Assignment 4.1 – PTSD Case Part 2 – Appraise and Apply (60 points)

Directions: Answer Questions 1 through 6 to examine the internal validity of the interventional trial.

Appraise	

Question 1: Does the study address a clearly focused research question? (5 points)
 	
To receive full credit for this question, you should consider:
• Was the study designed to assess the outcomes of an intervention?
• Is the research question 'focused' in terms of:
  ○ Population studied,
  ○ Intervention given
  ○ Comparator chosen
  ○ Outcomes measured?
	The study was designed assess the outcome of an intervention, but the PICO question was incomplete. The comparator component was missing.

Question 2: Was the assignment of participants to interventions randomized? (5 points) Randomization can minimize: • **Allocation bias:** Allocation bias is a type of selection bias that happens when individuals are not randomly assigned (allocated) to groups. Allocation bias results in a systematic difference between participants in study groups (other than the intervention being studied). Randomization minimizes allocation bias because individuals are randomly assigned to groups • **Confounding:** Confounding happens when there is third variable that is related to both the exposure and the outcome. Confounders distort the observed association because the exposure is also correlated with another risk factor. Randomization minimizes confounding because all potential confounding variables, both known and unknown, should be equally distributed between the study groups. **To receive full credit for this question, you should consider:** • How was randomization carried out? Was the method appropriate? • Was the allocation sequence concealed from investigators and participants?	The study was not randomized. Each participant received the same dosage of 2.5mg of THC in the beginning of the study and each one of them received the increased dosage of 5mg after 2 days. The allocation of the THC was not concealed from neither investigator nor the participants.

Question 3: Were all participants who entered the study accounted for when the study concluded? (5 points) Accounting for participants minimizes: • **Attrition bias**: Attrition bias is a form of selection bias that can happen when there are more participants lost from one arm of the study. This can make it difficult to compare the groups and generalize the results of the study **To receive full credit for this question, you should consider:** • Were losses to follow-up and exclusions after randomization accounted for? • Was the study stopped early? If so, what was the reason?	The full study term of 3 weeks was completed and none of the participants dropped out of the study.
Question 4: Were the participants, investigators, and people assessing/analyzing the outcomes blinded? (5 points) In a randomized controlled trial, double blinding occurs when BOTH investigators and participants do not know who is in the treatment or control groups. Blinding minimizes different types of **information bias**, such as: • **Observer bias:** Observer bias may be a result of the investigator's prior knowledge of the hypothesis under investigation or knowledge of an individual's exposure or disease status. Such information may influence the way information is collected, measured or interpretation by the investigator for each of the study groups • **Interviewer bias:** Interviewer bias occurs where an interviewer asks leading questions that may systematically influence the responses given by interviewees • **Performance bias:** Performance bias refers to when study personnel or participants modify their behavior/ responses where they are aware of group allocations. **To receive full credit, you must address:** • Were the participants 'blind' to intervention they were given? • Were the investigators 'blind' to the intervention they were giving to participants? • Were the people assessing/analyzing outcome/s 'blinded'?	This was not a blind study. All participants and investigators knew that THC would be received/provided as well as the dosage. The assessors were not blinded.
Question 5: Apart from the experimental intervention, did each study group receive the same level of care (that is, were they treated equally)? (5 points)	The study protocol was clearly defined. The participant was aware that they would be assessed for adverse effects after

Development of a protocol for the collection, use of standardized questionnaires or calibrated instruments, and training of interviewers/analysts about how to interpret information minimizes different types of **information bias** such as: • **Detection bias:** Detection bias occurs where the way in which outcome information is collected differs between groups. • **Instrument bias:** Instrument refers to where an inadequately calibrated measuring instrument systematically over/underestimates measurement **To receive full credit for this question, you must address:** • Was there a clearly defined study protocol? • If any additional interventions were given (e.g. tests or treatments), were they similar between the study participants? • Were the follow-up intervals the same for each study participant?	days and that the experiment would last 3 weeks. Each participant was treated equally. They were all assessed after 2 days for adverse effects and assessed weekly after the initial assessment. The amount of THC provided was the same for each participant.
Question 6: Now that you have answered Questions 1 – 5, what do you think about the internal validity of this study? (10 points) **To receive full credit, you must address:** • Based on the methodology of the study, how confident are you about the "truthfulness" of the results of this study?	I believe the study was truthful in the idea that using cannabis along with the traditional medications was helpful to the participants in the study. Without the comparative component, the results were limited to the assessment of the participants who were provided the THC. The reliability of the results is questionable because the study was short, and the long-term effects could not be determined. There was systematic bias due to the lack of randomization, but it did state that the study was meant to provide preliminary data and further research is needed.

Directions: Answer questions 7 – 9 to examine the external validity of this trial and determine if this trial can be applied to your patient.

Apply	
Question 7. Were the baseline characteristics of each study group (e.g. age, sex, socio-economic group) clearly outlined? (5 points) **To receive full credit for this question, you must address:** • Were there any differences between study participants that could affect the outcome/s?	In this study there weren't an equal number of women and men (7 men, 3 women). There is possibility it could have affected the outcome if PTSD in men is different than in women. The median age was around 52, all the participants were on more than one traditional medication, and all had nightmares.
Question 8. Can the results be applied to your patient? (10 points) **To receive full credit for this question, you must address:**	The median age of the study participants is slightly younger than may patient (52 compared to 66). Some of the patients had the same trauma that caused PTSD as my patient (war related). Age could be a

• Are the study participants similar to the patient in your care? • Would any differences between your patient and the study participants would alter the outcomes reported in the study? • Are the outcomes important to your patient? • Are there any outcomes you would have wanted information on that have not been studied or reported? • Are there any limitations of the study that would affect your decision?	factor that would alter the outcome, but there isn't enough evidence to support that factor. The patients in the study were all on multiple medications just like the patient in my care. The reported outcome of this study would be important to my patient as he would like to use cannabis to reduce his nightmares. The outcome that I would have wanted more information on would be the effects on a patient with PTSD and a placebo to compare the data. This is the limitation that would affect my decision along with the length of study time. It was too short to determine the long-term effects of cannabis usage on the patient.

Question 9. Would the experimental intervention provide greater value to your patient than any of the traditional treatment options? (10 points)
To receive full credit for this question, you must address:
• Do you think this patient would be a good candidate for medical cannabis? Describe the benefits and risks of cannabinoid therapy in this patient. In your assessment, consider:
  ○ Has your patient tried all traditional treatment and non-pharmacological options before trying this therapy?
  ○ What benefit does this experimental intervention have over traditional therapy options?
	The intervention could be an option for the patient as an addition to the traditional treatment starting with a low dosage and titrating upward if needed while under observation. The benefit would be decreased nightmares, but there could be a risk of the patient building a tolerance and cannabis not working for him if used long-term. The patient has tried traditional treatments, changing medications that caused intolerable side effects.