HHS Public Access

Author manuscript

Paediatr Perinat Epidemiol. Author manuscript; available in PMC 2022 June 06.

Published in final edited form as:

Paediatr Perinat Epidemiol. 2022 May ; 36(3): 435–445. doi:10.1111/ppe.12861.

Reasons for participation in a child development study: Are cases with developmental diagnoses different from controls?

Chyrise B. Bradley[1], **Amanda L. Tapia**[1], **Carolyn G. DiGuiseppi**[2], **Marti W. Kepner**[1], **Joy M. Kloetzer**[1], **Laura A. Schieve**[3], **Lisa D. Wiggins**[3], **Gayle C. Windham**[4], **Julie L. Daniels**[1]

[1]Department of Epidemiology, Gillings School of Global Public Health, The University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, USA

[2]Department of Epidemiology, Colorado School of Public Health, University of Colorado Anschutz Medical Campus, Aurora, Colorado, USA

[3]National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention, Atlanta, Georgia, USA

[4]California Department of Public Health, Environmental Health Investigations Branch, Richmond, California, USA

Abstract

Background: Current knowledge about parental reasons for allowing child participation in research comes mainly from clinical trials. Fewer data exist on parents' motivations to enrol children in observational studies.

Objectives: Describe reasons parents of preschoolers gave for participating in the Study to Explore Early Development (SEED), a US multi-site study of autism spectrum disorder (ASD) and other developmental delays or disorders (DD), and explore reasons given by child diagnostic and behavioural characteristics at enrolment.

Methods: We included families of children, age 2–5 years, participating in SEED (n = 5696) during 2007–2016. We assigned children to groups based on characteristics at enrolment: previously diagnosed ASD; suspected ASD; non-ASD DD; and population controls (POP). During a study interview, we asked parents their reasons for participating. Two coders independently coded responses and resolved discrepancies via consensus. We fit binary mixed-effects models to evaluate associations of each reason with group and demographics, using POP as reference.

Results: Participants gave 1–5 reasons for participation (mean = 1.7, SD = 0.7). Altruism (48.3%), ASD research interest (47.4%) and perceived personal benefit (26.9%) were most common. Two novel reasons were knowing someone outside the household with the study

Correspondence: Chyrise B. Bradley, Department of Epidemiology, Gillings School of Global Public Health, The University of North Carolina at Chapel Hill, Chapel Hill, NC, USA. chyrise@unc.edu.

AUTHOR CONTRIBUTION

None to report.

CONFLICT OF INTEREST

None to declare.

SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

conditions (peripheral relationship; 14.1%) and desire to contribute to a specified result (1.4%). Odds of reporting interest in ASD research were higher among diagnosed ASD participants (odds ratio [OR] 2.89, 95% confidence interval [CI] 2.49–3.35). Perceived personal benefit had higher odds among diagnosed (OR 1.92, 95% CI 1.61–2.29) or suspected ASD (OR 3.67, 95% CI 2.99–4.50) and non-ASD DD (OR 1.80, 95% CI 1.50–2.16) participants. Peripheral relationship with ASD/DD had lower odds among all case groups.

Conclusions: We identified meaningful differences between groups in parent-reported reasons for participation. Differences demonstrate an opportunity for future studies to tailor recruitment materials and increase the perceived benefit for specific prospective participants.

Keywords

case-control studies; child development; parental consent; participation reason

1 | BACKGROUND

Adults often participate in research out of altruism, for personal benefit (real or perceived), or 'trust'.[1–8] Other reasons for participation include having symptoms of the condition under investigation,[9] degree of risk involved,[3] or knowing someone affected by the condition.[4] There are comparatively few data on what motivates parents to enrol their children in research, although this knowledge could benefit study planning related to recruitment.[10,11] Most available data are from clinical trials that have potential to directly benefit the child.[12–22] These trials reported altruism, direct benefit to the child and trust in research as reasons parents consented to their child's participation. Only one study compared reasons for participation between children with and without illness–parents of 126 healthy and 135 'sick' children, reported being motivated by direct benefit with low risk to their child. Other motivators differed between groups, for example, general benefit to science motivated families of healthy but not sick children.[22]

Studies of parental reasons for allowing child participation in observational research also identified altruism and perceived personal benefit as reasons for participation,[23–27] along with reputation of, or trust in, the investigators or institution conducting the research.[28] Most were conducted outside the United States (US), and only two reported reasons for participation in autism spectrum disorder (ASD) or neurodevelopment research.[28,29] The few studies conducted in the United States have examined reasons within hypothetical or general health research,[28,30,31] biobanking for genetics research,[29–32] or focussed on specific medical conditions.[15,17]

The range of reasons reported may be truncated because many studies provided only fixed-choice responses.[14,16,24,27,28] Studies that asked open-ended questions were small, convenience-sampled subsets of participants approached after study participation was complete, rather than at enrolment or during participation.[12,13,25,26,29] Thus, the time lag since enrolment or the benefits experienced from participation may have altered parents' perception of why they initially decided to participate. Although existing research suggests altruism, perceived personal benefit and some form of trust/reputation may motivate parents to allow children's research participation, those motivations may differ by study design/

context, so data are needed about motivation for families' participation in observational studies of developmental issues.[33]

2 | METHODS

The present study is an analysis of reasons families gave for participating in the Study to Explore Early Development (SEED). SEED is a multi-site, US-based, case-control study of risk factors and correlates of ASD that took place between 2007 and 2016. Full details on the study methods have been published elsewhere.[34] Briefly, SEED enroled preschool children, with and without a diagnosis of ASD, for participation in a complex protocol that included multiple components: several questionnaires, a phone interview and in-person developmental assessments with the child. Eligibility included child's birthdate in one of the two ranges (September 2003–August 2006 or January 2008–December 2011), age 2–5 years at enrolment, residence at birth and during study participation in a study catchment area (regions in six states: California, Colorado, Georgia, Maryland, North Carolina and Pennsylvania), and a consistent caregiver since six months of age (or younger) who spoke English (all sites) or Spanish (two sites).

2.1 | Case-control identification

Children with an ASD or other non-ASD developmental disorder (DD) were identified through health care and education providers and population controls (POP) from birth records.

Families were invited by mail and/or phone. During enrolment, we asked whether the child had ever been diagnosed with ASD and asked a parent to complete the Social Communication Questionnaire (SCQ)[35] as an ASD screener. Children with the previously diagnosed ASD or who scored 11 points or higher on the SCQ were assigned to an ASD protocol. This protocol included ASD-specific developmental assessments completed by the parent and child and a child early learning assessment. All other children were assigned to a non-ASD protocol that included the child early learning assessment. Families were offered financial incentives for each study component and results of the developmental assessments.

Phone interview respondents (mother for 99.0%) reported about the mother's health and pregnancy experiences. During that interview, we asked about mother's education, race, ethnicity and household income as well as all past pregnancies, including any developmental or medical diagnoses each live-born child may have received. At the end of the interview, we asked an open-ended question, 'Why did you decide to be in this study?'. Interviewers entered responses verbatim into an electronic data-capture system. We conducted this interview prior to scheduling the developmental assessments and, thus, prior to the parent receiving any feedback about their child's development.[34]

2.2 | Exposures

Primary exposure was assignment to study group: (1) those with an existing ASD diagnosis assigned to the ASD protocol (diagnosed ASD); (2) those without an existing ASD diagnosis assigned to the ASD protocol based on positive ASD screen (suspected ASD); (3) those with a previously diagnosed DD identified by a health care or education provider and

assigned to the non-ASD protocol based on negative ASD screen; and (4) those recruited from birth records assigned to the non-ASD protocol based on negative ASD screen (POP) (Figure 1). Potential confounders were obtained at the enrolment screening or from the phone interview and included child's and mother's age at enrolment and mother's education, race/ethnicity, household income and number of children other than the study child with health or developmental issues.

2.3 | Outcomes

We reviewed responses to the phone interview question about decision to participate and coded them into one or more reason categories. We established six categories, a priori, based on the existing literature and anecdotal reports from site interviewers: altruism (help others), perceived personal benefit (wants assessment or answers), peripheral relationship with ASD/DD (knows people outside their household with ASD or DD), ASD research interest (stated finding answer/cures/causes of ASD/DD), financial incentive and reputation of agency/investigator (wants to assist, or admires, inviting agency or investigator).[1–9,14–24] We added four additional reason categories during the initial coding pass to accommodate the breadth of responses [general research interest (noted research other than ASD/DD), social encouragement (someone asked or encouraged them to consider the study), desired specific study result (stated a specific outcome of interest) and miscellaneous], resulting in ten final categories plus ‘no reason’.

We used an independent coding process–first coder (JK) review, second coder (MK) review and consensus review. All reviews were blinded to all other study data. The first and second coders agreed on 62.9% of reasons. For 37.1%, consensus was achieved through discussion among both coders and first author. We used final consensus coding in analyses.

2.4 | Statistical analyses

We examined differences in reasons for participation by study group while accounting for potential confounding by demographic and other family characteristics. We analysed each reason as a dependent dichotomous variable (reason given/not given). We fit unadjusted binary mixed-effects models (binomial family and logit link) to evaluate associations of study group with each coded reason (except ‘no reason’), using study site as a random effect to account for site-specific correlation among subjects and the POP group as the normative reference. Additionally, we fit adjusted binary mixed-effects models (with site as a random effect) to evaluate potential confounding from demographic and other family characteristics (child's age at enrolment, sex and number of siblings with special needs; mother's age, race/ethnicity, education and household income) on associations of study group with each coded reason, as well as to assess the specific associations that these characteristics have with each coded reason. The reference group in these models was determined by the category with the largest sample size because we did not assume a normative reference group. Odds ratios and 95% Wald confidence intervals were estimated in unadjusted and adjusted regression analyses.

2.5 | Missing data

Data were missing for only two variables: 'siblings with special needs' (0.5%) and 'household income' (2.9%). Therefore, regression analyses were performed on those with complete data (96.6%).

2.6 | Sensitivity analysis

We performed a sensitivity analysis to account for excluded participants (ie did not start, or did not finish, phone interview) using inverse probability weights (IPW). The IPW model weighted participants by the inverse of the probability that they were included in the analysis, estimated using a logistic regression model, to compensate for underrepresentation of persons with characteristics associated with incomplete data. The logistic regression model included maternal age, education, and race/ethnicity, child sex and age at enrolment, study site and study period, as well as all three-way interactions between variables. We used forward selection with a threshold of $p = .15$ to select the terms to be added to the model. Model fit was evaluated using Hosmer–Lemeshow goodness-of-fit statistic, and weights were examined for stability and normalised to the sample size by inclusion status. SAS version 9.4 was used for all analyses.

2.7 | Ethics approval

The study was approved by the Institutional Review Board of the US Centers for Disease Control and Prevention as well as that of each participating site.

3 | RESULTS

A total of 7271 children were enroled in SEED. We excluded 155 siblings (retaining the invited child), one child older than 69 months at enrolment, 1194 children whose caregiver did not participate in the phone interview and 225 whose interview was terminated prior to reaching the final reasons question, resulting in 5696 families included in this analysis (1775 diagnosed ASD, 808 suspected ASD, 1357 non-ASD DD and 1756 POP).

Table 1 describes the categories used to code reasons for participating and their respective frequencies as the sole reason or one of multiple reasons. Many participants gave only one reason for participation (45.3%); others gave two reasons (41.6%), or three-to-five reasons (13.1%) (mean 1.7, SD 0.7).

Demographic characteristics of participants differed across the four study groups, as did reasons for participating (Table 2). Overall, the most common reasons for participating were altruism (48.3%), ASD research interest (47.4%) and perceived personal benefit (26.9%).

Figure 2 and Table 3 show the relative differences in reasons for participation across study groups. Adjusted results were similar to unadjusted results, with most adjusted results attenuated. The reasons for participation that had the strongest association with study group were ASD research interest, perceived personal benefit, peripheral relationship with ASD/DD and financial incentive. Participating because of an interest in ASD research had higher odds among the diagnosed ASD group (odds ratio [OR] 2.89, 95% confidence interval [CI] 2.49–3.35), compared with the POP group. Perceived personal benefit had

higher odds among all case groups, particularly the suspected ASD group (OR 3.67, 95% CI 2.99–4.50). Compared with POP controls, all case groups were less likely to report motivation related to a peripheral relationship with ASD/DD or financial incentive.

Reasons for participation did not vary greatly across sociodemographic factors except race/ethnicity and income (Table S1). For example, altruism had higher odds of being reported as a participation reason among those who were White, non-Hispanic, had a household income over 100,000 US dollars (USD) (vs. ≤USD 30,000) and did not have other children with special needs. Perceived personal benefit had higher odds among those who were non-White or had a household income of USD 30,000 or lower. Peripheral relationship with those with ASD/DD had higher odds of being reported among White non-Hispanic mothers, those with at least a college degree and those with household income of USD 70,000 or above. Giving social encouragement as a reason had higher odds among families where the mother was under age 30 or had a household income of under USD 10,000.

3.1 | Sensitivity analysis

IPWs corrected for differences in inclusion status on key covariates (Table S2). IPW results showed no substantive differences in the direction or magnitude of odds ratio estimates compared with unweighted results (Tables S3 and S4).

4 | COMMENT

4.1 | Principal findings

In this study, we analysed data from 5,696 SEED families to explore whether reasons differed by child's diagnostic and behavioural characteristics at enrolment (ie study group). As with other childhood studies,[13–18,22,24–29] we found that families participating in this study frequently stated altruism (ie wanting to help other children or families) and perceived personal benefit (ie learning something specific about their child's development) as reasons for participating.

4.2 | Strengths of the study

This study was considerably larger than many other prior studies and reflects input from both affected participants and population controls. Further, SEED targeted a geographically and racially diverse sample of US families. The study diversity and size along with an open-ended solicitation of reasons may reflect more diverse opinions about motivation for participation compared with prior studies, particularly those that had parents endorse pre-established reasons.

4.3 | Limitations of the data

In acquiring reasons for participation, SEED staff asked each caregiver a single, open-ended question without further prompting. It is possible that parents provided reasons they perceived as socially desirable because they were talking to an interviewer.[7] However, this open-ended method would likely elicit ideas most important to parents in making an enrolment decision. Mothers most often gave the responses; the father's motivation was not represented and may have differed from the mother's motivation. Given that consent was

required from only one parent for this minimal risk study, and the fact that the mother was most often reached for enrolment and usually made a decision at that time, the mother's report of reasons during the interview seems unlikely to have been influenced by the father's perspectives. We acknowledge that we did not solicit reasons for non-participation among those who did not enrol so are unable to address whether knowing these reasons may help overcome enrolment refusals.

Further, coding open-text reasons for participation is subject to interpretation. For the few studies that describe their process for coding open-ended text, they most often used independent, manual coders with consensus review[2,4] or team review.[3,6,8,26] The consensus review we performed on the portion for which the reviewers did not code the same helped minimise individual biases and simple coding errors that could occur when using only a single coder.

4.4 | Interpretation

Unlike other studies,[6–8,12,15,19,28,30] ours showed low percentages of parents reported trust in research and financial incentive as a reason for their participation. Trust in research (reputation of agency, institution or investigator) may be more important in clinical trials or interventional studies where there is direct risk to the child. Financial incentive/compensation may be more important among population controls or studies of healthy populations. It is possible that, in other studies, parents select these reasons when offered as a fixed-choice option, but they do not come to mind when asked in an open-ended manner, as in our study.

Similar to other studies reporting ‘participation of friends’,[1] ‘doctor suggestion’,[12] ‘external influence’,[15] ‘encouraged by medical staff’ and ‘influence of friends’,[17,21] we found social encouragement/engagement was a reason for participating, albeit a low proportion (5.4%). Reporting this reason had higher odds among families with younger mothers or household income less than USD 10,000/year suggesting these groups may need more encouragement from, or invitation by, someone they know or trust.

While other studies of children sometimes included interest in research or ‘contribution to science’ as altruism,[17,23,27] we distinguished between altruism and interest in general research versus ASD/DD-specific research to assess potential variability by study group. We found distinctions between these categories (altruism, ASD/DD research interest and general research interest); nearly a quarter of parents giving each of these reasons reported it as the sole reason for participation (24.2%, 26.0% and 28.3%, respectively). However, the patterns differed across the study groups. A higher proportion of those in the diagnosed ASD group stated ASD/DD research interest as a reason, while a higher proportion in the POP group stated a general research interest.

Our study revealed a reason for participating not previously cited by earlier publications–desiring the research enterprise to produce a specified result. Nearly, one-tenth of parents reporting this reason stated it as their sole reason for participating. This reason did not vary by study group and may suggest that some research participants were motivated by the potential to contribute to a particular hypothesis and/or may reflect a history of controversy

surrounding causes of ASD in the United States and extensive, sometimes charged, media attention. This novel finding highlights the importance of considering the research context (eg conditions that are subject to much public interest or debate) when exploring reasons for research participation. Further, in the interest of patient-centered research, these types of responses could serve to drive the development of future research questions.

We also found one reason that has been cited only in adult studies–association with someone who has the condition under study.[9] Compared with population controls, those in the diagnosed or suspected ASD groups less often cited a peripheral relationship with ASD/DD as a reason for participating (26.8% vs. 2.6%, 6.3%, respectively). It is possible that association with those who have ASD/DD may be an extension of altruism in the POP group, such that an individual wants to help someone whom they know personally. The separation of this concept (‘participating for someone I know with this condition’) from the idea of generic altruism (‘want to help others in general’) may matter more in studies recruiting both affected individuals along with unaffected controls. For studies that allow participants to self-refer or volunteer, asking those who are affected by the condition to refer others who are not affected might increase participation among a control group.

Several reasons did not fit well into any category and were not represented with any frequency, leading to a heterogeneous group of miscellaneous reasons. Many unique reasons serve as a reminder that what might motivate an individual to contribute to research is not always predictable. This set of heterogeneous reasons and lack of difference between study groups suggests the possibility that recruitment conversations may enhance potential parent participants' understanding of a research study and allow them to feel more invested in the study goals when considering enroling their child in observational research.

As highlighted in this study, and as noted by Vanhelst et al.,[22] the motivation to participate differed between those in affected versus unaffected groups. In this study, these between-group differences persisted after adjustment for key covariates. Two key practice implications arise from this finding–first, tailoring study recruitment materials to highlight opportunities or outcomes that might be especially influential for recruiting particular groups; second, offering what may be perceived as a personal benefit, even if it is not a direct benefit. Recruitment materials can be targeted to appeal to certain groups using the various factors that influence decisions to participate in research. For example, altruism can be promoted among population control recruits by including a description of the potential benefit to other children or families in the future. When recruiting participants in an affected, or potentially affected, group, materials should clearly describe not only the research goals, but also incentives such as test results or special evaluations that individuals might find valuable. In our study, those in the suspected ASD group had the highest odds of stating they wanted the study evaluation or to learn more about their child's abilities (perceived personal benefit) as the reason they participated. Of those giving this reason, 37.1% gave it as the only reason. Those of non-White race/ethnicity and lower income (<USD 30,000) were also more likely to give this reason, even when controlling for other covariates such as study group, which may suggest some disparities in access to developmental evaluations. In the United States, access to developmental evaluations often requires referrals from primary care doctors and a long wait time for developmental specialist appointments.[36]

The evaluation offered as part of this study, along with the promise of receiving results, seems to have motivated many parents to participate. Offering evaluation or test results that are challenging to obtain or potentially less accessible by certain groups, or in certain regions/areas, may motivate mothers of children with many types of developmental issues to consent to observational research. This contrasts with financial incentives, which may be more influential in recruiting controls. The combination of tailored recruitment and offering what may be perceived as a personal benefit may further improve enrolment among underrepresented groups.

5 | CONCLUSIONS

SEED provided a unique opportunity to explore spontaneously provided reasons for participation in child development research. Reasons for participation in this study are largely similar to those elucidated by paediatric clinical trials. Most importantly, differences in reasons for participation by study group demonstrate an opportunity for future studies to target recruitment materials and to increase the perceived benefit for specific prospective participants. The myriad reasons reported highlight an opportunity to enhance recruitment through conversation, allowing potential participants and research staff to discuss fully the merits of the study and participation requirements, rather than simply relying on written or generic solicitations.

Future research could explore whether there are specific clusters or patterns of reasons given by particular groups (affected vs unaffected) that may help tailor the development of recruitment materials or recruitment conversations. Additionally, as suggested by research among women of colour,[10,11] future analyses could examine interactions between covariates such as race/ethnicity, parent age, education, income and other family characteristics to target recruitment approaches to specific subgroups and potentially contribute to more equitable inclusion in paediatric research participation across all segments of society. In general, research planning that carefully considers the values and motivations of the target sample may influence recruitment success.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

ACKNOWLEDGEMENTS

Some of these data were supplied by the Bureau of Health Statistics and Research–Pennsylvania Department of Health, Harrisburg, PA. The PA Department of Health specifically disclaims responsibility for any analysis interpretations or conclusions. The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the US Centers for Disease and Control and Prevention.

Funding information

This publication was supported by twelve cooperative agreements from the US Centers for Disease Control and Prevention (CDC): Cooperative Agreement Number U10DD000180, Colorado Department of Public Health; Cooperative Agreement Number U10DD000181, Kaiser Foundation Research Institute (CA); Cooperative Agreement Number U10DD000182, University of Pennsylvania (PA); Cooperative Agreement Number U10DD000183, Johns Hopkins University (MD); Cooperative Agreement Number U10DD000184, University of North Carolina at Chapel Hill (NC); Cooperative Agreement Number U10DD000498, Michigan State University (DCC); Cooperative Agreement Number U01000750, University of Colorado Denver; Cooperative Agreement

Number U01000748, Kaiser Foundation Research Institute (CA); Cooperative Agreement Number U01000752, University of Pennsylvania; Cooperative Agreement Number U01000746, Johns Hopkins University; Cooperative Agreement Number U01000749, University of North Carolina at Chapel Hill; and Cooperative Agreement Number U10DD000901, Michigan State University.

DATA AVAILABILITY STATEMENT

Research data are not shared.

REFERENCES

1. Bongartz H, Rubsamen N, Raupach-Rosin H, Akmatov MK, Mikolajczyk RT. Why do people participate in health-related studies? Int J Public Health. 2017;62:1059–1062. [PubMed: 28861618]
2. Locock L, Smith L. Personal benefit, or benefiting others? Deciding whether to take part in clinical trials. Clin Trials. 2011;8:85–93. [PubMed: 21163854]
3. McCann SK, Campbell MK, Entwistle VA. Reasons for participating in randomized controlled trials: conditional altruism and considerations for self. BioMed Central. 2010;11:31–41.
4. Mein G, Seale C, Rice H, et al. Altruism and participation in longitudinal health research? Insights from the Whitehall II Study. Soc Sci Med. 2012;75:2345–2352. [PubMed: 23031604]
5. Sheridan R, Martin-Kerry J, Hudson J, Parker A, Bower P, Knapp P. Why do patients take part in research? An overview of systematic reviews of psychosocial barriers and facilitators. BMC Trials. 2020;21:259.
6. Slegers C, Zion D, Glass D, et al. Why do people participate in epidemiological research? Bioethical Inquiry. 2015;12:227–237. [PubMed: 25672617]
7. Soule M, Beale EE, Suarez L, et al. Understanding motivations to participate in an observational research study: why do patients enroll? Soc Work Health Care. 2016;55(3):231–246. [PubMed: 26933943]
8. Wasan AD, Taubenberger SP, Robinson WM. Reasons for participation in pain research: can they indicate a lack of informed consent? Pain Med. 2009;10(1):111–119. [PubMed: 18657219]
9. Dunn KM, Jordan K, Lacey RJ, Shapley M, Jinks C. Patterns of consent in epidemiologic research: evidence from over 25,000 responders. Am J Epidemiol. 2004;159:1087–1094. [PubMed: 15155293]
10. Gilliss CL, Lee KA, Gutierrez Y, et al. Recruitment and retention of healthy minority women into community-based longitudinal research. J Womens Health Gend Based Med. 2001;10(1):77–85. [PubMed: 11224947]
11. Moorman PG, Newman B, Millikan RC, Tse CJ, Sandler DP. Participation rates in a Case-Control Study: the impact of age, race, and race of interviewer. Ann Epidemiol. 1999;9:185–195.
12. Chappuy H, Doz F, Blanche S, Gentet J-C, Pons G, Treluyer J-M. Parental consent in paediatric clinical research. Arch Dis Child. 2006;91:112–116. [PubMed: 16246853]
13. Gammelgaard A, Knudsen LE, Bisgaard H. Perceptions of parents on the participation of their infants in clinical research. Arch Dis Child. 2006;91:977–980. [PubMed: 16820387]
14. Harth SC, Thong YH. Sociodemographic and motivational characteristics of parents who volunteer their children for clinical research: a controlled study. BMJ. 1990;300:1372–1375. [PubMed: 2372582]
15. Hoberman A, Shaikh N, Bhatnagar S, et al. What factors influence parental decisions to participate in clinical research: consenters versus non-consenters. JAMA Pediatrics. 2013;167(6):561–566. [PubMed: 23546617]
16. Nieminen H, Syrjänen RK, Puumalainen T, Sirén P, Palmu AA. Health benefit for the child and promotion of the common good were the two most important reasons for participation in the FinIP vaccine trial. Vaccine. 2015;33:3695–3702. [PubMed: 26073011]
17. Rothmier JD, Lasley MV, Shapiro GG. Factors influencing parental consent in pediatric clinical research. Pediatrics. 2003;111(5):1037–1041. [PubMed: 12728085]
18. Sammons HM, Atkinson M, Choonara I, Stephenson T. What motivates British parents to consent for research? A Questionnaire Study. BMC Pediatr. 2007;7:12–19. [PubMed: 17349034]

19. Tait AR, Voepel-Lewis T, Malviya S. Participation of children in clinical research: factors that influence a parent's decision to consent. Anesthesiology. 2003;99:819–825. [PubMed: 14508312]
20. Tromp K, Zwaan M, van de Vathorst S. Motivations of children and their parents to participate in drug research: a systematic review. Eur J Pediatr. 2016;175:599–612. [PubMed: 27041121]
21. van Stuijvenberg M, Suur MH, de Vos S, et al. Informed consent, parental awareness, and reasons for participating in a randomized controlled study. Arch Dis Child. 1998;79:120–125. [PubMed: 9797591]
22. Vanhelst J, Hardy L, Bert D, et al. Effect of child health status on parents' allowing children to participate in pediatric research. BMC Med Ethics. 2013;14:7–16. [PubMed: 23414421]
23. Hayman RM, Taylor BJ, Peart NS, Galland BC, Sayers RM. Participation in research: informed consent, motivation and influence. J Paediatr Child Health. 2001;37:51–54. [PubMed: 11168870]
24. Maayan-Metzger A, Kedem-Friedrich P, Kuint J. Motivations of mothers to enroll their newborn infants in general clinical research on well-infant care and development. Pediatrics. 2008;121:e590–e596. [PubMed: 18310179]
25. Morgan AT, Reilly S, Eadie P, Watts A, Simpson C. Parental consent for neuroimaging in paediatric research. Child Care Health Dev. 2009;36(2):241–248. [PubMed: 19645826]
26. Trottier M, Roberts W, Drmic I, et al. Parents' perspectives on participating in genetic research in autism. J Autism Dev Disord. 2013;43:556–568. [PubMed: 22782649]
27. Vecchi Brumatti L, Montico M, Russian S, et al. Analysis of motivations that lead women to participate (or not) in a newborn cohort study. BMC Pediatr. 2013;13:53–60. [PubMed: 23577644]
28. Fletcher-Watson S, Larsen K, Salomone E; Members of the COST ESSEA Working Group. What do parents of children with autism expect from participation in research? A community survey about early autism studies. Autism. 2019;23(1):175–186. [PubMed: 29126359]
29. Singh JS. Narratives of participation in autism genetics research. Sci Technol Human Values. 2015;40(2):227–249.
30. Engster SA, Fascetti C, Daw K, Cohen Reis E. Parent perceptions of and preferences for participation in child health research: results from a pediatric practice-based research network. J Am Board Fam Med. 2019;32:685–694. [PubMed: 31506364]
31. Halverson CME, Friedman RL. Attitudes of African-American parents about biobank participation and return of results for themselves and their children. J Med Ethics. 2012;38:561–566. [PubMed: 22573882]
32. Klima J, Fitzgerald-Butt SM, Kelleher KJ, et al. Understanding of informed consent by parents of children enrolled in a genetic biobank. Genet Med. 2014;16(2):141–148. [PubMed: 23807615]
33. Fisher HR, McKevitt C, Boaz A. Why do parents enrol their children in research: a narrative synthesis. J Med Ethics. 2011;37:544–551. [PubMed: 21478415]
34. Schendel DE, DiGuiseppi C, Croen LA, et al. The Study to Explore Early Development (SEED): a multisite epidemiologic study of autism by the Centers for Autism and Developmental Disabilities Research and Epidemiology (CADDRE) network. J Autism Dev Disord. 2012;42(10):2121–2140. [PubMed: 22350336]
35. Rutter M, Bailey A, Lord C. SCQ: Social Communication Questionnaire. Western Psychological Services; 2003.
36. Gordon-Lipkin E, Foster J, Peacock G. Whittling down the wait time: exploring models to minimize the delay from initial concern to diagnosis and treatment of autism spectrum disorder. Pediatr Clin North Am. 2016;63(5):851–859. [PubMed: 27565363]

Synopsis

Study question

What are reasons families participate in child development research and are there differences by child diagnostic and behavioural characteristics at enrolment (ie study group)?

What is already known

Altruism, personal benefit (real or perceived), risk versus benefit and association with someone who has the condition under study are reasons adults participate in research. Less is known about why parents agree to paediatric research participation, particularly in observational research.

What this study adds

This is the largest analysis to date examining reasons for participation in an observational child development study. We found similar reasons to those elucidated by paediatric clinical trials and identified previously unreported reasons. We highlight differences in reasons given by study group and make specific recommendations for targeting recruitment.

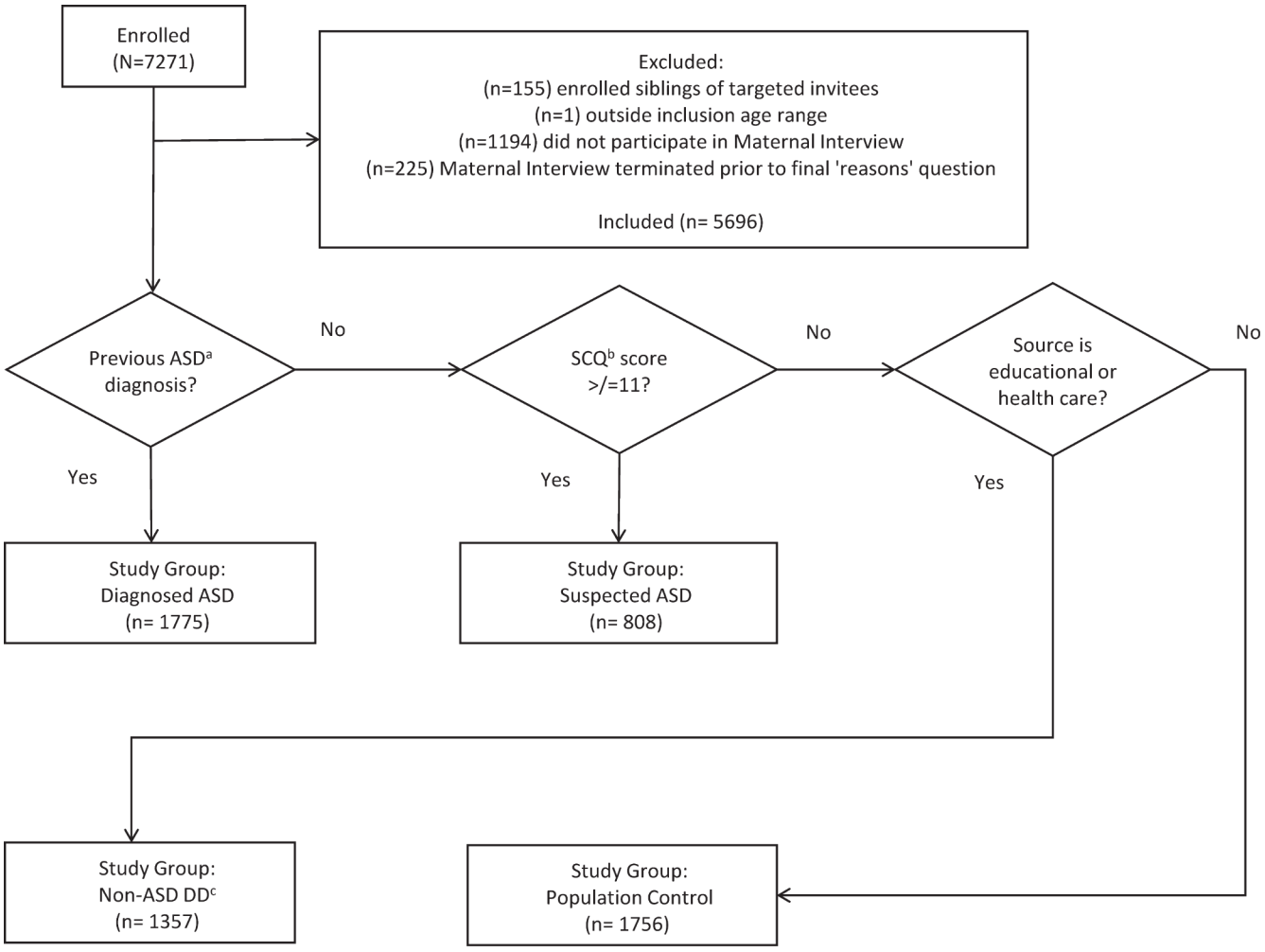

FIGURE 1.

Participant flow for the Study to Explore Early Development, 2007–2016. [a]Autism spectrum disorder. [b]Social Communication Questionnaire. [c]Developmental delay or disorder

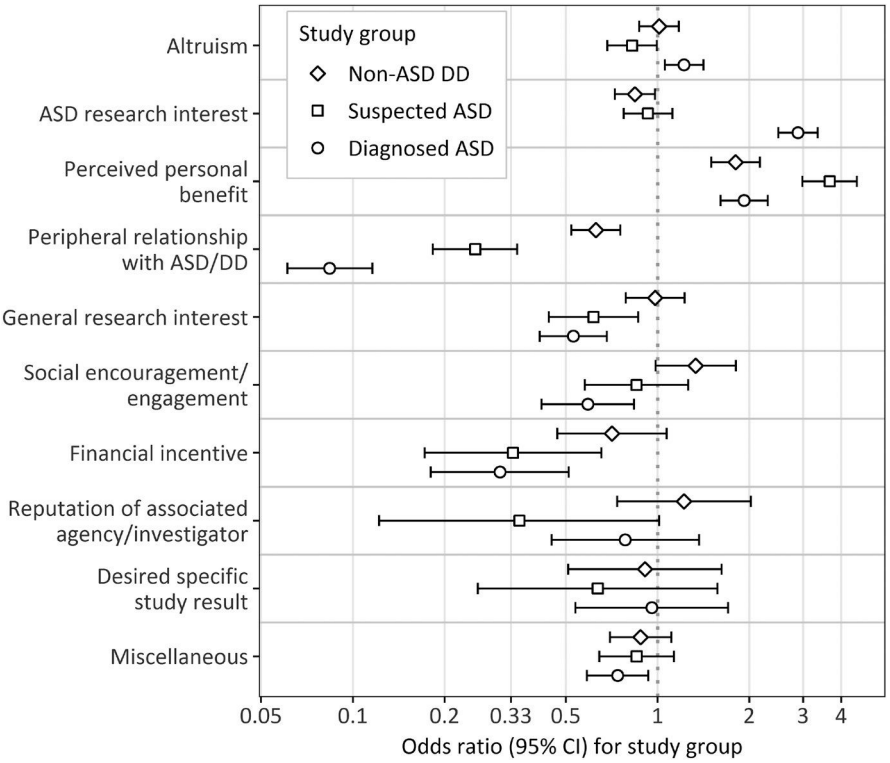

FIGURE 2.

Adjusted odds ratios and 95% confidence intervals for each reported reason by study group as compared to population control group in the Study to Explore Early Development, 2007–2016

TABLE 1

Description and frequencies of reasons[a] given for participating in the Study to Explore Early Development (SEED), 2007–2016

Reason	Description	*N*	Given as sole reason (%)	Given as one of 2 reasons (%)	Given as one of 3–5 reasons (%)
Altruism	Wants to help other kids/families	2749	24.2	53.7	22.2
ASD[b] research interest	Interested in ASD research, wants to know what causes ASD/DD[c], wants to find 'a cure', thinks SEED is interesting/worthwhile	2701	26.0	52.6	21.4
Perceived personal benefit	Wants to get assessment for their child or get some answers about their child	1530	37.1	40.7	22.3
Peripheral relationship with ASD/DD	Knows someone outside their household, or works with people outside their household, with ASD or DD	801	16.1	52.3	31.6
General research interest	Works in research, interested in research, wants experience of being in a study (no specific mention of ASD or DD or child development)	575	28.3	44.3	27.3
Social encouragement/ engagement	Someone (e.g. family member, friend, healthcare provider, study staff) asked, encouraged, or invited them	309	32.4	45.3	22.3
Financial incentive	Wants the monetary incentive	140	10.0	54.3	35.7
Reputation of associated agency/ investigator	Wants to assist (or admires) a specific agency, institution, or investigator associated with the study	95	8.4	40.0	51.6
Desired specific study result	Wants to help SEED show a specific outcome such as 'pollution causes autism' or 'older moms can have healthy kids' or 'vaccines do/do not cause autism'	82	9.8	43.9	46.3
Miscellaneous	Various reasons that did not fit in other categories nor fit together as a unique category	621	30.9	42.2	26.9
No reason	Stated 'no reason' or 'don't know'	30	100.0	0.0	0.0

[a] Multiple reasons could be given by each respondent.

[b] Autism spectrum disorder.

[c] Developmental delay or disorder.

TABLE 2

Characteristics of study participants in the Study to Explore Early Development, 2007–2016

		Study group			
	Overall	**Diagnosed ASD[a]**	**Suspected ASD**	**Non-ASD developmental delay or disorder**	**Population control (POP)**
N	5696	1775	808	1357	1756
Child age (months) at enrolment, mean (SD)	53.4 (8.7)	53.9 (8.1)	52.5 (9.3)	53.8 (8.7)	52.9 (9.1)
Female, *N* (%)	1933 (33.9)	327 (18.4)	271 (33.5)	488 (36.0)	847 (48.2)
Maternal age (years) at enrolment, *N* (%)					
<30	931 (16.3)	295 (16.6)	223 (27.6)	197 (14.5)	216 (12.3)
30–34	1446 (25.4)	463 (26.1)	228 (28.2)	312 (23.0)	443 (25.2)
35–39	1888 (33.1)	599 (33.7)	192 (23.8)	448 (33.0)	649 (37.0)
40+	1431 (25.1)	418 (23.5)	165 (20.4)	400 (29.5)	448 (25.5)
Maternal race/ethnicity, self-reported, *N* (%)					
White, not Hispanic	3234 (56.8)	875 (49.3)	349 (43.2)	802 (59.1)	1208 (68.8)
Black, not Hispanic	1153 (20.2)	419 (23.6)	263 (32.5)	241 (17.8)	230 (13.1)
Other, not Hispanic	561 (9.8)	217 (12.2)	70 (8.7)	113 (8.3)	161 (9.2)
Hispanic	748 (13.1)	264 (14.9)	126 (15.6)	201 (14.8)	157 (8.9)
Maternal education, self-reported, *N* (%)					
HS diploma or less	888 (15.6)	285 (16.1)	248 (30.7)	202 (14.9)	153 (8.7)
Associate's degree or some college	1566 (27.5)	593 (33.4)	277 (34.3)	329 (24.2)	367 (20.9)
Bachelor's degree	1779 (31.2)	531 (29.9)	172 (21.3)	441 (32.5)	635 (36.2)
Advanced degree	1463 (25.7)	366 (20.6)	111 (13.7)	385 (28.4)	601 (34.2)
Maternal household income (US dollars), self-reported, *N* (%)[b]					
Less than 10,000	454 (8.0)	142 (8.0)	137 (17.0)	92 (6.8)	83 (4.7)
10,000 to 30,000	797 (14.0)	314 (17.7)	180 (22.3)	159 (11.7)	144 (8.2)
30,000 to 50,000	718 (12.6)	242 (13.6)	121 (15.0)	178 (13.1)	177 (10.1)
50,000 to 70,000	704 (12.4)	254 (14.3)	90 (11.1)	167 (12.3)	193 (11.0)
70,000 to 90,000	689 (12.1)	202 (11.4)	71 (8.8)	185 (13.6)	231 (13.2)
90,000 to 110,000	646 (11.3)	174 (9.8)	64 (7.9)	158 (11.6)	250 (14.2)
Over 110,000	1524 (26.8)	404 (22.8)	107 (13.2)	377 (27.8)	636 (36.2)
Missing	164 (2.9)	43 (2.4)	38 (4.7)	41 (3.0)	42 (2.4)

		Study group			
	Overall	**Diagnosed ASD[a]**	**Suspected ASD**	**Non-ASD developmental delay or disorder**	**Population control (POP)**
Number of siblings with special needs, *N*(%)					
0	4296 (75.4)	1285 (72.4)	578 (71.5)	997 (73.5)	1436 (81.8)
1	1074 (18.9)	366 (20.6)	156 (19.3)	283 (20.9)	269 (15.3)
2+	297 (5.2)	114 (6.4)	67 (8.3)	71 (5.2)	45 (2.6)
Missing	29 (0.5)	10 (0.6)	7(0.9)	6 (0.4)	6(0.3)
Study site, *N*(%)					
California	963 (16.9)	304 (17.1)	99 (12.3)	250 (18.4)	310 (17.7)
Colorado	984 (17.3)	282 (15.9)	141 (17.5)	246 (18.1)	315 (17.9)
Georgia	1064 (18.7)	360 (20.3)	137 (17.0)	269 (19.8)	298 (17.0)
Maryland	808 (14.2)	258 (14.5)	110 (13.6)	175 (12.9)	265 (15.1)
North Carolina	1021 (17.9)	285 (16.1)	179 (22.2)	254 (18.7)	303 (17.3)
Pennsylvania	856 (15.0)	286 (16.1)	142 (17.6)	163 (12.0)	265 (15.1)
Reasons for participating, *N*(%)					
Altruism	2749 (48.3)	911 (51.3)	314 (38.9)	646 (47.6)	878 (50.0)
ASD research interest	2701 (47.4)	1166 (65.7)	309 (38.2)	504 (37.1)	722 (41.1)
Perceived personal benefit	1530 (26.9)	528 (29.7)	362 (44.8)	364 (26.8)	276 (15.7)
Peripheral relationship with ASD/DD[c]	801 (14.1)	46 (2.6)	51 (6.3)	233 (17.2)	471 (26.8)
General research interest	575 (10.1)	106 (6.0)	52 (6.4)	163 (12.0)	254 (14.5)
Social encouragement/engagement	309 (5.4)	64 (3.6)	49 (6.1)	100 (7.4)	96 (5.5)
Financial incentive	140 (2.5)	22 (1.2)	11 (1.4)	39 (2.9)	68 (3.9)
Reputation of associated agency/investigator	95 (1.7)	24 (1.4)	4(0.5)	31 (2.3)	36 (2.1)
Desired specific study result	82 (1.4)	24 (1.4)	7 (0.9)	20 (1.5)	31 (1.8)
Miscellaneous	621 (10.9)	170 (9.6)	96 (11.9)	148 (10.9)	207 (11.8)
No reason	30 (0.5)	7 (0.4)	4 (0.5)	11 (0.8)	8 (0.5)

[a] Autism spectrum disorder.

[b] Past 12 months; categories are presented as offered to participants.

[c] Developmental delay or disorder.

TABLE 3

Unadjusted and adjusted[a] odds ratios and 95% confidence intervals of reasons for participating in the Study to Explore Early Development, 2007–2016, by study group compared to population control group ($N = 5503$)

	Diagnosed ASD[b]		Suspected ASD		Non-ASD DD[c]	
	Unadjusted	**Adjusted**	**Unadjusted**	**Adjusted**	**Unadjusted**	**Adjusted**
Altruism	1.08 (0.94, 1.23)	1.22 (1.06, 1.41)	0.64 (0.53, 0.76)	0.82 (0.68, 0.99)	0.93 (0.81, 1.08)	1.01 (0.87, 1.17)
ASD research interest	2.80(2.44,3.22)	2.89 (2.49, 3.35)	0.89 (0.75, 1.06)	0.93 (0.77, 1.12)	0.84 (0.72,0.97)	0.84 (0.72, 0.98)
Perceived personal benefit	2.28 (1.93, 2.70)	1.92(1.61,2.29)	4.60 (3.78, 5.59)	3.67 (2.99,4.50)	1.97 (1.64, 2.35)	1.80(1.50,2.16)
Peripheral relationship with ASD/DD	0.07 (0.05, 0.10)	0.08 (0.06, 0.12)	0.18 (0.13, 0.25)	0.25(0.18,0.35)	0.58 (0.48, 0.69)	0.63 (0.52, 0.75)
General research interest	0.39 (0.31, 0.49)	0.53 (0.41, 0.68)	0.38 (0.28, 0.53)	0.62 (0.44, 0.86)	0.83 (0.67, 1.03)	0.98 (0.79, 1.22)
Social encouragement/engagement	0.64 (0.46, 0.90)	0.59 (0.42, 0.84)	1.10 (0.76, 1.59)	0.85(0.58, 1.26)	1.38(1.02, 1.85)	1.33(0.98, 1.81)
Financial incentive	0.30 (0.19, 0.50)	0.30(0.18,0.51)	0.35 (0.18, 0.67)	0.33 (0.17, 0.65)	0.72 (0.48, 1.08)	0.71 (0.47, 1.07)
Reputation of associated agency/investigator	0.66(0.39, 1.11)	0.78 (0.45, 1.37)	0.23 (0.08, 0.66)	0.35 (0.12, 1.01)	1.11(0.68, 1.81)	1.22 (0.74, 2.02)
Desired specific study result	0.76 (0.45, 1.31)	0.96(0.54, 1.70)	0.42 (0.17, 1.01)	0.64 (0.26, 1.57)	0.84 (0.47, 1.47)	0.91(0.51, 1.62)
Miscellaneous	0.81(0.65, 1.00)	0.74 (0.59, 0.93)	0.99 (0.76, 1.29)	0.85 (0.64, 1.13)	0.93 (0.74, 1.17)	0.88 (0.70, 1.11)

[a]Adjusted for child age, sex, and number of siblings with special needs, maternal age, and maternal self-reported race/ethnicity, current education, current household income.

[b]Autism spectrum disorder.

[c]Developmental delay or disorder.