eRegQual analysis - Time and motion study analysis

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# Introduction

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# Methods

Times (durations) are non-negative and their distributions are positively skewed (e.g., there are many consultations of “typical” duration, but some that are much longer). Further, we anticipated that the intervention is likely to have a multiplicative rather than additive effect. We therefore analyzed times on the log scale. We used mixed-effects linear regression to estimate relative differences in time between treatment and control. We adjusted for the stratification variable (CHMP 2015) and the variables used to constrain randomization (cluster size and lab availability; Li 2016) as fixed effects. We estimated the effect of observer and whether a visit was a booking visit (fixed effects) because we anticipated that these would affect time measurements. We modelled cluster as a random effect. It was not possible to obtain reliable variance estimates using a model that adjusted for observer as a random effect. However, an exploratory analysis that modelled observer as a random effect showed that point estimates and confidence intervals comparing treatment to control were almost identical for the primary outcome. We exponentiated to obtain estimates of relative difference and 95% confidence intervals. We followed the intention-to-treat principle for all analyses: participants were analyzed in the arms to which they were randomized, and all participants were included in the analyses. No data were missing. Statistical analyses were performed using Stata 16 (StataCorp LLC, College Station, Texas, USA). The statistician was not involved in data collection and was blinded to treatment allocation during analysis. Protocol deviations are documented in Appendix 1.

# Results

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| --- | --- | --- | --- | --- | --- | --- |
| Table 1. HIM time per consultation (mins) | | | | | | |
|  | Rel. Time | Std. Err.\* | z\* | P>|z|\* | [95% Conf. Interval] | |
| arm |  |  |  |  |  |  |
| B | 0.70 | 0.16 | -2.25 | 0.02 | 0.51 | 0.95 |
| \* The standard error, z-score, and P-value are from the analysis performed on the log scale. | | | | | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Table 2. Consultation time (mins) | | | | | | |
|  | Rel. Time | Std. Err.\* | z\* | P>|z|\* | [95% Conf. Interval] | |
| arm |  |  |  |  |  |  |
| B | 0.85 | 0.11 | -1.43 | 0.15 | 0.68 | 1.06 |
| \* The standard error, z-score, and P-value are from the analysis performed on the log scale. | | | | | | |

# References

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

Li, F., Lokhnygina, Y., Murray, D. M., Heagerty, P. J., & DeLong, E. R. (2016). An evaluation of constrained randomization for the design and analysis of group‐randomized trials. Statistics in Medicine, 35(10), 1565-1579.

# Appendix 1 — Protocol Deviations

We did not originally plan to model relative times via transformation to the log scale. Nor did we originally plan to adjust for observer but chose to do so as it is plausible that systematic differences may exist between observers.

# Appendix 3 — Full Regression Results

The following tables show the full regression results. Note that time was modelled on the log scale and the full estimation results have not been exponentiated.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Table 3. HIM time per consultation (mins) | | | | | | |
| him\_time | Coef. | Std. Err. | z | P>|z| | [95% Conf. Interval] | |
| arm |  |  |  |  |  |  |
| B | -0.36 | 0.16 | -2.25 | 0.02 | -0.68 | -0.05 |
|  |  |  |  |  |  |  |
| strat\_var |  |  |  |  |  |  |
| Ramallah | -0.15 | 0.37 | -0.40 | 0.69 | -0.88 | 0.58 |
| Nablus | -0.32 | 0.37 | -0.85 | 0.39 | -1.05 | 0.41 |
| Salfit | -0.38 | 0.34 | -1.13 | 0.26 | -1.05 | 0.28 |
| Jenin | -0.51 | 0.33 | -1.57 | 0.12 | -1.15 | 0.13 |
|  |  |  |  |  |  |  |
| cluster\_size | -4.59 | 2.59 | -1.77 | 0.08 | -9.68 | 0.49 |
|  |  |  |  |  |  |  |
| lab\_available |  |  |  |  |  |  |
| Lab | -0.03 | 0.16 | -0.21 | 0.83 | -0.34 | 0.27 |
|  |  |  |  |  |  |  |
| bookingvisit |  |  |  |  |  |  |
| Booking visit | 0.78 | 0.09 | 8.80 | 0.00 | 0.60 | 0.95 |
|  |  |  |  |  |  |  |
| observer |  |  |  |  |  |  |
| 2 | 0.12 | 0.23 | 0.50 | 0.62 | -0.34 | 0.57 |
| 3 | -0.14 | 0.24 | -0.56 | 0.58 | -0.61 | 0.34 |
| 4 | -0.01 | 0.22 | -0.05 | 0.96 | -0.43 | 0.41 |
|  |  |  |  |  |  |  |
| \_cons | 2.93 | 0.37 | 8.00 | 0.00 | 2.21 | 3.65 |
| Data were analyzed on the log scale. Estimates have not been exponentiated. | | | | | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Table 4. Consultation time (mins) | | | | | | |
| consult\_time | Coef. | Std. Err. | z | P>|z| | [95% Conf. Interval] | |
| arm |  |  |  |  |  |  |
| B | -0.16 | 0.11 | -1.43 | 0.15 | -0.38 | 0.06 |
|  |  |  |  |  |  |  |
| strat\_var |  |  |  |  |  |  |
| Ramallah | 0.54 | 0.26 | 2.05 | 0.04 | 0.02 | 1.06 |
| Nablus | 0.41 | 0.26 | 1.55 | 0.12 | -0.11 | 0.92 |
| Salfit | 0.41 | 0.24 | 1.71 | 0.09 | -0.06 | 0.89 |
| Jenin | 0.50 | 0.23 | 2.16 | 0.03 | 0.05 | 0.96 |
|  |  |  |  |  |  |  |
| cluster\_size | -2.01 | 1.77 | -1.14 | 0.26 | -5.47 | 1.46 |
|  |  |  |  |  |  |  |
| lab\_available |  |  |  |  |  |  |
| Lab | 0.02 | 0.11 | 0.22 | 0.83 | -0.19 | 0.24 |
|  |  |  |  |  |  |  |
| bookingvisit |  |  |  |  |  |  |
| Booking visit | 0.80 | 0.08 | 9.67 | 0.00 | 0.63 | 0.96 |
|  |  |  |  |  |  |  |
| observer |  |  |  |  |  |  |
| 2 | 0.18 | 0.16 | 1.12 | 0.26 | -0.13 | 0.49 |
| 3 | 0.41 | 0.17 | 2.35 | 0.02 | 0.07 | 0.74 |
| 4 | 0.00 | 0.15 | 0.02 | 0.98 | -0.29 | 0.29 |
|  |  |  |  |  |  |  |
| \_cons | 2.04 | 0.26 | 7.76 | 0.00 | 1.53 | 2.56 |
| Data were analyzed on the log scale. Estimates have not been exponentiated. | | | | | | |