Official title of the study

Long-Term Adherence To Monitoring/Treatment In Underserved Asian Americans With Chronic HBV

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1) Abstract of the study

Although Asian Americans make up 6% of total U.S. population, they account for over 50% of Americans with chronic hepatitis B (CHB), which is associated with 75% of hepatocellular carcinoma (HCC). Asian Americans as a liver cancer disparity population are 8-13 times more likely to develop liver cancer with 60% higher death rate than non-Hispanic whites (NHWs). Research indicates that blood tests every six months and an abdominal ultrasound every 12 months, combined with antiviral treatment (e.g. entecavir or tenofovir) when appropriate, is the gold standard of care to reduce the risk of liver disease (including HCC). However, adherence to monitoring and antiviral treatment guidelines among Asian American patients with CHB is as low as 40% to 53%. Poor healthcare access and significant cultural barriers may prevent long-term adherence to monitoring and optimal treatment, placing Asian Americans at a disproportionately high risk for HCC and increased healthcare costs. Building on previous studies, we developed and pilot tested a virtual patient navigation toolkit system (VPN toolkit, a web/mobile application that helps patients with chronic HBV infection management) to replace our traditional patient navigator-led CHB management. Since our preliminary data and other studies indicate that text messaging (TM) interventions have potential to significantly improve adherence to treatment across illnesses, we propose to test the effectiveness of TM versus enhanced mHealth intervention (VPN Toolkit + TM) designed to help sustain and improve long-term adherence (i.e., 18 months follow ups) to monitoring and antiviral treatment guidelines, thereby reducing cancer health disparities among underserved at-risk Asian Americans with CHB leveraging our existing cohort of CHB subjects.

2) Protocol Title

Long-Term Adherence to Monitoring/Treatment in Underserved Asian Americans with Chronic HBV

3) Objectives

The specific aims are: 1) Evaluate the comparative effectiveness of TM vs VPN+TM for improving long-term adherence to monitoring (doctor visit and blood tests) at 12- and 18-month follow-ups; 2) Compare the effectiveness of TM vs VPN+TM in improving and sustaining medication adherence (measured through self-report and electronic monitoring) among Asian Americans with CHB who meet antiviral treatment guidelines; 3) Examine mediators of intervention effectiveness, including dose-response (i.e., utilization of the TM and VPN toolkit), information (knowledge), motivation, and self-efficacy.

Our comparative study of mHealth approaches will demonstrate how technology-based interventions can be integrated most effectively into real-world clinical settings to reduce HBV-related liver cancer disparities. If effective, this VPN+TM intervention is a highly disseminable intervention with the potential to have a significant impact on reducing viral-related cancer disparities among underserved Asian Americans and other highest-risk populations.

4) Resources and Setting

The study will be conducted in Philadelphia (Temple University,) and New York City (Hunter College). Our long-term collaborating local health care providers, communities and organizations, together with our well-trained research staff will identify and recruit qualified subjects for this research study.

5) Study Design

a) Recruitment Methods

N=436 (male=218 and female=218) will be recruited.

The study will start on 01/01/2019,   at Temple University and Hunter College.

Recruitment flyer will be used.

Each subject will receive a $25 gift card as compensation for completion at each assessment point including baseline survey and 12-m and 18-m follow ups in this study. So the total compensation for each participant will be $75 (3x$25.00) for completing the study.

b) Inclusion and Exclusion Criteria

Eligibility: Subjects will be included in the study if they meet the following criteria:

1. Age 18 and above
2. Self-identified Chinese, Korean or Vietnamese ethnicity
3. Chronic HBV infection with positive HBV surface antigen (HBsAg)
4. Diagnosed for over 12 months
5. Non-compliant to HBV monitoring and treatment guidelines for more than 6 months
6. Cell phone accessible by receiving text messaging
7. Not enrolled in any other HBV Management intervention (to prevent a potential program impact).

c) Study Procedures, Method, and Data Analysis Plan

Subjects will be mainly recruited from a cohort of participants in a previous study who have known their chronic HBV infection status. That was a 2-arm randomized controlled trial (RCT) with individual subjects as the unit of randomization. We will correspondingly enroll the randomized subjects from the cohort to form the 2-arm groups in this study.

We propose to compare the effectiveness of Text Messaging (TM) versus enhanced eHealth intervention of Virtual Patient Navigation + Text Messaging (VPN Toolkit + TM) designed to help sustain and improve long-term adherence to chronic HBV monitoring (doctors' visit and blood tests) and medication across 18-month follow ups in underserved at risk Asian Americans with chronic hepatitis B. VPN toolkit and TM will be delivered via e-Platform. VPN-led CHB education has interactive features of multilingual voice over and plain texts and knowledge questions with feedback to subjects.

For primary aim 1, we will compare 4 adherence outcomes: doctors' visits and blood tests at 12 and 18 months. We have at least 80% power to detect a 20% difference between arms for adherence to doctors' visits and blood tests, with a 2-sided Bonferroni adjusted type-I error of 0.01 (0.05/5 outcomes= 0.01).