Data processing in the DMagic cluster randomised controlled trial

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Our Article1 in The Lancet Diabetes & Endocrinology provides evidence on the effectiveness of mHealth and Participatory Learning and Action (PLA) community mobilisation interventions for reducing populationlevel prevalence of intermediate hyperglycaemia and type 2 diabetes and the incidence of type 2 diabetes in rural Bangladesh. These primary outcomes were measured in large random sample surveys of fasting and 2-h blood glucose among adults aged 30 years and older. The observed effects of a greater than 60% reduction in prevalence and incidence outcomes in the PLA community mobilisation compared with control was robust to sensitivity analysis, including use of different arbitrary fasting and 2-h blood glucose cutoffs for classifications of intermediate hyperglycaemia or diabetes.1

We report that our trial primary outcome is based on WHO categorisations of blood glucose into normoglycaemia, intermediate hyperglycaemia and diabetes, with fasting blood glucose of less than 6·1 mmol/L used to classify individuals as having normal blood glucose.2 We recently identified a data processing error, whereby individuals with fasting blood glucose readings of exactly 6·1 mmol/L were misclassified as having readings of less than 6·1 mmol/L, thus deviating from the standard WHO definition.

This error affects 317 (2·8%) of 11 375 individuals from our random population sample, and 61 (2·9%) of 2094 individuals in our cohort of individuals with intermediate hyperglycaemia. These cases of misclassification are distributed across all trial groups. The consequence of this misclassification means that the absolute numbers and proportions of our study sample categorised in the intermediatehyperglycaemia group is slightly underestimated. However, this misclassification resulted in a negligible impact on our results, with no change in the estimate of relative difference in the PLA group compared with control and a difference of less than 1% in absolute effect. Corrected distributions of glycaemic categories and primary outcome results are reported in the table, which corresponds to table 3 in our Article.1

The resulting interpretations and study conclusions remain unchanged. Our data still provide strong evidence to support the use of PLA to prevent intermediate hyperglycaemia and type 2 diabetes in rural Bangladesh, and a replication trial and implementation research are currently underway (ISRCTN42219712).

We declare no competing interests.

References

1. Fottrell, Edward et al. Community groups or mobile phone messaging to prevent and control type 2 diabetes and intermediate hyperglycaemia in Bangladesh (DMagic): a cluster-randomised controlled trial The Lancet Diabetes & Endocrinology, Volume 7, Issue 3, 200 - 212
2. World Health Organisation. Global report on diabetes. Geneva: WHO, 2016.

Table 1 Corrected endline frequency, proportions and relative (odds ratio) and absolute (coefficient) effects and 95% confidence interval comparing of normoglycaemia and intermediate hyperglycaemia and diabetes according to WHO diagnostic criteria a) among the endline random survey population (primary outcome 1), and b) among the baseline intermediate hyperglycaemia cohort (primary outcome 2).

Outcome 1: Corrected population prevalence of intermediate hyperglycaemia and diabetes			
Glycaemic status†	**Control**	**mHealth**	**PLA**
Normoglycaemic	1858 (48.6%)	1875 (49.4%)	2599 (69.2%)
Diabetic or intermediate hyperglycaemic	1963 (51.4%)	1922 (50.6%)	1158 (30.8%)
Total	3821 (100%)	3797 (100%)	3757 (100%)
Relative difference odds ratio (95% CI)	**Control**	**mHealth**	**PLA**
(i) Unadjusted (allowing for stratified clustered design)	Reference	0.97 (0.77, 1.22) p=0.805	0.37 (0.28, 0.49) p<0.001
(ii) Adjusted for household wealth quintile and allowing for stratified clustered design	Reference	0.96 (0.76, 1.20) p=0.701	0.36 (0.27, 0.48) p<0.001
Absolute risk difference (95% CI)	**Control**	**mHealth**	**PLA**
(i) Unadjusted (allowing for stratified clustered design)	Reference	-0.66 (-6.26, 4.94) p=0.817	-20.4 (-26.5, -14.2) p<0.001
(ii) Adjusted for household wealth quintile and allowing for stratified clustered design	Reference	-1.02 (-6.73, 4.68) p=0.725	-21.0 (-27.2, -14.8) p<0.001
Outcome 2: Corrected two-year cumulative incidence among intermediate hyperglycaemic cohort			
Glycaemic status‡	**Control**	**mHealth**	**PLA**
Normoglycaemic	230 (32.3%)	252 (35.2%)	393 (59.1%)
Intermediate hyperglycaemic	356 (50.0%)	343 (47.8%)	213 (32.0%)
Diabetic	126 (17.7%)	122 (17.0%)	59 (8.9%)
Total	712 (100%)	717 (100%)	665 (100%)
Relative difference odds ratio (95% CI)	**Control**	**mHealth**	**PLA**
(i) Unadjusted (allowing for stratified clustered design)	Reference	0.99 (0.70, 1.39) p=0.941	0.41 (0.24, 0.68) p=0.001
(ii) Adjusted for household wealth quintile and allowing for stratified clustered design	Reference	1.02 (0.73, 1.43) p=0.912	0.39 (0.24, 0.65) p<0.001
Absolute risk difference (95% CI)	**Control**	**mHealth**	**PLA**
(i) Unadjusted (allowing for stratified clustered design)	Reference	-0.04 (-5.34, 5.25) p=0.987	-8.41 (-13.8, -2.99) p=0.002
(ii) Adjusted for household wealth quintile and allowing for stratified clustered design	Reference	0.36 (-4.74, 5.47) p=0.889	-8.74 (-14.0, -3.48) p=0.001

Data are n or n (%), unless otherwise indicated. All p-value comparisons are versus control. PLA=participatory learning and action. †Anthropometry participants with missing blood glucose data: eight in the control group, 15 in the mHealth group, and 41 in the PLA group. ‡Anthropometry participants with missing blood glucose data: one in the control group, two in the mHealth group, and three in the PLA group.