AWARD NUMBER: W81XWH-14-2-0007

TITLE: Early Intervention to Reduce Alcohol Misuse and Abuse in the Ohio Army National Guard

PRINCIPAL INVESTIGATOR: Joseph R. Calabrese, MD

CONTRACTING ORGANIZATION: Case Western Reserve University

REPORT DATE: SEPTEMBER 2020

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PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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Distribution Unlimited

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6. AUTHOR(S)
Joseph R. Calabrese, MD; Frederic Blow, PhD

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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Case Western Reserve University
10900 Euclid Ave.
Cleveland, OH 44106-1712

8. PERFORMING ORGANIZATION REPORT NUMBER

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U.S. Army Medical Research and Materiel Command
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13. SUPPLEMENTARY NOTES

14. ABSTRACT

The proposed project is a fully-powered randomized controlled trial of a smartphone-based alcohol brief intervention (SP-BI) versus an Enhanced Usual Care (EUC) condition for National Guard members in the State of Ohio who meet criteria for at-risk drinking in the previous 4 months. After tailoring the content of the SP-BI intervention for NG soldiers, the proposed study will screen ~ 3,100 individuals over the three year enrollment period as part of the larger ongoing longitudinal assessment of ONG members in the OHARNG MHI, to identify 850 participants with at-risk drinking. These ONG members will be randomized to either the SP-BI (n=425) or the EUC condition (n=425) and followed for one year.

15. SUBJECT TERMS
Ohio National Guard, Mental Health, Alcohol Use Disorders, Risky alcohol use, SBIRT (Screening, Brief Intervention, Referral to Treatment) model, Risky

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	39	19b. TELEPHONE NUMBER *(include area code)*

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Page

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

   This project is a fully-powered randomized controlled trial of a smartphone-based alcohol brief intervention (SP-BI) versus an Enhanced Usual Care (EUC) condition for National Guard members in the State of Ohio who meet criteria for unhealthy drinking in the previous 3 months. After tailoring the content of the SP- BI for National Guard soldiers, the proposed study intended to screen ~ 3,100 different individuals over the three year enrollment period as part of the larger yearly ongoing longitudinal assessment of ONG members enrolled in the Ohio Army National Guard Mental Health Initiative (OHARNG MHI), to identify 750 participants with unhealthy drinking. Additional subjects were subsequently added to the pool of potential subjects through in-person recruitment at National Guard annual PHA events. Guard members will be randomized to either the SP-BI (n=375) or the EUC condition (n=375) and followed for one year post-enrollment.

   The specific aims are to compare SP-BI and EUC in:
   1. Reducing the frequency and intensity of at-risk drinking at 4 -, 8- and 12-months;
   2. Decreasing binge drinking at 4 -, 8- and 12 months.

   The secondary aims are to:
   1. Compare the SP-BI and EUC conditions in reducing the frequency of illicit drug use and depressive symptoms at 4 -, 8- and 12-months;
   2. Examine if deployment status moderates the effect of intervention assignment (SP-BI or EUC) on post-intervention drinking, depressed feelings, and other substance use.

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

   Alcohol screening, brief intervention, drinking, military, eHealth, mHealth, social support

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

   What were the major goals of the project?

   Task #1: Customize mobile phone app – and text-based alcohol brief intervention for National Guard (NG) population
   Subtask 1
   Facilitate focus groups, consisting of Ohio NG leadership and soldiers to develop, refine, and tailor the screening questionnaires, assessments, and risk management procedures.
   Subtask 2
   Create mobile phone app – and text-based alcohol brief intervention program and a project management tracking system in the first 9 months of Year 1.

   Task #2: Data Collection
   Subtask 1
   Hire (as necessary) and train all study personnel in Year 1, with ongoing trainings held each year as needed.

Subtask 2
Starting in the 4th quarter of Year 1 through Year 4, enrollment of up to 750 participants (~250 participants/year over 3 years) utilizing the Ohio Army National Guard Mental Health Initiative platform for recruitment

Subtask 3
Participant follow-up at 4, 8, and 12 months through Year 5 (N=750)

Task #3: Data Dissemination
Subtask 1
Starting in Year 2, performance of descriptive analysis of the data including, but not limited to hazardous alcohol use and deployments, and hazardous alcohol use with co-morbid illnesses, i.e. PTSD, depression.
Subtask 2
Upon completion of data collection, at least 1 submission to a peer-reviewed journal will be derived from the study data
Subtask 3
Starting in Year 2, presentations each year of the most recent alcohol data, i.e. at advisory board meetings, poster/symposium presentations at scientific conferences, and presentations for the Ohio NG, as requested.

Task #4: Oversight Meetings
Subtask 1
External Scientific Advisory Board, providing critical feedback on the scientific merit of the project, will be held once annually, Years 1-5.
Subtask 2
Administrative Advisory Board, providing guidance on non-scientific issues, will be held once annually, Years 1-5.
Subtask 3
Sponsor Scientific Meeting (as requested) consisting of programmatic and scientific leaders to provide a scientific and fiscal update.
Subtask 4
Data Safety Monitoring Board, provide information as needed to the quarterly DSMB meetings, held by the Coordinating Center

Task #5: Regulatory & Reporting
Subtask 1
Initial Submission in Year 1, Continuing Reviews in Years 2-5, and addendum submissions as needed, to applicable local IRBs of record
Subtask 2
Obtain Certificate of Confidentiality from DHHS in Year 1
Subtask 3
Initial Submission in Year 1, Continuing Review in Years 2-5, and applicable submissions to the DoD Office of Research Protections
Subtask 4
Quarterly financial reporting to USAMRAA, as required, in Years 1-5

Subtask 5
Annual progress report to USAMRMC in Years 1-4, with a Final Report at the end of Year 5.

Subtask 6
Progress reports to sponsoring agency (as requested)

What was accomplished under these goals?

Task #1: Customize mobile phone app – and text-based alcohol brief intervention for National Guard (NG) population – 100%

University of Michigan Center for Health, Communications, and Research (CHCR) continues to provide ongoing technical support for the app and addresses app issues as they arise.

Task #2: Data Collection – 69% completed
Enrollment for this study began on March 7, 2017 once all the necessary approvals were secured. Abt. Associates, referred 3,669 participants of which 789 were eligible to pre-screen for the study. From this group, 230 participants consented and continued with the screening procedures and of those, 168 were randomized; 88 to the control group and 80 to the Smartphone group.

On February 24, 2018, we began in-person recruitment at Soldier Readiness Processing (SRP; formerly Periodic Health Assessment (PHA)) events held in Columbus, OH. We also attended contract events held at local armories in Ohio. We attended PHA/SRP events on 25 weekends. In mid-2019 the ONG changed the format in which these events are held. Instead of being held on multiple weekends every month, they are now held daily, 7-12 days at a time, every other month. We attended 3 of these week long events. We pre-screened 4,402 soldiers at these in person events, of which 1,036 were eligible to participate in the study. Nine hundred and thirty four (934) of those subjects consented and continued with the screening procedures either in person that day or over the phone the following week. Of those consented, 680 were randomized; 339 to the control group and 341 to the Smartphone group.

In addition, 35 potential participants reached out to sites in response to advertising (n=33) or being referred by a current participant (n=2). Eighteen (18) of them were pre-screened and 2 were eligible to participate. Both of these subjects completed their baseline surveys and we randomized; 1 to the control group and 1 to the Smartphone group.

More detailed enrollment information can be found in the flow charts and enrollment graph at the end of this report.

	Enrolled (Randomized)
Case Western Reserve University	480
University of Toledo	370
Total	850

During this past reporting period, the research coordinator at the University of Toledo (UT) site resigned her position. Her last day on the project was February 14, 2020. A memo was submitted

on February 10, 2020 to USAMRMC informing them that UT would no longer be a recruiting site/involved in subjects follow-up and that all this would take place at the CWRU site, and that the remaining funds UT had for study coordinator effort would also be transferred to CWRU. USAMRMC approved this on February 20, 2020.

Because we are still working to get participants to complete follow up surveys, we submitted and received a 1 year no cost extension, extending the project to August 31, 2021.

Task #3: Data Dissemination – 10% completed
Study investigators have begun preparing a manuscript that describes the methods of this study, as well as reporting on participant engagement with the Project GUARD app that we developed. They have worked on the literature review, preliminary analysis of app engagement data and have started drafting a manuscript.

Task #4: Oversight Meetings – 90% completed
Substance Abuse in Progress Review (IPR)
The 2020 Scientific Advisory Board and Administrative Advisory Board meetings were held concurrently on May 14, 2020. Attendees this year included:

- **Lori Davis, M.D.** - Chief of the Research and Development Service, Tuscaloosa VA Medical Center
- **Colin Fowler, MS, LPCC-S** - Psychological Health Coordinator. Ohio Army National Guard
- **Matthew J. Friedman, MD, PhD** - Professor of Psychiatry, Dartmouth Geisel School of Medicine
- **Joel Gelernter, M.D.** - Professor, Psychiatry, Genetics & Neurobiology, Yale University School of Medicine
- **Robert K. Gifford, Ph.D.** - Senior Project Director, Study to Assess Risk & Resilience Among Service Members (STARRS); Executive Officer, Center for the Study of Traumatic Stress, Department of Psychiatry, USUHS
- **Richard A. McCormick, Ph.D.** - Senior Scholar, Center for Healthcare Research & Policy, MetroHealth Medical Center, Case Western Reserve University
- **Thomas A. Mellman, M.D.** - Prof Psychiatry, Director, Clinical and Translational Research and Stress and Sleep Studies, Howard University College of Medicine

Please see the attached slides for an overview of the presentation.

Task #5: Regulatory & Reporting – 90% completed
University Hospitals Institutional Review Board (IRB)

- The University Hospitals Institutional Review Board (IRB) - The most recent continuing review was approved on June 11, 2020. The current expiration date for the study is June 10, 2021.
- USAMRMC ORP HRPO – The most recent UHCMC IRB approval was submitted to HRPO on July 10, 2020 and is currently pending the acknowledgment memo.

University of Toledo (UT)

- The University of Toledo Biomedical Institutional Review Board - The most recent continuing review was approved December 19, 2019. The current expiration date for the study is December 18, 2020.
- USAMRMC ORP HRPO – The most recent UT IRB approval was sent to HRPO on January 1, 2020 and is currently pending the acknowledgment memo.

University of Michigan (UM)

- University of Michigan Medical School Institutional Review Board (IRBMED) - The most recent continuing March 11, 2021.
- USAMRMC ORP HRPO – The most recent UM IRB approval was sent to HRPO on April 10, 2020. The acknowledgment memo was received May 1, 2020.

Over the past year, the Data Safety Monitoring Board has met three times. As there have been no AEs or SAEs since the study began, they had no concerns with the study continuing as is.

What opportunities for training and professional development has the project provided?
Nothing New to Report

How were the results disseminated to communities of interest?
Nothing to Report

What do you plan to do during the next reporting period to accomplish the goals?

Task #1: Customize Computer Intervention for National Guard (NG) population
CHCR will continue to provide ongoing support for the app throughout the enrollment period.

Task #2: Data Collection
Over the next year, study staff will continue call, email and text participants to complete their follow-up surveys. Study staff will also continue to do risk assessments as needed.

We anticipate data collection to end in April 2021.

Data management staff will continue to maintain the study database in REDCap and complete real time quality assurance of data. Once all subjects have completed their follow-up surveys, data management staff will export the data from REDCap, clean the data and provide the data to data analysts at UM so they may complete data analysis.

Task #3: Data Dissemination
Study investigators will continue on the methods manuscript. In addition, once data collection is cone, the data has been cleaned and the data has been analyzed, the primary outcome manuscript will be written and submitted for publication.

Task #4: Oversight Meetings
We will continue to hold oversight meetings as required.

Task #5: Regulatory & Reporting
Over the next reporting period, we will continue to submit quarterly financial and technical reports to USAMRAA as required. In addition, we wait to hear from the USAMRMC Office of Research Protections Human Research Protection Office regarding approval to begin enrollment.

4. **IMPACT:** Describe 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?
Nothing to report.

What was the impact on other disciplines?
Nothing to report.

What was the impact on technology transfer?
Nothing to report.

What was the impact on society beyond science and technology?
Nothing to report.

5. **CHANGES/PROBLEMS:** The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer 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
Noting to report

Actual or anticipated problems or delays and actions or plans to resolve them
Recruitment was our major challenge in the previous years of this award. However, through a number of parallel initiatives and approved changes to the protocol procedures, we were able to not only meet, but also exceed our original recruitment goal of 750 subjects by enrolling 850 subjects.

Changes that had a significant impact on expenditures
Noting to report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
Noting to report

Significant changes in use or care of human subjects
Noting to report

Significant changes in use or care of vertebrate animals.
No activities involving the use or care of vertebrate animals will be performed to complete this project.

Significant changes in use of biohazards and/or select agents
No activities involving the use biohazards and/or select agents will be performed to complete this project.

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**
  Nothing to Report
- **Books or other non-periodical, one-time publications.**
  Nothing to Report
- **Other publications, conference papers, and presentations.**
  Nothing to report.
- **Website(s) or other Internet site(s)**
  Nothing to Report
- **Technologies or techniques**
  Project GUARD app
- **Inventions, patent applications, and/or licenses**
  Licenses to place Project GUARD app on iPhone and Android app stores
- **Other Products**
  Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

Name: Joseph R. Calabrese, MD
Project Role: Principal Investigator
Researcher Identifier (e.g. ORCID ID): ERA Commons - jcalabrese
Nearest person month worked: 0.3 calendar months
Contribution to Project: Oversight and ongoing administration of all aspects of the Ohio Army National Guard Mental Health Initiative. Dr. Calabrese provides oversight of the sites and serves as the liaison between the Scientific PI and the Steering Committee of the primary platform project. Dr. Calabrese is also the primary liaison with the Ohio Army National Guard leadership.

Name: Carla Conroy, MPH
Project Role: Project Manager
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1.8 calendar months
Contribution to Project: Ms. Conroy provided administrative support during this reporting period and ongoing grant and fiscal management including payment of subcontracts, employee reimbursement, and sub-contract execution and monitoring. She has also been responsible for managing IRB and HRPO submissions, oversight of regulatory documents, and ensuring ongoing

compliance with reporting requirements. In addition, she has coordinated with the sites and provided feedback regarding ongoing enrollment and recruitment and has assisted with in person recruitment as needed.

Name: Brittany Brownrigg, BS
Project Role: Data Coordinator
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 0.90 calendar months
Contribution to Project: Ms. Brownrigg provided ongoing data management support and worked with the sites to quality assure data in real time. She provides ongoing maintenance to the database as needed.

Name: Nicole Woods, BA
Project Role: Research Coordinator II
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 9.60 calendar months
Contribution to Project: Ms. Woods has been responsible for the recruitment and enrollment of participants. She has worked with participants to expedite the completion of the consent process and baseline intervention. She follows up with participants as needed and continues to work on the content for the application and responding to participant questions and concerns.

Name: Nicole Jones, MS
Project Role: Research Coordinator II
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 0.6
Contribution to Project: Ms. Jones has assisted with the recruitment and enrollment of participants. Ms. Jones last day on the project was in March 2020.

Name: Janice Lee, RN
Project Role: Research Coordinator
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 4.5 calendar months
Contribution to Project: Ms. Lee is responsible for following up with participants who need to complete the 4-, 8- and 12-month surveys via email, phone and text messaging.

Name: Mandy Rivera, RRT
Project Role: Research Coordinator
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 4.5 calendar months
Contribution to Project: Ms. Rivera is responsible for following up with participants who need to complete the 4-, 8- and 12-month surveys via email, phone and text messaging.

Name: Matt DeLuca
Project Role: Research Coordinator
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 6.0 calendar months

Contribution to Project: Mr. DeLuca is responsible for following up with participants who need to complete the 4-, 8- and 12-month surveys via email, phone and text messaging.

Name: Kathryn Clark
Project Role: Research Coordinator
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 4.8 calendar months
Contribution to Project: Ms. Clark is responsible for following up with participants who need to complete the 4-, 8- and 12-month surveys via email, phone and text messaging.

Name: John Wryobeck, PhD
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID): N/A
Nearest Person Month: 0.6 calendar months
Contribution to Project: Dr. Wryobeck has returned as of January 1 2020 at 5%. He is overseeing the closing down of the Toledo site as a participant recruiting/follow-up site.

Name: Cheryl McCullumsmith, MD PhD
Project Role: Interim Site Principal Investigator
Researcher Identifier (e.g. ORCID ID):
Nearest Person Month: 3 calendar months
Contribution to Project: Dr. McCullumsmith assumed responsibility as interim site PI when Dr. Wryobeck went on medical leave in June 2019. She is responsible for the oversight of the efforts committed by the University of Toledo and is at a no-cost effort on this project.

Name: Ann Mary Mercier
Project Role: Research Assistant
Researcher Identifier (e.g. ORCID ID): N/A
Nearest Person Month: 12 calendar months
Contribution to Project: Ms. Mercier continues to utilize RedCap through University Hospitals (UH) in Cleveland for participant recruitment and assessment. She is handling IRB amendments and renewals at the University of Toledo for this project. She has contributed the following: 1) maintained app content for the brief intervention (newsfeeds for 12 weeks, Health Coach introductions and tips planner messages), 2) maintained a list of app and newsfeed-related issues and monitored issue progress, 3) maintained a project EndNote account with content references, 4) maintained all aspects of the app newsfeed (blog postings, confederate comments, replies to participant comments), 5) monitored the app health coach function, 6) conducted multiple pre-screening/consenting, follow-up sessions and risk assessments with participants including in-person recruiting at ONG PHA/SRP events in Columbus and other locations in Ohio, and 7) updated literature regarding MHealth app utilization in behavioral health and substance use prevention and other study-related topics. In addition, Ms. Mercier has participated in bi-weekly inter-institutional project teleconferences, PI meetings, and supervisory meetings. Ms. Mercier worked to close out participant recruitment and follow-up files at the Toledo site and transferred any files and tasks to the UH recruitment/follow-up site prior to her leaving employment. Ms. Mercier's last day on the project was February 14, 2020.

Name: Frederic C. Blow, PhD
Project Role: Scientific Principal Investigator
Researcher Identifier (e.g. ORCID ID): ERA Commons - fredblow
Nearest person month worked: 1.72 calendar months
Contribution to Project: Dr. Blow has provided ongoing oversight of the initiative.

Name: Kristen Barry Haenchen, PhD
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID): ERA Commons - kbarry
Nearest person month worked: 2.4 calendar months
Contribution to Project: Dr. Haenchen provided input on intervention content for the mobile phone app and with the recruitment and follow-up phases of the study.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
Nothing to report

What other organizations were involved as partners?
Nothing to report.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: For collaborative awards, independent reports are required from BOTH the Initiating PI and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to **https://ers.amedd.army.mil** for each unique award.

Not applicable

QUAD CHARTS: If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.

Quad Chart attached

9. APPENDICES

Study Enrollment Graph
Study Flowcharts
Scientific/Administrative Advisory Board Meeting Slides

Early Intervention to Reduce Alcohol Misuse and Abuse in the Ohio Army National Guard

Log Number: 13277015

Award Number: W81XWH-14-2-0007

PI: Joseph R. Calabrese, M.D **Org:** Case Western Reserve University **Award Amount:** $3,667,349

Study Aims

Specific Aims

1. Compare the SP-BI and EUC conditions in reducing the frequency and intensity of at-risk drinking at 4, 8, and 12 months post-intervention.
2. Compare the SP-BI and EUC conditions for binge drinking at 4-, 8- and 12 months

Secondary Aims

1. Compare the SP-BI and EUC conditions in reducing the frequency of illicit drug use and depressive symptoms at 4-, 8- and 12 months.
2. Examine the impact of the interaction of deployment status with intervention condition (SP-BI or EUC) on 4-, 8- and 12-month measures of alcohol and drug use

Approach

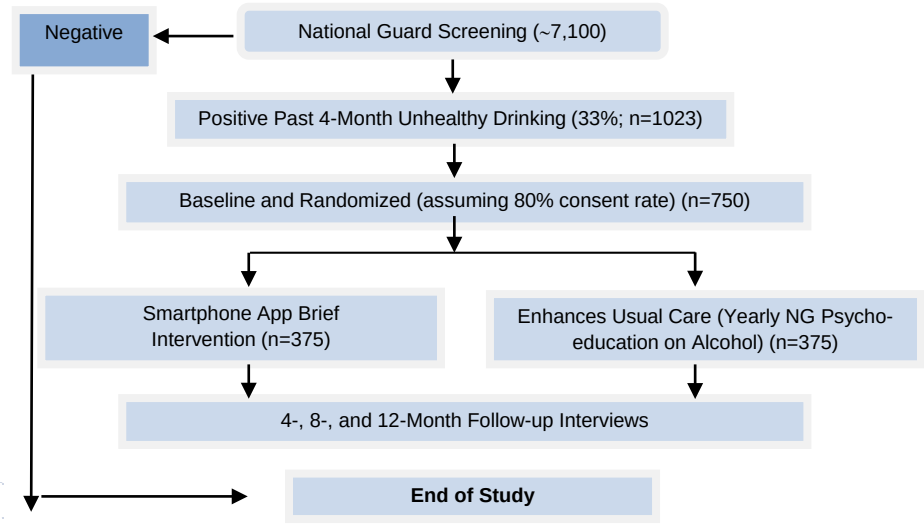
- The proposed project is a fully-powered randomized controlled trial of a smartphone app-based alcohol brief intervention (SP-BI) versus an Enhanced Usual Care (EUC) condition for National Guard members in the State of Ohio who meet criteria for unhealthy drinking in the previous 4 months.
- After tailoring the content of the MT- BI intervention for National Guard soldiers, the proposed study will screen ~ 3,100 different individuals over the three year enrollment period as part of the larger yearly ongoing longitudinal assessment of ONG members enrolled in the OHARNG MHI, to identify 750 participants with unhealthy drinking.
- These Guard members will then be randomized to either the SP-BI (n=375) or the EUC condition (n=375) and followed for one year post-enrollment.

Timeline and Cost

Activities CY	14-15	15-16	16-17	17-18	18-19	19 - 20
Customize Intervention/ App for National Guard (NG) population						
Data Collection						
Data Dissemination						
Oversight Meetings						
Estimated Budget	$1.1mil	$623K	$631K	$644K	$652K	NCE

Updated: 9/22/2020

Study Design Overview



Goals/Milestones

CY14-15 Goals: ☑ Customize Intervention/App ☑ Data Collection ☑ Oversight Meetings

CY15-16 Goals: ☑ Customize Intervention/App ☑ Data Collection ☑ Oversight Meetings

CY16-17 Goals: ☑ Data Collection ☑ Oversight Meetings

CY17-18 Goals: ☑ Data Collection ☑ Data Dissemination ☑ Oversight Meetings

CY18-19 Goals: ☑ Data Collection ☑ Data Dissemination ☑ Oversight Meetings

CY19-20 Goals: ☐ Data Collection ☐ Data Dissemination ☑ Oversight Meetings

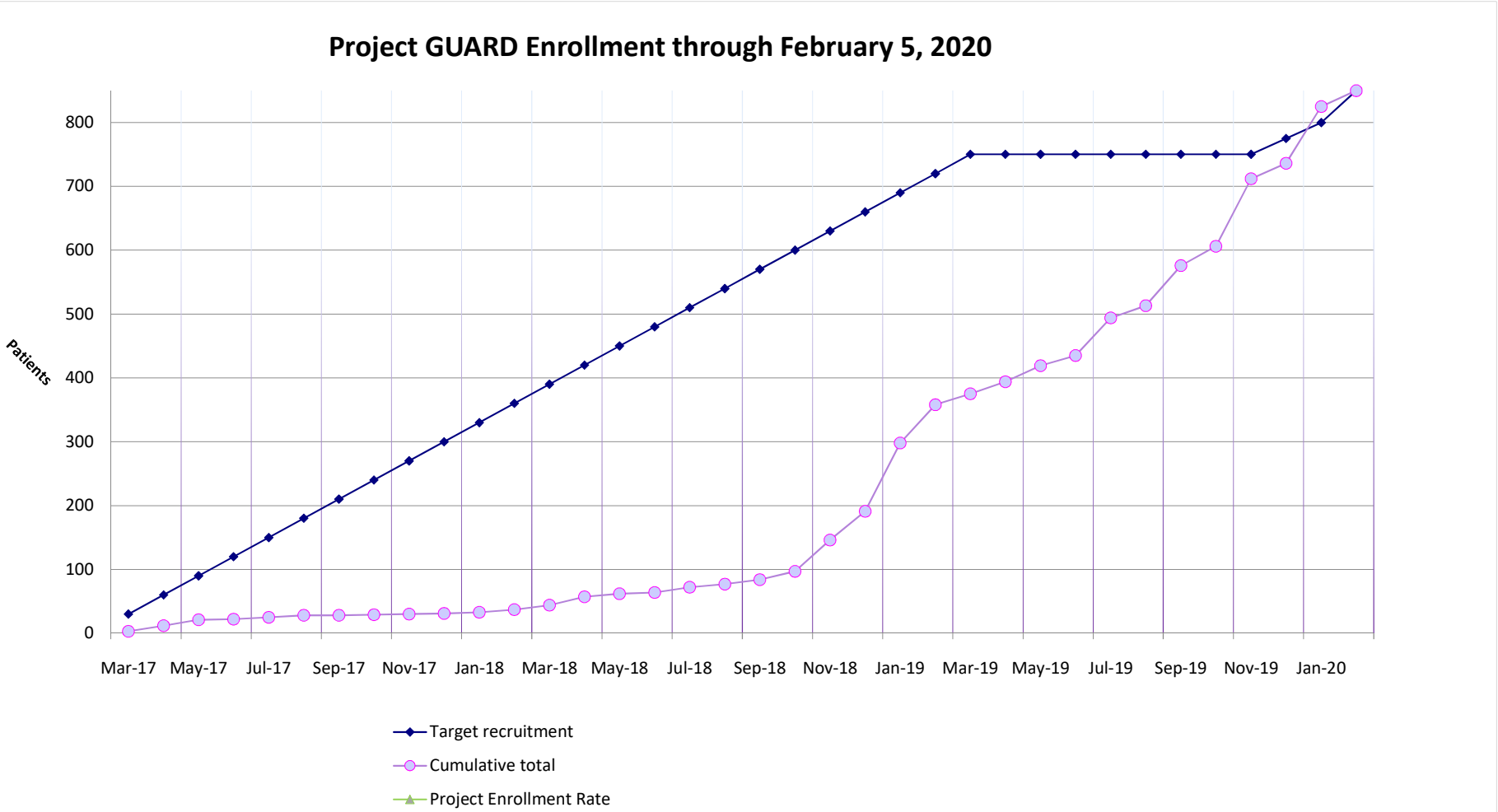
Comments/Challenges/Issues/Concerns

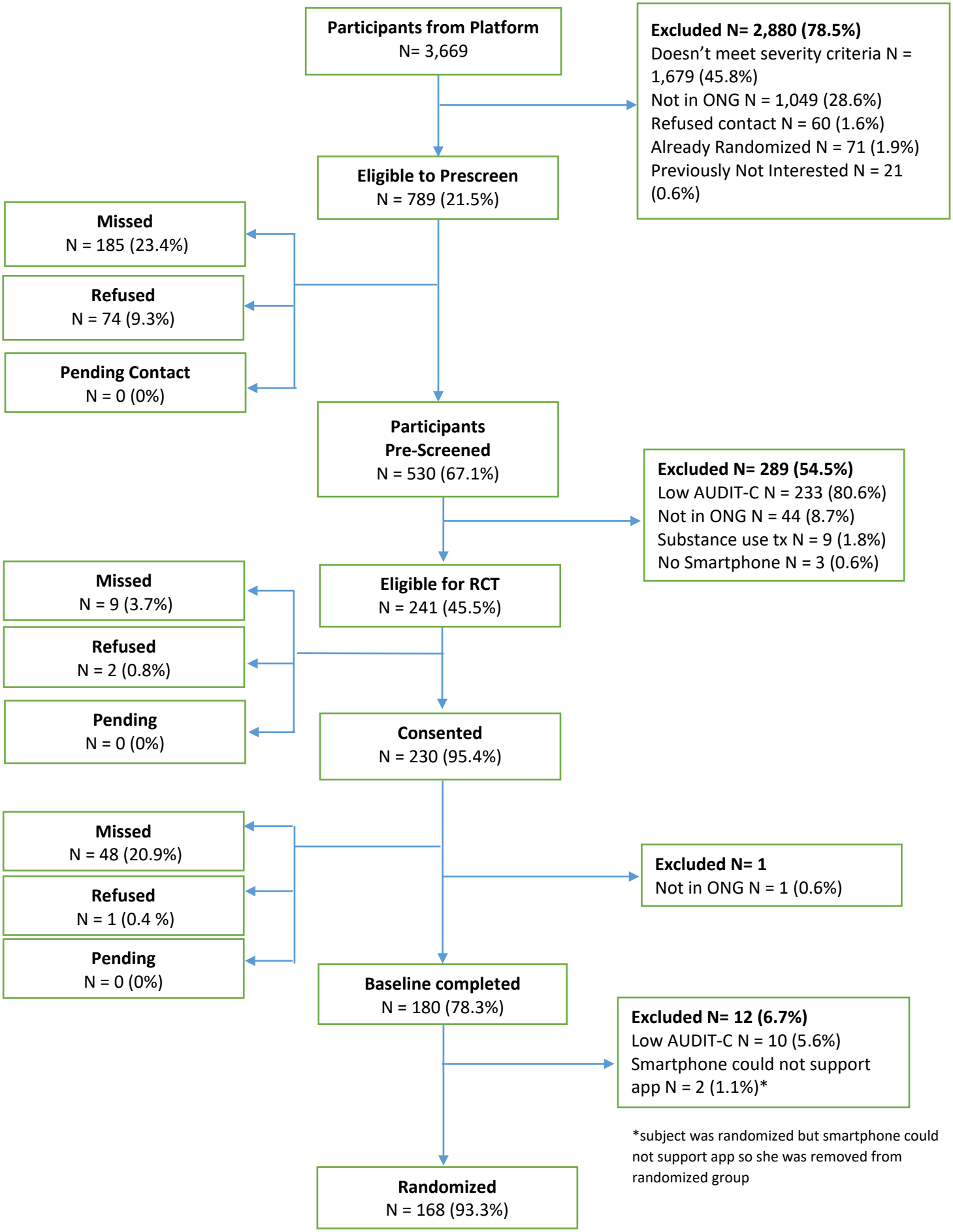
Enrollment has been slower than expected as a large number of subjects in the primary platform study are no longer active in the OHARNG (54.2%), which is an inclusion criteria for participation in the study. We are currently recruiting outside of the OHARNG study and are enrolling former National Guard solders to assist with meeting our recruitment goal.

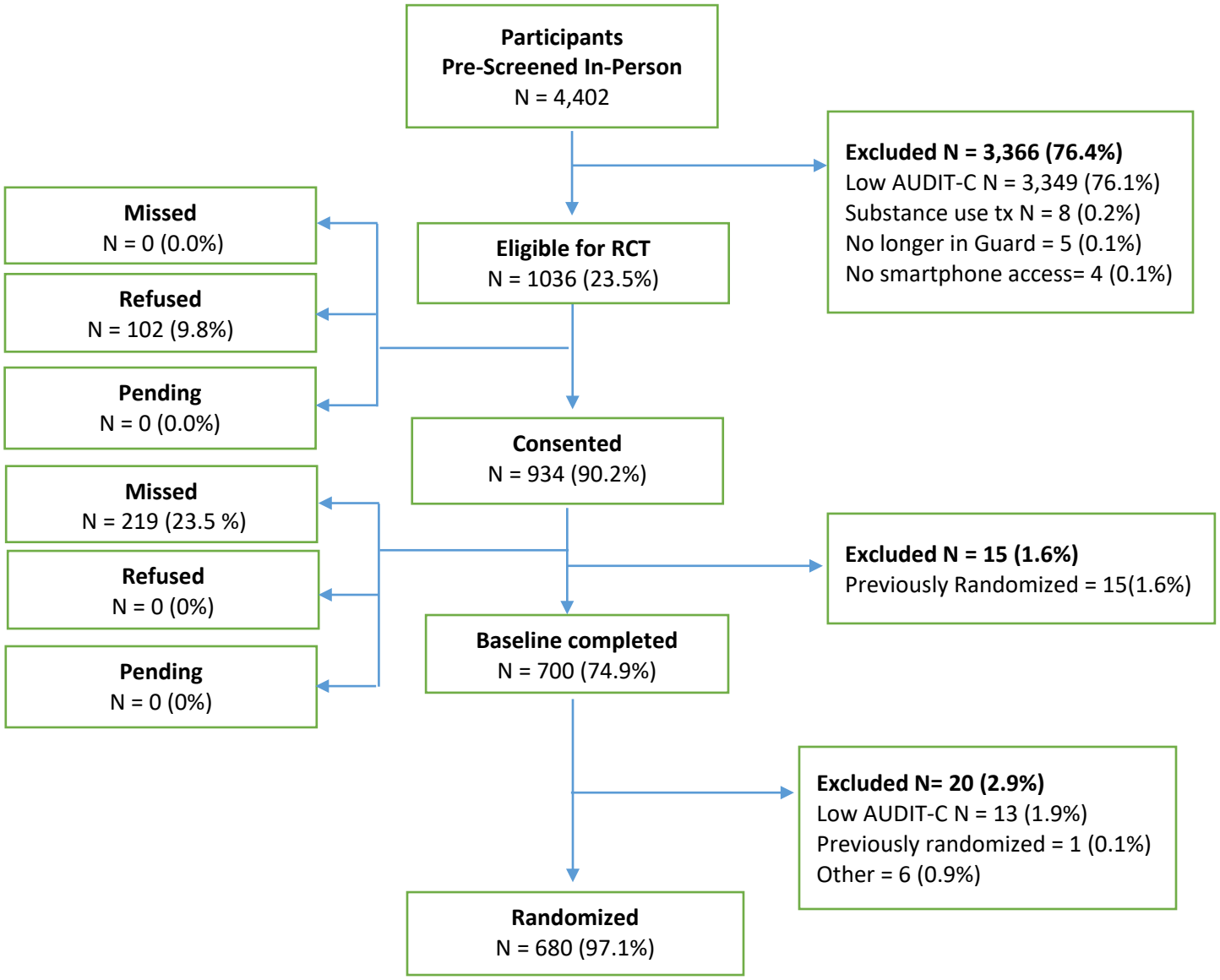
Budget Expenditure to Date (Expenditures below include expenses through August 2020)

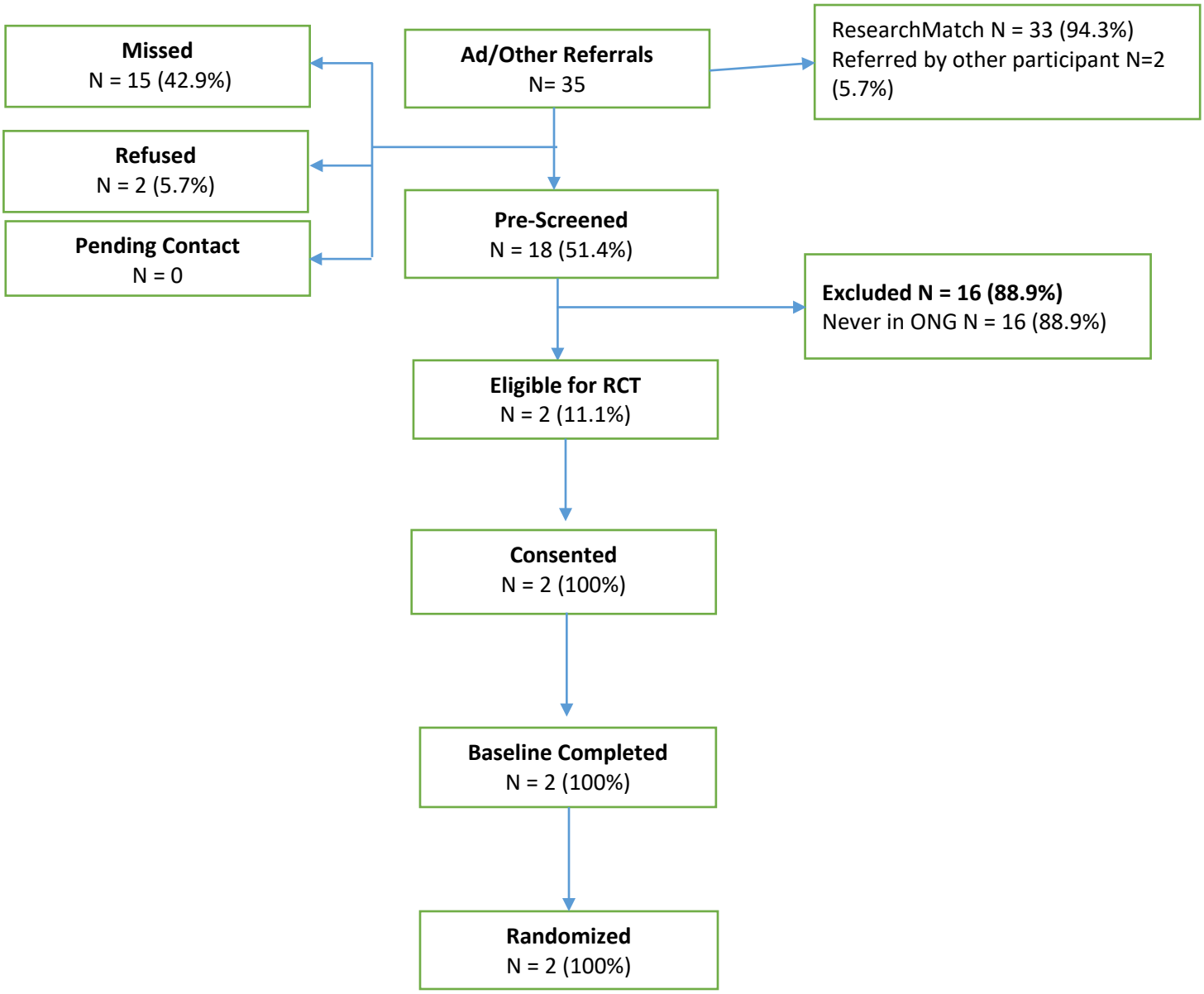
Projected Expenditure: $3,667,349

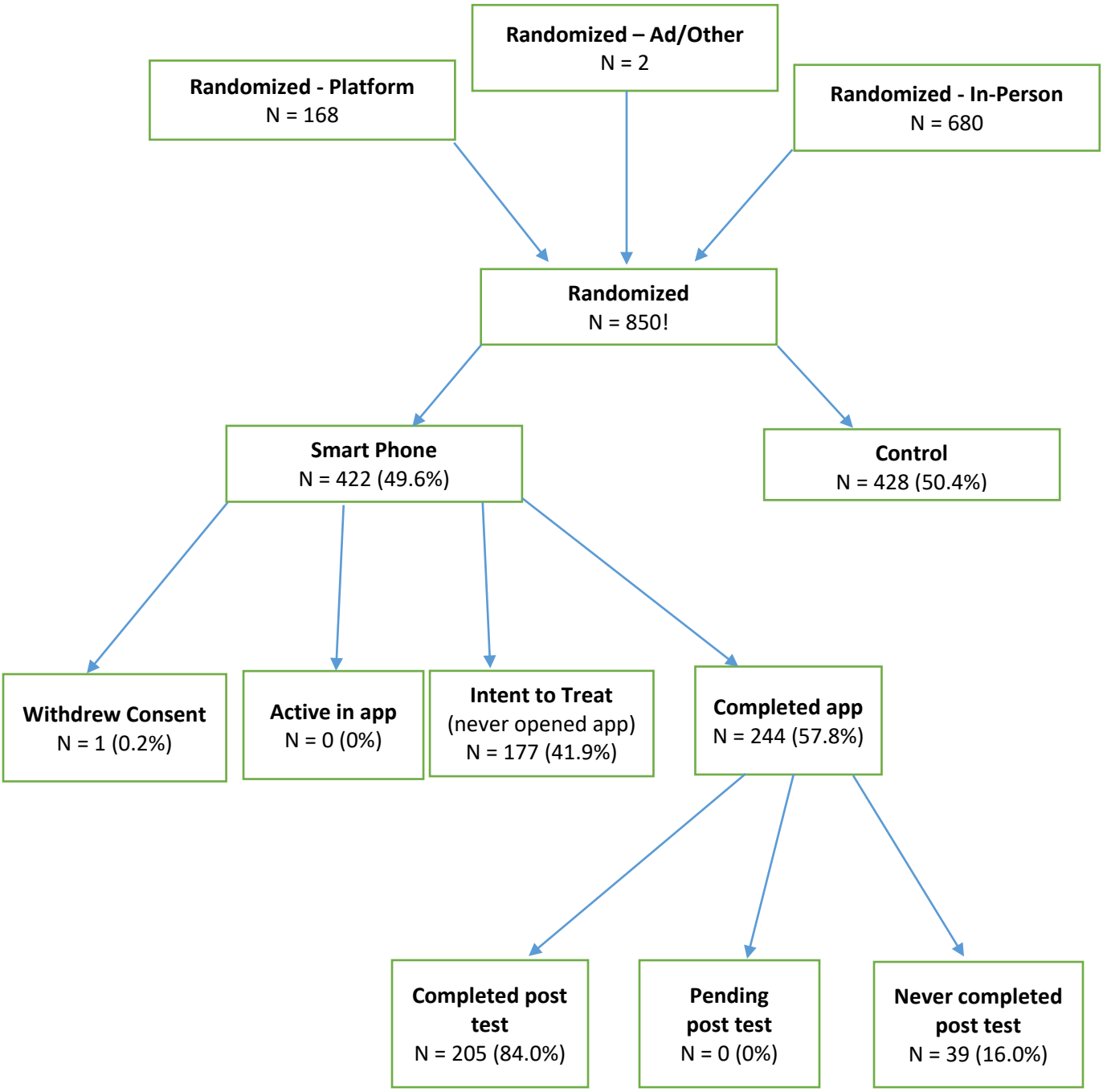
Actual Expenditure: $2,923,156


Project GUARD Enrollment through February 5, 2020
Patients
0
100
200
300
400
500
600
700
800
Mar-17
May-17
Jul-17
Sep-17
Nov-17
Jan-18
Mar-18
May-18
Jul-18
Sep-18
Nov-18
Jan-19
Mar-19
May-19
Jul-19
Sep-19
Nov-19
Jan-20
Target recruitment
Cumulative total
Project Enrollment Rate


Participants from Platform
N= 3,669
Excluded N= 2,880 (78.5%)
Doesn't meet severity criteria N = 1,679 (45.8%)
Not in ONG N = 1,049 (28.6%)
Refused contact N = 60 (1.6%)
Already Randomized N = 71 (1.9%)
Previously Not Interested N = 21 (0.6%)
Eligible to Prescreen
N = 789 (21.5%)
Missed
N = 185 (23.4%)
Refused
N = 74 (9.3%)
Pending Contact
N = 0 (0%)
Participants Pre-Screened
N = 530 (67.1%)
Excluded N= 289 (54.5%)
Low AUDIT-C N = 233 (80.6%)
Not in ONG N = 44 (8.7%)
Substance use tx N = 9 (1.8%)
No Smartphone N = 3 (0.6%)
Missed
N = 9 (3.7%)
Refused
N = 2 (0.8%)
Pending
N = 0 (0%)
Eligible for RCT
N = 241 (45.5%)
Consented
N = 230 (95.4%)
Missed
N = 48 (20.9%)
Refused
N = 1 (0.4 %)
Pending
N = 0 (0%)
Excluded N= 1
Not in ONG N = 1 (0.6%)
Baseline completed
N = 180 (78.3%)
Excluded N= 12 (6.7%)
Low AUDIT-C N = 10 (5.6%)
Smartphone could not support app N = 2 (1.1%)*
*subject was randomized but smartphone could not support app so she was removed from randomized group
Randomized
N = 168 (93.3%)


Participants
Pre-Screened In-Person
N = 4,402
Excluded N = 3,366 (76.4%)
Low AUDIT-C N = 3,349 (76.1%)
Substance use tx N = 8 (0.2%)
No longer in Guard = 5 (0.1%)
No smartphone access= 4 (0.1%)
Missed
N = 0 (0.0%)
Refused
N = 102 (9.8%)
Pending
N = 0 (0.0%)
Eligible for RCT
N = 1036 (23.5%)
Consented
N = 934 (90.2%)
Missed
N = 219 (23.5 %)
Refused
N = 0 (0%)
Pending
N = 0 (0%)
Excluded N = 15 (1.6%)
Previously Randomized = 15(1.6%)
Baseline completed
N = 700 (74.9%)
Excluded N= 20 (2.9%)
Low AUDIT-C N = 13 (1.9%)
Previously randomized = 1 (0.1%)
Other = 6 (0.9%)
Randomized
N = 680 (97.1%)


Missed
N = 15 (42.9%)
Refused
N = 2 (5.7%)
Pending Contact
N = 0
Ad/Other Referrals
N= 35
ResearchMatch N = 33 (94.3%)
Referred by other participant N=2 (5.7%)
Pre-Screened
N = 18 (51.4%)
Excluded N = 16 (88.9%)
Never in ONG N = 16 (88.9%)
Eligible for RCT
N = 2 (11.1%)
Consented
N = 2 (100%)
Baseline Completed
N = 2 (100%)
Randomized
N = 2 (100%)


Randomized – Ad/Other
N = 2
Randomized - Platform
N = 168
Randomized - In-Person
N = 680
Randomized
N = 850!
Smart Phone
N = 422 (49.6%)
Control
N = 428 (50.4%)
Withdrew Consent
N = 1 (0.2%)
Active in app
N = 0 (0%)
Intent to Treat
(never opened app)
N = 177 (41.9%)
Completed app
N = 244 (57.8%)
Completed post test
N = 205 (84.0%)
Pending post test
N = 0 (0%)
Never completed post test
N = 39 (16.0%)

4 Month Follow Up

	Smart Phone		Control		Total	
	422		428		850	
	N	%	N	%	N	%
In Progress (<= 14 days)	0	0.0%	0	0.0%	0	0.0%
Outstanding (>15 days)	5	1.2%	7	1.6%	12	1.4%
Completed	246	58.3%	305	71.3%	551	64.8%
Not Completed	171	40.5%	116	27.1%	287	33.8%

8 Month Follow Up

	Smart Phone		Control		Total	
	357		368		725	
	N	%	N	%	N	%
In Progress (<= 14 days)	3	0.8%	2	0.5%	5	0.7%
Outstanding (>15 days)	37	10.4%	30	8.2%	67	9.2%
Completed	194	54.3%	221	60.1%	415	57.2%
Not Completed	123	34.5%	115	31.3%	238	32.8%

12 Month Follow Up

	Smart Phone		Control		Total	
	249		258		507	
	N	%	N	%	N	%
In Progress (<= 14 days)	0	0.0%	1	0.4%	1	0.2%
Outstanding (>15 days)	19	7.6%	23	8.9%	42	8.3%
Completed	146	58.6%	162	62.8%	308	60.7%
Not Completed	84	33.7%	72	27.9%	156	30.8%

Updated 8/31/2020

Early Intervention to Reduce Alcohol Misuse and Abuse in the Ohio Army Reserve National Guard

Scientific Advisory Board Meeting

May 14, 2020

Principal Investigators

Coordinating PI:	Joseph R. Calabrese, MD Case Western Reserve University
Scientific PI:	Frederic Blow, PhD Department of Veterans Affairs and University of Michigan
Site PI:	Cheryl McCullumsmith, M.D., Ph.D. University of Toledo

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Colin Fowler, LPCC-S

Background and Rationale

Problem Addressed

- **Hazardous use of alcohol is a significant problem in the National Guard members that contributes to and complicates other problems including PTSD, depression, suicidality, lowered resilience and work performance.**
- **Studies consistently find that substantial number of Guard members misuse alcohol.**
- **Addressing misuse is particularly challenging in reserve component soldiers who are geographically dispersed and must divide their time between military and civilian responsibilities.**

Theoretical Rationale

- **Screening, Brief Intervention and Referral to Treatment model has been shown to effectively impact misuse on population basis.**
- **An eHealth intervention, tailored to National Guard, could provide a cost effective tool to enhance alcohol programming. New surveys verify that over half of Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF) veterans willing to use E-mental health (highest rates for youngest)**

Research Questions and Hypotheses

The specific aims are to compare SP-BI and EUC in:

1. Reducing the frequency and intensity of at-risk drinking at 4 -, 8- and 12-months;
2. Decreasing binge drinking at 4-, 8- and 12 months.

Hypotheses for specific aims:

1. Participants randomized to the SP-BI condition will report significantly fewer days/week drinking and fewer drinks/day than participants in the EUC condition at follow-ups.

2. Participants randomized to the SP-BI condition will report significantly fewer binge drinking episodes compared to the EUC participants at follow-ups.

Design and Methodology

Phase I: Development of Phone App Intervention

- Informed by literature and initial experience in NIAAA-funded Michigan National Guard Web-based study
- Investigators and app developers, in collaboration with a team of Ohio Guard members, brainstormed best options for phone app
- Focused on shortening initial interaction (compared to web approaches) and maximizing engagement in an ongoing therapeutic/educational interaction
- Emphasized relevance to complex life patterns of Guard members (e.g. military commitment, civilian employment, other civilian roles, deployment disruptions and stress)

Design and Methodology

Phase II: Randomized Trial of App Intervention

- Participants were pre-screened for eligibility, then consented
- Eligibility:
  - Past 4-month AUDIT-C score of 5 for men and 4 for women
  - Current or former member of the OHARNG
  - Not in substance use treatment
  - Own a smartphone
- Complete baseline assessment (~40 minutes)
- Randomization stratified by gender and severity of use
- Two groups:
  - Smart Phone App Brief Intervention (SP-BI) (12 weeks)
  - Enhanced Usual Care (EUC) (Brochure with Resources)
- 4, 8, 12 month follow-up assessments
- Payment: $35 for Baseline, 4-month and 8-month surveys; $40 for 12-month survey; additional $15 for those in SP-BI who complete a post-app survey

Study Progress

Regulatory:

- All sites have Instructional Review Board (IRB) and U.S. Army Medical Research and Materiel Command Human Research Protections Office (USAMRMC) approval
- Certificate of Confidentiality obtained from NIH

Phase I: Development of Intervention App

- App modified and IRB changes made for removal of contingency management functions as requested by USAMRMC
- App has been fully developed, beta tested for both iOS and Android platforms, and is available in app stores
- Early enrollees carefully monitored for glitches in app that might reduce compliance

Study Progress

Phase II: Recruitment

- Enrollment began March, 2017 and was completed February, 2020.
- Enrollment was conducted with three parallel approaches:

1) Ohio Army National Guard Mental Health Initiative (OHARNG-MHI) longitudinal platform study, ongoing cohort: These subjects (N=3,651) have participated for the past six years in an annual assessment, and have participated in other studies. For this study we will include only those who are still presently in the Guard (~45%) and meet drinking criteria.
2) OHARNG-MH longitudinal platform, replenishment cohorts: Each year new subjects are added to the platform to replenish the sample, we will have access to the 2017 and 2018 samples (N=1,000). All will be currently in the ONG.
3) Active Ohio Army National Guard members recruited at their Periodic Health Assessments (PHA): ONG brings all units to a central location early in the calendar year for a full day to complete the PHA. We have obtained the required approvals and now have a physical presence at the PHA's to recruit in person.

Study Progress

Changes implemented to improve recruitment

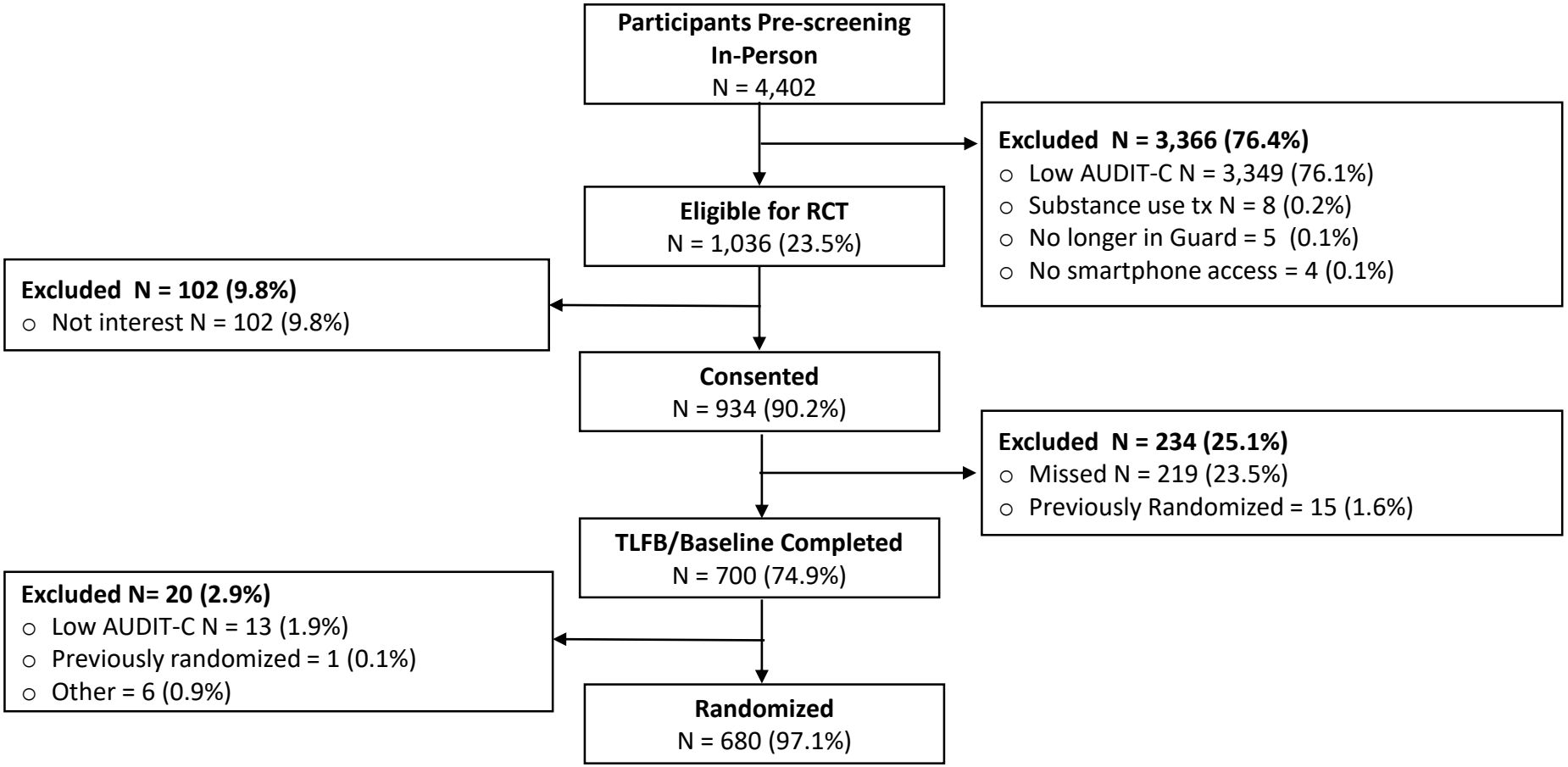
- Changed inclusion criteria to allow for OHARNG members who were no longer active in the Guard
- Provided those who pre-screened with a $10 Amazon e-gift card and small gifts as a thank you (mini-notebooks and small wallets)

Changes implemented to improve retention

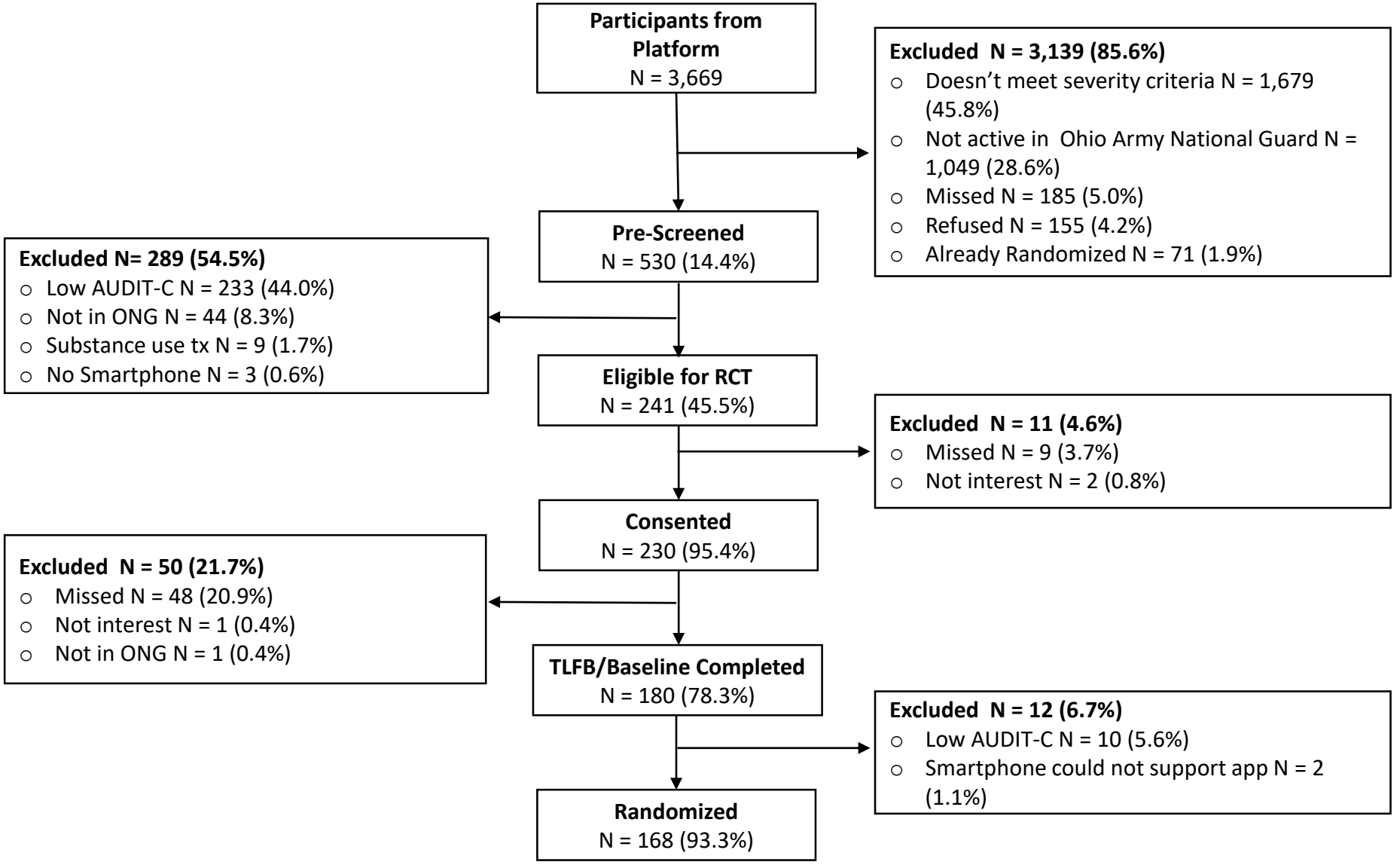
- Provided small gifts in between survey time points (calendar magnets, letter openers, ear buds, cellphone pockets)
- Working to increase 12-month stipend from $40 to $50

In order to account for lower than anticipated follow-up rates, we increased the total number of subjects randomized from 750 to 850

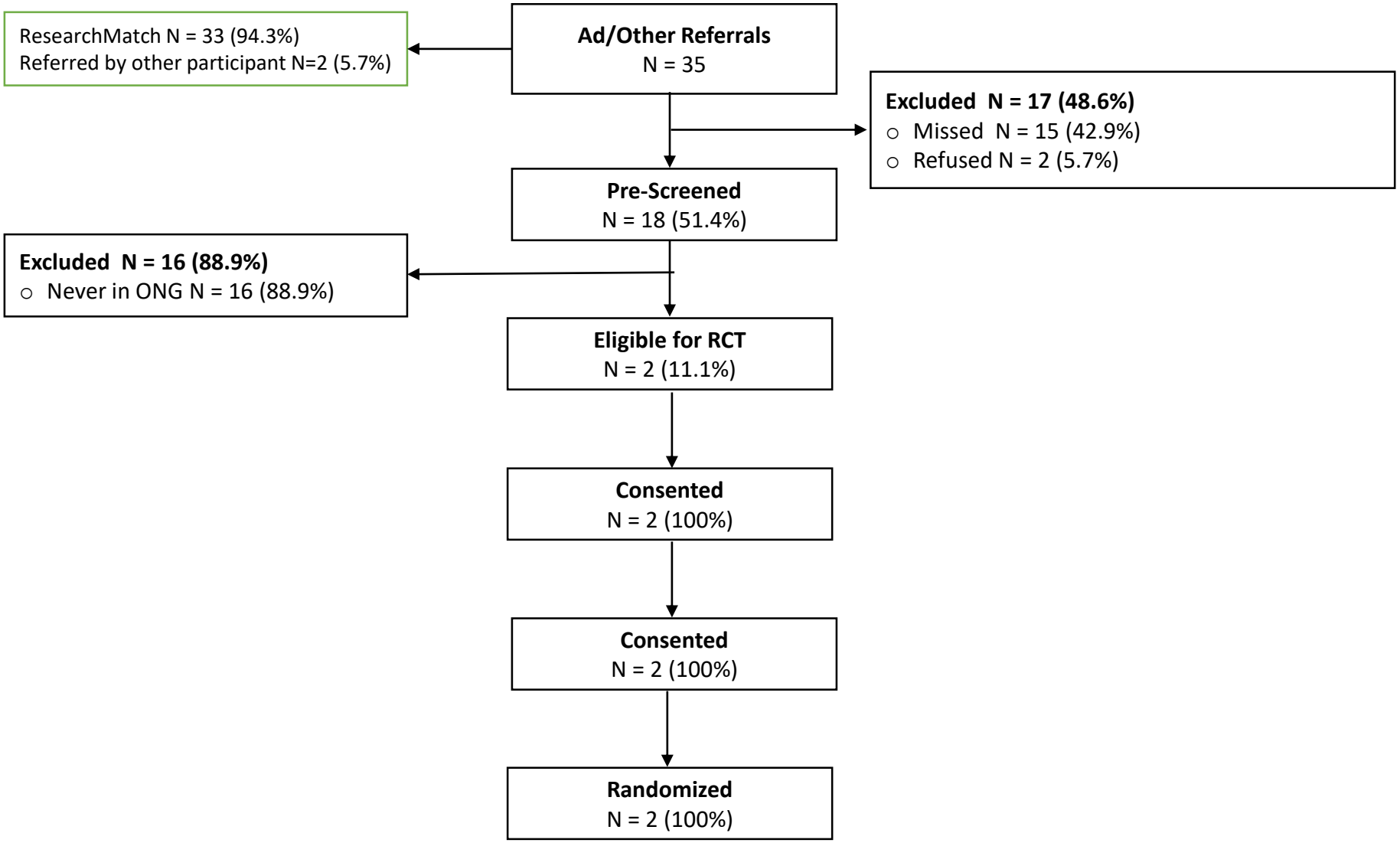
Enrollment – In-Person



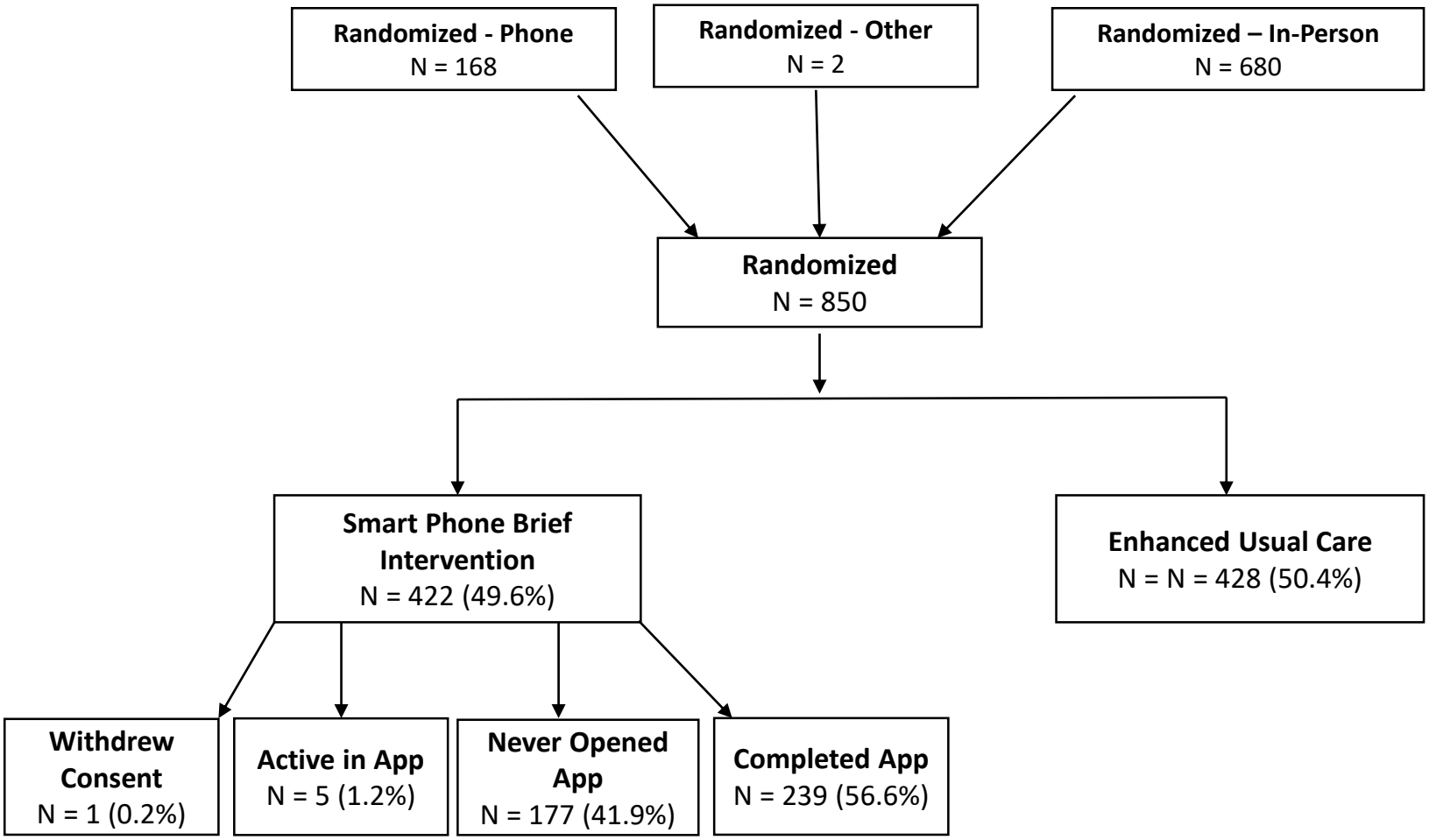
Enrollment - Phone



Enrollment – Ad/Other Referrals



Randomization



4 Month Follow Up

	Smart Phone		Control		Total	
	372		378		750	
	N	%	N	%	N	%
In Progress (<= 14 days)	7	1.9%	5	1.3%	12	1.6%
Outstanding (>15 days)	43	11.6%	24	6.3%	67	8.9%
Completed	190	51.1%	256	67.7%	446	59.5%
Not Completed	132	35.5%	93	24.6%	225	30.0%

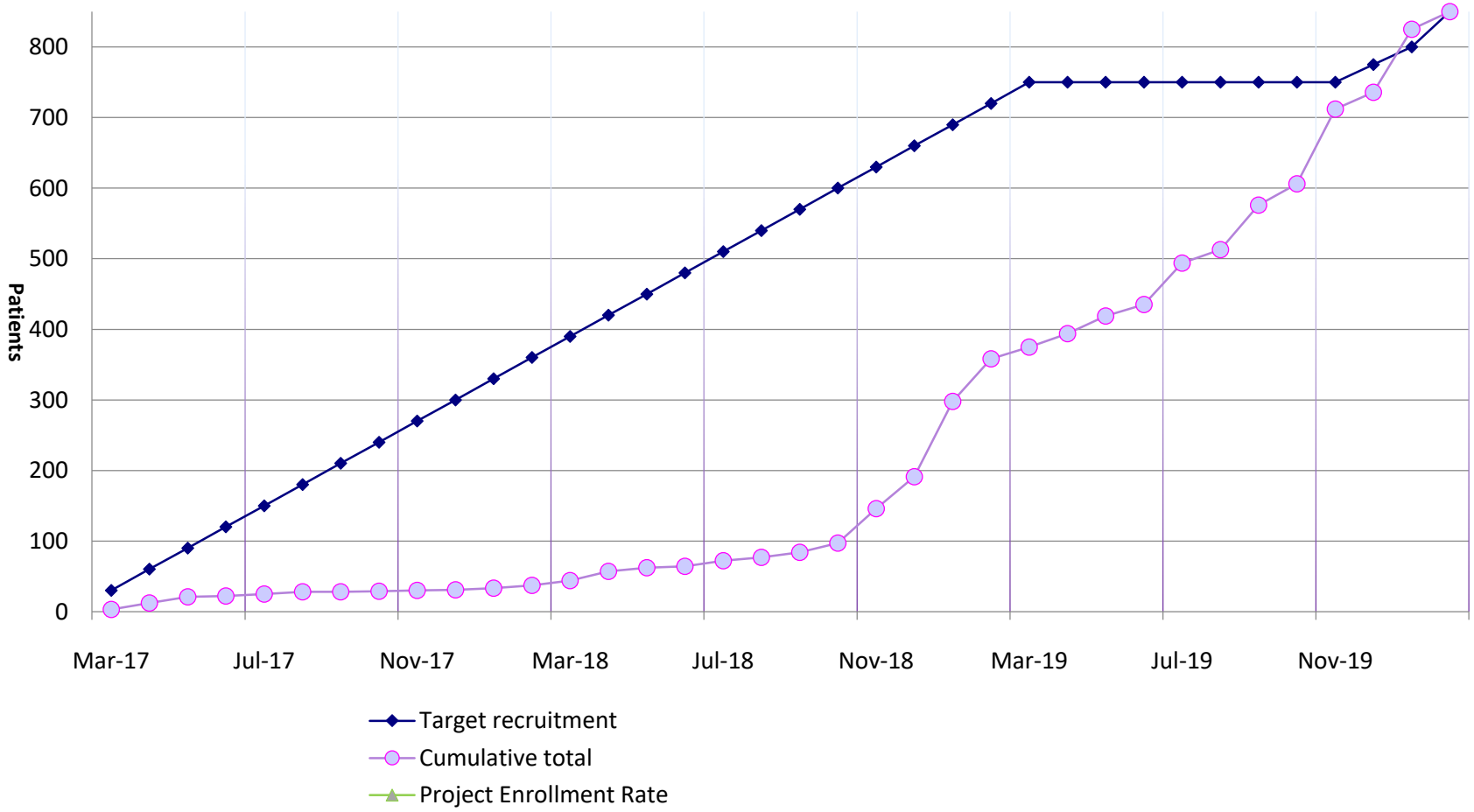
8 Month Follow Up

	Smart Phone		Control		Total	
	256		265		521	
	N	%	N	%	N	%
In Progress (<= 14 days)	6	2.3%	7	2.6%	13	2.5%
Outstanding (>15 days)	14	5.5%	18	6.8%	32	6.1%
Completed	127	49.6%	141	53.2%	268	51.4%
Not Completed	109	42.6%	99	37.4%	208	39.9%

12 Month Follow Up

	Smart Phone		Control		Total	
	198		206		404	
	N	%	N	%	N	%
In Progress (<= 14 days)	6	3.0%	5	2.4%	11	2.7%
Outstanding (>15 days)	32	16.2%	29	14.1%	61	15.1%
Completed	111	56.1%	123	59.7%	234	57.9%
Not Completed	49	24.7%	49	23.8%	98	24.3%

Enrollment


800
700
600
500
400
300
200
100
0
Patients
Mar-17
Jul-17
Nov-17
Mar-18
Jul-18
Nov-18
Mar-19
Jul-19
Nov-19
Target recruitment
Cumulative total
Project Enrollment Rate

Follow On Work

- eHealth app interventions have many advantages, including the ability to present detailed interactive interventions and allow the Guard member to establish personalized plans for change and receive frequent reminders, updated information and virtual support services.

- Based on results of these two studies (this phone app intervention and the NIAAA Web-based intervention) additional innovations will be proposed and tested in National Guard and other Reserve components.

- Results from this study will inform future studies that attempt to further refine and increase the impact of population eHealth interventions on key substance use and other mental health problems in reserve component members.