eRegQual analysis

Chris Rose, Norwegian Institute of Public Health (26 Jun 2020)

Generated using git revision: 078ad37

# Introduction

This document presents the methods used to analyze the adverse pregnancy outcome and process outcome data for the eRegQual trial and presents the corresponding results.

# Methods

We used random-effects logistic regression to estimate the relative odds of success for each of the process outcomes under the treatment versus control conditions. We modelled the clustering of multiple opportunities for success within each pregnancy using random-effects, and computed cluster-robust standard errors to account for the cluster-randomized design (i.e., clustering of pregnancies within clinics). No data were missing for these analyses.

We adjusted for the stratification variable (CHMP 2015) and the variables used to constrain randomization (Li 2017) as fixed effects in all analyses, using individual- rather than cluster-level measurements where possible. We followed the intention-to-treat principle for all analyses: participants were analyzed in the arms to which they were randomized and — with the exception of the complete case analyses for the adverse pregnancy analysis — all participants were included in the analyses. We computed 95% confidence intervals and used the significance criterion P<0.05 throughout. Statistical analyses were performed using Stata 16 (StataCorp LLC, College Station, Texas, USA).

# Results

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Table 1. Successful attendance | | | | | | |
|  | Odds Ratio | Robust |  |  |  |  |
| y |  | Std. Err. | z | P>|z| | [95% Conf. Interval] | |
| arm |  |  |  |  |  |  |
| F | 0.33 | 0.13 | 2.55 | 0.01 | 0.08 | 0.58 |

# References

Committee for Medicinal Products for Human Use (CHMP) (2015). Guideline on adjustment for baseline covariates in clinical trials. London: European Medicines Agency.

van Buuren, S. (2007). Multiple imputation of discrete and continuous data by fully conditional specification. Statistical methods in medical research, 16(3), 219-242.

Li, F., Turner, E. L., Heagerty, P. J., Murray, D. M., Vollmer, W. M., & DeLong, E. R. (2017). An evaluation of constrained randomization for the design and analysis of group‐randomized trials with binary outcomes. Statistics in medicine, 36(24), 3791-3806.

Little, R. J. (1988). A test of missing completely at random for multivariate data with missing values. Journal of the American statistical Association, 83(404), 1198-1202.

Rubin, D. B. (2004). Multiple imputation for nonresponse in surveys (Vol. 81). John Wiley & Sons.

# Appendix