RPN Workshop cases
2/24/2021

Case Study 1: NIH-funded socio-behavioral study

You are a Research Coordinator at Boston Medical Center. The PI of your team received a notification of award grant from the National Institute of Diabetes, Digestive, and Kidney Diseases to conduct a pilot feasibility trial. The pilot portion of the study aims to evaluate the feasibility and efficacy of a diabetes self-management education and support (DSME/S) intervention hosted in the virtual environment. This study offers weekly synchronous DSME/S classes in an online platform.

Study Design: a single group, pre-to-post measure design. Weekly 1-hour DSME/S classes (facilitated by nurse practitioner) will be held during the daytime and evening to allow participants flexibility for attendance. Participants' perceived virtual environment usability, usefulness, and self-efficacy is assessed using validated survey measures (0, 3, and 6-months). Metabolic indicators (HbA1c, BP, BMI) are also collected at the aforementioned time points.

What are key considerations in conducting study visits remotely? In terms of:

- **Recruitment?**
- **Screening and Consent? Enrollment and Group Visit?**
- **Data Collection?**

Case Study 2: Industry funded Phase III Clinical Trial Involving New Drug Intervention in COVID-19 Positive Inpatients

- Drug to be dispensed inpatient
- Recruitment on COVID designated Floor
- Follow-up Surveys will need to be conducted inpatient/outpatient
- Follow-up blood collection will need to be collected inpatient/outpatient

How do we get this started? Discuss:

- **Screening**
- **Consent**
- **Materials/PPE**
- **Specimen Collection**
- **Follow Up Visits**

Case Study 3: COVID-19 vaccine

- You are a research coordinator. Your PI/site has been selected to conduct a Phase III study to evaluate a new COVID-19 vaccine for efficacy and durability. The enrollment goal is to enroll 300 people in an 8 week period. Community response to the trial is overwhelming with approximately 3,000 interested potential volunteers for 300 available spots.
- **Study Design:** Randomized clinical trial, vaccine vs. placebo - 2:1 ratio. Weekly visits and additional illness visits for those volunteers who develop COVID-like symptoms during study participation. This study lasts for 2 years.

What are key considerations in conducting study visits remotely? In terms of ….

- **Recruitment?**
- **Screening and Consent?**
- **Enrollment and Group Visit?**
- **Mitigation strategies for infection prevention?**
- **Data Collection?**