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The clinical and cost effectiveness of a personalised living well support package on health-related quality of life in older people with knee and/or hip joint pain and at least one other long term health condition

Submission date
05/10/2023

Recruitment status
No longer recruiting

Registration date
16/10/2023

Overall study status
Ongoing

Last Edited
10/08/2026

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Knee and hip osteoarthritis affect 1 in 2 adults aged over 70 years with nearly 7 in 10 osteoarthritis sufferers having more than one medical condition, resulting in complex health needs. Demand for treatment is high but care across services is often fragmented and not based on individual user needs and preferences. The complex interaction of painful arthritis and long-term conditions is associated with reduced independence and quality of life in terms of self-care, mobility, activity levels, pain, anxiety, and depression. Individuals with arthritis and multiple long-term conditions (MLTC) are also less active than the general population, which has a negative impact on their physical and mental health. They often struggle with the knowledge, confidence, and skills to self-manage their health alongside their arthritis. Overall, arthritis and MLTCs can lead to high demand for coordinated care across different services, and admission to hospital, which is costly to the individual and society. Holistic personalised treatments for older adults that help them live well alongside managing their arthritis and MLTCs are urgently needed.

The aim of the study is to evaluate how effective this new TIPTOE living well support is and see whether it can help individuals with knee and/or hip joint pain and other long-term conditions understand their conditions more and be able to cope with the challenges they experience in everyday life.

Who can participate?
People aged 65 years and older who are living independently in the community, or with carer support or in assisted living. You must also have knee and/or hip joint pain, which is impacting on daily living, and at least one other long-term mental or physical health condition.

What does the study involve?
Participants who are randomised to receive the personalised living well support package

(TIPTOE intervention) will receive up to six, one-to-one coaching sessions with trained healthcare practitioners and be sent a living well book which features stories and tips from people living with joint pain. Those who are randomised to the control group will continue to receive their usual care.

What are the possible benefits and risks of participating?
At this stage of the research, we don't know if there will be any direct benefits for you but by being involved you will help us gather evidence about different ways that may help individuals with knee and/or hip joint pain and other long-term condition(s) manage better in everyday life. There is a chance that you might find some topics sensitive or challenging whilst taking part in one-to-one support sessions or whilst answering questionnaires.

Where is the study run from?
The study is being sponsored by Cardiff University and the Centre for Trials Research at Cardiff University is managing the study on a day-to-day basis. We have worked extensively with a Patient and Public Involvement (PPI) group who have helped us shape the study.

When is the study starting and how long is it expected to run for?
January 2023 to July 2027

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
The study team can be contacted at TIPTOE@cardiff.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Elizabeth Randell

Contact details
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Additional identifiers

Integrated Research Application System (IRAS)
324783

Central Portfolio Management System (CPMS)
58743

Study information

Scientific Title
MulTI-domain Self-management in Older People wiTh OstEoarthritis and Multi-Morbidities

Acronym
TIPTOE V1.0

Study objectives
Participants receiving the TIPTOE, personalised multi-dimensional self-management intervention, in addition to treatment as usual will have different outcomes as measured by the Musculoskeletal Health Questionnaire, than those receiving treatment as usual alone.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/09/2023, Wales REC 2 (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 2922 941119; Wales.REC2@wales.nhs.uk), ref: 23/WA/0221

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Knee and hip osteoarthritis

Interventions
Intervention Name: TIPTOE personalised living well support intervention

Intervention Details: The trial intervention is a self-management-based approach described as TIPTOE living well support. It will involve six one-to-one (lasting up to 60 minutes) personalised living well support coaching sessions (over 6 months) incorporating digital, and paper-based living well support resources applicable to this population. Individual coaching sessions will primarily be delivered face-to face through clinics, community services or within participants homes, with the option of remote delivery where required. The available resources will include stories and narratives of the experiences, challenges and successes of other people living with Osteoarthritis and Multiple Long-Term Conditions, which might act as a source of ideas or motivation.

Participants allocated to the intervention arm will receive coaching sessions by Healthcare Professionals (HPs), including physiotherapists, occupational therapists, and nurses, who have experience of working with people with complex health problems from primary and secondary care or community settings. Participants will also gain access to the co-designed Living Well with Joint Pain book. Space within the book will allow individuals to record goals and plans, explore personal social networks and reflect on progress. The book will also be available as an interactive PDF with links to digital resources and updates. All HPs will be trained in Bridges self-management that has been adapted for TIPTOE. This will mean that practitioners will develop the knowledge, skills, and confidence to facilitate the coaching sessions in a collaborative and non-directive way whilst also addressing concepts such as polypharmacy, physical activity, weight management, nutrition, safety, and frailty in their conversations (if required). The training will allow HPs to reflect on the social context of the individual and to value the skills and experiences of individuals and their nominated supporter.

The control group will receive usual care.

Intervention Type
Behavioural

Primary outcome(s)
Musculoskeletal Health Questionnaire (MSK-HQ) measured at baseline, 6- and 12-month follow up

Key secondary outcome(s)
1. Chronic disease self-efficacy as measured on the Self-Efficacy Scale for managing Chronic Diseases (SESMCD) at baseline, 6- and 12-months follow up.
2. Directly measured step count, using an ActivPAL physical activity monitor. Physical activity monitoring will be completed at baseline, and at 12-months follow-up.
3. Aspects of health related QoL as measured on the EQ-5D-5L questionnaire at baseline, 6- and 12-month follow up.
4. Self-Assessment of frailty as measured on the Pictorial Fit-Frail Scale (PFFS) at baseline, 6- and 12-month follow up.
5. Number of falls recorded using a Falls History Questionnaire at baseline and at 6- and 12-months follow-up.
6. Healthcare resource use, obtained through consented linkage to NHS Digital and SAIL. Datasets will include primary care (where available), hospital admissions, surgery, outpatient, and emergency care. A CSRI will also be used to capture additional healthcare resource use, which cannot be obtained through NHS Digital or SAIL in the detail required (e.g., primary care data, social care data, prescription data). Completed at baseline, 6- and 12-month follow up.
7. Health literacy as measured on the Health Literacy Questionnaire (HLQ). The HLQ evaluates the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in a way that promotes and maintains good health. We will be employing a sub-set of domains from the HLQ which cover basic/functional health literacy and communicative/interactive health literacy. The HLQ will only be completed at baseline only.

Completion date
31/07/2027

Eligibility

Key inclusion criteria
Current inclusion criteria as of 10/10/2024:
1. Aged 65 years or older
2. Living in the community independently, or with carer support, or in assisted living
3. With self-reported knee and/or hip joint pain in the osteoarthritis affected joint, with an average pain severity in the past week of 4 or greater on a 0-10 numerical rating scale
4. Osteoarthritis and at least one other co-morbidity identified using the self-administered co-morbidity questionnaire or
5. Osteoarthritis and mild to moderate clinical frailty on the CHSA Clinical Frailty Scale (for clinician referral routes only)

Previous inclusion criteria:
1. Aged 70 years or older
2. Living in the community independently, or with carer support, or in assisted living
3. With self-reported knee and/or hip joint pain in the osteoarthritis-affected joint, with an average pain severity in the past week of 4 or greater on a 0-10 numerical rating scale
4. Osteoarthritis and at least one other co-morbidity identified using the self-administered co-morbidity questionnaire or
5. Osteoarthritis and mild to moderate clinical frailty on the CHSA Clinical Frailty Scale (for clinician referral routes only)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
837

Key exclusion criteria
1. Joint pain attributed to a palliative condition or fracture
2. Knee and/or hip surgery or joint replacement in the last 12 months
3. Living in a care home (residential or nursing care)

Date of first enrolment
10/01/2024

Date of final enrolment

31/07/2026

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
Centre for Trials Research
College of Biomedical & Life Sciences
7th Floor, Neuadd Meirionnydd
Heath Park
Cardiff
Wales
CF14 4YS

Study participating centre
Cardiff & Vale University Lhb
Woodland House
Maes-y-coed Road
Cardiff
Wales
CF14 4HH

Study participating centre
University Hospitals Dorset NHS Foundation Trust
Management Offices
Poole Hospital
Longfleet Road
Poole
England
BH15 2JB

Study participating centre
Homerton Healthcare NHS Foundation Trust
Homerton Row
London
England
E9 6SR

Study participating centre
Llandaff Campus (podiatry)
Cardiff Metropolitan Uiniversity
200 Western Avenue
Cardiff
Wales
CF5 2YB

Study participating centre
Sheffield Teaching Hospitals NHS Trust - Optical Site
8 Claremont PLACE
Sheffield
England
S10 2TB

Study participating centre
Cwm Taf Morgannwg University Local Health Board
Dewi Sant Hospital
Albert Road
Pontypridd
Wales
CF37 1LB

Study participating centre
Betsi Cadwaladr University Lhb Colwyn Bay Office
Princes Park
Princes Drive
Colwyn Bay
Wales
LL29 8PL

Study participating centre
Powys Teaching Local Health Board
Glasbury House
Bronllys Hospital
Brecon
Wales
LD3 0LY

Study participating centre
Swansea Bay University Local Health Board
Tonna Hospital
Tonna Uchaf
Tonna
Neath
Wales
SA11 3LX

Study participating centre
Wigan and Leigh Health Services NHS Trust
Royal Albert Edward Infirmary
Wigan Lane
Wigan
England
WN1 2NN

Study participating centre
Newquay Health Centre
St Thomas Road
Newquay
England
TR7 1RJ

Study participating centre
Compass House Medical Centre
2 Langdon Ln
Galmpton
Brixham NO COUNTRY SPECIFIED, assuming England
England
Q5 0PG

Study participating centre
East Quay Medical Centre
East Quay
Bridgwater
England
TA6 4GP

Study participating centre

Bovey Tracey & Chudleigh Practice
Riverside Surgery
Le Molay-littry Way
Bovey Tracey
Newton Abbot
England
TQ13 9QP

Sponsor information

Organisation
Cardiff University

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Data can be requested via the Centre for Trials Research (CTR) at Cardiff University through the completion of a data request form Data requests - Centre for Trials Research - Cardiff University.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		23/08/2024	27/08/2024	Yes	No
Participant information sheet	Participant information sheet		20/08/2025	No	Yes
Participant information sheet		11/11/2025	11/11/2025	No	Yes
Study website			20/08/2025	No	No

Study website	Study website	11/11/2025	11/11/2025	No	Yes