AWARD NUMBER: W81XWH-20-9-F001-0033

TITLE: Mobile Stress and Anger Management Tool (MSAT)

PRINCIPAL INVESTIGATOR: Brent Winslow

PERFORMING ORGANIZATION: Design Interactive, Inc.

REPORT DATE: 25-OCT-2020

TYPE OF REPORT: Annual Report

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

MTEC
Medical Technology Enterprise Consortium

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Annual Technical Status Report for

Research Project No. MTEC-17-08-MT-0313
MT17008.313
Reporting Period: 14-NOV-2019 – 30-SEP-2020

MTEC Research Project Awardee
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Submitted: <23-OCT-2020>

1. Project Status

a. Accomplishments

Award Executed with MTEC	14-NOV-2019
Kickoff Meeting, Project Planning, and Stakeholder Brainstorm	21-NOV-2019
Submission of IRB materials to Center for Deployment Psychology (CDP)	02-DEC-2019
Internal Rapid Prototyping Event (RPE)	09-DEC-2020
Revised submission of IRB materials to CDP	17-JAN-2020
System Enhancement Document	24-JAN-2020
Software Release 1	01-MAR-2020
Software Release 2	15-APR-2020
Software Release 3	01-JUN-2020
Software Development Complete	01-JUL-2020
Pilot Trials Begin	03-AUG-2020

b. Reportable Outcomes

- As part of the internal RPE, all software releases were planned – features that will be developed in each of the 3 releases (SOW Tasks 4-6) were identified, the development roadmap was created – agile development structure created and prioritized, and prototype designs were developed – based on the feedback from the group (UI design, researchers, developers, and QA analysts), updated user interface (UI) prototypes were created.
- Software Release 1 – focused on developing the database to store information, setting up the data collection capabilities, developing the login/registration function, developing OSI functionality for Android and iOS, and setting up the user stress alerts. DI completed this tasking and submitted a software release report on 01-MAR-2020.
- Software Release 2 – focused on implementation of relaxation techniques, user prompts, and therapist portal updates.
- Software Release 3 – implemented the sleep and fatigue functionality in the application, including visualization and sleep/wake timeframes. Mobile resources including emergency contacts for self-help have been implemented, and homework and journaling were added as additional features. The bulk of the web portal was developed in preparation for final QA.
- Software Development Complete – The mobile platform was QA tested and bugs were resolved in preparation for sending the system out for initial testing. The full web portal was implemented with views of stress, sleep, relaxation, and homework for the therapists.
- The Android and iOS builds were sent to Garmin for testing and approval to gain access to permanent license keys to leverage Garmin's SDK.
- Pilot trialing was completed with the clinicians at CDP for both the Android and iOS builds. CDP clinicians provided written feedback, and weekly updates regarding their use of MSAT while DI has continued to iterate on the MSAT application and send updates to the testing group.

c. Progress Detail

SOW Task 1 – Kickoff meeting, project planning, and stakeholder brainstorm.

This task was completed on 31-DEC-2019. The team at DI performed a Design Sprint to develop the conceptual design of the MSAT application and web portal. The Design Sprint consisted of 4 days of development and ended with a prototype design of the MSAT system which is displayed below. During this initial planning period DI identified various smartwatches that could potentially be used in the study including Garmin, Empatica, and Suunto. Due to Garmin allowing developers access to their SDK DI ultimately chose to go with the Garmin Vívoactive 4 smartwatch.

SOW Task 2 – IRB submission.
The IRB submission has been completed. The team is now awaiting approval from BAMC human subjects research office which is forthcoming. COVID-19 has led to a series of delays across IRBs as they seek to focus on protocols specifically targeting COVID. MSAT is anticipated to not be delayed much longer due to its telehealth approach. The CDP group is updating the IRB to specify these telehealth approaches due to the COVID-19 pandemic to help accelerate the approval process.

SOW Task 3 – System enhancements documented (see Appendix 1) and reviewed with stakeholders/agile development begins.
This task was completed on 28-JAN-2020. Discussions from the kickoff meeting and notes gathered from the internal RPE were used to develop a list of updates and enhancements DI wanted to make to the original MSAT application. Specifically, DI wanted to focus on adding in sleep and fatigue tracking, optimize the application to run on both Android and iOS devices, and develop a web portal for clinicians to track patient progress.

Main task	Sub task	Description/Purpose
Sleep and Fatigue		The current SHARPR application tracks sleep and mental acuity, and important features of this will be incorporated into MSAT.
	Optimize sleep baseline procedure	The ability to track "normal" sleep is very important to identify changes/disruptions to sleep that may impact stress.
	Improve adaptive data visualizations	The data collected is only useful if the users can understand how it impacts them. The current visualizations could use an update to improve user's ability to control exactly what they see.
OSI Algorithm		The OSI algorithm currently operates utilizing heart rate and/or electrodermal activity on an Android or Windows device.
	Digital phenotyping	The OSI algorithm currently requires physiological responses from a wearable sensor. The long-term goal of this effort is to identify stress and sleep levels solely with a non-contact mobile device.
	Optimize for iPhone devices	The OSI was originally developed and deployed on the Android ecosystem. The algorithm has been ported to iOS, but further testing is needed to ensure that the results are the same across platforms.
	Reduce OSI baseline time requirement	The current baseline process takes 5 minutes. There is data that we have collected that shows 2 minutes will provide the same results, which would significantly reduce the impact on the user's day-to-day activities.
	Smart baselines	We have explored the possibility of implementing "smart baselines" which would continuously collect data and update the baseline file based on activity. This would allow for a different baseline to be used when in a resting state vs. exercise.
MSAT Mobile Application		The MSAT mobile application currently exists on Android and calculates the OSI and provides relaxation techniques.
	Peer Support	The ability to reach out to approved peers when needed will be added to the MSAT system. This will pull from a therapist approved list from the user's contacts.
	Knowledge Resources	We plan to implement a "Resources" page within the app, which will provide the user with information about PTSD and sleep disorders.

	iOS application development	The MSAT application currently exists on Android, and will be ported to iOS, including the connection to the therapist portal and relaxation techniques.
	Incorporate sleep data	Sleep data (from SHARPR) will be incorporated into the MSAT application. The user will be shown how the amount of sleep they get can affect their stress level the next day(s)
Provider Portal		The provider portal is a website that allows providers to view data collected/analyzed on the patient's MSAT mobile application.
	Improve Calendar View	The current calendar view shows stress in time boxes throughout the day. We would like to add specific events (i.e. meetings) to the calendar to provide more context to the therapist.
	Improve Map View	The map view will be updated to more easily identify locations based on context instead of GPS location. For example, stress events would be tagged to "Work" instead of 3504 Lake Lynda Dr.
	Login/Registration	The login/registration process will be streamlined.

SOW Task 4 – Software Release 1
This task was completed on 1-MAR-2020 (see Appendix 2). Software Release 1 consisted of the database development, data collection, login and registration, OSI functionality in Android and iOS devices, and user stress alerts. DI completed the tasking for Software Release 1 and submitted a release report to the contract SOTR on 01-MAR-2020.

SOW Task 5 – Software Release 2
This task was completed on 15-APR-2020 (see Appendix 3). Software Release 2 consisted of the relaxation techniques being developed and implemented, user prompts regarding stress events and homework assignments being implemented, and initiation of the therapist portal development.

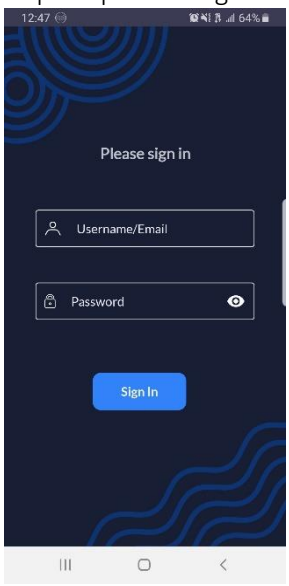
SOW Task 6 – Software Release 3
This task was completed on 01-JUN-2020 (see Appendix 4). Software Release 3 consisted of the sleepiness/fatigue integration in the mobile app, cognitive therapy homework implemented in the app and web portal, and the addition of knowledge resources in the mobile application.

SOW Task 7 – Software Development Complete
This task was completed on 01-JUL-2020 (see Appendix 5). The final software release was demonstrated to the SOTR and subcontractor organizations for external review and feedback. A series of screenshots below indicates the process flow of the MSAT application from initial installation through use of the app.

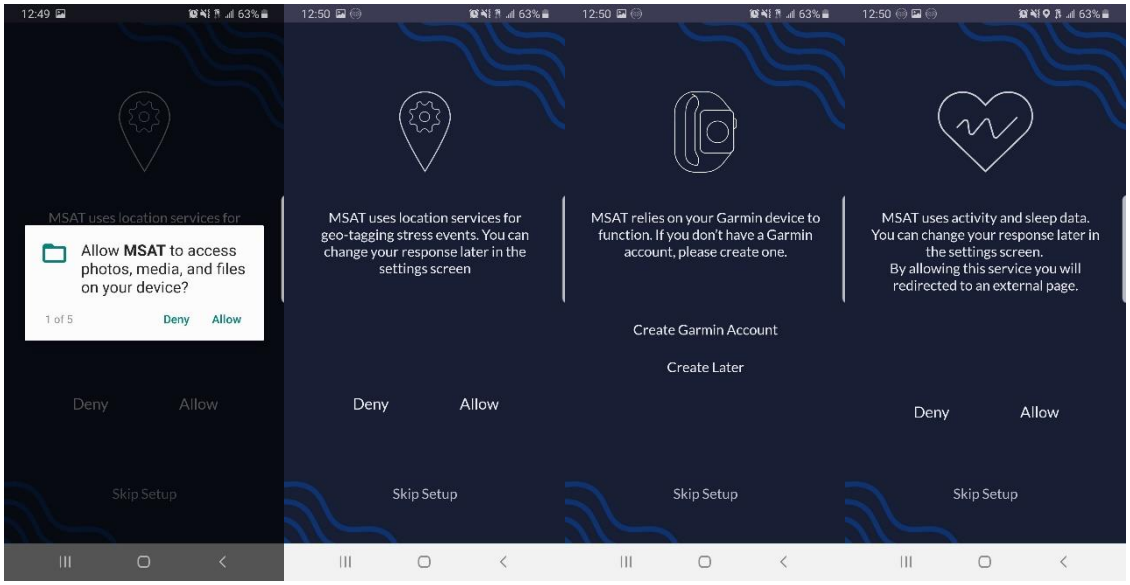
Mobile Application

1. Login and Permissions

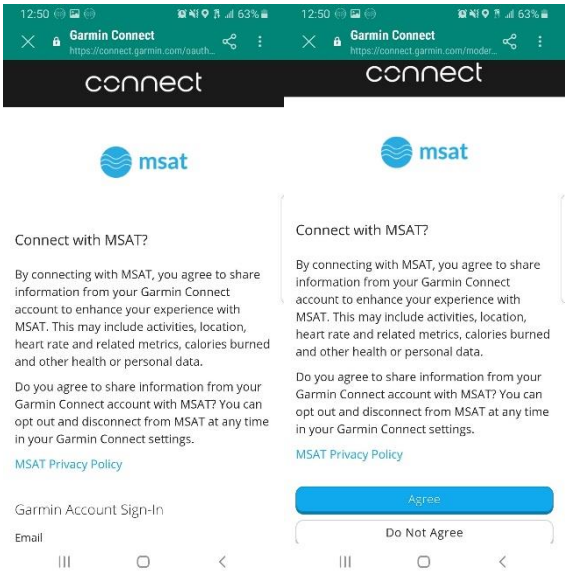
a. Upon installation, users will be prompted to login with their provided credentials



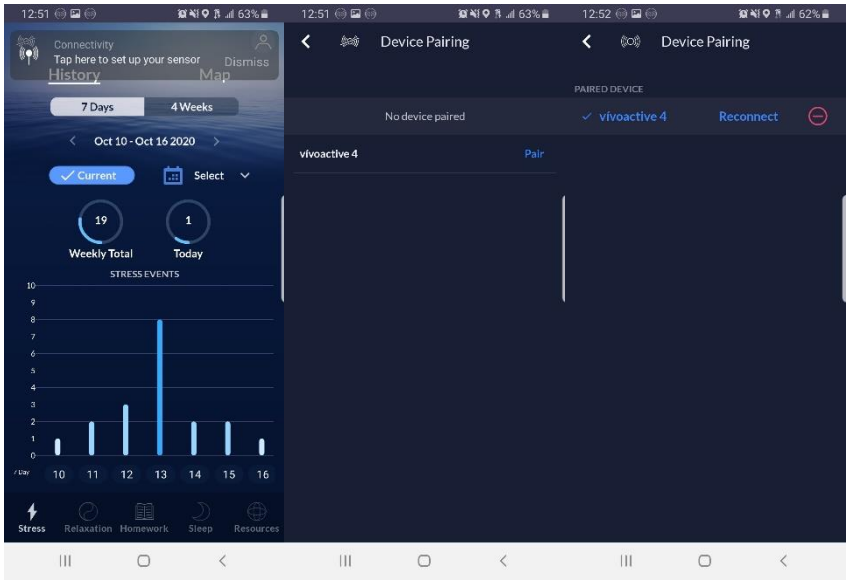
b. MSAT will prompt users for access mobile permissions
   i. Access to the contacts screen is needed for adding to the emergency contacts
   ii. Phone permissions are needed to navigate to the phone app
   iii. Mic permissions are needed for recording decibel levels for the digital phenotype
   iv. Access to media is needed for users to add their own images to the relaxation screens
   v. Location services are optional – no addresses are sent to clinicians
   vi. A Garmin Connect account is necessary for sleep tracking



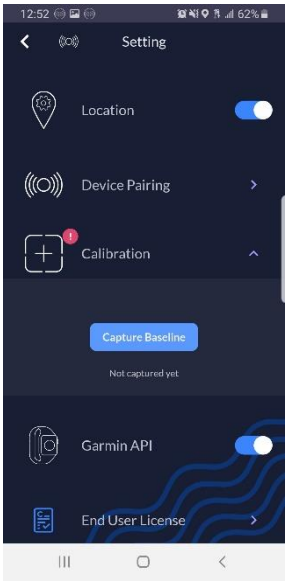
c. Users will be asked to sign into their Garmin account
   i. If the user does not have an account, they can create it through a link in the MSAT app



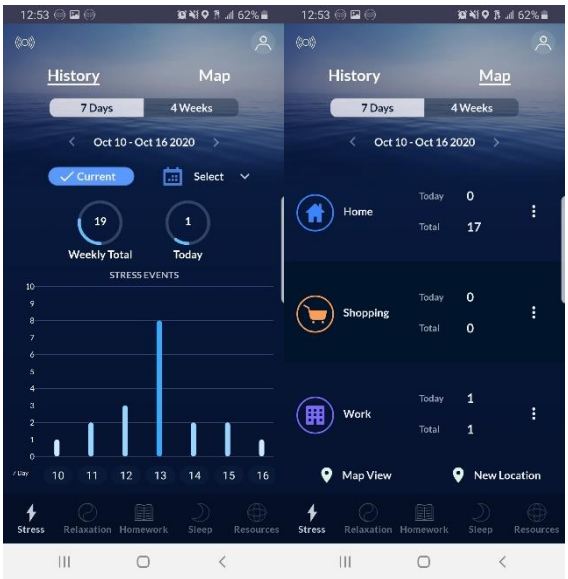
2. Garmin setup
    a. Upon successful login, users will be navigated to the Stress screen where they will be prompted to connect their Garmin device to the MSAT application



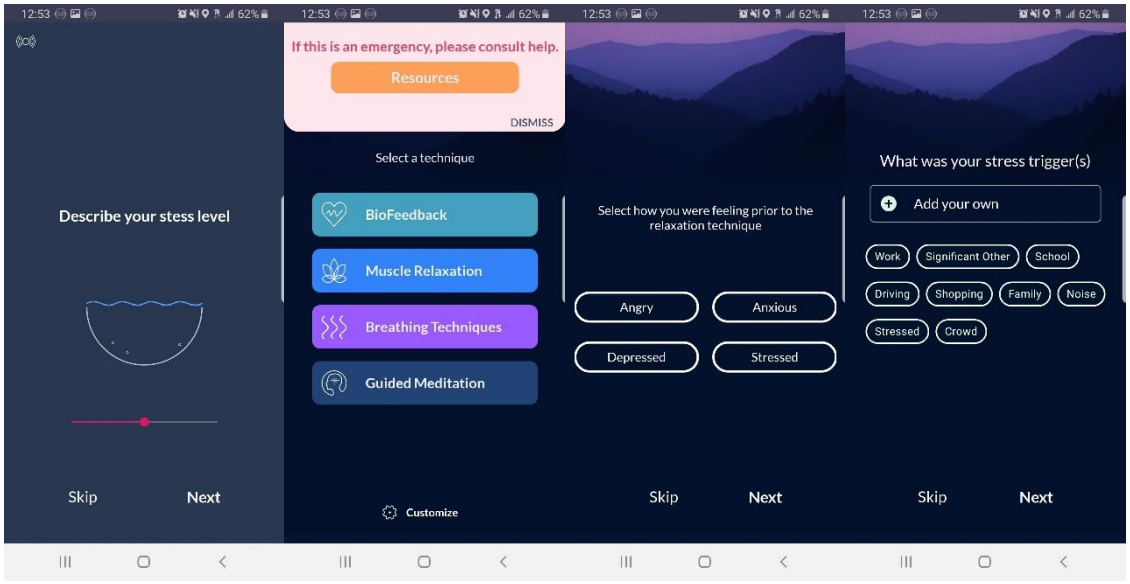
    b. Following device pairing, users will need to perform a baseline to calibrate MSAT
        i. Users will be advised to remain seated and in a calm environment for the 5-minute baseline



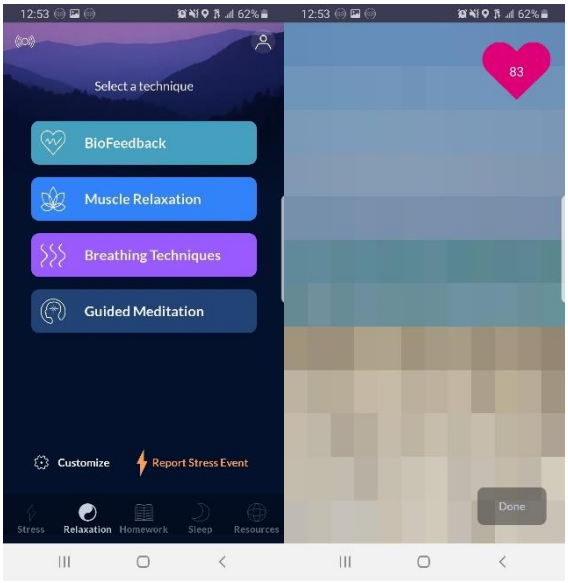
3. Stress
    a. The stress screen will display the number of stress events the user experienced over a 7 day or 4-week period
    b. Users can add common locations (home, school, work)
        i. Users will be asked to name the location, add an address, and select a pre-made image
        ii. When the system detects a stress event, it will attempt to geotag the stress event to a set location



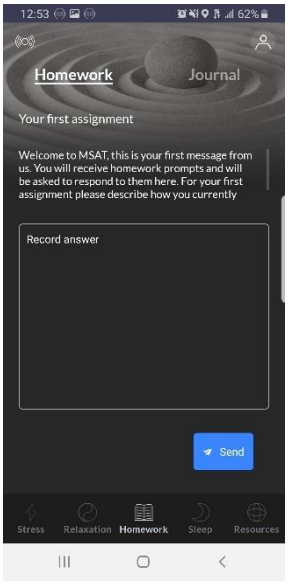
    c. When users receive a stress alert, they will be prompted to perform the stress survey
        i. Users will first be asked to rate their stress on a scale of 1-10
        ii. Users will then be prompted to undergo a relaxation technique or contact an emergency resource
        iii. Users will be asked to identify the cause of their stress (Anger, Anxiety, Depression, or Stress)
        iv. Finally, users will be asked to identify a trigger for their stress



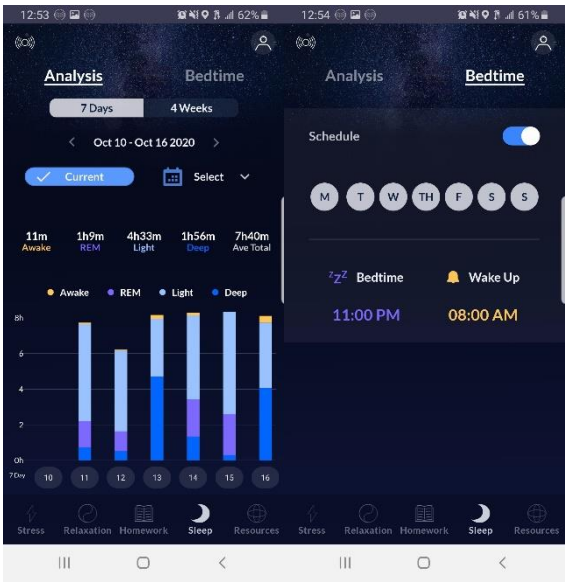
4. Relaxation
    a. Four relaxation techniques are provided on the Relaxation page
        i. Biofeedback displays a pixelated image and the user's heart rate with the objective being to lower the user's heart rate to de-pixelate the image on screen.
        ii. Muscle Relaxation displays a 3D anatomical model of a person and walks the user through a muscle relaxation script
        iii. Breathing Techniques is a meditation script to help control breathing patterns
        iv. Guided Meditation is a calming, generic meditation script
    b. Users can add their own images as backgrounds for the relaxation techniques
    c. Users can self-report a stress event and go through the stress survey if they are feeling stressed, but the system has not reported an event



5. Homework
    a. Users can receive homework prompts from their clinicians and send real-time responses
    b. Users can log journal entries which are saved locally and only visible to the patient



6. Sleep
    a. Sleep data is only accessible if users pair their Garmin Connect account with MSAT
    b. Users can also set a bedtime schedule which sets MSAT quiet hours and provides an alert 1 hour before the scheduled bedtime

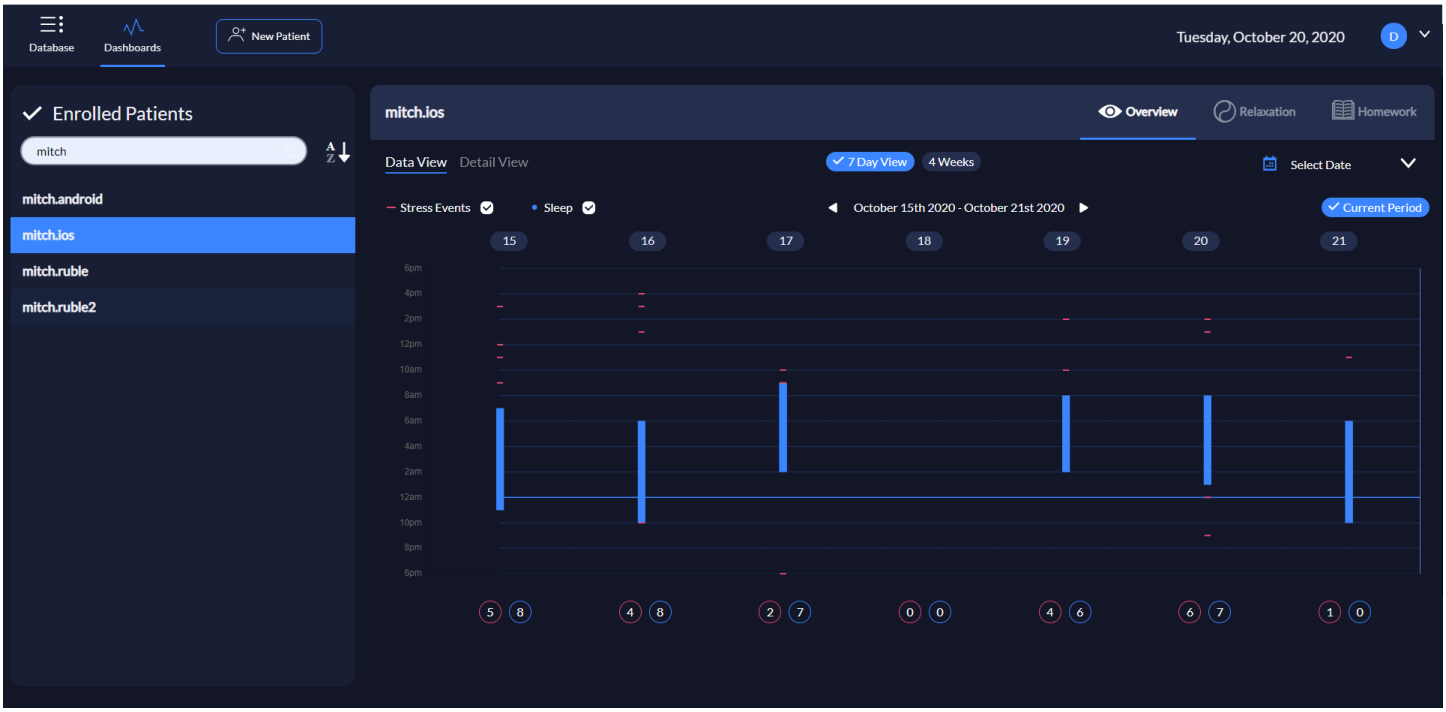


7. Resources
    a. A set of critical resources is provided to the patients, selecting a phone number or website will navigate the user to the appropriate tool to access the resource
    b. Users can add contacts to the emergency contacts list
    c. The education tab provides users with access to additional content and resources regarding stress and sleep

Web Portal

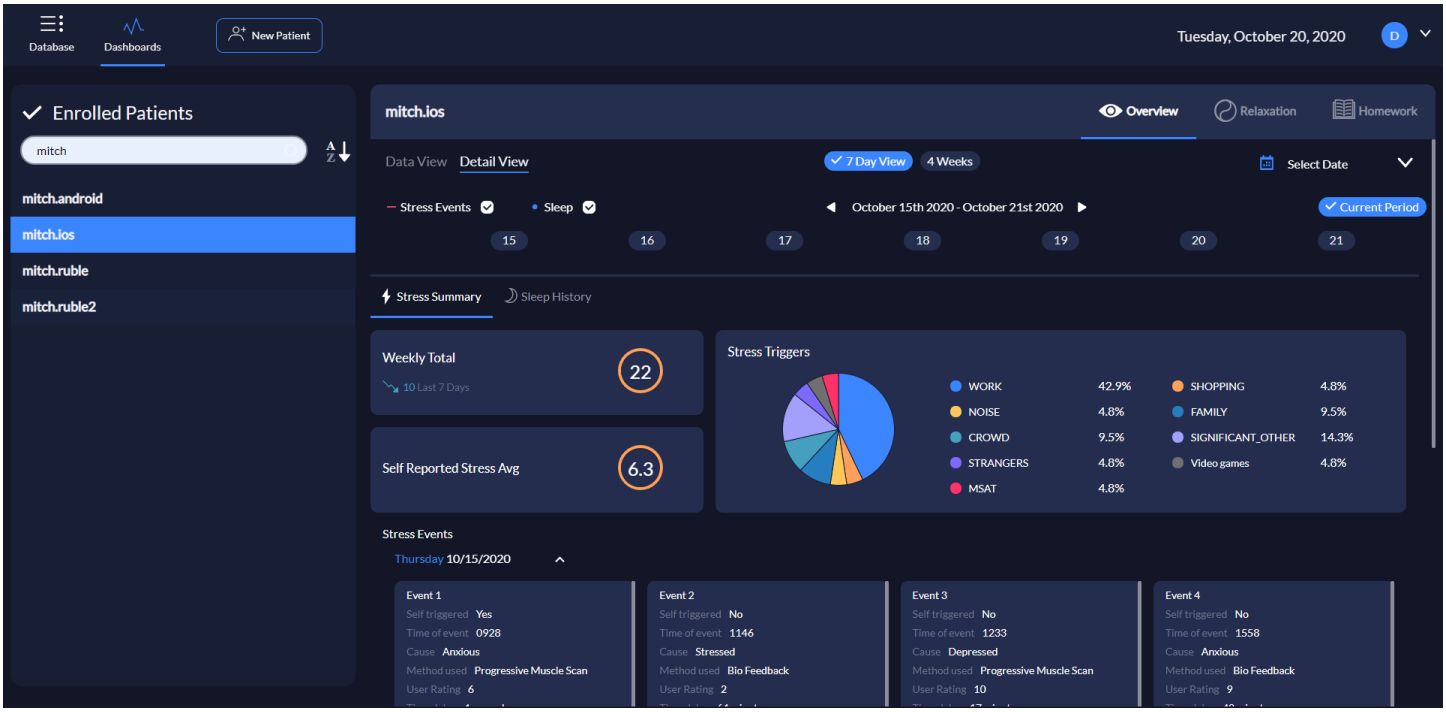
https://msat.designinteractive.net/login

1. From the web portal, clinicians can view the stress and sleep information for their patients
    a. The Data View displays the stress (red hashes) and sleep (blue bars) on a 7 day or 4-week view
        i. Users can toggle stress or sleep to change the view
        ii. The total number of stress events are displayed in the red circle under each period
        iii. The amount of hours slept is displayed in the blue circle

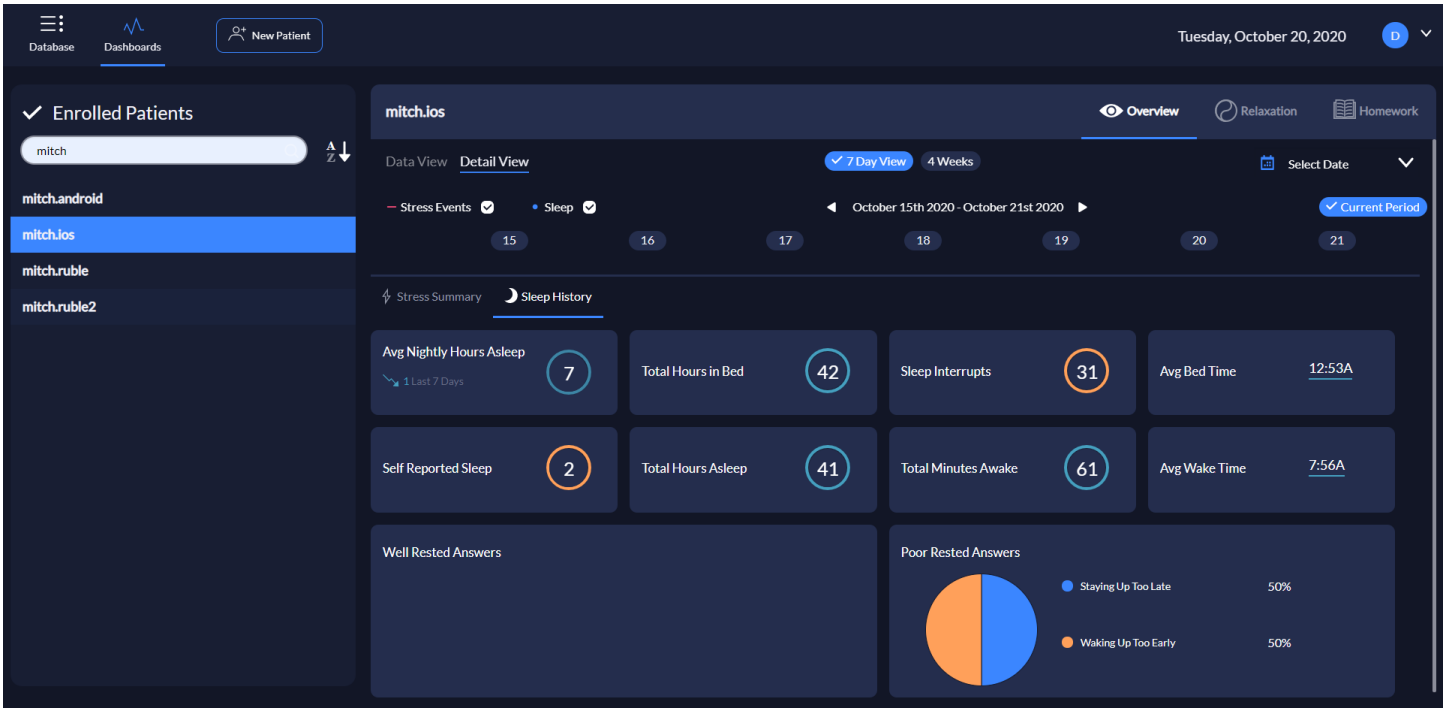


2. From the Detailed view, clinicians can view specific detailed information regarding stress and sleep information
    a. Stress Summary

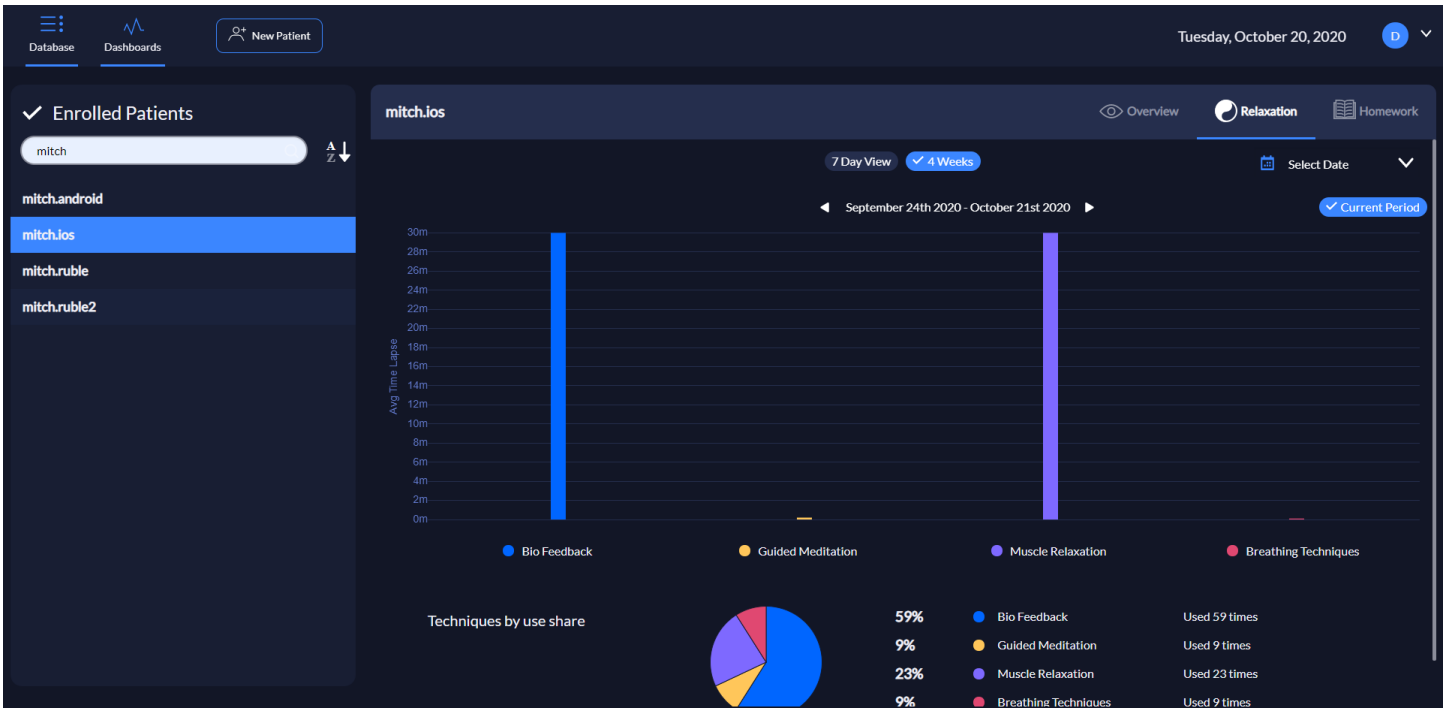
i. Clinicians can view the weekly total of stress events, self-reported stress average, and breakdown of stress triggers
ii. Clinicians can view detailed information regarding each of the stress events a user experienced including if the event was self-triggered or not, the time of the event, the cause, the relaxation method used, the self-reported stress level, the delay between the stress event and the survey response, the location of the stress event, and the trigger.



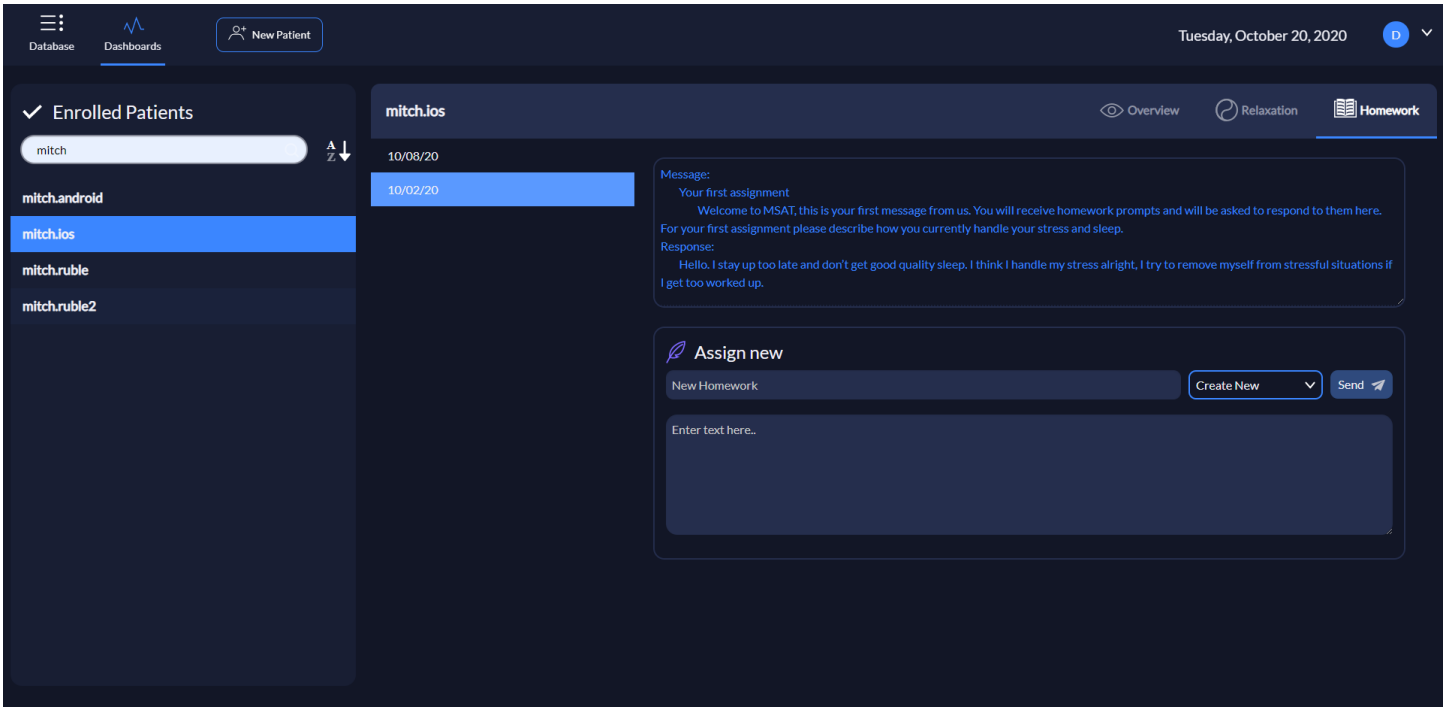
b. Sleep Summary
i. Clinicians can view sleep related information including the average hours slept, time in bed, sleep interrupts, self-reported sleep level, hours asleep, time awake during the night, average bedtime, and average wake time
ii. Clinicians can also view the sleep survey responses for what caused the patients to sleep well or poorly over the 7 day or 4-week period



3. Relaxation
    a. Clinicians can see a plot of the average time it took the patients to respond to a survey after a stress event for each relaxation technique
    b. Clinicians can also see the amount of times the patients accessed the relaxation techniques in MSAT



4. Homework
    a. Providers can send homework assignments to their patients and review the responses



SOW Task 8 – Pilot Clinical Trials Begin Complete
This task was completed on 19-AUG-20. DI shared the Android and iOS version of the MSAT application with the providers at CDP who provided back a list of feedback and recommended updates which DI has implemented into later versions of MSAT. DI and the CDP clinicians have been meeting on a weekly basis to cover the MSAT application and IRB progress. In these meetings DI solicited feedback from the CDP clinicians to ensure development met their expectations and recommendations.

SOW Task 9 – Clinical trials group 1 data collection complete

- Begin first set of clinical trials
- Targeted completion 02-NOV-2020

SOW Task 10 – Clinical trials group 2 data collection complete

- Begin second set of clinical trials
- Analyze data from first set of clinical trials
- Targeted completion 01-FEB-2021

SOW Task 11 – Clinical trials group 3 data collection complete

- Begin third set of clinical trials
- Analyze data from second set of clinical trials
- Targeted completion 03-MAY-2021

SOW Task 12 – Clinical trials group 4 data collection complete

- Begin first set of clinical trials
- Analyze data from third set of clinical trials
- Targeted completion 02-AUG-2021

SOW Task 13 – Data Analysis Complete

- Complete analysis of data from clinical trials
- Targeted completion 15-SEP-2021

SOW Task 14 – Out brief & Report results

- Draft report of analysis
- Present findings from MSAT study
- Present findings on digital phenotyping
- Targeted completion 25-OCT-2021

2. Future Plans

SOW Task 9 – Clinical trials group 1 data collection complete
Under the next quarterly period of performance, the first round of clinical trials will be underway. DI has submitted and received approval on their local IRB to collect healthy control participants. HRPO approval is underway and expected to occur before the milestone is due. The first round of participants in the clinical trials is expected to be the healthy control participants, further, the IRB and HRPO documents for San Antonio sites are expected to be approved which will allow for collection with the full set of participants.

3. Problems / Issues

a. Current Problems / Issues

Full IRB approval is pending. Due to COVID-19 the team has been working with BAMC to ensure the safety of the patients by migrating to a more virtual implementation of the study. COVID-19 has led a delay in IRB acceptance across multiple sites as they focus on COVID related protocols. DI and CDP have been updating the IRB documentation to indicate the telehealth approach of MSAT to mitigate IRB related delays and COVID risks for the study. In order to remain on time, DI submitted a second IRB to Copernicus Group IRB/HRPO focusing on asymptomatic control patients in September, 2020. HRPO returned with questions in October, 2020, and DI is expecting an approved IRB from HRPO by the end of October, 2020.

b. Anticipated Problems / Issues

N/A

4. Financial Health

The effort is financially on track.

Task Number	Milestone Description	Due Date	Government Funds
1	Kickoff meeting, project planning, and stakeholder brainstorm	27-NOV-2019	$100,000
2	IRB Submission Complete	16-DEC-2019	$150,000
3	System enhancements documented and reviewed with stakeholders/ agile development begins	24-JAN-2020	$150,000
4	Software Release 1 Complete	2-MAR-2020	$100,000
5	Software Release 2 Complete	15-APR-2020	$100,000
6	Software Release 3 Complete	01-JUN-2020	$74,935
7	Software Development Complete	01-JUL-2020	$50,000
8	Pilot Clinical Trials Begin (Study preparation complete)	03-AUG-2020	$150,000
9	Clinical trials group 1 data collection complete	02-NOV-2020	$0
10	Clinical trials group 2 data collection complete	01-FEB-2021	$0

11	Clinical trials group 3 data collection complete	03-MAY-2021	$0
12	Clinical trials group 4 data collection complete	02-AUG-2021	$0
13	Data Analysis Complete	15-SEP-2021	$0
14	Out brief & Report Results	25-OCT-2021	$0
	Total Expenditures		$874,935

5. Personnel Effort

Personnel	Role	Percent Effort
Brent Winslow	Principal Investigator (PI)	30%
Mitch Ruble	Project Manager (PM)	40%
Jeff Hullfish	Data Scientist	40%
Hank Cheng	Software Developer	35%
Allen Kendrick	Software Developer	80%
Stephen Deming	UI/UX Developer	25%
Adam Lynch	Senior Research Associate	20%

6. Protocol and Activity Status

a. Human Use Regulatory Protocols

TOTAL PROTOCOLS: 2 human subject research protocols will be required to complete the Statement of Work.

PROTOCOLS: List all human use protocols to be performed to complete the project, an include approved target number for clinical significance, followed by type of submission and type of approval with associated dates, and performance status for each.

Protocol [HRPO Assigned Number]: E01375.1a
Title: Mobile Stress and Anger Management Tool (MSAT)
Target required for clinical significance: 30
Target approved for clinical significance: Not yet approved. Asymptomatic subjects evaluation under review by HRPO.
Submitted to and Approved by: Symptomatic subjects IRB submitted to BAMC IRB

STATUS:

- Protocol not yet approved.

b. Use of Human Cadavers for RDT&E, Education or Training

No RDT&E, education or training activities involving human cadavers will be performed to complete the Statement of Work (SOW).

c. Animal Use Regulatory Protocols

No animal use research will be performed to complete the Statement of Work.

Quarterly Business Status Report for

Research Project No. MTEC-17-08-MT-0313

MT17008.313

Reporting Period: 14-NOV-2019 – 30-SEP-2020

MTEC Research Project Awardee

Brent Winslow

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Submitted: <23-OCT-2020>

1. Current Staff

Personnel	Role	Percent Effort
Brent Winslow	Principal Investigator (PI)	30%
Mitch Ruble	Project Manager (PM)	40%
Jeff Hullfish	Data Scientist	40%
Hank Cheng	Software Developer	35%
Allen Kendrick	Software Developer	80%
Stephen Deming	UI/UX Developer	25%
Adam Lynch	Senior Research Associate	20%

2. Current Expenditures

MTEC Milestone Number	Milestone Description	Due Date	Government Funds
1	Kickoff meeting, project planning, and stakeholder brainstorm	27-NOV-2019	$100,000
2	IRB Submission Complete	16-DEC-2019	$150,000
3	System enhancements documented and reviewed with stakeholders/ agile development begins	24-JAN-2020	$150,000
4	Software Release 1 Complete	02-MAR-2020	$100,000
5	Software Release 2 Complete	15-APR-2020	$100,000
6	Software Release 3 Complete	01-JUN-2020	$74,935
7	Software Development Complete	01-JUL-2020	$50,000
8	Pilot Clinical Trials Begin (Study preparation complete)	03-AUG-2020	$150,000
9	Clinical trials group 1 data collection complete	02-NOV-2020	$0
10	Clinical trials group 2 data collection complete	01-FEB-2021	$0
11	Clinical trials group 3 data collection complete	03-MAY-2021	$0
12	Clinical trials group 4 data collection complete	02-AUG-2021	$0
13	Data Analysis Complete	15-SEP-2021	$0
14	Out brief & Report Results	25-OCT-2021	$0
	Total Expenditures		$874,935

3. Status of Milestones

MTEC Milestone Number	Milestone Description	Due Date	% Completed this Reporting Period	Cumulative % Complete
1	Kickoff meeting, project planning, and stakeholder brainstorm	27-NOV-2019	**100%**	**100%**
2	IRB Submission Complete	16-DEC-2019	**100%**	**100%**
3	System enhancements documented and reviewed with stakeholders/ agile development begins	24-JAN-2020	**100%**	**100%**
4	Software Release 1 Complete	02-MAR-2020	**100%**	**100%**
5	Software Release 2 Complete	15-APR-2020	**100%**	**100%**
6	Software Release 3 Complete	01-JUN-2020	**100%**	**100%**
7	Software Development Complete	01-JUL-2020	**100%**	**100%**
8	Pilot Clinical Trials Begin (Study preparation complete)	03-AUG-2020	**100%**	**100%**
9	Clinical trials group 1 data collection complete	02-NOV-2020	**0%**	**0%**
10	Clinical trials group 2 data collection complete	01-FEB-2021	**0%**	**0%**
11	Clinical trials group 3 data collection complete	03-MAY-2021	**0%**	**0%**
12	Clinical trials group 4 data collection complete	02-AUG-2021	**0%**	**0%**
13	Data Analysis Complete	15-SEP-2021	**0%**	**0%**
14	Out brief & Report Results	25-OCT-2021	**0%**	**0%**

4. Deviation from Project Plan

The IRB submission was expected to be completed as of 16-DEC-2019, however there have been delays due to subcontract finalization with CDP through the Henry Jackson Foundation (HJF). Design Interactive has worked closely with the CDP in finalizing the IRB documentation. Despite the delay in IRB there should be no issues with the rest of the milestone deliverables.

The COVID-19 pandemic may lead to a delay in the data collection start time or a shift toward telehealth interviews with participants. At this time, potential collection sites identified by the CDP have been reporting delays regarding site's capability to work with outside organizations until such a time as the pandemic clears up. DI is working closely with its subcontractors and its government sponsor to monitor the projected timeline.

Appendices

(note – double click on document image to open full report pdfs)

Appendix 1: System Enhancement Document

MSAT System Enhancements

MTEC Contract Number: 2018-677

Prepared By:
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3504 Lake Lynda Dr. Ste 400
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(407) 706-0977

Principal Investigator: Dr. Brent Winslow

Date: 1/24/2020

Points of Contact:
SOTR: Dr. Sara Alger (sara.e.alger.civ@mail.mil)
MTEC COR: Randall Fernanders (mtec-contracts@ati.org)

1

Appendix 2: Software Release 1 Report

Software Release 1 Report for

Mobile Stress and Anger Management Tool (MSAT) Research Project No. MTEC-17-08-MT-0313

MTEC Research Project Awardee

Design Interactive, Inc.

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Submitted: March 2, 2020

Appendix 3: Software Release 2 Report

Software Release 2 Report for

Mobile Stress and Anger Management Tool (MSAT) Research Project No. MTEC-17-08-MT-0313

MTEC Research Project Awardee

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Submitted: April 15, 2020

Appendix 4: Software Release 3 Report

Software Release 3 Report for

Mobile Stress and Anger Management Tool (MSAT) Research Project No. MTEC-17-08-MT-0313

MTEC Research Project Awardee

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Submitted: June 1, 2020

Appendix 5: Final Software Release Report

Software Release Final Report for

Mobile Stress and Anger Management Tool (MSAT) Research Project No. MTEC-17-08-MT-0313

MTEC Research Project Awardee

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