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# BMJ Open ezPreemie study protocol: a randomised controlled factorial trial testing webbased parent training and coaching with parents of children born very preterm

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#### **ABSTRACT**

Introduction Children born very preterm (VPT: gestational age <32 weeks) are twice as likely to demonstrate behaviour problems such as aggression, non-compliance, temper tantrums and irritability compared with their term-born peers. While behavioural parent training (BPT), also referred to as behaviour therapy is a gold standard for prevention and treatment of childhood problem behaviours, there are limited accessible and effective BPT interventions for families with children born VPT. The purpose of this paper is to describe a multicentre, randomised controlled protocol for a factorial design trial evaluating the independent and combined effects of the ezParent BPT intervention plus brief, weekly coaching calls on parent and child outcomes for families with toddlers born VPT.

Methods and analysis The study employs a 2×2 factorial randomised design. Parents (n=220) of children aged 20-30 months corrected age who were born VPT (<32 weeks) will be recruited from two large metropolitan Neonatal Intensive Care Units follow-up clinics and randomised to one of four conditions: (1) ezParent (2) ezParent +coach, (3) Active control or (4) Active Control +coach. Data on parenting and child behaviour outcomes will be obtained from all participants at baseline and 3, 6 and 12 months postbaseline. All analyses will use an intention-to-treat approach, independent of their actual dose of each intervention.

Ethics and dissemination The study protocol has been approved by The Ohio State University Institutional Review Board (IRB) using a single IRB. Study results will be disseminated through presentations at regional and national conferences, publications in peer-reviewed journals, and sharing research reports with participating families and recruiting sites.

Trial registration number NCT05217615.

### INTRODUCTION

Given remarkable medical progress, the survival rate of very preterm (VPT) infants (gestational age <32 weeks at birth) is 80%-90%. Unfortunately, former VPT

#### STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The ezParent programme—the web-based delivery of the Chicago Parent Programme—is a behavioural parent training programme intentionally created to be culturally relevant for low-income, ethnically diverse parents, who are disproportionately more likely to deliver very preterm infants.
- ⇒ A factorial design evaluates the separate and combined effects of ezParent and coaching calls to inform mechanisms of parent engagement, efficacy outcomes and models of care.
- ⇒ The hybrid approach of ezParent +coach may address some of the personal connection that is lost when traditionally in person programmes transition to a digital format and promotes parent engagement and satisfaction with the programme, without the access issues.
- ⇒ While web-based care delivery has increased exponentially since the COVID-19 pandemic, there exists limitations for populations with little-to-no internet access or other technology-related barriers.

infants (hereafter referred to as children born VPT) are twice as likely to demonstrate behaviour problems such as aggression, non-compliance, temper tantrums and irritability compared with their term-born peers due to unique neurodevelopmental vulnerabilities.<sup>2-9</sup> Preterm birth disrupts the timing of neural development causing structural brain differences and altered structural connectivity to the frontal cortex. The frontal cortex is associated with behavioural inhibition and regulation and related to hyperactivity and poor social behaviour in children born VPT.<sup>7 8 10</sup> While undoubtedly related, behaviour problems and neurodevelopmental delay among children born VPT are distinct entities. <sup>1 2</sup> 10 Investigations that methodologically control for neurodevelopmental functioning continue to



demonstrate elevated rates of behaviour problems and studies of structural brain development describe a distinct 'neuroanatomical basis for behaviour problems' in this population. <sup>2</sup> <sup>10</sup> Despite the burden of behaviour problems in the VPT population, early intervention and neonatal intensive care unit (NICU) follow-up focus almost entirely on identification and treatment of developmental delays and dedicate fewer resources to addressing behaviour. <sup>11–13</sup>

Without treatment, behaviour problems in children born VPT are persistent and can have long-term consequences for family and child functioning. 6 14-16 Behavioural parent training (BPT) is a gold standard for prevention and treatment of child behaviour problems in children born full term. <sup>1718</sup> BPT teaches parents child management skills and positive strategies to promote prosocial child behaviour and enhance the parent-child relationship. 19 Little is known about the use and effect of BPT programmes for the children born VPT with their unique interplay between neurodevelopmental and behavioural functioning.<sup>20 21</sup> In addition, prior studies employing traditional, weekly in-person BPT sessions identify barriers of long waitlists and childcare, logistical and transportation issues. 22 23 These barriers result in only 40% of referred parents receiving services with only one-third of those who receive services completing traditional, in-person, BPT. 24 25 Furthermore, families facing socioeconomic adversity—those at greatest risk for VPT birth and child behaviour problems<sup>26</sup> <sup>27</sup>—are the least likely to complete weekly BPT.<sup>20</sup> Our goal is to develop a widely accessible, culturally sensitive, tailored and effective intervention to address the unmet and unique behavioural needs of parents of children born VPT.

Our previous research and the existing literature support the feasibility and efficacy of BPT and telephone coaching as individual treatment components for families of full-term children. <sup>28–33</sup> The Chicago Parent Programme (CPP) and its web-based application, the ezParent programme, is a BPT programme explicitly designed to be culturally responsive and sensitive for Black and Latinx families across a range of socioeconomic backgrounds and is effective in promoting prosocial child behaviour and improving parenting confidence and behaviour.<sup>30</sup> ezParent was designed to be self-directed to provide parent-controlled access as a feasible and potentially costeffective approach to address challenges in parent participation in face-to-face delivery. 28 34 Weekly coaching calls designed to promote families' use and tailored application of digitally delivered BPTs have demonstrated reductions in behaviour problems for term-born children up to 2 years postintervention. 31 32 However, no existing studies have rigorously evaluated the independent and combined effects of accessible, culturally sensitive BPTs and coaching components with families of children born at term, or, children born VPT.

#### STUDY OBJECTIVES AND HYPOTHESES

The purpose of this study is to test the effects of ezParent and coaching calls on outcomes of parents and children born VPT after 3, 6 and 12 months. Parents (n=220) will be randomised using a 2×2 factorial design to: ezParent +coach, ezParent, Active Control +coach, or Active Control. Our specific objectives and hypotheses for the study are:

- 1. Determine the independent and combined effects of ezParent and coaching calls on parent outcomes. Hypothesis 1: The ezParent and ezParent +coach groups will report greater improvements in parenting skills and self-efficacy and reductions in harsh and negative discipline; and exhibit observed improvements in parenting behaviour versus active control. Hypothesis 2: There will be a synergistic effect of ezParent and coaching calls on parent outcomes such that ezParent +coachwill provide greater benefit than the sum of the main effects of ezParent or coaching calls independently.
- 2. Determine the independent and combined effects of ezParent and coaching calls on child outcomes. Hypothesis 3: The ezParent and ezParent +coach groups will report greater reductions in child behaviour problems and will result in observable improvements in child behaviour versus active control. Hypothesis 4: There will be a synergistic effect of ezParent and coaching calls on child outcomes such that ezParent +coach will provide greater benefit than the sum of the main effects of ez-Parent or coaching calls independently.
- 3. Determine differences in *ez*Parent engagement with and without coaching calls. Engagement will be assessed by frequency (the number of times parents use the programme), activity (proportion of material completed) and duration (amount of time parents use the programme). Hypothesis 5: Relative to the *ez*Parent only group, the *ez*Parent +coach group will exhibit higher engagement with the *ez*Parent curriculum.

# METHODS AND ANALYSIS

### Design

The study employs a 2×2 factorial randomised design, a rigorous and efficient method used to test the main effects and synergistic effects of the intervention components.<sup>35</sup> Parents (n=220) of children age 20–30 months corrected age (CA) who were born VPT will be randomised to one of four conditions. Data will be collected at four time points. The anticipated study start date is June 2022 and completion June 2026.

#### **Eligibility criteria**

The inclusion criteria for parents in this study are that the individual is the parent/legal guardian (referred to as parent) of a child born VPT and 20–30 months CA at enrolment. Because the programme is only in English and web based, parents must speak English and have a smartphone, tablet or computer with internet access.



According to the Pew Research Foundation, 77% of US adults have broadband service at home, 85% have smartphones (96% aged 18–29, 95% aged 30–49), and only 7% do n't use the internet at all.  $^{36}$ 

Parents will be excluded if their children demonstrate a profound developmental and adaptive skill impairment (standard score of 55, 3 SDs below the M, below the first percentile) via parent report on the Vineland Adaptive Behaviour Scale (third edition) Communication or Socialisation Index (see the Measures section).<sup>37</sup> Scores will be based on age appropriate norms for CA. Exclusion criteria are similar to those employed by other BPT programmes with VPT children who do not have the language or social skills to respond to BPT parenting strategies.<sup>20</sup>

#### Sample size calculation

Power estimates for this study used SAS Proc Power (V.9.4). Assuming a two-tailed alpha of 0.05 and a correlation of 0.7 between assessments, we estimate 80% power to detect an effect (ie, interaction or main effects) of d=0.35 with N=196 participants. This effect size is reasonable given effect sizes in general population of online BPT approximating 0.30<sup>38</sup>; effect size estimates in referred populations from meta-analysis for parent-reported child externalising behaviour outcomes range from 0.23 to 0.81. We will recruit 220 participants to account for 10% attrition.

#### **Study setting**

Parents will be recruited from medical centres that care for diverse populations of children born VPT (Nationwide Children's Hospital (NCH), Columbus, OH and Rush University Medical Center (RUMC), Chicago, IL). Both medical centres house NICUs which provide the highest possible level of care in their respective states. The source population at NCH includes patients of the Division of Neonatology which manages >260 NICU beds and cares for preterm children to age 3, with >5000 follow-up visits/year, including ongoing developmental assessment for clinical purposes. The NICU Follow-up Programme at RUMC provides care, including developmental assessment, for VPT infants at 4, 8 and 20 months CA, with 300 follow-up visits/year. While recruitment efforts include participant interaction in hospital-based follow-up clinics, the informed consent process, intervention delivery and data collection will occur remotely, through web-based content and telephone contact. This remote approach allows for maximal participant convenience and aligns with the degree of flexibility that has become a standard societal expectation since the COVID-19 pandemic.

#### Recruitment

Our team has developed multiple ways to contact parents of eligible VPT children. First, parents will be recruited in-person by trained research assistants (RAs) at scheduled NICU follow-up clinic appointments at NCH and RUMC. RAs will receive information when an age-eligible child is

scheduled for a visit. RAs will approach families, provide information regarding the study, assess participation interest, schedule an in-person or virtual appointment to conduct eligibility screening and to initiate the informed consent process and baseline data collection. Scheduling a separate appointment for eligibility screening, consent and baseline data collection ensures minimal disruption of clinical protocols which protects time for the participants' clinical needs and promotes engagement of clinic staff. Second, information cards and posters will advertise the study in clinics. Ongoing engagement of clinic staff will occur via information sessions. If recruitment falls below the expected targets, we will employ a third strategy of email and postal mailings to eligible families from NCH and RUMC to inform them of the study and provide methods for them to learn more about and/or participate in the study.

Finally, more than one parent or caregiver may participate, but each family will designate one parent as the 'primary' parent for data analysis. We will test the impact of multiple parents with exploratory analyses testing moderation by single/dual parent participation.

#### **Randomisation and interventions**

Using block randomisation and a 1:1 allocation ratio, participants will be randomised into (1) ezParent (2) ezParent +coach, (3) Active Control or (4) Active Control +coach.

#### ezParent

The ezParent programme is a digital adaptation of the group-based CPP. The CPP is an evidence-based, 12-session programme for parents of young children. <sup>39</sup> ezParent was developed to be consistent with the underlying theory and core components of the CPP<sup>34</sup> and uses 28 strategies in 6 modules to promote skill development in parents. Each ezParent module includes: a video narrator describing parenting strategies; video vignettes of parents and children as examples of how parenting strategies work; reflection questions following each vignette; interactive activities for parents to complete; knowledge questions to assess parent understanding of the strategies; and practice assignments. Parents will be instructed to complete the interactive modules over 10 weeks. In a previous study, average module completion time was 37 min. <sup>28</sup>

To tailor for parents of children born VPT, developmental *tips* are included in *ez*Parent. *Tips* describe how parenting strategies can be modified to address neurodevelopmental delays common in VPT children. The tips are informed by findings from our feasibility study<sup>33</sup> and literature of neurodevelopmental functioning, parental psychological distress and sensitive parenting in VPT children. <sup>40</sup> <sup>41</sup>

#### Active control: Health-e kids

Health-*e* Kids is a web-based programme to match attention and technology use, allow for testing of the interaction effect, and to estimate a comparison of participation



with the ezParent condition. Health-e Kids is an adaptation of a digital application used in our previous studies. 42 43 The programme includes health and safety information typically provided during well-child or NICU follow-up visits but unrelated to parenting or child development and behaviour. Six topic areas are: Immunisations, Common Medical Illnesses, Nutrition, Oral Health, and Indoor and Outdoor Safety. The programme includes digital resources, handouts, videos and websites. Parents will be instructed to review each topic over 10 weeks to match the dose and timing of contact that the ezParent group will receive.

#### Coaching

The brief (~15 min) weekly telephone coaching calls gives parents an opportunity to receive clarification of intervention content (ezParent or Health-e Kids), encouragement and reinforcement of programme completion (accountability), and support tailoring of programme content for their child. Coaches will be assigned to ezParent or Health-*e* Kids, with no crossover to avoid contamination. The coaching calls are guided by a semistructured script to support parent learning and motivation. Each call will include an opportunity for parents to identify and discuss questions regarding the materials and content received in their respective groups, identify challenges and strategies to overcome barriers for programme completion, and follow-up on discussion points from previous calls. In both groups, coaches will have access to a digital usage tool (including timestamp of last log-in, last page completed, content completed) to guide the discussion. Calls are scheduled weekly for 10 weeks with a 1 month booster call. If a parent completes the programme content in fewer than 10 weeks, coaching calls will continue as planned. Coaches will track all calls and record case notes that include structural aspects of the call and thematic content. All calls will be recorded.

#### **Intervention fidelity**

We will have a high level of consistency in delivery of intervention components as the content in ezParent and Health-*e* Kids is standardised and web delivered. To assure delivery fidelity (adherence to and competence with the coaching protocol), all coaches receive standardised training and coaching supervision. Training includes content on social and emotional development in children born VPT children, common issues and developmental and social concerns, medical concerns in this population, and active listening, problem-solving and facilitation skills. 44 Coaches will be assigned to one group and receive standardised training on the intervention content. After each call, the coach will assess their performance using an assessment as a measure of adherence to the protocol. The assessment identifies whether the coach addressed: parental concerns with their child, parent questions regarding the materials and content received in their intervention, identification of potential barriers and strategies to complete the content, and follow-up

on discussion points from previous calls. All calls will be recorded and 15% will be audited to evaluate fidelity and to determine if any further training is required.

To assess programme receipt (parent engagement and satisfaction), digital tracking of use of the ezParent and Health-e Kids control will be ongoing throughout the study period. Digital tracking will provide a measure of intervention engagement. Three usage data points will be collected to assess engagement: (1) frequency (each time the parent uses the programme); (2) activity (proportion of material completed (# of pages and activities viewed) and (3) duration (amount of time parent uses the programme). Usage data will be collected throughout the study period and accessible via the usage tool. At the end of each module (ezParent and Health-e Kids), parents rate how helpful they found the module on a 4-point scale (not helpful to very helpful). In the coach condition, after each call, coaches will rate parent engagement (interest and involvement) in the coaching call on a 4-point scale (no engagement to high engagement). At 3 months postbaseline, participant satisfaction with the format and content of the assigned intervention will be assessed using an end of programme survey.

#### **Variables and measures**

#### Eligibility screen

The Vineland-3 eligibility screen (Communication and Socialisation Indices) will be individually administered via semi-structured interview with the RA and will assess child functional and adaptive skills.<sup>37</sup>

#### Covariates and demographics

Demographics (eg, age, race/ethnicity, household structure) will be collected using a 21-item inventory. Income and economic hardship will be assessed using three questions assessing personal and household income and a seven-item economic hardship scale. Neighbourhood and community characteristics will be collected using 14 items from the National Survey of Children's Health. The family home environment, specifically level of environmental confusion and disorganisation in the home, will be measured using the 15-item Confusion, Hubbub and Order Scale. Finally, we will assess general parent perception of life stress using the 10-item Perceived Stress Scale.

## Outcome measures

#### Parent outcomes

Parenting behaviour is assessed using the Parenting Styles Dimensions Questionnaire (PSDQ) and the follow-through on discipline scale of the Parent Questionnaire (PQ). The PSDQ is a 32-item questionnaire that is grouped into three styles and seven dimensions of parenting behaviours and styles. <sup>49</sup> The follow-through on discipline scale of the PQ has 6-items related to parents' perception of their behaviour in following through on instructions and discipline. <sup>50</sup>



The Parenting Sense of Competence Scale has 17 items, with 2 subscales: satisfaction (liking of the parenting role) and efficacy (perceived competence in the parenting role). <sup>51</sup> <sup>52</sup> Parenting stress will be measured using the Parenting Stress Index-Short Form (PSI-SF). <sup>53</sup> The PSI-SF is a 36-item survey with three scales: parental distress, parent–child dysfunction, difficult child. <sup>54</sup>

#### Child outcomes

The Child Behaviour Checklist 1½–5 (CBCL) is a 99-item parent-report measure of frequencies of problem behaviours of children aged 1½–5.<sup>55</sup> The CBCL has two scales, Externalising (disruptive behaviour problems, aggression and hyperactivity) and Internalising (anxiety, inhibition, depression and social withdrawal). The CBCL is a well-cited assessment of behaviour among VPT children. The Eyberg Child Behaviour Inventory is a 36-item measure designed to measure the presence and intensity of problem behaviour. The control of the

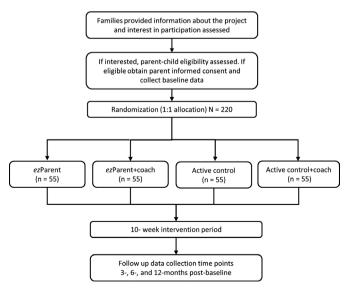
#### Parent-child observation

Observed parentchild interactions as objective measures of parenting and child behaviour will be assessed from video recorded play sessions coded using the Dyadic Parent–Child Interaction Coding System (DPICS).<sup>58</sup> The DPICS is a behavioural coding system used to evaluate parent-child interactions. Video sessions include a 15 min play and clean up semistructured task with the parent and child. DPICS coding categories will focus on parenting and child behaviours including parents' use of child-centred play, parents' commands and child follow-through on commands.

#### Data collection, management, analysis

#### Data collection and visits

See figure 1 for participant flow through the study. All questionnaire measures will be administered as a computer assisted self-interviews through Research Electronic Data



**Figure 1** Participant flow through recruitment and study participation.

Capture (REDCap).<sup>59 60</sup> RAs will be available (in person or by phone) if participants have technical issues or require clarification about survey items. RAs will follow up to clarify missing items or illogical survey responses. Parents will receive a total of US\$165 incentive across the study. Parents do not receive incentives for intervention completion.

At baseline, parents will complete informed consent procedures and all baseline survey measures in a face-to-face interview, either in person or virtually (online supplemental material for consent form). At completion of baseline surveys, parents will be informed of their random group assignment. Randomisation occurs at the individual level immediately following completion of the baseline interview using the randomisation module in REDCap concealed from all study. To decrease the risk for bias, the RA will be naïve to the randomisation group until after baseline surveys are completed. In addition, follow-up data collection are participant self-administered.

The RA will provide standardised training on the use of the assigned digital intervention (ezParent or Health-e Kids control). All parents will receive a digital manual describing how to use the programme and contact information for technical issues or questions. The RA will schedule the first coaching call for parents in the coaching groups (ezParent +coach or Health-e Kids+coach). After the 10-week intervention period (3 months postbaseline) all participants will complete outcome measures, an end of programme survey corresponding to their intervention group, and videorecorded parent-child interaction for DPICS coding. Finally, parents will complete data collection at 6-month post baseline and 1-year postbaseline. See table 1 for study measures/variables and collection schedule.

#### Data management

REDCap will be used to manage recruitment, scheduling and tracking.  $^{59\ 60}$  Data exported from REDCap (using study ID variables) will be stored on secured servers and backed up regularly. SAS will be used for data cleaning, management and analysis. Distributions will be examined for non-normality and outliers and transformed if necessary. Outcome measures that cannot be transformed to achieve normality will be analysed by appropriate generalised linear models in SAS. All statistical tests will use  $\alpha{=}0.05.$ 

#### Statistical methods

All analyses will use an intention-to-treat approach, where participants are analysed according to the treatment group assigned and independent of their actual dose of each intervention. Analyses for aims 1 and 2 will employ multilevel mixed models with repeated observations (baseline, 3, 6 and 12 months postbaseline) nested within participants. Three parameters for the factorial design will be included in the models: (1) exParent main effect, (2) Coach main effect and (3) exParent x Coach interaction effect.



	Measure/variable	T1	T2	Т3	T4
Screen	Vineland-3	Χ			
Control	Demographics	Χ			
	Income and economic hardship	Χ			
	Neighbourhood and Community Characteristics	Χ			
	Confusion, Hubbub and Order Scale	Χ	Χ	Х	Х
	Perceived Stress Scale	Χ	Χ	Х	Х
Parent outcomes	Parenting Styles Dimension Questionnaire	Χ	Χ	Х	Χ
	Parenting Questionnaire (Follow-Through Scale)	Χ	Χ	Х	Х
	Parenting Sense of Competence Scale	Χ	Χ	Х	Х
	Parenting Stress Index-Short Form	Χ	Χ	Х	Χ
	Dyadic Parent-Child Interaction Coding System (DPICS)		Χ		
Child outcomes	Child Behaviour Checklist 1 1/2-5 (parent report)	Χ	Χ	Х	Х
	Eyberg Child Behaviour Inventory (parent report)	Χ	Χ	Х	Х
	DPICS		Χ		

Time of assessments (in months from baseline) and interactions of time with the factorial design parameters will be included in the models. Potential covariates in the multilevel mixed models are in table 1. All models will control for child sex and study site. Exploratory analyses will examine moderation of treatment effects by relevant constructs (eg, child sex, family size/composition and intervention participation) and baseline levels of child behaviour problems and parenting behaviours.

Time can be handled flexibly with multilevel mixed models, 61 allowing us to model the hypothesised patterns of change over time that deviate from linear or quadratic patterns. Aim 1 tests the main and interaction effects of ezParent and coaching calls on change over time in parent outcomes (table 1). Significant ezParent  $\times$  Time, Coach  $\times$  Time and ezParent  $\times$  Coach  $\times$ Time interaction effects will provide evidence of intervention main and interaction effects, respectively. Aim 2 tests the main and interaction effects of ezParent and coaching calls on change over time in child outcomes (table 1). Significant ezParent × Time, Coach × Time, and ezParent × Coach × Time interaction effects will provide evidence of intervention main and interaction effects, respectively. Aim 3 examines differences in ezParent engagement with or without coaching calls. Intervention engagement will be assessed by frequency (the number of times parents use the programme), activity (proportion of material completed) and duration (amount of time parents use the programme). Using only data from those participants in the ezParent and ezParent +coach cells, an analysis of covariance will be used to test differences in ezParent engagement by coaching group, controlling for covariates related to engagement and study site.

#### Patient and public involvement

Patients or the public were not involved in the design of this clinical trial or in the plans for study conduct, reporting or dissemination.

#### **ETHICS AND DISSEMINATION**

The Ohio State University institutional review board approved the study protocol. The study was determined to have minimal risk for participants. All participating parents will sign informed consent for themselves and their child. Study participation is voluntary and will not replace any clinical referrals or treatment options for the family. All stored data will be deidentified and password protected. The study will be implemented according to the Consolidated Standards of Reporting Trials statement. Plans for the sharing research findings include disseminating the results through presentations at regional and national conferences, publications in peer-reviewed journals and sharing research reports with participating families and recruiting sites.

#### SIGNIFICANCE AND OUTLOOK

Despite evidence of higher rates of behaviour problems in children born VPT and evidence for the effectiveness of BPT delivered in-person, there has been little to no empirical investigation of hybrid delivery of digital BPT as a potentially accessible, efficacious and scalable intervention for parents of children born VPT. Combining exParent with coaching calls for this highly vulnerable population addresses limitations of the current evidence and provides opportunities to inform prevention and intervention models for BPT. Furthermore, coaching



calls in conjunction with ezParent (ezParent +coach) provides the ability to tailor and adapt programme content to the unique neurodevelopmental needs of the VPT population. Additionally, coaching calls provide the deeper, personal connection afforded by individual and group BPT programmes including CPP and Triple P, which promote parent engagement and programme satisfaction, while mitigating access issues. The hybrid approach of ezParent +coach may address some of the personal connection that is inevitably lost when traditionally in-person programmes transition to a fully self-administered, digital formats.

This study has practical implications. ezParent and coaching calls could be integrated into routine medical care for the VPT population. NICU follow-up clinics provide regular care and assessments for VPT infants in the first years of life, 11 12 and may provide an ideal venue for families to solicit advice and receive intervention for child behaviour problems and parenting challenges. In addition, while this study aims to address specific needs of the VPT population, other paediatric medical conditions associated with disproportionately elevated rates of behaviour problems and neurodevelopmental delays could similarly benefit from a tailored, flexible and accessible BPT programme. 63-66 As such, the present investigation may pave the way for a nimble intervention for a number of populations with chronic medical conditions. Furthermore, if parents and children benefit from a low intensity, easily administered intervention, such as ezParent±coaching calls, there is potential for a decreased need for more intensive face-to-face interventions, thus lowering cost and lessening the burden on families and the behavioural healthcare system overall. Finally, providing low intensity interventions might serve to promote 'buyin' and reduce stigma surrounding the broad concept of behavioural health services, thereby priming parents to be open to pursuing other behavioural health services in the future.

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#### Collaborators n/a.

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and protocols and assisted in the updates and development of the Health-e Kids programme content. All authors contributed to the writing and revising of the paper and approved the final submission.

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#### **REFERENCES**

- 1 Patel RM, Rysavy MA, Bell EF, et al. Survival of infants born at periviable gestational ages. Clin Perinatol 2017;44:287–303.
- 2 Delobel-Ayoub M, Kaminski M, Marret S, et al. Behavioral outcome at 3 years of age in very preterm infants: the EPIPAGE study. Pediatrics 2006;117:1996–2005.
- 3 Pascal A, Govaert P, Oostra A, et al. Neurodevelopmental outcome in very preterm and very-low-birthweight infants born over the past decade: a meta-analytic review. Dev Med Child Neurol 2018;60:342–55.
- 4 Gerstein ED, Woodman AC, Burnson C, et al. Trajectories of externalizing and internalizing behaviors in preterm children admitted to a neonatal intensive care unit. J Pediatr 2017;187:111–8.
- 5 Gray RF, Indurkhya A, McCormick MC, Prevalence MMC. Prevalence, stability, and predictors of clinically significant behavior problems in low birth weight children at 3, 5, and 8 years of age. Pediatrics 2004;114:736–43.
- 6 Campbell SB, Shaw DS, Gilliom M. Early externalizing behavior problems: toddlers and preschoolers at risk for later maladjustment. *Dev Psychopathol* 2000;12:467–88.
- 7 Limperopoulos C, Chilingaryan G, Sullivan N, et al. Injury to the premature cerebellum: outcome is related to remote cortical development. Cereb Cortex 2014;24:728–36.
- 8 Rogers CE, Lean RE, Wheelock MD, et al. Aberrant structural and functional connectivity and neurodevelopmental impairment in preterm children. J Neurodev Disord 2018;10:38.
- 9 Inder TE, Volpe JJ. Mechanisms of perinatal brain injury. Semin Neonatol 2000:5:3–16.
- 10 Rogers CE, Anderson PJ, Thompson DK, et al. Regional cerebral development at term relates to school-age social-emotional development in very preterm children. J Am Acad Child Adolesc Psychiatry 2012;51:181–91.

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- 11 Bockli K, Andrews B, Pellerite M, et al. Trends and challenges in United States neonatal intensive care units follow-up clinics. J Perinatol 2014;34:71–4.
- 12 Kuppala VS, Tabangin M, Haberman B, et al. Current state of highrisk infant follow-up care in the United States: results of a national survey of academic follow-up programs. J Perinatol 2012;32:293–8.
- 13 Delobel-Ayoub M, Arnaud C, White-Koning M, et al. Behavioral problems and cognitive performance at 5 years of age after very preterm birth: the EPIPAGE study. Pediatrics 2009;123:1485–92.
- 14 Daly BP, Creed T, Xanthopoulos M, et al. Psychosocial treatments for children with attention deficit/hyperactivity disorder. Neuropsychol Rev 2007:17:73–89.
- 15 Foster EM, Connor T. Public costs of better mental health services for children and adolescents. *Psychiatr Serv* 2005;56:50–5.
- 16 Currie J, Stabile M. Child mental health and human capital accumulation: the case of ADHD. J Health Econ 2006;25:1094–118.
- 17 Pearl ES. Parent management training for reducing oppositional and aggressive behavior in preschoolers. Aggress Violent Behav 2009;14:295–305.
- 18 Barlow J, Bergman H, Kornør H, et al. Group-Based parent training programmes for improving emotional and behavioural adjustment in young children. Cochrane Database Syst Rev 2016:CD003680.
- 19 Feinfield KA, Baker BL. Empirical support for a treatment program for families of young children with externalizing problems. J Clin Child Adolesc Psychol 2004;33:182–95.
- 20 Bagner DM, Sheinkopf SJ, Vohr BR, et al. Parenting intervention for externalizing behavior problems in children born premature: an initial examination. J Dev Behav Pediatr 2010;31:209–16.
- 21 Schappin R, Wijnroks L, Uniken Venema M, et al. Primary care triple P for parents of NICU graduates with behavioral problems: a randomized, clinical trial using observations of parent-child interaction. BMC Pediatr 2014;14:305.
- 22 NSCH 2011/12. Received mental healthcare/counseling during the past 12 months, nationwide. Available: http://www.childhealthdata. org/browse/survey/results?q=2504&r=1 [Accessed 19 Jun 2017].
- 23 Forgatch MS, Patterson GR, Gewirtz AH. Looking forward: the promise of widespread implementation of parent training programs. Perspect Psychol Sci 2013;8:682–94.
- 24 Bagner DM, Graziano PA. Barriers to success in parent training for young children with developmental delay: the role of cumulative risk. Behav Modif 2013;37:356–77.
- 25 Garvey C, Julion W, Fogg L, et al. Measuring participation in a prevention trial with parents of young children. Res Nurs Health 2006:29:212–22.
- 26 Räisänen S, Gissler M, Saari J, et al. Contribution of risk factors to extremely, very and moderately preterm births - register-based analysis of 1,390,742 singleton births. PLoS One 2013;8:e60660.
- 27 Behrman RE, Butler AS. Outcomes I of M (US) C on UPB and AH. Sociodemographic and Community Factors Contributing to Preterm Birth. National Academies Press, 2007. https://www.ncbi.nlm.nih. gov/books/NBK11388/
- Breitenstein SM, Brager J, Ocampo EV, et al. Engagement and adherence with ezPARENT, an mHealth parent-training program promoting child well-being. Child Maltreat 2017;22:295–304.
- 29 Breitenstein SM, Fogg L, Ocampo EV, et al. Parent use and efficacy of a self-administered, tablet-based parent training intervention: a randomized controlled trial. JMIR Mhealth Uhealth 2016;4:e36.
- 30 Gross D, Belcher HME, Budhathoki C, et al. Reducing preschool behavior problems in an urban mental health clinic: a pragmatic, non-inferiority trial. J Am Acad Child Adolesc Psychiatry 2019;58:572–81.
- 31 Taylor TK, Webster-Stratton C, Feil EG, et al. Computer-based intervention with coaching: an example using the incredible years program. Cogn Behav Ther 2008;37:233–46.
- 32 Sourander A, McGrath PJ, Ristkari T, et al. Internet-assisted parent training intervention for disruptive behavior in 4-year-old children: a randomized clinical trial. JAMA Psychiatry 2016;73:378–87.
- 33 Greene MM, Patra K, Czyzewski P, et al. Adaptation and acceptability of a digitally delivered intervention for parents of very low birth weight infants. Nurs Res 2020;69:S47–56.
- 34 Breitenstein SM, Shane J, Julion W, et al. Developing the eCPP: adapting an evidence-based parent training program for digital delivery in primary care settings. Worldviews Evid Based Nurs 2015;12:31–40.
- 35 Collins LM, Dziak JJ, Kugler KC, et al. Factorial experiments: efficient tools for evaluation of intervention components. Am J Prev Med 2014;47:498–504.
- 36 Perrin A. Mobile technology and home broadband 2021 Pew Research Center: Internet, Science & Tech; 2021. https://www. pewresearch.org/internet/2021/06/03/mobile-technology-and-home-broadband-2021/ [Accessed 7 Feb 2022].

- 37 Sparrow S, Cicchetti D, Saulnier C. Vineland Adaptive Behavior Scales, third edition (Vineland - 3. 3rd. Bloomington: MN:Pearson, 2016.
- 38 Thongseiratch T, Leijten P, Melendez-Torres GJ. Online parent programs for children's behavioral problems: a meta-analytic review. Eur Child Adolesc Psychiatry 2020;29:1555–68.
- 39 Gross D, Garvey C, Julion W, et al. Efficacy of the Chicago parent program with low-income African American and Latino parents of young children. Prev Sci 2009;10:54–65.
- 40 Forcada-Guex M, Borghini A, Pierrehumbert B, et al. Prematurity, maternal posttraumatic stress and consequences on the motherinfant relationship. Early Hum Dev 2011;87:21–6.
- 41 Zelkowitz P, Papageorgiou A, Bardin C, et al. Persistent maternal anxiety affects the interaction between mothers and their very low birthweight children at 24 months. Early Hum Dev 2009;85:51–8.
- 42 Breitenstein SM, Fehrenbacher C, Holod AF, et al. A randomized trial of digitally delivered, self-administered parent training in primary care: effects on parenting and child behavior. J Pediatr 2021;231:207–14.
- 43 Breitenstein SM, Schoeny M, Risser H, et al. A study protocol testing the implementation, efficacy, and cost effectiveness of the ezParent program in pediatric primary care. Contemp Clin Trials 2016;50:229–37.
- 44 Nezu AM, Nezu CM, McMurran M. Problem-Solving therapy. In: general principles and empirically supported techniques of cognitive behavior therapy. Hoboken, NJ, US: John Wiley & Sons Inc, 2009: 500–5.
- 45 Takeuchi DT, Williams DR, Adair RK. Economic stress in the family and children's emotional and behavioral problems. *Journal of Marriage and the Family*1991;53:1031–41.
- 46 Blumberg SJ, Foster EB, Frasier AM. Design and operation of the national survey of children's health, 2007. Vital and health statisticsSer1, Programs and collection procedures 2012;55:1–149.
- 47 Matheny AP, Wachs TD, Ludwig JL, et al. Bringing order out of chaos: psychometric characteristics of the confusion, hubbub, and order scale. J Appl Dev Psychol 1995;16:429–44.
- 48 Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. *J Health Soc Behav* 1983;24:385–96.
- 49 Robinson CC, Mandleco B, Olsen SF. The Parenting Styles and Dimensions Questionnaire (PSDQ). In: Perlutter BF, Touliatos J, Holden GW, eds. *Handbook of family measurement techniques*. Thousand Oaks: Sage.
- 50 McCabe KM, Clark R, Barnett D. Family protective factors among urban African American youth. J Clin Child Psychol 1999;28:137–50.
- 51 Ohan JL, Leung DW, Johnston C. The parenting sense of competence scale: evidence of a stable factor structure and validity. Can J Behav Sci 2000;32:251–61.
- 52 Johnston C, Mash EJ. A measure of parenting satisfaction and efficacy. J Clin Child Psychol 1989;18:167–75.
- 53 Abidin R. Parenting stress index. 3rd. Odessa: FL: Psychological Assessment Resources, 1995.
- 54 Roggman LA, Moe ST, Hart AD, et al. Family leisure and social support: relations with parenting stress and psychological well-being in head start parents. Early Child Res Q 1994;9:463–80.
- 55 Achenbach TM, Becker A, Döpfner M, et al. Multicultural assessment of child and adolescent psychopathology with ASEBA and SDQ instruments: research findings, applications, and future directions. J Child Psychol Psychiatry 2008;49:251–75.
- 56 Bröring T, Oostrom KJ, van Dijk-Lokkart EM, et al. Attention deficit hyperactivity disorder and autism spectrum disorder symptoms in school-age children born very preterm. Res Dev Disabil 2018;74:103–12.
- 57 Eyberg S, Pincus D. Eyberg child behavior inventory and Sutter-Eyberg student behavior Inventory-revised: professional manual, 1999.
- 58 Eyberg SM, Nelson MM, Ginn NC. Dyadic Parent-Child Interaction Coding System: Comprehensive Manual for Research and Training. fourth edition. PCIT International, Inc, 2013.
- 59 Harris PA, Taylor R, Minor BL, et al. The REDCap Consortium: building an international community of software platform partners. J Biomed Inform 2019;95:103208.
- 60 Harris PA, Taylor R, Thielke R, et al. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009;42:377–81.
- 61 Singer JD, Willett JB, Willett JB. Applied longitudinal data analysis: Modeling change and event occurrence. Oxford university press, 2003.
- 62 Yalom ID. The theory and practice of group psychotherapy. Basic books (AZ), 1995.



- 63 Grieco J, Pulsifer M, Seligsohn K, et al. Down syndrome: cognitive and behavioral functioning across the lifespan. Am J Med Genet C Semin Med Genet 2015;169:135–49.
- 64 Cassidy AR, White MT, DeMaso DR, et al. Executive function in children and adolescents with critical cyanotic congenital heart disease. *J Int Neuropsychol Soc* 2015;21:34–49.
- 65 Hardiman RL, McGill P. How common are challenging behaviours amongst individuals with fragile X syndrome? A systematic review. Res Dev Disabil 2018;76:99–109.
- 66 Liamlahi R, von Rhein M, Bührer S, et al. Motor dysfunction and behavioural problems frequently coexist with congenital heart disease in school-age children. Acta Paediatr 2014;103:752–8.