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FEASIBILITY AND ACCEPTABILITY OF PHEEZEE™: A MOBILE PHONE BASED WEARABLE PROGNOSTIC DEVICE FOR PHYSICAL REHABILITATION

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Abstract

Measuring Range of Motion and muscle activity during therapy is crucial to set remedial goals for patients to achieve and recover during the continuum of care for persons with physical disabilities. However, standard techniques and tools are neither part of initial assessments nor the final discharge evaluation in the context of physical rehabilitation in most of the low and middle-income countries (LMICs). This context warrants development of innovative strategies to establish therapeutic practice standards especially in terms of assessment of physical impairments such as limited ROM and muscle activity.

Keywords: Digital Device for Prognosis in Rehabilitation; EMG for Physiotherapist; Portable tool for Physiotherapist; Assessment; Wearable technology in Rehabilitation; Stroke rehabilitation.

1. Introduction

Predicting recovery in physical rehabilitation has always been using a surrogate measure¹. This is so true in the context of low and middle-income countries (LMICs) where even initial assessments for patients with disabling health conditions were conducted using non-standardized techniques and tools². Therapists evaluate and patients accessing physical rehab services appreciate recovery based on something that they could achieve functionally³. However, objectivity in physical rehabilitation therapy services cannot be established without measuring the actual recovery that was targeted during therapy using specific standard assessment tools⁴.

Measuring Range of Motion (ROM) and muscle activity during therapy is crucial to set remedial goals for patients to achieve and recover during the continuum of care for persons with physical disabilities (PWPD)⁵.

Goniometry and manual muscle testing are the two important, globally validated, standardized tools to measure ROM and muscle activity respectively⁶. Although these are still being used as a part of standard practice in High-Income Countries (HICs)⁷. These standard techniques and tools are neither part of initial assessments nor the final discharge evaluation in the context of physical rehabilitation in most of low and middle-income countries⁸. This is especially because assessment and therapeutic intervention are priced within a single therapy session and most persons with physical disabilities accessing therapy cannot afford as well as may not be willing to pay for a separate therapy session for specialized assessments⁹. Physical rehabilitation in most of the low and middle-income countries settings is available only in private hospitals located in urban cities for a substantial out-of-pocket price and at a significant opportunity cost¹⁰. Eyeballing and non-standardized assessments have been the predominant practice pattern for measuring ROM and muscle activity from the perspective of the therapists in these settings¹¹.

This context warrants development of innovative strategies to establish therapeutic practice standards especially in terms of assessment of physical impairments such as limited ROM and muscle activity. Such strategies are also envisaged to enhance awareness and knowledge about impairment-specific recoveries among persons with physical disabilities to facilitate active participation in their continuum of rehabilitation and care. Pheeze is one such innovation to address the practice gaps and meet the growing need for objective assessments of good quality to persons with physical disabilities in low and middle-income countries. The device is innovative, technology-driven, and can be a game-changer for both therapists and persons with physical disabilities in low and middle-income countries settings like India. Therefore evaluation of the innovation for its feasibility and acceptability among therapists who use this innovation is warranted.

2. Objectives of the study

To assess the feasibility and acceptability of using Pheeze as a tool for assessing, monitoring, and tracking recovery in the rehabilitation of persons with physical disabilities by rehabilitation providers.

3. Methods

3.1 Study Design: Cross-sectional pilot study using mixed methods.

This study will apply mixed research methods to have a deeper understanding of the feasibility and acceptability of Pheeze.

3.2 Study Setting: Two physical rehabilitation centers that provide therapy services for persons with physical

disabilities in Hyderabad, India.

3.3 Participants:

- Physical therapists
- Qualified from recognized universities in India
- Have a minimum of two years of experience
- Currently practicing
- Providing therapy services to persons with physical disabilities

3.4 Criteria for inclusion:

An eligibility assessment was conducted by the investigator to identify participants to be recruited for the study.

3.5 Participant recruitment for the pilot study

Participants for the study were identified and recruited from two rehabilitation centers in Hyderabad India. The participants were contacted and briefed about the study by the investigator in person. They were informed about the purpose and processes of the study. Written informed consent was obtained from the participant who was willing to take part in the study. Consent procedures were completed at the rehabilitation centers.

3.6 The sample size for the pilot study:

Sampling was purposive. Each rehabilitation center is expected to have at least four qualified physical therapists. The investigators obtained permission from two rehabilitation centers and have recruited a total of 12 physiotherapists for the study.

4. Pheeze Innovative Device

Pheeze is an innovative device that measures, the range of motion (ROM) and Electromyogram (EMG) from the joints and muscles of the human body in real-time. Pheeze is a prognostic device consisting of two wearable modules, a supporting custom android application, and cloud-based processing services and data storage. The device is battery-operated and is re-chargeable (Figure-1). The device is worn by the patient during therapy sessions. The two wearable modules are worn above and below the joint that needs to be monitored or assessed for ROM and muscle activity. The surface EMG electrodes are placed on the particular muscle that is responsible for the motion of the joint. Both the ROM and the EMG are acquired by the phone app in real-time for immediate view on the phone's display screen. The acquired data is transferred to the

cloud-based server where it is further processed and analyzed to understand the prognosis in terms of the consistency and control of the joint and muscle functions. The detailed results can also be downloaded in the form of a report which can later be shared electronically or can be printed and attached to the patient reports and clinical case notes.



Fig-1: Pheeze toolkit with its parts and as a package the supporting phone app.

5. Assessment procedures:

5.1 Provider Training: Physiotherapists who consented to participate in this pilot study were made to participate in a two-hour group training and discussion on using the Pheeze device in their day-day practice. The training was structured as two sessions; 1. A lecture session on the Pheeze device, 2. Practical demonstration and practice session on how to use the Pheeze device. The training was provided by the principal investigator and an expert physiotherapist who has extensively used the Pheeze device before.

5.2 Eligibility Assessment: At the end of the training session, the participants were asked to try using the device. A couple of errorless attempts to use the device were considered as eligibility for recruitment in the study. Participants who demonstrated these errorless attempts were included in the study.

5.3 Device Utilization: Those who were deemed fit to be recruited for the study were provided with the Pheeze device for using it in their everyday practice for four weeks. The investigator ensured weekly telephonic or in-person follow-up with the therapists recruited for the study in the rehabilitation centers.

6. Assessment of outcomes:

The primary outcomes of the pilot phase will be the feasibility and acceptability of the intervention. Participants were provided with a semi-structured questionnaire to complete at the end of four months. They were also requested to participate in interviews to explore their experience of using the Pheeze device in their practice. Also, the usage of the device was monitored using the device for triangulation of information. These three different methods of assessment were envisaged to provide information related to the feasibility and acceptability of the

Pheezee device.

6.1 Study tools: Separate questionnaire and topic guide were developed for the participants and it was piloted and revised before starting the study.

6.2 Analysis plan for the study: The data collected from the participants were analyzed descriptively to understand feasibility and acceptability. Microsoft Excel was used to organize and conduct a descriptive analysis of quantitative data and a thematic description based on a framework approach to qualitative analysis was followed for the data obtained through interviews.^{12, 13}

7. Ethics approval: The study was approved by the Institutional Ethics Committee (IEC) of the Indian Institute of Public Health – Hyderabad (Vide IIPHH/TRCIEC/208/2020). All eligible participants were informed about the study, and written consent was obtained from those who were found eligible and willing to participate. The purpose and processes of the study were explained to the participants and consent was obtained from potential participants in person.

8. Results

8.1 Quantitative Survey:

Twelve (12) physiotherapists were found eligible to participate in this study and all twelve (12) physiotherapists were involved till the end of the study. Results from the quantitative survey revealed that most of the participants felt that Pheezee will be time-consuming but were enthusiastic to use it and learn about it to enhance clinical practice. About 67% of the participants required either training or supervision to use the Pheezee device and 33% reported that they can manage to use the Pheezee on their own. Close to 58% of the participants reported that they received sufficient training and 42% of the participants reported that they received training to some extent indicating an additional training will be of use (Figure–2).

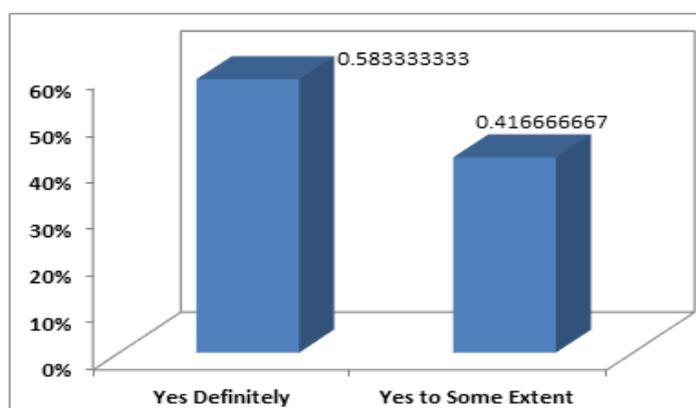


Fig-2: Percentage satisfaction with Pheezee device training.

About 75% of the participants accessed the content of the Pheezee device and managed to use it independently.

25% of the participants required assistance from other trained colleagues. All the participants reported that it was easy for them to navigate every page of the Pheeze application using the interface while accessing it. Also none of the participants had difficulty in accessing the contents of the Pheeze device.

All the participants reported that the entire content of the Pheeze device was very interesting for them to use it on patients. 75% of the participants reported that the content of the Pheeze were relevant to the needs of the patients to some extent and 25% reported that it was definitely relevant to patient needs (Figure-3). None of the participants reported about any content that was not interesting.

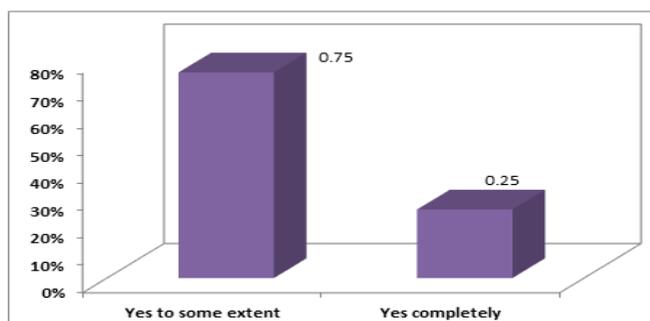


Fig-3: Relevance and Satisfaction with the Content of the Pheeze.

Answering to the question related to the utilization of Pheeze during the four week period. 8% of the participants had utilised Pheeze once or more every day. 50% had utilised it once or more weekly and 42% of the participants had utilised Pheeze whenever necessary (Figure -4). When the participants were asked to rate the content, user-friendliness and the credibility of Pheeze, 50% of the participants rated it as “very good”. 33% rated it as “Good” and 17% rated it as “Fair” (Figure – 5).

When participants reported that the three key aspects they liked about the Pheeze device was its accurate, real time display of results that can be viewed by both patients and providers. Participants also felt the device is easy to use, portable with features that help generate session as well as monthly reports and share it instantly using emails and other communication medium. In terms of the aspects that participants felt it could improve, it was the streaming speed, internet and connectivity issues and issues with generating report etc.

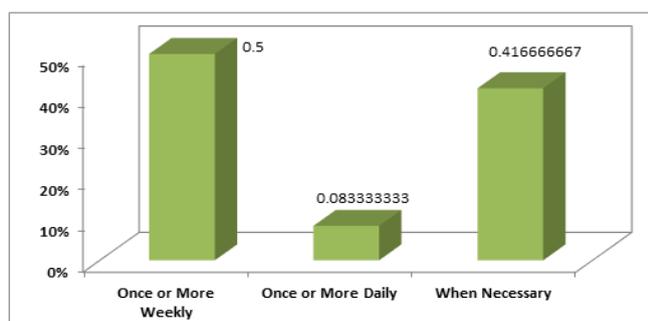


Fig-4: Utilization of the Pheeze Device.

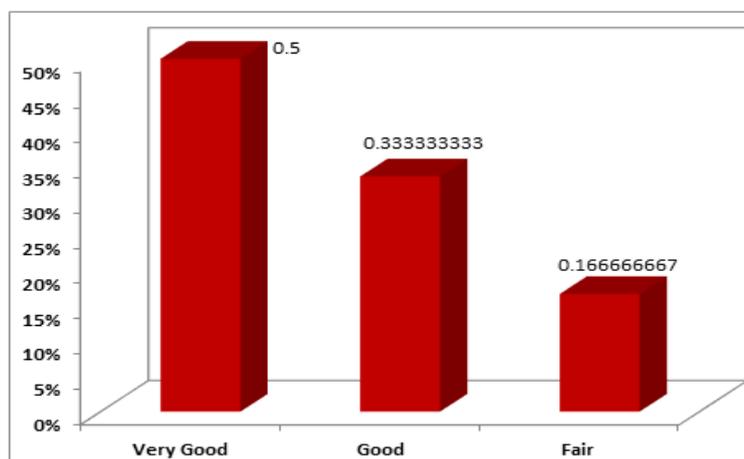


Fig-5: Rating for the content, user-friendliness and the credibility of Pheeze.

8.2 Qualitative Interviews:

The findings from the quantitative survey were supported by the results of the interviews from the participants. Specific themes related to the feasibility and acceptability aspects of Pheeze were identified in the interviews.

8.2.1 Training:

The initial training given to the participants was felt very useful by all the participants however, the general opinion was to gain more experience and understand using innovations such as Pheeze for more number of patients to achieve skills for using Pheeze. The participants felt that there are several competencies required to utilize Pheeze. Some of them are a. using EMG machines and electronic equipment to measure muscle strength and assess ROM. b. ensuring the patients understand the use of technological innovations such as Pheeze and actively engage in the assessment session. C. Interpreting the findings from the Pheeze in a scientific way to set goals and implement therapy sessions for patients. More patients and more time was envisaged to help achieve the confidence and competencies for using Pheeze in every day clinical practice.

"We certainly need to practice with more patients and it might take some time. It will be great to have refresher training in the process." P12

"Patients will ask 1000 questions because technology is involved and we are using appliances like electrodes which can scare them sometimes... As physios, we need to be skilled and competent to use Pheeze on patients and help them accept it." P4

8.2.2 Credibility of the design and content

All the participants felt that the content of the Pheeze device was innovative and objective. Some of the components within Pheeze that was felt to be game changers in the assessment of ROM and muscle strength was a. the digital content from ROM and Muscle strength assessment that can provide instant results of the assessment and that's easy to use for patients. b. The objectivity of the assessment using contact electrodes and electronic

display of the joint and muscle activity. c. automatic report generation for individual sessions as well as the compilation of results over a period of time. d. portability of the device. e. data sharing and remote assessment possibilities. f. Cloud server for data management. g. An opportunity for self-assessment and patient centred goal setting and rehabilitation.

"It is like a stethoscope for physios.. We are very satisfied. I must say.. Its accurate and handy. Easy to document and explain to patients "

P7

"Many patients like using technology for therapy reasons and when we use Pheeze for assessment and show the results of the assessment instantaneously to the patients, they are willing to engage proactively in therapy sessions".

P2

"What we are showing them is an accurate measure and that makes it an objective assessment for setting goals unlike the usual eyeballing methods for assessing ROM and muscle strength"

P8

Participants felt that Pheeze has been a timely innovation for enabling therapists to use technology for objective assessment. Pheeze was perceived as a device that was easy to use and there was not any specific difficulty in using the device for patients. Some participants felt that their patients were able to help them place the electrodes and handle the machine themselves after one or two sessions. Given the portability, objectivity and user-friendliness of Pheeze, participants felt that this could be used even by newly graduated therapists without much difficulty. In terms of the need, all the participants expressed that this is the need of the hour in rehabilitation especially during COVID-19 times where patients are consulted and provided therapy virtually. The innovation was considered very feasible and much relevant to the needs of the patients as well as the rehabilitation service providers to incorporate objectivity in assessing an important component and major component for setting functional goals. Participants also felt that in a context where objectivity in assessment of ROM or strength and its impact on recovery is not usually justified or documented, Pheeze can be a very useful tool to promote standards for assessment and enable transparent reasoning for patient prognosis during rehabilitation.

"This device has got Great Scope for physios in the future. Even a fresher can use. We measure basic but important parameters and is accurately done by Pheeze"

P10

"It is absolutely helping us a lot. Nothing negative about it at all. Saves time for us. It may not be accurate when we do it manually – we do not objectively assess too when we do this manually in most cases .. I am being honest but with Pheeze, there is an objective quick and comprehensible assessment for patients which they are happy about. The satisfaction amongst us and the patients are great".

P6

“We have data to compare and relate to setting goals for patients using Pheeze. We can spot the improvements or down falls and can decide on therapy interventions that could help patients. Storing data is a huge advantage in Pheeze. We can bring in standards for documentation and therapy using this wonderful tool.”

P1

9. Suggestions

Key suggestions from participants were related to a. Pheeze incorporating the aspects of small muscles and joints assessment. Especially because the current version is limited to big joints and muscles. b. The providers need to be trained enough in placement of electrodes, measurement, use of technology for managing data and using it ethically for patient benefits. c. Incorporating patients and caregivers and evaluating Pheeze as a self-assessment tool could enhance continuum of care especially outside the hospital setting that could potentially meet the rehabilitation needs of persons with disabilities during any pandemic situation as well. Participants also expressed that making Pheeze available to providers at an affordable cost could help cater to the needs of more number of patients requiring such services. Participants also suggested to evaluate the effectiveness of Pheeze to generate evidence for innovations such as these in the field of rehabilitation especially in the context of LMICs.

10 Pheeze usage statistics

During the entire study duration, the device was used consistently by the participants. Pheeze was used on a total of 36 patients. Forty two (42) assessment sessions were done on the patients with average duration of each assessment session being 1.6 minutes. The Figure 6 given below shows the session-wise device usage assessment profile.

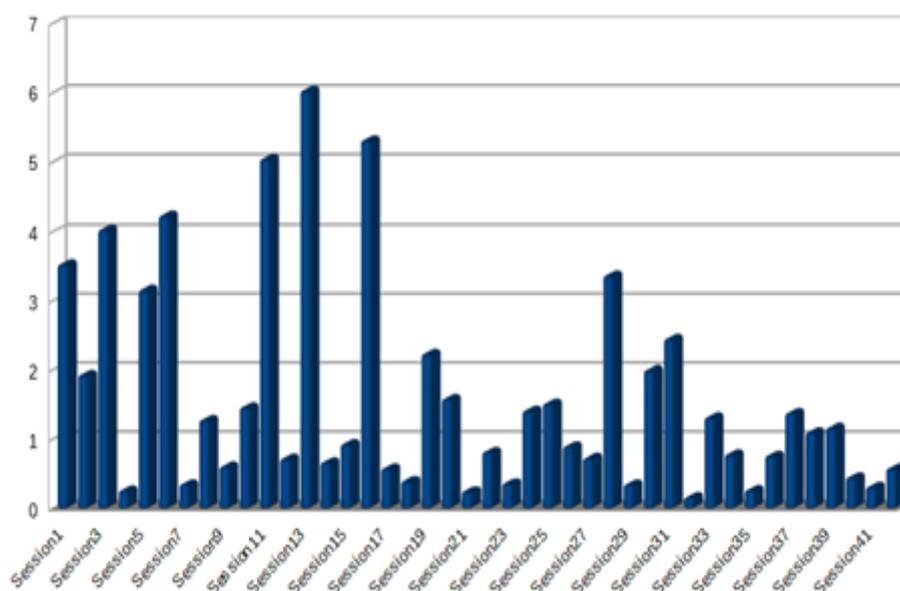


Fig-6: Session-wise assessment duration (in minutes).

11. Discussions

The results from the pilot very clearly shows the feasibility and acceptability of Pheeze among physiotherapists treating persons with disabilities. Participants liked the intervention and had showed enthusiasm to utilise the intervention with interest. Participants also felt the Pheeze device to be very useful and have expressed their acceptance and need for Pheeze in this study. The suggestions from the participants were valid and must be given due considerations in order to make Pheeze an evidence-based device for rehabilitation professionals as well as patients. The intervention needs to be refined for encompassing providers with various skills and competencies as well as patients with various disabilities. It must also be refined for small muscles and joints assessment in the future. There is certainly a need to be evaluate the effectiveness of Pheeze in quantifying recovery and patient improvements through a large randomized controlled trial in India and similar countries within the LMICs as a priority.

This study had several strengths as well as few limitations. Most of the technological innovations do not go through the process of feasibility and acceptability assessment. Pheeze is now evaluated for the same. Even if such assessments were done, they may not always be methodologically rigorous. This evaluation included a combination of methods to establish the feasibility and acceptability of this innovation. The sample selection was purposive and small given the pandemic situation as well as the rehabilitation centres with organized systems in place to test this innovation. This must be definitely considered when Pheeze is tested for its clinical and cost effectiveness in the future through a large trial.

There are several innovations that come to the healthcare market to support either the patients or the providers but Pheeze is an innovation that meets the needs of both the patients as well as the providers in the field of rehabilitation. Feasibility and acceptability is now a massive advantage for Pheeze, which to our knowledge is not available in any other rehabilitation assessment tools that exists in LMICs. Tapping the strengths of this innovation for supporting the rehabilitation professionals and meeting the rehabilitation assessment needs of persons with disabilities can help address the burden of disability and rehabilitation management not just in LMICs but globally.

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