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PROTOCOL TITLE: A prospective study showing the effect of video interactive education on medical decision making in patients on opiate replacement therapy (ORT) with a history of Hepatitis C.

Objectives

The purpose of this study is to assess the effect of education as a determinant for hepatitis-C related literacy rate and improvement in decision-making capacity in patients with current or past history of hepatitis C who are currently on opiate replacement therapy.

Hypothesis

We anticipate better outcomes in literacy and decision-making capacity with more interactive intervention i.e. video educational session as compared to education delivered via a brochure.

Scientific Endpoints
Response:

As a result of participation in the interactive educational sessions, we aim to demonstrate

1. Improved health literacy in Opioid Agonist Treatment (OAT) patients

2. Improved decision making among OAT patients

Background

Hepatitis C virus (HCV) infection infects more than 150 million people worldwide as per the World Health Organization. Acute infection is rarely diagnosed and the majority of patients develop chronic infection, which eventually can lead to liver cirrhosis and further complications including hepatocellular carcinoma. People using intravenous drugs have high prevalence of hepatitis C virus infection[1] and very few receive treatment because of the lack of knowledge about HCV infection and its treatment modalities[2].The education of the population who is at risk for, or have been diagnosed with, chronic hepatitis C infection can improve their participation in the disease control and treatment[3]. To date strategies are not clear for patient education in regard to effectiveness.

We plan to conduct our study to identify the impact of different education delivery modalities on overall patient health literacy about hepatitis C and its effect to motive patients on opioid replacement therapy to pursue HCV evaluation and treatment.

Include complete citations or references.

Response:

1. Page K, Morris MD, Hahn JA, Maher L, Prins M. Injection Drug Use and Hepatitis C Virus Infection in Young Adult Injectors: Using Evidence to Inform Comprehensive Prevention. Clinical Infectious Diseases: An Official Publication of the Infectious Diseases Society of America. *2013;57(Suppl 2):S32-S38. doi:10.1093/cid/cit300.*

2. Butt G, McGuinness L, Buller-Taylor T, Mitchell S. Reasons for Nonattendance across the Hepatitis C Disease Course. ISRN Nursing. 2013;2013:579529. doi:10.1155/2013/579529.

3. Shah HA, Abu-Amara M. Education provides significant benefits to patients with hepatitis B virus or hepatitis C virus infection: a systematic review. Clin Gastroenterol Hepatol. 2013;11:922–933. [PubMed]

Study Design

We will start with a retrospective chart review to extract information about patient demographics, which will include age, gender, race/ethnicity, educational status, marital status, and history of mental health problems, information about substance abuse & status of hepatitis C, occupational and employment status. Some of this information will be required to decide matching factors between the clinics.

We will employ an observational two-group method design to evaluate the effect of video or computer-based education as a determinant of seeking treatment for HCV among patients on opioid agonist therapy (OAT). Group A will receive the video class intervention on the computer administered by an on-site facilitator, while "group-B" will receive an HCV educational brochure. The two groups are matched in 1:1 fashion to make the two groups similar with respect to the certain key characteristics, such as race, sex, age etc. The outcome variable is the percentage of the individuals in the two groups that retain HCV-knowledge. We expect up to 2-3 clinics to participate.

These intervention will occur after pre-test assessment by a designed questionnaire, which will include questions from different aspects of hepatitis-C infection disease process. Patients will not be notified of their questionnaire score. We will assess the questionnaires reliability and accuracy among a patient sample drawn from the clinics where the questionnaires will be deployed. We will also convey a committee of experts who will provide input on the design of the educational intervention. The last step before analysis will be post interventional assessment with the same questionnaire used for pre-intervention assessment. At the end of the study, we plan to utilize the data for analysis and manuscript preparation.

Inclusion and Exclusion Criteria

Describe the criteria that define who will be included in your final study sample.

1. Must be at least 18 years of age
2- Currently on suboxone therapy
3. Patients with English as their primary language

Describe the criteria that define who will be **excluded** from your final study sample.

1. Less than 18 years of age
2. Not treated with suboxone.
3. Non-English speaking patients

Indicate whether you will include non-English speaking individuals in your study. ***Provide justification if you will exclude non-English speaking individuals.***

The intervention in our study involves educational information regarding different aspects of hepatitis C including pathogenesis, diagnosis and treatment. This material will be only presented in English, therefore only patients who are able to comprehend English language would be able to complete the study pre-and post-test instrument as well as questionnaire to measure the effectiveness of the intervention.

Procedures Involved

We plan to conduct a study involving 2 groups. One group consists of the intervention subjects and other of the control subjects. The intervention subjects will receive the computer-based video education, while the "control group" will receive the brochure-based intervention. The goal is to evaluate the effect of education on health literacy in people with hepatitis C and currently on opiate replacement therapy. We also plan to evaluate the willingness for treatment in people with active hepatitis C infection.

We will start with a feasibility survey to assess the patient demographics at all clinic sites where this study will be conducted. We will also conduct cognitive testing of the survey instruments to be administered to ensure reliability and accuracy. We will also request that patient partners and subject matter experts provide guidance on the educational intervention to be delivered. The study flyers for advertisement will be distributed at all the clinic sites. Patients will be given information about the study. In case of agreement to participate, informed consent will be obtained. After enrollment of the population of interest, we will start the retrospective chart review in order to extract information about patient demographics, which will include age, gender, race/ethnicity, educational status, marital status, and a history of mental health problems, information about substance abuse & status of hepatitis C, occupational and employment status.

After that information is collected, we plan to designate the population in 2 groups i.e. Intervention & Control. The next step will be the educational intervention in group A which will consist of distribution of HCV educational brochure. Similarly group B will have the video class intervention on the computer administered by an on-site facilitator. These interventions will occur after the pre-test assessment by a designed questionnaire which will include questions on different aspects of hepatitis-C infection disease processes. Finally, we will administer a post interventional assessment with the same questionnaire used for pre-intervention assessment. For patients with history of HCV infection irrespective of treatment, an additional section will be added to check their willingness for treatment.

Study Timelines

The anticipated time frame review of the records is up to 1-2 months. We estimate it will take 12 months to complete enrollment in the study.

Risks to Subjects

This study involves only minimal risk to study participants. Breach of confidentiality is the primary potential risk. However, the data will be kept in secure, encrypted, password-protected flash drives made available only to study personnel. All study personnel are well-versed in

HIPAA compliance and use the electronic medical record on a daily basis. Moreover, study personnel are CITI trained in HIPAA compliance.