Treating Maternal Mental Health Problems with an App-Based Program: A Randomized Control Trial of BEAM, for Mothers of Young Children

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Key points

Question: Does participation in the BEAM program reduce mental health problems (symptoms of depression and anxiety) and harsh parenting, compared to services-as-usual, among mothers of children aged 18 to 36 months?

Findings: In this two-arm, phase III RCT, BEAM out-performed the unrestricted services-as-usual control condition in reducing anxiety symptoms. Among participants with more severe symptoms at baseline, there were significant decreases in mental health symptoms and harsh parenting compared to the control group.

Meaning: BEAM is a promising and highly scalable mental health and parenting intervention that provides the potential of reaching traditionally underserved groups in need of support.

Abstract

Importance: Exposure to maternal mental illness in the first 3 years of life is associated with poor child outcomes. Maternal mental health problems increased dramatically during the COVID-19 pandemic with many parents not having access to evidence-based treatments. Mobile health (mHealth) treatments show promise for adult mood and anxiety disorders but rarely include parenting strategies and have high dropout rates.

Objective: This study aimed to evaluate the efficacy of the Building Emotion Awareness and Mental Health (BEAM) app-based program, which responds to maternal mental health and parenting needs while building social connection between participants.

Design: A two-arm, phase III randomized controlled trial (RCT) was conducted to evaluate the BEAM intervention compared to unrestricted services-as-usual (US). Participants completed self-report measures at eligibility screening (baseline assessment, T0), prior to randomization (pre-intervention, T1) and immediately following the intervention (post-intervention, T2).

Setting: Individuals were recruited and completed surveys online.

Participants: A final sample of 119 mothers with children aged 18 to 36 months, who self-reported moderate-to-severe symptoms of depression and/or anxiety.

Intervention: Individuals randomized to treatment participated in the 10-week BEAM program. It was hypothesized that the treatment group would report decreases in mental health symptoms (anxiety, depression, anger, alcohol use, sleep problems) and harsh parenting (overreactive parenting, conflictual parent-child interactions) compared to the US group.

Results: BEAM out-performed the US condition in reducing anxiety symptoms. Participants in both groups experienced significant decreases in depression. Participants with higher levels of anxiety and depression symptoms at screening, experienced significant decreases in mental health symptoms and harsh parenting composite scores, if they received the BEAM program, compared to US. This included specific declines in anxiety, anger, and dysfunctional parenting interactions. There were no significant effects for sleep problems, alcohol misuse, or overactive discipline.

Conclusion and Relevance: BEAM is a highly scalable intervention that has the potential to rapidly reach underserved groups in need of mental health and parenting support. Next steps include improving the user interface and exploring engagement and implementation of the program within existing health and social service systems for long-term improvements in family health and well-being.

Introduction

Children are highly sensitive to adversity in the first three years of life, and exposure to maternal mental illness (MI) during this period is linked to negative outcomes such as irritability, sleep problems and socio-emotional developmental impairments. [1-5] Mechanisms include maternal modelling of poor emotion coping (e.g., avoidance, aggression) and harsh parenting (e.g., reactive discipline, conflictual interactions). [6-8] In early childhood, exposure to chronic maternal mental illness predicts risk for children's own mental health problems, developmental delays, asthma, and injury risk. [4,9] For mothers themselves, poor mental health contributes to physical health problems and low quality of life. [7] Notably, these harms are most pronounced when mental illness persists, thus highlighting the importance of intervening early to prevent intergenerational health impairments. [6,10]

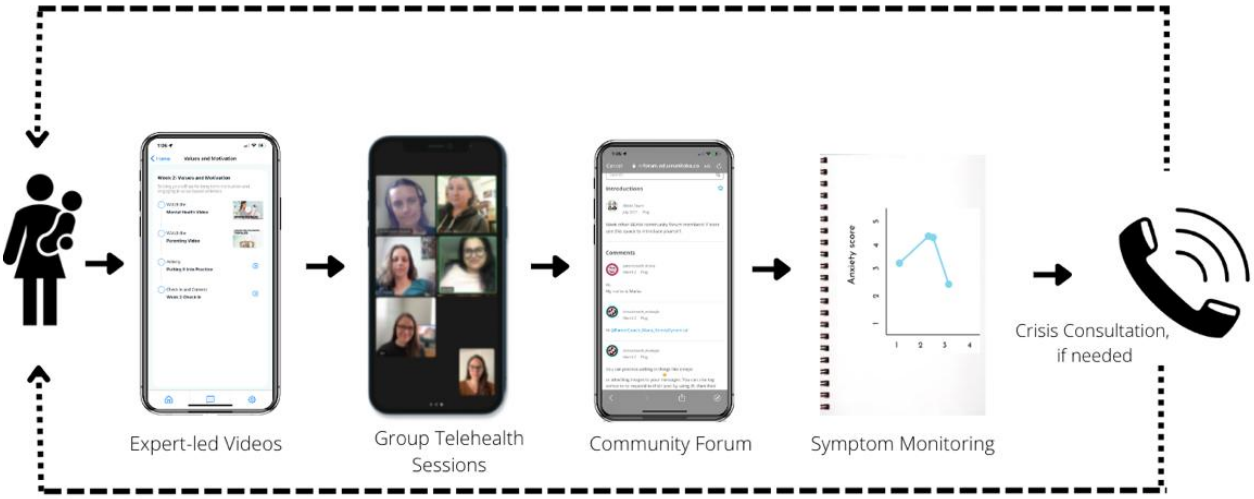
Maternal mental health problems increased dramatically during the COVID-19 pandemic, with meta-analyses documenting 25-30% of mothers experienced clinically significant symptoms of depression and anxiety. [11] Our research identified stressors of isolation, domestic conflict, and a lack of parenting support as key risk factors. [12] Maternal anger is also common, and is associated with increased risk for depression and higher likelihood of engaging in harsh parenting.[4] Assessment and treatment of anger is often gendered, meaning that mothers are not assessed and intervention to improve mood and parenting often overlook the construct. However, given the risks for children associated with harsh parenting, it is important to assess and target. [13] Absence of standard screening and a backlog at existing services means that the majority of parents will not have access to evidence-based treatments. [3,6]

Programs designed to prevent child MI have small effects with minimal improvements in the past 20 years. [14] Although programs that address both mother and child mental health have 50% larger impacts than treating either alone, these are typically costly, require expert clinicians, and have lengthy waitlists, challenging scalability. [15] Early models of mobile health (mHealth) treatments show promise for treating adult depression but rarely include parenting and have average dropout rates of 50%. [16]

Our early pandemic research identified parent MI as a key risk factor for young children's exposure to a range of adversities, including harsh discipline, social isolation and domestic conflict. [12] In response, we conducted qualitative research and consulted our parent advisory board, who wanted services to be accessible, online, and based on expert research. [12,17,18] This was consistent with our priority-setting research prior to the pandemic, which highlighted the importance parents place on addressing their children's emotional development alongside their own mental health needs. [15]

We designed the App-based Building Emotion Awareness and Mental Health (BEAM) Program as an mHealth solution to mitigate impacts of pandemic stress on maternal-child mental health, while building a sense of community. BEAM targets both maternal mental health problems and harsh parenting, key mechanisms through which children come to develop emotional and behavioral problems. BEAM is aligned with best practices in mHealth programs including patient-driven priorities, rapid-cycle iterations to facilitate continual improvements, and a commitment to evidence-based care. [9,19,20] Key elements of the BEAM program are depicted in Figure 1 and include (1) expert-led educational videos using transdiagnostic cognitive-behavioral therapy [21,22] and emotion-focused parenting strategies [23]; (2) brief group sessions to consolidate therapeutic content and promote social support [24,25]; (3)

a community forum to enhance social connection [26]; and (4) symptom monitoring to track progress. In case of a mental health or parenting-related crisis, clinical coaches are available to consult via phone. BEAM builds on evidence from our knowledge synthesis work that mHealth therapeutics can address parent MI and appeal to parents. [9,19,27]



BEAM was developed from July 2020 - February 2021. We co-designed BEAM with our parent-advisory board (PAB) of mothers holding lived experience with mental health challenges who participated in prior clinical research programs. The PAB highlighted priorities to connect with therapists and mothers in a secure online setting. Our PAB advised that, instead of standard 2-hour therapy, an adaptation with brief videos and a 1-hour group was preferred. This aligned with our knowledge synthesis work on showing impacts of mHealth programs that include both online material and therapist contact. [27] Notably, this trial tests a minimum viable product (MVP; i.e., a prototype with a minimum set of features [28]) of an App-based program, with ongoing learning by our research team on the potential benefits and limitations of this MVP.

Our BEAM trials to date show promising results. In both an open pilot [29] and a pilot RCT [30] with mothers of young children (6–36 months), those who received BEAM showed significant reductions in aggregate mental illness symptoms (depression, anxiety, anger, sleep, and substance use). Retention in the pilots was promising with dropout rates of ~ 35% compared to attrition of up to 50% across many online therapies. [16] In qualitative feedback, participants described that the mental health and parenting skills gained from both videos and group sessions improved their quality of life and parenting [31]. They also emphasized the value of social support, facilitated by the online community. Following the ORBIT model for behavioural trials [32], we sought feedback in focus groups and developed strategies to improve function in the App, improve communication in forums, and synergize mental health and parenting content. Most participant feedback centred on how the App interface could be improved to enhance user experience and ease of use (e.g., increased organization of forum page, videos glitching or not opening within the App). However, our capacity to address previously identified limitations in App-functionality (e.g., limited forum features, a desire for more interactive videos) was limited by the considerable financial investments required to update technology infrastructure and thus, we strategically put team resources into improving participants' experiences within limits of the available grant budget. For example, we made program revisions such as increasing the options for telehealth group therapy times and eliminating weekly assignments for forum posts, but were unable to make any large-scale App interface changes with the MVP budget.

The present study

Here, we present results from a phase III efficacy RCT of version 1.2 of BEAM [33] on mental health symptoms and harsh parenting for mothers of toddlers (N=140), conducted

from April – June 2021. The primary aim was to evaluate the efficacy of the BEAM App-based program for improving maternal mental health symptoms compared to an unrestricted services as usual (US) control group, with potential moderation by baseline symptom severity. We hypothesized that participants who received the BEAM intervention would report fewer mental health problems, including depression and anxiety (primary outcomes), anger, alcohol use, and sleep problems compared to the control group at post-treatment. We also hypothesized that participants with higher symptoms at baseline would show greater reductions if they received the BEAM intervention. [33]

The secondary aim was to determine the benefits of BEAM on reducing harsh parenting, a key pathway through which maternal health problems have negative impacts on child health and development. We hypothesized that participants who received the BEAM intervention would report less harsh parenting (i.e., dysfunctional interactions, over-reactive discipline) relative to the control group at posttreatment. Like the mental health symptoms, we hypothesized that those parents with higher harsh parenting at baseline would have greater reductions if they received the active intervention. [33]

Other child (e.g., behavioural and emotional problems), exploratory (e.g., parent-child relationship quality and child emotional reactivity), health (e.g., Fitbit measured heart rate, steps, sleep), and long-term outcomes will be investigated in future publications. Finally, we explored the extent to which participants engaged in different components of the program in relation to symptom remission.

Methods

Study Design

Potential participants were asked to complete an eligibility screener, including measures of depression and anxiety, prior to enrollment (T0 = baseline assessment). Those who met criteria for the trial were then assessed prior to randomization (T1 = pre-intervention assessment; *M = 21.06* days post T0*,* SD = 13.02) and immediately following the 10-week intervention period (T2 = post-intervention assessment) on all outcomes: primary (depression and anxiety symptoms), secondary mental health symptoms (anger, alcohol use, and sleep problem symptoms) and parenting outcomes (dysfunctional interactions, over-reactive discipline).

Participants

Online advertisements recruiting "mothers/moms struggling with/experiencing depression and/or anxiety" were posted on social media platforms including Twitter, Instagram, and Facebook lab accounts between November 2021 and February 2022. Recruitment emails were also sent to community organizations and daycare centres. Inclusion criteria were (a) reporting clinically elevated levels of depression and/or anxiety, (b) identifying as a mother or female primary caregiver with a child aged 18-36 months, (c) being 18 years or older, (d) living in the Canadian provinces of Manitoba or Alberta, (e) being English speaking, (f) consenting to wear a Fitbit and availability to attend Zoom telehealth groups, (g) acceptance of random allocation, and (f) attending a pre-test Zoom assessment or tech check-in. Exclusion criteria were reporting a history of suicide in the past year or self-harm in the past 6 months, as the BEAM program is not suitable to treat acute mental health needs.

Potential participants who clicked the study link were directed to an online consent form. Those who provided informed consent were then screened via an online eligibility

screener for the presence of clinically elevated symptoms of depression and/or anxiety using the Patient Health Questionnaire (PHQ-9) and the General Anxiety Disorder (GAD-7) scale moderate-to-severe thresholds of (≥10) and other study inclusion/exclusion criteria. Those who provided informed consent and met inclusion criteria were invited to the pre-intervention assessment with their child via Zoom, which involved observational measures of parent-child relationship quality, maternal sensitivity, and child emotional reactivity.

Allocation Strategy

Prior to randomization, participants were stratified into subgroups based on their reported availability for telehealth sessions. Participants were then allocated by a research staff member who was not associated with the trial to either US alone or the BEAM plus US (abbreviated as BEAM) using an online randomization tool (https://www.randomlists.com/team-generator). Randomization occurred in increments of at least 6 participants. Following allocation, a research assistant checked the computer-generated assignment after the completion of pre-intervention assessments and informed participants of their condition in the study.

Interventions

BEAM

BEAM is a 10-week App-based therapist-guided program with five main components: 1) psychoeducational videos, 2) telehealth group sessions, 3) online forum, 4) symptom monitoring, and 5) suggested (homework) assignments, such as reflection activities and practice exercises. The BEAM program is delivered via mobile application and weekly Zoom telehealth group sessions. BEAM includes approximately 20 minutes of weekly asynchronous psychoeducational videos on parenting and mental health, which are accessed via the App.

Mental health videos provided participants with evidence-based emotion-regulation strategies that draw on third wave cognitive-behavior therapy (CBT) practices including the Unified Protocol [21,34], Dialectical Behaviour Therapy Skills [35], and Mindfulness-based CBT. [36] Self-compassion was also a central focus of the mental health content. [37,38] Transdiagnostic group CBT is efficacious in treating emotional disorders and tends to be more helpful for those with more severe clinical profiles. [39] Supportive parenting videos provided parents with emotion-focused parenting strategies aimed to help understand and respond to children's challenging emotions and behaviours. The weekly group telehealth sessions occurred via Zoom and were led by clinical coaches (i.e., a psychologist or psychologist trainee) and parent coaches (i.e., mothers who recently completed another research group-based intervention for their own mental health needs who were interested in being involved with the BEAM community to promote mental wellness). The group telehealth sessions provided an opportunity for participants to discuss content with each other and ask the coaches questions, with the purpose of promoting social support and fostering a sense of community. The online forum provided a space for participants to reflect on their learned skills and connect with other participants in the program. Participants also completed weekly mood tracking, which involved completing brief surveys (depression, anxiety, parenting stress) and encouragement to write their scores in notebooks provided by the research team.

The BEAM program was revised for the current trial following challenges with feasibility that arose in the initial pilot testing of the BEAM program. [30] Revisions included the addition of an orientation meeting with a parent coach prior to program start, to motivate participant engagement. There were also challenges related to the functionality of the App identified in the pilot, which were possible to partially address in this RCT. For instance,

many participants, particularly those who used Android (versus iPhones), reported being unable to access the weekly videos directly from the App, video restarting from the beginning every time, and having issues with videos freezing. In response, we compressed videos and provided video access via YouTube links for participants with outstanding problems. However, the App developers did not have the capacity within budgets to make it possible for the App to save participant progress, so the videos re-started each time a participant opened the App. In response to pilot trial feedback about ways that video content could be improved, we revised videos (e.g., added more visuals and connection between mental health and parenting content). We were not able to fully re-develop content to professional standards of video production within the budget. Similarly, there were challenges with the community forum being difficult to navigate, which we addressed through a simpler approach to thread organization, but given it was third-party software we did not have the capacity to add additional requested features (e.g., responding directly to comments or tagging specific participants).

BEAM telehealth groups were led by a qualified MA level counsellor with extensive training and experience in delivering mental health and parenting programming. Supervision was provided by senior authors and developers of the BEAM program content, who monitored both adherence to the BEAM treatment protocol and competence in delivering it.

Unrestricted services (US)

There is considerable variation in treatment-as-usual comparison conditions. Therefore in this study, the term *unrestricted services* (US) was used to describe the comparison condition. Those allocated to US were informed that the purpose of the study was to assess the impact of BEAM in comparison to the provision of usual services. Participants in both groups were

provided with a list of parenting and mental health resources available in their community and encouraged to seek out resources for their mental health and parenting needs.

Measures

Mental Health Problems

Primary Outcomes

Depression. Symptoms of depression were assessed at T0, T1, and T2 using the PHQ-9. [40] The PHQ-9 is a self-administered 9-item questionnaire that assessed the presence and severity of depressive symptoms; 0–4 (minimal or none), 5–9 (mild), 10–14 (moderate), 15–19 (moderately severe), and 20–27 (severe).

Anxiety. Symptoms of general anxiety were assessed were assessed at T0, T1, and T2 using the GAD-7. [41] The GAD-7 has 7 items that are rated on a 4-point Likert scale (i.e., 0 = *not at all*; 3 = *nearly every day*) and is a self-administered scale. Scores range from 0 to 21, with higher scores indicating more severe symptoms of GAD. The following suggested cutoff scores were used; 10-14 (moderate), and 15 (severe).

Secondary Outcomes

Anger. Anger frequency and severity was assessed at T1 and T2 using the Patient-Reported Outcomes Measurement Information System (PROMIS) Short Form. [42] The PROMIS Anger is a self-report scale with 5 items in which participants rate how often they felt symptoms of anger in the past seven days. Items are rated on a 5-point Likert scale ranging from 1 = *never* to 5 = *always.* Scores range from 5-25, with higher scores indicating more anger.

Sleep. Sleep problems were measured at T1 and T2 using the PROMIS Sleep Disturbance Scale. [43] The self-report scale consists of 8 items measuring perceptions of sleep

quality, depth, and restoration within the past seven days. Items are rated on a 5-point Likert scale ranging from 1 = *Not at All* to 5 = *Very Much*. Scores range from 8-40, with higher scored indicative of greater severity of sleep disturbance.

Alcohol Misuse. Alcohol consumption, drinking behaviours and related problems were assessed T1 and T2 using the Alcohol Use Disorder Identification Test (AUDIT). [44] The AUDIT is a self-report that has 10 items in which participants rate their alcohol use. Scores range from 0-40, with higher scores indicating more hazardous alcohol use.

Harsh Parenting

Dysfunctional Interactions. Levels of dysfunctional parent-child interactions were assessed at T1 and T2 using the Parent-Child Dysfunctional Interaction (P-CDI) subscale of the Parenting Stress Index. The P-CDI self-report scale includes 12 items that measure the extent to which parents feel satisfied with their child and their interactions with them. [45] The P-CDI is rated on a 5-point Likert scale (1=*Strongly Disagree*; 5=*Strongly Agree*). Items were summed to produce a total score ranging from 12 to 60, with higher scores indicating higher dysfunctional parent-child interactions. The P-CDI has high internal consistency and is a useful assessment tool for clinical interventions for parents of young children. [46-49]

Overreactive Discipline. Parenting behaviour and dysfunctional discipline was measured T1 and T2 using the Overreactive Parenting subscale of the Parenting Scale (PS). [50] The Overreactive Parenting (OP) subscale includes 10 self-rated items that assess the discipline practices in parents of young children. Scores range from 10-70, with higher scores indicating more overreactive parenting discipline practices.

Program Engagement and Adherence

Several methods were used to measure program engagement: Google Analytics data was used to track engagement with the App and the forum, the number of forum posts was obtained with back-end forum data, and weekly telehealth group session attendance (yes/no) was compiled by the clinical team. Due to challenges in the App design phase and the App being a minimum viable product,[51] some of these measures were not ideal, particularly in terms of video usage. The video player embedded in the App could not track watch time, thus we had to use the time spent on the video screen as a proxy for time spent watching the video. The videos also did not load for some participants due to incompatibility of the video player and format with their device. Solving this issue required sending YouTube links to all participants in weeks 2 and 3. To determine which participants used the YouTube links, the question "Where did you watch the parenting and mental health videos?" was added to the weekly survey on these weeks, to which participants replied either (1) in the app, or (2) on YouTube. To recover *amount* usage data, we used our weekly survey to ask participants if they watched those videos (for number of videos watched). For *duration* data, we asked participants about the average time per week, instead of total time across the tria. [52,53]

Data Analytic Strategy

A percent of possible score was calculated for each mental health and parenting measure by dividing a participant's total score by the maximum possible score for the scale. A mental health composite was created to by averaging the percent possible scores across the five mental health measures (PHQ-9, GAD-7, PROMIS Anger, PROMIS Sleep disturbance, AUDIT). [30] A harsh parenting composite was created averaging the percent possible scores across the two parenting measures (P-CDI, OP). Change scores were then computed by

subtracting T1 from T2 percent possible or composite scores to assess pre to post intervention change.

Descriptive and correlation analyses were conducted in SPSS 27. [54] Regression-based moderation analyses [55] were conducted in Mplus 8.1 [56], to test the differential effect of treatment (BEAM = 1, US = 0) on change in symptoms by baseline severity. [57] PHQ-9 and GAD-7 scores from T0 were each used as the baseline moderator (i.e., in the interaction term with treatment group) for change models of depression and anxiety symptoms, respectively. An aggregate of PHQ-9 and GAD-7 scores from T0 was computed to use as the baseline moderator for all other outcome models. Simple slopes were estimated for low (1SD<M) and high (1SD>M) baseline values to probe interactions with a significance level of $p < .10$. Potential control variables included sociodemographic factors (child age, maternal age, maternal education, household income, urbanicity) that differed between groups at $p < .10$ to be included as covariates. An intent-to-treat (ITT) approach was used as per CONSORT guidelines. [58] Regardless of participant's adherence to the intervention or attrition, data for every participant who was randomized to either the control or intervention group was included in the analyses. Missing data was handled using maximum likelihood estimation. [59,60] To further examine variability in patterns of program engagement, an exploratory latent class analysis of the total weekly time spent on the app and forum across the trial was conducted (see supplementary materials for details on the analytic procedure).

Power Calculation

Based on findings from a meta-analysis, digital interventions for depression that include a human therapeutic guidance component (as is the case with the BEAM program group therapy sessions) have a moderate effect on depression ($g = .63$). [61] We initially

proposed a one-tailed power calculation (using G*Power) using a moderate effect size (d = .50), which indicated that we would need 51 participants per group to reach 80% power (α = .05) to detect clinically significant change in depression. Thus, a sample of 140 (with 70 in each group) was determined to give sufficient power for primary comparisons, while accounting for attrition. We deviated from initial clinical trial protocol plans based on recruitment timelines and pilot trial results (BEAM improved maternal anxiety but not depression, compared to control) to enroll eligible participants based on meeting clinically elevated level of depression *or* anxiety on the screener. Accordingly, we consider both depression and anxiety as primary outcomes with a power analysis using a Bonferroni corrected α of .025 and a moderate effect size (d = .50) indicating that we would need 64 participants per group to reach 80% power.

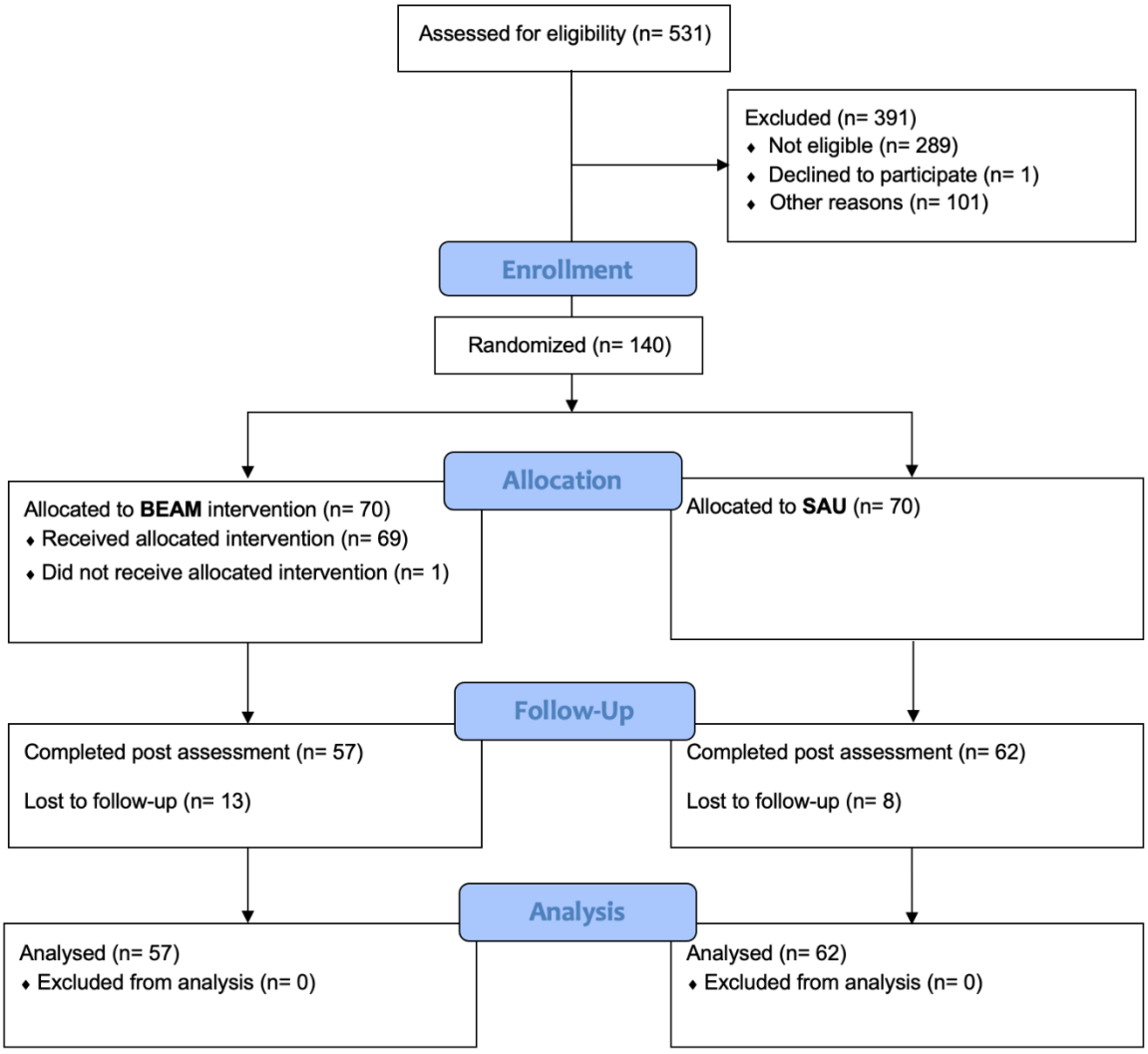
Results

Participant flow and recruitment

Participant enrolment, allocation, and retention information is provided in the CONSORT flow diagram (Figure 2). Recruitment ran from November 15th 2021 to February 8th 2022. In total, 531 individuals completed the eligibility screener. Out of the 242 who met inclusion criteria, 140 (57.9%) were enrolled and completed the T1 assessment, then subsequently randomized to the BEAM program (n = 70) or US (n = 70) groups. Among the 140 participants, 9 (6.43%) met the criteria for experiencing clinically significant symptoms of anxiety, 9 (6.43%) for depression, and 122 (87.14%) met the criteria for both. The program began on February 28th 2022 and ended on May 9th 2022. T2 post assessment were completed from May 10th – June 1st 2022. There was no difference between the BEAM and US groups in the average time between completing the eligibility questionnaire and pre-intervention

assessment; respective means were 21.1 days (*SD* = 14.34) versus 21.2 days (*SD* = 11.9). The mean delay between the pre-intervention assessment and commencement of the intervention period (allocation to BEAM or US) in this study was comparable to that reported in other trials of group interventions. [62] In terms of attrition, 16 (22.9%) BEAM and 12 (17.1%) US participants were lost by the T2 post assessment, this was not a statistically significant difference on Fisher's exact test (p = 0.527).

Figure 2. CONSORT Flow Diagram



Baseline characteristics

Characteristics of the BEAM and US groups are shown in Table 1 along with the results of t-tests for continuous variables and chi-square or Fisher's exact tests for categorical variables. There were no significant differences between the two groups in baseline symptoms. However, there was a significant difference for urbanicity with a larger proportion of participants from the US group (57%) compared to BEAM the group (43%) living in a large city ($\chi 2$ = 3.191, p = .074). There were also more participants from the US group (64.8%) than the BEAM group (39.6%) who reported accessing other mental health or parenting services in the past three months at T2 ($\chi 2$ = 6.81, p = .009). Therefore, urbanicity and other services were included as covariates in treatment effects analyses.

Table 1. Participant characteristics in the BEAM and US groups

	Group		
Baseline characteristics	**BEAM (*n* = 70)**	**US (*n* = 70)**	**Group comparison (*t* or x^2)**
Number of children (%)			
1	41.43	37.14	x^2 = 3.25, p = .66
2	32.86	31.43	
3+	25.71	31.43	
Age of child (months; M, SD) †	25.75, 5.67	26.61, 5.38	*t* = 0.91, p = .18
Age range (months)			
Age (M, SD)	32.17, 4.85	32.85, 5.16	*t* = 0.78, p = .44
Age range			
Household income > 90K CAD (%)	41.54	47.83	x^2 = 0.54, p = .46
White (%)	68.12	64.29	x^2 = 0.29, p = .63
Indigenous (%)	21.4	21.4	
Latin American (%)	1.4	5.7	
South East Asian (%)	1.4	4.3	
Other	7.68	10.01	
Education (%)			
Less than high school	5.71	8.57	x^2 = 0.68, p = .98
High school	17.14	14.29	
College/Technical school	31.43	31.43	
Bachelor’s degree	32.86	34.29	
Graduate or professional degree	12.86	11.43	

Married/Common Law (%)	74.29	79.10	$x^2 = 0.44$, p = .51
Community Type (%)			
Large city	43	57	$x^2 = 3.191$, $p = .074$
Other (e.g., town or small city)	57	43	
Employment status (%)			
On leave	15.71	17.39	$x^2 = 0.78$, p = .85
Unemployed	34.29	28.99	
Part or full-time work	50	53.62	
Service Utilization (%)	39.6	64.8	$\chi 2 = 6.81$, $p = .009$

Note. M = Mean. SD = Standard Deviation. CAD = Canadian Dollar.
† Child refers to child that is participating in BEAM

Program engagement

Of the 70 participants allocated to BEAM, 65 (94.2%) participants logged in the App or attended group at least once. Among these 65 participants, mHealth engagement metrics in terms of amount, duration, and frequency of engagement [52,53] were examined. Table 2 shows that, on average, participants attended about half the group telehealth sessions ($M = 5.98$, $SD = 3.29$) and watched about a third of the videos. The amount of page views on the forum were relatively high, but of short duration. Weeks of engagement were highest for group attendance, followed by videos and the forum. Standard deviations show that all metrics had high variability.

In weeks 2 and 3, 12 unique participants reported watching the videos on YouTube (week 2, $n = 9$; week 3, $n = 6$, 3 of whom also reported using the YouTube links in week 2). Four participants received YouTube links at additional points throughout the trial. One participant, who did not report using the YouTube links in weeks 2 and 3, received YouTube links for the remainder of the trial starting at week 4. Three participants received YouTube links in weeks 9, 10, and 11 (two of whom had previously received links in weeks 2 and 3). In total, 14 participants reported using YouTube links to watch the weekly videos at least once

during the trial. Because the videos in the App did not work for these participants in these weeks, their Google Analytics for videos were missing due to being considered unreliable.

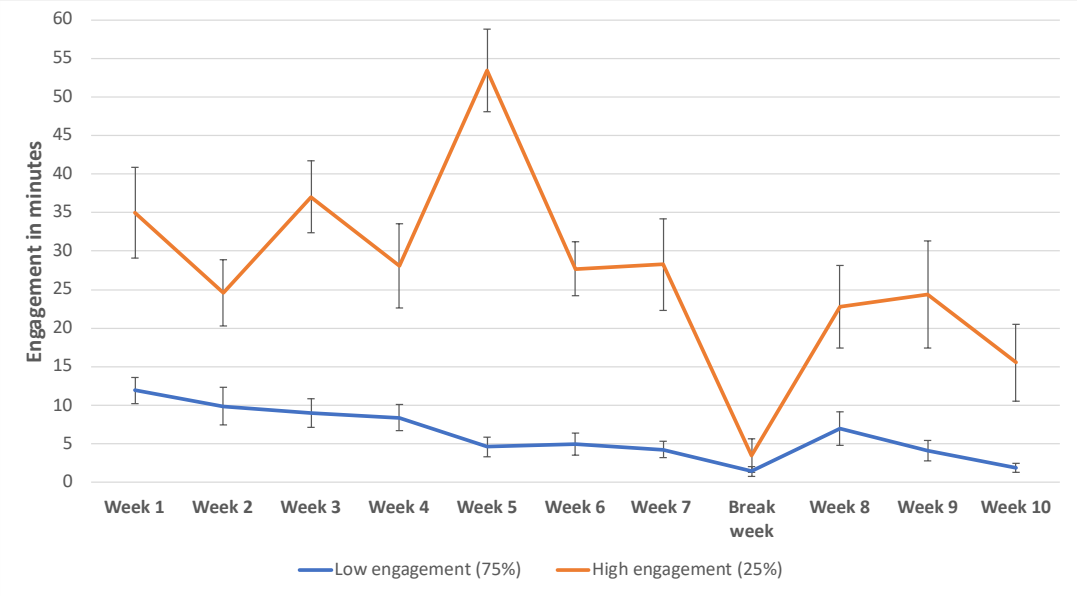
Results of the exploratory latent class analysis showed that participants could be classified into two classes (see Figure 2). The majority of participants (75%) had low stable engagement, with a mean of 12 minutes at week 1, and engagement decreasing for the remainder of the trial (below 10 minutes every week; under 5 minutes for half the trial). The other quarter of participants had high engagement, with averages between 15 and 53 minutes a week. Interestingly, results also showed that participants did not engage with the App during break week (between week 7 & 8), but resumed at similar levels of engagement after break week. Thus, having a break week does not seem to have led to a loss of engagement. Amount, duration, and frequency of engagement within each class are found in Table 2.

Table 2. Frequency, amount, and duration of program engagement among 65 participants with at least one App login or group attended.

	All participants (n = 65)	**Low engagement (n = 49)**	**High engagement (n = 16)**
Engagement metrics	**mean (SD)**	**mean (SD)**	**mean (SD)**
Amount			
Number of mental health videos watched to 50%	3.69 (3.55)	2.07 (2.59)	7.75 (2.05)
Number of parenting videos watched to 50%	2.79 (3.27)	1.17 (1.97)	6.83 (2.17)
Number of page views on the forum	80.51 (126.66)	54.37 (80.99)	160.56 (195.94)
Number of posts/comments on the forum	4.06 (6.13)	2.82 (4.37)	7.88 (8.85)
Number of group sessions attended	5.98 (3.29)	5.31 (3.37)	8.06 (1.88)
Duration			
Weeks between first and last video watched	8.42 (3.11)	7.86 (3.39)	9.86 (1.56)
Weeks between first and last session on the forum	5.62 (4.02)	4.90 (4.04)	7.53 (3.38)
Weeks between first and last group session attended	6.03 (3.66)	5.37 (3.90)	8.06 (1.57)
Time spent watching videos per week (minutes)	7.13 (8.82)	3.04 (4.35)	19.67 (6.99)
Time spent on forum per week (minutes)	2.69 (4.06)	1.60 (2.52)	5.43 (6.27)
Frequency			
Number of sessions on App and/or forum per week	2.75 (3.09)	1.96 (1.98)	5.15 (4.49)

Note. The number of videos watched was computed-based on the time spent on the video screen as the best proxy available as the app built did not allow tracking the video player itself. Low and high engagement groups based on latent class analyses (see Figure 2).

Figure 3. Latent classes of weekly engagement.



Note. See supplementary materials for details on analysis. Captures total time spent on App and forum. Lines show mean within-class engagement with within-class standard errors.

Additional Treatment

BEAM

Of the 53 BEAM participants who completed the post-intervention assessment, 21 (39.6%) reported receiving additional psychological treatment during the past three months: 10 received clinical mental health services, 2 received parenting services, 2 received a combination of mental health and parenting services, 2 received alternative/self-directed services, 6 received mental health and alternative/self-directed services, and 1 received parenting and alternative/self-directed services.

US alone

Of the 54 US participants who completed the post-intervention assessment, 35 (64.8%) reported receiving psychological treatment during the past three months: 18 received clinical mental health services, 2 received parenting services, 4 received clinical mental health and parenting services, 2 received alternative/self-directed services, 6 received mental health and alternative services, and 4 received a mix of mental health, parenting, and alternative services.

Treatment effects

Results of regression-based moderation analyses for primary and secondary outcomes are presented in Table 3. Significant baseline moderations are depicted in Figure 4. Overall, 14.6% of data was missing on variables to be included in analyses and appear to be missing at random (Little's MCAR test $\chi 2 = 47.24$, $p = .545$).

Primary outcomes

In terms of change in depression symptoms, both groups had a significant decrease in symptoms, but there was no statistically significant treatment effect ($b = 1.357$, $p = .680$, 95% CI: -5.081, 7.794) or baseline moderation ($b = -.110$, $p = .570$, 95% CI: -.489, .269). There was a statistically significant treatment effect of BEAM on change in anxiety symptoms ($b = 8.029$, $p = .022$, 95% CI: .1.169, 14.889). There was also a baseline moderation for anxiety ($b = -.655$, $p = .005$, 95% CI: -1.111, -.200), with simple slopes analyses indicating that participants with higher levels of anxiety (1SD>M) at enrollment had a greater decrease in symptoms ($b = -4.100$, $p = .002$, 95% CI: -6.684, -1.517) if they received the BEAM program (see Table 3).

Secondary outcomes

There was not a main effect of BEAM on the mental health composite score (b = .120, p = .192, 95% CI: -.060, .300); however, a baseline moderation for the mental health composite emerged (b = -.240, p = .082, 95% CI: -.510, .031), with simple slopes analyses indicating that participants with higher aggregate scores for depression and anxiety (1SD>M) at enrollment had a significant decrease in mental health symptoms (b = -.072, p = .021, 95% CI: -.132, -.011) if they received the BEAM program. The treatment effect of BEAM on change in anger symptoms was p $< .10$ (b = 4.855, p = .083, 95% CI: -.634, 10.345); however, there was a baseline moderation for anger symptoms (b = -9.452, p = .025, 95% CI: -17.695, -1.210), with simple slopes analyses indicating that participants with higher aggregate scores for depression and anxiety (1SD>M) at enrollment had a significant decrease in anger symptoms (b = -2.695, p = .004, 95% CI: -4.549, -.842) if they received the BEAM program. There were no statistically significant treatment effects or baseline moderation for sleep problems or alcohol misuse.

In terms of parenting, there was a baseline moderation for dysfunctional interactions (b = -15.722, p = .030, 95% CI: -.29.903, -1.542), with simple slopes analyses indicating that participants with higher aggregate scores for depression and anxiety (1SD>M) at enrollment had a significant decrease in dysfunctional interaction (b = -4.961, p = .002, 95% CI: -8.145, -1.777) if they received the BEAM program. There was no statistically significant treatment effect or baseline moderation for overreactive discipline. However, there was a baseline moderation for the harsh parenting composite (b = -.157, p = .058, 95% CI: -.318, .005), with simple slopes analyses indicating that participants with higher aggregate scores for depression and anxiety (1SD>M) at enrollment had a significant decrease in harsh parenting (b = -.051, p = .006, 95% CI: -.087, -.014) if they received the BEAM program.

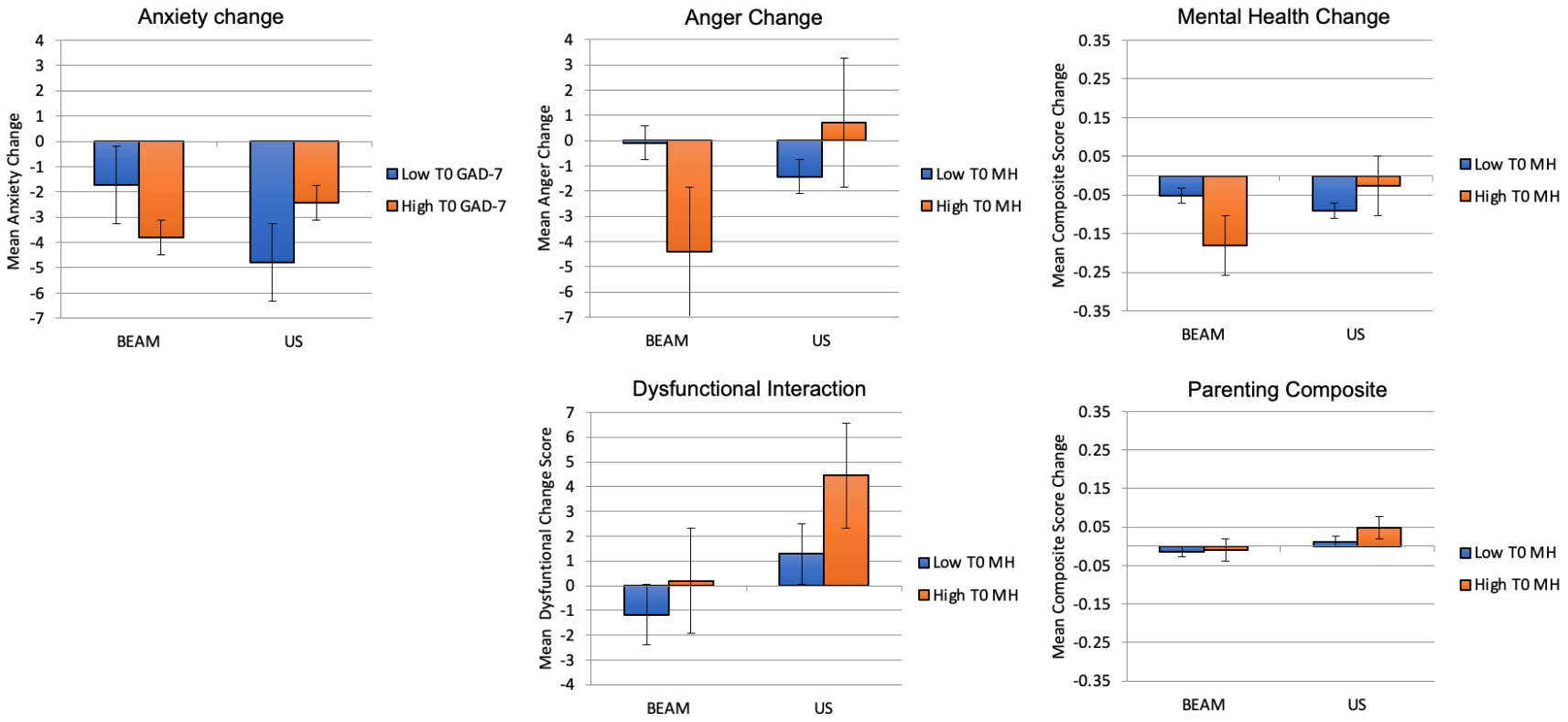
Table 3. Model results for change in outcomes

	Primary Outcomes		Secondary Outcomes						
Estimate (SE)	Depression	Anxiety	Anger	Sleep Problems	Alcohol Misuse	Mental Health	Dysfunctional Interactions	Overreactive Discipline	Harsh Parenting
Control Variables									
Other services	-.090	-.888	-.023	.802	-.219	-.006	-.075	.259	-.001
	(.973)	*(.917)*	(*.677*)	1.156)	*(.292)*	*(.023)*	*(1.158)*	*(.189)*	*(.014)*
Urbanicity	-.314	-1.205	**-1.457***	-.236	-.214	-.033	-1.849	.46	-.019
	(.970)	*(.902)*	***(.678)***	*(1.182)*	*(.293)*	*(.022)*	*(1.162)*	*(.186)*	*(.013)*
Predictors									
Baseline severity	-.102	.214	2.204	-4.550	.026	.036	**8.559**	.736	.082
	(.139)	*(.159)*	2.902)	*5.050)*	*(1.257)*	*(.095)*	**(4.*989*)†**	*(.798)*	*(.057)*
Treatment group	1.357	**8.029***	**4.855†**	-.267	.362	.120	7.598	.935	.074
	(3.284)	***(3.500)***	**(*2.801*)**	*4.873)*	*(1.213)*	*(.092)*	*(4.815)*	*(.770)*	*(.055)*
Moderation									
Baseline severity	-.110	**-.655****	**-9.452***	-1.225	-.855	**-.240†**	**-15.722***	-1.454	**-.157†**
*Treatment group	*(.194)*	***(.232)***	**(*4.205*)**	*7.318)*	*(1.821)*	***(.138)***	***(7.235)***	*(1.157)*	***(.083)***

Note. Other services = reporting accessing other mental health or parenting services in the past three months at T2. Urbanicity = reporting living in a large city. Depression was measured using the PHQ-9, Anxiety was measured using the GAD-7, Anger was measured using the PROMIS Anger scale, Sleep Problems was measured using PROMIS Sleep Disturbance scale, Alcohol Misuse was measured using the AUDIT, the Mental Health composite was measured using an aggregate (PHQ-9, GAD-7, PROMIS Anger and Sleep Disturbance, AUDIT), Dysfunctional Interactions was measured using the P-CDI, Overreactive Discipline was measured using the PS, the Harsh Parenting composite was measured using the aggregate (P-CDI, PS). PHQ-9 and GAD-7 scores from T0 were each used for Baseline severity in Depression and Anxiety models, respectively. The aggregate of PHQ-9 and GAD-7 scores from T0 was used for Baseline severity for all other outcome models. Percent possible scores were used to measure change in outcomes. Unrestricted services (US) is the reference group.

† p < .01 * p < .05 ** p < .01 *** p < .001

Figure 4. Baseline moderation depicted as mean change score by group



Discussion

This clinical trial examined the immediate effects of version 1.2 of the BEAM app-based program, versus unrestricted services, in treating mental health problems and reducing harsh parenting interactions for mothers of toddlers. The intervention took place from March – May 2022, and was designed to provide accessible support for mothers of toddlers managing clinically significant depression and anxiety in the context of the COVID-19 pandemic. For mothers with elevated symptoms at screening, BEAM outperformed US in reducing mental health & harsh parenting symptom composite scores, with specific reductions for anxiety, anger, and dysfunctional parent-child interactions. Symptoms of depression were significantly reduced in both trial arms. We adapted multiple methods based on learning from our pilot RCT trial with improved feasibility metrics and largely replicated effects. Notably, there was strong interest in the program, engagement with families with diverse sociodemographic representation, and improved retention in pre- and post-intervention assessments.

Multiple metrics of maternal mental health problems (i.e., primary and secondary treatment targets) were significantly reduced for BEAM (vs. US) participants for mothers presenting with elevated emotional symptoms at baseline screener. This included significantly greater reductions in mental health composite scores as well as anxiety (primary outcome) and anger (secondary outcome) symptoms, consistent with pilot trial results. Such impacts across diverse emotional problems are consistent with the transdiagnostic therapeutic approach which included semi-structured group therapy and psychoeducation content adapted from evidence-based treatment techniques (The Unified Protocol, Dialectical Behaviour Therapy, Self-Compassion Focused therapy). This is particularly notable given that we sent US participants a tailored list of mental health and parenting resources (e.g., counselling, group therapy, and other

App-based services) in their health jurisdiction, and US participant sought out these services at a high rate (64.8%).

There were no treatment effects or changes over time in alcohol use in this trial. This may reflect low reporting of symptoms at baseline (9.2% had moderate or higher symptoms). [63] It is also possible the lack of treatment effect for alcohol use may be partially explained by the a lack of content targeting substance use or health. [64]. In contrast to the pilot study [30], where the BEAM program did include an additional drop-in telehealth group session on parent and child sleep during the summer break, there were no treatment effects in sleep problems in the current trial. This too could reflect lower base rates, with 40.0% of participants exhibited clinically significant elevations in symptoms. Future interventions may benefit from additional modules specifically targeting sleep drawing from CBT-I for insomnia protocols. [65].

Depression symptoms (primary outcome) were significantly reduced for participants across BEAM and the US control groups. This may reflect the cyclical nature of depression and the timing of our program. Our program started in the winter and ended in summer, in central Canadian provinces where winter weather and darkness can exacerbate seasonal mood symptoms. COVID-19 restrictions were also lifted towards the end of the trial. [66] Additionally, meta-analyses shows that high intensity (i.e., majority of individuals seeking mental health treatment), unrestricted treatment as usual groups rarely outperform active controls in the treatment of depression. [67] This is particularly relevant given the high use of services seen in our control group. It is also possible that the services accessed by the US group aided in depression symptom remission or that the type of light-touch therapeutic intervention used here was insufficient to address depressive symptoms beyond the other resources available, which the US group was encouraged to explore.

The positive impacts of BEAM on reducing harsh parenting (i.e., overreactive discipline and negative parent-child interactions) are particularly important, because harsh parenting is a key pathway through which maternal mental health problems come to negatively impact child health and development. [68,69] Improvements in parental mental health over the course of an intervention can lead to positive changes in child outcomes. [70] The superiority of BEAM over the US control group in reducing harsh parenting suggests a unique role of the BEAM parenting content in improving parenting. BEAM content is specifically tailored to help parents respond in emotionally supportive ways to their young children. BEAM encourages parents to recognize and predict difficult parenting situations, prevent child dysregulated behaviors when possible, and respond in validating ways to toddlers' big emotions (e.g., screaming, crying, clinging). BEAM also teaches parents to avoid engaging with children's emotions or behaviors in ways that increase dyadic dysregulation and conflict

Taken together, these results largely replicate and improve upon prior pilot research with BEAM for mothers of toddlers. [30] Replication includes strong interest and satisfaction with the program, perception that BEAM was a good source of social support, and impacts on a variety of mental health problems. Both trials found a statistically significant treatment effect of BEAM on change in anxiety symptoms indicating that parental anxiety may be responsive to digital intervention. Areas of improvement included trial retention (87 vs 75 %), streamlined participant contact for enrollment coordination, increased attendance in telehealth groups through offering multiple time slots, increased forum engagement, and sending critical reminders to participants via text and email to mitigate participants missing information (e.g., Zoom link for telehealth session). [30] Our results advance the science of digital health interventions for addressing common emotion-related mental health problems. BEAM also shows promise for preventing harsh

parenting in families managing considerable psychosocial risk who are likely to be underserved by existing programs.

Limitations include those inherent to the App-based intervention methods in which we were testing a minimum viable product, as opposed to a more refined technology better aligned with user-experience preferences (e.g. forum functionality, integrated symptom monitoring and group sessions, usage-related push notifications; see [51]). We are planning to improve upon each of these in future program iterations. After attrition, we were slightly underpowered (n = 57 and n = 62 in the intervention and control groups, respectively) to detect treatment effects. However, the trial was adequately powered to examine both depression and anxiety as primary outcomes, consistent with the recruitment protocols. Given the cyclical nature of depression, the seasonality effects of time of year on mood symptoms in our geographical location (e.g., deep cold, long nights) may have affected results.

Across trials, the BEAM intervention has shown positive transdiagnostic impacts on mental health symptoms in addition to positive impacts on parenting. The intervention can be delivered remotely and has the potential to reach traditionally underserved groups who are in need of mental health and parenting support. BEAM produces similar impacts to in-person therapy [29,71], but with lower clinical investments from time, training, and expected costs perspectives, making it highly scalable. BEAM was also developed with best practices including knowledge synthesis, continual improvement, and patient-partner co-development [33], leading to a timely product that parents want. Next steps for the BEAM program include alignment with digital health regulatory standards, improved user interface, and exploring engagement and implementation within existing health systems, community agencies, hospitals, and schools to

understand opportunities to scale-up the program and maximise mental health and economic impacts.

Becoming a parent is an incredibly hopeful time for families, but too often parents face significant and persistent mental health problems during this time of transition. Mental health supports tailored to family-identified needs are critical across child ages. They may improve the lives of families and reduce harsh parenting, with the ultimate goal of improving family quality of life as well as child health and development outcomes for future generations.

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