

1 Online 1-Day Cognitive Behavioral Therapy-Based Workshops for Postpartum Depression: A
2 Randomized Controlled Trial

3 **Authors' Note: The study submitted to the Hamilton Integrated Research Ethics Board below*
4 *contains a second objective relating to health economic analyses. These are not included in the*
5 *present manuscript as they will be described in a separate report.*

6 **COVID-19 and Postpartum Depression:** The COVID-19 pandemic has further exposed the
7 vulnerabilities in social and economic systems that lead to inequalities for mothers with mental health
8 problems and their children, worsening unintended systematic biases that exist within the healthcare
9 system. These women may be among the most affected by the pandemic, experiencing substantial
10 worry, isolation, loneliness, lack of control, and insomnia, all of which have increased PPD rates. They
11 also have more responsibilities than ever before, providing care to their infants, toddlers, and older
12 children, while managing their households and supporting their partners. They are also profoundly
13 worried about job losses, reduced income, and food insecurity, all of which have disrupted family
14 routines, increased partner conflict, and rates of intimate partner violence.

15 Postpartum depression (PPD) typically affects up to 1 in 5 women,¹⁻³ increasing the risk of later
16 depressive episodes,² parenting problems,³ poor mother-infant attachment,⁴ and emotional, behavioural,
17 and school problems in offspring.^{7,8} A single case of PPD has been estimated to cost as much as
18 \$150,000 over the lifespan,⁵ or \$57 billion for each annual cohort of Canadian births. Even under ideal
19 conditions, the healthcare system is poorly equipped to provide care for problems requiring urgent
20 psychotherapy like PPD (e.g., just 1 in 10 women with PPD receive evidence-based care).¹⁷ Barriers to
21 care include women's preference for psychotherapy over medication, a lack of time, and a reluctance to
22 travel to regular appointments.^{6,7} The healthcare system is now even less able to help these women as
23 public health units that previously supported the mental health of mothers have shifted their priorities
24 to direct COVID response. Moreover, social distancing recommendations aimed at reducing COVID-
25 19 risk have inadvertently increased psychological distress and decreased access to resources that
26 protect against PPD including social and practical support from family, friends, and professionals. The
27 need for safe and accessible PPD treatment is further highlighted by the uptake of recent
28 recommendations (written by the NPI) on managing PPD during COVID-19 which have been read
29 40,000 times since their posting.⁸

30 Only interventions that are considered safe and that can be rapidly upscaled can have an impact on PPD
31 at the population level during COVID-19.⁹ Ideal large-scale interventions for PPD during COVID-19
32 are not only safe (i.e., delivered online), but are brief, utilize the treatments most preferred by women
33 (i.e., non-pharmacological), easily accessible (i.e., self-referred), provide skills that can be used over
34 the long-term, and delivered in large groups to increase social support. At present time, no
35 interventions exist that meet all of these criteria.

36 **The Potential of Online 1-Day CBT-Based Workshops:** The delivery of psychotherapy in large
37 groups (up to 30 participants) is a relatively new phenomenon,⁹ but may be capable of treating PPD on
38 the scale required to address its prevalence during COVID-19. CBT-based psychoeducational
39 workshops have been used in the UK to reduce stress and treat generalized anxiety disorder,^{9,10} with
40 gains retained up to 2 years after treatment.¹¹ Brown and colleagues delivered 1-Day CBT-Based
41 Workshops to an older general population sample of adults with depression in the UK and found them
42 to be effective (with larger effects for women).¹² Given the unique features of PPD (more comorbid
43 anxiety, social isolation self-deprecatory cognitions,) and the unique impact COVID-19 has on
44 mothers, face-to-face workshops should be adapted for women with PPD, delivered online, and tested.

46 **Primary Research Question:** Can Online 1-Day CBT-Based Workshops for PPD added to care as
47 usual during the COVID-19 pandemic improve PPD more than usual care alone?

48 **Secondary:** Are the workshops cost-effective?

49 **Tertiary:** Can these workshops reduce the impact of the common comorbidities and complications of
50 PPD (anxiety, support, mother-infant attachment, temperament)?

51 **Hypotheses:** Online 1-Day CBT-Based Workshops will be an effective (and cost-effective) way to
52 rapidly improve PPD and its comorbidities during COVID-19 and beyond.

53 **The Urgent Need for a Trial:** Practice guidelines for PPD suggest that structured
54 psychotherapies(e.g., CBT) are cost-effective,^{13,14} though these studies generally involve small groups
55 (<10) and consist of 12-15 sessions.^{15,16} Antidepressants are effective but women are reluctant to use
56 them,¹⁷ and nutritional¹⁸ and exercise¹⁸ interventions have small effect sizes and often require clinician
57 support.

58 Group psychotherapy is preferred by many women for the support, symptom normalization, and
59 opportunity to learn via modeling it provides.¹⁹ It reduces the profound social isolation and loneliness
60 women are experiencing, increases connectedness, empowers women to give and receive care, and
61 grows the support networks these mothers need during COVID-19.²⁰ However, most women cannot
62 attend 12-15 weekly sessions, and so a shift toward interventions that safely reach large numbers of
63 sufferers with maximum efficiency is needed.

64 In order to determine if any very brief psychotherapeutic interventions for PPD currently exist, a
65 systematic search of Medline, Embase, CINAHL, PsycINFO and Web of Science was conducted on
66 June 29, 2020. It identified 1256 potentially relevant articles, but no trials or observational studies. No
67 existing trials were present in clinical trials databases.

68 **Existing RCT and Feasibility Data:** We previously conducted an RCT of three sets of *face-to-face* 1-
69 Day CBT-Based Workshops for PPD with 91 women. 75 women provided data at follow-up (18%
70 attrition). Mean Edinburgh Postnatal Depression Scale (EPDS) scores were 17/30 at baseline, and score
71 reductions were larger in the experimental group ($d=0.40$, medium effect size) and clinically
72 significant (7.5 vs. 3.3 points).

73 **Uptake and Impact:** The proposed online workshop is consistent with the proportionate universalism
74 approach to public mental health which attempts to address the whole population while providing
75 additional (selective/targeted/indicated) support for groups at risk. Treatment guidelines for PPD
76 (including those written by the NPI) recommend a stepped approach where the least expensive and
77 intrusive interventions are offered first and others only if necessary.^{21,22} If effective, Online 1-Day
78 CBT-Based Workshops would be an important low-intensity first step in international PPD treatment
79 pathways, effectively treating some women, and identifying those in need of more intensive treatment.

80 **Knowledge Translation:** The proposed study and its KT plan will rapidly lead to the mobilization of
81 knowledge to postpartum maternal care during COVID-19, as well as incorporation into practice
82 guidelines. The results of our study will be communicated to knowledge users via end-of-grant KT
83 methods that leverage our integrated (iKT) design. Our study team includes public health professionals,
84 community experts, women with PPD, and mental health leaders. Women with PPD in a previous
85 study⁵⁹ identified issues relevant to their needs and helped plan, design, and implement our workshops.

86 **End of Grant KT.** All KT strategies will focus on making our findings meaningful to users and
87 highlight their relevance and implications for action. We will engage the media and circulate printed
88 materials. We will also hold outcome seminars for participants online. Communication with

89 community and public health knowledge users will occur through webinars. Traditional methods of KT
90 (journal and conference presentations) will also be used.

91 **Trial Design:** A parallel-group RCT with experimental (immediate workshop) and waitlist control
92 (treatment 12 weeks later) groups will address our objectives. Participants complete emailed study
93 questionnaires at baseline (T1, just before the experimental workshop) and 12 weeks later (T2, just
94 prior to waitlist control workshop). Participants and the research coordinator cannot be blinded to
95 group condition, but staff making reminders and data analysts will not be aware of group status.
96 Therapists delivering groups will be randomly assigned to workshops and not notified of group status.

97 **Intervention:** The experimental (immediate workshop) group will receive the online workshop at
98 baseline (T1), and the control (waitlist) group will receive the intervention twelve weeks later. Both
99 groups can also receive care as usual from their healthcare providers.

100 The online workshop was developed by the NPI (a perinatal psychiatrist who has developed and tested
101 effective brief group CBT for PPD interventions),²³ Peter Bieling (author of the world's leading group
102 CBT manual), and June Brown (developer of 1-Day CBT-Based workshops for depression in the UK).⁹
103 It is a day-long intervention delivered in 4 modules. Each participant is given a professionally designed
104 manual (Attached) to facilitate learning. Weekly reminder emails are sent for 6 weeks after workshop
105 completion to encourage practice. We also provide a list of PPD resources and a copy of the Canadian
106 Practice Guidelines for the Treatment of PPD (written by NPI).

107 To expedite intervention delivery, 3 previously trained therapists from our *in-person* RCT (a clinical
108 psychology trainee, registered psychotherapist, psychiatrist) will deliver the workshops. We have
109 developed protocols to handle emergencies (e.g., suicidality, child protection), and will refer to clinical
110 services as indicated.

111 **Randomization:** There will be 9 sets of online workshops (each set consisting of one experimental and
112 one control workshop). Women will undergo block randomization to the experimental or waitlist
113 control group using permuted block sizes of 4, 6, and 8. The randomization scheme will be generated in
114 the statistical computing program R. The randomization of participants will be delivered to the research
115 coordinator via the online REDCap (Research Electronic Data Capture) system. We will track reasons
116 for loss to follow-up.

117 **Recruitment:** We will recruit participants via social and online media, our public health and
118 community partners, midwifery groups, and obstetrical and family practices, (techniques utilized
119 during our prior RCT/online feasibility work, and in the past with community PPD samples).^{24,25}

120 **Minimizing Bias:** Staff making reminder calls and our data analyst will be unaware of participant
121 status. Therapists will not be notified of group status and are randomly assigned to online workshops.
122 In our *face-to-face* RCT and the study proposed here, we utilize gold standard measures, ask about
123 current symptoms, and collect questionnaire responses via REDcap. This method is preferred by
124 women of childbearing age, and reduces dropout rates and missing data.²⁶ We utilize Dillman's Method
125 adapted for email surveys, with professionally designed/personalized emails, advance warning of
126 questionnaires via email and telephone, assure anonymity, and minimize questionnaire number/length.
127 We optimize screen format, designed error messages to help respondents troubleshoot difficulties,
128 allow them to stop surveys and continue later, and provide a \$10 WalMart gift card for completing each
129 set of questionnaires.²⁷ Predictors of attrition will be assessed and adjusted for in the analysis phase.
130 While we permit co-interventions (e.g., medication use, concurrent psychotherapy), we will examine
131 their impact.

132 **Study Eligibility:** Women who are >18 years old, have an infant <12 months at the time of
 133 recruitment, fluent in written/spoken English, and have an EPDS score of ≥ 10 are eligible.

134 **Primary Outcome:** EPDS: The gold standard measure of PPD in clinical practice/research. A change
 135 of 4 points is recognized as a clinically meaningful/significant improvement.⁵⁸ Differences between
 136 experimental and control groups from T1 to T2 will be compared.

137 **Secondary Outcome (Cost-Effectiveness):**

138 Cost-effectiveness will be measured using incremental cost per quality-adjusted life year ratio.

139 **a) Costs:** Healthcare resource utilization data will be collected using a questionnaire based on the
 140 Canadian Community Health Survey and the Service Use and Resources Form adapted for the
 141 postpartum period and used in previous PPD research.^{24,28} We will measure resources consumed over
 142 the 6-week trial period from the perspective of public healthcare payer. Costs will be calculated using
 143 provincial or other standard billing rates.

144 **b) Quality-Adjusted Life Year (QALY):** The EQ-5D-5L, a utility-based health-related quality of life
 145 instrument²⁹ will be used. Its validity in measuring the impact of depression is established.³⁰ Its
 146 Canadian scoring algorithm will be used.³¹ For each participant, a QALY will be calculated by
 147 multiplying the health utility for the matching time period (i.e., the area under the curve approach).

148 **Tertiary Outcomes:**

149 i) GAD-7: A 7-item self-report scale of symptoms of generalized anxiety disorder, the most common
 150 PPD comorbidity (and a condition known to respond clinically to CBT).³²

151 ii) Postpartum Bonding Questionnaire: 25-item maternal-report scale of the mother-infant
 152 relationship.³³

153 iii) The Social Provisions Scale (SPS) is a 24-item self-report measure of the degree to an individual
 154 perceives their current social relationships to provide support.³⁴ The total scale score will be used in
 155 this study.

156 iv) The Infant Behavior Questionnaire – Revised (Very Short Form) (IBQR): 37-item maternal report
 157 measure of infant behavior and temperament.³⁵

158 **Sample Size** The sample size for this study is 300 (type I error of 0.01, 90% power to detect a medium
 159 effect size of 0.40). Anticipating 30% attrition of enrolled women (estimated to be higher during
 160 COVID-19 because of increased levels of responsibility at home), we will approach 388 women to
 161 participate (194 in each treatment arm). We conservatively estimate that 22 women will attend each
 162 online workshop, and so in order to meet our target sample size (N=388), we will need to deliver 18
 163 online workshops (nine sets of one experimental plus one control workshop). *In-person* RCT data show
 164 that intervention brevity, study reminders, and ease of accessibility minimize compliance issues.

165 **Statistical Analyses:** All outcome data will be analyzed on an intention-to-treat basis. Between-group
 166 intervention effects from baseline (T1) to T2 will be compared using longitudinal mixed effects (LME)
 167 models.³⁶ LME models utilize all data on each subject, can accommodate outcome data that are
 168 conditionally missing at random, and can flexibly model the effect of time and potential confounders
 169 on continuous treatment outcomes (e.g., EPDS scores). They will also account for women being
 170 clustered within workshop group using a random effects intercept, and control for the fixed effect of
 171 differences between workshop facilitators. These models will utilize a restricted maximum likelihood
 172 estimator method with an unstructured covariance matrix, which allows for maximum flexibility
 173 estimating model variance components. Finally, multivariate logistic regression will determine if the

174 proportion of women achieving a clinically meaningful change (4 points on the EPDS) is different
175 between the two treatment arms at T2, controlling for differences in workshop facilitator.

176 Our economic analyses will use the methods consistent with guidelines for economic evaluation.^{82,83}
177 We will calculate the incremental cost per QALY ratio by comparing the intervention group with the
178 control. Clustered non-parametric bootstrapping will be used to calculate the 95% confidence interval
179 for the ratio according to the trial design. The decision uncertainty will be presented using cost-
180 effectiveness acceptability curves which show the probability of the intervention being cost-effective
181 compared with the control group at a wide range of willingness-to-pay for a QALY.

182 **Subgroup Analyses:** We will examine the impact of therapist type.

183 Study Challenges and Mitigation Strategies

184 **Waitlist Controls:** This was selected because placebo-controlled trials in PPD are avoided on ethical
185 grounds,³⁹ rates of adverse effects with counseling intervention RCTs are low,⁶⁵ and our *in-person* RCT
186 data show that waitlist participants neither worsen nor use less mental health resources while waiting.
187 PPD is not characterized by worsening over periods of twelve weeks, and all women in the trial can
188 access healthcare unimpeded.^{40,41} They are sent practice guidelines and other PPD resources at
189 enrolment, and weekly emails reminding them of indications for seeking treatment (subjective
190 worsening, suicidal ideation), who to contact (family doctor, emergency services), and the importance
191 of doing so.

192 **Effectiveness:** Despite its brevity and large-group format, online workshops may be capable of
193 producing meaningful improvements, and we utilize a range of different therapists to optimize
194 generalizability and uptake. Even if not as effective as longer and more intensive CBT protocols, online
195 workshops have greater reach, safely engaging and treating more women, enabling much larger
196 numbers to receive treatment during COVID-19, and playing a role in large-scale PPD treatment.

197 Study Importance, Innovation, and Novelty

198 While a vaccine is sought and social distancing remains the norm, healthcare systems are in urgent
199 need of safe, efficient, scalable means of treating PPD. The proposed study maximizes innovation and
200 impact by using a novel online treatment that respects women's preferences, and an intervention (CBT)
201 that can also improve postpartum anxiety. An existing RCT of workshops conducted *face-to-face* has
202 enabled us to develop the trial infrastructure to begin immediately, and so Online 1-Day CBT-Based
203 Workshops for PPD could represent a significant component of the next successfully implemented,
204 research-enabled Canadian public health strategy, enhancing collaborative efforts to mitigate the
205 negative consequences of COVID-19 on women with PPD and their families.

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