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A hybrid care model for maternal mental health: a cohort study on peripartum patients

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Thesis

A HYBRID CARE MODEL FOR MATERNAL MENTAL HEALTH: A COHORT STUDY ON PERIPARTUM PATIENTS

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A HYBRID CARE MODEL FOR MATERNAL MENTAL HEALTH:

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ABSTRACT

Peripartum mood and anxiety disorders are prevalent among pregnant women, yet few seek or adhere to treatment. Given the accessibility barriers of current mental health resources, smartphone applications have emerged as a potential self-help tool. However, research for standalone applications have noted limited clinical efficacy suggesting a need for more novel intermediary interventions. These remarks have introduced hybrid care models combining synchronous telehealth with asynchronous psychoeducation and tools on smartphone applications. This cohort study evaluates the clinical efficacy of one such hybrid care model, the Digital Clinic. As the Digital Clinic is an ongoing virtual clinic that sees a variety of psychiatric diagnoses, this is a secondary analysis of maternal peripartum patients seen since 2021. Thirteen peripartum patients' data from a larger sample of 224 patients from the general Digital Clinic were studied. Statistical analyses revealed an average PHQ-9 score of 5.46 (SD = 3.1) and an average GAD-7 score of 7.53 (2.8) at the clinic endpoint. Effect sizes were 1.10 (0.29, 1.90) and 0.74 (0.20, 1.28), respectively indicating a medium to large effect size in both outcomes. These clinical outcomes were not correlated with any data quality outcomes. Thus, this analysis demonstrated preliminary clinical efficacy for the implementation of the hybrid care model in peripartum patients.

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LIST OF ABBREVIATIONS

EPDS..... Edinburgh Postnatal Depression Scale

FDA .....Food and Drug Administration

GAD-7..... Generalized Anxiety Disorder Questionnaire-7

PD .....Peripartum Mental Health Disorders

PHQ-9 .....Patient Health Questionnaire-9

USPSTF ..... United States Preventative Services Task Force

Introduction

Prevalence of Maternal Mental Health

The time between conception and one year after childbirth is known as the perinatal period, which is commonly a vulnerable time period for maternal mental health (Seimyr et al., 2004). Due to the biological, social, and behavioral changes that occur with a change in sex hormones during the course of pregnancy, this time period also places risk for peripartum mental disorders such as peripartum depression and anxiety (Martini et al., 2015). Postpartum depression on the other hand, is on the rise, so that between 1996 and 2021 its prevalence rose from 13 (O'Hara & Swain, 1996) to 17% (Wang et al., 2021). Furthermore, peripartum anxiety has a comparable prevalence of 20% (Fawcett et al., 2019). While the pregnancy experience and childbirth are expected to be a positive experience, there are also added societal and social pressures that cause exacerbation of mental health symptoms. Peripartum mental health disorders (PD) are gaining attention in higher-income countries, but this is not the case in lower and middle-income countries (Mitchell et al., 2023). On average, those in low and middle-income countries experience poverty, domestic, violence, and gender oppression at higher rates than high income countries, which emphasizes the need to increase accessibility and education over maternal mental health and focus the field's efforts on prevention (McNab et al., 2022). To add on, suicide related to peripartum disorders are the second-leading cause of death for these women, and the risk for developing future depressive disorders in these individuals is 50-60 percent (Llewellyn et al., 1997; Rathi et al., 2022).

Important Factors in Maternal Mental Health

Aside from the health of the mother, maternal mental health remains crucial as it can have devastating effects on the infant's health, forming insecure attachment styles and becoming more prone to developmental delays and behavioral instability (Saharoy et al., 2023). It has been shown to negatively impact the child's language acquisition with more devastating effects with longer durations of post-partum depression (Parsons et al., 2012). Despite the high prevalence of PD concerns, this emphasizes a need for preventative care; however, there are many barriers that cause access to be so challenging. In fact, it is shown that while approximately 900,000 women annually are affected by PDs, only 6% seek psychological help (Grissette et al., 2018).

Although there are many consequences of poor maternal mental health, the current state of mental health resources and attitudes towards receiving care are also significant factors in worsening these gaps in care. For many mothers, taking medication during pregnancy or breastfeeding is often met with hesitancy and distress due to concerns about potential negative health effects for the child (Daehn et al., 2022). However, many studies have shown that antidepressants such as SSRIs are clinically effective and safe for use during pregnancy and lactation. In fact, patients not taking SSRIs were more likely to experience future depressive episodes (Sie et al., 2012).

Due to ethical constraints on conducting research with pregnant and lactating populations, there is a lack of double-blind, randomized controlled trials of antidepressants in these groups. As a result, the United States Preventive Services Task Force (USPSTF) recommends psychotherapy as the first-line treatment for peripartum

depression and anxiety (Curry et al., 2019). Psychotherapy can be effective, but it may take weeks to show results, and new mothers may struggle to engage with long-term therapy due to busy schedules. This has led to increased interest in new approaches to augment peripartum mental health care, such as virtual, hybrid care models with digital therapeutics that can be used in conjunction with virtual therapy sessions (Chan et al., 2014).

Current state of Smartphone mHealth Interventions for PD

Smartphone technology has been of particular interest in the field of mHealth interventions (Marzano et al., 2015). Since 2015, smartphones have been one of the fastest growing technologies and have been shown to be effective in mHealth interventions and with high ownership in the United States corresponding to 98% (Pew Research Center, 2024), indicating the feasibility of smartphone technology to be used as a tool to aid mental health. Further, smartphone ownership by women in general is around 79% with even high rates of ownership at 90% by women of child-bearing age (18-49) (Pew Research Center, 2024). The current literature has shown the feasibility and acceptability of depressive and anxiety smartphone applications which show promise in peripartum cohorts who may exhibit similar subset of symptoms (Jake Linardon et al., 2024). In the current literature, reviews in smartphone applications (mHealth) for peripartum mothers show that they are abundant in quantity but are not study-validated or do not demonstrate clinical efficacy with clinician-administered care (Feldman et al., 2021). Importantly, these evidence-based applications are not commercially available for patient use, further complicating accessibility to such resources (Messner et al., 2019).

Despite these current gaps and challenges in mHealth for peripartum mothers, the potential for smartphone mHealth application should not be dismissed entirely. For instance, a recent meta-analysis of 176 randomized controlled trials, found an effect size of g =0.28 for depression (J. Linardon et al., 2024). This potential is further supported by the high rates of smartphone mHealth app usage among peripartum patients. Therefore, in adherence with more validated research, the implementation of these digital tools should still strongly be considered given its clinical need for this vulnerable population.

Due to the limitations of standalone apps, hybrid models of care have been of increasing interest. These models combine self-guided app use with traditional clinical visits (or telehealth), offering a blend of in-person and app-based approaches (Chen, Huang, et al., 2024). The goal of hybrid models is to improve the scale and delivery of evidence-based treatments. Recent reviews suggest that hybrid models of care can be effective for depression even when offered over a shorter timeframe than traditional therapy. As the USPSTF continues to recommend psychotherapy as a first line of treatment for PD, hybrid care models may present a novel means to meet the USPSTF recommendations for offering evidence-based psychotherapy that is accessible to peripartum patients (Curry et al., 2019).

The hybrid care model is particularly well-suited for the peripartum population, whose demanding schedules require flexible, remote options that reduce logistical barriers such as transportation and childcare required for traditional mental health care appointments. Peripartum patients may also experience distressing symptoms at unpredictable times and be faced with variable stressors that may add to their demanding

schedules. Thus, this alludes to the importance of interventions that are accessible at all hours. Such on-demand approaches provide support and accessibility that traditional care models, constrained to scheduled appointments during standard business hours, cannot offer. By addressing these unique temporal and logistical challenges, hybrid care models represent an innovative and practical solution tailored to the specific needs of the perinatal population, potentially enhancing engagement and improving clinical outcomes. Emerging research already suggests such hybrid care models are acceptable (Chan et al., 2014), but less is known about their clinical impact.

One such hybrid care model for depression and anxiety that has been well-studied across diverse populations is the Digital Clinic (Calvert et al., 2025). This model offers 8 weeks of treatment with a blend of clinical sessions led by a therapist, self-guided app use with the mindLAMP smartphone app, self-tracking with the same mindLAMP smartphone app, and app engagement and troubleshooting support offered by a coach trained as a Digital Navigator. Being active since 2018, the Digital Clinic has proven effective, and we have treated patients with PD in the clinic (Feldman et al., 2021). While the Digital Clinic serves a wide range of mental health concerns and has no age limit, an assessment of clinical efficacy of the peripartum population has not yet been evaluated.

Specific Aims

Given the lack of reliable studies, we designed a study that included 3 specific aims:

1) Evaluate of the clinical effectiveness of our hybrid care model in addressing symptoms of anxiety and depression among peripartum women by determining changes in depressive and anxiety symptoms from intake (baseline), interim (midpoint), and completion of therapy.
2) Analyze any correlations between the anxiety and depressive symptoms with other psychiatric scales that were measured at the three timepoints.
3) Correlate data quality to clinical outcomes and clinical implementation via a case study.

Methods

Recruitment

The 8-week blended hybrid model, Digital Clinic, is based at the Beth Israel Deaconess Medical Center in Boston, MA. Patients were referred to the Digital Clinic via local mental health centers such as local universities, local mental health providers, and other clinical referrals of patients from outpatient clinics across the Beth Israel Lahey Health (BILH) system. Additionally, we also supported the Beth Israel Needham Emergency Departments' (ED) psychiatry care needs by accepting referrals from patients who come into the ED with psychiatric chief complaints. Our cohort of peripartum patients included those who participated in our hybrid care model between August 2022 and December 2024. Eligible participants were at least 18 years old, lived in Massachusetts, spoke English, owned an Android or Apple smartphone, had access to WIFI, and were able to access the Zoom application. Because the Digital Clinic provides short-term therapy virtually and is unable to help patients in psychiatric emergencies, referral sources are also informed and further screened to ensure that patients are not at the level of needing inpatient psychiatric care as we focus on lower acuity psychiatric patients. Additionally, the Digital Clinic serves a wide range of psychiatric disorders and demographics; thus, the maternal cohort included in this study were analyzed from the larger Digital Clinic pool of patients; thus, this was considered a secondary analysis study. Referred patients included in this study either had generalized anxiety disorder (GAD) or major depressive disorder (MDD) with peripartum onset. Peripartum was defined as pregnant or up to one year postpartum.

Getting Started in the Digital Clinic

When patients filled out the screening form, they filled out typical demographic information along with filling out questionnaires related to the following psychiatric scales: PHQ-9, GAD-7, Sheehan Disability Scale-Functioning Assessment, and Flourishing Scale. Lastly, given that the study involved patient data collection, patients were required to agree to the acknowledgement of services in the use of their smartphone data to augment clinical care. After this screening process, participants met with a Digital Navigator who detailed the aspects of treatment and the role of mindLAMP in treatment as an app used alongside typical psychotherapy. Thus, The Digital Navigator also assisted in helping patients install the mindLAMP 2 application on their smartphone and log into the patient portal. While the Digital Clinic did not have a digital literacy requirement besides using the Zoom application and having WiFi access, Digital Navigators also served as technological support, helping patients navigate their smartphones. Patients were shown the following image to allow them to visualize their course of care. At this time, any confusions about the Digital Clinic were addressed. As digital phenotyping and data tracking are often sensitive topics, this first Digital Navigator meeting was added to ensure patients were comfortable with this extra step of care.

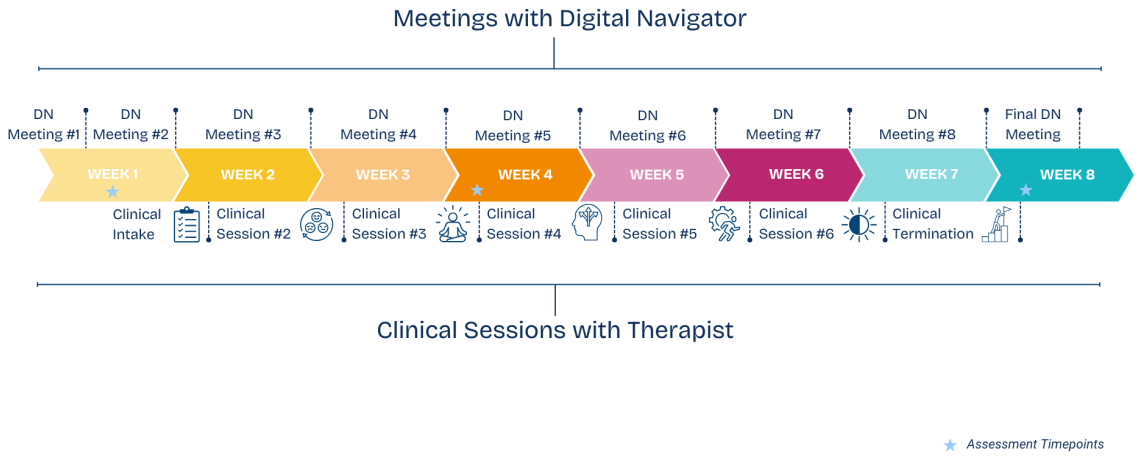

Figure 1. The Digital Clinic Timeline.

This image depicts the entire course of the hybrid-care model in the Digital Clinic. This image is often shown for patients to visualize the appointments that are required of them. The star marked at Week 1, just above clinical intake shows when the intake form should be completed. See Table 1 for all intake corresponding questionnaires and scales. The identical star between the "Clinical Session 3" and "Clinical Session 4" shows when the interim form should be completed. Lastly, the star at Week 8 after clinical termination shows when the completion form should be completed.

Role of the Digital Navigator

In the clinic, Digital Navigators were typically clinical research interns or undergraduate volunteers from local universities in the New England area. While the role of the Digital Navigator is not providing clinical care to patients like clinicians are, they are present to serve as a bridge, allowing the mindLAMP 2 application and clinical care to be seamless and for patients to understand the utility of data collection. Furthermore, the presence of the Digital Navigator is also to provide another member of the mental health

support team to ensure the patient feels supported, as social support remains a high barrier to mental health care (Chen, Lane, et al., 2024).

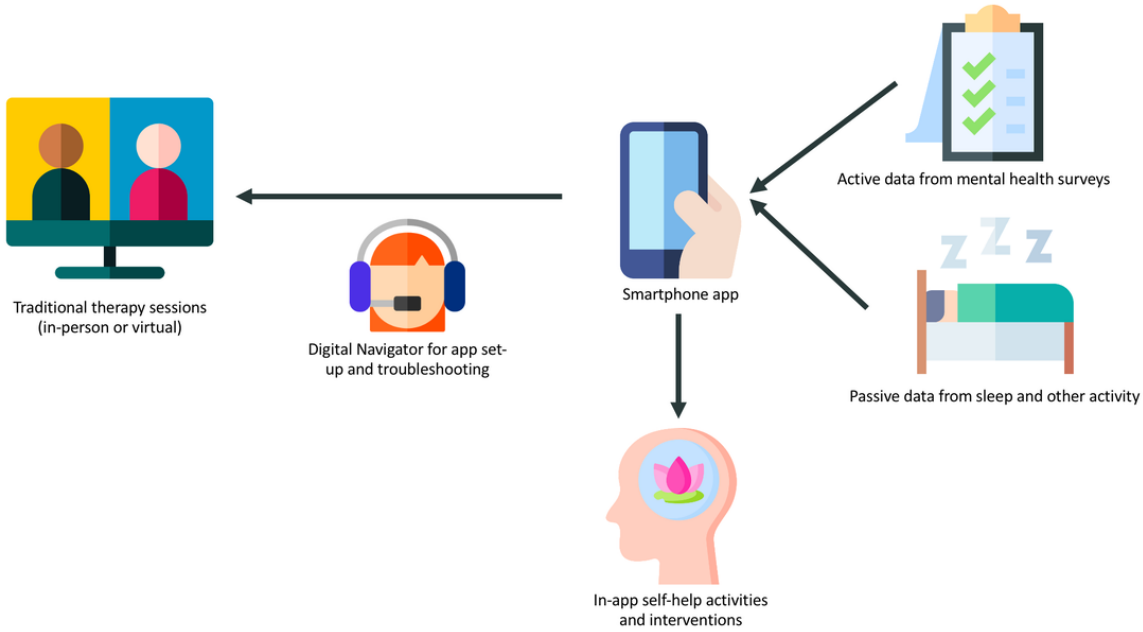

Figure 2. Visualizing the role of a Digital Navigator.

Patient smartphone data from the mindLAMP application are defined as active data (survey and questionnaire data) and passive data (digital phenotyping data). These sources of data in addition to self-help activities in the application such as CBT-base modules are then used for clinical purposes. The Digital Navigator depicted in between the smartphone data and the traditional therapy sessions acts as a liaison between app engagement and clinical sessions.

Once enrolled in the clinic, the Digital Navigator scheduled the patients' first therapy appointment with a clinician and administered an electronic intake form designed to get a baseline assessment of clinical outcome measures. This form collected demographic data and responses to the following scales:

Depressive Symptoms (PHQ-9). The 9-item Patient Health Questionnaire (PHQ-9) has been validated in prenatal depression (Cox et al., 2016) and was used at intake and at each

follow-up visit to assess severity of depressive symptoms over the preceding two weeks. Each of the nine items is scored on a scale from 0 (not at all) to 3 (nearly every day), allowing for a total possible score of 0–27.

Anxiety Symptoms (GAD-7). The 7-item Generalized Anxiety Disorder (GAD-7) has been validated in parental anxiety (Zhong et al., 2015) and used at intake and at each follow-up visit to assess the presence and severity of anxiety symptoms over the preceding two weeks. Each of the seven items is scored on a scale from 0 (not at all) to 3 (nearly every day), yielding a total possible score of 0-21.

Emotional Self- Awareness. This was a scale developed by the Digital Psychiatry team that started Digital Clinic. This was implemented to assess Emotional Self-Awareness. Perceived emotional self-awareness was measured using a single question, "I feel as though I am aware of and in tune with emotions", which was rated from 1 (I am not at all confident) to 5 (I am very confident). Higher scores indicated higher levels of self-awareness.

Self- Efficacy for Managing Emotions. Self-efficacy in managing emotions was measured using the PROMIS Item Bank v1.0 – Self-Efficacy for Managing Emotions Short Form 8a (Gruber-Baldini et al., 2017). Items are rated on a scale of 1 (I am not at all confident) to 5 (I am very confident), with a total possible score of 8-40. Higher scores indicated higher levels of self-efficacy for managing negative emotions.

Self-Management Behaviors (Motivation). The Partners in Health Scale (PIH) (Petkov et al., 2010) is a 12-item assessment with 3 subscales: knowledge, adherence and symptom management. Item responses were rated from 0 (Very little', Never', Not very well') to 8

(A lot', 'Always', 'Very well') and yield a total summed score 0 to 96; higher scores indicated more motivation. The word motivation was used to describe these scale scores to patients.

Functional Impairment (Flourishing Scale). The Sheehan Disability Scale (SDS) (Luciano et al., 2010), 5-item assessment of impairment in 3 domains: work/school, social life, and family life. Three items assessing these three domains are rated from 0 (not at all) to 10 (extremely) and yield a total summed score of 0 (unimpaired) to 30 (highly impaired). For patients, the word Flourishing is used to describe these scales as functional impairment can be sensitive for some populations.

Overall Digital Clinic Workflow

Enrolled patients received 7-8 weeks of evidence-based cognitive-behavioral therapy (CBT) from a trained clinician, following the Unified Protocol (UP) for Transdiagnostic Treatment of Emotional Disorders. The UP can be used for a variety of mental health concerns but places emphasis on negative affectivity, emotional reactivity, and avoidant coping. Treatment was administered through weekly therapy sessions with the clinician, weekly check-ins with the Digital Navigator, and regular use of the mindLAMP app throughout the program (Figure 2). During check-ins, the Digital Navigator addressed any technical or motivational challenges related to the app and reviewed the patients' active and passive digital data, providing insights and explanations. Notably, both therapy sessions and check-ins were conducted virtually via Zoom. As the intake form serves as a baseline, patients were also required to fill out the interim form

which serves a midpoint assessment of the same scales in the intake form. The only added element is a short-answer question for patients to report recent stressful life events that may impact their mental health such as loss of loved ones, financial difficulties, other challenges. Furthermore, a Digital Navigator Satisfaction scale is also included to assess Digital Navigator alliance.

Lastly, after the sixth and last clinical session, the patients are required to fill out the completion form, which is identical to the interim form. This is often described as the final questionnaire to assess if the Digital Clinic has been able to improve patients' mental health symptoms.

MindLAMP application: App-Augmented Care

The app itself offers psychoeducation, self-assessments, CBT exercises, and real-time feedback, among other features. A series of screenshots of the app are shown in Figure 3.

Figure 3. mindLAMP

This figure shows the different pages (Feed, Learn, Assess, Manage, Portal) of mindLAMP in addition to the resources as follows:

a) **Feed tab:** This is a patient's list of surveys to complete. On Mondays, patients were be notified to do weekly surveys and every day, patients will be notified to do the daily survey.
b) **Learn Tab:** This tab is self-guided for patients to learn about different aspects of mental health. This was typically suggested specifically for patients who were new to therapy or mental health in general. We included resources such as emergency services for suicide prevention or support groups for mental health.
c) **Assess Tab:** This tab was often used the most by patients. There were weekly surveys to assess depression, anxiety, and sleep. In addition to these surveys, there are also feedback based surveys that assess therapist alliance, digital navigator alliance, and app satisfaction surveys. This tab also contains cognitive games such as trail-making tests and Jewels tests and assessments for risk-taking behavior such as the balloon risk game. Lastly, there are also daily surveys for patients to assess their daily depression, anxiety, and difficulty functioning. There is also a daily survey for self-report questions of waking time, sleeping time, and quality of sleep.
d) **Manage Tab:** This tab contains more cognitive behavioral therapy (CBT) based modules, created by current and past clinicians. In addition to CBT techniques, DBT related activities are also included here for more patient practice such as the DEARMAN module. The most used modules are typically the “Thinking More Flexibly" and the “Mindfulness” modules.
e) **Portal Tab:** This tab helps gauge patient engagement. A patient’s activity history on the app can be tracked in this tab. This can be a good resource for patients to make sure their surveys were submitted or for them to go back and view prior data.

MindLAMP engagement

Engagement with the mindLAMP app was evaluated through a set of usage metrics: the number of days daily surveys were completed (0–56), the number of weekly PHQ-9 and GAD-7 assessments completed (0–8), the number of weekly sleep surveys completed (0–8), the number of days active in the clinic (0–56) defined by the days on which patients engaged in any app-based activity during treatment and finally the total time spent using mindLAMP (with a minimum threshold of 10 hours).

Data collection and analysis procedures

Demographic data were pooled from screener, intake, interim and completion forms as mentioned above. We also collected information about patients' financial statuses and their current household information. This was collected to further analyze if these factors were correlated with worse mental health outcomes or other distinct factors. Furthermore, electronic medical records from the EPIC records system provided more information about patient medical history such as their maternal medical history, social history, and their medication intake. We also were able to record comorbid mental health disorders or disorders related to their chief complaints from other providers' notes as well. The EPIC records system is where Digital Clinic clinicians documented patient visits. More qualitative information was further extracted from the "Notion" application used to record patient visit notes in earlier Digital Clinic participants. Notion was also used to record digital navigator meeting notes.

Statistical Analysis

For this secondary analysis, many statistical analyses were completed to draw relationships between variables. For the general psychiatric scales listed in Table 3 for intake, interim, and completion surveys, a repeated measures ANOVA was completed. PHQ-9 and GAD-7 scores are known to follow a normal distribution in the general population, so this was assumed for the statistical analysis. Furthermore, a repeated measures method was chosen because the same patients were taking the intake, interim, and completion surveys at different timepoints. A paired T test was completed to compare intake and completion scores. An effect size with a 95% confidence interval was utilized as an additional measure of how clinically meaningful our results were. The values for the general Digital Clinic population were also analyzed and used as a comparison to the maternal cohort. The general Digital Clinic population includes all patients enrolled in the Digital Clinic that had also completed intake, interim, and completion surveys (N = 224).

A Pearson correlation was used to measure relationships between different psychiatric scales among patients. For instance, perceived social support was correlated with anxiety and depressive symptoms. For further analysis, correlations between intake (beginning) and completion (endpoint) were compared using a Steiger's Z test which is used to show a statistical difference between two correlations. Peason correlations were also used to measure any relationships between app-related measures such data quality and survey completion and clinical scale measures.

RESULTS

Demographics of the Maternal Cohort

Table 1 shows the demographic characteristics of the maternal cohort included in this study. There was a total of 13 patients with a mean participant age of 35.8 years (SD = 5.1) with 92% of the cohort being postpartum. The youngest participant was 27 years old while the oldest was 46 years old. Of note, the oldest participant delivered her child 4 years ago. Fifteen percent of patients were pregnant at the time of Digital Clinic while the rest of patients were post-partum. Particularly, one patient gave birth to their child during the eight weeks of the Digital Clinic. Furthermore, 85% patients had just recently given birth within the past year. While enrolled in the Digital Clinic, 31% (4/13) patients had just recently experienced their first pregnancy. For 39% (5/13) participants this was their first time attending therapy.

Fifty four percent (7/13) of the patients obtained post-graduate degrees while 15% (2/13) had attended some form of college. Of note, none of the participants had an educational level lower than college. Most of the maternal cohort were racially identified as white (69%; 9/13). There were two self-described African American, one self-described Asian, and one self-described Middle Eastern or North African.

Table 1. Baseline Characteristics of the Maternal Cohort.

Shown here are the Demographics of the thirteen patients in this Maternal Cohort. Information on this table pertaining to "Education" and "Race" are extracted from the Intake form filled by the patients after their first digital navigator meeting and before their first clinical session. Further demographic information about "Age", "Sex", and details about "Maternal Status" was extracted from the EPIC Medical Records system. Multiple notes and patient charting were reviewed by the author to ensure accuracy of information. Of note, numbers without units labeled should be assumed as the number of participants with the specific characteristic.
Notes about units: in Column 2, this is how many participants had a certain characteristic. Furthermore, in Column 3, either a percentage or standard deviation was included when applicable. For instance, a percentage was provided when counting the number of participants with the specific characteristic and a standard deviation was provided when an average of participants was taken (i.e. Age).

Characteristic	Mean (count)	%/Standard Deviation
Age	35.8	5.1
Education		
Some College	2	15
College Graduate	4	31
Postgraduate Degree	7	54
Race		
Asian	1	7.7
Black or African American	2	15
Middle Eastern or North African	1	7.7
White	9	69
Maternal Status		
Pregnant	2	15
Postpartum	12	92
First Pregnancy	4	31

Patient Medical and Social History

In terms of medical history, patients had other psychiatric disorder diagnoses. The most common comorbid disorder was Generalized Anxiety Disorder with 9/13 patients being previously diagnosed. Of these diagnosed patients, all were prescribed an anti-anxiety medication at the time of enrollment into Digital Clinic. Notably, there was one patient who had a medical history of obsessive-compulsive disorder and bipolar disorder, managed with quetiapine and lamotrigine. There were four patients who had a history of passive suicide ideation, but no participants had history of suicide attempts. While in the Digital Clinic, none of the patients were actively endorsing suicide ideation. There were also two patients who enrolled in the Digital Clinic for postpartum depression and anxiety after their second child; however, they do recount experiencing similar symptoms after their first pregnancy to lesser extent. Per the electronic medical records, there was only one patient who endorsed body image concerns. Common concerns that brought the patients to therapy were worries surrounding other individuals' perceptions of them as a mother, worries about catastrophes with their children, self-blame about children's failures, and an inability to connect with their young children after childbirth. Notably, the children of the post-partum depression and anxiety participants (92%; 12/13) were on average 10.3 months old (SD = 12.4), indicating that mental health concerns arose quite recently after childbirth. There was only one participant pregnant with her first child. It is important to note that the most recent childbirth experience for two participants was

over one year ago. Furthermore, two patients had a history of miscarriage and infertility issues, which was the source of some depression and anxiety.

In terms of patient social history, 100% (13/13) participants were still in a relationship with their child's father and 92% (12/13) were married. The average median household income was 138,000 dollars with 62% (8/13) of the maternal cohort owning their current home. Two participants did not share their annual income information. There were no patients who endorsed a history of substance misuse. In terms of phone use, 92% (12/13) patients were Apple users while the remaining participant was an Android user.

Table 2. Patient Medical and Social History.

The factors shown were extracted from the EPIC Medical Records system and Notion record keeping, which was an additional source of patient details. Units in Table 2 are interpreted in the same way as Table 1.
*2 patients had a history of postpartum depression and anxiety after their first child and joined the Digital Clinic after the birth of their second child.

Medical History	Number of Patients	%
Psychiatric Disorders Diagnoses		
Bipolar disorder (BD)	1	7.7
Post-Traumatic Stress Disorder (PTSD)	2	15.4
Obsessive Compulsive Disorder (OCD)	2	15.4
Generalized Anxiety Disorder (GAD)	9	69.2
Major Depressive Disorder (MDD)	8	61.5
Postpartum Depression or Anxiety	2*	15.4
Current Medication Status		
During	10	76.9
After	2	15.3
No Medication Taken	1	7.7
Medication Type		
Selective Serotonin Reuptake Inhibitors (SSRIs)	8 (Sertraline)	61.5
Norepinephrine and Dopamine Reuptake Inhibitors (NDRIs)	2 (Bupropion)	15.3
5-HT1A receptor agonists	1 (Busprione)	7.7
Antihistamines	1 (Hydroxyzine)	7.7
Atypical Antipsychotics	1 (Quetiapine)	7.7
Phenyltriazine	1 (Lamotrigine)	7.7
Benzodiazepines	5 (Lorazepam, Alprazolam)	38.5
Family Social History		
Marital Status- Married	12	92

Children Age (at time of Digital Clinic)	10.3 (months)	12.4
Substance misuse	0	0

Statistical Analysis of 3 Timepoints: Intake, Interim, and Completion

For our cohort of 13 patients, there was a higher severity of anxiety as indicated by the higher average scores at intake. Overall, there was a statistically significant reduction in both depressive and anxiety symptoms ($p < 0.01$) when comparing intake (baseline) scores to completion scores using a paired T-test. No other measured scales showed a statistical significance using this method of analysis.

When performing ANOVA statistical analysis (considering interim (midpoint) scores), the depressive and anxiety symptoms were not statistically significant. There were no other measured scales which showed a statistical significance.

Table 3. Statistical analysis using ANOVA and paired T test.

Depressive symptoms, Patient Health Questionnaire-9 [score range: 0–27]. ***Anxiety symptoms***, Generalized Anxiety Disorder-7 [score range: 0–21]. ***Functional Impairment***, Sheehan Disability Scale [score range: 0–30]. ***Perceived Social Support***, Multidimensional Scale of Perceived Social Support [score range: 12–84]**.** ***Self-Efficacy at Managing Emotions***, PROMIS Item Bank v1.0 - Self-Efficacy for Chronic Conditions – Managing Emotions – Short Form 8a [score range: 8–40] . ***Emotional Self-Awareness*****,** Emotional Self-Awareness Assessment [score range: 1-5]. ***Digital Literacy***, Digital Health Care Literacy Scale [score range: 0–12]. ***Self-Management Behaviors***, Partners in Health Scale [score range: 0–96]

	Intake		Interim		Completion		ANOVA Statistics					Paired T-tests
Characteristic	**M[1]**	**SD[2]**	**M[1]**	**SD[2]**	**M[1]**	**SD[2]**	**df**	**Sum sq**	**Mean sq**	**F-value**	**p-value**	**p-value**
Anxiety Symptoms (GAD-7)	11.7	6.0	8.8	5.2	7.5	2.8	2	45.1	22.57	0.882	0.424	<0.01
Depressive Symptoms (PHQ-9)	9.38	3.9	7.0	5.0	5.5	3.1	2	1.7	0.864	0.053	0.949	<0.01
Functional Impairment	16.5	9.0	15.3	7.5	12.0	10.0	2	1.2	0.62	0.008	0.992	0.12
Perceived Social Support	73.2	11.7	64.3	7.6	70.0	16.0	2	53	26.67	0.184	0.833	0.80
Self-Efficacy at Managing Emotions	19.0	3.7	23.6	5.1	27.0	8.0	2	4.7	2.34	0.074	0.929	<0.01
Self-Management Behaviors	83.2	16.4	90.0	15.3	94.0	14.0	2	310	155.1	0.671	0.519	0.03
Emotional Self Awareness	3.8	0.8	3.7	1.3	3.7	0.9	2	0.80	0.3996	0.334	0.719	>0.9
Digital Health Literacy Skills	11.8	0.8	11.4	1.1	11.7	0.9	2	2.716	1.3579	1.8	0.183	0.56

In addition to the statistical analyses, line graphs were created to determine if these overall trends were linear. In terms of PHQ-9 scores across the three different surveys– intake, interim, and completion, there are three patients who had increases in PHQ-9 scores within the first four weeks of the Digital Clinic, with the largest increase going from a score of 11 on the intake form to 14 on the interim form (Figure 4). When reviewing chart information, it appeared that the patient had been anticipating a separation between her and her newborn for the first time around the time of the third clinician session (when patients would normally take the interim survey). On the other hand, the majority of patients had decreases in PHQ-9 scores from intake to interim (8/13) with the largest decrease being 10. Interestingly, when reviewing the clinician's notes about the timeframe of the third clinician session there was qualitative evidence that the patient's mood had been better with similar trends in the data report at the time, that the patient had decreased weekly anxiety and depressive symptoms. While the patient was self-critical about her being a good mother because of a recent criticism from a surrounding person, she worked with the clinician to form alternate thoughts about the situation and understand cognitive flexibility (Figure 4).

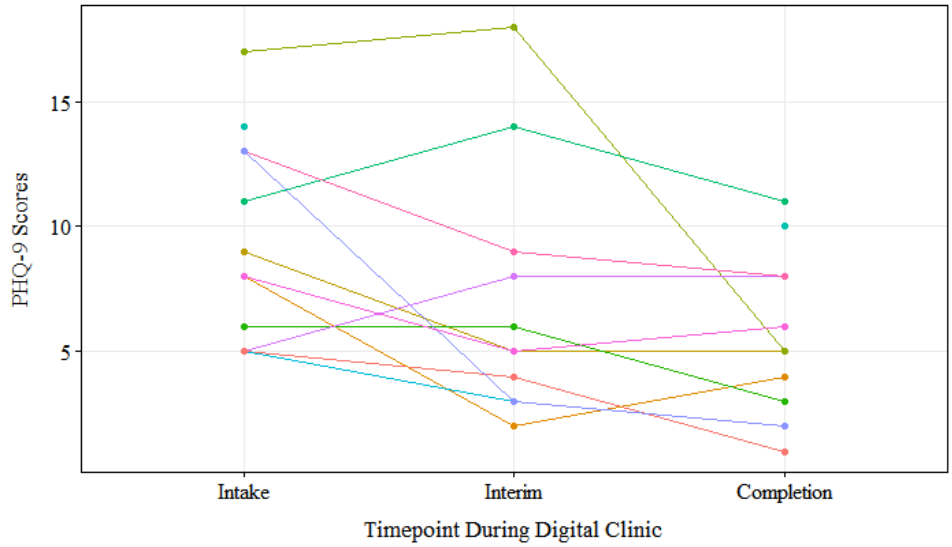

Figure 4: PHQ-9 Scores at Different Timepoints.

This graph shows the individual PHQ-9 scores for the 13 total patients. There are overall downward trends from intake to completion of PHQ-9 scores; but interestingly, these decreases were not consistent when looking at the interim survey scores. Of note, 2 patients did not fill out the interim survey and therefore were unable to have a complete dataset.

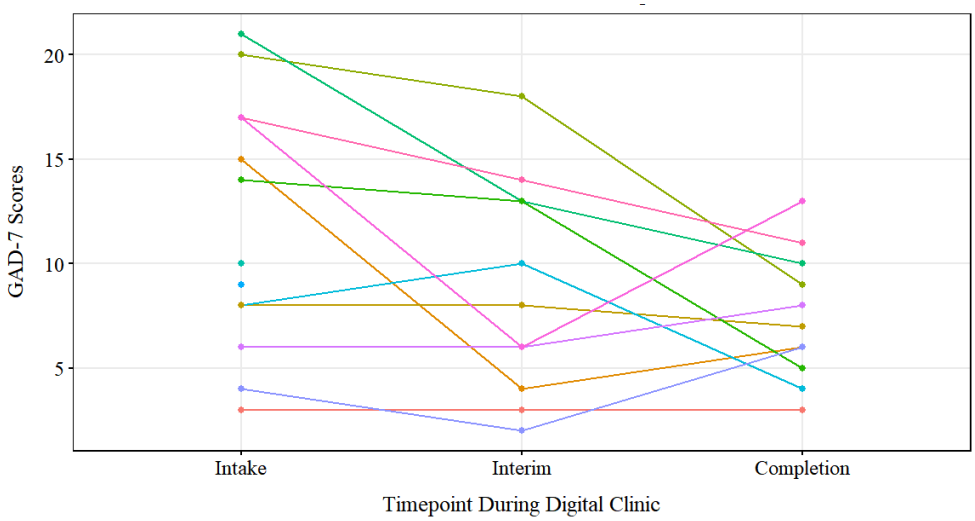

Figure 5: GAD-7 Scores at Different Timepoints.

This graph shows the individual GAD-7 scores for the 13 total patients. There are overall downward trends from intake to completion of PHQ-9 scores; but interestingly, these decreases were not consistent when looking at the interim survey scores. Of note, 2 patients did not fill out the interim survey and therefore were unable to have a complete dataset.

A statistical analysis was also performed to understand the differences from baseline and completion in each of the measured scales (Table 4). In particular, depressive (PHQ-9) and self-efficacy scores revealed the largest effect sizes (greater than absolute of 1). Furthermore, depressive symptoms were significantly decreased with a mean difference of 3.92 (SD = 4.0). Conversely, it was observed that self-efficacy increased from intake to completion with an average mean difference of 8.27 (SD = 6.6). Digital literacy and perceived social support reveal small effect sizes and insignificant differences between intake and completion (Table 4).

When comparing the maternal cohort (N = 13) to the overall Digital Clinic, the maternal cohort's PHQ-9 scores demonstrated a significantly larger effect size than the Digital Clinic as a whole. Conversely, GAD-7 symptoms for both groups demonstrated similar effect sizes. In terms of emotional self-awareness, there was a medium effect size in both the maternal cohort and the entire Digital Clinic.

Table 4. Descriptive Statistics of Psychiatric Scales

Intake and Baseline scores are included. GAD-7- Generalized Anxiety Disorder, PHQ-9- Patient Health Questionnaire-9, SDS- Sheehan Disability Scale, MSPSS- Perceived Social Support, SE- Self efficacy, PIH- Partners in Health (Motivation), ESA- Emotional Self Awareness, DL- Digital Literacy

Variable group	Baseline, mean (SD)	Follow-up, mean (SD)	Change, mean (SD)	*P* value	Effect size (95% CI)
GAD-7[a]					
Peripartum	11.69 (5.7)	7.53 (2.8)	-4.15 (4.7)	<0.01	0.74 (0.20, 1.28)
Digi. Clinic	9.65 (5.4)	6.37 (4.5)	-3.27 (5.0)	<0.01	0.63 (0.48, 0.77)
PHQ-9[b]					
Peripartum	9.38 (3.9)	5.46 (3.1)	-3.92 (4.0)	<0.01	1.10 (0.29, 1.90)
Digi. Clinic	10.13 (6.0)	6.33 (4.8)	-3.79 (5.3)	<0.01	0.65 (0.52, 0.79)
SDS					0.52 (0.005, 1.04)
Peripartum	16.54 (8.9)	10.72 (9.6)	-5.45 (6.9)	0.02	0.50 (0.37, 0.63)

Digi. Clinic	16.25 (7.6)	12.20 (8.4)	-4.05 (7.6)	<0.0001	
MSPSS					
Peripartum	73.23 (11.7)	72.9 (15.6)	-0.09 (5.3)	0.91	0.01 (-0.20, 0.22)
Digi. Clinic	65 (13.3)	67.97 (13.6)	2.97 (10.4)	2.945	-0.22 (-0.32, -0.12)
SE					
Peripartum	19.0 (3.7)	27.36 (7.6)	8.27 (6.6)	0.0036	-1.23 (-2.11, -0.25)
Digi. Clinic	21.39 (5.5)	27.57 (5.8)	6.27 (5.8)	<0.0001	-1.09 (-1.25, -0.93)
PIH					
Peripartum	83.23 (16.4)	94.54 (15.4)	-8.27 (6.6)	0.0025	-0.59 (-0.91, -0.27)
Digi. Clinic	83.89 (13.4)	92.38 (11.8)	0.16 (1.7)	<0.0001	-0.67 (-0.79, -0.55)
ESA					
Peripartum	3.76 (0.8)	3.82 (1.0)	0.09 (1.0)	0.5554	-0.21 (-0.92, 0.51)
Digi. Clinic	3.36 (1.0)	3.77 (0.9)	0.41 (1.0)	<0.0001	-0.44 (-0.59, -0.30)
DL					
Peripartum	11.85 (0.6)	11.64 (0.9)	0.18 (1.2)	0.6193	0.25 (-0.77, 1.27)
Digi. Clinic	10.99 (1.9)	11.15 (1.7)	0.16 (1.7)	0.174	-0.09 (-0.21, 0.04)

Perceived Social Support was also a qualitatively endorsed factor that contributed to patients' depressive and anxiety symptoms, per patient charting. Thus, this was further explored throughout the course of the eight weeks to observe evidence of improvement of symptoms. As depicted in Figure 6, panels A-C indicate higher negative correlations between perceived social support and depressive symptoms as patients progressed through the eight weeks of therapy. In fact, from intake (beginning) to completion (end) timepoints there was a 0.51 difference. To further analyze these correlations, a Steiger's Z test was performed, which implied that these correlations were not statistically significant from one another. Thus, the negative correlation between perceived social support and depressive symptoms supports the notion that Digital Clinic eight-week short-term hybrid care model can provide improvements in cognitive restructuring of perceived social support and hence, decreased depressive symptoms as well.

Anxiety symptoms also showed a negative correlation with perceived social support but weaker than that observed with depressive symptoms (Figure 6, panels D-F). Interestingly, while the PHQ-scores follow a linear upward trend for correlation values, there is more variability in these correlations. A Steiger's Z test was also performed, which similarly showed no statistical significance between the correlations at intake and completion.

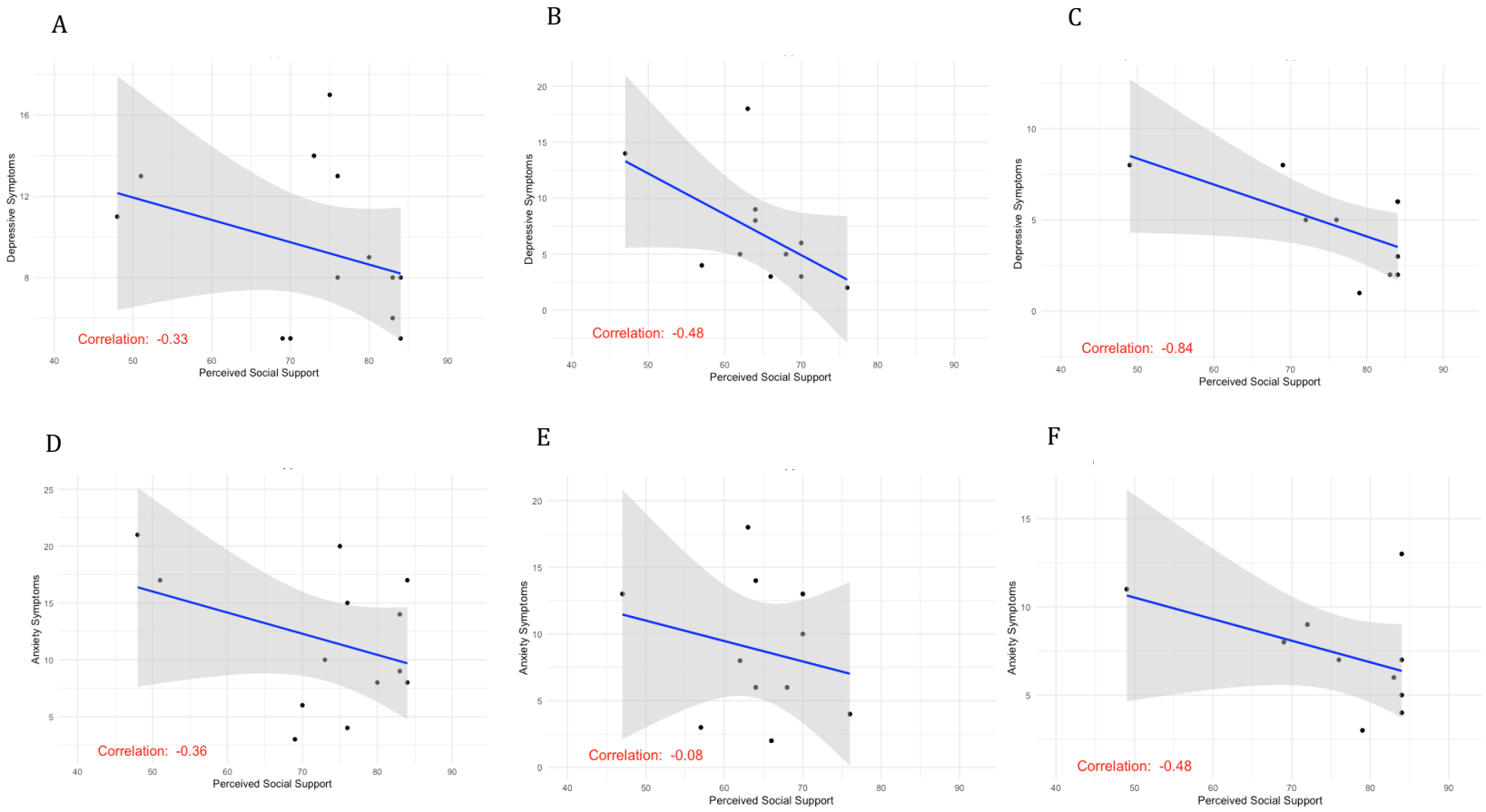

Figure 6: Correlation graphs between PHQ-9, GAD-7 scores vs. Perceived Social Support.

Panels A-C represent correlations between Perceived Social Support and PHQ-9 scores. Panels 6D-F represent correlations between Perceived Social Support and GAD-7 scores.

As part of the hybrid care model, we encourage patients to use the mindLAMP application as a way for tracking symptoms, reinforcing cognitive behavioral skills learned in therapy, and gaining awareness about personal behavioral patterns. Thus, the measured data quality can often be a large factor of a patient's experience in the Digital Clinic. On average, data quality was 76.8% (SD = 25.7) in this cohort of 13 patients, which is almost twice as large as the overall Digital Clinic data quality for all patients of 56.6% (SD = 29.2). Furthermore, to understand how data quality relates to app engagement, we analyzed correlations between mindLAMP survey completion and average data quality. While only a negative correlation of 0.19 was obtained between survey completion and data quality (Figure 7), average survey completion among the cohort was 33 surveys completed (SD = 8.1), four survey points lower. Compared with the general Digital Clinic population with an average of 37 surveys completed (SD = 20.2). Thus, on average, the maternal cohort completed slightly less; however, these values are not statistically significant. It is important to consider the expected survey completion for all patients is 88 total surveys with a daily survey completed every day and 4 weekly surveys which are to be completed weekly within the 8-week period.

Conversely, clinical symptom changes were also correlated with data quality. It was found that the difference of anxiety symptoms from baseline to completion exhibited a correlation of -0.62, indicating that patients with lower differences in anxiety from baseline to completion tended to have higher data quality or vice versa (Figure 8A and B).

To add on to the discussion of app usage, survey completion was also correlated with changes in anxiety and depression. Interestingly, survey completion was positively correlated with anxiety scores (r = 0.46), whereas there was no significant correlation between survey completion and depressive symptoms (r = 0.02).

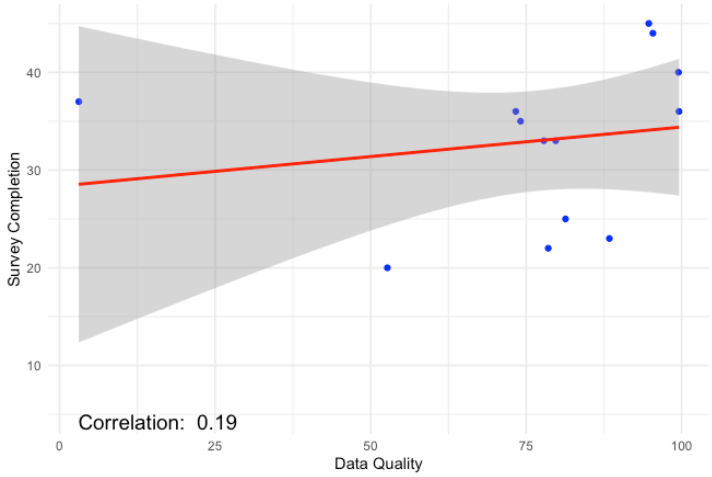

Figure 7: Correlation between Data Quality and Survey Completion

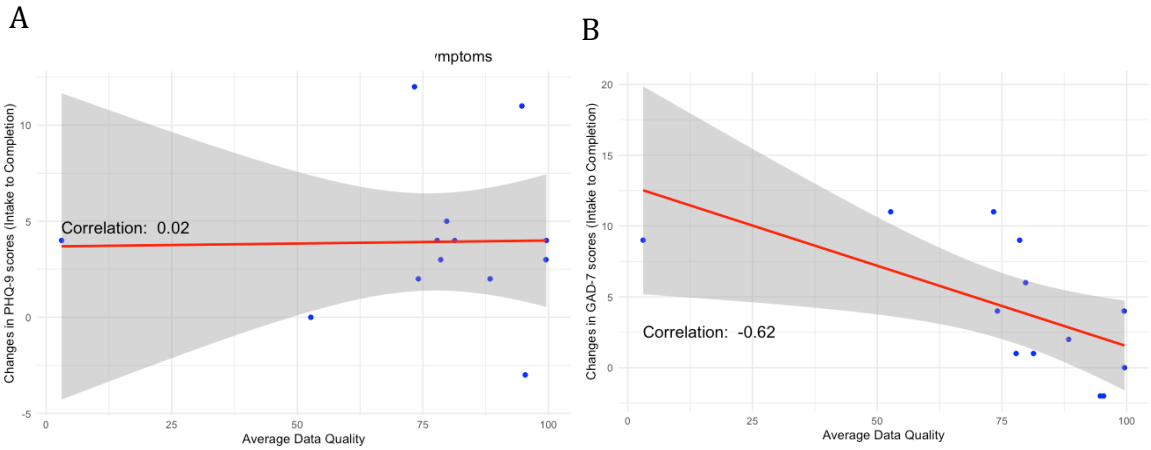

Figure 8: Correlation between Data Quality and Depressive and Anxiety Symptoms

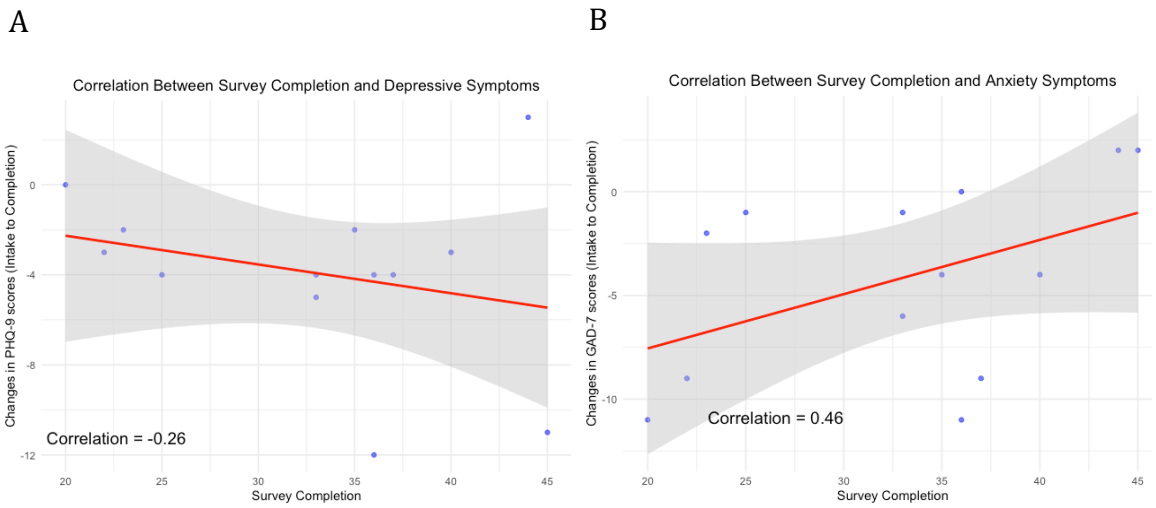

Figure 9: Correlation between Survey Completion and Changes in Depressive and Anxiety symptoms.

Case study on ADU

This study involves a 27-year-old African American woman currently pregnant with her first child while enrolled in the Digital Clinic. I was also assigned as her digital navigator. In terms of medical history, she has struggled with generalized anxiety and clinical depression secondary to being pregnant but no other significant medical history. This is her first time attending therapy. Prior to enrolling in the Digital Clinic, she was prescribed sertraline and is still on this medication during her 8-week program. For her social history, she is currently an elementary school teacher and is still working normal 8 am to 4 pm shifts throughout pregnancy. She currently has a boyfriend who is the father of the child; however, she does not feel that he is supporting her well. Her symptoms are also exacerbated with pregnancy because she does not have the finances to move out of her parents' house and get some privacy. She also notes that living at home is a large stressor due to her father's alcohol misuse. Figure 10 depicts screenshots of her final data report, which is a report we show patients weekly during the 8 weeks of their care.

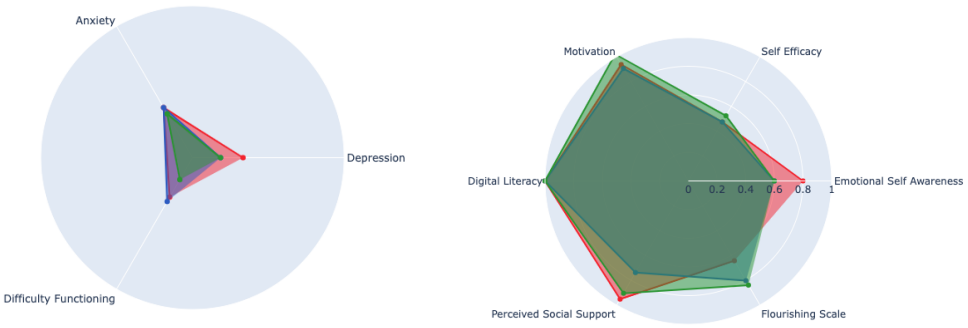

Figure 10: Psychiatric scale measures at intake, interim, and completion.

Comparing intake and completion scores, her depressive symptoms have significantly decreased while her anxiety and difficulty functioning have stayed roughly the same. Furthermore, on the right figure are more positively valence measures. From her baseline, her perceived social support has been non-linear, aligning with her narrative and current circumstances. She notes that with emotional self-awareness, it is unexpectedly decreasing after the 8-weeks therapy because this was her first time attending therapy and she received psychoeducation on what mental health terms meant and emotional labeling. Thus, she endorsed possible uninformed bias in her initial intake survey scores. Over the course of the Digital Clinic hybrid care model, she had significant drops in weekly PHQ-9 scores, as indicated by the weekly survey scores. Quantitatively, her PHQ-9 scores from intake to completion dropped 4 points from 9 to 5, indicating significant improvement in symptoms. Of note, from her interim (midpoint) to completion, PHQ-9 scores did not change.

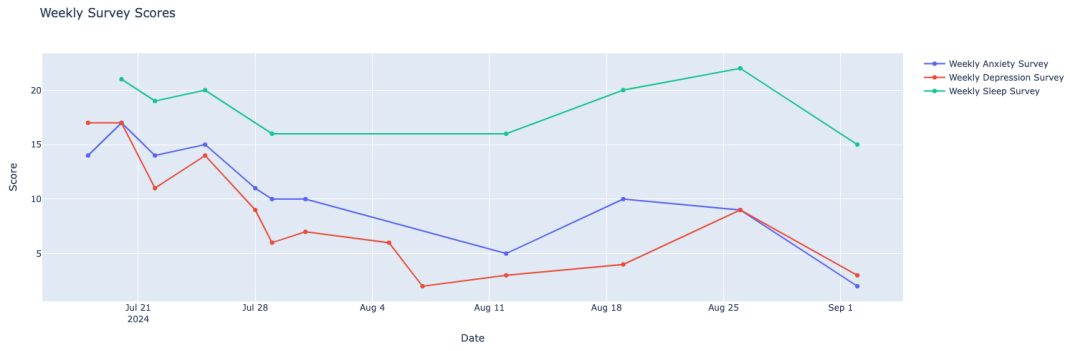

Figure 11: Weekly Survey Scores over the course of 8 weeks of care.

In addition, the patient's digital phenotyping revealed interesting findings. For instance, screen duration was relatively high for the patient at baseline because she used her smartphone to cope with her depression and anxiety. Furthermore, because she was pregnant at the time, she limited movement, representing the lower average entropy, increased home time, and low number of steps.

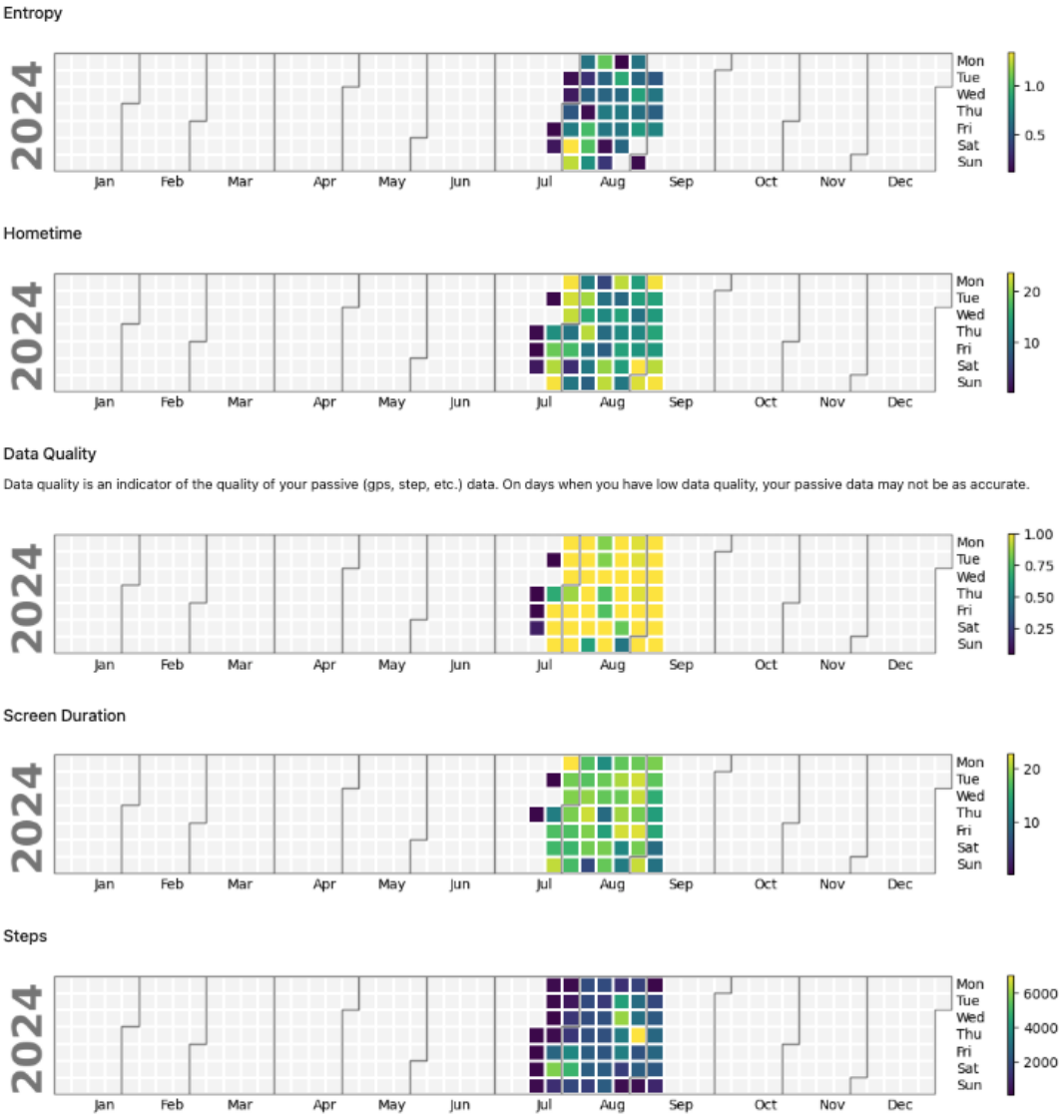

Figure 12. Passive Smartphone Data of ADU.

Shown above are all the passive smartphone sensor data that is collected from patients. Entropy is defined as the number of different GPS locations one has at a given location. If this value is high, more movement indicates higher entropy. Home time is defined as the place the patient spends the most time, which is typically their home. Data quality is a measure of how reliable the digital phenotyping data is. Screen duration is referring to smartphone screen time collectively. Steps is referring to how many steps a patient takes in a day from their smartphone movement or their wearable device. Interpreting calendar view graphs: Yellow squares indicate high hours of screen duration while purple squares indicate low hours. This scale is adjusted based on the patient's typical screen usage so if a patient happens to use more screentime on a given day, those will be indicated as deviating from their normal.

Patients in the Digital Clinic were also shown a correlation matrix to reveal any correlations between the active and passive data or correlations within those categories. For ADU, there was a consistent high positive correlation between depressive and anxiety scores along with difficulty functioning which was also positively correlated with both subset of symptoms. Furthermore, the patient also noted some added stress with her maternal leave at her job and not being able to find a job replacement. She elaborated on this while discussing the digital navigator report with me and explained that the positive correlation between difficulty functioning and entropy could be due to her increased need to perform well at her job as a teacher but with the added stress of being pregnant. Of note, entropy is defined as how many different GPS data points are prevalent in a person's daily life. For instance, because she was going to work and moving around teaching the grade school children, she had increased entropy. She also notes high screen usage at home watching YouTube to cope with symptoms as already indicated above in As shown in Figure 12, the patient had an average data quality of 77.84, which makes the data report results reliable. This is also indicated by the yellow calendar boxes under data quality.

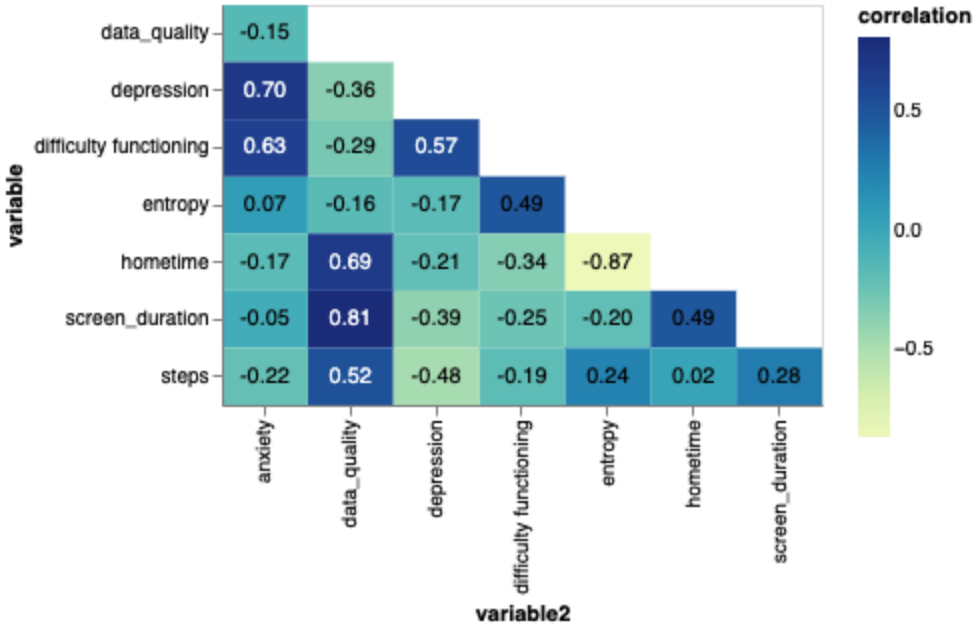

Figure 13: Correlation matrix from the weekly digital navigator report.

This correlation matrix is provided for patients to draw relationships between active (depression, difficulty functioning, and anxiety) and passive (data quality, entropy, home time, screen duration, steps) digital phenotyping data. On the X and Y axes are a mix of passive and active variables. Yellow values indicate high negative correlations, whereas blue values indicate high positive correlations. For instance, this patient particularly has high positive correlations in between depression and anxiety; anxiety and difficulty functioning; depression and difficulty functioning. Values greater than 0.5 or -0.5 were considered sufficient correlations to draw relationships. A negative correlation that is always present on the correlation matrix is the entropy and home time correlation, which is always negatively correlated because they have opposing definitions.

Discussion and Future Directions

The findings from this secondary analysis indicate that the Digital Clinic, a hybrid care model, effectively reduces depressive and anxiety symptoms while promoting app engagement. Additionally, digital phenotyping analysis suggests that clinical improvements occur independently of data quality and instead, may be associated with participation in CBT exercises and therapy attendance.

Pertaining to demographics, the average age of the cohort's children was 10.3 months while enrolled in the Digital Clinic which is later than the average time of postpartum depression and anxiety onset in the literature (Liu et al., 2022); however, this may be due to the referral process of the Digital Clinic as patients typically consult their primary care provider before they get referred to the Digital Clinic program.

While the maternal cohort showed large effect sizes between intake (baseline) and completion (endpoint) in both PHQ-9 and GAD-7 scores, there was also a notably large effect size in self-efficacy. In fact, many skills related to cognitive reappraisal and the management of emotional avoidance were highlighted in clinical notes. These skills are also strongly emphasized in the Unified Protocol, used during the 8-week program. These findings indicate that providing maternal patients with therapy in a hybrid care model is feasible and shows preliminary clinical efficacy. On the other hand, there was a small effect size on perceived social support within the 8-week program. A larger, yet still small effect size was obtained for perceived social support in the general Digital Clinic population. This may suggest that patients entering hybrid care models may need some form of social support structure before committing to a short-term therapy program. For

instance, it was noted that all patients were still married to their child's father and were residing in the same household, which were factors that contributed to the high perceived social support.

Another notable result that was obtained by repeated analysis using ANOVA across intake, interim, and completion revealed no statistical significance (Table 3). This may be unexpected given the statistical significance and large effect sizes from intake to completion; however, the lack of statistical significance among the 3 time points may suggest a steady downward trend in PHQ-9 and GAD-7 scores. Furthermore, these results may also capture possible significant life events or momentary triggers that impact these scores, which may be more representative of fluctuation in depressive and anxiety symptoms.

The digital clinic passive data quality was an average of 76.8%, which indicates high reliability in the data. While there is still ambiguity in the clinical utility of data quality to use generally with depression and anxiety patients, there have been studies that demonstrate problematic smartphone usage has been correlated to elevated risk of poor sleep quality, anxiety, and depression (Yang et al., 2020). In the Digital Clinic, data quality has been used heterogeneously, as demonstrated in ADU's case study for providing contexts to patient behavior. However, it has also been useful in detecting behavioral changes that may indicate improvements or deterioration in symptoms.

Importantly, all but one patient were on medication during the 8-week program, most commonly, sertraline (8/13). All patients were started on medications at least 1 month prior to joining the Digital Clinic. Reviewing qualitative reports, there were no

significant concerns about usage of anti-depressants during the breastfeeding period; however, one patient who did not use medication endorsed concern over the safety of medication usage. Previous reports have shown that medication attitudes is a large factor in maternal mental health. For instance, some reviews have highlighted discomfort during the decision making process with a lack of reassurance from providers for medication safety, leading to an attitude of medication avoidance (Bjørndal et al., 2022; Eakley & Lyndon, 2022). Further, there is an absence of high-quality evidence from randomized controlled trials on safety of medication during breastfeeding, which may also contribute to concerns with medication usage and adherence (Schrempp et al., 2001). While medication usage was a common factor in majority of the patients, it is difficult to discern if this was a major barrier to care for our cohort of patients. Given this, future questionnaires have implemented additional questionnaires about attitudes towards medication.

New mothers and pregnant mothers have stressful schedules and thus, such virtual hybrid care models are likely to be most feasible for their lifestyles (Moosa et al., 2024). Reviewing qualitative interviews and feedback questionnaires, common themes were that the maternal cohort found the hybrid care model extremely helpful, although app engagement was challenging given their schedules. While the maternal cohort patients endorsed that app engagement was difficult and felt that they were not meeting the standards of typical patient participation, their survey completion averages were not statistically significant from the general Digital Clinic population. These remarks may be due to perceived lower self-efficacy in this cohort. While the values on self-efficacy

scales did not reflect a significant difference from the general Digital Clinic population, this was qualitatively noted by clinicians and patients, per charting review.

A scoping review published in 2020 revealed that the landscape of mHealth for peripartum mood disorders is a growing area of research. Over half of the studies were focused on peripartum depression with over 75% placing emphasis on psychoeducation (Hussain-Shamsy et al., 2020). While this review did not focus on app availability, another review revealed that only 6% of applications were commercially available (Martínez-Pérez et al., 2013), highlighting the gap in research and the actual use of mHealth tools.

In April 2024, the Food and Drug Administration (FDA) cleared MamaLift Plus, which is the first smartphone and tablet application providing digital tools to postpartum depression patients after success with a small cohort of patients. A feasibility and acceptability study in 2022 had shown that MamaLift Plus was a feasible smartphone application for the post-partum population (Tang et al., 2022); however, there are few clinical efficacy studies published on MamaLiftPlus in the current literature besides results published by the FDA. There are many similarities between the Digital Clinic model and MamaLift Plus. Firstly, it utilizes an 8-week hybrid care model that is also intended to be used in adjunct with clinician-managed care. Additionally, it is also intended for use in mild-moderate PD patients and provides patients with various therapeutic techniques such as traditional cognitive behavioral therapy but also skill sets from dialectical behavioral therapy or behavioral activation therapy. The application's approval was based on a successful randomized control trial featuring 141 participants,

randomized into a sham-control and MamaLift Plus arm, which showed an 86% reduction in EPDS scores (U.S. Food and Drug Administration, 2022). MamaLift Plus' success in their preliminary studies reinforced the notion that hybrid care models are feasible for the maternal peripartum population. Furthermore, while their model had a similar architecture to the Digital Clinic, they adopted PD-specific techniques such as the assessments with EPDS or CBT for PD. While our results show preliminary efficacy with PHQ-9 and GAD-7 scores, the Digital Clinic model was not created to treat PD patients only and was created with a transdiagnostic approach to mental disorders. Such implementations that MamaLiftPlus used such as the EPDS are clinically more representative of the PD population; thus, this was a limitation in analyzing results from the maternal cohort using the Digital Clinic model.

In terms of data collection, there was difficulty obtaining accurate information in different places as the documentation for Digital Clinic exists on different platforms. Since the Digital Clinic's start in 2018, many procedures have been put in place such as corrections to intake forms and documentation specifications differ per clinician, limiting the amount of complete information obtained from all patients. Furthermore, as we were able to obtain average Digital Clinic values for the scales, this was also limited by patients completing all three surveys intake, interim, and completion as instructed.

In terms of smartphone digital phenotyping data, the mindLAMP application provides higher quality data from patients with Apple smartphone devices; therefore, because those with Android smartphone data were also analyzed in the same way as the Apple users, this could've affected our results in the secondary analysis. Of note, there was

only one Android user in this cohort. The level of phenotyping data affects the quality of the hybrid care model as the use of mindLAMP can reinforce skills learned in clinical therapy.

As our cohort was very small (N = 13), with white-identifying women who were economically stable, the conclusions about overall peripartum depression and anxiety are limited. Further studies including larger, more diverse sample size and a more targeted depression and anxiety treatment model for peripartum patients will be required for validation of these preliminary results.

Overall, our findings indicate that maternal patients are open to a hybrid care model; however, further rigorous research, including randomized controlled trials and studies with larger, more diverse samples, is necessary to better understand how to optimize hybrid are models for peripartum patients.

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