Psychological Mental Health Interventions in Prisons: An Exploration of Intervention Efficacy & Treatment Non-Completion

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Contents

List of Tables

Chapter 1: Systematic Review

Chapter 2: Major Research Project

List of Figures

Chapter 1: Systematic Review

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Lastly, I would like to thank myself

This one's for me

Coronavirus-19 Pandemic Impact Statement

The initial study protocol was designed prior to the outbreak of the COVID-19 pandemic. A full copy of the original protocol and research design can be viewed in Appendix 3.

Unfortunately, as a result of the COVID-19 pandemic, clinical services (and concurrent data collection) within Her Majesty's Prison (HMP) Shotts were abruptly paused in March 2020.

In the subsequent months, a combination of ongoing COVID restrictions, recruitment changes among the staff team, and an incidental change in Scottish Prison Service (SPS) policy regarding data access, the data collection process was significantly disrupted. Unfortunately, this combination of circumstances meant that once services resumed, it was not possible to retrospectively collect data from beyond March 2020 in a way that allowed for reliable statistical analyses.

As such, we were limited to exploring a smaller dataset, with fewer variables, that had been collected prior to the outbreak of Coronavirus-19.

Chapter 1: Systematic Review

The Efficacy of The *'Concurrent Treatment of PTSD & SUD using Prolonged Exposure'* (COPE): A Systematic Review

(2022)

Prepared in accordance with the author requirements of the Journal of Consulting and Clinical Psychology. Submission Guidelines;

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Abstract

Background & Objective

Post-Traumatic Stress Disorder (PTSD) and Substance Use Disorders (SUD) are highly prevalent and frequently co-occur. However, there is little consensus regarding how to treat these disorders simultaneously. This systematic review sought to synthesise the evidence of efficacy for the 'Concurrent Treatment of PTSD & SUD using Prolonged Exposure' (COPE), a trauma-focused, integrated psychological intervention for co-occurring PTSD & SUD.

Method

CINAHL, APAPsycArticles, MEDLINE, APAPsycINFO and the 'Psychology & Behavioural Sciences Collection' were systematically searched for Randomised Controlled Trials of COPE. The Crowe Critical Appraisal Tool Version 1.4 was used to appraise the studies.

Results

Six studies were included. The results suggest that COPE is more effective than non-trauma focused interventions with regard PTSD outcomes. Although COPE also resulted in significant improvements in SUD symptoms, these improvements were not significantly greater than controls. The results also suggest that relative to controls, COPE does not result in an exacerbation of PTSD and/or SUD symptoms, and that abstinence from substances is not necessary to experience positive therapeutic outcomes.

Conclusions

Studies of high methodological quality suggest that people with co-occurring PTSD & SUD may benefit from relatively readily available, manualised interventions. However, there is a critical need to further improve treatment engagement and treatment completion rates among this population.

Introduction

Post-Traumatic Stress Disorder (PTSD) and Substance Use Disorders (SUD) are highly prevalent and frequently co-occur (Jacobsen et al., 2001). Research demonstrates that traumatic exposure(s) among people with SUD is almost universal, and that up to 62% of those with a primary SUD diagnosis experience co-morbid PTSD. Similarly, up to 65% of people with a primary PTSD diagnosis will experience a co-morbid SUD (Hassan et al., 2017).

The relationship between these diagnostic categories is complicated by the distinction between 'simple' and 'complex' trauma that has been recognised by clinicians for many years, notably since 1992 (Herman, 1992). In 2018 the 11th edition of the *International Classification of Diseases and Related Health Problems* (ICD-11; World Health Organisation, 2018) formally acknowledged this distinction. ICD-11 includes two distinct sibling diagnoses, ('simple') Post-Traumatic Stress Disorder (PTSD) and Complex Post-Traumatic Stress Disorder (CPTSD). ICD-11 PTSD is comprised of three symptom clusters including: (1) re-experiencing of the trauma in the here and now, (2) avoidance of traumatic reminders and (3) a persistent sense of current threat that is manifested by exaggerated startle and hypervigilance. These symptoms define PTSD as a response characterised by some degree of fear or horror related to a specific and isolated traumatic event.

ICD-11 CPTSD includes the three 'core' PTSD clusters and three additional clusters that reflect 'disturbances in self-organisation' (DSO); (1) affect dysregulation, (2) negative self-concept and (3) disturbances in relationships. This formulation and characterisation of CPTSD follows from a long history of clinical observation that individuals who experienced chronic, prolonged, and repeated forms of traumatic exposure (e.g., genocide, childhood sexual abuse, war), that reflect a loss of emotional, psychological and social resources, tend to experience more complex reactions beyond those typically observed in PTSD, including problems with substance misuse.

Given the recency of CPTSD as a formal diagnosis most of the research described below is based on PTSD diagnostic criteria. However, evidence indicates that CPTSD may be more prevalent than PTSD in the UK and US population-based research (Karatzias et al., 2019); suggesting that most samples will have included people with CPTSD.

Importantly, regardless of how traumatic experiences are categorised conceptually, compared to either condition alone, co-occurring PTSD & SUD is associated with more severe illness, greater co-morbidity and functional impairment, worse treatment outcomes, and high chronicity (Berenz & Coffey, 2012; Ouimette et al., 2003). Despite this, and the availability of 'gold-standard', evidence-based interventions for each individual condition (e.g., Prolonged-Exposure (PE); Foa, 2007; Relapse Prevention (RP), Kauffman, 2006), there is a lack of evidence regarding how to treat these problems when they co-occur. Much of the existing evidence on the effectiveness of trauma-focused psychological interventions concern adults experiencing 'simple' PTSD, and although some participants who would meet CPTSD criteria were likely to have been included, people with active substance misuse problems were explicitly excluded from most trials. Similarly, the evidence on the effectiveness of psychological interventions for SUD generally excluded participants with PTSD. Recent meta-analytic evidence suggests that the benefits of these problem-specific interventions are smaller for individuals with more complex clinical problems (Gerger, 2014).

At present, when someone with co-occurring PTSD & SUD seeks treatment, they are typically offered intervention independently and sequentially (Van Dam et al., 2012). Under this treatment model, known as the '*sequential model*', SUD treatment is prioritised, and PTSD intervention is deferred until an arbitrary and mutually agreed period of abstinence (e.g., 6 months) has been achieved. Thereafter, the patient is referred for treatment within a different service and with a different clinician. Within the sequential model the approach to trauma

intervention may vary as a function of the complexity a patient's presentation. A key principle of treatment that is endorsed by many clinicians in the trauma field is that treatment for individuals with CPTSD should be phased (Herman, 1992), with an emphasis on interventions aimed at promoting a sense of safety and stabilisation of symptoms through improving self-management and emotional regulation, prior to the onset of trauma-reprocessing interventions. Patients who present with 'simple' PTSD may be deemed not to require the safety and stabilisation phase and may be offered a single element trauma-reprocessing intervention, most likely PE. The sequential model for co-occurring PTSD & SUD was derived from the *'Pandoras's Box'* hypothesis, which posits that the development of self-management and/or coping strategies is required before trauma-focused work can begin, or else intervention is likely to exacerbate the symptoms of both conditions (Becker et al., 2004; Souza & Spates, 2008). However, there is little evidence to support these concerns, nor a great deal of evidence that the sequential model is clinically effective.

An alternative and more recent view is that intervention for co-occurring PTSD & SUD should be delivered simultaneously. Under this treatment model, known as the *'integrated model'* of treatment, PTSD & SUD are treated concurrently, by the same clinician, within a single treatment episode. The integrated model posits that there is a reciprocal relationship between PTSD & SUD symptoms, and that by providing relief from PTSD symptoms early in treatment, SUD symptoms are also likely to improve (Back, 2010).

The last 20 years have seen the publication of several manualised, integrated approaches to the treatment of co-occurring PTSD & SUD. These intervention protocols can be broadly dichotomised as either;

- A) Integrated, Non-Trauma Focused Interventions:

Where PTSD & SUD are treated concurrently, but treatment does not contain any systematic trauma-reprocessing. Intervention tends to focus on psychoeducation regarding the impact of trauma, and the development of cognitive-behavioural self-management and/or coping strategies for specific symptoms.

Three manualised protocols have been published to date: Integrated – Cognitive Behavioural Therapy (I-CBT; McGovern et al., 2015), Seeking Safety (SS; Najavits et al., 2018), and Trauma Affect Regulation: Guidelines for Education & Therapy (TARGET; Frisman et al., 2007)

I-CBT comprises 3 learning and skill components to improve PTSD & SUD symptoms, including: 1) Patient education about PTSD and its relation to substance use and treatment; 2) Breathing retraining. and 3) Cognitive restructuring. Although cognitive-restructuring in I-CBT does not call for in vivo or imaginal exposure *per se*, it aims to address avoidance symptoms by teaching the cognitive processing of trauma-related thoughts, affects, and experiences.

SS is a present-focused therapy that aims to help patients attain safety from trauma and substance misuse via the development of 25 coping skills. Every skill applies to both trauma and addiction. The main aim of these skills is to help patients attain safety in their relationships, thinking, behaviour, and emotions.

TARGET aims to help people experiencing co-occurring PTSD & SUD regulate intense emotions and solve social problems. It has three components: 1) Education regarding the biological and behavioural components of PTSD & SUD; 2) The guided implementation of emotional regulation skills; 3) The development of an autobiographical narrative of the patient's current experience that incorporates the impact of trauma and substance misuse. The overarching aim is to provide a framework for understanding and managing traumatic memories and emotional dysregulation.

- B) Integrated, Trauma-Focused Psychological Interventions:

Where PTSD & SUD symptoms are treated concurrently and the intervention contains an element of trauma-reprocessing.

Two manualised protocols have been published: 'Treatment of Integrated Post-Traumatic Stress and Substance Use (TIPSS; Galovski et al., 2015) and the *'Concurrent Treatment of PTSD & SUD using Prolonged Exposure'* (COPE; Back et al., 2010).

TIPPS is comprised of 12 individual, 60-minute sessions that integrate Cognitive Processing Therapy (CPT; Resick et al., 2008) for PTSD with cognitive-behavioural Relapse Prevention (RP; Kauffman, 2006) for SUD. The CPT treatment components are designed to re-process trauma-related cognitions. The SUD treatment components are based upon cognitive-behavioural relapse prevention principles that are intended to facilitate awareness and management of cravings, review coping skills for high-risk substance-related cognitions and situations and provide a greater understanding of the associations between thoughts, feelings, and substance use behaviours and cravings.

The *'Concurrent Treatment of PTSD & SUD using Prolonged Exposure'* (COPE) represents the integration of two evidence-based psychological treatments: Prolonged Exposure (PE) therapy for PTSD (Foa, 2007), and Relapse Prevention (RP; Kauffman, 2006) for SUD. In COPE, both PTSD & SUD are addressed concurrently in therapy by the same clinician over 12, 60-minute sessions. The COPE protocol is comprised of three key stages: 1) Psychoeducation regarding PTSD & SUD, and their reciprocal relationship; 2) Prolonged imaginal & in-vivo exposure for PTSD; 3) Cognitive-Behavioural relapse prevention for SUD.

Interventions for co-occurring PTSD and SUD have recently become a topic for systematic review. The earliest reviews (e.g. van Dam et al., 2012; Najavits & Hien, 2013) included trials evaluating myriad integrated and sequentially delivered, trauma- and non-trauma focused interventions, of various design. They reported positive preliminary findings in relation to integrated, trauma-focused psychological interventions relative to integrated, non-trauma focused and sequential interventions. However, they identified significant methodological limitations in most studies and concluded that little of the evidence was high-quality.

Roberts et al., (2016) published the first systematic review & meta-analysis of Randomised Controlled Trials (RCTs) of psychological interventions for co-occurring PTSD & SUD. They sought to determine the efficacy of various trauma- and non-trauma focused psychological therapies targeting PTSD symptoms alone, SUD symptoms alone, or both, in people with PTSD & SUD, relative to various comparators (usual care, wait-list conditions, and no treatment) and other psychological therapies. They found that manualised, integrated, trauma-focused treatments were more effective than 'Treatment-as-Usual' (TAU) and no/minimal treatment for PTSD both at post-treatment and follow-up, and for SUD at follow-up, but also associated with significantly poorer treatment retention, again relative to TAU and no/minimal treatment. They found little evidence for the efficacy of integrated, non-trauma-focused treatments, and little evidence for trauma-focused interventions that targeted PTSD symptoms without also targeting SUD symptoms. In line with previous reviews, they found that many studies were poorly designed, had small sample sizes, and that most evidence was of 'low or very low' quality.

The number of RCTs evaluating the efficacy of integrated PTSD & SUD interventions doubled between 2015 and 2020, and Simpson et al., (2021) published an updated systematic review and meta-analysis. In addition to comparing trauma- and non-trauma focused interventions to various active comparators (manualized SUD treatment, SUD TAU, and no/minimal

treatment), they also included comparisons involving trials that only included a manualised SUD treatment. They did so because manualised SUD interventions generally account for time, attention, and therapist training, thus allowing evaluation of the unique contributions of trauma-focused and non-trauma-focused treatments above and beyond common therapeutic elements. They found evidence that trauma-focused, non-trauma-focused, manualised SUD treatments, and SUD 'TAU' are all associated with significant improvements on both PTSD and SUD outcomes. Trauma-focused treatments were more efficacious relative to all comparators regarding PTSD outcomes, although manualised SUD treatments were more efficacious relative to trauma-focused and non-trauma-focused treatments regarding SUD outcomes. It is, however, important to consider the context for the findings regarding the effectiveness of manualised SUD interventions. This was a small set of RCTs wherein both investigators and participants acknowledged the presence and clinical relevance of participants' co-occurring conditions, where both were thoroughly assessed over time, and treatment was delivered individually with the support of specific training and supervision. In contrast to Roberts et al. (2016), they did not find evidence that trauma-focused treatments were associated with significantly poorer treatment retention relative to comparators. Although the reason for this discrepancy is unclear, one possible explanation is that only one of the four trauma-focused RCTs included in the Roberts et al., (2016) review had active comparators, compared to eight from twelve in their review. They suggested that people with PTSD & SUD may have difficulty remaining in active treatment (i.e., that which is structured and encourages at home practice) regardless of whether the intervention has trauma-focused elements.

In summary, the evidence for the efficacy of interventions for co-occurring PTSD & SUD is mixed. Although there is support for various interventions, integrated, trauma-focused treatments appear to show slight indications of advantage relative to comparators regarding PTSD outcomes, although findings regarding SUD outcomes are less clear. Existing reviews also highlight several methodological issues in the evidence base which limit the strength of any

conclusions that can be drawn. Firstly, due to an insufficient number of RCTs evaluating a specific intervention protocol, the review literature is comprised of RCTs of a heterogeneous set of interventions. Many studies were poorly controlled in design, lacked randomisation, or were underpowered. They often failed to include follow-up data, lacked consideration of the training levels required of therapists to deliver the intervention(s), and included little or no monitoring of treatment adherence. Moreover, although integrated, trauma-focused interventions appear to show promise it is unclear whether they are associated with significantly poorer treatment retention than comparators. Existing reviews are comprised of trials that relied upon between-group, mean based statistics. While this provides information regarding the overall efficacy of an intervention within a specific population, these data do not provide any information regarding individual participant change, including the prevalence and/or severity of symptom exacerbation among individual participants. It is possible that for a sub-group of participants, the initiation of exposure-therapy leads to a reliable exacerbation of symptoms, and that this contributes to their drop out from treatment, even if overall group means indicate that treatment was successful. This is particularly important because the current literature does little to address the concerns raised by clinicians (e.g., Becker et al., 2004; van Minnen et al., 2010), that trauma-focused, exposure-based therapies could result in an exacerbation of the symptoms of both conditions (the '*Pandora's Box Hypothesis')*.

Of the two manualised, integrated, trauma-focused interventions (TIPPS: Galovski et al., 2015 & COPE; Back et al., 2010), the recent empirical interest in this topic area has led to an increase in the publications of RCTs evaluating one in particular, such that an updated review is warranted.

The *'Concurrent Treatment of PTSD & SUD using Prolonged Exposure'* (COPE) is particularly promising for various reasons. Firstly, COPE represents the integration of two manualised, 'gold-standard', evidence-based psychological interventions for either condition alone: Prolonged Exposure (PE) therapy for

PTSD (Foa, 2007), and Relapse Prevention (RP; Kauffman, 2006) for SUD. PE & RP are interventions that form a core part of clinical psychology training in the UK, and if found to be effective and acceptable, it should be possible to disseminate and implement COPE within existing services without additional training. In COPE, PTSD & SUD are addressed concurrently in therapy by the same clinician, over 12 sessions, reducing the need for patients to be passed between services to access appropriate care. Although the COPE literature does not distinguish between 'simple' and 'complex' trauma presentations, most trials include military sample populations, and in similarity with population-based research, CPTSD has been shown to be more prevalent than PTSD in clinical samples of veterans (Murphy et al., 2020). The likelihood is that the COPE literature includes a combination of participants who meet criteria for PTSD and CPTSD, and there are currently no evidence-based interventions for people with complex presentations. Lastly, there are now enough publications for COPE to be reviewed independently, and the comprehensive nature of the data collected in COPE trials has led to the recent publication of two studies designed to directly address the 'pandoras box' hypothesis for the first time, by evaluating whether the initiation of exposure therapy in COPE leads to an exacerbation of the symptoms of PTSD & SUD relative to non-trauma focused comparators.

Research Questions

The aim of this review is to synthesise evidence of the efficacy of COPE in the treatment of co-occurring PTSD & SUD.

Primary Question

- How effective is COPE in the treatment of co-occurring PTSD and SUD relative to various active comparators

Secondary Question

- Does the initiation of exposure therapy via COPE lead to greater exacerbation of the symptoms of PTSD and/or SUD, relative to non-trauma-focused comparators

Method

This systematic review follows 'Preferred Reporting Items for Systematic Reviews and Meta-analyses' guidelines (PRISMA; Moher et al. 2009). Searches of the Cochrane Database of systematic reviews and the Database of Abstracts of Reviews of Effects (DARE) were completed to identify previous literature reviews.

Search Strategy

A search of CINAHL, APAPsycArticles, MEDLINE, APAPsycINFO and the 'Psychology & Behavioural Sciences Collection' was carried out on 21/01/2022. Search terms were derived from terms used in previous reviews and meta-analyses (e.g., Simpson et al., 2017; 2021). Reference lists of previously reviewed papers were manually searched to locate potentially relevant articles. Other articles of interest were then submitted to 'Connected Papers' (www.connectedpapers.com). Connected Papers is an online, visual search tool that can be used to find and explore links between published research papers. When a paper is submitted to Connected Papers, a graph is produced that displays publications according to their 'connectedness'. 'Connected Papers' similarity metric is based on the concepts of 'Co-citation' and 'Bibliographic Coupling'. According to these measures, two papers that have highly overlapping citations and references are presumed to have a higher chance of discussing a related subject matter, and would are highlighted as being 'connected', regardless of whether they cite one another. Records between

2012 – 2022 were reviewed, as the first RCT evaluating COPE was published in 2012. The search and selection process were not checked by a second-rater.

The search algorithm was:

“Stress Disorders, Post-Traumatic"[Mesh] OR ptsd OR "posttraumatic stress" OR "post traumatic stress" OR "war neurosis" OR shell shock* OR shellshock* OR "combat neurosis"

AND

"Substance-Related Disorders"[Mesh] OR "Behavior, Addictive"[Mesh] OR alcohol* OR cannabis OR cocaine* OR heroin OR methamphetamine* OR amphetamine* OR "substance use" OR "substance abuse" OR “drug abuse” OR “drug dependence” OR marijuana OR inhalant* OR opiate* OR stimulant* OR addiction

AND

"Randomized Controlled Trial" [Publication Type] OR "Randomized Controlled Trials as Topic"[Mesh] OR random* OR "Controlled Clinical Trial" [Publication Type] OR “Controlled Clinical Trials as Topic"[Mesh] OR (controlled AND examination*) OR (controlled AND study) OR (controlled AND studies) OR (controlled AND trial) OR (controlled AND trials)

Inclusion Criteria

- Adults aged 18+
- RCTs evaluating the efficacy of the ‘Concurrent Treatment of PTSD & SUD using Prolonged Exposure’ therapy (COPE)
- Study samples comprised of people currently experiencing co-occurring PTSD & SUD. Studies involving a mix of participants with threshold and sub-threshold DSM or ICD diagnoses of PTSD were included, as were studies with participants who screened positive for PTSD (i.e., if diagnostic interviews were not conducted). This is because sub-

threshold PTSD is associated with significant distress and impairment (Pietrzak et al., 2011).

- Similarly, studies were included if they used an accepted alcohol or drug use screen with a cut-off score indicating likely disordered use AND recent unsafe use (e.g. alcohol consumption in excess of safe drinking guidelines)
- Reliable and valid PTSD & SUD outcome measures that were administered pre- and post-intervention and/or or on a session-by-session basis
- Published between 2012-2022

Exclusion Criteria

- Case studies, reviews, dissertations, book chapters, study protocols, or non-peer reviewed articles
- Studies evaluating integrated, trauma-focused interventions other than COPE
- Secondary analyses of prior experimental data that is irrelevant to the question(s) at hand (e.g., studies investigating predictors of treatment completion)
- Unpublished articles

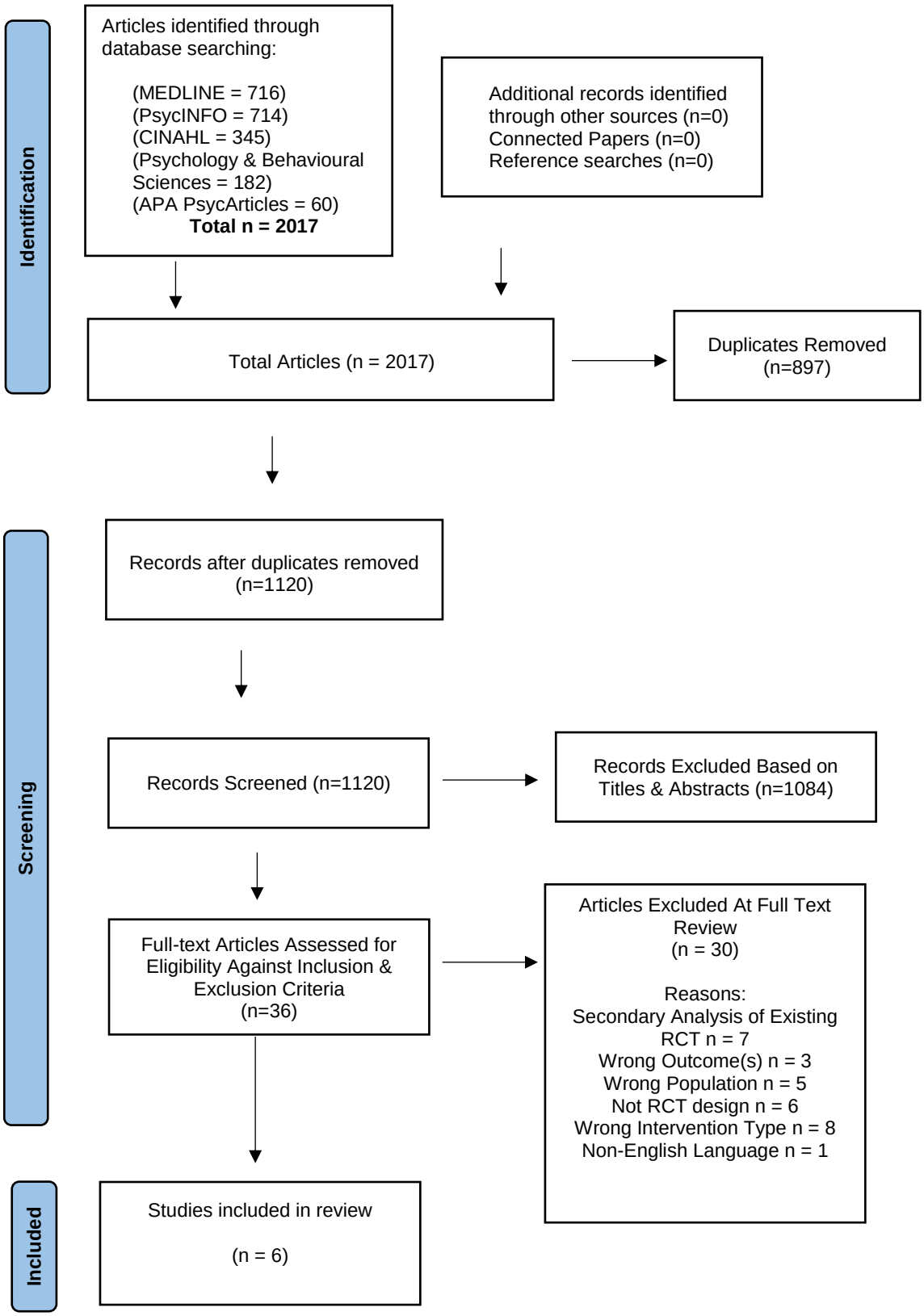

Figure 1. Study selection process in accordance with PRISMA guidelines

Quality Rating

The Cochrane Handbook recommend the Cochrane Risk-of-Bias tool (RoB2) to assess the risk of bias in systematic reviews of RCTs (Higgins et al., 2022). Although this is their recommendation, use of the RoB2 is not mandated. There is evidence to suggest that the RoB2 is highly complex and that without intensive training in its' application reliability is likely to be poor, even for highly experienced researchers (Minozzi et al., 2022). Instead, we used the Crowe Critical Appraisal Tool (CCAT; Appendix 1.2; Crowe & Sheppard, 2011). This decision was made to increase confidence in the reliability of the appraisal as both the researcher and their research supervisor are familiar with its application. This tool has a good construct validity and good inter-rater reliability with an interclass correlation coefficient of 0.83 (Crowe & Sheppard, 2011; Crowe, et al., 2012). A second-rater was not involved in the appraisal process.

A full description of the CCAT and the scoring guidelines can be read in Appendix 1.3.

Data Extraction

Data from the included studies was extracted and tabulated. This consisted of research design, participant demographics, intervention description and duration, outcome measures, and study results (Tables 2 & 3). We did not conduct a meta-analysis. Although the experimental intervention was the same in all trials, there was variation in comparators, sample populations (owing to differences in inclusion criteria's), as well as in the choice and timing of outcome measure(s). This clinical and methodological heterogeneity prevents us from pooling and comparing the data in a meaningful way.

Results

Search Results

The initial search returned 2017 results. After duplicates were removed and articles were screened by title and abstract, the full texts of 36 papers were assessed for eligibility. Six papers were selected as meeting the inclusion criteria and were included in the final review.

Four of the six papers (study 1, Mills et al., 2012; study 2; Ruglass et al., 2017; study 3a, Norman et al., 2019; and study 4a, Back et al., 2019) were reviewed with regards question 1.

Study 3b (Tripp et al., 2020) was a secondary analysis of the experimental data from study 3a (Norman et al., 2019) and study 4b (Lancaster et al., 2020) was a secondary analysis of the experimental data from study 4a (Back et al., 2020). However, due to employing additional and distinct statistical analyses that are relevant to the second review question, these two papers have been reviewed separately.

Study Characteristics

There were 413 participants across 6 studies. Study 3b (Tripp et al., 2020) and study 4b (Lancaster et al., 2020) were secondary analyses of experimental data collected during studies 3a (Norman et al., 2019) and 4a (Back et al., 2020), respectively, and included the same participants. All trials took place in America other than one, which took place in Australia (Mills et al., 2012).

5 studies were comprised of military veteran samples (studies 2, 3a, 3b, 4a, and 4b) and one was comprised of adults in the community (study 1). All studies included male and female participants; however, most participants were male.

Study Quality

The methodological quality of the included studies was generally high, with scores ranging between 78% and 83% on the CCAT (Table 1). Although there is no specified cut-off score, a higher percentage is considered indicative of a higher quality study, and consideration of individual criterion scores is important to its interpretation (Crowe et al., 2013; Appendix 1.3)

Paper	Preliminaries /5	Introduction /5	Design /5	Sampling /5	Data Collection /5	Ethical Matters /5	Results /5	Discussion /5	Total /40	Total %
(1) Mills et al., 2012	4	5	3	3	4	4	5	5	33	83
(2) Ruglass et al., 2017	4	5	5	4	5	3	3	4	33	83
(3a) Norman et al., 2019	5	4	3	4	3	4	5	4	32	80
(4a) Back et al., 2019	4	4	4	2	4	4	5	4	31	78
(3b) Tripp al., 2020	4	4	4	4	3	4	4	4	31	80
(4b) Lancaster et al., 2020	4	4	4	4	3	4	4	5	32	80

Table 1. CCAT Score

1. How effective is COPE in the treatment of co-occurring PTSD and SUD?

In all trials COPE led to significant improvements in PTSD symptoms from pre- to post-treatment that were significantly greater than controls. COPE also led to significant improvements in SUD symptoms; however, these improvements were not significantly greater than controls.

Study 1 (Mills et al., 2012) compared COPE & 'Treatment-as-Usual' (TAU) to TAU alone. Significant reductions in PTSD symptoms on the CAPS were observed in the COPE (mean difference, −38.24 [95% CI, −47.93 to −28.54]) and control group (mean difference, −22.14 [95% CI, −30.33 to −13.95]). However, COPE led to significantly greater reductions than controls (mean difference, −16.09 [95% CI, −29.00 to −3.19]). A mean difference of -16.09 also represents a clinically significant improvement on the CAPS.

No significant between-group difference was found in relation to improvement in severity of substance dependence (0.43 vs 0.52; incidence rate ratio, 0.85 [95% CI, 0.60 to 1.21).

Two studies (2 & 4a) compared COPE to a Relapse Prevention (RP), an evidence-based and manualised, cognitive-behavioural SUD only intervention.

Study 2 (Ruglass et al., 2017) compared COPE to RP, and an Active Monitoring Control Group (AMCG). At post-treatment, participants randomised to COPE and RP demonstrated greater reductions in PTSD symptoms on the CAPS, relative to AMCG (COPE-AMCG=−34.06, p<.001; RP-AMCG=−22.58, p=.002). Further analysis revealed that participants in the COPE group who met the full DSM-5 PTSD diagnostic criteria at baseline experienced greater reductions in symptoms relative to RP (COPE-RP =−21.32, 95% CI: −42.37 to −0.28, p=.047). However, among participants with sub-threshold PTSD, COPE was not

significantly different from RP (p=.92). COPE and RP were both superior to AMCG in reducing the days of primary substance misuse (COPE-AMCG = −0.97, p=.01; RP-AMCG=−2.07, p<.001). However, relative to COPE, RP demonstrated significantly greater improvements (RP-COPE = −1.10, p=.047). At 3-month follow-up, COPE and RP maintained their treatment gains and were not significantly different in terms of PTSD severity or days of primary substance use.

Study 4a (Back et al., 2019) compared COPE to RP. PTSD symptom severity on the CAPS and PCL-M were significantly reduced in both groups; however, relative to RP, COPE resulted in significantly greater reductions in CAPS (d=1.4, p < .001) and PCL-M scores (d=1.3, p=.01), as well as higher rates of PTSD diagnostic remission at follow-up (OR = 5.3, p <.01). At session 12, COPE participants scored approximately 25.6 points lower on the CAPS (d=1.4) and 13.3 points lower on the PCL-M (d=1.3) than RP participants, both of which represent clinically significant improvements. Both groups evidenced significant and comparable reductions in SUD severity during treatment, with improvement occurring more rapidly early in treatment (MΔ=−29.3%, −36.5%, for any substance use and alcohol use, respectively). These improvements were maintained during follow-up in both groups. In comparison to post-treatment, the average number of drinks per day between groups was similar at 3-months [M within-group Δ =−0.09 (SD=3.5)] and 6-months follow up [M within-group Δ=0.5 (SD=3.6)]. At 6-months a significant group difference favouring COPE in the average number of drinks per drinking day (COPE; M=4.5 vs. RP; M=8.3, p=.05).

Study 3a (Norman et al., 2019) compared COPE to 'Seeking Safety' (SS), a non-trauma focused, integrated intervention for PTSD & SUD. PTSD symptom severity on the CAPS was significantly reduced in both groups, with a significantly greater reduction in the COPE group (treatment × time interaction, −2.83; F3,233.1 = 4.92; Cohen d = 0.41; P = .002). The percentage of heavy drinking days was reduced in both conditions, but the difference was not

statistically significant (treatment × time interaction, 1.8%; F3, 209.9 = 0.18; Cohen d = 0.04; P = .91).

Study findings of effectiveness with regards research question 1 are summarised in Table 2.

Table 2. Summary of Study Findings of Effectiveness

Paper No.	Title/Author(s)/Year/ Country	Design & Conditions	Sample Characteristics	Primary Outcome Measure(s)	Statistical Analyses	Conclusions
1	**Title:** Integrated Exposure-Based Therapy for Co-occurring Post traumatic Stress Disorder and Substance Dependence: A Randomized Controlled Trial **Authors:** Mills KL, Teesson M, Back SE, Brady KT, Baker AL, Hopwood S, Sannibale C, Barrett EL, Merz S, Rosenfeld J, Ewer PL. **Year:** 2012 **Location:** Australia	**Design:** Randomised Controlled Trial Between-Groups Pre- and Post-Intervention **Conditions** **Experimental:** COPE & Treatment-as-Usual (TAU) **Control(s)**: TAU	**Sample:** 103 participants who met DSM-IV-TR criteria for both PTSD and substance dependence **COPE** (n = 55) Mean age = 33.4 (SD = 7.4) Male = 22 (40%) Female = 33 (60%) **TAU** (n = 48) Mean Age = 33.5 (SD = 8.6) Male = 17 Female = 31 (64.6%)	**PTSD:** CAPS **SUD:** CIDI Administered at baseline and at 9 month follow-up A change of 15 points on the CAPS scale and 1 dependence criterion on the CIDI were considered clinically significant	**CAPS** **COPE:** Baseline: M = 91.13 (87.03 to 95.23 95% CI) 9-Month Follow-Up: 52.89 (43.72 to 62.06, 95% CI) within-group mean difference (95% CI): Mean Difference = −38.24 (−47.93 to −28.54) **TAU:** Baseline: M = 89.38 (84.70 to 94.06, 95% CI) 9-Month Follow-Up: M = 67.23 (59.21 to 75.25, 95% CI) within group mean difference (95% CI): MD = −22.14 (−30.33 to −13.95) **Between-Group Mean Difference (95% CI)** The COPE + TAU group demonstrated a significantly greater reduction in PTSD symptom severity (mean difference, −16.09 [95% CI,−29.00 to −3.19]). **CIDI** **SUD Dependence Criteria Met (95% CI)** **COPE:** Baseline IRR = 5.33 (5.09 to 5.57) to 9-month follow- up 2.27 (1.58 to 2.96) within group change 0.43 (0.31 to 0.58) **TAU:** Baseline IRR = 5.58 (5.36 to 5.80) 9-Month Follow-Up 2.98 (2.27 to 3.69) Within group change 0.52 (0.41 to 0.66) The degree of change did not differ significantly between groups (0.43 vs 0.52; IRR, 0.8 [95% CI, 0.60 to 1.21])	COPE treatment was found to be efficacious in reducing PTSD symptom severity when combined with usual treatment; however, no other between-group differences were observed in relation to severity of substance dependence or in the types of substances being used. Importantly, participants randomized to receive the exposure based intervention did not demonstrate poorer substance use outcomes relative to those randomized to receive usual treatment only

Paper No.	Title/Author(s)/Year/ Country	Aim, Design & Conditions	Sample Characteristics	Primary Outcome Measure(s)	Statistical Analyses	Conclusions
2	**Title:** Concurrent treatment with prolonged exposure for co-occurring full or subthreshold posttraumatic stress disorder and substance use disorders: A randomized clinical trial **Authors:** Ruglass LM, Lopez-Castro T, Papini S, Killeen T, Back SE, Hien DA **Year:** 2017 **Location:** USA	**Aim**: The primary aim was to evaluate whether COPE and RP would show significantly greater reductions in PTSD & SUD symptom severity than AMCG; and secondarily, whether COPE would be superior to RP on PTSD and/or SUD outcomes **Design:** Randomised Controlled Trial Between-Groups Pre- and Post-Intervention **Conditions:**	**Sample:** 110 participants who met criteria DSM-IV criteria for full, or sub-threshold PTSD, and DSM-IV criteria for current or past (within 90 days) criteria for SUD **COPE:** (n = 39) Mean age = 43.08 (SD = 10) Male = 28 (71.8%) Female = 11 (28.2%) **RP:** (n = 43) Mean Age = 44.21 (SD=9.05) Male = 27 (62.8%) Female = 16 (37.2%) **AMCG:** (n = 28) Mean Age = 47.18 (SD=8.21) Male = 15 (53.6%) Female = 13 (46.4%)	**PTSD:** CAPS MPSS-SR **Substance Misuse:** SUI ASI	**<u>CAPS (M (SD))</u>** COPE: Baseline: 55.38 (16.40), 1-Month Follow-Up: 29.50 (27.88) COPE= −27.12, 95% CI: −35.84 to −18.40, p<.001 3-Month Follow-Up: 28.40 (23.09) COPE=−28.31, 95% CI: −36.01 to −20.60, p<.001 RP: Baseline: 57.70 (20.80), 1-Month Follow-Up: 29.00 (22.99) RP=−25.38, 95% CI: −33.12 to −17.64, p<.001 RP 3-Month Follow-Up: 28.91 (22.91) RP=−26.71, 95% CI: −34.28 to −19.14, p<.001 AMCG: Baseline: 46.39 (11.07), Post-Treatment: 41.89 (24.52) (Non-Significant & No Follow-Up Data) **<u>CAPS Between-Group Comparison</u>** There was no evidence of differential treatment effects as indicated by the lack of a Group-by-Time interaction (p=.86), and the lack of between-groups differences in CAPS scores at the follow-ups. **<u>MPSS-SR (M (SD))</u>** COPE: Baseline: M = 54.26 (SD = 24.60), Post-Treatment: M = 19.40 (SD = 17.70) COPE=−42.99, 95% CI: −56.30 to −29.68, p<.001 RP Baseline: M = 57.49 (SD = 24.33), Post-Treatment: M = 26.80 (SD = 20.87) RP=−31.51, 95% CI: −40.64 to −22.38, p<.001 AMCG: Baseline: M = 50.21 (SD=23.58). Post-Treatment: M = 40.00 (SD=28.10 Non-Significant **<u>MPSS-SR Between-Group Comparisons</u>** COPE & RP were both associated with significantly greater symptom reduction than AMCG (COPE-AMCG=−34.06, 95% CI: −51.36 to −16.75, p<.001; RP-AMCG=−22.58, 95% CI: −36.92 to −8.24, p=.002).	COPE and RP reduced PTSD and SUD severity in participants with PTSD+SUD. Findings suggest that among those with full PTSD, COPE improves PTSD symptoms more than a SUD-only treatment. Use of PE for PTSD was associated with significant decreases in PTSD symptoms without worsening of substance use .

		Experimental: COPE **Control(s):** Relapse Prevention (RP) Active Monitoring Control Group (AMCG)			The difference between COPE and RP was non-significant (COPE-RP=−11.48, 95% CI:-27.62 to 4.67, p=.16). **<u>SUI (M(SD))</u>** COPE: Baseline: M=3.90 (SD=2.69), Post-Treatment: M=1.60 (SD=2.46) COPE=−2.31, 95% CI: −3.23 to −1.39, p<.001 RP: Baseline: M=4.05 (SD=2.35), Post-Treatment: M=0.40 (SD = 0.52) RP=−3.28, 95% CI: −4.03 to −2.53, p<.001 AMCG: Baseline: M=3.79 (SD=2.27), Post-Treatment: M=2.85 (SD=2.48) Non-Significant Change **<u>SUI Between-Group Comparisons</u>** COPE & RP demonstrated significantly greater improvements relative to AMCG (COPE-AMCG=−0.97, 95% CI: −1.72 to −0.22, p=.01; RP-AMCG=−2.07, 95% CI: −2.92 to −1.21, p<001). RP demonstrated significantly greater improvements relative to COPE (RP-COPE=−1.10, 95% CI: −2.18 to −0.02, p=.047) **<u>ASI (M (SD))</u>** COPE: Baseline: M=18.23 (SD = 10.55), 1-Month Follow-Up: M=8.65 (SD=11.34) COPE=−9.67, 95% CI: −13.65 to −5.73, p<.001 3-Month Follow-Up: M=8.08 (SD=9.95) COPE=−10.45, 95% CI: −14.27 to −6.63, p<.001 RP: Baseline: M=18.16 (SD=10.31), 1-Month Follow-Up: M=3.45(SD=5.64) RP=−13.40, 95% CI: −16.97 to −9.83, p<.001 3-Month Follow-Up: M=3.88 (SD=7.38) RP=−13.36, 95% CI: −17.97 to −8.74, p<.001 **<u>ASI Between-Group Comparisons</u>** There was no evidence of differential treatment effects as indicated by the lack of a Group-by-Time interaction and the lack of between-groups differences in primary substance use at the follow-ups	

Paper No.	Title/Author(s)/Year/ Country	Aim, Design & Conditions	Sample Characteristics	Primary Outcome Measure(s)	Statistical Analyses	Conclusions
3a	**Title** Efficacy of Integrated Exposure Therapy vs Integrated Coping Skills Therapy for Comorbid Posttraumatic Stress Disorder and Alcohol Use Disorder: A Randomized Clinical Trial **Author(s)** Norman SB, Trim R, Haller M, Davis BC, Myers US, Colvonen PJ, Blanes E, Lyons R, Siegel EY, Angkaw AC, Norman GJ, Mayes T **Year** 2019 **Location** USA	**Aim** To compare the efficacy of COPE therapy with Seeking Safety (SS) therapy, in reducing PTSD & SUD symptoms **Design** Randomised Controlled Trial Between-Groups Pre- and Post-Intervention **Conditions** **Experimental** COPE **Control(s)** Seeking Safety (SS)	**Sample** 119 veterans experiencing concurrent who met PTSD & SUD DSM-IV criteria **COPE** (n =63) Mean age = 43.2 (SD=13.5) Male = 56 (88.9%) Female = 7 (11.1%) **Seeking Safety** (n = 56) Mean Age = 39.7 (SD=11.3) Male = 52 (91.1%)	**PTSD** CAPS **SUD** TLFB (% of Heavy Drinking Days & % of Days Abstinent)	**<u>CAPS</u>** **COPE** Baseline: 43.2 (40.0-46.4), Post-Treatment: 25.8 (22.1-29.6), 3-Month Follow-Up: 26.4 (22.6-30.3) & 6-Month Follow-Up: 22.5 (18.2-26.8) **SS** Baseline: 42.1 (38.7-45.5). Post-Treatment: 32.9 (29.3-36.6), 3-Month Follow-Up: 31.0 (27.0-35.1) & 6-Month Follow Up: 29.8 (25.6-33.9) **<u>CAPS Between-Group Comparisons</u>** CAPS scores decreased in both arms, with a significantly greater reduction observed in the COPE group (treatment × time interaction, −2.83; F3,233.1 = 4.92; Cohen d = 0.41; P = .002) Rates of PTSD remission (CAPS score <12) were also compared for participants at each time point using $\chi 2$ tests. COPE demonstrated significantly greater rates of PTSD remission at post-treatment ($\chi 2$ = 3.96; P = .047) and at 3-month follow-up ($\chi 2$ = 4.72; P = .03) There was a marginal but non-significant group difference in favour of COPE at 6-month follow-up ($\chi 2$ = 3.08;P = .08) **<u>TLFB - % of Heavy Drinking Days (PHDD ((95% CI))</u>** **COPE** Baseline: 52.5 (46.5-58.6), Post-Treatment 21.0 (13.4-28.6), 3-Month Follow-Up 14.2 (6.9-21.4) & 6-Month Follow-Up 20.2 (11.9-28.5) **SS** Baseline: 50.4 (44.1-56.7). Post-Treatment: 17.4 (10.4-24.5), 3-Month Follow-Up: 15.0 (7.1-22.8) & 6-Month Follow-Up: 19.9 (12.1-27.6) **<u>TLFB – Days Abstinent (PDA (95% CI))</u>** **COPE** Baseline: 34.3 (27.1-41.6). Post-Treatment: 67.5 (58.9-76.1), 3-Month Follow-Up: 65.6 (57.0-74.2) & 6-Month Follow-Up: 66.2 (56.5-75.9)	COPE was more efficacious than SS with regards PTSD outcomes and did not lead to a worsening of SUD symptoms.

			Female = 5 (8.9%)		**SS** Baseline: 31.2 (23.5-38.8), Post-Treatment: 63.1 (54.9-71.4), 3-Month Follow-Up: 68.4 (59.3-77.4) & 6-Month Follow-Up: 64.0 (54.8-73.3) **<u>Between-Group Comparisons</u>** PHDD decreased in both arms, but between-group differences were non-significant (treatment × time interaction, 1.8%; F3,209.9 = 0.18; Cohen d = 0.04; P = .91). The PDA had the same pattern of results as the PHDD. COPE was more efficacious than SS with regards PTSD outcomes and did not lead to a worsening of SUD symptoms.	

Paper No.	Title/Author(s)/Year/ Country	Aim, Design & Conditions	Sample Characteristics	Primary Outcome Measure(s)	Statistical Analyses	Conclusions
4a	**Title** Concurrent treatment of substance use disorders and PTSD using prolonged exposure: A randomized clinical trial in military veterans **Author(s)** Back SE, Killeen T, Badour CL, Flanagan JC, Allan NP, Ana ES, Lozano B, Korte KJ, Foa EB, Brady KT. **Year** 2019 **Location** USA	**Aim** To evaluate the efficacy of COPE among military veterans vs RP **Design** Randomised Controlled Trial Between-Groups Pre- and Post-Intervention **Conditions** **Experimental** COPE **Control(s)** RP	**Sample** 81 military veterans experiencing concurrent PTSD & SUD according to DSM-IV criteria **COPE** (n = 54) Mean age = 39.7 (SD=11) Male = 50 (92.6%) Female = 4 (7.4%) **RP** (n = 27) Mean Age = 41.9 (SD=10.3) Male = 23 (85.2%) Female = 4 (14.8%)	**PTSD** CAPS PCL-M **SUD** TLFB	**<u>CAPS – Completer Sample (All 12 Sessions)</u>** **COPE** Baseline: M=77.4 (SD=18.1, Mid-Treatment: M=45.2 (SD=18.5) , Post-Treatment: M=26.2 (SD=19.4) Baseline to Post-Treatment: [M within-group Δ=−51.2; 95% CI (−59.7, −42.8)] **RP** Baseline: M=84.7 (SD=17.8), Mid-Treatment: M=65.9 (SD=28.6), Post-Treatment: M=49.7 (SD=25.3) Baseline to Post-Treatment: CAPS (M within-group Δ=−35.9; 95% CI (−48.8, −23.0)) **<u>ITT Between-Groups Comparison</u>** A significantly higher proportion of participants in COPE, as compared to RP, achieved diagnostic remission and no longer met criteria for PTSD [59.3% vs. 22.2%, p=.002; OR=5.3; 95% CI (1.8, 15.7)]. **<u>PCL-M</u>** COPE: Baseline to Post-Treatment (M within-group Δ=−22.3; 95% CI (−29.3, −15.3)] RP: Baseline to Post-Treatment: (M within-group Δ=−10.9; 95% CI (−18.0, −3.9)] At session 12, COPE participants scored approximately 25.6 points lower on the CAPS (d=1.4) and 13.3 points lower on the PCL-M (d=1.3) than RP participants. This is a clinically significant between-groups difference. PTSD treatment gains were maintained during follow-up with only slight decay at 3-months [CAPS, M within-group Δ=7.6 (SD=22.3); PCL-M, M within-group Δ=3.3 (SD=11.2)], and 6-months follow-up [CAPS, M within-group Δ=4.1 (SD=33.6); PCL-M, M within-group Δ=2.4 (SD=12.0)], with no significant group differences. **<u>TLFB</u>** Both groups evidenced significant and comparable reductions in SUD severity during treatment. At 6-months' follow-up, participants in COPE evidenced significantly fewer drinks per drinking day than participants in RP (p=.05)	In this sample of veterans with extensive military related trauma, COPE resulted in significantly greater reductions in PTSD severity, higher rates of PTSD diagnostic remission, and comparable reductions in SUD, as compared to RP

Key to Abbreviations Used in Tables 2 & 3.

Δ: Delta ASI: Addiction Severity Index CAPS: Clinician Administered PTSD Scale CI: Confidence Interval CIDI: Composite International Diagnostic Interview COPE: The Concurrent Treatment of PTSD & SUD using Prolonged Exposure Therapy ES: Effect Size	IRR: Incidence Rate Ratio ITT: Intent-to-Treat Analysis MPSS-SR: Modified PTSD Symptom Scale: Self-Report OR: Odds Ratio PCL-C: PTSD Checklist – Civilian Version PCL-M: PTSD Checklist – Military Version PCL-S: PTSD Checklist – Specific Trauma Version	PTSD: Post-Traumatic Stress Disorder RP: Relapse Prevention SD: Standard Deviation SS: Seeking Safety SUD: Substance Misuse Disorder(s) SUI: Substance Use Inventory TLFB: Timeline Follow-Back

2 Does the initiation of exposure therapy via COPE lead to greater exacerbation of the symptoms of PTSD and/or SUD, relative to non-trauma focused comparators?

Two secondary analyses of existing RCT data found that the initiation of exposure therapy via COPE did *not* lead to greater symptom exacerbation than non-trauma focused comparators.

Study 3b (Tripp et al., 2020) was a secondary analysis of experimental data from study 3a (Norman et al., 2019). Using the reliable deterioration calculation as described by Devilly & Foa (2001) the authors evaluated whether there were between-group differences in the frequency of participants who experienced a meaningful exacerbation of PTSD, SUD, depression, or Suicidal Intent (SI) from session 3 – 5 (to coincide with the initiation of exposure-therapy in COPE).

Across both conditions (n = 78), 15.3% (n = 12) participants experienced a clinically meaningful exacerbation (based on a reliable exacerbation of 6.11 points on the PCL-5). Eight participants (20.5%) in the COPE group exhibited a clinically meaningful exacerbation in PTSD symptoms versus four (10.3%) in the SS control (OR = 2.26; 95% CI = .62, 8.24; p = .22). This difference was non-significant.

There were no significant differences between treatments in number of participants who exhibited clinical exacerbation in PTSD, depression, alcohol use, or SI: $X2$(N = 78) = .01–1.58, ps >.05, Cs = .01–.14.

Study 4b (Lancaster et al., 2020) was a secondary analysis of experimental data from study 4a (Back et al., 2019). Using reliable change analyses, the authors assessed the frequency of reliable exacerbations in PTSD (CAPs & PCL-M) & SUD (TLFB) symptoms. Chi-squared (or Fisher's exact) tests were performed to

evaluate differences between COPE and RP in the frequency of symptom exacerbation on each outcome between all treatment sessions. Of 44 analyses carried out, only one significant difference emerged. From session 10 to 11, participants were more likely to experience reliable exacerbation of PTSD symptoms if they were in RP rather than COPE (Fisher's exact test, p = .006, 31% in RP versus 0% in COPE). However, the authors note that given the number of analyses conducted, this single statistically significant result should be interpreted with caution.

A further analysis that only included treatment completers found no between group differences in the average number of exacerbations for depression symptoms (t(39) = −1.08, p = .29), the per cent of days using any psychoactive substance (t(39) = −1.16, p = .25), or the per cent of days using alcohol (t(39) = −1.06, p = .29). However, there was a tendency for participants receiving COPE to experience slightly fewer exacerbations of PTSD symptoms (COPE; mean = 1.04, SD = 1.04), relative to RP (RP; mean = 1.77, SD = 1.17; t(39) = −2.03, p = .05, d = .67).

Study findings regarding clinical exacerbations are summarised in Table 3.

Paper No.	Title/Author(s)/Year/ Country	Aim, Design & Conditions	Sample Characteristics	Primary Outcome Measure(s)	Statistical Analyses	Conclusions
3b	**Title** Does exposure exacerbate symptoms in veterans with PTSD and alcohol use disorder? **Author** Tripp JC, Haller M, Trim RS, Straus E, Bryan CJ, Davis BC, Lyons R, Hamblen JL, Norman SB. **Year** 2020 **Location** USA	**Aim** To examine whether initiating exposure (via COPE) would cause exacerbation of PTSD, alcohol use, depression, or suicidal ideation (SI) among patients with PTSD/SUD participating in COPE **Design** Randomised Controlled Trial – Secondary Analysis Within-Participant Reliable Change Analysis **Conditions** **Experimental:** COPE **Control(s**): Seeking Safety (SS)	**Sample** 81 veterans experiencing concurrent PTSD & SUD according to DSM-IV criteria who completed at least 5 treatment sessions (capturing the pre- post-window for the start of exposure in COPE). **COPE** (n = 40) **SS** (n = 41) Between-Group Demographic Information Not Available	**PTSD** PCL-5 **SUD** SUI	**PCL-5** Reliable Exacerbation: 6.11 points on the PCL-5 N (%) exacerbated in COPE: 8 (20.5%) N (%) exacerbated in SS: 4 (10.3%) Odds Ratio (95% CI) 2.26 (0.62, 8.24) Based on a reliable exacerbation of 6.11 points in PTSD symptoms on the PCL-5, eight individuals in COPE exhibited clinically meaningful exacerbation during treatment (20.5% within COPE) versus four individuals in SS (10.3% within SS; OR = 2.26; 95% CI =0 .62, 8.24; p 0 .22). This difference was non-significant. **SUI** Reliable Exacerbation: 1.75 points on the SUI N (%) exacerbated in COPE: 3 (7.5%) N (%) exacerbated in SS: 1 (2.6%) Odds Ratio (95% CI) 3.00 (0.30), 30.18) This between-group difference was non-significant (2.6% within SS; OR = 3.00; 95% CI = 0.30, 30.18); p = >0.05)	The authors found that few participants across both conditions experienced exacerbations in symptoms. There were no significant differences between-groups in terms of symptom exacerbations.

Paper No.	Title/Author(s)/Year/ Country	Aim, Design & Conditions	Sample Characteristics	Primary Outcome Measure(s)	Statistical Analyses	Conclusions
4b Secondary analyses of data collected during Back 2019 RCT	Title: Does trauma-focused exposure therapy exacerbate symptoms among patients with comorbid PTSD and substance use disorders? Authors: Lancaster, C. L., Gros, D. F., Mullarkey, M. C., Badour, C. L., Killeen, T. K., Brady, K. T., & Back, S. E. Year: 2020 Location: USA	**Aim** This study compared the exacerbation of PTSD & SUD symptoms among participants with comorbid PTSD and SUD who received either COPE vs RP **Design** Randomised Controlled Trial Within-Participant Session-by-Session Reliable Change Analyses **Conditions** **Experimental** COPE **Control(s)** RP	**Sample** Military veterans with co-occurring PTSD & SUD, according to DSM-IV criteria (n=71) **COPE** (n = 49) **RP** (n = 22) Between-Group Demographic Information Not Available **PTSD** CAPS **SUD** PCL-M	**PTSD** CAPS **SUD** PCL-M	Chi-squared (or Fisher's exact) tests were performed to evaluate differences between COPE and RP in the frequency of symptom exacerbation on each outcome between each treatment session. Of 44 analyses, just one significant difference emerged. From session 10 to 11, participants were more likely to experience reliable exacerbation of PTSD symptoms if they were in RP rather than COPE (Fisher's exact test, p = .006, 31% in RP versus 0% in COPE).	The findings from this study add to a growing literature demonstrating that exposure-based treatments for PTSD does not increase the risk of symptom exacerbation relative to a non-exposure based comparator. The authors concluded that COPE can be used safely and effectively in patients with comorbidities such as alcohol and drug use disorders

Table 3. Summary of study findings regarding clinical exacerbations.

Discussion

The primary aim of this review was to synthesise evidence of the efficacy of COPE in the treatment of co-occurring PTSD & SUD.

A secondary aim was to evaluate whether the initiation of exposure therapy via COPE lead to greater symptom exacerbation relative to non-trauma focused comparators.

1 How effective is COPE in the treatment of co-occurring PTSD & SUD relative to various active comparators?

4 studies (1, 2, 3a, and 4a) were reviewed with regards question 1.

In all 4 trials both COPE and control conditions led to significant improvements in PTSD & SUD outcomes. Relative to controls, the reductions in PTSD symptoms in COPE were significantly greater. Although COPE also resulted in significant improvements in SUD symptoms, these improvements were not significantly greater than controls.

All 4 primary studies were rated as being of high methodological quality.

Previous reviews included studies of varying quality, experimental designs, and often did not include active control conditions. This review only included randomised, between-group, experimental research designs, and in 3 (2, 3a, and 4a) of 4 (study 1) studies COPE was compared to a manualised evidence-based intervention, matched for time and therapeutic attention. However, the lack of a 'no-treatment' control condition in any trials prevents us from ruling out that the observed reductions in symptoms did not simply reflect natural fluctuations over time or the non-specific effects of intervention.

COPE is a manualised treatment and all studies included a detailed description of the number, duration, and setting of sessions; and clear information on the therapists, their professions, and level of competence, all of which increases the likelihood that reliable and valid replication studies can take place. All trials also included blind and independent treatment fidelity assessments that were rated as 'good' to 'excellent'. High treatment fidelity reduces the risk of the introduction of random and unintended variation in intervention delivery, which can affect statistical power, and further strengthens our ability to draw accurate conclusions regarding intervention efficacy (Sanetti et al., 2021).

A further strength of all trials was the use of Intent-to-Treat statistical analyses. ITT analyses include data for all participants within a trial, based on the group they were initially (and randomly) allocated to, regardless of whether they dropped out, fully adhered to treatment, or switched to an alternative treatment mid-trial. ITT analyses are often used to assess clinical effectiveness because they mirror actual practice, when not everyone adheres to the treatment, and the treatment people have may be changed according to how their condition responds to it. If an intervention is truly effective, ITT analyses should provide an unbiased estimate of the efficacy of the intervention at the level of adherence in the study. ITT analyses are more conservative, and as such, increases confidence in the results observed here (McCoy, 2017).

Although the overall quality of the studies was high, the results must be interpreted within the context of the limitations of each paper, which are outlined below.

All studies included a priori power calculations, however, difficulties with recruitment led to 3 of 4 studies being underpowered. A study with low statistical power has a reduced chance of detecting a true treatment effect; however, it also reduces the likelihood that a statistically significant result reflects a true treatment effect. The consequences of this include the over-estimation of effect sizes, and the low reproducibility of results. In the context

of intervention research that could lead to the implementation of treatment(s) to vulnerable populations, an underpowered sample adds is also an ethical issue (Button et al., 2013).

Aside from measures of treatment outcome, reasons for and rates of treatment attrition is an important indicator of an intervention's acceptability. High treatment non-completion rates remain one of the largest barriers to treatment outcomes, and attrition was high across studies. However, it is important to note that rates of attrition among studies of individual SUD and/or PTSD interventions are also high, and comparable to those reported here (e.g., Lewis et al., 2020; Roberts et al., 2015). Attrition was evaluated statistically in all studies, and although the attrition rate was significantly higher among those randomised to receive COPE in 1 study (3), there were no between-group differences in baseline characteristics or pre-treatment symptom severity, and the reason for this result is unclear.

Lastly, almost all participants were white, male, western, military veterans experiencing combat-related PTSD. Research has demonstrated differential rates of response to treatment between civilian (often female samples) and military populations (predominantly male), and a variety of ethnocultural variables have been shown to exercise influence over the clinical parameters of PTSD and SUD (i.e., onset, course, and prognosis) and response to intervention (Marsella, 2010). As such, it is unclear whether the results can be generalised to populations which include women, those from a non-Western ethnocultural background and/or those who have experienced non-combat related trauma.

2 Does the initiation of exposure therapy via COPE lead to greater session-to-session symptom exacerbation than non-trauma focused comparators?

2 studies (3b; 4b) were reviewed with regards question 2.

People experiencing co-occurring PTSD & SUD are typically offered sequential treatment, whereby SUD intervention is delivered first, and trauma-focused work is deferred until this treatment is complete and abstinence from substance misuse has been maintained. The model was derived from the 'Pandora's Box' hypothesis, which posits that any engagement in trauma-focused work in the early stages of SUD intervention is likely to exacerbate the symptoms of both conditions, due to the patient not yet possessing the requisite self-management or coping strategies (Souza & Spates, 2008). Although the COPE outcome literature is promising, clinical trials have primarily relied upon mean-based statistics to evaluate efficacy. While this provides information about the overall efficacy of an intervention, reliance on means does not provide information about individual change, including the prevalence of reliable and/or clinically meaningful symptom exacerbation among individual study participants.

Two studies (3b, 4b) sought to address this directly by conducting secondary analyses of experimental data from trials 3a and 3b. Neither study found a statistically significant association between the initiation of exposure therapy (via COPE) and an exacerbation of symptoms, relative to non-trauma focused comparators. Notably, this included no increased risk directly after sessions in which exposure-therapy was implemented. Although the difference in symptom exacerbation between groups was non-significant, in study 3b, double the number of participants in COPE exhibited a clinically meaningful exacerbation in symptoms relative to controls (8; 20.5% vs 4; 10.3%). This pattern of difference in addition to the small sample size mean that these findings should be interpreted with caution.

These studies are the first to evaluate within-participant symptom exacerbation among people with co-occurring PTSD & SUD. However, studies of this kind have been conducted among participants receiving exposure therapy for PTSD without SUD (Larsen et al., 2016). The overall frequency of symptom exacerbation among people with PTSD & SUD are slightly higher (55%) than

among those experiencing PTSD without SUD (20%; Larsen et al., 2016). There are several potential explanations for the slightly higher rates observed here. Firstly, study 3b limited their data analysis to the two sessions within which exposure therapy was initiated, while study 4b analysed symptom exacerbation after every single session until treatment was completed. Larsen et al., (2016) evaluated symptom exacerbation among participants experiencing PTSD without SUD on a bi-weekly basis, beginning at session 4 (after exposure was initiated), and it is possible that the trials reviewed here were able to evaluate exacerbation on a more sensitive basis. Of course, another potential explanation is that people with PTSD & SUD represent a more complex patient population than people with PTSD without SUD. Irrespective of this, the results demonstrate that people who receive COPE, who experience increased PTSD symptoms at some point during treatment, still experience significant reductions in PTSD symptoms by the time treatment is complete.

Both studies were rated as being of high quality.

A strength of both studies is their choice of design, which provides important information about within-treatment changes for study participants. A more granular understanding of what happens during treatment at the individual level may be more persuasive to clinicians that exposure-based therapies can be safely and effectively implemented whilst patients are still using substances, or are recently abstinent, and that trauma-focused interventions are not more likely to lead to symptom exacerbations than non-trauma focused interventions.

In terms of limitations, in study 3b there were very low rates of symptom exacerbation in both groups, which made it difficult to evaluate between-group differences. Another limitation was the high treatment attrition rate. Although the between-group differences were non-significant, a slightly higher number of participants dropped out of COPE treatment than control conditions in both trials. Both studies conducted their statistical analysis to coincide with the

initiation of exposure in COPE, and it is possible that participants in the COPE group dropped out of therapy prior to the initiation of exposure due to anticipatory anxiety regarding the potential consequences of this work.

Strengths & Limitations of Review Process

A strength is the sole inclusion of RCT designed studies comparing COPE to active, manualised control interventions. Treatment fidelity in all studies was high, which should enable reliable replication. Lastly, no participants withdrew from the research due to adverse incidents or reactions, and this review is the first to provide evidence that the initiation of COPE does not lead to the greater exacerbation of symptoms than non-trauma-focused comparators.

In terms of limitations, a single researcher defined the inclusion/exclusion criteria, conducted the searches, selected the studies, and was responsible for their appraisal. It was not possible to identify a second-rater, which could impact the inter-rater reliability of the results. The narrow focus of the review questions and the parameters of the inclusion and exclusion criteria mean that some potentially important variables that could influence clinical outcomes were not subject to evaluation; for example, the moderators of clinical change, or the profile of residual symptoms experienced by participants post-treatment. Moreover, trials with positive findings are more likely to be published than trials with negative or null findings (Hopewell et al., 2009). As this review exclusively included papers published in peer-reviewed journals our review is at risk of publication bias.

Other limitations relate to review sample itself. 3 of 4 studies were underpowered, which is particularly important when it comes to between-group comparisons where smaller effects are to be expected. Sample populations were primarily white, military men, and as such, the generalisability of the findings to other demographics is significantly limited. Lastly, treatment completion and assessment completion across studies was

low, which can introduce a host of biases even when ITT analyses are conducted (i.e., biases due to data not missing at random; Graham, 2009).

Clinical Implications

Despite these limitations, the results provide promising evidence that people experiencing co-occurring PTSD & SUD can both tolerate and benefit from integrated, trauma-focused treatment, without experiencing a greater exacerbation in the symptoms of PTSD or SUD than non-trauma focused alternatives. Participants in all trials experienced improvements on all primary outcome measures, despite the majority continuing to use substances throughout treatment, which also suggests that abstinence is not necessary to achieve positive therapeutic outcomes. Importantly, the two secondary analyses demonstrate that COPE does not result in clinical exacerbation to a greater degree than non-trauma focused control interventions and provides evidence against the Pandora's Box hypothesis. COPE is an intervention derived from PE and RP; two existing interventions most clinical psychologists should already be trained in the delivery of. This suggests that there is the significant potential to upskill the existing workforce in the delivery of COPE, even within the context of limited resources and increasing demand. Given that ICD-11 CPTSD is a new diagnostic category, it will take a substantial amount of time before an evidence-base accumulates regarding its treatment. Although the COPE intervention literature is based on PTSD criteria, CPTSD is more prevalent than PTSD among military populations in general, and this increased prevalence is even greater among clinical military samples (Murphy et al., 2020). This suggests that at least some participants in these studies would meet CPTSD criteria. Given that existing 'gold-standard' interventions for either condition alone have been shown to be less effective for people with more complex presentations, the finding that COPE led to significant improvements in PTSD & SUD outcomes in all 4 trials suggests that COPE holds promise as an intervention for people experiencing CPTSD. When considering the place of COPE in clinical practice relative to existing phase-based or single element

interventions we are limited in our ability to draw firm conclusions. As stated previously, it is likely that several participants in all trials would meet CPTSD criteria, and if COPE were found to be effective for this population it would suggest that a safety & stabilisation period may not be necessary. Alternatively, it could be that the participants with more complex presentations experienced a deterioration in symptoms as a consequence of not taking part in safety & stabilisation, which may in part explain the high attrition rates.

Recommendations for Future Research

Although it is likely that it all 4 COPE trials are likely to have included participants with 'simple' and 'complex' trauma presentations and we have discussed the results with this in mind, it is important to emphasise that CPTSD is not identical to PTSD and its co-morbidity but is a distinct disorder with a specific symptom profile. Future studies would benefit from including samples from both diagnostic categories, which may help delineate what works for whom by identifying which clinical characteristics are associated with greater improvements in exposure- or coping-based interventions, which could facilitate the development of personalised patient/intervention matching.

Most samples within the published literature are dominated by white males from a Western cultural background who are experiencing combat related PTSD. Future research should assess the impact of gender, co-morbid diagnoses, ethno-racial factors, and the type of trauma experienced, on clinical outcomes, by incorporating diverse samples more representative of the wider PTSD population to which results would ideally generalise. Future studies would also benefit from the inclusion of a 'no-treatment' control condition to allow increased confidence that improvements do not reflect spontaneous recovery.

Lastly, consistently low treatment completion suggests that psychology has yet to develop intervention options and/or study retention methods that are either appealing or compelling enough to offset the substantial emotional

dysregulation (Westphal et al., 2017), social instability (Simpson et al., 2019), and avoidance (Simpson et al., 2006) common for people with co-occurring PTSD & SUD. Future studies should seek include enhanced batteries of pre-treatment measures that could be used to predict treatment non-completion among study participants, and/or should co-design their research to include people with lived experience of PTSD & SUD.

Conclusions

A small number of studies of high methodological quality provide evidence that COPE, an integrated, trauma-focused intervention for co-occurring PTSD & SUD, is more effective than non-trauma focused interventions with regard PTSD outcomes. The results also suggest that relative to controls, COPE does not result in an exacerbation of PTSD and/or SUD symptoms, and that abstinence from substances is not necessary to experience positive therapeutic outcomes. Our results suggest that people with co-occurring PTSD & SUDs may benefit from relatively readily available, manualised interventions that could be delivered by the current clinical psychology workforce without additional training. However, future research regarding how to optimise patient-treatment matching and an increased understanding of role of trauma-complexity in clinical outcomes required, and there is a critical need to further improve treatment engagement and treatment completion rates among this population.

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Chapter 2: Major Research Project

The Factors Associated with Treatment Non-Completion among Male Prisoners Accessing Psychological Mental Health Interventions

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Plain Language Summary

Title

The Factors Associated with Treatment Non-Completion among Male Prisoners Accessing Psychological Mental Health Interventions

Background

Prisoners are more likely to experience mental health problems than non-offenders and these problems are associated with various other factors, including: self-harm, violence inside prison, and an increased risk of re-offending upon release. Researchers studying the effectiveness of mental health interventions in prisons often note that a high number of prisoners do not complete treatment and have suggested that the reasons for this should be researched.

Research Questions

1. How prevalent is psychological treatment non-completion in a sample of long-term male prisoners?
2. What characteristics are associated with treatment non-completion in prisoners?

Method

This project made use of data that is routinely collected within the Psychological Therapies service within Her Majesty's Prison (HMP) Shotts, a prison for long-term (>4 years) adult male offenders. This project was approved by NHS Lanarkshire Research & Development, and the Scottish Prison Service (SPS) Ethics Committee. The study evaluated the prevalence of treatment non-completion, and whether there were any specific clinical, demographic, or institutional factors associated with not completing treatment. No prisoners were required to actively participate in this project as all data required for the statistical analysis was contained within existing databases.

Main Findings

11 of 27 (40.74%) people in our sample did not complete treatment. The results indicated that there was no significant association between age and treatment completer status (i.e., treatment complete versus treatment non-complete). The results indicated that patients were less likely to complete treatment when they had more severe symptoms, if they accrued disciplinary reports during treatment, or accrued a report for being under the influence of substances during treatment. We also found that participants who were actively receiving support to the prison addictions service, which is primarily for the purposes of opioid substitution, were also less likely to complete treatment.

Conclusions

This study is the first to investigate psychological clinical treatment non-completion in a prisoner population. The significant findings are consistent with similar research conducted in other settings and/or with different populations. However, significant limitations in the quality of the data prevent us from being able to generalise our results more widely. The study did provide important information that can be used to improve the design of larger scale studies of this kind in future.

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Abstract

Background

Studies evaluating the effectiveness of psychological interventions among offenders often report high levels of treatment non-completion; however, little is known about the factors which contribute to this.

Aims

To investigate the factors associated with treatment non-completion in a sample of adult male prisoners.

Method

A non-experimental retrospective research design was used to investigate whether there are any significant associations between various demographic, behavioural, and clinical characteristics, and treatment completer status (i.e., treatment complete versus non-complete). The study made use of routine clinical data from the Psychological Therapies Service in one prison in Scotland collected between July 2017 and March 2020.

Results

In our sample 11 of 27 (40.74%) people in our sample did not complete treatment. The results indicated that there was no significant association between age and treatment completer status (i.e., treatment complete versus treatment non-complete). The results indicated that patients were less likely to complete treatment when they had more severe symptoms, if they accrued disciplinary reports during treatment, or accrued a report for being under the influence of substances during treatment. We also found that participants who were actively receiving support to the prison addictions service, which is primarily for the purposes of opioid substitution, were also less likely to

complete treatment. However, our small sample size led to wide confidence intervals which limit the precision of our conclusions.

Conclusions

Although the results are generally consistent with the existing treatment non-completion literature, significant limitations prevent us from drawing any firm inferences about our results. However, the study does provide important information to aid the design of future studies of this kind.

Keywords

Treatment Non-Completion, Prisoner Mental Health, Prisoner Attrition

Introduction

Prisoners experience mental health problems that are often severe, complex, co-morbid with other conditions, and at a higher rate than the general population (Fazel et al., 2016). These problems are associated with an increased risk of self-harm (Hawton et al, 2014), suicide (Fazel et al, 2016), violence inside prison (Gonçalves et al., 2014) and an increased risk of recidivism upon release (Baillargeon et al., 2009).

In Scotland, NHS psychological therapies services have adopted a matched-stepped care service delivery model. Stepped Care is a system of delivering and monitoring mental health treatment so that the most effective, yet least resource intensive treatment, is delivered first, only "stepping up" to intensive/specialist services as required and depending on the level of patient distress or need. For stepped-care to be effective, an appropriate range of evidence-based interventions of differing intensity of need are required. For example, 'low intensity' interventions such as bibliotherapy or self-help, through to more 'high intensity' treatments such as individual psychological therapy.

In prisons, psychological treatment delivery is guided by a combination of the 'Forensic Mental Health Matrix' (Scottish Government, 2014) and the larger, generic services 'Matrix' (Scottish Government, 2014), which outlines evidence-based treatment for variety of psychological needs based on the above matched/stepped care model. The 'Forensic Matrix' was published in recognition that a forensic clinical population are likely to have additional treatment needs related to their offending behaviours and provides a summary of the available evidence for these problems. The matched-stepped care model has been implemented across forensic mental health services in Scotland and a key next step is to empirically evaluate its effectiveness and applicability.

A lack of prison-specific research means that most interventions delivered to prisoners are derived from the generic 'Matrix', which was compiled from research comprising non-offender participants in the community . The only comprehensive systematic review and meta-analysis analysis of prisoner clinical outcomes (Yoon et al., 2017) suggests that cognitive-behavioural and mindfulness-based therapies are moderately effective overall. However, myriad limitations inherent in most studies limit the generalisability of the findings. For example, the largest effect sizes were observed in studies with no active or waitlist-control groups and improvements in symptoms may have reflected natural fluctuations over time, non-specific benefits of treatment or placebo effects (Yoon et al., 2017). Further, effectiveness in most studies has been quantified according to symptom improvement as measured by single, disorder-specific outcome measures that have not been validated for use among prisoners (Goff et al., 2007). Prisoners are likely to experience multiple problems (Fazel et al., 2016) and a single outcome measure may not be sensitive to the true effect(s) of treatment. Effect sizes were also larger in studies with high rates of treatment non-completion and statistical analyses was rarely conducted on an intention-to-treat basis which can positively bias estimates of treatment effects (Nüesch et al., 2009). Yoon et al (2017) also included a qualitative analysis of the discussion sections of each paper in their meta-analysis in an attempt to identify the challenges associated with delivering psychological therapies in prisons which may not be apparent from the results of quantitative analysis alone. They found that across studies prisoners were often liberated or moved establishment mid-treatment and were regularly prevented from attending therapy for institutional reasons (e.g., indiscipline). They noted that several papers raised treatment non-completion as an issue in their discussion, but that detailed attrition data was rarely reported. They concluded their qualitative analysis by suggesting that the limitations inherent in the prisoner outcome literature would not be improved via improved research design, as many of the issues appear to be related to barriers to engaging in and/or completing treatment. They suggested that

there is a need for research into the factors that contribute to treatment non-completion in this setting.

The factors contributing to treatment non-completion among prisoners accessing mental health interventions have received no empirical attention. In the absence of a specific literature, clinical psychologists working in prisons are currently faced with trying to derive an understanding of this problem from two related, but distinct literatures, with theoretical roots in two distinct paradigms: a clinical, mental health paradigm and a forensic risk assessment and management (e.g., offender rehabilitation) paradigm. These paradigms in their contemporary form emerge from distinct institutional systems (i.e., mental health and criminal justice) with disparate purposes, societal functions, and approaches to treatment (Forshaw, 2008). The following is a summary of the factors known to contribute to treatment non-completion from both of these literatures, in addition to an explanation as to why neither is adequately representative of prisoners accessing psychological mental health interventions.

The clinical and forensic rehabilitation intervention non-completion literatures are occupied by two central questions:

1) How prevalent is treatment non-completion?
2) Are there specific factors which predict non-completion?

Clinical Treatment Non-Completion – Adults in the General Population

This literature relates specifically to adults from the general population (i.e., non-offenders) taking part in psychological interventions addressing mental health problems, mainly in the community. Broadly speaking, clinical interventions focus on the treatment of mental ill health. These interventions emanate from empirical psychological models of mental ill health and the primary objective is the alleviation of psychological distress (Barnao et al.,

2015). Participation is voluntary, treatment goals are patient-generated, and the values of individual well-being, choice and autonomy are cardinal (Barnao et al., 2015). Among adults in the general population accessing clinical interventions the average treatment non-completion rate is 20% (Swift & Greenberg, 2014). Treatment non-completion rates do not differ by treatment orientation (e.g., CBT v Psychodynamic), setting (e.g., inpatient or outpatient), or format (e.g., individual or group). Treatment non-completion has been shown to be more likely where patients have severe and/or multiple diagnoses, or a personality disorder diagnosis, and in those who are younger in age (Swift & Greenberg, 2014). Treatment non-completion in this context is associated with poorer clinical outcomes, low morale among staff, reduced clinical capacity and cost inefficiencies for services (Barret et al., 2008).

Offending Behaviour Treatment Non-Completion – Forensic Populations

This literature relates specifically to adults from a forensic population taking part in psychological interventions addressing offender behaviours, rather than mental health needs, in a variety of forensic settings. In contrast to clinical interventions, forensic interventions tend to focus on the thoughts, attitudes and behaviours that are thought to be implicated in criminogenic needs (Barnao et al., 2015). These interventions emanate from empirically derived predictors of criminal behaviour and the primary objective is the protection of the public through the reduction of recidivism; not the alleviation of psychological distress (Barnao et al., 2015). Participation may be court ordered with little or no patient choice in goal setting. Engagement in treatment may be motivated by a desire for liberation and not the reduction of offender behaviours and/or the risk of re-offending (Ward, 2013; Sadoff, 2011). Among adults in an offender population accessing offence-focused interventions the average treatment non-completion rate is 50% (Holdsworth et al, 2014). Treatment non-completion in this literature has been shown to be more likely among offenders with a diagnosis of personality disorder, higher symptom severity, and in those who have no formal educational attainment. It is also

more likely among offenders who have been involved in recent violence, and in those with substance misuse problems (Cullen et al., 2011). Non-completion in this context is associated with an increased risk of recidivism, an increased sentence length, an increased risk of violence, self-harm, or suicide, and a negative impact on patient and staff morale (Casey et al., 2007). Worryingly, there is evidence suggesting that treatment non-completion may be associated with an increased risk of recidivism when compared with offenders who complete treatment and when compared to *untreated* offenders, suggesting that incomplete treatment may *cause* harm (McMurran & Theodosi, 2007).

Thus, studies of treatment non-completion among adults accessing clinical interventions have not included participants from a forensic population, and studies that do include forensic populations have evaluated the factors predicting treatment non-completion in non-clinical (i.e., forensic rehabilitation) interventions. The philosophical and theoretical underpinnings, principles, and approaches to forensic rehabilitation interventions appear in many ways antipodal to those encompassed by clinical interventions and despite their similarities with regards some of the variables associated with treatment non-completion, neither literature is adequately representative of a prisoner population accessing psychological interventions for traditional mental health needs. As such, attempting to derive an understanding of prisoner clinical treatment non-completion from the existing research is both confusing and of limited applied value, and there is a need for theory to be expanded via specific research investigating the factors predicting clinical treatment non-completion among prisoners.

Current Study

Reasons for and rates of treatment non-completion provide important population and context-specific information regarding treatment acceptability and effectiveness (Swift & Greenberg, 2014). An understanding of the factors

predicting clinical treatment non-completion could be used to develop targeted pre-treatment strategies that could improve treatment completion rates and improve service planning. For example, it may allow for a more precise identification of specific needs and the more appropriate application of clinical interventions. Moreover, within the current literature the problem of treatment non-completion is conceptualised theoretically as being internal (i.e., individual clinical or demographic characteristics) to the individual and there is a lack of consideration of external, environmental, or institutional characteristics. A prison environment is unique in various ways and there are several institution specific characteristics that may be implicated in treatment non-completion that are outside of the control of either the patient or therapist. For example, prisoners may move establishment at short notice whilst mid-treatment. The inclusion of external factors such as these may highlight the importance of systemic, institutional barriers to treatment completion, in which case it may be necessary, for example, to reconsider the ways in which custodial staff are involved in clinical care. In the context of a matched-stepped care this could improve service efficiency, increased access to psychological services, improve clinical outcomes and prisoner and staff morale.

Using routinely collected data this study retrospectively investigated associations between various internal (e.g., demographic, behavioural, and clinical), and external (e.g., institutional) characteristics, and clinical treatment non-completion status, among a sample of long-term (>4 years) adult male prisoners.

This is the first study of its kind, and it is hoped that we can provide the first treatment non-completion prevalence estimate for prisoners accessing mental health interventions. We also sought to evaluate for the first time which specific internal and external characteristics are associated with clinical treatment non-completion among prisoners. We included the internal factors that have been shown to predict non-completion among both literatures

discussed above, in addition to external, institution specific factors, that are yet to be evaluated empirically.

Research questions:

1. How prevalent is psychological treatment non-completion in a sample of long-term male prisoners?
2. What characteristics are associated with treatment non-completion in prisoners?

Method

Design

A non-experimental, retrospective research design was used to investigate whether there are any significant associations between a range of variables and psychological therapy completer status (i.e., treatment complete versus non-complete).

Research Procedures

Ethical Approvals

This project was approved by NHS Lanarkshire Research & Development (16/07/2021; Appendix 2.2), and the Scottish Prison Service (SPS) Ethics Committee (06/07/2021; Appendix 2.3).

COVID-19 Impact

The original study protocol was designed shortly prior to the outbreak of the COVID-19 pandemic. Unfortunately, because of the pandemic, clinical services (and concurrent data collection) were abruptly paused in March 2020. In the subsequent months, a combination of ongoing COVID restrictions, recruitment changes among the staff team, and an incidental change in SPS policy regarding

data access, meant that the data collection process was significantly affected. Unfortunately, this confluence of circumstances meant that it was not possible to retrospectively collect data post March 2020. As such, we were limited to exploring a smaller dataset, with fewer variables, that had been collected prior to the pandemic. Below we have sought to outline our original intended methodological plans & analyses in addition to what was feasible considering the impact of the pandemic.

Participants & Setting

The source of the dataset was the Psychological Therapies service within Her Majesty's Prison (HMP) Shotts, a Scottish prison for long-term (> 4 years) adult male offenders. Data relating to the variables of interest for this study were stored within two separate electronic databases: one hosted by the NHS, and one by the SPS – both of which clinical staff had routine access to in the normal course of their duties. These databases contain a range of demographic, behavioural, clinical, and institutional data that are routinely collected for all prisoners who are referred to and who commence psychological therapy.

Data Management & Protection

A single research database which only contained data relevant to the research questions was created. The database was encrypted to the NHS security standard and was saved on an encrypted NHS network drive for the duration of the study. Identifiable information was removed, and participants were assigned with an identification number to preserve their anonymity.

Inclusion Criteria

We had originally intended to include all who were referred to the clinical psychology service between 31/07/2017 and 31/10/2021 who commenced psychological therapy. The impact of COVID-19 led us to narrow our data

collection window to those referred between 31/07/2017 and 01/03/2020. All interventions were direct, one-to-one therapies.

Exclusion Criteria

Prisoners referred to the service for reasons other than treatment e.g., for team consultation or assessment purposes only.

Intended Sample Size & Power Calculations

We intended to investigate 12 predictor variables. When the protocol was written we had partial data for 47 prisoners from referral to discharge between 31/07/2017 and 31/01/2020. This represented an average throughput of approximately two prisoners per month, however, this was likely to increase as two new psychologists had recently been recruited. Based on our initial planned data collection window we anticipated a minimum sample size of 80 and a maximum sample size of 110. Our study was exploratory, and an accurate sample size estimation was not possible. However, in a study of the factors predicting treatment non-completion among offenders taking part in forensic rehabilitation treatment (Cullen et al, 2011), a sample size of 42 was appropriately powered to identify significant predictors of treatment non-completion. Some of the predictor variables they included are also being investigated in this study. We anticipated a sample size that would be at minimum double this number, which was likely to be of benefit for the multivariate analyses we had initially intended.

Revised Sample Size

After applying the inclusion and exclusion criteria and taking in to account the impact of COVID-19, data for 27 participants referred to the psychological therapies service between 31/07/2017 & 01/03/2020 were included in our

sample for analysis. As HMP Shotts is a male only prison our sample was restricted to males. The sample characteristics are summarised in Table 1.

Predictor Variable Selection

The following criteria was used in determining which independent measures were included for analysis:

(1) The factor has been shown to predict non-completion among offenders accessing forensic rehabilitation interventions
(2) The factor has been shown to predict non-completion among non-offenders accessing mental health interventions
(3) There is a reasonable expectation that the factor could predict non-completion
(4) The data was available to us within the existing databases

Originally Intended Internal Predictor Variables

Age

In years, at the beginning of treatment.

Symptom Severity at Pre-Treatment

The Clinical Outcomes in Routine Evaluation – Outcome Measure (CORE-OM; Evans et al., 2000) is a 34-item self-report, generic measure of psychological distress and is administered to all prisoners who access the psychological therapies service within HMP Shotts. It is pan-theoretical (i.e., not specific to a therapeutic modality), pan-diagnostic (i.e., not specific to a single diagnostic category), and is designed to measure changes in the mental health of adults, particularly those taking part in psychological therapies. It assesses four separate domains, including client well-being, specific problems and symptoms,

overall functioning, and risk. The Clinical Outcomes in Routine Evaluation – 10 Items (CORE-10; Barkham et al., 2013) questionnaire is an abbreviated, 10-item short-form version of the CORE-OM. Both measures have good internal consistency (0.75–0.95), and good test–retest reliability with clinical samples (ICC>0.87) and have been shown to be highly sensitive to clinical change (Barkham et al., 2013). Both measures produce continuous scores for each sub-scale, with higher scores indicating a higher symptom severity. The total scores in both questionnaires have been standardised and categorised in to four 'bands' of scores above the clinical cut-off that have been established as representative of 'mild', 'moderate', 'moderate-to-severe', or 'severe' levels of general distress.

Personality Disorder Diagnosis*

The presence of a personality disorder diagnosis was dichotomised as: (1) Yes and (2) No.

Recent Violence

We defined 'recent violence' as any form of physically violent behaviour which had been registered by the Scottish Prison Service within the 6 months (or less if incarcerated <6 months) prior to beginning treatment. This presence of this predictor was dichotomised as: (1) Yes and (2) No.

Multimorbidity*

The presence of co-morbid diagnoses was dichotomised as either: (1) Yes and (2) No.

Substance Misuse Problems*

This presence of this predictor was dichotomised as: (1) Yes and (2) No.

*Data for variables marked with an asterisk were contained within an existing clinical database and were based on a combination of formal diagnoses/assessment and/or subjective clinical judgement. The validity of this data will be considered in the discussion of the results.

External Predictor Variables

Sentence Length Remaining

In years and months, at treatment onset. We included this as a predictor variable because anecdotal evidence suggests that patients are more likely to complete treatment when they are approaching their estimated date of liberation

Sentence Served To-Date

In years and months, at treatment onset. We included this as a predictor variable because anecdotal evidence suggests that patients are more likely to complete treatment when they have been recently convicted.

Moved Establishment Mid-Treatment

We included this as a predictor variable because anecdotal evidence suggests that patients often move-establishment at very short notice whilst mid-treatment. For example, for the purposes of completing a court-mandated course. This variable was dichotomised as: (1) Yes and (2) No.

Disciplinary Reports Accrued During Treatment

Anecdotal evidence suggests that poor mental health often contributes to prisoners breaching prison rules and accruing a disciplinary 'report', that may indirectly impact upon their ability to consistently attend treatment. Whether or not a prisoner was placed on report whilst attending therapy was investigated. Reports generally consist of failures to attend work, incidents of aggressive behaviour, or any other breach of prison rules. It is important to note that incidents of physical violence, which are known to predict treatment non-completion, are reported separately within HMP Shotts, and were included separately. Disciplinary reports accrued was dichotomised as either: (1) Yes and (2) No.

Revised Predictor Variables

The impact of COVID restrictions meant that the quantity and quality of the data available was significantly reduced. Below is a summary of the revised predictor variables and, where appropriate, a description of where they overlap and/or are different from our original intended plan.

Age

In years, at the beginning of treatment. Included as intended.

Disciplinary Reports Accrued During Treatment

Included as intended. Disciplinary reports accrued was dichotomised as either: (1) Yes and (2) No.

Symptom Severity at Pre-Treatment

All participants included in our analyses completed either a CORE-10 or CORE-OM during their initial assessment. Although we were able to include this predictor variable as intended, we were unable to access individual participant, sub-score date, and our analyses were restricted to the categorical bands of scores above the clinical cut-off that have been established as representative of 'mild', 'moderate', 'moderate-to-severe', or 'severe' levels of general distress.

Open to The Addictions Service During Treatment

Included as intended. Defined in terms of whether the person was actively engaged with the addictions service within the prison during treatment. In practice, for most prisoners this was for Opioid Substitution Treatment (OST) Open to addictions was dichotomised as: (1) Yes and (2) No.

'Management of the Risk of Substances' policy (MoRS)

Included as intended. Under the 'Management of the Risk of Substances' (MoRS), any incidence of prisoners who are suspected to present as being under the influence of substances is formally recorded. MoRS reports can be created by health centre clinicians or members of the prison service staff. Whether prisoners accrued a MoRS report during psychological treatment was dichotomised as: (1) Yes and (2) No.

Dependent Measures

Classifying Treatment Completers vs. Non-Completers

Treatment Complete

Treatment was defined as complete where the termination of treatment was mutually agreed between patient and therapist, either due to a satisfactory improvement in symptoms, where it was determined that an alternative treatment or intervention was more appropriate, or where it was felt that further intervention was likely to be of further benefit.

Treatment Not-Complete

Treatment was defined as non-complete where an individual began treatment that was later terminated and the completion criteria were not met, and/or where the termination of treatment was determined by factors out with the control of either the therapist or patient.

Originally Intended Analysis Plan

1. Univariate Logistic Regression Analysis (Completers vs Non-Completers)

We intended to use univariate logistic regression to assess the ability of each independent variable to predict completer status. Odds ratios with 95% confidence intervals and their *p* values would be presented alongside the descriptive data. Correlations between predictor variables would also be checked for multi-collinearity.

2 - Multivariate Logistic Regression Analysis – Non-Completers

Variables that were significant in univariate analysis would then be entered together into a forward stepwise multivariate logistic regression model using a probability of 0.05 or less for variable entry. A stepwise model was selected as there were no a priori hypotheses regarding the importance of individual predictor variables. Multivariate logistic regression was selected as it enables two or more predictor variables to be taken into consideration simultaneously to predict the value of a dichotomised dependent variable (i.e., treatment complete or not complete).

Revised Analysis Plan

Our statistical analysis was undertaken using IBM SPSS v28 (IBM, 2021). Unfortunately, multivariate regression analysis was no longer feasible due to insufficient data. Instead, between-group differences in completer status for continuous variable data were evaluated using independent samples t-tests. Associations between categorical variable data and completer status were evaluated either via Fisher's Exact test. Descriptive summary data are presented as measures of central tendency (mean and standard deviation) or percentages. All inferential tests were two-tailed ($\alpha = 0.05$). We had no missing data. Our statistical analyses were exploratory and might help to inform power calculations for a future, larger study.

Results

1. How prevalent is psychological treatment non-completion in a sample of long-term male prisoners?

According to our definition of completer status, 11 of 27 (40.74%, 95% CI [22%, 61%]) people did not complete treatment. Summary data for completers and non-completers are presented as measures of central tendency (mean and standard deviation) percentages in Table 1.

	Total Sample (n = 27)	Treatment Completers (n=16)	Treatment Non-Completers (n= 11)
Age at Treatment Beginning (Mean, SD, Range)	M = 34.5 SD = 9.22 Maximum Age = 58 Minimum Age = 23 Range = 35	M = 34.8 SD = 9.25 Maximum Age = 58 Minimum Age = 24 Range = 34	M = 34 SD = 9.6 Maximum Age = 48 Minimum Age = 23 Range = 25
Participants with MoRS Report Accrued (%)	8 (29.6%)	2 (12.5%)	6 (54.5%)
Symptom Severity at Pre-Treatment on the CORE (%)	**Mild** 3 (11.1%) **Moderate** 7 (25.9%) **Moderate-to-Severe** 14 (51.9%) **Severe** 3 (11.1%)	**Mild** 3 (18.8%) **Moderate** 6 (37.5%) **Moderate-to-Severe** 6 (37.5%) **Severe** 1 (6.3%)	**Mild** 0 (0%) **Moderate** 1 (9.1%) **Moderate-to-Severe** 8 (72.7%) **Severe** 2 (18.2%)
Open to Addictions (%)	15 (55.6%)	6 (37.5%)	9 (81.8%)
Participants with a Disciplinary Report Accrued During Treatment (%)	17 (63%)	7 (43%)	10 (90%)

Table 1. Sample Descriptive Characteristics

2) What characteristics are associated with clinical treatment non-completion in prisoners?

Age

There was no significant difference in age between treatment completers and non-completers; $t(25)= 0.22$, $p = 0.83$, $d = 0.09$, 95% CI; [-0.68, 0.85].

MoRS Report Accrued During Treatment

Fishers-Exact analyses revealed that those who accrued a MoRS report during treatment were significantly less likely to complete treatment; $p = 0.03$, OR = 0.12, 95% CI [0.02, 0.8].

Open to the Addictions Service During Treatment

Fishers-Exact analyses revealed that patients who were open to the addictions service were significantly less likely to complete treatment $p = 0.047$, OR = 0.13, 95% CI [0.02, 0.84].

Disciplinary Reports Accrued During Treatment

Fishers-Exact analyses revealed that patients who accrued a disciplinary report during treatment were significantly less likely to complete treatment $p = 0.02$, OR = 0.08, 95% CI [0.01, 0.76]

Symptom Severity at Pre-Treatment: CORE-OM & CORE-10

Given the small sample size and small expected cell frequencies, we collapsed 'mild' and 'moderate' into one category, and 'moderate-to-severe' and 'severe' into one category, to enable a 2x2 analysis.

Fishers-exact analyses revealed that patients with a lower symptom severity were significantly more likely to complete treatment $p = 0.02$, OR = 12.9, 95% CI [1.31 – 125.8].

Discussion

Prisoners with mental health problems represent a complex population with substantial clinical needs (Fazel et al., 2016). A small, but growing evidence base suggests that psychological therapies are moderately effective overall, but that rates of treatment non-completion are consistently high (Yoon et al., 2016). Reasons for and rates of treatment non-completion provide important population and context-specific information regarding treatment acceptability and effectiveness of treatment (Swift & Greenberg, 2014). Despite this, treatment non-completion in the context of prisoner mental health has received no empirical attention. This study sought to identify the prevalence of treatment non-completion among a sample of long-term (>4 yrs) male offenders accessing psychological mental health interventions. The study also sought to evaluate whether there were any significant differences between treatment completers and non-completers on a range of clinical and non-clinical variables.

1. How prevalent is clinical treatment non-completion in a sample of long-term male prisoners?

The treatment non-completion rate was 40.74% (95% CI; 22% - 61%), which is slightly lower than the non-completion rate from offender-behaviour focused interventions (50%; e.g., Cullen et al., 2011; Young et al., 2010), but higher than the average non-completion rate from psychological mental health interventions in the community (20%; Swift & Greenberg, 2014). However, it is not possible to draw firm conclusions about the precision of this estimate due to the width of the confidence intervals.

Previous research in samples of both offenders and non-offenders has found that a high number of people who take part in an assessment, and are subsequently offer treatment, do not go on to begin an intervention (e.g., Sheldon et al., 2010). As this study did not have data regarding 'treatment refusers', the results may have been influenced by sample bias. A better understanding of the rate of refusal, and the factors associated with refusal, could allow for improvements to be made to the initial assessment process to increase engagement.

2) What characteristics are associated with clinical treatment non-completion?

Age

The difference in age between completers and non-completers was not significant. This finding is not consistent with previous research which demonstrates that those younger in age are less likely to complete treatment (Swift & Greenberg, 2014). However, people who spend time in prison are younger in age on average than the population in Scotland as a whole. Indeed,

the average age of the sample was 34.8, which is consistent with the average age of the Scottish prisoner population (35.9; Scottish Government, 2020). The average age of the Scottish population is 42. Moreover, only 7% of the prisoner population are aged 55 or older, versus 32.6% of the Scottish population as a whole (Office for National Statistics, 2022). As such, a prisoner sample is far less likely to include participants older in age in the first instance, and age is therefore less likely to influence completer status in this context.

Open to the Addictions Service & The 'Management of Risk from Substances (MoRS) Reports

There was a significant association between treatment non-completion and being open to the addictions service during therapy, and a significant association between treatment non-completion and the accrual of a MoRS report during therapy.

The findings are consistent with existing research which demonstrates that patients who experience co-morbid substance misuse problems are more likely to drop out of treatment prematurely (Swift & Greenberg, 2014). Unfortunately, the nature of the dataset and subsequent analysis means that we were unable to analyse these variables together and we are not able to determine whether those who accrued MoRS reports represent the same individuals who were also open to the addictions service. Interestingly, among the completer group, more participants accrued a MoRS report than were open to the addictions service (8 v 6). This is consistent with anecdotal reports from clinicians in this setting who opine that problems with substance misuse are likely to be a significant background issue for many patients, regardless whether they are being supported by the addictions service and/or their primary presenting problem. This suggests that clinicians in this setting should pay particular attention to the presence of substance misuse during their assessment process, for all prisoners who access the service.

Clinical Symptom Severity at Pre-Treatment

We found that prisoners experiencing higher levels of symptom severity at baseline were less likely to complete treatment, which is consistent with existing research. The CORE outcome measures assess the individual domains of well-being, symptom severity, functioning, and risk, four 'bands' of scores above the clinical cut-off have been established as representative of 'mild', 'moderate', 'moderate-to-severe', or 'severe' levels of general distress. Unfortunately, the impact of COVID-19 restrictions on our ability to collect data meant that the analyses here were limited to these categorical bands of general distress. Due to our small sample size we also combined 'mild' and 'moderate' into one category, and 'moderate-to-severe' and 'severe' into one category for statistical analysis.

Prisoners are disproportionately like to have multiple mental health problems and a growing body of evidence shows that a host of associated problems such as Attention-Deficit Hyperactivity Disorder (ADHD; Young et al., 2018), Autism Spectrum Disorders (ASD; Young et al., 2018), and Foetal-Alcohol Spectrum Disorder (FASD; Flannigan et al., 2018) are also vastly over-represented and underdiagnosed among prisoners. Many of the diagnoses prisoners are likely to present with are characterised by specific overlapping symptoms that in community based research have been shown to reliably predict treatment non-completion (e.g., impulsivity, emotional dysregulation, relational problems; Gilmore et al., 2020; Tetley et al., 2012). If future research fails account for this complexity and multimorbidity and focuses on the presence and severity of specific diagnostic categories, it may be difficult to identify and/or interpret the true predictive effect of individual clinical characteristics or traits. It may be that our theoretical understanding of the factors predicting clinical treatment non-completion among prisoners would be more helpfully expanded by

adopting a transdiagnostic approach that evaluates the predictive value of specific symptoms or traits.

Disciplinary Reports Accrued During Treatment

The results indicated that there was a significant association between completer status and the accrual of disciplinary reports during treatment. As this is the first study of its kind it is not possible to make comparisons with existing literature. However, this variable was included because expert opinion indicates that poor mental health often contributes to a prisoner accruing disciplinary reports. Reports are generally accrued for breaching prison rules, including failing to attend work, failing urinary analysis drug tests, and/or incidents of aggression or hostility. Importantly, incidents of recent violence are known to predict treatment non-completion, but this data was not available for analysis. Anecdotal opinion also indicates that prisoners who regularly accrue reports are less likely to complete treatment. The accrual of reports can lead to disciplinary proceedings being raised against a prisoner and can impede their progression through the criminal justice system.

Unfortunately, the statistical analysis here was restricted to a dichotomised 'Yes' or 'No' in terms of whether a prisoner had been placed on report. However, more detailed explanations of the reasons for reports being accrued are available to clinicians working within prison mental health settings. The findings suggest that it may be useful for clinicians to routinely check whether prisoners have been placed on report, and if so, why, prior to conducting their assessment. Specifically, it would seem pertinent to suggest that clinicians routinely check whether prisoners have been involved in recent incidents of physical violence.

Strengths & Limitations

In terms of strengths, this is the first known study investigating psychological mental health treatment non-completion among a prisoner population. Although the sample was small, the results indicate significant associations in the data that allow us to make some important suggestions for future studies.

In terms of limitations, the impact of COVID-19 significantly circumscribed the scope of this study in almost all regards. It meant that the sample size was significantly smaller than originally anticipated and the statistical power of the analyses was low. A study with low statistical power has a reduced chance of detecting an association; however, it also reduces the likelihood that a statistically significant result reflects a true association. The consequences of this include the over-estimation of effect sizes, and the low reproducibility of results (Button et al., 2013). Our small sample also led to wide confidence intervals which limits our confidence in the precision and/or true effect size of each predictor variable.

The quality of the data available to us in terms of its validity was also significantly reduced. For example, statistical analyses of clinical symptom severity on the CORE outcome measures were restricted to comparisons of the overall, categorical scoring 'bands'. It was not possible to analyse the impact of potentially important sub-domains (e.g., risk) or clinical symptoms, and although our results were statistically significant, they are of limited clinical or theoretical value.

Where we did find significant associations in the data, we were restricted to analysing the variables on a dichotomous 'yes' or 'no' basis. For example, with regards the accrual of disciplinary and/or MoRS reports, we are unable to state whether participants accrued 1 or more report(s), and the reasons for which report(s) were accrued.

The results are also significantly limited by the data that we were unable to include at all. Other than age, we were unable to include other important demographic information such as educational attainment which has been shown to predict treatment non-completion (Cullen, 2011).

Lastly, and perhaps most importantly, we were unable to include several institutional variables that previous qualitative studies (Yoon et al., 2011) and anecdotal opinion suggest contribute to treatment non-completion. For example, prisoners often move establishment mid-treatment, at short-notice, or leave for an undefined period to complete offender focused programme work. Where a prisoner is deemed to have committed a serious breach of prison rules, they may be temporarily moved to a segregation unit, which can make the scheduling of clinical appointments difficult.

These limitations meant that our data was no longer suitable for regression analyses. As such, each variable was evaluated individually, and we are unable to say anything about the relative strength of each variable in predicting completer status.

Recommendations

Our recommendations are primarily related to the limitations inherent in our study. Future research should seek to include a larger sample size, and a more sensitive and comprehensive battery of demographic, clinical, behavioural, and institutional variables.

It may also be beneficial to make use of a mixed methodology, with a qualitative component investigating prisoners' perceptions of accessing psychological mental health treatment whilst incarcerated.

Conclusions

This study is the first to investigate psychological mental health treatment non-completion among a prisoners. The results provide the first prevalence estimate of psychological therapy treatment non-completion that can be used as a comparison in future research. Although the results were generally consistent with the existing offender and non-offender treatment non-completion literature, significant limitations in the quality of the data and the statistical techniques employed prevent us from drawing any firm inferences about our results. However, the study does provide very important information to aid the design of future studies of this kind.

Despite these limitations our study is the first to include an evaluation of institutional barriers to treatment completion. Traditionally, treatment non-completion is cited as evidence of non-engagement on behalf of the patient. However, practicing at the intersection of two institutions (e.g., the NHS & SPS), clinicians report being aware that non-completion is not just a product of internal, client characteristics, but external, institutional characteristics (e.g., moving establishment) that are out with the control of either the patient or the therapist. Although we were only able to include some variables in a very general way, the finding that the accrual of disciplinary and MoRS reports during treatment is associated with non-completion suggests that the inclusion of external, institutional characteristics in the theoretical conceptualisation of non-completion in this setting is merited. A focus upon internal, person-centred characteristics risks further locating the reason for treatment non-completion as solely residing within the individual patient, at the expense of important external factors.

A more comprehensive, systemic understanding of internal, person-centred characteristics and external, institutional characteristics, as well as their dynamic interactions, is required to properly understand treatment completion among prisoners accessing mental health problems. A better understanding of

treatment non-completion could help clinicians and services better prepare for interventions and to actively seek to minimise the factors associated with the issue.

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Appendices

Appendix 1: Systematic Review

Appendix 1.1: Submission Guidelines for the Journal of Consulting and Clinical Psychology

Appendix 1.1 Submission guidelines for the Journal of Consulting and

Clinical Psychology

The Journal of Consulting and Clinical Psychology® (JCCP) publishes original contributions on the following topics:

- the development, validity, and use of techniques of diagnosis and treatment of disordered behavior
- studies of a variety of populations that have clinical interest, including but not limited to medical patients, ethnic minorities, persons with serious mental illness, and community samples
- studies that have a cross-cultural or demographic focus and are of interest for treating behavior disorders
- studies of personality and of its assessment and development where these have a clear bearing on problems of clinical dysfunction and treatment
- studies of gender, ethnicity, or sexual orientation that have a clear bearing on diagnosis, assessment, and treatment studies of psychosocial aspects of health behaviors

Studies on the following topics will be considered if they have clear implications for clinical research and practice:

- epidemiology
- use of psychological services
- health care economics for behavioral disorders

Although JCCP largely publishes research that is empirical and quantitative in method, rigorous theoretical papers on topics of broad interest to the field of clinical psychology will be considered, as will critical analyses and meta-analyses of treatment approaches on topics of broad theoretical, methodological, or practical interest to the field of clinical psychology. JCCP also considers methodologically sound single-case designs (e.g., that conform to the recommendations outlined in the "What Works Clearinghouse (WWC) Single-Case Design" paper).

JCCP does not consider manuscripts dealing with the etiology or descriptive pathology of abnormal behavior (which are more appropriate for the Journal of Abnormal Psychology).

Similarly, the journal does not consider articles focusing primarily on assessment, measurement, and diagnostic procedures and concepts (which are more appropriate for Psychological Assessment). Editors reserve the right to determine the most appropriate location of a manuscript.

Masked Review

This journal uses a masked reviewing system for all submissions. The first page of the manuscript should omit the authors' names and affiliations but should include the title of the manuscript and the date it is submitted.

Footnotes containing information pertaining to the authors' identities or affiliations should not be included in the manuscript, but may be provided after a manuscript is accepted. Make every effort to see that the manuscript itself contains no clues to the

authors' identities. Please ensure that the final version for production includes a byline and full author note for typesetting. Keep a copy of the manuscript to guard against loss.

Cover Letter

The cover letter accompanying the manuscript submission must include all authors' names and affiliations to avoid potential conflicts of interest in the review process. Addresses and phone numbers, as well as electronic mail addresses and fax numbers, if available, should be provided for all authors for possible use by the editorial office and later by the production office

Length and Style of Manuscripts

Full-length manuscripts should not exceed 35 pages total (including cover page, abstract, text, references, tables, and figures), with margins of at least 1 inch on all sides and a standard font (e.g., Times New Roman) of 12 points (no smaller). The entire paper (text, references, tables, etc.) must be double spaced. Until May 31st 2020, prepare manuscripts (instructions on preparing tables, figures, references, metrics, and abstracts) according to the Publication Manual of the American Psychological Association using the 6th or 7th edition. Starting June 1st 2020, all manuscripts should be submitted in the 7th edition. Manuscripts may be copyedited for bias-free language (see Chapter 3 of the 6th edition or Chapter 5 of the 7th edition). Authors submitting manuscripts that report new data collection, especially randomized clinical trials (RCTs), should comply with the newly developed Journal Article Reporting Standards for Quantitative Research in Psychology: The APA Publications and Communications Board Task Force Report (PDF, 222KB) (JARS; see American Psychologist, 2018, 73(1), 3–25 or Appendix in the APA Publication Manual). For papers that exceed 35 pages, authors must justify the extended length in their cover letter (e.g., reporting of multiple studies), and in no case should the paper exceed 45 pages total. Papers that do not conform to these guidelines may be returned without review. The References section should immediately follow a page break.

Brief Reports

In addition to full-length manuscripts, the JCCP will consider Brief Reports of research studies in clinical psychology. The Brief Report format may be appropriate for empirically sound studies that are limited in scope, contain novel or provocative findings that need further replication, or represent replications and extensions of prior published work. Brief Reports are intended to permit the publication of soundly designed studies of specialized interest that cannot be accepted as regular articles because of lack of space. Brief Reports must be prepared according to the following specifications: Use 12-point Times New Roman type and 1-inch (2.54-cm) margins, and do not exceed 265 lines of text including references. These limits do not include the title page, abstract, author note, footnotes, tables, or figures. An author who submits a Brief Report must agree not to submit the full report to another journal of general circulation. The Brief Report should give a clear, condensed summary of the procedure of the study and as full an account of the results as space permits.

Title of Manuscript

The title of a manuscript should be accurate, fully explanatory, and preferably no longer than 12 words. The title should reflect the content and population studied (e.g., "treatment of generalized anxiety disorders in adults"). If the paper reports a randomized clinical trial (RCT), this should be indicated in the title. Note that JARS criteria must be used for reporting purposes.

Abstract and Keywords

All manuscripts must include an abstract containing a maximum of 250 words typed on a separate page. After the abstract, please supply up to five keywords or brief phrases. Manuscripts published in the Journal of Consulting and Clinical Psychology will include a

structured abstract of up to 250 words. For studies that report randomized clinical trials or meta-analyses, the abstract also must be consistent with the guidelines set forth by JARS or MARS (Meta-Analysis Reporting Standards) guidelines, respectively. Thus, in preparing a manuscript, please ensure that it is consistent with the guidelines stated below. Please include an Abstract of up to 250 words, presented in paragraph form. The Abstract should be typed on a separate page (page 2 of the manuscript), and must include each of the following sections:

Objective: A brief statement of the purpose of the study

Method: A detailed summary of the participants (N, age, gender, ethnicity) as well as descriptions of the study design, measures (including names of measures), and procedures

Results: A detailed summary of the primary findings that clearly articulate comparison groups (if relevant), and that indicate significance or confidence intervals for the main findings

Conclusions: A description of the research and clinical implications of the findings

Participants: Description and Informed Consent

The Method section of each empirical report must contain a detailed description of the study participants, including (but not limited to) the following: age, gender, ethnicity, SES, clinical diagnoses and comorbidities (as appropriate), and any other relevant demographics.

In the Discussion section of the manuscript, authors should discuss the diversity of their study samples and the generalizability of their findings.

The Method section also must include a statement describing how informed consent was obtained from the participants (or their parents/guardians) and indicate that the study was conducted in compliance with an appropriate Internal Review Board.

Measures

The Method section of empirical reports must contain a sufficiently detailed description of the measures used so that the reader understands the item content, scoring procedures, and total scores or subscales. Evidence of reliability and validity with similar populations should be provided.

Statistical Reporting of Clinical Significance

JCCP requires the statistical reporting of measures that convey clinical significance. Authors should report means and standard deviations for all continuous study variables and the effect sizes for the primary study findings. (If effect sizes are not available for a particular test, authors should convey this in their cover letter at the time of submission.) JCCP also requires authors to report confidence intervals for any effect sizes involving principal outcomes (see Fidler et al., Journal of Consulting and Clinical Psychology, 2005, pp. 136–143 and Odgaard & Fowler, Journal of Consulting and Clinical Psychology, 2010, pp.287–297).

In addition, when reporting the results of interventions, authors should include indicators of clinically significant change. Authors may use one of several approaches that have been recommended for capturing clinical significance, including (but not limited to) the reliable change index (i.e., whether the amount of change displayed by a treated individual is large enough to be meaningful; see Jacobson et al., Journal of Consulting and Clinical Psychology, 1999), the extent to which dysfunctional individuals show movement into the functional distribution (see Jacobson & Truax, Journal of Consulting and Clinical Psychology, 1991), or other normative comparisons (see Kendall et al., Journal of Consulting and Clinical Psychology, 1999).

Articles must include a discussion of the clinical implications of the study findings or analytic review. The Discussion section should contain a clear statement of the extent of clinical application of the current assessment, prevention, or treatment methods. The extent of application to clinical practice may range from suggestions that the data are too preliminary to support widespread dissemination to descriptions of existing manuals available from the authors or archived materials that would allow full implementation at present.

Data Transparency

In order to reduce the likelihood of duplicate or piecemeal publication, authors are required to provide, in their cover letter, a list of published, in press, and under review studies that come from the same dataset as the one in the submitted manuscript, as well as a narrative description of how the submitted manuscript differs from the others. This narrative description should include how the manuscript differs (or does not) in terms of research question and variables studied.

Authors also are required to submit a masked version of the narrative description that can be provided to reviewers. Please add this as an appendix table on the last page of the submitted manuscript. Please base your description on the following examples, edited according to your specific data circumstances.

Do not provide the title of the manuscript, authors, or journal in which it was published. Do provide the names of the relevant variables (i.e., substitute the numbers in the examples below for actual names, such as depressive symptoms, therapeutic alliance, etc.).

Data and Stimulus Materials

Should your paper ultimately be accepted for publication, JCCP would like to encourage you to determine if posting materials and/or data is right for your study and, if so, to make your data and materials publicly available, if possible, by providing a link in your paper to a third-party repository.

Making your data and materials publicly available can increase the impact of your research, enabling future researchers to incorporate your work in model testing, replication projects, and meta-analyses, in addition to increasing the transparency of your research.

The APA's data sharing policy does not require public posting, so you are free to decide what is best for your project in terms of public data, materials, and conditions on their use. Note, however, that APA policy does require that authors make their data available to other researchers upon request.

Manuscript Preparation

Until May 31st 2020, prepare manuscripts according to the Publication Manual of the American Psychological Association using the 6th or 7th edition. Starting June 1st 2020, all manuscripts should be submitted in the 7th edition. Manuscripts may be copyedited for bias-free language (see Chapter 3 of the 6th edition or Chapter 5 of the 7th edition). Review APA's Journal Manuscript Preparation Guidelines before submitting your article. Double-space all copy. Other formatting instructions, as well as instructions on preparing tables, figures, references, metrics, and abstracts, appear in the Manual. Additional guidance on APA Style is available on the APA Style website. Below are additional instructions regarding the preparation of display equations, computer code, and tables.

Tables

Use Word's Insert Table function when you create tables. Using spaces or tabs in your table will create problems when the table is typeset and may result in errors.

References

List references in alphabetical order. Each listed reference should be cited in text, and each text citation should be listed in the References section.

Figures

Graphics files are welcome if supplied as Tiff or EPS files. Multipanel figures (i.e., figures with parts labeled a, b, c, d, etc.) should be assembled into one file. The minimum line weight for line art is 0.5 point for optimal printing. For more information about acceptable resolutions, fonts, sizing, and other figure issues, please see the general guidelines.

When possible, please place symbol legends below the figure instead of to the side. APA offers authors the option to publish their figures online in color without the costs associated with print publication of color figures.

The same caption will appear on both the online (color) and print (black and white) versions. To ensure that the figure can be understood in both formats, authors should add alternative wording (e.g., "the red (dark gray) bars represent") as needed.

Permissions

Authors of accepted papers must obtain and provide to the editor on final acceptance all necessary permissions to reproduce in print and electronic form any copyrighted work, including test materials (or portions thereof), photographs, and other graphic images (including those used as stimuli in experiments). On advice of counsel, APA may decline to publish any image whose copyright status is unknown.

Publication Policies

APA policy prohibits an author from submitting the same manuscript for concurrent consideration by two or more publications.

Ethical Principles

It is a violation of APA Ethical Principles to publish "as original data, data that have been previously published" (Standard 8.13). In addition, APA Ethical Principles specify that "after research results are published, psychologists do not withhold the data on which their conclusions are based from other competent professionals who seek to verify the substantive claims through reanalysis and who intend to use such data only for that purpose, provided that the confidentiality of the participants can be protected and unless legal rights concerning proprietary data preclude their release" (Standard 8.14). APA expects authors to adhere to these standards. Specifically, APA expects authors to have their data available throughout the editorial review process and for at least 5 years after the date of publication. Authors are required to state in writing that they have complied with APA ethical standards in the treatment of their sample, human or animal, or to describe the details of treatment.

Appendix 1.2: CCAT Rating Form

Crowe Critical Appraisal Tool (CCAT) Form (v1.4) Reference Reviewer

This form must be used in conjunction with the CCAT User Guide (v1.4); otherwise validity and reliability may be severely compromised.

Citation

	Year

Research design (add if not listed)

❑ Not research		Article | Editorial | Report | Opinion | Guideline | Pamphlet | ...
❑ Historical		...
❑ Qualitative		Narrative | Phenomenology | Ethnography | Grounded theory | Narrative case study | ...
❑ Descriptive, Exploratory, Observational		A. Cross-sectional | Longitudinal | Retrospective | Prospective | Correlational | Predictive | ...
		B. Cohort | Case-control | Survey | Developmental | Normative | Case study | ...
Experimental	❑ True experiment	Pre-test/post-test control group | Solomon four-group | Post-test only control group | Randomised two-factor | Placebo controlled trial | ...
	❑ Quasi-experiment	Post-test only | Non-equivalent control group | Counter balanced *(cross-over)* | Multiple time series | Separate sample pre-test post-test [no Control] [Control] | ...
	❑ Single system	One-shot experimental *(case study)* | Simple time series | One group pre-test/post-test | Interactive | Multiple baseline | Within subjects *(Equivalent time, repeated measures, multiple treatment)* | ...
❑ Mixed Methods		Action research | Sequential | Concurrent | Transformative | ...
❑ Synthesis		Systematic review | Critical review | Thematic synthesis | Meta-ethnography | Narrative synthesis | ...
❑ Other		...

Variables and analysis

Intervention(s), Treatment(s), Exposure(s)	Outcome(s), Output(s), Predictor(s), Measure(s)	Data analysis method(s)

Sampling

	Group 1	Group 2	Group 3	Group 4	Control
Total size					
Population, sample, setting					

Data collection (add if not listed)

Audit/Review	a) Primary | Secondary | ... b) Authoritative | Partisan | Antagonist | ... c) Literature | Systematic | ...	Interview	a) Formal | Informal | ... b) Structured | Semi-structured | Unstructured | ... c) One-on-one | Group | Multiple | Self-administered | ...
Observation	a) Participant | Non-participant | ... b) Structured | Semi-structured | Unstructured | ... c) Covert | Candid | ...	Testing	a) Standardised | Norm-ref | Criterion-ref | Ipsative | ... b) Objective | Subjective | ... c) One-on-one | Group | Self-administered | ...

Scores

Preliminaries		Design		Results	Total [/40]
Introduction		Sampling		Discussion	Total [%]

General notes

Appraise research on the merits of the research design used, not against other research designs.

Category Item	Item descriptors [☑ Present; ☒ Absent; ■ Not applicable]	Description [Important information for each item]	Score [0–5]
1. Preliminaries			
Title	1. Includes study aims ☐ and design ☐		
Abstract (assess last)	1. Key information ☐ 2. Balanced ☐ and informative ☐		
Text (assess last)	1. Sufficient detail others could reproduce ☐ 2. Clear/concise writing ☐, table(s) ☐, diagram(s) ☐, figure(s) ☐		
		Preliminaries [/5]	
2. Introduction			
Background	1. Summary of current knowledge ☐ 2. Specific problem(s) addressed ☐ and reason(s) for addressing ☐		
Objective	1. Primary objective(s), hypothesis(es), or aim(s) ☐ 2. Secondary question(s) ☐		
	Is it worth continuing?	**Introduction [/5]**	
3. Design			
Research design	1. Research design(s) chosen ☐ and why ☐ 2. Suitability of research design(s) ☐		
Intervention, Treatment, Exposure	1. Intervention(s)/treatment(s)/exposure(s) chosen ☐ and why ☐ 2. Precise details of the intervention(s)/treatment(s)/exposure(s) ☐ for each group ☐ 3. Intervention(s)/treatment(s)/exposure(s) valid ☐ and reliable ☐		
Outcome, Output, Predictor, Measure	1. Outcome(s)/output(s)/predictor(s)/measure(s) chosen ☐ and why ☐ 2. Clearly define outcome(s)/output(s)/predictor(s)/measure(s) ☐ 3. Outcome(s)/output(s)/predictor(s)/measure(s) valid ☐ and reliable ☐		
Bias, etc	1. Potential bias ☐, confounding variables ☐, effect modifiers ☐, interactions ☐ 2. Sequence generation ☐, group allocation ☐, group balance ☐, and by whom ☐ 3. Equivalent treatment of participants/cases/groups ☐		
	Is it worth continuing?	**Design [/5]**	
4. Sampling			
Sampling method	1. Sampling method(s) chosen ☐ and why ☐ 2. Suitability of sampling method ☐		
Sample size	1. Sample size ☐, how chosen ☐, and why ☐ 2. Suitability of sample size ☐		
Sampling protocol	1. Target/actual/sample population(s): description ☐ and suitability ☐ 2. Participants/cases/groups: inclusion ☐ and exclusion ☐ criteria 3. Recruitment of participants/cases/groups ☐		
	Is it worth continuing?	**Sampling [/5]**	
5. Data collection			
Collection method	1. Collection method(s) chosen ☐ and why ☐ 2. Suitability of collection method(s) ☐		
Collection protocol	1. Include date(s) ☐, location(s) ☐, setting(s) ☐, personnel ☐, materials ☐, processes ☐ 2. Method(s) to ensure/enhance quality of measurement/instrumentation ☐ 3. Manage non-participation ☐, withdrawal ☐, incomplete/lost data ☐		
	Is it worth continuing?	**Data collection [/5]**	
6. Ethical matters			
Participant ethics	1. Informed consent ☐, equity ☐ 2. Privacy ☐, confidentiality/anonymity ☐		
Researcher ethics	1. Ethical approval ☐, funding ☐, conflict(s) of interest ☐ 2. Subjectivities ☐, relationship(s) with participants/cases ☐		
	Is it worth continuing?	**Ethical matters [/5]**	
7. Results			
Analysis, Integration, Interpretation method	1. A.I.I. method(s) for primary outcome(s)/output(s)/predictor(s) chosen ☐ and why ☐ 2. Additional A.I.I. methods (e.g. subgroup analysis) chosen ☐ and why ☐ 3. Suitability of analysis/integration/interpretation method(s) ☐		
Essential analysis	1. Flow of participants/cases/groups through each stage of research ☐ 2. Demographic and other characteristics of participants/cases/groups ☐ 3. Analyse raw data ☐, response rate ☐, non-participation/withdrawal/incomplete/lost data ☐		
Outcome, Output, Predictor analysis	1. Summary of results ☐ and precision ☐ for each outcome/output/predictor/measure 2. Consideration of benefits/harms ☐, unexpected results ☐, problems/failures ☐ 3. Description of outlying data (e.g. diverse cases, adverse effects, minor themes) ☐		
		Results [/5]	
8. Discussion			
Interpretation	1. Interpretation of results in the context of current evidence ☐ and objectives ☐ 2. Draw inferences consistent with the strength of the data ☐ 3. Consideration of alternative explanations for observed results ☐ 4. Account for bias ☐, confounding/effect modifiers/interactions/imprecision ☐		
Generalisation	1. Consideration of overall practical usefulness of the study ☐ 2. Description of generalisability (external validity) of the study ☐		
Concluding remarks	1. Highlight study's particular strengths ☐ 2. Suggest steps that may improve future results (e.g. limitations) ☐ 3. Suggest further studies ☐		
		Discussion [/5]	
9. Total			
Total score	1. Add all scores for categories 1–8		
		Total [/40]	

Appendix 1.3: CCAT Scoring Guidelines

Overview of scoring a paper

The Form is divided into eight categories and 22 items. Each item has multiple item descriptors that make it easier to appraise and score a category. Each category receives its own score on a 6 point scale from 0–5. The lowest score a category can achieve is 0, and 5 is the highest score. Categories can only be scored as a whole number or integer, i.e. 0, 1, 2, 3, 4, or 5, that is half marks are not allowed.

There are tick boxes (❑) beside item descriptors. The tick box is useful to indicate if the item descriptor is

- Present (☑) – For an item descriptor to be marked as present, there should be evidence of it being present rather than an assumption of presence.
- Absent (☒) – For an item descriptor to be marked as absent, it is implied that it should be present in the first place.
- Not applicable (■) – For an item descriptor to be marked as not applicable, the descriptor must not be relevant given the characteristics of the paper being appraised and is, therefore, not considered when assigning a score to a category.

Whether an item descriptor is present, absent, or not applicable is further explored in the section *Guidelines for scoring categories and items*. All categories must be scored because all categories are applicable in all research designs. Only item descriptors may be marked 'not applicable'.

While it may be tempting to add up all the present marks (☑) and all the absent marks (☒) in each category and to use the proportion of one to the other to calculate the score for the category, this is not appropriate. It is incorrect because not all item descriptors in a category have equal importance. For example, in the *Introduction* category there are two items (*Background* and *Objective*) and a total of five tick boxes. If a paper being appraised has all boxes marked as present (☑) except for *Primary objective(s), hypothesis(es), or aim(s)*, which is marked as absent (☒), should the paper be scored 4/5 for that category? It could be argued that a research paper without a primary objective, hypothesis, or aim is fundamentally flawed and, as a result, should be scored 0/5 even though the other four tick boxes were marked as present.

Therefore, the tick marks for present, absent, or not applicable are to be used as a guide to scoring a category and not as a simple check list. It is up to you as the appraiser to take into consideration all aspects of each category and based on both the tick marks and judgement assign a score to a category.

Similarly, the research design used in each paper should be appraised on its own merits and not relative to some preconceived notion of a hierarchy of research designs or 'gold standard'. What is most important is that the paper used an appropriate research design based on the research question being addressed, rather than what research design was used.

The total score given to a paper can be expressed as a percentage by dividing the *Total* by 40 (that is, eight categories multiplied by the maximum score of five) and writing the result on the first page of the Form. The *Total* % should be written to the nearest full percent (Table 1). There is no need for decimal places because they do not add anything to the accuracy of the score obtained.

Finally, the *Total* or *Total* % score a paper obtains is not the sole criterion on which an overall assessment of a paper is based. The *Total* or *Total* % score is a useful summary but may not be applicable in all cases. When reporting an appraisal using the CCAT, the score obtained in

3

CCAT User Guide (version 1.4)

every category must be stated along with the *Total* or *Total* % score. This prevents papers that score high overall but very poor in one or more categories being hidden amongst papers which scored high throughout all categories. Based on the reasons for the appraisal, some papers which have a low score in certain category but which have a high total score may be ranked lower than those with a lower total score but a high score in that particular category. These processes are up to you, as the appraiser, to detail before you begin appraising papers.

Table 1 *Total* and corresponding *Total* %

Total	Total %	Total	Total %	Total	Total %	Total	Total %
0	0	10	25	20	50	30	75
1	3	11	28	21	53	31	78
2	5	12	30	22	55	32	80
3	8	13	33	23	58	33	83
4	10	14	35	24	60	34	85
5	13	15	38	25	63	35	88
6	15	16	40	26	65	36	90
7	18	17	43	27	68	37	93
8	20	18	45	28	70	38	95
9	23	19	48	29	73	39	98

Appendix 2: Major Research Project

Appendix 2.1: Author Guidelines for Submission to the Journal of Mental Health

About the Journal

Journal of Mental Health is an international, peer-reviewed journal publishing high quality, original research. Please see the journal's Aims & Scope for information about its focus and peer-review policy.

Please note that this journal only publishes manuscripts in English.

Journal of Mental Health accepts the following types of article:

Original Article, Review Article, Research and Evaluation, Book Review, Web Review. Book Reviews All books for reviewing should be sent directly to Martin Guha, Book Reviews Editor, Information Services & Systems, Institute of Psychiatry, KCL, De Crespigny Park, PO Box 18, London, SE5 8AF

Peer Review

Taylor & Francis is committed to peer-review integrity and upholding the highest standards of review. Once your paper has been assessed for suitability by the editor, it will then be double blind peer reviewed by independent, anonymous expert referees. Find out more about what to expect during peer review and read our guidance on publishing ethics.

Preparing Your Paper

Structure

Your paper should be compiled in the following order: title page; abstract; keywords; main text introduction, materials and methods, results, discussion; acknowledgments; declaration of interest statement; references; appendices (as appropriate); table(s) with caption(s) (on individual pages); figures; figure captions (as a list).

Word Limits

Please include a word count for your paper.

Style Guidelines

Please refer to these quick style guidelines when preparing your paper, rather than any published articles or a sample copy. Any spelling style is acceptable so long as it is consistent within the manuscript. Please use double quotation marks, except where “a quotation is ‘within’ a quotation”. Please note that long quotations should be indented without quotation marks.

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Appendix 3. Approved Research Proposal

Major Research Project Proposal

Date: 07/05/2021

Author

Fraser Anderson

Title

Predictors of treatment non-completion among male prisoners accessing psychological mental health interventions

University Supervisors

Project Beginning – March 2021: Professor Tom McMillan

April 2021 – Project Completion: Dr. Karen McKeown

Field Supervisor

Project Beginning – March 2021: Dr. Claire Stark

April 2021 – Project Completion: Dr. Fiona Mair

Student ID

Word Count

3297

(excluding tables, appendices & plain language summary)

Abstract

Background: Prisoners experience mental health problems at a higher rate than the general population. Studies evaluating the effectiveness of clinical interventions among offenders often report high levels of treatment non-completion however little is known about the factors which contribute to this. Establishing the predictors of prisoner mental health treatment non-completion could provide important population and context specific information that could contribute to the development of strategies to reduce attrition and improve service planning and clinical outcomes.

Aim: To evaluate the factors predicting treatment non-completion in a sample of adult male prisoners.

Method: A non-experimental retrospective research design will be used to investigate the ability of patient (demographic, behavioural, and clinical) and institutional (e.g., liberated mid-treatment) factors to predict treatment non-completion. The project will use routine clinical data from the Psychological Therapies Service within HMP Shotts. A sample size of 80-110 is anticipated. This is a database project and approval from NHS research ethics committee is not to be required; however, the NHS Research Ethics Service will be contacted to confirm this. The local NHS Caldicott Guardian and NHS Research & Development will be contacted for approval of NHS data access. Some variables of interest are contained within the Scottish Prison Service (SPS) database and SPS ethical approval will also be sought. The ability of various client (e.g., demographic and clinical) and institutional (e.g., sentence length) to predict treatment non-completion will be assessed using multivariate logistic regression.

Applications: The identification of factors predicting treatment non-completion could enable a better use of resources and the development of responsive pre-treatment strategies which increase treatment completion in a prison setting.

Introduction

Prisoners experience mental health problems that are often severe, complex, and co-morbid, and at a higher rate than the general population (Fazel, 2016). These problems are associated with an increased risk of self-harm (Hawton et al, 2014), suicide (Fazel et al, 2016), violence inside prison (Goncalves et al., 2014) and an increased risk of recidivism upon release (Baillargeon et al., 2009).

NHS Scotland psychological therapies services have adopted a matched-stepped care service delivery model. In prisons, this is guided by a combination of the 'Forensic Mental Health Matrix' (2015) and the larger, generic services 'Matrix' (2015). The 'Forensic Matrix' was published in recognition that offenders are likely to have additional treatment needs related to their offending behaviours and provides a summary of the available evidence for these problems. The matched-stepped care model has been implemented across the forensic network and a key next step is to empirically evaluate its effectiveness and applicability.

Despite the publication of the 'Forensic Matrix' a lack of prison-specific research means that most clinical interventions inmates receive are derived from the generic 'Matrix', which was compiled from research comprising non-offender samples in the community (Forensic Matrix, 2012). There is a paucity of prison-specific clinical intervention literature however the results of the only comprehensive systematic review and meta-analysis of prisoner clinical outcomes (Yoon et al., 2017) suggests that cognitive-behavioural and mindfulness-based therapies are moderately effective overall. However, myriad limitations inherent in most studies limit the generalisability of the findings. For example, the largest effect sizes were observed in studies with no active or waitlist-control groups and improvements in symptoms may have reflected natural fluctuations over time, non-specific benefits of treatment or placebo effects. Further, effectiveness in most studies has been quantified according to symptom improvement as measured by single, disorder-specific outcome measures that have not been validated for use among prisoners (Goff et al., 2007). Prisoners are likely to experience multiple problems (Fazel, 2016) and a single outcome measure may not be sensitive to the true effect(s) of treatment. Effect sizes were also larger in studies with high rates of treatment non-completion and

statistical analyses was rarely conducted on an intention-to-treat basis which can positively bias estimates of treatment effects (Nüesch et al., 2009). Yoon et al (2017) also included a qualitative analysis of the discussion sections of each paper in their meta-analysis in an attempt to identify the challenges associated with delivering psychological therapies in prisons which may not be apparent from the results of quantitative analysis alone. They found that across studies prisoners were often liberated or moved establishment mid-treatment and were regularly prevented from attending therapy for institutional reasons (e.g., indiscipline). They noted that several papers raised treatment non-completion as an issue in their discussion, but that detailed attrition data was rarely reported. They concluded their qualitative analysis by suggesting that the limitations inherent in the prisoner outcome literature would not be improved via improved research design, as many of the issues appear to be related to barriers to engaging in and/or completing treatment.

Treatment non-completion in the context of prisoner mental health interventions has not been researched and in the absence of this literature psychologists working in prisons must attempt to understand this problem from two related, but separate literatures, with theoretical roots in two distinct paradigms: a clinical psychopathology (e.g., mental health) paradigm and a forensic risk assessment and management (e.g., forensic rehabilitation) paradigm. These paradigms in their contemporary form emerge from distinct institutional systems (i.e., mental health and criminal justice) with disparate purposes, societal functions, and approaches to treatment (Forshaw, 2008). This evidence is summarised below.

The mental health and forensic rehabilitation intervention non-completion literatures are occupied by two central questions:

3) How frequent is treatment non-completion?
4) Are there specific factors which predict non-completion?

Mental Health Treatment Non-Completion – Non-Offender Populations

Broadly speaking, mental health interventions tend to focus on the treatment of mental illness. These interventions emanate from empirical psychological models of mental disorder and the primary objective is the alleviation of psychological

distress (Barnao, 2015). Participation is voluntary, treatment goals are patient-generated, and the values of individual well-being, choice and autonomy are cardinal (Barnao, 2015). Among non-offenders accessing these interventions the average treatment non-completion rate is 20% (Swift & Greenberg, 2014). Treatment non-completion rates do not differ by treatment orientation (e.g., CBT v Psychodynamic), setting (e.g., inpatient or outpatient), or format (e.g., individual or group). Treatment non-completion has been shown to be more likely where patients have severe and/or multiple diagnoses, or a personality or eating disorder diagnosis, and in those who are younger in age (Swift & Greenberg, 2014). Treatment non-completion in this context is associated with poorer clinical outcomes, low morale among staff, reduced clinical capacity and cost inefficiencies for services (Barret et al., 2008).

Forensic Rehabilitation Treatment Non-Completion – Offender Populations

In contrast, forensic rehabilitation interventions tend to focus on the thoughts, attitudes and behaviours that are thought to be implicated in re-offending (Barnao, 2015). These interventions emanate from empirically derived predictors of criminal behaviour and the primary objective is the protection of the public through the reduction of recidivism; not the alleviation of psychological distress (Barnao, 2015). Participation may be mandatory with little or no patient choice in goal setting and may even be intended to serve to punish and deter. Engagement in treatment may be motivated by a desire for liberation and not the reduction of offender behaviours and/or the risk of re-offending (Ward, 2013; Sadoff, 2011). Treatment non-completion in this context is associated with an increased risk of recidivism, an increased sentence length, an increased risk of violence, self-harm, or suicide, and a negative impact on patient and staff morale (Casey et al., 2007). Worryingly, there is evidence suggesting that treatment non-completion may be associated with an increased risk of recidivism when compared with offenders who complete treatment **and** when compared to *untreated* offenders, suggesting that incomplete treatment may actually *cause* harm (McMurran & Theodosi, 2007).

The philosophical and theoretical underpinnings, principles, and approaches to forensic rehabilitation interventions appear in many ways antipodal to those encompassed by mental health interventions and neither and neither literature is adequately representative of a prisoner population and the environment within

which they reside. As such, attempting to derive an understanding of prisoner mental health treatment non-completion from the current evidence is both confusing and of limited applied value and there is a need for specific research investigating the factors predicting mental health treatment non-completion among prisoners.

Current Study

Reasons for and rates of treatment non-completion provide important population and context-specific information regarding treatment acceptability and effectiveness of treatment (Swift & Greenberg, 2014). An understanding of the factors predicting clinical treatment non-completion could be used to develop targeted pre-treatment strategies that could improve treatment completion rates and improve service planning. For example, it may allow for a more precise identification of specific needs and the more appropriate application of clinical interventions. Alternatively, it may highlight the importance of systemic, institutional constraints, in which case it may be necessary, for example, to reconsider ways in which custodial staff are involved in care. In the context of a matched-stepped care this could improve service efficiency, increased access to psychological services, improve clinical outcomes and prisoner and staff morale.

Aims & Research Questions

To model the factors predicting treatment non-completion among a sample of long-term (> 4 years) adult male prisoners.

This is the first study of its kind and the research questions are:

1. How frequent is treatment non-completion among prisoners accessing mental health interventions?
2. What client characteristics are associated with an increased risk of treatment non-completion?
3. What institutional characteristics are associated with an increased risk of treatment non-completion?

Design, Method & Procedure

Design: A non-experimental ex post-facto research design will be used to investigate the ability of each independent variable to predict completer status. No recruitment is required as this is a database project.

Participants: The source of the dataset will be the Psychological Therapies service within HMP Shotts. Shotts is a prison for long-term (> 4 years) adult male offenders.

Inclusion Criteria: Prisoners referred to the clinical psychology service between 31/07/2017 and 31/10/2021 who begin intervention.

Exclusion Criteria: Prisoners referred to the service for reasons other than treatment e.g., for consultation or assessment purposes only.

Data Access & Research Procedures: A range of demographic, behavioural, and clinical factors are routinely collected during clinical assessment and are available via NHS electronic databases and/or physical case files held within the prison health centre. Additional relevant institutional characteristics are available via the Scottish Prison Service (SPS) electronic system(s) which is also accessible from the prison health centre. Where there are gaps in the database, where available, information will be collected from physical case notes. No patient files will be removed from the prison health centre at any time. As the existing databases contain patient identifiable information and data superfluous to this study, a bespoke research database will be created using Microsoft Excel that will only contain anonymised data directly relevant to the research question. This database will be stored on an encrypted NHS network drive until the project is complete and will be accessible to the researcher remotely; however, only via an NHS laptop with comprehensive hard-drive encryption and security software installed.

Measures: The following criteria were used in determining which data will be collected for predictor analyses:

(1) The factor has been shown to predict non-completion among offenders accessing forensic rehabilitation interventions
(2) The factor has been shown to predict non-completion among non-offenders accessing mental health interventions
(3) The data is likely to be available within the existing databases

Predictor Variables

Client Characteristics

Age: In years (at treatment onset)
Personality Disorder Diagnosis*: Yes/No
Recent Violence: Yes/No - Defined as any form of physically violent behaviour which has been registered by the Scottish Prison Service within the 6 months (or less if incarcerated <6 months) prior to beginning treatment.
Known Head/Brain Injury*: Yes/No
Clinician Impression of Presenting Problem*: E.g., DSM-5 Diagnostic category
Reason for Referral: As stated by referrer
Multimorbidity*: Yes/No
Symptom Severity: The Clinical Outcomes in Routine Evaluation – 10 Items (CORE-10) questionnaire is a brief outcome measure comprising 10 items drawn from the CORE-OM which is a 34-item assessment and outcome measure. The CORE-OM has been widely adopted in the evaluation of counselling and the psychological therapies in the UK. Although there may be a blend of CORE-10/34 data these questionnaires produce categorical evaluations of symptom severity (e.g., Mild/Moderate) as well as continuous scores. It may be necessary to compare participants based on these categories.
Historical/Active Substance Misuse*: Yes/No
Educational Attainment: High-school qualification or higher – Y/N
DNA 2 or More Sessions: Y/N

*Data for variables marked with an asterisk is contained within the existing clinical database and is based on a combination of formal diagnoses/assessment and/or subjective clinical judgement. The validity of this data will be commented upon in the discussion of the results.

Institutional Characteristics

Sentence Length: Total

Sentence Length: Remaining (at treatment onset)

Length of Sentence Served to Date: Years (at treatment onset)

Liberated Mid-Treatment: Yes/No

Moved Establishment Mid-Treatment: Yes/No

Disciplinary Issues: Anecdotal evidence suggests that poor mental health often contributes to variety of issues which lead to prisoners accruing a report and/or punishments that can impede access to the health centre. The number of incident reports accrued whilst prisoners attended therapy will be collected. Reports generally consist of failures to attend work, or any other breach of prison rules.

Outcome Variables

Treatment Complete: Treatment will be considered complete where its termination was mutually agreed between patient and therapist either because of a satisfactory reduction in symptom/problem severity or where it was determined by the therapist that continued intervention was unlikely to yield further benefit.

Treatment Not Complete: Treatment will be considered non-complete where an individual begins treatment that is later terminated where the completion criteria are not met and/or where the termination of treatment is determined by factors out with the control of either the therapist or prisoner.

Ethics, Governance & Data Protection

NHS Ethics:

This study relies upon NHS clinical data and approval and guidance will be sought from NHS Lanarkshire Research & Development. This is a database project and prisoners are not required to actively participate. The study is unlikely to require formal approval from an NHS research ethics committee, however, the NHS Research Ethics Service will be contacted to confirm this. The local NHS Caldicott

Guardian will be contacted for approval of access to the anonymised research database.

Scottish Prison Service (SPS) Ethics:

Some variables of interest in this study may be contained within SPS databases. This data is routinely available to clinical staff within the prison health centre and formal SPS ethical approval is unlikely to be required, however, confirmation of this will be sought in writing prior to collecting data. Dr. Claire Stark (field supervisor) has contacted the deputy Governor at HMP Shotts and is currently awaiting their response. Formal confirmation that ethical approval is not required will also be requested from the Scottish Prison Service.

Data Management & Protection:

A research database which only contains data relevant to the research question will be created; this will be encrypted to the NHS security standard and will be saved on an encrypted NHS network drive. Identifiable information will be removed, and participants will be assigned with an identification number to preserve anonymity. This database will be accessible by the field researcher and field supervisor. Clinicians within the forensic mental health team have agreed to input relevant clinical data for prisoners on their caseload and as such will have access to the database until data collection is complete.

Once data collection is complete a copy of this database will be transferred via encrypted USB to a University of Glasgow laptop that is encrypted to the NHS security standard and will only be accessible to the field researcher and academic supervisor.

A copy of the database will be retained on the NHS server until the project is complete so that any missing data identified during the analysis stage can be input. Once the project is complete this copy will be deleted by the researcher. An electronic copy of the database will be securely archived on the University of Glasgow (Enlighten) server for 10 years.

Analysis Plan

1. Univariate Logistic Regression Analysis (Completers vs Non-Completers)

Univariate logistic regression will be used to assess the ability of each independent variable to predict completer status. Odds ratios with 95% confidence intervals and their p values will be presented alongside the descriptive data. Correlations between predictor variables will be checked for multi-collinearity.

2 - Multivariate Logistic Regression Analysis – Non-Completers

Variables that are significant in univariate analysis will be entered together into a forward stepwise multivariate logistic regression model using a probability of 0.05 or less for variable entry. A stepwise model will be used as there are no a priori hypotheses regarding the importance of individual predictor variables. Multivariate logistic regression has been selected as it enables us to take two or more independent variables into consideration simultaneously to predict the value of a dichotomised dependent variable (i.e., treatment complete or not complete).

Justification of Sample Size

This study will investigate 15 predictor variables. There are currently full data for 47 prisoners from referral to discharge between 31 July 2017 and January 2020. This represents an average throughput of approximately two prisoners per month, however, this is likely to increase as two new psychologists have recently been recruited. The minimum n in our study at present is 47, however; I have been unable to access the clinical database for nearly 12 months due to Covid-19 restrictions. There are existing data for the past 12 months that will be added to the database shortly. Data collection will continue until 31 October 2021. Based on the length of the data collection window and an estimation of the service throughput I anticipate a minimum sample size of 80 and a maximum sample size of 110

The multivariate regression analysis here is exploratory and an accurate sample size estimation is not possible. However, in a study of the factors predicting treatment non-completion among offenders taking part in forensic rehabilitation treatment (Cullen, 2011), a sample size of 42 was appropriately powered to identify significant predictors of treatment non-completion. Some of the predictor variables they included are also being investigated in this study. For example, a diagnosis of Anti-Social Personality Disorder significantly increased the likelihood of treatment non-completion (Odds Ratio = 4.06, n = 21). Our sample will be at minimum double this number and is likely to be of benefit for the multivariate analysis.

Health & Safety Issues

a) Researcher Safety Issues: The field researcher will not have any direct contact with prisoners. The researcher is working clinically in this setting and has completed NHS Violence and Aggression training in addition to the Scottish Prison Service 'Personal Protection Training'.
b) Participant Safety Issues: None identified.

Financial Issues

No costs attached to this project other than minimal travel fees which will be covered by the NHS.

Provisional Timetable

Date	Action
28 September 2020	Proposal Draft Submission
25 January 2021	Proposal submission for university review
February 2021	Ethics Application – Scottish Prison Service NHS Research & Development Approval

	Confirmation from the NHS ethics committee that formal approval not required Caldicott Guardian contacted for confirmation and approval
March 2021 (Pending Ethics Approval)	Anonymised research database will be created. Routine data relevant to the study has been continuously collected since October 2017, is ongoing at present, and will be copied into this database once the requisite approval has been provided.
March 2021 – October 2021	Ongoing data collection and write up of introduction and method section
October 2021	Data collection ends
November 2021	Data analysis
December 2021/January 2022	Final write up period
February 2022	Final submission – Mid February 2022
April 2022	Viva Voce

Practical Applications & Dissemination

It is anticipated that the results of this study will help to determine the extent of treatment non-completion and the factors which contribute to

this in a prison setting. It is hoped that the identification of factors predicting treatment non-completion could enable a better use of resources and the development of responsive pre-treatment strategies which increase treatment completion in a prison setting. This may also highlight important avenues for future research specific to prisoner mental health treatment non-completion.

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