Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of Visceral Manipulation combined with Kinesio Taping on Diastasis Recti, Pain Intensity, Stress Incontinence, Pelvic Floor Strength, and Overall Wellness in Postpartum Women

Protocol summary

Study aim
To investigate the combined and individual effects of Visceral Manipulation (VM) and Kinesiotaping (KT) on Diastasis Recti Abdominis (DRA), overall wellness, pain intensity, stress incontinence, and pelvic floor strength in postpartum women through a randomized controlled trial.

Design
randomized controlled trial (RCT) design

Settings and conduct
Research setting and duration This study will be conducted across four major maternity hospitals in Karachi, Pakistan, namely Jinnah Post Graduate Medical Centre, National Medical Centre, Ashfaque Memorial Hospital, and Naila Maternity and General Hospital.

Participants/Inclusion and exclusion criteria
Post-partum female will be included on the basis of: • DRA: Finger width palpation shows >2.5 cm • Postpartum females bearing at least 1 child • Age between 35 to 45 years old • Post-partum females who had gone through normal vaginal delivery, vacuum delivery, forceps delivery, and lower section caesarian section (at least 1 month after) Postpartum female will be excluded if she has: • Any other abdominal surgery • Sensitivity with taping (specific for those will have KT) • Diagnosed with abdominal hernia • Open abdominal wound

Intervention groups
Group A: This group will be treated with Kinesio Taping (KT) alone. Group B: Participants in this group will receive Visceral Manipulation (VM) alone. Group C: This group will receive a combined treatment of Visceral Manipulation (VM) and Kinesio Taping (KT). Group D: Known as the Exercise group, participants here will engage in core strengthening exercises specifically designed for postpartum rehabilitation.

Main outcome variables
Pain Urinary Distress Inventory-6 (UDI-6)

General information

Reason for update

Acronym
VITAL-MOMS

IRCT registration information
IRCT registration number: **IRCT20241104063588N1**
Registration date: **2024-12-06, 1403/09/16**
Registration timing: **retrospective**

Last update: **2024-12-06, 1403/09/16**
Update count: **0**

Registration date
2024-12-06, 1403/09/16

Registrant information

Name
Hafiz Sheraz Arshad Arshad

Name of organization / entity
Health and Research Insights

Country
Pakistan

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-04-01, 1403/01/13

Expected recruitment end date
2024-09-30, 1403/07/09

Actual recruitment start date
2024-04-01, 1403/01/13

Actual recruitment end date
2024-09-30, 1403/07/09
Trial completion date
2024-09-30, 1403/07/09

Scientific title
Effects of Visceral Manipulation combined with Kinesio Taping on Diastasis Recti, Pain Intensity, Stress Incontinence, Pelvic Floor Strength, and Overall Wellness in Postpartum Women

Public title
Effects of Visceral Manipulation and Kinesio Taping on Abdominal Separation, Pain, Bladder Control, Pelvic Strength, and Overall Wellness in Postpartum Women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
• DRA: Finger width palpation shows >2.5 cm • Postpartum females bearing at least 1 child • Age between 35 to 45 years old • Post-partum females who had gone through normal vaginal delivery, vacuum delivery, forceps delivery, and lower section caesarian section (at least 1 month after)
Exclusion criteria:
• Any other abdominal surgery • Sensitivity with taping (specific for those will have KT) • Diagnosed with abdominal hernia • Open abdominal wound
Age
From **35 years** old to **45 years** old
Gender
Female

Phase
1
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **72**
Actual sample size reached: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
all participants in the groups to which they were originally assigned, regardless of whether they completed the intervention or followed the protocol.
Blinding (investigator's opinion)
Double blinded
Blinding description
double -blind experiment where participants & treatment provider will be unaware of the specific treatment group to which they have been assigned. The trial will include four distinct groups to compare the effects of different treatment modalities on Diastasis Recti Abdominis (DRA) and overall well-being in postpartum women. The groups are organized as follows:
Placebo
Used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Lincoln University College
Street address
2, Jalan Stadium SS 7/15, Ss 7, 47301 Petaling Jaya, Selangor
City
Petaling Jaya
Postal code
47301
Approval date
2024-03-29, 1403/01/10
Ethics committee reference number
LUC/CPGS/PHDE/PTR/20240329/001

Health conditions studied

1

Description of health condition studied
Diastasis Recti
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
PAIN
Timepoint
Before the Intervention (Baseline), 2 Weeks, 4 Weeks, 6 Weeks After the Intervention Commences
Method of measurement
viual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group 1: Kinesio Taping (KT) Alone. Designation: Experimental. Description: This group will receive Kinesio Taping (KT) as the sole intervention. Kinesio Tape will be applied directly to the abdominal area affected by Diastasis Recti Abdominis (DRA). The taping will be done using a crisscross pattern to provide mechanical support to the weakened abdominal muscles,

aiming to decrease the Inter-Recti Distance (IRD) and alleviate associated discomfort such as lower back pain and pelvic instability. Taping will be applied by trained professionals and maintained throughout the study period, with changes and adjustments made during weekly visits over the six-week intervention period. This method is expected to improve muscle functionality and contribute to the recovery of abdominal integrity postpartum.

Category

Rehabilitation

2

Description

Intervention Group 2: Visceral Manipulation (VM) Alone. Designation: Experimental. Description: Participants in this group will undergo Visceral Manipulation (VM) therapy, which involves gentle manual techniques aimed at restoring the natural mobility of the internal organs and associated connective tissues. This intervention focuses on addressing the structural and functional aspects of abdominal health affected by Diastasis Recti Abdominis (DRA). The manipulation will be performed by a skilled physical therapist with expertise in visceral techniques. Treatments will occur once a week over a six-week period, with each session designed to progressively enhance organ function and support abdominal recovery.

Category

Rehabilitation

3

Description

Intervention Group 3: Visceral Manipulation (VM) and Kinesio Taping (KT). Designation: Experimental. Description: This group will receive a combined treatment of Visceral Manipulation (VM) and Kinesio Taping (KT). The dual approach aims to synergize the benefits of manual therapy with supportive taping. VM will address the internal dynamics of the abdominal cavity, improving organ mobility and reducing tension, while KT will provide external support to the abdominal muscles, enhancing muscle function and stability. The combination is intended to offer comprehensive treatment for DRA, potentially leading to improved outcomes in terms of abdominal muscle separation and overall postpartum recovery. Therapy sessions will be administered weekly for six weeks.

Category

Rehabilitation

4

Description

Intervention Group 4: Core Strengthening Exercises. Designation: Active Comparator. Description: This group, known as the Exercise group, will participate in a series of core strengthening exercises specifically tailored for postpartum rehabilitation. The exercise regimen will focus on strengthening the transverse abdominis, multifidus, pelvic floor muscles, and other core muscles critical for postpartum recovery. The exercises will be supervised by a physical therapist to ensure proper form and progression, aiming to enhance core stability and reduce IRD. Participants will engage in these exercises three times per week over a six-week period, designed to incrementally build core strength and support overall pelvic and abdominal health.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Naila Maternity Hospital

Full name of responsible person

Dr Naila

Street address

Address: Plot 3 A, Block, 1, Block 1 Shah Faisal Colony 1 Shah Faisal Colony, Karachi, Karachi City, Sindh 75230, Pakistan

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Karachi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Lincoln University College

Full name of responsible person

Prof. Dr. Sandeep Poddar

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Grant name

NA

Grant code / Reference number

NA

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

NA

Proportion provided by this source

1

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Lincoln University College

Full name of responsible person
Mehwish Khan

Position
PhD Scholar

Latest degree
Master

Other areas of specialty/work
Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
demographics and outcomes

When the data will become available and for how long
March 2025 2 years after publication

To whom data/document is available
open access

Under which criteria data/document could be used
open access policy

From where data/document is obtainable
DOI number

What processes are involved for a request to access data/document
NA

Comments

NA