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Trauma-Informed Care for Adults Involved in the Correctional System: A Review of the Clinical Effectiveness, Cost-Effectiveness, and Guidelines

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Authors: Dinsie Williams, Nina Frey

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Abbreviations

EMDR	Eye movement desensitization and reprocessing
RCT	Randomized controlled trial
TIC	Trauma-informed care

Context and Policy Issues

Trauma refers to the experience of and response to physically and emotionally harmful incidents including, but not limited to, violence, abuse or assault, neglect, loss, and disaster.[1]Trauma, regardless of the type, may have debilitating effects on an individual's functioning and mental, physical, social, emotional, and spiritual well-being.[2] Specifically, sexual abuse has been identified as a risk factor for crime, resulting in higher instances of arrests and exposure to additional trauma.[3] In Canada, 32% of adults are reportedly abused when they are children.[4] While 30% of women[a] have been physically and/or sexually assaulted globally, as many as 90% of women who are incarcerated have experienced violence in the United States.[3] Given the higher rate of trauma history in populations who are incarcerated, administrators of correctional systems are increasingly expressing interest in trauma-informed care (TIC).[5]

TIC is an approach used to engage individuals with histories of trauma by acknowledging the symptoms of trauma and their effects.[1] Trauma-informed care is guided by four principles: recognizing that trauma is prevalent, recognizing the signs and symptoms of trauma, integrating information about trauma into policies, procedures, and practices, and minimizing retraumatization.[1] There remains some uncertainty regarding the effectiveness and appropriateness of using TIC to manage adults in the correctional system. Correctional settings may inherently trigger memories of trauma and promote distress, particularly in women who have experienced trauma.[6] A person who is incarcerated may be retraumatized as a result of interaction with therapists, limitations to their autonomy, forced medication, seclusion, the use of restraints, close personal inspection, removal of privacy, authoritarian control, and threats of violence.[6]

The purpose of this report is to review the clinical effectiveness, cost-effectiveness, and evidence-based guidelines on TIC for the management of adults involved in the correctional system. Acknowledging that there is a range of gender expressions and terms for expressing them, references to the sex or gender of study participants in this review reflect the terminology used in the cited articles.

[a] Acknowledging that there is a range of gender expressions, references to the sex or gender of study participants in this review reflect the terminology used in the cited articles.

Research Questions

1. What is the clinical effectiveness of trauma-informed care for adults involved in the correctional system?
2. What is the cost-effectiveness of trauma-informed care for adults involved in the correctional system?
3. What are the evidence-based guidelines regarding the use of trauma-informed care for adults involved in the correctional system?

Key Findings

One single centre randomized controlled trial and one prospective, nested non-randomized study were found that addressed the clinical effectiveness of trauma-informed care for adults in the correctional system. The results of these studies suggest that there was a trend toward higher program completion rate and lower incidence of recidivism with trauma-informed care relative to treatment as usual (or program as usual). Trauma-informed care appeared to have no impact on admission into community-based treatment and no clear patterns emerged regarding the impact of trauma-informed care on substance use relapse. No information was found on change in symptoms, safety, or harms associated with trauma-informed care. No relevant studies reported on cost-effectiveness of trauma-informed care for adults in the correctional system and no relevant evidence-based guidelines were found.

The limited number of studies, important methodological limitations of the available studies, and differences in the interventions, comparators, and the reported outcomes limits confidence in the findings on clinical effectiveness. Generalizability of the evidence to the Canadian context is limited given that all of the evidence came from studies that were conducted in the United States. Additional RCTs or prospective non-randomized studies that evaluate mutual TIC programs and outcomes in Canada would enhance the evidence regarding the effectiveness of TIC.

Methods

Literature Search Methods

A limited literature search was conducted on key resources including PubMed, the Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) Medline, Embase, PsycINFO, Canadian and major international health technology agencies, as well as a focused Internet search. No methodological filters were applied to limit retrieval. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 01, 2008 and August 07, 2018.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Adults involved in the correctional system who have experienced trauma (e.g. physical, emotional, substance-use disorders, mental health issues, etc.)
Intervention	Trauma-informed care within the correctional system (specific programs may include: Seeking Safety, Project Links, etc.)
Comparator	No trauma-informed care, usual care, other trauma-informed care approaches
Outcomes	Clinical effectiveness (e.g., reduced criminal behavior, change in symptoms, safety, harms, etc.) Cost-effectiveness Evidence-based guidelines
Study Designs	Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, economic evaluations, guidelines

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table **1**, if they were duplicates, or if they were published prior to 2008.

Critical Appraisal of Individual Studies

All studies were critically appraised by one reviewer. The RCT and non-randomized study were critically appraised using the Downs and Black checklist.[7] Summary scores were not calculated for the included studies; rather, a review of the strengths and limitations of each included study were described narratively.

Summary of Evidence

Quantity of Research Available

A total of 156 citations were identified in the literature search. Following screening of title and abstracts, 130 citations were excluded and 26 potentially relevant reports from the electronic search were retrieved for full-text review. Seven potentially relevant publications were retrieved from the grey literature search for full text review. Of these 33 potentially relevant articles, 31 publications were excluded for various reasons, and two publications met the inclusion criteria and were included in this report. Appendix 1 presents the PRISMA[8] flowchart of the study selection.

Summary of Study Characteristics

Study characteristics are summarized below and details are available in Appendix 2, Table 2.

Study Design

One single centre RCT that was published in 2016[9] and one prospective, nested non-randomized study that was published in 2015[10] were included in this review.

Country of Origin

Both studies were conducted in the United States.[9,10]

Patient Population

The RCT enrolled 42 women who were incarcerated following conviction for a violent offense.[9] All participants had substance dependency or a positive drug screen during incarceration, were required to participate in violence-prevention programming, and were eligible for release on parole within 18 to 24 months of enrollment in the study.[9] None of the participants had a serious mental health issue that required housing in a mental health unit.[9] Seven participants were lost to follow up, five of whom remained in the prison during the outcomes measurement period and two were transferred out of state following their release.[9]

The prospective, nested non-randomized study enrolled 220 men and women who were charged with a non-violent felony drug or property crime, 150 of whom had Criterion A trauma history and were therefore included in this review.[10] The participants were enrolled in a drug court program and were not incarcerated.[10] Examples of the types of trauma that participants reported were physical, emotional, and sexual abuse or assault; physical and emotional neglect; witnessing parental abuse; loss of child custody through jail or child protective services; being homeless and active in addiction; using drugs during pregnancy; traumatic deaths; medical traumas; and motor vehicle accidents.[10] Thirty-eight participants left the study prior to the start of enrollment in the intervention arm, leaving 112 (53 women and 59 men) in the study.[10] Researchers documented pretreatment levels of depression for all participants in the program through assessments of Beck Depression Inventory II and Index of Self-Esteem scores while levels of posttraumatic stress were assessed through measurements on the Clinician-Administered Posttraumatic Stress Disorder scale in participants 1 through 90 and the Detailed Assessment of Posttraumatic Stress scale in the remaining participants.[10] The authors reported that those who opted in to EMDR therapy had higher pretreatment scores for measures of depression and posttraumatic stress.[10] Those who opted in to EMDR therapy had an average Beck Depression Inventory-II score of 15 (mild depression) compared to 10 in the comparator group.[10] Measurements on the Index of Self-Esteem were similar at an average of 33 (low self-esteem) relative to an average of 31 (slow self-esteem).[10] The average Clinician-Administered Posttraumatic Stress Disorder scores were 55 (moderate) in the EMDR therapy group versus 33 in the comparator group, while the average Detailed Assessment of Posttraumatic Stress scores were 68 (clinically significant) versus 75, respectively.[10] Participants were excluded from the study if they had previously been convicted of a violent felony crime such as a first or second-degree robbery, assault, sex offense or any crime involving the use of a weapon.[10]

Interventions and Comparators

The intervention of interest in the studies was TIC for the prevention of recidivism or substance use relapse in convicted offenders. In the RCT, participants were enrolled in the Beyond Violence program (n = 24) and compared with those (n = 18) who received treatment as usual.[9] Beyond Violence is a 20-session, gender-specific and TIC intervention for violent women within the correctional system.[9] Its primary objective is to prevent recidivism and future violence by women who have a history of being violent.[9] It takes into account victimization history, gender socialization, anger expression, and the likelihood of co-morbidities such as substance use and mental health disorders.[9] Treatment as usual in this study referred to a 44-session Assaultive Offender Programming intervention designed for males convicted of a violent crime.[9]

The prospective, nested non-randomized study was part of a three-phase drug court program that lasted 12 to 18 months.[10] Phase 1 (orientation/stabilization) was three to four

months long, phase 2 (intensive counseling) was five to eight months long, and phase 3 (application/transition) lasted four to six months.[10] During the first two phases (eight to 12 months), a modified Seeking Safety program was offered along with Program as Usual (PAU) to 150 participants who endorsed Criterion A trauma history.[10] Thirty-eight of these participants dropped out of the program before the end of the second phase.[10] In phase three (four to six months), the modified Seeking Safety program was terminated and Eye movement desensitization and reprocessing (EMDR) therapy was offered as an optional replacement.[10] For the purpose of this review, 65 participants who accepted EMDR therapy in phase 3 were considered to be in the intervention group while 47 participants who opted out of EMDR but continued with PAU were in the comparator group. An additional group of 70 participants who did not endorse Criterion A trauma history were treated in the drug court's PAU but the results are not included in this review.

Seeking Safety is a cognitive behavioural therapy program that integrates trauma and substance abuse treatment.[10] The program centres around five concepts: safety, integrated treatment for posttraumatic stress disorder and substance abuse, focus on ideals, attention to cognitive, behavioural, interpersonal and case management content areas, and attention to therapist processes.[10] A modified version of Seeking Safety that consisted of 15 out of 25 possible sessions was offered in groups that were facilitated by regionally-certified chemical dependency professionals and trained drug court paraprofessional support staff.[10] EMDR therapy is grounded in the adaptive information processing model which suggests that unprocessed past traumatic incidents prevent adaptive functioning in the present.[10] EMDR encompasses elements of cognitive behavioural therapy along with elements of psychodynamic, experiential, interpersonal, and body-oriented therapies.[10] EMDR includes unique activities related to side-to-side eye movements and tactile tapping or auditory tones for reprocessing patients.[10] In this study, EMDR therapy was offered by eight therapists, two of whom were EMDR certified.

PAU included developing an individual treatment plan, weekly substance abuse education, moral reconation therapy, counselling, cognitive self-change process, drug court progress review (weekly in phase 1 and bi-weekly in phase 2), and recovery support group meetings (at least 4 times per week in phase 1 and at least 3 times per week in phase 2).[10] In phase 3, PAU had the same elements as in the first two phases except weekly substance abuse education was replaced by enhancement group Gorski relapse prevention, and drug court progress reviews occurred monthly rather than bi-weekly.[10]

Outcomes

The outcomes of interest were program completion rate,[9,10] recidivism rate,[9,10] substance use (i.e., drug) relapse rate,[9] and involvement in community-based treatment.[9] Participants enrolled in the RCT between July and November 2011 and outcomes were evaluated between January and December 2014 (i.e., 29 to 40 months after study enrollment started).[9] In the non-randomized study, participants enrolled between August 2004 and December 2009, and outcomes were evaluated five years from each participant's date of program completion.[10]

Program completion rate referred to the proportion of participants who completed the treatment program.[9,10] Recidivism involved return to prison for a parole violation,[9] new arrests related to any offense,[9] jail confinement,[9] or re-convictions,[10] and time to recidivism (i.e., the number of months to the first recidivism event).[9] Substance use relapse was evaluated in terms of the presence of a positive drug screen,[9] the time to first positive drug screen (i.e., the number of months to the first positive screen),[9] and the proportion of

positive drug screen results relative to the number of drug screens administered.[9] Involvement in community-based treatment was defined as the proportion of participants referred to treatment by the parole officer or the proportion of participants admitted to treatment in the community.[9]

Summary of Critical Appraisal

A summary of the critical appraisal of the studies is provided below and details are available in Appendix 3, Table 3.

The RCT and non-randomized study were appraised using the Downs and Black checklist.[7] Strengths of the RCT were that the study objective, inclusion criteria, included patients' characteristics, the interventions being compared, and the findings were described clearly.[9] As well, probability values for the main outcomes were calculated. The statistical tests used to assess the main outcomes were appropriate and compliance with the intervention and comparator was reliable given the setting. Importantly, participants in both groups were recruited from the same population and at the same time. Sequential randomization was completed by a deputy prison warden and the study's principal investigator. Finally, some consideration was given to confounding when assessing the data on recidivism.

Several limitations of the RCT were identified with respect to reporting, external validity, internal validity, and power, examples of which are provided here.[9] The authors stated that there were no differences in the measures of mental health of the participants who were lost to follow-up and those that remained in the study; yet, a comparison of the characteristics was not described. As such, it is unclear whether the participants who were enrolled and those who were included in the final analyses were representative of the prison population. Unplanned covariate analyses were conducted on drug use relapse and recidivism suggesting that the authors selectively assessed the data. There was evidence that the selection of the follow-up period may have been biased. Participants were enrolled in the study during a five-month span from July to November 2011, and released from prison on different dates, however, the authors evaluated outcomes during a fixed 12-month span from January to December 2014 (i.e., 29 to 40 months after study enrollment started). This means that the participants would not have had the same amount of time to recidivate or relapse. Assessors were not blinded to treatment allocation, allowing the potential for bias in the evaluation of outcomes. Finally, the study was insufficiently powered (at 0.6) to detect clinically or operationally important effects.

The non-randomized study similarly had fewer strengths than limitations.[10] The strengths included reporting the objective, main outcomes, inclusion and exclusion criteria, the interventions of interest, and the main findings. Basic fidelity checks were conducted of the Seeking Safety program that was offered to all participants, providing assurance that therapists were following the program as instructed.

Multiple limitations were documented with respect to reporting, external validity, internal validity, and power.[10] Although an account was given of all of the participants who were lost to follow-up, their characteristics were not compared with those who remained in the study; therefore it is unclear whether the participants who completed the study were representative of the population from which they were recruited. The study lost over 25% of the 150 participants who endorsed Criterion A trauma history and terminated treatment in the first two phases of the drug court program.[10] Without adequate reasons provided for dropping out of the study, it is possible that the characteristics of those included in the final cohort were different from those enrolled at the start of the study. Regarding internal

validity, the researchers evaluated compliance with EMDR therapy prior to the start of participant enrollment for three of eight therapists. The researchers did not conduct compliance checks during the study for any of the therapists. Participant enrollment was not randomized to the intervention and comparator groups and participants were offered EMDR in a phased sequence following eight to 12 months of a modified Seeking Safety protocol and PAU. Phased introduction of EMDR therapy means that the study provided a comparison of the incremental impact of EMDR therapy after participants were treated with a modified Seeking Safety protocol as an adjunct to PAU. The sequential protocol may limit opportunities to synthesize the results from this study with others in the future. The authors noted that participants who selected EMDR therapy had higher pretreatment scores for measures of depression and posttraumatic stress than those who declined, suggesting that those who opted in may have been more motivated to accept additional treatment for trauma. Finally, it was not clear whether the study was sufficiently powered to detect clinically or operationally important effects.

Summary of Findings

Findings are summarized below and details are available in Appendix 4, Table 4.

Clinical effectiveness of trauma-informed care

Program completion

More participants completed at least 75% of the Beyond Violence program sessions compared with participants who were treated as usual (100% out of 19 versus 69% out of 61) in the RCT.[9] Similarly, more participants in the non-randomized study who opted in to EMDR therapy completed their program versus those who opted out (91% out of 65 versus 57% out of 47).[10]

Recidivism

Recidivism was assessed differently in the two studies. In the RCT, recidivism was calculated as the incidence of returning to prison, being arrested and/or being jailed following release.[9] In the non-randomized study, recidivism was defined as reconviction.[10] In the RCT, none of the participants in either group returned to prison during the 12-month span in which outcomes were evaluated.[9] Approximately 10.5% in the TIC group and 37.5% in the treatment as usual group were arrested.[9] Similarly, 15.8% versus 50% were jailed, respectively.[9] The difference was statistically significant for the incidence of being held in temporary custody.[9] The odds of being arrested or held in custody were 19% lower following TIC relative to treatment as usual.[9] On average, it took participants in the TIC group longer to recidivate than those who were treated as usual (2 months versus 1 month).[9] Within five years of program completion, the authors of the non-randomized study reported that recidivism (i.e., reconviction) rate was lower at 12% in the EMDR therapy group compared with 33% in the group that opted out of EMDR therapy.[10]

Substance use relapse

While a lower proportion of participants relapsed (i.e., had positive drug screens) in the Beyond Violence group relative to those under treatment as usual (26% out of 19 versus 50% out of 16), the difference was not statistically significant.[9] The proportion of positive drug screen results relative to the number of drug screens administered was 0.09 ± 0.23 in the Beyond Violence group versus 0.20 ± 0.30 in the treatment as usual group.[9] The difference was also not statistically significant.[9] The time to first positive drug screen was not reported.[9]

Community-based treatment (referral and admission)

Relative to treatment as usual, a significantly smaller percentage of participants in the Beyond Violence group were referred by parole officers to community-based treatment (i.e., 16% out of 19 versus 69% out of 16). Conversely, a higher percentage of participants in this group self-referred, leading to a non-statistically significant difference in the proportion that were admitted to community-based treatment (i.e., 68% out of 19 versus 75% out of 16).[9]

Cost-effectiveness of trauma-informed care

No information on cost-effectiveness was identified.

Evidence-based guidelines

No evidence-based guidelines on TIC specific to adults in the correctional system were identified.

Limitations

The primary limitations of the body of evidence in this review are the limited quantity and quality of studies on clinical effectiveness, the lack of evidence on cost-effectiveness, and the lack of evidence-based guidelines on TIC for adults in the correctional system. The two included studies had methodological limitations ranging from uncertainty regarding whether the enrolled participants adequately represented the general population in the correctional system to uncertainty regarding whether the studies were sufficiently powered to detect clinically and operationally important effects.[9,10] In the non-randomized study, the intervention group was created for our review from a group of participants who opted to have a second form of TIC (i.e., EMDR therapy), having previously received a modified version of Seeking Safety as an adjunct to PAU.[10] Participants in the comparator group, PAU, had also previously received a modified version of Seeking Safety.[10] As such, it may be challenging to synthesize the results from the non-randomized study with other studies.

Both studies were conducted in the United States. As such, there may be differences in the correctional systems that could preclude generalizability of the findings to the Canadian context. In addition, results from the randomized controlled trial may not be generalizable beyond a population of women who are incarcerated, as it evaluated a gender-based program. The non-randomized study involved participants who were diverted to a drug court program to avoid incarceration.[10] The availability of drug court programs and EMDR therapy training for therapists, for example, may differ between the correctional systems of the United States and Canada, making it challenging to replicate the outcomes in Canada.[10] Furthermore, the information on TIC was limited to those programs that were used in the United States. Other forms of TIC programming were not described.

Conclusions and Implications for Decision or Policy Making

In this review, there was a limited quantity and quality of evidence on the clinical effectiveness, no evidence on cost-effectiveness, and no relevant evidence-based guidelines on TIC for adults in the correctional system identified. One single centre RCT[9] that enrolled 42 women and one prospective, nested non-randomized study[10] that enrolled 150 men and women (112 of whom were eligible for analysis) were included. The findings from the RCT suggest that a higher proportion of participants who received TIC (specifically Beyond Violence) adhered to treatment relative to those who were treated as usual.[9] According to the non-randomized study, a higher proportion of participants who choose to

enroll in EMDR therapy following Seeking Safety and PAU adhered to treatment compared with those who opted out of EMDR and continued with PAU alone.[10] Regarding the impact of TIC on criminal behaviour, recidivism (i.e., incidence of being arrested or held in custody, or incidence of reconviction) was lower in the respective intervention groups than in their comparator groups.[9,10] No clear pattern emerged regarding the impact of TIC on substance use relapse in women.[9] Although parole officers referred more participants who enrolled under treatment as usual to community-based treatment, TIC appeared to have no impact on actual admission into community-based treatment.[9] No study reported on change in symptoms, safety, harms, or cost-effectiveness of TIC for adults in correctional systems and no relevant evidence-based guidelines were found.

The generalizability of the available evidence to the Canadian context is limited given that all of the evidence came from studies that were conducted in the United States.[9,10] Furthermore, the studies had important methodological limitations that weaken confidence in the available results.[9,10] Caution should be taken in interpreting the information presented here due to the small quantity of studies and the differences in the interventions, comparators, and definitions of the reported outcomes.[9,10] Additional RCTs or prospective non-randomized studies that evaluate TIC programs and outcomes in Canada would enhance the evidence regarding its effectiveness.

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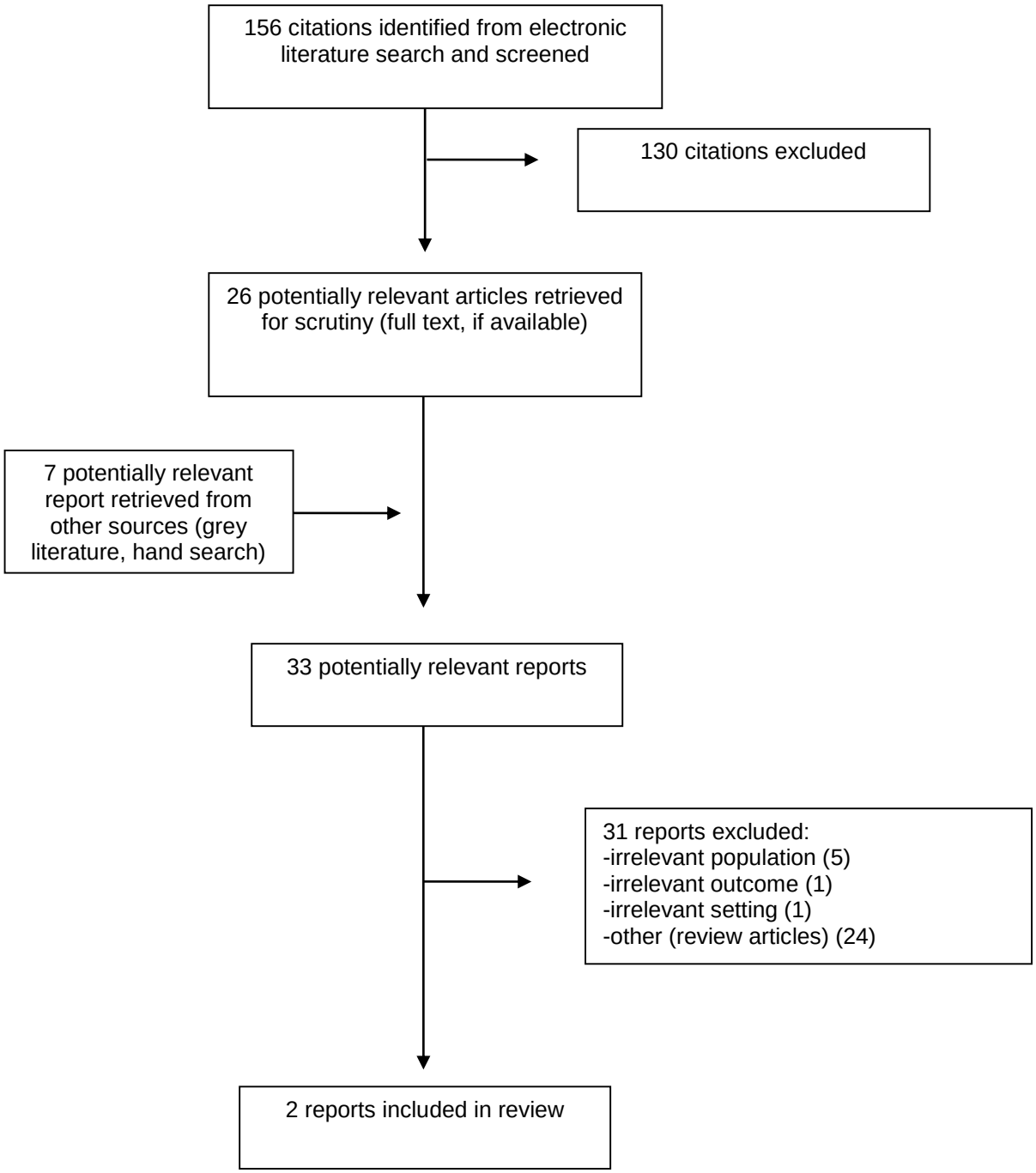
Appendix 1: Selection of Included Studies



Appendix 2: Characteristics of Included Publications

Table 2: Characteristics of Included Primary Studies

First Author, Publication Year, Country	Study Design	Population Characteristics	Intervention and Comparator(s)	Clinical Outcomes
Randomized Controlled Trial				
Kubiak, 2016, United States	Single centre randomized controlled trial	42 women[a] incarcerated following conviction and incarceration for a violent offense; had substance dependency or positive drug screen during incarceration, had no serious mental health issue that specifically involved housing on the mental health unit, and were eligible for release on parole within 18 to 24 months; required to participate in violence-prevention programming Mean age (SD): 33.66 (8.91) years (n = 35)	Intervention: Beyond Violence (n = 24) starting between July and November 2011 Comparator: Treatment as usual (n = 18)	Program completion rate, recidivism (i.e., return to prison for a parole violation, arrest or jail incidence), time to recidivism, substance use (i.e., drug use) relapse, proportion of positive drug-screen results relative to the number of drug screens administered, time to first positive drug screen, involvement in community-based treatment Follow-up period: 29 to 40 months after participant enrollment started
Non-Randomized Studies				
Brown, 2015, United States	Prospective, nested non-randomized study	220 adults (≥ 18 years) charged with a felony drug or property crime; enrolled in the Thurston County Drug Court Program between 2004 and 2009; with substance use disorder; n = 150 endorsed criterion A trauma history Exclusion criteria: previously been convicted of a violent felony crime such as a first or second-degree robbery, assault, sex offense or any crime involving the use of a weapon Mean age: 32 years	Intervention (n = 65; 36 women[a] and 29 men[a]): 4 to 6 months of EMDR + PAU (following 8 to 12 months of modified Seeking Safety + PAU) Comparator (n = 47; 17 women and 30 men): 4 to 6 months of PAU (following 8 to 12 months of modified Seeking Safety + PAU)	Program completion rate, recidivism (i.e., post-program reconviction) Follow-up period: 5 years from date of program completion (i.e., graduation), termination, or declining enrollment Data for those who terminated Seeking Safety and PAU prior to availability of EMDR (n = 38) or did not endorse criterion A trauma history (n = 70) were not included in this report.

EMDR = Eye Movement Desensitization and Reprocessing; PAU = Program as Usual; SD = standard deviation

[a]Acknowledging that there is a range of gender expressions, references to the sex or gender of study participants in this review reflect the terminology used in the cited articles.

Appendix 3: Critical Appraisal of Included Publications

Table 3: Strengths and Limitations of Clinical Studies using the Downs and Black Checklist[7]

Strengths	Limitations
Randomized controlled trial	
Kubiak, 2016, United States	
Reporting • The objective, main outcomes, included patients' characteristics, the interventions of interest, and the main findings of the study are clearly described • Probability values for the main outcomes were reported External validity • The staff, places, and facilities where the participants were treated, were representative of the treatment the majority of participants receive Internal validity - bias • The statistical tests used to assess the main outcomes were appropriate • Compliance with the intervention and comparator was reliable • The main outcome measures were accurate Internal validity - confounding • Participants in both groups were recruited from the same population over the same time period • Participants were randomized to intervention groups • There was adequate consideration for confounding in the analyses from which the findings on recidivism were drawn	Reporting • Exclusion criteria and potential confounders, were not described *a priori* • Adverse events were not reported • Characteristics of participants lost to follow-up were not described • Estimates of the random variability in the data for the main outcomes were not reported External validity • It is unclear whether the participants who were asked to participate were representative of the population from which they were recruited. The study did not report the proportion of the source population from which the participants were derived. • It is unclear whether the participants who agreed to participate were representative of the entire population from which they were recruited. A comparison of the characteristics of those who were invited and those who enrolled in the study was not presented. Internal validity - bias • Unplanned, retrospective co-variate analyses were conducted involving drug use relapse and recidivism • The time period between the intervention and outcome was not the same for all participants as data was collected at the same time irrespective of release date • Blinding of participants and outcomes assessors was not discussed Internal validity - confounding • It is unclear whether the randomized intervention assignment was concealed from both participants and health care staff • Although an account was made of participants who were lost to follow-up, suggesting that here were no differences in the measures of mental health in the remaining participants, a comparison of the characteristics of the general, invited, enrolled, and analyzed populations was not documented. Power • The study was insufficiently powered to detect clinically or operationally important effects. Statistical power was limited to 0.6 for recidivism and relapse.

Table 3: Strengths and Limitations of Clinical Studies using the Downs and Black Checklist[7]

Strengths	Limitations
Non-randomized study	
Brown, 2015, United States	
Reporting • The objective, main outcomes, inclusion and exclusion criteria, the interventions of interest, and the main findings of the study are clearly described External validity • The staff, places, and facilities where the participants were treated, were representative of the treatment the majority of participants receive Internal validity - bias • No unplanned retrospective subgroup analyses were reported • The drug court's clinical program supervisor randomly evaluated intervention groups for basic fidelity as instructed by the developer of the Seeking Safety program Internal validity - confounding • An account was made of participants who were lost to follow-up	Reporting • Principal confounders in either group were not clearly described • Adverse events were not reported • Characteristics of participants lost to follow-up were not described • Estimates of the random variability in the data for the main outcomes were not reported. • Probability values for the main outcomes were not reported External validity • It is unclear whether the participants who were asked to participate were representative of the population from which they were recruited. The study did not report the proportion of the source population from which the participants were recruited. • It is unclear whether the participants who agreed to participate were representative of the entire population from which they were recruited. Internal validity - bias • Information on one of the main outcomes was not provided • The time period between the intervention and outcome was the same for cases and controls. Participants were on EMDR therapy for a shorter period than on Seeking Safety. • Blinding of participants and outcomes assessors was not discussed • Compliance with the intervention was partially verified. Three out of eight EMDR therapists submitted two random audio tapes of previous therapy sessions to an EMDR Institute trainer for basic fidelity check. The remaining EMDR therapists were not audited. • It is unclear whether the main outcomes were accurate Internal validity - confounding • Participants in both groups were recruited from the same population but not over the same time period. Eye movement desensitization and reprocessing therapy was offered after all participants had been treated with Seeking Safety. • Cases and controls were not randomized • Confounding was not discussed Power • It is unclear whether the study had sufficient power to detect clinically or operationally important effects

EMDR = Eye Movement Desensitization and Reprocessing

Appendix 4: Main Study Findings and Authors' Conclusions

Table 4: Summary of Findings of Included Clinical Trials

Main Study Findings	Authors' Conclusion
Randomized controlled trial	
Kubiak et al, 2015[9]	
Lost to follow up: 5 participants remained in prison, and 2 were transferred out of state Follow-up: January to December 2014 (i.e., approximately 12 to 24 months after being released) Beyond Violence (n = 19) vs. TAU (n = 16) Time between treatment and parole (days): 562.32 ± 195.54 vs. 378 ± 180.23; *P* = 0.007; indicating that there was a longer period of time between admission to treatment and parole in the intervention group **Program completion** • Proportion who completed ≥ 75% of the sessions: 100% (19/19) vs. 69% (11/16); *P* = NR; indicating that a higher percentage of participants completed the Beyond Violence program than TAU **Recidivism (return to prison for a parole violation)** • Incidence: None **Recidivism (arrest or jail confinement)** • OR = 0.19 (CI 0.04 to0.91; *P* = 0.04); indicating that participants in the Beyond Violence group are less likely to recidivate • Time to recidivism (average): 2 months vs. 1 month **Substance use relapse (positive drug screen)** • Any indication of drug use: 26% (5/19) vs. 50% (8/16); OR = 0.38 (CI 0.09 to1.47); *P* = 0.15; indicating that there were fewer incidents in the Beyond violence group relative to the TAU group but the difference was not statistically significant • Proportion of positive drug screen results relative to the number of drug screens administered: 0.09 ± 0.23 vs. 0.20 ± 0.30; *P* = 0.23; indicating that the difference was not statistically significant between the groups • Time to first positive drug screen (months): NR **Involvement in community-based treatment** • Treatment referral rate: 16% (3/19) vs. 69% (11/16); *P* = 0.001; indicating that fewer participants were referred to community-based treatment in the Beyond Violence group • Admission rate following referral: 68% (13/19) vs. 75% (12/16); OR = 0.72 (CI 0.16,3.20); *P* = 0.67; indicating that there was no statistically significant difference in the proportion of participants admitted to community-based treatment programs	*"Women in the Beyond Violence condition interfaced significantly less with the criminal/legal system than their counterparts in the TAU condition."* [p. 675]

Table 4: Summary of Findings of Included Clinical Trials

Main Study Findings	Authors' Conclusion
Non-randomized study	
Brown et al., 2015[10]	
Loss to follow-up: 38 prior to phase 3 and 26 after the start of phase 3 Follow-up: 5 years after program completion EMDR + PAU (n = 65) vs. PAU (n = 47); following eight to twelve months involving modified Seeking Safety + PAU **Program completion** Program completion rate: 91% (59/65) vs. 57% (27/47); indicating an incremental benefit of EMDR over PAU (following modified Seeking Safety + PAU). The statistical significance of the benefit was not assessed. **Recidivism (reconviction)** Recidivism rate: 12% (7/59) vs. 33% (9/27); indicating an incremental benefit of EMDR over PAU (following modified Seeking Safety + PAU). The statistical significance of the benefit was not assessed.	*"It is possible that the additional attention paid to participants because of the addition of an Integrated Trauma Treatment Program, as well as the educational information, may have had a positive impact on program graduation outcomes."* [p. 133]

CI = 95% confidence interval; EMDR = Eye Movement Desensitization and Reprogramming; NR = not reported; OR = odds ratio: PAU = program as usual; TAU = treatment as usual

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Appendix 5: Additional References of Potential Interest

General information on trauma-informed care in the correctional system

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