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To attend, or not to attend: Examining caregiver intentions and study compliance in a pediatric, randomized controlled trial

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Abstract

Background/Aims: The *Intent to Attend* is a brief questionnaire recommended by the National Research Council to address dropout concerns and improve prediction of missing data in clinical trials, although implementation has been very limited. As a formative study in pediatric research, the relationship between caregiver intentions and study compliance was investigated in a 180-day trial of dietary supplementation of preterm toddlers. Treatment effect estimation in the context of missing data was also explored.

Methods: Study compliance (i.e. study completion, supplement adherence, and diary completion) was tracked over three study visits. Baseline questionnaires asked caregivers about intentions concerning study completion via the *Intent to Attend*, screened for mental health symptoms (depression, trait anxiety), and captured family demographics. Simple and multiple logistic regression models were built to examine associations between caregiver intent and compliance outcomes. The *Intent to Attend* was also employed as an auxiliary variable to account for missing data within mixed models estimating the treatment effect on the primary outcomes.

Results: Of the 316 caregiver-child dyads included, 95% of caregivers with low intentions had a child complete the study, but only 87% of caregivers with high intentions had a child complete the study. Low intentions to complete the study were associated with a more than 60% lower odds of study non-completion, but the confidence interval included the null (OR: 0.36; 95% CI: 0.11, 1.20). No effect measure modification by caregiver mental health, child sex, or annual income was detected. Income was the only significant predictor of study non-completion; the lowest income group was almost four times more likely to be study non-completers compared to the highest income group, even after adjustment for child sex and caregiver mental health (adj OR=3.59, 95%

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CI: 1.38, 9.31). When using *Intent to Attend* as an auxiliary variable, similar results were obtained when compared to the original treatment effect estimates on the primary outcomes.

Conclusions: Contrary to prior adult studies, there is no clear relationship between caregiver intentions and study compliance. Findings elucidate the complexities of caregiver-child interactions during pediatric trial participation.

Keywords

Attrition; attendance; clinical trial; dropout; *Intent to Attend*; participation

Introduction

Missing data due to attrition can reduce statistical power, counteract randomization benefits, and lead to false inferences in clinical trials.^{1, 2} To combat the impact of attrition, the National Research Council¹ endorsed the *Intent to Attend* measure,³ a self-report of personal intentions to participate in future study activities, as a covariate to improve missing data models^{1, 2, 4–7} and to allow assumptions of analytic approaches such as mixed-effects models to be met.⁸

Nevertheless, application of the *Intent to Attend* has been limited to six studies; the original simulation study,⁸ one clinical treatment study,⁹ and two randomized controlled trials.^{2, 10–12} While some have explored caregiver intentions as predictors of study enrollment¹³ or attrition,¹⁴ to our knowledge no pediatric trials have utilized the *Intent to Attend*. As trial participation requires caregiver consent and continued involvement, especially for young children, assessing caregiver intentions through a standardized, predictive measure may further elucidate reasons for attrition.

Yet, clinical trials require engagement beyond visit attendance. The participant-centered approach encourages researchers to identify population-specific participation barriers, including barriers that influence attrition and compliance.^{15, 16} Previously identified barriers to caregiver study completion include caregiver psychopathology and socioeconomic status.^{17–23} These factors are similarly associated with elements of study non-compliance. For example, caregiver psychopathology is associated with attrition^{20–22} and poor treatment adherence²⁴ in clinical trials. To our knowledge, no trials have examined the relationship between caregiver *Intent to Attend* scores and elements of study compliance. Caregiver and family individualities may modify this relationship, and merit further exploration.

We investigated the relationship between caregiver *Intent to Attend* scores and child study compliance in a sample of toddlers born preterm. We also examined whether caregiver mental health and demographics moderated this relationship. Finally, to emulate the conceptual approach proposed by Leon and colleagues,³ we examined *Intent to Attend* as an auxiliary variable²⁵ to more appropriately account for missing data in analyses, and to determine if intentions substantially changed results for treatment effect estimates on the primary outcomes when compared to the original results.

Methods

Participants and trial procedures

Children admitted as preterm neonates to a neonatal intensive care unit affiliated with Nationwide Children's Hospital (NCH; Columbus, OH) or referred to the NCH Neonatology Clinic for clinical follow-up and had reached 10–16 months of age (corrected for prematurity) were invited to enroll in the Omega Tots trial. The study was approved by the Institutional Review Board (NCT01576783).²⁶ Primary trial outcomes were cognitive development and effortful control and activity level, measured by the Bayley Scales of Infant and Toddler Development-3 and Early Childhood Behavior Questionnaire, respectively.^{27, 28} Of the 4142 children assessed for eligibility, 377 enrolled. Children were randomized (1:1) to take a daily oral dietary supplement or placebo for 180 days (Supplementary Figure 1), and asked to participate in three study visits: baseline (0 days), interim (+45 days, via the Internet for most families), and final (+180 days).²⁶ All caregiver-child dyads with baseline *Intent to Attend* data were included in analyses.

Measures

The *Intent to Attend*⁸ measured baseline caregiver intentions regarding study completion. Immediately following informed consent, caregivers were asked “On a scale of 1 meaning ‘Not at all’ to 10 meaning ‘Extremely’, how likely is it that you will complete the study?” This module was added after the first 22 children enrolled. Baseline caregiver depressive symptoms were assessed via the Centers for Epidemiologic Studies-Depression Scale (CES-D),^{29, 30} and trait anxiety via the Spielberger State-Trait Anxiety Inventory (STAI-T).^{31, 32} Baseline questionnaires included family demographics. Dietary supplement/placebo adherence was tracked via daily paper diaries and returned supplement/placebo packets. Visit attendance was recorded. Child developmental outcomes were assessed at baseline and the final visit.

Analytic variables

Three dependent variables related to study compliance were examined. Study completion was dichotomized according to whether the caregiver-child dyad attended the first and last study visit (i.e. “study non-completion” vs “study completion”). The other two were supplement adherence (i.e. “poor supplement adherence” (< 80% of supplement packets taken based on diary data) vs “sufficient supplement adherence” (≥ 80%)), and diary entry completion (i.e. “incomplete diaries” (< 100% bi-weekly diary pages returned) vs “complete diaries” (100% returned)). Supplement adherence was dichotomized to replicate parent trial methods²⁶ and previous adherence literature.³³ Diary entry completion was dichotomized for ease of interpretation, and according to trial protocol requirements; because caregivers were asked for 100% completion, missing entries were considered non-compliant.

Intent to Attend was the main independent variable. Caregivers who indicated the maximum score (“10 / extremely”) were coded as having “high intentions”, while <10 constituted “low intentions” for this analysis. Caregiver mental health (depression, trait anxiety), child sex, and annual household income were considered covariates based on prior reported relationships with research participation.^{17–21, 24, 34–38} Caregiver CES-D scores were

dichotomized per the instrument developers (≥ 16 coded as “depressed at baseline”, < 16 as “not depressed at baseline”) ^{29, 30} (Table 1). No consistent cutoffs for the STAI-T have been applied across prior studies, ^{31, 32} so STAI-T score was treated as a continuous variable but categorized to describe the sample.

Data analysis

Associations among caregiver *Intent to Attend* scores and the dependent variables were examined using simple logistic regression. Effect measure modification by caregiver mental health, child sex, and income was tested using interaction terms. When no effect modification was observed (interaction term $p > 0.20$), those variables were included in adjusted models as confounders. Partially adjusted (controlling for child sex, income), and fully adjusted (additionally controlling for caregiver mental health) logistic regression models were built.

Caregiver mental health, annual income, and child sex were then examined as independent variables for their relationship to the dependent variables using simple logistic regression and the same approach to effect modification and adjustment.

The *Intent to Attend* was also used as an auxiliary variable based on the approach described by Carpenter. ³⁹ Specifically, in the context of a mixed effects model for pre-post change in each primary outcome of the trial, the continuous *Intent to Attend* score was included in the vector for the outcome variable and was allowed to have different means for each of the two randomized groups. This approach allowed the *Intent to Attend* variable to influence the treatment effect estimates based on the characteristics of the missing data process without conditioning on this variable in the statistical model.

Results

Sample characteristics

Of 377 dyads in the trial, 355 were eligible to complete the *Intent to Attend*, and 316 had complete data for it. More than one-third of children were non-white (37.3%), males (50.3%), and caregivers were typically married or living with a partner (64.0%). While few caregivers screened positive for depression at baseline (18.5%), over half experienced moderate or high levels of trait anxiety relative to the rest of the sample (51.9%; Table 1).

Study non-completion

Most caregivers (81.0%) expressed high intentions to complete the trial, and 88.6% of children attended the first and last study visit. While 87.0% of caregivers with high intentions had a child complete the study, 95.0% of caregivers with low intentions also had a child complete the study. Accordingly, low intentions were associated with lower odds of study non-completion compared to those with high intentions, although the confidence interval reflected imprecision and included the null (OR=0.36, 95% confidence interval (CI): 0.11, 1.20) (Table 2). No effect measure modification by caregiver mental health, child sex, or income was detected. Partially and fully adjusted results were similar to unadjusted results. Unlike child sex or caregiver mental health, income was associated with study non-completion. The lowest income group (annual income $< \$20,000$) was almost four times

more likely to be study non-completers compared to the highest (adj OR=3.59, 95% CI: 1.38, 9.31).

Poor supplement adherence, incomplete diaries

Caregiver intentions were unassociated with poor supplement adherence and incomplete diaries. Elevated caregiver depressive symptoms at baseline were moderately associated with poor supplement adherence in unadjusted and partially adjusted models, but this effect estimate was attenuated after adjusting for trait anxiety (adj OR=2.14, 95% CI: 0.89, 5.13).

The lowest income families were somewhat more likely to have poor supplement adherence, and much more likely to have incomplete diaries, even after adjustment for child sex (adj OR=3.04, 95% CI: 1.47, 6.28; adj OR=8.52, 95% CI: 3.96, 18.30). This relationship was attenuated but persisted for incomplete diaries even after controlling for caregiver mental health (adj OR=4.36, 95% CI: 2.00, 9.48; Table 2).

We also examined the continuous *Intend to Attend* score as an auxiliary variable when examining treatment effects for primary outcomes from the original randomized clinical trial (RCT) using mixed-effects models. The purpose of this analysis was to examine the degree to which the results of these analyses might change when considering the *Intend to Attend* score as an auxiliary variable in the statistical model. The effect sizes and p-values for these analyses can be found in Table 3 along with results found in the original analyses of the primary outcomes. P-values and effect sizes were similar when comparing the original analysis and the analysis with the *Intend to Attend* score as an auxiliary variable for each of the five outcomes. No results were statistically significant ($p > .05$).

Discussion

This pediatric RCT of a dietary supplement in toddlers born preterm found no evidence that low caregiver intentions were associated with a lower odds of study completion. Rather, results suggested the opposite, even after controlling for caregiver mental health and sociodemographic characteristics, although effect estimates were imprecise. Furthermore, low intentions were unassociated with other elements of study compliance.

Our findings contrast two prior adult trials where lower *Intent to Attend* scores consistently predicted attrition;^{2,9} one trial was an RCT for patients with bipolar disorder, while the other was a trial of depression treatment. The three remaining studies used the *Intent to Attend* as a covariate to satisfy statistical assumptions and reduce attrition bias, but did not discuss direct relationships between attrition and reported intentions.^{8, 10, 11} One reason our results may differ is because *Intent to Attend* was administered only at baseline in Omega Tots, while it was analyzed as an indicator of intent over time by Warden and colleagues. Results may also differ due to the cognitive^{40, 41} and behavioral deficits^{42, 43} premature children commonly face. Along with RCT demands, caregivers with high baseline intentions may not have considered personal barriers (e.g. child developmental difficulties), which ultimately deterred visit attendance and consequently reduced the *Intent to Attend*'s utility within this sample. Future studies should examine caregiver intentions within both preterm and full-term samples. Moreover, caregivers may have interpreted the *Intent to Attend* in

various ways; qualitative work is needed to further discern how this item is construed amongst caregivers.

Results suggest caregiver mental health may not impact study compliance for lower risk, pediatric research participation despite previous associations between caregiver psychopathology and pediatric clinical care attendance^{34, 38} or RCTs.^{21, 22} Income, particularly low income, was the only major predictor of study non-completion and incomplete diaries that was consistent with previous findings.^{20, 34, 36} However, study-specific features such as design demands or relevance to the participant are sometimes more indicative of attrition.^{19, 37} For example, one trial exploring dropout amongst minority, low income parents found mental health was unrelated to attrition, but parents with similar goals to study tasks were significantly more likely to continue.⁴⁴ It is possible that our goals to improve child development matched caregiver goals within our sample, ultimately encouraging continued participation.

Taken together, caregivers reporting intentions about their child's participation differ from adults reporting their own intentions to participate. Study strengths include the novel application of *Intent to Attend* in a pediatric population, and the examination of multiple dependent variables regarding study compliance. As this was a single-site, neonatal trial with a small attrition rate and high completion and adherence rates, generalizability of results is limited. Additionally, some analyses may have been underpowered to detect small associations precisely, and our choice to dichotomize variables to aid in interpretation may have reduced power.

As the call for improved methods to predict attrition and manage missing data remains, results reinforce the need to explore caregiver intentions in future pediatric trials.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1.

Demographics, Clinical Characteristics, Caregiver Intentions, and Study Compliance, Overall and By Treatment Group, Omega Tots Trial (n=316), 2012–2017

Characteristics	All (n = 316) No. (%)	DHA+AA Group (n=164)	Placebo Group (n=152)
Sociodemographic Characteristics	-	-	-
Caregiver education (n, %) – high school/GED or less	95 (30.2)	43 (26.4)	52 (34.2)
Some college/Associate's Degree	113 (35.9)	61 (37.4)	52 (34.2)
Bachelor's Degree or higher	107 (34.0)	59 (36.2)	48 (31.6)
Caregiver marital status (n, %) – married or living with partner	201 (64.0)	107 (65.6)	94 (62.3)
Separated or divorced	15 (4.8)	7 (4.2)	8 (5.3)
Single never married or not living with partner	98 (31.2)	49 (30.1)	49 (32.5)
Public or no health insurance (n, %)	167 (53.4)	85 (52.2)	82 (54.7)
Annual household income <\$20,000 (n, %)	73 (23.3)	36 (22.1)	37 (24.7)
\$25,000–35,000	75 (24.0)	37 (22.7)	38 (25.3)
\$35,000–45,468	63 (20.1)	36 (22.1)	27 (18.0)
\$45,468+	102 (32.6)	54 (33.1)	48 (32.0)
Caregiver Mental Health Outcomes	-	-	-
Caregiver depression at baseline (CES-D 16 vs < 16)	58 (18.5)	26 (16.1)	32 (21.1)
Caregiver trait anxiety at baseline – low (score of 0–30)	151 (48.1)	84 (51.9)	67 (44.1)
Moderate (score of 31–39)	91 (29.0)	47 (29.0)	44 (29.0)
High (score of 40+)	72 (22.9)	31 (19.1)	41 (27.0)
Intentions and Study Compliance	-	-	-
Caregiver Intentions – low intentions (score < 10, unlikely to complete study)	60 (19.0)	34 (20.7)	26 (17.1)
High intentions (score 10, likely / not unlikely to complete study)	256 (81.0)	130 (79.3)	126 (82.9)
Child supplement adherence – poor supplement adherence (less than 80% adherence)	79 (29.8)	37 (25.9)	42 (34.4)
Supplement adherence (greater than 80% adherence)	186 (70.2)	106 (74.1)	80 (65.6)
Diary entries – incomplete diaries (< 100% bi-weekly diary pages returned)	78 (24.7)	35 (21.3)	43 (28.3)
Complete diaries (100% bi-weekly diary pages returned)	238 (75.3)	129 (78.7)	109 (71.7)
Study non-completers (less than three study visits complete)	36 (11.4)	17 (10.4)	19 (12.5)
Study completers (attended first and last study visits)	280 (88.6)	147 (89.6)	133 (87.5)
Child Demographics	-	-	-
Female sex (n, %)	157 (49.7)	76 (46.3)	81 (53.3)
Child's race (n, %) – Caucasian/White	198 (62.7)	102 (62.2)	96 (63.2)
Black/African-American	87 (27.5)	42 (25.6)	45 (29.6)
Asian/Pacific Islander	2 (0.6)	1 (0.6)	1 (0.7)
Other or multiple	29 (9.2)	19 (11.6)	10 (6.6)
Child's ethnicity (n, %) – Hispanic	14 (4.4)	5 (3.1)	9 (5.9)
Small for gestational age (n, %)	54 (17.1)	25 (15.3)	29 (19.1)

Note: There was missing data for education (1), marital status (2), insurance (3), income (3), depression (2), anxiety (2), adherence (51), and small for gestational age (1)

Table 2.

Associations Between Intent to Attend, Caregiver Mental Health, Child Sex, and Annual Household Income and Study Non-Completion, Poor Supplement Adherence, and Incomplete Diaries, Omega Tots Trial (n=316), 2012–2017

Characteristics	Study Non-Completion			Poor Supplement Adherence			Incomplete Diaries		
	Unadj.	Partial Adj.	Full Adj.	Unadj.	Partial Adj.	Full Adj.	Unadj.	Partial Adj.	Full Adj.
	OR (CI)	OR (CI)	OR (CI)	OR (CI)	OR (CI)	OR (CI)	OR (CI)	OR (CI)	OR (CI)
Low Caregiver intentions (Intent to Attend <10 vs 10)	0.36 (0.11, 1.20)	0.38 (0.11, 1.30) ^a	0.35 (0.10, 1.24) ^b	0.90 (0.45, 1.78)	1.01 (0.50, 2.06) ^a	1.05 (0.50, 2.17) ^b	0.72 (0.36, 1.44)	0.84 (0.39, 1.82) ^a	0.82 (0.38, 1.81) ^b
Caregiver trait anxiety (STAI-T, continuous)	1.01 (0.97, 1.04)	1.00 (0.96, 1.03) ^a	1.01 (0.96, 1.06) ^d	1.04 (1.02, 1.07) ^{**}	1.04 (1.01, 1.07) ^{*a}	1.02 (0.98, 1.06) ^d	1.04 (1.01, 1.06) ^{**}	1.02 (0.99, 1.04) ^a	1.01 (0.97, 1.05) ^d
Caregiver depression at baseline (CES-D 16 vs < 16)	1.06 (0.44, 2.52)	0.71 (0.28, 1.81) ^a	0.60 (0.17, 2.06) ^c	3.28 (1.75, 6.15) ^{***}	2.73 (1.40, 5.32) ^{**a}	2.14 (0.89, 5.13) ^c	2.41 (1.35, 4.31) ^{**}	1.37 (0.72, 2.61) ^a	1.14 (0.46, 2.79) ^c
Child sex (male vs female)	0.93 (0.48, 1.79)	0.80 (0.41, 1.58) ^e	0.76 (0.38, 1.51) ^g	1.11 (0.67, 1.85)	1.05 (0.62, 1.77) ^e	1.00 (0.57, 1.65) ^g	1.11 (0.69, 1.79)	1.02 (0.61, 1.72) ^e	0.98 (0.58, 1.66) ^g
Annual household income: <\$20,000 (reference > \$45,468) ⁱ	3.19 (1.28, 7.93) [*]	3.25 (1.30, 8.11) ^{*f}	3.59 (1.38, 9.31) ^{**h}	3.06 (1.48, 6.30) [*]	3.04 (1.47, 6.28) ^{*f}	2.18 (1.01, 4.71) ^h	8.53 (3.97, 18.32) ^{***}	8.52 (3.96, 18.30) ^{***f}	4.36 (2.00, 9.48) ^{***h}
\$25,000–35,000 ⁱ	1.99 (0.76, 5.18)	2.01 (0.77, 5.23) ^f	1.90 (0.71, 5.06) ^h	1.62 (0.79, 3.31)	1.61 (0.78, 3.30) ^f	1.42 (0.68, 2.97) ^h	4.64 (2.15, 10.02) [*]	4.64 (2.15, 10.01) ^f	1.73 (0.70, 4.24) ^h
\$35,000–45,468 ⁱ	1.10 (0.32, 3.23)	1.01 (0.32, 3.22) ^f	1.04 (0.325, 3.330) ^h	1.89 (0.92, 3.87)	1.89 (0.92, 3.87) ^f	1.83 (0.88, 3.81) ^h	1.73 (0.71, 4.24)	1.73 (0.71, 4.24) ^f	1.01 (0.97, 1.05) ^h

* Note: p < .05

** p < .01

*** p < .001

OR: odds ratio; CI: confidence interval; CES-D: Centers for Epidemiologic Studies – Depression Scale; STAI-T: State-Trait Anxiety Inventory (trait scale only). Unadj.: unadjusted model; Partial adj.: partially adjusted model; Full adj.: fully adjusted model.

^a Adjusted for income and child sex

^b Adjusted for income, child sex, caregiver trait anxiety (continuous variable), caregiver depression (dichotomous, diagnostic variable)

^c Adjusted for income, child sex, caregiver trait anxiety (continuous variable)

^d Adjusted for income, child sex, caregiver depression (dichotomous, diagnostic variable)

^e Adjusted for income

^f Adjusted for child sex

^g Adjusted for income, caregiver trait anxiety (continuous variable), caregiver depression (dichotomous, diagnostic variable)

^h Adjusted for child sex, caregiver trait anxiety (continuous variable), caregiver depression (dichotomous, diagnostic variable)

ⁱ Annual household income is a categorical variable. OR and CI are presented in the following order for all models: 1 vs 4, 2 vs 4, 3 vs 4

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Table 3.

Comparison of Original Results to Those Obtained When Including Intent to Attend Scores as Auxiliary Variable to Account for Missingness in Model.

Outcome	Original Analyses		Intent to Attend Included as Auxiliary Variable	
	Difference in Change	p-value	Difference in Change	p-value
Cognitive composite	0.5	.66	0.3	.77
Language composite	−0.7	.55	−0.9	.48
Motor composite	0.2	.88	0.0	.97
Effortful control	−0.1	.13	−0.1	.07
Activity level	0.0	.76	0.0	.94