

Supplementary material for:

Effect of intervention aimed at increasing physical activity, reducing sedentary behaviour, and increasing fruit and vegetable consumption in children: Active for Life Year 5 (AFLY5) school based cluster randomised controlled trial

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Supplementary Table A: Dealing with missing data for main analyses and sensitivity analyses

	Dealing with missing data	Assumptions	Implications / rationale
Main^a	All participants are included if they have the particular outcome being assessed measured at the follow-up. An indicator variable (indicating whether baseline data are missing or not for each outcome) together with allocation of a ‘temporary’ value to those with baseline missing data, will be used to deal with missing baseline data.(1)	Data are MAR	The number included in these main analyses will differ for each outcome e.g. based on comments above regarding likely levels of missing data for each specific outcome measure it is possible that fewer participants will contribute to accelerometer outcomes than questionnaire outcomes.
S1	Participants are included for each measurement only if they have both baseline and follow-up data observed for each outcome. This does not require use of a baseline indicator variable or any imputation for baseline or outcome.	As above	Numbers will differ for each outcome. Allows assessment of whether those with missing baseline data differ in terms of the trial effect compared with those who do not have missing baseline data.
S2	Participants are only included if they have both baseline and follow-up data for all three primary outcomes. As above for secondary outcomes if there are any that have outcome data for the particular measure (e.g. BMI) but not baseline data, after exclusion of those with missing baseline or outcome data for the three primary outcomes, an indicator variable will be used for baseline missing measurement (e.g. of BMI) as in the main analyses (first row).	As above	For the three primary outcomes number of included participants will be the same and equal to the number of participants who have complete data on all three primary outcomes at baseline and follow-up. Numbers may differ for each secondary outcome, for example if there are some participants who have no missing data on the three primary outcomes at baseline or follow-up but have missing data for a particular secondary outcome at follow-up. Allows assessment of whether any apparent differences in effect for the three primary outcomes are due to differences in missing data mechanisms between these outcomes.
S3	Similar to the main analyses but for any child with a missing follow-up measure the child is allocated a value that is 10% ‘healthier’ for a given outcome than all	Those with missing outcome data on average	Numbers will be the same for all outcomes. Allows assessment of the possibility that missing data

	<p>participants with observed data (irrespective of randomised group). This will be done by calculating the 10% value of the mean or median follow-up measure for each outcome and then adding or subtracting (depending on whether healthier levels are higher or lower for the particular outcome) this value to the outcome mean or median; this final value will then be imputed to the outcome value for every child with missing follow-up data.</p>	<p>behave in a relatively healthy way.</p>	<p>may be more likely to occur in families from higher SEP who may have missing data because of moving from state to private education. And to assess whether this form of missing data biases our assessment of the trial effect. This will also test whether selection bias occurs as a result of limiting analyses only to those with the required wear-time for the accelerometer based outcomes (this outcome is likely to have more missing data than other outcomes), since these analyses include all recruited participants.</p>
S4	<p>Similar to the main analyses but for any child with a missing follow-up measure the child is allocated a value that is 10% 'less healthy' for a given outcome than all participants with observed data (irrespective of randomised group). This will be done by calculating the 10% value of the mean or median follow-up measure for each outcome and then adding or subtracting (depending on whether less healthy levels are higher or lower for the particular outcome) this value to the outcome mean or median; this final value will then be imputed to the outcome value for every child with missing follow-up data.</p>	<p>Those with missing data on average behave in less healthy ways than those who do not have missing data through mechanisms that are not captured by observed data.</p>	<p>Numbers will be the same for all outcomes. Allows assessment of the possibility that missing data may be more likely to occur in families from lower SEP and who may have missing data because of being more dysfunctional and perhaps having to care for a relative at home or having higher rates of truancy. And to assess whether this form of missing data biases our assessment of the trial effect. This will also test whether selection bias occurs as a result of limiting analyses only to those with the required wear-time for the accelerometer based outcomes (this outcome is likely to have more missing data than other outcomes), since these analyses include all recruited participants.</p>

^a Note for other baseline characteristics that will be included in the model (gender, age and the school stratifying variables – school involvement in other health promoting activities and area deprivation) there should be no missing data. Thus, using a method that allows inclusion of those with missing baseline data in this analysis allows all recruited participants who have an outcome measure to be included in the analyses.

S: Sensitivity analysis; MAR: Missing at Random, unlike the technical term missing completely at random (MCAR) this does not mean that distributions of variables are the same in those with no missing data and those with missing data. It means that the main effect of the intervention does not differ between those with and without missing data.

Supplementary Table B: Sensitivity analysis 1: intention to treat analyses of the effect of AFLY5 intervention on primary and secondary outcomes assessed immediately after the end of the intervention. Numbers vary by outcome as indicated in the table. In these analyses participants were only included for each outcome if they had a baseline and a follow-up measurement of that outcome.

Outcome	Main comparison between the two groups (Intervention versus Control)		
	Np	Difference in means or odds ratio (95%CI)	p-value
Continuous outcomes:			
Time spent in MVPA (minutes per day)	1200	-1.56 (-5.42 to 2.30)	0.43
Time spent in sedentary behaviour (minutes per day)	1200	-0.25 (-10.12 to 9.63)	0.96
Servings of fruit and vegetables (number per day)	2025	0.11 (-0.09 to 0.30)	0.27
Time spent screen-viewing (minutes per day weekday)	2038	-15.53 (-33.28 to 2.22)	0.09
Time spent screen-viewing (minutes per day Saturday)	2038	-21.92 (-38.26 to -5.57)	0.009
Body mass index (z(sd)-score) ^a	1640	-0.03 (-0.07 to 0.02)	0.23
Waist circumference (z(sd)-score) ^a	1816	-0.11 (-0.22 to -0.01)	0.03
Servings of snacks (number per day)	2025	-0.21 (-0.37 to -0.05)	0.01
Servings of high fat foods (number per day)	2025	-0.10 (-0.24 to 0.03)	0.13
Servings of high energy drinks (number per day)	2025	-0.26 (-0.42 to -0.09)	0.003
Binary outcomes:			
Generally overweight/obese	1640	0.80 (0.49 to 1.30)	0.37
Centrally overweight/obese	1816	0.68 (0.46 to 1.01)	0.05

Np: number of participants; MVPA: moderate or vigorous physical activity; CI: confidence interval

Outcomes in bold are primary outcomes ($p < 0.05$ indicates statistical significance); all others are secondary outcomes ($p < 0.01$ indicates statistical significance, after taking account of multiple testing).

All differences in means / odds ratios with their 95%CI have been estimated using a multi-level model to account for clustering (non-independence) among children from the same school. Multi-level multivariable linear regression was used for effects of the intervention on continuously measured outcomes and multi-level multivariable logistic regression was used for binary outcomes.

The following baseline / school stratifying covariables were included: age, gender, the baseline measure of the outcome under consideration, school involvement in other health promoting behaviours, school area level deprivation.

MVPA: moderate and vigorous physical activity (accelerometer assessed), SB: sedentary behaviour (accelerometer assessed), BMI: body mass index, WC: waist circumference, F&V fruit and vegetables.

^a Internally standardised

Supplementary Table C: Sensitivity analysis 2: intention to treat analyses of the effect of AFLY5 intervention on primary and secondary outcomes assessed immediately after the end of the intervention. In these analyses participants were only included for each outcome if they had a baseline and a follow-up measurement for all three primary outcomes. Numbers included are identical for the three primary outcomes (N = 901) but can vary by outcome for secondary outcomes (though none of these can be higher than 901) as indicated in the table.

Outcome	Main comparison between the two groups (Intervention versus Control)		
	Np	Difference in means or odds ratio (95%CI)	p-value
Continuous outcomes			
Time spent in MVPA (minutes per day)	901	-2.98 (-7.56 to 1.61)	0.20
Time spent in sedentary behaviour (minutes per day)	901	0.28 (-10.29 to 10.85)	0.96
Servings of fruit and vegetables (number per day)	901	0.04 (-0.20 to 0.28)	0.77
Time spent screen-viewing (minutes per day weekday)	901	-7.51 (-26.40 to 11.39)	0.44
Time spent screen-viewing (minutes per day Saturday)	901	-21.61 (-46.75 to 3.54)	0.09
Body mass index (z(sd)-score) ^a	809	0.01 (-0.06 to 0.08)	0.83
Waist circumference (z(sd)-score) ^a	863	-0.06 (-0.18 to 0.05)	0.30
Servings of snacks (number per day)	901	-0.17 (-0.38 to 0.04)	0.11
Servings of high fat foods (number per day)	901	-0.19 (-0.36 to -0.02)	0.03
Servings of high energy drinks (number per day)	901	-0.22 (-0.43 to -0.02)	0.04
Binary outcomes			
Generally overweight/obese	809	0.84 (0.44 to 1.60)	0.60
Centrally overweight/obese	863	0.87 (0.51 to 1.46)	0.59

Np: number of participants; MVPA: moderate or vigorous physical activity; CI: confidence interval

Outcomes in bold are primary outcomes ($p < 0.05$ indicates statistical significance); all others are secondary outcomes ($p < 0.01$ indicates statistical significance, after taking account of multiple testing).

All differences in means / odds ratios with their 95%CI have been estimated using a multi-level model to account for clustering (non-independence) among children from the same school. Multi-level multivariable linear regression was used for effects of the intervention on continuously measured outcomes and multi-level multivariable logistic regression was used for binary outcomes.

The following baseline / school stratifying covariables were included: age, gender, the baseline measure of the outcome under consideration, school involvement in other health promoting behaviours, school area level deprivation.

MVPA: moderate and vigorous physical activity (accelerometer assessed), SB: sedentary behaviour (accelerometer assessed), BMI: body mass index, WC: waist circumference, F&V fruit and vegetables.

Missing baseline data for secondary outcomes (once those with missing baseline primary outcomes are excluded) were managed as in the main analyses.

^a Internally standardised

Supplementary Table D: Sensitivity analysis 3: intention to treat analyses of the effect of AFLY5 intervention on primary and secondary outcomes assessed immediately after the end of the intervention, with missing data for either baseline or follow-up measure of an outcome assumed to be 10% healthier than the average value in the study sample.

N = 2121

Outcome	Main comparison between the two groups (Intervention versus Control)		
	Np	Difference in means or odds ratio (95%CI)	p-value
Continuous outcomes			
Time spent in MVPA (minutes per day)	2221	-1.25 (-4.67 to 2.18)	0.48
Time spent in sedentary behaviour (minutes per day)	2221	-0.11 (-9.27 to 9.05)	0.98
Servings of fruit and vegetables (number per day)	2221	0.08 (-0.12 to 0.28)	0.42
Time spent screen-viewing (minutes per day weekday)	2221	-15.56 (-33.56 to 2.45)	0.09
Time spent screen-viewing (minutes per day Saturday)	2221	-20.86 (-37.30 to -4.42)	0.01
Body mass index (z(sd)-score) ^a	2221	-0.01 (-0.06 to 0.04)	0.61
Waist circumference (z(sd)-score) ^a	2221	-0.11 (-0.22 to -0.01)	0.03
Servings of snacks (number per day)	2221	-0.22 (-0.38 to -0.05)	0.01
Servings of high fat foods (number per day)	2221	-0.10 (-0.24 to 0.03)	0.13
Servings of high energy drinks (number per day)	2221	-0.26 (-0.43 to -0.10)	0.002
Binary outcomes			
Generally overweight/obese	2221	0.99 (0.75 to 1.31)	0.94
Centrally overweight/obese	2221	0.72 (0.50 to 1.04)	0.08

Np: number of participants; MVPA: moderate or vigorous physical activity; CI: confidence interval

Outcomes in bold are primary outcomes ($p < 0.05$ indicates statistical significance); all others are secondary outcomes ($p < 0.01$ indicates statistical significance, after taking account of multiple testing).

All differences in means / odds ratios with their 95%CI have been estimated using a multi-level model to account for clustering (non-independence) among children from the same school. Multi-level multivariable linear regression was used for effects of the intervention on continuously measured outcomes and multi-level multivariable logistic regression was used for binary outcomes.

The following baseline / school stratifying covariables were included: age, gender, the baseline measure of the outcome under consideration, school involvement in other health promoting behaviours, school area level deprivation.

MVPA: moderate and vigorous physical activity (accelerometer assessed), SB: sedentary behaviour (accelerometer assessed), BMI: body mass index, WC: waist circumference, F&V fruit and vegetables.

In these analyses participants all participants are included (N = 2,221 (the number of participants recruited to the study)). Missing baseline data is managed as in the main analyses and missing outcome data are imputed on the basis of those with missing data being 10% healthier than all participants in the study for a given outcome.

^a Internally standardised

Supplementary Table E: Sensitivity analysis 4: intention to treat analyses of the effect of AFLY5 intervention on primary and secondary outcomes assessed immediately after the end of the intervention, with missing data for either baseline or follow-up measure of an outcome assumed to be 10% less healthy than the average value in the study sample. N = 2121

Outcome	Main comparison between the two groups (Intervention versus Control)		
	Np	Difference in means or odds ratio (95%CI)	p-value
Continuous outcomes			
Time spent in MVPA (minutes per day)	2221	-1.01 (-4.52 to 2.51)	0.58
Time spent in sedentary behaviour (minutes per day)	2221	-1.83 (-10.18 to 6.52)	0.67
Servings of fruit and vegetables (number per day)	2221	0.08 (-0.12 to 0.28)	0.42
Time spent screen-viewing (minutes per day weekday)	2221	-15.56 (-33.56 to 2.45)	0.09
Time spent screen-viewing (minutes per day Saturday)	2221	-20.86 (-37.30 to -4.42)	0.01
Body mass index (z(sd)-score)	2221	-0.01 (-0.06 to 0.04)	0.61
Waist circumference (z(sd)-score)	2221	-0.11 (-0.22 to -0.01)	0.03
Servings of snacks (number per day)	2221	-0.22 (-0.38 to -0.05)	0.01
Servings of high fat foods (number per day)	2221	-0.10 (-0.24 to 0.03)	0.13
Servings of high energy drinks (number per day)	2221	-0.26 (-0.43 to -0.10)	0.002
Binary outcomes			
Generally overweight/obese	2221	0.99 (0.75 to 1.31)	0.94
Centrally overweight/obese	2221	0.72 (0.50 to 1.04)	0.08

Np: number of participants; MVPA: moderate or vigorous physical activity; CI: confidence interval

Outcomes in bold are primary outcomes ($p < 0.05$ indicates statistical significance); all others are secondary outcomes ($p < 0.01$ indicates statistical significance, after taking account of multiple testing).

All differences in means / odds ratios with their 95%CI have been estimated using a multi-level model to account for clustering (non-independence) among children from the same school. Multi-level multivariable linear regression was used for effects of the intervention on continuously measured outcomes and multi-level multivariable logistic regression was used for binary outcomes.

The following baseline / school stratifying covariables were included: age, gender, the baseline measure of the outcome under consideration, school involvement in other health promoting behaviours, school area level deprivation.

MVPA: moderate and vigorous physical activity (accelerometer assessed), SB: sedentary behaviour (accelerometer assessed), BMI: body mass index, WC: waist circumference, F&V fruit and vegetables.

In these analyses participants all participants are included (N = 2,221 (the number of participants recruited to the study)). Missing baseline data is managed as in the main table and missing outcome data are imputed on the basis of those with missing data being 10% less healthy than all participants in the study for a given outcome.

^a Internally standardised

Supplementary Table F: Main intention to treat analyses of the effect of AFLY5 intervention on accelerometer-assessed outcomes separately for week and weekend days. Numbers vary by outcome as indicated in the table.

Outcome	Main comparison between the two groups (Intervention versus Control) on week days			Main comparison between the two groups (Intervention versus Control) on weekend days		
	Np	Difference in means or odds ratio (95%CI)	p-value	Np	Difference in means or odds ratio (95%CI)	p-value
Time spent in MVPA (minutes per day)	1252	-1.28 (-6.16 to 3.61)	0.61	1053	0.28 (-3.73 to 4.29)	0.89
Time spent in sedentary behaviour (minutes per day)	1252	2.04 (-9.51 to 13.58)	0.73	1053	-6.11 (-18.73 to 6.51)	0.34

Np: number of participants; MVPA: moderate or vigorous physical activity; CI: confidence interval

All differences in means with their 95%CI have been estimated using a multi-level model to account for clustering (non-independence) among children from the same school. Multi-level multivariable linear regression was used for effects of the intervention on continuously measured outcomes.

The following baseline / school stratifying covariables were included: age, gender, the baseline measure of the outcome under consideration, school involvement in other health promoting behaviours, school area level deprivation.

MVPA: moderate and vigorous physical activity (accelerometer assessed), SB: sedentary behaviour (accelerometer assessed).

In these analyses, participants were only included for each outcome if they had a follow-up measurement of that outcome. For partial missing baseline data we used an indicator variable as describe by White & Thompson,(1) which means for each outcome participants are included even if they do not have a baseline measurement.

Only participants included in the main analyses (i.e. with at least 3 valid days of accelerometer data) are included in this sensitivity analysis.

^a Internally standardised

References

1. White IR, Thompson SG. Adjusting for partially missing baseline measurements in randomized trials. *Stat Med.* 2005;24:993-1007