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**CADTH RAPID RESPONSE REPORT:**
**SUMMARY WITH CRITICAL APPRAISAL**

# Adapted or Tailored Psychological Interventions for Treating Women with Mental Illness: A Review of Clinical Effectiveness and Guidelines


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## Context and Policy Issues

Mental illness refers to recurrent or chronic altered states of thought, mood or behaviour associated with significant distress and impaired functioning.[1] Examples of mental illnesses are anxiety disorders, depressive disorders, and substance-related and addictive disorders.

Anxiety disorders are the most common forms of mental illness and are characterized by overwhelming anxiety and fear.[2] These disorders include but are not limited to panic disorder, agoraphobia, social phobia, generalized anxiety disorder, obsessive-compulsive disorder, and posttraumatic stress disorder (PTSD).[2] The lifetime prevalence rates for panic disorder, agoraphobia, and social phobia in Canada are 3.7%, 1.5%, and 13%, respectively. Panic disorder is defined by unexpected and recurrent panic attacks, while agoraphobia manifests as an intense fear of public places. Individuals with social phobia fear situations in which they can be judged by others. Individuals with generalized anxiety disorder have persistent unprovoked anxiety while those with obsessive-compulsive disorder have persistent thoughts that produce anxiety, and need to fulfill a compulsion in order to relieve the anxiety. PTSD is a form of heightened anxiety triggered by a life-threatening or otherwise traumatic event that is outside the normal realm of human experience, such as rape, assault, torture, being kidnapped or held captive, military combat, severe car accidents, and natural or manmade disasters. An estimated 11.1% of the members of the Regular Canadian Armed Forces have met the diagnostic criteria for PTSD at some point in their lives although the proportion of members diagnosed by health care professionals is reported to be as high as 8%.[3]

Depressive disorders include major depression disorder, dysthymic disorder, and depressive disorder not otherwise specified. These conditions are associated with significant morbidity, with the World Health Organization (WHO) predicting that unipolar major depression will surpass road traffic accidents, chronic obstructive pulmonary disease, and human immunodeficiency virus, as a leading cause of disability by 2020.[4] Substance-related and addictive disorders refer to abuse or dependence involving alcohol, cannabis or other drugs.[5] Approximately 21.6% of Canadians meet the criteria for a substance use disorder during their lifetime.[6] Risk factors for mental illness are varied and include: family history, sex, age, and stress.[1]

Treatment options for mental illnesses, particularly the common anxiety disorders, are primarily pharmacological or psychological.[7] Antidepressants and antianxiety medications constitute pharmacological treatment.[7] Psychological interventions include cognitive processing therapy (CPT), cognitive behavioural therapy (CBT), prolonged exposure CBT for trauma, and eye movement desensitization and reprocessing (EMDR).[7] CPT involves determining and addressing cognitive distortions by disrupting the patient's beliefs and replacing them with balanced thinking patterns.[8] CBT strategies include cognitive restructuring, exposure, and relaxation training.[7] EMDR involves exposure to the sensation(s) that are the source of trauma or anxiety while performing repetitive eye movements.[9] Psychological interventions may be offered to groups, couples, or individuals.[7]

Given that women are more likely to suffer from depression and anxiety than men and may experience symptoms of some types of mental illnesses differently than men,[10] there is increasing interest in treatments that are adapted for or tailored to groups of women (such as female veterans or incarcerated women) with mental illnesses. Changes in hormone levels associated with pregnancy, menstruation, and menopause may cause women to experience mental illnesses differently from men.[10] Gender-responsive treatment programmes, for example, are tailored to provide a secure environment where women are allowed to discuss histories of trauma, abuse, and addiction in a safe environment without fear of judgment.[11]

The purpose of this review is to provide evidence surrounding the effectiveness of psychological interventions that are adapted or tailored to women for the treatment of anxiety disorders (including PTSD), depressive disorders, and substance-related and addictive disorders, and to identify relevant evidence-based guidelines.

## Research Question

1. What is the clinical effectiveness of psychological interventions that have been adapted or tailored to treat women with mental illness?
2. What are the evidence-based guidelines associated with adapted or tailored psychological interventions for the treatment of women with mental illness?

## Key Findings

There is a limited quantity of data on adapted or tailored psychological interventions for women with anxiety disorders, depressive disorders, and substance-related and addictive disorders. One systematic review and three randomized controlled trials provided evidence on the use of adapted/tailored psychological interventions for women with depression, and substance abuse. The outcomes of interest included depression severity, substance use, intimate partner violence (IPaV), health status and quality of life, patient satisfaction with therapy, and treatment engagement.

The published evidence is insufficient to make conclusions on the impact or comparative efficacy of adapted or tailored psychological interventions for women with anxiety disorders, depressive disorders, and substance-related and addictive disorders. Nonetheless, the findings suggest that Mom-Net, an Internet-facilitated cognitive behavioural therapy (CBT) program has the potential to reduce prevalence of depressive symptoms relative to Motivational Interview and Referral to Services. The findings also suggest that IPaV Therapy-CBT relative to motivational interviewing, relapse prevention and counselling may (in the short-term i.e., 3 months or less) lower incidents of psychological abuse in the relationships of women being treated for substance abuse.

One relevant set of guidelines was identified. The World Health Organization (WHO) recommends that professionals with relevant experience should treat women with diagnosed mental health disorders who suffered intimate partner violence, as recommended in the WHO Mental Health Gap Action Programme guidelines. The guidelines do not discuss adapted or tailored psychological interventions, specifically.

## Methods

### Literature Search Methods

A limited literature search was conducted on key resources including PubMed, Medline, PsycInfo, The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. Methodological filters were applied to limit retrieval to health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, and guidelines. The search was also limited to English language documents published between January 1, 2012 and September 7, 2017.

Rapid Response reports are organized so that the evidence for each research question is presented separately.

### 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**

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| **Population** | Adult women with mental illness (anxiety disorders [including PTSD], depressive disorders, substance-related and addictive disorders) |
| **Intervention** | Psychological interventions (provided in a group or individually) that have been adapted or tailored to women:<br>• CPT<br>• CBT<br>• Prolonged Exposure CBT for trauma<br>• EMDR |
| **Comparator** | Q1: Regular (non-adapted/tailored) psychological interventions (provided in a group or individually):<br>• CPT<br>• CBT<br>• Prolonged Exposure CBT for trauma<br>• EMDR<br>• Treatment as usual (including motivational interviewing)<br>• Waitlist (including delayed intervention)<br>• No treatment<br>Q2: No comparator |
| **Outcomes** | Q1: Clinical effectiveness (reduction in symptoms, increased quality of life, perspectives of women for effectiveness, etc.) and safety; not post-partum<br>Q2: Guidelines |
| **Study Designs** | Health Technology Assessments, Systematic Reviews, Meta-Analyses, Randomized Controlled Trials, Evidence-based guidelines |

CBT = Cognitive Behavioural Therapy; CPT = Cognitive Processing Therapy; EMDR = Eye Movement Desensitization and Reprocessing; PTSD = posttraumatic stress disorder.

### Exclusion Criteria

Articles and guidelines were excluded if they did not meet the selection criteria outlined in Table 1, they were duplicate publications, or were published prior to 2012.

### Critical Appraisal of Individual Studies

The included systematic review was critically appraised using the AMSTAR checklist,[12] randomized studies were critically appraised using the Downs and Black Checklist,[13] and the guideline document was appraised using the AGREE II Instrument.[14] 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 631 citations were identified in the literature search. Following screening of titles and abstracts, 611 citations were excluded and 20 potentially relevant reports from the electronic search were retrieved for full-text review. 8 potentially relevant publications were retrieved from the grey literature search. Of these potentially relevant articles, 23 publications were excluded for various reasons, while 5 publications met the inclusion criteria and were included in this report. Appendix 1 describes the PRISMA flowchart of the study selection.

Additional references of potential interest are provided in Appendix 5.

### Summary of Study Characteristics

A summary of characteristics of included articles is presented in Appendix 2.

#### *Study Design*

One systematic review,[15] three randomized controlled trials (RCTs),[16-18] and one set of evidence-based guidelines[9] met eligibility criteria for this report.

Systematic review

Perry et al.[15] searched 14 electronic bibliographic databases up to May 2014 and five additional website resources (between 2004 and November 2011) for RCTs designed to reduce, eliminate or prevent relapse of drug use or criminal activity in female drug-using offenders.[15] They contacted experts in the field for further information. The quality of included studies was assessed by the authors using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group's grades of evidence. Of the included RCTs, three were relevant to the current report. A meta-analysis of the data on psychological interventions was not included in the review. The evidence was narratively described.

RCTs

Schreeber et al.[16] conducted an RCT in 2017 in which 266 women were randomized to an Internet-facilitated CBT and motivational interview and referral to services; Tirado-Muñoz et al.[17] in 2015 randomized 14 women to a CBT group intervention and to motivational interviewing, relapse prevention and counseling; while Schreeber et al.[18] conducted an

RCT in 2012 in which they randomized 70 economically disadvantage women to an Internet-facilitated CBT and delayed intervention/treatment as usual.[18]

Guidelines

The WHO guidelines were created by searching the scientific literature and evaluating the evidence using GRADE, following the process outlined in the WHO Handbook for Guideline Development. The authors identified questions related to clinical practice and health policy; retrieval of up-to-date evidence; assessed and systematically synthesized the evidence; formulated recommendations with inputs from a wide range of stakeholders (including academics, clinicians/service providers and policy-makers, working on women's health and violence against women in low- and middle- income countries), thereby ensuring the representation of a wide range of user opinion; considered the balance between benefits and harms, women's preferences and their human rights, and the cost implications in various countries and communities worldwide; and formulated plans for dissemination, implementation and updating the guidelines.

### *Country of Origin*

The systematic review was conducted by groups in the United Kingdom.[15] Two of the RCTs were conducted in the United States,[16,18] and one was conducted in Spain.[17] The guidelines were developed in Switzerland.[9]

### *Patient Population*

Systematic Review

Perry et al.[15] conducted a systematic review aiming to evaluate the evidence surrounding the effectiveness of clinical and psychological interventions for incarcerated, adult female drug-users in reducing criminal activity and/or drug use. The systematic review included three RCTs that were relevant to this report (total n = 633). Two of the included studies had overlapping populations of patients.

Randomized Controlled Trials

The first RCT enrolled 266 economically disadvantaged women, the majority of whom met the Diagnostic and Statistical Manual for Mental Disorders-Fourth Edition (DSM-IV) criteria for major or minor depressive disorders;[16] the second enrolled 14 women with an incident of intimate partner violence (IPaV) within the past month who were receiving treatment for substance abuse;[17] while the third (conducted by the same research group as the first) enrolled 70 economically disadvantaged women with full or sub-threshold syndrome depression.[18] All three RCTs enrolled adult women.[16-18]

Evidence-based Guidelines

The WHO guidelines[9] focused on responding to intimate partner violence (IPaV) and sexual violence against women. It included women who may not have been experiencing mental illness along with women who had mental illness.

### *Interventions and Comparators*

Systematic Review

The systematic review[15] assessed interventions that were designed to reduce, eliminate, or prevent criminal activity and/or relapse of drug use in incarcerated, adult female drug-users.

Findings from this review that compared adapted or tailored therapeutic community programmes with standard therapeutic community regimen are reported.

Randomized Controlled Trials

The first RCT[16] compared the Mom-Net program to Motivational Interview and Referral to Services (MIRS). The Mom-Net program is an Internet-facilitated, cognitive behavioral treatment (CBT) for sub-threshold and full syndrome depression. It includes core CBT skills and is adapted from the Coping with Depression Course (CWDC). It is tailored to economically disadvantaged mothers of young children. The program was designed to facilitate providers' delivery of treatment services remotely. Compared to the original CWDC, Mom-Net emphasizes positive affect and behavioral activation. MIRS incorporated biweekly motivational calls from research staff who used a motivational interview approach to facilitate engagement in services or other behavioral change activities.

The second RCT[17] compared a manualized small-group, CBT intervention to treatment-as-usual. The CBT intervention (IPaViT-CBT) was designed to reduce IPaV and improve depressive symptoms in female drug users. The IPaViT-CBT intervention involved multiple adaptations including: (1) reducing the number of manualized group Women's Wellness Treatment intervention sessions from 12 to 10 to address IPaV and depressive symptoms among females receiving drug treatment in Spain, (2) adapting the Behavioural Therapy for Depression in Drug Dependence Manual to address negative mood, (3) offering free activities at the community centre to facilitate pleasant activities and address negative mood, and (4) adapting the original session on human immunodeficiency virus to include education on hepatitis C transmission. Treatment-as-usual was described as motivational interviewing, relapse prevention, and counselling (MIRPC).

The third RCT,[18] was conducted by the same research group as the first RCT.[16] The authors evaluated Mom-Net as the intervention and delayed intervention/treatment-as-usual as the comparator treatment. For this report, treatment-as-usual was considered MIRS.

Evidence-based Guidelines

In the section relevant to this Rapid Response, the guidelines addressed psychological/mental health interventions for women who had experienced IPaV.

### *Outcomes*

The systematic review[15] reported on reduction of subsequent drug use and/or re-incarceration in incarcerated adult, female drug users. The RCTs reported on changes in depression severity,[16-18] substance use,[17] IPaV,[17] health status and quality of life,[17] participant satisfaction,[16-18] and treatment engagement.[18] Depression severity was measured using the Patient Health Questionnaire-9 (PHQ-9) as an index of depressive symptoms,[16,18] modules relevant to diagnosis of depressive disorders on the Structured Clinical Interview for DSM-IV-Trauma (SCID) Axis I Disorders,[16] the Hamilton Depression Rating Scale (HDRS),[16] and the Beck Depression Inventory II (BDI-II).[17,18] The diagnostic accuracy and reliability of the PHQ-9, HDRS, and BDI-II are well-established with Cronbach's α of 0.85,[16] 0.82,[16] and 0.88,[17] respectively. The SCID is known to have high interrater reliability.[16]

Substance use was measured using a substance consumption table.[17]

IPaV was measured using the Composite Abuse Scale (CAS) and the Psychological Maltreatment of Women Inventory (PMWI) while assertiveness and aggression in intimate

relationships were measured with the Spouse Specific Assertion/Aggression Scale (SSAAS).[17] The CAS and PMWI have been shown to have good reliability and validity with Cronbach's α reported as >0.85 and 0.88, respectively.[17] The reliability and validity of the SSAAS were not addressed.

Health status and quality of life were measured using a visual analogue scale.[17] This scale is associated with test-retest reliability correlation of 0.87.[17]

Participant satisfaction was assessed with the System Usability Scale[16] and a series of 5-point Likert-like rating scales.[16-18]

Computer-generated indices and reports from coaches were used to ascertain treatment engagement.[18] The validity of these tools was not addressed.[18]

## Summary of Critical Appraisal

A summary of the critical appraisal of included reports is presented in Appendix 3.

### Systematic Review

The systematic review by Perry et al.[15] was of moderate to poor quality. The quality of included studies was described as 'moderate to low' and the evidence was compiled 2 years prior to the review's publication. Regarding strengths, the literature search was comprehensive, study selection and data extraction was done in duplicate, and the scientific quality of each included study was assessed and documented. Although the authors used the GRADE Working Group's grades of evidence, the risk for the majority of bias metrics was reported as "unclear" making it challenging to come to conclusions on the impact of various interventions studied.

### Randomized Controlled Trials (RCTs)

The three RCTs[16-18] had more strengths than limitations. The objectives, main outcomes, patient characteristics, interventions, and main findings were clearly described. Estimates of variability were reported as standard deviation or 95% confidence intervals. Follow-up times were consistent between study groups. Important outcome measures were valid and reliable. All patients were recruited from the same populations, enrolled over the same period, and randomly assigned. Two[16,18] out of three described possible confounders.

With regard to weaknesses, the potential links between interventions or comparators and possible side effects were not discussed, nor was a conflict of interest statement included in any of the studies. Also, it was unclear whether the participants were representative of the source population or whether they were treated by representative staff or in representative places and facilities. One RCT did not report on sample size calculations.[17] This study enrolled 14 participants, three (21%) of whom were lost to follow-up.[17] The study may not have been powered to detect measurable differences between the intervention and the comparator.

### Evidence-based Guidelines

The WHO guidelines were developed according to the process outlined in the WHO handbook for guideline development.[9] The guidelines had a clear scope and purpose, rigorous methods of development as outlined in the WHO Handbook for Guideline Development, and support for their application is provided. The guideline development committee included subject-matter experts such as academics, clinicians/service providers

and policy-makers working on women's health and violence against women in low- and middle- income countries. Women's health and rights advocates were also involved to ensure that a wide range of user opinion was included. Scientific evidence for the clinical interventions was synthesized using GRADE methodology.

Regarding limitations, evidence on policy and healthcare provision was not synthesized systematically. Input from peer reviewers and a range of stakeholders was sought; however the method for incorporating their comments was not described. Furthermore input from women who had experienced IPaV was not considered. A procedure for updating the guidelines was not articulated.

## Summary of Findings

A summary of main findings of included reports is presented in Appendix 4.

*What is the clinical effectiveness of psychological interventions that have been adapted or tailored for women in the treatment of women with mental illness?*

*Depression severity*

Recent evidence suggests that 134 economically disadvantaged mothers of young pre-school aged children with major or minor depressive disorder who were treated with Mom-Net, an Internet-facilitated CBT program, had significantly lower odds of meeting diagnostic criteria for depression compared to 132 women who were treated with MIRS.[16] A similar study with a smaller sample size of 70 was completed 5 years earlier by the same research group.[18] This second study suggested that depressed, economically disadvantaged mothers of pre-school aged children treated with the same Internet-facilitated CBT, demonstrated greater odds of remission from depression and better parenting behavior and experiences in comparison to women who were treated with delayed intervention or facilitated treatment-as-usual (i.e., MIRS).[18] On the other hand, IPaViT-CBT had no statistically significant impact on reducing self-reported depressive symptoms in seven women with substance abuse compared with seven women treated with MIRPC.[17] The IPaViT-CBT and MIRPC groups reported fewer symptoms of depression (i.e., had lower BDI-II scores) relative to baseline.

*Substance Use*

IPaViT-CBT helped to reduce the frequency of alcohol use in seven women with substance abuse compared with seven women treated with MIRPC one month after treatment.[17] The women treated with IPaViT-CBT reported on average 6.42 days of alcohol use compared to 10.0 reported by women in the control group at one month. The difference was statistically significant (*p* value = 0.035). At three and twelve months, the difference in the reduction of alcohol use between the two study groups was not statistically significant.

When compared to a standard therapeutic community programme (n=55), gender-responsive treatment (n=60) had a greater impact on reducing subsequent drug use in incarcerated female drug-users.[15]

*IPaV*

Seven women with substance abuse undergoing IPaViT-CBT were likely to report fewer incidents of isolation or dominance maltreatment up to three months following treatment, than seven women undergoing MIRPC.[17]

*Re-incarceration*

When compared to a standard therapeutic community programme (n=55), gender-responsive treatment (n=60) had a greater impact on reducing re-incarceration rates.[15]

*Health Status and Quality of Life*

IPaViT-CBT had no statistically significant impact on improving self-reported health status or quality of life in seven women with substance abuse compared with seven women treated with MIRPC.[17]

*Participant-rated Satisfaction and Treatment Engagement*

On average, 134 economically disadvantaged women with major or minor depressive disorder who were treated with Internet-facilitated CBT were equally satisfied with coaching assistance as 132 women with MIRS.[16] In an earlier study, women in the same demographic who had Internet-facilitated CBT were equally satisfied in general, and specifically with skills and materials learned and website usage as women who had delayed intervention/facilitated treatment-as-usual (i.e., MIRS).[18] In a group of 7 women who were treated with IPaViT-CBT, 83% felt "very comfortable" during sessions, 90% considered the therapist's performance was "excellent", and 80% evaluated sessions overall as "excellent".[17]

With regard to treatment engagement, 27 women treated with Mom-Net, an Internet-facilitated CBT, completed more treatment modules, program visits, bulletin board visits, and spent more hours on the program than 23 women who had delayed intervention or treatment-as-usual (i.e., MIRS).[18] The statistical significance of the differences between the groups was not reported.

*What are the evidence-based guidelines associated with adapted or tailored psychological interventions for the treatment of women with mental illness?*

The WHO's 2013 Responding to IPaV and Sexual Violence Against Women guidelines included two recommendations involving psychological interventions for women with mental illness. Based on indirect evidence, the WHO strongly recommends that women with a pre-existing diagnosis of partner violence-related mental disorder (such as depression, or alcohol use disorder) who are experiencing IPaV should receive mental health care for the disorder in accordance with WHO Mental health Gap Action Programme intervention guidelines, delivered by health care professionals with relevant experience. The guidelines do not specifically describe adapted or tailored interventions but based on low to moderate evidence, the WHO strongly recommends CBT or eye movement desensitization and reprocessing interventions, delivered by health care professionals who are conversant with issues relevant to violence against women for women with PTSD who are no longer in situations where they are being mistreated.[9]

## Limitations

There are a number of limitations with the evidence on adapted or tailored psychological treatments for women with mental illness (i.e., anxiety disorders, depressive disorders, and substance-related and addictive disorders). None of the included primary studies focused on cognitive processing therapy, prolonged exposure CBT for trauma, or eye movement desensitization and reprocessing interventions. None of the studies addressed the safety of the interventions and none enrolled participants in Canada.

Seven relevant publications were found in the published literature and they reported on disparate populations, interventions, outcomes, and outcome measures making it difficult to come to a conclusion on the comparative efficacy of any of the interventions of interest. Two RCTs conducted by the same research group[16,18] enrolled economically disadvantaged women with depression, and one enrolled women with IPaV.[17] One of the RCTs involved adaptations of treatments that had previously been tailored to women.[17] The three RCTs assessed change in depression severity using similar but non-identical sets of scales.[16-18] Similarly, measurements of participant satisfaction were reported using similar but non-identical sets of scales.[16-18] One study each reported on IPaV,[17] health status and quality of life,[17] and treatment engagement.[18] The systematic review reported on the impact of treatment on substance abuse and re-incarceration.[15] It did not include a meta-analysis of the outcomes of interest, nor did it provide raw data from the three relevant RCTs that it included.[15]

The included guidelines do not describe tailored or adapted interventions specifically, although they suggest that women with mental illness who had experienced IPaV or sexual assault should be treated by health care professionals who are conversant with issues relevant to violence against women.[9]

## Conclusions and Implications for Decision or Policy Making

There is insufficient evidence to make conclusions about the comparative effectiveness of adapted or tailored psychological interventions for women with anxiety disorders, depressive disorders, and substance-related and addictive disorders. Though findings from individual studies suggest that adapted or tailored psychological interventions reduce depression rates, substance use, and criminal behavior, the comparisons relative to non-tailored interventions are not substantive.

Increasing interest in interventions adapted or tailored to women may lead researchers to generate more information that can be aggregated in the future. Until then, policy-makers may consider basing their decisions on evaluations of standard interventions in women.

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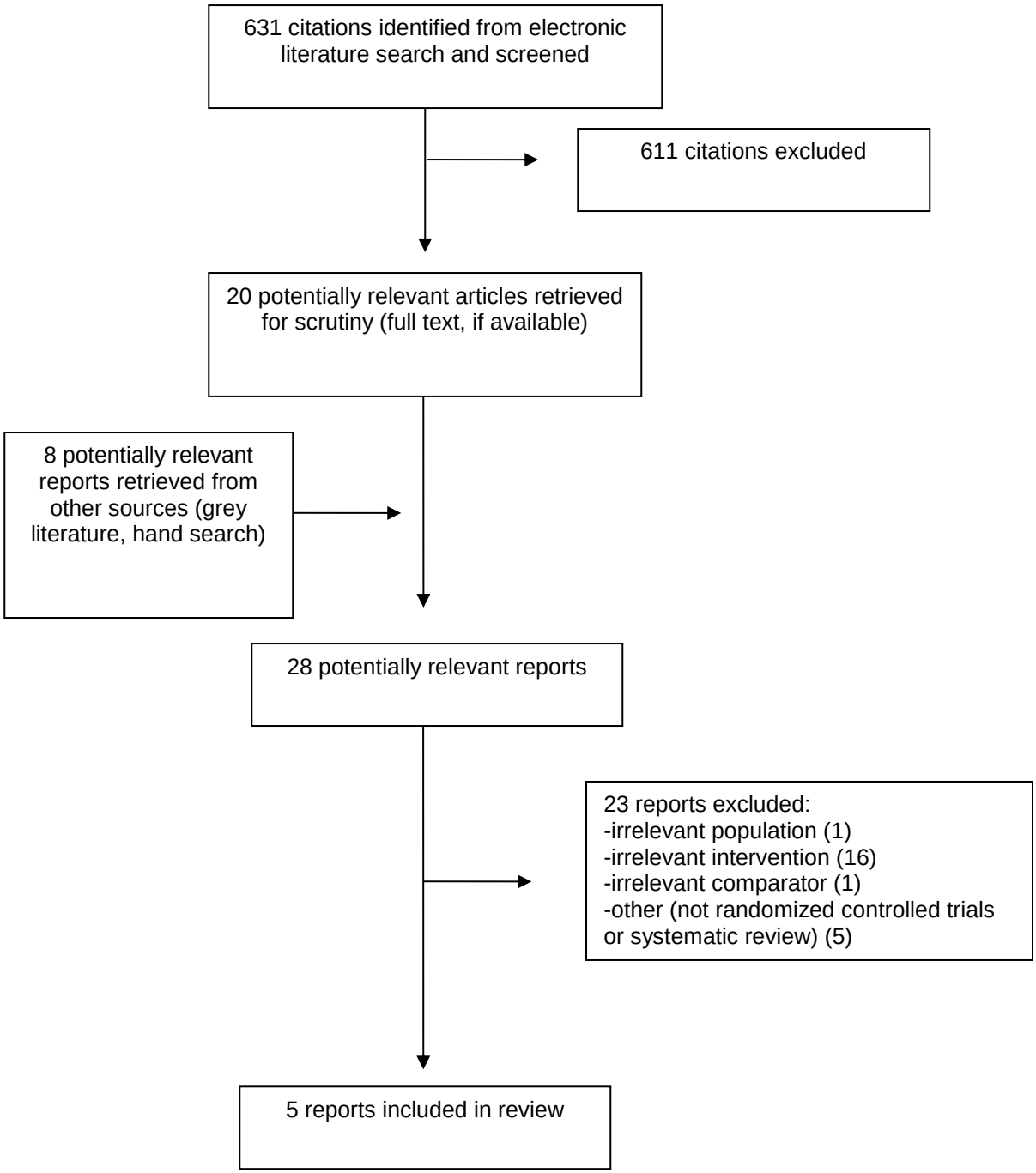
18. Sheeber LB, Seeley JR, Feil EG, Davis B, Sorensen E, Kosty DB, et al. Development and pilot evaluation of an Internet-facilitated cognitive-behavioral intervention for maternal depression. J Consult Clin Psychol [Internet]. 2012 [cited 2017 Sep 12];80(5):739-49. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3435487/pdf/nihms375963.pdf

## Appendix 1: Selection of Included Studies



# Appendix 2: Characteristics of Included Publications

## Table 2: Characteristics of Included Systematic Reviews

| First author, publication year, country | Aim | Search date<br><br>Number and type of included studies | Summary of population characteristics | Intervention(s) vs. comparison(s) | Outcome(s) |
|---|---|---|---|---|---|
| **Perry, 2015, United Kingdom**[15] | "To assess the effectiveness of interventions for female drug-using offenders in reducing criminal activity, or drug use, or both."[15] (page 7) | Up to May 2014.<br><br>3 RCTs (total n=633)<br><br>Excludes studies without gender-responsive therapy. | Incarcerated, adult female drug-users*<br><br>Mean age ranged from 31.8 years to 35.6 years<br><br>* Review included incarcerated youth | Any intervention that was designed to reduce, eliminate or prevent relapse to drug use and/or criminal activity in female offenders.<br><br>This review evaluated only results specific to comparison of specifically-adapted gender responsive therapy to standard therapeutic community regimen or therapeutic community therapy with gender-specific aspects to CBT | Reduction of subsequent drug use, reduction of re-incarceration |

CBT = cognitive behavioural therapy; RCT = randomized controlled trial.

## Table 3: Characteristics of Included Randomized Controlled Studies

| First author, publication year, country | Study design, length of follow-up | Patient characteristics, sample size (n) | Intervention | Comparator(s) | Outcome(s) |
|---|---|---|---|---|---|
| **Sheeber, 2017, United States**[16] | RCT (dates NR)<br><br>Duration: 26.2 weeks | n=266 women with major or minor depressive disorder (62.1%), dysthymia (2.6%), or bipolar conditions (5.3%); living at or below 185% of the federal poverty level; with preschool age children; mean age 31.8 years (range: 17.7 to 59.8); lost to f/u=11% | Mom-Net, an internet-facilitated intervention adapted from the Coping with Depression Course and tailored to mothers of young children | MIRS | Maternal depression (using PHQ-9, SCID, and HDRS), participant satisfaction (using SUS- and 5-point Likert-like rating scales) |

| First author, publication year, country | Study design, length of follow-up | Patient characteristics, sample size (n) | Intervention | Comparator(s) | Outcome(s) |
|---|---|---|---|---|---|
| **Tirado-Muñoz, 2015, Spain**[17] | RCT (pilot) from March 2011 to June 2012<br><br>Duration: 1 month (n=12), 3 months (n=11), 12 months (n=10) | n=14 women with an incident of IPaV in the past month and receiving outpatient treatment for substance abuse; age ≥18 years; mean age 40 years (SD: 8.81); lost to f/u=21% | IPaViT-CBT group intervention adapted from the Women's Wellness Treatment manualized group intervention to address IPaV and depressive symptoms among females receiving substance abuse treatment | Treatment as usual i.e., Motivational interviewing, relapse prevention and counselling | IPaV (using CAS, PMWI, and SSAAS), depression (using BDI-II), health status (using a VAS), quality of life (using a VAS), substance use (using a substance consumption table), participant satisfaction (using 5-point Likert-like rating scales) |
| **Sheeber, 2012, United States**[18] | RCT (dates NR)<br><br>Duration: 26 weeks | n=70 economically disadvantaged mothers of young children; with sub-threshold and full syndrome depression; CES-D score≥21; mean age 31 years (range: NR); lost to f/u=0.01% | Mom-Net, an internet-facilitated intervention adapted from the Coping with Depression Course and tailored to mothers of young children | Delayed intervention/ facilitated treatment as usual (i.e., MIRS) | Maternal depression (using PHQ-9 and BDI-II), participant satisfaction (using 5-point Likert-like rating scales), treatment engagement (using computer-generated indices, reports from coaches) |

BDI-II = Beck Depression Inventory; CAS = Composite Abuse Scale CES-D = Center for Epidemiological Studies Depression Scale; f/u = follow up; HDRS = Hamilton Depression Rating Scale; IPaV = Intimate Partner Violence; IPaViT-CBT = IPaV Therapy-Cognitive Behavioural Therapy; MIRS = Motivational Interview and Referral to Services; NR = not reported; PHQ = Patient Health Questionnaire; PMWI = Psychological Maltreatment of Women Inventory; RCT = Randomized Controlled Trial; SCID = Structured Clinical Interview for DSM-IV-Trauma; SD = standard deviation; SSAAS = Spouse Specific Assertion/Aggression Scale; SUS = System Usability Scale;; VAS = Visual Analogue Scale.

## Table 4: Characteristics of Included Guidelines

| First author/group, year, country | Objectives | Guideline development group, target users | Methodology |
|---|---|---|---|
| **WHO, 2013**[9]<br>**Switzerland** | *"These guidelines aim to provide evidence-based guidance to health-care providers on the appropriate responses to intimate partner violence and sexual violence against women, including clinical interventions and emotional support. They also seek to raise awareness, among health-care providers and policymakers, of violence against women, to better understand the need for an appropriate health sector response to violence against women.."*[9,18] (page 1) | The Guideline Development Group: academics, clinicians/service providers and policy-makers, working on women's health and violence against women in low- and middle-income countries, and women's health and rights advocates<br><br>Target users: Healthcare providers, policy-makers and others in charge of planning, funding and implementing health services and professional training within health ministries | The guidelines were developed according to the process outlined in the WHO handbook for guideline development. |

WHO = World Health Organization.

# Appendix 3: Critical Appraisal of Included Publications

## Table 5: Strengths and Limitations of Systematic Reviews and Meta-Analyses using AMSTAR[12]

| Strengths | Limitations |
|---|---|
| Perry, 2015[15] | |
| • Study selection and data extraction was done in duplicate<br>• A comprehensive literature search was done<br>• Experts were asked to provide information on published or unpublished reports<br>• A list of included studies was provided<br>• A list of excluded studies was provided<br>• The scientific quality of each included study was assessed and documented | • A dedicated protocol was unavailable as this was a revision of an existing review<br>• The quality of the studies was not discussed when formulating conclusions<br>• The risk for majority of bias metrics was reported as "unclear" |

## Table 6: Strengths and Limitations of Randomized Controlled Trials using the Downs and Black Checklist[13]

| Strengths | Limitations |
|---|---|
| Sheeber, 2017[16] | |
| • The objective, main outcomes, patient characteristics, interventions, principal confounders, and main findings were clearly described<br>• Estimates of variability were reported as standard deviation and 95% confidence intervals<br>• Reported 11% of participants were lost to f/u<br>• Reported actual probability values<br>• No retrospective sub-group analysis was done<br>• Follow-up times were consistent between groups<br>• Reported on appropriate statistical tests<br>• Compliance with the interventions was reliable<br>• Outcome measures were valid and reliable<br>• Cases and controls were recruited from the same population and enrolled over the same period<br>• Participants were randomly assigned to study groups<br>• Calculated and met sample size for 80% statistical power | • Potential link between intervention or comparator and adverse events was not discussed<br>• Participants were selectively invited based on location<br>• Did not report the proportion of the source population from which patients were derived<br>• Unable to determine whether participants were representative of the source population<br>• Unable to determine whether participants were treated by representative staff or in representative places and facilities<br>• A conflict of interest statement was not included<br>• 13-18% of data was missing following treatment |
| Tirado-Muñoz, 2015[17] | |
| • The objective, main outcomes, patient characteristics, interventions, and main findings were clearly described<br>• Intention-to-treat analyses was completed<br>• Estimates of variability were reported as standard deviation<br>• Reported actual probability values<br>• No retrospective sub-group analysis was done<br>• Follow-up times were consistent between groups<br>• Reported on appropriate statistical tests<br>• Compliance with the interventions was reliable | • Potential link between intervention or comparator and adverse events was not discussed<br>• Confounders were not described<br>• Did not report the proportion of the source population from which patients were derived<br>• Unable to determine whether participants were representative of source population<br>• Unable to determine whether participants were treated by representative staff or in representative places and facilities |

| Strengths | Limitations |
|---|---|
| • Outcome measures were valid and reliable<br>• Cases and controls were recruited from the same population and enrolled over the same period<br>• Participants were randomly assigned to study groups | • 21% of participants were lost to f/u<br>• Sample size calculations were not described<br>• A conflict of interest statement was not included |
| Scheeber, 2012[18] | |
| • The objective, main outcomes, patient characteristics, interventions, principal confounders, and main findings were clearly described<br>• Estimates of variability were reported as standard deviation and 95% confidence intervals<br>• Reported that 0.01% of participants were lost to f/u<br>• Reported actual probability values<br>• No retrospective sub-group analysis was done<br>• Follow-up times were consistent between groups<br>• Reported on appropriate statistical tests<br>• Compliance with the interventions was reliable<br>• Outcome measures were valid and reliable<br>• Cases and controls were recruited from the same population and enrolled over the same period<br>• Participants were randomly assigned to study groups<br>• Calculated and met sample size for 75% statistical power | • Potential link between intervention or comparator and adverse events was not discussed<br>• Participants were given a computer, monitor, and printer, which were theirs to keep<br>• Did not report the proportion of source population from which patients were derived<br>• Unable to determine whether participants were representative of source population<br>• Unable to determine whether participants were treated by representative staff or in representative places and facilities<br>• A conflict of interest statement was not included |

f/u = follow-up.

## Table 7: Strengths and Limitations of Guidelines using AGREE II[14]

| Strengths | Limitations |
|---|---|
| WHO, 2013[9] | |
| • The overall objective of the guideline is specifically described.<br>• The health questions covered by the guideline are specifically described.<br>• The population to whom the guideline is meant to apply is specifically described.<br>• The guideline development group includes individuals from relevant professional groups as well as people who worked directly with women experiencing violence.<br>• The target users of the guideline are clearly defined.<br>• The criteria for selecting the evidence are clearly described.<br>• The strengths and limitations of the body of evidence are clearly described<br>• The methods for formulating the recommendations are clearly described.<br>• There is an explicit link between the recommendations and the supporting evidence.<br>• The recommendations are specific and unambiguous.<br>• The different options for management of the condition or health issue are clearly presented.<br>• Key recommendations are easily identifiable. | • The guidelines are not centered on women with mental illness nor on psychological interventions<br>• The views and preferences of the target population were not sought.<br>• Although the guidelines states that systematic methods were used to search for evidence, they do not describe these methods<br>• Peer reviewers were not described<br>• A procedure for updating the guideline is not provided.<br>• The guideline does not describe barriers to its application.<br>• The potential resource implications of applying the recommendations have not been considered.<br>• The guideline does not discuss monitoring or auditing criteria<br>• It is unclear whether the views of the funding body have influenced the content of the guideline. |

| Strengths | Limitations |
| --- | --- |
| • The guideline provides advice or tools on how the recommendations can be put into practice.<br>• The guideline suggests facilitators for its application<br>• Competing interests of members of the guideline development group have been recorded and addressed. | |

# Appendix 4: Main Study Findings and Author's Conclusions

## Table 8: Summary of Findings of Systematic Reviews

| Main Study Findings | Author's Conclusion |
|---|---|
| Perry, 2015[15] | |
| Findings from three RCTs were reported individually in the systematic review:<br><br>One study (n=573) found that therapeutic community programmes with gender-specific aspects or standard treatment and CBT groups improved significantly on variables of mental health, substance use, criminal behaviour and human immunodeficiency virus risk, at six months. During the follow-up study (n=468), the therapeutic community programme with gender-specific aspects was found to be more beneficial than CBT at reducing re-incarceration rates and lengthening the amount of time spent in the community before subsequent re-incarceration.<br><br>When compared to a standard therapeutic community programme (n=55), the third RCT found that gender-responsive treatment (n=60) had a greater impact on reducing both subsequent drug use and re-incarceration. Participants who voluntarily underwent gender-responsive treatment stayed in aftercare treatment for longer periods and were less likely to be re-incarcerated within 12 months of parole. | *"The current evidence suggests that therapeutic community programmes and the gender-responsive treatment programmes may have some effect in reducing re-incarceration rates, but we do not know how such treatments facilitate the rehabilitation of female offenders. Additionally, we can say nothing about whether such treatments are effective in reducing drug use and subsequent criminal behavior in court."*[15] (page 21) |

CBT = Cognitive behavioral therapy; RCT(s) = randomized controlled trial(s).

## Table 9: Summary of Findings of Randomized Controlled Trials

| Main Study Findings | Author's Conclusion |
|---|---|
| Schreeber, 2017[16] | |
| *Mom-Net (n=134) versus MIRS (n=132)*<br>Depression remission rates: 39.7% versus 28.18%<br><br>Mom-Net effect estimate[a]<br>PHQ-9: -1.51, *t*=2.44, *p*=0.015, *d*=0.27[b]<br>HDRS: -1.85, *t*=-2.35, *p*=0.019, *d*=0.24 [b]<br>Depression rates (adjusted OR): 0.53[c] (95% CI: 0.29, 0.98); *p*=NR<br><br>*Mom-Net (n=134) versus MIRS (n=132)*<br>Mean (SD) participant-rated satisfaction[d]<br>Skills and materials (Mom-Net only): 4.2 (0.8)<br>Website usability (Mom-Net only): 4.2 (0.7)<br>Coach assistance: 4.3 (0.7) versus 4.4 (0.8) | Relative to coach-supported, facilitated usual care, *"the Mom-Net group had significantly lower odds of meeting DSM-IV criteria for a depression diagnosis at posttest compared with MIRS participants… "*[16] (page 361). |
| Tirado-Muñoz, 2015[17] | |
| *IPaViT-CBT versus MIRPC*<br>Depression severity in the past week based on the BDI-II instrument (21 items scored 0 for absence of symptoms to 3 for | The findings suggest that women receiving the IPaViT-CBT intervention were likely to report less psychological abuse than those being treated as usual. The difference was significant in |

| Main Study Findings | Author's Conclusion |
|---|---|
| more presence of symptoms)<br>@Baseline: 22.42 (SD:8.34) versus 23.42 (SD:12.73); *p=NR*<br>@1 mo: 14.42 (SD: 8.16) versus 17.00 (SD: 10.36); *p*=0.535<br>@3 mos: 11.28 (SD: 5.18) versus 15.28 (SD: 10.95); *p*=0.535<br>@12 mos: 14.57 (SD: 8.96) versus 12.28 (SD: 9.60); *p*=0.620<br><br>Number of days (SD) of alcohol, heroin, cocaine, cannabis and benzodiazepine use in the past week based on a substance use consumption table<br>@1 mo: 6.42 (12.83) versus 10.0 (17.29); *p*=0.035[e]<br><br>No statistically significant differences were found between the groups in the frequency and amount of other substance use in the past week based on a substance use consumption table<br><br>Incidence of IPaV (SD) in the past mo based on the 30-item CAS≥7<br>@1 mo: 2 versus 5; *p*=0.558<br>@3 mos: 2 versus 5; *p*=0.242<br>@12 mos: 1 versus 3; *p*=0.524<br><br>Isolation/dominance maltreatment (SD) in the past 12 mos based on the 58-item PMWI scale (each item was rated 1 for never to 5 for very frequently)<br>@1 mo: 8.80 (1.64) versus 11.71 (3.81); *p*=0.048[e]<br>@3 mos: 8.20 (0.83) versus 12.33 (3.50); *p*=0.030[e]<br>@12 mos:12.00 (5.61) versus 8.60 (2.07); *p*=0.690<br><br>Emotional/verbal maltreatment (SD) in the past 12 mos based on the 58-item PMWI scale (each item was rated 1 for never to 5 for very frequently)<br>@1 mo: 11.00 (2.00) versus 14.85 (4.59); *p*=0.073<br>@3 mos: 10.60 (1.34) versus 17.16 (2.31); *p*=0.126<br>@12 mos: 11.60 (1.67) versus 12.80 (4.76); *p*=0.421<br><br>Aggressiveness (SD) in the past 12 mos based on the SSAAS scale (degree of agreement with 29 statements, ranging from -3 for extremely unlike me to +3 for extremely like me)<br>@1 mo: -18.80 (7.32) versus 1.00 (12.21); *p*=0.030[e]<br>@3 mos: -16.80 (7.19) versus -1.40 (9.44); *p*=0.056<br>@12 mos: -12.60 (5.12) versus -3.60 (14.80); *p*=0.841<br><br>Assertiveness (SD) in the past 12 mos based on the SSAAS scale (degree of agreement with 29 statements, ranging from -3 for extremely unlike me to +3 for extremely like me)<br>@1 mo: 26.40 (12.44) versus 15.33 (11.97); *p*=0.017[e]<br>@3 mos: 31.40 (14.62) versus 19.20 (9.65); *p*=0.056<br>@12 mos: 17.00 (15.41) versus 16.00 (7.14); *p*=0.151<br><br>Health status score (SD) based on a visual analogue scale (from 0 for low to 100 for high)<br>@1 mo: 48.71 (33.78) versus 55.71 (13.04); *p*=0.209<br>@3 mos: 76.42 (15.73) versus 55.00 (23.80); *p*=0.165<br>@12 mos: 62.85 (23.42) versus 48.57 (25.44); *p*=0.805 | incidents of isolation/dominance maltreatment at 1 month and 12 months following treatment. There was no statistically significant difference between the groups in reduction in self-reported depressive symptoms, reduction in IPaV, or improvement in self-reported health status and quality of life metrics.[17] |

| Main Study Findings | Author's Conclusion |
|---|---|
| Quality of life score (SD) based on a visual analogue scale (from 0 for low to 100 for high)<br>@1 mo: 29.78 (27.27) versus 49.00 (12.79); *p*=0.209<br>@3 mos: 55.71 (17.18) versus 52.85 (19.11); *p*=1<br>@12 mos: 59.28 (20.08) versus 54.28 (19.02); *p*=0.620<br><br>*IPaViT-CBT*<br>Participant satisfaction: 83% felt "very comfortable" during sessions, 90% considered the therapist's performance was "excellent", and 80% evaluated sessions overall as "excellent".<br><br>Participants rated their comfort level during the session on a scale from 1 (very uncomfortable) to 5 (very comfortable), the skill/ability of the therapist on a scale from 1 (excellent) to 5 (poor).<br><br>Mean score for content knowledge acquired during sessions: 4.5 (SD: 0.50) out of 5 | |
| **Scheeber, 2012[18]** | |
| Depression severity<br><br>*Mom-Net (n=27) versus DI/TAU (n=23) @ 14 weeks*<br>Remission from index depressive episode (minor or major depression based on CES-D, PHQ-9, and BDI-II): 69% versus 30%; OR=5.1 (95% CI: 1.5, 17.4); *p*=NR<br>Mom-Net participants were significantly more likely than DI/TAU participants to have remitted from their index depressive episode based on PHQ-9 score<br><br>Intervention Effect @ over 14 weeks (*Mom-Net versus DI/TAU)*<br>BDI: -4.03, *p*<0.001[e], *g*=0.89[f]<br><br>Maintenance Effect @ over 26 weeks (*Mom-Net versus DI/TAU)*<br>BDI: 7.58, *p*<0.001[e]<br><br>Participant satisfaction<br><br>Mean (SD) Participant-Rated Satisfaction @ 26 weeks[d] (*Mom-Net, DI/TAU*)<br>Skills and materials: 4.5 (0.4), 4.1 (0.7)<br>Website usability: 4.4 (0.4), 4.1 (0.6)<br>Coach assistance: 4.6 (0.5), 4.2 (0.7)<br>General satisfaction: 4.7 (0.4), 4.4 (0.6)<br><br>Treatment engagement<br><br>Mean (SD) Computer-Generated Indices (@ 26 weeks (*Mom-Net, DI/TAU)*<br>Number of modules completed (out of 8): 6.4 (2.6), 6.0 (2.7)<br>Number of program visits: 31.0 (23.7), 23.5 (23.7)<br>Number of bulletin board visits: 13.4 (9.1), 11.7 (10.3)<br>Hours on program: 15.1 (6.2), 13.0 (5.9)<br><br>Mean (SD) Coach Reports @ 26 weeks (*Mom-Net, DI/TAU)* | "Relative to facilitated usual care, the Mom-Net intervention demonstrated large effects on the primary outcome of depressive symptoms and moderate effects on parenting [behaviour] and experiences."[18] (page 12) |

| Main Study Findings | Author's Conclusion |
|---|---|
| Number of coach calls: 6.5 (2.4), 6.9 (1.9)<br>Duration of calls in minutes: 19.12 (6.21), 18.34 (6.02)<br>Participant Comprehension: 3.1 (0.6), 3.0 (0.4)[g]<br>Therapeutic Alliance: 3.4 (0.5), 3.2 (0.6)[g]<br>Homework Experience: 2.09 (0.4), 2.07 (0.3)[h] | |

BDI = Beck Depression Inventory; CAS = Composite Abuse Scale; CES-D = Center for Epidemiological Studies Depression Scale; CI = confidence interval; DI/TAU = delayed intervention/treatment-as-usual; DSM-IV = Diagnostic and Statistical Manual for Mental Disorders-Fourth Edition; HDRS = Hamilton Depression Rating Scale; IPaV = Intimate Partner Violence; IPaViT-CBT= IPaV Therapy-Cognitive Behaviour Therapy; MIRPC = Motivational interviewing, relapse prevention, and counselling; MIRS = Motivational Interview and Referral to Service; mo(s) = month(s); NR = not reported; OR = odds ratio; PHQ = Patient Health Questionnaire; PMWI = Psychological Maltreatment of Women Inventory; SD = standard deviation; SSAAS = Spouse Specific Assertion/Aggression Scale.

[a] The condition X moderator effects for recruitment source, depression severity, self-reported anxiety level, substance use, marital status, family income, and economic stress, and presence of bipolar disorder were not statistically significant for PHQ-9, HDRS, and depression rates. Negative scores indicate lower depression scores relative to MIRS.
[b] Cohen's *d* statistic for continuous outcomes effects were rated 0.2 small, 0.5 medium, and 0.8 large.
[c] ORs for the dichotomous depression diagnosis were rated 1.48 small, 2.48 medium, and 4.28 large.
[d] On a 5-point Likert-like scale bounded by 1 strongly disagree, 5 strongly agree.
[e] Differences were statistically significant
[f] Hedges' *g* demonstrates effect sizes of 0.2, 0.5, and 0.8 are considered small, medium, and large, respectively
[g] 1 for minimal to 4 for excellent
[h] 0 for no attempt to use skill to 3 for multiple successful use of skills

CADTH

# Appendix 5: Additional References of Potential Interest

Reviews that do not meet criteria for systematic reviews:

King EA. Outcomes of trauma-informed interventions for incarcerated women. Int J Offender Ther Comp Criminol. 2017 May;61(6):667-88.

Dorrepaal E, Thomaes K, Hoogendoorn AW, Veltman DJ, Draijer N, van Balkom AJ. Evidence-based treatment for adult women with child abuse-related Complex PTSD: a quantitative review. Eur J Psychotraumatol. 2014;5:23613.