Online Supplemental Information

Effects of a Multipronged Beverage Intervention on Young Children's Beverage Intake and Weight: A Cluster-Randomized Pilot Study

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Supplemental Table 1. Recommended beverages for children ages 2-5 years.

Beverage	American Academy of Pediatrics & National Academies	Robert Wood Johnson Foundation Healthy Eating Research Expert Panel[1]
Water	• Water should be promoted as an alternative to sugar-sweetened beverages, though milk is seen as the primary beverage to encourage children to consume[2]	• Water should be available and promoted in all settings where beverages are offered
Milk	• Milk should be low-fat (1%) or fat-free (skim) • Sweetened milk can be part of a healthy diet[2]	• Milk should be low-fat (1%) or fat-free (skim) and served in no more than 8-ounce portions • Discourage sweetened milk
Fruit juice	• Encourage whole fruit consumption over fruit juice[3] • Limit fruit juice consumption to 100% juice (not fruit-flavored drinks) and to 6 ounces or less per day[3]	• Encourage consumption of whole fruit over fruit juice • No more than one 0- to 4-ounce portion of 100% fruit or vegetable juice or fruit juice combined with water per day
Sugar-sweetened beverages	• Limit consumption of sugar-sweetened beverages[2] • Sports drinks, soft drinks, and energy drinks are not appropriate beverages for young children[2]	• Reduce or eliminate consumption of sugar-sweetened beverages • Sugar-sweetened beverages are not recommended for children of any age

Supplemental Table 2. Beverage categories assessed in survey of children's beverage consumption.

Beverage category	**Examples Provided (if any)**
Plain whole milk	
Plain 2% or reduced-fat milk	
Plain 1% or low-fat milk	
Plain skim or fat-free milk	
Flavored milk	Chocolate or strawberry
Plain rice or soy milk	
Flavored rice or soy milk	Chocolate, vanilla, or strawberry
Horchata	
Smoothies or licuados with added sugar	
Smoothies or licuados without added sugar	
100% fruit juice	
Fruit drinks[a]	Capri Sun, Sunny D, or Hi-C
Kool-Aid[a]	
Sports drinks	Gatorade, Powerade, Propel, Vitamin Water
Regular (non-diet) soda	Coca-Cola, Fanta, Sprite, Jarritos
Diet drinks	Crystal Light, diet sodas
Coffee or tea with added sugar[b]	
Coffee or tea without added sugar	
Tap water	Water from the sink, faucet, refrigerator door, or water fountain
Plain (non-flavored) bottled water	Dasani, Aquafina, Arrowhead Alhambra
Flavored bottled water[c]	Crystal Geyser Lemon, Strawberry Dasani, Blackberry Hint
Aguas frescas	
Anything else? Specify.	(Answers were coded by research team into above categories as applicable).

[a]Kool-Aid consumption was assessed separately from other fruit drinks based on feedback received during survey pilot testing. Kool-Aid was considered an SSB in analyses of total SSB consumption.
[b]Only one parent reported that their child consumed coffee or tea without added sugar at baseline, and only two parents reported that their children consumed these beverages at follow-up. We excluded consumption of these beverages from analyses because: (i) consumption was very uncommon and (ii) these beverages cannot clearly be categorized as healthy or unhealthy for young children because the survey did not query caffeine content of the beverages.
[c]Excluded from estimates of total water consumption in the event that parents inadvertently counted caloric water in this category. Average consumption of this category was low (about 0.10 oz/day in both the intervention and control group). Including flavored water in estimates of total water consumption had no impact on the pattern of results.

Supplemental Table 3. Intraclass correlation coefficients (ICC) by outcome variable.

	Child-level		Classroom-level		Center-level	
	Unadjusted	**Adjusted**	**Unadjusted**	**Adjusted**	**Unadjusted**	**Adjusted**
Beverage consumption (ounces/day)						
All less-healthy beverages	0.25	0.27	<0.01	<0.01	<0.01	<0.01
All healthier beverages	0.22	0.12	0.03	0.03	<0.01	<0.01
100% juice	0.31	0.40	<0.01	<0.01	0.01	<0.01
Total SSBs excluding sweetened milk	0.18	0.15	<0.01	<0.01	<0.01	<0.01
Unsweetened high-fat (2% or whole) milk	0.33	0.39	0.01	0.01	<0.01	<0.01
Sweetened milk	0.25	0.26	<0.01	<0.01	<0.01	<0.01
Total water	0.14	0.07	0.05	0.07	0.02	<0.01
Tap water	0.21	0.12	0.01	<0.01	<0.01	<0.01
Bottled water	0.28	0.25	0.01	<0.01	0.01	<0.01
Unsweetened, low- or non-fat milk	0.50	0.43	<0.01	<0.01	<0.01	<0.01
Weight status & body mass index (BMI)						
Overweight/obese status[a]	-	-	<0.01	<0.01	<0.01	<0.01
BMI percentile	0.93	0.92	<0.01	<0.01	<0.01	<0.01
Absolute BMI (kg/m^2)	0.94	0.95	<0.01	<0.01	<0.01	<0.01

Abbreviations: BMI, body mass index; SSBs, sugar-sweetened beverages.

Note. ICCs were calculated using Stata's *mixed* command for continuous variables and the *melogit* command for binary variables. Adjusted ICCs adjust for study group, time period (baseline vs. follow-up), the interaction between study group and time period, children's characteristics (age and sex; excluded in models for overweight/obese status and BMI percentile) and parent/household characteristics (Hispanic ethnicity, educational attainment, marital status, income, and household size).

[a]ICCs for overweight/obese status were calculated using baseline data only (not repeated measures) due to model convergence issues. Thus, child-level ICCs for this outcome are not reported.

Supplemental Table 4. Estimated intervention impact on calories and added sugar from beverages.

Intervention Impact on Volume of Beverages Consumed, Survey Data[a]		Calorie and Added Sugar Content of Beverage Categories, Supertracker Data[(4)]			Estimates of Intervention Impact on Beverage Calories and Added Sugar, Combining Survey and Supertracker Data	
Beverage Category	**Intervention Impact (oz/day)**	**Beverage Category**	**Calories per Fluid Ounce**	**Grams of Added Sugar[b] per Fluid Ounce**	**Beverage Calories[c] (kcal/day)**	**Added Sugar from Beverages (g/day)[d]**
Promoted Beverages						
Total water	+2.59	Water	0	0	0.00	0.00
Unsweetened, low-fat or skim milk	+0.92	Milk, low-fat (1%)	13	0	11.96	0.00
Discouraged Beverages					-29.76	0.00
100% juice	-1.86	Juice blend, 100% juice	16	0	-30.94	-5.90
Total sugar-sweetened beverages (sum of soda, fruit drinks, Kool-Aid, sports drinks, sweetened smoothies, sweetened coffee/tea, horchata, aguas frescas, and flavored waters)	-2.38	Soft drink, cola	11	3	-30.94	-5.90
		Fruit flavored drink (Snapple, lemonade, Kool-Aid Bursts, Little Hugs)	20	5		
		Fruit-flavored thirst-quencher beverage (sports drink)	8	2		
		Odwala smoothie[e]	17	3		
		Coffee, regular, with sugar	5	1		
		Tea, sweetened with sugar	9	2		
		Horchata, with reduced fat milk	28	3		
		Generic agua fresca – Piña[f]	6	1		
		Average across SSB categories	**13.00**	**2.48**		
Unsweetened, high-fat (2% or whole) milk	-0.99	2% milk	15	0	-14.85	0.00
Sweetened milk	+0.06	Milk, chocolate-flavored, fat-free	17	1	1.02	0.06
Net impact[g]					**-62.57 calories/day**	**-5.84 g/day**

Notes. Some of the beverage categories we assessed via survey could be matched to more than one beverage category on Supertracker. For example, our survey asked about consumption of unsweetened low-fat and skim milk combined, while Supertracker provides estimates of calories/ounce for unsweetened low-fat (1%) milk and unsweetened skim (fat-free) milk separately. When more than one beverage category on Supertracker could be applied, we used the category that would provide the more conservative estimate of net caloric impact from the intervention (i.e., the higher estimate when the intervention increased intake of the beverage, and the lower estimate when the intervention decreased intake of the beverage).

[a]Estimated as the difference in changes in consumption from baseline to follow-up comparing the intervention to the control group. Estimated using generalized linear regressions controlling for ethnicity (Hispanic vs. non-Hispanic), parental educational attainment (high school degree/GED or less vs.

more than high school/GED), number of household members, marital status (married or living with a partner vs. not), and child's age and sex. Models accounted for clustering within classroom by including an indicator for classroom and within children by clustering standard errors at the child-level.
[b]Excludes intrinsic sugar in milk and 100% juice.
[c]Calculated as change in volume consumed (oz/day; column 2) * calories/oz (column 4).
[d]Calculated as change in volume consumed (oz/day; column 2) * grams/oz (column 5).
[e]Data from myfitnesspal.com because this beverage was not listed in the SuperTracker database. Source: https://www.myfitnesspal.com/food/calories/80306526#. Odwala brand smoothies were selected to represent a popular brand.
[f]Data from myfitnesspal.com because this beverage was not listed in the SuperTracker database. Source: https://www.myfitnesspal.com/food/calories/238265627.
[g]Net impact of the intervention on calories/day from beverages and grams of added sugar/day from beverages, calculated by summing intervention impact on these outcomes across all beverage categories.

References

1. Story M (2013) *Recommendations for Healthier Beverages*. Robert Wood Johnson Foundation.

2. National Academies of Sciences, Engineering, and Medicine (2017) *Strategies to Limit Sugar-Sweetened Beverage Consumption in Young Children: Proceedings of a Workshop*. National Academies Press.

3. Heyman MB & Abrams SA (2017) Fruit juice in infants, children, and adolescents: Current recommendations. *Pediatrics* **136**, e20170967.

4. United States Department of Agriculture (2018) Food-A-Pedia. *Supertracker*. https://www.supertracker.usda.gov/foodapedia.aspx?CatgoryID=-1&FoodDescription=soda (accessed June 2018).

Table 1: CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	Title page
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)[1,2]	See table 2	1
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	3-4
	2b	Specific objectives or hypotheses	Whether objectives pertain to the cluster level, the individual participant level or both	4
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		NA
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	4
	4b	Settings and locations where the data were collected		4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	4-6, Figure 1
Outcomes	6a	Completely defined pre-specified primary and	Whether outcome measures pertain to the cluster level, the	7-8

		secondary outcome measures, including how and when they were assessed	individual participant level or both	
	6b	Any changes to trial outcomes after the trial commenced, with reasons		NA
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty	NA, pilot trial only (for determining sample size for subsequent trials)
	7b	When applicable, explanation of any interim analyses and stopping guidelines		NA
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		4
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	4
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	4
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	4
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	4

	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	Figure 2 (CONSORT flow diagram)
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	4
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		NA
	11b	If relevant, description of the similarity of interventions		4-6
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	8-9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		8-9
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 2
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	Figure 2

Recruitment	14a	Dates defining the periods of recruitment and follow-up		7
	14b	Why the trial ended or was stopped		NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Baseline characteristics for the individual and cluster levels as applicable for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	Figure 2 (CONSORT flow diagram)
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	9-11, Table 2, Supplemental Table 3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		Table 2
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		9-11
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[3])		NA
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		13
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	13

Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	11-14
Other information			
Registration	23	Registration number and name of trial registry	9
Protocol	24	Where the full trial protocol can be accessed, if available	NA
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Title page

** Note: page numbers optional depending on journal requirements*

Table 2: Extension of CONSORT for abstracts[1,2] to reports of cluster randomised trials

Item	Standard Checklist item	Extension for cluster trials
Title	Identification of study as randomised	**Identification of study as cluster randomised**
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	
Methods		
Participants	Eligibility criteria for participants and the settings where the data were collected	**Eligibility criteria for clusters**
Interventions	Interventions intended for each group	
Objective	Specific objective or hypothesis	**Whether objective or hypothesis pertains to the cluster level, the individual participant level or both**
Outcome	Clearly defined primary outcome for this report	**Whether the primary outcome pertains to the cluster level, the individual participant level or both**
Randomization	How participants were allocated to interventions	**How clusters were allocated to interventions**
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	
Results		
Numbers randomized	Number of participants randomized to each group	**Number of clusters randomized to each group**
Recruitment	Trial status[1]	
Numbers analysed	Number of participants analysed in each group	**Number of clusters analysed in each group**
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	**Results at the cluster or individual participant level as applicable for each primary outcome**
Harms	Important adverse events or side effects	
Conclusions	General interpretation of the results	
Trial registration	Registration number and name of trial register	
Funding	Source of funding	

[1] Relevant to Conference Abstracts

REFERENCES

1 Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, et al. CONSORT for reporting randomised trials in journal and conference abstracts. *Lancet* 2008, 371:281-283

2 Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG at al (2008) CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. *PLoS Med* 5(1): e20

3 Ioannidis JP, Evans SJ, Gotzsche PC, O'Neill RT, Altman DG, Schulz K, Moher D. Better reporting of harms in randomized trials: an extension of the CONSORT statement. *Ann Intern Med* 2004; 141(10):781-788.