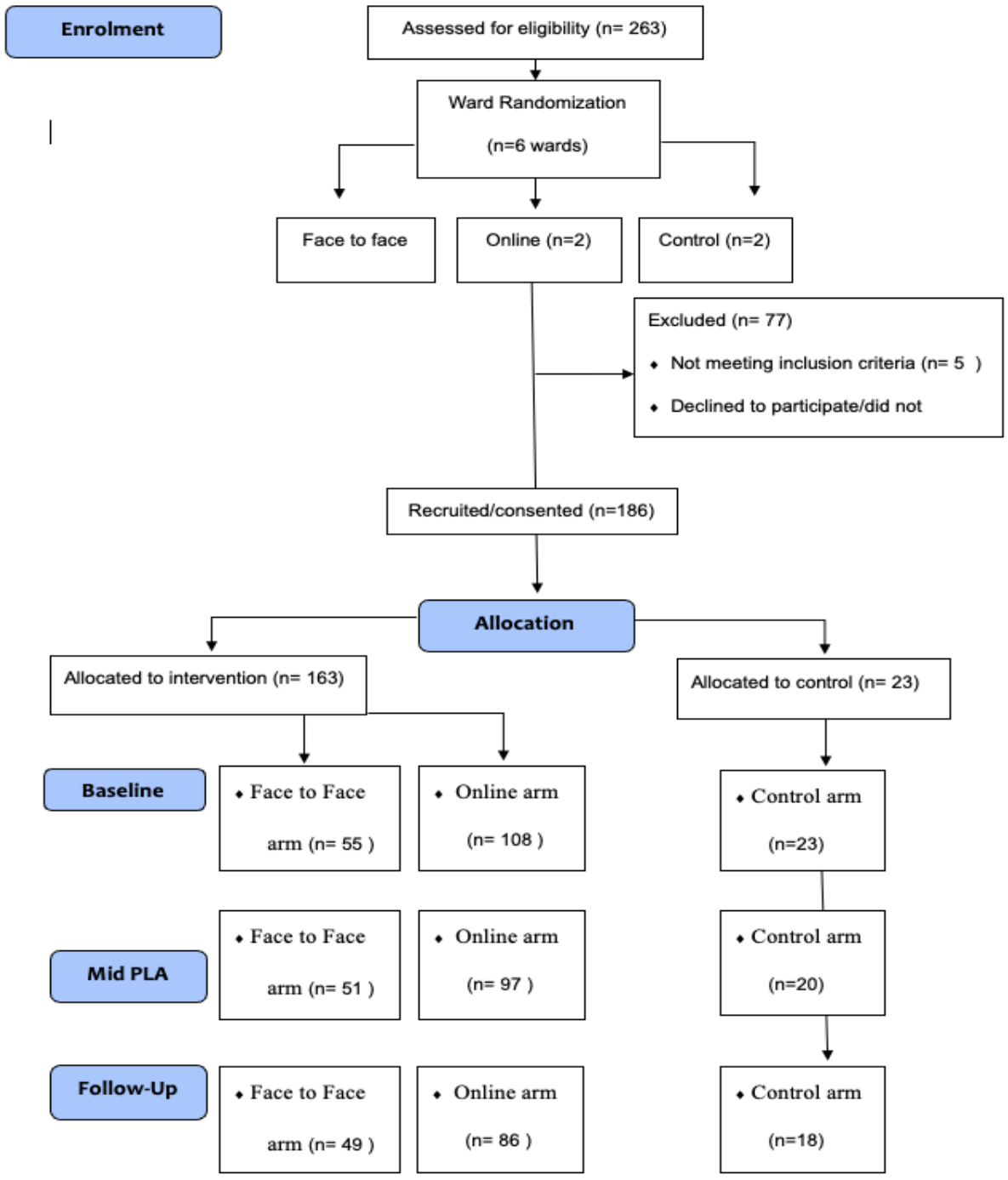
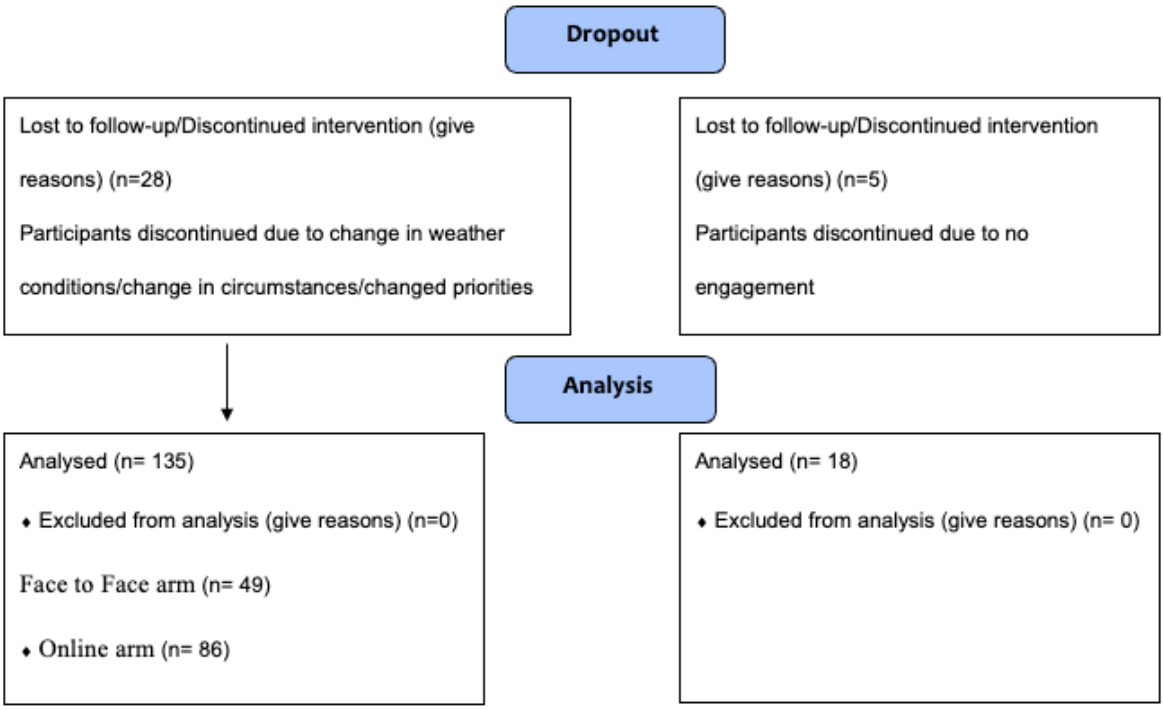
Basic Results summary - Acceptability, feasibility and pilot study of a culturally sensitive parental and caregiver, community-based intervention using participatory learning and action groups to optimise infant nutrition, feeding, and dental practices in children from South Asian families: NEON (Nurture Early for Optimal Nutrition)

Participant Flow: A flow diagram showing participants involved at each stage of the study (namely enrolment, intervention allocation, follow-up, and data analysis).

Figure 1. NEON RCT Consort Flow Diagram





Baseline Characteristics: Table(s) showing demographic data for participants at baseline, as well as any measures assessed at baseline

Table 1. Participants' Characteristics

	Categories	**N (%)**
Mother's Age (Years)	Not Applicable	Mean: 32 years SD: 5.98
Infant's Age (Months)	Not Applicable	Mean: 12.4 months SD: 5.19
Infant's Sex	Male Female	60 (45.1%) 73 (54.9%)
Borough of Residence	Newham Tower Hamlets	200 (78.1%) 56 (21.9%)
Mother's Ethnicity	Bangladeshi Pakistani Sri Lankan/ Tamil Indian Punjabi	151 (65.4%) 39 (16.9%) 17 (7.4%) 16 (6.9%)

	Indian Gujarati	8 (3.5%)
Infant's Ethnicity	Bangladeshi Pakistani Sri Lankan Indian Punjabi Indian Gujarati	137 (64.0%) 37 (17.3%) 13 (6.1%) 13 (6.1%) 14 (6.5%)
Mother's Marital Status	Single Married Widowed Divorced	8 (3.1%) 247 (96.1%) 1 (0.4%) 1 (0.4%)
Mother's Highest Education Level	Less than Secondary Education Secondary Education Associate Degree Tertiary Education	48 (18.7%) 104 (40.5%) 31 (12.1%) 74 (28.8%)
Mother's Employment Status	Unemployed/sick/retired Part-time employee Full Time employee	173 (70.0%) 25 (10.1%) 49 (19.8%)
Mother's English Literacy Level	Little to None Moderate Fluent	63 (24.5%) 79 (30.7%) 115 (44.7%)
Housing	Rent Own of Mortgage Temporary Accommodation Rent-Free	180 (74.4%) 43 (17.8%) 4 (1.7%) 15 (6.2%)
Average Family Income	£0-£5,475 £5,476 - £12,097 £12,098 - £20,75 £20,754 - £31,494 £31,495 or more Did not disclose	34 (14.7%) 25 (10.8%) 15 (6.5%) 16 (6.9%) 15 (6.5%) 129 (55.6%)

Outcome Measures

Process Outcomes

Screening, Eligibility, and Registration

Of the 263 individuals enrolled based on inclusion/exclusion criteria, only 186 consented, marking a significant decline. Nevertheless, with 71% of eligible participants consenting, surpassing the >=50% benchmark, the trial proceeded. Figure 1 provides a CONSORT diagram detailing enrolment, allocation, and attrition rates.

NH had participants from Pakistani (13.9%), Punjabi (9.6%), Gujarati (11.3%), Tamil (8.7%), and Bangladeshi (56.5%) backgrounds. TH included 37 Bangladeshi participants. Refer to supplemental material 2 for the participant counts and ethnic breakdowns.

Supplemental Material 2. Breakdown of participants recruited by ethnicity at the start of the trial and at the end of the trial

Originally	Pak	Punj	Guj	Tamil	Bangla	Total	TH -Bangla
F2F	8	7	9	0	35	59	28
Online	24	8	11	16	43	102	18
UC	9	2	11	1	20	43	11
Total	43	17	31	17	98	204	57

Current	Pak	Punj	Guj	Tamil	Bangla	Total	TH -Bangla
F2F	5	3	4	0	17	29	17
Online	3	6	1	9	29	48	12
UC	8	2	8	1	15	34	8
Total	16	11	13	10	65	115	37

Sessions Planned and Delivered

The PLA sessions, initially comprising 25 groups (20 NH, 5 TH), experienced a reduction in numbers by the third cycle due to a participant drop from 186 to 167. This led to a decrease in sessions to 11 in NH and 4 in TH. By the fifth meeting, further reductions resulted in 4 face-to-face and 6 online sessions in NH, and 2 of each in TH. Concurrently, usual care participants decreased in NH, while remaining constant in TH.

Participant Attendance

In NH, the combined attendance rate for both intervention arms was 29%, while in TH, the attendance rate reached 59%. The overall attendance rate across all intervention arms was 37%, meeting the predefined "Go" criterion. For detailed attendance rates for PLA sessions, refer to supplemental material 3.

Supplemental Material 3. Attendance Rate for the PLA sessions

	PLA 1	**PLA 2**	**PLA 3**	**PLA 4**	**PLA 5**	**PLA 6**	**PLA 7**	**PLA 8**
Newham								
Face to Face n=59	8	10	5	3	5	5	4	6
Online n=103	22	25	24	19	14	16	14	18
							Total rate NH	**29%**
Tower Hamlets								
Face to Face n=28	2	5	7	7	3	5	5	6
Online n=18	15	16	15	17	15	10	12	15
							Total Rate TH	**59%**
Total Attendance								**37%**

Retention Rates

The overall trial retention rate was 65%. In NH, retention rates were 50% face-to-face (29 of 59), 67% online (69 of 103), and 34% in the control arm, resulting in a total retention rate of 48%. In TH, retention rates were 71% in face-to-face (20 of 28), 88% in online (16 of 18), and 33% in the control arm, yielding a total retention rate of 78%. Height and weight measurements were completed by 65% of total participants, with TH at 79% and NH at 67% (29/39 in TH, 87/128 in NH).

Intervention Support

Participants' Feedback

The questionnaire was distributed digitally via email, and due to a lack of responses, phone and face-to-face interviews were conducted with willing participants, garnering feedback from 46 individuals. Participants in the face-to-face arm appreciated in-person meetings, providing the chance to meet other mothers. However, they suggested an option for online attendance when face-to-face was impractical. The 2-hour session duration was deemed too lengthy for most participants. Sessions were conducted in native languages, with participants expressing a desire for translated toolkit content in future sessions.

Facilitators' Feedback

A thematic analysis was conducted on participant and facilitator feedback to identify recurring patterns and comments. The objective was to explore their perspectives on intervention delivery and optimize the design, provision, and reach of a future definitive trial. Detailed results of the thematic analysis are summarized in a separate article.

Direct Observation of Intervention Delivery

CRs ensured PLA cycle consistency in women's groups. Facilitator adherence was digitally assessed by independent observers using a 1-4 scale, with perceptions captured via open-ended questions (refer to supplemental material 4). Non-attendance led to undelivered sessions. Despite schedule changes, Bangladeshi CFs covered most delivery phase components. Challenges such as late arrivals and low attendance shortened sessions to 15-30 minutes. High-attendance sessions received positive feedback and fostered discussions. CFs demonstrated adaptability, modifying sessions in response to challenges, notably in PLAs

3 and 4. Online sessions prioritized crucial content, addressing some issues. However, time constraints prevented the implementation of solutions proposed in PLA 7. PLA 8, deviating from its primary objective of evaluating implemented solutions, scored the lowest.

Supplemental Material 4. Direct observation score from each session

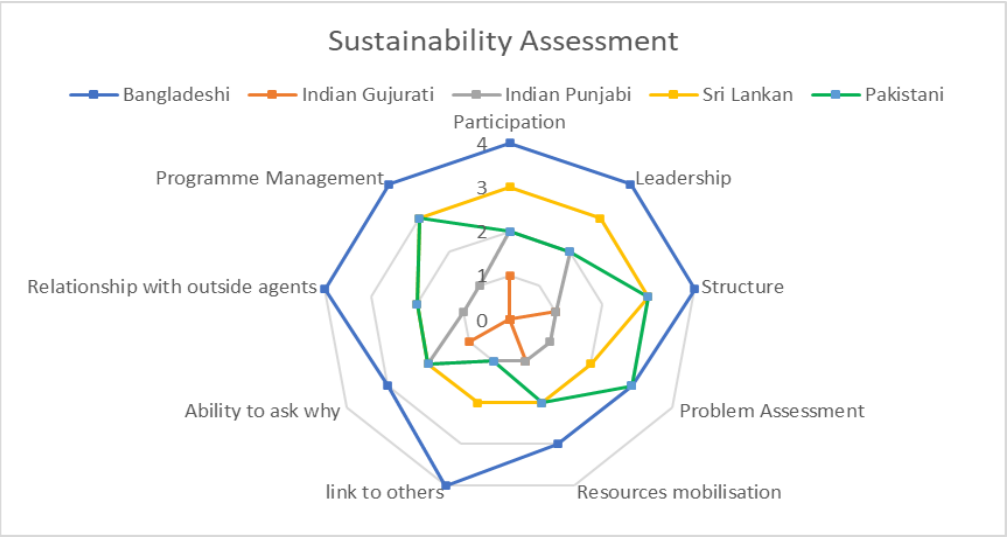
	PLA 1: Group Formation	PLA 2: Explore Infant Growth and Development	PLA 3: Learn Recommended Practices	PLA 4: Identifying Barriers	PLA 5: Identify Solutions	PLA 6: Community Meeting	PLA 7: Plan Solutions	PLA 8: Evaluate Solutions
Newham (Online)								
Bangladeshi	4		2	3	3	2	3	3
Gujarati	1	1						
Punjabi	1	1		1		1		1
Tamil	1	2	2	2		2		1
Pak	1	1				2	3	1
Newham (F2F)								
Bangla	3	4	2	2	3			1
Punjabi	1	1	1	0	1			1
Pakistani	3	2	2	2	3			3
Tower Hamlets (Online)								
Bangla Group 4	4			3		Cancelled		1
Bangla Group 5	4	4	2	3		Cancelled		1
Tower Hamlets (F2F)								
Bangla Group 1&3	3	4	2	2	3	Cancelled		1

	PLA 1: Group Formation	PLA 2: Explore Infant Growth and Development	PLA 3: Learn Recommended Practices	PLA 4: Identifying Barriers	PLA 5: Identify Solutions	PLA 6: Community Meeting	PLA 7: Plan Solutions	PLA 8: Evaluate Solutions
Newham (Online)								
Bangla Group 2	3	4	2	2	3	Cancelled		1

Sustainability Assessment

CRs employed a sustainability assessment tool to self-assess group capacity across nine key domains for sustainability and community empowerment. The Bangladeshi group consistently scored highest in every domain. Figure 2 illustrates diverse strengths and weaknesses across groups. Notably, participation scores appear to influence other domains, with higher participation correlating with increased mean scores and higher ratings in other components.

Figure 2. Visual representation of sustainable assessment scores



Outcomes measures for the definitive trial

- ***Child Feeding Behaviour Questionnaire***

  Our study, initially designed to compare infant feeding behaviours, was limited to intervention arm data due to the absence of filled control arm questionnaires. Eight domains at different post-intervention time points were analysed. Notably, 'food responsiveness' and 'food enjoyment' increased from 29% to 72% and 61% respectively, while 'emotional overeating' decreased from 15% to 5%. Other improvements were observed in 'emotional under-eating', 'slowness', 'food fussiness', and 'responsiveness to food satiety and drinks'. However, response rates declined from 65 to 15 at the 6-month follow-up.

- ***Parental Feeding Style***

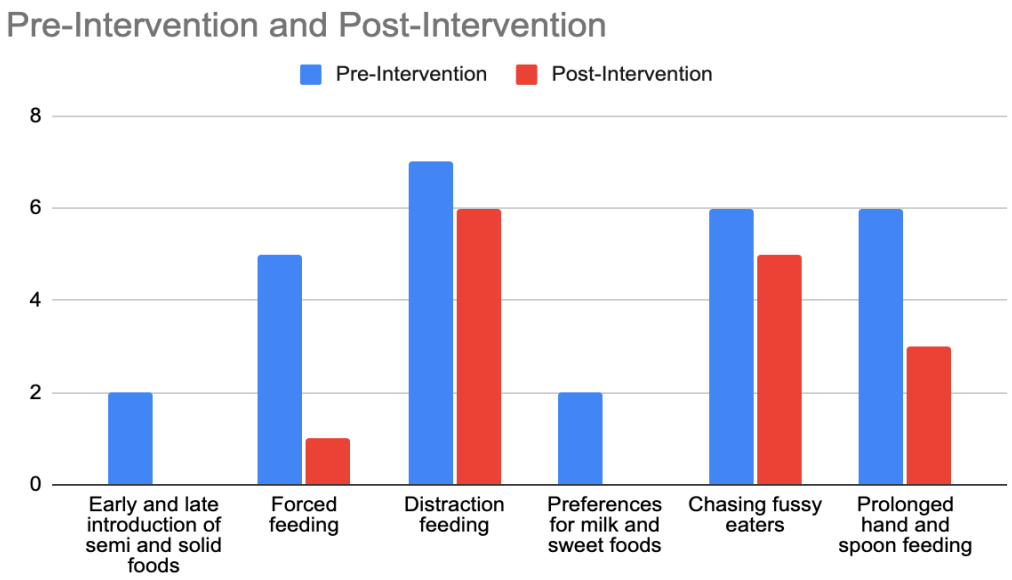
  Emotional feeding decreased from 20% to 15% and further to 11% at the 6-month follow-up. Instrumental feeding dropped from 65% to 49% and then to 38% at 6 months. 'Encouragement to eat' decreased from 50% to 45%, maintaining this level at the 6-month follow-up. 'Control overeating' increased from 40% to 49% and then reduced to 35% at the 6-month follow-up.

- ***Feeding Videos***

  ELAN Linguistic Annotator software analysed feeding videos; coding gestures linked to associated vocabulary. The feeding styles of mothers during the first month were compared with the seventh session of the intervention. In total, 27 feeding videos were collected. No force-feeding was observed in face-to-face sessions, but it occurred in six videos from online sessions. Online mothers were more likely to use

toys and media for distraction (12 videos vs. 1 video). Videos before the intervention showed a tendency to overfeed, including force-feeding, distraction feeding, feeding to fill the belly, and prolonged parent-led feeding style. Follow-up videos showed a reduction in force-feeding (1/7 vs. 3/7) but an increase in using objects or phones for distraction during feeding (6/7 vs. 3/7). Three mothers actively assisted children despite their ability to self-feed, and three children fed themselves using hands rather than utensils.

Figure 3. Comparison of feeding styles according to behavioural themes both before and after the intervention



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- ***Network Diffusion***

The intended assessment of study material distribution via e-redbook downloads encountered obstacles. The e-redbook application was unprepared for selective material sharing, risking exposure to unintended recipients. Complications in app

registration and inadequate responses to the dissemination survey further exacerbated these issues.

- ***Four-Day Food Diary***

  Response to the food diary survey was exceptionally low due to its detailed nature, perceived burden, and challenges in literacy levels. The CEQ and PFQ surveys, simpler with CF support, were more successful. Low English literacy within the population hindered participants from completing the diary, highlighting the need for user-friendly tools.

- ***Equality Impact Assessment (EIA)***

  EIA systematically assessed the intervention's impact on equality aspects, considering disability, gender, race, age, sexual orientation, and religion/belief. The intervention was adapted to accommodate diverse needs, respecting differences in ethnicity, language, location, and age. Partners reported an inclusive intervention with no potential discrimination areas. Suggestions included involving fathers and acknowledging the intervention's specific focus on the SA population.

- ***Assessment of BMI Z-scores***

  ANOVA analysis assessed the intervention's impact on mean BMI z-scores across the three trial arms and data collection points. Significant differences were noted in baseline weight and BMI z-scores among the arms (see supplemental material 5). At the project's end, weight and BMI z-scores remained significantly different, with the face-to-face arm showing the highest values. The control arm exhibited a reduction in

mean Z-score, and after six months, no significant differences were observed in height, weight, or BMI z-scores among the three arms.

- ***Sample Size Calculations***

  G*Power Software estimates an effect size of 0.457 for BMI Z-scores at the project's end. To achieve this effect size with a 0.05 alpha error and 80% power in a three-group ANOVA, aiming for a critical F value of 10.66, the total estimated sample size is 51. Planning for a 20% loss to follow-up, each arm is targeted to enrol 21 participants.

Supplemental Material 5. Comparison of mean weight and BMI z-scores among the participants of face-to-face PLA, online, and the control groups

Arm	Face-to-Face Mean (SD)	Online Mean (SD)	Control Mean (SD)	F-Value*	P-value
Baseline	**(n=27)**	**(n=41)**	**(n=25)**		
Weight	09.1 (1.9)	07.4 (1.7)	08.2 (1.3)	8.278	<0.0001
BMI z-score	0.79 (1.4)	-0.53 (1.9)	-0.15 (1.2)	5.704	0.004
End of PLA	**(n=27)**	**(n=41)**	**(n=25)**		
Weight	10.3 (1.9)	08.5 (1.8)	09.2 (1.4)	7.966	<0.0001
BMI z-score	0.62 (1.1)	-0.46 (1.5)	-0.19 (1.4)	5.421	0.006
6 months after PLA	**(n=19)**	**(n=24)**	**(n=16)**		
Weight	10.4 (1.8)	9.3 (2.1)	10.3 (1.8)	2.388	0.100
BMI z-score	0.15 (1.1)	-0.39 (1.37)	0.23 (1.4)	1.432	0.247

*ANOVA test

Note: only data of those with gender recorded was included

- **Adverse Events:** There were no adverse events associated with this study."