



Nasal Irrigation for Chronic Rhinosinusitis and Fatigue in Patients with Gulf War Illness: Methods and Initial Data

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Objective: To assess the effects of nasal irrigation in improving sinus and fatigue-related quality of life in participants with Gulf War Illness

Introduction

Context

- Gulf War Illness (GWI) - a multisystem condition affecting 1 in 7 veterans (>50,000) who returned from the first Persian Gulf War 1990-91.
- Cause: multifactorial; quality of life impact: high.
- Chronic rhinosinusitis (CRS) and fatigue common.

Nasal Irrigation

- Nasal irrigation (NI): adjunctive therapy for CRS
- Originally used in the Yogic tradition; increasingly used in the West
- NI is reported to improve sinus symptoms and fatigue in the general population.¹
- Popular nasal irrigants include saline and xylitol solutions.
- Nasal Irrigation with saline (NI-S) may improve sinus symptoms by thinning, cleaning and clearing mucus and by improving the protective function of the nasal mucosa.
- Nasal Irrigation with xylitol (NI-X) has been reported to change the salinity of the nasal surface² resulting in improved antimicrobial properties of local cellular immunity.

Methods

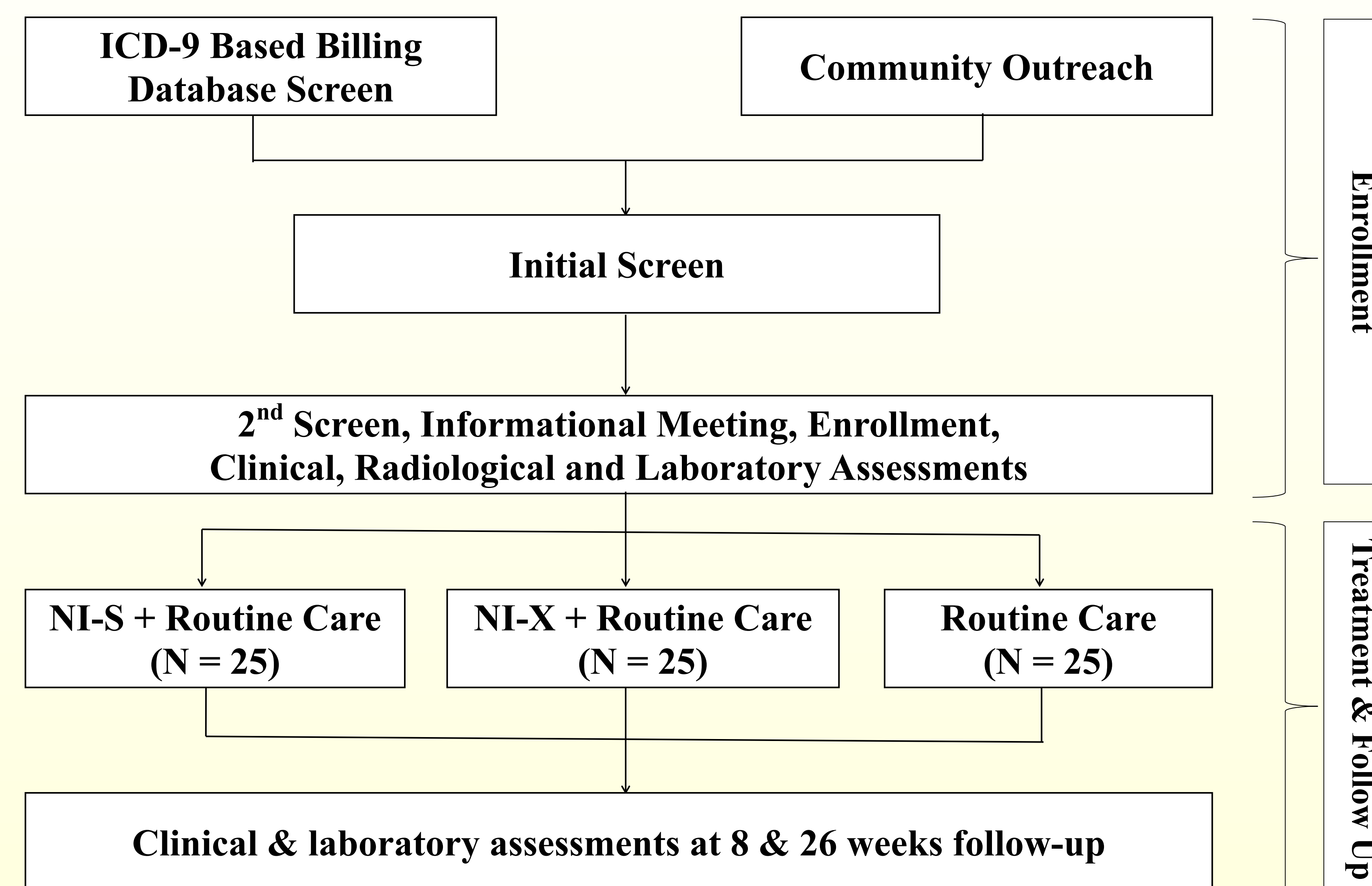
Design

- Random assignment of participants (N = 75) to one of three groups in addition to routine care; (1) NI-S twice daily, (2) NI-X twice daily, or (3) routine care only.
- Data collection personnel blinded to participant group status.

Participant Eligibility

- Adults 30-65 Y.O. meeting diagnostic criteria for GWI.³
- Deployed to the Persian Gulf during the first Gulf War (1990-91).
- Meets criteria for diagnosis of chronic rhinosinusitis.⁴
- Willingness to participate in study protocol.

Screening, Enrollment & Randomization



1. Irrigant is mixed with lukewarm distilled water.
2. The irrigant solution is introduced into the nasal cavity via one nostril and allowed to flow around the nasal septum & out the contralateral nostril.

3. Subject gently blows nose into a tissue
4. The procedure is repeated with the contralateral nostril.



Primary Clinical Outcome Measure:

- Sinonasal Outcome Test: a 20-item multidimensional questionnaire based outcome measure at 8 and 26 weeks.

Secondary Outcome Measures:

- Multidimensional Fatigue Inventory at 8 and 26 weeks.
- Pro-inflammatory cellular and cytokine profiles
- Cost-benefit analysis; participant satisfaction

Results: Study in progress

- Administrative approvals obtained (UW IRB and others)
- Currently enrolling participants (N = 4)
- Study procedures tested and operational
- Data collection rate: 100%; participants satisfied
- NI-S and NI-X reported improvements at 8 weeks

Conclusion

The study is enrolling subjects and the protocol has been working well. Positive results for either form of NI would suggest that these treatments can improve the quality of life for affected patients.

Citations

1. Rabago D, Zgierska A, Mundt M, Barrett B, Bobula J, Maberry R; *Efficacy of daily hypertonic saline nasal irrigation among patients with sinusitis: A randomized controlled trial.* J Fam Pract 2002; 51:1049-1055.
2. Uhari M, Kontiokari T, Niemelä M. A novel use of xylitol sugar in preventing acute otitis media. *Pediatrics.* 1998;102(4):879-974.
3. Steele L. Prevalence and patterns of Gulf War illness in Kansas veterans: Association of symptoms with characteristics of person, place and time of military service. *Am J of Epidemiol.* 2000;10(152):992-1002.
4. Benninger MS, Ferguson BJ, Hadley JA, et al. Adult chronic rhinosinusitis: definitions, diagnosis, epidemiology, and pathophysiology. *Otolaryngol Head Neck Surg.* 2003;129(3 (suppl)):S1-32.