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Effectiveness of splinting in the treatment of trigger finger

Submission date
21/09/2022

Recruitment status
No longer recruiting

Registration date
28/09/2022

Overall study status
Completed

Last Edited
29/12/2023

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aim
Trigger finger is a common clinical disorder that affects about 2.6% of the general population and is characterized by clicking and/or catching during finger movement. A trigger finger often results in pain and functional limitations, which often affect one's performance in activities of daily living, work, and leisure. Hand therapy and splinting offer alternative options for patients who do not wish to endure steroid injections or surgery. Hand therapy intervention and splinting are non-invasive and may provide relief for the idiopathic trigger finger. However, the evidence for their effectiveness remains limited. The aim of the study is to evaluate the effect of hand therapy in comparison to hand therapy and the use of a splint in the treatment of trigger fingers.

Who can participate?
Individuals with a trigger finger

What does studying involve?
An occupational therapist assesses the hand's movement and pain and will provide intervention (either a finger splint or an exercise program). The study will run in Kuwait, and each participant will be followed for six months

What are the benefits and risks of taking part in this study?
This study will help us understand which treatment method is more effective in treating trigger fingers. There are no risks to participating in this study.

Where is the study run from?
Physical Medicine & Rehabilitation Hospital (Kuwait)

When is the study starting and how long is it expected to run for?
September 2020 to August 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Mohammed Sh. Nadar (Kuwait)
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Contact information

Type(s)
Principal Investigator

Contact name
Dr Mohammed Nadar

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Splinting versus exercise for the treatment of adult idiopathic trigger fingers

Study objectives
Splinting is more effective than hand therapy in treating adult idiopathic trigger finger

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/04/2022, Kuwait University Health Sciences Center Ethical Committee (Centre for Research Support & Conferences, Office of the Vice Dean for Research & Postgraduate Studies, HSC, Faculty of Medicine, P.O. Box 24923, Safat 13110, Kuwait; +965 24634524; hsc.ethicalcommitee@ku.edu.kw), ref: VDR/EC – 4019

Study design
Double-blind randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Idiopathic trigger finger

Interventions
The study has two groups:
1. The hand therapy control group
2. The experimental group, with splinting of the proximal interphalangeal (PIP) joint of the involved finger, in addition to the hand therapy program.

A simple randomization procedure of computer-generated random numbers was used to assign patients to hand therapy alone versus hand therapy in combination with joint blocking splinting trial arms.

The participants from both groups were required to attend one session of therapy per week, for six consecutive weeks, in addition to following a hand therapy home program. The participants were instructed to perform their therapy program three times a day as a home program.

For the experimental splint group, the participants received a static ready-made Oval-8 splint that immobilizes the PIP joint of the involved digit at approximately zero degrees, while maintaining the metacarpophalangeal (MCP) and distal interphalangeal (DIP) joints unrestricted. The PIP joint was immobilized day and night for 6 weeks. The splint allowed full movement of the MCP and DIP joints. In addition to the splint, the experimental group received the same hand therapy intervention as the control group.

At a four-month follow-up, the discharged participants were asked to return to the clinic for a final assessment.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Proximal interphalangeal joint blocking splint

Primary outcome measure
The outcome measures were collected at baseline, 6 weeks, and 4 months:
1. Pain measured using a Numeric Pain Rating Scale (NPRS)
2. Severity of triggering measured using Green's classification of triggering
3. Upper extremity function in daily life activities measured using the short-form version of the Disabilities of the Arm Shoulder and Hand (QuickDASH).

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/09/2020

Completion date
30/08/2022

Eligibility

Key inclusion criteria
1. Confirmed clinical diagnosis of trigger finger at the A1 pulley
2. Affecting a single digit
3. Trigger finger of idiopathic origin
4. Green’s grade 2 or 3

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
56

Total final enrolment
49

Key exclusion criteria

1. Trigger thumb
2. Multiple digit involvements
3. Presence of an associated condition (i.e., diabetes mellitus, de Quervain's tenosynovitis, carpal tunnel syndrome, osteoarthritis, rheumatoid arthritis, gout, or hypothyroidism)
4. Caused by trauma (i.e., presence of chronic trauma or repetitive strain)
5. Use of a nonsteroidal anti-inflammatory drug (NSAID)
6. Previous treatments for the involved trigger digit

Date of first enrolment
01/05/2022

Date of final enrolment
15/08/2022

Locations

Countries of recruitment
Kuwait

Study participating centre
Physical Medicine & Rehabilitation Hospital
Ibraheem Dhahi Al Dhahi St
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Sponsor information

Organisation
Kuwait University

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Sponsor type
University/education

Website
http://kuweb.ku.edu.kw/ku/index.htm

ROR
https://ror.org/021e5j056

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planning publication in a high-impact peer-reviewed journal

Intention to publish date
01/10/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be available upon reasonable request from the study author (Mohammed Nadar, mohammed.nadar@ku.edu.kw). The data can be available in Excell format, with no time restriction, to any researcher.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		20/10/2023	29/12/2023	Yes	No