Effectiveness of start approach in reducing functional disability and pain in individuals with chronic non-specific low back pain

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Abstract

Background: Sub-grouping individuals with chronic non-specific low back pain (CNSLBP) based on prognostic factors and targeting treatment to address these factors is been advocated in recent trials. This study investigated the effects of the sub-grouping for targeted treatment (STarT) approach and non-stratified treatment approach in reducing functional disability (FD) and pain intensity (PI) in individual with CNSLBP.

Methods: Forty individuals, with CNSLBP participated in this single blind randomized clinical trial. Participants were randomly assigned into one of two groups: Targeted treatment group (TTG; n = 20) or Non-targeted treatment group (NTTG; n = 20).

Treatment was applied 3 times weekly for eight weeks. Outcomes assessed were pain intensity (PI) using Visual Analogue scale and functional disability (FD) using Roland and Morris disability questionnaire (RMDQ). Data were analyzed using descriptive statistics, paired and independent t-tests at $\alpha_{0.05}$.

Results: Participants in both groups were comparable in age (44.65±9.03 vs 46.40±7.39) years. At baseline, PI, FD and anthropometric values were comparable in both groups. Within-group comparison between the baseline and 8 weeks post intervention revealed that the different treatment regimens had significant effects on PI and FD ($p<0.05$). There was also a significant difference between the 2 groups in pain intensity ($p<0.05$) with no significant difference in terms of functional disability ($p > 0.05$).

Conclusion: STarT and non-targeted treatment approaches were effective in reducing pain and functional disability in individuals with chronic non-specific low back pain. However, STarT approach was more effective in reducing pain among participants.

Key words: Chronic low back pain; STarTs approach; Pain intensity; Functional disability

Introduction

Chronic non-specific low back pain (CNSLBP) is a common and costly musculoskeletal disorder, which results in significant personal, social and economic burden [1]. Evidence has shown that CNSLBP is associated with a complex interaction of factors. These factors include physical factors such as maladaptive postures and movement patterns [2], cognitive factors such as unhelpful beliefs and maladaptive coping strategies [3], psychological factors such as anxiety and depression [4], lifestyle factors such as physical inactivity and sleep problems [5], neurophysiological factors such as peripheral and central nervous system sensitization [6] and social factors such as socioeconomic status, work, and culture [7]. Despite this complex interaction of factors in CNSLBP, researchers [8, 9] have identified that most interventions for treating low back pain, most often neither target multiple aspects of an individual's symptom nor

individualize the targeting of such factors for each patient. It is therefore, not surprising that various treatments such as manual therapy, exercise and cognitive behavioral therapy are not superior to each other in improving patient outcomes [10, 11].

There is growing evidence suggesting that sub-classifying patients and offering them tailored interventions matching their disorder improves patient outcome [8, 12, 13]. Based on this, different classification schemes have emerged, such as Mechanical Diagnosis and Treatment (MDT), Treatment Based Classification (TBC), Pathoanatomic Based Classification (PBC), Movement System Impairment Classification (MSI), and O'Sullivan Classification System (OCS) schemes. Although evidence supporting reliability of some of these systems have been documented, none has proven its superiority over others in identifying subgroups of patients with better outcomes from a specific treatment compared to others [10, 11].

The existing classification systems do not eliminate the need for development of alternative ones. Previous researchers have mentioned that to acknowledge the accepted concept of low back pain patient heterogeneity, there is need to test the effectiveness of the approach. Some recent studies [14,15] found that a novel stratified primary care management approach, the 'STarT approach' based on the use of a prognostic screening tool (to allocate patients into one of three risk-defined groups) combined with matched treatment pathways improves patient outcomes compared with current best practice.

Sub-grouping for targeted Treatment (STarT) approach, target treatment to subgroups of people according to estimated risk of poor prognosis using a sub-grouping tool – the STarT Back Tool [15]. The STarT back tool categorizes back pain patients into 3 subgroups for targeted treatment. This include people at low risk of developing future disabling low back pain (LBP), people at medium risk with physical and psychosocial indicators for poor outcome, but without high levels of psychological indicators and lastly, people at high risk with high levels of psychological prognostic indicators with or without physical indicators [16]. According to Hay *et al* [14], alongside the development of the STarT Back tool, targeted treatments for patients allocated to the low, medium and high-risk subgroups was developed and designed to address the specific modifiable prognostic indicators identified by the tool. The STarT approach is in cognizance with evidence-based assessment and treatment approaches for LBP patients and it follow a stepped-care format. The focus of the interventions is directed towards the secondary prevention of disabling back pain. Presently, only 1 randomized controlled trial on STarT approach carried out by Hill *et al.*, [15] in the UK has revealed better outcomes for individual with low back pain within primary care health setting in a way that is cost-effective. Implementation of this approach within the context of this study environment, Nigeria, will be justified due to difference in healthcare system and differences in individual and work- related psychosocial factors (such as attitude, beliefs, culture, family, compensation issues and work) which have been documented to influence response to treatment. There is therefore need for more RCTs to substantiate the effectiveness of STarT approach in the management of low back pain.

Material/Methods

This study employed a single blinded randomized controlled clinical trial design, registered with Pan Africa Clinical Trial Registry PACTR 201701001976214. The experiments were done in agreement with the Helsinki Declaration and was approved by the Research and Ethics committee of Aminu Kano Teaching Hospital,

Kano (AKTH/MAC/SUB/12A/P-3/VI/1632) before the commencement of the study. Consecutive sampling technique was used to recruit participants for the study as they become available. The subjects were screened to determine whether they met the inclusion criteria for the study. The participants for this study were patients with CNSLBP, who were able to comprehend instruction in English or Hausa language, who were not involved in any other treatment during the course of the study.

The following categories of patients were excluded from the study: Patients with history of a prior surgery to the lumbosacral spine; patients with evidence of systemic disease, carcinoma or organ diseases; patients with evidence of pregnancy and patients who are below 18 years. They were recruited from the Aminu Kano Teaching Hospital, Kano. The consented participants were randomly allocated into two groups: Targeted treatment group (TTG; n = 20) and the Non-targeted treatment group (NTTG; n = 20).

Instruments

The following instruments were used to collect data during the course of carrying out this study:

1. **Roland-Morris Disability Questionnaire (RMDQ):** This questionnaire was used to assess functional disability level of participants before and after the intervention.
2. **Visual Analog Scale (VAS)**: Pain Intensity was measured with a visual analogue scale (0 – 10 cm) for current pain level.
3. **STarT back tool:** This was used to categorize participants into the following risk group: Low risk, Medium risk and High risk with matched treatments.
4. **Back Book** [17] was issued to participants to give back care education

Treatments:

Targeted Treatment

All participants in the TTG received an initial 30-minute intervention (first session) which included the following:

1. Reassurance to address concerns related to participant' back pain and any resulting loss of function.
2. Advice which focused on appropriate levels of activity including return to work (if appropriate) and avoiding bed rest.
3. Addressing participant fears.
4. Addressing an individual's uncertainty about issues such as use of pain relief (medication), the role of further investigations, work issues, and the participant's likely future prognosis including methods to deal with future episodes of back pain.
5. Back book [17] was issued to participants for back care education.

Low risk group

Participants allocated to the low risk-group received no further treatment in addition to the intervention described above. They were reassured that further treatment was unlikely to be beneficial or necessary and was encouraged not to seek further treatment. Participants were, however, advised that if their symptoms deteriorated they should re-visit their general practitioner.

Medium risk group

In addition to the first intervention session described above, all medium-risk participants received additional intervention which include the following:

1. Thirty (30) minute physiotherapy sessions focused on restoring function and targeting physical characteristics (disabling back pain, referred leg pain and co-morbid pain).
2. Advice, reassurance, education, exercise, manual therapy as appropriate to each participant.

3. Bed rest, traction, massage and electrotherapy were not included in the treatment protocol.

High risk group

Further treatment session after the first intervention session described above included 45 minute physiotherapy sessions that focus on restoring function using combined exercises, manual therapy, electrotherapy and psychological approaches targeting physical and psychological obstacles to recovery.

Non-targeted treatment group

Participants assigned to NTTG received individualized treatments lasting 45 minutes. This involved 15 minutes infra - red therapy session with 30 minutes treadmill walk using Bruce protocol:

Warm-up:

Speed – 3.3 miles per hour (mph), 0% inclination and duration of 5 minutes.

Weeks 1 – 4:

Speed: 3.3 – 5.0 mph (increase 0.5mph/ minute for 10 minutes), 1-4 % inclination (increase 1% per week) and total duration of 20 minutes.

Weeks 5 – 8:

Speed: 3.3 – 5.0 mph (increase 0.5mph/ 2minutes 20 minutes), 5-8 % inclination (increase 1% per week) and total duration of 30 minutes.

Cool down phase:

Speed – 3.3 miles per hour (mph), 0% inclination and total duration of 5 minutes.

Data Analysis

Data obtained from the study was summarized, presented and analyzed as follows:

Descriptive statistics of mean and standard deviation were used to summarize the demographic data. Independent t-test was used to test for significant difference in demographic data between the two groups. Paired t-test was used to test for significant difference in pain intensity and functional disability before and after intervention in each group. Independent t-test was used to test for significant difference between the post intervention scores of the two groups. Alpha level was set at 0.05. All analysis were performed using the statistical package for social science (SPSS) version 20.

Results

Characteristics of participants

A total of 40 participants completed the study. They were randomly assigned to one of two groups: targeted treatment group (TTG; n=20) and non-targeted treatment group (NTTG; n=20). The age and anthropometric indices of the two groups are shown in table 1. The mean age for the TTG was 44.65 ± 9.03years, while the mean age of the NTTG was 46.40 ± 7.39years. The mean height of participants in TTG was 1.62 ± 0.53m while that of NTTG was 1.68 ± 0.60m. The mean weight of participants in TTG and NTTG were 61.59 ± 7.2kg and 68.30 ± 7.9kg respectively. While the mean body mass index (BMI) of the TTG was 23.47 ± 2.12kg/m^2, and that of the NTTG were 24.20 ± 1.54kg/m^2.

Table 1: Comparison of demographic and anthropometric indices of participants in TTG and NTTG

Variable	TTG X±SD n=20	NTG X±SD n=20	t	p-value
Age(years)	44.65±9.03	46.40±7.39	0.67	0.507
Height(m)	1.62±0.53	1.68±0.60	0.93	0.36
Weight(kg)	61.59±7.2	68.30±7.9	0.58	0.56
BMI(kg/m^2)	23.47±2.12	24.20±1.54	1.24	0.22

At baseline, the mean pain intensity, functional disability score and duration of pain of both groups are shown in table 2 and no significant difference was observed between the groups. The mean pain intensity and functional disability score of TTG were 6.72 ± 1.62 and 15.5 ± 4.29 respectively while that of NTTG was 6.85 ± 1.11cm and 16.1 ± 3.35respectively. No significant difference was observed in pain intensity and functional disability scores of both groups at baseline.

Result of the study indicated a significant reduction in the mean pain intensity scores of participants in TTG between the baseline score (6.72±1.62) and at the end of eight week targeted treatment (4.28±1.52) with $p<0.05$. The functional disability scores also showed a reduction that was significant between the mean functional disability at baseline (15.5±4.29) and at the end of the targeted treatment program (10.95±4.49) with $p<0.05$. See table 3.

The pain intensity and functional disability scores of participants in NTTG are shown in Table 4. There was a significant difference in the mean pain intensity scores of participants in this group between baseline (6.85±1.0cm) and at the end of eight week exercise (5.21±1.0cm) with $p<0.05$. There was equally a significant reduction in the mean functional disability scores between the baseline (16.1±3.35) and at the end of the NTTG (13.1±3.57) with $p<0.05$.

Comparison of post intervention scores of the 2 groups showed that significant difference was observed in the mean pain intensity between groups ($p<0.05$). But the difference was not significant in the mean functional disability between TTG and NTTG ($p>0.05$). However, a greater reduction in pain intensity and functional disability was seen in the TTG than the NTTG after 8 weeks of interventions. See table 5.

Discussion

The main finding of this study was that, stratified care which allocates patients to targeted treatment pathways based on their screened prognostic

Table 2: Comparison of mean pain intensity and functional disability scores of participants in both groups at baseline

Variable	TTG n=20 X±SD	NTTG n=20 X±SD	t	p-value
PI(cm)	6.72±1.62	6.85±1.11	0.29	0.77
FD	15.5±4.29	16.1±3.35	0.49	0.63

Keys:
TTG - Targeted treatment group
NTTG - Non-targeted treatment group
PI – Pain intensity
FD – Functional disability

Table 3: Mean changes in pain intensity and functional disability scores of TTG at baseline and at end of week 8

Variable	Baseline X±SD n=20	Week8 X±SD n=20	MD	t	p-value
PI(cm)	6.72±1.62	4.28±1.52	2.44±0.85	12.913	0.000*
FD	15.5±4.29	10.95±4.49	4.55±2.06	9.858	0.000*

Abbreviations:
PI – Pain intensity
FD – Functional disability
MD - mean difference
*significant difference at $p\leq0.05$

Table 4: Mean changes in pain intensity and functional disability scores of participants in NTTG at baseline and at end of week 8

Variable	Baseline X±SD n=20	Week 8 X±SD n=20	MD	t	p-value
PI	6.85±1.0	5.21±1.00	1.64±0.69	10.586	0.000*
FD	16.1±3.35	13.1±3.57	2.95±1.87	7.028	0.000*

Keys:
PI – Pain intensity
FD – Functional disability
MD - mean difference
*significant difference at p≤0.05

Table 5: Between groups mean changes in pain intensity and functional disability scores of TTG and NTTG after 8 weeks interventions.

Variables	TTG X±SD	NTTG X±SD	MD	t	p-value
PI(cm)	4.28±1.53	5.22±1.00	0.94	2.287	0.028*
FD	10.95±4.49	13.15±3.57	2.20	1.715	0.095

Keys:
PI – Pain intensity
FD – Functional disability
MD - mean difference
*significant difference at p≤0.05

risk category, provided by a Physiotherapist, was more effective in reducing pain intensity among individuals with CNSLBP when compared with current practice of advice, exercise and manual therapy.

It was observed in this study that there was variation in participants response' to pain intensity and functional disability with sub-grouping for targeted treatment approach. This might be due to prompt identification of participants risk status through the use of the STarT back tool and targeting treatment to address specific physical, psychosocial and psychological obstacles to recovery identified by the tool through combined used of advice, education, reassurance, self-care, exercise, manual therapy. Borkan *et al*, [18] documented that identifying valid LBP subgroups should be the first priority as it improve clinical decision making, accuracy of outcome prediction and treatment outcomes. This interest is due to the fact that CNSLBP involve complex interaction of different potential modifiable factors and most current intervention neither stratify patient based on risk of poor outcome nor target treatment to those risks. In addition, there are evidence that non- stratified, treatment such as manual therapy, exercise and cognitive behavioral therapy while reducing pain and disability in LBP patients are not superior to each other [10, 11, 19, 20]. The observed changes in pain intensity and functional disability scores of participant in TTG were clinically meaningful with a minimum clinical important change of 2 cm and 3.5 of VAS and RMDQ respectively (see table 3). However, the observed changes in the pain intensity and functional disability among participant in NTTG and also between the two groups may not be clinically significant and this could be as a result of smaller sample size and duration of data collection (see table 4 and 5).

Result of this study showed that individuals in the TTG displayed significantly reduced pain intensity and functional disability scores after 8 weeks of the program in comparison with their

pre-intervention scores. This could suggest that although, sub-grouping and targeted treatment approach incorporate treatments that have been shown to be effective but may help identify subgroup of patients that would benefits more from a tailored treatment by identifying prognostic indicators through the use of the STarT back tool. Findings of this study thus, corroborates previous studies suggesting that CNSLBP patients would be treated more effectively if they could be assigned to more homogenous subgroups on the basis of a valid criteria [21, 22]. Moore, et al., [23] affirmed that intervention for back pain patients design to provide accurate information about back pain, instill attitudes that is favorable towards self-care, reduce fears and worries, which are components of the targeted treatment approach, has significant effect on pain ratings as its evidence in the present study.

There is emerging evidence that patient-centered multidimensional approach in management of CNSLBP result in improved outcomes. In spite of this emerging evidence, recent research highlights that health professionals including physiotherapists dealing with LBP disorders have difficulty accurately identifying psycho-social risk in their patients, limiting their capacity to target management [13]. However, this was negated in the present study as the researcher who is a Chief Physiotherapist in work cadre, was able to make use of the STarT back tool to classify patients and match them with appropriate treatment as indicated by the tool. This lead to prompt diagnosis and cost effective management system.

Conclusion

Sub grouping and targeted treatment (STarT) approach is more effective than non-stratified care in the reduction of pain intensity among individuals with chronic non-specific low back pain.

Conflict of interest

The authors declare no any conflict of interest and there was no any external funding received for the study.

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