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## Clinical and Cost-effectiveness analysis of telerehabilitation intervention for people with nonspecific chronic low back pain

Francis Fatoye, Chidozie E Mbada, Clara Fatoye, Tadesse Gebrye, Mistura I Olaoye, Adesola C Odole, Olumide O Dada

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## Clinical and Cost-effectiveness analysis of telerehabilitation intervention for people with nonspecific chronic low back pain

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### Abstract

**Background:** Physiotherapy is the main stay management strategy for nonspecific chronic low back pain (NCLBP), however, its availability in resource-limited countries can be challenging. Therefore, telerehabilitation may be a potential management strategy for NCLBP in resource-limited countries.

**Objective:** This study evaluated the clinical and cost-effectiveness of a telerehabilitation compared to clinic-based intervention for people with NCLBP in Nigeria.

**Methods:** A cost-utility analysis alongside a randomised controlled trial from a healthcare perspective was conducted. Patients with NCLBP were assigned into either telerehabilitation (TG) or clinic-based intervention group (CBIG). Interventions were carried out three times weekly for a period of eight weeks. Patients' level of disability was measured using Oswestry Disability Index (ODI) at baseline, week 4 and week 8. In order to estimate the health related quality of life of patients used for cost-effectiveness analysis the ODI was mapped to SF-6D to generate quality adjusted life years (QALYs). Healthcare resource use questionnaire was administered to assess the costs of interventions after 8 weeks. Descriptive and inferential data analyses were also performed to assess the clinical effectiveness of the interventions. The incremental cost effectiveness ratio (ICER) was calculated. The effect of changing the values of some variables on the ICER were examined by sensitivity analysis.

**Results:** A total of 47 patients (TG, n = 21; CBIG, n = 26) with the mean ( $\pm$  SD) age of 47 $\pm$  (11.62) years for telerehabilitation and 50  $\pm$  (10.67) years for clinic-based intervention participated in this study. The mean costs estimate of telerehabilitation and clinic-based interventions per person per year were N22, 200.00 (\$61.70) and 38,200.00 (\$106.22), respectively. QALY gained was 0.13 for the TG and 0.11 for the CBIG. The TG arm was associated with an extra of 0.02 QALYs [95% CI -0.01, 0.03] per participant compared to the CBIG arm. Thus, the ICER for TG was –N800,000 (-\$2,213.0)/QALY gained. The incremental cost and effectiveness of TBMT by half of the base case values led to a 1/3 reduction of the ICER.

**Conclusions:** The findings of the study suggested that telerehabilitation is cost-effective and cost saving. Given the small number of participants in this study, further examination of effects and costs of the interventions are needed within a larger sample size. In addition, future studies are required to assess the cost-effectiveness of this intervention in the longer-term from patient and societal perspective. Clinical Trial: Registration number.: IPH/OAU/12/515

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## **Original Manuscript**



# Clinical and Cost- effectiveness analysis of Telerehabilitation Intervention for People with Non-specific Chronic Low Back Pain

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#### Abstract

**Background:** Telerehabilitation can facilitate multidisciplinary management for people with non-specific chronic low back pain (NCLBP). It provides access to healthcare to individuals who are physically and economically disadvantaged.

**Objective:** This study evaluated the clinical and cost-effectiveness of a telerehabilitation compared to clinic-based intervention for people with NCLBP in Nigeria.

Methods: A cost-utility analysis alongside a randomised controlled trial from a healthcare

perspective was conducted. Patients with NCLBP were assigned into either Telerehabilitation-Based McKenzie Therapy (TBMT) or Clinic-Based McKenzie Therapy (CBMT). Interventions were carried out three times weekly for a period of eight weeks. Patients' level of disability was measured using Oswestry Disability Index (ODI) at baseline, week 4 and week 8. In order to estimate the health related quality of life of patients used for cost-effectiveness analysis the ODI was mapped to SF-6D to generate guality adjusted life years (QALYs). Healthcare resource use and costs were assessed based on the McKenzie extension protocol in Nigeria in 2019. Descriptive and inferential data analyses were also performed to assess the clinical effectiveness of the interventions. Bootstrapping technique was conducted to generate the point estimate of incremental cost effectiveness ratio (ICER).

**Results:** A total of 47 patients (TBMT, n = 21; CBMT, n = 26) with the mean ( $\pm$  SD) age of 47 $\pm$  (11.6) years for telerehabilitation and 50  $\pm$  (10.7) years for clinic-based intervention participated in this study. The mean costs estimate of TBMT and CBMT interventions per person were N22,200 (\$61.7) and N38,200 (\$106), respectively. QALY gained was 0.085 for the TBMT and 0.084 for the CBMT. The TBMT arm was associated with an extra of 0.001 QALY [95% CI 0.001, 0.002] per participant compared to the CBMT arm. Thus, the ICER showed that TBMT arm was less costly and more effective than CBMT.

**Conclusion:** The findings of the study suggested that telerehabilitation for people with NCLBP was cost saving. Given the small number of participants in this study, further examination of effects and costs of the interventions are needed within a larger sample size. In addition, future studies are required to assess the cost-effectiveness of this intervention in the long-term from patient and societal perspective.

Keywords: effectiveness, cost-effectiveness, telerehabilitation, low back pain, Africa

#### Introduction

Low-back pain (LBP) can result from several different abnormalities or diseases. It is commonly accompanied by pain in one or both legs, between the lower rib margins, and the buttock creases [1]. Almost 90% and 10% cases of LBP are of non- specific and specific causes, respectively [2]. The prevalence of LBP in those 9 -18 years old in high income, medium income, and low income countries was around 40.0% [3]. It has also been reported that most adults will have LBP at some point during their lifetime [4]. LBP was responsible for around 60.1 million years lived with disability globally in 2015, and there will be an overall increase in its global burden due to population increase and ageing [5]. The working age groups in middle-income and low-income countries, have the highest disability from LBP [6]. A review of studies on LBP cost-of-illness in the United States and internationally suggested that the costs of treating LBP are extremely high, where indirect costs represented a majority of the overall costs associated with LBP [7]. Dagenais and colleagues also indicated that the largest proportion of direct medical costs for LBP was spent on physical therapy and inpatient hospital services followed by pharmacy and primary care. In relation to NCLBP, there are no specific treatments that can be provided. The reason for this is that the pathoanatomical cause for non-specific LBP is unknown [8].

Many clinical practice guidelines are recommended for the prevention and management of LBP [9]. These practice guidelines include education that supports self-management and resumption of normal activities and exercise, use of medication, imaging and surgery. Research studies from high-income countries suggests that exercise alone, and exercise in combination with education reduces the risks of an episode of LBP [10]. Compared to no treatment, a supervised exercise on children and adolescents can improve average pain intensity by 2.9 points (95% CI 1.6 - 4.1) in patients with LBP [11]. On the other hand, Steffens and colleagues concluded that physiotherapy interventions such as education alone, back belts, and shoe insoles; did not appear to prevent LBP [10].

Despite the availability of many clinical guidelines for managing LBP, a substantial difference in their applicability exists in high-income as well as low-income and middle-income countries [12]. Identifying best intervention for LBP can not only improve the health outcomes for patients but also reduce healthcare utilization and costs associated with the

management of the condition. Telerehabilitation, in the form of a mobile phone app platform extension exercise that enables patient to perform exercise using a smartphone, may be a practical intervention for LBP in geographically remote areas with shortage of services and lack of access to physical therapy rehabilitation services. Telerehabilitation uses communication technology for the remote delivery of care to patients, and has the potential to manage multiple components of health including functional independence, self-care, and self-management of illness [13].

The findings from a review of 29 articles indicated that telehealth had a moderate, positive and significant effect on clinical outcomes for different patient population including LBP, heart and psychiatric conditions [14]. The use of telerehabilitation for patients with LBP was reported in a few studies included in the systematic review to have positive clinical outcomes and in return might lead to fewer visits to emergency room and physician; fewer admission to hospitals; shorter length of stay in hospitals and lower costs [14]. Despite of the methodological differences in studies and the healthcare system of various countries, understanding clinical outcomes and economic costs of Telerehabilitation interventions may improve their efficiency. The use of telerehabilitation in low and middle income countries (LMIC), like Nigeria is just emerging, as a result, data on clinical and cost-effectiveness of telerehabilitation are scarce [15, 16]. To date, we are not aware of any study that has investigated the clinical and cost effectiveness of physiotherapy using telerehabilitation in these countries. To study the clinical and cost effectiveness of telerehabilitation, we developed a telerehabilitation based McKenzie exercises intervention for people with NCLBP. This study therefore, assessed the clinical and cost effectiveness of TBMT compared to CBMT for people with NCLBP in Nigeria.

#### Methods

#### Trial design

This study was an experimental research design, and was conducted at the department of physiotherapy, LAUTECH Teaching Hospital Osogbo and the physiotherapy department, State Hospital, Ejigbo. Ethical approval for this study was obtained from the Health Research Ethical Committee of the Institute of Public Health, Obafemi Awolowo University Research and Ethical Committee (Registration number: IPH/OAU/12/515).

#### Study population

The sample size for this study was determined from the equation [17]:

m (size per group) =  $c \times \pi_1 (1 - \pi_1) + \pi_2 (1 - \pi_2)/(\pi_1 - \pi_2)^2$ ,

Where c = 7.9 for 80% power, and  $\pi_1$  and  $\pi_2$  are the proportion estimates ( $\pi_1$  = 0.25 and  $\pi_2$  = 0.65).

Therefore, n = 7.9 \* (0.25 (1 - 0.25) + 0.65 (1 - 0.65)/(0.25 - 0.65) = 20.49 which is approximately 21. Hence, calculated N was 42 (21 per group). In order to account for 10% possible attrition (i.e., 4.2), the estimated minimum sample size was 46.

Patients with NCLBP who attended Out-Patients Physiotherapy Departments were recruited into this study. At the start of the recruitment process, the purpose of the research was explained to the participants. All participants (n = 70), who were assessed for eligibility in the study, were provided an informed written consent translated by experts into local language.

A research assistant recorded the number of participants who were invited to participate, the number who declined to participate, and the number of screened patients who were not eligible and their reasons for declining participation. Eligibility for participation in this study was based on physician referral and physiotherapists' diagnosis of NCLBP. Participants with clinical diagnosis of long-term NCLBP between the ages of 20 and 65 years, and those without any obvious deformities affecting the trunk or upper and lower extremities were included. The terms 'long-term' was used in this study instead of chronic. Using the International Classification for Functioning, Health and Disability (ICF) framework, it is believed that the word "chronic" may be associated with negative expectations, therefore, the word "long-term" is preferred [18]. In addition, these patients were those without any apparent deformities in the trunk, upper and lower extremities respectively. In order to have a homogeneous sample of LBP type that is amenable to the McKenzie therapy, directional preference for extension was a major inclusion criterion. Directional preference is defined as the movement or posture that decreases or centralizes pain that emanates from the spine and/or increases range of movement [19]. Excluded from the study were patients with LBP who had a known co-morbidity or history of cardiovascular disease for which exercise was contra-indicated. Also, patients who were pregnant and those who had previous back surgery or experience of the McKenzie therapy; as well as, those with directional preference for flexion or no directional preference based on the McKenzie assessment.

#### Randomisation

A research assistant who was not involved in the assessment and treatment of the participants randomly allocated participants to the different treatment groups. The same assistant who was not involved in the assessment and treatment of the participants randomly allocated participants who volunteered to participate and satisfied the eligibility criteria to the different treatment groups (A or B). In order to ensure equal-sized treatment groups, random permuted blocks was used [20] and a block size of 4 was chosen (i.e. AABB, ABAB and all the other possible restricted permutations). The block permutations were computer-generated using a factorial equation formula:

$$(4!) / ((2!)(2!) = 24$$

The consecutive participants were randomized following the computer-generated block

permutations. The printout of all the 24 restricted computer-generated block permutation sequence was sequentially numbered, cut and placed in sealed envelope.

This study utilized blocked randomization because of its advantage to ensure equal size treatment group. Hence, this rigorous assignment method was intended to be a strength to the design of the study. However, the differences in sample size between group was not as a result of random assignment but decline or refusals to participate which was beyond the control of the researchers. The participants were randomly assigned to either the CBMT group or the TBMT group.

#### **Telerehabilitation-based McKenzie therapy**

The TBMT group received mobile phone-based application of the Mechanical Diagnosis and Therapy (MDT). Most of the participants in the TBMT group were provided with smartphones within the available budget. Others with their own phones were recruited into that arm of the study to be able to achieve minimum sample size, while those without an android phone that could run the app were excluded.

TBMT is a comparable version of CBMT performed in the home with the assistance of a mobile phone app. The mobile app is a combination of the McKenzie extension protocol and back care education developed and enabled to run on a smartphone or android phone with Operating System of 3.5. TBMT is a mobile phone video app designed for patients with chronic low back pain. The App incorporated personalized and guided self-therapy using the same protocol in the McKenzie protocol (i.e. extension lying prone, extension in prone and extension in standing). Performance feedback and progress tracking was telemonitored through enhanced caregiver support in order to improve patient engagement and therapy compliance.

#### **Clinic-based McKenzie therapy**

The CBMT group received the McKenzie extension protocol and a set of back care

education instructions comprised 9-item instructional guide on standing, sitting, lifting and other activities of daily living for home [19]. The protocol involves a course of specific lumbosacral repeated movements in extension that cause the symptoms to centralize, decrease or abolish [21]. The extension activities include extension lying prone, extension in prone, and extension in standing repeated up to ten times [19,21]. The determination of the directional performance for extension was followed by the extension protocol. The details of the protocol has been described in an earlier publication [22]. Extension lying prone: participant laid prone, with elbows placed under the shoulders so that he/she could lean on the forearms; and stayed in this position for five minutes. The movement was repeated up to ten times.

Extension in prone: participant positioned in prone, placed his/her hands under the shoulders in the press – up position. The participant then straightened the elbows and pushed the top half of the body up as far as his/her pain permits. The participant maintained the position for up to two seconds. The movement was repeated up to ten times.

Extension in standing: participant stood upright with the feet slightly apart and placed his/her hands in the small of the back with the fingers pointing backwards. The participant then stretched the trunk backwards at the waist level as far as he/she can, using the hands as a fulcrum while keeping the knees straight. The movement was repeated up to ten times.

#### **Outcomes and Assessment**

Baseline assessment was carried out for each participant that was recruited into the study. Anthropometric variables like weight and height were measured. Information such as age, gender, educational level, occupation, marital status, onset of back pain, recurrence, duration of complaint, previous intervention were recorded for each participant accordingly. The participants were also assessed for directional preference. It involved repeated movements, between 5-10 sets of each movement and it include movements in standing and lying and in sagittal and frontal planes while the participants' symptomatic and mechanical responses were assessed. Following the repeated-movement testing, the participants returned to the same standing position and following standardized instructions in the McKenzie Institute's Lumbar Spine Assessment Algorithm (MILSAA), they were asked whether pain was centralizing or peripheralizing during and after movements or there was no effect. The MILSAA is a well-defined algorithm that leads to the simple classification of spinal-related disorders. This is based on a consistent "cause and effect" relationship between historical pain behaviour as well as the pain response to repeated test movements, positions and activities during the assessment process. The participants' mechanical response to repeated movements was used to establish their directional preference.

Treatment health outcomes were assessed at 4 weeks, and 8 weeks of the study, and the outcome evaluators were blinded to the groups and the interventions. A primary outcome of the low back pain disability was used as health outcome, that was measured by Oswestry Disability Index (ODI). The ODI is a self-administered questionnaire on a 10-item scale with 6 response categories [18]. Each item scores from 0 (better) to 5 (worse).Each score was transferred into a 0 to 100 scale. The ODI score each patient participants was recorded. In order to estimate the health related quality of life of LBP patients used for cost-effectiveness analysis, the ODI score was mapped to SF-6D using the equation below [23].

#### SF-6D = 0.78275 - 0.00518 (ODI)

Where, SF-6D = Short-form six-dimension; ODI = Oswestry Disability Index The SF-6D is a preference-based health state classification system [24]. The SF-6D values obtained using the above formula were important for measuring the health outcomes of patient participants, and this enabled the researchers to perform a cost-utility analysis (CUA). CUA is used to determine the cost in terms of utilities, and it combines the quantity and quality life. An increased quality of life of low back pain participants can be expressed as a utility value on a scale of 0 (dead) to one (perfect quality of life). After obtaining the SF-6D values of each participants, the quality adjusted life year (QALY) of each participants was calculated. QALY was calculated by multiplying the SF-6D values and the duration of time (years). For the purpose of this study, the average of QALYs at 4 weeks and 8 weeks period was considered for the participants of the study.

#### **Resource use and costs**

Healthcare resource use and costs were assessed based on the McKenzie extension protocol, focusing on direct implementation of costs' of TBMT and CBMT. The direct healthcare resources included for implementing were back treatment DVD that was used for dummy App development before the real app was developed; development of the mobile phone-based application of the MDT for smartphones and android phones with operating system of 3.5. In addition to these smartphones with installed App for patients who may not have smartphones, phone credits for calls, internet data use for the entire project period, and fee for consultations were among the resources used. These resources were documented from McKenzie therapy protocols. Personal costs associated with CBMT was not included in this analysis. As the patients were those attending outpatient physiotherapy departments, cost of medications were not included in this study. Moreover, in the context of this study, most of the patients can access healthcare through out-of-pocket means, in addition to undisclosed self-medication practices that is often encouraged by over the counter access to more than the regulated medications.

#### Statistical and cost-effectiveness analysis

A descriptive statistics of the mean or standard deviation and inferential data analysis were performed using Statistical Packages for the Social Sciences (SPSS) Version 23. A nonparametric Mann-Whitney U test and Friedman's test were used to compare the mean effects between the treatment regimen across 4th and 8th week period and the changes of the effects of the interventions from baseline at  $4^{th}$  week and 8th week for the categorical variables, respectively. Significance level p = 0.05 was adopted for those comparisons. The incremental cost-effectiveness ratio (ICER) was used to assess the cost-effectiveness of TBMT compared to CBMT using the formula below [25].

ICUR =  $\Delta$  Cost / $\Delta$  Effectiveness

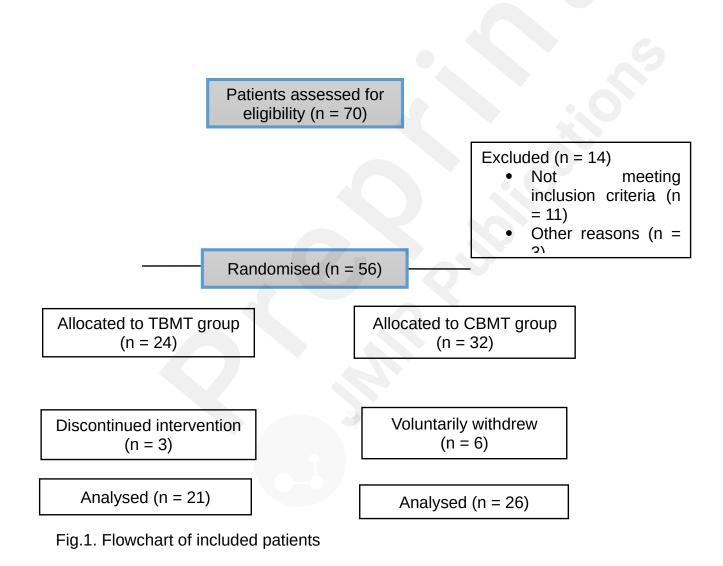
= (Cost of TBMT - Cost of CBMT) *I* (QALY for TBMT – QALY for CBMT)

The incremental cost-effectiveness ratio is the differential costs and outcomes between new intervention (TBMT) and the control (CBMT). The numerator in the cost-effectiveness ratio is the monetary cost of the TBMT intervention minus the monetary cost of CBMT. The annual costs of the projects were calculated by converting the 8 weeks costs, the time period used for implementation. The denominator is the QALY gained by TBMT minus the QALY gained by CBMT. Bootstrapping was used for pair wise comparison for the mean costs and effects between the TBMT and CBMT groups. Confidence intervals for the mean differences in effects were obtained by bootstrapping (1000 replications). The bootstrapped costs and effects pairs were also graphically represented on a cost effectiveness plane [26].

#### Results

A total of 47 participants (CBMT, n = 26; TBMT, n = 21) were randomised and provided baseline data (Fig.1). Table 1 shows the baseline characteristics of these participants. The occupations of the participants were trading (n = 13), teaching (n = 7), nursing (n = 3), tailoring (n = 6), and others (18). The mean age of the participants was 47.3 ± (11.6) and 50 ± (10.7) years for TBMT group and CBMT group, respectively. The participants in the TBMT group had higher weight and body mass index (BMI) by 8.1 kg and 1.5 kg/m<sup>2</sup>, respectively than the group of CBMT. A pain duration of 9.8 ± (2.7) months was reported for the participants in the TBMT group which was less than the group of the CBMT group, pain duration of 8.3 ± (3.2) months. From this study, weight (kg) was the only anthropometric

characteristic that was significantly different between groups at baseline. However, BMI was not statistically different between both groups. The most common cause of chronic low back pain to the participants were lifting, poor posture, prolonged sitting, bending, standing and rigorous act.



	TBMT Group	CBMT Group	
Variables	(n = 21)	(n = 26)	p-value
	x ± SD	x ± SD	
Age (years)	47.3 ± 11.6	50.0 ± 10.7	0.403
Weight (Kg)	79.1 ± 13.1	71.0 ± 7.8	0.011
Body Mass Index (Kg/	27.9 ± 3.6	26.4 ± 3.4	0.155
m <sup>2</sup> )			
Height (m)	$1.7 \pm 0.1$	$1.6 \pm 0.1$	0.107
Pain duration (months)	9.8 ± 2.7	8.3 ± 3.2	0.104
Occupation			
-Trading	(n = 4)	(n = 9)	
-Teaching	(n = 2)	(n = 5)	
-Nursing	(n = 2)	(n= 1)	
-Tailoring	(n = 2)	(n = 4)	
-Artisan	(n = 4)	(n = 2)	
-Driver	(n = 0)	(n = 1)	
-Civil service	(n = 6)	(n = 4)	
-Student	(n = 1)	(n = 0)	

#### Table 1: Baseline characteristics of TBMT group and CBMT group

#### **Resources use and costs**

Participants in the CBMT and TBMT provided the cost data (Table 2). The costs estimate for SMS messages & reminder calls were N50 (\$0.14) per unit and the cost estimate of owning a compactible phone for the App was N20,000.00 (\$55.56). The costs for CBMT included cost of each clinic visit (3 visits per week) estimate is N1,000.00 (\$2.78) per visit, and transportation and refreshments for each clinic visit estimate was N500.00 (\$1.39) per visit. Moreover, the common costs to both groups were costs of physiotherapy consultation (before randomization into group), and were estimated N1,000.00 (\$2.78).

	Cost per visit (\$)		Total cost per participant (\$)	
Resources	TBMT	CBMT	TBMT	CBMT
SMS messages & reminder calls	0.14	0.14	3.4	3.4
(3 times per week)				
Compactable phones for the App	55.6	-	55.6	-
Clinic visit (3 visits per week)	-	2.8	-	66.7
Consultation fee	2.8	2.8	2.8	2.8
Transportation and refreshment	-	1.4	-	33.4
Total cost			61.8	106.3

Table 2: Cost associated with implementation of TBMT and CBMT.

#### Effectiveness

The mean clinical effectiveness of CBMT and TBMT, measured by ODI, at week 4 and 8 from baseline to the participants are presented (Table 3). The changes of health outcomes from baseline at week 4 and week 8 have shown a significant difference (p < 0.001) within CBMT and TBMT groups. However, no significant or clinically relevant mean treatment difference was observed at week 4 and week 8 measurements between groups for the CBMT and TBMT (p > 0.05).

Table 3: Estimates of clinical effectiveness at week 4 and 8 after randomisation

Oswestry	Mean change from base	Mean treatment	_	
Disability Index	(p < 0.001)		difference (95% CI) p-valu	
	CBMT	TBMT		
Week 4	8.5 (5.45 to 11.55)	10.43 (7.74to 11.54)	1.61 (-2.1 to 5.43)	0.238
Week 8	14.50 (10.63 to 18.36)	15.71 (12.85 to 18.57)	0.81 (-2.39 to 4.01)	0.583

#### Cost effectiveness

Table 4 reports the point estimates of the incremental costs and effects per patients. A reduction of in total health-care cost in those participants who received the TBMT, N16,000 (\$44.26) was reported than those received clinic based therapy. On the other hand, participants who received TBMT had additional health benefit (0.001) compared to those CBMT. Thus, the ICER showed that TBMT arm was less costly and more effective than CBMT. Figure 2 plots the results of the 1000 bootstrap from incremental costs and effects.

 Table 4: Incremental cost-effectiveness analysis (ICER)

	Cost	Incremental cost,	Effects, mean (95% CI)	Incremental effect,	ICER Naira
Intervention	Naira (\$)	Naira (\$)	(QALY)	mean (95% CI), (QALY)	(\$)/QALY gained)
СВМТ	38,200	-	0.084 [0.084 to 0.085]	-	
твмт	(106.22) 22,200 (61.7)	-16000 (-44.26)	0.085 [0.80 to 0.09]	0.001[0.001 to 0.002]	Dominant

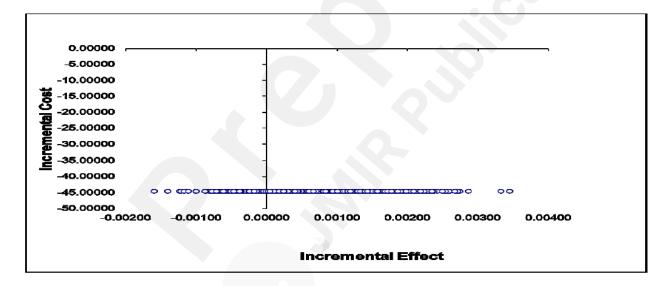


Fig.2. Incremental cost-effectiveness plane. Plot of 1000 bootstrap incremental costs and effects resample means.

#### Discussion

This is the first study to examine the clinical and cost effectiveness of telerehabilitation

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compared with clinic-based therapy. The mean treatment effect of the participants were assessed at week 4 and week 8. A significant difference was found from baseline for the clinical effectiveness within the groups of TBMT and CBMT at week 4 and week 8. On the other hand, no significance difference of mean treatment was reported between the two intervention groups. The findings of the current study is in line with the results of Kosterink et al, who investigated the effects of a four weeks teletreatment service in subjects with nonspecific neck and shoulder pain, where they showed that the treatment was effective in reducing pain intensity and disability over time [27]. They also reported that there was no significant difference between the teletreatment and conventional care - where subjects did not receive any specific intervention such as osteopathy, chiropractice, ergonomic counselling, medication, physiotherapy, acupuncture, stress management and relaxation training.

Parallel to the study carried in Amensie-West District, Ghana, the results of the current study indicated that telerehabilitation therapy was cost saving [28]. It is understood that both cost and health benefit of the two interventions could have impact on the cost-effectiveness of telerehabilitation. The current study showed that telerehabilitation was less costly than clinic based treatment. In line with our study, a cost analysis of telemedicine study in northern Queensland, Australia also concluded that telemedicine saves money mainly due to avoidance of travel costs for patients and for specialist [29]. Moreover, a study in northern Norway has also indicated that teledermatology service was less costly than the cost of a combination of a visiting service and patient level to hospital, and a locally employed dermatologist services [30].

The increment or reduction of the costs and effectiveness of the TBMT by half from the base case values were unlikely to affect its cost effectiveness in the current study. The findings of the current study are consistent with the results the cost-effectiveness analysis

study on telemedicine for primary care delivery, where telemedicine was shown to be cost saving as long as the its effectiveness was greater than the controlled intervention [28]. However, the reduction of its effectiveness from the base case could lead to the costineffective of telerehabilitation. The findings of the one-way sensitivity analysis has also indicated that it is important that patients adhere to telerehabilitation services and improve their health for the new intervention to be cost-effective.

TBMT was approximately 50% cheaper than CBMT; this is due to the less requirement of clinic-based facility and less contact with physiotherapist for its delivery. In other words, there is an opportunity to implement telerehabilitation programme across numerous geographic locations if needed. In low-income countries like Nigeria access to physiotherapy services is a challenge due to shortage of physiotherapists and limited access to clinic-based programmes [31]. Unlike CBMT, TBMT could overcome barriers to accessing physiotherapy services and could deliver numerous benefits to the patients with reduced cost in Nigeria. However, the key challenges to its implementation strategies are the existence of effective internet services and patient reluctance to engage [32].

The major strength of this study was that it is the first study in Nigeria to evaluate the costeffectiveness of telerehabilitation therapy for patients with NCLBP using a randomised controlled trial. In addition, the findings of this study could inform clinicians and decision makers about whether to implement TBMT as a complimentary option of CBMT services in Nigeria. On the other hand, the findings reported here should be viewed in the context of the limitations of this study. The cost analysis did not include costs of medications and indirect costs. It is believed that the exclusion of costs of medications and indirect costs to the cost-effectiveness analysis may underestimate the total cost of therapies. The second limitation of the study was in relation the time of follow up, the effects of the telerehabilitation therapies might be different in the long-term follow up. Thus, evidence of health benefit from a long-term follow up of patient is important to be incorporated in the cost effectiveness analysis of telerehabilitation.

#### Conclusion

The findings of the present study showed that telerehabilitation was associated with greater health benefits and lower costs suggesting that it was a cost saving therapy compared to clinic based therapy. This suggests that the implementation of TBMT could help to overcome barriers to access to physiotherapy services, particularly in low-income countries like Nigeria, thereby improving the health outcomes of patients in these countries. Future studies are required to assess the cost-effectiveness of the intervention in the longer-term from patient and societal perspective.

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#### References

- Dionne CE, Dunn KM, Croft PR, Nachemson AL, Buchbinder R, Walker BF, Hartvigsen JA. Consensus approach toward the standardization of back pain definitions for use in prevalence studies. Spine 2008; 33(1), 95-103.
- Krismer M, Van Tulder M. Low back pain (non-specific). Best Practice & Research Clinical Rheumatology. 2007 Feb 1; 21(1):77-91.
- 3. Calvo-Muñoz I, Gómez-Conesa A, Sánchez-Meca J. Prevalence of low back pain in children and adolescents: a meta-analysis. BMC paediatrics 2008; 13(1), 14.
- Lemeunier N, Leboeuf-Yde C, Gagey O. The natural course of low back pain: a systematic critical literature review. Chiropractic & Manual Therapies 2012; 20 (1), 33.
- Kassebaum NJ, Arora M, Barber RM, Bhutta ZA, Brown J, Carter A, Cornaby L. Global, regional, and national disability-adjusted life-years (DALYs) for 315 diseases and injuries and healthy life expectancy (HALE), 1990–2015: a systematic analysis for the Global Burden of Disease Study 2015. The Lancet 2016; 388(10053), 1603-1658.
- Vos T, Allen C, Arora M, Barber RM, Bhutta ZA, Brown A, Coggeshall M. Global, regional, and national incidence, prevalence, and years lived with disability for 310 diseases and injuries, 1990–2015: a systematic analysis for the Global Burden of Disease Study 2015. The Lancet 388(10053). 2016; 1545-1602.
- Dagenais S, Caro J, & Haldeman S. A systematic review of low back pain cost of illness studies in the United States and internationally. The spine journal 2008; 8(1), 8-20.
- 8. Maher C, Underwood M, Buchbinder R. Non-specific low back pain. The Lancet.

2017 Feb 18;389(10070):736-47.

- Foster NE, Anema JR, Cherkin D, Chou R, Cohen SP, Gross DP, Turner JA. Prevention and treatment of low back pain: evidence, challenges, and promising directions. The Lancet 2018; 391(10137), 2368-2383.
- Steffens D, Maher CG, Pereira LS, Stevens ML, Oliveira VC, Chapple M, Hancock MJ. Prevention of low back pain: a systematic review and meta-analysis. JAMA Internal Medicine 2016; 176(2), 199-208.
- 11. Michaleff ZA, Kamper SJ, Maher CG, Evans R, Broderick C, Henschke N. Low back pain in children and adolescents: a systematic review and meta-analysis evaluating the effectiveness of conservative interventions. European Spine Journal 2014; 23(10), 2046-2058.
- 12. Scott N, Moga C, Harstall C. Managing low back pain in the primary care setting: the know-do gap. Pain Research and Management 2010; 15(6), 392-400.
- 13. Halamandaris VJ. Aging with health and dignity. Caring: National Association for Home Care Magazine 2004; 23(10):6.
- 14. DelliFraine JL, Dansky KH. Home-based telehealth: a review and meta-analysis. Journal of Telemedicine and Telecare 2008; 14(2), 62-66.
- 15. Lin CW, Haas M, Maher CG, Machado LA, van Tulder MW. Cost-effectiveness of guideline-endorsed treatments for low back pain: a systematic review. European Spine Journal. 2011 Jul 1; 20(7):1024-38.
- 16. Oliveira VC, Ferreira PH, Maher CG, Pinto RZ, Refshauge KM, Ferreira ML. Effectiveness of self-management of low back pain: Systematic review with metaanalysis. Arthritis Care & Research. 2012 Nov;64(11):1739-48.
- 17. Chan YH. Randomised controlled trials (RCTs)-sample size: the magic number?. Singapore Medical Journal. 2003 Apr;44(4):172-4.

- 18. Ljungquist T. Physical performance tests and spinal pain: Assesing impairments and activity limitations. Institutionen för klinisk neurovetenskap/Department of Clinical Neuroscience; 2002 May 9.
- 19. McKenzie RA. The Cervical and Thoracic Spine: Mechanical Diagnosis and Therapy. Waikanae, New Zealand, Spinal Publications; 1990.
- 20. Pocock SJ. Allocation of patients to treatment in clinical trials. Biometric 1979; 183-197.
- 21. McKenzie R, May S. The lumbar spine: mechanical diagnosis and therapy. Orthopedic Physical Therapy; 2003 Jun 1.
- 22. Mbada C, Olaoye M, Ayanniyi O, Johnson O, Odole A, Dada O. Comparative Efficacy of Clinic-Based and Telerehabilitation Application of Mckenzie Therapy in Low-Back Pain. Archives of Physical Medicine and Rehabilitation. 2017 Oct 1;98(10):e46-7.
- Carreon LY, Glassman SD, McDonough CM, Rampersaud R, Berven S, Shainline
   M. Predicting SF-6D utility scores from the Oswestry disability index and numeric rating scales for back and leg pain. Spine 2009; 34(19), 2085.
- 24. Brazier J, Usherwood T, Harper R, Thomas K. Deriving a preference-based single index from the UK SF-36 Health Survey. Journal of Clinical Epidemiology 1998; 51(11), 1115-1128.
- 25. Gafni A, Birch S. Incremental cost-effectiveness ratios (ICERs): the silence of the lambda. Social Science & Medicine 2006; 62(9), 2091-2100.
- 26. Chaudhary MA, Stearns SC. Estimating confidence intervals for cost-effectiveness ratios: an example from a randomized trial. Statistics in medicine. 1996 Jul 15;15(13):1447-58.
- 27. Kosterink SM, Huis in't Veld RM, Cagnie B, Hasenbring M, Vollenbroek-Hutten MM.

The clinical effectiveness of a myofeedback-based teletreatment service in patients with non-specific neck and shoulder pain: a randomized controlled trial. Journal of Telemedicine and Telecare 2010: 10(34); 316-321.

- 28. Otsen B, Agyei-Baffour P. Cost-effectiveness analysis of telemedicine for primary healthcare delivery in the Amansie-West District, Ghana. African Journal of Health Economics 2016; 5, 1-11.
- 29. Thaker DA, Monypenny R, Olver I, Sabesan S. Cost savings from a telemedicine model of care in northern Queensland, Australia. Medical Journal of Australia 2013; 199(6), 414-417.
- 30. Bergmo TS. A cost-minimization analysis of a realtime teledermatology service in northern Norway. Journal of Telemedicine and Telecare 2000; 6(5), pp.273-277.
- 31. Mbada C, Olawuyi A, Oyewole OO, Odole AC, Ogundele AO, Fatoye F. Characteristics and determinants of community physiotherapy utilization and supply. BioMed Central health services research. 2019 Dec;19(1):168
- 32. Palazzo C, Klinger E, Dorner V, Kadri A, Thierry O, Boumenir Y, Martin W, Poiraudeau S, Ville I. Barriers to home-based exercise program adherence with chronic low back pain: Patient expectations regarding new technologies. Annals of physical and Rehabilitation Medicine. 2016 Apr 1; 59(2):107-13.