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E-coaching for parents of children with autism spectrum disorder: Protocol for a randomized controlled trial

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Abstract

Autism spectrum disorder (ASD) is a neurodevelopmental condition that significantly affects children's development, posing a significant challenge in pediatric healthcare. Early parent-mediated interventions (PMIs) aim to improve a child's social communication skills through joint engagement in daily activities. However, widespread access to this type of intervention is heavily limited due to implementation barriers and logistical challenges. The use of technology may offer promising alternatives to reach more families. This randomized controlled trial will assess the efficacy of an innovative e-coaching program designed to provide parents of young children with ASD with effective strategies via an online learning platform combined with personalized debriefings. It will compare e-coaching to standard Pediatric Autism Communication Therapy and to the absence of a PMI, with all three arms combined with community assistance as usual, in a cohort of 99 families with preschool children with ASD. The primary outcome will be the quality of parent–child interaction, measured through behavioral assessments and simultaneous dual gaze recording with head-mounted eye-tracking during semi-structured standardized play sessions. Secondary outcomes will include the child's developmental level and parental well-being. If validated, e-coaching could be disseminated to reach more families and have a positive impact on their quality of life.

KEYWORDS
autism, early intervention, parent-mediated intervention, RCT protocol

INTRODUCTION

Background and rationale

Autism spectrum disorder (ASD) is a highly heritable and heterogeneous neurodevelopmental condition characterized by significant and persistent difficulties in social communication and by restricted and repetitive sensorimotor behaviors.[1] Over the past two decades, the global prevalence of ASD has steadily increased;[2] once considered a rare neuropsychiatric disorder, current prevalence estimates indicate that ASD affects 1% of children worldwide[3] and up to 2.8% of 8-year-old children in the United States.[4] Therefore, ASD currently presents a significant challenge for pediatric healthcare and developmental psychology. Current international guidelines advocate for early screening

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and diagnosis of ASD, aiming to enable timely intervention and parental support.[5–8]

Early intervention strategies include parent-mediated interventions (PMIs)[9] and therapist-delivered interventions.[10] Contemporary perspectives increasingly acknowledge parents of children with ASD as essential contributors to their child's care.[5] Consequently, helping parents to develop strategies to improve social interaction and management of challenging behaviors is fundamental to provide optimal early intervention. Some studies have shown that parental participation in early intervention programs could be a way to enhance their quality of life.[11] Furthermore, providing training for parents can improve child communication skills and parent–child interaction, as well as adaptive functioning and disruptive behavior.[12] Nevertheless, many of these studies have been hampered by methodological limitations.[13] Among the different PMIs aimed at boosting social communication competences in preschool children with ASD, Pediatric Autism Communication Therapy (PACT) has demonstrated robust and sustained improvements in parent–child dyadic interactions and the child's social communication.[14] A 6-year follow-up into mid-childhood reported lasting moderate reductions in overall ASD symptomatology.[15] PACT involves filming free play between the child and the parent followed by a video-feedback session with the therapist in which parents are encouraged to identify successful episodes of reciprocal interaction. The therapist helps the parent to increase the sensitivity to the child's social communication cues and to apply strategies to promote the development of social communication skills. PACT focuses on improving parent–child interaction to enhance child communication competences based on the principle that children with ASD require an adapted interaction style matched to their level of social communication.[16]

However, widespread access to PMIs remains limited due to implementation barriers and logistical challenges, particularly in French-speaking countries. First, most PMI models are manualized in English, and very few are translated into other languages. The language barrier thus makes the adoption of these options particularly difficult. In addition, recognized PMIs require, in most cases, formal training by certified trainers in the specific model, and the certification process is very often tedious and lengthy. The cost of such training and certification is generally high, and few trainers are available in languages other than English. As a result, most of the professionals who undertake this type of training are therapists already experienced in autism or working in expert centers, limiting the dissemination of PMIs in the community. Moreover, the geographical distance from these expert centers, as well as limited parental availability and overload significantly restrict the number of families that can benefit from this type of intervention.[17]

Therefore, there is growing interest in the use of technology to deliver parental coaching, including video conferencing, webinars, and/or online training modules. These technological approaches, facilitated by therapists, provide viable alternatives and have shown promising outcomes.[18,19] Previous studies have demonstrated the feasibility of delivering PMIs via videoconferencing, such as telehealth or self-directed versions of P-ESDM,[20,21] Project ImPACT,[22] or RUBI.[23] Notably, some PACT sessions have also been delivered remotely in a recent randomized controlled trial (RCT),[24,25] and an ongoing study evaluating PACT delivered entirely via videoconferencing[26,27] has shown promising feasibility. Providing interventions via videoconferencing overcomes the issue of geographical distance and access to trained professionals for families. However, training and certification processes remain necessary. Self-directed versions of PMI models (e.g., online modules, e-learning) offer the advantage of allowing families to access the strategies and material without professional assistance, but at the cost of potentially limiting the level of support and guidance they receive. Moreover, the majority of self-directed models are not accessible to the public, thus resulting in their limited dissemination within the community. If they are (e.g., HIIYH; www.helpisinyourhands.org[28]), they are available in very few languages. A further limitation of existing models relates to content, which predominantly focuses on specific topics such as either disruptive behaviors or social communication competences. While some PMI models aim to be comprehensive, a wide range of relevant topics for parents such as feeding, sleep disorders, and autonomy management are not always covered.

In this context, we have developed an innovative 6-month program of parental coaching via e-learning, referred to as e-coaching, and specifically designed for parents of preschool children with ASD. This comprehensive program consists of 11 online modules based on evidence-based practices from naturalistic developmental behavioral interventions (NDBIs).[29,30] These modules include strategies to promote engagement, model skills, encourage communication, and teach new abilities to children.[31] This program also incorporates material on domains such as autonomy, sleep, eating behavior, and screen time management, areas often overlooked by other PMIs.

Objectives of the current study

In this study, we propose a protocol for a large RCT to evaluate the efficacy of our e-coaching program for parents of preschool children with ASD. The effect of e-coaching will be compared to a standard PACT intervention and to a control group receiving no PMI. Children in all three groups will receive community assistance as usual (CAU). The primary objective is to assess the impact of e-coaching on the quality of parent–child interaction. This outcome will be measured at three time points: right before the onset of the intervention, immediately after the intervention, and 6 months post-intervention. We hypothesize that e-coaching will improve the quality of parent–child interaction in a way that is comparable to PACT and significantly better than CAU alone, with effects persisting 6 months after the end of e-coaching. We also expect that a higher quality of parent–child interaction will enhance children's social communication and language skills.

Changes in parent–child interaction will be measured using the Dyadic Communication Measure for Autism (DCMA; see Methods for details) and by monitoring parent and child gaze patterns using two head-mounted eye-tracking (HMET) systems during semi-structured standardized play sessions. Eye tracking is a safe, affordable, noninvasive, and well-tolerated technology that can detect early differences in social attention through the recording and quantification of gaze patterns.[32] HMET devices can measure eye movements in more

unrestricted and naturalistic environments,[33] providing a unique opportunity to study active visual exploration during social interactions as children engage in everyday tasks.[34] In this study, we aimed to identify objective, quantifiable indicators of the effect of e-coaching on the quality of parent–child interaction using simultaneously acquired gaze recording from two HMETs worn by both the child and the adult during toy play. Secondary outcomes will assess whether e-coaching leads to broader indirect improvements in the child's development as well as the enhancement of parental well-being. We hypothesize that children whose parents receive e-coaching will show greater improvements in social communication skills and a decrease in ASD-related symptoms and behaviors compared to children receiving CAU alone, and that these effects will be as positive as those from the PACT intervention. Finally, we will measure the impact of the e-coaching program on parental well-being through several standardized parent-report questionnaires (see Methods). We expect that improving the quality of dyadic interaction will exert a positive effect on the well-being of parents.

METHODS AND DESIGN

Trial design

This is a monocentric, three-arm, parallel group, equivalence RCT. Ninety-nine children diagnosed with ASD and aged between 2 and 4 years 6 months will be recruited along with their parent or primary caregiver. They will be randomized and allocated on a 1:1:1 ratio into one of three groups: the e-coaching intervention group (n = 33), in which parents will receive our e-coaching parental program in addition to CAU; the PACT intervention group (n = 33), where parents will follow a standard on-site PACT intervention in addition to CAU; and the control group (n = 33), which will receive CAU alone. This RCT will be conducted by a team of researchers and psychologists from the Service des Troubles du Spectre de l'Autisme (STSA) at the Centre Hospitalier Universitaire Vaudois (CHUV) in Lausanne (Switzerland). Our center has an ASD diagnostic unit independent from the early intervention service which provides PMI by accredited clinical psychologists. The diagnostic team sees an average of 300 children per year, including 150 preschool children. Our research team works closely with the clinical team that provides the diagnosis assessments. Each patient is informed of current research projects and, if they wish to participate, they are contacted by the researchers once the diagnostic process has been completed. The clinical trial started in October 2023 and is expected to last approximately 3 years.

Participants

The study will recruit preschool children diagnosed with ASD, along with their parent or primary caregiver. To be eligible, children must: (i) be between 2 and 4.5 years old at enrollment; (ii) have an established ASD diagnosis according to the DSM-5-TR[1] and meet criteria for ASD using the two gold-standard diagnostic tests (Autism Diagnostic Observation Schedule, ADOS-2;[35] and Autism Diagnostic Interview-Revised, ADI-R[36]) (iii) have a French-speaking parent or primary caregiver; and (iv) have signed the consent form to take part in the study. Exclusion criteria include: (i) prematurity (< 36 weeks of gestation); (ii) known neurological or physical condition requiring medication (e.g., traumatic brain injury); (iii) known genetic disorders, such as fragile X syndrome; (iv) severe visual and/or hearing impairment; and (v) the inclusion in an early intensive intervention program such as the Early Start Denver Model (>6 h/week). Parents or primary caregivers will be excluded if they (i) have a severe psychiatric disorder; (ii) are not fluent in French; (iii) lack internet access; or (iv) have a severe visual and/or hearing impairment that could interfere with the intervention.

Trial interventions

E-coaching

Hosted on the CHUV's Moodle platform, e-coaching consists of six compulsory modules sequentially structured to address specific developmental domains in the order they typically emerge. These are: "I help my child to play," "I help my child to imitate," "I help my child to understand his environment," "I help my child to use body language," "I help my child to communicate verbally," and "I help my child to learn." There are also five optional modules covering topics such as sleep, autonomy, eating habits, and screen time management, as well as behavioral management strategies. As mentioned above, the content of certain modules is inspired by the essential elements of NDBIs aiming to teach parents strategies such as face-to-face interaction, the following of child's needs, the use of positive affect, modeling appropriate language, sensitivity to child's attempts to communicate, as well as providing communication opportunities and/or direct teaching.[31] Other modules focus on structured TEACCHing strategies such as organizing the environment and the use of visual support.[37] The content of each module is meticulously selected to provide a structured and effective learning experience. To enhance the learning process, modules incorporate illustrative material such as videos, pictures, and animations. We developed a user-friendly interface designed to accommodate a wide range of users. In addition to the module's content, we provide links to other valuable resources, including websites, to ensure that parents have access to a wealth of information beyond the scope of our program. A test phase has already been carried out in which a preliminary version of our e-coaching program was offered to parents of children with and without ASD and to health professionals, with the sole purpose of assessing the suitability of the e-coaching content. Their remarks, corrections, and comments were carefully considered, and the content was subsequently adapted in accordance with these contributions.

E-coaching intervention will be delivered over 6 months. Parents will work on two modules per month at home and at their own pace. Once a month, they will meet with their designated professional therapist for a 90-min videoconference session. These meetings will be used to discuss lessons learned, review practice, and adapt strategies tailored to the child's profile. All compulsory modules follow a common

structure: (i) the module begins with a few questions (not graded) to assess the parent's initial attitude and to stimulate their thinking about the topic; (ii) it then provides some theoretical background on the topic followed by the module's overarching goal; (iii) three to five concrete strategies are proposed and illustrated with videos, animations, infographics, and links to other resources; (iv) a quiz follows to help parents assess their newly acquired knowledge and review strategies; (v) homework assignments are then suggested, such as taking videos or pictures to demonstrate how strategies are implemented at home with their child; and (vi) a FAQ is included to answer additional questions. The quiz is purely indicative and passing the quiz is not required to continue with the module. If needed, printable sheets are provided to support the implementation of strategies at home. Optional modules include video presentations from experts in the field. Before each online debriefing, parents submit their completed homework assignments via a secure internal platform at Lausanne University Hospital for the transfer of large files. The therapist will provide feedback about the tasks performed at home during the debriefing session. Parents can also review and discuss their assignments and the recorded material with the therapist, who then suggests strategies tailored to the child's profile. During the 6 months of e-coaching intervention, parents will benefit from six 90-min online debriefings with a therapist, in addition to the eleven 45-min modules, for a total of approximately 17 h of intervention.

Pediatric Autism Communication Therapy

In this study, PACT will be delivered as described in the manual, that is, with 12 fortnightly sessions over 6 months and structured in six sequential stages.[38] The first session is dedicated to discussing the goals for the intervention, the parents' beliefs and aspirations for their child, and an explanation of the procedure. The rest of the sessions start with a short review of the practice. The parent is then invited to play with the child for approximately 10 min, while the therapist is filming the interaction. After the play session, the parent joins the therapist to watch the recording. The therapist helps the parent to select clips that illustrate the achievement of the goals, and to introduce PACT strategies linking to the ongoing stage. At the end, the parent and therapist discuss together and select a few objectives to train daily at home until the next session. The parent also receives a written report of the session. During the 6 months of PACT intervention, parents will benefit from twelve 90-min sessions with a therapist, for a total of around 18 h of intervention. All our PACT therapists are certified and received formal training and supervision from an official PACT trainer. Fidelity to the PACT model is monitored throughout the study, with sessions recorded for review to ensure therapists maintain at least 80% fidelity.

Community assistance as usual

All children participating in the study will receive the usual community support to promote children's autonomy and integration. This assistance may include speech therapy, occupational therapy, and/or educational support at home (1 h per week). The type, intensity, and duration of therapy will be documented and accounted for in subsequent analyses.

Randomization and blinding

We will use a modified two-stage Zelen model,[39] previously used in early ASD intervention trials.[40] This approach minimizes selection bias by randomizing participants before consent is obtained. Initially, all of the parent–child dyads will consent to participate in a 12-month longitudinal observational study, including baseline and follow-up assessments (Figure 1). Afterward, they will be randomized into one of the three groups: PACT, e-coaching, or the control group with CAU. Only the parents of dyads allocated to the PACT and the e-coaching groups will be informed about the trial and asked to provide a second written consent for the intervention. Participants who sign the first consent form, and are randomized into an intervention group but refuse to sign the second consent form may, if they wish, benefit from the longitudinal follow-up provided by the first consent form. However, this follow-up will take place out of the present study, and the data collected will not be analyzed within the framework of the present RCT. This delayed consent mitigates biases related to participants' expectations. To account for potential group imbalances and to minimize rejection of intervention programs, we put in place a compensation procedure for all groups in each of the three evaluation time points. The randomization procedure assigns participants to one of the three groups in a 1:1:1 ratio and will be performed by generating a randomization sequence using an online sequence generator,[41] overseen by a biostatistician. A blocked randomization list with variable random block sizes (3,6,9) will be created, in which the eligible participants will be assigned a unique code.

Owing to the nature of the intervention, parents of the children allocated to either the PACT or the e-coaching groups cannot be blind to the allocation procedure. Nevertheless, they ignore the existence of a control group without intervention. Parents in the control group will not be informed about the trial or the existence of the other two groups, reducing potential disappointment and withdrawal. PACT therapists will not participate in the assessment of ASD diagnosis, which will be conducted by independent trained psychologists blinded to the allocation groups. The coding of the primary and secondary outcomes from video recordings will be performed by trained researchers blind to group allocation. Finally, the data manager and biostatistician will as well be blinded to the allocation groups.

Outcome measures

Primary outcome—Quality of parent–child interaction

The primary outcome will be the quality of parent–child interaction, measured at three time points using: the DCMA,[14,15] and HMET.

DCMA is a tool to evaluate communication quality between parents and children with ASD. This tool consists of a coding scheme presented within the framework of the PACT therapy as a valuable

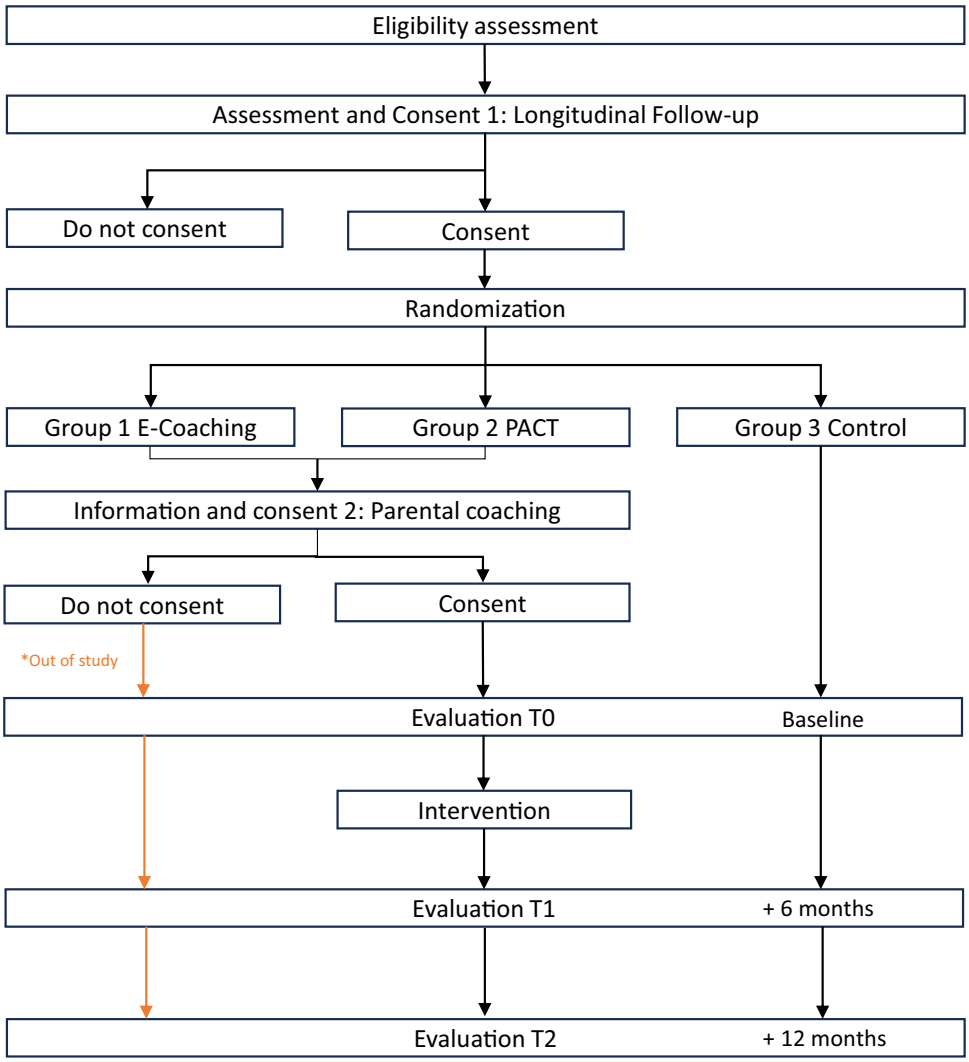

FIGURE 1 Flowchart of the RCT following the guidelines of the Consolidated Standards of Reporting Trials (CONSORT). Abbreviation: PACT, Pediatric Autism Communication Therapy.

measure of proximal response to treatment. Specifically designed for ASD populations, DCMA focuses on capturing the subtle aspects of dyadic communication. The assessment occurs in a naturalistic setting by recording a 12-min play session with standardized toys. Blinded trained raters will review the video recordings offline and code communication behaviors exhibited during the observed interactions, such as verbal and nonverbal behaviors, mutual engagement, responsiveness, and the overall quality of parent–child interaction. Five measures will be derived and used as indices of the quality of the dyad's interaction.[42]

Eye movements of both dyad members will be simultaneously recorded using two HMETs. The children will be invited to sit with their parents around a table or on a mat that will serve as the play area. Once the dyads are settled, we will set up each member of the dyad with a HMET (Positive Science, LLC). Both the infant's and the adult's HMETs are equipped with an infrared camera that points at the participant's right eye to track and record gaze in real-time, and a small forehead-mounted camera that captures the frontal view. The quality assessment of the eye-tracking data and the coding of gaze patterns will be performed by highly trained human coders. The continuous gaze stream will be split into individual fixations based on eye movement dynamics using Yarbus software (Positive Science, LLC). Coders will determine the target of each individual fixation and label them (object, dyad, undetermined). Frequency, duration, and rate of fixations for each category will be calculated for the gaze stream of each member of the dyad. Frequency and duration of shared attention episodes will also be computed. A second coder will code a randomly selected subset of five participants to assess inter-coder reliability. Prior to the onset of the trial, we assessed the feasibility of HMET implementation with four pilot participants. The data collected served no other purpose than the validation of the HMET setting. Sensory particularities and disruptive behaviors may present potential methodological constraints to the collection of high-quality HMET data. In our RCT, we have implemented several pre-evaluation strategies to maximize tolerance and acceptance of the HMET. First, we request that parents anticipate the visit, by explaining to the child what is going to happen.

We often suggest to parents to encourage their child to wear a bonnet in the days leading up to the assessment, and even to bring the child's own bonnet to the visit. During the evaluation, we first propose a free play session on arrival to make the child feel at ease. The subsequent step involves the explanation of the forthcoming procedures, verbally or with visual aids such as pictograms, using reinforcers if deemed necessary. Furthermore, we provide several options for the cap: different sizes, colors, materials, or the possibility of a headband. In some cases, the system can also be installed on the child's own cap, which is easier for most children to accept. Several attempts are sometimes required for the child to get used to wearing the cap on his or her head. Once the HMET is in place, we quickly engage the child in games that we have found to be of his/her interest, so that the sensation of wearing the HMET becomes more familiar. Consistent with other studies,[43] we have also implemented additional pre-evaluation strategies to maximize HMET tolerance, such as practice with nonfunctional equipment and breaking down study tasks into incremental steps, as well as the modeling wearing the HMET device and the reinforcement of appropriate responses.

Secondary outcomes

A range of secondary outcomes will evaluate the effect of e-coaching on the child's development, behavior, ASD symptoms, and parental well-being.

Child's behavior and ASD core signs

The Brief Observation of Social Communication Change (BOSCC).[44] The BOSCC is a tool designed to assess and quantify changes in social communication behaviors in individuals with ASD. The BOSCC consists of a quick 12-min standardized observational evaluation during which specific social communication indicators are systematically recorded. The coding scheme consists of 16 items assessing social communication and restricted and repetitive behaviors. Both the clinician and the child will wear an HMET during the BOSCC evaluation.

The Mullen Scales of Early Learning (MSEL).[45] The MSEL is a standardized assessment commonly used in clinical psychology as a developmental measure of cognitive and motor development in children. It encompasses five subscales: gross motor, fine motor, visual reception, receptive language, and expressive language.

The Child Behavior Checklist (CBCL/1.5-5).[46] The CBCL/1.5-5 is a 99-item caregiver report questionnaire designed to assess the social, emotional, and behavioral functioning of young children. This instrument is structured into several subscales: emotionally reactive, anxious/depressed, somatic complaints, withdrawn, attention problems, aggressive behavior, and sleep problems.

The Child Eating Behavior Questionnaire (CEBQ).[47] The CEBQ is a 35-item parent-report questionnaire designed to evaluate eating behaviors and feeding patterns in children. CEBQ consists of eight scales: food responsiveness, enjoyment of food, emotional overeating, desire to drink, satiety responsiveness, slowness in eating, emotional undereating, and fussiness.

The Pediatric Sleep Questionnaire (PSQ).[48] The PSQ is a parent-report questionnaire that contains 22 items that provide a comprehensive overview of a child's sleep habits and identify potential sleep-related issues. Subscales within the PSQ include a 4-item sleepiness scale, a 4-item snoring scale, and a 6-item attention/hyperactivity scale.

Parental well-being

The Parental Stress Index (PSI).[49] The PSI is a 36-item standardized questionnaire, designed to measure the extent of stress experienced by parents in the context of their parenting role. This tool is widely used to measure stress across six scales: hyperactivity/distraction, adaptability, reinforcement, demands, mood, and acceptability.

The Parenting Sense of Competence Scale (PSOC).[50] The PSOC is composed of 17 statements to measure parents' subjective perceptions of their competence in the parenting role. The PSOC is self-administered, and the scale gauges two main dimensions: seven statements concern the feeling of efficacy and 10 others relate to the feeling of satisfaction.

The Brief Coping Orientation to Problems Experienced (Brief-COPE).[51] The Brief-COPE is a 28-item self-report questionnaire designed to measure effective and ineffective ways to cope with stressful life events. The scale covers a range of coping mechanisms, including problem-focused, emotion-focused, and dysfunctional coping strategies.

The Child Adjustment and Parent Efficacy Scale-Developmental Disability (CAPES-DD).[52] The CAPES-DD is a 30-item parent-report questionnaire designed to evaluate the child's behavioral and emotional adjustment and assess parental efficacy in managing their children's needs.

Procedures

All procedures of this study adhered to the Consolidated Standards of Reporting Trials (CONSORT) reporting guideline for nonpharmacological interventions.

Data collection

Data will be collected by trained psychologists through standardized observations and parent-report questionnaires. For each of the three time points (T0, T1, T2), the parent and their child will be invited to an evaluation session lasting approximately 90 min that can be divided into two separate appointments if it is more convenient for the family (Table 1). Visits will be flexibly scheduled at times that are suitable for the families. The parent and the child will be invited to start the evaluations to collect data for the primary and secondary outcomes. All therapy sessions and time point evaluations will be videotaped. It is possible that a child could be disturbed or not tolerate the HMET system on the head. If the child refuses to wear the HMET, DCMA and

TABLE 1 Schedule of interventions and assessments.

	T0		T1 (+6 months)	T2 (+12 months)
Interventions				
E-coaching + CAU		x		
PACT + CAU		x		
CAU		x		
Assessments				
DCMA + HMET	x		x	x
BOSCC + HMET	x		x	x
MSEL	x		x	x
CBCL	x		x	x
CEBC	x		x	x
PSQ	x		x	x
PSI	x		x	x
PSOC	x		x	x
Brief-COPE	x		x	x
CAPES-DD	x		x	x

Abbreviations: BOSCC, Brief Observation of Social Communication Change; Brief-COPE, Brief Coping Orientation to Problems Experienced; CAPES-DD, Child Adjustment and Parent Efficacy Scale-Developmental Disability; CAU, community assistance as usual; CBCL, Child Behavior Checklist; CEBQ, Child Eating Behavior Questionnaire; DCMA, Dyadic Communication Measure Autism; HMET, head-mounted eye-tracking; MSEL, Mullen Scales of Early Learning; PACT, Pediatric Autism Communication Therapy; PSI, Parental Stress Index; PSOC, Parenting Sense of Competence Scale; PSQ, Pediatric Sleep Questionnaire.

BOSCC evaluations will be performed without the HMET on the child's head.

Concurrently, parents will be provided with a link to complete the questionnaires at home in the days following the session. Any discontinuation of the study will be reported with the specific reasons. Taking part in this study does not involve any particular risk for the participants. Nevertheless, adverse events will be monitored in all families throughout the study and will be reported to the principal investigator and the monitoring institutional board.

Data management

Study data will be collected in a secure electronic case report form (eCRF). All participants will be anonymized by assigning a unique identification number to each parent–child dyad included in the study. In this way, participants will only be identified by their unique identification number on all study-related documents and in the study database. Anonymized data from all participants will be managed and stored in the online data capture tool REDCap (Research Electronic Data Capture[53]). Hosted by the Polyclinique Médicale Universitaire (PMU) in Lausanne, REDCap is a secure and widely recognized application designed to support data collection for research studies. No sensitive identifying information will be collected on the eCRF. An encrypted master file linking participant identification numbers to the participants' identifying information will be compiled outside REDCap. This password-protected document will be kept separate and stored in a secure directory on a server of Lausanne University Hospital under the responsibility of the principal investigator. The same server will host and store all eye-tracking data and video recordings generated in the study. Printed documents from the study will be stored in a secure file cabinet at Lausanne University Hospital and access will be restricted to researchers involved in the study.

For quality assurance purposes, an independent monitoring institutional board from the Institut Universitaire de Formation et Recherche en Soins (IUFRS) will have biannual meetings with the trial manager and the main members of the research team. Direct access to source data and all study-related files will be granted on these visits. The ultimate purpose of the monitoring activities will be to ensure that the rights and welfare of human subjects are protected; that the reported data from the study are accurate, complete, and verifiable from the source documents; and that the conduct of the study complies with the latest approved study protocol, good clinical practice guidelines, and applicable regulations. No unauthorized personnel will have access to the data or to the participants' unique identification number. No publication or report of any kind will contain unique identification numbers.

Ethics

The study protocol (V.5, Ref. 2022–02196) has been approved by the local ethics committee (Commission cantonale d'éthique de la

recherche sur l'être humain, CER-VD), ensuring that all procedures adhere to the highest ethical standards. The research team will obtain written informed consent from parents before the baseline assessment. The consent forms of this study were carefully reviewed and approved by the ethics review board. Substantial changes to the setup and organization of the study will be submitted to the ethics committee for approval before implementation. Once their participation in the study is officially finished and the efficacy of e-coaching is assessed, parents allocated to the control group will be offered the most effective PMI, between the PACT and the e-coaching program, to compensate for their allocation to a nonintervention group. Once these participants have finished the last evaluation time point, they are considered to have finished their participation in the study and no additional data within the framework of the present RCT is collected. It is only then when we will offer them access to the most effective PMI.

Statistical analysis

Sample size calculation

We powered our study based on effect sizes from a prior PACT trial with young ASD children.[14] In that study, treatment effect was positive for parental synchronous response to the child ($d = 1.22$), child initiations with parent ($d = 0.41$), and for parent–child shared attention ($d = 0.33$). Under these premises, we used G*Power[54] to perform a power calculation to be able to detect a comparable effect with our primary outcome measure. Our power calculation concluded that a sample size of $n = 99$ would be required to detect the smallest reported effect size ($d = 0.33$) with a power of 80% and an a priori statistical threshold of 0.05, within a repeated-measures ANCOVA modeling of intervention effect with four predictors (group and three relevant covariates). Thus, a target of 99 families (33 families per arm) is planned to be enrolled and randomized in the study. With an expected drop-out rate of 10%, we predict that a total of 110 families will be recruited for this study. To facilitate this recruitment effort, a strong partnership with ASD associations and orientation platforms has been implemented in the canton of Vaud. A broad network of pediatricians, occupational therapists, and other healthcare professionals has been reached through several communication channels (conferences, flyers, trainings) to ensure that our team reaches the target sample size by the end of 2026.

Analysis plan

All statistical tests will be performed according to intention-to-treat principles using R (R Foundation for Statistical Computing). Baseline descriptive characteristics will be reported for each group. Summary statistics will be presented for procedural variables, such as the number of screened/recruited children, number of PACT/e-coaching sessions completed, number of dropouts, and the number of completed interventions by following the CONSORT 2010 guidelines. The primary analysis of the study will estimate the effect of the e-coaching intervention on the quality of parent–child interaction using intention-to-treat longitudinal ANCOVA over the 12-month study period. Intervention group (e-coaching, PACT, control) will be the between-subjects factor and the DCMA synchrony score will be the within-subjects factor repeated over time. Scores will be adjusted by age, gender, and primary outcome scores at baseline. The interaction between intervention group and time (T0, T1, T2) will be tested.

A separate comparable model will be conducted to estimate the treatment effect on the HMET-based synchrony indices. Treatment effects and 95% CIs will be reported. Missing data from all randomized families will be handled using maximum likelihood estimation, thus assuming data to be missing randomly. All secondary outcomes will be analyzed following the same statistical approach. Additional analyses such as the influence of baseline parental and child features on the response to treatment, as well as the association between primary and secondary outcomes, will be explored and potentially approved by the principal investigators of the study.

Trial results

The results of this RCT will be disseminated through peer-reviewed publications and scientific conferences. No personal data will be shared publicly. No online or written document or communication will refer to participants' personal data, and all public presentations will respect the integrity of the major goals of this RCT.

DISCUSSION

There are several unique and relevant aspects about this trial. Despite significant advances in the development of effective PMIs, parents of young children with ASD continue to face substantial gaps in early assistance. This reality underscores the need for new, more accessible intervention models that can overcome the barriers currently limiting widespread community implementation. Through this RCT, we introduce an innovative model of online parental coaching designed to be less restrictive for both families and professionals while still delivering evidence-based strategies. Our approach is distinguished by its ambition to offer a comprehensive intervention model. E-coaching covers areas such as supporting parent–child interaction, managing challenging behaviors, resolving sleep issues, and others, aiming to meet the diverse needs of families. By adopting a holistic approach, we hope to provide parents with a resourceful tool to guide them through the many challenges they face daily.

Currently, assessing objective responses to treatment remains a major challenge in studies evaluating the efficacy of early intervention in the field of ASD.[55] Eye tracking is a safe, noninvasive, and easily tolerated technique that represents a powerful approach for the identification of biomarkers of social attention in heterogeneous conditions such as ASD.[56] Conventional tools often focus on observable behaviors but may lack the sensitivity to detect subtler yet

significant changes. Recent work has suggested that eye-tracking-based measures can be used for clinical assessments[57] and to track response to behavioral interventions.[58] Thanks to HMETs, we now have a nonintrusive, wearable solution to quantify early gaze patterns within the infant's field of view during naturalistic interactions, which can be particularly valuable for mapping developmental pathways that may lead to atypical social and communication development, such as in ASD.[59] This approach may not only enrich our understanding of the underlying mechanisms of social attention in ASD, but also contribute to refining evaluation methodologies in future studies.

If our e-coaching model proves its effectiveness, it could be widely disseminated among the community of health and education professionals. Such dissemination would significantly increase the number of families benefiting from parental coaching, an intervention strategy not only recommended by international guidelines but also crucial for the well-being and development of children with ASD and their families. Moreover, translating our modules into multiple languages would ensure effective support for allophone families who are often marginalized in traditional interventions due to linguistic and cultural barriers. In conclusion, this RCT is not merely about proposing a new intervention model, it also aims to test a new evaluation methodology. The success of this initiative could mark a step forward in improving support for families of children with ASD, ensuring that no family is left behind.

AUTHOR CONTRIBUTIONS

C.P., J.A.O., S.M., N.C., and B.R.-H. conceived and designed the study. C.P. and B.R.-H. obtained the ethical approval. C.P., N.C., and B.R.-H. acquired funding to support the study. C.P. and E.A. developed the e-coaching program. C.P., M.-P.A., and B.R.-H. wrote the paper with input from all the authors. All authors read, reviewed, and approved the final manuscript.

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COMPETING INTERESTS

N.C. receives support from Fondation Dora and Fondation Hoffmann; she declares having no other competing interests. The other authors declare no competing interests.

TRIAL REGISTRATION

This RCT is registered on Clinicaltrials.gov with the identifier NCT05726708.

DATA AVAILABILITY STATEMENT

The principal investigator (N.C.) and the project coordinators (C.P. and B.R.-H.) will manage the access to the final study dataset for analysis. Data will not be made publicly available due to ethical restrictions with respect to the sharing of the participant's data. Nevertheless, investigators who aim to conduct or replicate specific analyses conducted within the framework of the present RCT by the project coordinators will be granted access to the final study dataset upon reasonable request. Once the RCT comes to an end, code used for analyses and summary statistics will be openly available via the Open Science Framework (OSF).

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PEER REVIEW

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