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Research Article

Clinical Trial Design for Remote Patient Monitoring in Nigeria using MEDLINK -

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ABSTRACT

Remote Patient Monitoring (RPM) devices are used by physicians today to monitor patients discharged from the hospital when they are in their homes. Remote Patient Monitoring (RPM) is relatively new in the medical industry and has not yet been introduced in Nigeria. MEDLINK is a Remote Patient Monitoring (RPM) device that verbally interacts with the physician to acquire the specific physiological parameters the physician wishes to monitor for a particular patient. After successful programming, the physician can then give MEDLINK to the patient to take home for Remote Patient Monitoring (RPM) monitoring. When the patient gets home and switches on the device, MEDLINK guides the patient through the process of acquiring the physician-requested data, transmits it to the physician's phone and e-mail, and allows for physician-patient communication *via* text messages, if there are data abnormalities detected by the physician. This paper presents the design of a Clinical Trial to evaluate the effectiveness of MEDLINK in providing Remote Patient Monitoring (RPM) for five diseases in Nigeria (Diabetes, Hypertension, Heart Failure, Chronic Obstructive Pulmonary Disease COPD, and Myasthenia Gravis). The Clinical Trial consists of three phases: Phase 1 Clinical Trial with 20 volunteers, Phase 2 Clinical Trial with 150 volunteers, and Phase 3 Clinical Trial with 450 volunteers. The data acquired during this trial will be used to analyze if Remote Patient Monitoring (RPM) helped the physicians identify things they would not otherwise have been able to (e.g. deteriorating condition, fatality triggers, fatality fore-warning data, ineffective dosage, non-working dosage, and non-hospital detected abnormalities) after discharging the patient from the hospital, and if Remote Patient Monitoring (RPM) helped the physicians adjust their treatment protocol for any of the five diseases.

Keywords: Remote patient monitoring; Hypertension; Diabetes; Heart failure; Chronic obstructive pulmonary disease; Myasthenia gravis

INTRODUCTION

Remote Patient Monitoring (RPM) devices are used by physicians today to monitor patients discharged from the hospital when they are in their homes. These devices are generally used by the patient to measure the physiological parameter desired by the physician, and transmit it to the physician for him or her to check and ascertain if the patient is improving and okay. This capability assists in early and real-time detection of illness, prevention of worsening of illnesses and untimely deaths, cost reduction in hospitalization, and reduction in the number of hospitalizations [1]. The cost of 1 hospital stay for Chronic Obstructive Pulmonary Disease (COPD) and chronic heart failure in Canada was estimated to be $6038 CAD and $6222 CAD respectively [2]. The number and cost of ER visits and hospitalizations is significantly reduced for patients with COPD or CHF using Remote Patient Monitoring (RPM) [3]. Remote Patient Monitoring (RPM) can be performed on patients diagnosed with mobility issues, patients with chronic illnesses, post-surgery patients, neonatal patients, and elderly patients [1]. To date, the use of Remote Patient Monitoring (RPM) in treating patients in Nigeria has not been documented in the literature. Remote Patient Monitoring (RPM) is relatively new in the field of medicine and has not yet been introduced in the Nigerian Medical Society as a viable means to enhance patient treatment. MEDLINK is the first medical Remote Patient Monitoring (RPM) device intended to be introduced into the Nigerian Medical field on a large scale. The innovative design is owned, patented, and produced by RACETT NIGERIA LTD., and RACETT CANADA INC.

A thorough introduction to the MEDLINK device can be found at Ejofodomi et al. [3]. A working demonstration of MEDLINK can be viewed at https://www.youtube.com/watch?v=0uWSEL1_EzA. MEDLINK verbally interacts with the physician to acquire the specific physiological parameters the physician wishes to monitor for a particular patient. After successful programming, the physician can then hand over MEDLINK to the patient for them to take home for Remote Patient Monitoring (RPM) monitoring. When the patient gets home and switches on the device, MEDLINK verbally greets him or her by name and then guides the patient through the process of acquiring the physician-requested data, transmits it to the physician's phone and e-mail, and allows for physician-patient communication if there are data abnormalities detected by the physician. The physician has the ability to send such physician-patient communication *via* text messages to the MEDLINK device, and these messages are read aloud to the patient by the MEDLINK device whenever it is turned on. The verbal interaction ensures that the patient does not need to look at a device manual before he or she can effectively use MEDLINK for Remote Patient Monitoring (RPM).

A fully functional model of MEDLINK is shown in figure 1. It has been successfully used to measure the electromyography data, pulse, body temperature, and heart rate of a simulated patient, and that data has been successfully transmitted to a physician's phone *via* text message, as shown in figure 1. Test data obtained from using MEDLINK is presented in table 1.

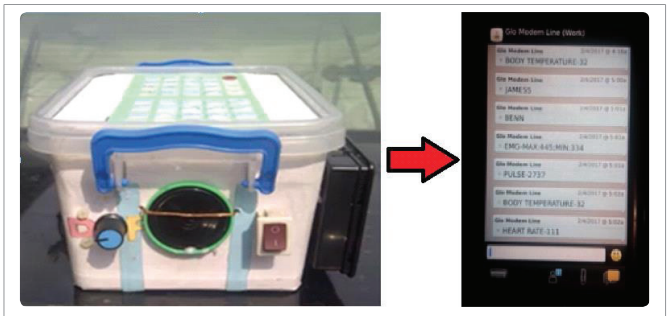


Figure 1: MEDLINK device for Remote Patient Monitoring (RPM).

MEDLINK is entirely non-invasive, portable and capable of measuring a wide range of physiological parameters, including blood pressure, heart rate, pulse, blood glucose, blood oxygen saturation, temperature, Electromyography (EMG) data, Electrocardiography (ECG) and respiration parameters. To ensure maintenance and support of the highest ethical standards (including device regulation), to obtain test results and provide quality data to guarantee the confidence of the medical field from the onset, the authors have designed a clinical trial to be conducted for MEDLINK prior to mass commercialization.

MATERIALS AND METHODS

Materials

The materials used in the Clinical Trial for MEDLINK are the MEDLINK units, designed, created, and produced by Product

Engineers in RACETT NIGERIA LTD (Figure 1). In addition to this, the following two documents will be utilized:

- Patient reporting form
- Physician reporting form

Both are simple assessment forms to be filled by the physician after the patient returns the MEDLINK device back to his or her possession.

Methods

The Clinical Trial is has been tentatively scheduled to commence June 1, 2020, and will be registered with the Pan African Clinical Trials Registry prior to this date. The trial will be conducted in three phases:

Phase 1 clinical trial: The Phase 1 Clinical Trial will be performed on twenty (20) volunteers and will last for approximately 3 months.

Phase 2 clinical trial: The Phase 2 Clinical Trial will be performed on a hundred and fifty (150) volunteers and will last for approximately 1 year.

Phase 3 clinical trial: The Phase 3 Clinical Trial will be performed on four hundred and fifty (450) volunteers and will last for approximately 2 years.

Table 1: Physiological data obtained from using MEDLINK to acquire patient medical information.

No	Physiological parameter	Measured value	Measured value
1	Electromyography Data (EMG):		
	Minimum	345	
		334	
		320	
		360	
		390	349.8 ± 24
2	Maximum	1005	
		975	
		1117	
		445	
		1114	931.2 ± 249.7
3.	Pulse	2737	
		36	
		48	
		24	
		36	576.2 ± 1080
4.	Body Temperature	31	
		31	
		31	
		32	
		32	31.4 ± 0.5
5	Heart Rate	79	
		111	
		82	
		84	
		76	86.4 ± 12.6

Volunteers for the Clinical Trial will be selected by participating physicians. Volunteers should be adults (above 18 years) for the first phase of clinical testing of MEDLINK. Subsequently, the device can be assessed for children. Volunteers could be either male or female and can originate from any part of the country, to ensure gender and ethnic diversity in the trial.

The effect of remote monitoring of patients with specific ailments will be studied. MEDLINK has the capability of measuring physiological parameters necessary to monitor and evaluate cardiovascular diseases, respiratory diseases and musculoskeletal diseases. This Clinical Trial will endeavour to study the effect of Remote Patient Monitoring (RPM) using MEDLINK on cardiovascular diseases (Diabetes, Hypertension, and Heart Failure), respiratory diseases (COPD), and musculoskeletal diseases (Myasthenia Gravis) in patients in Nigeria.

- **Diabetes** - The International Diabetes Federation (IDF) reports that Nigeria has the highest population of people living with diabetes and impaired fasting glucose in Africa [4-5]. Over 5.5% of the country's population suffers from diabetes and its prevalence has a wide range across the country [6-8]. RPM could prove useful in monitoring the blood glucose level and blood pressure of patients diagnosed with diabetes to see if meal plan recommendations for managing the disease are effective, both in the short-term and for long-term purposes.
- **Hypertension** - Hypertension has been reported to have a prevalence rate as high as 44.5% in Nigeria [9-11]. Uncontrolled hypertension is associated with several complications such as heart failure, ischemic heart disease, stroke and chronic renal failure. RPM could help in monitoring this condition.
- **Heart Failure** - Heart Failure contributes 3-7% of all medical admissions to hospitals in most African countries [12]. The most common cause of heart failure in Nigeria is untreated hypertension [12]. Heart failure is characterized by dyspnea, fatigue, and clinical signs of congestion leading to frequent hospitalizations, poor quality of life and shortened life expectancy [13]. RPM monitoring of heart failure patients in Nigeria could prove beneficial in managing this disease.

COPD - COPD is characterized by chronic airflow limitation and lung parenchymal damage due to exposure to noxious gases and particles [14]. RPM can be used to monitor the respiratory parameters of COPD patients after hospital discharge.

- **Myasthenia Gravis** - Myasthenia Gravis is an autoimmune neurologic disease that affects postsynaptic portion of the neuromuscular junction, and is characterized by weakness and fatigue of skeletal muscles due to repetitive use. It is a challenge to treat this condition in resource poor settings due to unavailability of diagnostic aids and pharmacologic therapy [15]. Remote Patient Monitoring (RPM) can be used to monitor limb muscle strength of myasthenia gravis after thymectomy and hospital discharge. It can also be used to measure and monitor lung function if the disease affects the respiratory system.

Participating Physicians will be introduced to the MEDLINK device by the Founders of RACETT NIGERIA LTD., and will each be given a MEDLINK unit to participate in the clinical trial. Physicians will learn how to interact with and program the MEDLINK prior to utilizing it in their clinical profession. It is the physician who will

screen volunteers and select those who meet the criteria to participate in the trial (18 years of age and above) and presenting with one of the five (5) diseases identified above.

Once the physician has selected and informed a volunteer, the physician will program MEDLINK to input the patient's name, a patient's ID (for privacy and security purposes), the physician's mobile phone number (to receive the patient's measured data in the form of a text message), and the physiological parameters he or she would like to obtain from the patient during RPM. After successfully programming MEDLINK, the physician will give it to the volunteer, explain the importance of Remote Patient Monitoring (RPM) and guide the patient on how to use MEDLINK to acquire the medical data the physician has requested. It is a simple step by step procedure with verbal instructions from the MEDLINK unit to make the process simple, efficient and user friendly.

Once the physician is sure that the patient can use the MEDLINK unit by him or herself, the physician will instruct the patient on the required frequency of medical reporting. It could be three times a day (morning, afternoon, and evening), once a day at a particular time, once every other day, or once a week. The frequency of reporting is determined solely by the physician and can be adjusted on a case-by-case basis. The length of time under which the volunteer will undergo Remote Patient Monitoring (RPM) with MEDLINK is also determined solely by the physician, as he or she deems necessary for each case. When the period of RPM reporting established by the physician is completed, the volunteer will return the MEDLINK unit to the physician. The physician will ask the volunteer a few questions (to rate the ease of using MEDLINK during the RPM period) and complete the patient reporting form for the patient. The physician will also complete the Physician Reporting Form for that particular patient to assess the effectiveness of MEDLINK in treating the discharged patient during the Remote Patient Monitoring (RPM) period. The physician is then free to re-program MEDLINK to be used by the next volunteer he or she selects for the clinical trial.

RESULTS

Patient reporting data

After Remote Patient Monitoring (RPM) has been successfully conducted for a volunteer, he or she will be required to return the MEDLINK unit back to the physician. At this point the physician will ask the patient five key questions:

- On a scale of 1 to 10, did you feel like you had a link to your doctor to watch over your health when you have left the hospital?
- On a scale of 1 to 10, did you feel safe with your recovery because your doctor was able to communicate with you in your home?
- On a scale of 1-10, how easy was it for you to use MEDLINK to report your health data to your physician?
- On a scale of 1-10, did you enjoy your home communication with your physician using the unit?
- On a scale of 1 to 10, did MEDLINK help to increase your trust in your physician's ability to take care of your health-wise?

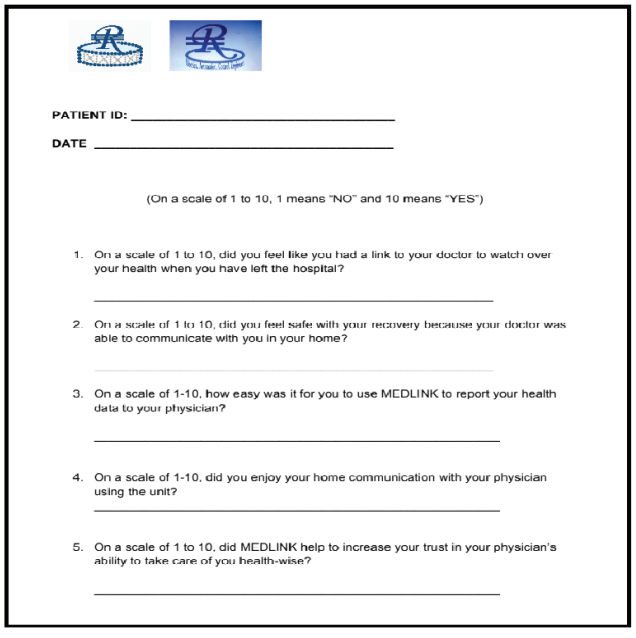
On the researcher-designed scale of 1 to 10, a response of '1' means "NO", and a response of '10' indicates "YES". These questions are contained in the Patient Reporting Form shown in Figure 2, and will enable the physicians and the researchers to gauge:

1. If MEDLINK was successful in providing Remote Patient Monitoring (RPM).
2. If MEDLINK helped to increase the patient's confidence and trust in the Physician's ability to provide medical care.
3. If MEDLINK is user-friendly for by patients.
4. If RPM is beneficial from the patient's point of view.

Physician reporting data

After Remote Patient Monitoring (RPM) is completed for a patient, the physician will also complete the Physician Reporting Form to evaluate the effect RPM has on their confidence and ability to operate as a physician. The Physician Reporting Form is shown in figure 3. The physician will answer the following key questions:

- On a scale of 1 to 10, did I feel I was able to medically monitor my patients during the Remote Patient Monitoring (RPM) as well as I do when they were in the hospital?
- On a scale of 1 to 10, how much satisfaction did I feel knowing I was able to effectively keep track of and monitor this discharged patient?
- Was I able to detect any abnormalities during Remote Patient Monitoring (RPM) with MEDLINK that I would not have otherwise? (If "Yes", State them)
- Did Remote Patient Monitoring (RPM) help me detect any of the following for this patient (circle where applicable): deteriorating condition, fatality triggers, fatality fore-warning data, ineffective dosage, non-working dosage, non-hospital detected abnormalities.
- Was I able to effectively communicate with my patient during Remote Patient Monitoring (RPM) (to give them encouragement, instructions for change in drug dosage, or instructions to come to the hospital)?



PATIENT ID: _____

DATE _____

(On a scale of 1 to 10, 1 means "NO" and 10 means "YES")

1. On a scale of 1 to 10, did you feel like you had a link to your doctor to watch over your health when you have left the hospital?

_____

2. On a scale of 1 to 10, did you feel safe with your recovery because your doctor was able to communicate with you in your home?

_____

3. On a scale of 1-10, how easy was it for you to use MEDLINK to report your health data to your physician?

_____

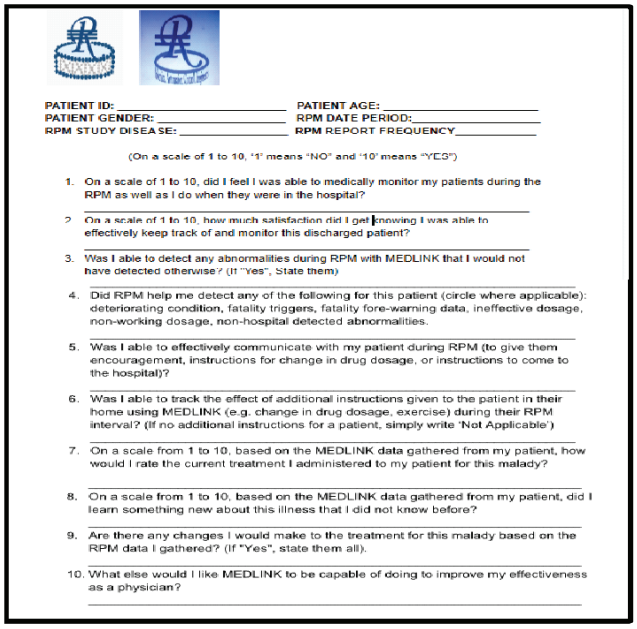
4. On a scale of 1-10, did you enjoy your home communication with your physician using the unit?

_____

5. On a scale of 1 to 10, did MEDLINK help to increase your trust in your physician's ability to take care of you health-wise?

_____

Figure 2: Patient Reporting Form for MEDLINK RPM.



PATIENT ID: _____ PATIENT AGE: _____
PATIENT GENDER: _____ RPM DATE PERIOD: _____
RPM STUDY DISEASE: _____ RPM REPORT FREQUENCY_____

(On a scale of 1 to 10, '1' means "NO" and '10' means "YES")

1. On a scale of 1 to 10, did I feel I was able to medically monitor my patients during the RPM as well as I do when they were in the hospital?
2. On a scale of 1 to 10, how much satisfaction did I get knowing I was able to effectively keep track of and monitor this discharged patient?
3. Was I able to detect any abnormalities during RPM with MEDLINK that I would not have detected otherwise? (If "Yes", State them)
4. Did RPM help me detect any of the following for this patient (circle where applicable): deteriorating condition, fatality triggers, fatality fore-warning data, ineffective dosage, non-working dosage, non-hospital detected abnormalities.
5. Was I able to effectively communicate with my patient during RPM (to give them encouragement, instructions for change in drug dosage, or instructions to come to the hospital)?
6. Was I able to track the effect of additional instructions given to the patient in their home using MEDLINK (e.g. change in drug dosage, exercise) during their RPM interval? (If no additional instructions for a patient, simply write 'Not Applicable')
7. On a scale from 1 to 10, based on the MEDLINK data gathered from my patient, how would I rate the current treatment I administered to my patient for this malady?
8. On a scale from 1 to 10, based on the MEDLINK data gathered from my patient, did I learn something new about this illness that I did not know before?
9. Are there any changes I would make to the treatment for this malady based on the RPM data I gathered? (If "Yes", state them all).
10. What else would I like MEDLINK to be capable of doing to improve my effectiveness as a physician?

Figure 3: Physician reporting form for MEDLINK RPM.

- Was I able to track the effect of additional instructions given to my patient in their home using MEDLINK (e.g. change in drug dosage, exercise) during their Remote Patient Monitoring (RPM) interval? (If no additional instruction for a patient, simply write 'Not Applicable')
- On a scale from 1 to 10, based on the MEDLINK data gathered from my patient, how would I rate the current treatment I administered to my patient for this malady?
- On a scale from 1 to 10, based on the MEDLINK data gathered from my patient, did I learn something new about this illness that I did not know before?
- Are there any changes I would make to the treatment for this malady based on the Remote Patient Monitoring (RPM) data I gathered? (If "Yes", state them all).
- What else would I like MEDLINK to be capable of doing to improve my effectiveness as a physician?

On the researcher-designed scale of 1 to 10, a response of '1' means "NO", and a response of '10' indicates "YES". These questions are shown in the Physician Reporting Form in Figure 3, and will enable the physicians to gauge the effectiveness of MEDLINK Remote Patient Monitoring (RPM) in aiding them in patient treatment. It will also help them evaluate and analyze the data they gathered from their patients using Remote Patient Monitoring (RPM), and assist in planning and recommending alternative and superior treatment options to current existing ones that prove to be substandard and unsatisfactory. The physicians are also given the opportunity to recommend improvements to MEDLINK that will better assist them in their profession.

Data gathered by means of the patient reporting forms and the physician reporting forms will be collected and analysed by RACETT NIGERIA LTD. The patients' names and identities are concealed from all, except the recruiting physician. Only the volunteers' ages and genders are identified in order to ensure that the diversity in the Clinical Trial participation is recorded.

DISCUSSION

Physicians participating in MEDLINK Remote Patient Monitoring (RPM) Clinical Trial will be briefed on every aspect of the Clinical trial, and are at liberty to select the physiological malady they wish to perform Remote Patient Monitoring (RPM) for. The patients selected for Remote Patient Monitoring (RPM) is at the sole discretion of the participating physician. It is important to note that the physicians are free to set the time limit for Remote Patient Monitoring (RPM) for any patient for the physiological malady that they select. They are also the ones who determine which physiological parameter(s) they wish to monitor for a patient undergoing Remote Patient Monitoring (RPM). After programming the MEDLINK unit for the patient, the physician will demonstrate its use to the patient in his or her office to make sure they can use it to report to them. At this point, the physician also tells the patient how often he or she requires reporting (e.g. every morning or morning and night). After passing this crucial information to the patient, the physician can then discharge his or her patient, knowing that he/she is still watching over the patient's health.

The authors of the Clinical trial will make available a RACETT MEDLINK Engineer to check with the participating physicians once a week to ensure they and their patients have no trouble with the MEDLINK unit for the entire duration of the Clinical trial. Each physician will acquire and accumulate vital medical data during this period that will serve them well in creating and making medical recommendations for the maladies they selected for Remote Patient Monitoring (RPM) investigation.

The Clinical trial intends to determine if MEDLINK successfully provides the Remote Patient Monitoring (RPM) requested by the physician, and if it is user-friendly for both physicians and patients. It also seeks to ascertain if Nigerians are prepared to utilize Remote Patient Monitoring (RPM) to improve their access to quality health care offered by their physicians. Most importantly, the trial will ascertain if RPM is necessary and useful for any of the five (5) diseases (Diabetes, Hypertension, Heart Failure, COPD, and Myasthenia Gravis) that will be investigated in Nigeria. The data acquired by means of the Patient Reporting Forms and the Physician Reporting Forms will be used to analyze if Remote Patient Monitoring (RPM) helped the physicians identify things they would not otherwise have been able to (e.g. deteriorating condition, fatality triggers, fatality fore-warning data, ineffective dosage, non-working dosage, and non-hospital detected abnormalities) after discharging the patient from the hospital, and if RPM helped the physicians adjust their treatment protocol for any of the five (5) diseases.

The data acquired from this clinical trial will be collected and analysed by RACETT NIGERIA LTD., and will be published in scientific literature to enhance the medical community. Physicians who participate in the Clinical Trial will also be at able to utilize the Remote Patient Monitoring (RPM) data to publish their findings in medical literature. It is expected that the benefits of Remote Patient Monitoring (RPM) will be observed from this clinical trial, as has been documented in other countries, and that the Nigerian Medical Society will welcome this technological advancement that improves the quality of health care delivered to patients by their physicians.

CONCLUSION

MEDLINK is a Remote Patient Monitoring (RPM) device that can be used by Physicians to remotely monitor their patients after

discharging them from the hospital. This paper presents the design of a Clinical Trial to evaluate the effectiveness of MEDLINK in providing RPM for five diseases in Nigeria (Diabetes, Hypertension, Heart Failure, COPD, and Myasthenia Gravis). The Clinical Trial consists of three phases: Phase 1 Clinical Trial with 20 volunteers, Phase 2 Clinical Trial with 150 volunteers, and Phase 3 Clinical Trial with 450 volunteers. The data acquired during this trial will be used to analyze if RPM helped the physicians identify things they would not otherwise have been able to (e.g. deteriorating condition, fatality triggers, fatality fore-warning data, ineffective dosage, non-working dosage, and non-hospital detected abnormalities) after discharging the patient from the hospital, and if RPM helped the physicians adjust their treatment protocol for any of the five (5) diseases.

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