Research Methods in Health Promotion
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Lecture 18: Experimental Research Designs

So, we were discussing regarding the research methods in health promotion. In this lecture we will be discussing on the experimental research methods or more commonly we call them the interventional research designs. So, regarding the experimental research designs we shall be covering these concepts. First we will be covering the importance of experimental designs in health promotion, then the truly experimental research designs we will be covering the concept of randomization a bit and the quasi experimental research designs that we employ in health promotion. Also please note that the quasi experimental research designs are a bit more important in terms of the health promotion research because often we find certain situations where we actually cannot implement the truly experimental research designs. So, we will discuss regarding these things as we go on with this lecture.

So, to start with what are the experiments in health promotion research? So, the health promotion the concept of health promotion it basically deals with you know the idea of preventing diseases through bringing certain behavioral change or as we colloquially call it is the preventive medicine or the preventive aspect of health care. So, it is basically improving the public health by inducing certain behavior change and we have certain lectures regarding the behavior change techniques, what are the different determinants of behavior and we have been discussing these issues throughout as well. Now to implement certain programs or intervention in health promotion we must understand whether the particular intervention or the particular health promotion program that is there that has been implemented basically is effective or not. So, in order to understand the effectiveness or as we have mentioned whether these are efficacious or not.

So, in order to understand the efficacy of the program we must undertake certain causal research. Causal research means as we have already understood during the previous lecture that it means we have to understand whether the particular independent variable or as we call it the determinant or the predictor is actually causing the outcome. So, that kind of causal research is essential ok. So, it is essential why to determine whether a particular program or intervention is actually useful or not the concept of efficacy is there and why do we need to undertake all these research because from observation research we can have a hypothesis, we can have our research question and we can develop our intervention or our program based on the findings from the observation research, but it is ultimately the experiment or the intervention that we are actually going to do that will determine whether the program is in a larger context of a particular intervention whether that particular intervention or program is

going to help the community or not. Whether it is going to bring the desired behavior change whether that is going to protect the people from certain diseases or not.

Now, these aspects will be dealt in the experimental research process because in experimental research we have typically one intervention that is there you know to understand whether the causative agent or the factor that is actually related to the adverse health related event can be modified and whether that modification that we are proposing through health promotion is going to help at all or not. That is the basically the prelude for you know experimental research design in health promotion. Before we move on to subsequent discussions let us just have a look on the different terminologies that will be using throughout the different lectures in this course. First is independent variable. Now we have been discussing regarding the association part whether certain factors are associated with the behavior that we see in the population in the observation research we know that there are different factors or determinants that are related to the to the outcome that we are studying.

So, independent variable and dependent variable are these two terms that will be discussing more when we discuss about the causal research. What is an independent variable? It is the variable that is chosen by the investigator that means, when we are determining or we are investigating some something. So, we are choosing the independent variable. It is not something like if we are not selecting that particular variable to be in our study that can come into and we can just observe it. So, we have to first choose the independent variable that is basically chosen by the investigator to modify or administer to determine its effect on the dependent variable.

That means, in experimental research basically it is the independent variable that we are going to alter. Now, let me give you an example regarding this. Because we want to understand how a particular health promotion intervention consider a health education message regarding family planning services is going to you know have an effect on the community regarding their family planning related behavior. Now, this program this particular program it is basically changing the behavior of the beneficiaries who already have a particular mindset regarding the family planning practices or who already have their own choice regarding family planning. Now, when we are implementing this intervention this program we are basically manipulating that pre-existing behavior or practice ok.

So, that pre-existing part that is already there within the subjects and that is basically independent of the outcome. Because the outcome for example, if we consider the number of children that the couple may have if we consider this as the outcome it is basically dependent on their particular you know preventive their family planning related practices. So, here the family planning related practices that is basically independent and we can actually modify it or we can manipulate it through interventions. One way of looking at the interventions in

health promotion research is to consider the interventions themselves as an independent variable because the interventions even may have you know certain changes in different communities or in fact, the intervention can be given to one group of people and may not be given to one group of people. So, with this philosophy some you know analyst they consider the particular intervention as a sort of independent variable and obviously, when we will be analyzing the data that we have from our research we have to consider this as a predictor the intervention.

Because ultimately it is the intervention we are studying we are studying the effect of the intervention ok it is as simple as that. So, that is why the independent variable is chosen by the investigator that we can actually modify or administer determine its effect on the dependent variable. When we administer it to determine its effect it is typically the intervention that we are talking about and when we are trying to modify it may be the intervention or it may be something that the intervention is actually modifying. So, that is the intervention may not directly act you know it may modify some behaviors or some practices and through that the intervention may act there are different scenario we will discuss these issues later when we discuss the analysis component. But please understand this is the concept of independent variable in terms of you know experimental research or causal research.

Next comes the issue of dependent variable. So, the dependent variable is basically the primary outcome or the main variable of interest that means, in our example the family planning practices or as we have mentioned the number of children that the couple is having is the dependent variable because that is the main variable that is the main outcome that we are interested in. So, that is the concept of the dependent variable and often it is the crux of the hypothesis that we are going to test through our causal research. The hypothesis is you know the research question is made based on the outcome that means, whether our intervention is going to change that particular behavior for example, whether if we if we perform certain intervention regarding family planning practices whether that is going to you know bring the bring the fertility level or bring the family planning practices to a certain degree. If a couple is in a in a particular community for example, the average number of children eligible couples are having for example, may be 5.

Now, we are now in providing certain interventions and after that intervention we can observe the average number of children the eligible couples in that particular community is having. So, here the eligible couple and their children the number of average number of children that the eligible couples are having in a particular community is our outcome and in fact, it is the dependent variable. There is another concept called the extraneous variable. So, as the term suggests this is something external to what we actually get. So, these are the variables outside of investigators purview it does not mean that you do not choose it, outside investigators purview means it is not something that we are basically focusing on, but it can you know influence the outcome of this study ok.

So, the the extraneous variable although we are not directly choosing it, but it can you know influence the outcome of the study. So, this brings us to the next question of the different factors and the levels why because we have been discussing that the intervention that we are giving that may act directly or may not act directly and the independent variables they they may have certain you know groups or categories like that. So, one way of looking at it in a more you know analytical mechanism is factor and levels. What is a factor? A factor is what the investigator is manipulating. So, a factor means basically the independent variable right because we are manipulating the independent variable either that may be the intervention directly or the intervention may manipulate the certain independent variables.

So, now, that is a factor. The level refers to the variations in the factor ok. For example, say we have age as a factor. Now we consider age as 3 different groups less than 18 years, then from 18 to 65 years and then we may consider more than 65 years basically adolescence, adulthood and you know elderly. Now these parts these 3 categories as we call them they are the different levels because these are the variations in age.

Also if we consider age as continuous like 1, 2, 3, 4 in this way then the variations will be huge again those are the different levels ok. So, basically the categories as we simply see them during our analysis they are considered as the levels. There is another concept that is basically out of scope for this particular course, but I will just introduce the concept that is called the multi level models or multi level research. In that case also the variables that we are studying they have different levels and we study or we model based on those different levels ok. So, that is the concept of factor and levels.

What is a factorial design? Factorial design means as we have understood age here is a factor. So, if we are considering a single factor for example, IV will be considered as the independent variable it is affecting the DV that means, the dependent variable. Now IV if we are considering only one independent variable or one factor ok so that means, it is a single factor design and if we are considering more than one factor that means, it will be a factorial design. Sometimes in experimental research because of certain resource related issues we may have to consider different factors for example, we may have to implement two or three interventions all together and in various combinations to see whether the interventions are alone effective or in what combination they are effective that is called a factorial design. So, these are the basic concepts regarding the experimental research designs that we will be studying next.

You can consider single factor or factorial design to be implemented in the subsequent designs that we will be studying ok. Now the next question is actually experiment and quasi experiment. What is the difference between these two? Only the difference is randomization.

What is randomization? We are studying a group of people. So, now suppose we are dividing the group of people in a group of two.

Our objective is we will be giving intervention to one group and we will be just observing the other group that means, we want to understand whether the particular intervention is having an effect or not. Now see here the intervention if we consider it as an independent variable there are variations the factor here is the intervention and the levels are one group is being given the intervention and one group is not given the intervention these are the levels yes or no something like that. Now when we want to you know divide the recruited participants in these two groups we may take help of randomization that means, we do not choose which people will be going to which group rather certain there are certain algorithms there are certain softwares that basically randomly assign the participants the recruited participants in the different study groups. What happens here? Here neither the researcher nor the participants will have any say on which group which participant will be ultimately allocated that is the concept of randomization. Now when randomization is there that is a truly experimental research design and when randomization is not there that we consider as a quasi experimental research design that is not truly experimental, but since we are basically giving an intervention it is considered as a quasi experimental research design.

So, it basically you know depends on which level we are observing or which level we are studying. So, this diagram it basically shows you the hierarchy of different levels of our enquiry. See if we want to study the individuals for example, individual knowledge attitude skills then it is easier to perform true experiments because we really can you know randomize. Now consider the situation related to a particular community. Sometimes you will be faced with certain challenges that if you randomize the members in a particular community if we consider a single community to be our research cohort.

Now you are randomizing some people of the community of that particular community to one group and some to the other group. The difference in health promotion research is like this because the health promotion research it mostly prevents it mostly changes the behavior and it is not simply something like providing certain molecular or biological intervention that one particular person will do and one will not do. What happens here some people who are being given the intervention simply consider a health education intervention will ultimately talk to the other people in that community and those other people they may be part of that control group. So, what happens here even though you have you have decided to randomize, but there are certain situations where the randomization would not be effective. There will be this phenomena may I mean we call it the diffusion of the intervention.

So, there are situations where these kind of hindrances will be there and in that scenario we really cannot perform randomization because even after randomization the results will be more

biased because of these scenarios. So, in that situation we have to do quasi experimental research. So, as we move up the ladder as we move up the levels the it is very difficult to you know perform experimental research and it is easier and more effective to perform the quasi experimental research. Now basically this is the main area of discussion in this lecture ok. What are the true experimental research designs and what are the quasi experimental research designs? As we have already mentioned the quasi experimental designs they do not employ randomization and in some situations they may be ethically appropriate.

So, in health promotion research ethics is again of utmost importance as with any other research with humans and animal beings. Now what happens in ethical issue is if you are giving certain intervention that actually is going to be helpful for a certain group of people then you cannot consider randomization. Let us take an example if you are providing certain intervention that is going to prevent a group of adolescents from you know taking up the habit of drug abuse. Now that is we know the intervention what may be the effect of intervention the intervention ultimately may not be effective, but it really cannot harm the group of people rather the philosophy is like this because you have developed one intervention the health promotion intervention that is going to alter their behavior for good. So it is your ethical responsibility so that the maximum number of participants they get the benefit of it that again brings us to the principle of ethics.

So, in that scenario we really cannot randomize what we can really do in this case we can ask the participants this is the health promotion intervention that we are giving this is the health education that we are giving. So are you interested or you are you not interested in it? See if some people they are not interested in those interventions they may choose to be in the control group what happens in that scenario is although as a researcher you have offered the intervention the good intervention to the participants, but the participant have refused and for that the participant is being allocated to the control group. But here the control group it is or the intervention group the two groups they are not derived through randomization they are derived by the choice of the participant or in some situations you can choose on your own as a investigator to put some people in the intervention and some people in the control group again there may be certain ethical underpinnings. So, in that case quasi experimental research design becomes very much important and since in public health and mostly in the preventive behavior related research the interventions you have the obligation to provide that intervention to the larger group of people sometimes there are ethical responsibilities that prevents us from actually implementing some true experimental designs and as we have mentioned in the previous slide as we move up the ladder that responsibility grows more and more and your scope of implementing intervention I mean randomly it also comes down. So, what are the true experimental research designs? One is the post test control group design, one is the post test pretest post test control group design, another one is called the matched pair group design, one is called the within subjects repeated measures designs.

Now, I will mark this one because see this particular design it although it is considered as a true experimental research in, but when we discuss you will understand that even though it is classified within this part, but it it basically belongs to this group because there is no per say randomization involved in this particular design then there are crossover trials. Now, as you can understand that these designs they are mostly you know related to the standard epidemiological intervention designs that we have although in standard epidemiological designs we may sometime you know not encounter the simple post test control group designs this is particularly something that we see in health promotion research more and more often because of the different issues that is related to the particular populations. In quasi experimental design we will be discussing these major four designs ok. Now in these major four designs as you can understand the non equivalent control group design the NCGD we call it in abbreviation it has two different types of designs first is the post test only design and the next is the pretest post test design. So, we will be discussing these all together and there is one thing called the interrupted time series design this is considered the most robust design in the quasi experimental research.

So, what is basically the post test control group design? This is important because here in subsequent a few more designs we will be focusing more on between subjects design. So, between subject means we have this is one subject, this is another, this is another, this is another ok. This is your intervention group. Now we are considering typically two groups over here this is your control group. So, between subjects design means we are comparing this individual from the intervention with that from the control.

We are not comparing somebody with that particular person that becomes a within subjects design we will be discussing again that in this lecture. So, this is the concept of between subjects design and these designs mostly are the between subject designs. What happens in post test control group design is first you have certain group of people then you know you simply randomize or I mean you allocate them randomly into intervention and control group, but the interesting part here is we do not take any pre intervention assessment. There are certain interventions that is been given and after employing the intervention we actually assess whether there is any change or not. Now as you can understand that there are certain problems with this kind of only post test assessment.

Although we are providing the intervention to both the groups intervention and control groups, but without taking any pre intervention baseline or pre intervention survey as you can call it there will be certain differences because we do not know whether the respondents are really homogeneous to start with that is one very important question. You know also another consideration when choosing the post test control group design is whether to understand whether the tool the you know the baseline survey tool. For example, certain survey tools may have leading questions on whether the person is doing something or not. There are instances where that implementing that particular questionnaire may actually change the behavior. So,

the behavior change basically we expect it to be there from the intervention from onset of the intervention.

But here because of the questionnaire there may be certain changes. So, in that scenario we may omit the pre intervention survey we can directly focus on the post intervention. So, in that scenario as you have mentioned in the last point can the test change the participant behavior if implemented before intervention. So, that is one very important consideration there are only a few scenarios, but again in health promotion research as we say it is very much important and that can be actually you know implemented. But you have to understand whether the groups are homogeneous to start with or not because if they are not homogeneous then ultimately during the time of analysis we have to perform certain analysis based on what we call it different statistical adjustments.

Now comes the issue of pre test post test control design. What is a pre test post test control design? See you have your participants ok, they have agreed to be part of your study. You allocate them as intervention as control. Now you will be giving them the intervention who will get the intervention? Obviously, the intervention group will give get the intervention and finally, you will observe the post test. What happens here before the intervention and after the intervention you take the same survey if we are considering about only the behavior we you take the same survey or you observe the participants for the same things before the intervention and after the intervention ok.

So, that is what is pre test post test control because you have a control group you are implementing one pre test interval survey or baseline and you are again doing one post test. Here basically test means the survey that I am referring to ok. So, again this is a between subjects design because similarly we are comparing the individual in the intervention group with the control group as we have seen in the in the previous design and sometimes this is called the gold standard because this gives you the typical framework of a randomized control trial as we typically study during our classes in epidemiology ok. We randomize we get a control group we assess the participants before intervention and we assess the participants after intervention because of randomization we take care of the known and unknown confounding effects ok. That is why it is called a gold standard, but because of the resource requirements for this particular design as you can understand you know for a study with say thousands of participants and if you have to randomize and then we have to implement the whole process of research it will require a huge amount of resources.

So, the resource requirement for RCTs particularly in health promotion settings that is one constraint for this research another constraint is sometimes there may be low external validity. Now please pay attention to this word sometimes it is not always that an RCT in health promotion research may have low external validity because sometimes what may happen is

you focus your intervention on certain priority groups because it is our principle that we must serve those who basically need it first. So, if you focus your intervention sometimes on that priority group what happens is the results of that intervention the results of your study may not be generalized to the whole population ok that may result into certain low external validity or sometimes how you select your participants whether you sample them or not that is another consideration ok. So, these are your problems that you may encounter with the with this kind of design. Next is the matched pairs group design what happens with the matched pair group design? For example, we have the participants now we are dividing the participants based on certain characteristics.

For example, here we have 10 participants who have a similar character, here we have 2 participants who have the similar character, here we have again 4 participants who have a similar character. If we consider a 2 group design that means, now from these participants we have to divide them into one intervention group I and one control group C. What we shall do for matched pair we will take 5 participants from here and 5 participants in here for 2, 1 in here, 1 again in here for 4, 2 in here again 2 in here. What happens is this ensures your baseline comparability, randomization itself is a robust method and if you implement this matched pair you know format sometimes we can call it you know it is considered similar in some sense to stratified randomization or you know sometimes the block randomization techniques.

So, those are similar things. So, if you implement this matched pair design it helps you in establishing baseline comparability even in a more robust way ok. I have given you certain example one example is the matching adolescents on alcohol and drug use who are enrolled in a 2 armed sexual risk reduction intervention prior to randomization into groups. See here the alcohol and drug use they may not be I mean they may not be causally related to the through to the sexual risk behavior that that they are performing. Please note the term causally related that means, there may not be certain biological possibility of these 2 variables, but they are definitely influencing the behavior. So, this is what is more important in health promotion research which variables are influencing the behavior.

We can consider these variables for this matched pairing ok. In that case what will happen the baseline comparability will be more robust and we can infer more strongly whether the intervention that we have given is going to is effective or not ok. Obviously there will be significant reduction confounding and it also selects you know controls for differential selection because in this scenario there may be certain differential selection that means, of this 10 people there might have been 7 in this group may have been 3. What will happen in that case again the comparability will not be established. So, that is why matched pair group designs they will help you when you conduct these kind of studies.

Now this brings us to the next part that is the repeated measure design. Pre We usually the same model independent variable predicts dependent variable and during our analysis we get that the independent variable may only predict a percentage of the change in the dependent variable. So, the remaining for example, if independent variable can predict 60 percent of change independent variable the remaining 40 percent change independent variable that may not be predicted by the independent variable and that may be you know simply due to the change of human subjects because we are comparing one individual from intervention group and one individual from the control group. There are certain factors that we have not even considered in this study those may be certain extraneous factors or those may be certain factors we do not even know about. So, in that situation the error variance you know it goes high that is the concept of error variance ok.

So, the error variance that is due to the change of human subjects between the two groups that is controlled in the repeated measure design why because we are observing the same individual. So, this is the group these are the participants we are observing them in time 1 again we are observing them in time 2. So, because of this is an this is an within group or within subjects design that means, same subject is being observed ok. As you can understand since we are observing the same subject may be with intervention and without intervention for example, here in T 1 this phase we are not giving any intervention and say for in this phase we are giving an intervention. So, we are observing the same subject with intervention without intervention we can understand that there is no scope of actually employing randomization because a particular individual cannot be randomized into intervention and control group right.

So, that is why I have mentioned that it cannot be considered a true experimental design because there is no randomization, but since I mean you can understand that since we are comparing the same individual there may be other confounding or other factors that influence the behavior change those are taken care of in this particular research design. Crossover trial this is the last part of the truly experimental research designs that we have been discussing now. This is again what happens here is you have two groups now we are starting directly from the intervention and the control group you give them certain intervention you have given the intervention you have observed them and next what you do you just cross over the intervention. If you have given the intervention to I group that means, intervention group now you are giving the intervention to control group and next you again observe. So, as you can understand this is an improvement over the repeated measure or the within subjects design here we can compare the within subjects as well and also in different time points between subjects.

So, this is you know crossover trials will give you even more robust result and you can find answers to certain hidden questions that certain anomalies that we you can get if you simply compare in this time point that means, only the intervention and the control right. Now, the next component is called the non equivalent control group as we have mentioned this is the most one of the more you know frequently implemented research design in quasi experimental

research. As you know there is no randomization and the problem with non equivalent control group or NCGD design is the groups that we have they may not be equivalent to start with because they are your recruited participant. For example, now you are choosing which participant to put in intervention which participant to put in control group. If you choose although you try to match them as closely as possible, but there are certain inherent factors that may contribute to you know unbalancing the population because what can happen here you have 10 people our objective is to put them in 5 5 group.

Now, what you do is you select the participant based on certain characteristics then certain participants may deny that no I do not want this intervention then that participant goes into the control group. So, that makes it 4 and 6 and interestingly it is not only about this number interesting thing is now since you have 6 in the control group now it is your responsibility as a researcher to again find one participant who can be there in the intervention group. So, what happens is even though you have initially started with matching the participants as closely as possible, but because of this denial from the participant to be in the intervention group you have to shift you may have to a basically shift one participant from the control group to the intervention that can hamper you know the equivalence between the between the different groups that you have in your study. This is the NCGD post test design it is very similar to the only post test design that we have discussed in the truly experimental studies what happens here you have non non equivalent groups you give them the intervention and you assess only during the post test phase. For example, you have given one intervention to a high school regarding certain sexual risk behaviors and the school authority they now decide that since you have given the intervention perform a post test to check whether the participants behavior have changed or not.

Typically during earlier days of studies in schools what we used to find that we were given certain task or we were taught something and then there was this exam. You consider this exam as your post test understand is that during the early days we were not given any pre test or we were not given any baseline as to what we know and how our knowledge has improved. The teachers used to implement only the post test that means, after the class has been completed now you answer these questions. So, that is the non equivalent group post test design where you only have the post test situation ok. Again there is a question of differential selection that we have been discussing for the NCGD as well.

The pre test post test design what happens with the pre test post test design? Here you have the pre test and you also have the post test. For example, consider the different online assessments you have one online assessment before you have been given certain video to study or given certain online materials to study and then you have your post test as your post intervention assessment. So, in NCGD also even though you have non equivalent groups, but the designs are somewhat similar. What happens with interrupted time series? As I mentioned earlier during the lecture that it is the you know strongest quasi experimental design to

understand the longitudinal effects. What happens here? You observe the group for example, if you consider two groups over time here you observe time 1, again you observe in time 2 like this.

So, this helps you in having a trend within the individuals and also between the individuals ok. So, that is the importance of interrupted time series. Even though with the non equivalent groups because in interrupted time series in health promotion you often will have certain non equivalent groups because you may not be able to randomize them properly. And for that lack of randomization you control with the interrupted times you get the trend sometimes there may be certain maturational trend, sometimes there may be certain seasonal trends these are the trends that you have to account for during your analysis and also during the conduct of your study, but overall they will give you a whole picture. Over T 1 you will have certain differences over T 2 certain differences over T 3 you can compare and also between T 2 and T 1, T 2 and T 3 that is between the times.

So, in this lecture what we have studied we have studied basically the different you know experimental research designs that we employ in health promotion research I have just elaborated a few design few key designs there may be a certain a few more designs and interestingly you can combine the two designs based on your need. So, it is basically important to understand the causal effect causal effect of the intervention on bringing about the desired change ok. So, in this section if it is possible we call it the truly experimental design and if it is not possible we call it the quasi experimental designs. Now, in the next lecture we will be discussing regarding the different challenges or the issues that we may face when we actually trying to implement certain intervention or perform certain interventional studies. So, I would recommend you to go through the references that I have put in over here. So, that is all for this lecture. Thank you.