioural therapy for psychosis (forensic)

In Table 13, further analysis of the data enabled each theme and sub-theme to be categorised as a barrier or facilitator, or both, to CBTp (f) implementation. The data shows there are more barriers than facilitators, and most were therapist-related factors.

Table 13. Themes and sub-themes from thematic analysis identified as barriers and/or facilitators to CBTp (f)* implementation

Theme	Sub-theme	Barrier or facilitator to CBTp (f) implementation?	
		Barrier	Facilitator
Environment-related factors:			
• *Context-specific barriers*	• *Access to patients*	✓	
	• *Fear of consequences of disclosures*	✓	
	• *Limitations to clinical autonomy*	✓	
	• *Security and/or risk issues*	✓	
Manual-related factors:			
• *Challenges to adherence to manual*	• *Difficult to use and apply with patients*	✓	
	• *Overwhelming for therapist*	✓	
	• *Presentation cumbersome and barrier to its use*	✓	
	• *Working practices independent of manual*	✓	✓
• *Perception of efficacy of manual*	• *Acceptability to patients*		✓
	• *Assisted clinical team working*		✓
	• *Changed symptoms or problems*		✓
Therapist-related factors:			
• *Determining patient readiness to engage with CBTp (f)*	• *Moving on to next stage*		✓
	• *Preparedness of therapist to deliver CBTp (f)*	✓	✓
	• *Therapist assessment of readiness*	✓	✓
• *Therapists' clinical supervision*	• *Delivery format*		✓
	• *Structure and content*		✓
	• *Value and importance*	✓	✓
• *Therapist training*	• *Gaps in knowledge*	✓	
	• *Timing of training*	✓	

*CBTp (f), cognitive-behavioural therapy for psychosis (forensic)

Participants spoke about their experiences of delivering CBTp (f) as being influenced by three overlapping factors. Firstly, the *environment they work in*, secondly the *manual* used to guide therapy, and thirdly, the personal and professional *experience of the individual* [therapists]. Overall, six main themes and 19 sub-themes were identified across these areas. Participants spoke more frequently about factors related to the *manual* which reflected the higher number of coded references (55%, n=199/364), followed by those for *therapist* (35%, n=129/364) and *environment* (10%, n=36/364).

5.2.1 Environment-related factors

When asked about their experiences, most participants talked about the nature and context of the HSH and their interactions with it. This was therefore identified as one of the three overall significant factors. A number of clear themes subsequently

emerged from this, all of which were identified by participants as constraints to their delivery of CBTp (f) in this environment.

Main theme: *Context-specific barriers*

This was the single main theme identified for this factor. Four sub-themes emerged from this, as follows.

Access to patients

Four out of the nine participants spoke about their experience of working in the hospital and the complexity of the environment in providing optimum therapy. This was referred to as a barrier to CBTp (f) implementation. Participant four talked about how things sometimes get in the way of gaining access to patients:

- *"So, I guess the environment and, you know, the forensic environment… there's going to be stuff that happens and patients having tribunals and stuff like th*at…." (P4)

This issue also resonated with Participant 5:

- *"Your ability to see your clients consistently and routinely* [is problematic] *because they've got other places that they have to be and other clinicians to see".* (P5)

Fear of consequences of disclosures

Patients' reluctance to disclose information to the therapist due to fear this might lead to recommendations for medication or length of stay to be altered, was described by three participants. They believed this could be a barrier over the course of CBTp (f). Examples of this given by two participants were:

- *"I think some of our patients sometimes don't want to always be that upfront about some of the delusional beliefs, because it feels like it's going to lead to more medication, or longer stay, so being able to safely kind of explore that".* (P6)

— *"Sometimes a patient will disclose something to you and when you pass it on to the clinical team there can be repercussions; for example, increased observations".* (P5)

Limitations to clinical autonomy

The participants talked about clinical autonomy and how this can be compromised within a forensic environment. One participant recalled a situation when their clinical autonomy was affected and spoke about this.

— *"I've had disruption where groups are starting and people I see go into a group that maybe other people think would suit, so it detracts from the CBT. There's a conflict of interest there and sometimes I don't think I'm at a place where we should be stopping and moving* [on]*, so that's just for discussion between clinicians. But sometimes that can feel jarring in the journey for the patient*". (P5)

Another participant spoke about their experience of the sudden discharge of patients without due warning.

— *"Sometimes, unbeknown to you, a client will suddenly move on. So that's another thing that we do; we have these discharge CPAs that can be quite quick".* (P1)

Security and/or risk issues

Two thirds of participants described the security risks posed through working in this environment and the additional complexity this brings when providing CBTp (f). One participant noted how this contrasted with working within a community mental health service.

— *"The patients are significantly more complex than you may get in the community due to index offences and* [the] *need to cover that as part of the work".* (P2)

Another participant spoke about trying to conduct a CBTp (f) session when several other staff members were present to help manage the assessed level of risk:

- *"I've had a patient in the room with three staff trying to do CBT or trying to engage them at least in a CBT process. So, there's lots… I mean, I think high secure brings its own problems… So, there's lots of different obstacles".* (P4)

5.2.2 Manual-related factors

All participants talked about their experiences with the CBTp (f) manual. Whilst they identified both barriers and facilitators in relation to this, most talked about how they consider the manual, in its present form, to be a significant barrier to the delivery of CBTp (f). However, some participants also shared more positive views about the manual, mainly around its perceived efficacy. Overall, two main themes and seven sub-themes were identified for this factor.

Main theme one: *Challenges to adherence to manual*

This first main theme had four sub-themes.

Difficult to use and apply with patient

All the participants described using the manual as a perceived barrier. One participant commented:

- *"I guess it's the nature of the treatment. It's not just flip a page, on to the next bit. It's really complex. Even developing the formulation, I found really, really difficult and I still do".* (P4)

Another participant spoke about their difficulty getting through the manual:

- *"… then here's the manual and I was like, whoa! It was quite a big read to get through the manual and get your head round the sessions…".* (P6)

Overwhelming for therapist

Half the participants spoke about the manual being so detailed that is was a barrier to its use. This participant described their feelings when faced with reading the manual.

- *"I remember feeling a bit overwhelmed when I was starting CBT with somebody. I was like, 'God, it's going to take me three weeks to read all this again!'. I don't know if that's just the nature of the intervention 'cos it covers so many problems"*. (P4)

This participant described their feelings about using the manual as a newly qualified practitioner:

- *"I remember feeling a bit bamboozled at the time and thinking I was missing something because I was quite newly qualified and thinking I just wasn't getting it".* (P9)

Presentation cumbersome and barrier to its use

Two-thirds of participants identified this as a significant barrier to CBTp (f) implementation. Participants also made several suggestions about ways that the presentation of the manual might be improved. For example, this participant commented:

- *"It doesn't feel user-friendly at the moment; maybe because it feels like it's very heavy with information. And maybe a bit more structure would be helpful? Even just making it feel easier to kind of flick through and find certain bits of information that might be relevant, rather than… I remember thinking I don't know where to find what I might need or look for in the manual".* (P6)

Another participant agreed that the manual could be more user-friendly:

- *"I definitely think the protocol could be more user-friendly, more refined, less populated".* (P4)

Working practices independent of manual

This was the most frequently coded sub-theme, accounting for 13% (n=46/364) of all references made. This perceived barrier and facilitator was commented on by all participants. One participant talked about going off model to try and better meet their patients' needs:

- (F) *"I think most people do go off model. I think it's the complexity here, isn't it? It's… you're working with such challenging patients with multiple needs that sometimes one model on its own isn't enough…"*. (P1)

Another participant talked about their struggle with problem lists, a core component of the CBTp (f) intervention:

- (B) *"I've kind of always struggled with problem lists I have to say. Just, it's something I don't really find that helpful so we didn't do that, or we wouldn't have done that"*. (P3)

Main theme two: *Perception of efficacy of manual*

This second main theme had three sub-themes, all of which appeared to be perceived as *facilitators* to CBTp (f) implementation.

Acceptability to patients

All participants commented about this sub-theme, which was the second most frequently coded in the sample and accounted for 11% (n=41/364) of all references made. Participants spoke about this as a perceived facilitator. This participant spoke about several patients finding CBTp (f) helpful:

- *"There was one or two* [patients] [who] *were very clear that they recognise that it had been helpful to them and it helped with their symptom management and they were able to move on from the hospital quite soon after finishing the treatment. So, they were quite grateful and recognised that CBTp had helped them".* (P2)

This participant spoke about the role of formulation in helping to build a patient's understanding of his difficulties:

- *"The patient found developing the shared formulation really helpful in understanding the difficulties. I think that was helpful coming from a place where they kind of don't really know how to make sense of the experience, so that really helped to focus that and develop the kind of alternative positions".* (P6)

Assisted clinical team working

Almost all participants made at least one comment about this subtheme which was perceived as another facilitator. For example, this participant spoke about how formulation might help inform the clinical team about the nature of a patient's communication difficulties:

- *"It helps the patient because maybe they have trust issues, communication problems… they can't always communicate their needs, and so the formulation helps inform the staff caring for them and the clinical team that's looking after them".* (P5).

This participant spoke about how formulation might be used to help other clinical team members to reconsider their views about some patients:

- *"In the ward I hear all these quite resistant* [views]*… I think that if you feed that into your formulation and you're sharing it with the team and things, it maybe helps them view it a little bit differently"*. (P8)

Changes symptoms or problems

All participants commented on this perceived facilitator, which accounted for 8% (n=30/364) of all sub-theme references. One participant spoke about changes for one patient that also extended to their risk assessment and future management plan:

- *"I think maybe we changed* [things] *for him a lot and he just was able to spend more time in the day room. He was able to be around others more. He was able to approach us and join in group activities which he hadn't ever wanted to*

do before, and I think obviously his index offence was largely due because of his psychosis. So, there was a whole lot of work around his risk and his risk of becoming unwell and what that meant which really influenced his risk assessment, his HCR-20 and how he was managed in the future". (P8)

Another participant reflected on their experience of observing a range of changes to some patients' symptoms or problems:

- *"Some patients, they get masses out of it. And then others, its maybe just wee shifts in their delusions but it's still a shift".* (P4)

5.2.3 Therapist-related factors

This set of factors had the most subthemes that were categorised as barriers, facilitators, or both. Within the range of themes and subthemes identified, participants spoke about their clinical decision-making and their experiences of training and supervision related to the delivery of CBTp (f). Three main themes and eight sub-themes were identified as follows.

Main theme one: *Determining patient readiness to engage with CBTp (f)*

This main theme encompassed the following three sub-themes.

Moving on to next stage

Participants made comments across seven coded references about this perceived facilitator. This participant spoke about the importance of having an identified problem list to help prioritise moving through different stages of treatment:

- *"Agreeing everything around the problem list, even agreeing the order that we did things in".* (P2)

This participant spoke about the importance of formulation in helping with the process of moving therapy along:

- *"I did find it useful especially kind of thinking about the formulation* [when] *you're a bit stuck with somebody. It just kind of just helps seeing you through that time when it feels like it could be a bit stagnant".* (P8)

Preparedness of therapist to deliver CBTp (f)

Participants spoke about this sub-theme as being both a potential barrier and a potential facilitator to CBTp (f) delivery. Examples of both are given below:

- (B). *"Probably the reasons that I've not done a lot of CBTp is because the research on it is so contested. And you know, whether it's in the NICE guideline, there are very vocal people who think that it's useless basically".* (P3)

- (F). *"I think it's just about adapting your treatment sessions to that person so although it was once a week, it was every week routinely. But you might start, you know, with about 20 minutes and then you kind of build up as you got a bit more rapport and you felt more comfortable. So, I think there is scope for building that into what the patient needs*". (P8)

Therapist assessment of readiness

This was another sub-theme where participants spoke about their experiences as being both potential barriers and facilitators to CBTp (f) delivery. This participant spoke about undertaking a long period of engagement work before they considered their patient was ready to do CBTp (f):

- (B). *"One patient I had been working with for probably about five years before beginning the CBT psychosis process. It was always engagement sort of a work we were doing, and we just had to wait until he was ready and that was it".* (P1).

This participant talked about how having a shared problems and goals list and a patient who was receptive, helped them to establish their readiness to engage in CBTp (f):

- (F). "*Yeah, they* [the identified problems] *were very much shared and* [the patient was] *very open from the beginning, this is why we are going to do this piece of work"*. (P7)

Main theme two: ***Therapists' clinical supervision*

Three sub-themes were identified under this main theme.

Delivery format

One-third of the participants each made one comment about this perceived facilitator. This was therefore one of the least frequently commented on sub-themes. Two participants spoke about the perceived helpfulness of group supervision:

- "*We used to have a CBTp supervision group. I felt that was really helpful".* (P8)

- *"I think even group supervision for the practitioners that are delivering CBTp may be a help*". (P2)

Structure and content

Participants talked about their experiences of this aspect of clinical supervision as being either a potential barrier or a facilitator to CBTp (f) delivery. Participants' comments focused mainly on the perceived usefulness and importance of receiving CBTp-specific supervision:

- (B). *"I had my supervisor for my generic kind of work which I probably took the case along to, but as* [for] *a bit more specific CBT focused psychosis supervision; I don't think I really had that, but I think that would have been probably really helpful for me".* (P8).

- (F). "*The supervision was definitely helpful. I think because it was my first case doing that protocol as well. It was helpful to have that extra kind of guidance…"* (P6).

Value and importance

All participants spoke about this sub-theme. All their comments focused on the importance of clinical supervision as a perceived facilitator to CBTp (f) implementation. As one participant put it…

- "[Its] crucial, absolutely crucial!". (P4)

This participant also highlighted its value and importance in helping with their practice:

- *"I think I would feel pretty vulnerable and lost if I didn't have supervision"*. (P4)

Main theme three: *Therapist training*

Two sub-themes were identified here as follows.

Gaps in knowledge

Eighty-nine percent of participants shared 9% (n=34/364) of references about this perceived barrier to CBTp (f) delivery, making this the fourth most frequently coded sub-theme. One therapist spoke about seeking more training and knowledge about working with specific symptoms:

- *"If you're working with voices it would be different than if you were working with paranoia or delusions. Just maybe a bit more specific* [training and knowledge], *you know, I mean, just to kind of think about, well, if you hear a voice that's quite a useful tool to work with that. Or, if you think about paranoia, that's the kind of thing you're going to use a bit more…"* (P8).

Another participant talked about specific gaps in their knowledge about the process of CBTp (f) delivery:

- *"I'm trying to think what we do next* [but don't know]*".* (P5)

Timing of training

Participants spoke about their poor recall of earlier training and the need to update this. Two participants specifically commented on this:

- *"The original training on the manual must be a good four or five years ago anyway, so it's that long ago I wouldn't really be able to remember that much about it. Certainly, probably could do with more training in it".* (P2)

- *"I think the training in it was a long time ago as I had just started so it was 10 years ago".* (P9)

Summary

Overall participants' [therapists'] feedback suggested a range of barriers and facilitators to the implementation of CBTp (f). These were related to the forensic environment, therapists' supervision, knowledge, skills and training; and perceptions about the acceptability, utility and content of the treatment manual for CBTp (f) in its present form. The significance of these themes and sub-themes is considered at length in Chapter 6 – Discussion.

5.3 PHASE THREE – DELPHI SURVEY

The Delphi survey was designed based on the results from phase one (case note review) and two (therapists' interviews). The method used to synthesise these results to produce the 45-item questionnaire used in Round One (see Appendix 10) is described in Chapter 4.

Initially 20 experts were invited to participate in three rounds of questions. However, due to the unexpectedly high degree of consensus achieved during Rounds One and Two, the researcher, in discussion with their primary supervisor, took the pragmatic decision to stop surveying the panel after Round Two. At this point the researcher emailed all participants thanking them for their help and informing them that a third round would not be required.

From the initial group of 20 experts who were approached, a panel of 14 individuals (70%, n=14/20) consented and took part in Round One. Demographic information related to this cohort are provided in Table 14.

Table 14. Demographic data related to Delphi experts – Round 1 (*n*=14)

Variable	Total Sample (*n* = 14)
Gender:	
- Male, *n* (%)	2 (14.3%)
- Female, *n* (%)	11 (78.6%)
- Prefer not to specify	1 (7.1%)
Professional background:	
- Clinical psychology - non-forensic, *n* (%)	1 (7.1%)
- Clinical psychology - forensic, *n* (%)	12 (85.7%)
- Other	1 (7.1%)
Clinical or non-clinical role:	
- Direct clinical – forensic service, *n* (%)	13 (92.9%)
- Academic role, *n* (%)	1 (7.1%)

Eleven of these experts (79%, n=11/14) then responded again in Round Two (Appendix 11). However, since no identifiable information was used to continue to track their demographic details after Round One (to protect their anonymity), it was not possible to identify the gender, professional background or clinical/non-clinical role of the three participants who dropped out at the second and final round.

A total of 32 items from across the two rounds were included in the final list of results. These are presented in Table 15.

Table 15. Principles and elements of CBTp (f)* delivery for inclusion in treatment manual

Recommended principles and elements of CBTp (f)*	Round included
Alignment with clinical guidelines and current evidence-base:	
CBTp (f) should be delivered…	
... on a one-to-one basis, over at least 16 sessions.	1
… by appropriately trained and supervised therapists.	1
… in accordance with an established treatment manual (preferably one with evidence for its efficacy).	1
CBTp (f) should be delivered so that...	
... people can establish links between their thoughts, feelings or actions and their current or past symptoms, and/or functioning.	1
... the re-evaluation of people's perceptions, beliefs or reasoning relates to the target symptoms.	1
CBTp (f) should be delivered so that it also includes...	
... people monitoring their own thoughts, feelings or behaviours with respect to their symptoms or recurrence of symptoms.	1
... promoting alternative ways of coping with the target symptoms.	1
... reducing distress.	1
... improving functioning.	1
Where a specific model or intervention is chosen, e.g. CBTp, this should always be delivered in accordance with the associated evidence-base – e.g. through adherence to a specifically chosen evidence-based treatment manual.	2
Presentation of treatment manual:	
A CBTp (f) treatment manual should have the following contents:	
1) summary of background theory (including principles and values of therapy)	
2) stages of therapy described – assessment, engagement, socialisation to treatment and use of normalising rationale, agreement of problems and goals list, formulation, use of cognitive and behavioural change strategies (informed by agreed formulation and problems and goals list), ending therapy, report writing,	
3) treatment evaluation (e.g. recommended psychometric measures)	1**
4) reference list	
5) additional reading materials or other resources – e.g. reference to other CBTp manuals or self-help books.	
All information should be presented using written, diagrammatic and pictorial formats.	
It should include case examples and examples of incremental steps in treatment process, e.g. emerging and completed formulations, homework sheets.	
Therapist training and competences:	
All therapists delivering CBTp (f) should be appropriately trained such that they can:	
...demonstrate the (Roth & Pilling, 2013) CBTp range of competences.	1
...demonstrate a working knowledge and understanding of the components of the specific treatment manual for CBTp (f) used in their area of practice.	1
... demonstrate an appropriate range of specific 'forensic' competencies (e.g. violence risk assessment and management skills).	1
"In addition,	
... CBTp (f) therapists' training should be regularly reviewed and repeated.	1
... CBTp (f) therapists' competencies should be regularly reviewed and rated using a recognised therapy adherence and competency measure, e.g. The Revised Cognitive Therapy for Psychosis Adherence Scale (R-CTPAS; Rollinson et al. 2008).	1
…CBTp (f) therapists' training should span a range of different CBTp models (including e.g. Freeman's persecutory delusions, Morrison's model of intrusions and auditory hallucinations, Birchwood's model for command hallucinations)	1**
Therapist clinical supervision:	
Supervisors should have clinical supervision training, > 2 years' experience of using CBTp and specific forensic competencies (e.g. violence risk assessment and management skills).	
Supervisors should have knowledge and awareness of the CBTp (f) treatment manual underpinning therapy.	1**
Format of supervision should follow the CBT model, i.e. be structured by an agenda and follow CBT process.	
Frequency of supervision should be individually determined but should be a minimum of 1 hour/month for experienced therapists or 1 hour/fortnight for trainee/novice therapists	
Individual supervision should be provided but can be augmented by group supervision.	
Therapist's assessment of patient readiness, willingness and ability to engage and when to move on to next stage:	
Problems such as patient non-collaboration, patient not 'getting' the model, relational difficulties leading to apparent treatment resistance, or patient making very limited or no progress, would generally be taken as indicators that a CBTp (f) intervention is probably not effective or likely to be helpful at this stage in the patient's recovery, and an alternative approach should therefore be considered.	2
Patients must be willing and/or able to engage in CBTp (f).	2
Patients must have an ability to form an agreed set of goals and tasks for therapy.	2
Therapist's assessment of mid-point of treatment:	
The stage after formulation and when moving on to the intervention/use of change strategies phase could reasonably be taken as an approximate mid-point of CBTp (f) treatment.	1**

Range and use of psychometric measures:	
Psychometric measures should…	
…be specific for the individual and match up with their experiences and problems list.	
…be reliable and validated, e.g. PANSS, PSYRATS, IIP-32.	1**
…allow monitoring pre, during (mid) and post therapy.	
It may be helpful for these tools to assess psychotic symptoms, emotional distress, daily functioning and interpersonal relationships.	
There are some occasions, e.g. where it may adversely affect the patient's engagement, when it is not appropriate to undertake psychometric assessment or evaluation of a CBTp (forensic) intervention.	2
Regardless of whether any formal psychometric assessment or evaluation of a CBTp (forensic) intervention is undertaken, we do nonetheless always need to document the impact and outcome/s of this work.	2
Assessment of impact of CBTp (f) on risk of future violence:	
When a course of CBTp (forensic) is delivered to help target difficulties related to offending behaviour, e.g. threat-control override symptoms leading to violence, it is **essential** that the response (or lack of response) to this is fed back into the risk assessment process, e.g. via HCR-20 narrative updates and, if indicated, through making HCR-20 score revisions.	2
Formulation:	
It is possible to deliver good quality CBTp (f) using a brief, maintenance formulation only.	1
It is possible to deliver good quality CBTp (f) without moving on to complete a longitudinal formulation, providing there is at least an agreed maintenance formulation	1
It is NOT possible to deliver good quality CBTp (f) without having an agreed formulation with the patient.	2
It is NOT possible to deliver good quality CBTp (f) without sharing the emerging formulation with the patient.	2
Recording outcomes and record-keeping	
As a minimum, i.e. 'best practice' standard…	
… therapists should record session number; agenda; content of session; agreed actions and date of next session, in the clinical notes after each CBTp (f) session.	2
… therapists should always provide an 'end of treatment' report at the end of a course of CBTp (f). This should detail: the assessment process and its outcome; the agreed formulation and goals for therapy; the patient's response to therapy in the context of the agreed formulation and goals (including any specific information that may have been elicited about engagement and risk).	2

*CBTp (f), cognitive-behavioural therapy for psychosis (forensic)
**item included based on qualitative comments aligned with appropriate literature, professional practice standards, local governance structures and evidence-base

Further explanation of this series of results is given below.

Alignment with clinical guidelines and current evidence-base

When asked a series of questions related to the need for a CBTp (f) intervention to be aligned with clinical guidelines and current evidence base, the expert panel reached consensus and agreed that certain factors were necessary. Consensus was reached for the majority of these questions (n=9 /10) in Round One. Experts were of the view that CBTp (f) should be delivered generally on a one to one basis; over at least 16 sessions; by appropriate trained and supervised staff; and in accordance with an established treatment manual. Experts also expressed the view that CBTp (f) should be delivered in a manner that establishes links between a patients' thoughts, feelings and actions and their current of past symptoms and functioning, and that the treatment should incorporate the re-evaluation of people's perceptions, beliefs or reasoning related to their target symptoms. In addition, experts were of the view that CBTp (f) delivery should also include people monitoring their own thoughts, feelings

and behaviours in relation to their symptoms or recurrence of symptoms; should include promotion of alternative ways of coping with target symptoms; should aim to reduce distress; and should aim to improve functioning. At the end of Round Two the panel also reached consensus about the need to deliver any specified model or treatment in accordance with the established evidence-based manual that supports it.

Presentation of treatment manual

At the end of Round One and in response to a qualitative question, several expert panel members gave detailed views about what to include in a CBTp (f) treatment manual and how best to present this. These experts recommended that the manual should contain a summary of the background theory, a description of the stages of the intervention, advice about how to evaluate the treatment, a reference list and bibliography, and additional resources such as recommended reading lists that included reference to other CBTp models or self-help books. They also recommended that information in the manual should be presented in a variety of ways including using diagrams and pictures, not just written text. Experts also recommended that material presented in the manual should include case examples and worked examples of different stages in the treatment process.

Therapist training and competences

The expert panel also reached consensus about the inclusion of all items in this cluster at the end of Round One. Here experts helped to operationalise what they considered the term “appropriately trained” to mean. Experts recommended that this should be taken to mean that all therapists delivering CBTp (f) should be able to demonstrate: the Roth and Pilling (2013) CBTp range of competences, a working knowledge and understanding of the specific treatment manual used for CBTp (f) delivery in their local area, and a range of specific forensic competences, including risk assessment and management skills. The experts also recommended that therapists’ training should be regularly reviewed (including using recognised therapy adherence scales), should be regularly repeated, and should span a range of different CBTp models.

Therapist clinical supervision

This was another area where all items included were drawn from qualitative responses made by several experts at the end of Round One. In this cluster experts made recommendations about both CBTp (f) supervisors and supervisees. For supervisors, experts recommended that they should have formal training in supervision, should have >two years clinical experience of delivery of CBTp (f), and forensic competences. Experts also recommended that supervisors should have knowledge of the specific CBTp (f) treatment manual used by their supervisees. Experts further recommended that the format of supervision should follow the CBT model, should be delivered at a minimum rate of one hour/month for experienced therapists and one hour/fortnight for novice therapists, but with additional scope to vary these rates according to the assessed needs of the individual supervisee. Experts recommended that supervision should be delivered on an individual basis, but that group supervision can be added to this.

Therapists' assessment of patient readiness, willingness and ability to engage and when to move on to next stage

Consensus for all recommendations made by the expert panel in this cluster was reached at the end of Round Two. Here experts offered specific guidance to therapists about several potential factors that may indicate that CBTp (f) is unlikely to be working, and that an alternative approach should be considered. Experts also reached consensus that patients should be willing/and or able to engage in CBTp (f) and should be able to form an agreed set of goals and tasks for therapy.

Therapist's assessment of mid-point of treatment

One item was included under this heading. This related to comments made by several experts in response to a qualitative question asked in Round One. Experts supported the view that the stage after formulation and when moving on to the intervention/use of change strategies phase, could be considered a reasonable approximation of the mid-point of treatment.

Range and use of psychometric measures

Experts were first asked to give a qualitative response about the use of psychometric measures in Round One. At that point several experts recommended that such measures should be specific for the individual, match up with their experiences and problem list, be reliable and validated, allow for pre, mid and post therapy monitoring and assess areas such as psychotic symptoms, distress, daily functioning and personal relationships. In Round Two experts achieved consensus about the view that sometimes it may not be appropriate to complete psychometric measures in CBTp (f), e.g. if this might adversely affect a patient's engagement. Further, expert consensus was also reached about the need for the impact and outcomes of any CBTp (f) work to be appropriately documented in clinical notes, regardless of whether any formal evaluation measures were used or not.

Assessment of impact of CBTp (f) on risk of future violence

One item was included under this heading. At the end of Round Two experts achieved consensus in their view that it is essential that any CBTp (f) work delivered to help target difficulties with violence, needs to be fed back into the risk assessment process. For example, by updating relevant items in the HCR-20 (Webster et al. 1997), where applicable.

Formulation:

When asked a series of questions about formulation, experts achieved consensus in Round One about two items when they agreed that good quality CBTp (f) could be delivered without moving on to complete a longitudinal formulation; however, this was providing a brief, maintenance only formulation was agreed and could be used. In Round Two the panel reached consensus on two further aspects of formulation by agreeing that it was not possible to deliver good quality CBTp (f) without having an agreed formulation, or without sharing the emerging formulation with the patient.

Recording outcomes and record-keeping

When asked about minimum 'best practice' standards, the panel reached consensus and agreed that therapists should record session number, agenda, content of session, agreed actions and date of next session, after each CBTp (f) session. They also agreed that therapists should provide an end of treatment report which details the outcome of the assessment process, the agreed formulation and goals for therapy, the patient's response to therapy relative to the formulation and goals, and any specific information that may have been given about engagement and risk.

Items with consensus that were not included in the list of recommendations for the manual are presented in Table 16.

Table 16. Elements of CBTp (f) with consensus not recommended for inclusion in the treatment manual.

Element of CBTp (f) not recommended for inclusion in treatment manual	**Round included**
Formulation:	
It is possible to deliver good quality CBTp (f) when using a formulation framework that is non-CBT based, e.g. '5Ps-based formulation'.	2
Longitudinal formulation needs to be an essential component of CBTp with forensic patients; without this, we would be unable to understand how psychological distress and difficulties potentially interrelate with offending behaviour and risk	2
Governance/other forms of service delivery:	
When working with forensic patients with difficulties associated with psychosis, it is important for therapists to be able to be "flexible" in their overall approach. "Flexible" in this context means, "Able to draw from a number of different therapeutic models and choices of interventions and to apply these as/when indicated".	2
It would be helpful to consider the future development and of a 'psychosis pathway' as many forensic (and indeed non-forensic) patients with psychosis might only require and/or be able to manage to undertake phase 1, i.e. 'low intensity' work. Not all may therefore require a higher intensity intervention such as this CBTp (f) programme.	2

Further explanation of this second series of results is given below.

Formulation

Although consensus was reached by the expert panel that good quality CBTp (f) could be delivered using a formulation framework that is non-CBT based, this was not included as it appears to represent a significant deviation from the current literature and evidence-base for manualised CBTp. The panel's second area of consensus, that longitudinal formulation needs to be included as an essential component of CBTp (f) to help us understand how psychological distress and difficulties potentially

interrelate with offending behaviour and risk, was also excluded. This was on the basis that it conflicted with several other statements about formulation that also reached consensus and were included in the final list in Table 15.

Governance/other forms of service delivery

These last two items achieved consensus but were not included in the final list of recommendations as they did not relate directly to manualised CBTp. Rather, these related to attempts to define what was meant by a "flexible" approach to treatment (not specifically a CBTp (f) intervention) and the other related to suggestions that were made by several experts about a potential 'psychosis pathway' for patients.

Summary

Overall experts reached consensus on the vast majority of items. There were also three items where consensus could not be reached, and results were not included. The first of these items, about the use of psychometric measures, was subsequently re-worded and presented as a new question in Round Two. The second item related to what might constitute acceptable variances to the delivery of manualised CBTp (f) (including possibly combining this with other therapy models). The failure to achieve consensus concerning this item was of particular note as this related directly to one of the key research objectives for the overall study. The third item related to whether CBTp (f) should be delivered at the same time as other psychological interventions.

There were also a number of other areas where experts did reach consensus with each other, but their collective view was either not aligned with current evidence, or it conflicted with several other areas where they had also reached consensus.

All results reported above are considered further in the remaining chapters of this thesis – i.e. Chapter Six (Discussion) and Chapter Seven (Conclusions and Recommendations).

CHAPTER SIX: Discussion

Chapter Six begins by drawing together the significant findings from the results that were presented in Chapter Five. These results will then be considered within the context of the preceding content of this thesis. The results will first be reviewed in relation to the evidence presented in the literature review. Areas where results appear to confirm pre-existing theory or evidence will be remarked upon, and areas where results appear to make new and/or unique contributions to the evidence for the researcher's area of practice, will be specifically highlighted and discussed. The overall results achieved though this research will then be discussed in relation to the current version of the CBTp (f) programme and its associated manual. This chapter will conclude with a summary of these discussion points leading into the conclusions and recommendations that will be presented in Chapter Seven, the final chapter of was this thesis.

To reconnect with the four original objectives of this research (p. 10), and to check whether these have been addressed, the ensuing discussion is presented under four abridged subheadings that relate directly to each of these.

6.1 Processes required for implementation of CBTp (f)

In keeping with a process evaluation model, a logic model (Moore et al. 2015) was constructed to help clearly identify the CBTp (f) intervention components, proposed mechanisms of change, and intended outcomes. Phase One of the study involving a case note review sought to answer, *what* was delivered and *how* was it delivered in this HSH?

Based on demographic information, the case note review indicated that an appropriate cohort of patients were selected for treatment (i.e. patients with a diagnosis of Sz, schizoaffective, or other psychosis); as well as a notable proportion of patients with co-morbid personality disorder (32%). In contrast, there was a lower

rate of co-morbid substance misuse than anticipated (29%), in comparison with the incidence rate normally expected in this group, i.e. this usually runs at a rate of over 80% (Kelly 2019). This disparity may have been due to information being lost, not recorded, or it may be due to 'diagnostic-overshadowing' meaning that due to other, more prevalent diagnoses, this issue may not have been specifically focused upon within treatment.

Prior research suggests that CBTp treatment outcome is most effective when treatment is offered at as early a stage as possible – the so called 'critical period' hypothesis. According to this hypothesis, there can be rapid deterioration in the prognosis for untreated psychosis, if duration of illness from onset to start of treatment exceeds five years or more (Birchwood et al. 1998; Zaytseva 2011). However demographic characteristics indicated that the length of illness for this patient group was on average almost 14 years (ranging from 1 to 30 years) and that patients had already been in hospital for over 4.5 years (1 month to 30 years) when treatment commenced. It would therefore be important to consider how to encourage mental health professionals to make a more concerted effort to refer a patient to CBTp (f) at an earlier stage with the aim of maximising the opportunity to potentiate treatment response, and support an overall improved prognosis sooner in their treatment pathway.

Results of the case note review found that 20% of the case notes demonstrated no indication of CBTp (f) having been attempted, and instead related to other treatment interventions (e.g. CBT for offending behaviour or non-CBT based intervention). It therefore appeared that there was a propensity for psychological interventions to be mislabelled, and for information to be stored inappropriately on a database that had no bearing on this group of individuals' subsequent psychological treatment. It is anticipated that the new General Data Protection Regulation (GDPR) legislation (UK Government 2019) will ensure that these errors will not be repeated going forward.

Only 10% of the remaining cases were deemed to resemble the CBTp (f) as outlined in the treatment manual (i.e. formulation underpinned by protocol). It was notable that only five cases (10%) were formulated in line with the model outlined in the CBTp (f) treatment manual (Allan et al. 2002). In terms of the degree to which the phases of treatment were completed within therapy; in 23% of cases all phases of treatment were completed in $\geq$ 16 sessions (even though there were additional elements that were not completely in keeping with the manual); in 40% of cases, not all phases of treatment were completed and treatment ended < 16 sessions; and in 37% of cases, not all phases were completed and treatment ended after >16 sessions. Overall, the case flow was difficult to determine in almost every case. CBTp (f)-based formulation was noted to be absent in the majority of cases (90%). There was also a general absence of clear treatment goals or a problem list; with a clear problem list present in less than half of the cases (48%). The presence of CBTp (f)-specific change strategies varied. Engagement was present in almost every case (92%). However, all other 'change strategies' were present in less than half of the cases (e.g. coping strategies in 48%; and only one case (2%) reported using the 'seeking alternative explanations' strategy). Flach et al's (2015) study found that the *development of a formulation* and the *completion of homework* were related to treatment outcome, with the presence of these factors associated with a decrease in symptom severity. It may therefore be important (given the low rate of usage of these components in this study) to emphasise the importance of these factors in future development of the treatment manual. Also, as a part of the evaluation process, formal objective monitoring of desired outcomes had been planned, to check whether these had been attained (e.g. distress reduction, improved functioning, goal attainment, and risk reduction, if relevant). However, it was noted that pre, mid and post psychometric evaluation of these factors had been completed in only one case. Otherwise, in the remainder of cases (n=47), psychometric assessments were either partially completed, or absent.

Before starting this study there was an indication that there were a number of cases where treatment was incomplete. However, the extent of partial completion was unexpected, and the limited use of CBTp strategies was also greater than envisaged.

Dunn et al's (2012) research indicated that partial treatment (consisting of assessment and engagement phases only) had no benefit and could even be potentially harmful (please cross-refer to pages 24 and 32 of this thesis for further detail). In view of this, the above finding raises potential concerns regarding the partial completion of treatment within this HSH. Furthermore, due to non-completion of the psychometric measures it was not possible to establish whether there may have been iatrogenic effects from the partial completion of treatment, and if so, to what extent. Nonetheless, in 30% of cases therapists provided comments in case notes or end of treatment reports stating that patients had made improvement. However, other than clinical impression and/or the therapists' subjective views, no collateral evidence was offered to support these claims.

6.2 Variation from treatment manual guidance

On review of the CBTp (f) *assessment* information contained in the manual, it was expected that six keys areas would be included in this process. I.e. assessment of: early experiences, schema, critical incidents, problematic thoughts, emotions and behaviours. Whilst assessment of early experiences was evident within the records in 69% of cases; the other key aspects of assessment were present in only 40-60% of cases. It is possible that this may reflect a lack of documentation by therapists (in which case training in improved record-keeping would be useful); however, alternatively, this may reflect therapists not implementing the model comprehensively. The potential non-compliance with the manual at such an early stage in therapy, may, in part, explain subsequent drift from the manual as described below. There is evidence that *engagement* strategies were used widely by therapists and were noted in over 90% of cases.

Socialisation to the CBTp (f) model is another key component of the intervention and yet it was recorded in only approximately half of cases. Once again, if this is another early key stage of therapy that is being missed, this too may have impacted on patients' understanding and expectations of therapy. In addition, use of *normalising*

was only recorded in approximately one fifth of cases. Previous authors (Kingdon and Turkington 1999) have found that service users particularly value a normalising approach when often facing stigma as a consequence of mental ill health. For a forensic group of patients who may be doubly-stigmatised (suffering mental illness and history of offending), this may be a particularly important aspect of treatment to be overlooked.

There was evidence of some form of clinical formulation in approximately two thirds of cases, and, as described above, in only 10% of cases was a CBTp (f) programme formulation utilised. The absence of formulation, which applied in a third of cases, can lead to a number of difficulties. For example, it would be difficult to focus therapy around a shared understanding if no such understanding had been achieved. Also, it could potentially result in a situation when patients and therapists have a limited understanding about the 'functionality' of the psychotic symptoms (including the potential protective function of symptoms). For example, a grandiose delusion may serve the function of protecting an individual's fragile self-esteem. Therefore, without having 'formulated' this connection, it is possible that any non-formulation-driven treatment may inappropriately target trying to reduce this delusion, which may well have a protective function for the patient. Such strategies should only be attempted in the light of a formulated understanding of a case, and whilst ensuring that the patient has access to other/alternative esteem-building strategies, e.g. positive data-log.

A problem list was identified in only approximately half of the cases. And in only two fifths of all cases, did therapists then target the items on the problem list. Therapeutic alliance was noted as a treatment priority in only around half of cases. Risk assessment and management was also an expected key focus for CBTp (f) treatment in this HSH setting. This included monitoring for any over-developed and/or under-developed behavioural strategies (after Davidson 2000) that may have been implicated in the maintenance of risk in some patients. However, the existence of such strategies and their documentation as a treatment priority was found in only

around one third of cases. An essential component of CBTp (f) (and generic CBT) is that it should be problem orientated. The absence, in half of the cases, of an established problem list or other manner of identifying what the target problems were, made it impossible to determine what the key focus for therapy involved.

In terms of use of specific *cognitive and behavioural change strategies* - there was evidence of patients *learning to identify connection between thoughts feelings and behaviour* in approximately one third of cases and *learning to monitor link to risk* in about one tenth of cases. All other specific change strategies (as described above), with the exception of engagement, were noted in less than half of cases. And so, overall, it would seem that there was a limited active phase of treatment for most patients. This would further support the finding noted earlier about partial therapy and reinforce the importance of monitoring this potential occurrence more vigilantly in future.

Review of the *ending phase* including *consolidation* and *relapse prevention* also highlighted some divergence from the manual. A discernible *ending phase* of treatment was identified in approximately one quarter of cases; a *staying well / relapse prevention plan* was completed in a quarter of cases; and an *end of treatment report* was completed in approximately two third of cases. Without an identified ending phase there may be limited opportunity for therapist and patient to review progress on identified goals and agree whether treatment targets have been met.

Overall, in a third of the cases it seemed difficult for therapists to move beyond the engagement process, with many case notes reading as if therapy was caught up in continuous engagement. This leads the researcher to reflect and ask why were people getting stuck in engagement, rather than progressing through to the other stages of treatment within the manual? Further, given that almost all problems lists that did exist, had ‘therapeutic alliance’ as a treatment priority, this would suggest that, potentially, this is a client group with challenges relating to interpersonal relationships, which may be a barrier to progressing with CBTp (f). This would concur

with Benn's (2002) earlier noted findings about potential difficulties when trying to engage patients in HSHs in a CBTp intervention. Prior research indicates that a key factor in the [successful] implementation of a manualised approach to CBTp might relate to the experience of the therapists delivering treatment (e.g. Kuipers et al. 1997; Sensky et al. 2000; Morrison et al. 2004; Haddock et al. 2009). In the present study it was difficult to fully understand the reasons why such a high degree of non-adherence to the manual was noted. (The researcher commented earlier – see Chapter 4, p. 78 about how having a lack of opportunity to investigate this issue further and more directly with therapists was a distinct limitation in one of the methods used, i.e. semi-structured interviews conducted by an independent interviewer, which has resulted in this particular question not being fully answered during this study).

When therapists were interviewed about the use and implementation of the manual in the Phase Two study, certain key themes emerged including manual-related factors, therapist-related factors, and environment-related factors. Within manual-related factors, the most frequently reported sub-theme related to " working practices independent of the manual". This accounted for 13% of all references made during interviews and was commented on by all therapists, with all discussing, at times, "going off model". This finding also concurs with much of the data obtained from case note review, i.e. very few of the key components of CBTp (f), as described in the manual, were located in the case notes. (One of the most helpful aspects of using mixed-method process evaluation in this study, has been the ability to integrate findings from across both the phase one (quantitative) and phase two studies (qualitative) in this way. According to Moore et al (2015) this can strengthen the analysis and is preferable to mono-method studies. "Knowing what was delivered allows qualitative data on participant responses to be understood in light of a clear definition of the intervention with which participants interacted" (Moore et al. 2015, p.76).

Considering there were so many reports of non-adherence to the manual, the other comments therapists made about manual-related factors appear unsurprising. The

other key sub-themes elicited referred to challenges in adherence due to difficulty in using and applying the manual with patients; the manual being overwhelming for therapists; and presentation of the manual being cumbersome and a barrier to its use.

There were a number of other themes that emerged in the therapist interviews that related to either therapists or the manual and that might provide further insight. Therapists noted issues related to their training, including gaps in knowledge, and described limited knowledge of the CBTp (f) manual and/or specific techniques contained within it. It therefore follows that if a therapist does not know what the key components of manual are, it would not then be possible to apply aspects of the manual within CBTp (f) treatment. In addition, therapists highlighted the importance of the timing of training - and in particular, referred to the distance in time between the training and the implementation of CBTp (f). As a result, quite a few therapists could not remember a number of the components of the manual, and so it is unlikely that a component will be used if it cannot be recalled.

Therapists also highlighted uncertainty regarding their skills in determining a patient's readiness to engage, including agreeing treatment targets and managing sensitive areas within therapy. Previous research has suggested that clinicians can be concerned that patients are too ill to engage in treatment, despite clinical trials demonstrating that CBT is effective even with patients who have high symptom severity, and who may be very unwell at the start of treatment (e.g. Morrison et al. 2004).

Clinical supervision was raised as an important element of the treatment process with many comments from therapists being that there was not sufficient supervision provision. Therapists also valued having clear CBTp (f)-based supervision to help them identify where therapy may have become stuck and obtain guidance from their supervisors. It may therefore be that lack of a sufficient quantity of supervision, or sufficient direction within supervision, would again help to explain why therapeutic drift occurred and may have increased the likelihood of non-adherence to the manual.

Despite the apparent challenges for therapists in adhering to the manual, many reported a perception of the manual as efficacious. In these cases, the manual was viewed as acceptable to patients, as assisting in clinical team working (e.g. supporting the team to understand the patient's difficulties), and as having a role in changing symptoms or problems for patients (e.g. improving quality of life, reducing risk related factors). The reason for this possible contradiction could be that it is difficult or uncomfortable for therapists to accept that CBTp (f) may not have been effective or may not have led to change. Alternatively, therapists may have both experienced the manual as having areas for improvement in utility, but still found it valuable, which may explain why the still felt able to make clinical progress with patients. The highly tentative nature of these conclusions, however, appear to further reinforce the importance of gathering more objective outcome data to corroborate whether improvements were in fact experienced by patients.

6.3 Facilitators to CBTp (f) implementation

Therapist feedback indicated that there were gaps in therapist knowledge and, at times, a significant distance in time between their CBTp (f) training and the delivery of treatment, which may have impeded implementation. There therefore appears to be a need to potentially review training, complete additional training, and offer booster training to ensure ongoing knowledge and skills maintenance.

Another factor identified that would perhaps enable therapists to implement CBTp (f), is some form of support to help them determine the patient's readiness and/or suitability for treatment, perhaps by having some clearer guidance on this aspect of intervention implementation. Morrison (2017) suggests, for example, that if no problem list for CBTp has been agreed by session three, then therapy is unlikely to progress meaningfully. Prior to Morrison's (2017) suggestion, Durham et al (2000) produced a paper addressing many of the difficulties that generalist CBT practitioners have when working with more complex patients. To help manage issues of collaboration and complexity, Durham et al (2000) suggested: having a trial of CBT

for about three to four sessions, to test whether building collaboration is possible; using a screening interview process to assess problem complexity and severity; using a specially developed algorithm to help guide therapists to sources of additional support should they get ‘stuck’ in terms of lack of apparent progress with a particular case; periodic team review of cases; and peer-aided supervision. It may therefore be helpful to provide additional guidance within the manual, similar to that suggested by Durham et al (2000) and Morrison (2017), to help therapists to identify the stage of treatment and whether treatment is progressing, and to support them to reflect on whether to end therapy or not.

In addition, there is a suggestion that therapists may lack confidence in this therapeutic approach for patients who have chronic symptoms or complex needs, and so developing therapists' knowledge regarding the applicability of such treatment to this client group may be helpful. This might be aided by the new NICE (2020) clinical guideline for working with adults with complex psychosis.

Therapists indicated that supervision is important and valued by them when doing this work, and that CBTp (f)-specific supervision was also particularly important. Therapists will therefore need support and access to both. They should also have sufficient time and commitment to attend supervision.

Therapists’ also highlighted factors related to adherence to the manual, which, if changed, might also support improved implementation. Therapists identified difficulty in using and applying the manual with patients; the manual being overwhelming for therapists; and presentation of the manual being cumbersome. A re-write of the manual therefore seems essential. The format of the re-write should ensure that it is simplified, that there is clarity, and that there are clear case examples to demonstrate the application of therapeutic techniques. Therapists clearly identified that "working practices independent of the manual" were common. To support future manual adherence, a review of governance processes for the service might also be essential. This should help to ensure that, in future, therapists are following the prescribed

manual, particularly if it includes episodic audit of CBTp (f) implementation (perhaps using the specifically designed pro-forma for the case note review (Appendix 2) as a future audit tool). Future adherence to the manual may also be assisted by the adoption of a particular therapy adherence scale by therapists and their supervisors.

Therapists raised a number of [environment-related] factors related to the wider context of delivering psychological treatment within a HSH. For example, therapists highlighted barriers related to being able to gain regular access to patients to ensure consistent therapeutic input. Therefore, to aid CBTp (f) implementation more widely across the hospital, and to enable therapists to manage some of the more context-specific issues, an awareness-raising/education initiative could help familiarise the wider staff group with factors that can help support a more psychologically-informed therapeutic milieu. This might include information, not only about criteria for referral to CBTp (f), but also the importance of the timing of a referral (i.e. referring patients as early as appropriate) and the need for the environment to support regular treatment appointments.

Therapists also raised the issue of therapy sometimes being inhibited by patients' fear about disclosing information related to active symptoms (e.g. being reluctant to report distressing episodes of voice-hearing for fear of receiving increased medication, or temporary suspension of their access to the hospital grounds). To overcome this type of barrier, it may be important to support therapists in the development of skills to strengthen therapeutic alliance and trust; in acquiring specific skills or strategies to overcome ambivalence about the sharing of information; and, again, enhance awareness training with the wider clinical team about the need for sensitivity when responding to such disclosures by patients.

Therapists also noted how unexpected changes to a patient's treatment plan, or an unexpected transfer to another hospital setting can sometimes have an unhelpful impact upon treatment delivery (therapists viewed these practices as a limitation to their clinical autonomy). Once again, awareness-raising and education for the wider

clinical team might help to overcome this. Such awareness-raising could include information on for example, CBTp (f) inclusion criteria, one aspect of which is that the patient is likely to remain in the hospital for a further six months; and the potential consequences of delivery of partial treatment.

Finally, therapists noted the impact of risk and security-related issues specific to a forensic setting. For example, a patients' risk of violence within therapy, the impact of security-related issues that can occasionally result in access to patients being prevented (e.g. suspension of grounds access, 'lockdown' of specific patient areas), or risk concerns limiting the willingness of the system to enable behavioural experiments (e.g. use of cameras/video equipment, other digital media for skills rehearsal. Many of these modern forms of technology are prohibited items within HSHs). Once again it is speculated that enhanced awareness-training with the wider clinical team may assist in overcoming such barriers. Having more of a 'whole-system' approach to care delivery, such as through the use of 'structured clinical care' programmes (which includes awareness of the patient's formulation, model of treatment, aims of treatment and factors that can help or hinder attainment of treatment goals), might also help raise awareness within the 'system' about how best to support patients' psychological recovery. In addition, through suggestions in the manual, and the more creative components of training and supervision, it will be important to assist therapists to create opportunities for behavioural experiments whilst working within a restricted environment.

6.4 Elements of current treatment manual that may need changed

In the Phase Three study, a panel of experts were surveyed who had either been involved in the development of CBTp treatment protocols; led clinical trials; or had experience in the delivery of CBTp or the provision of CBTp clinical supervision, in a forensic setting. When asked to consider the important components of a CBTp treatment, experts largely confirmed the principles and elements of delivery that were proposed to them. Experts confirmed the importance of the presentation of the treatment manual and the need for therapists to adhere to the manual. The experts'

views included specific recommendations regarding the detailed structure of a revised treatment manual.

The need for regular CBTp (f) training, assessment of therapists' competence, and the need for regular supervision were similarly confirmed by experts as key to the delivery of effective CBTp (f). In particular, experts strongly endorsed the use of the Roth and Pilling (2013) competency framework, (Thomas's (2015) comments about this notwithstanding - i.e. that they had set a "high and exclusive bar for delivery". (See also p.26). Experts also endorsed the need for therapists to have specific forensic competencies; the need for CBTp (f) competencies to be regularly reviewed using a recognised competency measure; the need for therapists to have a good working knowledge of the manual; and the need for therapists to demonstrate knowledge from a wide range of CBT models.

Experts also endorsed the importance of key stages of the therapy process. This included the importance of assessing patient readiness, assessing patient willingness and ability to engage; completing formulation; assessing when it is appropriate to move to the next stage of treatment; and assessing the mid-point of treatment. In addition, experts also confirmed the importance of factors associated with governance and service evaluation including alignment with clinical guidelines and current evidence base; the range and use of psychometric measures; and the importance of formally recording outcome and record keeping. All experts endorsed the need for all aspects of current clinical guidelines to be integral components of the CBTp (f) intervention. In addition, experts referred to the concept of developing a 'psychosis pathway'. The new NICE (2020) guideline, which focuses on the rehabilitation of adults with complex psychosis, is also leaning towards the creation of more of a pathway for people with psychosis, prior to accessing full clinical guideline-level CBTp. For example, by suggesting that patients might access lower-intensity psychologically-informed interventions. These include brief interventions such as relaxation and stress-reduction techniques.

Summary

There are many suggested implications for this HSH arising from this study. Several key implications are considered in four areas:

1. The delivery of the CBTp (f) intervention.
   i. One of the key implications related to delivery is for the PSI/Psychological Therapies Service to consider whether it would be prudent to move away from the current use of 'generalist' practitioners to deliver CBTp (f), in favour of e.g. setting up a small team of specialists to deliver this instead. Whilst this latter option was tested by other services and found to be expensive, with very little impact on a patient group of 7000 (Jolley et al. 2015), this is unlikely to happen in this HSH where we have an existing team of high intensity/specialist/highly specialists practitioners and an eligible patient population of less than 100, i.e. 80% of current inpatient population.
   ii. Another key implication is to recognise the value in using this research to finally kick-start increased implementation of CBTp (f) in this HSH, whilst working to enable this to be further researched using a more experimental design, i.e. complete the processes required to enable a future phase 1 RCT of the intervention.
   iii. A further key implication for the service/department as a whole is to note the issue of potential iatrogenic effect arising from partial therapy and address this as a priority – i.e. check current status of progress with patients who are currently in receipt of CBTp (f).

2. Staff training/supervision
   i. The first key implication in this section is to address the need to develop a training programme for staff to enable them to deliver CBTp (f) and a further training programme for supervisors to enable them to deliver CBTp (f)-specific supervision.
   ii. Another implication is to perhaps consider developing a CBTp (f) severity and complexity algorithm, similar to Durham et al's (2000) to enable therapists and

supervisors to have clearer guidance on when CBTp (f) may be indicated, and when not.

iii. The final key implication in this section is the need for the Service to address non-adherence to the therapy manual. Consideration might then be given to the adoption of a particular therapy adherence scale and use of 'close' (i.e. via direct observation or recordings of therapy delivery sessions) supervision.

3. Adaptations to manual

i. The key implication here is that the current manual needs to be revised and rewritten and its refreshed contents should reflect the findings from this study.

ii. Mixed media should be used throughout the manual to help illustrate aspects of this complex intervention, e.g. case studies, video clips, 'in vivo' skill rehearsal opportunities, use of diagrams, as well as clearly structured text.

iii. Another key implication is that this manual needs to contain clear instructions on use of psychometrics and other means of 'evidencing' CBTp (f) impact or lack of impact.

4. Operational and resource issues

i. Consideration should be given to development of operational policies to support CBTp (f) implementation, e.g. strategies that might ensure early referral, raise awareness of duration of psychosis, and enable consistent access to patients.

ii. There may be resource implications if resources are diverted away from other areas to enable creation of a small specialist team of CBTp (f) therapists.

iii. Final implications include, the need to review governance structures for CBTp(f) delivery, implementation of episodic audit of referral, uptake, implementation and evaluation, and to consider quality improvement initiatives related to CBT(f).

CHAPTER SEVEN: Conclusions and Recommendations

Chapter Seven begins by drawing on the discussion of the evidence gathered (as set out in Chapter Six) and synthesised from the results presented (in Chapter Five), of the mixed-methods process evaluation which was the focus of this thesis. This will be used to determine whether the overall study aim and objectives were appropriately answered, before leading on to making a series of conclusions and recommendations based upon the findings from this study. This chapter and this thesis will then end by highlighting the unique contribution that this research will make to the evidence base for the researcher's specific area of practice, and the implications that this will also have for practice more generally. Specific plans for the future dissemination of this information via appropriate peer-reviewed journals and at national and international conferences will also be stated.

Overall, the findings of this study appear to demonstrate significant difficulties for this HSH in implementing a CBTp (f) intervention that is congruent with clinical guidelines and the current evidence base. Findings concur with experiences of the problematic implementation of CBTp on a national basis, especially findings in relation to organisational-related and therapist-related factors.

In particular, this study highlights the few patients in this HSH who receive CBTp (f) (due to low incidence of referral) despite an estimated need in 80% of the patient population at any given time. From a complex-systems perspective, the information about the lack of recent referrals to CBTp (f) also appeared to suggest that there are likely to be significant contextual factors operating within the 'system' that are affecting the uptake and implementation of this intervention. This finding appears to affirm the view posited by Hawe et al (2009, p.270), who described complex [healthcare] interventions, such as the CBTp (f) intervention, as "events in systems, which either leave a lasting footprint or wash out, depending how well system dynamics are harnessed".

For those patients who do access CBTp (f) treatment, very few received full CBTp treatment (≥16 sessions), in contrast to a comparatively high proportion of patients who receive partial treatment. Furthermore, the study demonstrates that partial treatment has tended to mean intervention involving only assessment and engagement, without progressing to an active treatment phase. Given that prior research has indicated the possibility of iatrogenic effects associated with partial treatment (Dunn et al. 2012 reported an association with potential worsening of symptoms), then it would be recommended that the potential for this to occur should be monitored in any future treatment implementation and outcome evaluation.

With regard to organisational factors that may be implicated in CBTp (f) implementation, then it seems that, similar to Switzer and Harper (2019), this was viewed as having an impact by providing limited appropriate training, occasional problems enabling patient contact, and lack of supervision; as well as the view that the complexity of patients also impacted on treatment delivery. In addition, Switzer and Harper (2019) identified a number of therapist-related factors in their study. These included problem in terms of lack of knowledge and confidence, and similarly within this study it was noted that staff at times felt overwhelmed by the manual and struggled to use and apply this with patients. This current study also noted the high proportion of CBTp (f) implementation that included working practices that varied and were independent from that set out in the manual, including use of other therapeutic models. Both practices represent significant deviations from current clinical guidelines for CBTp delivery (SIGN 2013; NICE 2014; NICE 2020) and are contrary to current available evidence for effective CBTp treatment. This research study did not however focus directly on patient factors, as some prior research has done (Cawthorne 2003), and this should therefore be regarded as a limitation.

The study findings indicated a high incidence of poor completion or non-completion of written and recorded information – i.e. mislabelled cases, as well as incomplete or absent psychometrics, notes, reports, and entries in risk assessments. It would therefore be recommended that additional governance processes be implemented,

and that the service consider the introduction of an episodic audit of service delivery; perhaps utilising the 60-item pro-forma designed for the Phase one study (Appendix 2) as an audit tool. Furthermore, the service could consider the need for clear recommendations regarding the content of end of treatment reports; and in particular the need to incorporate forensic risk-relevant information obtained through the CBTp (f) intervention process.

The study demonstrated that the average length of hospital admission prior to accessing CBTp (f) was found to be almost five years. Prior research regarding the importance of early intervention (Whiting et al. 2019) and the relevance of a 'critical period' (Birchwood 1998) highlights the need to refer for CBTp (f) at as early a stage as possible in the recovery journey. This would help to ensure that optimum opportunity for treatment to be of benefit can be created and supported. It would therefore be recommended that consideration be given to conducting a needs-analysis for patients with psychosis in this HSH. Such a needs-analysis would align with other current national initiatives that are being rolled out to support patient access to early intervention for psychosis services (Early Intervention in Psychosis Network (EIPN) 2019). A needs-analysis would also enable the service to check whether patients with psychosis have been referred for CBTp (f), and if not, whether they are being offered another evidence-based intervention that is likely to lead to similar benefit. Furthermore, a needs-analysis would enable the service to check the time window in which patients are being referred, given the importance of being seen within a critical time period.

The outcomes suggest that therapists found the manual to be complex and not straight forward to utilise; found the format cumbersome; and therapists experienced a lack of knowledge in relation to the manual. It would therefore be recommended that there be an extensive revision and rewrite of the manual for the CBTp (f) intervention; and that revision incorporates advice and suggestions from the expert panel. Such views included advice regarding the re-structuring of the manual content; that the presentation include diagrams rather than only narrative content; and

that the manual should incorporate case examples to provide a step-by-step description for therapists of the implementation of the treatment intervention. The structure of the manual should also be underpinned by the logic model developed within this study (Figure 3a). This sets out a clear treatment trajectory and so may offer a useful structure to organise the information for therapists. The logic model specifies who the intervention is for, what the intervention is, what the potential change mechanisms are, and what difference the intervention is intended to make. It would be hoped that if the manual is revised and there is clearer guidance, then it would be possible for the therapists to more consistently implement CBTp (f), and the more standardised and consistent implementation of the manual might then lend itself more to outcome evaluation. One of the key aims of this research was to help develop the CBTp (f) intervention and its implementation further, such that, at the conclusion of this study, it would be feasible to undertake a phase one RCT of the intervention. This has not been achieved. However, what has been achieved is that the service now has the information it needs to enable it to revise and rewrite the manual, develop therapist training, supervision and governance structures, and potentially consider service re-configuration, moving from its present model of CBTp (f) generalist practitioner implementation, to implementation by a smaller, highly specialist team.

Interestingly however, the study found that there was a lack of consensus amongst the expert group regarding the degree of variation from protocol that was deemed acceptable when using a CBTp (f) manual. For example, initially experts supported the option of incorporating an alternative therapeutic model on some occasions, which would appear in contradiction to current evidence-based guidance (e.g. NICE 2014). In contrast, there was consensus that the manual should be used in line with the evidence base. And in further contrast, there was no consensus about whether the only acceptable variation would involve flexibility relating to a CBT based intervention addition (e.g. if a patient hears voices, use other CBT-model based interventions designed to assist coping with this). It was therefore challenging to fully understand the expert panel position regarding variability. This too should be

regarded as a limitation – i.e. that this issue was not probed further. In addition, it would be recommended that future research should explore this variation/failure to reach consensus more fully. Similarly, there were other somewhat surprising findings from expert panel consensus regarding the appropriateness of implementing CBTp (f) with no CBTp-based formulation. Again, this would not be in line with the evidence base; and so further research might assist in elaborating upon an understanding of this discrepancy. There was also no consensus between experts about whether another psychological treatment could be delivered simultaneously; and so again further research might be able to elucidate this.

Findings indicated that experts were of the view that there is value in considering the development of a "psychosis pathway" - a tiered approach to treatment including the availability of low intensity interventions for psychosis. Interestingly again, this is not in keeping with current clinical guidelines, although signs are starting to appear in newer clinical guidelines that things may be moving more in this general direction (e.g. NICE 2020). Nonetheless, current clinical practice within this HSH commonly involves the delivery of low intensity (e.g. mental health awareness) interventions for patients. Consequently, it would be recommended that ongoing research to evaluate the outcome of low intensity interventions be conducted, to either support or not the suggestion of a psychosis pathway; and indeed, the Forensic Matrix Implementation Group (Forensic Network 2011) has prioritised the implementation and evaluation of a range of low intensity interventions across forensic mental health settings, and outcomes from this research are currently awaited.

In line with previous competency framework guidance (Roth and Pilling 2013) and the governance manual and associated competency framework for the Forensic Matrix Implementation Group (Slesser 2017), the expert panel agreed the need to demonstrate the Roth and Pilling (2013) range of CBTp competencies, a working knowledge of components of the specific manual of CBTp (f) used in their area, and an appropriate range of forensic competencies (e.g. violence risk assessment and management skills). In addition, the expert panel recommended regular review of

competencies, that regular training should be made available, and the use of a therapy adherence scale should also be adopted. The importance of this was further emphasised by findings which indicated that therapists also reported many gaps in their knowledge and viewed there to be too great a gap between training and delivery. Therefore, it would be recommended that the service provide training in the revised manual; that the training be offered on a regular and continuous basis; that competencies be assessed formally; and that the service adopts a specific adherence scale to assess therapists' competency development as a part of the supervision process.

Findings also indicated that whilst therapists very much valued supervision, their supervision experience often involved a general model and was non-CBTp (f) specific. In line with clinical guidelines, the expert panel also recommended the provision of appropriate supervision; and considered such to involve supervisors who have had clinical supervision training; more than two years' experience of delivering CBTp; specific forensic competencies; knowledge and awareness of the specific CBTp (f) treatment manual; and the format of supervision to follow the CBT model with use of adherence scales; and with the frequency of supervision to be individually determined (but with a recommendation of a minimum one-hour per month for experienced therapists or one-hour per fortnight for trainee or novice therapists). Further, supervision can be provided on an individual basis and can also be augmented by group supervision. It would therefore be recommended that there be further exploration of the expert panel recommendations for supervision with future research potentially exploring the impact of the frequency of supervision on adherence to manual and/or treatment outcome. In the meantime, based upon the outcome from the expert panel, it would be important for this HSH to offer regular supervision on an established frequency and that this recommendation be embedded within the governance manual for CBTp (f).

It is envisaged that the overall findings from this study may contribute to the mechanistic literature regarding the implementation of CBTp and CBTp (f) more

particularly, especially given the dearth of studies that currently exist within forensic services. Multiple publications arising from this study will be pursued in peer-reviewed journals and presentations will be offered at national and international conferences. (It is also likely that the revised version of the CBTp (f) treatment manual will be published).

The use of process evaluation as a method is recommended in the MRC guidance (Craig et al 2008) as a first step in developing and evaluating complex interventions. This is the first study to conduct a process evaluation within a HSH in Scotland. The study appears to have yielded valuable information and given that the hospital offers numerous other complex interventions, there may be value in adopting a process evaluation approach to evaluating some of these other interventions.

Given that findings indicate the poor implementation of CBTp (f) within this service and that this in line with national research, it would be recommended that there be a focus upon increasing the capacity in the workforce to deliver CBTp (f).

Main conclusions

A considerable part of the researcher's motivation for embarking on this research was to address the issue of possible health inequality related to CBTp (f) implementation in this HSH. This thesis concludes by arguing that this health inequality is now confirmed as actual, rather than probable. This is a significant finding; particularly when considered within the context of current mental health legislation in Scotland (see also page 8).

Another significant finding is that this thesis also confirms a serious gap in the evidence base for CBTp (f). With the exception of one small RCT conducted 12 years ago, research into the delivery of CBTp within a HSH is confined to only a handful of case studies and a theoretical paper, which is now also over a decade old. This has implications not just for this HSH, but for other HSHs and forensic mental

health services nationally and internationally (CBTp is being increasingly recommended as a treatment intervention in the United States and other countries).

This thesis has argued and demonstrated that, somewhat ironically, the very area where this complex intervention may be expected to have most impact, not just by supporting mental health recovery, but also in helping to reduce risk, is the area where it is also the most under-developed and under-researched.

Main recommendations

The main conclusions outlined above should be read as a 'red flag' not just for our service, but for all other HSHs and forensic mental health services.

Steps should be taken quickly to prioritise addressing the health inequality issue that has been confirmed. It is therefore recommended that all other recommendations related to addressing this issue, e.g. undertaking needs-analysis, and delivering staff awareness-raising sessions, should be taken forward a service priority.

The therapy manual for the CBTp (f) intervention should also be revised and rewritten as a matter of priority. This should help ensure that it can then act as a clearer guide to consistent, evidence-based CBT (f) implementation, which, in turn, would then be more amenable to experimental research enquiry. Teaching and training in the use of the manual should also be rolled out within this HSH and other forensic mental health services, and supervision structures should also be developed to support therapist delivery of CBTp (f).

Steps should be taken to address the other areas requiring development of the CBTp (f) programme (e.g. record-keeping, independent evaluation, treatment access for patients) to ensure that conditions to support an experimental research enquiry can be met. This should be adopted as a priority area for future research.

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APPPENDIX

Appendix 1 Scoping Review - Full Search Details

(EMBASE, MEDLINE, PsycINFO, CINAHL and the Cochrane Library)

Embase <1974 to 2021 February 07>

1 Cognitive Behavioral Therapy.mp. or exp cognitive behavioral therapy/ 24734

2 cognitive behavioural therapy.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] 6347

3 cognitive behavioral therapy.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] 23846

4 cbt.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] 17928

5 1 or 2 or 3 or 4 36174

6 psychosis.mp. or exp psychosis/ 301038

7 Schizophrenia.mp. or exp schizophrenia/ 210201

8 6 or 7 318396

9 5 and 8 2995

10 cbtp.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] 173

11 (cognitive behaviour therapy adj7 psychosis).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] 111

12 9 or 10 or 11 3050

13 Forensic Psychiatry.mp. or exp forensic psychiatry/ 13658

14 forensic psychology.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] 515

15 forensic psychologist.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] 34

16 forensic mental health.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] 862

17 high secure.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] 213

18 medium secure.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] 403

19 low secure.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] 114

20 mentally disordered offender.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] 70

21 mdo.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] 410

22 Insanity Defense.mp. or exp forensic psychiatry/13090

23 secure hospital.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] 209

24 secure.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] 36982

25 forensic psychiatric patient.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] 25

26 forensic psychiatric inpatient.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] 31

27 forensic patient.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] 74

28 forensic inpatient.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] 103

29 forensic service.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] 176

30 forensic.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] 100665

31 mental health law.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] 516

32 mental health legislation.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] 555

33 severe mental illness.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] 6101

34 detained.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] 2032

35 Prisons.mp. or exp prison/ 17667

36 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 160989

37 12 and 36 120

Ovid MEDLINE(R) ALL <1946 to February 07, 2021>

1 Cognitive Behavioral Therapy.mp. or exp Cognitive Behavioral Therapy/ 34199

2 cognitive behavioural therapy.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 4325

3 cognitive behavioral therapy.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 30630

4 cbt.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 11864

5 1 or 2 or 3 or 4 38776

6 psychosis.mp. or exp Psychotic Disorders/ 73963

7 exp Schizophrenia/ or Schizophrenia.mp. 147137

8 6 or 7 194914

9 5 and 8 2475

10 cbtp.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 124

11 (cognitive behaviour therapy adj7 psychosis).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 71

12 9 or 10 or 11 2492

13 exp Forensic Psychiatry/ or Forensic Psychiatry.mp. 39908

14 forensic psychology.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 180

15 forensic psychologist.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 11

16 forensic mental health.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 585

17 high secure.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 119

18 medium secure.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 202

19 low secure.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 59

20 mentally disordered offender.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 30

21 mdo.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 315

22 Insanity Defense.mp. or exp Insanity Defense/ 1842

23 secure hospital.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 124

24 secure.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 25898

25 forensic psychiatric patient.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary

concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 18

26 forensic psychiatric inpatient.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 21

27 forensic patient.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 39

28 forensic inpatient.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 77

29 forensic service.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 108

30 forensic.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 71596

31 mental health law.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 429

32 mental health legislation.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 422

33 severe mental illness.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 4577

34 detained.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 1552

35 Prisons.mp. or exp Prisons/ 13022

36 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 143847

37 12 and 36 102

APA PsycInfo <1987 to February Week 1 2021>

1 exp Cognitive Behavior Therapy/ or Cognitive Behavioral Therapy.mp. 28993

2 cognitive behavioural therapy.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh] 3848

3 cognitive behavioral therapy.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh] 17006

4 cbt.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh] 14732

5 1 or 2 or 3 or 4 32338

6 exp Psychosis/ or psychosis.mp. 106854

7 exp Schizophrenia/ or Schizophrenia.mp. 110019

8 6 or 7 133973

9 5 and 8 2352

10 cbtp.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh] 162

11 (cognitive behaviour therapy adj7 psychosis).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh] 117

12 9 or 10 or 11 2380

13 Forensic Psychiatry.mp. or exp Forensic Psychiatry/ 7008

14 forensic psychology.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh] 4958

15 forensic psychologist.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh] 217

16 forensic mental health.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh] 1380

17 high secure.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh] 232

18 medium secure.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh] 443

19 low secure.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh] 181

20 mentally disordered offender.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh] 90

21 mdo.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh] 47

22 Insanity Defense.mp. or exp Insanity Defense/ 1724

23 secure hospital.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh] 214

24 secure.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh] 15217

25 forensic psychiatric patient.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh] 22

26 forensic psychiatric inpatient.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh] 29

27 forensic patient.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh] 99

28 forensic inpatient.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh] 135

29 forensic service.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh] 130

30 forensic.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh] 20558

31 mental health law.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh] 557

32 mental health legislation.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh] 476

33 severe mental illness.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh] 5296

34 detained.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh] 1644

35 Prisons.mp. or exp Prisons/ 10182

36 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 52990

37 12 and 36 112

CINAHL - Saturday, February 07, 2021 10:38:19 AM

Query Limiters/Expanders Last Run Via Results

S37 S12 AND S36 Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 79

S36 S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 38,560

S35 (MM "Correctional Facilities") OR "Prisons" OR (MM "Prisoners") Search modes - Boolean/PhraseInterface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 10,097

S34 detained Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 817

S33 severe mental illness Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 2,981

S32 mental health legislation Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 1,178

S31 mental health law Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 264

S30 forensicSearch modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 14,443

S29 forensic service Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 215

S28 forensic inpatient Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 88

S27 forensic patient Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 184

S26 forensic psychiatric inpatient Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 44

S25 forensic psychiatric patient Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 97

S24 secure Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 10,400

S23 secure hospital Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 171

S22 (MM "Insanity Defense") OR "Insanity Defense" Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 253

S21 mdo Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 71

S20 mentally disordered offender Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 194

S19 low secure Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 108

S18 medium secure Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 300

S17 high secure Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 139

S16 forensic mental health Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 485

S15 forensic psychologist Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 40

S14 forensic psychology Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 98

S13 (MH "Forensic Psychiatry+") OR "Forensic Psychiatry" Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 2,083

S12 S9 OR S10 OR S11 Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 2,814

S11 cognitive behaviour therapy NEAR7 psychosis Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 0

S10 "cbtp" Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 70

S9 S5 AND S8 Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 2,807

S8 S6 OR S7 Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 136,061

S7 (MH "Schizophrenia+") OR "Schizophrenia" Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 33,614

S6 (MH "Psychotic Disorders+") OR "psychosis" Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 130,707

S5 S1 OR S2 OR S3 OR S4 Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 39,046

S4 cbt Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 5,894

S3 cognitive behavioral therapy Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 7,911

S2 cognitive behavioural therapy Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 7,911

S1 (MH "Cognitive Therapy+") OR (MH "Behavior Therapy+") OR "Cognitive Behaviour Therapy" Search modes - Boolean/Phrase Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 35,547

Search Name: COCHRANE LIBRARY 19 Sept 2020

Date Run: 07/02/2021 23:14:27

ID	Search	Hits
#1	MeSH descriptor: [Cognitive Behavioral Therapy] explode all trees	9079
#2	cognitive behavioural therapy	21275
#3	cognitive behavioral therapy	21275
#4	cbt	8835
#5	#1 OR #2 OR #3 OR #4	23708
#6	MeSH descriptor: [Psychotic Disorders] explode all trees	3008
#7	psychosis	6748
#8	MeSH descriptor: [Schizophrenia] explode all trees	7578
#9	#6 OR #7 OR #8	14055
#10	#5 AND #9	1446
#11	cbtp	91
#12	#10 OR #11	1479
#13	MeSH descriptor: [Forensic Psychiatry] explode all trees	193
#14	forensic psychology	223
#15	forensic psychologist	16
#16	forensic mental health	191
#17	high secure	1079
#18	medium secure	201
#19	low secure	882
#20	mentally disordered offender	9
#21	mdo	60
#22	MeSH descriptor: [Insanity Defense] explode all trees	9
#23	secure hospital	1261
#24	secure	3236
#25	forensic psychiatric patient	92

#26 forensic psychiatric inpatient 39

#27 forensic patient 198

#28 forensic inpatient 53

#29 forensic service 97

#30 forensic873

#31 mental health law 370

#32 mental health legislation 184

#33 severe mental illness 2971

#34 detained 71

#35 MeSH descriptor: [Prisons] explode all trees 126

#36 #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 7584

#37 #12 AND #36 265

Appendix 2

Pro-forma for use in patient case notes review

DEMOGRAPHIC INFORMATION

[1] Patient Case Note Number (1 – 60**):**

[2] Gender: (Tick whichever applies).		
Male:	Female:	Unspecified:

[3] Age at start of CBTp intervention (in years and months).		
Years:	Months:	Don't know or no information about this located in case note records:

[4] Marital status.			
Single:	Married/cohabiting:	Divorced/separated:	Widowed:

[5] Ethnicity: Choose the option that best describes the patient's ethnic group or background.

White

1. Scottish
2. Other British
3. Irish
4. Gypsy/Traveller
5. Polish
6. Any other White ethnic group, please describe

Mixed or Multiple ethnic groups

7. Any Mixed or Multiple ethnic groups, please describe

Asian, Asian Scottish or Asian British

8. Pakistani, Pakistani Scottish or Pakistani British
9. Indian, Indian Scottish or Indian British
10. Bangladeshi, Bangladeshi Scottish or Bangladeshi British
11. Chinese, Chinese Scottish or Chinese British
12. Any other Asian, please describe

African

13. African, African Scottish or African British
14. Any other African, please describe

Caribbean or Black

15. Caribbean, Caribbean Scottish or Caribbean British
16. Black, Black Scottish or Black British
17. Any other Caribbean or Black, please describe

Another ethnic group

18. Arab, Arab Scottish or Arab British
19. Any other ethnic group, please describe

[6] Ward/location:

Old hospital site (i.e. up to mid-September 2011), and designated ward

1. Alexandra (women only)
2. Arran
3. Clyde
4. Cromarty
5. Earn
6. Forth
7. Kelvin
8. Lomond
9. Solway
10. Tay
11. Tweed

New hospital site (i.e. from late-September 2011 onwards), and designated hub/ward

12. Arran Hub – Arran 1
13. Arran Hub – Arran 2
14. Arran Hub – Arran 3
15. Iona Hub – Iona 1
16. Iona hub – Iona 2
17. Iona Hub – Iona 3
18. Lewis Hub – Lewis 1
19. Lewis Hub – Lewis 2
20. Lewis Hub – Lewis 3
21. Mull Hub – Mull 1
22. Mull Hub – Mull 2
23. Mull Hub – Mull 3

[7] Educational qualifications: Please indicate which, if any, of the following qualifications the patient has. Please indicate all that may apply.

- ☐ School leaving certificate, National Qualification Access Unit
- ☐ Grade, Standard Grade, GCSE, GCE O Level, CSE, National Qualification Access 3 Cluster, Intermediate 1 or 2, Senior Certificate or equivalent.
- ☐ GNVQ/GSVQ Foundation or Intermediate, SVQ Level 1 or 2, SCOTVEC/National Certificate Module, City and Guilds Craft, RSA Diploma or equivalent
- ☐ Higher Grade, Advanced Higher, CSYS, A Level, AS Level, Advanced Senior Certificate or equivalent
- ☐ GNVQ/GSVQ Advanced, SVQ Level 3, ONC, OND, SCOTVEC National Diploma, City and Guilds Advanced Craft, RSA Advanced Diploma or equivalent
- ☐ HNC, HND, SVQ Level 4, RSA Higher Diploma or equivalent
- ☐ First Degree, Higher Degree, SVQ Level 5 or equivalent
- ☐ Professional qualifications e.g. teaching, accountancy
- ☐ Other school examinations not already mentioned

- ☐ Other post-school but pre Higher education examinations not already mentioned
- ☐ Other Higher education qualifications not already mentioned
- ☐ No qualifications
- ☐ Don't know or no information about this located in case note records

[8] Socio-economic status.

1. Skilled/professional
2. Semi-skilled
3. Unskilled
4. Don't know or no information about this located in case note records.

[9] Duration of illness (in years).

Years: Don't know or no information about this located in case note records:

[10] Index offence/other offending behavior.

1. Murder
2. Culpable homicide/'Not Guilty by Reason of Insanity'
3. Attempted murder
4. Assault
5. Sexual assault/rape
6. Breach of the Peace
7. Fire-raising
8. Drug-related
9. Other violent behavior – no formal/criminal charges
10. Don't know or no information about this located in case note records

[11] Primary diagnosis (include ICD-10 code if located).

1. Schizophrenia. ICD-10:
2. Schizoaffective Disorder. ICD-10:
3. Other psychosis (e.g. drug-induced). ICD-10:
4. Don't know or no information about this located in case note records.

[12] Secondary/supplementary diagnosis/es. (Include ICD-10 code if located)

1. Personality disorder (please specify). ……..... ICD-10:
2. Learning disability. ICD-10:
3. Other (please specify). …….. ICD-10:
4. Don't know or no information about this located in case note records

[13] Previous CBTp input?

Yes: No: Don't know or no information about this located in case note records:

[14] Concurrent psychological treatment? Please indicate all that may apply.

1. Low intensity intervention (e.g. psychoeducation, basic coping skills work).
2. Other high intensity (e.g. Tune-in, Relating Well, Planning for the Future).
3. Specialist (e.g. offence disclosure, fantasy modification, anger treatment, PD therapies).

4. Highly specialist (e.g. bespoke motivational/engagement work, challenging behavior interventions, system-led PD interventions).
5. Other (please specify).
6. No concurrent psychological treatment.
7. Don't know or no information about this located in case note records.

[15] Length of time in hospital at start of the CBTp intervention:
Years: Months: Don't know or no information about this located in case note records:

[16] CBTp intervention START date.	**[17] CBTp intervention END date.**
Date:	Date:
Don't know or no information about this located in case note records.	Don't know or no information about this located in case note records.

[18] Total CBTp treatment duration.
Years: Months: Don't know or no information about this located in case note records:

[19] Time period that corresponds to original referral and start of CBTp intervention.

1. 2002 – 2006
2. 2007 – 2011
3. 2012 – 2016
4. 2017 – present
5. Don't know or no information about this located in case note records

[20] Number of CBTp sessions completed:

1. …….. (Where located/accurately identified, insert actual number here)
2. Not confirmed, but estimated to be < 16 sessions
3. Not confirmed, but estimated to be > 16 sessions
4. Don't know or no information about this located in case note records

[21] Allocated treating therapist. (Please tick which description best applies).

1. Qualified clinical or forensic psychologist (i.e. where core component of training included at least diploma level equivalent training in CBT)
2. Trainee clinical or forensic psychologist
3. Nurse therapist (with CBT diploma level training and 2 or more years post-qualification experience)
4. Nurse therapist (with CBT diploma or other level training and less than 2 years post qualification experience)
5. Don't know or no information about this located in case note records
6. Professional mix (e.g. where allocated therapist has changed, or x 2 therapists are working together with same patient)

[22] Case note review verified by: . (Only required if case note records relate to a CI's former case.

REFERRAL PROCESS AND ACCESS TO TREATMENT

[23] Was the patient formally referred for this intervention? (i.e. was a referral letter or form completed?)

Yes: No: Don't know or no information about this located in case note records:

[24] If/where located, what detail was shown on the referral form/letter re the patient's presenting difficulties and/or underlying psychological needs? Please tick all that apply.

1. Current/active positive symptoms (i.e. hallucinations or delusions).
2. Current/active negative symptoms (e.g. social isolation, blunted affect).
3. Current/active thought disorder (e.g. tangential thinking, thought block).
4. No active symptoms, currently in remission.
5. Depression.
6. Anxiety.
7. Other emotional dyregulation.
8. Behavioural difficulties/dysregulation.
9. Relationship difficulties.
10. Other psychological difficulties/needs (please describe)
11. Don't know or no information about this located in case note records

[25] CBTp intervention – Inclusion Criteria. Did the patient meet all or some of the following 4 inclusion criteria? Please tick all that apply.

1. **Currently experiencing <u>active positive symptoms</u>? (Where present, please describe):…….**

Yes: No: Don't know or no information about this located in case note records:

2. **Expresses a <u>willingness to engage</u> in the CBTp intervention?**

Yes: No: Don't know or no information about this located in case note records:

3. **Is currently <u>distressed</u> by the experiences described in Question 1 of this section?**

Yes: No: Don't know or no information about this located in case note records:

4. **Is likely to <u>remain in TSH for the next 6 – 9 months period?</u>**

Yes: No: Don't know or no information about this located in case note records:

[26] Where the patient did not meet any or all of the above inclusion criteria, but they were still entered into this treatment, were there any other factors that facilitated or led to their inclusion? (E.g. did they agree that there was perhaps an impassé between their views and their CTM's and therefore agree nonetheless to give it a try?)

N/A: Yes*: No: Don't know or no information about this located in c/note records:

*Please provide detail if located:

[27] Was the patient interviewed by a member of the PSI Service staff (or someone else acting on their behalf) in response to their referral, prior to beginning the CBTp

intervention? (I.e. was the patient given information and explanations about the treatment or other support in relation to their referral and the opportunity to ask questions about it?)
Yes: No: Don't know or no information about this located in case note records:

[28] Was the patient given a copy of the PSI Service's Patient Information Booklet?
Yes: No: Don't know or no information about this located in case note records:

[29] How soon did CBTp begin after the patient was referred and accepted into this treatment?
1. Within < 18 weeks (where/if possible, please provide exact detail) 2. Within ≥ 18 weeks (where/if possible, please provide exact detail) 3. Don't know or no information about this located in case note records.

[30] Where it took > 4 – 18 weeks (or more) to start the CBTp intervention, what reason was given for this?
1. N/A 2. Delayed because no suitable treating therapist currently available. 3. Delayed/deferred because of current deterioration in patient's mental health. 4. Delayed/deferred because patient in concurrent psychological treatment or referred for higher priority psychological intervention at this time. 5. Other reason (please specify). 6. Don't know or no information about this located in case note records

TREATMENT – Stage 1: Assessment

[31] Did the assessment process include exploration and identification of information related to the following key areas?
1. Early experiences? **(including social adversity, trauma, childhood attachment history?).** Yes (All areas): Yes (Partial coverage of specified areas): Please provide detail of those covered: …. No: Don't know or no information about this located in case note records:
2. Schema? (i.e. cognitive vulnerabilities, core beliefs and dysfunctional assumptions related to self, others/World and future) Yes (All areas): Yes (Partial coverage of specified areas): Please provide detail of those covered: …. No: Don't know or no information about this located in case note records:
3. Critical incidents? This should include <u>experience of psychosis</u> (including other possible cognitive vulnerabilities, e.g. illness appraisals and attributional biases; 'search for meaning' related to symptoms); <u>offending</u>, <u>life events</u>, <u>hospitalisation</u> and <u>interpersonal environment</u> (including relationships – esp.

where there are high levels of criticism and hostility, personality functioning, and any perceptions of stigma, humiliation and shame)

Yes (All areas):
Yes (Partial coverage of specified areas): Please provide detail of those covered: ….

No:
Don't know or no information about this located in case note records:

4. **Current problematic thoughts? (Inc. thinking style, reflective capacity, beliefs, values and any imagery?)**

Yes (All areas):
Yes (Partial coverage of specified areas): Please provide detail of those covered: ….

No:
Don't know or no information about this located in case note records:

5. **Current problematic emotions?**

Yes (All areas):
Yes (Partial coverage of specified areas): Please provide detail of those covered: ….

No:
Don't know or no information about this located in case note records:

6. **Current problematic behaviours (i.e. either hypothesised as over-developed or under-developed?)**

Yes (All areas):
Yes (Partial coverage of specified areas): Please provide detail of those covered: ….

No:
Don't know or no information about this located in case note records:

[32] Was a timeline completed to aid the assessment/formulation process?

Yes: No: Don't know or no information about this located in case note records:

[33] PSYCHOMETRIC ASSESSMENT – Please complete all scores where available.

MEASURE	PRE	MID	POST	F/UP
Calgary Depression Scale for Schizophrenia (CDSS) – Total				
Calgary Depression Scale for Schizophrenia (CDSS – Depressed Mood				
Calgary Depression Scale for Schizophrenia (CDSS – Hopelessness				
Calgary Depression Scale for Schizophrenia (CDSS – Self-depreciation				
Calgary Depression Scale for Schizophrenia (CDSS – Guilty Ideas of Reference				
Calgary Depression Scale for Schizophrenia (CDSS – Pathological Guilt				
Calgary Depression Scale for Schizophrenia (CDSS –				

Morning Depression				
Calgary Depression Scale for Schizophrenia (CDSS – Early Wakening				
Calgary Depression Scale for Schizophrenia (CDSS – Suicide				
Calgary Depression Scale for Schizophrenia (CDSS – Observed Depression				
Personal Beliefs About Illness Questionnaire (PBIQ) - Total				
Personal Beliefs About Illness Questionnaire (PBIQ) - Attribution				
Personal Beliefs About Illness Questionnaire (PBIQ) - Loss				
Personal Beliefs About Illness Questionnaire (PBIQ) - Entrapment				
Personal Beliefs About Illness Questionnaire (PBIQ) - Shame				
Personal Beliefs About Illness Questionnaire (PBIQ) - Humiliation				
PSYRATS – Auditory Hallucinations Rating Scale - Total				
PSYRATS – Auditory Hallucinations Rating Scale - Frequency				
PSYRATS – Auditory Hallucinations Rating Scale - Duration				
PSYRATS – Auditory Hallucinations Rating Scale - Location				
PSYRATS – Auditory Hallucinations Rating Scale - Loudness				
PSYRATS – Auditory Hallucinations Rating Scale – Beliefs about Origin				
PSYRATS – Auditory Hallucinations Rating Scale – Amount of Negative Content				
PSYRATS – Auditory Hallucinations Rating Scale – Degree of Negative Content				
PSYRATS – Auditory Hallucinations Rating Scale – Amount of Distress				
PSYRATS – Auditory Hallucinations Rating Scale – Intensity of Distress				
PSYRATS – Auditory Hallucinations Rating Scale - Disruption				
PSYRATS – Auditory Hallucinations Rating Scale - Control				
PSYRATS – Delusions Rating Scale - Total				
PSYRATS – Delusions Rating Scale – Amount of Preoccupation				
PSYRATS – Delusions Rating Scale – Duration of Preoccupation				
Conviction				
PSYRATS – Delusions Rating Scale – Amount of Distress				
PSYRATS – Delusions Rating Scale – Intensity of Distress				
PSYRATS – Delusions Rating Scale - Disruption				

Inventory of Interpersonal Problems (IIP-32) - Total				
Inventory of Interpersonal Problems (IIP-32) – Domineering/Controlling				
Inventory of Interpersonal Problems (IIP-32) – Vindictive/Self-Centred				
Inventory of Interpersonal Problems (IIP-32) – Cold/Distant				
Inventory of Interpersonal Problems (IIP-32) – Socially Inhibited				
Inventory of Interpersonal Problems (IIP-32) – Non-assertive				
Inventory of Interpersonal Problems (IIP-32) – Overly Accommodating				
Inventory of Interpersonal Problems (IIP-32) – Self-Sacrificing				
Inventory of Interpersonal Problems (IIP-32) – Intrusive/Needy				
Dysfunctional Attitudes Scale (DAS) - Total				
Dysfunctional Attitudes Scale (DAS) - Approval				
Dysfunctional Attitudes Scale (DAS) - Love				
Dysfunctional Attitudes Scale (DAS) - Achievement				
Dysfunctional Attitudes Scale (DAS) - Perfectionism				
Dysfunctional Attitudes Scale (DAS) - Entitlement				
Dysfunctional Attitudes Scale (DAS) - Omnipotence				
Dysfunctional Attitudes Scale (DAS) - Autonomy				
Belief about Voices Questionnaire R (BAVQ- R) - Malevolence				
Belief about Voices Questionnaire R (BAVQ- R) - Benevolence				
Belief about Voices Questionnaire R (BAVQ- R) - Omnipotence				
Belief about Voices Questionnaire R (BAVQ- R) – Resistance - Emotion				
Belief about Voices Questionnaire R (BAVQ- R) – Resistance - Behaviour				
Belief about Voices Questionnaire R (BAVQ- R) – Resistance Total				
Belief about Voices Questionnaire R (BAVQ- R) – Engagement - Emotion				
Belief about Voices Questionnaire R (BAVQ- R) – Engagement - Behaviour				
Belief about Voices Questionnaire R (BAVQ- R) – Engagement - Total				
The Safety Behaviour Questionnaire – Persecutory Beliefs (SBQ)				
Thought Control Questionnaire - Total				
Thought Control Questionnaire - D				
Thought Control Questionnaire - P				
Thought Control Questionnaire - R				
Thought Control Questionnaire - W				

Thought Control Questionnaire - S				
Beck Depression Inventory II (BDI-II) - Total				
Beck Anxiety Inventory (BAI) - Total				
Revised Impact of Events Scales (RIES) - Intrusion				
Revised Impact of Events Scales (RIES) - Avoidance				
Positive and Negative Syndrome Scale (PANSS) – Total				
Positive and Negative Syndrome Scale (PANSS) – Positive Symptoms				
Positive and Negative Syndrome Scale (PANSS) –Negative Symptoms				
Positive and Negative Syndrome Scale (PANSS) – General Psychopathology				
Other additional psychometric used – please specify.				

TREATMENT – Stage 2: Engagement, socialisation to treatment and use of normalising rationale

[34] Did the therapist record any information about having 'socialised' the patient to this intervention? E.g. did they discuss treatment expectations, how this intervention might work, potential benefits?
Yes: No: Don't know or no information about this located in case note records:

[35] Did the therapist record having spent some time discussing and exploring 'normalising' rationale with the patient? (E.g. did they provide psychoeducation and data re prevalence of and circumstances re voice-hearing in general population or amongst famous/well known people?)
Yes: No: Don't know or no information about this located in case note records:

[36] Was the level of engagement and collaboration achieved by the therapist with this patient recorded?
Yes: No: Don't know or no information about this located in case note records:

[37] Where noted/completed, please indicate (✓) the apparent/implied level of engagement that was achieved with this patient.

1. None, or very little engagement, such that the intervention either could not start or could not continue shortly after it began.
2. A modest level of engagement, such that the intervention could begin and progress but was subject to fairly frequent patient refusals/otherwise missed sessions – e.g. when the patient may have opted out for a variety of reasons. However, this was not so severe that it brought the treatment to an abrupt end.
3. A moderate level of engagement, such that the intervention could begin and progress and was subject to very few patient refusals/otherwise missed sessions – e.g. when the patient may have opted out for a variety of reasons. However, overall interruptions to engagement were very few and did not adversely affect the course of the treatment.
4. A high level of engagement, such that the intervention could begin and progress and was rarely subject to breaks in contact. If/when any breaks did occur, they arose due to mainly therapist factors (e.g. illness or holidays) or situations outwith the patient's

control that precluded their attendance (e.g. D & V outbursts, clinical outing, etc).
5. Don't know or no information re this located in case note records.

[38] How frequently was the patient seen for CBTp sessions? Please indicate below.

1. Once per week.
2. Once per fortnight.
3. Other frequency. (Please specify)
4. Don't know or no information about this located in case note records

TREATMENT – Stage 3: Formulation, developing shared understanding, establishing problem list and treatment priorities

[39] Did the patient and therapist develop an agreed formulation or shared understanding about the patient's presenting problems?

1. Yes
2. No
3. Don't know or no information about this located in case note record

[40] Did this formulation incorporate or otherwise make reference to the model underpinning this protocol, i.e. Garety et al's (2001) 'Positive symptoms of psychosis'?

1. N/A, no formulation achieved
2. Yes
3. No, but another model was discernable in formulation, e.g. '5Ps', 'generic CBT', 'Cognitive-Analytical Therapy model', 'Schema-focused model', 'Morrison's CBTp formulation model'. Please specify……..
4. No, and no other model discernible
5. Don't know or no information about this located in case note records

[41] Did the formulation/shared understanding include collaborative exploration and identification of information related to the following key areas?

1. **Early experiences**? **(including social adversity, trauma, childhood attachment history?).**

Yes (All areas):
Yes (Partial coverage of specified areas): Please provide detail of those covered: ….

No:
Don't know or no information about this located in case note records:

2. **Schema? (i.e. cognitive vulnerabilities, core beliefs and dysfunctional assumptions related to self, others/World and future)**

Yes (All areas):
Yes (Partial coverage of specified areas): Please provide detail of those covered: ….

No:
Don't know or no information about this located in case note records:

3. **Critical incidents? This should include <u>experience of psychosis</u> (including other possible cognitive vulnerabilities, e.g. illness appraisals and attributional**

biases; 'search for meaning' related to symptoms); <u>offending</u>, <u>life events</u>, <u>hospitalisation</u> and <u>interpersonal environment</u> (including relationships – esp. where there are high levels of criticism and hostility, personality functioning, and any perceptions of stigma, humiliation and shame)

Yes (All areas):
Yes (Partial coverage of specified areas): Please provide detail of those covered: ….

No:
Don't know or no information about this located in case note records:

4. **Current problematic thoughts? (Inc. thinking style, reflective capacity, beliefs, values and any imagery?)**

Yes (All areas):
Yes (Partial coverage of specified areas): Please provide detail of those covered: ….

No:
Don't know or no information about this located in case note records:

5. **Current problematic emotions?**

Yes (All areas):
Yes (Partial coverage of specified areas): Please provide detail of those covered: ….

No:
Don't know or no information about this located in case note records:

6. **Current problematic behaviours (i.e. either hypothesised as over-developed or under-developed?)**

Yes (All areas):
Yes (Partial coverage of specified areas): Please provide detail of those covered: ….

No:
Don't know or no information about this located in case note records:

[42] This question relates only to possible non-formulation driven CBTp interventions. If/where not formulation-driven CBTp was delivered, does the case note record what CBTp strategies were used and does it explain why these were applied?

1. N/A
2. Yes. Please specify…….
3. Don't know or no information re this located in case note records

[43] Was a problem list collaboratively established and agreed with the patient?

1. Yes
2. No
3. Don't know or no information about this located in case note records

[44] Was the following suggested 'Order of Treatment Priorities' followed by the therapist and collaboratively agreed with the patient?

Priority 1. Identify and target behaviours which increase risk to self or others.
Yes (All areas):

Yes (Partial coverage of specified areas): Please provide detail of those covered: ….

No:
Don't know or no information about this located in case note records:

Priority 2. Identify and target beliefs and behaviours that impact on therapeutic alliance.
Yes (All areas):
Yes (Partial coverage of specified areas): Please provide detail of those covered: ….

No:
Don't know or no information about this located in case note records:

Priority 3. Target beliefs and symptoms on problem list.
Yes (All areas):
Yes (Partial coverage of specified areas): Please provide detail of those covered: ….

No:
Don't know or no information about this located in case note records:

Priority 4. Target underlying beliefs via overdeveloped and under-developed behavioural strategies.
Yes (All areas):
Yes (Partial coverage of specified areas): Please provide detail of those covered: ….

No:
Don't know or no information about this located in case note records:

TREATMENT – Stage 4: Specific application of CBT change strategies/intervention components

[45] POTENTIAL PATIENT BARRIERS: Did anything prohibit direct targeting of agreed problem areas (e.g. co-occurring anxiety, panic, trauma, physical health issues, fear of disclosures, etc)?

1. Yes, completely. Please specify……
2. Yes, partially. Please specify……
3. No.
4. Don't know or no information about this located in case note records

[46] POTENTIAL THERAPIST BARRIERS: Did anything prohibit direct targeting of agreed problem areas (e.g. illness, re-allocation of workload, end of employment issues, difficulty applying CBTp protocol)?

1. Yes, completely. Please specify……
2. Yes, partially. Please specify……
3. No.
4. Don't know or no information about this located in case note records

[47] Did the patient learn to identify and monitor links between their *thoughts, feelings* and *behaviours?*

1. Yes
2. No.
3. Don't know or no information about this located in case note records

[48] Did this include how the above 3 factors (Ts, Fs and Bs) were potentially linked to their actual or perceived level of risk?

1. N/A
2. Yes
3. No.
4. Don't know or no information re this located in case note records

[49] Please identify which of the following other CBT/CBTp change strategies and interventions were used to help target problem areas. Please tick all that apply and specify details where available.

1. Engagement / relationship building / telling their story (specify/justify if it is the only one)
2. Work on problem and goals / motivational work / increase self-expectations
3. Maintenance (mini-) formulation / recent incident analysis (please specify)
4. Longitudinal formulation
5. Examining attributions for psychotic phenomena
6. Normalisation (including personal disclosure)
7. Use of continuum
8. Examining advantages and disadvantages (cost-benefit analysis)
9. Coping strategies / rational responding / sleep hygiene
10. Role play / skills practice
11. Evidential analysis / peripheral questioning
12. Generating alternative explanations
13. Survey planning / review
14. Safety behaviours / behavioural experiments in-session / therapist assisted / exposure
15. Metacognitive beliefs (e.g. positive / negative beliefs about paranoia/rumination/worry)
16. Metacognitive strategies (e.g. postponing perseverative processing: detached mindfulness)
17. Attentional strategies (e.g. external focus)
18. Imagery modification / enhancement / correcting memory biases
19. Core beliefs / schema change / interpersonal schema – power/origins of voices
20. Beliefs / expectations about success and pleasure
21. Reducing social isolation / graded activity scheduling / mastery and pleasure / schedule success
22. Relapse prevention
23. Other intervention/change strategy not specified above. Please provide details…….
24. Don't know or no information about this located in case note records

[50] Was information about the patient's CBTp formulation/shared understanding and the agreed management/intervention strategies to address their problem list shared with the patient's wider clinical team?

1. N/A, e.g. where no formulation achieved
2. Yes, completely. Please specify……
3. Yes, partially. Please specify……

4. No. 5. Don't know or no information about this located in case note records

[51] Was the patient allocated and did they manage to complete 'between-session' tasks (i.e. homework)?
1. Yes, always. Please specify…… 2. Yes, sometimes. Please specify…… 3. Yes, but only very rarely. Please specify…….. 4. No. 5. Don't know or no information about this located in case note records

OUTCOMES – Health improvement, efficiency, goal attainment/desired outcomes

[52] By the end of the CBTp interventions did the patient engage in a process of re-evaluation of their perceptions, feelings or manner of reasoning?
1. Yes, completely. Please specify…… 2. Yes, partially. Please specify…… 3. No. 4. Don't know or no information about this located in case note records

[53] By the end of the CBTp intervention, did the patient achieve….		
…a reduction in their level of distress?	1. N/A 2. Yes 3. No 4. Don't know or no information about this located in case note records	Please provide further detail…..
…a reduction in their experience of problematic symptoms?	1. N/A 2. Yes 3. No 4. Don't know or no information about this located in case note records	Please provide further detail…..
...an increase in their level of functioning? (both intra- and inter-personal)	1. N/A 2. Yes 3. No 4. Don't know or no information about this located in case note records	Please provide further detail…..

[54] RISK. Was a reduction in the patient's level of risk (as recorded on the HCR-20 risk assessment tool) noted at the end of the CBTp intervention?
1. Yes, shifts in both 'C' (clinical) and 'R' (risk) items were noted and attributed to progress as an apparent result of the patient's participation in this treatment. Please specify.

2. Yes, however shifts were noted in only 'C' **or** 'R' items. Please specify.
3. No.
4. Don't know or no information about this located in case note records

[55] Was an end of treatment report or summary completed?

1. Yes
2. No
3. Don't know or no information about this located in case note records

[56] To what degree was the CBTp intervention completed? Please indicate (✓).

1. All phases of treatment appear to have been completed and treatment ended after < 16 sessions.
2. Not all phases of treatment appear to have been completed and treatment ended after < 16 sessions.
3. All phases of treatment appear to have been completed and treatment ended after ≥ 16 sessions.
4. Not all phases of treatment appear to have been completed and treatment ended after > 16 sessions
5. Don't know or no information about this located in case note records

[57] Did the end phase of the CBTp treatment include 'doing an ending'?

1. Yes
2. No
3. Don't know or no information about this located in case note records

[58] Did the end phase of the CBTp treatment include developing a 'Staying Well'/relapse-prevention plan?

1. Yes
2. No
3. Don't know or no information about this located in case note records

And finally…

[59] Is there anything else that you have elicited from your review of these case notes that you think may be indicative of…

…potential *barriers* to successful implementation of the CBTp intervention?

1. Yes. Please detail…….

2. No.
3. Don't know or no information about this located in case note records.

[60] …potential *facilitators* to successful implementation of the CBTp intervention?

1. Yes. Please detail……..

2. No.
3. Don't know or no information about this located in case note records.

Appendix 3

Interview schedule for individual interviews with therapists

Therapist ID Code:	Age: Gender: (Please tick: male ; female ; unspecified……)
Core profession:	Formal CBT qualification/s:
Length of experience working with psychosis by delivering psychological therapy: Yrs:……. Months:…..	Estimated number of patients treated by you using the TSH CBTp programme:
Core profession of your CBTp supervisor:	Frequency of CBTp supervision meetings:

1. Did you receive training re use of the treatment manual? If so, please tell me more about this, e.g. content of training and your response to it? If not, can you tell me why not, e.g. not offered, didn't feel I needed it, etc?
2. Can you tell me about the patient's referral and their preparation for treatment? I.e. did they meet all or some of suggested inclusion criteria? Who undertook their preparation for this treatment and why? Please tell me more about this.
3. Can you tell me about your patient's specific underlying treatment needs and your expectations for their inclusion in this treatment intervention? I.e. What were your and your patients 'desired outcomes'? Were these shared? If not, how did they differ?
4. Did you find the guidance in the manual (for the CBTp intervention) sufficient to help direct your subsequent treatment of the patient? Please tell me more about this…
5. Did you use any other 'off-model' material? E.g. different formulation framework? Other strategies? If so, please tell me about this.
6. Did you achieve a formulation and identify a targeted problem list prior to beginning to deliver specific change strategies? Please tell me more about this…
7. Were there any particular obstacles or challenges to delivering the treatment? Please tell me about these…
8. Were there any particularly helpful or unhelpful components to the intervention? Can you identify these and tell me more about them?

9. How frequently did you deliver treatment sessions? Can you tell me more about this?
10. Did you or your representative (e.g. psychology assistant) complete pre, mid and post psychometric questionnaires? Can you tell me more about this?
11. Was there any disruption to your delivery of treatment? Please tell me more about this.
12. Please tell me about your experience of clinical supervision for this work.
13. Can you describe the suggested 'steps in treatment' for this intervention to me?
14. Were there specific aspects of the intervention that you found to be helpful for your patient?
15. What, if anything, did you consider the 'key active ingredients' of the intervention to be?
16. Were you given dedicated time to undertake this work? Please tell me more about this…
17. What is/was your impression of the possible efficacy of this intervention with your specific patients? Please tell me more about this (include prompt re whether they think outcomes attained had a bearing on overall risk assessment and management) .
18. Can you tell me how your patient responded to treatment?
19. Did your patient complete this treatment? If so, within how many sessions? If not, can you tell me more about this?
20. Did your patient comment about their experience of the intervention at the end of treatment? Please tell me more about this.
21. Are there any changes/suggested refinements that you would make to this intervention and to the guidance contained in the treatment manual? Please tell me more about this.
22. Are there any other comments or feedback about your experience of delivering this intervention that you wish to tell me about?

Appendix 4 TSH Research and Development Committee: Study Approval

Pat Cawthorne
Consultant Nurse
The State Hospital

Friday the 27th of October 2017

Dear Pat,

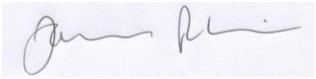
Re: A process evaluation to determine the barriers and facilitators to successful implementation of a cognitive behavioural therapy for psychosis treatment programme in a high secure setting

Many thanks for your revised research proposal that was reviewed by the TSH Research Committee on Thursday the 26th of October 2017. The committee found the proposal to be an interesting piece of work, and given that you have addressed all of the points raised within the initial review, are happy to approve the study. This letter will be copied to the Associate Medical Director along with evidence of your ethical approval once received and will subsequently provide final management approval for the study to take place within TSH.

One condition of the research committees' approval is that you provide the committee with regular 6-monthly progress report and a final report focused on the study findings and any implications for practice. This is an important mechanism by which the committee track progress, and is also a key component of our research governance processes.

If you require any further assistance, or have any feedback on the Research approval process then please do not hesitate to contact me.

Yours sincerely



JAMIE PITCAIRN
Research & Development Manager
The State Hospital

Appendix 5 University of Stirling – Study Approval

NHS, Invasive or Clinical Research (NICR) Committee

Room G10
Pathfoot Building
University of Stirling
Stirling FK9 4LA

Tel: +44 (0) 1786 467390
Email: nicr@stir.ac.uk

JE/SF

7 November 2017

Mrs P Cawthorne
(Personal Address)
XXXXXXXXX
XXXXXXXXX
XXXXXXXXX

Dear Patsy

A process evaluation to determine the feasibility of implementing a Cognitive Behavioural Therapy for psychosis treatment programme in a high secure setting
NICR 16/17 – Paper No.73

Thank you for your email in response to the NICR correspondence dated 23 October 2017 which included the following attachments:

- Covering Letter
- App 1 - Proforma for patient case note review V2
- App 2 - Interview schedule for individual interviews with therapists V2
- App 3a - Individual Therapist – Information Sheet – V2
- App 3a1 - Individual Therapist Participant – Consent Form – V2
- App 3b - Delphi Study PIS – V2
- App 3b1 - Delphi Study Consent – V2
- App 4 - Proposed thesis completion timetable – V4
- App 5 – IRAS
- App 6 – NICR Cover Sheet – 19-10-17
- App 7 – P Cawthorne CV
- App 8 – Confidentiality Statement
- Research Proposal – Final – V2
- TSH R&D Feedback letter 17-10-

I am pleased to advise that your study has been granted approval, and wish you and your team all the best.

May I remind you of the need to inform NICR (nicr@stir.ac.uk) prior to making any amendments to this protocol, or any changes to the duration of the project and provide notification of study completion. A site file of all documents related to the research should be maintained throughout the life of the project, and kept up to date at all times.
The site file template can be found on the NICR webpage at:
http://www.stir.ac.uk/research/integritygovernanceethics/researchethics/formsandguidan ce/

Please bear in mind that your study could be audited for adherence to research governance and research ethics protocols.

NICR 16/17 – Paper No17

Please quote this number on all correspondence

Yours sincerely

Dr Josie Evans
(Depute Chair)

Appendix 6

NHS
Greater Glasgow and Clyde

WoSRES
West of Scotland Research Ethics Service

Mrs Patricia Cawthorne
110 Lampits Road
ML11 8RP

West of Scotland Research Ethics Service
Clinical Research & Development
West Glasgow Ambulatory Care Hospital
Dalnair Street
Glasgow G3 8SW

Date	15th Jan 2018
Our Ref	WoS ASD
Direct line	0141 232 1784
E-mail	Judith.Godden@ggc.scot.nhs.uk

Dear Mrs Cawthorne

Full title of project: *A process evaluation to determine the barriers and facilitators to successful implementation of a cognitive behavioural therapy for psychosis treatment programme in a high secure setting*

You have sought advice from the West of Scotland Research Ethics Service Office on the above project. This has been considered by the Scientific Officer and you are advised that based on the submitted documentation (IRAS application submitted 10th Jan 2018) it does not need NHS ethical review under the terms of the Governance Arrangements for Research Ethics Committees (A Harmonised Edition). This advice is based on the following.

- The participants are neither patients nor relative or carers of patients (recruited for this reason). Where patient data will be used in the first phase of the study this will involve patient data already familiar to the clinical team through their routine clinical practice. It is also noted that Caldicott Guardian approval forms part of the overall approval before commencing the study.

Note that this advice is issued on behalf of the West of Scotland Research Ethics Service and does **not** constitute a favourable opinion from a REC. It is intended to satisfy journal editors and conference organisers and others who may require evidence of consideration of the need for ethical review prior to publication or presentation of your results.

However, if you, your sponsor/funder or any NHS organisation feels that the project should be reviewed by an NHS research ethics committee or that ethical review by a NHS REC is essential, please write setting out your reasons and we will be pleased to consider further.

Kind regards

Dr Judith Godden, WoSRES Scientific Officer/Manager

The State Hospital

The State Hospital
Carstairs
Lanark
ML11 8RP
Telephone 01555 840293
Fax 01555 840024

Statement of Verification

Study Title: 'A process evaluation to determine the barriers and facilitators to implementation of a cognitive behavioural therapy for psychosis treatment programme in a high secure setting'.

Statement of Verification Regarding Data Extraction Process: Phase 1 Study – Review of Case Notes

I ~~Helen Walker~~

can confirm that I have examined and extracted data from 3 sets of clinical notes using the same data extraction tool used by Patricia Cawthorne, Consultant Nurse when she extracted this information from these same records. I did this to check that my findings concur with Patricia Cawthorne's. I understand that I was asked to do this to independently verify this information as these notes contained information that was inputted by Patricia Cawthorne herself, in her role as treating therapist with the patients involved.

I can confirm that my findings agreed with Patricia Cawthorne's in all cases.

P. CAWTHORNE	P. Cawthorne	29.11.19.
Researcher (Print Name)	(Signature)	(Date)
Helen Walker	Helen Walker	29-11-19
Verifier (Print Name)	(Signature)	(Date)

Appendix 8a

Individual Therapist Participant – Information Sheet

(This will be on State Hospital headed paper)

Study title: 'A process evaluation to determine the barriers and facilitators to successful implementation of a cognitive behavioural therapy for psychosis treatment programme in a high secure setting'

Research objectives. This proposed study will seek:

- To explore and identify the processes that are required for successful implementation of this complex intervention within this specific setting.
- To explore whether there is any variance in compliance among the CBTp (f) therapists with the guidance contained in the current version of the treatment manual for the intervention.
- To elicit the views and experiences of the CBTp (f) therapists to establish what factors would enable them to successfully implement the intervention, within this HSH setting, with forensic patients, and
- To establish what elements of the treatment manual may potentially need changed to enable further, more robust, outcome evaluation of the intervention.

Phase Two – Interviews with current therapists. The results of this study will help us address objectives two and three (above).

Why am I being asked to take part?

You have been identified as a current expert practitioner in this area. This study will help us understand how therapists like you are currently implementing the CBTp (f) intervention, e.g. whether you use the therapy manual, make some adaptations to this, or whether you use anything else. It will also help us to gain your views about what factors you think best enables, or would enable, you to successfully implement CBTp (f) in this hospital.

What will it involve?

A semi-structured interview schedule has been designed to gather information for this purpose. This contains 22 questions that will be asked by an independent interviewer. The independent interviewer (HW) will arrange to meet with you to conduct an interview. This will last about 30 – 40 minutes and will be recorded (using a Dictaphone). This will then be transcribed verbatim (buy an independent transcriber) to ensure it accurately reflects your views. Your confidentiality and anonymity will be protected at all times during this process. The primary investigator (PC) will only receive a final (anonymised) transcript of your interview after you have read over this and agreed its content.

What will happen to this information?

The primary investigator (PC) will then undertake thematic analysis of all therapist transcripts. This will result in a number of key themes being identified that should help develop our understanding about what therapists think works, doesn't work, or might work better in relation to the CBTp (f) intervention. This should help us to improve our implementation of this intervention in future. No information gathered will be personally identifiable. It is likely that some anonymised quotes from transcripts may be used in future publications related to the outcome of this part of the overall research study.

What if I don't want to take part?

No problem. You have the right to refuse to participate in this study and this, of course, will be respected. You also have the right to withdraw from the study at any time, should you wish to do so.

What will happen next?

The independent interviewer (HW) will telephone you and ask if you want to take part. If you agree, an interview date will be set up during which time you will be asked to sign a consent form, prior to proceeding with the 30 -40 minute interview.

Will I find out the results of the study?

Yes. The outcomes of the study will be presented to the department at a future date.

Thank you for your consideration of this request.

Patricia Cawthorne
Principal Investigator

12 October 2017

Appendix 8b

Individual Therapist Participant – Consent Form

(This will be on State Hospital headed paper)

Study title: 'A process evaluation to determine the barriers and facilitators to successful implementation of a cognitive behavioural therapy for psychosis treatment programme in a high secure setting'

Principal Investigator: Patricia Cawthorne, Consultant Nurse

Name of Participant
(printed)…….

(delete as appropriate)

- I confirm that I have read and understand the information for the above study and have had the opportunity to ask questions.
  YES/NO **Initials:** ☐
- I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason
  YES/NO **Initials:** ☐
- I understand that I will be interviewed by an independent interviewer and that this interview will be recorded on an audio digital device which will later be transcribed
  YES/NO **Initials:** ☐
- I understand that the results of the study will be written up for submission to a peer reviewed journal.
  YES/NO **Initials:** ☐
- I understand that anonymised findings will be published
  YES/ NO **Initials:** ☐
  (details that identify you will not be published)
- I agree to take part in the above study
  YES/NO **Initials**: ☐

Participant’s signature:…….

Date:……

Principal Investigator’s signature:……
Date……

1 for participant; 1 for researcher;

Appendix 9a

The State Hospital

The State Hospital
Carstairs
Lanark
ML11 8RP
Telephone 01555 840293
Fax 01555 840024

Delphi Study

Expert Participant – Information Sheet

Study title: 'A process evaluation to determine the barriers and facilitators to successful implementation of a cognitive behavioural therapy for psychosis treatment programme in a high secure setting'

Research objectives/questions

The proposed study will seek:

1. To explore and identify the processes that are required for successful implementation of this complex intervention within this specific setting.
2. To understand the reasons for the high variance in compliance among therapists with the guidance contained in the current version of the treatment manual for the intervention.
3. To identify what factors would enable therapists to successfully implement the intervention within this setting, and
4. To establish what elements of the treatment manual may potentially need changed to enable further, more robust, outcome evaluation of the intervention

Study Phase 3 – Delphi study.

Following a series of case note reviews (study Phase 1) and interviews with current treating therapists (study Phase 2) the researcher is now seeking a consensus among a panel of experts (study Phase 3) to understand what elements of the current treatment manual may need changed to enable further outcome evaluation of the intervention.

Why am I being asked to take part?

You have been invited to take part in this phase of the study as you have been identified as an expert in this area. For example, you may have used this treatment protocol with a number of patients sometime in the past, or you may be a leading researcher and/or author in the field of CBTp interventions, or you may be an author and/or clinician who is involved in the design and/or delivery of similar complex psychological interventions used in high-secure or other forensic inpatient settings.

What am I being asked to do?

This survey will consist of 3 rounds of questions. For Round 1 you will be asked, based on your expert opinion, to:

a) Answer the 14 questions on the attached questionnaire
b) Indicate whether you approve or disapprove of the questions being asked
c) Suggest any additions or changes to the wording of the questions
d) Comment on the questions
e) Provide a supporting rationale for your comments

Thematic analysis of the returned Round 1 questionnaires will be undertaken and used to create a new 'Likert-style' questionnaire for Round 2. Descriptive analysis of the returned Round 2 questionnaires will then be undertaken and presented in the form of percentages. At the Round 3 stage, expert panellists will receive a table detailing the overall percentages assigned to the range of answers on the Likert scales and will be asked to further review their answers based on these findings. It is anticipated that an appropriate level of consensus for each answer will be achieved at this 3rd stage.

How long will this take?

It is estimated that the Round 1 questionnaire will take about 20 – 30 minutes to complete and the questionnaires for Rounds 2 and 3 will take about 10 – 15 minutes to complete. After each questionnaire is sent out, there will be a 2-week period in which to complete it. A gentle reminder will be sent out one-week before each round of questionnaires are due back.

How will my information be gathered and what will happen to it?

This survey will be conducted electronically. Questionnaires will be sent to you by Patricia Cawthorne (Lead Researcher) from a secure NHS email address. Responses to this survey will be reported anonymously and will be accessible only by the Lead Researcher.

Results of this study may be reported in a peer reviewed journal. However, no identifiable data from the study will be published at any time.

Thank you for your interest.

Appendix 9b

Phase 3 – Delphi Study
'Expert' Participant – Consent Form

(This will be on State Hospital headed paper)

Study title: 'A process evaluation to determine the barriers and facilitators to successful implementation of a cognitive behavioural therapy for psychosis treatment programme in a high secure setting'

Principal Investigator: Patricia Cawthorne, Consultant Nurse

Name of Participant
(printed)…….

(delete as appropriate)

- I confirm that I have read and understand the information for the above study and have had the opportunity to ask questions.
  YES/NO **Initials:** ☐
- I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason
  YES/NO **Initials:** ☐
- I understand that the results of the study will be written up for submission to a peer reviewed journal.
  YES/NO **Initials:** ☐
- I understand that anonymised findings will be published
  YES/ NO **Initials:** ☐
  (details that identify you will not be published)
- I agree to take part in the above study
  YES/NO **Initials**: ☐

Participant’s signature:…….

Date:……

Principal Investigator’s signature:……
Date……

1 for participant; 1 for researcher;

The State Hospital NHS SCOTLAND UNIVERSITY of STIRLING

A process evaluation to determine the barriers and facilitators to successful implementation of a cognitive behavioural therapy for psychosis treatment programme in a high secure setting

Page 1: Participant Information and Consent

The results of this survey will help us understand what elements of the current treatment manual may need changed to successfully implement this intervention and enable further outcome evaluation of it.

Ultimately the goal we all share is to provide effective psychological interventions that reduce distress, promote alternative ways of coping, improve functioning, and reduce any associated risk. Your support with this work is very important to us.

Before you proceed, please take time to read the information sheet about the study. This can be accessed by clicking this link: https://static.onlinesurveys.ac.uk/media/account/175/survey/392090/question/eDelphi_-_PIS_k8iuw89.docx

Next, after reading the information sheet, please indicate whether you consent to take part in this survey in the section below. Thank you.

1. I confirm that I have read and understood the participant information sheet and I consent/do not consent to take part in this survey. (Please indicate your chosen

response below). ✱ *Required*

- ○ I consent to taking part in this survey
- ○ I do not consent to taking part in this survey

Page 2: Introduction

Delphi Questionnaire – Round 1

PLEASE READ THE INFORMATION SHEET THAT ACCOMPANIES THIS QUESTIONNAIRE PRIOR TO ANSWERING IT. THIS PROVIDES INSTRUCTIONS ABOUT WHAT IS REQUIRED. THANK YOU.

INTRODUCTION

A recent census[1] established that 80% (96/120) of patients in a high-secure hospital in Scotland have a primary diagnosis of schizophrenia or other psychosis as identified in the ICD-10 manual's diagnostic coding range F20 – F29[2]. Comorbid personality difficulties are also estimated to occur in a further 35% of this same group (i.e. 34/96), but this is considered to be a likely under-estimation of the true incidence of this co-occurring difficulty. To help address the complex psychological treatment needs of this group of patients, a specifically-designed cognitive behavioural therapy for psychosis (CBTp) [forensic] treatment protocol was developed and has been delivered over the past 16 years. However, for some time now it has been recognised that there are a number of ongoing issues that are adversely affecting its continued implementation. A process evaluation study is being conducted by Patricia Cawthorne (Lead Researcher) to determine what the barriers and facilitators are to successful implementation of this CBTp treatment programme.

Following a review of case notes and interviews, the researcher is now seeking a consensus among experts (Delphi technique) to understand what elements of the current treatment manual may need changed to enable further outcome evaluation of the intervention.

This CBTp treatment protocol and manual are theoretically underpinned by Garrety et al's (2001) 'A cognitive model of the positive symptoms of psychosis'[3] (Please see Appendix 1 for a copy of this model using the link: https://static.onlinesurveys.ac.uk/media/account/175/survey/392090/question/appendix_1_-_garrety_et_al_20.docx). However, this model has been augmented to include a focus on the role of underdeveloped and overdeveloped behavioural strategies, based upon the work of Davidson (2000)[4]. This helps provide a more expansive formulation of the complex and problematic relational and behavioural aspects of personality functioning,

arising from core beliefs, that are often found in this specific population. Further, this addition of Davidson's (2001) conceptualisation framework also helps to give an enhanced understanding of how these behavioural and relational patterns might also be implicated in the maintenance of psychotic symptoms (e.g. delusions) and/or their appraisals in this group (Please see Appendix 2, Table 1 for a copy of this framework using the link: https://static.onlinesurveys.ac.uk/media/account/175/survey/392090/question/appendix_2_-_table_1_a_dimensi.docx).

We understand that not everyone we have asked to participate in this Delphi study works within a specialist forensic setting. However, for those who do not work in this area, we believe that the majority of you may, at some point, have either attempted to deliver CBTp with forensic patients (perhaps as part of a clinical trial), or may have supervised other treating therapists working with this patient group. Some of you may not work specifically with this patient group but have extensive expertise in other significant and relevant areas – e.g. in the development of other CBTp protocols or conducting large scale clinical trials of CBTp and we would appreciate your view on some of the more 'generic' issues related to the delivery of CBTp in this area. **Your assistance in answering the following questions is therefore deeply appreciated.**

[1] The Forensic Network and University of Edinburgh, 2014.

[2] World Health Organisation, 2016.

[3] Garety, P.A., Kuipers, E., Fowler,D., Freeman, D. and Bebbington, P.E. (2001). A cognitive model of the positive symptoms of psychosis. *Psychological Medicine*, 31 (2) 189-195.

[4] Davidson, K. (2000). *Cognitive therapy for Personality Disorders*. Butterworth-Heinemann.

Page 3: Background information

2. Please choose all that apply: What is your professional background? ✱ *Required*

Please select at least 1 answer(s).

- ☐ Clinical Psychology - Non-Forensic Service
- ☐ Clinical Psychology - Forensic Service
- ☐ Nursing - Non-Forensic Service
- ☐ Nursing - Forensic Service
- ☐ Psychiatry - Non-Forensic Service
- ☐ Psychiatry - Forensic Service
- ☐ Other

2.a. If you selected Other, please specify:

2.b. Are you: ✱ *Required*

- ○ Male
- ○ Female
- ○ Prefer not to specify

2.c. Clinical or non-clinical role. Do you work in: ✱ *Required*

- ○ A direct clinical role in a forensic service?
- ○ A non-direct clinical role in a forensic service?
- ○ A direct clinical role in a non-forensic service?
- ○ A non-direct clinical role in a non-forensic service?
- ○ An academic role?
- ○ Other

2.c.i. If you selected Other, please specify:

Page 4: Delphi Questionnaire - Round 1

Thinking about your own beliefs and experience of working in the field of CBTp, please rate your level of agreement with the following statements (which are taken from the current NICE guideline for schizophrenia and echoed within the current SIGN guideline for the same). Please base your answer on **how you think these recommendations relate to the delivery of CBTp in a high-secure or other forensic setting.**

"CBT should be delivered...

3. *... on a one-to-one basis over at least 16 planned sessions"* ✱ *Required*

- Agree strongly
- Agree somewhat
- Neither agree nor disagree
- Disagree somewhat
- Disagree strongly
- Don't know/cannot comment as never worked with high-secure or other forensic patients

3.a. *... by appropriately trained and supervised therapists"* ✱ *Required*

- Agree strongly
- Agree somewhat
- Neither agree nor disagree
- Disagree somewhat
- Disagree strongly
- Don't know/cannot comment as never worked with high-secure or other forensic patients

3.b. *… in accordance with an established treatment manual* (those that have evidence for their efficacy from clinical trials are preferred)" ✱ *Required*

- Agree strongly
- Agree somewhat
- Neither agree nor disagree
- Disagree somewhat
- Disagree strongly
- Don't know/cannot comment as never worked with high-secure or other forensic patients

"CBT should be delivered so that...

3.c. *... people can establish links between their thoughts, feelings or actions and their current or past symptoms, and/or functioning"* ✱ *Required*

- Agree strongly
- Agree somewhat
- Neither agree nor disagree
- Disagree somewhat
- Disagree strongly
- Don't know/cannot comment as never worked with high-secure or other forensic patients

3.d. *... the re-evaluation of people's perceptions, beliefs or reasoning relates to the target symptoms"* ✱ *Required*

- Agree strongly
- Agree somewhat
- Neither agree nor disagree
- Disagree somewhat
- Disagree strongly
- Don't know/cannot comment as never worked with high-secure or other forensic patients

"CBT should be delivered so that it also includes at least one of the following components:...

3.e. *... people monitoring their own thoughts, feelings or behaviours with respect to their symptoms or recurrence of symptoms"* ✱ *Required*

- Agree strongly
- Agree somewhat
- Neither agree nor disagree
- Disagree somewhat
- Disagree strongly
- Don't know/cannot comment as never worked with high-secure or other forensic patients

3.f. *... promoting alternative ways of coping with the target symptom"* ✱ *Required*

- Agree strongly
- Agree somewhat
- Neither agree nor disagree
- Disagree somewhat
- Disagree strongly
- Don't know/cannot comment as never worked with high-secure or other forensic patients

3.g. *... reducing distress"* ✱ *Required*

- Agree strongly
- Agree somewhat
- Neither agree nor disagree
- Disagree somewhat
- Disagree strongly
- Don't know/cannot comment as never worked with high-secure or other forensic patients

3.h. ... improving functioning" ✱ *Required*

- Agree strongly
- Agree somewhat
- Neither agree nor disagree
- Disagree somewhat
- Disagree strongly
- Don't know/cannot comment as never worked with high-secure or other forensic patients

3.i. In your opinion, are there any suggested changes, additions or modifications that you would make to the above recommendations when working specifically with forensic patients? Please use the free text box below to enter your additional comments. Thank you.

VIEW/COMMENTS ON QUESTION. (In this next sub-section you are asked to consider your views about the relevance of the question asked above, the clarity of wording used and the likelihood of the expert Panel to answer it).

Please indicate whether you...

3.j. ... approve of this question? ✱ *Required*

- Yes
- No
- Neither approve or disapprove

3.j.i. Please use the free text space below for any additional comments:

3.k. ... wish to add/change the wording of the question? ✱ *Required*

- Yes
- No

3.k.i. If your response is 'Yes', please add a comment in the free text space below specifying what changes you think should be made.

3.l. Do you wish to comment further on this question? ✱ *Required*

- Yes
- No

3.l.i. If you have chosen ‘Yes’ above, please add your comments in the free text space below:

3.l.ii. If you have made any comment/s in (3.l.i) above, please provide a supporting rationale for this in the free text space below:

4. In your opinion what is the 'best', i.e. most user-friendly, way of presenting information in a CBTp treatment manual? Please provide any comments or suggestions below, including perhaps any current examples of treatment manual design and content that you know of, and that you perhaps would recommend or otherwise think might help illustrate your answer. [Free text response] ✱ *Required*

VIEW/COMMENTS ON QUESTION. (In this next sub-section you are asked to consider your views about the relevance of the question asked above, the clarity of wording used and the likelihood of the expert Panel to answer it).

Please indicate whether you…

4.a. ... approve of this question? ✱ *Required*

- ○ Yes
- ○ No
- ○ Neither approve or disapprove

4.a.i. Please use the fee text space below for any additional comments:

4.b. ... wish to add/change the wording of the question? ✱ *Required*

- Yes
- No

4.b.i. If your response is 'Yes', please add a comment in the free text space below specifying what changes you think should be made.

4.c. Do you wish to comment further on this question? ✱ *Required*

- Yes
- No

4.c.i. If you have chosen 'Yes' above, please add your comments in the free text space below:

4.c.ii. If you have made any comment/s in (4.c.i) above, please provide a supporting rationale for this in the free text space below:

Thinking about your own beliefs and experience of working in this field, please rate your level of agreement with the following **statements about therapists' adherence to a**

5. *"It is never useful or acceptable for the therapist to vary their delivery of CBTp in relation to their compliance with the treatment manual"* ✱ *Required*

- Agree strongly
- Agree somewhat
- Neither agree nor disagree
- Disagree somewhat
- Disagree strongly
- Don't know/cannot comment as never worked with high-secure or other forensic patients

5.a. *"There are some occasions, e.g. when the patient does not appear amenable to this form of CBT, that adding in other variants of CBT – e.g. acceptance and commitment therapy (ACT), compassion-focused therapy (CFT), or other therapy approaches such as cognitive analytical therapy (CAT), would be an acceptable and/or useful variance in the therapist's compliance with a CBTp manual"* ✱ *Required*

- Agree strongly
- Agree somewhat
- Neither agree nor disagree
- Disagree somewhat
- Disagree strongly
- Don't know/cannot comment as never worked with high-secure or other forensic patients

5.b. *"There are some occasions ...* (please specify/give an example of these in this section):

5.b.i. *... when it is both helpful and acceptable for the therapist to vary their compliance with a CBTp manual".* ✱ *Required*

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- ☐ Agree strongly
- ☐ Agree somewhat
- ☐ Neither agree nor disagree
- ☐ Disagree somewhat
- ☐ Disagree strongly
- ☐ Don't know/cannot comment as never worked with high-secure or other forensic patients

5.b.ii. (If/where you have stated some occasions of variance in the earlier part (i.e. 5b) of this answer, in this section please give further detail below about what **form** such a variance would take (e.g. another formulation model, etc)

VIEW/COMMENTS ON QUESTION. (In this next sub-section you are asked to consider your views about the relevance of the question asked above, the clarity of wording used and the likelihood of the expert Panel to answer it).

Please indicate whether you…

5.c. ... approve of this question? ✱ *Required*

- ○ Yes
- ○ No
- ○ Neither approve or disapprove

5.c.i. Please use free text space below for any additional comments:

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5.d. … wish to add/change the wording of the question? ✱ *Required*

- ☐ Yes
- ☐ No

5.d.i. If your response is ‘Yes’, please add a comment in the free text space below specifying what changes you think should be made.

5.e. Do you wish to comment further on this question? ✱ *Required*

- ☐ Yes
- ☐ No

5.e.i. If you have chosen ‘Yes’ above, please add your comments in the free text space below:

5.e.ii. If you have made any comment/s in (5.e.i) above, please provide a supporting rationale for this in the free text space below:

Thinking about your own beliefs and experience of working in this field, please rate your level of agreement with the following **statements about therapists' training and competences** to deliver a CBTp treatment protocol to forensic patients in accordance with an agreed manual.

"All therapists delivering CBTp to patients in forensic services should be appropriately trained such that they can:

6. *...demonstrate the (Roth & Pilling, 2013) CBTp range of competences".* *Click here for a PDF of the Competency Framework (opens in new window)* ✱ *Required*

- ☐ Agree strongly
- ☐ Agree somewhat
- ☐ Neither agree nor disagree
- ☐ Disagree somewhat
- ☐ Disagree strongly
- ☐ Don't know/cannot comment as never worked with high-secure or other forensic patients

6.a. *...demonstrate a working knowledge and understanding of the components of the specific treatment manual for CBTp used in their area of practice".* ✱ *Required*

- ☐ Agree strongly
- ☐ Agree somewhat
- ☐ Neither agree nor disagree
- ☐ Disagree somewhat
- ☐ Disagree strongly
- ☐ Don't know/cannot comment as never worked with high-secure or other forensic patients

6.b. *... demonstrate an appropriate range of specific 'forensic' competencies (e.g. violence risk assessment and management skills) in support of the delivery of psychological therapy in their specialist area as detailed in, e.g. the Forensic Matrix Implementation Group's Competency Framework"* *Click here for a PDF of the Competency Framework (opens in new window)* ✱ *Required*

- ☐ Agree strongly
- ☐ Agree somewhat
- ☐ Neither agree nor disagree
- ☐ Disagree somewhat
- ☐ Disagree strongly
- ☐ Don't know/cannot comment as never worked with high-secure or other forensic patients

"In addition to the above level of training and familiarisation with the specific CBTp protocol used in the therapist's own service...

6.c. *... CBTp forensic therapists' training in the use of such service-specific protocols should additionally be regularly reviewed and repeated, e.g. by providing a 'booster' training every 2 years, or by providing a full repeat of the training if necessary".* ✱ *Required*

- ☐ Agree strongly
- ☐ Agree somewhat
- ☐ Neither agree nor disagree
- ☐ Disagree somewhat
- ☐ Disagree strongly
- ☐ Don't know/cannot comment as never worked with high-secure or other forensic patients

6.d. *... CBTp forensic therapists' competencies should be regularly reviewed and rated using a recognised therapy adherence and competency measure, e.g. The Revised Cognitive Therapy for Psychosis Adherence Scale (R-CTPAS; Rollinson et al. 2008)".*

✱ *Required*

- ☐ Agree strongly
- ☐ Agree somewhat
- ☐ Neither agree nor disagree
- ☐ Disagree somewhat
- ☐ Disagree strongly
- ☐ Don't know/cannot comment as never worked with high-secure or other forensic patients

6.e. In your opinion, and if different from any of the above, what would be the suggested content of therapists' training in CBTp for working specifically with forensic patients? Please use the free text box below to enter your additional comments.

VIEW/COMMENTS ON QUESTION. (In this next sub-section you are asked to consider your views about the relevance of the question asked above, the clarity of wording used and the likelihood of the expert Panel to answer it).

Please indicate whether you…

6.f. … approve of this question? ✱ *Required*

- ☐ Yes
- ☐ No
- ☐ Neither approve or disapprove

6.f.i. Please use free text space below for any additional comments:

6.g. … wish to add/change the wording of the question? ✱ *Required*

- ☐ Yes
- ☐ No

6.g.i. If your response is ‘Yes’, please add a comment in the free text space below specifying what changes you think should be made.

6.h. Do you wish to comment further on this question? ✱ *Required*

- ☐ Yes
- ☐ No

6.h.i. If you have chosen ‘Yes’ above, please add your comments in the free text space below:

6.h.ii. If you have made any comment/s in (6.h.i) above, please provide a supporting rationale for this in the free text space below:

7. In your opinion, what would be the most appropriate way of providing clinical supervision to CBTp forensic therapists? Please include your views on *who should deliver this*, *how frequent it should be*, *how it should be structured* and *its content*. Please use the free text box below to record your comments and answer. ✱ *Required*

VIEW/COMMENTS ON QUESTION. (In this next sub-section you are asked to consider your views about the relevance of the question asked above, the clarity of wording used and the likelihood of the expert Panel to answer it).

Please indicate whether you…

7.a. … approve of this question? ✱ *Required*

- ☐ Yes
- ☐ No
- ☐ Neither approve or disapprove

7.a.i. Please use free text space below for any additional comments:

7.b. … wish to add/change the wording of the question? ✱ *Required*

- [ ] Yes
- [ ] No

7.b.i. If your response is 'Yes', please add a comment in the free text space below specifying what changes you think should be made.

7.c. Do you wish to comment further on this question? ✱ *Required*

- [ ] Yes
- [ ] No

7.c.i. If you have chosen 'Yes' above, please add your comments in the free text space below:

7.c.ii. If you have made any comment/s in (7.c.i) above, please provide a supporting rationale for this in the free text space below:

8. In your opinion what would be appropriate ways of assessing patients' readiness for CBTp (forensic) treatment? [Free text response] ✱ *Required*

VIEW/COMMENTS ON QUESTION. (In this next sub-section you are asked to consider your views about the relevance of the question asked above, the clarity of wording used and the likelihood of the expert Panel to answer it).

Please indicate whether you…

8.a. … approve of this question? ✱ *Required*

- ☐ Yes
- ☐ No
- ☐ Neither approve or disapprove

8.a.i. Please use free text space below for any additional comments:

8.b. … wish to add/change the wording of the question? ✱ *Required*

- ☐ Yes
- ☐ No

8.b.i. If your response is 'Yes', please add a comment in the free text space below specifying what changes you think should be made.

8.c. Do you wish to comment further on this question? ✱ *Required*

- ☐ Yes
- ☐ No

8.c.i. If you have chosen ‘Yes’ above, please add your comments in the free text space below:

8.c.ii. If you have made any comment/s in (8.c.i) above, please provide a supporting rationale for this in the free text space below:

9. In your opinion what would be appropriate ways of assessing patients’ willingness and/or ability to engage with CBTp (forensic) treatment? [Free text response] ✱ *Required*

9.a. In your opinion what would be appropriate strategies to use to try and strengthen patients’ willingness and/or ability to engage with CBTp (forensic) treatment? [Free text response] ✱ *Required*

VIEW/COMMENTS ON QUESTIONS. (In this next sub-section you are asked to consider your views about the relevance of the questions asked above, the clarity of wording used and the likelihood of the expert Panel to answer them).

Please indicate whether you…

9.b. … approve of these questions? ✱ *Required*

- ☐ Yes
- ☐ No
- ☐ Neither approve or disapprove

9.b.i. Please use free text space below for any additional comments:

9.c. … wish to add/change the wording of the questions? ✱ *Required*

- ☐ Yes
- ☐ No

9.c.i. If your response is 'Yes', please add a comment in the free text space below specifying what changes you think should be made.

9.d. Do you wish to comment further on these questions? ✱ *Required*

- ☐ Yes
- ☐ No

9.d.i. If you have chosen ‘Yes’ above, please add your comments in the free text space below:

9.d.ii. If you have made any comment/s in (9.d.i) above, please provide a supporting rationale for this in the free text space below:

10. In your opinion what would be appropriate ways of assessing patients’ readiness to move on to the next stage of CBTp treatment – e.g. from the ‘assessment and engagement phase’ to the ‘change strategy phase’? [Free text response] ✱ *Required*

VIEW/COMMENTS ON QUESTION. (In this next sub-section you are asked to consider your views about the relevance of the question asked above, the clarity of wording used and the likelihood of the expert Panel to answer it).

Please indicate whether you…

10.a. … approve of this question? ✱ *Required*

- ☐ Yes
- ☐ No
- ☐ Neither approve or disapprove

10.a.i. Please use free text space below for any additional comments:

10.b. … wish to add/change the wording of the question? ✱ *Required*

- ☐ Yes
- ☐ No

10.b.i. If your response is ‘Yes’, please add a comment in the free text space below specifying what changes you think should be made.

10.c. Do you wish to comment further on this question? ✱ *Required*

- ☐ Yes
- ☐ No

10.c.i. If you have chosen ‘Yes’ above, please add your comments in the free text space below:

10.c.ii. If you have made any comment/s in (10.c.i) above, please provide a supporting rationale for this in the free text space below:

11. In your opinion what would be appropriate ways of delineating the 'mid' point of a course of CBTp treatment? [Free text response] ✱ *Required*

VIEW/COMMENTS ON QUESTION. (In this next sub-section you are asked to consider your views about the relevance of the question asked above, the clarity of wording used and the likelihood of the expert Panel to answer it).

Please indicate whether you…

11.a. … approve of this question? ✱ *Required*

- ☐ Yes
- ☐ No
- ☐ Neither approve or disapprove

11.a.i. Please use free text space below for any additional comments:

11.b. … wish to add/change the wording of the question? ✱ *Required*

- ☐ Yes
- ☐ No

11.b.i. If your response is ‘Yes’, please add a comment in the free text space below specifying what changes you think should be made.

11.c. Do you wish to comment further on this question? ✱ *Required*

- ☐ Yes
- ☐ No

11.c.i. If you have chosen ‘Yes’ above, please add your comments in the free text space below:

11.c.ii. If you have made any comment/s in (11.c.i) above, please provide a supporting rationale for this in the free text space below:

12. In your opinion what would be an **appropriate range of psychometric measures** to use to evaluate how effective CBTp (forensic) is? [Free text response] ✱ *Required*

12.a. In your opinion what would be appropriate ways of assessing how effective CBTp is in relation to the assessment of risk of future violence? [Free text response] ✱ *Required*

Thinking about your own beliefs and experience of working in this field, please rate your level of agreement with the following **statement about potential NON-COMPLETION of psychometric evaluation measures and risk assessment and monitoring plans** in relation to the impact of undertaking a course of CBTp (forensic).

12.b. *"There are occasions when it is not appropriate to undertake psychometric assessment or to detail the impact and/or outcome of CBTp (forensic) work in a patient's risk assessment and management plan".* ✱ *Required*

- ☐ Agree strongly
- ☐ Agree somewhat
- ☐ Neither agree nor disagree
- ☐ Disagree somewhat
- ☐ Disagree strongly

☐ Don't know/cannot comment as never worked with high-secure or other forensic patients

12.b.i. Please provide any additional information in support of your answer to 12 (b) in the free text box below.

VIEW/COMMENTS ON QUESTIONS. (In this next sub-section you are asked to consider your views about the relevance of the questions asked above, the clarity of wording used and the likelihood of the expert Panel to answer them).

Please indicate whether you…

12.c. … approve of these questions?

☐ Yes
☐ No
☐ Neither approve or disapprove

12.c.i. Please use free text space below for any additional comments:

12.d. … wish to add/change the wording of the questions? ✱ *Required*

☐ Yes
☐ No

12.d.i. If your response is 'Yes', please add a comment in the free text space below specifying what changes you think should be made.

12.e. Do you wish to comment further on these questions? ✱ *Required*

- [ ] Yes
- [ ] No

12.e.i. If you have chosen 'Yes' above, please add your comments in the free text space below:

12.e.ii. If you have made any comment/s in (12.e.i) above, please provide a supporting rationale for this in the free text space below:

13. Unlike a lot of other adult mental health services, in some forensic mental health services it is often possible – and indeed likely – that patients are referred for and/or are participating in a number of different psychological interventions at the same time. In your opinion would it be appropriate for CBTp to be delivered at the same time as other psychological interventions? [Please respond in the form of free text in the box below. Please give rationale for your answer, i.e. if you agree or disagree with this statement, please explain why you have given your particular response]: ✱ *Required*

VIEW/COMMENTS ON QUESTION. (In this next sub-section you are asked to consider your views about the relevance of the question asked above, the clarity of wording used and the likelihood of the expert Panel to answer it).

Please indicate whether you…

13.a. … approve of this question? ✱ *Required*

- ☐ Yes
- ☐ No
- ☐ Neither approve or disapprove

13.a.i. Please use free text space below for any additional comments:

13.b. … wish to add/change the wording of the question? ✱ *Required*

- ☐ Yes
- ☐ No

13.b.i. If your response is 'Yes', please add a comment in the free text space below specifying what changes you think should be made.

13.c. Do you wish to comment further on this question? ✱ *Required*

- ☐ Yes
- ☐ No

13.c.i. If you have chosen 'Yes' above, please add your comments in the free text space below:

13.c.ii. If you have made any comment/s in (13.c.i) above, please provide a supporting rationale for this in the free text space below:

Thinking about your own beliefs and experience of working in this field, please rate your level of agreement with the following **statements about the use of formulation** in CBTp with forensic patients.

14. *"It is possible to deliver good quality CBTp without having an agreed formulation with the patient"* ✱ *Required*

- ☐ Agree strongly
- ☐ Agree somewhat
- ☐ Neither agree nor disagree
- ☐ Disagree somewhat
- ☐ Disagree strongly
- ☐ Don't know/cannot comment as never worked with high-secure or other forensic

patients

14.a. *"It is possible to deliver good quality CBTp when using a formulation framework that is non-CBT based, e.g. '5Ps' based formulation"* ✱ *Required*

- ☐ Agree strongly
- ☐ Agree somewhat
- ☐ Neither agree nor disagree
- ☐ Disagree somewhat
- ☐ Disagree strongly
- ☐ Don't know/cannot comment as never worked with high-secure or other forensic patients

14.b. *"It is possible to deliver good quality CBTp without sharing the emerging formulation with the patient"* ✱ *Required*

- ☐ Agree strongly
- ☐ Agree somewhat
- ☐ Neither agree nor disagree
- ☐ Disagree somewhat
- ☐ Disagree strongly
- ☐ Don't know/cannot comment as never worked with high-secure or other forensic patients

14.c. *"It is possible to deliver good quality CBTp using a brief, maintenance formulation, only"* ✱ *Required*

- ☐ Agree strongly
- ☐ Agree somewhat
- ☐ Neither agree nor disagree
- ☐ Disagree somewhat
- ☐ Disagree strongly

- [ ] Don't know/cannot comment as never worked with high-secure or other forensic patients

14.d. *"It is possible to deliver good quality CBTp without moving on to complete a longitudinal formulation, providing there is at least an agreed maintenance formulation"* ✱ *Required*

- [ ] Agree strongly
- [ ] Agree somewhat
- [ ] Neither agree nor disagree
- [ ] Disagree somewhat
- [ ] Disagree strongly
- [ ] Don't know/cannot comment as never worked with high-secure or other forensic patients

14.e. *"Longitudinal formulation needs to be an essential component of CBTp with forensic patients; without this, we would be unable to understand how psychological distress and difficulties potentially interrelate with offending behavior and risk"* ✱ *Required*

- [ ] Agree strongly
- [ ] Agree somewhat
- [ ] Neither agree nor disagree
- [ ] Disagree somewhat
- [ ] Disagree strongly
- [ ] Don't know/cannot comment as never worked with high-secure or other forensic patients

VIEW/COMMENTS ON QUESTION. (In this next sub-section you are asked to consider your views about the relevance of the question asked above, the clarity of wording used and the likelihood of the expert Panel to answer it).

Please indicate whether you…

14.f. … approve of this question? ✱ *Required*

- ☐ Yes
- ☐ No
- ☐ Neither approve or disapprove

14.f.i. Please use free text space below for any additional comments:

14.g. … wish to add/change the wording of the question? ✱ *Required*

- ☐ Yes
- ☐ No

14.g.i. If your response is ‘Yes’, please add a comment in the free text space below specifying what changes you think should be made.

14.h. Do you wish to comment further on this question? ✱ *Required*

- ☐ Yes
- ☐ No

14.h.i. If you have chosen ‘Yes’ above, please add your comments in the free text space below:

14.h.ii. If you have made any comment/s in (14.h.i) above, please provide a supporting rationale for this in the free text space below:

15. In your opinion what would be appropriate ways of writing and recording the details about CBTp (forensic) work in the clinical notes and clinical record? (I.e. what information should be included in the session record and what format would you suggest that this takes?) [Free text response] ✱ *Required*

VIEW/COMMENTS ON QUESTION. (In this next sub-section you are asked to consider your views about the relevance of the question asked above, the clarity of wording used and the likelihood of the expert Panel to answer it).

Please indicate whether you…

15.a. … approve of this question? ✱ *Required*

- ☐ Yes
- ☐ No
- ☐ Neither approve or disapprove

15.a.i. Please use free text space below for any additional comments:

15.b. … wish to add/change the wording of the question? ✱ *Required*

- ☐ Yes
- ☐ No

15.b.i. If your response is ‘Yes’, please add a comment in the free text space below specifying what changes you think should be made.

15.c. Do you wish to comment further on this question? ✱ *Required*

- ☐ Yes
- ☐ No

15.c.i. If you have chosen ‘Yes’ above, please add your comments in the free text space below:

15.c.ii. If you have made any comment/s in (15.c.i) above, please provide a supporting rationale for this in the free text space below:

16. Is there anything else you would like to add about the elements of the current treatment manual that may potentially need changed to enable further, more robust, outcome evaluation of this intervention [Free text response] ✱ *Required*

VIEW/COMMENTS ON QUESTION. (In this next sub-section you are asked to consider your views about the relevance of the question asked above, the clarity of wording used and the likelihood of the expert Panel to answer it).

Please indicate whether you…

16.a. … approve of this question? ✱ *Required*

- ☐ Yes
- ☐ No
- ☐ Neither approve or disapprove

16.a.i. Please use free text space below for any additional comments:

16.b. … wish to add/change the wording of the question? ✱ *Required*

- [ ] Yes
- [ ] No

16.b.i. If your response is ‘Yes’, please add a comment in the free text space below specifying what changes you think should be made.

16.c. Do you wish to comment further on this question? ✱ *Required*

- [ ] Yes
- [ ] No

16.c.i. If you have chosen ‘Yes’ above, please add your comments in the free text space below:

16.c.ii. If you have made any comment/s in (16.c.i) above, please provide a supporting rationale for this in the free text space below:

Page 5: Final page

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE!

CBTp Forensic Delphi Survey - Round 2

Page 1: Cover letter explaining Round 2

Dear **Expert Panel Member**

Re: CBTp Forensic Delphi Survey - Round 2

Thank you for returning the first round Delphi questionnaire.

You will now find enclosed the second-round Delphi questionnaire. This next questionnaire is made up of a further small set of questions, each of which can be answered based upon a range of responses presented in the form of a **Likert scale**. Please read the instructions carefully (these are given below in p.2), and complete the questionnaire as fully as you can.

Thank you for your continued participation in this study.

Patricia Cawthorne

Lead Researcher

Page 2: Instructions for Round 2

PLEASE NOTE. IF YOU HAVE NOT COMPLETED ROUND 1 OF THIS SURVEY, YOU SHOULD NOT COMPLETE ROUND 2. THANK YOU.

This second round of the Delphi study is presented in the form of a **Likert scale** and is based on responses received from expert panel members in Round 1, all of which have been content analysed.

(Please note. It has not been necessary to include the reponses to all questions raised in Round 1 as the panel has already reached consensus in relation to quite a number of these). However, where indicated, the wording of some original questions has also been slightly modified to help clarify specific points raised, and these modified questions are presented in Round 2.

Additionally, a small series of five questions (i.e. questions 4 - 8) have been repeated *verbatim*, where consensus has not yet been reached amongst the panel. In respect of these repeated questions, we would appreciate it if you would reconsider your original response to these in the context of the reported group response. If you then wish to change your response, please do so by chosing the appropriate box on the scale. Please note that you do not have to change your original repsonse if you do not wish to. However, if you do change your response, it would also be helpful if you could indicate whether you have done so in the additional box provided for this. Thank you.

The choice of responses on the Likert scale correspond to the list given below, i.e.

1 - Agree strongly

2 - Agree somewhat

3 - Neither agree nor disagree

4 - Disagree somewhat

5 - Disagree strongly

Please don't select more than 1 answer (s) per row

Page 3: CBTp Forensic - Delphi Questionnaire: Round 2

1. When working in forensic services with patients with difficulties associated with psychosis, it is important for therapists be able to be “flexible” in their overall approach. “Flexible” in this context is operationalised as meaning, *“Able to draw from a number of different therapeutic models and choices of interventions and to apply these as/when indicated”*. ✱ *Required*

Please don't select more than 1 answer(s) per row.

Please select at least 1 answer(s).

Please don't select more than 1 answer(s) in any single column.

	Agree strongly	Agree somewhat	Neither agree nor disagree	Disagree somewhat	Disagree strongly	
1	☐	☐	☐	☐	☐	5

1.a. Where a specific model or intervention is chosen, e.g. CBTp, this **should always be delivered in accordance with the associated evidence-base** – e.g. through adherence to a specifically chosen evidence-based treatment manual. ✱ *Required*

Please don't select more than 1 answer(s) per row.

Please select exactly 1 answer(s).

Please don't select more than 1 answer(s) in any single column.

	Agree strongly	Agree somewhat	Neither agree nor disagree	Disagree somewhat	Disagree strongly	
1	☐	☐	☐	☐	☐	5

1.b. The only acceptable variances to 1a above are: a) increased time spent on engagement, motivation, psychoeducation/recovery work **before CBTp**, and/or b) using different CBTp models within CBTp (e.g. CBTp for voice-hearing, intrusions, command hallucinations, working with delusions, etc), otherwise it’s not CBTp. ✱ *Required*

Please don't select more than 1 answer(s) per row.

Please select exactly 1 answer(s).

Please don't select more than 1 answer(s) in any single column.

	Agree strongly	Agree somewhat	Neither agree nor disagree	Disagree somewhat	Disagree strongly	
1	☐	☐	☐	☐	☐	5

1.c. Problems such as patient non-collaboration, patient not 'getting' the model, relational difficulties giving rise to apparent treatment resistance, or patient making very limited or no progress, would generally be taken as indicators that a specifically chosen CBTp (or other) intervention is probably not effective or likely to be helpful at this stage in the patient's recovery, and an alternative approach should therefore be considered. ✱ *Required*

Please don't select more than 1 answer(s) per row.

Please select exactly 1 answer(s).

Please don't select more than 1 answer(s) in any single column.

	Agree strongly	Agree somewhat	Neither agree nor disagree	Disagree somewhat	Disagree strongly	
1	☐	☐	☐	☐	☐	5

The following two criteria (i.e. as highlighted in questions 2. and 2.a) are **essential requirements** for prospective participants' inclusion in any CBTp (forensic) intervention...

2. ... participants **must be willing and/or able to engage** in this work ✱ *Required*

Please don't select more than 1 answer(s) per row.

Please select exactly 1 answer(s).

Please don't select more than 1 answer(s) in any single column.

	Agree strongly	Agree somewhat	Neither agree nor disagree	Disagree somewhat	Disagree strongly	
1	☐	☐	☐	☐	☐	5

2.a. ... participants **must have an ability to form an agreed set of goals and tasks** for therapy ✱ *Required*

Please don't select more than 1 answer(s) per row.

Please select exactly 1 answer(s).

Please don't select more than 1 answer(s) in any single column.

	Agree strongly	Agree somewhat	Neither agree nor disagree	Disagree somewhat	Disagree strongly	
1	☐	☐	☐	☐	☐	5

3. There are some occasions, e.g. where it may adversely affect the patient's engagement, when it is **not appropriate to undertake psychometric assessment or evaluation** of a CBTp (forensic) intervention ✱ *Required*

Please don't select more than 1 answer(s) per row.

Please select exactly 1 answer(s).

	Agree strongly	Agree somewhat	Neither agree nor disagree	Disagree somewhat	Disagree strongly	
1	☐	☐	☐	☐	☐	5

3.a. Regardless of whether any formal psychometric assessment or evaluation of a CBTp (forensic) intervention is undertaken, we do nonetheless **always need to document the impact and outcome/s** of this work. ✱ *Required*

Please don't select more than 1 answer(s) per row.

Please select exactly 1 answer(s).

Please don't select more than 1 answer(s) in any single column.

	Agree strongly	Agree somewhat	Neither agree nor disagree	Disagree somewhat	Disagree strongly	
1	☐	☐	☐	☐	☐	5

3.b. When a course of CBTp (forensic) is delivered to help target difficulties related to offending behaviour, e.g. threat-control override symptoms leading to violence, it is **essential** that the response (or lack of response) to this is fed back into the risk assessment process, e.g. via HCR-20 narrative updates and, if indicated, through making HCR-20 score revisions. ✱ *Required*

Please don't select more than 1 answer(s) per row.

Please select exactly 1 answer(s).

Please don't select more than 1 answer(s) in any single column.

	Agree strongly	Agree somewhat	Neither agree nor disagree	Disagree somewhat	Disagree strongly	
1	☐	☐	☐	☐	☐	5

PLEASE NOTE. THE FOLLOWING SERIES OF 5 QUESTIONS PROVIDE SPECIFIC NUMERIC (i.e. %) DETAILS OF SOME RESPONSES GIVEN BY OUR EXPERT GROUP IN ROUND 1.

Question 4. *"It would be appropriate for CBTp (forensic) to be delivered at the same time as other psychological interventions".* When this statement was first put to our expert panel in Round 1, the group response to this was as highlighted below. (Please note, due to the limited nature of the content of reponses given to this question, it has only been possible to present this information in a 3-part scale, where 1 = Yes, I agree; 2 = No, I do not agree, and 3 = Undecided):

Response	Yes, I agree	No, I do not agree	Undecided	
Overall percentages	36	36	28	100% N = 14

4. We would appreciate it if you would now reconsider your original response to this statement, in the context of the overall group response, and if you subsequently wish to change your response please do so by indicating this in an alternative box below. Please note, you do not have to change your original response if you do not wish to. ✱ *Required*

Please don't select more than 1 answer(s) per row.

Please select exactly 1 answer(s).

Please don't select more than 1 answer(s) in any single column.

	Yes, I agree	No, I do not agree	Undecided	
1	☐	☐	☐	3

4.a. Please also indicate whether you did/did not change your original view on Question 4 in the appropriate box below. Thank you. ✱ *Required*

- ☐ Yes
- ☐ No
- ☐ Can't remember

Question 5. *"It is possible to deliver good quality CBTp without having an agreed formulation with the patient".* When this statement was first put to our expert panel in Round 1, the group response to this was as highlighted below.

Response	Agree strongly	Agree somewhat	Neither agree nor disagree	Disagree Somewhat	Disagree Strongly	
Overall percentages	0	22	14	14	50	100% N = 14

5. We would appreciate it if you would now reconsider your original response to this statement, in the context of the overall group response, and if you subsequently wish to change your response please do so by indicating this in an alternative box below. Please note, you do not have to change your original response if you do not wish to. ✱ *Required*

Please don't select more than 1 answer(s) per row.

Please select exactly 1 answer(s).

Please don't select more than 1 answer(s) in any single column.

	Agree strongly	Agree somewhat	Neither agree nor disagree	Disagree somewhat	Disagree strongly	
1	☐	☐	☐	☐	☐	5

5.a. Please also indicate whether you did/did not change your original view on Question 5 in the appropriate box below. Thank you. ✱ *Required*

Please select exactly 1 answer(s).

- ☐ Yes
- ☐ No
- ☐ Can't remember

Question 6. *"It is possible to deliver good quality CBTp when using a formulation framework that is non-CBT based, e.g. '5Ps based formulation".* When this statement was first put to our expert panel in Round 1, the group response to this was as highlighted below.

Response	Agree strongly	Agree somewhat	Neither agree nor disagree	Disagree Somewhat	Disagree Strongly	
Overall percentages	29	29	7	7	28	100% N = 14

6. We would appreciate it if you would now reconsider your original response to this statement, in the context of the overall group response, and if you subsequently wish to change your response please do so by indicating this in an alternative box below. Please note, you do not have to change your original response if you do not wish to. ✱ *Required*

Please don't select more than 1 answer(s) per row.

Please select exactly 1 answer(s).

Please don't select more than 1 answer(s) in any single column.

	Agree strongly	Agree somewhat	Neither agree nor disagree	Disagree somewhat	Disagree strongly	
1	☐	☐	☐	☐	☐	5

6.a. Please also indicate whether you did/did not change your original view on Question 6 in the appropriate box below. Thank you. ✱ *Required*

Please select exactly 1 answer(s).

- ☐ Yes
- ☐ No
- ☐ Can't remember

Question 7. *"It is possible to deliver good quality CBTp without sharing the emerging formulation with the patient".* When this statement was first put to our expert panel in Round 1, the group response to this was as highlighted below.

Response	Agree strongly	Agree somewhat	Neither agree nor disagree	Disagree Somewhat	Disagree Strongly	
Overall percentages	0	21	14	29	36	100% N = 14

7. We would appreciate it if you would now reconsider your original response to this statement, in the context of the overall group response, and if you subsequently wish to change your response please do so by indicating this in an alternative box below. Please note, you do not have to change your original response if you do not wish to. ✱ *Required*

Please don't select more than 1 answer(s) per row.

Please select exactly 1 answer(s).

Please don't select more than 1 answer(s) in any single column.

	Agree strongly	Agree somewhat	Neither agree nor disagree	Disagree somewhat	Disagree strongly	
1	☐	☐	☐	☐	☐	5

7.a. Please also indicate whether you did/did not change your original view on Question 7 in the appropriate box below. Thank you. ✱ *Required*

Please select exactly 1 answer(s).

- ☐ Yes
- ☐ No
- ☐ Can't remember

Question 8. *"Longitudinal formulation needs to be an essential component of CBTp with forensic patients; without this, we would be unable to understand how psychological distress and difficulties potentially interrelate with offending behaviour and risk"* . When this statement was first put to our expert panel in Round 1, the group response to this was as highlighted below.

Response	Agree strongly	Agree somewhat	Neither agree nor disagree	Disagree Somewhat	Disagree Strongly	
Overall percentages	21	43	21	15	0	100% N = 14

8. We would appreciate it if you would now reconsider your original response to this statement, in the context of the overall group response, and if you subsequently wish to change your response please do so by indicating this in an alternative box below. Please note, you do not have to change your original response if you do not wish to. ✱ *Required*

Please don't select more than 1 answer(s) per row.

Please select exactly 1 answer(s).

Please don't select more than 1 answer(s) in any single column.

	Agree strongly	Agree somewhat	Neither agree nor disagree	Disagree somewhat	Disagree strongly	
1	☐	☐	☐	☐	☐	5

8.a. Please also indicate whether you did/did not change your original view on Question 8 in the appropriate box below. Thank you ✱ *Required*

Please select exactly 1 answer(s).

- ☐ Yes
- ☐ No
- ☐ Can't remember

PLEASE NOTE. THE LAST TWO QUESTIONS DO NOT REQUIRE YOU TO RECONSIDER SCORES FROM ROUND 1.

9. As a minimum, i.e. 'best practice' standard, the CBTp therapist should record the following information in the clinical notes after each CBTp (f) session: *session number; agenda* (which may include a review of any between-session tasks)*; content of session* (including any specific information that may have been elicited about engagement and risk)*; agreed actions; date of next session* ✱ *Required*

Please don't select more than 1 answer(s) per row.

Please select exactly 1 answer(s).

Please don't select more than 1 answer(s) in any single column.

	Agree strongly	Agree somewhat	Neither agree nor disagree	Disagree somewhat	Disagree strongly	
1	☐	☐	☐	☐	☐	5

9.a. At the end of a course of CBTp (f) treatment, as a minimum, i.e. 'best practice' standard, the CBTp therapist should always provide an 'end of treatment' report. This report should provide details about: t*he assessment process and its outcome; the agreed*

formulation and goals for therapy; the patient's response to therapy in the context of the agreed formulation and goals (including any specific information that may have been elicited about engagement and risk) ✱ *Required*

Please don't select more than 1 answer(s) per row.

Please select exactly 1 answer(s).

Please don't select more than 1 answer(s) in any single column.

	Agree strongly	Agree somewhat	Neither agree nor disagree	Disagree somewhat	Disagree strongly	
1	☐	☐	☐	☐	☐	5

10. It would be helpful to consider the future development and use of a psychosis pathway for patients. For example, similar to the NHS Education for Scotland trauma pathway (link for further details: https://www.nes.scot.nhs.uk/media/3971582/nationaltraumatrainingframework.pdf). The rationale for this is that it is hypothesised that many forensic (and indeed non-forensic) patients with psychosis might only require and/or be able to manage to undertake phase 1, i.e. 'low intensity' work, and therefore would not typically be referred for a higher intensity intervention such at this current CBTp protocol. ✱ *Required*

Please don't select more than 1 answer(s) per row.

Please select exactly 1 answer(s).

Please don't select more than 1 answer(s) in any single column.

	Agree strongly	Agree somewhat	Neither agree nor disagree	Disagree somewhat	Disagree strongly	
1	☐	☐	☐	☐	☐	5

Page 4: Final page

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE!

Summary

Draft Article

Journal Psychosis

Psychological, Social and Integrative Approaches

Article title: A process evaluation to determine the most effective way to deliver a cognitive behavioural therapy for psychosis treatment programme in a high secure setting

Cawthorne P[a]* Cruickshank S[a] and Bugge C[a]

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Provide full correspondence details here including e-mail for the *corresponding author

A process evaluation to determine the most effective way to deliver a cognitive behavioural therapy for psychosis treatment programme in a high secure setting

Abstract

Background

Up to 80% of patients in a high secure hospital in Scotland have a diagnosis of schizophrenia or other psychosis. However, despite limitations in delivering cognitive behavioural therapy for psychosis (CBTp) in forensic settings, clinical guidelines continue to recommend that all patients who experience persisting psychotic symptoms and /or depression, or patients with psychosis in remission, should receive CBTp. A process evaluation was therefore conducted to understand the barriers and facilitators to delivering a bespoke forensic CBTp intervention in this setting.

Method

The study had three distinct phases. Phase One was a retrospective review of case notes (n=60); Phase Two involved interviews with therapists (n=9) who were providing CBTp; and Phase Three was a Delphi survey of experts informed by phases one and two.

Results

There was poor adherence to the current psychological intervention. There were three main *barriers*; manual related factors (e.g. manual complexity); therapist related factors (e.g. preparedness of therapist to deliver CBTp); and environmental factors (e.g. negotiating security or risk issues). *Facilitators* also included factors related to the therapist (e.g. structure and content of clinical supervision) and factors related to the manual (e.g. acceptability to patients). Expert consensus was much in keeping with the established evidence base and clinical guidelines for CBTp delivery in non-forensic settings.

Conclusions

To support consistent implementation of a manualised CBTp treatment intervention within a forensic setting, a clearly structured treatment manual for therapists should be provided. Therapists' training should be updated and repeated on a regular basis. It is necessary to ensure governance and supervision structures are in place; and it is advisable to utilise a CBTp adherence scale to support therapist development. Potentially it may also be appropriate for CBTp to be delivered by a small group of specialist practitioners, rather than a larger group of generalist practitioners.

Keywords: cognitive behavioural therapy; psychosis; complex intervention; process evaluation; high secure setting.

Introduction

The treatment of patients in high secure hospital settings (HSHs) is challenging. It is known that up to 80% of patients in a HSH in Scotland have a diagnosis of

schizophrenia or other psychosis (The Forensic Network and University of Edinburgh 2014). Guidelines by the National Institute for Health and Care Excellence (NICE 2014) and the Scottish Intercollegiate Guidelines Network (SIGN 2013) have specifically set out recommendations that this group of patients with persisting symptoms or those who are in remission should be offered CBTp. In practice the delivery of CBTp has faced a number of challenges nationally (Switzer and Harper 2019); specifically, patients gaining access to CBTp, limited availability of trained therapists, and the heterogeneity and complexity of patients (Ince et al. 2016). In short, there appear to be organisational barriers, barriers relating to workforce capability, and acceptability of treatment for service users (Haddock et al. 2014).

To date no HSH or other forensic mental health service has developed a bespoke individual CBTp (f) programme for use in a HSH, which is manualised, and otherwise in keeping with the core elements of CBTp as recommended in current clinical guidelines (SIGN 2013: NICE 2014). However, Haddock et al (2009) did conduct a trial of an integrated programme of CBTp for use in a mixture of settings, including a HSH. This intervention comprised CBTp with additional CBT strategies for dealing with concomitant problems with anger and violence (Haddock et al. 2009). One of the chief limitations of this approach, however, was that it did not address issues related to personality functioning, either in the intervention manual, or in relation to outcomes attained. Other authors, (e.g. Adshead et al. 2018) have highlighted the need to address personality-related risky psychological attitudes (such as lack of empathy, or cruel and derogatory attitudes toward others), as well as attitudes toward violence within treatment interventions in HSHs; as these are likely to have been implicated in the reason for the individual's admission to such environments in the first place.

Further, Slater (2011) completed an individual case study, defined by him as CBTp in a HSH. However, on closer inspection, this intervention did not reflect the core elements of CBTp as outlined in e.g. NICE (2014), but instead comprised of "transdiagnostic and symptom focused interventions", designed to address an

individual's "chief complaint" (which was also transdiagnostic in nature) (Slater 2011, p.161).

Other authors have reported on the use of non-adapted individual CBTp programmes for use in a HSH (e.g. Bentall and Haddock 2000; Benn, 2002), and some have also delivered group-based CBTp using a non-forensic specific protocol (e.g. Williams 2014).

Some researchers have also looked at possible obstacles to the delivery of CBT in general in HSHs (e.g. Ferrito and Moore 2017); and CBTp more specifically, either in HSHs (e.g. Slater and Townend, 2016), or other forensic mental health units (e.g. Haddock et al. 2004). However, these tended to be small and somewhat limited studies conducted at a brief qualitative, exploratory hermeneutic review, or case series/case study level, i.e. there have been no in-depth multi-method evaluations, and no other process evaluations. These studies were also mainly outcome-focused, not process focused.

Whilst there has been no published research investigating the implementation of forensic-specific, individual manualised CBTp - referred to as 'CBTp (f)' (Allan et al. 2002), within forensic settings; findings from research that explored the implementation of non-forensic manualised CBTp within a forensic context, have indicated a degree of symptom improvement can be achieved (e.g. in reduction in level of delusional conviction) (Benn, 2002; Bentall & Haddock, 2000).

A bespoke CBTp (f) protocol was developed specifically for use within a HSH in Scotland in 2002 (Allan et al. 2002). This bespoke intervention was underpinned by Garety et al's (2001) 'A cognitive model of the positive symptoms of psychosis'. However, this model was also augmented to include a focus on the role of underdeveloped and overdeveloped behavioural strategies, based upon the work of Davidson (2000). This helps provide a more expansive formulation of the complex and problematic relational and behavioural aspects of personality functioning, arising

from core beliefs, that are often found in this specific population. The addition of Davidson's (2000) conceptualisation framework helps to give an enhanced understanding of how these behavioural and relational patterns might also be implicated in the maintenance of psychotic symptoms (e.g. delusions) and/or their appraisals in this group. As a complex intervention, CBTp (f) is designed to be delivered according to the manual and on an individual basis; with a minimum of 16 sessions; delivered by trained and supervised therapists.

The aim of this study was twofold:

1. To understand and explore the factors that have prevented the CBTp (f) intervention being implemented consistently in practice, including determining both barriers and facilitators to implementation
2. To gain a consensual position among experts about how to improve the consistency of implementation of the CBTp (f) intervention moving forward, by establishing what elements of the current treatment manual may potentially need changed.

Method

A process evaluation study was undertaken used a mixed methods design conducted over three phases: Phase One involved a retrospective review of the case notes; Phase Two involved interviews with therapists; and Phase Three used a synthesis of data collected in phase one and two to inform a Delphi survey of experts. The overall design was informed by the Medical Research Council Guidance for Conducting Process Evaluation of Complex Interventions (Craig et al. 2008).

Measures and Procedures

In Phase One a case note review was undertaken between February and June 2018. Notes were included from 2002-2017. These dates span the time period when the CBTp (f) intervention has been available for treatment in this HSH. One third of the total case notes (n=60) was selected and stratified according to four different groups of therapists (qualified psychologists; trainee psychologists; nurse therapists (with

CBT diploma level training and > two years' experience of delivering CBT), and newly qualified nurse therapists (with CBT diploma or other level training and < two years' experience of delivering CBT).

In Phase Two, semi structured interviews with nine therapists were completed. These were undertaken by a third party and used a specifically designed interview schedule to explore in depth the experiences of therapists. The schedule included 22 questions that focused on therapists' training, therapists' knowledge and understanding of the manual and any variation in practice from the manual, and their perceptions of obstacles or challenges to delivery of CBTp (f) in a high-secure setting.

In Phase Three, a Delphi Survey was conducted. Following analysis of data gathered over phase one and two, a questionnaire was developed to support this. This questionnaire consisted of 45-items. Its purpose was to gain a consensus from a range of experts in the field CBTp who worked either in academia, or forensic or non-forensic clinical settings. Two rounds of the Delphi survey were conducted. Twenty experts were approached to participate. Fourteen experts (70%, n=14/20) consented and participated in the first round, and 11 (79%, n=11/14) continued to participate through to the second and final round. These experts were asked to give their views about the best way to systematically deliver a CBTp (f) intervention in a high secure forensic metal health setting and to offer recommendations about the changes that might be required to the accompanying treatment manual to allow this to happen.

Data Analysis

Data gathered from case notes was inputted to IBM Statistical Package for Social Sciences (SPSS; Version 25) and a descriptive analysis was conducted.

All qualitative interviews were managed using thematic analysis using NVivo12 software. This involved developing initial coding; identifying emerging themes; and then establishing a final set of themes.

The Delphi survey involved analysing the content of experts' responses. Items were included if there was clear consensus reached by >70% of the panel members and if the results were in keeping with the literature and evidence base for the delivery of manualised CBTp. Items were also included if qualitative responses were made by more than one expert and were clearly aligned with clinical guidelines, recognised professional practice standards, local governance structures and the current evidence-base. Further, if there was clear consensus (>70%) at the Round One stage, but the result was not in keeping with evidence-based literature, the item was reworded and included in Round Two. Similarly, if qualitative answers were minimal or suggested a lack of understanding of the intent of the original question in Round One; these were reworded and included in Round Two.

Results

Case notes

Sixty case notes were reviewed. Twelve (20%) case notes were excluded from the analysis for the following reasons. One was selected where treatment was never started. Three were duplications of other cases. Eight had no discernible components of the specific CBTp (f) programme, or of CBTp in general.

The data was extracted using a template which gathered information related to patient demographics, target information (i.e. diagnosis, presence of persisting psychotic symptoms or depression, or symptoms in remission, and inclusion criteria for intervention); intervention information (i.e. assessment, engagement, socialisation to treatment, use of normalising rationale, formulation, establishment of problems list and goals, use of cognitive and behavioural changes strategies, and an ending phase including consolidation and relapse prevention; and change mechanisms (i.e. patient's ability to engage, patient's capacity to collaborate in the development of an agreed formulation, and in establishing a problems list and set of goals; patient's ability to learn to make links between thoughts, feelings and actions and their current of past symptoms, treatment priorities and /or functioning: patient’s ability to learn re-

evaluate their thoughts, feelings and actions, and patient completion of homework); outcomes (i.e. reduced distress, improved functioning, goal attainment, and where relevant, helped to inform risk assessment and management and reduce risk, meeting national psychological standards for access to treatment, demonstrating efficient use of resources).

Specific data related to national waiting time standards showed that 71% (n=34/48) of patients entered into the CBTp (f) intervention within 18 weeks of being referred, with 23% (n=11/48) of patients waiting longer than 18 weeks for justifiable reasons. Results indicated that all treatment was delivered on a one-to-one basis. Results also indicated that in relation to efficient use of resources in less than one-quarter of cases, 23% (n=11/48) all phases of CBTp (f) were completed and treatment ended in $\geq$ 16 sessions. This left a reported 77% (n=37/48) of cases where treatment was deemed to have been incomplete. 64% (n=31/48) of cases had an 'end of treatment' report or summary, 27% (n=13/48) had a recorded ending phase, and 25% (n=12/48) completed a relapse-prevention plan.

Results demonstrated that across six key areas of assessment there was evidence that information had been gathered about '*early experiences'* (69%, n=33/48); '*problematic emotions'* (63%, n=29/48); *'schema'* (46%, n=22/48); *'critical incidents'* (54%, n=26/48); *'problematic thoughts'* (57%, n=27/48), and *'problematic behaviours'* (48%, n=23/48). Use of a timeline was a recommended part of the assessment process and this was completed in 21% (n=21/48) of cases.

'*Willingness to engage* was recorded for most of the sample. Level of *actual engagement achieved* was recorded by therapists in 88% (n=42/48) of cases, with 69% (n=33/48) reporting this as being at a 'modest', 'moderate' or 'high' level. 'None or very little' engagement or 'don't know' was noted in 31% (n=15/48) of cases. A small amount of qualitative information gathered also highlighted 'poor engagement' as a frequently reported *barrier* to CBTp (f) implementation. Socialisation to CBTp (f) was undertaken in 85% (n= 41/48) of cases. The use of normalising rationale, which

is intended to be another key component of CBTp (f), was recorded in only 19% (n=9/48) of cases. One therapist noted normalisation to be a potential *facilitator* to CBTp (f) implementation.

With regard to content of treatment, formulations were located for less than two-thirds of the sample, 63% (n=30/48). Formulation in accordance with the specific CBTp (f) programme guidance was located in only 10% (n=5/48) of cases. An agreed problem list was noted in less than half the sample, 48% (n=23/48). Treatment priorities related to risk behaviours were noted as either 'present' or 'partially present' in about one-third, 35% (n= 17/48) of the sample. Presence/partial presence of treatment priorities related to therapeutic alliance was given the highest attention, at 79% (n=38/48) of cases. Presence/partial presence of treatment priorities related to problem lists was noted in 39% (n=18/48) of cases. Presence/partial presence of treatment priorities related to over- or under-developed behaviours, which are hypothesised to often play a key role in maintaining specific areas of difficulty, was noted to receive the least amount of attention in this section, with this being noted in only one-third, 33% (n=16/48). It was reported that 8% (n=4/48) of patients learned to monitor links between their risk and target symptoms, but none of these assertions by therapists were independently verifiable. Results also indicated that only 31% (n=15) of patients completed any homework during the course of treatment.

Results for all identified 'individual/clinical' outcomes, noted that some degree of favourable response was reportedly achieved in all three areas. For example, a reduction in distress was reported in 31% (n=15/48) of the cases, improved functioning was reported in 29% (n=14/48) cases and goal attainment (specific to problematic symptom reduction) was reported in 29% (n=14/48) of the cases. However, these results reflected the frequency by which subjective statements were recorded in the notes by therapists about their impressions of patients' progress. Objective psychometric data was available in only one case.

Therapist interviews

Interviews were undertaken with nine therapists. Demographic information for this group is presented in Table 1.

Table 1. Demographic data related to current therapists

Variable	Total Sample (*n* = 9)
Gender:	
- Male, *n* (%)	3 (33%)
- Female, *n* (%)	6 (67%)
Age (years):	
- 25 – 44 years, *n* (%)	4 (44%)
- 45 and over, *n* (%)	5 (56%)
Core profession:	
- Clinical psychologist, *n* (%)	5 (56%)
- Mental health nurse, *n* (%)	4 (44%)
Estimated number patients treated using CBTp (f)* protocol	10 (*mean*) (range 1 - 30) **

*CBTp (f), cognitive-behavioural therapy for psychosis (forensic)
**calculated by dividing number patients treated by each therapist by x 9 therapists

During interviews these therapists offered insight into the barriers and facilitators to undertaking CBTp (f) in this service, and with highly challenging clients. All information from transcripts was inputted into NVivo12 (QSR International 2018) and analysed using a thematic analysis approach (Braun and Clarke 2006). After familiarising themselves with the data by reading and re-reading transcripts, the researcher then coded the transcripts and began to build an initial coding framework. This emerging framework was then reviewed, and refined and discussed with the researcher's supervisors, and an independent reviewer, until a final set of main themes and sub-themes were agreed and identified. Participants spoke about their experiences of delivering CBTp (f) as being influenced by three overlapping factors. Firstly, the *environment they work in*, secondly the *manual* used to guide therapy and thirdly the personal and professional *experience of the individual* [therapists]. Overall, 6 main themes and 19 sub-themes were identified across these areas (see Table 2). Participants spoke more frequently about factors related to the *manual* which

reflected the higher number of coded references (55%, n=199/364), followed by those for *therapist* (35%, n=129/364) and *environment* (10%, n=36/364).

Table 2. Thematic analysis

Themes	Sub-themes	Therapist Interviews	
		Number interviews mapped to themes/sub-themes (Total interviews = 9, 100%)	Frequency of references
Environment-related factors:			
• *Context-specific barriers*	• *Access to patients*	2, 4, 5, 7. (*n*=4, 44%)	11
	• *Fear of consequences of disclosures*	1, 4, 6. (*n*= 3, 33%)	3
	• *Limitations to clinical autonomy*	2, 4, 5, 6. (*n*=4, 44%)	9
	• *Security and/or risk issues*	1, 2, 4, 5, 6, 9. (*n*=6, 67%)	13
Manual-related factors:			
• *Challenges to adherence to manual*	• *Difficult to use and apply with patient*	1, 3, 4, 5, 6, 7, 8, 9. (n=9, 100%)	35
	• *Overwhelming for therapist*	2, 4, 6, 8, 9. (n=5, 56%)	15
	• *Presentation cumbersome and barrier to its use*	3, 4, 6, 7, 8, 9. (n=6, 67%)	20
	• *Working practices independent of manual*	1, 3, 4, 5, 6, 7, 8, 9. (n=9, 100%)	46
• *Perception of efficacy of manual*	• *Acceptability to patients*	1, 3, 4, 5, 6, 7, 8, 9. (n=9, 100%)	41
	• *Assisted clinical team working*	1, 3, 4, 5, 6, 7,8. (n=8, 89%)	12
	• *Changed symptoms or problems*	1, 3, 4, 5, 6, 7, 8, 9. (n=9, 100%)	30
Therapist-related factors:			
• *Determining patient readiness to engage with CBTp (f)*	• *Moving on to next stage*	2, 4, 7, 8. (*n*=4, 44%)	7
	• *Preparedness of therapist to deliver CBTp (f)*	1, 2, 3, 5, 6, 8, 9. (n=7, 78%)	19
	• *Therapist assessment of readiness*	1, 2, 4, 5, 7, 8, 9. (n=7, 78%)	20
• *Therapists' clinical supervision*	• *Delivery format*	2, 4, 8. (*n*= 3, 33%)	3
	• *Structure and content*	2, 3, 4, 5, 6, 7, 8, 9. (n=8, 89%)	17
	• *Value and importance*	1, 2, 3, 4, 5, 6, 7, 8, 9. (n=9, 100%)	21
• *Therapist training*	• *Gaps in knowledge*	1, 2, 4, 5, 6, 7, 8, 9. (n=8, 89%)	34
	• *Timing of training*	1, 2, 3, 6, 8, 9. (n=6, 67%)	8
			TOTAL 364

Themes and sub-themes were further organised according to those that were considered barriers and those that were considered facilitators (see Table 3).

Table 3. Themes and sub-themes of thematic analysis identified as barriers and/or facilitators to CBTp (f) implementation

Theme	Sub-theme	Barrier or facilitator to CBTp (f) implementation?	
		Barrier	Facilitator
Environment-related factors:			
• *Context-specific barriers*	• *Access to patients*	✓	
	• *Fear of consequences of disclosures*	✓	
	• *Limitations to clinical autonomy*	✓	
	• *Security and/or risk issues*	✓	
Manual-related factors:			
• *Challenges to adherence to manual*	• *Difficult to use and apply with patients*	✓	
	• *Overwhelming for therapist*	✓	
	• *Presentation cumbersome and barrier to its use*	✓	
	• *Working practices independent of manual*	✓	
• *Perception of efficacy of manual*	• *Acceptability to patients*		✓
	• *Assisted clinical team working*		✓
	• *Changed symptoms or problems*		✓
Therapist-related factors:			
• *Determining patient readiness to engage with CBTp (f)*	• *Moving on to next stage*		✓
	• *Preparedness of therapist to deliver CBTp (f)*	✓	✓
	• *Therapist assessment of readiness*	✓	✓
• *Therapists' clinical supervision*	• *Delivery format*		✓
	• *Structure and content*	✓	✓
	• *Value and importance*		✓
• *Therapist training*	• *Gaps in knowledge*	✓	
	• *Timing of training*	✓	

MANUAL-RELATED FACTORS

All participants talked about their experiences with the CBTp (f) manual. Whilst they identified both barriers and facilitators in relation to this, most talked about how they consider the manual, in its present form, to be a significant barrier to the delivery of CBTp (f). However, some participants also shared more positive views about the manual, mainly around its perceived efficacy. Overall, two main themes and seven sub-themes were identified for this factor.

Main theme 1: ***Challenges to adherence to manual***.

Difficult to use and apply with patient

All the participants described using the manual as a perceived barrier. One participant commented:

- *"I guess it's the nature of the treatment. It's not just flip a page, on to the next bit. It's really complex. Even developing the formulation, I found really, really difficult and I still do".* (P4)

Overwhelming for therapist

Half the participants spoke about the manual being so detailed that is was a barrier to its use. This participant described their feelings when faced with reading the manual.

- *"I remember feeling a bit overwhelmed when I was starting CBT with somebody. I was like, 'God, it's going to take me 3 weeks to read all this again!'. I don't know if that's just the nature of the intervention 'cos it covers so many problems"*. (P4)

Presentation cumbersome and barrier to its use

Two-thirds of participants identified this as a significant barrier to CBTp (f) implementation. Participants also made several suggestions about ways that the presentation of the manual might be improved. For example, this participant commented:

- *"I definitely think the protocol could be more user-friendly, more refined, less populated".* (P4)

Working practices independent of manual

This was the most frequently coded sub-theme, accounting for 13% (n=46/364) of all references made. This perceived barrier and facilitator was commented on by all participants. One participant talked about going off model to try and better meet their patients' needs:

- (F) *"I think most people do go off model. I think it's the complexity here, isn't it? It's… you're working with such challenging patients with multiple needs that sometimes one model on its own isn't enough…"*. (P1)

Another participant talked about their struggle with problem lists, a core component of the CBTp (f) intervention:

- (B) *"I've kind of always struggled with problem lists I have to say. Just, it's something I don't really find that helpful so we didn't do that, or we wouldn't have done that"*. (P3)

Main theme 2: *Perception of efficacy of manual*

This second main theme had three sub-themes, all of which appeared to be perceived as *facilitators* to CBTp (f) implementation.

Acceptability to patients

All participants commented about this sub-theme, which was the second most frequently coded in the sample and accounted for 11% (n=41/364) of all references made. Participants spoke about this as a perceived facilitator. This participant spoke about several patients finding CBTp (f) helpful:

- *"There was one or two* [patients] [who] *were very clear that they recognise that it had been helpful to them and it helped with their symptom management and they were able to move on from the hospital quite soon after finishing the treatment. So, they were quite grateful and recognised that CBTp had helped them".* (P2)

THERAPIST-RELATED FACTORS

This set of factors had the most subthemes that were categorised as barriers, facilitators, or both. Within the range of themes and subthemes identified, participants spoke about their clinical decision-making and their experiences of training and supervision related to the delivery of CBTp (f). Three main themes and eight sub-themes were identified as follows.

Main theme 1: *Determining patient readiness to engage with CBTp (f)*

This main theme encompassed the following three sub-themes.

Moving on to next stage

Participants made comments across seven coded references about this perceived facilitator. This participant spoke about the importance of having an identified problem list to help prioritise moving through different stages of treatment:

- *"Agreeing everything around the problem list, even agreeing the order that we did things in".* (P2)

Preparedness of therapist to deliver CBTp (f)

Participants spoke about this sub-theme as being both a potential barrier and a potential facilitator to CBTp (f) delivery. Examples of both are given below:

- (B). *"Probably the reasons that I've not done a lot of CBTp is because the research on it is so contested. And you know, whether it's in the NICE guideline, there are very vocal people who think that it's useless basically".* (P3)
- (F). *"I think it's just about adapting your treatment sessions to that person so although it was once a week, it was every week routinely. But you might start, you know, with about 20 minutes and then you kind of build up as you got a bit more rapport and you felt more comfortable. So, I think there is scope for building that into what the patient needs*". (P8)

Therapist assessment of readiness

This was another sub-theme where participants spoke about their experiences as being both potential barriers and facilitators to CBTp (f) delivery. This participant spoke about undertaking a long period of engagement work before they considered their patient was ready to do CBTp (f):

- (B). *"One patient I had been working with for probably about 5 years before beginning the CBT psychosis process. It was always engagement sort of a work we were doing, and we just had to wait until he was ready and that was it".* (P1).

This participant talked about how having a shared problems and goals list and a patient who was receptive, helped them to establish their readiness to engage in CBTp (f):

- (F). "*Yeah, they* [the identified problems] *were very much shared and* [the patient was] *very open from the beginning, this is why we are going to do this piece of work"*. (P7)

Main theme 2: *Therapists' clinical supervision*

Three sub-themes were identified under this main theme, as follows.

Delivery format

One-third of the participants each made one comment about this perceived facilitator. This was therefore one of the least frequently commented on sub-themes. Two participants spoke about the perceived helpfulness of group supervision:

- "*We used to have a CBTp supervision group. I felt that was really helpful".* (P8)
- *"I think even group supervision for the practitioners that are delivering CBTp may be a help*". (P2)

Structure and content

Participants talked about their experiences of this aspect of clinical supervision as being either a potential barrier or a facilitator to CBTp (f) delivery. Participants' comments focused mainly on the perceived usefulness and importance of receiving CBTp-specific supervision:

- (B). *"I had my supervisor for my generic kind of work which I probably took the case along to, but as* [for] *a bit more specific CBT focused psychosis supervision; I don't think I really had that, but I think that would have been probably really helpful for me".* (P8).
- (F). "*The supervision was definitely helpful. I think because it was my first case doing that protocol as well. It was helpful to have that extra kind of guidance…"* (P6).

Value and importance

All participants spoke about this sub-theme. All their comments focused on the importance of clinical supervision as a perceived facilitator to CBTp (f) implementation. As one participant put it…

- "[Its] crucial, absolutely crucial!". (P4)

Main theme 3: *Therapist training*

Two sub-themes were identified here as follows.

Gaps in knowledge

Eighty-nine percent of participants shared 9% (n=34/364) of references about this perceived barrier to CBTp (f) delivery, making this the fourth most frequently coded sub-theme. One therapist spoke about seeking more training and knowledge about working with specific symptoms:

- *"If you're working with voices it would be different than if you were working with paranoia or delusions. Just maybe a bit more specific* [training and knowledge], *you know, I mean, just to kind of think about, well, if you hear a voice that's quite a useful tool to work with that. Or, if you think about paranoia, that's the kind of thing you're going to use a bit more…"* (P8).

Timing of training

Participants spoke about their poor recall of earlier training and the need to update this. For example:

- *"I think the training in it was a long time ago as I had just started so it was 10 years ago".* (P9)

ENVIRONMENT-RELATED FACTORS

When asked about their experiences, most participants talked about the nature and context of the high secure environment and their interactions with it. A number of clear themes subsequently emerged from this, all of which were identified by participants as constraints to their delivery of CBTp (f).

Main theme: *Context-specific barriers*

This was the single main theme identified for this factor. Four sub-themes emerged from this, as follows.

Access to patients

Four out of the nine participants spoke about their experience of working in the hospital and the complexity of the environment in providing optimum therapy. This was referred to as a barrier to CBTp (f) implementation. Participant 4 talked about how things sometimes get in the way of gaining access to patients:

- *"So, I guess the environment and, you know, the forensic environment… there's going to be stuff that happens and patients having tribunals and stuff like that…".*

Fear of consequences of disclosures

Patients' reluctance to disclose information to the therapist due to fear this might lead to recommendations for medication or length of stay to be altered, was described by three participants. They believed this could be a barrier over the course of CBTp (f). An example of this is given by this participant:

- *"Sometimes a patient will disclose something to you and when you pass it on to the clinical team there can be repercussions; for example, increase observations".* (P5)

Limitations to clinical autonomy

The participants talked about clinical autonomy and how this can be compromised within a forensic environment. One participant spoke about their experience of the sudden discharge of patients without due warning:

- *"Sometimes, unbeknown to you, a client will suddenly move on. So that's another thing that we do; we have these discharge CPAs that can be quite quick".* (P1)

Security and/or risk issues

Two thirds of participants described the security risks posed through working in this environment and the additional complexity this brings when providing CBTp (f). One participant spoke about trying to conduct a CBTp (f) session when several other staff members were present to help manage the assessed level of risk:

- *"I've had a patient in the room with 3 staff trying to do CBT or trying to engage them at least in a CBT process. So, there's lots… I mean, I think high secure brings its own problems… So, there's lots of different obstacles".* (P4)

Delphi Survey

A total of 32 items from across the two rounds were included in the final list of results (see Figure 1. Flowchart showing number and outcomes of items in each Delphi round).

INSERT FIGURE 1 ABOUT HERE

Items were included if there was clear consensus reached by >70% of the panel members and the results were in keeping with the literature and evidence base for the delivery of manualised CBTp. Both the *definition* and *level* of consensus chosen for this study was set by the researcher with regard to the literature in this area (Jorm 2015; Keeney et al. 2011). For this study, the researcher based their decision-making on the following factors. First, the *diversity of expertise* in the expert panel, their *independence* to each other, their high level of professional *autonomy,* and the use of the Delphi process to gather their *collective views*, was in keeping with Surowiecki's (2004) 'wisdom-of-crowds' construct. This construct suggests that the presence of these four factors in this group would have made them inherently 'wise', and therefore not requiring an exceptionally high level of consensus when expressing similar views. Second, in keeping with the overall rationale for this study, the delivery of CBTp (f) is an under-researched area, meaning that it was not possible for the expert group to form their views based on a large body of literature and evidence. If such a large body of evidence had been available to them, this may have led to a much greater range of opinions, which might then have justified setting the level of consensus higher (e.g. at >80% or 90%).

Items were also included if qualitative responses (e.g. comments relating to recommendations for training, delivery or the manual) were made by more than one expert and were clearly aligned with clinical guidelines, recognised professional practice standards (e.g. for record-keeping), local governance structures and the current evidence-base. Further, if there was clear consensus (>70%) at the Round One stage, but the result was not in keeping with evidence-based literature, the item was reworded and included in Round Two. Similarly, if qualitative answers were minimal or suggested a lack of understanding of the intent of the original question in Round One; then these were reworded and included in Round Two. The researcher

then grouped related items under 10 sub-headings as a means of further ordering the final list (see Table 4. Principles and elements of CBTp (f) delivery for inclusion in treatment manual)

INSERT TABLE 4 ABOUT HERE

By the end of Round Two, a total 26 items were excluded (three did not achieve consensus; three achieved consensus >70% but were rated as too ambiguous and requiring revision; 16 were qualitative responses (comprising six questions that added no new information or duplicated information over several other responses, and ten that shaped new quantitative questions for Round Two) and four that achieved consensus >70%, one of which was not aligned with the current literature and evidence-base, one that conflicted with several other recommendations where consensus >70% was achieved, and two that did not relate directly to the delivery of manualised CBTp). Thirty-two items were included in the list of items at the end of the Delphi survey.

Items with consensus that were not included in the list of recommendations for the manual are presented in Table 5.

Table 5. Elements of CBTp (f) with consensus not recommended for inclusion in the treatment manual.

Element of CBTp (f) not recommended for inclusion in treatment manual	**Round included**
Formulation:	
It is possible to deliver good quality CBTp (f) when using a formulation framework that is non-CBT based, e.g. '5Ps-based formulation'.	2
Longitudinal formulation needs to be an essential component of CBTp with forensic patients; without this, we would be unable to understand how psychological distress and difficulties potentially interrelate with offending behaviour and risk	2
Governance/other forms of service delivery:	
When working with forensic patients with difficulties associated with psychosis, it is important for therapists to be able to be "flexible" in their overall approach. "Flexible" in this context means, "Able to draw from a number of different therapeutic models and choices of interventions and to apply these as/when indicated".	2
It would be helpful to consider the future development and of a 'psychosis pathway' as many forensic (and indeed non-forensic) patients with psychosis might only require and/or be able to manage to undertake phase 1, i.e. 'low intensity' work. Not all may therefore require a higher intensity intervention such as this CBTp (f) programme.	2

Discussion

Based on demographic information, the case note review indicated that the appropriate patients were selected for treatment (i.e. patients with a diagnosis of schizophrenia, schizoaffective, or other psychosis); as well as a notable proportion of patient with co-morbid personality disorder (32%). In contrast, there was a lower rate of co-morbid substance misuses than anticipated (29%) in comparison to expectation of over 80%reported among this group of patients in the literature; This disparity may have been due to information being lost, not recorded, or due to diagnostic overshadowing then this issue may not have been focused upon within treatment. Prior research has suggested that there is a critical period in the early phase of psychosis when psychosocial and symptomatic deterioration can progress rapidly if the individual is left untreated (Birchwood et al. 1998). Some authors have also shown that CBTp can be an acceptable and efficacious intervention to offer during this critical period, and that it can be beneficial either when used with medication (Mc Gorry et al. 2002) or sometimes without it (Morrison et al. 2004), This focus on early intervention is therefore important. However demographic characteristics of the patient group whose notes were reviewed in phase one of this study, indicated that the length of illness for this client group was on average almost 14 years (ranging from 1 to 30 years) and that patients had already been in hospital for over 4.5 years (1 month to 30 years) when treatment commenced. It would therefore be important to consider how to encourage mental health professionals to make a more concerted effort to refer a patient to CBTp at an earlier stage with the aim of maximising the opportunity to potentiate treatment response and support an overall improved prognosis sooner in their treatment pathway.

Results of the case note review also found that 20% of the case notes demonstrated no indication of CBTp being attempted and instead related to other treatment interventions (e.g. CBT for offending behaviour or non-CBT based intervention); it therefore appeared that there was a propensity for psychological interventions to be mislabelled.

Only 10% of the remaining cases were deemed to resemble the CBTp as outlined in the treatment manual (i.e. formulation underpinned by protocol). In terms of the degree to which the phases of treatment were completed within therapy then in 23% of cases all phases of treatment were completed in more than or equal to 16 sessions (even though there were elements that were not completely in keeping with the manual); in 40% of cases not all phases of treatment were completed and treatment ended after less than 16 sessions; and in 37% not all phases were completed and treatment ended after more than 16 sessions. Overall, the case flow was difficult to determine in almost every case. There was commonly an absence of CBT-formulation in the majority of cases (90%). There was also a general absence of clear treatment goals or a problem list; with a clear problem list in less than half of the cases (48%). The presence of CBT-specific change strategies varied - engagement was present in almost every case (92%); however, all other strategies were present in less than half of the cases (e.g. coping strategies in 48%; and in only one case was there use of seeking alternative explanations). Flach et al (2015) found that the development of a formulation and the completion of homework were related to treatment outcome, and that these factors were associated with a decrease in symptom severity. It may therefore be important (given the low rate of usage in this study of these components) to emphasise the importance of these factors in future development of the manual. As a part of the process it had been intended to review the extent to which outcomes had been monitored (e.g. reduce distress, improved functioning and attained therapy goals, and risk reduced if relevant). It was however found that only in one case had pre, mid and post psychometrics been completed and instead were partial or absent in the remaining cases.

Prior to the outset of research there was an indication that there were a number of cases in which treatment was incomplete; however, the extent of partial completion was unexpected, and the limited use of CBT strategies was also greater than envisaged. Dunn et al (2012) research indicated that partial treatment consisting of assessment and engagement only had no benefit and could even be potentially harmful; the above finding therefore raises potential concerns regarding the partial

completion of treatment within this forensic setting. Furthermore, due to non-completion of the psychometric measure it was not possible to establish whether there may have been iatrogenic effects from the partial completion of treatment. Nonetheless, in 30% of cases therapists provided comments in case notes or end of treatment reports that patients had made improvement but there was no collateral evidence to support this.

In an attempt to try to understand more fully the reasons for such a degree of non-adherence to the manual then further therapists' feedback may provide some additional insight.

When therapists were interviewed about the use and implementation of the manual certain key themes emerged including manual related factors, therapist related factors, and the environment. And within manual related factors the most frequently reported sub theme related to " working practices independent of the manual" accounting for 13% of all references made during interviews and commented on by all therapists with all discussing at times "going off model". When considering there was such high reports of non-adherence to the manual it is perhaps not so surprising given the other comments that therapists made regarding implementation of the manual. The other key sub themes referred to challenges in adherence related to difficulty in using and applying the manual with patients, the manual being overwhelming for therapists, and presentation of the manual being cumbersome and a barrier to its use.

There were a number of themes that emerged in the interviews that were related to either therapists or the manual that might provide further insight.
Therapists noted issues related to therapist training including gaps in knowledge, with therapists describing limited knowledge of manual and/or specific techniques contained within the manual for CBTp. It therefore follows that if a therapist does not know about what the key components of treatment are, then it is understandable that it would then not be possible to apply aspects of the manual within treatment. In

addition, therapists highlighted the importance of the timing of training - and in particular referred to the distance in time between the training and the implementation of treatment - and as a result quite a few could not remember a number of the components of the protocol and so it is unlikely that a component will be used if it can't be recalled.

Therapists also highlighted uncertainty regarding their skills in determining a patient's readiness to engage - including agreeing treatment targets and managing sensitive areas within therapy. Previous research has suggested that clinicians can be concerned that patients are too ill to engage in treatment despite clinical trials demonstrating that CBT is effective even with patients who are treatment resistant. It may therefore be that therapists in this study were also hesitant to discuss risk related issues, or to commence active treatment.

Clinical supervision was raised as an important element of the treatment process with many comments relating to therapists being of the view that there was not sufficient supervision, and therapists valuing clear CBT based supervision to identify where therapy may have become stuck and obtain guidance from their supervisors. It may therefore be that without sufficient quantity of supervision or sufficient direction within supervision then again there was therapeutic drift and an increase in the likelihood of non-adherence to the manual.

Despite the apparent challenges for therapists in adhering to the manual, therapists reported a perception of the manual as efficacious - that is to say that the manual was viewed as acceptable to patients (e.g. through their regular attendance and self-reports of finding it helpful) reported benefit, as assisting in clinical team working (e.g. supporting the team to understand the patient's difficulties), and as having a role in changing symptoms or problems for patients (e.g. improving quality of life, reducing risk related factors). The reason for this possible contradiction maybe that it is difficult or uncomfortable for therapists to accept that intervention may not have been effective or may not have led to change. Alternatively, therapists may both have

experienced the manual as having areas for improvement in utility however found the manual valuable and felt still able to make clinical progress with patients. These conclusions however appear to further reinforce the importance of gathering more objective outcome data to corroborate whether improvements were in fact experienced by patients.

A panel of experts were surveyed who had either been involved in the development of CBTp treatment protocols; led clinical trials; or had experience in the delivery of CBTp in a forensic setting or the provision of clinical supervision in a forensic setting. When asked to consider the important components of a CBTp treatment, experts largely confirmed the principles and elements of delivery that were proposed to them.

Experts confirmed the importance of the presentation of the treatment manual and the need for therapists to adhere to the manual. This included recommendations regarding the detailed structure of a treatment manual.

Training, therapists' competence and supervision were similarly confirmed by experts as key to the delivery of CBTp treatment. In particular, experts strongly endorsed the use of the Roth and Pilling (2003) competency framework; the need for therapists to have specific forensic competencies; that competencies should be reviewed using a recognised competency measure; the need for therapists to have a good working knowledge of the manual; and the need for training to be regularly reviewed and repeated; and the need for therapists to demonstrate knowledge from a wide range of CBT models.

In addition, experts also endorsed the importance of key stages of the therapy process; this included the importance of assessing patient readiness, assessing patient willingness and ability to engage; formulation; assessing when it is appropriate to move to the next stage of treatment; and assessing the mid-point of treatment. In addition, experts also confirmed the importance of factors associated with governance and service evaluation including alignment to clinical guidelines and

current evidence base; the range and use of psychometric measures; as well as recording outcome and record keeping. All experts endorsed the need for all aspects of clinical guidelines. In addition, experts referred to the concept of developing a psychosis pathway.

From a complex-systems perspective, the information about the lack of recent referrals to CBTp (f) also appeared to suggest that there are likely to be significant contextual factors operating within the 'system' that are affecting the uptake and implementation of this intervention. This finding appears to affirm the view posited by Hawe et al (2009), who described complex [healthcare] interventions, such as the CBTp (f) intervention, as "events within systems, which either leave a lasting footprint or wash out, depending how well system dynamics are harnessed".

In this particular HSH, over 80% of patients have a form of schizophrenia or psychosis that would warrant a CBTp intervention and this is viewed as not only good practice but a necessary part of the client's rehabilitation (SIGN 2013; NICE 2014). However, this study found that translating what is good practice into effective delivery is challenging.

Conclusion

To support consistent implementation of a manualised CBTp treatment intervention within a forensic setting, a clearly structured treatment manual for therapists should be provided. Therapists' training should be updated and repeated on a regular basis. It is necessary to ensure governance and supervision structures are in place; and it is advisable to utilise a CBTp adherence scale to support therapist development. Potentially it may also be appropriate for CBTp to be delivered by a small group of specialist practitioners, rather than a larger group of generalised practitioners.

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Figure 1. Flowchart showing number and outcomes of items in each Delphi round

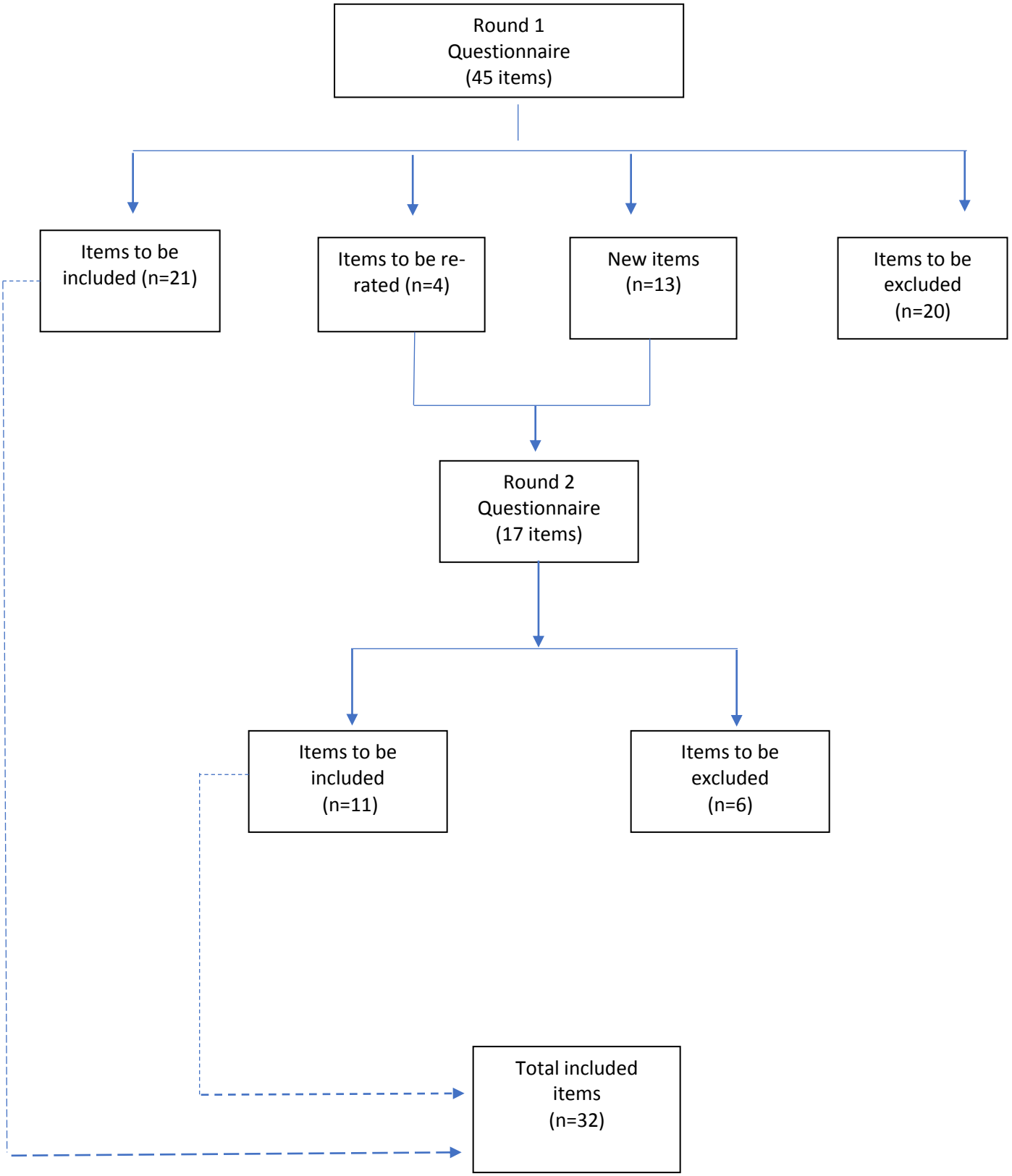


Table 4. Principles and elements of CBTp (f)* delivery for inclusion in treatment manual

Recommended principles and elements of CBTp (f)*	Round included
Alignment with clinical guidelines and current evidence-base:	
CBTp (f) should be delivered…	
... on a one-to-one basis, over at least 16 sessions.	1
… by appropriately trained and supervised therapists.	1
… in accordance with an established treatment manual (preferably one with evidence for its efficacy).	1
CBTp (f) should be delivered so that...	
... people can establish links between their thoughts, feelings or actions and their current or past symptoms, and/or functioning.	1
... the re-evaluation of people's perceptions, beliefs or reasoning relates to the target symptoms.	1
CBTp (f) should be delivered so that it also includes...	
... people monitoring their own thoughts, feelings or behaviours with respect to their symptoms or recurrence of symptoms.	1
... promoting alternative ways of coping with the target symptoms.	1
... reducing distress.	1
... improving functioning.	1
Where a specific model or intervention is chosen, e.g. CBTp, this should always be delivered in accordance with the associated evidence-base – e.g. through adherence to a specifically chosen evidence-based treatment manual.	2
Presentation of treatment manual:	
A CBTp (f) treatment manual should have the following contents:	
1) summary of background theory (including principles and values of therapy)	
2) stages of therapy described – assessment, engagement, socialisation to treatment and use of normalising rationale, agreement of problems and goals list, formulation, use of cognitive and behavioural change strategies (informed by agreed formulation and problems and goals list), ending therapy, report writing,	
3) treatment evaluation (e.g. recommended psychometric measures)	1**
4) reference list	
5) additional reading materials or other resources – e.g. reference to other CBTp manuals or self-help books.	
All information should be presented using written, diagrammatic and pictorial formats.	
It should include case examples and examples of incremental steps in treatment process, e.g. emerging and completed formulations, homework sheets.	
Therapist training and competences:	
All therapists delivering CBTp (f) should be appropriately trained such that they can:	
...demonstrate the (Roth & Pilling, 2013) CBTp range of competences.	1
...demonstrate a working knowledge and understanding of the components of the specific treatment manual for CBTp (f) used in their area of practice.	1
... demonstrate an appropriate range of specific 'forensic' competencies (e.g. violence risk assessment and management skills).	1
"In addition,	
... CBTp (f) therapists' training should be regularly reviewed and repeated.	1
... CBTp (f) therapists' competencies should be regularly reviewed and rated using a recognised therapy adherence and competency measure, e.g. The Revised Cognitive Therapy for Psychosis Adherence Scale (R-CTPAS; Rollinson et al. 2008).	1
…CBTp (f) therapists' training should span a range of different CBTp models (including e.g. Freeman's persecutory delusions, Morrison's model of intrusions and auditory hallucinations, Birchwood's model for command hallucinations)	1**
Therapist clinical supervision:	
Supervisors should have clinical supervision training, > 2 years' experience of using CBTp and specific forensic competencies (e.g. violence risk assessment and management skills).	
Supervisors should have knowledge and awareness of the CBTp (f) treatment manual underpinning therapy.	1**
Format of supervision should follow the CBT model, i.e. be structured by an agenda and follow CBT process.	
Frequency of supervision should be individually determined but should be a minimum of 1 hour/month for experienced therapists or 1 hour/fortnight for trainee/novice therapists	
Individual supervision should be provided but can be augmented by group supervision.	
Therapist's assessment of patient readiness, willingness and ability to engage and when to move on to next stage:	
Problems such as patient non-collaboration, patient not 'getting' the model, relational difficulties leading to apparent treatment resistance, or patient making very limited or no progress, would generally be taken as indicators that a CBTp (f) intervention is probably not effective or likely to be helpful at this stage in the patient's recovery, and an alternative approach should therefore be considered.	2
Patients must be willing and/or able to engage in CBTp (f).	2
Patients must have an ability to form an agreed set of goals and tasks for therapy.	2
Therapist's assessment of mid-point of treatment:	
The stage after formulation and when moving on to the intervention/use of change strategies phase could reasonably be taken as an approximate mid-point of CBTp (f) treatment.	1**

Range and use of psychometric measures:	
Psychometric measures should…	
…be specific for the individual and match up with their experiences and problems list.	
…be reliable and validated, e.g. PANSS, PSYRATS, IIP-32.	1**
…allow monitoring pre, during (mid) and post therapy.	
It may be helpful for these tools to assess psychotic symptoms, emotional distress, daily functioning and interpersonal relationships.	
There are some occasions, e.g. where it may adversely affect the patient's engagement, when it is not appropriate to undertake psychometric assessment or evaluation of a CBTp (forensic) intervention.	2
Regardless of whether any formal psychometric assessment or evaluation of a CBTp (forensic) intervention is undertaken, we do nonetheless always need to document the impact and outcome/s of this work.	2
Assessment of impact of CBTp (f) on risk of future violence:	
When a course of CBTp (forensic) is delivered to help target difficulties related to offending behaviour, e.g. threat-control override symptoms leading to violence, it is **essential** that the response (or lack of response) to this is fed back into the risk assessment process, e.g. via HCR-20 narrative updates and, if indicated, through making HCR-20 score revisions.	2
Formulation:	
It is possible to deliver good quality CBTp (f) using a brief, maintenance formulation only.	1
It is possible to deliver good quality CBTp (f) without moving on to complete a longitudinal formulation, providing there is at least an agreed maintenance formulation	1
It is NOT possible to deliver good quality CBTp (f) without having an agreed formulation with the patient.	2
It is NOT possible to deliver good quality CBTp (f) without sharing the emerging formulation with the patient.	2
Recording outcomes and record-keeping	
As a minimum, i.e. 'best practice' standard…	
… therapists should record session number; agenda; content of session; agreed actions and date of next session, in the clinical notes after each CBTp (f) session.	2
… therapists should always provide an 'end of treatment' report at the end of a course of CBTp (f). This should detail: the assessment process and its outcome; the agreed formulation and goals for therapy; the patient's response to therapy in the context of the agreed formulation and goals (including any specific information that may have been elicited about engagement and risk).	2

*CBTp (f), cognitive-behavioural therapy for psychosis (forensic)

**item included based on qualitative comments aligned with appropriate literature, professional practice standards, local governance structures and evidence-base

Figure 2a. A cognitive model of the positive symptoms of psychosis (after Garety et al., 2001)

Case Study Example – 'James'

Bio-psycho-social predisposition

- 1st child in sibship of 3. (Has brother who is 1 year younger and sister 2 years younger).
- Born via emergency C-section delivery (due to mother having severe asthma attack during labour?). Mother suffered post-natal depression.
- Family history of psychotic illness, i.e. aunt suffered from paranoid schizophrenia and grandmother suffered from depression (with occasional psychotic episodes).
- Father "not a great coper" and left much of James' care to his mother, despite her poor mental health at times. This (as well as other things) caused marital tensions. As these tensions grew and other pressures arose, James' father began drinking to excess and became an alcoholic.
- Family/home life characterised by frequent high levels expressed emotion. (Mainly due to mother's ongoing emotional distress, father's poor coping, and stress of having 3 young children to care for with very little social or financial support. Father's alcoholism also led to unemployment).
- Family socially isolated and avoidant of others. Inferred 'rule' = "You keep your problems to yourself; its nobody else's business".
- James "embarrassed" to bring friends into house due to father's drinking and mother's mental health. House often dirty, smelly and untidy.
- Becomes hypervigilant and hypersensitive re father's mood. Father occasionally violent towards James, his siblings and his mother, and James would often intervene, only to bear the brunt of the violence which was then displaced onto him.
- Insecure attachment history arising from multiple factors outlined above.
- Develops core schema, i.e. sense of self as "flawed, yet someone who needs to be able to protect others". Others/the world viewed as "cruel, hostile and uncaring".
- Parents eventually divorce. Mother recovers physically and mentally and works hard to [successfully] build stability and financial security.
- James and his siblings mature and also benefit from increased stability and security at home.

Triggering event/s

- When aged 18-years old, James experiences severe physical illness (unclear cause), but this leads to major bowel surgery, and problems become chronic…
- …Receives multiple misdiagnoses and gets 'lost' in a series of tests/medical consultations. Leads to sense of being "sent around the houses" by "so called experts" who "couldn't care a toss about me!"
- Eventual total colectomy followed by temporary ileostomy. Then 4-months later, reversal of ileostomy but lasting bowel difficulties.
- Frequent (daily) cannabis used to self-medicate abdominal pain and to "escape reality of situation"
- Father's sudden death
- Post-operative, James has difficulties picking up previous life, relationships, and career (higher education - financial services course) which had only just started
- Attends GP for pain-management consultation, but is under influence of cannabis. GP comments on this, saying it is unlikely to help with bowel problems.

Emotional responses

Physical and emotional pain
Intense fear and anxiety
Shock and despair
TRAUMA
Shame and embarrassment
Disgust

Disruption in cognitive processes

- Finds it "difficult to get head around" multiple triggering events. Can't think properly or reflect, especially when emotionally overwhelmed, which, he notices, is happening a lot at this stage
- Thinking seems to be becoming "unbalanced". Becomes increasingly 'self-focussed' and/or 'other-focussed'. Worries others might somehow smell or hear (stomach gurgling) or otherwise detect his ongoing bowel problems and disapprove of him.
- Notices he's becoming a lot more of wary of others. Also starts thinking he somehow "should have known" something horrible was going to happen to him

Anomalous conscious experiences

- Heightened perception and sense of pending doom and wondering "what's coming next?" Feels personally significant – i.e. senses that whatever's going to happen, it's going to happen to him.
- Racing thoughts, especially about other people's intentions towards him
- Becoming harder to tell whether his inner critical voice is his own voice and notices it seems to be changing somehow; as if it is similar to language used by GP.

Search for explanations

Interpreted as external experience

Interpreted as internal experience

- "I think I'm overstressed. So much has happened. Is it any wonder?"
- "If I wasn't thinking properly, I'd think I was going mad! Sometimes when I talk to myself in my head, it sounds like it might not be my voice, but I know that it is".

Biased appraisal processes

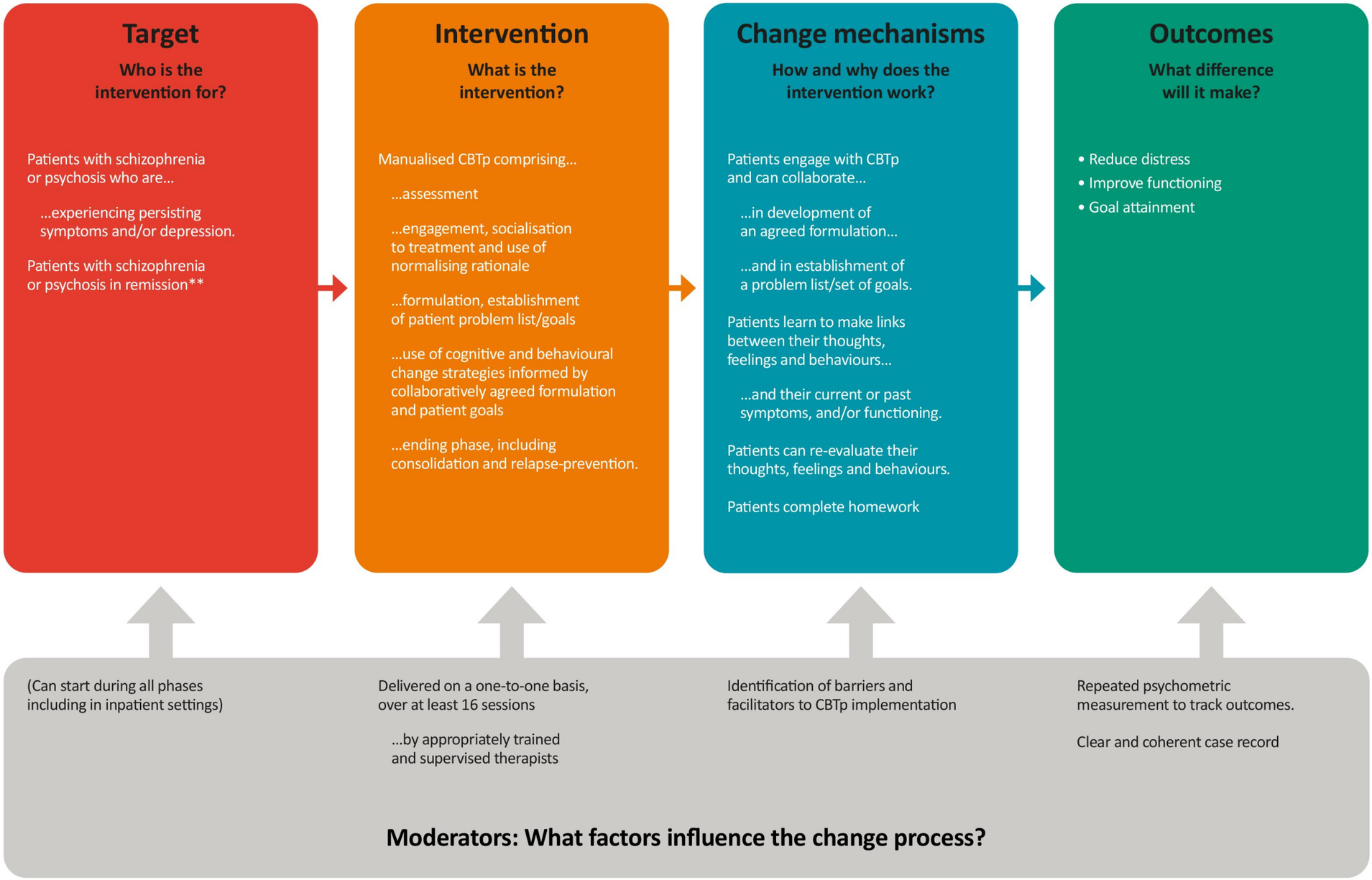
Maintained by…

- **Reasoning Processes**
  - **i. Thinking errors, ii. data-gathering biases, iii. externalising attributional style, iv. poor social understanding).**
  - i. Emotional reasoning, mental filter, jumping to conclusions – e.g. "I feel bad, so there must be something wrong"; Filters out all good encounters with GP, e.g. times when GP was warm and friendly. Reaches [delusional conclusion] "not suddenly ill", but "was likely poisoned". Not sure by whom or how.
  - ii. (and also aspects of iv). Pays attention to eyes/eye contacts with GP reception staff. If they are not maintaining consistent eye contact with him, James takes this as 'evidence' they have hostile intent towards him.
  - iii. Thinks, "He (GP) has put these voices in my head and is going to keep torturing me like this. He doesn't like me because I dared to complain about the poor medical care I was getting, so he's ganging up on me. They all are! The things he says to me! Calling me a "waster", "useless piece of shit", and badgering me all the time with saying, "You know your family would be better off without you" I can't take it any longer!"
  - iv. "I can't tell others as I can't prove it in the usual way. So I need to take matters into my own hands, or he'll just keep abusing me like this".
- **Dysfunctional schemas**
  - Sense of self as inherently 'flawed' in some way yet someone who needs to be able to protect others.
  - Others/the world viewed as as cruel, hostile and uncaring.
- **Emotions (and associated behaviour and cognitive processes)**
  - Mixture of intense emotions bound up with prevailing trauma/adjustment to new physical limitations
  - Extreme fear and sense of threat
  - Multiple and frequent physical sensations/stimulation, and/or heightened awareness and ↑attentional focus on bowels
  - Concludes "I can't live with this constant torment. I need to put a stop to it"
  - Waits for GP after surgery and attacks him with knife
- **Appraisals of illness**

"This is real. It's not illness".
"Others don't believe, but they're wrong!"
"Nobody gives a shit about me. I did nothing to deserve this!"

Refer to page 51

Figure 3. Logic model for CBTp* intervention



*CBTp, cognitive-behavioural therapy for psychosis ** (to assist promotion of recovery)

Refer to page 56

Figure 3a. Logic model for CBTp (f)* intervention

Target

Who is the intervention for?

Patients with schizophrenia or psychosis who are...

...experiencing persisting symptoms and/or depression

...currently distressed by experience of persisting symptoms and/or depression...

...willing to engage in CBTp (f)...

...likely to remain in hospital for next 6 – 9 months.

Patients with schizophrenia or psychosis in remission**

Intervention

What is the intervention?

Manualised CBTp (f) comprising...

...assessment (inc. co-morbidities, eg substance misuse, trauma and offending behaviour)

...engagement, socialisation to treatment and use of normalising rationale

...formulation (inc. all co-morbidities), establishment of patient problem list/ goals and treatment priorities

...use of cognitive and behavioural change strategies informed by collaboratively agreed formulation and patient goals and treatment priorities

...ending phase, including consolidation and relapse-prevention.

Change mechanisms

How and why does the intervention work?

Patients engage with CBTp (f) and can collaborate...

...in development of an agreed formulation...

...and in establishment of a problem list/set of goals and treatment priorities.

Patients learn to make links between their thoughts, feelings and behaviours...

...and their current or past symptoms, treatment priorities and/or functioning.

Patients can re-evaluate their thoughts, feelings and behaviours.

Patients complete homework

Outcomes

What difference will it make?

Individual/clinical:

- Reduce distress
- Improve functioning
- Goal attainment

Risk: (where relevant)

- Help to inform risk assessment and management
- Help to reduce risk

Organisational:

- Meet national standard for psychological therapies access, i.e. 18 weeks from referral to treatment
- Demonstrate efficient use of resources

(Can start during all phases including in inpatient settings)

Delivered on a one-to-one basis, over at least 16 sessions

...by appropriately trained and supervised therapists

Identification of barriers and facilitators to CBTp (f) implementation

Repeated psychometric measurement to track outcomes.

Clear and coherent case record and risk management plan

Moderators: What factors influence the change process?

*CBTp (f), cognitive-behavioural therapy for psychosis (forensic) ** (to assist promotion of recovery)

Refer to page 56

Table 3. Development of themes following thematic analysis

Working analytical framework			Final themes	
Codes	**Initial Categories**	**Emerging Themes**	**Sub-themes**	**Themes**
Lengthy, Too Much, Completion of Psychometrics, Possibility Adversely Affects Engagement	Assessment process - barriers	Challenges to adherence to manual	• *Difficult to use and apply with patients* • *Overwhelming for therapist* • *Presentation cumbersome and barrier to its use* • *Working practices independent of manual*	• *Challenges to adherence to manual*
Simpler Guidance, Complex, Needs Experts, Clarity	Complexity of information			
Too Much Information, Needs Refinement	Cumbersome in its presentation			
Vague, Flexibility, Risk of Drifting, Usefulness	Difficult to use and apply with patients			
Varied Response, Unsure about Ending, No Difference	Neutral or undesirable outcomes attained			
Overwhelming, Vulnerable, Lost, Concern, Sense of Not Doing it Right	Overwhelming for therapist			
Not User-Friendly, Not Structured, Not Manualised,	Presentation is barrier to use			
Can't Say, Long Duration, Could Have Been Less, High Variance	Treatment dose is < 16 sessions or indeterminable			
Vague, Absent, No Clear Goals/Problem List	Treatment needs and focus unclear			
Own Material, Other Material, No Psychometrics	Variances in compliance	Working practices independent of manual		
Other Models, Stop and Start, Integrated with other Work	Rationale for variance in compliance			
Psychometric Use, Varied Session Times, Helpful Process	Assessment process - facilitators	Adherence to manual	• *Acceptability to patients* • *Assisted clinical team working* • *Changed symptoms or problems*	• *Perception of efficacy of manual*
Helpful, Powerful, Key, Need to Make Sense	Formulation is facilitator			
Patient Feedback, Positive Impression, Worthwhile, Symptom Improvement, Risk Reduction	Positive or desirable outcomes attained			
Help Make Shifts, Normalising, Destigmatising, Continuum	Specific CBT change strategies are helpful			
Important, Key Ingredient, Most Helpful, Trust	Strong therapeutic relationship is facilitator			
Weekly Sessions, Session Count	Treatment 'dose' is determined and > 16 sessions			
Problem List, Joint Plan	Treatment needs and focus clear			
Room Space, Patients Off-Ward, Safety Behaviours, Quick Discharge or Transfer, Consequences of Disclosure, Other Clinical Team Members, Other Interventions/Activities	Other barriers – e.g. environmental, therapist leave periods, security, working with other disciplines		• *Access to patients* • *Fear of consequences of disclosures* • *Limitations to clinical autonomy* • *Security and/or risk issues*	• *Context-specific barriers*
Agreeing Treatment Targets, Managing Sensitive Areas	Moving on to the next stage	Patient readiness to engage with intervention	• *Moving on to next stage* • *Preparedness of therapist to deliver CBTp (f)* • *Therapist assessment of readiness*	• *Determining patient readiness to engage with CBTp (f)*
Complex Patients, Personal Motivation, Ambivalence about CBTp, Time Pressures	Preparedness of therapist to deliver CBTp (f)			
Pre-Engagement, Preparation, Low Intensity Work	Recognising readiness			
Too Soon, Not Suitable, Too Ill, Language and Cultural Differences	Therapist assessment of readiness			
Not CBTp-specific, General, Integrated, Group or Individual	Delivery format	Therapists' clinical supervision	• *Delivery format* • *Structure and content* • *Value and importance*	• *Therapists' clinical supervision*
Guidance and Advice, Objective Perspective, Time to Reflect, Prevent Drift, Manage Caseload and Time	Structure and content			
Important, Valuable, Useful	Value and importance			
Stress Levels, Feeling Criticised, Had to be Flexible	Emotional impact of delivery of CBTp (f)	Therapist training	• *Gaps in knowledge* • *Timing of training*	• *Therapist training*
Not Clear, Don't Know, Key Components and Stages,	Gaps in knowledge			
None, Too Long Ago, Can't Remember, Uniform Approach	Timing and frequency of training			

Refer to page 79