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Open-Label, Prospective Study for the Biofourmis Everion Armband Telemonitoring (BEAT) Solution for Patients during COVID-19 Home Isolation

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Abstract

Objective: This study aims to assess the feasibility and suitability of the Everion Armband Device in the telemonitoring and early detection of symptoms of COVID-19-positive patients during their home isolation period. **Methods:** This is an open-label, prospective study that was conducted in 2020. Included in the study were patients diagnosed with COVID-19 and medically stable at home isolation. Eligible participants after consent were provided with the Everion Armband Device adept at recording discrete measurements such as heart rate, oxygen saturation, respiration rate, and temperature, offered a comprehensive remote monitoring solution for COVID-19 patients in their homes. Clinical data was reviewed in a timely manner by the investigator team, for post COVID-19 related symptoms, such as increase in body temperature. **Results:** Nineteen participants with a mean age of 42 years old, were recruited in the study. The temperature recorded was <35 degrees Celsius for 67% of measuring intervals on average (S.D. ± 24.13). The Armband Device provided accurate vital signs' data. Participants reported that the device was user-friendly. While the participants responded positively to the Armband Device and monitoring process, and there was evidence that monitoring resulted in early detection of clinical deterioration, this study identified several issues that would need to be addressed to make wider use of this technology feasible and useful. **Conclusions:** The use of smart devices for remote patient

monitoring, especially during a pandemic, was a novel approach that could enhance healthcare delivery and early symptom detection.

Keywords

COVID-19, SARS-CoV-2, Vital Signs, Wearable Monitoring System, Telehealth, e-Health, Remote Patient Monitoring

1. Introduction

Coronavirus Disease 2019 (COVID-19) is a respiratory tract infection caused by coronavirus SARS-CoV-2 (Lai et al., 2020). This disease emerged throughout the world and led to a significant toll surpassing over 12 million cases and resulting in 560,000 deaths globally in 2020 (Chu et al., 2020). The virus is readily transmissible, with a large proportion of the population susceptible and certain groups exhibiting substantial mortality, including the elderly and those with comorbidities (Lai et al., 2020). To manage risk and to help meet the demand for an alternate care pathway, temporary Flu Assessment Clinics (FACs) were established across southwestern Sydney (SWSLHD, 2020). The FACs primarily catered for ambulant patients and healthcare workers who require screening for COVID-19. If a member of the community or staff member tested positive for COVID-19 from one of the FACs and was well enough to self-isolate at home, follow-up would occur daily by phone by the Primary & Community Health (P&CH) clinical staff.

The presence of the COVID-19 pandemic has significantly increased its digital health applications and development as a key factor in mitigating the disease and breaking the cycle of disease transmission, despite the fact that digital technology in healthcare services was first introduced decades ago as telehealth or remote healthcare services (Alghamdi & Alghamdi, 2022). Telehealth enables patients to stay away from enormous crowds of people in clinical centre waiting for areas, reinforcing social distancing (Blandford et al., 2020). As a high temperature (fever) was one of the symptoms of COVID-19 in 2020, infrared thermal cameras and thermometers were installed in crowded places like airports and other areas of public transportation, schools, and workplaces to identify and screen infected people and monitor their temperature (Alghamdi & Alghamdi, 2022). According to a systematic review, using digital technology services has been the most effective tactic during the epidemic, particularly for those who isolate themselves (Monaghesh & Hajizadeh, 2020). Maintaining social distance and lowering the danger of virus transmission are two important benefits of telehealth. Numerous telehealth tools have been employed, including WhatsApp, social media websites, and live video conferencing through FaceTime or Skype. Additionally, telemedicine can be used to provide elective treatment and regular check-ups for patients who don't require urgent care or invasive procedures (Monaghesh & Hajizadeh, 2020).

Most people with COVID-19 do not require admission to hospital as they are able to recover at home. With a disease as infectious as COVID-19, remaining in isolation plays a key role in preventing transmission however it is also necessary to ensure patients are receiving the care they need. In 2020, individuals who were triaged to home isolation would be provided with the necessary information to keep them and those residing with them safe in line with the NSW Health home isolation guidance for people confirmed to have COVID-19 infection.

Sensors and commercial wearable devices have been widely used to monitor vital signs in COVID-19 patients over long periods of time (Zhang et al., 2021; Radin et al., 2021; Mekhael et al., 2022; Georghiou, 2022). Virtual, in-home digital healthcare programs for confirmed COVID-19 cases have been implemented globally and in Australia in response to the pandemic, however, more evidence is needed on their adaptation. Remote monitoring solutions can play an important role in providing care for patients and better understanding disease progression and implementation (Alghamdi & Alghamdi, 2022). This paper reports our experience on the feasibility and usability of using wearable biosensor band monitoring of COVID-19 patients isolated in their homes.

2. Method

2.1. Study Aim

This study aimed to assess the feasibility and suitability of wearable biosensor armband monitoring of COVID-19 patients isolated in their homes. This study was conducted in south western Sydney.

2.2. Study Design and Intervention

This is an open-label, prospective investigation, the study employed Everion Armband's reflective photoplethysmography (PPG) measurements to monitor physiological parameters. The model of care utilised bio-instrumentation technologies to measure and monitor clinical vital signs via mobile phone application which allowed clinicians to review the results via a cloud-based platform. These devices were approved for clinical use by the Therapeutic Goods Authority (TGA).

Biofourmis Infection monitor (*Sentinel*) *solution*

Biofourmis put a solution in place combining its experience in remote vital signs monitoring, symptoms tracking, and prediction of physiological changes into the Sentinel Platform. The Biofourmis Infection monitor (Sentinel) solution allowed caregivers to remotely monitor patients who were suspected of COVID-19 (Van Vliet et al., 2010). The remote monitoring solution was designed to capture all vitals and symptoms necessary for the diagnosis of infection of COVID-19 by using a wearable sensor (Everion® Armband Device—FDA and TGA approved), on-phone microphone, and patient-reported outcomes (PROs) using surveys (Filho et al., 2021). The Sentinel Platform could be used by overloaded authorities to monitor quarantined patients, exposed healthcare staff, family members,

or others that are suspected of being infected. The lightweight Everion Armband Device, seamlessly integrated with cloud technology, facilitated continuous monitoring, providing real-time access to vital signs 24 hours a day. This proved invaluable, allowing clinicians to receive immediate alerts if a patient's condition raised concerns, enabling timely intervention or hospital transportation (Wong et al., 2020).

The Everion Armband Device, adept at recording discrete measurements such as heart rate, oxygen saturation, respiration rate, and temperature, offered a comprehensive remote monitoring solution for COVID-19 patients in their homes. Some of the monitored parameters include:

- Skin temperature (and derived core body temp)
- Heart rate
- Respiration rate
- SpO_2 (and raw PPG)
- Inter-beat-interval (and HRV)
- Blood Pulse Wave

Patients also submit symptom surveys:

- Fatigue levels
- Cough (Dry or with Mucus)
- Nasal (Blocked, Runny, Normal)
- Sneezing (Yes or No)
- Watery eyes (Yes or No)
- Pain (Muscle, Joint, Chest, Sinuses)

2.3. Participants

The FACs team in southwestern Sydney provided a list of patients who were diagnosed with COVID-19. Inclusion criteria necessitated participants to be 18 years or older, capable of completing the questionnaire, and willing to provide informed consent. Those at high risk of hospitalization and who did not consent were excluded from the study. After a careful examination of eligibility criteria, individuals were given sufficient time to decide on participation, with informed consent being a mandatory prerequisite. The study sample comprised patients enrolled over a 22-week period starting from May 2020, identified through the FACs under the governance of the Primary & Community Health. Participants were onboarded with the Everion Armband Device, following guidelines outlined in the Product Operations Manual and under the guidance of the clinical staff.

2.4. Data Collection

Real-time data from the Everion Armband Device was seamlessly transmitted to the investigator's mobile device. The investigator diligently scrutinized the data, marking findings that warranted escalation. These marked findings were promptly sent to the investigator team's medical officer for further review and

intervention. These interventions included but were not limited to the following:

- If the participant was determined at clinical risk, this information was shared with their treating doctor immediately via phone call.
- If the participant was found to be experiencing a medical emergency, they were advised to present to the nearest hospital or call the ambulance for assistance.
- If no further action was required outside of ongoing monitoring, the summary was provided to the participant and their doctor for their records.

2.5. Analysis

All statistical analyses were performed using IBM SPSS Software (Version 29.0). Continuous and discrete variables were expressed as mean ± standard deviation and percentage respectively.

2.6. Ethical Considerations

This study was approved by the Human Research Ethics Committee in south-western Sydney. The participants provided written informed consent to take part in this study.

3. Results

Nineteen participants with a mean age of 42 years old, provided consent for participation. Compliance data were provided as the number of hours each participant's device was active for each day. Aggregating data from full monitoring days only (as the number of hours the device should have been active on these days is known – i.e., 22 hours), participants were being actively monitored on average of 15.4 hr/day (S.D. ± 5.4 hr). Throughout the entire study, we observed and recorded activities for a total of 87.35 hours, with a standard deviation of 65.51. Two patients had no full days of monitoring. Table 1 summarizes the total time monitored (in hours) for each participant across their time participating in the study.

Participants were provided with feedback surveys to complete before and after their monitoring period. Participants who did not complete and return the surveys were contacted by phone by an independent researcher to seek feedback. Eleven participants completed feedback surveys and reported that the Everion Armband Device and Sentinel Platform were user-friendly. Six (n = 6) participants felt that the remote monitoring was beneficial in terms of providing peace of mind and information about their health. One participant reported that it took much time to manage the device and would not wear it again.

Clinical staff who were involved in fitting Everion Armband Devices and carried out monitoring via the Sentinel Platform were also provided with feedback surveys to complete. Three staff (100%) completed the feedback survey. Staff was asked to rate the user-friendliness of various aspects of the system on a 1 - 10 scale (1 = "Not at all use friendly", 10 = "very user friendly"). The average ratings were as follows:

Table 1. Total time monitored (in hours) for each participant.

Patient ID	Total time monitored (hrs)
BTS004	58.45
BTS005	26.35
BTS006	208.48
BTS007	21.18
BTS008	135.53
BTS009	70.27
BTS010	63.38
BTS011	52.20
BTS012	78.88
BTS013	20.47
BTS019	105.73
BTS020	6.33
BTS021	192.23
BTS022	215.77
BTS024	170.32
BTS026	91.32
BTS027	0.53
BTS029	0.60
BTS038	156.10
Mean	87.35
S.D.	68.51

- Device = 4.7/10
- Smartphone App = 4/10
- Monitoring Platform = 5.3/10

They were also asked to rate how beneficial they felt the Everion Armband Device was in terms of improving patient care (1 = "Not at all beneficial", 10 = "Very beneficial"). The average rating provided was 4.3/10.

One staff member reported that some participants were happy with the device. Staff felt the device was difficult to connect, often requiring multiple devices to be trialled before successfully pairing one with the participant's phone. Some participants could not be fitted as a result. Staff also reported that the devices did not stay connected to the participants' phones continuously. Concerns were also raised in relation to the time taken to set up the device, with staff reporting that it could take anywhere from five minutes to an hour to connect successfully. The device was also described as being "fiddly" to reset between patients and staff were not confident that devices had been reset properly. Staff also reiterated the patient reported of discomfort from wearing the device.

This study identified several issues that would need to be addressed to make wider use of the device feasible and useful. Vital signs data were provided in Table 2, indicating that even during "active" monitoring times above, not all vital signs were being monitored consistently. Monitoring clinical data files provided one reading per second for each parameter while the device was activated. In some cases, this reading was "0", indicating no data was recorded for that 1-second monitoring period for the relevant parameter. For the parameters relevant to COVID-19 monitoring, taking the average % of missing readings across patients: heart rate was not recorded on average 8.52% of the time (S.D. ± 11.12%) and respiration rate was not recorded on average 5.76% of the time (S.D. ± 6.06%). Oxygen saturation was never recorded as "0", however, a reading of "60%" was recorded for many monitoring periods and for these periods, the "quality" rating for the saturation measurements (as determined according to Biofourmis' protocols for the clinical validity of the data) was "0". These "0" quality measurements for SPO_2 occurred on average 69.20% of the time (S.D. ± 27.21%) as shown in Table 2.

Table 2. Vital signs data of each participant.

Patient ID	Heart rate	Respiration rate	SPO_2 "quality" = 0	Temp < 35
BTS004	0.22%	1.33%	75.21%	87.61%
BTS005	18.42%	17.04%	60.13%	39.78%
BTS006	0.06%	0.29%	37.28%	34.46%
BTS007	13.12%	6.24%	100.00%	73.80%
BTS008	0.12%	0.35%	4.49%	35.78%
BTS009	0.06%	0.48%	60.33%	94.91%
BTS010	27.54%	14.35%	92.97%	87.36%
BTS011	4.14%	7.14%	78.54%	81.36%
BTS012	3.23%	1.03%	45.49%	53.82%
BTS013	0.03%	0.08%	23.77%	31.37%
BTS019	1.65%	9.02%	56.70%	17.37%
BTS020	6.15%	14.06%	74.70%	77.37%
BTS021	0.85%	1.38%	49.81%	73.57%
BTS022	0.11%	1.45%	76.69%	71.64%
BTS024	13.72%	5.16%	99.02%	63.71%
BTS026	19.96%	2.01%	80.36%	78.60%
BTS027	0.72%	4.79%	100.00%	100.00%
BTS029	41.12%	19.77%	100.00%	100.00%
BTS038	10.63%	3.43%	99.31%	70.74%
Average % readings missing	8.52%	5.76%	69.20%	67.01%
S.D.	**11.12%**	**6.06%**	**27.21%**	**24.13%**

Skin temperature was recorded for all monitoring periods (Table 2); however, the reliability of readings was often questionable – i.e., barely above the environmental temperature (also recorded by the device) and not plausible temperatures for a live human body. The temperature recorded was <35 degrees Celsius for 67.01% of measuring intervals on average (S.D. ± 24.13). Three participants were successfully identified via the Sentinel Platform and escalated for urgent interventions: transferred to hospital admission (n = 2) and, an urgent home visit by a clinical staff from the Primary and Community Health (n = 1). There were no reported near misses or adverse events.

4. Discussion

COVID-19, which emerged in December 2019, was expanding far beyond the capacity of many healthcare systems. Australia's success in containing the initial waves of infection in 2020, could be attributed to its effective measures, including contact tracing, local lockdowns, travel restrictions, and social distancing (Monaghesh & Hajizadeh, 2020). Our study and experience in the Everion Armband Device and adaptation during the pandemic is another example of using advanced technology to support virtual, in-home digital health. This model of care helps in curbing the spread of the virus preventing a large-scale outbreak and also protects the healthcare staff. Despite effective vaccines, COVID-19 continues to be a serious public health problem. The significant negative economic impact has driven government policy decisions to remove mask mandates and lift most COVID-19 restrictions (Chow et al., 2023a). However, with the emergence of new variants and increasing surges in case numbers, the ultimate health impact is huge. A validated model for digital health solutions that supports virtual remote monitoring of clinical deterioration early and reduces the burden on hospital-based clinical care will benefit patients, primary and secondary health carers, and acute-care hospitals (Chow et al., 2023b).

In this study, participants were actively monitored on an average 15.45 hours per day. Different physiological parameters were recorded to monitor the patient remotely. The reliability of measurements, particularly oxygen saturation and skin temperature, was frequently questionable, and the source of these inconsistencies had negative impact on the wider adaptation. These challenges mirrors other published experiences that consistency with which devices could record and upload data also presented problems, whether due to interruptions in the device's functioning, to pairing with the patient's mobile device or to the availability of an internet connection (Monaghesh & Hajizadeh, 2020). With technological advancement and the introduction of artificial intelligence, some of these technical issues will be resolved with the release of updated versions of the device.

Participants in this study reported that the Everion Armband Device and the application were easy to use or user-friendly. While participants responded positively to the Everion Armband Device and monitoring process, and there was

evidence that monitoring resulted in early detection of clinical deterioration, this study identified technological and also compliance issues that would need to be addressed to make wider use of the device feasible and useful.

Feedback from the clinical staff who were involved in fitting the Everion Armband Devices and carrying out monitoring via the Sentinel Platform was mostly negative. The negative feedback was centered primarily on the technical aspects of the device and its application. The challenges identified in this study relate to the knowledge, attitudes, and needs of staff and patients regarding the device and monitoring system. Large gaps in the data recorded for many participants indicates either a problem with the device or a lack of consistent wearing by the participants. Participants identified problems with the comfort and usability of their devices which may have acted as a disincentive to consistent wearing. These issues need to be addressed in any future use of similar technologies. This negative feedback and inadequate onboarding and training might be due to the nature of the pandemic when intervention was required to be implemented urgently and without proper design.

Various remote home monitoring models have been designed and implemented for COVID-19 patients who were stable enough to be monitored at home providing early detection of deterioration, managing care escalation, avoid unwarranted hospital visits and further reducing strain on the hospitals (Aalam et al, 2021). This study and the model have reinforced the importance of monitoring patients during their infectious period and providing an equitable service. The investigator team has developed early screening via virtual, in-home healthcare program and activate appropriate interventions if required. This study has developed guided strategies to determine a feasible and usable monitoring protocol.

4.1. Implication to Clinical Practice

Despite reasonably effective vaccines, COVID-19 continues to be a serious public health problem. The significant negative economic impact has driven government policy decisions to remove mask mandates and lift most COVID-19 restrictions. However, with the emergence of new variants and increasing surges in case numbers, the ultimate health impact is huge. Furthermore, there is no definite understanding of the chronic impacts of COVID-19 on heart, lungs, organs and brain. This warrants the development of innovative and alternate approaches to designing collaborative models of care. A validated model for digital health solution that detects health deterioration early and reduces the burden on hospital-based clinical care will benefit patients, primary and secondary health carers, and acute-care hospitals. Therefore, early screening of convalescing patients via a virtual, in-home healthcare program may reduce the population burden of long-term CVD from COVID-19 or any other public health.

4.2. Strengths and Limitations

This study was limited by the relatively small sample size. Not all the vital signs

were measured consistently. Although technically appealing, potential privacy issues can arise when an individual patient's physiologically sensitive data is transmitted and stored in the network, this requires management for privacy protection before large-scale deployment. Secondly, the Everion Armband Device was studied for only 14 days (about 2 weeks) and compliance may be different during long-term use. The results from this study will provide information on the feasibility and benefit of a broader implementation of the Everion armband technology for patient monitoring in the primary and community setting. To further validate the clinical value of this wearable biosensor and machine learning-based remote monitoring platform, conduct a randomized controlled trial with sufficient power to demonstrate efficacy in improving patient outcomes is needed.

5. Conclusion

The use of smart devices for remote patient monitoring, especially during a pandemic, was a novel approach that could enhance healthcare delivery and early symptom detection. Implementation to virtual, in-home remote monitoring program is anticipated to result in healthcare cost reduction, improve the inequality in healthcare and promote the use of advance technologies.

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The ethical aspects of this research project were approved by the Human Research Ethics Committee at South Western Sydney Local Health District. This project was carried out according to the National Statement on Ethical Conduct in Human Research.

Data Available Statement

The datasets used and/or analyzed for this study are available from the corresponding author on reasonable request.

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Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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