

## Results

The difference between the two groups using all of the questionnaire data in the participant mean of the weekly scores was  $-2.8$  (95% CI  $-3.9$  to  $-1.8$ ) in favour of the intervention group,  $n = 147$  control,  $n = 145$  intervention). Repeating this analysis using data only from the questionnaires at weeks 8, 16 and 24 showed a difference of  $-2.6$  (95% CI  $-3.9$  to  $-1.3$ ),  $n = 134$ ,  $n = 137$  respectively, and using clinic data at 2, 4 and 6 months was  $-2.3$  (95% CI  $-3.5$  to  $-1.1$ ),  $n = 141$ ,  $n = 142$  respectively.

Several parents felt that questionnaire completion had been useful in prompting more regular use of usual treatments whilst others felt they were repeating themselves each week and this may not be helpful (Qualitative study).

## Conclusion

The results were very similar for all three analyses and conclusions would not have changed if less data had been collected. Therefore, weekly data collection may not be needed when summary measures are used to compare groups. More frequent data collection may be useful in other circumstances for example if there is a need to identify sudden flares.

The process of data collection should also be considered. Frequency of data collection needs to be balanced against the potential for data collection itself to act as an intervention and influence behaviour in pragmatic trials.

Further work is needed to determine the optimum frequency of data collection to capture both the chronic relapsing nature of eczema and changes in condition due to an intervention. This is planned as part of the Harmonising Outcome Measures for Eczema long term control outcome domain.

## P206

### Beyond maximum grade: a novel longitudinal toxicity over time (TOXT) adverse event analysis for targeted therapy trials in lymphoma

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This abstract is not included here as it has already been published.

## P207

### Prediction model for developmental outcome at 2 years of age for babies born very preterm

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## Background

Children who are born preterm are known to be at increased risk of a range of developmental problems. The Preterm and After (PANDA) study aims to provide information about the long term outcome of children born very preterm (less than 31 gestational weeks) admitted for acute neonatal care in the east of England. Within PANDA, the PARCA-R questionnaire is completed by parents in order to measure cognitive and language development at 2 years of age. These data are added to obstetric and neonatal data collected by The Neonatal Survey (TNS), an ongoing study of neonatal intensive care activity in the same geographic area. It includes clinical information on the child and their neonatal care as well as the developmental outcome of the child; alive with no developmental delay (DD), alive with DD and death before 2 years of age.

## Aim

The aim of this project was to investigate developmental outcome at 2 years of age for children born very preterm. The PARCA-R survey completed by the parent was used and failure to do so led to a

missing outcome response. An investigation into the missingness and its assumptions were also investigated as almost half the dataset had a missing outcome which this abstract will concentrate on.

## Subjects

The dataset is a subset of TNS and contained 2028 participants, which included babies born very preterm admitted to neonatal care between 2009 and 2010.

## Methods

The three nominal outcomes were modelled using multinomial logistic regression. Missingness was investigated by complete case analysis, Inverse Probability Weighting (IPW) and multiple imputation. To allow for comparison between the three methods, the same covariates were adjusted for in the final multinomial logistic regression outcome models. Probabilities, odds ratios, log odds and standard errors were used to compare the three different approaches.

## Results

Missing completely at random was disregarded as the IPW missingness model highlighted that the deprivation area, mother's age and mother's ethnicity had an effect on whether the PARCA-R survey was completed. For instance, mothers aged 34+ were 3.4 times more likely to respond than mothers younger than 23 years, when controlling for deprivation area and mother's ethnicity. The imputation model also produced strong evidence of covariates predicting non-responders. Once the investigation of missingness had been conducted the same multinomial logistic regression was produced. The optimal model predicting developmental outcome contained gestational age, sex of the baby and CRIB II score as well as a quadratic term for gestational age. Unsurprisingly, complete case analysis yielded very different results to the models that used IPW and multiple imputation. Odds ratios and probabilities of each outcome were broadly similar with multiple imputation yielding smaller standard errors of the odds ratios in the multinomial logistic regression.

## Conclusions

IPW and multiple imputation both vary methodologically and there are a number of limitations with both methods, however, it is proven to produce very similar results and can be effective to use the data available to predict the missing outcome. It is concluded multiple imputation is more flexible than IPW when modelling missing outcomes.

## P208

### A comparison of baseline as response and missing indicator methods for missing baseline data in a mixed design cluster randomised control trial

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To investigate treatment efficacy in randomised control trials, repeated observations are taken on a cohort of participants and the change in response following treatment is assessed. The commitment required of participants to stay involved in the study, however, makes this design open to both recruitment issues and attrition. A cross-sectional design may be used in conjunction with the cohort design to protect against these problems, recruiting additional participants who only contribute once to the study, resulting in a 'mixed' design.

The EQUIP cluster randomised control trial was designed to evaluate the efficacy of a training intervention for community mental health teams (CMHT), employing such a mixed design. The 'cluster cohort' sample provided baseline data on service users prior to randomisation and follow up data at six months following baseline assessment, via face-to-face interviews. The 'cluster cross-sectional' sample involved all service users under the care of the cmhts not in the cohort sample to be sent a postal questionnaire six months after randomisation. Comparison of the results of the two designs would allow external validity of the intervention to be investigated. The combined sample was intended to increase power to detect the intervention