Study title: Evaluating the Effect of a Written Action Plan on Comfort and Understanding of Hidradenitis Suppurativa

NCT04600375

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1. Study Protocol

Hypothesis and Objectives

The primary objective of this study is to investigate the effectiveness of the addition of a written action plan (WAP) on patient understanding and management of HS.

Hypothesis 1: Subjects randomized to the intervention group will self-report increased understanding of their HS and management plan, as compared to the verbal consultation (VC).

The secondary objective is to investigate the patients' comfort level in following their individualized WAPs at home.

Hypothesis 2: Subjects receiving a WAP will self-report increased comfort level in managing their HS at home with guidance from a WAP.

The tertiary objective is to investigate whether patients randomized to the control group prefer VC alone, WAP alone, both VC and WAP combined, or neither the VC nor the WAP.

Hypothesis 3: Subjects randomized to the control group will prefer their providers to use a combination of VC and WAP during their office visits.

The quaternary objective is to investigate the patients' anxiety level in managing their HS at home.

Hypothesis 4: Subjects receiving a WAP will self-report lower levels of anxiety in managing their HS at home.

Study Design and Procedures

Patient recruitment will take place during a routine dermatology. If the HS patient meets the inclusion criteria, he/she will be approached by a study coordinator about this study. If he/she agrees, he/she will sign an informed consent form.

Subjects will then be randomized to one of two groups:

- A control group – VC alone
- An intervention group – VC with WAP

In order to randomize subjects, randomization lists, which are concealed to all parties involved in this study, will be created using a computer software program. As each subject is enrolled, they will be assigned a subject number. After assignment of a subject number, the investigators will refer to the computer-generated randomization scheme corresponding to the assigned subject number to complete the randomization process.

After group assignment, the study coordinator will administer Survey A which will take approximately 10 minutes to both groups. All subjects will be asked to refrain

from asking any questions regarding HS or its treatment until the end of the office visit to ensure controlled delivery of information to all subjects.

The principal investigator will then conduct a routine office visit for the HS patients, consisting of an introduction, history taking, and assignment of Hurley stage. Next, the subjects in the control and intervention groups will receive an individualized VC and VC+WAP, respectively. Subjects from both groups will then complete Survey B which will take approximately 10 minutes. At the completion of Survey B, subjects in the interventional group will have completed the study. Those in the control group will then receive a VC+WAP, followed by completion of Survey C which will take approximately 10 minutes. This is to ensure that all subjects receive the same caliber of care. All Surveys and WAP documents that will be used in our study of written action plans in hidradenitis suppurativa are a standard of care intervention.

Information collected into the medical record during the routine office visit (specifically duration of disease, tobacco use, and disease severity) will be used for this research.

Both groups will take Survey D at a routine follow up visit. Survey D (which will take approximately 10 minutes) is to evaluate if the action plan has had any long-term impact or if it results in behavior change.

2. **Statistical Analysis Plan**

Comparative statistics were completed between the control group and intervention groups using the student t-test. P-values <0.05 were considered statistically significant. Analyses were completed in RStudio (v1.2.1335).