

Amendments to the HeLP Analysis Plan V5 (3/11/15) September 14th 2016

Section 1: Summary of Amendments Original Planned Analysis	Section Number (page) in Analysis Plan V5 (date)	Summary of Amendment
Secondary analysis of primary outcome - multiple imputation	7.1.3 (pages 17-18)	<p>Multiple imputation of missing BMI SDS data at 24 months will not be undertaken. Alternative “Best Case / Worst Case” sensitivity analyses will be performed:</p> <p>Best Case: will assume no change in BMI SDS for children allocated to intervention group; change in BMI SDS for children allocated to the control group will be imputed from (marginal) mean change in BMI SDS for the control group</p> <p>Worst Case: will assume that children who were not obese at baseline and who were allocated to the intervention group, were obese at 24 months, with BMI SDS imputed from Public Health England thresholds; change in BMI SDS for children allocated to the control group will be imputed from (marginal) mean change in BMI SDS for the control group</p>
Secondary analysis of primary outcome – CACE analysis	7.1.3 (pages 18-19)	CACE analysis will not be undertaken
Mediational analysis	9.1.3 (page 24)	Both exploratory and confirmatory factor analyses will be carried out on the MLQ. In the Analysis Plan only ‘confirmatory factor analyses’ was specified.

Section 2: Rationale and Further Details of Amendments

Secondary analyses of the primary outcome

(a) Multiple imputation modelling

It was stated in analysis plan V5 that multiple imputation would be used to impute any missing BMI scores at 24 months (primary outcome) based on the assumption of data being missing at random, see section 6.2.1. Given the low proportion of missing BMI data at 24 months (5.6% (74/1324) of recruited children; 5.2% (68/1312) of children with baseline BMI SDS), compounded by the low amount of data deemed missing at random, the appropriateness of this planned sensitivity analysis was discussed at the HeLP Trial Steering Committee held on 20th July 2016. Following discussions, it was agreed that multiple imputation modelling was not required, however, an alternative sensitivity analyses approach to examine the effect of missing primary outcome data, was agreed, namely a “Best Case / Worst Case” scenario analyses. The first set of these analyses are based on hypothetically driven assumptions. Given the hypothetical preventative nature of the HeLP intervention, the *best case scenario* will:

assume no change between baseline and 24 months in BMI SDS for children allocated to the intervention group i.e. the baseline BMI SDS value will be carried forward to replace the missing 24 month BMI SDS value

impute missing 24 month BMI SDS values for children allocated to the control group with their corresponding baseline BMI SDS value plus the (marginal) mean change between baseline and 24 months for the children allocated to the control group with complete baseline and 24 month BMI SDS data.

The *worst case scenario* will:

assume that children allocated to the intervention group who were not obese at baseline were obese at the 24 month follow-up: the 24 month BMI SDS value will be set at the Public Health England threshold for obesity (i.e. the 95th percentile; this is 1.645). For children allocated to the intervention group who were obese at baseline, the baseline BMI SDS value will be carried forward to replace the missing BMI SDS value.

impute missing 24 month BMI SDS values for children allocated to the control group with their corresponding baseline BMI SDS value plus the (marginal) mean change between baseline and 24 months for the children allocated to the control group with complete baseline and 24 month BMI SDS data.

After imputing the missing 24 month BMI sds scores for both scenarios, the primary analyses model will then be fitted to the full intention-to-treat data set, to ascertain if the missing primary outcome data significantly influenced the results of the primary effectiveness analysis.

(b) Complier Average Causal Effect of Treatment (CACE) analysis

In analysis plan V5, it was stated that a CACE analysis would be undertaken to “estimate the complier average causal effect of treatment (CACE), as a potentially unbiased estimate of receiving HeLP.” Non-compliers were defined as children who did not receive at least 4 sessions of drama and the 1-1 goal setting session. Given the very proportion of children categorised as non-compliers (there were only 24 out of 675 children allocated to the intervention group who were categorised as non-compliers (3.6%) and four of these children did not provide primary outcome data), the appropriateness of this planned sensitivity analysis was discussed at the HeLP Trial Steering Committee held on 20th July 2016. Following discussions, it was agreed that a CACE analysis will not be undertaken.

9.1.3 Mediation analysis

In analysis plan V5, it was stated that a “**confirmatory** factor analysis” would initially be undertaken on the MLQ. This was an error in the analysis plan, which should have read “factor analysis”. We designed the MLQ at two theoretical levels; the first overarching theoretical framework was the IMB model of behaviour change (Information – Motivation – Behavioural Skills) and the second was a more detailed level comprising between six and 14 potential constructs, three of which were single items. We therefore did not have a firm idea of the exact number of constructs in the new measure and there are no published findings from other factor analyses to draw upon. Hence it is appropriate to use exploratory factor analysis in the first half of the data set and follow this with a confirmatory factor analysis in the second half.