WHELD WP3 work plan

SAP for WP3 has currently not been executed in full. Some of this analysis will inform the analysis of WP5.

Tasks

1. YS to gather all reports given to Rhiannon ◯
2. YS to do demographics/descriptive analysis ◯
    a. This is to include an assessment of those who did not complete FU. ◯

With agreement from the PMG we will analyse as an independent data set (this requires as a minimum to take clustering into account in the models).

Care home 3006 will be analysed as it was allocated to PCC intervention group, but not to its originally allocated interventions, i.e. all the other three interventions in addition to PCC. The analysis will be run including and excluding this care home to notionally describe the effect.

Drug data

Antipsychotics

Binary data at baseline was provided by the trial team.

Follow up data for initial analyses completed using binary data constructed by YS using drug assessment date. We now understand that this should have been the main assessment date.

A reasonable assumption to make at this point would be to assume that this binary data has been constructed correctly**.**

It has now been decided that the variable has been constructed correctly. Drug assessment date and main assessment date may be up to 1 month apart. This is to be considered as one time point.

YS to provide the cases where this window is exceeded to allow a description of the distribution and and assess on a case by case basis what to do for each of these◯

The information has now been clarified for WP5.

Psychotropics

Binary data will be constructed at baseline and follow up using the same criteria as for antipsychotics. ◯

Essentially, we will use the assumption “no stop date implies still on drug” to construct the binary data on condition that the patient has used the drug(s) in the last 12 months.

A=Assessment date, DS =drug start date, DE=drug end date, (when constructing this variable ignore drug assessment date).

DS>DE>A Assign 0 not on drug

DS>A>DE Assign 1 on drug

A>DS>DE Assign 0

DS>A no DE Assign 1 on drug

A with NO DS or DE assume if drug recorded then assign 1 on drug . If this is a large proportion of cases we may need to check this with a sensitivity analysis.

Deaths

A complete case analysis will be carried out first, which means all deaths will be excluded from the analysis initially because they have not provided any data for outcome measures at follow up stage.

In the second step, analyses will be carried out to impute deaths as “best” and “worst” scenarios, where appropriate, to see how the results for complete case analyses will change.

Do a sensitivity analysis with the Y:-

1. Assign Y all 0 no drug◯
2. Assign Y all 1 on drug◯
3. Randomly assign 0/1’s in proportion with what is seen in the data set. This may be sensible to do on a MI level. ◯

1 and 2 will give the extremes of the assumption and 3 will give a feeling of what was likely to have happened.

For continuous variables multiple imputation in the usual way will be included in all analysis. This is for both the withdrawals and the deaths.

Finally the analysis plan should be run including the clustering◯