



## Parental Attitudes About Placebo Use in Children

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**Objective** To assess parental attitudes regarding placebo use in pediatric randomized controlled trials and clinical care.

**Study design** Parents with children under age 18 years living in the US completed and submitted an online survey between September and November 2014.

**Results** Among all 1300 participants, 1000 (76.9%; 538 mothers and 462 fathers) met the study inclusion criteria. The majority of surveyed parents considered the use of placebos acceptable in some pediatric care situations (86%) and some pediatric trials (91.5%), whereas only 5.7% of parents found the use of placebos in children always unacceptable. The clinical use of placebo was considered acceptable by a majority of parents for only 7 (mostly psychological) of the 17 conditions presented. Respondents' judgment about acceptability was influenced by the doctors' opinions about the therapeutic benefits of placebo treatment, the conditions for pediatric placebo use, transparency, safety, and purity of placebos.

**Conclusion** Most surveyed parents accepted the idea of using placebos in pediatric trials and within the clinic for some conditions without the practice of deception and with the creation of guidelines for ethical and safe use. This study suggests a need to reconsider pediatric trial design and clinical therapy in the light of generally positive parental support of appropriate placebo use. (*J Pediatr* 2017;181:272-8).

Placebos have been crucial for the evaluation of new therapies in clinical trials<sup>1</sup> and are an important therapeutic tool in clinical practice globally.<sup>2-8</sup> However, the use of placebos in clinical trials and practice poses ethical and scientific challenges, especially with children, who cannot exercise the principle of autonomy and are subject to parental decision making on their behalf.<sup>9,10</sup> Importantly, more than one-half of the pharmacologic agents used in pediatric care rely on evidence generated from adult populations that sometimes differ significantly in terms of safety and efficacy profiles when studied in the pediatric population.<sup>11-15</sup> On the other hand, placebo responses seem to be more marked in children than in adults,<sup>16-20</sup> emphasizing the relevance of this effect in the pediatric field and the importance of parental consent decisions.

Recent adult<sup>21-23</sup> and pediatric<sup>24</sup> trials have shown that clinically relevant placebo responses can be obtained in a nondeceptive, transparent manner (ie, open-label placebo). In line with this idea, survey findings consistently suggest that adult patients are open to placebo use, but that their attitudes depend on several factors, such as the purpose of treatment and transparency.<sup>25-28</sup> Children require special considerations, however.<sup>9,10,29</sup> The literature regarding parental attitudes toward their child's participation in clinical trials highlights a number of specific concerns, most notably treatment safety, but also the inconvenience of the research process and a greater need for clarity in the information provided.<sup>30-35</sup> Because safety is a major concern, placebos (usually assumed to be ineffective) may be perceived as an unacceptable risk.<sup>33,35</sup> Few parents seem to understand the rationale for placebo use, equating placebo with abandonment of treatment.<sup>35</sup>

Parents' perceptions have been shown to influence the placebo effect in their children.<sup>36</sup> Thus, parental education might result in a preference for placebo over pharmacotherapy owing to potential placebo effectiveness and decreased use of pharmacologic agents with potential side effects.<sup>37</sup> Understanding how parents weigh the risks and benefits related to placebo may be central to pediatrics. Within the field of pediatric research, there is a significant need for placebo-controlled data,<sup>11-15</sup> and within the pediatric clinic, the need for parental support for noninvasive interventions and minimal risk interventions is also important. Parents are invested stakeholders in the advancement of pediatric science and clinical care.

Despite the importance of placebos in the pediatric field<sup>2-8</sup> and the role of parental views in this context, parents' voices have been absent in the ongoing placebo debate. In this study, we aimed to explore parents' perspectives and concerns regarding the use of placebos in pediatric research and care, after providing current

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HIT Human Intelligence Task MTurk Mechanical Turk

information about how placebos are used in both domains. Insight into about how parents view placebo may aid the development of guidelines for physicians and enable educated parental decisions concerning the use of placebos in pediatrics.

## Methods

Participants ( $n = 1300$ ) living in the US were recruited with a Human Intelligence Task (HIT) posted on Mechanical Turk (MTurk),<sup>38</sup> an online crowdsourcing marketplace, concerning parental attitudes on placebo. We posted a link for a web-based survey administered by SurveyGizmo, an online software company, into an MTurk HIT. MTurk, run by Amazon.com, provides an online workforce that has been adopted by the research community to recruit online study participants. It was built specifically for surveys and thus finds unique workers/participants. A growing body of evidence has validated the use of MTurk in behavioral research, and no significant differences have been found between participants recruited through MTurk and those recruited through traditional channels.<sup>39-43</sup> From the original 1300 participants, 300 were excluded owing to inconsistent information regarding their parenthood ( $n = 16$ ), random responses ( $n = 234$ ), or no answers ( $n = 50$ ). Detailed information regarding inclusion and exclusion criteria is provided in [Appendix 1 \(available at \[www.jpeds.com\]\(http://www.jpeds.com\)\)](#). The study was approved by the Massachusetts Institute of Technology's Institutional Review Board.

The survey was developed to access parents' attitudes and perceptions regarding the use of placebo in pediatrics. The survey itself and a description of how it was organized are provided in [Appendix 2 \(available at \[www.jpeds.com\]\(http://www.jpeds.com\)\)](#). Some of the questions were adapted from a previous survey.<sup>26</sup>

## Statistical Analyses

Data were analyzed using SPSS version 22.0 (IBM, Armonk, New York). The Mann-Whitney  $U$  test was used to assess whether parents' attitudes differed based on the sex (ie, mother vs father) and on whether their child was or was not hospitalized. Spearman correlations were calculated to assess associations between parental age and education with parental attitudes toward placebo. To adjust for multiple comparisons, Bonferroni correction was applied, and significance levels were set at  $P < .001$ .

## Results

Data collection was performed between September and November 2014. We merged positive responses ([strongly agree, agree, and somewhat agree] or [a lot, a fair amount] or yes) vs negative responses ([somewhat disagree, disagree, and strongly disagree] or [a little, not at all] or no) for most questions. Additional analyses exploring differences in parental attitudes based on parental sex, age, and education and child's hospitalization were performed. No differences in parental attitudes were found between mothers and fathers, or between parents whose child had been hospitalized for more than 3 days

and those whose child had not been hospitalized. Moreover, no associations were found between parents' education and their attitudes. Small associations were found for parental age and the following items: "If a doctor is uncertain about whether a placebo treatment will benefit my child, it is acceptable for them to recommend it to my child as long as the doctor believes it is a safe treatment" ( $r_s = 0.12$ ;  $P = .0002$ ) and "Doctors should never recommend placebo treatments for children" ( $r_s = -0.11$ ;  $P = .0005$ ). No other significant associations were found.

## Parental Characteristics and Mind-Body Beliefs

**Table 1** presents parental demographic data. Participants were fairly balanced between mothers (53.8%) and fathers (46.2%), with an average age of  $35.5 \pm 8.9$  years. The majority of the parents had 2 children (81.1%). Although approximately one-fourth (22.9%) reported that their children had been hospitalized for more than 3 days, virtually all (98.8%) considered their children to be in good health.

When the parents were asked about their general perspective regarding mind-body therapeutic influences, most parents (83%; 95% CI, 80.6%-85.3%) reported believing that a person's mind can affect his or her health considerably, positive thinking can improve a physical symptom of an illness significantly (71%; 95% CI, 68.1%-73.8%), and instilling hope (81.6%; 95% CI, 79.2%-84%) and involving the patient in decision making (81.5%; 95% CI, 79.1%-83.9%) are the doctor's most salient characteristics contributing to treatment outcome (**Table II**; available at [www.jpeds.com](http://www.jpeds.com)). Notably, only 5.6% (95% CI, 4.1%-7%) of parents reported being unfamiliar with the term "placebo."

**Table 1. Parental demographic data (n = 1000)**

Characteristics	Value
Sex, %	
Male	46.2
Female	53.8
Age group (yr), %	
18-29	26.3
30-39	46.2
40-49	18.3
50+	9.2
Age, yr, mean (SD)	35.9 (15.8)
Ethnicity, %	
Caucasian	80.2
Black	7.9
Latino	4.4
Asian	5.4
Other	2.1
Educational level, %	
8th grade or less (no high school)	0.3
Some high school (grades 9-11)	0.2
High school diploma or equivalent	11.2
Technical/trade school	4
College	23.7
Associate degree from a community college (eg, AA, AS)	11.6
Bachelor's degree from a college or university (eg, BA, BS)	37.8
Graduate degree (eg, masters, doctorate, JD, MD)	11.2
Hospitalization of child >3 d, %	
Yes	22.9
No	77.1

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