

Community Engagement Strategies to Assist with the Development of an RCT Among People Living with HIV

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Abstract : Community Engagement Strategies to Assist with the Development of an RCT Among People Living with HIV Our research team focuses on developing and testing protocols to manage chronic symptoms. For many years, our team designed and implemented symptom management studies for people living with HIV (PLWH). We identify symptoms that are not curative and are not adequately controlled by conventional therapies. As an exemplar, we describe how we successfully engaged PLWH in developing and refining our research feasibility protocol for distal sensory peripheral neuropathy (DSP) associated with HIV. With input from PLWH with DSP, our research received National Institutes of Health (NIH) research funding support. Significance: DSP is one of the most common neurologic complications in HIV. It is estimated that DSP affects 21% to 50% of PLWH. The pathogenesis of DSP in HIV is complex and unclear. Proposed mechanisms include cytokine dysregulation, viral protein-produced neurotoxicity, and mitochondrial dysfunction associated with antiretroviral medications. There are no FDA-approved treatments for DSP in HIV. Purpose: Aims: 1) to explore the impact of DSP on the lives of PLWH, 2) to identify patients' perspectives on successful treatments for DSP, 3) to identify interventions considered feasible and sensitive to the needs of PLWH with DSP, and 4) to obtain participant input for protocol/study design. Description of Process: We conducted a needs assessment with PLWH with DSP. From our needs assessment, we learned from the patients' perspective detailed descriptions of their symptoms; physical functioning with DSP; self-care remedies tried, and desired interventions. We also asked about protocol scheduling, instrument clarity, study compensation, study-related burdens, and willingness to participate in a randomized controlled trial (RCT) with a placebo and a waitlist group. Implications: We incorporated many of the suggestions learned from the need assessment. We developed and completed a feasibility study that provided us with invaluable information that informed subsequent NIH-funded studies. In addition to our extensive clinical and research experience working with PLWH, learning from the patient perspective helped in developing our protocol and promoting a successful plan for recruitment and retention of study participants.

Keywords : clinical trial development, peripheral neuropathy, traditional medicine, HIV, AIDS

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