Research Methods in Health Promotion
Dr. Arista Lahiri
Dr. B.C. Roy Multi-Speciality Medical Research Centre,
Indian Institute of Technology Kharagpur
Week 04
Lecture 19: Experimental Research Designs: Issues and Challenges

 In our discussion regarding research methods in health promotion, we have covered the different aspects of observational studies and in the last lecture we discussed about the experimental research designs. We mentioned that the experimental research designs during their implementation part they face certain interesting problems or interesting challenges that as the researcher we have to take care or we have to understand and we have to mitigate those problems. Here we will be discussing regarding these problems, the experimental research designs, the issues and the challenges that we may face. Basically the topics that we will be discussing they are very limited for this particular lecture, but I can assure you they are very much interesting. We will be discussing the common threats to the internal validity, what do you mean by internal validity, whether the research design is appropriate, whether the study that we are conducting is appropriate and whether the answer that we are getting from this study is appropriate for the study participants that we have in our hand. Whether the study the result it is internally valid that means, whether the result it is applicable for the population that we have in our hand.

 And we will be discussing the specific issues that are related to the repeated measures design because repeated measures designs are growing you know they are very much important nowadays and they can help you with certain inferencing where you have different problems with randomization or you want to see the trends and everything all these parts we have discussed in the last lecture. So, there are certain specific issues with the repeated measures as well we will be discussing these in this part. These are a few challenges that we will be discussing now ok. The common challenges I have just given you a list you can find even a more exhaustive list if you can just go through the literature that discuss the health promotion research methods, but these are the main things that we have to look for and that we have to think when we are basically designing one interventional research in health promotion right.

So, what is a Hawthorne effect? Now Hawthorne effect as many of you may know it results due to observation or it results due to the attention that we pay to our study participants. Now typically the Hawthorne effect was observed with the workers who are being observed how much was the yield and everything. So, typically from a management standpoint in the Hawthorne effect was I mean it was devised, but it is also effective and it is also all everywhere there in the experimental research designs not only in the typical health promotion research, but also generally in epidemiological research. It is basically due to the time and attention paid to the participant because the participants know that you are observing them or you are seeing them. What can happen? The participant can intentionally change their behavior.

Say for example, in village let us have a drive regarding mitigating the you know the habit of open defecation. So, the open defecation free initiative may be rolled out in a particular village and as an investigator we may send a team or we may ourselves go to that particular village and we may regularly check whether the participants there you know I mean they are performing the behavior or not whether they are performing open defecation or they are not performing that thing it is as simple as that yes or no kind of thing, but the participant will know that the investigator or the team from the investigators they are actually observing them. What will happen? Say we have our resources limited and we have the plan to observe them for a month continuously for a month. So, if the behavior is actually not changed the participants may for some time for that particular one month perform that particular behavior that is they are not doing the open defecation, but after that when we are not observing them then the participants can again resort back to their old habit. This is called the Hawthorne effect the investigators is observing and the behavior of the participants are changing.

The example that I have given you is a very crude example, but in intervention research whenever you are providing intervention to certain groups then you have to be very certain that there is no Hawthorne effect underlying because otherwise you cannot really compare on what is going on and what is actually the effect of the intervention. Here is one important term for this you know particular issue that is called the placebo attention. Basically in pharmaceutical research we give the pharmaceutical molecule the test molecule to one group and one placebo to other group. That means, that is that may be a sugar coating or that may be something that will not have any effect on the individual that is called a placebo. So, in placebo

attention group what happens what is meant by placebo attention is you are giving the same attention to the placebo group how that can be done? You are preparing the for example, the pharmaceutical composition or the particular tablet in such a way that it looks similar to both the groups.

Now, they know that they are the same thing and you are also following up them in a similar duration of time. For example, if the participant who is actually taking the medicine you follow that particular participant in say in the afternoon or in the evening for the control group also for the or the placebo group also you maintain the same kind of format that helps them understand that ok. So, I am not being given something called a sham medicine or a placebo I am also being something that is that can work actually. That usually you know negates the Hawthorne effect because both the groups will have similar kind of observation or the effect of attention. This is important in the case of the health promotion research because often with the health promotion research that intervention that we are giving if it is typically you know the open level kind of or typically the health education kind of intervention we really cannot you know assure that the control group because we do not have any placebo group over there will be given the same kind of attention and they will not know that they are not being given the intervention because sometimes and mostly in health promotion research the blinding part is not possible and you must expect a degree of Hawthorne effect when you are conducting a particular health promotion research.

So, that you have to accommodate in your research design. There is one another thing called the diffusion effect. What is the diffusion effect? We discussed little bit about the diffusion effect during our last lecture. The results might be due to contamination of the control groups that means, in a particular community you have given intervention or given the health education through certain group of people and that certain group of people they are not talking to their peers and because of that you know communication the control group who are not being given the given the intervention they already now know what health education message you have already given. So, now, you may not have the true effect of the intervention that you actually wished for.

What can happen? You may find that there is an increase in knowledge for example, if we have considered the pretest also and also the post test you may consider a significant increase in knowledge from the pretest part in both the groups in intervention and also in the control group, but the difference in intervention and control group may not be significant, but what can be significant is if you you know compare the increase in knowledge that can be significant significantly different between the intervention and the control group. But still we try to mitigate the diffusion effect how by somewhat selecting certain distant clusters like this. For example, see if we if we are doing in a in a rural village this is one village and we select a nearby village there is a high chance of this diffusion if this is intervention and this is control. Now, see if we select one intervention village here and far away we select a control village where there is very minimal chance of diffusion related to these parts, but again the problem is with growing degree of communication and improved communication per say the diffusion effect can be expected more and more in health promotion research because people talk and your health education if it is typically the health education or typically something that the participants can talk about that is going to be diffused in the control group as well, but distance is a very important factor when we consider devising certain health promotion research to mitigate this particular diffusion effect. Effect of history what is the effect of history? The results that we get that might be affected due to an event that occurred between the observation we do not know what actually happened between the observation because in our previous slides during the interrupted time series we are observing the same participants in time point 1, in time point 2 and in time point 3 say those are 6 months apart.

There might have been certain incidents that may have happened in between time point 1 and time point 2 and that particular incidence that may have not been they may not be there with the intervention group that may they may not may be there with the control group. In that scenario even though we have given the intervention to the intervention group the particular event that the control group has suffered or has seen may change their behavior that is the effect of history what actually has happened in between the observations that is why when we design our intervention during every follow up we try to understand if there is any significant event that has happened since the last follow up. Maturation we understood the maturation trend that we have studied in the last lecture. So, it is somewhat similar it is the change in the result or it is the distortion in the result that may be there due to the participants growing older, wiser, stronger or you know more experience between observations and maturation even you

know because of the pre intervention survey that we are giving that can also affect the degree of maturation that we may have and this also we have to factor in when we are actually analyzing the data that we get from the research. Then there is the question of testing what can happen with testing the results might be I mean you know they may changed due to the number of times the responses were measured.

Every time you measure the response the participant will get seasoned. For example, I am measuring giving one question today you know for example, I am taking one test know simple knowledge based test how much the students know regarding a particular topic I am taking the test today and if I am implementing the same test tomorrow to the same group of students what what the what will happen the students will now know the question they know and they know the answers. So, the result the effect of of the next test it will be distorted because of what we call the testing effect the students already know the answers and now even without the intervention, what can be the intervention in this case a particular knowledge imparting imparting knowledge to students like this without that the result will be a very good one you will have a significant increase in the scores. So, that can happen with testing. Now see the effect of history effect of maturation and effect of testing they are more or less seen with the one group design.

That means, if you have a control group then you have a scope of mitigating these effects right what happens with history is if the history part or if that particular event it is not distributed homogeneously that means, if it if does not occur with the intervention and control group both then you may have a problem, but otherwise if you have a control group then the history maturation and testing they will mostly occur similarly or in a similar pattern with all the groups in intervention group and also in the control group and because the same thing is occurring in the intervention in the control group we really can negate the effect during our analysis. Again there is this concept of instrumentation now you have understood what is testing, testing means you are giving the same population the test ok. Instrumentation means it is the effect of the measuring instrument that means, first testing is regarding the population on whom or the number of measurements that we are doing we are doing the same measurement of the same population. The instrumentation means we are doing the same test on the same population ok and you know how this can change see if we are doing one

interventional study on for example, on anemia prevention and for anemia prevention we have a certain group of defined health promotion measures that we are promoting. Now, the interventional control group for example, if we have a single group the single group we are giving that particular intervention the anemia preventive interventions and in that same population in some time we may implement another intervention for healthy diet.

Now there are parts where the healthy dietary interventions they may intersect with the anemia preventive intervention. What will happen is because of the different instrument that may be from this same study that may be from some other study because of this instrument now what can be the instrument simply the pretest questionnaire or the pretest checklist whatever may be because of that the behavior of the same participant that may change ok. Please understand this is not the same as testing instrumentation is mostly related to the study instrument that we are you know implementing in between the baseline and also in between the follow up ok. Again this is more observed with the one group design because if we have two groups then the instrumentation problem may not be there because this instrumentation effect of instrumentation will be similar in intervention and also in the control group and if the participants in intervention and control group again are having similar degree of this effect we can negate that. Another thing is called statistical regression or sometimes we call it regression to the mean.

What happens is results might be distorted due to the selection of participants based on extreme scores. When measured again the scores might move back to an average level. That means, if you select the participant based on very high scores or very high degree of knowledge or other way very low score or very low degree of knowledge what you can expect is later or when you are you know finding when you are giving the intervention and you are taking the post test you may find a very average level of score or very average you know result. If you get that please be very sure to check whether there is any statistical regression or regression to the mean effect or not. Then what can happen is if you select participants based on a very high knowledge score for example, that very high knowledge score can be due to certain you know chance.

If you have given that that brings us to the question of how you have devised your questionnaire or the study tool. So, it all depends on all those things. Then there is a question of differential selection and differential attrition. Differential selection means you are taking some participants differentially into the study and differential attrition means some participants are differentially getting out of the study. What happens is differential selection means results might be affected due to the differences that existed between the participants in groups before treatment occurs.

Treatment means here before we have given our intervention. So, if you have selected if you have preference for some people to be in the intervention group for certain health promotion intervention that can ultimately be considered as a differential selection. Differential attrition one very common example of differential attrition may be due to the mortality because mortality patterns may not be same across the your two groups of individuals. For example, if you have this intervention group and control group the mortality suppose in intervention is M1 and in control group is M2. Now, they are not the same the resultant factor will be some participant during your follow up you will have certain degree of less participants.

If M1 is much much greater than M2 then ultimately this I1 means it is ultimately after the intervention has actually occurred you are taking the post test. Then the population in I1 obviously, it will be much much lesser than C1 that means, intervention group will have very less amount of people compared to the control group. Because of this the homogeneity that you had in the baseline that may not be ultimately there during the during the final analysis part and that is the very essence of taking a pretest and then taking a post test and the different comparisons that we have by subtracting the pretest score from the post test score. We will be discussing all these issues later when we discuss regarding the data analysis, but for you please understand these are the different issues that we have to consider when we are actually devising the research. We have to mitigate we have to minimize the differential attrition and we have to take care of the differential selection.

This brings us to the last concept that will be covering in this lecture that is the important issues that we have with repeated measures. Because repeated measures are kind of a very

robust design and they are very popular with the health promotion researchers. The major design that will be major issue that will be basically discussing is called the carry over effect. As you can see then later all the issues that we discuss that we will discuss eventually are different types of carry over effect. So, what is a carry over effect? As you can read effects that occur when the exposure to the first treatment affects the subjects performance during the subsequent treatment.

Now treatment means the intervention that means, you have you have your intervention group. Now here I am not considering the control group for example, I am taking only the intervention group. You have given one intervention and I1 is your first observation then you are giving another intervention maybe on the same intervention then I2 is your next observation. What can happen is because you have given the intervention after the baseline the effect of this intervention may follow or maybe there during the second intervention phase. For example, if we consider that same example of you know the anemia preventive behavior and healthy dietary practices.

We can consider the effect of anemia prevention and also healthy dietary practices in the same study and in that study if we if we have given already the dietary good dietary practices advices during the intervention first intervention. Suppose this here we have given the dietary later advice and subsequently we are providing the anemia preventive advices in the next part. What will happen? As these interventions they are very much linked with each other some part of the dietary intervention they will be retained within the individuals and that will ultimately boost the effect of anemia preventive intervention that we will implement later on ok. So, this is called the carryover the effect that is there from the previous intervention that is being carried over to the next intervention. What we have to do? We have to have a sufficient amount of washout period where the effect of this first intervention will be washed out for the next intervention ok.

Then there are issues of learning fatigue and habituation. What is learning? Learning again is a type of carryover effect in which what is learned in the first intervention it enhances the observed outcomes after subsequent interventions ok. Consider this example although these

two interventions are not the same interventions, but there are certain intersections and because of that intersection the effect of this next treatment it is getting boosted. So, there may be something called learning. The typical example is if you give the same questionnaire to the participants over and over again even though you have not given any intervention since the participants now know that the same questionnaire will be given to me over and over again they know the answers to the question you may get a very good result although that may not be the actual scenario ok.

You have given 10 questions the same 10 questions if you implement them in a very short duration of time there may be certain effect of learning. Now, the thing with learning is if there is an effect of learning that means, the study tool is the effect of the study tool is there and the participants already know the answers and they have already memorized it. Sometimes washout effect may not be sufficient to mitigate the effect of learning. So, in that case what you have to do you have to factor in the effect of learning in your research design as well. That means, when you report your research you have to mention that there might have been certain effect of learning.

What is fatigue? Fatigue is again a part of carryover effect in which deterioration in a subjects performance results from being tried from the first treatment. That means, if you test an individual over and over again ultimately the individual will be very much reluctant to perform that test. See if I am being rested with the same questionnaire over and over again during the during the later phases during say the third or fourth time I may just abruptly randomly tick the answers and that will ultimately hamper my question I mean my response that is the fatigue and fatigue again is basically on the part of the participants because of implementing the same thing over and over again. Habituation what is habituation? Again it is a typical carryover effect it is in which a subjects repeated exposure to stimulus leads to reduced responsiveness. Learning the effect is getting boosted, fatigue the effect is reduced, performance is reduced and in habituation what happens? See habituation the responsiveness how well the participant is going to response to your say the study tool that gets reduced.

What happens with sensitization? It is again a type of carryover effect response stronger to the stimuli stemming from initial exposure to a different stimuli. I hope this part is clear because learning and fatigue they are considered together and habituation and sensitization they are also considered together. How? Here the responsiveness is reduced and here the subjects respond stronger to the different stimuli. If you consider the same example where the diet related interventions were given and then again the anime preventive interventions were given. But as this is a typical scenario of sensitization you have already sensitize the individuals with healthy dietary practices.

Now, the response to the anime preventive practices or what to eat for prevention of anime like this they will be even more stronger because they already now know what is what to be done with good dietary behavior ok. Next the issue is called adaptation. It is a type of carryover effect in which a subjects adaptive changes to a stimulus leads to a change in outcome. Here the change to an individual is due to again the stimulus and that adaptive changes that means, the change is in real time. It is not like you have given the intervention and that change will stay forever.

It may so happen that in the intervention group there is certain there are groups for example, I 1 and I 2 the two different groups they have different types of adaptation to the to this intervention. I 1 may have accepted it is in a very good way, I 2 may have not accepted in a very good way what will happen ultimately the effect that is retained within I 1 will be better than I 2 and as a result the response to this second intervention that may be changed that is what is mentioned the adaptive changes to a stimulus leads to a change in outcome or what can happen? Then in the control group if you have given the dietary intervention to both the groups and you finally, want to see whether the anemia preventive behaviors is going to be very much effective in intervention group or not. What can happen is because the diet same dietary intervention was given to the control group as well when you observe without being given the anemia preventive prevent intervention that there will be you know favorable outcome during C 2 C 1 C 2 I mean that is the thing. But here see you have not given this particular intervention, but because of the other intervention that you have already given people have certain changes made certain changes to the to their lifestyle or to their behavior and there is ultimate change you know that is coming out even in the control group ok. So,

these are just a few examples arbitrarily given to you, you can think more and more about these examples and you can come up with your own example as well, but these are the basic concepts that you have to keep in mind when you are designing a repeated measures research.

Because for repeated measures research to be more robust obviously, it is better to take two groups than taking one group and if you can to start with you first try to randomize it is possible to combine randomization and taking repeated measures and you consider the effect these carry over effects that there may be because of the repeat in measurement ok? So, to conclude we discussed regarding the different challenges 9 challenges to be precise 9 general challenges for the experimental research designs. We discussed the carry over effect that may be there for the repeated measure studies and we also understood how we can very briefly basically how we can actually mitigate these effects and what should we do when we design these research. And lastly I have mentioned that the design should consider minimizing these effects if unavoidable then they must be clearly stated. That means, in your report or in your proposal you have to mention these as your limitation there may be situations where you really cannot avoid these effects there may be situations where you really cannot avoid the Hawthorne effect just mention it in your proposal or when you are mentioning in the article perhaps.

So, these are the resources for this lecture. Thank you.