PROTOCOL TITLE: Comparison between Interactive Internet-based Education and Counseling for the Management of Acne with that of Internet-based Education Alone.

1) Protocol Title: Comparison between Interactive Internet-based Education and Counseling for the Management of Acne with that of Internet-based Education Alone.

Author of Protocol: Audrey Wang, MD

☒ UC Davis Researcher
☐ Researcher from other institution
☐ Private Sponsor
☐ Cooperative Group
☐ Other: _________________

2) IRB Review History

→ This is not applicable

3) Objectives

Specific Aims of the Study:

1. Evaluate the effect on clinical outcomes in subjects receiving dermatological education for acne vulgaris through an interactive Internet-based education and counseling program compared to those receiving Internet-based education alone.

2. Evaluate the effect on quality of life in subjects receiving dermatological education for acne vulgaris through an interactive Internet-based education and counseling program compared to those receiving Internet-based education alone.

3. Evaluate the effect on acne vulgaris knowledge in subjects receiving dermatological education for acne vulgaris through an interactive Internet-based education and counseling program compared to those receiving Internet-based education alone.

4. We hypothesize that an interactive Internet-based education and counseling program will be more effective than Internet-based education alone in improving clinical outcomes and quality of life in acne patients.

4) Background

Acne vulgaris is a common skin condition affecting over 85% of adolescents and may cause significant cutaneous disease burden and psychological distress (Knutsen-Larson et al., 2012; White, 1998). Moreover, acne vulgaris accounts for over 5 million physician visits each year, leading to over 3 billion dollars per year in terms of treatment and loss of productivity (Bickers et al., 2006). Despite this, effective patient education on acne is lacking and represents an insufficiently studied area within clinical dermatological research.

Recently, the use of interactive Internet-delivered educational programs have shown promise in improving knowledge and promoting certain types of preventative health behavior (Kuijpers et al., 2013). Specifically, studies have used “virtual” coaching to develop therapeutic alliances between participants and non-human computer agents that increase self-efficacy and promote self-care behaviors (Napolitano et al., 2003; Norman et al., 2007; Tate et al., 2003; Watson et al., 2012).

This study will develop and evaluate the efficacy of an Internet-based education program incorporating virtual coaching. For this study, the virtual coach will consist of online videos aimed at providing acne education and promoting behaviors that support healthy skin (e.g., gentle skin cleansing). The use of Web-based technologies and virtual coaching in acne-related patient education is novel, and may significantly improve clinical outcomes and quality of life in acne patients.

5) Inclusion and Exclusion Criteria*
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Inclusion Criteria:
- 13 years of age or older at time of assent, may be men or women.
- Able read and understand English.
- Able to hear and see the educational videos.
- Access to computer with Internet access.
- Capable of giving informed consent.
- Not currently using any prescription acne treatment.

Exclusion Criteria:
- Non-English speaking individuals.
- Self-reported exposure to environmental or chemical comedogenic agents
- Women with self-reported hyperandrogenism (e.g., PCOS)
- Women self-reporting current use of any form of specific acne-directed hormonal therapy
- Men or women with self-reported history of Cushing syndrome or congenital adrenal hyperplasia

6) Study-Wide Number of Subjects

→ This is not a multicenter study.
→ As review: This is a single-center study performed only by UC Davis investigators. We will recruit 100 participants.

7) Study-Wide Recruitment Methods*

→ This is not a multicenter study.
→ As review: This is a single-center study performed only by UC Davis investigators. Potential study participants will be identified and recruited according to the following procedure:

A) Trained research personnel will approach students during their health education class to describe the study’s purpose, responsibilities of participation, and ascertain interest in participating in the study.
B) Interested students who are eligible to participate will review the assent and consent form with research staff.
C) Staff will provide a letter describing the study for the parent(s)/guardian(s) to review. Parental/guardian permission will be obtained from: Both parents/guardians unless one parent/guardian is deceased, unknown, incompetent, or not reasonably available, or when only one parent/guardian has legal responsibility for the care and custody of the child.
D) Once the signature(s) from parent(s)/guardian(s) is obtained, the student will return the signed consent to study staff. At this time, study staff will review the study procedures and expectations, assess interest, and obtain assent to participate from the student. Students must provide assent form and the parent/guardian must sign the consent form before the student can be part of the study.

8) Study Timelines*

- The duration of an individual subject’s participation in the study is 12 weeks.
- The duration anticipated to enroll all study subjects is approximately 12 weeks.
- The estimated date for the investigators to complete this study (complete primary analyses) is 03/01/14.

9) Study Endpoints*

Primary study endpoint is participants’ completion of the education program at 12 weeks. The Principal Investigator, Audrey Wang, MD, and Co-Investigator, William Tuong, will closely monitor all participants’ progress throughout the study. The safety of all participants, whether in the interactive Internet-based education and counseling program or Internet-based education alone, will
be assessed at each study point. If a concern arises between study points, both study group participants will be able to contact study staff or school staff by email, telephone, or in-person depending on the level of urgency and severity.

10) Procedures Involved*

We plan to conduct a randomized, controlled trial comparing the effect of an interactive Internet-based education and counseling program to Internet-based education alone on subject’s acne knowledge, skin care behavior, quality of life, and acne severity. After receiving a Letter of Support from necessary individuals, subjects will be recruited from local high schools in Sacramento and Stockton. The inclusion criteria and exclusion criteria are outlined above. Whether or not a student chooses to participate in the study will have no bearing on his/her classroom grade, and it will be emphasized that there will be no penalty for non-participation.

Potential study participants will be identified and recruited according to the following procedure:

A) Trained research personnel will approach students during their health education class to describe the study’s purpose, responsibilities of participation, and ascertain interest in participating in the study.

B) Interested students who are eligible to participate will review the assent and consent form with research staff.

C) Staff will provide a letter describing the study for the parent(s)/guardian(s) to review. Parental/guardian permission will be obtained from: Both parents/guardians unless one parent/guardian is deceased, unknown, incompetent, or not reasonably available, or when only one parent/guardian has legal responsibility for the care and custody of the child.

D) Once the signature(s) from parents(s)/guardian(s) is obtained, the student will return the signed consent to study staff. At this time, study staff will review the study procedures and expectations, assess interest, and obtain assent to participate from the student. Students must provide assent form and the parent/guardian must sign the consent form before the student can be part of the study.

Study staff will schedule a date/time to return during afterschool hours to conduct the remainder of the protocol with students who return signed consent and assent forms. After providing consent and assent forms to participate, students will also be randomized via 1:1 simple, non-stratified randomization scheme to the “Internet-based education only” arm (n=50), or “Internet-based education and counseling” arm (n=50) Subjects will be given a username, password, and instruction on how to access the education programs via Internet. They will receive training on how to use this website. Participants are expected to visit the website once per week but can view the online educational materials at any level of frequency. To facilitate weekly visits, the investigators will collect student’s e-mail addresses/mobile phone numbers in order to send out weekly reminders to access the online resources. Additionally, we anticipate participants spending approximately 30 minutes per week on the educational website. We anticipate that participants will view the educational website to which they are randomly assigned using his/her own time (i.e., separate from classroom time). In other words, we do not expect participants to use classroom time to review the educational websites. No medications will be prescribed in this study.

The Internet-based education will be a website newly developed for this study. Participants randomized to the Internet-based education and counseling arm will receive tailored online education delivered by a virtual online counselor. The virtual online counseling session will be an interactive session between the student (i.e., study participant) and an animated online character (i.e., virtual counselor). An example question would be, “What would you like to learn about today?” The virtual counselor will then give several options from which the participant can choose (e.g., “Would you like to learn about common treatments for acne?”). After the participant makes a selection, the virtual counselor will automatically direct the participant to the specific portion of the educational website containing information selected by the participant. For example, the virtual
counselor would lead the participant to the portion of the educational website discussing treatment options if the user wanted to learn more about common over-the-counter treatments for acne. The virtual counselor will also be able to read aloud the information contained in the educational website depending on the preferences of the participant. The online education and counseling are integrated and it is not possible to be completed separately. Moreover, the virtual counselor will be present each time the user accesses the website and will thus interface with the counselor at every visit (i.e., theoretically on a weekly basis). Due to the close integration of the virtual counseling and delivery of acne education, we anticipate that students will continue to require approximately 30 minutes per week to navigate the website. Importantly, the educational content across study groups will be equivalent. Moreover, the educational content of the website is provided to the IRB for review in a separate document entitled, “Acne Education”.

After randomization (Study Point 1), study staff will take digital photographs of the subject’s face to assess baseline acne severity. Specifically, study staff will only photograph a portion of the face (i.e., the whole face is not photographed). The same portion of the face will be photographed for each participant. Participants will be individually escorted out of the classroom and into an adjacent empty room/private area where the photograph will be taken. Subjects will then return to their original classroom to complete Survey #1, which includes the Dermatology Life Quality Index (DLQI) form and questionnaire items about their knowledge regarding acne. As previously stated, the review on how to access the website, photographs, and survey administration will be done afterschool (i.e., outside of classroom time); therefore, students who decide not to participate will not have their classroom time interrupted by this study. It will be emphasized that participation will have no impact on classroom grades. We expect that this afterschool session will last 35 minutes.

Following Study Point 1, the investigators will schedule another date to return during afterschool hours at approximately 12-weeks (Study Point 2). At Study Point 2, the participants will complete Survey #2, which includes the DLQI, acne vulgaris knowledge items, and a satisfaction survey. The research staff will again take digital photographs of the participant’s skin. The same portion of the face will be photographed as previously described. Again, we expect this afterschool session to last approximately 35 minutes.

Photographs taken at each visit will be forwarded to blinded study staff to complete the Investigator Global Assessment (IGA), a validated scale to assess acne severity.

11) Data and Specimen Banking*

→ This is not applicable as this study will not be collecting specimens

12) Data Management*

Participant information will not be disclosed to third party individuals except those authorized to oversee the research project (e.g., Institutional Review Board). William Tuong and Audrey Wang, MD, Julie Wu, Vicki Wells, and Tara Rachakonda will be the only individuals with access to participant information.

Data collected will be coded. A study number will be assigned to each participant, and data will be stored in a password-protected database. Digital photographs will be identified only by study number and stored in a password-protected electronic folder. The photographs will depict only a portion of the participants face, thereby decreasing identifiable potential. Identifiers and data will be separated and kept in different locked cabinets. Non-electronic information will be kept in a locked cabinet, in a locked office in the UC Davis Department of Dermatology at 3301 C Street, Suite 1400, Sacramento, CA 95816.

Data will be analyzed using SPSS. We plan to calculate mean, mode, range, standard error, standard deviation, etc. Also we plan on performing Pearson’s chi-squared test, Student’s t-Test, Fisher’s exact test, etc. With a total sample size of 100 subjects, the study has 80% power to detect
a 12% difference in the primary outcome measures between arms, assuming a standard deviation of 25%.

13) **Provisions to Monitor the Data to Ensure the Safety of Subjects***

→ This is not applicable as this study involves only minimal risk

14) **Withdrawal of Subjects***

This study involves minimal risk and we do not anticipate many circumstances under which subjects will be withdrawn from the research without their consent. However, one potential scenario is marked distress from learning and focusing on acne. If study or school staff notices a subject becoming distressed from participating in the study at any point, the subject may be withdrawn from the study. Withdrawn participants will no longer provide data. Data from withdrawn participants will be kept for potential subset analyses.

15) **Risks to Subjects***

Loss of confidentiality is a potential risk to participants. William Tuong and Audrey Wang, MD, Julie Wu, Vicki Wells, and Tara Rachakonda will be the only individuals with access to participant information. Assent forms from minors, parental consent forms, and survey responses will be securely stored in separate study binders. The study binders will be securely stored in a locked cabinet, in a locked office, in the UC Davis Department of Dermatology at 3301 C Street, Suite 1400, Sacramento, CA 95816. All HIPAA, IRB, State, and Federal policies and guidelines will be followed in ensuring confidentiality. Additionally, another potential risk to participants is feeling uncomfortable when talking about acne. Students will be reminded that participation is completely voluntary and they may withdraw at any time.

16) **Potential Benefits to Subjects***

Not all study participants will benefit directly from the study. However, all patients will receive education on acne and proper skin care behavior, which has the potential to be beneficial to participants on an individual basis. Participants exposed to this education may achieve healthier appearing skin.

17) **Vulnerable Populations***

Children over the age of 13 will be participating in this study. In order to protect the rights and welfare of children, we will use an assent form and obtain parental consent to participate in the study.

18) **Multi-Site Research***

→ This is not applicable as this is not a multi-center research study.

19) **Community-Based Participatory Research***

→ This study is not considered CBPR and the community was not formally involved in the design of this study. However, we will be working with local high schools in Sacramento and Stockton, which helped plan recruitment efforts.

20) **Sharing of Results with Subjects***

→ This is not applicable as individual subject results will not be shared with subjects or others.
21) Setting

Identification of potential subjects, recruitment, and research procedures will be conducted at local high schools in Sacramento and Stockton.

22) Resources Available

Audrey Wang, MD is the Principal Investigator. She has had experience in investigator-initiated clinical studies. Dr. Wang will offer her expertise in study design and will oversee all aspects of the study including recruitment of study subjects, data collection, and data analysis.

William Tuong is the Co-Investigator, former Medical Student Research Fellow, and current T32 Clinical Research Fellow. He will execute the project as outlined in the proposal, use sound management techniques, report the progress and any adverse events to the IRB as required, maintain accurate project records, and comply with all UC Davis policies and procedures related to project management and personnel practices. William Tuong will also design the study, recruit study subjects, consent subjects, interview subjects, and collect and analyze data.

He has previously conducted an IRB-approved study at a local Sacramento high school and was able to recruit the required number of subjects (50) within the agreed recruitment period. The UC Davis School of Medicine has developed an excellent relationship with the high schools chosen to participate in this study.

Julie Wu, Vicki Wells, and Tara Rachakonda are additional study personnel. They currently work with the Department of Dermatology on multiple large ongoing clinical trials conducted through the Department of Dermatology at UC Davis School of Medicine.

23) Prior Approvals

We will obtain Letter of Support from local high schools in Sacramento and Stockton.

24) Recruitment Methods

This will be a single-center study performed only by UC Davis investigators. After receiving a Letter of Support from the necessary individuals, we plan to recruit one hundred participants from the chosen local high schools in Sacramento and Stockton.

Potential study participants will be identified and recruited according to the following procedure:

A) Trained research personnel will approach students during their health education class to describe the study’s purpose, responsibilities of participation, and ascertain interest in participating in the study.

B) Interested students who are eligible to participate will review the assent and consent form with research staff.

C) Staff will provide a letter describing the study for the parent(s)/guardian(s) to review. Parental/guardian permission will be obtained from: Both parents/guardians unless one parent/guardian is deceased, unknown, incompetent, or not reasonably available, or when only one parent/guardian has legal responsibility for the care and custody of the child.

D) Once the signature(s) from parents(s)/guardian(s) is obtained, the student will return the signed consent to study staff. At this time, study staff will review the study procedures and expectations, assess interest, and obtain assent to participate from the student. Students must provide assent form and the parent/guardian must sign the consent form before the student can be part of the study.
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There will be no payments to subjects. Additionally, we will not be accessing personal health information to identify prospective subjects. No medications will be prescribed in this study.

25) **Local Number of Subjects**

One hundred subjects will be recruited. This is a single-center study performed only by UC Davis investigators.

26) **Confidentiality Maintenance for Multicenter study**

→ This is a single-center study performed only by UC Davis investigators. However, as review:

Participant information will not be disclosed to third party individuals except those authorized to oversee the research project (e.g., Institutional Review Board). William Tuong, Audrey Wang, MD, Julie Wu, Vicki Wells, and Tara Rachakonda will be the only individuals with access to participant information.

Data collected will be coded. A study number will be assigned to each participant, and data will be stored in a password-protected database. Digital photographs will be identified only by study number and stored in a password-protected electronic folder. The photographs will depict only a portion of the participants face, thereby decreasing identifiable potential. Identifiers and data will be separated and kept in different locked cabinets. Non-electronic information will be kept in a locked cabinet, in a locked office in the UC Davis Department of Dermatology at 3301 C Street, Suite 1400, Sacramento, CA 95816.

27) **Provisions to Protect the Privacy Interests of Subjects**

Precautions will be taken to maintain the privacy of the participants. These will include the following:

A) Participant information will not be disclosed to third party individuals except those authorized to oversee the research project (e.g., Institutional Review Board).

B) William Tuong and Audrey Wang, MD, Julie Wu, Vicki Wells, and Tara Rachakonda will be the only individuals with access to participant information.

C) Information will be kept in a locked cabinet, in a locked office in the UC Davis Department of Dermatology at 3301 C Street, Suite 1400, Sacramento, CA 95816.

28) **Compensation for Research-Related Injury**

→ This is not applicable as this study involves only minimal risk.

29) **Economic Burden to Subjects**

There will be no charge to the participants of this study. Neither the participants nor their insurance carriers will be charged for their participation in the research.

30) **Consent Process**

Potential study participants will be identified, recruited, and consented/assented according to the following procedure:

A) Trained research personnel will approach students during their health education class to describe the study's purpose, responsibilities of participation, and ascertain interest in participating in the study.

B) Interested students who are eligible to participate will review the assent and consent form with research staff.
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C) Staff will provide a letter describing the study for the parent(s)/guardian(s) to review. Parental/guardian permission will be obtained from: Both parents/guardians unless one parent/guardian is deceased, unknown, incompetent, or not reasonably available, or when only one parent/guardian has legal responsibility for the care and custody of the child.

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31) Process to Document Consent in Writing

We will obtain written documentation of consent following HRP-091

32) Drugs or Devices

This is not applicable as this study will not use any drugs or devices

REFERENCES


