A pilot randomized trial of a telephone coaching intervention for postpartum depression and anxiety

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1. Background

1.1 The Problem

Mental health problems affect up to 20% of women at some point during the perinatal period (i.e., from pregnancy to one year postpartum [1]). Perinatal mental health (PMH) problems have been associated with many negative obstetric outcomes, such as higher elective caesarean section, premature delivery, pre-eclampsia, lower fertility rates, and longer postpartum hospital stay[2-4]. PMH problems also affect the foetus and baby. For example, maternal depression has been associated with lower gestational age, preterm delivery, lower birth weight and changes in infant emotional regulation [4, 5]. Finally, PMH problems have economic costs associated with expenses such as prolonged hospitalization, psychological treatment, and follow-up of the mother, the baby and/or child, and the family as a whole.[6, 7]

St. Mary's Hospital Center (SMHC) has one of the largest birthing centers in Montreal, with about 4,000 deliveries per year. While there are some excellent mental health services currently available at SMHC for mothers with more serious mental health problems, mild to moderate cases may not be recognized by clinicians as systematic screening is not currently done and they may have more difficulty accessing appropriate services. We have conducted a pilot longitudinal study (Phase 1) to assess needs for post-partum mental health services (see section 1.3). The results indicated that web-based materials along with telephone support were preferred resources of information to address PMH issues as well as to facilitate easier access to services considering barriers like lack of time and transport. To address this need, Phase 2 of the research study is a pilot randomized controlled trial (RCT) to assess the feasibility, acceptability, and potential benefits of a low cost sustainable web-based intervention (WBI) with telephone coaching for these women with mild to moderate symptomatology.

1.2 Literature review

1.2.1. Prevalence of perinatal mood and anxiety disorder

The most common PMH problems include mood and anxiety disorders with differing levels of severity. They extend over a period of time and in some cases they last longer than 1 year after birth [6, 8-10]. Current estimates suggest that the presence of a minor or major depressive episode is between 7% and 13% during the first postnatal year [11] with an average of 12 % worldwide for perinatal depression [12]. Anxiety disorders often coexist with depression with the prevalence of anxiety higher in perinatal populations when compared to non-perinatal groups [13]. The prevalence for generalized anxiety disorder (GAD) is 4.4%-8.2% in the first postpartum year [13]. Therefore, it is important to consider effective treatment modalities for women experiencing a range of PMH symptoms.

1.2.2. Web-based interventions for PMH - Relevant Reviews and Meta-analyses

Systematic reviews and meta-analyses have shown encouraging results from studies addressing perinatal mood disorders using internet based interventions consisting of reading material and online modules providing information and support for women experiencing PMH issues [14-16]. These reviews incorporate a mix of prevention and treatment WBIs targeting prenatal as well as postpartum mental health issues. Although the interventions vary in timing and use (preventative vs postnatal) throughout the perinatal period, the use of WBIs showed effectiveness in the reduction of PMH issues particularly depression [12, 15].

In these reviews [14], only three RCTs used WBIs for postpartum depression (PPD), that included guided telephone support. The first one was Phase II of the web-based RCT that incorporated weekly telephone support from mental health workers with the 12 modules involving internet behavioral

activation treatment. 83 women were randomized to intervention (n=41) and treatment as usual (TAU) (n=42). Post-treatment follow up between group scores were clinically significant with an improvement in depression scores in the intervention group seen at 62.2% (n=23/37) compared to 29.4% (n=10/34) in the TAU group [17].

The second RCT focused on providing internet CBT for PPD using guided telephone support in the form of telephone coaching [18].The 6 week interactive *mummoodbooste*r intervention to facilitate behavior change provided participants (n=43) with session goals, self-monitoring and other exercises along with personalized workbooks. Coaches provided guided telephone support to encourage participants to practice strategies, point to relevant program content and answer questions. Participants in the intervention group showed scores decreasing (Improving at a greater rate (estimate=-0.34, SE 0.12, P-.01, partial r=-.23) when compared to TAU [18]. The third RCT, a recent Canadian trial also showed similar results with therapist –assisted internet CBT modules with email and telephone support (if significant distress was reported). EPDS scores in the intervention group at follow up showed significant improvement when compared to waitlist (WL) group ($t(14) = 4.13$, $p < .01$, $d = 1.10$) [19]. Both these trials [18, 19], showed high program engagement with 86% and 60% completion of all modules with the *mummoodbooste*r intervention showing high ratings towards helpfulness of coach calls (90% - 19/21 participants).

The 3 RCTs all compared the WBI to a non-treatment control group; there was no attempt to assess the incremental effect of the coaching. None of the RCTs addressed anxiety. The proposed RCT will address both these concerns.

1.3 Goals and Results of Phase 1 Needs Assessment

Phase 1 of the pilot study aimed to gather information on the needs, preferences, use of resources of women affected by PMH problems. A longitudinal study was conducted in 3 steps: 1) Recruitment of a sample of mothers 24 hours postpartum (T0); n=401 completed baseline questionnaires 2) Telephone and web-based screening for depression and anxiety at 2 weeks postpartum (T1); n=344 completed measures and 3) Among participants identified with postpartum depression or anxiety [≥10 on the Edinburgh Postnatal Depression Scale (EPDS) or ≥10 on the Generalized Anxiety Disorder-7 (GAD-7) questionnaire]n=73 at T1, a follow-up interview at 4 months postpartum (T2)n=57 at T2, to assess mood and anxiety symptoms, mental health resource and services access, unmet mental health needs, preferences, and access barriers. A self-guided, self-management intervention was provided to participants who screened positive at T1 that included a listing of resources and links were emailed to the eligible participants that included local information on the following: emergency contacts - 911 and crisis centre numbers; public health services and resources for mental health; resources for private psychotherapy; organizations that provide postpartum and breastfeeding support; and, resources for alcohol and tobacco cessation. Links to self-management workbooks on coping with anxiety and depression as well as references for two books were also provided.

Only 28% of the sample reported that they actually used the materials, but those that did use them reported that they were helpful. One quarter of the sample reported talking to a health professional, most often a nurse, about their mental health problems. Out of T2 participants 74% had at least one perceived need. The highest and lowest percentages of unmet needs out of those with perceived needs were reported for social intervention (70%) and information (24%) respectively. The internet, telephone, and booklets were the preferred approaches for receiving information. Many participants also considered that talking to peers would be helpful. Interestingly, only a very small number of participants reported actual use of a crisis telephone help-line or a support group.

Nearly 60% of the participants in this study were born outside of Canada. Immigrants had lower depression and anxiety scores at 2 weeks post-partum, but similar scores at 4 months in comparison to

women born in Canada. Immigrants had significantly lower rates of health professional contact. While a minority of women with PMH problems in our study sought professional mental health help or used intervention materials provided by the study, 37% reported unmet needs related to their mental health. Web-based materials with telephone support are preferred strategies in this population as they allow women to access materials at their convenience and without leaving home. Coaching of mental health self-management can be an effective adjunct to the provision of self-management materials in other populations [20, 21]. Coaching provides opportunities to tailor intervention components to individual needs and preferences, and provide the support and encouragement that are needed for women with PMH problems in response to these specific needs. Immigrant mothers are particularly likely to benefit from this type of intervention as they use fewer formal mental health services compared to Canadian-born women.

1.4 Rationale

The telephone coaching intervention aims to enhance the effectiveness of the WBI intervention with the help of a trained, lay coach for those in the intervention group. Previous trials have not directly assessed the incremental effect of telephone coaching of a WBI. Previous research in depression self-management in primary care suggests that coaching may increase participant's engagement with the web-based materials [20, 21] and hence increase the effectiveness of the intervention. The proposed intervention is designed to meet the needs identified in our phase 1 needs assessment for a low cost sustainable intervention comprising web-based materials with telephone coaching. Approaching participants starting at 5 weeks postpartum will present the opportunity to increase participation and engagement with the intervention materials rather than at an earlier time point after childbirth. An RCT of the coaching intervention can provide decision-makers with evidence on the benefits of implementation of this more costly component.

1.5. Research Questions:

Among women who present with symptoms of depression or anxiety within 5 – 12 weeks of giving birth:
1. Feasibility and Acceptability of the two intervention components - WBI and coaching:
a) Among women in the coached and non-coached groups:
i) What are rates of use of the WBI modules?
ii)What are participant perceptions of the usability of the WBI with regard to the layout, navigation and functionality at 3 months following randomization?
ii) What are the rates of satisfaction with the intervention at 6 months?
b) Among women in the coached group:
i) What are rates of completion of the planned telephone contacts?
ii) What are participant perceptions of the acceptability of the coaching at 6 months?
iii) What are coach perceptions of acceptability of coaching intervention?

2. Effectiveness: The EPDS is the primary outcome measure for depression and the GAD-7 is the primary outcome measure for anxiety (Section 2.5.1)
i) Primary outcomes: What is the effect of coaching on the severity of depression and/or anxiety symptoms at the 3 and 6 month follow-up?
ii). Secondary outcomes: What is the effect of coaching at 3 and 6 months on maternal functioning, parental stress and at 6 months on use of mental health services, and barriers to use of these services?

Hypothesis: We expect a decrease in scores in the EPDS and GAD-7 in the group with coaching when compared to the group without coaching at 6 months.

2. Methods

2.1. Design

We will conduct a pilot single –blind randomized control trial with lay telephone coaching with two groups of women, one assigned to the WBI with coaching and the other to the self-guided WBI. This RCT would consist of the following steps:

1) Contacting a sample of women immediately post-birth at SMHC and obtaining consent to contact them again within 5 - 12 weeks postpartum to determine their eligibility.
2) 5-12 weeks postpartum: Screen women for eligibility for RCT;
3) Request informed consent to RCT(Appendix 14)
4) Baseline measures (T0);
5) Follow up at 3 months (T1) post-randomization
6) Follow-up at 6 months (T2) post-randomization

Women who deliver elsewhere in the CIUSSS can be referred to the study before 12 weeks post-partum. Consent to contact them at 5-12 weeks postpartum would be obtained at the first contact to determine their eligibility (see 2.2.2.2). These women then follow steps 2-6.

2.2. Eligibility and Recruitment

2.2.1. Eligibility Criteria

Potential study participants will answer eligibility questions (Appendix 1) based on the criteria given below and be screened for symptoms of depression and anxiety.

Inclusion Criteria (at step 1):

- Age 18+ (at birth)
- Ability to speak English or French
- Livebirth
- Access to the internet and email

Inclusion criteria (at step 2):

- Score on either EPDS 10 – 19 or GAD-7 of 10+ (Section 2.5.1). Women with a GAD-7 score of 15+ will be referred to the mental health nurse (Section 2.6) and will be included in the study.
- Baby at home

Exclusion Criteria:

- Women currently undergoing psychological treatment and /or having a history of bipolar disorder or psychosis will be excluded
- Severe symptoms (Score of 20 or more on the EPDS, will be excluded (Section 2.5.1)

Any anti-depressant and/or psychological treatment will be managed by the participant's own physician and not by the research team.

2.2.2. Recruitment and follow-up

2.2.2.1 Clinical recruitment at SMHC

Recruitment will be conducted by the study co-ordinator who will work closely with hospital/clinic staff at SMHC to identify potentially eligible mothers. Staff will be informed of the study and a poster will be placed in the staff area indicating the eligibility criteria (Appendix 2) and the study co-ordinator will work with the staff to obtain a list of deliveries, and exclude those with a stillbirth, and other exclusion criteria. The nurse would help the study co-ordinator approach a potential participant by informing her of the study and checking her interest to be approached for recruitment. If the patient agrees, the study co-ordinator

will then introduce herself in person. She will then approach potentially eligible women to describe the study and request consent to be recontacted at 5 – 12 weeks postpartum (Appendix 1). A separate consent form to the RCT will be sent to participants electronically at the time of screening (5- 12 weeks postpartum) for those eligible (See 2.2.1). A flowchart of recruitment and consent is outlined in Figure 1.

Participants will be asked to identify a responsible physician and provide his/her contact information in case of suicidality or other adverse events. For participants who do not have a family physician, Dr. Hannah Schwartz or a replacing psychiatrist would be able to suggest appropriate recommendations for follow-up of participants in case of suicidality or severe symptoms of depression or anxiety and will be accessible for psychiatric assessments when deemed necessary (See section 2.6).

2.2.2.2 Community recruitment

Women will also be referred by nurses from obstetric and postpartum clinics and from referrals within the CIUSSS network. A recruitment flyer and staff poster will be distributed with the eligibility criteria and study contact information (Appendix 3 & 2). The CLSCs will be informed of the study and an informational poster will be provided. Nurses will provide the study co-ordinator's contact information to potential participants. Women interested in the study, will contact the study co-ordinator who in turn will provide them with a link to complete the online eligibility and screening form (Appendix 4). Women, who meet the eligibility criteria, would then be randomized into either one study arm after providing consent. Consent forms will be sent electronically once they meet the eligibility criteria (Section 2.2.1) Women recruited at SMHC and via referrals who do not meet the eligibility criteria for the RCT will still receive a list of community resources by email (Appendix 5).

2.3 Intervention

Self-directed web-based materials: The WBI titled *'HealthyMoms'* is a secure psychoeducational e-health platform. Participants in both groups will be provided with materials based on self-guided learning modules and tools such as emotional health, healthy living, mental fitness tools and parenting along with a physical activity challenge. The modules are based on CBT and mindfulness-based practices [13, 22]. Evidence-based strategies to promote maternal health behaviours [6, 8-10, 23-25] and enhance women's engagement with their antenatal care providers (e.g. preparing for appointments, formulating questions) [3, 26] are included.

A preliminary formative evaluation during the website development involved giving a subgroup of expectant and new mothers who had participated in the needs assessment (n=19) access to the prototype for two weeks and a semi-structured telephone interview elicited feedback related to usability, satisfaction and suggestions for refinement [27]. Women had positive impressions, rating the information as highly credible, relevant, useful and easy to navigate. Suggestions to include a module to manage challenges of breastfeeding, the inclusion of more community resources (i.e. local prenatal exercise groups), and to expand the exercise section to include more multimedia features were recommended. We have already addressed some of these recommendations (i.e. developed a breastfeeding module, added more community resources) and are making refinements.

This psychoeducational program covers 4 areas. The Emotional Health section is comprised of the following learning modules: emotional wellness; depression/low mood; anxiety, stress, your partner. The Healthy Living section is comprised of the following learning modules: exercise; nutrition; sleep; and time for you. The Mental Fitness module has 5 modules which teach strategies related to the following: reframing thoughts; relaxation exercises; mindfulness; positive emotions; and mobilizing social support. The parenting module has the following four modules: your couple relationship; mindful parenting; infant feeding; and infant sleep. These modules were developed by a multidisciplinary team consisting of clinical

psychologists, physicians, kinesiologist, nutritionist and input from expectant/new mothers[4]. To encourage use and help guide women through the program, motivational email messages will be sent to all women weekly for a period of 12 weeks. A list of community resources will be provided to the participants at the same time when they receive the intervention materials. These community resources will also be provided to the women who are not eligible for the RCT (scores on the EPDS & GAD-7 below 10) by email. The design of the intervention is shown in Figure 3.

Coaching: Intervention group participants will also be supported by telephone by a trained lay coach who will guide participants through the materials, help in navigating the modules, and provide positive reinforcement, and help to answer questions,. Coaching will start within the first week from randomization. The coaching protocol has been adapted from previous trials of depression self-management conducted by the Co-PI[20, 21]. The coach will call participants weekly during the 1st month, biweekly for the 2nd month and once by the end of the 3rd month of the intervention period. The coach will spend an average of 10 – 15 minutes for each call and will also receive a voice mail number and e-mail address to contact the study coordinator to reschedule planned contacts if necessary. A suggested script, including specific objectives, is provided for the coach as a framework for each call as well as training based on the drafted coach manual. Coach supervision meetings with the PI (Dr Schwartz) will take place once a week where difficulties /questions will be reviewed. The coach trainer and the PI will train the coach in a two day session with practice calls. The coach trainer will review coach logs and listen to recorded contacts periodically and provide feedback to the coach.

The control group will be provided with the intervention materials but will not receive telephone support from the coach. They will also receive a list of community resources at the same time when they have access to the intervention material. The study co-ordinator will keep track of all referred women and women recruited at SMHC with a recruitment log.

2.4 Randomization

For each recruitment site (SMHC and CIUSSS), the participant will be randomized to intervention and control by a computer-generated (SAS version 9.4) randomization schedule that uses random block sizes of 2 or 4, with an allocation ratio of 1:1. In order to ensure allocation concealment, the study coordinator will first verify eligibility and informed consent by completing a checklist (Appendix 1). Subsequently, the PID (Participant Identifier) number from the original screening log will be entered into the randomization schedule, along with: recruitment site, date of screening, and date of baseline interview, then an automated interface will assign the study arm.

2.5. Participant Measures (Both study groups)

Data collection will be conducted at 4 different time points - Recruitment, T0, T1, and T2 using SimpleSurvey. Reminders can be also sent using Simple Survey. After completion of T2, participants will be sent a 15$ amazon gift card as a token of appreciation. The approximate duration for completion of the online questionnaires will be: T0 (Baseline) about 10-15 minutes, T1 (3 month follow-up) and T2 (6 month follow-up) about 15-20 minutes.

2.5.1 Screening Interview (for Eligibility)

From 5 weeks postpartum (up to 12 weeks), women will be sent a link to access a screening questionnaire by email and will be screened using the EPDS and GAD-7 for symptoms of depression and anxiety (Appendix 7 & 8). A research assistant will make a reminder telephone call to participants who have not accessed the link or who have difficulty completing the questionnaire online. Eligible participants will be asked to consent to the trial and complete baseline measures (Appendix 6). A reminder telephone call by a research assistant or the study co-ordinator will be made to eligible participants to follow up on accessing

the link to the online consent form and the baseline questionnaire. Following consent, eligible women, and will be randomized to two groups – Intervention (WBI with coaching) and control (WBI without coaching).

1. Edinburgh Postnatal Depression Scale (EPDS): The EPDS is a 10-item self-report measure, with a four point response scale, and is designed to screen participants for depressive symptoms in the last seven days. The EPDS included one question (Item 10) about thoughts of self-harm. Sum scores for the 10 items were used to generate a total score. This measure has optimal sensitivity and specificity using a cut-off score of 12: the EPDS was found to have a sensitivity of 68% to 95%, and a specificity of 78% to 96%, when compared to a diagnosis of major depression made by psychiatric interview. The split-half reliability of the scale is 0.88, and the standardized alpha coefficient is 0.87. (34) For the purposes of this study, a cut off score of 10+ was used to identify participants with potentially clinically significant depressive symptoms [28]. Women who score 20 or over on the EPDS will be excluded. A score of 10-19 will be included.
2. Generalized Anxiety Disorder-7 (GAD-7): The seven-item, self-report GAD-7 questionnaire, designed to screen for and measure the level of anxiety symptoms during the last seven days was also used. An identified cut point of 10 optimized sensitivity at 89% and specificity at 82%.(26) The GAD-7 has shown excellent internal consistency (Cronbach alpha coefficient= 0.92) and good test-retest reliability (r=0.83) [29]. Women who have a GAD-7 of greater than 15 will be referred to a mental health nurse but also included in the study.

2.5.2 Baseline Measures - Time 0 (Appendix 6)

1. Sociodemographics: Participants will report: years of education completed, living arrangement (alone vs. with others); marital status (married, common-law vs. other); place of birth, years in Canada (Canada vs. other country); and employment (working at a paying job vs. not working), income and parity.

2. Prescription Medication: Current prescription medications will be listed.

3. Sleep & physical activity: Questions on sleep and on the current level of physical activity will be included and will be adapted from the Canadian Community Mental Health Questionnaire (CCMHS)

4. Use of services for mental health problems: Questions adapted from the Canadian Community Mental Health Questionnaire (CCMHS) will be used. These questions ask about visits to healthcare professionals or use of other community services for mental health problems during the previous 12 months and the barriers to seeking such help.

5. Questions on use of alcohol and/or drugs: Questions on the use of alcohol and/or drugs during the previous 12 months will be included.

6. Questions on pregnancy and breastfeeding: Participants will be asked about the number of pregnancies they have had, the type of delivery as well as their current method of feeding if they are breastfeeding, using formula or both and the level of difficulty they are facing if any.

7. Barkin Index of Maternal Functioning (BIMF): The BIMF (Appendix 9) is designed to measure maternal functioning in new mothers. It is known for its comprehensibility, patient-centered assessment style, and psychometric profile. The 20 item BIMF is based on the experiences of women experiencing new motherhood and has a possible range of 0 to 120 with a total score of 120 indicating optimal maternal functioning. The initial psychometric analysis revealed a Cronbach's alpha of 0.87 and adequate construct validity was observed [30]. Method of questionnaire administration and characteristics of the study and/or patient population should routinely be considered when implementing any type of self-reported health screening.

8. Parental Stress Questionnaire (PARSS): The PARSS (Appendix 10) developed by Berry and Jones in 1995 is an 18 item questionnaire designed to measure the positive aspects of parenting as well as the

negative stressful aspects. The self-report five point scale helps parents rate how they feel about the relationship with their child by agreeing or disagreeing on various themes of parenting. The tool would help to assess the change in level of stress and would inform the level of support or services need to improve parenting capacity. The 8 positive items are reverse scored so that possible scores on the scale can range between 18-90. Higher scores on the scale indicate greater stress. It has satisfactory levels of internal reliability (.83), and test-retest reliability (.81). The scale demonstrated satisfactory convergent validity with various measures of stress, emotion, and role satisfaction, including perceived stress, work/family stress, loneliness, anxiety, guilt, marital satisfaction, marital commitment, job satisfaction, and social support [31].

2.5.3 Outcome Measures - T1 & T2

T1 (Follow up at 3 months)

Outcome measures at T1, 3 months will include the EPDS, the GAD-7, the BIMF, the PARSS and questions on usability & acceptability of the *Healthymoms* website.

Questions on usability & acceptability (Appendix 11): All participants will complete a survey at 3 months after randomization to assess usability (layout, navigation, functionality) and acceptability (overall usefulness, usefulness of specific topics, utility of the site for improving mood and engaging in healthy behaviours, credibility and program length/duration). The on-line survey is guided by previous usability/acceptability studies[5, 7] and recommendations from the Science Panel on Interactive Communications and Health[20] for website usability evaluation. System usage data will complement users' self-reports and include frequency and duration of user log in, number of modules viewed. Given that a mean adherence rate of about 50% (defined as number of modules completed) has been observed in e-mental health interventions showing significant changes in outcomes[21, 32, 33], we have selected this cut-off as an acceptable usage metric.

T2 (Follow up at 6 months)

Outcome measures at 6 months will include the EPDS, the GAD-7, the BIMF and the PARSS. In addition, the following measures will be administered:

1. Client Satisfaction Questionnaire (CSQ-8) (Appendix 12): Satisfaction with the intervention will be measured with the 8-item open-ended questions that will ask participants what they liked most about the intervention and what could be improved. In a variety of studies, the internal consistency of the CSQ-8, as measured by coefficient alpha, ranged from .83 to .93, with values of .86 and .87. The CSQ-8 is a very brief instrument with good psychometric properties, and it has been tested in numerous studies on diverse client samples. It also appears useful for measuring satisfaction with a wide range of services.
2. Use of services for mental health problems (Appendix 13): Questions adapted from the Canadian Community Mental Health Questionnaire (CCMHS) will be used. These questions ask about visits to psychiatrists, psychologists, family doctors, nurse, social workers, self-help groups, and other community services for mental health problems since they entered the study. Any use or change of medication for mental health will be noted.

2.5.4 Measures in intervention group only:

1. The intervention group will receive an additional questionnaire at 6 months on the usefulness (positive and negative aspects) of having support and guidance from the coach, using questions adapted from our previous trials of coaching [34].

2. Coach logs and records: Adherence to the coaching will be tracked in coach logs that record attempted and completed, duration of contacts, topics covered, modules that were recommended and/or used, goals set, and problems that arose. Contacts will be tape-recorded for fidelity monitoring.
3. Coach exit interviews: At the end of the study, the coach will participate in a semi structured exit interview regarding their experiences, the challenges that arose in delivering this form of support, and how the intervention could be improved.

2.6 Referral for women with severe PMH problems

Any woman who screens in the severe range for depression or anxiety (>19/30 on the EPDS and >14 on the GAD-7) or endorses any response other than "none" on the EPDS self-harm question will be offered a telephone follow-up with a mental health nurse, or a replacing nurse, who will triage the patient and suggest appropriate recommendations for follow-up in psychiatry. Dr. Hannah Schwartz, a psychiatrist at St Mary's Hospital, or a replacing psychiatrist, will be accessible for psychiatric assessments when deemed necessary. If a participant endorses "Yes, quite often", "Sometimes" or "Hardly Ever" to the self-harm question and is otherwise eligible, the study co-ordinator will contact her by telephone and offer a referral to the mental health nurse, who will follow the standard medical protocol at St. Mary's hospital for patient follow –up. If the participant is not reachable by telephone, an email will be sent providing resources and the contact information for the mental health nurse to receive help if necessary. The participant will be informed about her options to seek immediate help by presenting herself at the local CLSC, her MD's office or to the Emergency Department. 9-1-1 always remains an option. The study co-ordinator will maintain a separate participant log to keep track of the number of referrals and the reason for referral.

2.6.1 Referral for women with hetero-aggressive behavior or infanticide ideation

Any participant who shows signs of hetero-aggressive behavior or infanticide ideation will be directed to the crisis resources (Section 2.3& Appendix 5) and provided with contact information to receive help. They will also be offered a telephone follow-up with a mental health professional from SMHC. In case of an emergency, the research staff will call an ambulance to ensure the safety of the baby. A separate script for alerts will be included in the coach manual.

2.7 Statistical methods

2.7.1 Data analysis

2.7.1.1 Feasibility and Acceptability

Descriptive statistics will be calculated for all the indicators of feasibility and acceptability. Difference between groups will be assessed with Pearson Chi-square or Fisher exact test [35] for comparing proportions across independent groups.

2.7.1.2 Effectiveness

Data analysis will be conducted and reported according to CONSORT guideline [36]. The analyses will be conducted using SAS version 9.4, STATA version 13.0 and R software.

Preliminary analyses: Descriptive analyses will compare characteristics of participants associated with participation and completion of both follow-up (T1 and T2). We will compare participants randomized to the 2 study arms with respect to the main primary and secondary outcomes at baseline (EPDS, GAD-7, BIMF and PARSS), and identify those who show potentially clinically significant differences across study

arms (balance imbalance). The appropriate baseline variable will include in the regression model to correct for potential confounding [37, 38].

General considerations: The main analysis will be restricted to the T2 completers only. However, for the primary outcome variables, and if the number of non-completers ranges between 10 and 30% of the total study sample, we will also carry out a sensitivity analysis by including non-completers and adopting an Intention to Treat (ITT) approach with the Inverse Probability Weighting (IPW) [39, 40].
All tests will be performed at an alpha-level of 0.05. For continuous outcomes, Cohen's effect sizes [41] will be computed with confidence interval (CI) of 95%; for binary outcomes, Odds Ratios and 95% CI will be computed.

Primary Research Question: The primary outcomes —EPDS and GAD-7 at T2—are continuous variables and for each outcome the comparison between intervention and control groups will be based on a simple t-test. If the baseline score of the outcome is selected for baseline imbalance (see above), we will also report an analysis based on the linear regression model [42], which will include the baseline score.

Secondary Research Question: The continuous outcomes —PARSS and BIMF at T2— will be compared across the study arms with a simple t-test. Linear regression [42] will be performed to correct for baseline imbalance (see above). All the binary outcomes (health use of services at T2) will be tested across study arms with Pearson Chi-square or Fisher exact test.

Additional analyses: In order to model outcome variables at T1 and T2 (EPDS, GAD-7, PARSS, and BIMF), linear mixed model [43] will be used to model the dependence between the two observations on the same participant. For each outcome, the model will include the study arm (intervention, control), time (T1, T2) and the pre-specified baseline variables if any; the interaction between study arm and time will be tested at alpha 0.1. If the interaction is significant separate linear regressions for each time point will be developed.

2.7.2 Sample size consideration for effectiveness testing

This pilot RCT is not designed or powered to evaluate the effectiveness of the intervention. However, the study data will be used to obtain an estimate of the standard deviation of the primary outcomes, in view of future sample size calculations for the full study. According to Whitehead [44] recommendation (based on the non-central t-distribution), a sample size of 20 participants in each study arm will warrant us an accurate estimate of the standard deviation of the outcome measure to detect a small effect size (0.2) in a full study that will include a minimum sample size per study arm of n=412.

For this RCT pilot study we had planned to recruit and randomize a total 50 participants.
Assuming an attrition rate of 20%, a sample of 20 participants per study arm will be assessed at T2. This sample size will allow us at least 80% of power to detect a minimum Cohen effect size of 0.9 (large) at alpha 0.05 (2 tailed test). According to the results in phase 1 for the GAD-7 outcome, an effect of 0.9 will represent a mean difference of 2.9 points between the study arms.

Using the two time-points (T1 and T2) of each outcome (when available), we will improve the power (if no interaction between the study arm and time). Under the same conditions described above the power will increase by 10% (assuming a Pearson's correlation of 0.6), and by 15% (Pearson's correlation of 0.40). An increase of 10% or 15% in the power, correspond respectively to a detectable effect size of 0.8 or 0.75.

3. Trial Management:

The study co-ordinator will schedule monthly meetings with the principal and co-investigators to keep track of recruitment and data collection. Referrals and contact with the mental health nurse will also be tracked in a separate log by the study co-ordinator. The statistician will monitor all data collection and logs for quality. Specific contribution of investigators is found in Section 6.

4. Estimated timeline

Details of the study timeline with a breakdown of planning, data collection and reporting are outlined in Figure 2.

5. Ethical Issues

In accordance with Canadian guidelines, [32, 33] study protocols, consent and confidentiality procedures will be submitted to institutional REBs. In these documents, we will clearly address the way in which we will handle privacy and confidentiality, involvement and over-participation, as well as the emergence of potential risks during data collection. More specifically, discussion of symptoms of depression and anxiety could be a sensitive issue for some participants [45]. For this reason, to minimize potential harm, we aim to:

1. Provide resources to those who score on the depression or anxiety scales during the screening. (See Section 2.3 & Appendix 5)
2. Offer referrals for severe symptoms (see section 2.6 & section 2.6.1).
3. Steps will be taken to maximize confidentiality within the norms of patient care by providing participants with an id number, ensuring recruitment and consent is done in a separate/private room and coach telephone calls conducted at a convenient time for the participant in order for them to provide information about their symptoms or answer questions if any. Any participant identifying information will not be included in databases for analysis. If a participant withdraws, any information collected until the point of withdrawal may still be used to help inform the design and content of the intervention. The identity of all participants will be protected at all times during and after the project completion.

6. Team members

Dr. Hannah Schwartz, **MDCM** – *Principal Investigator*

Dr. Hannah Schwartz is principal investigator and a psychiatrist specializing in Perinatal Mental Health. She will be responsible for the scientific conduct of the study, the PMH aspects of the study, the process of screening and providing referrals as described in section 2.2.2 and 2.6.

Dr. Jane McCusker, MD Dr.PH – *Co-Principal Investigator*

Dr.Jane McCusker is an epidemiologist and principal scientist at the Research Centre. She will be responsible for the quantitative methodology for the study.

Phyllis Zelkowitz, Ed.D, *Co-Investigator*

Phyllis Zelkowitz is a co-investigator. She is the Director of Research at the Institute for Community & Family Psychiatry (Jewish General Hospital). She will provide expertise in PMH research and in the clinical and research aspects of the study.

Dr. Santokh Singh, MDCM, *Co-Investigator*

Dr. Santokh Singh would provide clinical consulting on PMH aspects of the study. He will be assisting in psychiatric assessments as required.

Dr. Deborah Da Costa, *Co-Investigator*
Dr. Da Costa, a clinical psychologist is an associate professor at McGill University, and scientist at the RI-MUHC. Her team has developed the web-based psychoeducation intervention. She will provide expertise in the evaluation of the WBI.

7. Significance of the study

This trial represents a first step to implement a sustainable intervention for PMH problems in order to better serve women's PMH needs and preferences for support. This second phase will help inform the current gap in low cost web-based interventions for PMH.

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9. Figures and Tables - Figure. 1 Study Design and Planned flow of Recruitment

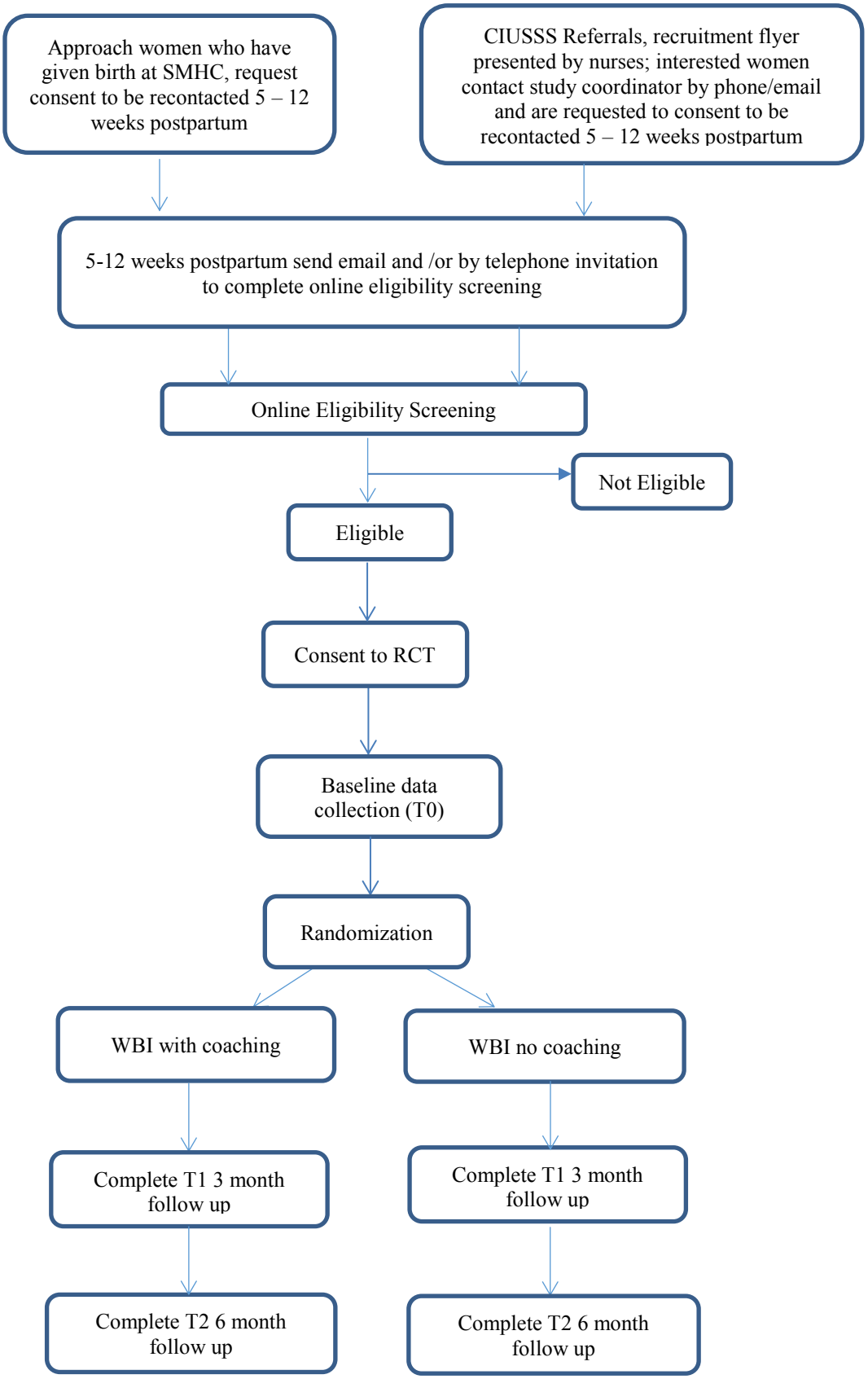

Figure 2. Study Timeline

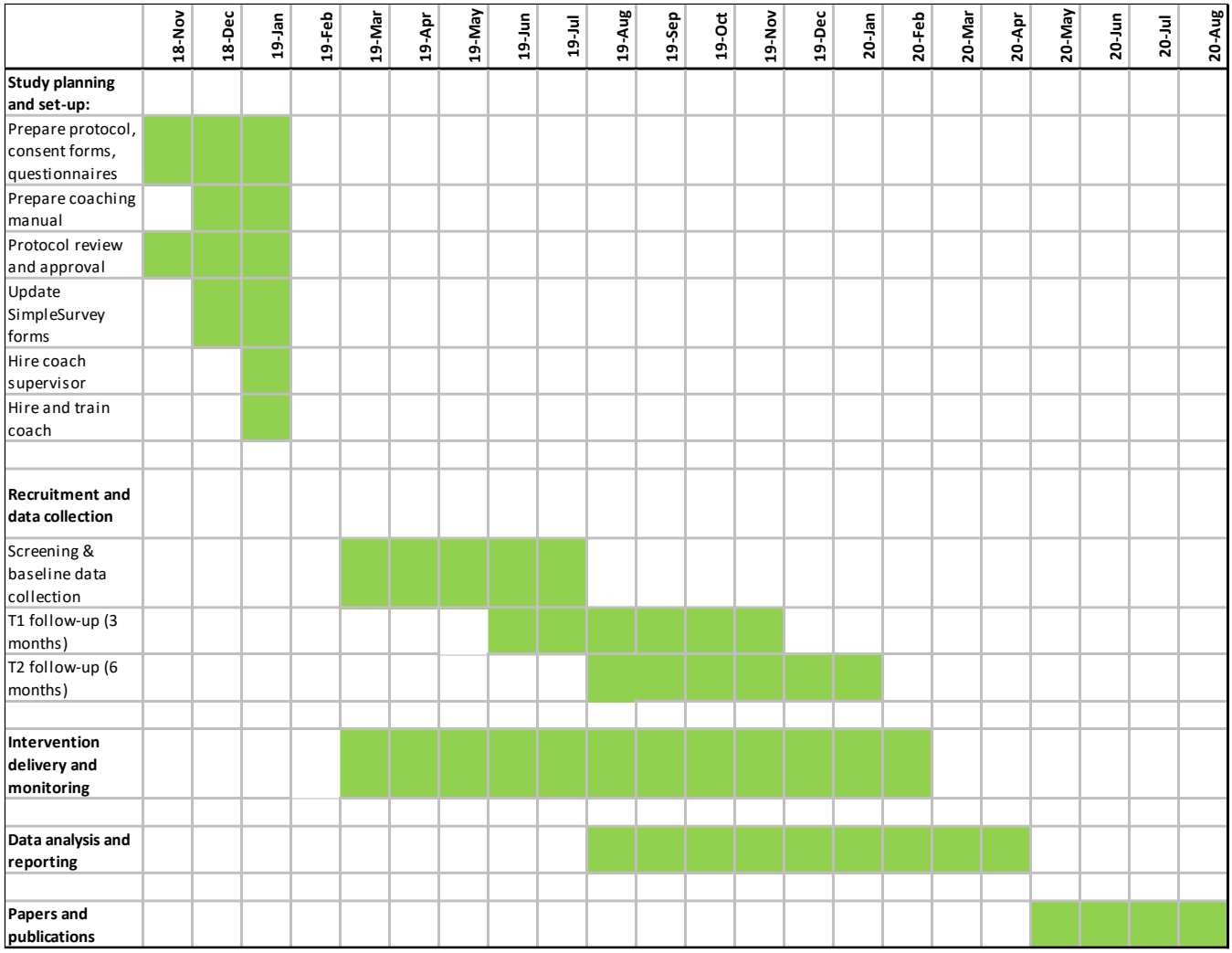

Figure 3: Design of Intervention

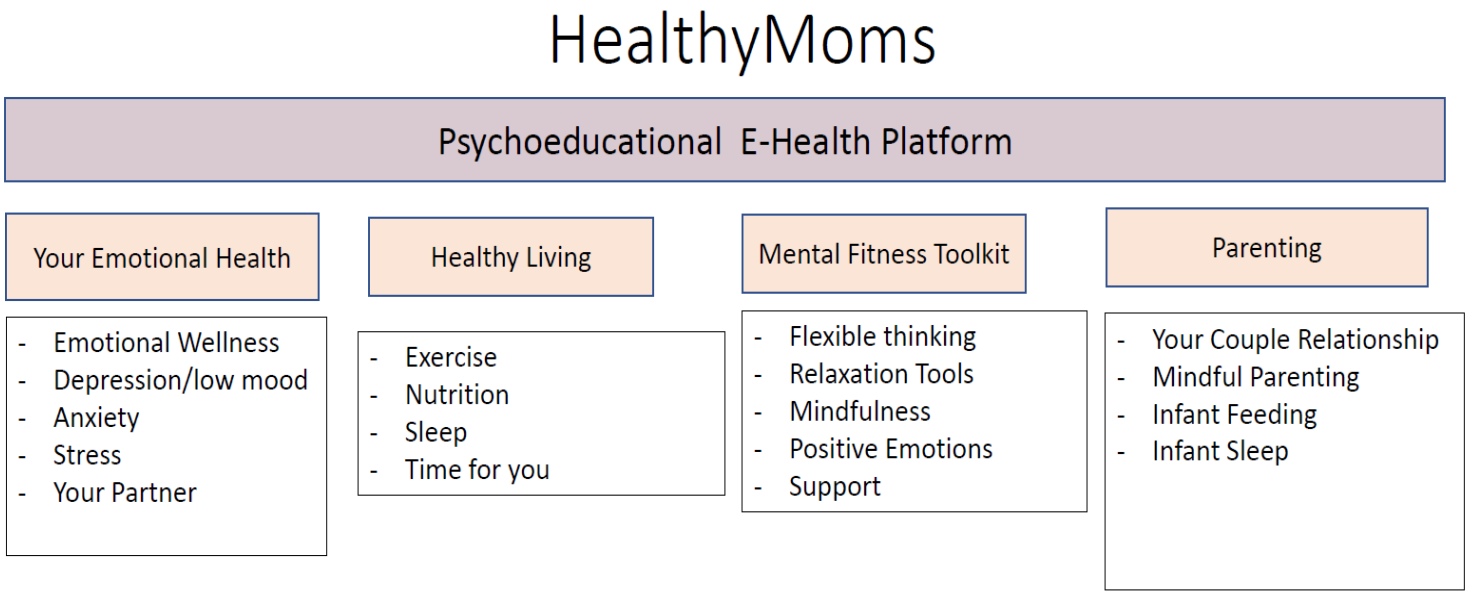

Table 1. Study Measures and Data Collection schedule

Forms & Measures	Recruitment	Baseline (T0)	3 Months Follow up (T1)	6 Months Follow up (T2)
Participant Recontact Form	I/C			
Online Eligibility Checklist for Screening	I/C			
Consent Form to RCT		I/C		
Baseline Questionnaire		I/C		
EPDS		I/C	I/C	I/C
GAD-7		I/C	I/C	I/C
BIMF		I/C	I/C	I/C
PARSS		I/C	I/C	I/C
CSQ				I/C
Use of mental health resources & barriers		I/C		I/C
Online Survey for usability and acceptability			I/C	
Coach logs & records Coach Exit Interview				I
Acceptability of coaching questions				I

I = Intervention Group; C= Control Group