

Task-sharing and telemedicine delivery of psychotherapy to treat perinatal depression: a pragmatic, noninferiority randomized trial

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Supplementary Materials

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Table S1. Comparing fidelity (Q-SUMMIT) scores between provider and modality

Outcome (measure; range)	Mean (95% CI)		t-test
	NSP (n=207)	SP (n=186)	
Treatment specific score (Q-SUMMIT; 0-4)	3.41 (3.32-3.49)	3.24 (3.14-3.34)	2.54*
General skills score (Q-SUMMIT; 0-4)	3.62 (3.56-3.69)	3.50 (3.43-3.58)	2.48*
Total fidelity score (Q-SUMMIT; 0-8)	7.03 (6.90-7.17)	6.74 (6.59-6.90)	2.80**
	TM (n=321)	IP (n=72)	
Treatment specific score (Q-SUMMIT; 0-4)	3.32 (3.24-3.39)	3.38 (3.23-3.52)	0.70
General skills score (Q-SUMMIT; 0-4)	3.57 (3.51-3.62)	3.57 (3.46-3.68)	0.09
Total fidelity score (Q-SUMMIT; 0-8)	6.88 (6.77-7.00)	6.95 (6.72-7.18)	0.49

Note. Confidence Interval (CI), Non-Specialist Provider (NSP), Specialist Provider (SP), Telemedicine (TM), In-Person (IP), Q-SUMMIT (Adapted from Quality of Healthy Activity Program: Q-HAP);

*p<0.05; **p<0.01.

Fidelity scores were significantly higher among NSPs vs. SPs. There were no differences in fidelity scores when comparing modality.

Table S2. Correlation analysis between selected process variables and primary and secondary outcomes

	Depressive Symptoms (EPDS) [‡]	Anxiety Symptoms (GAD-7) [‡]
Provider Preference at Baseline	0.11 ^{***}	0.11 ^{***}
Modality Preference at Baseline	0.02	0.01
Treatment Dosage (Number of Sessions)	-0.10 ^{***}	-0.06
Treatment Completion [¥]	-0.14 ^{***}	-0.09 ^{**}
Fidelity – Treatment Skills Score (Q-SUMMIT)	0.005	-0.01
Fidelity – General Skills Score (Q-SUMMIT)	0.02	0.005
Fidelity – Total Skills Score (Q-SUMMIT)	0.01	-0.006

Note. Edinburgh Postnatal Depression Scale (EPDS), Generalized Anxiety Disorder (GAD-7), Q-SUMMIT (Adapted from Quality of Healthy Activity Program: Q-HAP).

[‡]EPDS and GAD-7 at 3-months post-randomisation.

[¥]Treatment completion is defined as completing a minimum of four sessions over 120-day period.

For participants with multiple fidelity assessments, average scores were calculated and used to test the correlation with the 3-month outcomes.

p<0.01, *p<0.001

Table S3. Baseline characteristics of participants by hub (N=1230), n (%), unless otherwise specified

Variable [Total Respondents]	Overall (n=1230)	Toronto (n=823)	Northshore (n=226)	UNC (n=181)
Age [1226], mean (95% CI)^a	33.27 (33.00-33.55)	34.03 (33.71 -34.35)	31.85 (31.20-32.49)	31.60 (30.81-32.40)
Perinatal Period [1230]				
Pregnant	618 (50.24)	417 (50.67)	108 (47.79)	93 (51.38)
Postpartum	612 (49.76)	406 (49.33)	118 (52.21)	88 (48.62)
Gestational Age [1230]				
Weeks Pregnant	23.72 (23.17-24.27)	23.70 (23.05-24.34)	25.52 (24.28-26.76)	21.74 (20.11-23.38)
Weeks Postpartum	12.77 (12.20-13.34)	13.85 (13.13-14.58)	10.00 (8.95-11.06)	11.48 (10.04-12.91)
Race [1226]^a				
American Indian/Alaska Native	5 (0.41)	4 (0.49)	0 (0)	1 (0.56)
Asian	209 (17.05)	169 (20.53)	29 (12.83)	11 (6.21)
Black/African American	124 (10.11)	68 (8.26)	17 (7.52)	39 (22.03)
Hawaiian/Pacific Islander	4 (0.33)	4 (0.49)	0 (0)	0 (0)
White	614 (50.08)	408 (49.57)	119 (52.65)	87 (49.15)
Multi-race	100 (8.16)	75 (9.11)	13 (5.75)	12 (6.78)
Hispanic (Latino/Latina)	101 (8.24)	39 (4.74)	40 (17.70)	22 (12.43)
Other	35 (2.85)	31 (3.77)	4 (1.77)	0 (0)
Prefer to not answer	34 (2.77)	25 (3.04)	4 (1.77)	5 (2.82)
Born in country of your current residence? [1226]^a	860 (70.15)	537 (65.25)	179 (79.20)	144 (81.36)
Health Benefits Access [948]^b	654 (68.99)	438 (70.30)	150 (72.46)	66 (55.93)
Marital Status [1226]^a				
Married or Stable relationship	1052 (85.81)	724 (87.97)	192 (84.96)	136 (76.84)
Single	94 (7.64)	58 (7.05)	15 (6.64)	21 (11.86)
Dating or Uncommitted relationship	41 (3.34)	20 (2.43)	10 (4.42)	11 (6.21)
Other	21 (1.71)	9 (1.09)	6 (2.65)	6 (3.39)
Prefer to not answer	18 (1.47)	12 (1.46)	3 (1.33)	3 (1.69)
Gender Identity [1173]^b				
Female	1168 (99.57)	794 (99.50)	214 (99.53)	160 (100)
Sexual Orientation [1173]^b				
Straight/Heterosexual	1073 (91.47)	728 (91.23)	195 (90.70)	150 (93.75)
Bisexual	71 (6.05)	47 (5.89)	19 (8.84)	5 (3.13)
Other	7 (0.60)	7 (0.88)	0 (0)	0 (0)
Prefer to not answer	22 (1.88)	16 (2.01)	1 (0.47)	5 (3.13)
Highest Level of Education [1226]^a				
University degree	859 (70.07)	596 (72.42)	163 (72.12)	100 (56.60)
College/Trade School	216 (17.62)	148 (17.98)	34 (15.04)	34 (19.21)
High School or less	141 (11.50)	72 (8.75)	27 (11.95)	42 (23.73)
Prefer to not answer	10 (0.82)	7 (0.85)	2 (0.88)	1 (0.56)
Employment [1226]^a				
Full-time	484 (39.48)	299 (36.33)	107 (47.35)	78 (44.07)
Maternity leave	353 (28.79)	298 (36.21)	42 (18.58)	13 (7.34)
Part-time	111 (9.05)	58 (7.05)	31 (13.72)	22 (12.43)
Not employed	260 (21.21)	155 (18.83)	42 (18.58)	63 (35.59)
Other	18 (1.47)	13 (1.58)	4 (1.77)	1 (0.56)
Annual Income (USD) based on Postal/Zip Code in USD [1138], mean (95% CI)	43165.59 (42236.47-44094.70)	44897.34 (43800.30-45994.38)	44064.98 (41507.75-46622.21)	34989.25 (33310.52-36667.98)
Nulliparous [1226]^a	668 (54.49)	469 (56.99)	125 (55.31)	74 (41.81)
COVID Exposure [1064]^b	31 (2.91)	25 (3.46)	3 (1.35)	3 (2.52)

Self-Reported History of Depression/Anxiety [1226]^a	1051 (85.73)	715 (86.88)	181 (80.09)	155 (87.57)
Related to current Baby	321 (30.54)	222 (31.05)	52 (28.73)	47 (30.32)
Psychotropic medication Use at Baseline [1226]^c	288 (23.49)	199 (24.18)	37 (16.37)	52 (29.38)
Pregnancy conditions during current pregnancy (≥1) [1075]^b	265 (24.65)	158 (21.18)	57 (28.36)	50 (39.06)
Preeclampsia	52 (4.84)	27 (3.62)	8 (3.98)	17 (13.28)
High blood-pressure	127 (11.81)	75 (10.05)	26 (12.94)	26 (20.31)
Gestational diabetes	121 (11.26)	68 (9.12)	26 (12.94)	27 (21.09)
Preterm labor	69 (6.42)	43 (5.76)	13 (6.47)	13 (10.16)
Symptom Scores at Baseline				
Depressive Symptoms (EPDS) Total (0-30), mean (95% CI)	15.77 (15.56- 15.99)	16.12 (15.85- 16.38)	14.51 (14.03-14.99)	15.79 (15.29- 16.29)
Anxiety Symptoms (GAD-7) Total (0-21) mean (95% CI)	11.85 (11.58- 12.12)	12.41 (12.10-12.73)	9.83 (9.14-10.52)	11.81 (11.07-12.55)
Treatment/Provider Preference [1203]^b				
Telemedicine	747 (62.09)	-	-	-
In-Person	190 (15.79)	-	-	-
No Preference	266 (22.11)	-	-	-
Provider Preference Expressed at Baseline [1203]^b				
Specialist Provider	730 (60.68)	-	-	-
Non-Specialist Provider	22 (1.83)	-	-	-
No Preference	451 (37.49)	-	-	-

Note. Edinburgh Postnatal Depression Scale (EPDS); GAD=Generalized Anxiety Disorder (GAD-7); United States Dollar (USD). ^aFour participants did not complete the baseline assessment, ^bThis question was added after the trial commencement (in Spring 2020); ^cThis question is a sub-question of another question.

Table S4. Baseline characteristics of participants by arm (N=1230), n (%), unless otherwise specified

Variable [Total Respondents]	Overall (n=1230)	NSP-TM (n=472)	SP-TM (n=469)	NSP-IP (n=145)	SP-IP (n=144)
Age [1226], mean (95% CI)^a	33.27 (33.00-33.55)	33.08 (32.62-33.54)	33.04 (32.61-33.48)	33.84 (33.06-34.63)	34.10 (33.27-34.92)
Perinatal Period [1230]					
Pregnant	618 (50.24)	236 (50.00)	241 (51.39)	69 (47.59)	72 (50.00)
Postpartum	612 (49.76)	236 (50.00)	228 (48.61)	76 (52.41)	72 (50.00)
Gestational Age [1230]					
Weeks Pregnant	23.72 (23.17-24.27)	24.13 (23.26-25.00)	23.77 (22.90-24.65)	22.62 (20.84-24.39)	23.26 (21.58-24.94)
Weeks Postpartum	12.77 (12.20-13.34)	13.30 (12.38-14.22)	12.93 (11.98-13.88)	11.29 (9.69-12.88)	12.09 (10.44-13.74)
Race [1226]^a					
American Indian/Alaska Native	5 (0.41)	1 (0.21)	3 (0.64)	0 (0)	1 (0.69)
Asian	209 (17.05)	87 (18.47)	73 (15.67)	27(18.62)	22(15.28)
Black/African American	124 (10.11)	40 (8.49)	46 (9.87)	19 (13.10)	19 (13.19)
Hawaiian/Pacific Islander	4 (0.33)	1 (0.21)	1 (0.21)	1 (0.69)	1(0.69)
White	614 (50.08)	242 (51.38)	231 (49.57)	69 (47.59)	72 (50.00)
Multi-race	100 (8.16)	34 (7.22)	45 (9.66)	10 (6.90)	11 (7.64)
Hispanic (Latino/Latina)	101 (8.24)	38 (8.07)	39(8.37)	10 (6.90)	14 (9.72)
Other	35 (2.85)	15 (3.18)	14 (3.00)	4 (2.76)	2 (1.39)
Prefer to not answer	34 (2.77)	13 (2.76)	14 (3.00)	5 (3.45)	2 (1.39)
Born in country of your current residence? [1226]^a	860 (70.15)	330 (70.06)	323 (69.31)	103 ((71.03)	104 (72.22)
Health Benefits Access [948]^b	654 (68.99)	235 (70.15)	231 (68.75)	92 (66.67)	96 (69.06)
Marital Status [1226]^a					
Married or Stable relationship	1052 (85.81)	405 (85.99)	401 (86.05)	123 (84.83)	123 (85.42)
Single	94 (7.67)	36 (7.64)	35 (7.51)	11 (7.59)	12 (8.33)
Dating or Uncommitted relationship	41 (3.34)	14 (2.97)	17 (3.65)	5 (3.45)	5 (3.47)
Other	21 (1.71)	8 (1.70)	6 (1.29)	3 (2.07)	4 (2.78)
Prefer to not answer	18 (1.47)	8 (1.70)	7 (1.50)	3 (2.07)	0 (0)
Gender Identity [1173]^b					
Female	1168 (99.57)	441 (99.10)	440 (99.77)	144 (100)	143 (100)
Sexual Orientation [1173]^b					
Straight/Heterosexual	1073 (91.74)	405 (91.01)	405 (91.84)	126 (87.50)	137 (95.80)
Bisexual	71 (6.05)	27 (6.07)	25 (5.67)	15 (10.42)	4 (2.80)
Other	7 (0.60)	2 (0.45)	4 (0.91)	1 (0.69)	0 (0)
Prefer to not answer	22 (1.88)	11 (2.47)	7 (1.59)	2 (1.39)	2 (1.40)
Highest Level of Education [1226]^a					
University degree	859 (70.07)	330 (70.06)	325 (69.74)	102 (70.34)	102 (70.83)
College/Trade School	216 (17.62)	76 (16.14)	85 (18.24)	28 (19.31)	27 (18.75)
High School or less	141 (11.50)	61 (12.95)	51 (10.94)	15 (10.34)	14 (9.72)
Prefer to not answer	10 (0.82)	4 (0.85)	5 (1.07)	0 (0)	1 (0.69)
Employment [1226]^a					
Full-time	484 (39.48)	180 (38.22)	186 (39.91)	58 (40.00)	60 (41.67)
Maternity leave	353 (28.79)	136 (28.87)	132 (28.33)	46 (31.72)	39 (27.08)
Part-time	111 (9.05)	37 (7.86)	46 (9.87)	16 (11.03)	12 (8.33)
Not employed	260 (21.21)	111 (23.57)	96 (20.60)	22 (15.17)	31 (21.53)
Other	18 (1.47)	7 (1.49)	6 (1.29)	3 (2.07)	2 (1.39)

Annual Income (USD) based on Postal/Zip Code in USD [1138], mean (95% CI)	43165.59 (42236.47-44094.70)	43740.10 (42063.38-45416.82)	43253.46 (41806.65-44700.28)	42011.66 (39845.73-44177.59)	42270.01 (39677.21-44862.82)
Nulliparous [1226]^a	668 (54.49)	252 (53.50)	272 (58.37)	81 (55.86)	63 (43.57)
COVID Exposure [1064]^b	31 (2.52)	11(2.76)	11 (2.84)	5 (3.62)	4 (2.88)
Self-Reported History of Depression/Anxiety [1226]^a	1051 (85.73)	406 (86.20)	399 (85.62)	122 (84.14)	124 (86.11)
Related to current Baby	321 (30.54)	143 (35.22)	105 (26.32)	36 (29.51)	37 (29.84)
Psychotropic medication Use at Baseline [1226]^c	288 (23.41)	109 (23.14)	118 (25.32)	29 (20.00)	32 (23.09)
Pregnancy conditions during current pregnancy (≥1) [1075] ^b	265 (24.65)	93 (23.02)	99 (25.13)	32 (23.19)	41 (29.50)
Preeclampsia	52 (4.84)	17 (4.21)	19 (4.82)	10 (7.25)	6 (4.32)
High blood-pressure	127 (11.81)	42 (10.40)	40 (10.15)	24 (17.39)	21 (15.11)
Gestational diabetes	121 (11.26)	40 (9.90)	45 (11.42)	16 (11.59)	20 (14.39)
Preterm labor	69 (6.42)	25 (6.19)	26 (6.60)	5 (3.62)	13 (9.35)
Symptom Scores at Baseline					
Depressive Symptoms (EPDS) Total (0-30), mean (95% CI)	15.77 (15.56- 15.99)	15.63 (15.29-15.97)	15.96 (15.61-16.32)	15.68 (15.05- 16.31)	15.72 (15.07-16.37)
Anxiety Symptoms (GAD-7) Total (0-21) mean (95% CI)	11.85 (11.58- 12.12)	11.92 (15.29-15.97)	11.72 (11.23-12.19)	12.00 (11.25-12.74)	11.87 (11.03-12.70)
Treatment/Provider Preference [1203]^b					
Telemedicine	747 (62.09)	-	-	-	-
In-Person	190 (15.79)	-	-	-	-
No Preference	266 (22.11)	-	-	-	-
Provider Preference Expressed at Baseline [1203]^b					
Specialist Provider	730 (60.68)	-	-	-	-
Non-Specialist Provider	22 (1.83)	-	-	-	-
No Preference	451 (37.49)	-	-	-	-

Note. Edinburgh Postnatal Depression Scale (EPDS); GAD=Generalized Anxiety Disorder (GAD-7); United States Dollar (USD). ^aFour participants did not complete the baseline assessment, ^bThis question was added after the trial commencement (in Spring 2020); ^cThis question is a sub-question of another question.

Table S5. Representativeness of the trial participants

Category	Canada	Illinois	North Carolina
Condition	Perinatal depressive symptoms		
Special considerations:			
Sex and gender	Perinatal depressive symptoms affect pregnant and postpartum individuals.		
Age	Perinatal depressive symptoms affect those of reproductive age. Younger individuals (under 25) are more likely to report depressive symptoms compared to those older (25 or older).		
Race or ethnic group	Black and First Nation mothers report higher mean depressive symptom scores compared to White mothers in Canada.	Perinatal depression affects individuals of all races and ethnicities; however, BIPOC individuals are disproportionately affected in Illinois.	Perinatal depression affects Black women in the US at higher rates than other races or ethnicities. However, over the past decade, Asian and Pacific Islanders have seen the largest relative increase in rates of perinatal depression.
Overall representativeness of this trial	<p>The participants in the SUMMIT trial were either pregnant or postpartum at the time of enrollment.</p> <p>The inclusion criteria were restricted to adults (18+). In SUMMIT, we found that 2.7% of participants from the Canada sites were 18-24 years old vs. 6.4% among women (20-24 years old) in the general Toronto population.</p> <p>8.3% of the participants from the Canada sites reported identifying as Black (vs. 10.0% of women in the general Toronto population) and 0.5% identified as First Nation (vs. 0.9% of women identifying as Indigenous in the general Toronto population).</p> <p>Participants from Toronto and the surrounding area had an average individual income of approximately \$45,000 USD (vs \$40,000 USD for the general Toronto region, 2021).</p> <p>72.42% participants from Toronto and the surrounding area had a university degree (vs 46.5% for the general Toronto population).</p>	<p>The participants in the SUMMIT trial were either pregnant or postpartum at the time of enrollment. Non-birthing individuals (e.g., fathers of male sex) were excluded from the trial.</p> <p>Participants from the Illinois site had a higher average age of delivery than the average age of delivery in Illinois (32 years vs. 30.02 years, respectively).⁹The inclusion criteria was restricted to adults (18+). Thus, our results may not be representative of younger individuals.</p> <p>The Illinois study sample was fairly representative of both White and Hispanic participants (52.7% and 17.7%, respectively), under-representative of Black participants (7.5%), and over-representative of participants in other racial or ethnic groups (20.3%) compared to the delivery rates for each of these groups in Illinois (55.3%, 21.6%, 16.4%, and 6.7%, respectively).</p> <p>Participants from Illinois had an average income of approximately \$45,000 USD (vs \$48,842 USD for the state).</p> <p>72.12% participants from Illinois had a university degree (vs 36.7% for the state).</p>	<p>The participants in the SUMMIT trial were either pregnant or postpartum at the time of enrollment.</p> <p>At the Chapel Hill, North Carolina recruitment site, recruitment of racialized groups was higher than the demographic make-up of the state (47.2% in SUMMIT vs 39.3% in the state), with fewer White participants being enrolled than are representative of the recruitment area (50.1% in SUMMIT vs 60.7% in the state).</p> <p>Participants from Chapel Hill, North Carolina had an average income of approximately \$35,000 USD (vs \$43,431 USD for the state).</p> <p>56.60% participants from Chapel Hill, North Carolina had a university degree (vs 33.9% for the state).</p>

Table S6. Post-intervention means (95% CI) and non-inferiority results for primary and secondary per protocol outcomes at 3-months post-randomisation

Outcome (measure; range)	Non-adjusted Mean (95% CI)		95% CI Upper Bound [‡]	NIM*
Per Protocol (exclude n=21 protocol deviations) – TM vs. IP (13% NIM)				
	TM (n=836)	IP (n=244)		
Depressive Symptoms (EPDS; 0-30)	9.15 (8.79-9.50)	8.81 (8.26-9.37)	0.89	1.15*
	TM (n=834)	IP (n=243)		
Anxiety Symptoms (GAD-7; 0-21)	6.43 (6.09-6.78)	6.18 (5.58-6.78)	0.86	0.80
Per Protocol (without outliers) – TM vs. IP (13% NIM) [†]				
	TM (n=836)	IP (n=248)		
Depressive Symptoms (EPDS; 0-30)	8.92 (8.59-9.25)	8.81 (8.26-9.36)	0.65	1.15*
	TM (n=810)	IP (n=241)		
Anxiety Symptoms (GAD-7; 0-21)	5.83 (5.54-6.13)	5.82 (5.29-6.36)	0.52	0.76*

Note. *indicates that non inferiority met.

Confidence Interval (CI), Non-inferiority Margin (NIM), Telemedicine (TM), In-Person (IP), Edinburgh Postnatal Depression Scale (EPDS), General Anxiety Disorder-7 (GAD-7);

[†]Per protocol analyses refer to the condition (TM vs. IP) that the participant actually received and only apply to modality and primary and secondary outcomes (EPDS and GAD-7, respectively). Of the 21 protocol deviations, 16 received TM and 5 received IP and analyzed in the per protocol analyses accordingly.

[‡]95% upper bound is used when higher scores are worse; 95% lower bound is used when lower scores are worse.

Table S7. Baseline covariates

Covariate	Outcome (Range)
1. Perinatal period at enrollment	Pregnant (yes/no)
2. Site	Chapel Hill, Evanston, Toronto
3. Age at enrollment	Self-reported age (years)
4. Symptom score at baseline	<ul style="list-style-type: none"> • EPDS: Mean continuous score of a 10-item scale (0-30); OR • GAD-7: Mean continuous score of a 7-item scale (0-21)
5. Self-Reported Race/Ethnicity	White; BIPOC
6. Employment	Full-time; Maternity leave; Part-time; Not employed; Other
7. Modality preference expressed at baseline	Telemedicine; In-Person; No Preference
8. Provider preference expressed at baseline	Specialist Provider; Non-Specialist Provider; No Preference
9. Self-reported history of seeing a therapist within the last year	Number of months ago
10. Self-reported history of depression/anxiety	Yes/no
11. Number of years lived in current home	Duration (years) of residence in current home
12. Nulliparous	Yes/no
13. Time between randomisation and 3-month completion	Number of days
14. Psychotropic medication before 3-months	Yes/no
15. Started psychotropic medication after enrollment	Yes/no
16. Pregnancy conditions during current pregnancy (pre-eclampsia, high blood pressure, preterm labor, gestational diabetes)	Composite variable (0-4)
17. For NSP vs. SP analyses – control for modality	Telemedicine; In-Person
18. For TM vs IP analyses – control for provider	Non-Specialist Provider; Specialist Provider

Note. Non-Specialist Provider (NSP), Specialist Provider (SP), Edinburgh Postnatal Depression Scale (EPDS), General Anxiety Disorder-7 (GAD-7), Telemedicine (TM), In-Person (IP).

*Three variables were omitted due to high missingness and data sparseness: (1) Self-reported history of anxiety and/or depression related to the birth of a baby; (2) Ability to manage on family income; and (3) Number of times given birth before.

Table S8. Outliers for primary and secondary outcomes at 3-months post-randomisation

Outcome (measure)	Outliers, n* (%)	
ITT - NSP vs. SP (10% NIM)		
	NSP (n=547)	SP (n=551)
Depressive Symptoms (EPDS)	8 (1.46)	6 (1.09)
	NSP (n=545)	SP (n=550)
Anxiety Symptoms (GAD-7)	21 (3.85)	23 (4.18)
ITT - TM vs. IP (13% NIM)		
	TM (n=836)	IP (n=262)
Depressive Symptoms (EPDS)	14 (1.67)	0 (0)
	TM (n=834)	IP (n=261)
Anxiety Symptoms (GAD-7)	36 (4.32)	8 (3.07)
Per Protocol – TM vs. IP (13% NIM)†		
	TM (n=850)	IP (n=248)
Depressive Symptoms (EPDS)	14 (1.65)	0 (0)
	TM (n=848)	IP (n=247)
Anxiety Symptoms (GAD-7)	38 (4.48)	6 (2.43)
Per Protocol (exclude n=21 protocol deviations) – TM vs. IP (13% NIM)		
	TM (n=836)	IP (n=244)
Depressive Symptoms (EPDS)	14 (1.67)	0 (0)
	TM (n=834)	IP (n=243)
Anxiety Symptoms (GAD-7)	36 (4.32)	6 (2.47)

Note. Confidence Interval (CI), Non-Specialist Provider (NSP), Specialist Provider (SP), Telemedicine (TM), In-Person (IP), Edinburgh Postnatal Depression Scale (EPDS), General Anxiety Disorder-7 (GAD-7);

*Sample is based on non-imputed data.

†Per protocol analyses refer to the condition (TM vs. IP) that the participant actually received and only apply to modality and primary and secondary outcomes (EPDS and GAD-7, respectively). Of the 21 protocol deviations, 16 received TM and 5 received IP and analyzed in the per protocol analyses accordingly.

Outliers were defined as: greater than 1.5*Interquartile Range + the third quartile OR lower than the first quartile – 1.5*Interquartile Range.

Table S9. Post-intervention means (95% CI) and non-inferiority results for imputed outcomes at 3-months Post-randomisation (N=1230)

Outcome (measure; range)	Adjusted Mean (95% CI)		95% CI Upper Bound [‡]	NIM*
Primary and Secondary Outcomes				
ITT - NSP vs. SP (10% NIM)	NSP	SP		
Depressive Symptoms (EPDS; 0-30)	9.27 (8.85-9.69)	8.87 (8.45-9.29)	0.87	0.89*
Anxiety Symptoms (GAD-7; 0-21)	6.42 (5.99-6.83)	6.36 (5.95-6.76)	0.53	0.64*
ITT - TM vs. IP (13% NIM)	TM	IP		
Depressive Symptoms (EPDS; 0-30)	9.12 (8.77-9.47)	8.91 (8.36-9.47)	0.77	1.16*
Anxiety Symptoms (GAD-7; 0-21)	6.42 (6.08-6.75)	6.27 (5.70-6.85)	0.70	0.82*
Per Protocol – TM vs. IP (13% NIM) [†]	TM	IP		
Depressive Symptoms (EPDS; 0-30)	9.15 (8.79-9.50)	8.81 (8.23-9.39)	0.91	1.16*
Anxiety Symptoms (GAD-7; 0-21)	6.45 (6.12-6.78)	6.15 (5.57-6.73)	0.87	0.80
Exploratory Outcomes				
ITT – NSP vs. SP (10% NIM)	NSP	SP		
Quality of Life (EQ5D-5L Domains; 1-5)				
Mobility	1.35 (1.29-1.40)	1.33 (1.27-1.38)	0.08	0.13*
Self-care	1.23 (1.19-1.28)	1.25 (1.20-1.29)	0.04	0.12*
Usual Activities	1.74 (1.66-1.81)	1.70 (1.63-1.77)	0.11	0.17*
Pain/Discomfort	1.91 (1.84-1.98)	1.87 (1.80-1.94)	0.12	0.19*
Anxiety/Depression	2.26 (2.19-2.34)	2.26 (2.18-2.33)	0.09	0.23*
Disability (WHODAS 2.0; 12-60)	20.95 (20.21-21.68)	20.74 (20.08-21.40)	0.96	2.08*
ITT – TM vs. IP (13% NIM)	TM	IP		
Quality of Life (EQ5D-5L Domains; 1-5)				
Mobility	1.34 (1.29-1.39)	1.33 (1.25-1.41)	0.08	0.17*
Self-care	1.24 (1.20-1.28)	1.24 (1.17-1.31)	0.06	0.16*
Usual Activities	1.71 (1.65-1.77)	1.75 (1.65-1.85)	0.05	0.23*
Pain/Discomfort	1.89 (1.83-1.95)	1.91 (1.81-2.01)	0.07	0.25*
Anxiety/Depression	2.27 (2.21-2.33)	2.23 (2.12-2.33)	0.14	0.29*
Disability (WHODAS 2.0; 12-60)	20.75 (20.19-21.32)	21.14 (20.22-22.06)	0.50	2.75*
Outcome (measure; range)	Adjusted Mean (95% CI)		95% CI Lower Bound [‡]	NIM*
ITT – NSP vs. SP (10% NIM)	NSP	SP		
Client Satisfaction (CSQ-8; 1-4)	3.36 (3.30-3.42)	3.43 (3.38-3.48)	-0.13	-0.34*
Therapeutic Alliance (WAI-SR; 1-5)	4.13 (4.06-4.21)	4.10 (4.03-4.17)	-0.05	-0.41*
Patient Activation (PAAS; 0-4)	2.16 (2.09-2.24)	2.13 (2.06-2.20)	-0.05	-0.21*
Perceived Support (MSPSS; 1-7)	5.52 (5.43-5.62)	5.46 (5.35-5.56)	-0.05	-0.55*
ITT - TM vs. IP (13% NIM)	TM	IP		
Client Satisfaction (CSQ-8; 1-4)	3.42 (3.37-3.46)	3.32 (3.24-3.41)	0.02	-0.43*
Therapeutic Alliance (WAI-SR; 1-5)	4.15 (4.09-4.21)	4.01 (3.88-4.13)	0.05	-0.52*
Patient Activation (PAAS; 0-4)	2.14 (2.08-2.20)	2.17 (2.06-2.28)	-0.13	-0.28*
Perceived Support (MSPSS; 1-7)	5.47 (5.39-5.55)	5.54 (5.39-5.70)	-0.21	-0.72*

Note. *indicates that non inferiority met.

Confidence Interval (CI), Non-inferiority Margin (NIM), Intent-to-Treat (ITT), Non-Specialist Provider (NSP), Specialist Provider (SP), Telemedicine (TM), In-Person (IP), Edinburgh Postnatal Depression Scale (EPDS), General Anxiety Disorder-7 (GAD-7), EQ5D-5-level (EQ5D-5L), World Health Organization Disability Assessment Schedule 2.0 (WHODAS), Client Satisfaction Questionnaire (CSQ-8), Working Alliance Inventory – Short Revise (WAI-SR), Premium Abbreviated Activation Scale (PAAS), Multidimensional Scale of Perceived Social Support (MSPSS);

†Per protocol analyses refer to the condition (TM vs. IP) that the participant actually received and only apply to modality and primary and secondary outcomes (EPDS and GAD-7, respectively). Of the 21 protocol deviations, 16 received TM and 5 received IP and analyzed in the per protocol analyses accordingly.

*95% upper bound is used when higher scores are worse; 95% lower bound is used when lower scores are worse

Table S10. Comparing baseline and 3-months post-randomisation clinical severity depressive (EPDS) scores by provider and modality

Depressive Scores (EPDS) by Provider			
	Baseline Mean (95% CI)	3-Month Mean (95% CI)	t-test
<u>Mild</u>			
NSP (n=92)	10.48 (10.38-10.59)	6.54 (5.68-7.41)	9.02***
SP (n=82)	10.40 (10.30-10.51)	6.66 (5.63-7.68)	7.22***
<u>Moderate</u>			
NSP (n=363)	15.36 (15.15-15.57)	9.40 (8.92-9.88)	24.88***
SP (n=364)	15.33 (15.12-15.54)	8.82 (8.34-9.30)	26.65***
<u>Severe</u>			
NSP (n=92)	21.78 (21.44-22.13)	11.50 (10.23-12.77)	16.01***
SP (n=105)	21.92 (21.54-22.29)	10.98 (9.86-12.11)	19.09***
Depressive Scores (EPDS) by Modality			
	Baseline Mean (95% CI)	3-Month Mean (95% CI)	t-test
<u>Mild</u>			
TM (n=125)	10.44 (10.35-10.52)	6.74 (5.89-7.58)	8.62***
IP (n=49)	10.47 (10.33-10.61)	6.24 (5.31-7.18)	8.92***
<u>Moderate</u>			
TM (n=559)	15.30 (15.13-15.47)	9.01 (8.62-9.41)	31.86***
IP (n=168)	15.51 (15.20-15.81)	9.43 (8.78-10.08)	17.60***
<u>Severe</u>			
TM (n=152)	21.89 (21.59-22.19)	11.61 (10.62-12.60)	20.41***
IP (n=45)	21.73 (21.21-22.25)	9.91 (8.40-11.42)	15.48***

Note. Confidence Interval (CI), Non-Specialist Provider (NSP), Specialist Provider (SP), Edinburgh Postnatal Depression Scale (EPDS); Clinical severity EPDS scores were assessed at baseline. Severity groups based on baseline EPDS score: Mild (10-11), Moderate (12-19), Severe (20-30); *p<0.05; **p<0.01; ***p<0.001. Depressive scores at 3-months post-randomisation were significantly lower than baseline scores across severity groups by provider and modality.

Table S11. Comparing baseline and 3-months post-randomisation clinical severity anxiety (GAD-7) scores by provider and modality

Anxiety Scores (GAD-7) by Provider			
	Baseline Mean (95% CI)	3-Month Mean (95% CI)	t-test
<u>Mild</u>			
NSP (n=155)	7.17 (6.97-7.37)	4.95 (4.29-5.61)	6.51***
SP (n=153)	6.95 (6.75-7.15)	4.93 (4.31-5.55)	6.30***
<u>Moderate</u>			
NSP (n=193)	12.01 (11.83-12.20)	6.55 (5.91-7.20)	16.41***
SP (n=173)	11.89 (11.69-12.10)	5.99 (5.42-6.57)	19.02***
<u>Severe</u>			
NSP (n=172)	17.35 (17.08-17.61)	8.16 (7.28-9.03)	20.27***
SP (n=183)	17.46 (17.21-17.71)	8.52 (7.64-9.40)	20.37***
Anxiety Scores (GAD-7) by Modality			
	Baseline Mean (95% CI)	3-Month Mean (95% CI)	t-test
<u>Mild</u>			
TM (n=239)	7.09 (6.93-7.26)	5.12 (4.57-5.66)	7.12***
IP (n=69)	6.93 (6.65-7.22)	4.32 (3.61-5.03)	6.68***
<u>Moderate</u>			
TM (n=273)	11.93 (11.77-12.09)	6.02 (5.51-6.52)	22.50***
IP (n=93)	12.04 (11.76-12.32)	7.09 (6.22-7.95)	10.79***
<u>Severe</u>			
TM (n=270)	17.41 (17.21-17.62)	8.57 (7.87-9.27)	24.53***
IP (n=85)	17.37 (16.97-17.76)	7.62 (6.33-8.92)	15.12***

Note. Confidence Interval (CI), Telemedicine (TM), In-Person (IP), General Anxiety Disorder-7 (GAD-7);

Clinical severity GAD-7 scores were assessed at baseline. Severity groups based on baseline GAD-7 score: Mild (5-9), Moderate (10-14), Severe (15-21); *p<0.05; **p<0.01; ***p<0.001. Anxiety scores at 3-months post-randomisation were significantly lower than baseline scores across severity groups by provider and modality.

Table S12. Comparing serious adverse events (SAE) and adverse events (AE) by provider and modality (N=20)

Event Category	Overall n (%)	Provider			Modality		
		NSP n (%)	SP n (%)	p-value	TM n (%)	IP n (%)	p-value
Severe Adverse Events [21 (91.30%)]							
Fetal or infant death	6 (30)	5 (83.33)	1 (16.67)	0.35	6 (100)	0 (0)	0.52
Hospitalization	8 (40)	4 (50)	4 (50)	0.36	6 (75)	2 (25)	0.54
Life threatening events in the mother, fetus, neonate or infant	4 (20)	3 (75)	1 (25)	1.00	3 (75)	1 (25)	0.51
Maternal death*	1 (5)	1 (100)	0 (0)	1.00	1 (100)	0 (0)	1.00
Other serious important medical events	2 (10)	1 (50)	1 (50)	1.00	2 (100)	0 (0)	1.00
Adverse Events [2 (8.70%)]							
Imminent and active SI	1 (5)	0 (0)	1 (100)	0.35	0 (0)	1 (100)	0.15
Increase in depressive symptoms**	1 (5)	1 (100)	0 (0)	1.00	1 (100)	0 (0)	1.00

Note. Serious Adverse Event (SAE), Adverse Event (AE), Non-Specialist Provider (NSP), Specialist Provider (SP), Telemedicine (TM), In-Person (IP).

*Cause of death unknown.

**AE was reported early in the trial before definitions for AE/SAE were refined.

N=20 distinct AE and SAE events up to 3-months post-randomisation. Categories are not mutually exclusive. N=3 participants' SAEs fall under both the categories "Hospitalization" & "Life threatening events in the mother, fetus, neonate or infant". All were reviewed by an independent Data Safety and Monitoring Board (DSMB); none were deemed directly related or a result of the trial.

Table S13. Comparing group (SP, NSP) and phase (2 and 3) in relation to change in EPDS and GAD scores (N=788), mean (95% CI) at 3-months post-randomisation

Phase	NSP	SP	Phase interaction term (p-value)
Depressive Symptoms (EPDS; 0-30)			
	n=328	n=322	0.1329
Phase 2 [±]	9.01 (8.45-9.56)	9.26 (8.68-9.83)	
	n=66	n=72	
Phase 3 [‡]	9.86 (8.72-11.01)	8.67 (7.50-9.83)	
Anxiety Symptoms (GAD-7; 0-21)			
	n=327	n=321	0.4891
Phase 2 [±]	6.26 (5.72-6.80)	6.75 (6.17-7.34)	
	n=66	n=72	
Phase 3 [‡]	6.32 (5.15-7.49)	6.15 (5.10-7.21)	

Note. Confidence Interval (CI), Non-Specialist Provider (NSP), Specialist Provider (SP), Edinburgh Postnatal Depression Scale (EPDS), General Anxiety Disorder-7 (GAD-7);

*Phase 2 (1:1): participants were randomized to only two arms (NSP Telemedicine and SP Telemedicine). ‡Phase 3 (3:1): participants were randomized to all four arms weighted in favor of in-person.

A linear mixed model which included a group (SP, NSP) by phase (2 and 3) interaction term was used.

Phase 2 and 3 data can be combined without the concern that EPDS and GAD-7 scores were significantly different between these two phases. A comparison of Phase 1 (pre-COVID) to Phase 3 was not carried out as the sample size in the first phase (n=23) is too small to detect statistical differences.

Table S14. Comparing depressive (EPDS) and anxiety (GAD-7) symptom scores at 3-months post-randomisation between phases, mean (95% CI) at 3-months post-randomisation

Outcome (measure; range)	NSP			SP		
	Phase 2 [‡] (n=328)	Phase 3 [‡] (n=66)	t-test	Phase 2 [‡] (n=322)	Phase 3 [‡] (n=72)	t-test
Depressive Symptoms (EPDS; 0-30)	9.01 (8.45-9.56)	9.86 (8.72-11.01)	-1.26	9.26 (8.68-9.83)	8.67 (7.50-9.83)	0.87
	Phase 2 [‡] (n=327)	Phase 3 [‡] (n=66)	t-test	Phase 2 [‡] (n=321)	Phase 3 [‡] (n=72)	t-test
Anxiety Symptoms (GAD-7; 0-21)	6.26 (5.72-6.80)	6.32 (5.15-7.49)	-0.09	6.75 (6.17-7.34)	6.15 (5.10-7.21)	0.88

Note. Confidence Interval (CI), Non-Specialist Provider (NSP), Specialist Provider (SP), Edinburgh Postnatal Depression Scale (EPDS), General Anxiety Disorder-7 (GAD-7); *p<0.05; **p<0.01; ***p<0.001;

*Phase 2 (1:1): participants were randomized to only two arms (NSP Telemedicine and SP Telemedicine).

*Phase 3 (3:1): participants were randomized to all four arms weighted in favor of in-person. Depressive and anxiety symptom scores at 3-months post-randomisation were not significantly different between Phase 2 and Phase 3.

Table S15. Study management and committees

Committee	Role	Member Groups	Members	Frequency
Trial Management Committee (TMC)	Monitored all aspects of the conduct and progress of the trial, ensured the protocol was adhered to and took appropriate action to safeguard participants and the quality of the trial.	<ul style="list-style-type: none"> Principal Investigator from each Hub* Trial Coordinators Project Administrator Data Coordinator 	Study team members, inclusive of stakeholders, can be found at https://thesummit-trial.com/about-us/the-team/	Weekly**
Investigator & Advisory Committee	Monitored all aspects of the conduct and progress of the trial, including site-specific safety protocols within and across sites.	<ul style="list-style-type: none"> All Investigators Research Coordinators from each site Data Coordinator Stakeholders 		Biweekly to Monthly
Stakeholder Advisory Committee (SAC)	Provided overall supervision of the trial and ensured it was being conducted in accordance with the protocol and the relevant regulations. The SAC approved the trial protocol and any protocol amendments, and provided advice to the TMC on all aspects of the trial. Decisions about continuation or termination of the trial or substantial amendments to the protocol were the responsibility of the TMC.	<ul style="list-style-type: none"> Members of the TMC All Investigators Trial Advisors and Consultants All Stakeholders 		Six-monthly
Data Safety Monitoring Board (DSMB)	The DSMB reviewed the accruing trial serious adverse event reports to assess whether there were any safety issues that should be brought to participants' attention or any reasons for the trial not to continue. It was the only body that could make recommendations to unblind data and make further recommendations to the TMC.	<ul style="list-style-type: none"> Four members with expertise in randomized controlled trials assessing psychological treatments and perinatal populations 	<ul style="list-style-type: none"> Dr. Sheryl Goodman, PhD, clinical psychologist Dr. Robert Gibbons, PhD, biostatistician Dr. Catherine Monk, PhD, perinatal psychologist Dr. Tim Oberlander, MD, pediatrician 	Six-monthly

Note. *Hub refers to locality (Chapel Hill, Evanston, Toronto); **Weekly meetings also held within sites.

Table S16. Post-intervention means (95% CI) and non-inferiority results for primary outcomes at 3-months post-randomisation without phase 1 pre-COVID participants

Outcome (measure; range)	Non-adjusted Mean (95% CI)		95% CI	NIM
			Upper Bound [‡]	*
ITT (exclude n=23 Phase 1**) - NSP vs. SP (10% NIM)	NSP (n=535)	SP (n=542)		
Depressive Symptoms (EPDS; 0-30)	9.27 (8.84-9.70)	8.89 (8.46-9.32)	0.89	0.89*
ITT (exclude n=23 Phase 1**) - TM vs. IP (13% NIM)	TM (n=825)	IP (n=252)		
Depressive Symptoms (EPDS; 0-30)	9.14 (8.78-9.50)	8.90 (8.35-9.44)	0.79	1.16*

Note. *indicates that non-inferiority was met.

Confidence Interval (CI), Non-inferiority Margin (NIM), Telemedicine (TM), In-Person (IP), Edinburgh Postnatal Depression Scale (EPDS);

**Phase 1 participants recruited prior to the COVID-19 pandemic.

[‡]95% upper bound is used when higher scores are worse; 95% lower bound is used when lower scores are worse.

Table S17. Sensitivity analyses: comparing depressive (EPDS) and anxiety (GAD-7) symptom scores at 3-months post-randomisation

Outcome (Measure; range)	Provider Condition, Mean (95% CI)			Modality Condition, Mean (95% CI)		
	NSP	SP	t-test	TM	IP	t-test
Change in psychotropic medication between baseline and first session (n=83)						
Depressive Symptoms (EPDS; 0-30)	10.82 (9.01-12.62)	9.97 (8.17-11.77)	0.67 (ns)	10.67 (9.22-12.11)	9.65 (6.93-12.37)	-0.69 (ns)
Anxiety Symptoms (GAD-7; 0-21)	7.14 (5.56-8.72)	7.56 (5.60-9.53)	-0.35 (ns)	7.44 (6.03-8.86)	7.00 (4.40-9.60)	-0.31 (ns)
Change in psychotropic medication during treatment (n=113)						
Depressive Symptoms (EPDS; 0-30)	10.90 (9.61-12.19)	10.11 (8.80-11.42)	0.85 (ns)	10.39 (9.37-11.42)	10.75 (8.57-12.93)	0.32 (ns)
Anxiety Symptoms (GAD-7; 0-21)	7.55 (6.24-8.85)	7.28 (5.84-8.72)	0.27 (ns)	7.68 (6.55-8.82)	6.38 (4.53-8.22)	-1.10 (ns)
Participants who completed 3-month assessment later than 3-months post-randomisation (n=779)						
Depressive Symptoms (EPDS; 0-30)	9.39 (8.89-9.89)	8.69 (8.19-9.19)	1.94 (ns)	9.05 (8.63-9.47)	9.00 (8.35-9.65)	-0.13 (ns)
Anxiety Symptoms (GAD-7; 0-21)	6.59 (6.08-7.10)	6.13 (5.65-6.60)	1.32 (ns)	6.36 (5.96-6.77)	6.34 (5.66-7.03)	-0.05 (ns)
Change in GAD-7 response category (n=80)						
Depressive Symptoms (EPDS; 0-30)	10.30 (8.50-12.09)	8.78 (6.72-10.84)	1.13 (ns)	9.65 (8.20-11.10)	9.33 (5.51-13.16)	-0.15 (ns)
Anxiety Symptoms (GAD-7; 0-21)	7.25 (5.43-9.07)	5.92 (4.03-7.80)	1.02 (ns)	6.70 (5.32-8.09)	6.22 (1.76-10.68)	-0.23 (ns)
Participants who did not respond to marijuana consumption question at screening (n=211)						
Depressive Symptoms (EPDS; 0-30)	9.32 (8.32-10.33)	8.29 (7.33-9.24)	1.48 (ns)	8.69 (7.95-9.42)	10.00 (7.99-12.01)	1.07 (ns)
Anxiety Symptoms (GAD-7; 0-21)	6.71 (5.73-7.70)	5.84 (4.89-6.79)	1.27 (ns)	6.25 (5.52-6.97)	6.58 (4.60-8.56)	0.28 (ns)
Participants who saw an external therapist throughout treatment (n=223)						
Depressive Symptoms (EPDS; 0-30)	10.26 (9.31-11.21)	9.72 (8.75-10.69)	0.79 (ns)	10.04 (9.27-10.81)	9.79 (8.39-11.19)	-0.29 (ns)
Anxiety Symptoms (GAD-7; 0-21)	6.90 (6.01-7.80)	7.32 (6.28-8.35)	-0.60 (ns)	7.28 (6.50-8.06)	6.36 (5.00-7.72)	-1.05 (ns)
Randomized participants who did not start treatment but were asked to complete the follow up assessments (n=59)						
Depressive Symptoms (EPDS; 0-30)	11.69 (9.83-13.54)	10.08 (7.69-12.48)	1.10 (ns)	13.13 (9.38-16.87)	10.26 (8.80-11.71)	-1.51 (ns)
Anxiety Symptoms (GAD-7; 0-21)	8.14 (6.04-10.25)	7.50 (5.05-9.95)	0.40 (ns)	8.06 (5.36-10.77)	7.81 (5.87-9.75)	-0.14 (ns)
3-month FU was sent late and within the optimal period (n=410)						
Depressive Symptoms (EPDS; 0-30)	9.48 (8.82-10.14)	8.73 (7.99-9.47)	1.50 (ns)	8.96 (8.41-9.52)	9.77 (8.72-10.82)	1.27 (ns)
Anxiety Symptoms (GAD-7; 0-21)	6.82 (6.11-7.53)	6.10 (5.41-6.78)	1.44 (ns)	6.33 (5.79-6.87)	7.05 (5.84-8.26)	1.13 (ns)

Note. Confidence Interval (CI), Non-Specialist Provider (NSP), Specialist Provider (SP), Edinburgh Postnatal Depression Scale (EPDS), General Anxiety Disorder-7 (GAD-7). Not Significant (ns).

Depressive and anxiety symptom scores at 3-months post-randomisation were not significantly different by provider or modality in any of these analyses