ISRCTN13658487 https://doi.org/10.1186/ISRCTN13658487

Feasibility of using Cognitive Behavioural Therapy on patients with chronic low back pain in Blantyre, Malawi

Submission date
23/10/2024

Recruitment status
No longer recruiting

Registration date
24/10/2024

Overall study status
Completed

Last Edited
24/10/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Globally, low back pain has remained the top cause of disability since 1990. It restricts individuals from participating in social events or their day-to-day activities. Ninety percent of low back pain has no known specific cause; however, studies report psychosocial factors such as negative attitudes and beliefs, depression, and fear avoidance behaviour play a role in activity and participation restriction. In Malawi, 3.8% of people with disability believe that witchcraft is the cause of their disability, while others do not know the causes or any contributing factors. The lack of knowledge and negative beliefs about their condition might lead to adopting lifestyles that promote and prolong disability.
The purpose of the study is to assess the feasibility of conducting a future randomised trial on cognitive behavioural therapy for patients with chronic low back pain in Malawi.

Who can participate?
Adults of 18 years and above who have low back pain of more than 3 months.

What does the study involve?
Participants will be randomly allocated into one of two groups 1) Usual physiotherapy care (control), which will involve the use of infrared bulb, exercises and soft tissue manipulation or 2) CBT where participants will be involved in identifying unhelpful beliefs about their pain, pain education, cognitive restructuring exercise, general exercise and home exercise program.
Both groups will be asked to attend in-person sessions once every two weeks for three months. This is six sessions in total. Both groups will be asked to complete three questionnaires before and after the three-month period. These questionnaires will look at your attitudes and beliefs of low back pain, disability level and quality of life. These will take approximately 15 minutes to complete. Participants allocated to the CBT intervention will be invited to attend an optional interview (face to face) at the end of the intervention. This interview will explore the feasibility, benefits and challenges of receiving the CBT.

What are the possible benefits and risks of participating
Benefits: The study may help to improve the understanding of pain, reshape patients beliefs

about their pain and improve patient quality of life.
Risks: Participants will be required to share their fears and uncomfortable thoughts about their pain. As such, participants might be emotionally upset talking about their pain. Trained professionals are delivering the care within a hospital setting and are used to dealing with complex patients, as such, participants will be well taken care to avoid any emotional trauma.

Where is the study run from?
Queen Elizabeth Central Hospital in Blantyre, Malawi

When is the study starting and how long is it expected to run for?
June 2023 to February 2025

Who is funding the study?
Commonwealth scholarship

Who is the main contact?
Grace Mukoka-Bwezani, grace.mukoka@napier.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Mrs Grace Mukoka-Bwezani

ORCID ID
https://orcid.org/0000-0003-1893-6790

Contact details
Kamuzu University of Health Sciences
P.Bag 360
Blantyre
Malawi
P.Bag 360
+265 1 871 911
grace.mukoka@napier.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
P.08/23-0176

Study information

Scientific Title
Feasibility of using Cognitive Behavioural Therapy on patients with chronic low back pain in Blantyre, Malawi

Study objectives
The main aim of the study is to assess the feasibility of Cognitive Behavioural Therapy (CBT) in managing chronic low back pain in Malawi.
Considering that CBT in management of chronic musculoskeletal pain is a concept developed in western countries, and still new in Malawi, it is crucial to explore implementation processes needed for future trial.
The following are the research questions:
1. What proportion of eligible patients participate (uptake) and engage (adherence) with the feasibility RCT?
2. What data quality and completion rates can be obtained?
3. What sample size is required in a full study?
4. Are Back-PAQ, ODI and SF-20 questionnaires feasible and acceptable methods of assessing self-reported outcomes.
5. What do participants think about the feasibility and acceptability of study and intervention.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 27/09/2023, College of Medicine Research & Ethics Committee (COMREC) (Kamuzu University of Health Sciences, P.Bag 360, Blantyre, 360, Malawi; +265 996 141 000; comrecassadmin@kuhes.ac.mw), ref: P.08/23-0176

2. approved 23/07/2024, Edinburgh Napier University - School of Health and Social Care Integrity Committee (EH11 4BN, Edinburgh, EH11 4BN, United Kingdom; +44 (0)333 900 6040; ethics.shsc@napier.ac.uk), ref: SHSC3502561

Study design
Single-center randomized controlled feasibility study

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Participants will receive the intervention once every fortnight for a period of three months.

CBT will involve Identifying unhelpful and helpful thoughts and beliefs, provide information on the neurophysiology of pain, assist with identifying active coping strategies, teach general body exercises and encourage engagement with a home exercise programme.

Usual physiotherapy care (control) will involve the use of Manual therapy, Mackenzie, electrotherapy

The randomisation process will be done online using Dotmatics-graphpad application. With this online application, all participants will be automatically assigned to either an intervention group or control group.

Intervention Type
Behavioural

Primary outcome(s)
The following measures will be obtained during the recruitment and throughout data collection phase:
1. Recruitment and refusal rates (Frequencies and percentages)
2. Withdrawal rate and reason (Frequencies and percentages)
3. Adherence to the intervention (Frequencies and percentages)
4. Barriers and facilitators to CBT implementation

Key secondary outcome(s))
The following measures will be obtained at baseline and after 3 months (completion of the intervention):
1. Disability level will be measured using Oswestry Disability Index (ODI)
2. Quality of life using 20-item short form questionnaire
3.Attitudes and beliefs using Back Pain Attitudes Questionnaire (Back-PAQ)
4. Pain will be measured using Numerical Rating Scale (NRS)

Completion date
01/02/2025

Eligibility

Key inclusion criteria
1. Adult patients age ≥18 years suffering from non-specific low back pain for more than 3 months
2. Those who are currently attending physiotherapy treatment at QECH, in Blantyre, Malawi
3. Those who are willing to provide informed consent to participate in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Total final enrolment
30

Key exclusion criteria
Those presenting with chronic low back pain for other reasons such as cancer, tuberculosis, or spinal surgery

Date of first enrolment
28/10/2024

Date of final enrolment
30/11/2024

Locations

Countries of recruitment
Malawi

Study participating centre
Queen elizabeth central hospital
P.O.BOX 95
Blantyre
Malawi
P.O.BOX 95

Sponsor information

Organisation
Edinburgh Napier University

ROR
https://ror.org/03zjvnn91

Funder(s)

Funder type
Charity

Funder Name

Commonwealth Fund

Alternative Name(s)
The Commonwealth Fund, CF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study will be available upon request from Grace Mukoka-Bwezani; grace.mukoka@napier.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3.0	10/06/2024	24/10/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes