

Preregistration

Inez Myin-Germeys, Jeroen Weermeijer KU Leuven

General Assembly Meeting Heidelberg 11/04/2024



Pre-registration template



General preregistration template voor OSF https://doi.org/10.31222/osf.io/epgjd

Qualitative research preregistration template

https://journals.sagepub.com/doi/10.1177/1609406920976417

Preregistration for ESM studies https://osf.io/preprints/psyarxiv/seyq7

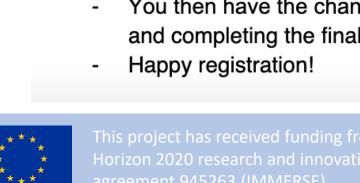
Some general recommendations



- Make an OSF page for your paper / preregistration
- Everything uploaded on the page is fixed you can still add changes later, but this will be visible and transparent
- The authors of the preregistration do not have to include all authors of the final paper
- Always write your introduction in parallel with the pre-registration
- Write your statistical code and upload it on the same osf page

How to register your study on the OSF using this template:

- Download and complete the Word/PDF version of this template
- When you are ready to register your study on the OSF, go to the "registrations" tab within the relevant OSF project and create a new registration.
- When presented with the different options for creating a new registration, select "openended" registration.
- After completing the "registration meta-data" form, you will be directed to the "summary" page. Cut and paste the completed ESM registration template document into this "summary" box.
- If you have code or equations within your registration document, it is best to also attach a PDF copy of the registration via the "add supplemental files or additional information" option, because equations/code do not render well when copy and pasting. Code files can also be attached as supplementary materials for the registration, e.g. as R or Stata files.
- You then have the chance to review your registration before hitting the "register" button and completing the final steps.





Study Information

- 1. Title (required)
 - 1.1. Provide the working title of your study. It may be the same title that you submit for publication of your final manuscript, but it is not a requirement.
 - **Example**: Effect of baking on positive affect in everyday life
 - 1.2. More info: The title should be a specific and informative description of a project. Vague titles such as 'Experience sampling study pre-reg' are not appropriate.
- 2. Authors (required)
- 3. Description (optional)
 - 3.1. Please give a brief description of your study, including some background, the purpose of the study, or broad research questions.
 - **Example**: Although previous self-report surveys have found an association between baking and positive mood, no studies have yet investigated whether or not baking may correlate with momentary changes in positive affect, measured in daily life.
 - 3.2. More information: The description should be no longer than the length of an abstract. It can give some context for the proposed study, but great detail is not needed here for your pre-registration.





4. Hypotheses (required)

4.1. List specific, concise, and testable hypotheses. Please state if the hypotheses are directional or non-directional. If directional, state the direction. A predicted effect is also appropriate here. If a specific interaction or moderation is important to your research, you can list that as a separate hypothesis.

Example: Participants who report engaging in baking at one measurement occasion will be more likely to report higher positive affect at the following measurement occasion.

DESIGN

In this section, you will be asked to describe the overall design of your study. Remember that this research plan is designed to register a single study, so if you have multiple experimental designs, please complete a separate preregistration. For large ESM datasets that will be used for multiple analyses by different people (and possibly different labs), for clarity, we recommend one registration per study/paper.



- 5. Study type (required)
 - 5.1. Observational study The majority of ESM studies will be observational in nature, and will not involve participants being exposed to different experimental conditions. Participants may be recruited to target or control groups based on presence or absence of particular characteristics, e.g. mental health status.
 - 5.2. Other
- Blinding (required for intervention studies)
 - 6.1. Blinding describes who is aware of the intervention and control group allocations within a study. Mark all that apply.
 - 6.1.1. No blinding is involved in this study.
 - 6.1.2. Participants will not know the intervention group to which they have been assigned.
 - 6.1.3. Personnel who interact directly with the participants will not be aware of the assigned intervention group. (Commonly known as "double blind")
 - 6.1.4. Personnel who analyze the data collected from the study are not aware of the intervention status of any given group.
- 7. Is there any additional blinding in this study?





Describe your study design. Examples include between- or within-participants designs, N=1 single-case or multi-observer designs. Typical study designs for observation studies include cohort, cross sectional, and case-control studies. **Example**: We have a cohort design.



Sampling Plan

In this section we'll ask you to describe how you plan to collect samples, as well as the number of samples you plan to collect and your rationale for this decision. Please keep in mind that the data described in this section should be the actual data used for analysis, so if you are using a subset of a larger dataset, please describe the subset that will actually be used in your study.

- 9. Existing data (required)
 - 9.1. Preregistration is designed to make clear the distinction between confirmatory tests, specified prior to seeing the data, and exploratory analyses conducted after observing the data. Therefore, creating a research plan in which existing data will

be used presents unique challenges. Please select the description that best describes your situation. Please do not hesitate to contact us if you have questions about how to answer this question (<u>prereg@cos.io</u>).



- 10. Explanation of existing data (if applicable)
 - 10.1. Name and briefly describe the data set(s), and if applicable, the subset(s) of the data you plan to use.

Example: The current study will use a subset of variables (see variables section for names) from Wave I of the RE-AL cohort study, using data from all participants within the dataset (N=220).

- 10.2. Specify whether this data is open or publicly available.
 - **Example**: Data are not publicly available.
- 10.3. How can the data be accessed? Provide a persistent identifier or link if the data are available online, or give a description of how you obtained the dataset.

 Example: Data will be obtained by application to the lead researcher of the RE-AL study (Cook, E. M. M. M.; e.cook@uchoc.be). Our application has already been approved (10th January 2020).

Example: Data have not yet been accessed or downloaded. Once this post-registration has been made on the Open Science Framework, data will be released to YUM with a time and date-stamped receipt.

- 10.5. If the data collection procedure is well documented, provide a link to that information. If the data collection procedure is not well documented, describe, to the best of your ability, how data were collected.
 - **Example:** The protocol of the RE-AL cohort study is published: Cook, E. M. M. M., Fondu. E., & Biccies, T. (2014). Protocol and sample for the RE-AL study: An adolescent experience sampling cohort study to investigate nutrition and mental health. *Nutrition Methods, 11*(3), 157-163.
- 10.6. Some studies offer codebooks to describe their data. If such a codebook is publicly available, link to it here or upload the document. If not, provide other available documentation. Also provide guidance on what parts of the codebook or other documentation are most relevant.





11. ESM data collection procedure (required)

Please specify the ESM data collection procedure in as much detail as possible, indicating your decisions for the options below.

Note that this pre-registration template is mainly intended for studies that involve multiple selfreport measures, where participants are assessed at least once per day in the context of their daily life. As there is a large variation in the methodology of these studies, not every option below may be applicable and may therefore be indicated as such.

- 11.1. Study duration (number of days)
 Example: The ESM period lasts for 6 days. If participants have filled out less than 30% of all beeps after this period, the ESM period is extended by 2 days.
- 11.2. Type of sampling scheme:

12. Sample size (number of participants) (required)

12.1. Describe the sample size of your study. If individuals are clustered in higherorder units, e.g. schools or groups according to diagnosis, then describe the size required for each unit.

Example: We will include a total of 2000 participants in our sample, 1000 12 year-olds, 500 14 year-olds, and 500 16 year-olds.

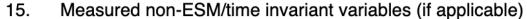
- 13. Rationale for sample size: Temporal design and number of participants (if applicable)
 - 13.1. Please provide a rationale justifying your decisions regarding the sample size. This includes the temporal design (number of days and number of measurement occasions per day) and the number of participants included within the study. For example, the temporal design can be selected taking into consideration protocols





Variables

In this section, you can describe all variables (both ESM and non-ESM variables and manipulated and measured variables) that will later be used in your confirmatory analysis plan. In your analysis plan, you will have the opportunity to describe how each variable will be used. If you have variables that you are measuring for exploratory analyses, you are not required to list them, though you are permitted to do so.



- 15.1. Describe each variable that you will measure, which is not measured during the ESM period. This will include outcome measures, as well as any predictors or covariates that you will measure outside of the ESM period. You do not need to include any non-ESM variables that you plan on collecting if they are not going to be included in the confirmatory analyses of this study.
- 16. Measured ESM/time-variant variables (required)
 - 16.1. Describe each variable that is measured during the ESM period. This will include outcome measures, as well as any predictors or covariates that you will measure during ESM, or that were measured during the ESM period (in the case of preexisting data). If the ESM questionnaire includes items other than those used in the current pre-registration, provide an appendix with the full ESM questionnaire. Specify the level at which each variable is measured and describe the response scale (Visual Analogue Scale, Likert scale, categorical, or other, in which case, specify). Also, indicate whether items were presented in a randomized or fixed order.





Prior knowledge of data (if applicable)

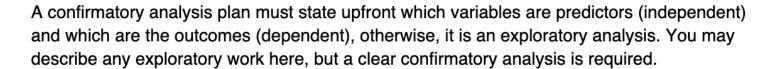
20. List the publications, conference presentations (papers, posters), and working papers (in prep, unpublished, preprints) you have worked on that are based on the data set. Describe which variables you have previously analyzed and which information you used in these analyses. Limit yourself to variables that are relevant to the current study. If the dataset is longitudinal, include information about which wave(s) of data were previously analyzed. Also, include any knowledge regarding missingness within the dataset or compliance, including at what level e.g. overall compliance, compliance for different types of reports, the mean level of compliance, range of compliance across participants. **Example:** YUM has previously used the RE-AL Wave I dataset to investigate the relationship between positive affect (variables: mood_cheerful, mood_relaxed and mood_satisfied) and frequency of snacking (variable: eat_snack). Both of these variables will be used in the current study. YUM's previous analyses using these variables were pre-registered (URL to pre-reg). They were published as: Munch, Y.U., Cook. E. &, Monster, M. M. M. (2016). Happy snacking: A real-time monitoring study of positive affect and snacking using the RE-AL cohort. Journal of Snack Studies, 21(3), 244-252, and were also presented by YUM as an oral presentation at the International Association of Nutrition conference, New York, 22-26th September, 2014 (link to abstract; link to slides). All of the authors of the current study are aware of these

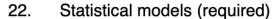




Analysis Plan

You may describe one or more confirmatory analyses in this pre-registration. Please remember that all analyses specified below must be reported in the final article, and any additional analyses must be noted as exploratory or hypothesis-generating.





- 22.1. What statistical model will you use to test each hypothesis? Please include the type of model (e.g. mixed effect models, repeated measurement ANOVA, SEM, etc.) and the specification of the model (this includes each variable that will be included as time-varying and time-invariant predictors and outcomes).
- 22.2. If a multilevel analysis is applied, a description of the following elements can be included:

24. Transformations (if applicable)

24.1. If you plan on transforming, centering, recoding the data, or will require a coding scheme for categorical variables, please describe that process.

Example: If you estimate a model that includes a lag-dependent variable as a predictor, then there should be information on how the overnight or missed beeps are going to be treated (e.g. for each day the first beep of the day will be set as a missing observation).

Example: The time-varying predictor will be centered using the individual means and the time-invariant predictor will be centered using the grand mean.





- 25. Inference criteria (if applicable)
 - 25.1. What criteria will you use to make inferences? Please describe the information you will use (e.g. p-values, Bayes factors, specific model fit indices), as well as the cut-off criterion, where appropriate. Will you be using one or two-tailed tests for each of your analyses? If you are comparing multiple conditions or testing multiple hypotheses, will you account for this?

Example: We will use a Likelihood ratio test to test the difference between two

- 28. Exploratory analysis (if applicable)
 - 28.1. If you plan to explore your data set to look for unexpected differences or relationships, you may describe those tests here. An exploratory test is any test where a prediction is not made upfront, or there are multiple possible tests that you are going to use. A statistically significant finding in an exploratory test is a great way to form a new confirmatory hypothesis, which could be registered at a later time.

Example: We expect that symptoms measured at the baseline are highly correlated (depressed mood, loss of interest, weight problems, fatigue, psychomotor disturbance). We are going to conduct a factor analysis to study the variability of the set of items.

Other

26.1. Expectations of missingness. This is a common feature of ESM studies, for example, a participant can drop out and all their data can be missing, participants can miss entire notifications resulting in missing (notification-level) observations, or a participant can have partially completed questionnaires resulting in (item-level) missingness. Provide a justification for your expectations.

Example: We expect fewer than 5 participants to drop out, approximately 20% of notifications to be missing within the non-dropouts, and approximately 90% of the notifications to be completed within the non-dropouts. These expectations are



IMMERSE



28. Exploratory analysis (if applicable)

28.1. If you plan to explore your data set to look for unexpected differences or relationships, you may describe those tests here. An exploratory test is any test where a prediction is not made upfront, or there are multiple possible tests that you are going to use. A statistically significant finding in an exploratory test is a great way to form a new confirmatory hypothesis, which could be registered at a later time.

Example: We expect that symptoms measured at the baseline are highly correlated (depressed mood, loss of interest, weight problems, fatigue, psychomotor disturbance). We are going to conduct a factor analysis to study the variability of the set of items.

Other





Questions?

