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A randomized clinical trial of the Health Evaluation and Referral Assistant (HERA): Research methods $\stackrel{\text{trial}}{\xrightarrow{}}, \stackrel{\text{trial}}{\xrightarrow{}}, \stackrel{\text{trial}}{\xrightarrow{}},$

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ABSTRACT

The Health Evaluation and Referral Assistant (HERA) is a web-based program designed to facilitate screening, brief intervention, and referral to treatment (SBIRT) for tobacco, alcohol, and drug abuse. After the patient completes a computerized substance abuse assessment, the HERA produces a summary report with evidence-based recommended clinical actions for the healthcare provider (the Healthcare Provider Report) and a report for the patient (the Patient Feedback Report) that provides education regarding the consequences of use, personally tailored motivational messages, and a tailored substance abuse treatment referral list. For those who provide authorization, the HERA faxes the individual's contact information to a substance abuse treatment provider matched to the individual's substance use severity and personal characteristics, like insurance and location of residence (dynamic referral). This paper summarizes the methods used for a randomized controlled trial to evaluate the HERA's efficacy in leading to increased treatment initiation and reduced substance use. The study was performed in four emergency departments. Individual patients were randomized into one of two conditions: the HERA or assessment only. A total of 4269 patients were screened and 1006 participants enrolled. The sample was comprised of 427 tobacco users, 212 risky alcohol users, and 367 illicit drug users. Forty-two percent used more than one substance class. The enrolled sample was similar to the eligible patient population. The study should enhance understanding of whether computer-facilitated SBIRT can impact process of care variables, such as promoting substance abuse treatment initiation, as well as its effect on subsequent substance abuse and related outcomes.

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[†] Note: The prototype of the HERA was called the Dynamic Assessment and Referral System for Substance Abuse (DARSSA). The name was changed to reflect our long-term plans to expand the system to provide SBIRT for other non-substance problems, like depression and interpersonal violence.

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1. Introduction

The burden of tobacco-, alcohol-, and drug-related injuries and diseases is staggering, accounting for more than 500,000 deaths and 510 billion dollars in lost productivity and medical costs every year in the United States [1,2]. Because screening, brief intervention, and referral to treatment (SBIRT) has proven effective for reducing tobacco use and SBI has proven effective for alcohol abuse, the United States Preventive Services Task Force (USPSTF) and the Substance Abuse and Mental Health Services Administration (SAMHSA) have recommended universal SBIRT for these substances in general medical settings, including emergency departments (EDs) and primary care [3,4]. Additionally, there is increasing evidence to support SBIRT for illicit drug abuse and SAMHSA state grants to promote SBIRT require assessment and intervention for both alcohol misuse and illicit drug use [5,6]. The Centers for Medicare and Medicaid Services (CMS) and the American Medical Association have authorized billing codes that reimburse SBIRT for tobacco, alcohol, and illicit drug abuse [7].

Despite their efficacy, cost-effectiveness, and potential for reimbursement by CMS, the majority of SBIRT programs collapse once grant funding ends. Two themes have emerged that account for the poor sustainability of traditional SBIRT programs:

- 1. Most physicians and nurses will not perform SBIRT themselves [8–11]. Physicians and nurses almost universally recognize the need for SBIRT but generally feel ill-prepared and too overwhelmed by clinical demands to comply with SBIRT recommendations. A fear of opening "Pandora's Box" prevents screening, especially in acute care settings like the ED. For these reasons, physicians and nurses strongly prefer the dedicated interventionist model, a team-based approach using on-site counselors or clinicians to provide the interventions. In this model, SBIRT is completed in parallel with medical care and often requires minimal involvement of the treating physicians and nurses. As long as the financial support for a team model is available, providers and patients are satisfied.
- 2. Dedicated interventionist models, however, have not proven sustainable [10,12–14]. Despite SBIRT's ability to reduce healthcare costs [12], the costs and complexities associated with hiring, training, supporting, and scheduling on-site interventionists have been prohibitive in most settings. Consequently, the evidence-based implementation model is scarcely implemented and treatment as usual prevails, represented by idiosyncratic provider screening and interventions.

Technological advances such as computerized assessments, personalized feedback reports, faxed referrals, and electronic health records hold tremendous potential for facilitating the implementation of SBIRT in healthcare settings [15–23]. Given such potential, Polaris Health Directions and the University of Massachusetts Medical School created the Health Evaluation and Referral Assistant (HERA), a web-based program designed to facilitate SBIRT. The prototype demonstrated strong acceptability among providers and patients and evaluation data provided initial support for its feasibility in ED and inpatient medical settings [24]. This paper describes the methods of a randomized controlled trial (RCT) to evaluate the efficacy of

the HERA for improving initiation of specialized treatment among ED patients abusing tobacco, alcohol, or illicit drugs and to examine the HERA's effect on use of and motivation to change these substances. An evaluation of the representativeness of the enrolled sample compared to non-enrolled patients is also presented.

2. Materials and methods

2.1. HERA overview

The HERA is comprised of three integrated modules (Fig. 1): (1) a web-based assessment of tobacco, alcohol, and illicit drug use, as well as other pertinent psychosocial variables, (2) a report generator, and (3) a referral generator. The HERA was funded by a Small Business Technology Transfer (STTR) grant from the National Institute on Drug Abuse (R42DA21455). Phase 1 created and pilot tested the prototype. Phase 2 made further modifications based on Phase 1 results and studied the program's efficacy, which is the subject of this paper. Because the Phase 1 program is described in depth elsewhere, we will provide a brief overview and describe the changes made in the system during the early stages of Phase 2 [24]. Innovations include: integration of patient-facing technology during the medical visit, poly-substance assessment and intervention, highly personalized referral matching capability, and dynamic referral capability, or the ability to automatically send an electronic referral to a "best match" substance treatment provider in the community.

2.1.1. Assessment module

The assessment module provides for the self-administered assessment of tobacco, alcohol, and illicit drug use and abuse. This represents a significant innovation, since many computerized systems, as well as most traditional SBIRT studies, only assess one substance category, such as studies of the Tobacco Expert System [25,26] and SBIRT studies on alcohol [12,27,28]. Focusing only on one substance category would limit adoption in clinical practice, where all three substances are prevalent and often co-morbid.

In the original version of the HERA, the foundation of the assessment consisted of an abbreviated version of the addiction severity index (ASI) [29]. However, during Phase 2, the assessment was replaced with the Heavy Smoking Index to assess tobacco use, the Alcohol Use Disorders Identification Test (AUDIT) to assess alcohol use and misuse, and the Drug Abuse Severity Test (DAST-10) to assess illicit drug use [30–32]. These scales were judged to be better than the ASI because they are: (1) briefer, (2) have been used extensively in clinical SBIRT research, and (3) are more accepted by credentialing agencies, such as the American College of Surgeons, and funding agencies, such as CMS.

In addition to these scales, the HERA also assesses history of injection drug use, readiness to change, readiness to enter treatment, treatment history, and withdrawal symptoms. For patients reporting any readiness to change, the HERA assesses interest in a faxed referral to a "best match" substance abuse treatment provider (i.e., a dynamic referral) which is further described in Section 2.1.3. Download English Version:

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