Analysis Plan for Providence: Main AIMS

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1 AIM 1.1: Does providing frequent feedback improve home-based mental health treatment of youth, ITT design

Because SFSS does not appear to have a normal distribution, we will use a natural logarithm transformation of YDSFSTLN, or SFS-Y Symptom Scale in CBCL units. This does not solve all normality problems, as there still appears to be a spike for the lowest value possible (i.e. more 1's than would be expected under a normal distribution). However, the remainder of the histogram appears to be bell-shaped and one can argue that normality assumptions are satisfied.

The shape of log SFSS over time does not appear to be linear. In general, there appears to be a definite quadratic shape and possible cubic shape for the respective Feedback groups, although this patterb does not appear to vary greatly by Feedback. This implies that patients generally tend to improve as CFIT begins, regardless of Feedback group, but this rate of improvement flattens over time and eventually increases. It might flatten again towards the end of follow-up. If CFIT is effective, one would expect a difference in slopes near the beginning of intervention. This gap would continue over time, but one would still expect to see a similar shape/pattern for each of the intervention groups. Hence, even in the presence of a quadratic/cubic pattern over time, the time by intervention interaction will be the main focus of the analysis. If we wanted to be more sophisticated, we could also include feedback by time quadratic and feedback by time cubic interactions, but I feel the added value of these interactions would be minimal, mainly because the parameters would be difficult to interpret and one would have to rely on the graphs to make sense of the model. We will include the following predictors in the multilevel linear model (degrees of freedom given for each variable)

- Time (time since starting CFIT): 1 df
- Time quadratic (time since starting CFIT, squared): 1 df
- Time cubic (time since starting CFIT, cubed): 1 df
- Treatment Type (Home-based,foster care, VRP) 2 df
- New patient (Y/N): 1 df
- Training: 1 df
- Training*Time interaction: 1 df

- Feedback (Y/N): 1 df
- Feedback*Time interaction: 1 df

Total degrees of freedom for fixed effects is 10 (sample size: 844 patients, 312 therapists, 38 sites). Also, we will include the following random effects (9 df)

- Patient: Random intercept and slope, unstructured covariance. This should not be nested in therapist because a patient can have multiple therapists (cross-nesting).
- Therapist: Random intercept and slope, unstructured covariance
- Site: Random intercept and slope, unstructured covariance

If the Feedback*Time interaction is non-significant at the $\alpha = 0.05$ level, we will declare no difference between the feedback and no feedback groups. Note the main effect of Feedback is the difference at time 0 in the feedback vs. no feedback group at the reference level of the other variables (treatment type, new patient, cohort, training). Since this effect should be 0 on the basis of randomization, it is not of interest for hypothesis testing.

One could also consider interactions of Feedback with Treatment Type, New Patient, and Cohort as secondary analyses. For example, if one would expect Feedback to be effective for new patients but ineffective for old patients, a Feedback*NewPatient interaction would be appropriate. If the trajectory across time differed by NewPatient status, then interaction terms for NewPatient*Time and NewPatient*Time*Feedback could also be included. However, these interactions will get out of hand quickly and are better left as secondary questions. The proposed analysis outline above will evaluate the effect of Feedback averaged over the various levels of cohort, NewPatient, Treatment Type, and training.

Note we are not adjusting for initial severity of SFSS. Instead, we will include the baseline measure (response at 1st CFIT visit) as part of the response, so that we are modeling the complete linear trajectory from time 0. Although one could potentially adjust for severity at intake, these measures are only available for new patients and hence cannot be incorporated into the main analysis. Regardless, the approach of modeling time 0 as the response while using a random intercept will take into account the fact that patients start with varying levels of severity. The correlation between the random slopes and intercepts will adjust for the fact that patients who start with greater severity have more room to drop, and hence may have steeper slopes.

We will include the following output:

1. A plot of raw means across time by feedback. This can be done by creating 2 week "bins" to group the observations.
2. Model-based parameter estimates, standard errors, p-values, and interpretations
3. Model-based group (feedback vs. no feedback) means and 95% confidence intervals at reference levels of covariables evaluated at a time agreed upon as the end of typical follow-up (85 weeks or median follow-up time?)
4. Model-based pairwise difference, 95% confidence interval, and p-value, at reference levels of covariables evaluated at a time agreed upon as the end of typical follow-up (85 weeks or median follow-up time?)
5. ANOVA table giving overall p-values for each variable
6. Plot of estimated means by time comparing Feedback vs. no Feedback.

The analysis can be repeated for the caregiver and therapist ratings, i.e. log(adsfstln): log of SFS-A Symptom Scale in CBCL units, and log(cdsfstln): log of SFS-C Symptom Scale in CBCL units.

2 AIM 1.2: Does providing training on common factors improve home-based mental health treatment of youth, ITT design

We use the same model as AIM 1.1, but we evaluate the Training*Time interaction. We will display the following output:

1. A plot of raw means across time by Training.
2. Model-based group (training vs. no trainin) means and 95% confidence intervals at reference levels of covariables evaluated at a time agreed upon as the end of typical follow-up (85 weeks or median follow-up time?)
3. Model-based pairwise difference, 95% confidence interval, and p-value, at reference levels of covariables evaluated at a time agreed upon as the end of typical follow-up (85 weeks or median follow-up time?)
4. Plot of estimated means by time comparing Training vs. no Training.

3 AIM 1.3: Does providing training on common factors in addition to frequent feedback improve home-based mental health treatment of youth, ITT design

We use the same model as AIM 1.1, but include the following predictors:

- Feedback*Training interaction: 1 df
- Feedback*Training*Time interaction: 2 df

First we evaluate the 3-way interaction. If significant, report this as our "final model". If not significant, remove 3-way interaction and evaluate Feedback*Training interaction. For the "final model", we will include the following output:

1. A plot of raw means across time for all 4 Feedback*Training combinations.
2. Model-based parameter estimates, standard errors, p-values, and interpretations
3. Model-based group (All 4 training*feedback combinations) means and 95% confidence intervals at reference levels of covariables evaluated at a time agreed upon as the end of typical follow-up (85 weeks or median follow-up time?)
4. Model-based pairwise difference, 95% confidence interval, and p-value, at reference levels of covariables evaluated at a time agreed upon as the end of typical follow-up (85 weeks or median follow-up time?)
5. ANOVA table giving overall p-values for each variable
6. Plot of estimated means by time comparing trajectories of each Feedback*Training combination