Think Biosolution

A Study – Clinical Efficacy of the Stress Monitoring Dashboard

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December - 2019

Abstract

Background

Health Innovation Hub Ireland (HIHI) is a government initiative funded by Enterprise Ireland and the HSE. HIHI's role is to support innovation and connect start-ups to the healthcare community who can validate and provide user feedback on new technologies. This early-stage feedback ensures that the voice of the healthcare community and the impact on patients is included in the design of these technologies. Learn more about how HIHI can also support ideas coming from our Healthcare Community at www.hih.ie '

Think Biosolution is a health tech start-up based in Dublin, which makes remote patient monitoring (RPM) platforms for at-home chronic care management. At the heart of their platform is the QuasaR™ wearable device that measures the patient's heart rate, respiratory rate, blood oxygen saturation, heart rate variability, temperature, movement, and location.

Objective

In this study, clinical and healthcare teams in Bantry Hospital Cork, Ireland, with expertise in stress monitoring were requested to review the Think Biosolution's Stress Monitoring Dashboard and to complete the questionnaire. All participants were provided with an anonymous code by our HIHI Clinical Liaison. The at-home stress monitoring dashboard is designed for clinicians to monitor daily stress levels in chronically ill at-home patients. The dashboard contains the summary of biometric information derived from an investigational wearable medical device (i.e., heart rate, rMSSD based heart rate variability, respiratory rate), as well as blood cortisol tests performed twice for each healthy volunteer.

Methods

Clinicians who are taking part in this study are expected to complete this questionnaire with grading metric 1-5 to evaluate the following:

(1) Usability of the Stress Monitoring Dashboard

(2) Efficacy of the Stress Monitoring Dashboard in determining stress events

(3) Ease of navigating the Stress Monitoring Dashboard

The survey is 15 questions long and took approximately less than ten minutes to complete.

Results

The results were obtained from 18 clinicians which includes - senior house consultant (SHO), advanced nurse practitioner, project officer, palliative care SHOs, quality patient safety and risk manager, nurse in stoke care, occupational therapist in stroke care, consultant gerontology, consultant neurology, gerontology with special interest in stroke, cardiac nurse specialist, diabetic nurse, diabetic nurse specialist, and CNM.

More than 50% of the clinicians knew about HRV and its significance in measuring stress. More than 60% found the document "Care Giver's Guide to Using the Stress Monitoring Dashboard" either "easy" or "very easy" to read. More than 70 % would like to see both numerical and plot-based results of the biometric information collected. Also, more than 50% found the experience regarding reading the numerical data as well as the plots" good" to "very good." More than 50% thinks blood cortisol indicative of stress compared to only 20% who thinks rMSSD indicative of stress (measured as a % that thinks it is "relevant" or "very relevant"). However, more than 50% still found that rMSSD data can be clinically interpreted as an overarching indicator of stress.

Conclusion

In conclusion, we believe that the Stress Monitoring Dashboard interface is easy to use and understand for a wide variety of clinicians.

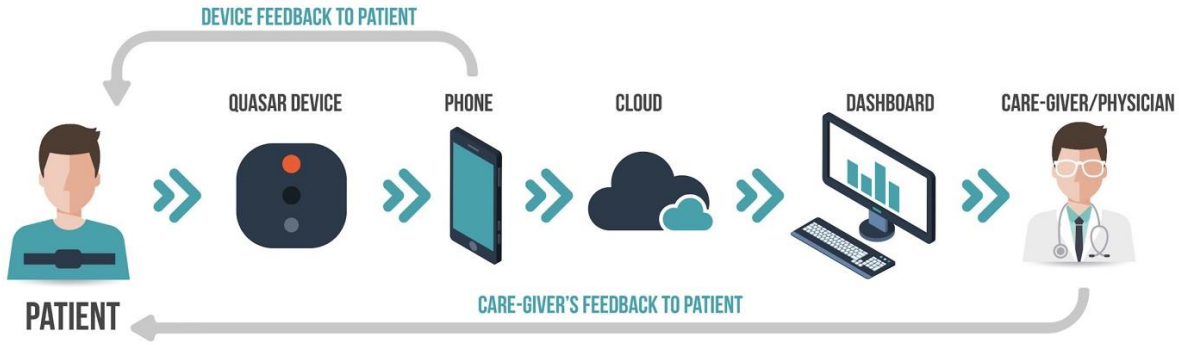
Introduction – What is Remote Patient Monitoring?

Remote patient monitoring (RPM) is a set of devices and associated technology that enables clinicians to monitor their patients outside of conventional clinical settings, such as in the home or a remote area. RPM is often deployed in conjunction with telemedicine for chronically ill or high-risk patients. The main advantages of RPM include the ability to continuously and regularly monitor patients in at-home settings and the ability to generate early warning signs. This, in turn, results in an increase in quality of care and reduction in the cost of care for the patients.

Think Biosolution is an original design manufacturer (ODM), building privately labeled remote patient monitoring platforms for telehealth brands in the USA and EU. At the heart of the platform is the QuasaR™ wearable device that is designed to be worn on the user's chest with a strap. The wearable device is built using a patented optical sensor for measuring biometric data such as heart rate, respiratory rate, blood oxygen saturation, heart rate variability. The wearable device has additional sensors to measure temperature, movement, and location. The data is then transferred to a HIPAA compliant cloud server using a smartphone or a hub. This information can be viewed by the user, physician, or a coach using a customized EMR compatible dashboard.

We are building RPM platforms with increasing feature sets for the remote health monitoring marketplace. In this whitepaper, we describe the efficacy of our second platform i.e., At-home Stress Monitoring with clinicians.

- Continuous Monitoring Platform: QuasaR™ Device and Bluetooth SDK periodically tracks the patient's vitals and motion.
- At-home Stress Monitoring Platform: An end-to-end RPM platform that includes the QuasaR™ Device, Phone App, HIPAA Compliant Cloud, and EHR integrated dashboard. The dashboard automatically tags and summarizes stress and clinical events.
- At-home Geriatric Care Platform: In addition to the features of the At-home Stress Monitoring Platform, the caregiver can to set up reminders for the patient to take their daily medication or to exercise. This platform has built-in fall-detection and alert.



II. Qualitative Understanding of Mental Stress

A. What is Mental Stress?

Mental stress is the physiological lack of recovery of the neuroendocrine reaction due to the dominance of the sympathetic function of the autonomic nervous system. To understand this in detail, we first have to understand how the human nervous system operates. The human nervous system consists of two parts, the central nervous system and the peripheral nervous system (PNS). The PNS is classified into voluntary and autonomic nervous systems (ANS). The autonomic nervous system (ANS) controls physiological functions that have less conscious control such as heart rate and breathing, whereas the voluntary nervous system dictates movement and sensation.

The ANS can be again sub-classified into the sympathetic and the parasympathetic nervous systems (Figure 1). The sympathetic system prepares the body for a fight or flight situation by rapidly increasing bodily functions. The parasympathetic system prepares the body for relaxation. The ANS controls the body's ability to rapidly react to extreme environmental stimulations by the balancing mechanism of the sympathetic and parasympathetic systems.

In the case of clinically presented stress patients (such as those working for long hours in highly demanding jobs), this delicate mechanism of the ANS is disrupted by repeatedly calling the sympathetic reaction. This results in reduced recovery of the neuroendocrine reaction [1] and sympathetic dominance of the ANS function, and suppression of the parasympathetic system.

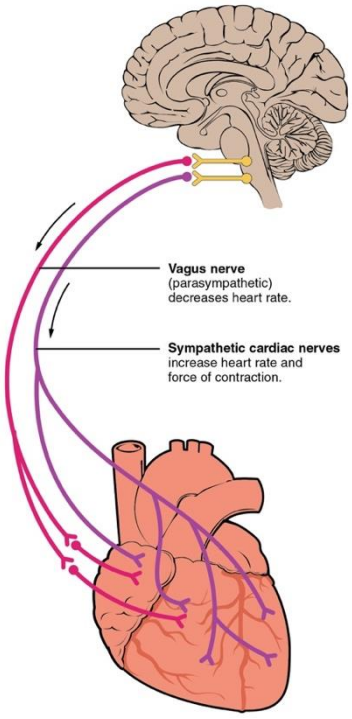


Figure 1. Autonomic Innervation of the Heart - Cardioaccelerator and cardioinhibitory areas are components of the paired cardiac centers located in the medulla oblongata of the brain. They innervate the heart via sympathetic cardiac nerves that increase cardiac activity and vagus (parasympathetic) nerves that slow cardiac activity.[2]

B. Measuring Stress Using Hormonal Measurements

Clinically measurement of stress is traditionally performed by measuring hormones such as cortisol or plasma catecholamines. Cortisol is measured from saliva, saliva, urine, or blood samples. In practice, blood cortisol measurements are the gold standard for measuring stress in the clinical environment. However, the primary challenge with blood cortisol measurements as they are dependent on the timing of sample collections due to

strong diurnal rhythms in hormonal secretion. Also, this result might not be suited for critical or long term at-home since it needs qualified personnel to collect blood samples and laboratory analysis.

C. Measuring Stress Using Heart Rate Variability (HRV)

Recent studies show that HRV as a principal indicator for monitoring stress both in the daily and monthly timescales. It is associated with reduced morbidity and mortality [3], quality of life [4], and the overall parameter of aging [5]. Moreover, acute stress has been associated with decreased HRV during sleep [6] and daytime [7]. Also, decreased HRV has been associated with work stress in multiple studies [8-9].

The most widely used methods can be grouped under time-domain and frequency-domain. A joint European and American task-force described standards in HRV measurements in 1996.[10] Other methods have been proposed, such as geometric and non-linear methods.

D. Time-domain methods

These are based on the beat-to-beat or NN intervals, which are analyzed to give variables such as:

- SDNN, the standard deviation of NN intervals. Often calculated over a 24-hour period. SDANN, the standard deviation of the average NN intervals calculated over short periods, usually 5 minutes. SDNN is, therefore, a measure of changes in heart rate due to cycles longer than 5 minutes. SDNN reflects all the cyclic components responsible for variability in the period of recording. Therefore it represents total variability.
- RMSSD ("root mean square of successive differences"), the square root of the mean of the squares of the successive differences between adjacent NNs.
- SDSD ("standard deviation of successive differences"), the standard deviation of the successive differences between adjacent NNs.
- NN50, the number of pairs of successive NNs that differ by more than 50 ms.
- pNN50, the proportion of NN50 divided by the total number of NNs.
- NN20, the number of pairs of successive NNs that differ by more than 20 ms
- pNN20, the proportion of NN20 divided by the total number of NNs.

E. Frequency-domain methods

Frequency domain methods assign bands of frequency and then count the number of NN intervals that match each band. The bands are typically high frequency (HF) from 0.15 to 0.4 Hz, low frequency (LF) from 0.04 to 0.15 Hz, and the very low frequency (VLF) from 0.0033 to 0.04 Hz.

Several methods of analysis are available. Power spectral density (PSD), using parametric or nonparametric methods, provides basic information on the power distribution across frequencies. One of the most commonly

used PSD methods is the discrete Fourier transform. Methods for the calculation of PSD may be generally classified as nonparametric and parametric. In most instances, both methods provide comparable results.

I. Our At-Home Stress Monitoring Dashboard

In this section, we discuss how to operate our at-home stress management dashboard

A. Logging In and Out

After logging in with the Username and Password, the caregiver can access the Stress Management Dashboard. At the end of each session, the caregiver should log out using the "Sign Out" dropdown at the top right of the screen.

B. Navigating the Dashboard

The caregiver can use the "User ID" dropdown menu to select the target subject. They can then use the "Select Date" dropdown to the day when t. In this study, each subject has data recorded for one day. A representative Dashboard is shown in Fig.2.

C. Daily All Biometric

This tab uses graphs to summarise at a minute interval the following biometric data heart rate, rMSSD (HRV), and respiratory rate. Heart rate is measured in beats per minute (BPM) and has a normal range of 60 to 100 BPM at rest. rMSSD (HRV) is expressed in millisecond (ms) and has a normal range between 50 to 250 ms at rest. Respiratory rate is also expressed in breaths per minute (bPM) and has a normal range of 18 to 30 bPM rest. Blood cortisol is measured in ng/ml and has the following range depending on time of day 3.7-9.5 ng/mL (morning); 1.2—3.0 ng/mL (noon); 0.6—1.9 ng/mL (evening). The stress level is defined in arbitrary units as 0 (complete rest), 20 (walking in office), 40 (jogging), and 60 (running).

D. Daily Summary

This tab summarizes the minimum, average, and maximum values for each biometric parameter for each subject for the duration of the day numerically. The biometric parameters are heart rate, rMSSD (HRV), and respiratory rate. This allows the caregiver to evaluate if the biometric is in the correct ranges quickly.

E. Daily Heart Rate Distribution

This tab shows the exact distribution of the heart rate of the user for a particular date. This allows the caregiver to evaluate if the user is suffering from bradycardia quickly (heart rate is too slow <60 BPM) or tachycardia (heart rate is too fast >100 BPM).

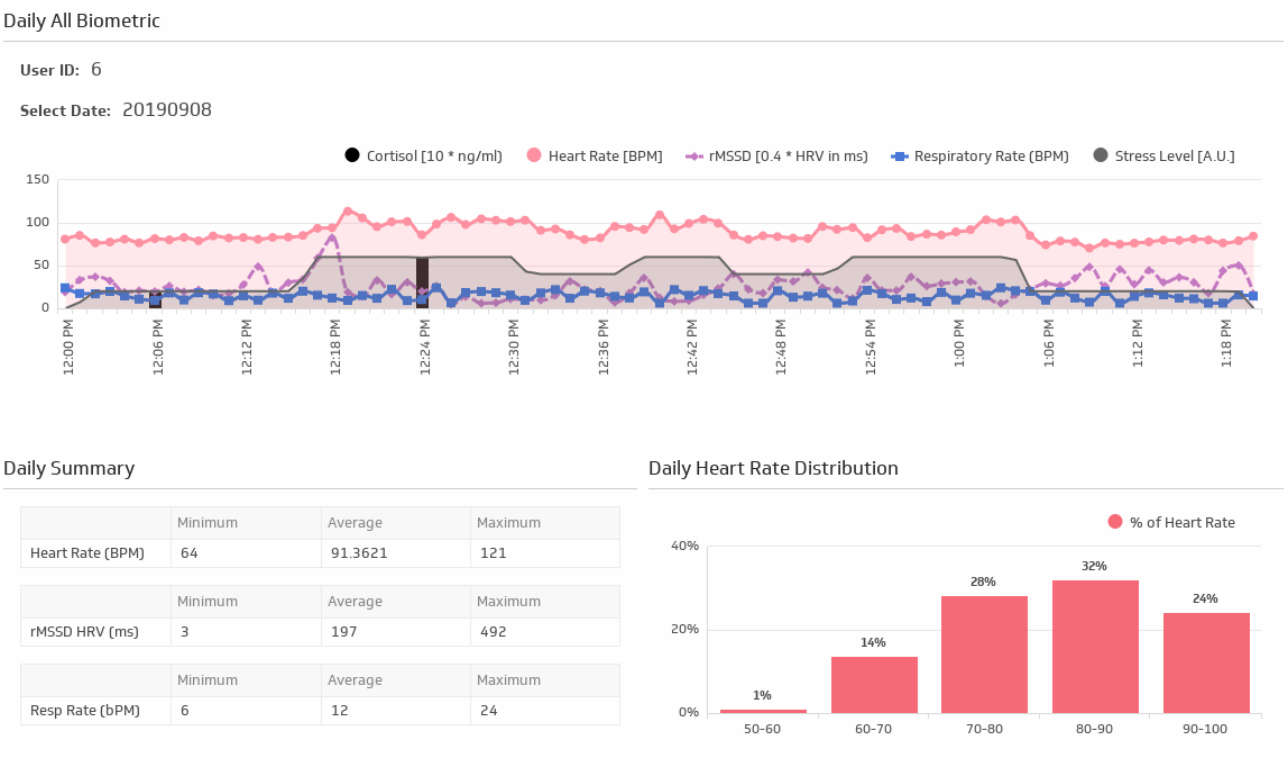


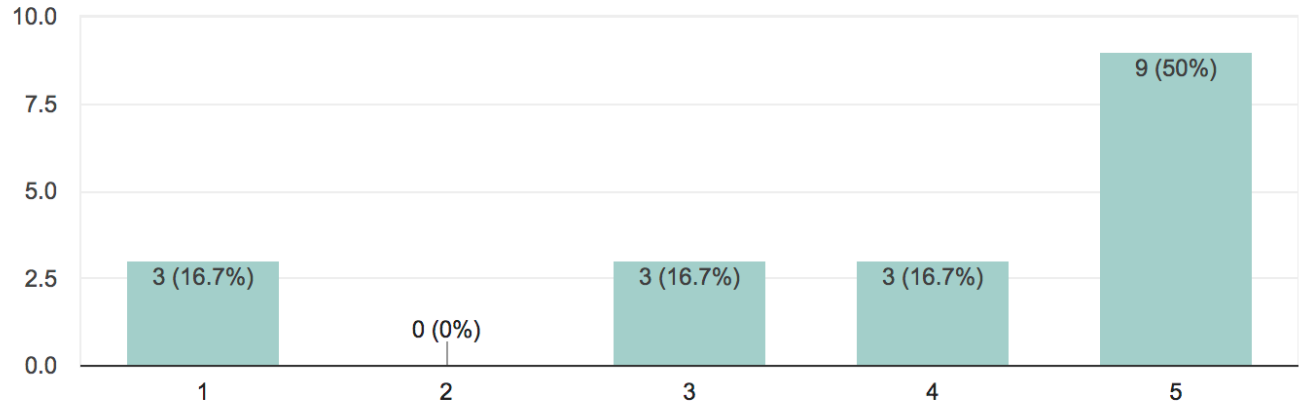
Fig.2. Sample stress monitoring dashboard presented in this study.

II. The questionnaire used in this Study and Results

A. Usability of Stress Monitoring Platform

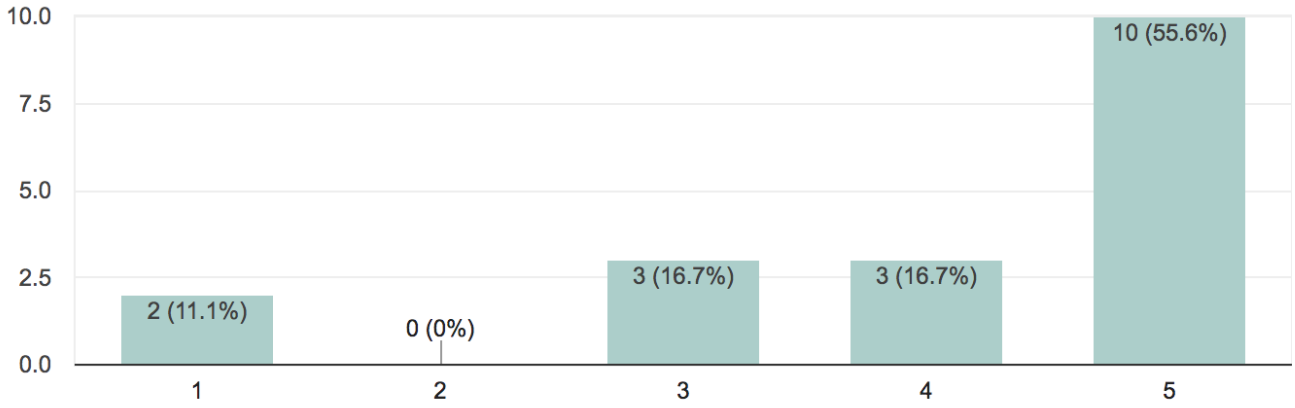
1. How much did you already know clinical significance of heart rate and heart rate variability?

   Answer - 1 - Not at all to 5 - A lot.



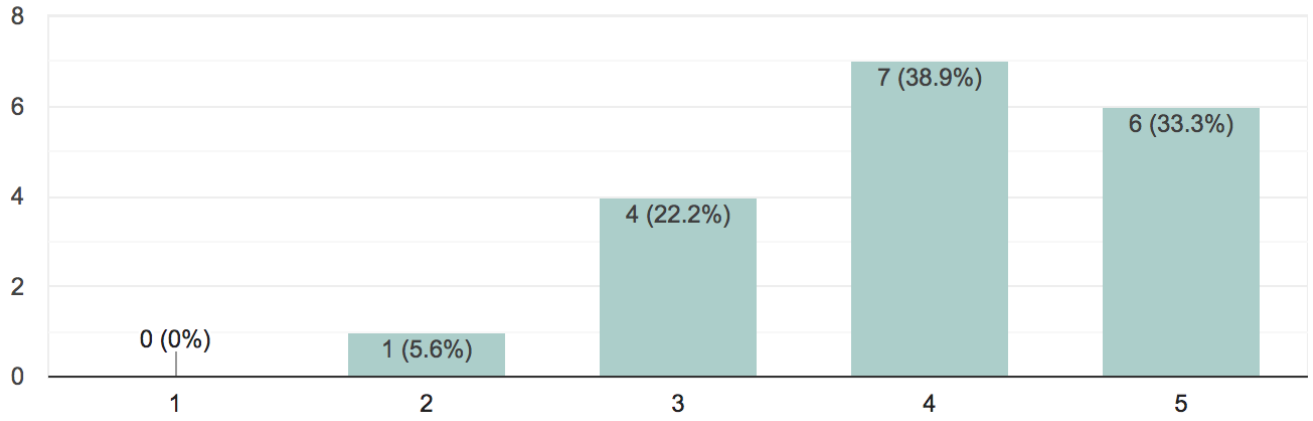
2. How much did you already know about the clinical significance of heart rate variability for measuring stress?

   Answer - 1 - Not at all to 5 - A lot.



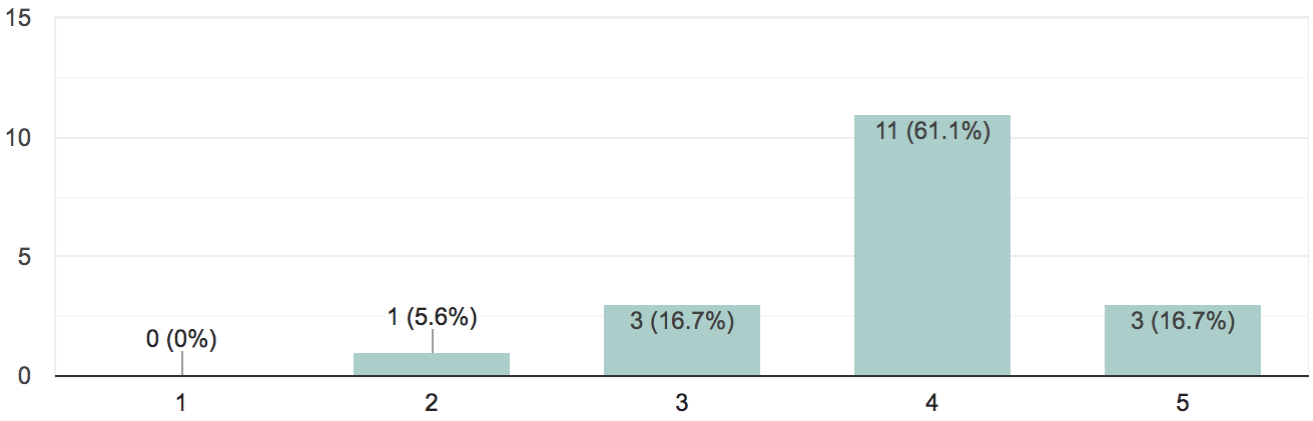
3. How difficult it was to navigate the document "Care Giver's Guide to Using the Stress Monitoring Dashboard"?

   Answer - 1 – Very difficult to 5 -Very easy.



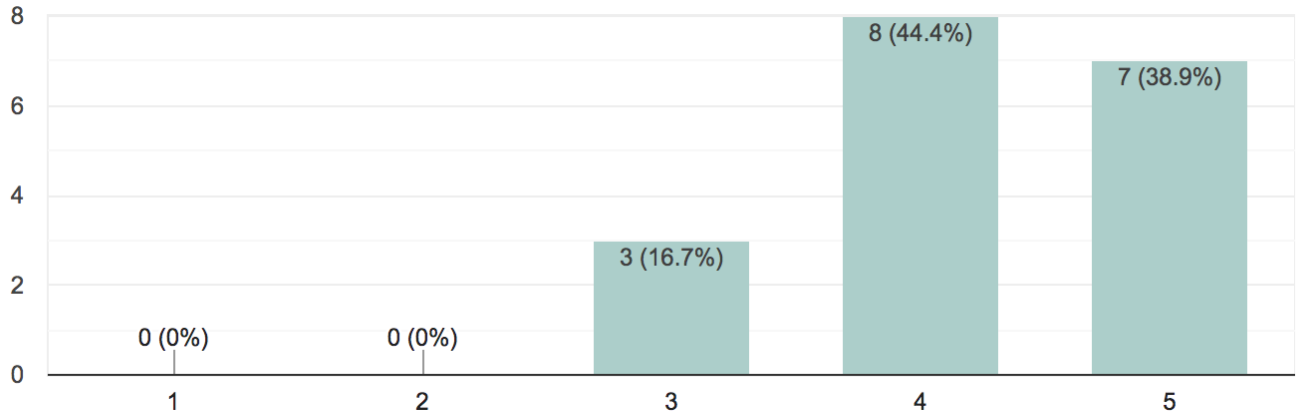
4. How would you rate the document based on length "Care Giver's Guide to Using the Stress Monitoring Dashboard"?

   Answer - 1 –Too short to 5 -Too long.



5. How would you rate the Q&A at the end of the document "Care Giver's Guide to Using the Stress Monitoring Dashboard"?

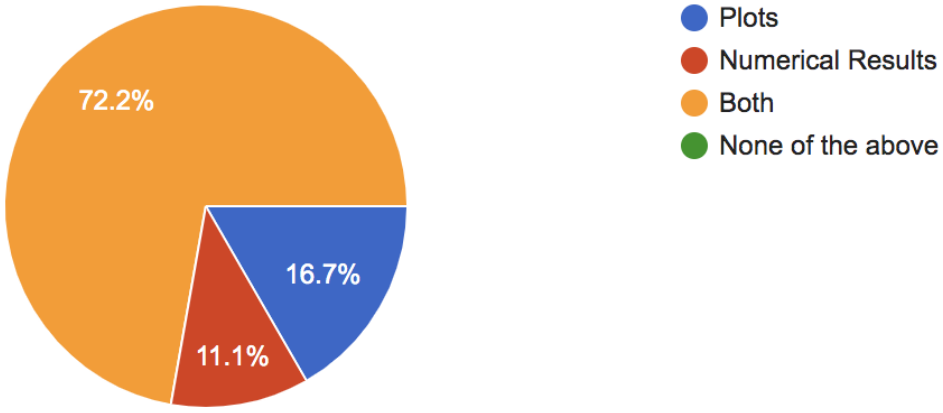
   Answer - 1 – Very difficult to 5 -Very easy.



B. *Efficacy of the stress monitoring dashboard in determining stress events*

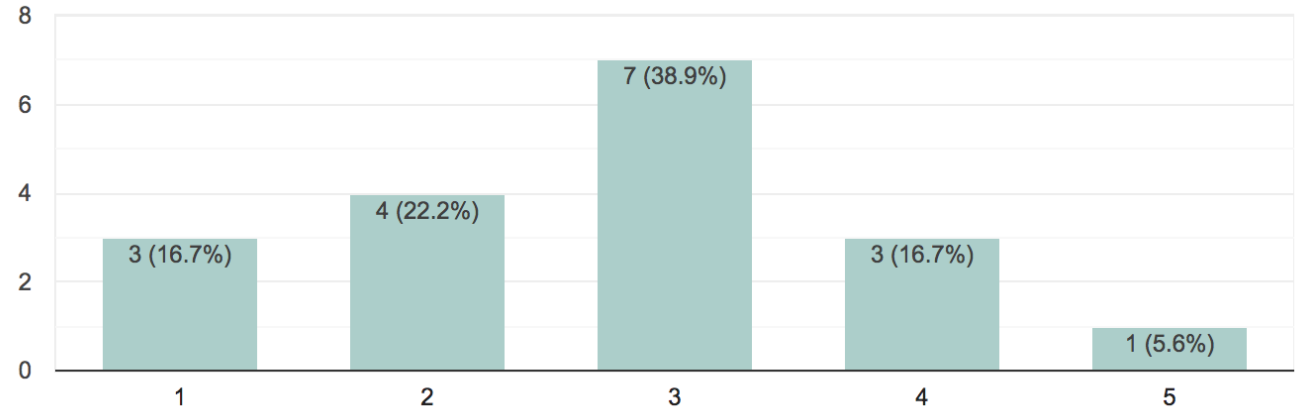
6. In the case of stress monitoring dashboard, what in your opinion is the most clinically significant way of presenting the data?

   Answer – Plots, Numerical Results. Both, None of the above



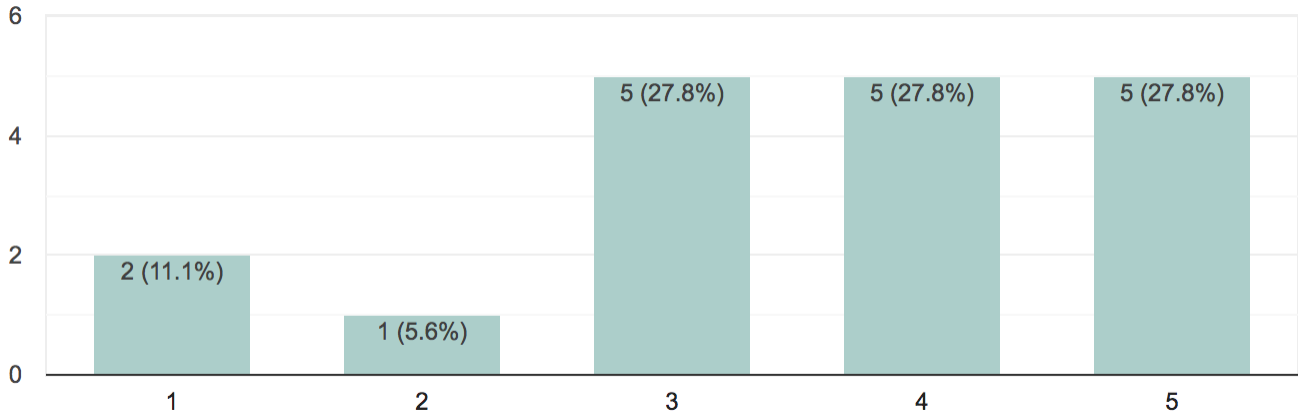
7. In your day to day clinical role, how indicative is rMSSD (a measure of Heart rate variability) in determining stress?

   Answer – 1 – Not indicative to 5 – Highly indicative



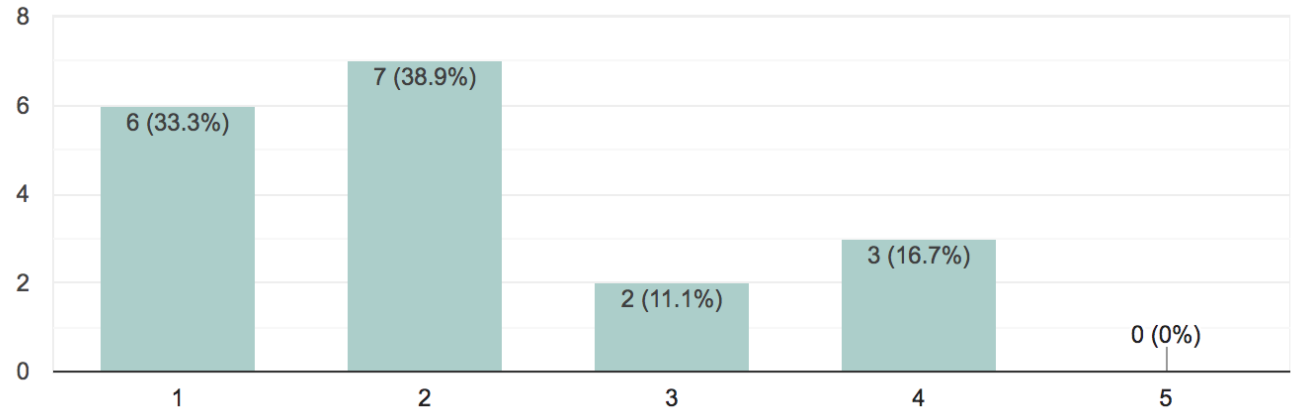
8. In your day to day clinical role, how indicative is blood cortisol testing in determining stress

   Answer – 1 – Not indicative to 5 – Highly indicative



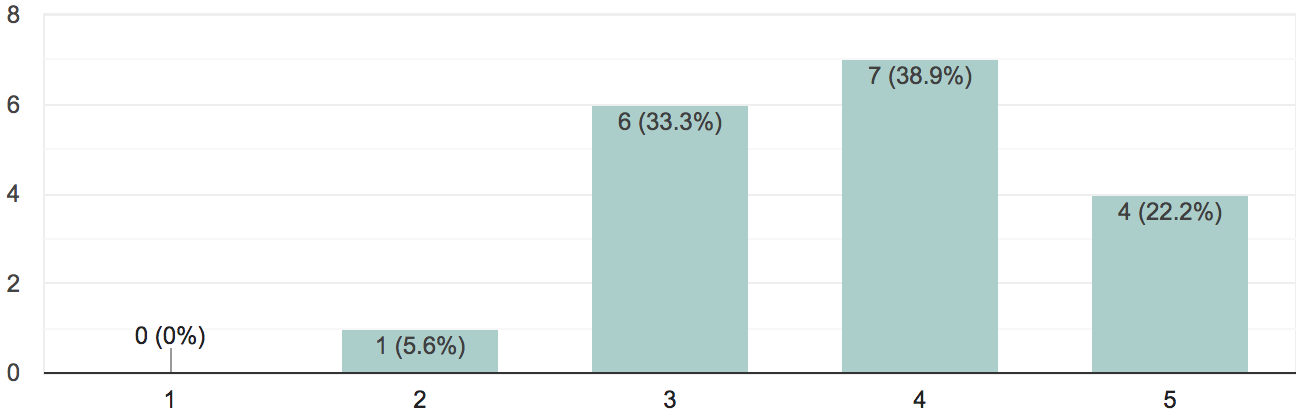
9. In your day to day clinical role, how indicative is saliva cortisol testing in determining stress

   Answer – 1 – Not indicative to 5 – Highly indicative



10. In reviewing the data shown in the stress monitoring dashboard, do the results meet your expectations in terms of the correlation between blood cortisol levels and rMSSD as a stress indicator?

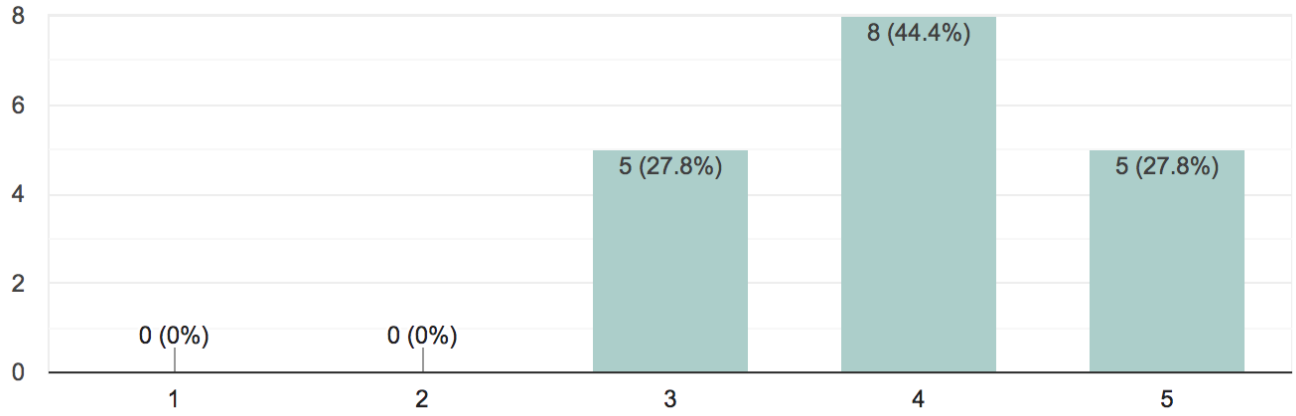
    Answer - 1- Very obvious to 5 - Highly unexpected



C. *Ease of navigating the stress monitoring dashboard*

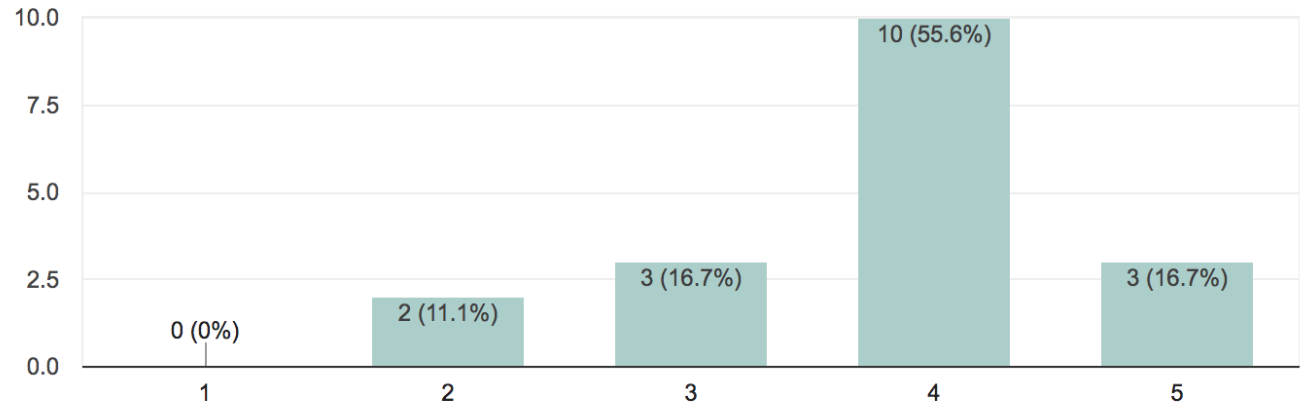
11. What was your experience regarding reading the plots on the dashboard?

    Answer - 1- Poor and 5 – Excellent



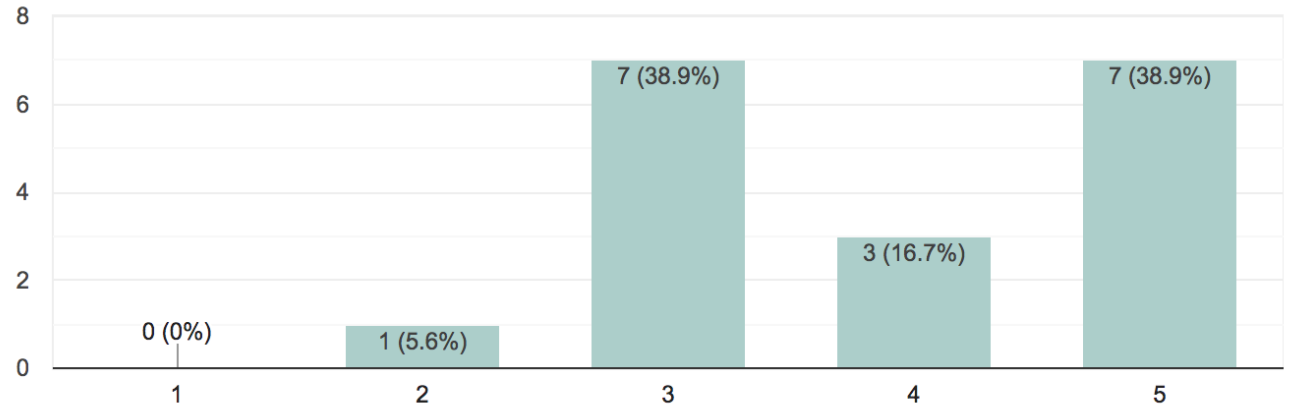
12. What was your experience regarding the reported numerical data on the dashboard?

Answer - 1- Poor and 5 – Excellent



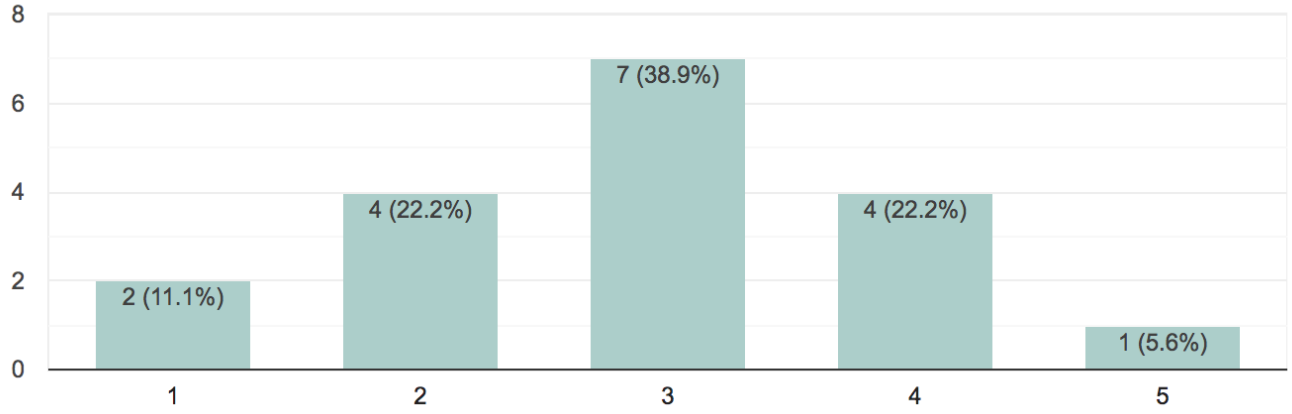
13. How relevant are the reported data in making medical decisions regarding stress?

Answer - 1- Poor and 5 – Excellent



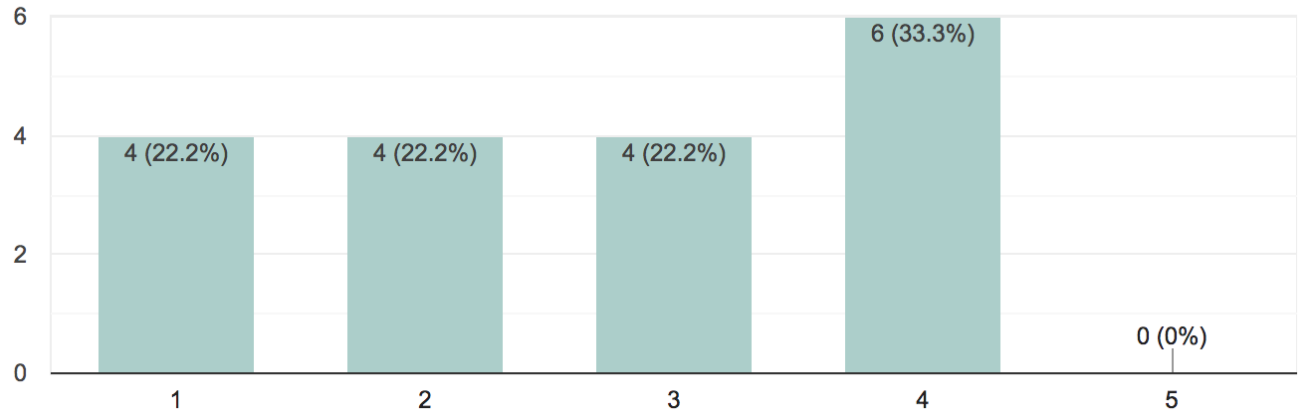
14. How difficult it was to log into the dashboard?

Answer - 1- Poor and 5 – Excellent



15. How difficult it was to locate the individual healthy volunteers on the dashboard?

Answer - 1- Poor and 5 – Excellent



D. Selected Additional Comments

"Quite innovative, good addition to clinician's decision making"

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