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Rishika Reddy

KerCheng Chen

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Study Methods, Times, and Events

Summary

- Study methods implement your plan to answer your research question in a transparent, reproducible manner.
 - Common study events include pre-intervention, randomization, intervention, and post-intervention/follow-up.
 - A time and events table outlines study events, assessments, and dates and allows for events to be presented in a clear, visual manner to researchers and, in a simplified form, to participants.
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Introduction

An important key to conducting a successful study is the careful planning of your study methods. These methods will allow you to set up your study, gather your data, and complete your study on time. In this chapter, you will learn the necessary study methods of a research proposal, which consists of different events and assessments. A useful tool to plan out your study methods is a time and events table. This table is a highly structured and organized table that outlines events, assessments, and timepoints, providing any user with an accurate overview and timeline of the study. You can use a time and events table for a variety of functions, including training research staff and building a clinical research database. As such, it is critical for you to learn how to design an effective time and events table.

What are Study Methods?

Study methods are strategies, processes, or techniques you will be using to conduct your study. It is important to note that there are many types of studies, such as observational studies, case-control, and randomized control studies. While each type has its own unique study methods, this chapter will primarily focus on methods for a randomized controlled study (RCT), a study design that randomly assigns participants to an experimental or control group. Study methods consist of different events and assessments that are described in the following sections. Many

errors in clinical studies are the result of planning poor study methods, so it is critical to plan things out in advance.

What is a Time and Events Table?

A time and events table organizes the events, assessments, and dates of your study methods. The table should be highly structured and organized so that it can be read and understood easily.

How to define events?

A typical study has four types of events: pre-intervention, randomization, intervention, and post-intervention/follow-up. You can add more events or break down the aforementioned events into more detailed events if necessary. Certain events such as study follow-up can be optional, as determined by the researchers and the aims of the study.

The study pre-intervention period is when you gather baseline measurements before the start of the intervention and it typically occurs after informed consent. You can compare baseline and intervention measurements and assess if your intervention or treatment had a significant result on the participants. Due to the clinical nature of the study, you can also use the pre-intervention period to review participants' medical history and medication prior to the study's inception. Similarly, you can compare and determine changes to the participant's health due to the intervention.

Randomization is a method to assign study participants to random treatment groups. It can occur between pre-intervention and intervention. You will randomize your participants within different arms, either an intervention/treatment arm or a control arm. In the control arm, participants receive no intervention or treatment, or they may receive "care as usual." For behavioral studies, they may receive an attention control consisting of structured sessions with the research team that are approximately the same duration as the sessions the intervention group receives. Randomization helps to eliminate bias that could compromise study findings and may arise if the research team intentionally (that is, not randomly) placed certain subjects in the intervention arm instead of the control arm.

The study intervention period is when the participants are provided with an intervention or placebo (control). Note that interventions are assumed to have a null effect until it is proven otherwise. Depending on the study design, there can also be multiple arms in the intervention.

The study post-intervention/follow-up visits is when you collect data from the participants after the monitored intervention period is over. Post-intervention can be optional depending on the study's aims. The purpose of having the study follow-up is to determine if the desired effect of the intervention or treatment continues for days or weeks after the administration of the intervention or treatment. In other words, does the intervention have long-lasting effects?

How to define assessments?

Common assessments used in clinical studies include the following: informed consent, eligibility and screening questionnaires, questionnaires and surveys, adverse event screening/safety assessments, and end-of-study feedback interviews. This section briefly explains the purpose of each assessment and the event during which they should be given. You can list the assessments you will use for each event under the assessments column of the time and events table.

Informed consent

In brief, informed consent is permission from the participant to conduct a research intervention or treatment with the participant. You *must* obtain informed consent before the start of the intervention and generally before baseline data collection. In order for the consent to be informed, you must provide participants with a complete overview of the study and explain their role in the study. The participant will then decide whether they wish to participate in the study. More details regarding informed consent are provided in the chapter on Subject Risks and Safety.

Eligibility & screening questionnaires

You can use eligibility and screening questionnaires to assess if the participants who expressed interest in your study meet your set inclusion and exclusion criteria, which is further elaborated on in Chapter 8. After determining eligibility per your study's inclusion and exclusion criteria, you can enroll the participant in the study.

Questionnaires and surveys

Questionnaires and surveys are tools consisting of a series of questions that you can use to collect data from participants. These questionnaires and surveys are accessible at multiple times: prior to the intervention, during the intervention, and after the intervention. To determine the type of questionnaires and surveys you should use, refer back to your literature review (see the Literature Review chapter and the Study Outcomes chapter), in which you identified three to five key studies similar to your study. You can use common overlapping questionnaires between your key studies to decide on the appropriate questionnaires for inclusion. Of note, there are several questionnaires that are similar in content. For example, in the context of sleep research, the Insomnia Severity Index (ISI) and the Pittsburgh Sleep Quality Index (PSQI) are commonly used questionnaires. After reviewing the purpose and qualities of each, you can determine the usage of one or both of these questionnaires in your study. For example, the purpose of the ISI is to be a brief screening measure of insomnia that participants can complete in five minutes or less (Smith 2003). On the other hand, PSQI takes up to ten minutes to complete and measures sleep disturbances over a one-month period and retrospective sleep quality (Smith 2003).

Safety assessments/adverse event screening

You can use safety assessments and adverse event screening to identify medical issues that arise during the study that were not previously present. This must be done at multiple timepoints, pre-intervention, intervention, and post-intervention. You must record any adverse events and submit them to the IRB for review. You can perform adverse event screenings through a review of the participants's medical diagnoses using an Electronic Medical Record (EMR).

End-of-Study feedback interview

Lastly, the end-of-study feedback interview is when participants provide their overall thoughts on the study, their experience during the study, and any additional questions. This interview provides valuable subjective information regarding how the participant viewed the study and its intervention or treatment. You can use the information collected from this interview in future qualitative analysis.

What is the Best Way to Define Study Visit Days?

Study event days are commonly identified underneath the event type column headings of the time and events table (i.e., pre-intervention, study intervention, and post-intervention/follow-up). This section describes how you should define the days for events and assessments in a time and events table. As a reference for the examples below, consider the first day of intervention as day 1.

How do you number pre-intervention days?

As described, pre-intervention is done before intervention (day 1). Logically, you can assign the days corresponding to events in the pre-intervention period using negative numbers.

Example: If you plan to do screening and consenting two weeks before intervention starts, you can assign screening and consenting as day -14. After screening and consenting a subject, if you schedule a safety assessment one week before intervention starts, you can date it as day -7. The pre-intervention days would then range from day -14 to day 0.

How do you number intervention days?

Before numbering intervention days, you must take into consideration the length of your intervention based on time constraints, budget, enrollment goals, and other factors that may be relevant to your study. For pilot projects, you should consider having a short intervention as you likely will have a small sample size and budget.

Example: If your intervention is two weeks long, then you should designate the first day of your intervention as day 1 and the last day of your intervention as day 14. You should assign intervention days with positive numbers. If you want your participants to complete a sleep diary every day of the intervention period, you would assign sleep diaries under the appropriate heading as

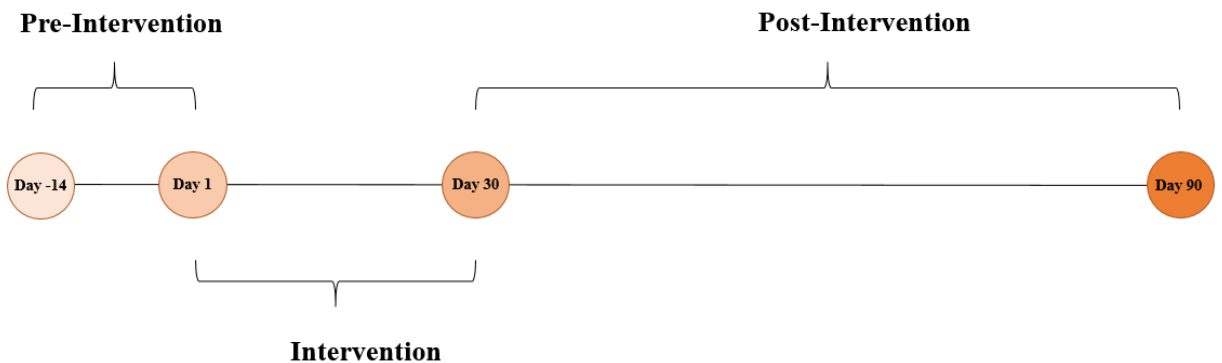
days 1-14. If you want your participants to complete a study questionnaire on the seventh day of intervention, you would date it as day 7.

How can you number post-intervention/follow-up days?

The post-intervention/follow-up visit can occur at any time after the study intervention is complete. You can choose to have either a single visit or multiple visits after your study intervention. You should leave a reasonable and consistent gap between the end of the intervention and the follow-up visit.

Example: If you planned to have two follow-up visits, one visit occurring a week after the intervention, and a second visit occurring two weeks after the intervention, then you would assign the first follow-up visit as day 21 and the second follow-up visit as day 28.

Figure 1. A Basic Timeline.



Who Uses the Time and Events Table?

A variety of people can use the time and events table, including researchers and participants. Principal investigators or lead researchers can use the time and events table to plan out and conduct their research study. They can also utilize the time and events table to design databases through web platforms such as REDCap.

Additionally, research coordinators/assistants can use the time and events tables for several purposes. First and foremost, research coordinators/assistants can use the table to outline a timeline for each participant consisting of concrete dates. Built properly, the time and events table can greatly relieve future confusion within the research team. Second, research coordinators/assistants can use the time and events table to train new members of the research team.

Other than researchers, study participants can also utilize the time and events table, through a simplified version within the consent form. The table serves as a clear, visual reminder for when the participants must come in for visits. Moreover, the table will list the assessments/tasks participants must complete on specific days. The time and events table should provide a clear and helpful overall timeline of the study to participants.

Practical Guides/Worksheets

How do you create a time and events table?

A method to format a time and events table is described below. Note that you can format the table however you see fit as long as it remains clear to the users.

The headings of the columns are labeled as assessments, pre-intervention, study intervention, and follow-up. With the exception of assessments, these headings are essentially the events of the study. Utilizing the bold and underline features for the headings allows the readers to see certain breakdown of the sections in a transparent manner.

Figure 2. Sample Headings.

<u>Assessment</u>	<u>Pre-Intervention</u>	<u>Study Intervention</u>	<u>Follow-Up Visit</u>

Under the assessments column, put in each assessment that is used in the study.

Table 1. Filling in the Assessments Column.

<u>Assessment</u>	<u>Pre-Intervention</u>	<u>Study Intervention</u>	<u>Follow-Up Visit</u>
Day of Event:			
Informed Consent			
Eligibility & Screening Questionnaires			
Randomization			
Study Treatment			
Study Questionnaires and Surveys (e.g., ISI, PSQI)			
Sleep Diary			
Safety Assessments/Adverse Event Screening			
Medical History & Medication Review			
End-of-Study Feedback Interview			

Under the pre-intervention, study intervention, and post/intervention/follow-up columns, assign the days when you will use the assessments during those stages. An example of a complete time and events table is provided below:

Table 2. Assigning Days.

<u>Assessment</u>	<u>Pre-Intervention</u>	<u>Study Intervention</u>	<u>Follow-Up Visit</u>
Day of Event:	Day -14 to 0	Day 1 to 30	Day 90
Informed Consent	Day -14 to 0		
Eligibility & Screening Questionnaires	Day -14 to 0		
Randomization	Day -14 to 0		
Study Treatment		Day 1 to 30	
Study Questionnaires and Surveys (e.g., ISI, PSQI)	Day 0	Day 14 & 30	
Sleep Diary	Day -14 to 0	Day 1 to 30	
Safety Assessments/Adverse Event Screening		Day 14 & 30	Day 90
Medical History & Medication Review	Day -14 to 0	Day 14 & 30	Day 90
End-of-Study Feedback Interview			Day 90

This is the recommended format of the time and events table. The table lists the days and events that are relevant to the example study. The headings of the columns listing the study events are bold and underlined, and the days you plan to use the assessments are written under each stage of the study. You can also break down the table further, as shown in the second column of Figure 5.

Conclusion

Study methods explain your study procedures through events and assessments. After knowing what your study methods entail, you can create a time and events table describing the particular dates on which key events will occur. This is a valuable tool that can be circulated to other members of the team to reach a consensus on the study design before actually writing a detailed study plan. It is also a useful tool, when presented in a simplified way, to explain the study to potential study participants in the informed consent document.

References

Smith, M.T. and Wegener, S.T. (2003), Measures of sleep: The Insomnia Severity Index, Medical Outcomes Study (MOS) Sleep Scale, Pittsburgh Sleep Diary (PSD), and Pittsburgh Sleep Quality Index (PSQI). *Arthritis & Rheumatism*, 49: S184-S196. doi:[10.1002/art.11409](https://doi.org/10.1002/art.11409)

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