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TITLE:
Alcohol Cessation Among Head and Neck Cancer Survivors: A Pilot RCT of a Tailored Text Message-Based Intervention

PRINCIPAL INVESTIGATOR: Michael A. Diefenbach, PhD

CONTRACTING ORGANIZATION: The Feinstein Institutes for Medical Research

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14. ABSTRACT

This report details activities in the first year of a project aimed to evaluate a text-message alcohol cessation intervention for head-and-neck cancer (HNC) survivors in both civilian and veteran populations. Investigators are currently working with HNC survivors and clinicians at Northwell Health and the Brooklyn VA Medical Center to adapt an existing evidence-based text message alcohol cessation intervention (Aim 1) to prepare to conduct a two-arm pilot RCT to evaluate acceptability, preliminary efficacy, and feasibility to conduct a future RCT (Aim 2). We hypothesize 1) the tailored intervention will be feasible and acceptable and 2) the tailored text messages will result in 30% increase in cessation among HNC survivors.

15. SUBJECT TERMS
Head and Neck Cancer; Alcohol Cessation; Veterans Health; Substance Abuse; Quality of life; Depression; Social Isolation; Text-Message Intervention; mHealth

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1. **INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

The goals of this project are to 1) to adapt an existing evidence-based text message alcohol cessation intervention for head-and-neck cancer (HNC) survivors in both civilian (Northwell Health) and VA settings (Brooklyn VA Medical Center), and 2) conduct a two-arm pilot RCT (n=138) to evaluate acceptability, preliminary efficacy, and feasibility to conduct a future RCT. We hypothesize 1) the tailored intervention will be feasible and acceptable and 2) the tailored text messages will result in 30% increase in cessation among HNC survivors.

2. **KEYWORDS:** *Provide a brief list of keywords (limit to 20 words).*

Head and Neck Cancer; Alcohol Cessation; Veterans Health; Substance Abuse; Quality of life; Depression; Social Isolation; Text-Message Intervention; mHealth

3. **ACCOMPLISHMENTS:** *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

What were the major goals of the project?
List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

- Major Task 1: Study Kickoff (Months 1-3) - 100% complete
- Major Task 2: Conduct individual interviews to adapt alcohol cessation intervention (Months 4-6) - 60% complete
- Major Task 3: Conduct pilot RCT for 69 HNC survivors from Northwell Health (Months 7-42) - Not yet started
- Major Task 4: Conduct study procedures for 69 HNC survivors from the VA (Months 7-42) - Not yet started
- Major Task 5: Study Closeout (Months 43-48) – Not yet started

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the

Accomplishments during this initial annual reporting period reflect our commitment to establishing a solid foundation to support safe and efficient future study activities. Our specific objectives in Year 1 were to adapt our existing alcohol cessation text-messaging platform (Aim 1) for use in our pilot RCT, and to begin enrolling for the pilot RCT (Aim 2).

We successfully completed all Major Task 1 study kick-off activities, including establishing and training site teams at both Northwell and the Brooklyn VA in the standardized delivery of our research protocol. All study activities have received review and approval to conduct research by the Northwell Institutional Review Board (IRB), the Brooklyn VA IRB, and the USAMRDC Office of Human and Animal Research Oversight. We registered the clinical trial portion of our study on the National Institutes of Health clinical trial registry. Finally, we built robust and HIPAA-compliant database that leverages electronic consent and participant tracking best practices.

Major Task 2 activities to conduct individual interviews with civilians and veteran HNC survivors and HNC clinicians are well underway. At the time of this report, Northwell has completed over 72% of planned interviews, and the Brooklyn VA has completed 53%. We are actively working with our technology vendor to prepare the system to incorporate final content changes by July 2023.

As described further in the "actual or anticipated problems or delays" section below, approval to begin study activities was significantly delayed and consequently impacted our ability to complete Aim 1 (Major Task 2) and begin Aim 2 (Major Tasks 3 and 4) in this initial reporting year. We are confident, however, in our ability to maintain our overall project timeline, and consider our project to be on-track for success.

What opportunities for training and professional development has the project provided?

If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Nothing to Report.

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to Report.

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

We look forward to completing all activities in Major Task 2 during the first quarter of the next reporting period. This will include completing remaining civilian and veteran HNC survivor and clinician interviews to inform the final content of the alcohol cessation program, as well as finalizing content changes to our existing platform to incorporate this language. We anticipate pilot RCT recruitment, enrollment, and randomization of civilian and veteran HNC survivors (Major Tasks 3 and 4) will begin July 2023. Pilot RCT study activities will continue through September 2025.

4. IMPACT: D*escribe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Nothing to Report.

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to Report.

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to Report.

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to Report.

5. CHANGES/PROBLEMS: *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

Changes in approach and reasons for change
Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Nothing to Report.

Actual or anticipated problems or delays and actions or plans to resolve them
Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

As detailed in the quarterly report submitted August 2022, Northwell Health's IRB board originally designated our alcohol cessation protocol as a non-significant risk medical device study. This designation would have categorized our intervention tool as an FDA-regulated product and would have introduced unanticipated regulatory burden and financial considerations. After discussing and receiving support from our Scientific Officer at the DOD on 29 July 22, we successfully appealed this decision to have the Northwell IRB reassess our protocol under FDA enforcement discretion. These activities unfortunately delayed our final OHRO approval to allow us to begin Major Task 2, and thus pilot RCT activities in Major Tasks 3 and 4. We do not believe this delay will have an impact on our overall award timeline.

Changes that had a significant impact on expenditures
Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

Due to the administrative delays explained above, the project has not yet begun enrollment for pilot RCT activities as originally planned to begin during Year 1. Consequently, these expenditures will need to shift to begin in Year 2. Additionally, this project has experienced unanticipated delays working with administration at the VA site to establish a purchase order to allow Northwell to pay the site for subaward expenses. The issue is ongoing at the time of this report.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Nothing to Report.

Significant changes in use or care of human subjects

Nothing to Report.

Significant changes in use or care of vertebrate animals

Nothing to Report.

Significant changes in use of biohazards and/or select agents

Not Applicable.

6. **PRODUCTS:** *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*

- **Publications, conference papers, and presentations**
  Report only the major publication(s) resulting from the work under this award.

  Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report.

  Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report.

  Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Nothing to Report.

- **Website(s) or other Internet site(s)**
  List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

https://clinicaltrials.gov/ct2/show/NCT05570851 - Public listing to share key study information and publish outcome results.

- **Technologies or techniques**
  Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

  Nothing to Report.

- **Inventions, patent applications, and/or licenses**
  Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

  Nothing to Report.

- **Other Products**
  Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:
  - *data or databases;*
  - *physical collections;*
  - *audio or video products;*
  - *software;*
  - *models;*
  - *educational aids or curricula;*
  - *instruments or equipment;*
  - *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
  - *clinical interventions;*
  - *new business creation; and*
  - *other.*

Nothing to Report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?
Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".

Name: Michael Diefenbach
Project Role: Principal Investigator
Researcher Identifier (ORCID ID): 0000-0003-2821-1507
Nearest person month worked: 2 (15% effort)
Contribution to Project: Dr. Diefenbach oversees and is responsible for all preparation, conduct, science, and administration of the project.

Name: Allison Marziliano
Project Role: Northwell Co-Investigator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1 (10% effort)
Contribution to Project: Dr. Marziliano assists Dr. Diefenbach with the preparation, conduct, and science of the project. She has contributed to the development of all study materials.

Name: Maged Ghaly
Project Role: Northwell Co-Investigator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1 (5% effort)
Contribution to Project: Dr. Ghaly is a HNC expert and has advised the protocol development and content created to-date.

Name: Jonathan Morgenstern
Project Role: Co-investigator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked:1 (10% effort)
Contribution to Project: Dr. Morgenstern is an expert in alcohol cessation programming and assists with the development of the technological platform to deliver alcohol cessation messaging. He has provided guidance to the development of content in Major Task 2.

Name: Svetlana Levak
Project Role: Bottle cap program manger
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1 (10% effort)
Contribution to Project: Dr. Levak is a text-message intervention expert and assists with the development of the technological platform to deliver alcohol cessation messaging and provides technical guidance. She has provided guidance to the development of content in Major Task 2.

Name: Stephanie Izard
Project Role: Biostatistician
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1 (5% effort)
Contribution to Project: Ms. Izard leads our data analysis efforts and has contributed to the development of our statistical plan.

Name: Priya Patel
Project Role: Northwell Clinical Research Coordinator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 6 (50% effort)
Contribution to Project: Ms. Patel is the lead Northwell coordinator and has contributed to developing all study materials and applications for institutional review, as well as conducting interviews for Aim 2 at the Northwell site.

Name: Yelena Linchevskaya
Project Role: Narrows (VA) Research Coordinator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 12 (100% effort)
Contribution to Project: Ms. Linchevskaya is the lead VA coordinator and has worked closely with the Northwell team to ensure the protocol received appropriate approvals at the VA. She has conducted interviews for Aim 2 at the VA site.

Name: Jonathan Wallach
Project Role: Narrows (VA) Site PI
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1(5%effort)
Contribution to Project: Dr. Wallach is responsible for overseeing all aspects of the study including subject screening, recruitment, and data collection at the VA.

Name: David Schwartz
Project Role: Narrows (VA) Co-Investigator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1(5% effort)
Contribution to Project: Dr. Schwartz assists with subject screening and recruitment and providing clinical guidance and expertise in all clinical matters at the VA site.

Name: Jennifer Itty
Project Role: Project Manager
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1(7% effort)
Contribution to Project: Ms. Itty has assisted with overall project and administrative management for the grant, working closely with Dr. Diefenbach to ensure milestones are progressing appropriately.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Nothing to Report.

What other organizations were involved as partners?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:
Organization Name:
Location of Organization: (if foreign location list country)
Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*

Organization Name: VA NY Harbor Healthcare System
Location of Organization: Brooklyn, NY
Partner's contribution to the project (identify one or more)

- Collaboration (e.g., partner's staff work with project staff on the project);

8. SPECIAL REPORTING REQUIREMENTS

Not Applicable.

9. APPENDICES: *Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.*

Not Applicable.