Research Methods in Health Promotion
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Week 12
Lecture 59: Report writing: quantitative research in health promotion (Part II)

After our discussion regarding the reporting guidelines for the observational studies in health promotion research, in this lecture we will be discussing about the reporting guidelines for the interventional quantitative studies. So, this is the part two of our discussion on how to report the quantitative research in health promotion. So, in this lecture we will be covering these basic concepts like how the reporting guidelines for interventional studies are to be used specifically the consort guidelines because this is the most widely used and perhaps the guideline for reporting the experiments and the different extensions of consort. So, to start our discussion let us have a brief look at what exactly is consort. As we discussed previously in the last lecture regarding stroke similarly for consort this is the full form that means, consort means consolidated standards of reporting trials. So, for trials the consort guidelines are applicable.

Now, typically whenever we we hear the term called trial typically we understand ah randomized control trials and truly the consort guidelines are applicable for the RCTs. Also whenever we hear the term RCTs we think of certain drug trials or pharmacological trials or certain ah specific treatment interventions. Now, so the next question will be if the RCTs or the trials they are mostly dealing with the specific treatment interventions and in our health promotion research we mostly deal with the prevention of diseases and certain behavior change interventions ah certain behavior constructs concepts which are mostly not tangible then how do we report with the same guideline. The basic idea is the same consort guideline can be utilized for reporting of the health promotion research because here in health promotion research what you have to do is you just simply report your intervention in a different way or ah the intervention ah the reporting of intervention in the consort will be coming to that later on ah the dose response and everything that we get for our for our health promotion research we have to simply mention how the the the dose in this situation may be equal or equated to the frequency of providing certain intervention or frequency of contact session like this.

So, you have to think in a similar way and the same consort guideline the method of presenting the intervention the effectiveness of intervention that is there with the consort can be utilized ah you know in the health promotion research reporting. Now, before we move on to the discussion of the consort guideline proper I will just briefly show you what are the different consort extensions. Now obviously, this over here the idea this is not a consort extension, but this is again another type of reporting guideline. As I have mentioned in the previous lecture ah that you should go through the equator network ah website to get the different guidelines of reporting different studies you can also ah find out more about the consort extensions from same website. The consort harms means it mostly deals with the reporting of harm non-

inferiority means it mostly deals with non-inferiority of a particular intervention compared to ah the standard of care.

Cluster means this may be utilized for cluster trials, herbal means it is mostly related with the with the herbal interventions or utilization of herbal products. The interesting part is non-pharmacological treatment interventions. Now non-pharmacological treatment interventions this not only include the different behavioral ah behavioral phenomena or ah in for that ah reason may include the psychological interventions or ah core you know non-molecule related intervention. By that I mean typical pharmaceutical products are not used that is why they call it non-pharmacological treatment interventions. Now, consider this example that if you are ah evaluating or if you are going to report a particular surgery then also it is better to utilize this non-pharmacological treatment intervention because again a particular surgery is not a pharmacological treatment.

So, the basic idea is whatever intervention falls under the domain of non-pharmacological treatment, we can utilize these guidelines for reporting. The pragmatic trials these are different methods of trials and the patient reported outcomes reporting these are also the different extensions of consort. Now, till this point ah from this discussion what we have understood is that the non-pharmacological treatment interventions may be or go to strategy whenever we are trying to ah you know write the promotion ah research article. But for a general understanding and for a for a better overview of what are the things that is actually recommended to be included in your article we shall be discussing the general consort guideline ok. But you can also download this part and see how your health promotion research can simply fit in with this guideline.

Now interesting part is this the TIDEA guideline that is the template for intervention description and replication. Why this is important because apart from consort this is again another guideline through which you can simply describe the intervention you have provided. Simply describing the intervention may be a very important manuscript for you because not always you are you are evaluating the intervention and you are checking for good or bad like this. What can happen is you just are doing one study and in in while doing the study you think that the intervention that you are simply performing is a very newer one and the world should know. In that situation you can just go on and describe the intervention with the help of this TIDEA guideline.

Obviously, you have to have certain ah background data and also a bit of evaluation data to put perspective ah into your manuscript. Next is the different diagnostic or prognostic accuracy reporting. Why we are discussing this because the diagnostic or prognostic accuracy reporting this also falls in the purview of somewhat in the purview of interventional research because we usually perform certain diagnostic tests may be for a screening purpose for a treatment purpose then again they are the interventions. Also you can consider this from a health promotion perspective in this way that if you are you know implementing certain intervention

for prevention of of you know some diseases that may be considered as a prognostic in a intervention in some way. See if you are giving certain behavior change intervention just simply to improve the the screening screening acceptance then also you can utilize the same intervention with the concept that by doing by by making the people accept screening in the long run we can ultimately improve the longevity or like this.

So, in a way you can also put a flavor of health promotion in this diagnostic and prognostic accuracy reporting if the situation permits, but again I would say that it is always better to look through this particular protocol. Now these are the different simple accuracy reporting for diagnostic and prognostic study that we use this is just for your understanding that these are the different guidelines ok. Now we finally, move on to the discussion of the consort guidelines. See again the consort guidelines similar to the stroke guideline are distributed and divided in the different segments. See the topics that we are discussing now the different guidelines that we are discussing now it is not always possible even for us to remember each and every reporting item or each and every recommendation.

You can always go through in these recommendations and items from the equator network website and you can have a printed copy with it or simply a copy a digital copy whenever you are preparing a manuscript or whenever you are finished preparing a manuscript and you are just checking whether you have included all these items or not. Here what you can do is typically the reporting guideline it consists another column that is the page number because it is framed in the form of a checklist, but you can do is you can just see title yes the reporting item is this you have mentioned yes I have mentioned like this you can just tick this off and the same thing you can do even for the stroke guideline that we discussed in the last lecture as well. So, in the consort guideline again we start with the title and the abstract see the reporting guidelines again as I have mentioned in the previous lecture they utilize the title and the abstract together. In the title part identify the title as a randomized trial typically since the consort guideline deals with the randomized trials that is why the guidelines is identified as a randomized trial. Now if you are doing certain other health promotion research which may not involve randomization then you have to clearly identify the study design ok.

So, here it means that you have to mention the study design in the title. In abstract what you can do is you have to present a structured summary of the trial design what you have done methods results and the conclusions. Now what happens here in the consort guideline is see in the stroke guideline we presented the summary of the methods what you have what we have we have used we have mentioned the study design mandatorily in the abstract again here also we are mentioning the study design mandatorily and also providing a well distributed a balanced summary of the methods results and the conclusions. Now what abstract exactly is required for a clinical trial or your health promotion intervention it again depends on the journals some of the journals they you know give you a very few topics or very few headings, but some other journals may provide you with some more headings like some provide design participants then tools and results and conclusion like this mostly depends on the journals. But

whenever you are preparing a manuscript before submission you have to identify whether you have utilized all these headings and all these recommendations or not.

Next moving on to the introduction part. So, the introduction typically we mentioned the background of the research that includes the ROL the justification the rationale and also the objectives. So, what the consort guidelines is somewhat similar the scientific background and explanation of the rationale again this is the same thing we discussed with the stroke guideline that we have to showcase why we are actually doing this research what exists in the in the field and what is the research gap or the knowledge gap and how we are trying to address that knowledge gap. So, that is how you and explain the rationale of the study and justify the conduct of your study again you specify the objective or the hypothesis. So, see the similarity between the strobe and the consort guidelines that again they focus on the objectives the specific ones and the hypothesis.

Although again you can consider the research question to be presented in the at the end of the background or even the research question can form a part of your title. Under the methods section the trial design see the trial design they have mentioned trial design trial design twice because there are the different reporting under 3A it is the description of the trial design such as whether the parallel or factorial these are the different types of clinical trials, but for our purpose the health promotion research purpose the different types of interventions that we discussed during the interventional research designs those are the things that we need to mention. Important changes to methods after trial commencement that for example, eligibility criteria and reasons this is one aspect which applies for the typical pharmacological trials and also for health promotion research. If we have conducted some changes to the inclusion criteria or the eligibility criteria after the start of our intervention then we have to specify why because it depends I mean it you know it changes the whole interpretation of the results and it may include certain biases. So, that is why you have to justify why despite knowing the fact that this can compromise the scientific integrity you are still changing the basic design.

For participants mention the eligibility criteria of the participants and under eligibility criteria we mentioned the inclusion and exclusion criteria. You specify the inclusion and exclusion criteria if required based on the two arms for example, the control arm or the intervention arm and if you are doing simply a pre post type of intervention then you simply go on with the mention of the inclusion and exclusion criteria without mentioning any arms like this. Then settings and location where the data were collected again here another important thing is like in the stroke guideline we mentioned that the timeline of collecting data or recruiting participant like this was important. Here also on the participant section you mentioned from where you have collected the data who are your participants and where do they belong and also if possible include the timeline concept as well. Next under interventions perhaps this is the most important area or the cracks of your whole method section because this is what separates the guideline from the other observational guidelines.

So, under intervention the recommendation says the experimental and the control interventions for each group sufficient details to allow replication including how and when they were actually administration. In a nutshell the details of the intervention the experimental and control interventions that means, it is not always that you only mention that I have given only this health behavior change intervention to the intervention group now that is not sufficient you have to also mention what the control group what intervention the control group received, but what usually happens in certain new programs in health promotion is that the intervention group they receive the new health promotion intervention, but the control groups interestingly they they get the usual intervention or usual health program that is there in the community, but you have to mention that specifically in your manuscript that which group received which kind of intervention. Also you have to mention when and how they were actually administered that means, how the intervention was provided to the participants and maintaining which timeline because without mention of how and when you actually do not know how much intervention was provided to each of those groups. So, see here the concept of dosage comes in with the with the health promotion research how much intervention means say we are providing one health behavior change intervention in terms of making. In one community we have conducting the miking activity say for 7 days and encompassing say 3 hours a day that means, we conducted 21 hours of miking and in another community we might have conducted 60 hours of miking, but both of these communities they fall under the intervention group.

Now, if we are not able to specify these details then while analyzing what we will do we will analyze both these communities together and it may so happen that the community receiving less amount of intervention that is less hours of miking may not show the desired behavior change. And if we are not specifying these differences we may not be able to understand or explain why the the results happened or why the there was no difference even after the the intervention. So, that that is why it is required to detail the intervention in your methods. Under outcomes what you have to report you have to completely define perspective as pre specified primary and secondary outcome measures including how and when they are assessed. So, in an interventional study the how and when concept is very important for interventions and also for measurement of outcomes because the outcomes are the end product of your intervention and through outcomes you can justify whether the interventions were effective or not.

So, that is why it is also essential to measure the outcome at predefined or pre specified points and through the predefined or pre specified methods. So, that is why if you have to already specify whenever you are you know writing your proposal the primary and secondary outcome what are your main outcomes and what are your associated outcomes. And when you are reporting your manuscript you should mention those same things that you mentioned in your protocol only. Also any changes to the trial outcomes after the trial coming so that means, any differences or any adaptations made to the trial you have to again report under the outcome setting. Sample size how was a sample size calculated and the the explanation for any interim analysis typically in pharmacological trials or any particularly health medical intervention trials.

We conduct the interim analysis to understand whether the whether there is any benefit of the intervention or not and if in some situations while trying that the interim analysis is showing sufficient amount of evidence so that the trial may not be continued at all. These are the different scenarios so that is why interim analysis is again a very important part and stopping guidelines are very important for typical pharmacological trials. So, whenever we are reporting or health promotion research see these concepts interim analysis and stopping guidelines they may not be that much appropriately applicable. So, we can omit them in this situation, but we have to mention the sample size how it was calculated and ultimately what what number of people were included in your study. So, if you have employed randomization in your research design the randomization may be an individual randomization it may be cluster randomization then you have to mention what how the sequence was generated and what type of randomization was used if you have used in restrictions like simple restriction use of restriction is blocking like you randomize in a block of 2s or 3s or 4s like this.

So, again you have to mention all of these under the method section. Again for randomization in the allocation of concealment I mean allocation concealment is an important part of completing the randomization process again that is also very important for the pharmacological measures. Usually for you know the health promotion interventions it is not always possible to conceal the allocation because the people they already know what is going to happen because blinding is not really possible because again the interventions the newer interventions they are quite different than what is actually being conducted. This is where the actual health promotion research differs from the typical medical intervention research or the pharmacological research. But again you have to mention how your randomization was finally, implemented which part you were able to conduct and what was not there and why that was not there you have to mention.

Then the statistical methods that you have used or that you will you have used in the manuscript. So, the recommendation says that the statistical methods used to compare the groups for primary and secondary outcomes. See we have mentioned that the reporting of interventional studies it is mostly important and mostly dependent on the outcome measurement why because the outcomes change because of the interventions that is where the statistical methods are required to compare regarding the primary and the secondary outcomes. We focus first on the primary outcome and after that we focus on the secondary outcomes. Any additional analysis this is somewhat similar to what we have mentioned in the stroke guideline also any such subgroup analysis here the subgroup analysis is very much important and any other adjustments made to the to the typical analysis if we have conducted anything of of among these three we have to mention as an additional analysis.

Sometimes the journals may ask you to put a separate paragraph for additional analysis within the methods section. Now what about the results? We have described methods ah in sufficient details the objective of this detailing was to enable the readers or other researchers to be able to replicate the same intervention and this is perhaps important whenever we are doing the health promotion research because health promotion research is mostly about being replicable

because you have different communities different cultures like this. So, you want your intervention to be effective in in all those different settings. So, health promotion research while you are writing the method section of your manuscript be very sure to mention all the details of your intervention properly and what you have actually done and also how the intervention can be replicated in the different communities as well. In result section we have described the participants I will be coming to the participant flow diagram the typical participant flow diagram that is recommended by consort and accepted by the different journal whenever you are going to present any any trial to a journal the journal will ask you to present the participant details in the flow diagram that will be that I will show you in the next slide.

What it should contain for each each group the number of participants were randomly assigned if randomization was applicable in this case and if not then in different groups. The intended treatment ah that was analyzed for the primary I mean and and the and number of people who were analyzed for the primary outcomes also mentioned the losses and exclusions the loss to follow ups like this the censoring may also happen also in that flow diagram itself. The flow diagram helps you to get a gross overview of how the trial actually went on. The recruitment you have to define the defined already the methods of selecting the participants and under recruitment surveying in result section the dates defining the periods of recruitment and the follow up. That means, how many people were ultimately follow up and the the the basic characteristics of the followed up participants that is what we mentioned in the baseline data you should provide a table showing the baseline demographic and clinical characteristics for each group and the this is where recruitment description of recruitment and baseline data they merge.

In that same table it is recommended to provide the characteristic of the follow up groups. For example, you may not be able to follow up all the 100 participants that you included for your SBCC intervention and you may end up with 80 individuals at the end of 1 year and then 60 individuals at their end of 2 years like this. So, in the same table of baseline data representation you just have to mention how the baseline data for the retained people they change. For example, the of all the 100 people the average age at baseline might have been say 60, but for the now the 80 people who are remaining at the end of 1 year the average age might be high like for 70 and then for 60 the remaining 60 at the end of 2 years the average age may even go up higher like 80. That means, younger people are either going out of the study or I mean they are getting censored.

So, the baseline data is important in this way and this is how you also establish the comparability of the follow up participants. That is what we were discussing in numbers analyzed for each group number of participants that is the denominator for you in this case included in each of the analysis that you will be describing I mean in in the method section you have already described what are the different analysis analytical techniques that you have used. So, this is where the numbers analyzed will be I mean the numbers actually utilized for each of those analysis you have to mention. Typically we utilize tables and figures to mention or to depict the different higher order analysis that we perform for for our interventional

studies. As mentioned this is the this is the consort participant flowchart that we have to utilize when we are writing our article.

These are the different phases which is mentioned in this flowchart for example, in the enrollment phase assessed for eligibility how many participants were assessed for eligibility. That means, in in a community say you are you want to include 100 participants, but you initially find out that you go to say 150 households and you assess them for the eligibility. So, here the assessed for eligibility will be 150 then you exclude some of those households based on certain criteria not meeting the inclusion criteria decline to participants or any other reason you have to specify that reason you mention over here and finally, randomized or if you have not randomized the the in your research you have to mention finally, included instead of randomization you mention included that gives you the recruited number of people. Then in two different groups like allocated to intervention this and allocated to control group whatever is there you have to mention accordingly and the number who were provided with such intervention or the the standard of care. Again it has different parts like receiving the intervention or not receiving the intervention precise reason of not receiving the receiving the intervention is of importance to us and that is what the guideline says you should break it down and mention.

Then at the after allocation you have to follow the participants who were lost to follow up also it is a good practice to mention why the participants were lost to follow up where they simply lost to follow up or they were lost to follow up because of certain design related issues like this you have to mention discontinuing intervention for discontinued intervention you have to specifically ask the participant why the participants want to discontinue the intervention or exit the study. So, you have to mention that reason also although these are more important typically for the pharmacological trials, but I think you can relate how for health promotion intervention as well these are important say some participants who on whom you are going to implement a smoking solution intervention is ultimately decided that no I will discontinue the intervention because I do not want to quit smoking this can happen. So, in that situation you have to give the reason. Then finally, analysis who are the final number of people who are analyzed for your inferences because not all those who have followed up will give you sufficient amount of data or quality data that you will be able to analyze. So, why the other people were analyzed from the final were excluded from the final analysis you have to mention.

Then under results finally, you have to mention the different outcomes and estimates for the outcomes and estimates for each primary and secondary outcome we discussed regarding the outcomes for each primary and secondary outcome you mentioned the estimates like description. Then if you have any effect size of it through the multivariate techniques you can mention the effect size with the 95 percent confidence interval that is the traditional method of presenting it. If you know for binary outcomes it is ideal though they recommend that presentation of both absolute and relative effect size is recommended say for example, binary outcomes what you can get you can get odds ratio or relative risk, but in what the consort

guidelines again says that it is always better to mention the absolute risk difference as well. So, this is again somewhat similar to what the stroke guidelines said. Ancillary analysis if you have performed any additional analysis then this is the place where you mention everything and if you have found out any extra information through subgroup analysis again this is the place where you mention all those extra information that you gathered that can help you put your analysis the primary analysis per say into perspective or guide you in certain future directions.

Harms typically is used for the pharmacological or medical intervention trials any report of harm should also be mentioned in your results section and also you have to mention if because of harm certain participants were excluded from the study or they just left the study. And a discussion the format is almost the same here you first mention the limitations although I mean it is not typically mentioned over here, but first you summarize the findings then again you compare the findings with the existing literature, but the important thing is as a checklist you should consider mentioning the limitations. It has it has been mentioned as trial limitations addressing sources of potential bias, imprecision and if relevant multiplicity of analysis. So, this is typically mentioned for a randomized trial, but in health promotion research as well you can mention your limitations and also the scope of any bias typically in in all type of a behavioral related research we usually get the social desirability bias in a much more way typically this is the case where utilize any participant reported outcomes that needs to be mentioned in the limitations section. Under generalizability again you have to provide the the information on how generalizable your results really are interpretation the interpretation consists is consistent with the results or the hypothesis whether the findings that you got are similar to what you have hypothesized if yes then why if not again then why not and and what are the the relevant evidences that you get.

Another important aspect in discussion is registration. Here you it is better to mention the registration number and the name of the trial registry in some place in the discussion section you can consider putting this information in the beginning of the discussion section also for your information journals may ask you to provide this registration related information in the method section itself because in the method section the journals usually ask for ethics related statement. So, some of the journals they ask you to provide the ethics statements and also the details of the registration of trials. For example, in India we have the the the trial registry where not only the pharmacological trials, but also the the health promotion trials they also you know register. See even my trials are also registered in that registry this is a good practice and this is necessary for reporting your report as well I mean the information of registration.

Some other information may be required like interpretation interpretation that is consistent with the result and balancing the benefits and harms and actually this is the repetition of this part. So, just forget about this other information means the registration related information again this is the repetition of this part again forget about this, but what you actually can do is this depends this this structure that we have mentioned here this depends on the journal guidelines. Some situation may happen that the journal may ask you to present this registration

information all through in a in a different section like as part of the the other information segment. So, there you can mention simply. You can also mention the protocol where the protocol was published if it is available online or not and the funding information as similar to the stroke guideline should also be mentioned right.

So, in conclusion the concert guideline and its extensions are the are the go to strategy when we are trying to report our interventional research. Typically the flowchart of the participants recruitment is the crux of reporting the the flow of the participant and is also very important aspect this particular figure is all almost always there in all the reports of the experimental research. And we must consider the health promotion research under the umbrella of non pharmacological intervention as well. We have discussed the different aspects of the guidelines of the consort. Now these are the references this is typically taken from the equator network and this reference although taken from the equator network guides you to the particular article where they have actually proposed the the particular tidier checklist.

So, it is an interesting read you can go through this as well. That is all for this lecture. Thank you. SUB_TEXT