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Effects of Dynamic taping on pain, disability, mobility and endurance among subjects with low back pain

Submission date
05/12/2019

Recruitment status
No longer recruiting

Registration date
14/12/2019

Overall study status
Completed

Last Edited
17/01/2023

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Low back pain (LBP) is a significant public health condition and is associated with a high rate of absenteeism from work, disability, and frequent use of health services. Current literature provides several possibilities for the treatment of LBP that vary according to the duration of symptoms and classification of this condition. These treatments range from educational programs to behavioral cognitive therapy, medication, electrophysical agents, manual therapy, general exercises, and specific spinal stabilization exercises, among others. Although the aforementioned treatments have been extensively adopted, they exert a moderate effect at most, with recurrences typically noted. Therefore, patients and clinicians critically require more effective therapeutic approaches. Several types of tape and their associated application methods are available, with different underlying philosophies regarding their modes of action. Kinesio tape, Dynamic tape, Rigid tape, Micropore tape, Athletic tape, and many other types are available to manage and/or rehabilitate the injuries. Dynamic taping (DT) is a relatively new treatment technique, which is increasingly becoming an adjuvant method to treat musculoskeletal problems. In the year 2009, Kendrick produced DT which is made up of visco-elastic nylon and lycra blend material which has the ability to stretch in four directions, strong elastic resistance and recoil, a high degree of stretch (more than 200%) with no rigid endpoint and visco-elastic properties. The primary mode of action of DT is mechanical (deceleration of eccentric action, load absorption, and assistance of movement) and the second mode of action is neurophysiological. However, no research has evaluated the effects of DT on LBP and the aim of the present study is to determine the effect of DT in the treatment of chronic non-specific low back pain (chronic NSLBP).

Who can participate?
Adults over the age of 18 and who attend the out-patient physiotherapy clinics of King Khalid University Hospital, Abha, Saudi Arabia

What does the study involve?
Participants are requested to join this study while they are at an out-patient physiotherapy clinic. Initial examination/assessment is done for inclusion in the study. A small piece of Dynamic tape

(DT) and Kinesiology tape (KT) is applied to the right and left forearms, respectively. The next day (after 24 hours), the researcher examines the forearm and makes sure that there is no allergic reaction. If any allergic reactions present then the participant is excluded from the study. The pre-test assessment is carried out and the participants are randomly allocated to one of three groups. Dynamic tape is applied parallel to the spine from the posterior superior iliac spine (PSIS) to T12 thoracic vertebra for the first group (Experimental Group 1). For those in the second group (Experimental Group 2), the Kinesiology tape is applied from the posterior superior iliac spine (PSIS) to T12 thoracic vertebra. No treatment is received by the control group. After the application of the tapes, the patients undergo the same pre-test measurements after 2 hours of tape application. The participants are instructed to re-visit after 3 days and the measurements are taken in the presence of tape. After completing the measurements, the routine treatment is given to all the participants (experimental group 1, experimental group 2, and control group).

What are the possible benefits and risks of participating?
The application of tape can be considered as an adjuvant for the main treatment for chronic non-specific low back pain. The tape may minimize/prevent wrong postural movements. There is no risk of participating in this study except allergic reactions to tape application.

Where is the study run from?
The study is being run by the King Khalid University, Abha, Saudi Arabia and takes place in out-patient physiotherapy clinics of King Khalid University.

When is the study starting and how long is it expected to run for?
December 2019 to February 2020

Who is funding the study?
King Khalid University (Saudi Arabia)

Who is the main contact?
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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ECM#2019-71

Study information

Scientific Title
Immediate and short-term effects of Dynamic taping on pain, disability, mobility and endurance among subjects with chronic non-specific low back pain – a randomized controlled trial

Acronym
DTCNSLBP (Dynamic Tape on Chronic Non-Specific Low Back Pain)

Study objectives
1. Application of Dynamic tape is more immediately effective than Kinesiology tape in decreasing pain, improving disability and range of motion and enhance back endurance capacity among subjects with chronic non-specific low back pain.
2. Application of Dynamic tape is more effective in the short term (3 days) than Kinesiology tape in decreasing pain, improving disability and range of motion and enhance back endurance capacity among subjects with chronic non-specific low back pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/10/2019, Research Ethics Committee of King Khalid University, Abha, Kingdom of Saudi Arabia (Chair of Ethical Committee of the Scientific Research, Deanship of Scientific Research, King Khalid University, Abha, Asir Region, Kingdom of Saudi Arabia; Tel: +966 (0)17 2418667; Email: ecm@kku.edu.sa), ref: ECM#2019-71 (HAPO-06-B-001)

Study design
Single-centre interventional randomized controlled trial

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Chronic non-specific low back pain

Interventions
The participants are allocated to the groups (three groups) using block randomization with concealed envelopes and the random table derived from the website randomization.com.
Group 1: Experimental 1 (Dynamic tape application)
Group 2: Experimental 2 (Kinesiology tape application)
Group 3: Control (No tape application)

The Dynamic tape is applied parallel to the spine both right and left from the posterior superior iliac spine (PSIS) to T12 (thoracic) vertebrae for the experimental group (Group 1). The Kinesiology tape is applied parallel to the spine both right and left from the posterior superior iliac spine (PSIS) to T12 (thoracic) vertebrae for the experimental group (Group 2). No treatment is received by the control group.

Once the participants allocated into groups, a small piece of tape (Dynamic or Kinesiology tape) applied on the forearm of participants. Next day (after 24 hours) the researcher will evaluate the allergic reaction to taping. Once the researcher confirms there is no allergic reaction, then the pre-test assessment will be done. After completing the pre-test assessment, the interventional tapes are applied to the participants according to the experimental groups (Group 1 or Group 2). The post-test assessment 1 will be done immediately after the application of the interventional tapes. The time interval (duration) between the pre-test assessment and the post-test assessment 1 will be 2 hours. The post-test assessment 2 will be done on the 3rd day in the presence of tape on the subject’s body.

The total duration of the study for each participant is 5 days. After completing the study, routine treatment will be given to all the participants of the study (subjects in the experimental and control group).

Intervention Type
Other

Primary outcome measure
1. Pain intensity is recorded by the participant using a 10-cm visual analogue scale (VAS), where 0 represented no pain and 10 represented unbearable pain. Pain assessed before application of

Dynamic tape or Kinesiology tape (Pre-test); it will be assessed immediately after the application of tapes (Post-test 1) and the pain assessed again after the 3rd day of tape application (Post-test 2).
2. Disability assessed using the English / Arabic version of the Oswestry Disability Index (ODI). It is a self-rating questionnaire used to evaluate the functional physical disability. It includes 10 sections of six propositions and each rated on a 0 – 5 scale. Relative values are reported (total score / total possible score X 100%). A higher score indicates a worse disability. Disability assessed before application of Dynamic tape or Kinesiology tape (Pre-test); it will be assessed immediately after the application of tapes (Post-test 1) and the disability assessed again after the 3rd day of tape application (Post-test 2).
3. Endurance: Back extensor muscle endurance assessed using by Biering-Sorensen test. Participants are positioned on a treatment table in prone, with the lower half of their body secured with 3 straps. For testing, the participant's ability to maintain a horizontal position is timed using a stopwatch/timer, and standardized verbal encouragement is provided at 30-second intervals. The participant is placed in the starting position for the test, prone on a plinth with the upper edge of the iliac crests aligned with the edge of the table. A second hydraulic table is transversely placed at the same height to the first one under the trunk and upper body, in order that the participants may be supported completely in prone position before initiation of the test. The lower limbs are fixed to the table in full extension, together, and with ankles in plantar flexion using three straps perpendicular to the midline. The first strap is located at the level of the greater trochanter, the second one at the level of the popliteal fossa and the last one at the level of the Achilles tendon insertion as close as possible to the malleoli. An inclinometer fixed to the participant's inter-scapular region by an elastic strap around the chest is used to measure changes in flexion or extension of the subjects during the test. On initiation of the test the second table is lowered and the subject is requested to place their arms across their chest and maintain a neutral spinal position The timer is started as soon as arms are positioned across the chest and the participant is maintaining this position without assistance However at no point is either the researcher or participant aware of the amount of time that had passed, as this has been shown to be a factor directly influencing test results. An oscillation of the inclinometer needle of 100 during the test is permitted, between 50 of extension and 50 of flexion. The test ended when any part of the participant's upper limb touched the table or when they are unable to recover the test position even with verbal encouragement. At this point, the timer is stopped and the test finished. The duration of the test documented in seconds.
Endurance assessed before application of Dynamic tape or Kinesiology tape (Pre-test); it will be assessed immediately after the application of tapes (Post-test 1) and the endurance assessed again after the 3rd day of tape application (Post-test 2). A blinded assessor will be used to measure the outcome measures.

Secondary outcome measures

1. Mobility: Spinal mobility assessed by two methods:
1.1. The lumbar range of motion assessed using a back range of motion (BROM) device. Lumbar flexion, extension, right side flexion, left side flexion, right lateral rotation, left lateral rotation are measured. It is a modified protractor goniometer to measure lumbar spinal mobility in all three plans. An advantage of the BROM device is that it can measure all lumbar motions independent of thoracic and hip motions.
1.2. Modified Schober test: Patient standing and measurements made 10 cm above and 5 cm below the lumbosacral junction (dimples of Venus). Repeat measurement with the patient in full forward flexion and back extension.
Mobility assessed before application of Dynamic tape or Kinesiology tape (Pre-test); it will be assessed immediately after the application of tapes (Post-test 1) and the mobility assessed again after the 3rd day of tape application (Post-test 2).

2. Movement fear-avoidance: The English / Arabic version of the Tampa Scale of Kinesiophobia (TSK) is a 17-item self-report checklist using a 4-point Likert scale that was developed as a measure of fear of movement or (re)injury. The total score ranges between 17 and 68. A high value on the TSK indicates a high degree of kinesiophobia 37 or over is considered a high score, while scores below 37 are considered low. Movement fear-avoidance is assessed before application of Dynamic tape or Kinesiology tape (Pre-test); it will be assessed immediately after the application of tapes (Post-test 1) and the movement fear-avoidance assessed again after the 3rd day of tape application (Post-test 2).

Overall study start date
10/12/2019

Completion date
10/02/2020

Eligibility

Key inclusion criteria
1. Patients with LBP of at least 30 days in duration and aged between 18 and 60 years
2. Pain intensity with minimum scoring of 3 on a Visual Analog Scale (VAS)
3. Disability with minimum scoring of 20 out of 100 in Oswestry Disability Index (ODI)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
45

Total final enrolment
45

Key exclusion criteria
1. Patients with any contraindications to the use of taping (skin diseases)
2. Pain radiating to the knee
3. Known or suspected serious congenital or acquired spinal pathology, spinal surgery history, lumbar disc herniation, spinal deformity, rheumatoid arthritis or spondyloarthropathy diagnosis
4. Unable to tolerate the Biering-Sorensen test

Date of first enrolment
15/12/2019

Date of final enrolment
31/01/2020

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
King Khalid University Hospital
Department of Medical Rehabilitation Sciences
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Sponsor information

Organisation
King Khalid University

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Funder(s)

Funder type
University/education

Funder Name
King Khalid University

Alternative Name(s)
, KKU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Saudi Arabia

Results and Publications

Publication and dissemination plan
The study protocol is not published in any journal. The research will be published in a peer-reviewed indexed journal. The results of the study will inform the immediate and short-term effects of a tape application for the chronic non-specific low back. The researchers intend to send for publication within one month after completing the study.

Intention to publish date
31/03/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available if required by the journal.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		29/09/2020	17/01/2023	Yes	No