

This is a repository copy of *Virtual Psychiatric Care for Perinatal Depression (Virtual-PND):A Pilot Randomized Controlled Trial*.

White Rose Research Online URL for this paper:

<https://eprints.whiterose.ac.uk/id/eprint/170365/>

Version: Published Version

---

**Article:**

Dalfen, Ariel, Wasserman, Lori, Benipal, Pardeep Kaur et al. (6 more authors) (2021) Virtual Psychiatric Care for Perinatal Depression (Virtual-PND):A Pilot Randomized Controlled Trial. *Journal of Affective Disorders Reports*. 100085. ISSN: 2666-9153

<https://doi.org/10.1016/j.jadr.2021.100085>

---

**Reuse**

This article is distributed under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs (CC BY-NC-ND) licence. This licence only allows you to download this work and share it with others as long as you credit the authors, but you can't change the article in any way or use it commercially. More information and the full terms of the licence here: <https://creativecommons.org/licenses/>

**Takedown**

If you consider content in White Rose Research Online to be in breach of UK law, please notify us by emailing [eprints@whiterose.ac.uk](mailto:eprints@whiterose.ac.uk) including the URL of the record and the reason for the withdrawal request.

## Journal Pre-proof

### Virtual Psychiatric Care for Perinatal Depression (Virtual-PND): A Pilot Randomized Controlled Trial

Ariel Dalfen , Lori Wasserman , Pardeep Kaur Benipal ,  
Andrea Lawson , Beverly Young , Claire de Oliveira ,  
Jennifer Hensel , Cindy Lee Dennis , Simone N. Vigod

PII: S2666-9153(21)00012-3  
DOI: <https://doi.org/10.1016/j.jadr.2021.100085>  
Reference: JADR 100085



To appear in: *Journal of Affective Disorders Reports*

Received date: 6 December 2020  
Revised date: 2 January 2021  
Accepted date: 15 January 2021

Please cite this article as: Ariel Dalfen , Lori Wasserman , Pardeep Kaur Benipal , Andrea Lawson , Beverly Young , Claire de Oliveira , Jennifer Hensel , Cindy Lee Dennis , Simone N. Vigod , Virtual Psychiatric Care for Perinatal Depression (Virtual-PND): A Pilot Randomized Controlled Trial, *Journal of Affective Disorders Reports* (2021), doi: <https://doi.org/10.1016/j.jadr.2021.100085>

This is a PDF file of an article that has undergone enhancements after acceptance, such as the addition of a cover page and metadata, and formatting for readability, but it is not yet the definitive version of record. This version will undergo additional copyediting, typesetting and review before it is published in its final form, but we are providing this version to give early visibility of the article. Please note that, during the production process, errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

© 2021 Published by Elsevier B.V.  
This is an open access article under the CC BY-NC-ND license  
(<http://creativecommons.org/licenses/by-nc-nd/4.0/>)

**Highlights**

- Novel protocol for home-based psychiatrist video-visits for perinatal depression.
- Positive experiences among users, including comfort with communication and convenience.
- Depressive symptom reduction in video-visit protocol similar to in-person only condition.

**Title:** Virtual Psychiatric Care for Perinatal Depression (Virtual-PND): A Pilot Randomized Controlled Trial

**Short Title:** Virtual-PND Study

**Authors:** Ariel Dalfen<sup>1,2</sup>, Lori Wasserman<sup>2,3</sup>, Pardeep Kaur Benipal<sup>3</sup>, Andrea Lawson<sup>3</sup>, Beverly Young<sup>1,2</sup>, Claire de Oliveira<sup>2,4</sup>, Jennifer Hensel<sup>2,3</sup>, Cindy Lee Dennis<sup>2,5</sup>, and Simone N. Vigod<sup>2,3</sup>

<sup>1</sup>Sinai Health System

<sup>2</sup>University of Toronto

<sup>3</sup>Women's College Hospital

<sup>4</sup>Centre for Addiction and Mental Health

<sup>5</sup>St. Michael's Hospital

**Correspondence to:**

Simone Vigod, MD, MSc, FRCPC

76 Grenville Street, Toronto, ON, M5S 1B2

416-323-6400

simone.vigod@wchospital.ca

**ABSTRACT (250)**

**Objectives:** Barriers to in-person mental health care are common in pregnant and postpartum women with depression. We assessed the feasibility of a trial protocol for evaluating the use of secure, in-home synchronous virtual psychiatric care.

**Methods:** In this pilot randomized controlled trial in Toronto, Canada, women aged  $\geq 18$  years, pregnant or 0-12 months postpartum, with Edinburgh Postnatal Depression Scale (EPDS) scores  $>12$ , were randomized 1:1 to in-person visits only, or to an intervention condition where they were offered the option of video-visits for some or all of their follow-up care. We assessed trial protocol feasibility, and secondarily EPDS score at 12 weeks post-randomization.

**Results:** 63 women were randomized (33 intervention, 30 control) of which 87.9% ( $n=29$ ) in the intervention group and 66.7% ( $n=20$ ) in control group completed the 12-week follow-up questionnaire. About 48.5% ( $n=16$ ) of intervention group participants used video-visits at least once, with high acceptability for participants and providers across a number of domains, and no adverse events. EPDS mean scores decreased from 16.6(SD 5.06) to 11.6(SD 4.77) and 16.9(SD 3.15) to 12.4(SD 3.96) for intervention and control groups, respectively (adjusted mean difference -0.64, 95%CI -2.95 to 1.67).

**Conclusion:** It was feasible to recruit for a protocol evaluating psychiatrist video-visits for perinatal depression. Video-visits were acceptable to users and the psychiatrists providing their healthcare. A future non-inferiority efficacy trial can assess treatment outcome moderators to explore variability in effectiveness by illness severity and other factors, and cost-effectiveness of various types of video-visit strategies for psychiatric care in this population.

**Keywords:** pregnancy, postpartum, depression, virtual care

Depression affects about 13% of women during pregnancy and postpartum (Vigod et al 2016; Stewart and Vigod, 2016). Untreated perinatal depression has been linked to problems with fetal development, parent-infant attachment, and child emotional and behavioural development (Stein et al. 2014) and can lead to chronic maternal depression, a leading cause of disability worldwide (Whiteford et al., 2013). Psychological therapies can successfully treat depression of mild and moderate severity and medications such as antidepressants are effective for more severe illness (Stewart and Vigod, 2016; Vigod et al., 2016), only 20% of affected pregnant and postpartum women access the care needed for remission (Byatt et al., 2015).

Individual and system-level barriers may contribute to the low treatment rates. Some women report stigma, shame and discomfort associated with mental health service use itself (Dennis and Chung-Lee, 2006). In pregnancy, barriers such as fatigue and work conflicts (particularly right before parental-leave) limit treatment uptake (Dennis and Chung-Lee, 2006). In the early postpartum - the highest risk period for mental illness perinatally - it can be physically difficult to attend appointments in-person. For example, women who have had caesarean sections cannot drive or lift objects such as infant car seats for 4-6 weeks post-operatively (Sedgley et al., 2012). Unpredictable infant schedules are also problematic (Dennis and Chung-Lee, 2006). Some women lack the resources needed to arrange travel or childcare for children in their care while they are attending appointments (Dennis and Chung-Lee, 2006). This may be especially challenging for low-income women and new immigrants, whose treatment rates are very low despite a high burden of illness (Sedgley et al., 2012).

Video-visits are an attractive solution to some of the aforementioned barriers. A systematic review (7 studies) showed that virtual therapy for postpartum depression delivered by allied health professionals via video-visits was as effective as in-person care (Ashford et al.,

2016). However, there is limited research about the use of video-visits in women with more severe symptoms that require physician-based diagnosis and treatment (Stewart and Vigod, 2016; Vigod et al., 2016). Especially prior to the rapid shift to virtual care that occurred during the containment efforts brought in during the global COVID-19 pandemic late in the year 2019 and early in the year 2020, video-visits with physicians were mainly applied to increase care in rural and remote regions. Therein, the patient would still attend an in-person appointment (usually at a primary care provider's office) to receive consultation from a specialist remotely. While this approach addresses the lack of regional specialist availability, it does not necessarily help women who struggle to attend in-person appointments due to unpredictable infant schedules, childcare challenges, inability to take time off work, or travel barriers.

New means of securely providing virtual care in any setting, such as mobile personal device video-conferencing, are emerging (Bashshur et al., 2015). Previous research shows that women are receptive to receiving perinatal psychiatrist care remotely and the number of individuals with personal smartphones and/or computers who have the ability to access virtual care is rapidly increasing (Rai et al., 2016). This study aimed to evaluate the feasibility of a trial protocol offering the option of secure, in-home, real time video-visits with a psychiatrist for pregnant and postpartum women with depressive symptomatology, to inform the design of a large-scale clinical trial. We evaluated the practicality of recruitment and retention procedures, and the acceptability of the video-visit option for participants and the psychiatrists providing their care. We also compared depressive symptom scores between those in the video-visit group and an in-person only control condition at 12 weeks post-randomization.

## METHODS

### *Study Design and Setting*

This was a parallel-group pilot randomized controlled trial (RCT) conducted from October 2017 to September 2018 in Ontario, Canada's largest province. Women referred to two specialized perinatal psychiatric clinics in the University of Toronto research hospital system in Toronto, Canada, were randomized 1:1 to in-person visits only (control group), or to an intervention condition where they were offered the option of video-visits for some or all of their follow-up psychiatric care (video-visit group). The primary trial endpoint for participants was 12 weeks post-randomization. Provider perspectives from the nine psychiatrists who provided psychiatric care to the patients randomized to the video-visit group were collected after participant data collection was complete. Based on prior research at the participating sites, it was estimated that a 12 month recruitment period would be sufficient to ensure the minimum of 20 participants per arm that allows for sufficient variability in assessing acceptability of an intervention and feasibility of trial procedures (Hertzog, 2008).

### *Participants*

Potential participants were approached for the study by clinical staff who conduct brief telephone assessments to triage all new clinic referrals. Interested women were directed to research personnel for explanation of the study, screening and consent. Women were considered for inclusion if they (1) were aged 18 years and older, (2) were pregnant or the primary caregiver of a baby aged up to 1 year, (3) had a score of  $> 12$  on the Edinburgh Postnatal Depressive Scale (EPDS)(Cox, 1987), (4) had internet access in a suitably private space and a device (i.e., mobile phone, tablet, personal computer) with video-visit capacity (including web camera and speakers),

and (5) were able to complete study measures online. Initial exclusion criteria were alcohol or substance use disorder in the previous 12 months, active suicidal ideation, mania or psychosis.

All consenting participants who met the initial selection criteria were assessed in-person by the clinic psychiatrist assigned to their case. As per standard care, this psychiatrist conducted an initial psychiatric assessment, provided treatment recommendations and developed a care plan in collaboration with the patient. Participants for whom the psychiatrist recommended follow-up care, and for whom the psychiatrist felt that follow-up care could be safely delivered via video, were eligible to be enrolled in the trial. The latter decision was left to the psychiatrists because of concerns they raised in the development of the protocol about whether the severity level of the participant might make them feel it would be unsafe to offer virtual care for some women.

### ***Study procedures***

Following informed consent procedures, baseline socio-demographic, obstetrical and psychiatric history data were collected via online participant-report questionnaires using an institutionally-approved secure electronic data capture system where participants were sent a personalized link to enter their responses. In addition, highly trained research personnel administered the *Mini Neuropsychiatric Interview (MINI)* over the telephone to assess current and lifetime psychiatric diagnoses (Sheehan, 1998). Participants were then allocated to study groups using a computer-generated randomized allocation sequence for 1:1 randomization, stratified by study site, with varying block size. Neither blinding of participants nor psychiatrists was possible due to the nature of the intervention, but neither were informed explicitly of the study hypotheses. Research personnel were not blinded to group allocation as they provided technological support to participants and psychiatrists, but all follow-up data were submitted online by the participant.

### ***Intervention***

Participants were eligible for follow-up psychiatric care from the psychiatrist who conducted their initial consultation visit. Individual follow-up care is primarily provided by psychiatrists in the clinics, including all prescribing. However, most evidence-based psychotherapy for depression in the participating clinics is delivered by highly trained masters-prepared social work psychotherapists; virtual psychotherapy delivered by these providers has been evaluated separately (Yang et al., 2019). Participants in the control group received only the option of in-person psychiatric follow-up clinic visits. Participants in the intervention group also had the option for some or all of their follow-up visits to occur by secure videoconferencing from their home or another secure location of their choosing. Whether a visit was to be by video or in-person was decided collaboratively by the participant and treating psychiatrist on a visit by visit basis. The protocol was designed in this manner due to psychiatrist concerns about their ability to deliver safe and effective care to participants with a mandated video-visit only protocol, given the severity and complexity of the population. All follow-up visits (video and in-person) were pre-scheduled, with frequency as per standard clinical care.

Video-visits were conducted using a secure platform hosted by the Ontario Telemedicine Network (OTN), the government-funded agency that provides video-visit services to patients across Ontario and allows for physician reimbursement. Connections to the OTN network (from both psychiatrists and participants) were made via a secure socket layer (SSL) connection. All traffic was AES 128 bit encrypted, a standard adapted by all major healthcare organizations to protect patient privacy. Women used their own devices (i.e. mobile devices, laptop or personal computers) and providers accessed the OTN system from their secure institutional desktops. Video-visits were conducted using the OTN tool, *SendInvite*, a secure audiovisual portal

compatible with PC and iOS operating systems. At the time of, or just prior to, the scheduled video-visit, the psychiatrist sent an electronic invitation from *SendInvite* directly to the participant's email address. This email contained a secure, unique link to the video portal. At the designated appointment time, the participant opened the secure link from their invitation email and the visit was initiated. Visits were conducted in real time and users could share their computer screens for educational material or visual models. No data from the video visits were recorded or archived on a server in any way, as per Ontario privacy regulations.

### **Outcomes**

The primary outcome was the feasibility of the trial protocol assessed by recruitment rates, video-visit acceptability, and the follow-up rate for outcome data collection at 12 weeks post-randomization. Acceptability for participants and psychiatrists was measured using online questionnaires modified from prior virtual care acceptability studies that comprised both 5-point Likert-type scale responses and open-ended questions (Yang et al., 2019). The participant acceptability questionnaire was completed by those in the intervention group at 12 weeks post-randomization; psychiatrist questionnaires were distributed after all participants reached the 12-week endpoint.

Secondary outcomes were participant-reported clinical outcomes at 12 weeks post-randomization, the length of active treatment recommended by the Canadian Network for Mood and Anxiety Treatments (CANMAT) guidelines for major depressive disorder (Kennedy, 2016). Participants completed the Edinburgh Postnatal Depressive Scale (EPDS), a self-report depression measure validated in perinatal populations (Cox, 1987), and the State-Trait Anxiety Inventory (STAI), a self-report anxiety screening measure that has shown good discriminate validity in perinatal populations (Spielberger, 1983).

### *Statistical Analysis*

We described recruitment and retention rates, and tabulated Likert scale responses from the participant and physician acceptability questionnaires. Comments made by participants and providers on the open-ended part of the acceptability questionnaires were collated. Follow-up mean scores on the EPDS and STAI were compared between intervention and control groups using analyses of covariance, where baseline score and study site were the covariates in an intention-to-treat analysis, with no imputation for missing data.

The trial was registered at [clinicaltrials.gov](https://clinicaltrials.gov) (NCT03291600). Research ethics approval was received at the recruiting University of Toronto academic health sciences centres: Women's College Hospital (REB#2017-0061-B); Sinai Health System (17-0167-E).

## **RESULTS**

### *Recruitment and Retention*

Over the 12-month study period, 112 women were assessed for eligibility, and 63 women were randomized (33 intervention, 30 control) (Figure 1). Several women were excluded because they did not attend their initial consultation visit with the psychiatrist, but none were excluded due to a psychiatrist's concern about their lack of suitability for video-visits. Participants were on average 33.2 (SD 3.95) years of age with the majority (85.7%) married or cohabitating with a partner (Table 1). Almost one third (28.6%) were born outside of Canada, 22.2% had not completed post-secondary education and 25.4% had a family income of less than \$40,000 CAD per year. Fewer women in the intervention group had been formally diagnosed with depression prior to enrollment (24.2% vs. 46.7%). Similarly, fewer were taking psychotropic medication (12.1% vs. 30.0%). Baseline EPDS scores in both intervention (mean 16.5, SD 4.66) and control

groups (mean 17.3, SD 4.17) were in the moderate to severe range. About 88.6% (n=29/33) of the intervention group and 64.5% (n=20/31) of controls completed the 12-week post-randomization follow-up questionnaire. Four controls withdrew participation after randomization due to their allocation status; the remainder of those who did not complete the 12-week questionnaire were lost to follow-up. Among those who completed at least some follow-up data, clinical outcome questionnaires were incomplete for 5 participants in each group.

### ***Participant outcomes***

No adverse events or serious adverse events were reported over the course of the trial. During the 12-week follow-up period, the median number of follow-up psychiatrist visits was 2 (IQR 1-3) in the intervention group and 1 (IQR 1-2) in the control group (Wilcoxon Rank-Sum Test 625.5,  $p = 0.134$ ). About 66.1% of all follow-up intervention group visits were conducted via video, and 16 participants (48.5%) had at least one video-visit. Among video-visit users, the majority felt comfortable communicating with their healthcare provider via video visits (93.8%) and did not require assistance using the videoconferencing system (87.5%) (Table 2). Almost all felt they received adequate attention from their psychiatrist (93.8%) and found video visits to be an acceptable modality to receive health care services. All participants felt time was saved from travelling to their appointment and all indicated that they would use the video visits again to receive services. Among the 41 participants providing full baseline and outcome EPDS data, scores dropped from 16.6 (SD 5.06) to 11.6 (SD 4.77) in the intervention group and from 16.9 (SD 3.15) to 12.4 (3.96) in control group at 12 weeks post-randomization, respectively (adjusted mean difference -0.64 (-2.95 to 1.67)(Table 3). About 60.0% in the intervention group had EPDS < 12 at 12-weeks post-randomization versus 61.1% of controls. Similarly, no clinically important differences were found between study groups related to STAI-State or STAI-Trait scores.

### ***Psychiatrist Acceptability***

All nine psychiatrists completed the provider follow-up questionnaire (Table 4). Only four psychiatrists felt at ease with video-visits before starting the trial, but eight reported that it was generally easy to learn the video technology and all indicated that it would be at least somewhat easy to conduct video-visits in the future. All felt that the video-visits significantly facilitated their patients' treatment or recovery. In open-ended questions, psychiatrists reported that the greatest benefits of using virtual care in this population were its convenience, especially for those who lived far away and pregnant women who were on bedrest or could not miss work, and its impact on cost for patients (no transportation or childcare costs), which made it "patient-centered". One psychiatrist commented that the video was useful to avoid last-minute rescheduling when a child was sick, and another commented that it provided access to care for women whose psychiatric symptoms were so severe that they were having difficulty leaving their home. While the extensive technological support by the research team was appreciated, problems with audio and inconsistent video were perceived as disruptive to care delivery and repeated technology failures due to problems with connecting led to wasted session time. Psychiatrists also reported difficulty integrating schedules for video-visits with the clinic administrative staff. Four psychiatrists indicated that clinical factors had dissuaded them from providing video-visits on some occasions, due to concerns about being able to accurately assess and effectively treat high-acuity patients. One commented that video was an excellent modality for medication management, but five psychiatrists indicated that video felt more challenging than in-person care for achieving a full therapeutic interaction due to difficulties interpreting non-verbal communication, and concerned about missing subtle interpersonal cues.

## DISCUSSION

To our knowledge, this is the first study to evaluate the feasibility of a video-visit psychiatric care model for the management of perinatal depression. This pilot trial demonstrated the feasibility of recruiting women into a virtual care clinical trial and of operationalizing a video-visit protocol, with very high acceptability of video-visits among women who used them. Most women found the video-visit system easy to use and felt comfortable communicating with their psychiatrist. Several psychiatrists were initially skeptical of the video-visit protocol due to concerns about patient safety, and their ability to deliver high-quality care over video. Yet, no patients were excluded due to psychiatrist concerns about lack of suitability, despite the group as a whole having a relatively high initial clinical symptom load, and provider comfort and confidence grew over time. Clinical outcomes were reassuringly similar between the video-visit option and in-person only groups, and there were no adverse events, which may serve to reassure psychiatrists about the safety of video-visits in this population and make a video-only study arm of a future trial feasible. Overall, the results suggest that proceeding to a larger non-inferiority trial would be feasible, with attention to implementing strategies to improve control group retention, maximize completeness of data collection, and ensure reliable technology for efficiency and effectiveness. In a future trial, a method to account for the possibility of treatment moderation by transition from pregnant to postpartum status during the intervention period will also be important to consider.

There were several key strengths to the pilot study protocol. We were able to recruit about one in every two women assessed for study eligibility, which speaks to the feasibility of further recruitment, in a population known to face substantial competing demands to enrollment in research (Frew et al., 2014). The study sample was ethnically diverse, and about one-quarter

were living in lower-income households, and without a college education. Further, the protocol was very flexible in terms of allowing for patient-provider collaborative decisions about when to use video, which was helpful for recruiting psychiatrist providers at the sites who had safety concerns about virtual care being delivered to women directly in their homes (i.e., as opposed to in another provider's office). Also, because the protocol required at least one in-person visit, there was no opportunity to recruit women who face the most barriers to health service use, such as stigma, shame, lack of access to referring providers or lack of ability to attend in-person appointments at all. In a future trial, including a video-visit only arm may make the study more attractive to women who face these barriers, with data plans and devices made available to women who would otherwise not be able to connect virtually (Gordon et al., 2016). Other key areas for improvement relate to the low follow-up rate in the control group and the incomplete data submitted through the electronic data capture system, reinforcing the need for rigorous attention to operational protocols using the best evidence to minimise attrition in a future study (Bructon et al., 2014).

The high acceptability of video-visits among participants is consistent with previous research in a wide range of clinical settings and samples (Shore, 2013). The clinical symptom results are also consistent with findings of non-inferiority in other populations (Shore, 2013). Only about 50% of women in the intervention group had a video-visit, however. Most participants were living in the local urban catchment area, so did not have long commutes to the study sites, and all had to come in-person at least once for their initial psychiatric assessment, such that this may have been a select population who did not face substantial barriers to in-person care. In this case, since psychiatric follow-up visits were fairly infrequent, it may be that a large proportion of the women simply preferred to come in-person to their appointments. This

aligns with research on psychotherapy video-visits delivered by trained masters of social work therapists where, while women found video-visits convenient, they preferred in-person appointments (Yang et al., 2019). Provider concerns about clinical appropriateness may have also contributed to non-use of video-visits in some cases, which has not been reported previously in virtual treatment trials for depression in pregnancy or postpartum (Loughnan et al., 2019). It is possible that the acuity of participants in this study might have been greater than in prior e-mental health perinatal treatment trials, which are mostly focused on the delivery of evidence-based psychotherapies by non-psychiatrists (Loughnan et al., 2019). In a future trial that recruits women from more remote communities where in-person visits with a psychiatrist are not possible, engaging a woman's local primary care or other community provider such as a public health nurse who could provide in-person follow-up if needed might mitigate such safety concerns.

Provider feedback highlighted key issues requiring attention. Although the women themselves did not seem to mind, psychiatrists found technology difficulties to be quite disruptive to the treatment sessions and also wasteful of time that could be spent seeing other patients. They found the lack of integration with their existing electronic health record to be an inconvenience. Processes to allow integration of video-visit technology with existing provider-facing systems along with seamless booking of video-visits will likely optimize implementation. Some psychiatrists were concerned that video-visits would be inadequate for the treatment of women with severe symptoms. A hybrid model is possible when women are *able* to attend in-person appointments, but that may not be possible for women living in more remote settings or who face other barriers to in-person treatment. Future data on treatment outcome moderators will help providers decide when video-visits are appropriate in their clinical populations. Further,

there is growing evidence video-visits may improve care coordination and provide cost-savings highlighting the importance to include a cost-effectiveness analysis in any future trial (Norman, 2006).

In summary, the results of this pilot study support the feasibility of proceeding to a large-non-inferiority trial to evaluate video-visits in perinatal psychiatric care. Improvements in video-visit technology making point of care use more reliable and more user-friendly are constantly being made. With the ongoing containment efforts related to the global COVID19 pandemic, more and more institutions are focused on virtual care delivery, integrating video-visits directly into their electronic medical record systems, with patients able to also communicate asynchronously with providers and administrative staff organizing clinic schedules. A large, rigorously designed trial to address questions of how well virtual care works, and what works for whom in this population, will be timely and critical to ensuring the provision of high-quality psychiatric care in this complex population.

#### **Author's Statement**

**Contributors:** All authors reviewed, revised, and approved the final version of the manuscript. SV was the principal investigator, obtained funding, designed the study, interpreted the data and drafted the manuscript.

**Role of Funding Source:** This pilot trial was funded by the University of Toronto Department of Psychiatry Excellence Funds. The funding agency had no role in study design; in the collection, analysis and interpretation of data; in the writing of the report; or in the decision to submit the article for publication.

### **Conflict of Interests**

Dr. Vigod reports royalties from UpToDate Inc, for authorship of materials on depression and pregnancy. No other authors have financial interests to declare.

**Acknowledgements:** We thank Neesha Hussain-Shamsy and Emily Vonderporten for their roles in the development and implementation of the pilot RCT protocol. This study was funded by a University of Toronto Department of Psychiatry Excellence Fund Award (PIs: Dalfen and Wasserman, Mentor: Vigod).

### **REFERENCES**

- Ashford, M.T., Olander, E.K., Ayers, S., 2016. Computer- or web-based interventions for perinatal mental health: A systematic review. *J Affect Disord* 197, 134-146.
- Bashshur, R.L., Shannon, G.W., Bashshur, N., Yellowlees, P.M., 2015. The Empirical Evidence for Telemedicine Interventions in Mental Disorders. *Telemedicine journal and e-health : the official journal of the American Telemedicine Association*.
- Brueton, V.C., Tierney, J.F., Stenning, S., Meredith, S., Harding, S., Nazareth, I., Rait, G., 2014. Strategies to improve retention in randomised trials: a Cochrane systematic review and meta-analysis. *BMJ open* 4, e003821.
- Byatt, N., Xiao, R.S., Dinh, K.H., Waring, M.E., 2015. Mental health care use in relation to depressive symptoms among pregnant women in the USA. *Arch Womens Ment Health*.
- Cox, J., Holden, J., & Sagovsky, R., 1987. Detection of Postnatal Depression: Development of the 10-item Edinburgh Postnatal Depression Scale. *British Journal of Psychiatry* 150(6), 782-786.
- Dennis, C.L., Chung-Lee, L., 2006. Postpartum depression help-seeking barriers and maternal treatment preferences: a qualitative systematic review. *Birth* 33, 323-331.
- Frew, P.M., Saint-Victor, D.S., Isaacs, M.B., Kim, S., Swamy, G.K., Sheffield, J.S., Edwards, K.M., Villafana, T., Kamagate, O., Ault, K., 2014. Recruitment and retention of pregnant women into clinical research trials: an overview of challenges, facilitators, and best practices. *Clin Infect Dis* 59 Suppl 7, S400-407.

Gordon, M., Henderson, R., Holmes, J.H., Wolters, M.K., Bennett, I.M., Group, S., 2016. Participatory design of ehealth solutions for women from vulnerable populations with perinatal depression. *J Am Med Inform Assoc* 23, 105-109.

Hertzog, M.A., 2008. Considerations in determining sample size for pilot studies. *Research in nursing & health* 31, 180-191.

Kennedy, S.H., Lam, R. W., McIntyre, R. S., Tourjman, S. V., Bhat, V., Blier, P., Hasnain, M., Jollant, F., Levitt, A. J., MacQueen, G. M., McInerney, S. J., McIntosh, D., Milev, R. V., Müller, D. J., Parikh, S. V., Pearson, N. L., Ravindran, A. V., Uher, R., & CANMAT Depression Work Group, 2016. Canadian Network for Mood and Anxiety Treatments (CANMAT) 2016 Clinical Guidelines for the Management of Adults with Major Depressive Disorder: Section 3. Pharmacological Treatments. *Canadian journal of psychiatry. Revue canadienne de psychiatrie*, 61(9), 540-560.

Loughnan, S.A., Joubert, A.E., Grierson, A., Andrews, G., Newby, J.M., 2019. Internet-delivered psychological interventions for clinical anxiety and depression in perinatal women: a systematic review and meta-analysis. *Arch Womens Ment Health* 22, 737-750.

Norman, S., 2006. The use of telemedicine in psychiatry. *Journal of Psychiatric and Mental Health Nursing* 13, 771-777.

Rai, M., Vigod, S.N., Hensel, J.M., 2016. Barriers to Office-Based Mental Health Care and Interest in E-Communication With Providers: A Survey Study. *JMIR mental health* 3, e35.

Sedgley, J., Rickard, K., Morris, J., 2012. A survey of women and health providers about information regarding the timing of driving a car after experiencing a caesarean section. *The Australian & New Zealand journal of obstetrics & gynaecology* 52, 361-365.

Sheehan, D.V., Lecrubier, Y., Sheehan, K. H., Amorim, P., Janavs, J., Weiller, E., Hergueta, T., Baker, R., & Dunbar, G. C., 1998. The Mini-International Neuropsychiatric Interview (M.I.N.I.): The development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10. *The Journal of Clinical Psychiatry* 59(Suppl 20), 22-23.

Shore, J.H., 2013. Telepsychiatry: Videoconferencing in the Delivery of Psychiatric Care. *The American Journal of Psychiatry* 170, 256-262.

Spielberger, C.D., Gorsuch, R. L., Lushene, R., Vagg, P. R., & Jacobs, G. A., 1983. *Manual for the State-Trait Anxiety Inventory*.

Stein A, Pearson R, Goodman S, Rapa E, Rahman A, McCallum M, Howard L and Pariante CM. Effects of perinatal mental disorders on the fetus and child. 2014 *Lancet* 384(9956):1800-19.

Stewart, D.E., Vigod, S., 2016. Postpartum Depression. *The New England journal of medicine* 375, 2177-2186.

Vigod, S.N., Wilson, C.A., Howard, L.M., 2016. Depression in pregnancy. *BMJ* 352, i1547.

Whiteford, H.A., Degenhardt, L., Rehm, J., Baxter, A.J., Ferrari, A.J., Erskine, H.E., Charlson, F.J., Norman, R.E., Flaxman, A.D., Johns, N., Burstein, R., Murray, C.J., Vos, T., 2013. Global burden of disease attributable to mental and substance use disorders: findings from the Global Burden of Disease Study 2010. *Lancet* 382, 1575-1586.

Yang, R., Vigod, S.N., Hensel, J.M., 2019. Optional Web-Based Videoconferencing Added to Office-Based Care for Women Receiving Psychotherapy During the Postpartum Period: Pilot Randomized Controlled Trial. *Journal of medical Internet research* 21, e13172.

**Table 1**

Baseline characteristics of 63 trial participants (presented as n (%), unless otherwise stated)

		Intervention (n = 33)	Control (n = 30)	Countries of Origin: Sri Lanka, Peru, USA [2], France, Ukraine [2], Mexico
Socio-Demographics	Age in Years* ( <i>Mean, SD</i> )	33.3 (2.82)	33.2 (4.82)	
	Married or Cohabiting/Common-law	27 (81.8)	27 (87.1)	
	Completed a University Degree	27 (81.8)	22 (73.3)	
	Annual Household Income > \$40,000	24 (72.7)	23 (76.7)	
	Born Outside of Canada*	10 (30.3)	8 (26.7)	
Medical & Psychiatric History	Pregnant	14 (42.4)	15 (50.0)	
	Number of Pregnancies – Including Current ( <i>Median, IQR</i> )	2 (1-3)	2 (1-3)	
	Lifetime Diagnosis of Depression	8 (24.2)	14 (46.7)	
	Lifetime Psychiatric Hospitalization	1 (3.0)	2 (6.7)	
	Any Current Alcohol Use	11 (33.3)	9 (30.0)	
	Any Current Smoking	2 (6.1)	1 (3.3)	
	Any Current Medication for Mental Health Concerns	4 (12.1)	9 (30.0)	
Maternal Clinical Symptoms	Edinburgh Postnatal Depression Scale (EPDS) <i>Mean (SD)</i>	16.5 (4.66)	17.3 (4.17)	
	State-Trait Anxiety Inventory-State (STAI-S) <i>Mean (SD)</i>	51.4 (12.2)	52.5 (11.9)	
	State-Trait Anxiety Inventory-Trait (STAI-T) <i>Mean (SD)</i>	53.5 (10.2)	55.8 (11.2)	

ico, China, Russia, Hong Kong, El Salvador, India, Bangladesh, UK, France, Venezuela, Lebanon, Eritrea **Languages Spoken:** Spanish, French, Mandarin, Amharic, Cantonese, Portuguese, Italian, Punjabi, Tigrinya, Russian

\*8 women in the intervention group and 5 women in the control group chose not to report their exact age

**Table 2**

Acceptability questionnaire completed by 16 women who used video visits during the study

Questionnaire Item	% Agree or Strongly Agree
Using the video technology, I can easily talk to my healthcare provider.	14 (87.5)
Using the video technology, I can clearly hear my healthcare provider.	14 (87.5)
My healthcare provider is able to understand my healthcare condition.	15 (93.8)
I can see my health care provider as if we meet in person.	12 (75.0)
I do not need assistance while using the system.	14 (87.5)
I feel comfortable communicating with my healthcare provider.	15 (93.8)
I think the healthcare provided by video visits is consistent.	12 (75.0)
I obtain better access to health care services by use of video visits.	11 (68.8)
Video visits save me time travelling to a hospital or specialist clinic.	16 (100)
I receive adequate attention from my healthcare provider.	15 (93.8)
Video visits provide for my health care needs.	14 (87.5)
I find video visits an acceptable way to receive health care services.	15 (93.8)
I would use video visits to receive health care again. <sup>1</sup>	15 (100)
Overall, I am satisfied with the quality of service being provided via the video visits. <sup>1</sup>	13 (86.7)

<sup>1</sup>not all participants answered these questions ( $n=15$ )

**Table 3.** Clinical depressive and anxiety symptom outcome data for the 29 intervention group participants and 20 control group participants who provided clinical outcome data.

	<b>Baseline Mean (SD)</b>	<b>Follow-up Mean (SD)</b>	<b>Adjusted mean difference* (95% CI)</b>
<b>EPDS</b>			
Intervention (n=24)	16.6 (5.06)	11.6 (4.77)	-0.64 (-2.95 to 1.67)
Control (n=17)	16.9 (3.15)	12.4 (3.96)	
<b>STAI-State</b>			
Intervention (n=27)	52.1 (11.9)	47.0 (13.6)	2.48 (-3.96 to 8.92)
Control (n=18)	53.4 (12.3)	45.4 (10.8)	
<b>STAI-Trait</b>			
Intervention (n=24)	58.3 (11.2)	50.9 (11.1)	1.97 (-3.56 to 7.50)
Control (n=15)	58.6 (8.81)	52.2 (8.59)	

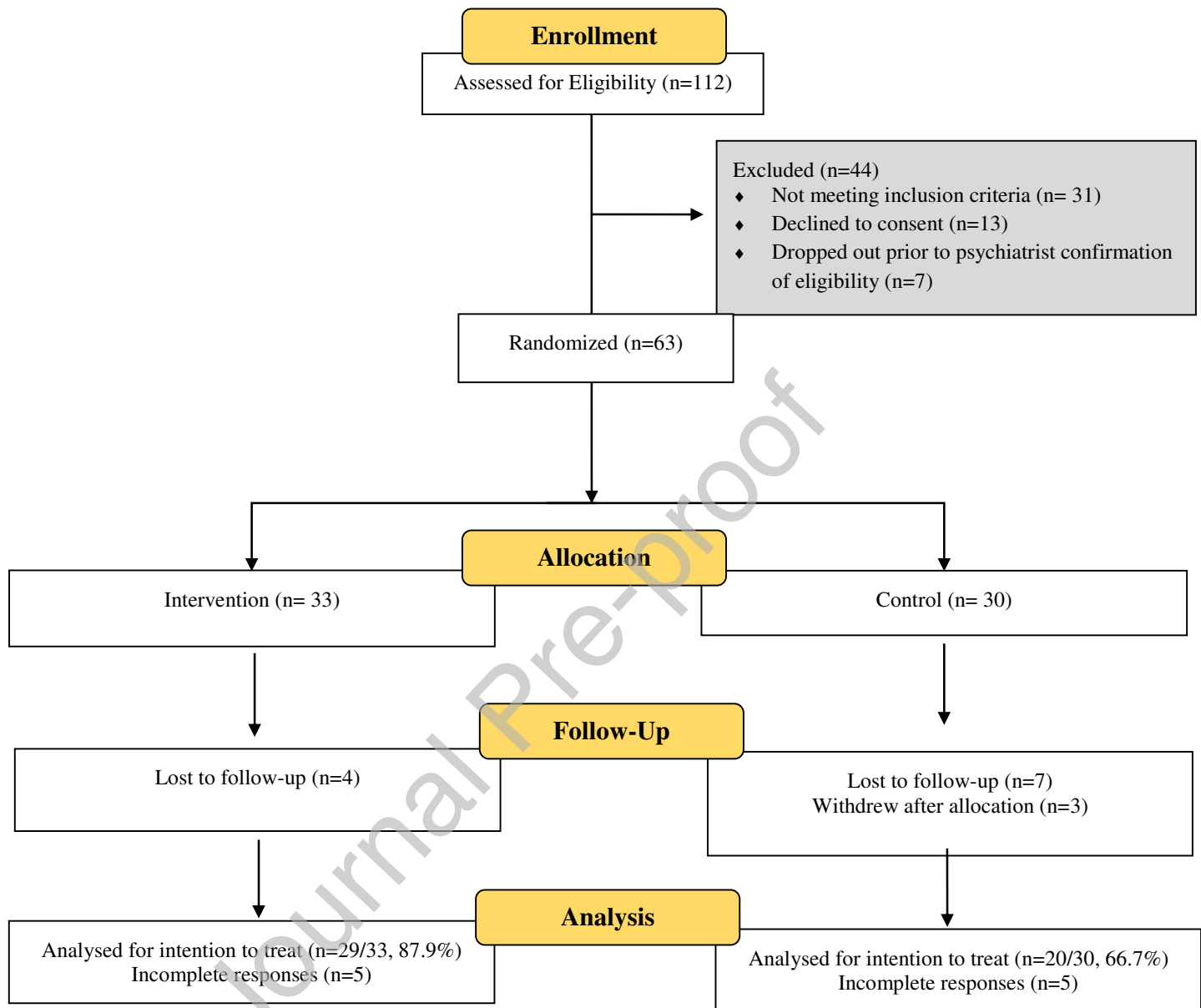
\*Mean difference adjusted for baseline clinical scale score, and study site.

**Table 4**

Program evaluation questionnaire completed by 9 psychiatrists who provided video visits during the study

Questionnaire Item	Mean (SD)
How were you feeling about the use of virtual care in mental health before you started?	4.13 (1.12)
How were you feeling about the use of virtual visits in your own clinical practice before you started?	3.22 (1.78)
How were you feeling about the set-up of the virtual care technology for use in your practice?	3.33 (1.11)
How was your experience learning how to use the virtual care technology?	3.66 (1.00)
Overall, how was your experience delivering care virtually?	4.22 (1.09)
How do you think your patients felt about the use of virtual visits?	4.11 (0.78)
What impact do you think virtual care services had in facilitating your patients' treatment/recovery?	3.11 (1.05)
Do you feel that virtual visits might be an option for care delivery for this patient population?	3.66 (1.32)
How are you feeling about the use of virtual care in mental health after participating in this study?	4.22 (0.97)

1 = Very Negative, 2= Somewhat Negative, 3 = Neutral, 4 = Somewhat Positive, 5 = Very Positive



**Figure 1.** Flowchart of participants' progress throughout the phases of the trial