BMJ Open Effectiveness and scalability of an electronic patient-reported outcome measure and decision support tool for family-centred and participation-focused early intervention: PROSPECT hybrid type 1 trial protocol

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To cite: Kaelin V, Villegas V, Chen Y-F, *et al.* Effectiveness and scalability of an electronic patient-reported outcome measure and decision support tool for family-centred and participation-focused early intervention: PROSPECT hybrid type 1 trial protocol. *BMJ Open* 2022;**12**:e051582. doi:10.1136/bmjopen-2021-051582

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2021-051582>).

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Received 24 March 2021
Accepted 01 December 2021

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ABSTRACT

Introduction Early intervention (EI) endorses family-centred and participation-focused services, but there remain insufficient options for systematically enacting this service approach. The Young Children's Participation and Environment Measure electronic patient-reported outcome (YC-PEM e-PRO) is an evidence-based measure for caregivers that enables family-centred services in EI. The Parent-Reported Outcomes for Strengthening Partnership within the Early Intervention Care Team (PROSPECT) is a community-based pragmatic trial examining the effectiveness of implementing the YC-PEM e-PRO measure and decision support tool as an option for use within routine EI care, on service quality and child outcomes (aim 1). Following trial completion, we will characterise stakeholder perspectives of facilitators and barriers to its implementation across multiple EI programmes (aim 2).

Methods and analysis This study employs a hybrid type 1 effectiveness-implementation study design. For aim 1, we aim to enrol 223 caregivers of children with or at risk for developmental disabilities or delays aged 0–3 years old that have accessed EI services for three or more months from one EI programme in the Denver Metro catchment of Colorado. Participants will be invited to enrol for 12 months, beginning at the time of their child's annual evaluation of progress. Participants will be randomised using a cluster-randomised design at the EI service coordinator level. Both groups will complete baseline testing and follow-up assessment at 1, 6 and 12 months. A generalised linear mixed model will be fitted for each outcome of interest, with group, time and their interactions as primary fixed effects, and adjusting for child age and condition severity as secondary fixed effects. For aim 2, we will conduct focus groups with EI stakeholders (families in the intervention group, service coordinators and other service providers in the EI programme, and programme leadership) which will be analysed thematically to explain aim 1 results and identify supports and remaining barriers to its broader implementation in multiple EI programmes.

Strengths and limitations of this study

- The broad range of activities the Young Children's Participation and Environment Measure covers might support relevance of the tool across a variety of early intervention (EI) eligible families.
- Continuous stakeholder engagement and site collaboration may strengthen intervention quality, protocol adherence and completion of the planned research.
- Due to the COVID-19 pandemic, caregivers might be better able to appraise their child's participation at home as compared with community.
- Due to the COVID-19 pandemic, there might be more challenges recruiting families due to increased challenges with accessing EI services.
- Limiting the inclusion criteria to English-speaking families may limit generalisability of the results to a subset of families that are enrolled in EI.

Ethics and dissemination This study has been approved by the institutional review boards at the University of Illinois at Chicago (2020-0555) and University of Colorado (20-2380). An active dissemination plan will ensure that findings have maximum reach for research and practice.
Trial registration number NCT04562038.

INTRODUCTION

Early intervention (EI) endorses a family-centred approach to designing and enacting the individualised family service plan (IFSP). According to a family-centred care approach, families are formal members of their child's EI team and are expected to engage in shared decision making about the design and enactment of their child's EI service plan.^{1,2} Family

engagement in shared decision-making can be achieved by intentionally leveraging family expertise about their care priorities and potential supports, barriers and strategies for goal attainment.

Electronic patient-reported outcome (e-PRO) measures are relevant tools to engage families in the EI service context, as they offer a means to systematically collect and integrate the family perspective about service quality and outcomes to supplement routine EI practitioner assessments.³ Additionally, EI programmes with electronic data capture systems can use e-PROs to: (1) expedite and expand provider reach in assessing the needs of individual families and (2) aggregate data across families to examine trends in EI service quality and outcomes over time for continuous quality improvement of EI services.^{4–6}

The development of the IFSP at the child's annual meeting is the earliest and one of the most meaningful opportunities to foster family engagement using patient-reported measures.^{7,8} The IFSP gets developed following EI eligibility determination. The service coordinator first conducts a family assessment via interview; then, the service coordinator, family, and EI provider use the results of the eligibility evaluation and family assessment to develop the IFSP, a written document listing the EI services (eg, occupational therapy, physical therapy) that will be provided and the target functional outcomes of interest. This IFSP is reviewed and revised on at least an annual basis during the entirety of the time the child is active in EI services. This process requires collaboration between families and providers to visualise a preferred future, develop mutually agreed on goals accordingly, and engage in shared decision-making to implement and evaluate intervention(s) for goal attainment.^{7,8} The use of e-PRO measures can scale to multiple programmes within the broader EI service system, giving families an online venue to organise and communicate their expertise and share in decisions as a full member of their child's EI team.

The Young Children's Participation and Environment Measure (YC-PEM) is an evidence-based e-PRO that was developed with provider and family input.^{9–11} It provides individual caregivers with a valid, reliable and feasible way to comprehensively communicate information about their child's current participation in valued activities and areas of unmet participation need.^{12–15} The YC-PEM electronic patient-reported outcome (e-PRO) yields a brief summary of family responses in the form of a report that can be shared with EI team members ahead of the child's annual IFSP meeting. The information in this report can integrate with standardised processes used to facilitate IFSP meetings, thereby helping to further structure provider–parent communication around intervention priorities and goal attainment strategies.^{16–19}

The YC-PEM e-PRO holds promise in improving EI service quality in two ways: (1) expediting and expanding EI provider reach for family-centred and participation-focused service design in partnership with individual families; and (2) aggregating the YC-PEM e-PRO data to

examine trends in participation over time as a function of EI service use for groups of families.^{13,20,21} It is therefore a promising electronic health systems intervention to strengthen the parent–practitioner relationship and equip programmes with a common data element for conducting robust patient-centred outcomes research to drive quality improvement efforts.^{22,23} Yet, it is not known, whether the YC-PEM e-PRO is a valuable option for implementation within the context of a routine EI workflow.

The Consolidated Framework for Implementation Research therefore guided our foundational efforts to explore the trialability of implementing the YC-PEM e-PRO in an EI service context.²⁴ We conducted two single-arm pilot studies to examine the tool's feasibility, acceptability, and value when implemented into an EI clinical workflow.^{13,14,21} We first tested the feasibility of the YC-PEM e-PRO within a small university-affiliated EI programme. Results indicated that the YC-PEM e-PRO could detect families' desire for change in their child's participation, and aggregate data could be used to show a significant association between EI service intensity and the child's level of participation in valued home activities.¹³ However, feasibility was mixed, and EI service providers suggested that the YC-PEM e-PRO be embedded in a child's annual IFSP meeting to improve its acceptability.¹³ We then transitioned to a larger clinical context (ie, a large non-university affiliated EI programme) to examine the feasibility of the revised use of the YC-PEM e-PRO, integrating feedback from the prior study. For this second pilot study, caregivers completed the YC-PEM e-PRO in preparation for their child's IFSP meeting. Preliminary evidence supported the feasibility (80% completion rate; mean completion time of 21.3 min vs 45–120 min for usual care), acceptability (>50% of families found it helpful, regardless of caregiver education or family income), and value of the YC-PEM e-PRO option (64% of families viewed their responses to share with other members of their child's EI team).¹⁴

Results of these prior two pilot research phases suggested the need to further tailor this intervention, strengthen stakeholder engagement, and plan for more rigorous scientific methods to build its evidence base.^{13,14,25,26} Therefore, for this current protocol, we adapted the YC-PEM e-PRO to the EI service context in two ways. First, the YC-PEM e-PRO was paired with a program-specific decision support tool to facilitate integration of results during the IFSP meeting. Second, the YC-PEM e-PRO instructions were enhanced to introduce users to the concept of participation and the importance of personal norms when appraising it, which differs from more routinely used norm-based assessments of developmental and functional skills.^{27,28} Increasing stakeholder engagement was a result of lower feasibility rates and stakeholder feedback in prior research.^{25,26} We, therefore, identified and sponsored a group of EI providers, specifically service coordinators, to champion the work by engaging them in research protocol development and YC-PEM e-PRO implementation.²⁶ To enhance scientific

rigour, this protocol introduces a control group and longitudinal data to interpret the effectiveness of the intervention, and a mixed-methods component to characterise salient supports and barriers to its longer-term implementation as a health systems intervention across multiple EI programmes.²⁸

Objectives

Our overarching objective of this project is to ascertain the value of implementing the YC-PEM e-PRO within a routine EI context. This will be achieved with the successful execution of two aims. Aim 1 will evaluate the effectiveness of the YC-PEM e-PRO option, when paired with a decision support tool, on valued outcomes of EI service quality (parent perceptions of family-centredness of services, parent activation for shared decision-making, and parent engagement in service plan implementation), service focus, and child developmental and functional skill gains. Aim 2 will characterise EI stakeholder perspectives of facilitators and barriers to implementing the YC-PEM e-PRO as a valued option across multiple EI sites.

For aim 1, we hypothesise that as compared with usual care, intervention participants (ie, caregivers) will (1) report greater satisfaction with enabling and partnership (primary outcome; H1); (2) report greater general and specific information exchange within the EI team for shared decision-making; coordinated and comprehensive

EI care; and respectful and supportive EI care (secondary outcome; H2); (3) report higher engagement and activation for shared decision making to design the EI service plan (secondary outcome; H3); (4) receive a greater breadth and intensity of participation-focused EI services (secondary outcome; H4) and (5) their children will demonstrate greater gains in developmental and functional skills (secondary outcome; H5).

METHODS AND ANALYSIS

Study design and setting

We will use a hybrid type 1 effectiveness-implementation study design to achieve two specific aims (see figure 1). In aim 1, we will conduct the Parent-Reported Outcomes for Strengthening Partnership within the Early Intervention Care Team (PROSPECT) community-based pragmatic trial, to test the effects of the YC-PEM e-PRO and a decision support tool intervention. The study protocol for aim 1 adheres to the Standard Protocol Items: Recommendations for Interventional Trials guidelines, as recommended for reporting of clinical trial protocols.²⁹ EI stakeholder perspectives guided the design of a PRagmatic Explanatory Continuum Indicator Summary 2 (PRECIS-2) Wheel describing the pragmatic trial design (see figure 2).^{30 31} In aim 2, we will gather stakeholder

Figure 1 Hybrid type-1 effectiveness-implementation study design. EI, Early Intervention; IFSP, Individualised Family Service Plan; YC-PEM e-PRO, Young Children's Participation and Environment Measure electronic Patient-Reported Outcome.

Figure 2 PRECIS-2 wheel for PROSPECT trial. PRECIS-2, PRagmatic Explanatory Continuum Indicator Summary 2; PROSPECT, Parent-Reported Outcomes for Strengthening Partnership within the Early Intervention Care Team.

perspectives on supports and barriers to implementation across multiple EI programmes. Aim 2 will use an explanatory sequential (quan > QUAL) mixed-methods design.³² This hybrid effectiveness-implementation study design has the internal validity advantages of a randomised control trial, yet study results can be more readily implemented into ‘real-world’ programming.³³

Note. PRECIS-2 has nine domains, each scored on a 5-point Likert scale (from 1=very explanatory to 5=very pragmatic).^{30 31}

Eligibility criteria and recruitment

For aim 1 (see figure 3), we aim to recruit caregivers from a large, urban, and non-university affiliated EI programme. We started recruitment in October 2020 and plan to end

recruitment in December 2021, or when we reach target enrolment. Caregivers are included if they: (1) are at least 18 years old; (2) identify as the parent or legal guardian of a child enrolled in EI; (3) read, write and speak English; (4) have internet and telephone access; and (5) have a child 0–3 years old who has received EI for 3 or more months.

A designated EI staff member identifies and calls potential caregivers 4 weeks before their child’s annual IFSP meeting. During this call, eligible and interested caregivers are directed to the project website where they identify their service coordinator, view a recruitment flyer, and create a user account to enrol in the project. After account creation, each caregiver confirms their eligibility, provides consent and HIPAA authorisation, and completes the baseline measures online via REDCap electronic data capture tools hosted at the University of Illinois at Chicago.^{34 35}

To support participant recruitment, participants who verbally consent to participate are reminded via email on a weekly basis, with up to three reminders. Three strategies are used to support participant retention during follow-up phases: (1) automated weekly email reminders; (2) participant compensation increases to US\$20 for completing surveys at 6 months and 12 months post-baseline; and (3) through the EI programme, families can apply for financial childcare support for their time needed for complete the surveys.

In aim 2, we will recruit three types of EI stakeholder groups: (1) families assigned to the intervention group during aim 1 and who indicated interest to participate in aim 2; (2) EI service coordinators involved in this trial (n=6) and EI service coordinators and practitioners that are not involved in this trial (n=6); and (3) EI programme leadership, including programme director, supervisors, and data and programme managers (n=10). EI service coordinators and leadership involved in this trial will be recruited by email, and we will use snowball sampling to expand enrolment to those employed by the EI programme but not involved in the PROSPECT trial.

Sample size

The aim 1 power analysis intends to maintain 80% power and total 5% type I error. We hypothesise that the change score of the primary outcome, the Measure of Processes of Care (MPOC) subdomain: enabling and partnership (H1), from pre-baseline to post-baseline at 1 month is approximately a medium Cohen’s *d* effect size, that is, 0.5,³⁶ between the intervention and control groups. This effect size is close to an empirically large effect size for rehabilitation studies in a category of skills and habits.³⁷ Although a medium effect size is observed at 26 weeks by Fonvig *et al*,³⁸ our hypothesised effect size is based on comparing the intervention scope (targeting improvements in family-centred care during IFSP development) to prior work evaluating interventions that are broader in scope, and therefore, expecting to detect a larger effect in a shorter time frame. Considering the cluster

Figure 3 Aim 1 flow chart.

randomisation at the level of the service coordinator, a design effect according to Eldridge *et al*³⁹ is used to take account of the cluster dependence, various cluster sizes, and the small number of clusters by assuming an intra-class correlation coefficient of 0.02, a range of cluster sizes as 15–25, an average cluster size of 20, and 6 clusters. Using two sample t-test with the design effect, total 178 families, that is, 89 families per group and 30 families per service coordinator, would be required to detect the targeted effect size. Given an attrition rate of 20%, we plan to recruit total 223 families, that is, 111–112 families per group and 37 families per service coordinator.

Randomisation

To avoid contamination, aim 1 will employ a cluster-randomised design at the EI service coordinator level.⁴⁰ Six EI service coordinators who are members of the High Value Early Intervention Research Group and expressed interest in the project were initially randomised into intervention group (n=3) and control group (n=3), using computer generated randomisation. Participating caregivers are therefore directed to either the intervention or control group, based on their assigned EI service coordinator's group assignment.

To reduce cross contamination among service providers, only service coordinators allocated to the intervention group were included in co-creating the decision support tool to be paired with the YC-PEM e-PRO. They were asked to not share this information with service providers assigned to the control group. Additionally, the research team meets with intervention and control group service coordinators separately during aim 1 completion to discuss experiences and potential concerns.

Blinding

EI service coordinators fulfil the role of a case manager and coordinate evaluations, care planning and outcomes monitoring for families. EI service coordinators cannot be blinded to the intervention as it involves modifying their clinical practice, nor can researchers be blinded to participants' group allocation. However, the statistician will be blinded to participants' group assignment while conducting all analyses. EI service providers are not trained or provided knowledge about the intervention. Since EI services are provided in the child's natural environment (eg, home), there are fewer interactions across service providers and service coordinators during a routine workday as compared with a clinic environment.

Intervention

Technical specifications

The intervention is administered via a project website that pairs with REDCap. For this website, HTML5, CSS3 and AngularJs were used to create the frontend, and NodeJS was used to create the back-end of the intervention. On entering the project website, participants select their assigned EI service coordinator, create a user account and log in. From the main menu on login, assignment into

the intervention or control group is automated based on EI service coordinator, and participants are routed to the applicable survey to be completed via REDCap.^{34 35}

Both the intervention and control group workflows are enabled with the following functionality: (1) confirmation logics in REDCap when caregivers are reviewing inclusion criteria and providing informed consent and HIPAA authorisation and (2) a back-end portal that is password protected and accessed by research staff who are granted administrative access to monitor enrolment and completion rates, completion time, email and phone queries, and confirmation of PDF reports when sent to the EI team. Research staff access a dashboard that was created using NodeJs, Express server and EJS with MySQL (postgress) and used to store these data into a database. Parts external to REDCap are hosted by the Amazon EC2 server for hosting the Linux Ubuntu server. For security, server alerts are configured and port blocking is allowed based on IP address.

The intervention group REDCap project includes additional functionality, including: (1) skip logic functionality for YC-PEM e-PRO completion and (2) a progress bar indicating the number of pages left to complete, beginning with the demographics page. On completing the REDCap surveys, intervention group participants are directed back to the main menu to access an online summary report of their YC-PEM e-PRO responses. The summary report is populated via REDCap application programming interface using Angularis and Kendo libraries. The summary report uses bar graphs to represent the data, provides options to customise it with the child's name and photo, and can be downloaded and saved as a PDF. This report is automatically sent to the EI team.

User experience

The YC-PEM e-PRO contains 13 types of home activities in four categories, and 11 types of community activities across four categories (eg, personal care management is a type of home activity within the category of basic care routines).^{12 15 41} For each activity, caregivers are asked about their 1) child's participation frequency (from never=0 to daily=7), (2) child's level of involvement (from not very involved=1 to very involved=5) and (3) desire for their child's participation to change (yes, no). When caregivers indicate 'yes, desire change' for one or more activities in a category, they are prompted to describe up to three strategies that they have used to support their child's participation in that category. After completing the participation items for a YC-PEM e-PRO section (eg, home), caregivers are asked to rate their perception of how environmental features and resources (eg, sensory qualities, equipment and supplies) impact their child's participation in that setting (from usually makes it harder=1 to usually helps=3).^{12 15 41} The information in this YC-PEM e-PRO summary report is systematically referenced by the EI service coordinator when administering a companion guide to support shared decision-making during the child's annual IFSP meeting.

This shared decision support tool, consisting of the IFSP template form with added prompts and placeholders for the service coordinator to transfer and build on information contained in the YC-PEM e-PRO summary report, was co-created with service coordinators assigned to the intervention group. The prompts and placeholders provide service coordinators with structure for consistently integrating YC-PEM e-PRO results into the IFSP meeting guide to elicit and focus family priorities in the context of EI service provision.

Intervention fidelity

Participating EI service coordinators have either a bachelor's degree in early childhood education and/or at least 5 years of related experience. They joined the High Value Early Intervention Research Group by completing an online research training programme (95–135 min), consisting of online learning modules delivered asynchronously, followed by a simulation experience whereby service coordinators review and contribute to a research product.²⁶ For this project, all EI service coordinators in the research group were invited to a 1-hour training for orientation to the project, with those allocated to the intervention group taking part in an additional workshop to co-create the shared decision support tool. To further promote intervention fidelity, monthly meetings are scheduled with EI service coordinators allocated to the intervention group. During meetings, case example(s) of using the YC-PEM e-PRO report and the shared decision support tool are shared and discussed. This fosters protocol adherence across service coordinators and provides opportunity for peer mentorship.²⁵ Additionally, the meetings will inform the development of qualitative questions for the aim 2 interview guide regarding supports and barriers to longer-term implementation.

Strategies for implementation

Two implementation strategies (see [table 1](#)) have been integrated into the project to support: (1) user navigation through the YC-PEM e-PRO and (2) EI coordinator engagement.

Standard care

Control group participants will receive standard care consisting of an annual IFSP meeting where families and service coordinator discuss the developmental assessment results and other service provider's (eg, occupational therapists, physical therapists) observations and conduct a family assessment (ie, semi-structured family interview) to elicit families' concerns, priorities and resources for IFSP development. The YC-PEM e-PRO is not part of standard care and will therefore not be completed by the control group.

Outcomes assessment

Information about select child and family demographics will be gathered at baseline, including the child's age, gender (ie, male, female, self-described), and caregiver race (ie, American Indian/Alaskan Native, Asian, Black or

African American, Caucasian, Hawaiian or other Pacific Islander, self-described).⁴² [Table 2](#) summarises primary and secondary outcome measures.

Qualitative data

Following trial completion, data will be collected through focus groups with three types of EI stakeholders using a semi-structured interview guide. Questions will centre on explaining quantitative results on the usefulness of the implementation strategies employed (eg, how helpful was the video for completing the YC-PEM e-PRO; how helpful the YC-PEM e-PRO report was to guide discussion at the annual IFSP meeting).

Focus groups with EI service coordinators and leadership will also revisit benefits and challenges with implementing YC-PEM e-PRO, as previously described during aim 1 monthly meetings with service coordinators and project coordinators. Additional questions will be posed about remaining barriers and facilitators to its broader and sustained deployment across multiple EI programmes, with an eye towards provider efficiency as now captured in the Quadruple Aim of healthcare.⁴³ This may include inquiring about expanding YC-PEM e-PRO report functionality to include programme dashboards that are tailored to the distinct informational needs of families, providers and EI leadership. Whereas families may benefit and be restricted to viewing their child's item-level e-PRO results, providers may need access to item-level results for multiple families on their caseload, and EI leadership may benefit from viewing e-PRO results in aggregate form instead (eg, average percent desired change across home activities for groups of EI families). Research staff without prior EI experience will facilitate focus groups, to ensure participant comfort in providing feedback on facilitators and barriers to implementation.

Patient and public involvement

The YC-PEM e-PRO has a 13-year history of EI programme leadership, service provider, and caregiver engagement to guide its design and use,^{9–11} including: (1) caregiver engagement to design, validate and begin to identify supports and barriers to its implementation in a single EI programme^{9 13 25 28 44}; (2) co-creation of an online knowledge hub with resources (eg, user guide, tip sheet) to increase its uptake by families, service providers and organisations⁴⁵; (3) caregiver and service provider engagement to upgrade and reduce the burden of delivering this intervention during the aim 1 trial (eg, designing animated instructional videos, creating activity illustrations and co-creating summary reports),^{46 47} and (4) caregiver and service provider engagement and capacity building to deliver the YC-PEM e-PRO with productive, sustainable community-academic collaboration.²⁵ The resulting research group infrastructure enables interested EI service coordinators to share in decisions about protocol design (research question and outcome measure selection), management of participant recruitment/retention, the use YC-PEM e-PRO information in

Table 1 Implementation strategies integrated during project preparation phase

Strategy	Description	Rationale
Strategies to Support YC-PEM e-PRO User Navigation		
Expand and enhance YC-PEM e-PRO instructions in REDCap using an embedded animated introductory video	<ul style="list-style-type: none"> ▶ New embedded YC-PEM animated instructional video script was written at a fifth grade reading level and introduced caregivers to key participation concepts 	Families indicated need for simplifying original instructions to optimise navigation and clarity on how an assessment of child's participation is distinct from assessment of developmental and functional skills. ^{14 27}
Embed activity illustrations within the YC-PEM e-PRO to augment text descriptions	<ul style="list-style-type: none"> ▶ A biomedical illustrator created 27 illustrations to represent multiple ways that children and caregivers might participate in a YC-PEM e-PRO activity (ie, for meal preparation, illustrations depict children participating in setting the table, unloading groceries and scooping ingredients) ▶ Illustrations were intentionally diversified according to child and caregiver age, gender and race/ethnicity 	This strategy aligns with current evidence that regardless of health literacy levels, individuals find it easier to imagine website content that includes visuals or animations. ⁶³
Improve layout of YC-PEM e-PRO report structure	<ul style="list-style-type: none"> ▶ Co-design a report with providers that includes upgrades to: <ul style="list-style-type: none"> – Content/Typography: personalised titles, introductions and conclusions – Colour: intentional use of calming and alerting colours – Structure/space: open text boxes strategically placed to offer caregivers opportunities to write down notes – Style/tone: report elicits specific emotions/tones (eg, sense of caregiver pride, professionalism) – Graphics/symbols: tables and bar graphs to display results 	Stakeholder engagement in designing ways to optimise the reporting of information from participation-focused tools will increase the likelihood of their adoption into existing organisational workflows. ^{25 64}
Strategies to Support EI Provider Engagement		
Launch and maintain a new research group at the EI study site	<ul style="list-style-type: none"> ▶ EI service coordinators co-designed a High Value Early Intervention Research Group to earn credit for their contributions to study design, implementation, interpretation and/or dissemination of results ▶ Ten members have so far: (1) shared in decisions about protocol design and strategies for participant recruitment and retention; (2) co-created the trial name and logo, video options for online consent and HIPAA authorisation, and the structure and schedule for EI service coordinator check-ins during trial completion 	Service coordinator workload, competing priorities and/or lack of familiarity with research may contribute to disengagement. ²⁶ This research group may be a key driver of protocol implementation, as most EI programmes are not university-affiliated and vary in research capacity

EI, early intervention; HIPAA, Health Insurance Portability and Accountability Act; REDCap, Research Electronic Data Capture; YC-PEM e-PRO, Young Children's Participation and Environment Measure Electronic Patient-Reported Outcome.

the IFSP planning meeting, and the training and retention of EI service coordinators during the aim 1 trial. An EI engagement specialist also joined the research group and provided input on caregiver recruitment and created video options for caregivers to provide informed consent and HIPAA authorisation. The research group, inclusive of the EI engagement specialist, will disseminate results to study participants via non-refereed internal newsletters and an external podcast.

Statistical analysis

Data will be exported from REDCap and into SAS V.9.4 for analyses.⁴⁸ For aim 1, the sample will be described at pre-intervention and analysed to accomplish the following tasks before the main analyses. We will depict univariate and bivariate data distributions using frequency with percentage for categorical variables and mean with SD or median with IQR for continuous variables. Baseline

imbalances between intervention and control groups will be identified using univariate generalised linear mixed model⁴⁹ with details provided in the main analysis below. Moreover, data anomalies, such as outliers and statistical assumptions for planned analyses, such as non-normality, will be checked and remedied with data transformations or more statistically robust approaches. Finally, the amount and patterns of missing data will be evaluated and handled by each method's assumption or by using multiple imputation with fully conditional specification approach⁵⁰ as appropriate.

Main data analyses will be based on intent-to-treat principle in this cluster-randomised clinical trial. To estimate the intervention effect on score changes over time compared with the control group, generalised linear mixed model will be fitted for each of the outcomes of interest, including MPOC subdomain enabling and

Table 2 Outcome measures

Outcome (Construct)	Outcome measure	Description	Primary outcome	Secondary outcome	Time point (Data Collection)
Service quality	MPOC-20; 20 Items	Assesses caregiver perceptions of family-centred care in four domains: (1) enabling and partnership; (2) providing general and specific information; (3) coordinated and comprehensive care and (4) respectful and supportive care. ⁶⁵ The MPOC-20 has acceptable to good reliability and validity. ^{65 66}	X	X	Baseline, 1, 6 and 12 months
Caregiver engagement for shared decision making	PPEM; 5 Items	Caregiver-rated questionnaire measuring perceived engagement in services		X	Baseline, 1, 6 and 12 months
Caregiver activation for shared decision-making	P-PAM-13; 13 Items	Measure that assesses caregiver knowledge, skills and confidence to manage their child's care. ^{67 68}		X	Baseline, 1, 6 and 12 months
Service plan focus	Retrieved via EI service record abstraction	Record abstraction will be used to collect and code data on the individual family service plan as finalised following the IFSP meeting, using established quality criteria, to derive an estimate of the proportion of participation-focused goals in the service plan. ¹⁶		X	Post-intervention
Child functioning	Retrieved via EI service record abstraction	Record abstraction will be used to collect the child's percent developmental delay in five developmental domains as derived from standardised developmental assessments (ie, adaptive behaviour, cognitive, communication, physical, social emotional) and COS scores. COS scores are a consensus rating by the EI team based on developmental scores and practitioner and parent perceptions of child function. ⁶⁹		X	Baseline and 12 months

COS, Child Outcomes Summary; EI, Early Intervention; IFSP, Individualised Family Service Plan; MPOC-20, Measure of Processes of Care; P-PAM, Parent Patient Activation Measure; PPEM, Parent Participation Engagement Measure.

partnership (H1) as the primary outcome, and the remaining MPOC subdomains (H2), partnership P-PAM and PPEM (H3), DS and COS (H5) as the secondary outcomes. Each model will include group (intervention vs control), time (1, 6 and 12 months post-baseline vs baseline), and their interactions as the primary fixed effects, while adjusting for appropriate factors, such as child age, and condition severity, as secondary fixed effects along with coordinator-level and subject-level random effects, if possible. This model controls for cluster dependence at three levels (coordinator, participant and repeated measures) through the random effects and permits the calculation of intercepts for each individual participant. Moreover, the model will estimate average slopes and intercepts in terms of coefficients, which provide the magnitude of the intervention effect between two groups especially via the interaction terms. Considering the small number of coordinator-level cluster as 6, the between-within approach⁵¹ will be applied for small-sample correction as suggested by Leyrat *et al.*⁵² Missing data can be handled by this model under the missing at random assumption with the maximum use of available data. The estimated intracluster correlation coefficient for the primary outcome and estimated coefficients in each model for every outcome will be presented along with the coefficients' SE, p values. Reports for aim 1 will follow the guidance by Campbell *et al.*⁵³ A two-sided $p < 0.05$ would be considered as statistical significance. The statistician will be blinded as to group assignment while conducting all analyses.

We will rate EI service plans using quality rating criteria,^{16 54} to derive estimates of the proportion of participation-focused goals before and after intervention. We will control for history of family interview completion (yes, no) to examine the effect of the upgraded YC-PEM e-PRO and decision support tool on the proportion of participation-focused goals in the EI service plan.

Qualitative analysis

Focus group interviews will be transcribed verbatim, and transcripts will be imported into NVivo V.11.0 for analyses.⁵⁵ We will use deductive and inductive content analysis⁵⁶ to group data into categories of common facilitators and barriers to implementing the YC-PEM e-PRO. We will initially use the CFIR to develop a draft codebook based on known implementation factors²⁴ and refine it iteratively. The data coding process will be as follows. First, two study staff will independently code 20% of data. Second, the researchers will meet to resolve coding discrepancies and collaboratively review and update the codebook. The remaining data will be split between the two coders and analysed separately using the updated codebook.

Categories will be labelled using participants' own words and reviewed by co-investigators to ensure homogeneity (ie, each theme is distinct and has multiple instances of supporting text). Illustrative quotes will also be identified and included. We will develop three sets of summaries (one per EI stakeholder type) to be shared

with members of a national advisory group comprised of EI practitioners who are employed across multiple states to review findings. Advisory group members will provide input on the relevance (a rating of impact and ease of implementation) of each support and barrier to the YC-PEM e-PRO in their EI programme. These inputs will inform systematic prioritisation of factors to implementation across multiple EI programmes nationally.

Funding, ethics, data sharing and dissemination

This work is supported by the American Occupational Therapy Foundation (AOTFIR20KHETANI) and institutional funds from the University of Illinois at Chicago (Khetani). The project described, including the use of Research Electronic Data Capture, was supported by the National Center for Advancing Translational Sciences, National Institutes of Health, through Grant UL1TR002003. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

We have obtained ethical approval by the Institutional Review Boards at the University of Illinois at Chicago (protocol # 2020-0555) and the University of Colorado (protocol # 20-2380). We follow the eligibility guidelines for authorship as outlined by the International Committee of Medical Journal Editors.⁵⁷ Changes in eligibility criteria, outcomes and main analyses will be reported to the ethics board per IRB approved procedures. Adverse events will be reported on as outlined in the informed consent and HIPAA authorisation forms.

A subset of data that underlie the results reported in the article, after deidentification and beginning 9 months and ending 36 months after publication of main results, will be available on reasonable request. Proposals should be directed to mkhetani@uic.edu.

Results of this research will be disseminated via refereed publications and conference presentations, as well as non-refereed internal newsletters and an external podcast. The process and timeline for sharing a final trial dataset are in progress.

DISCUSSION

The YC-PEM e-PRO, when paired with a decision support tool, holds promise for providing an alternative option for family-centred and participation-focused EI care as compared with the standard face-to-face semistructured interview.^{13 28} However, there is need to further optimise the YC-PEM e-PRO and examine its effectiveness and implementation within the EI service context, by including a control group for comparison, examining effects across multiple endpoints and over time, and collecting diverse stakeholder perspectives to appraise supports and barriers to its scalability across multiple EI programmes.²⁸ This protocol paper describes a hybrid type 1 effectiveness-implementation study consisting of two parts: (1) a pragmatic cluster randomised control trial to examine effectiveness on select child and family

outcomes (aim 1); and (2) an explanatory sequential mixed-methods approach to examining supports and barriers to longer-term implementation within an EI context (Aim 2).

While results on effectiveness will inform estimates about the value of this intervention, results on barriers and facilitators for intervention implementation are needed to support intervention uptake across multiple EI programmes.^{58 59} For the latter, we aim to gain diverse EI stakeholder perspectives to guide the design of implementation strategies that can support longer-term implementation as a health systems intervention. EI families may provide insights about potential upgrades to the YC-PEM e-PRO and decision support tool for family-centred and participation-focused care with individual families.^{60–62} In contrast, EI providers and leadership may provide greater insight about how to sustain this intervention in ways that reduce provider burden and increase leadership capacity for monitoring service trends and identifying targets for continuous quality improvement. Both perspectives are needed to advance its implementation as a health systems intervention in EI.

It is expected that the results of this research will provide evidence to guide hybrid type 2 and/or type 3 implementation research on the YC-PEM e-PRO across multiple EI programmes, to systematically support its implementation as a health systems intervention for advancing family-centred and participation-focused services in EI.

There are three anticipated limitations to the proposed study. First, limiting the inclusion criteria to English-speaking families for both parts may limit generalisability of the results from this phase of work to a subset of families that are enrolled in EI. Additionally, conducting this study during the COVID-19 pandemic poses limitations to timely participant recruitment and data collection. There might be more challenges recruiting families due to lower EI enrolment in the single EI programme. Similarly, caregivers who do access EI and choose to enrol might be better able to appraise their child's participation at home as compared with the community due, in part, to COVID-19 restrictions.

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Acknowledgements The content is solely the responsibility of the authors and does not necessarily represent the official views of the funding agencies. We wish

to acknowledge our colleagues Sanjeev Chauhan, Pankaj Sandhu, and Sumit Oberoi at Wegile for their technical expertise and partnership in developing the PROSPECT intervention described in this paper. The UIC Centre for Clinical and Translational Science UL1TR002003 provided access to REDCap and associated technical support. We thank Julia Sim from the Children's Participation in Environment Research Lab for assisting with tables, figures, checklists, and references.

Contributors MK took the lead in conceptualising the study, drafted the introduction, and provided oversight to the drafting of all remaining sections of the manuscript. VK and VV co-led the drafting of the methods and discussion sections and the generation of figures and tables. Y-FC drafted the Statistical Analysis section, and VM and MK drafted the Technical Specifications section. The High Value Early Intervention Research Group drafted the Article Summary and Figure 2 of the manuscript. NJM, EP, JL, NL and BM provided critical feedback during manuscript preparation. All authors edited and approved the final manuscript prior to submission.

Funding This work is supported by the American Occupational Therapy Foundation (AOTFIR20KHETANI) and institutional funds from the University of Illinois at Chicago (Khetani). The project described, including the use of Research Electronic Data Capture (REDCap), was supported by the National Center for Advancing Translational Sciences, National Institutes of Health, through Grant UL1TR002003.

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Competing interests The YC-PEM e-PRO is licensed for distribution through CanChild Centre for Childhood Disability Research. MK shares in revenue from YC-PEM sales for research and development activities in the Children's Participation in Environment Research Lab (CPERL) at the University of Illinois at Chicago.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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