Think before you do (Part 2): Pre-registration worked example

Niamh MacSweeney niamh.macsweeney@ed.ac.uk





Aim of today's lecture

 To apply our research checklist to a worked example of a preregistered report.

** Note: Today's example is from one my PhD projects on the association between pubertal development and adolescent depression. **



More OSF templates available here: https://osf.io/zab38/wiki/home/



Open Science Framework templates:

Data collection

https://docs.google.com/document/d/1DaNmJEt By04bq1l5OxS4JAscdZEkUGATURWwnBKLYxk/edi t?pli=1

Secondary data analysis

https://osf.io/jqxfz/

Qualitative study

ttps://osf.io/w4ac2/

Study Information

After you decide on your project **title** and provide a <u>brief</u> **description** (to give some context for the proposed study), you need to include:

Research Question:

RQ1: Is pubertal timing associated with depressive symptoms during adolescence?

Hypotheses:

HO: There is no association between pubertal timing and depression in adolescence.

H1: **Early** pubertal timing is associated with increased depressive symptoms in adolescence.

Points to note:

- Good practice to use only two concepts per research question (e.g., "Does X lead to Y?").
- This makes it easier to describe the statistical test for each RQ later.
- Make clear whether the hypotheses are directional. If directional, state the direction.

Study Design

This section varies depending on the nature of your project but the key is for you to give as much detail as possible.

Study Design:

To answer our research question, we will use data from the Adolescent Brain and Cognitive Development (ABCD) Study. ABCD is a **longitudinal**, **cohort** study that recruited ~12,000 9-10-year olds from 21 sites across the US. The current project will use data from the baseline assessment and 4 year follow-up. ABCD includes neuroimaging, biological, behavioural and socio-environmental measures.



Points to note:

- Include type of data (e.g., cross-sectional or longitudinal).
- General content of dataset
- Prior access to data (sec. analysis only)

Data collection and qualitative projects:

- Two-group, repeated measures design?
- Between or within-subject design?
- Case study or ethnography?

Sampling Plan

This section relates to the previous section but provides more detail about your sample characteristics.

Sampling Plan

We will use an unrelated **sub-sample** of ABCD participants in the current study (N= 9,981). Participants were recruited through schools and via snowballing methods at 21 sites across the US. Participants will only be included in analysis if both baseline (aged 9-11 years) and 4-year follow-up (aged 13-15 years) is available for the variables of interest.

Points to note:

If collecting your own data, include:

- Expected sample size
- Rationale (e.g., power analysis)
- Stopping rule
- Inclusion/exclusion criteria
- Sampling methods

Power analysis is a very important aspect of experimental design!

Statistical power: 1 - (Type II error) = probability of finding an effect that is there.

Variables

This is one of the most important sections of the pre-reg as each "ingredient" can significantly affect the reproducibility of your study

Independent variable: Pubertal timing

Pubertal timing will be derived using the **Pubertal Development Scale** (PDS), which examines secondary sex characteristics such as growth spurts, body hair growth, skin changes, breast development and menarche in girls, and voice changes and growth of testes in boys. The measure includes **five-items on a four-point scale**. Each characteristic is rated on a 4-point scale (1 = no development, 2 = development has barely begun,3 = development is definitely underway, and 4 = development is complete). The **PDS total score** was **regressed** on age for girls and boys separately and the standardised residual obtained was used as the pubertal timing measure. PDS **caregiver report** was used in all analysis. Code for data cleaning and preparation is available here.

Dependent Variable: Depressive symptoms (DS)

DS for adolescents were assessed using a computerised version of the **Kiddie Schedule for Affective Disorders and Schizophrenia (KSADS).** The scale included **28 binary items** on current and past DS that reached clinical significance. **Lifetime** measures DS were generated by combining reports on current and past symptoms (a positive answer for either current or past were grouped as positive for lifetime depression, and negative answers on both were grouped as negative). We **created a measure** of DS based on Diagnostic and Statistical Manual of Mental Disorders (DSM-V) criteria for the severity scale of depression. Levels of DS included: 'severe', 'moderate', 'mild' and 'none of the above' (encoded as 3-0, respectively). KSADS **adolescent-self report** will be used in all analysis.

Points to note:

- Detail is key!
- Clear journey from unprocessed to processed data ready for use in models.
- Ideal if you can include link to data cleaning code.



Variables continued...

You should pay just as much attention to your covariates as you would your IV and DV!

Covariates: Age, ethnicity, body mass index (BMI), study site

"Given that previous research has found BMI to be associated with pubertal development, BMI was included as a covariate in all models..."

Missing data: We will use complete case analysis to deal with missing data.

Skewed Data: Data that violates the normality assumptions for linear regression will be log10 transformed.

Outliers: We will conduct additional sensitivity analysis by re-running our models without datapoints that are ±3 standard deviations from the mean to determine whether extreme values are affecting our results.

Points to note:

- Really think about why you are including each covariate in your statistical model.
- Provide as much detail as given for your IV and DV.



Analysis Plan

This is perhaps the most important and most complicated question within the preregistration.



We will use a **general linear model** to test the association between pubertal timing and depressive symptoms using the **"glm"** function in R.

In our model, pubertal timing will be the **predictor** (independent) variable and depressive symptoms will be the **outcome** (dependent) variable. P-values will be corrected using family-wise error correction with FDR method using the "p.adjust" function in R. The code we will use for these analyses can be found here.

Inference criteria: We will make inferences about the associations between pubertal timing and depressive symptoms based on p-values and the size of the regression coefficient. We will conclude that a regression analysis supports our hypothesis if the p-value is smaller than 0.01 and the regression coefficient is larger than our minimum effect size of interest.

Points to note:

Include:

- Type of model
- Specification
- Interactions, sub-group analyses.
- Control for multiple comparisons.

Any test not included here must be noted as an **exploratory test** in your dissertation.

Main takeaway point...

Does my "recipe" have enough information for someone else to "make" the same research study?





niamh.macsweeney@ed.ac.uk



lklinkha@exseed.ed.ac.uk



alexandra.mitchell@ed.ac.uk

