

# 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

<b>Submission date</b> 05/10/2023	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 16/10/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 20/08/2025	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 August 2026

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](mailto:TIPTOE@cardiff.ac.uk)

## Contact information

### Type(s)

Scientific

### Contact name

Dr Elizabeth Randell

### Contact details

Centre for Trials Research  
College of Biomedical & Life Sciences  
7th Floor, Neuadd Meirionnydd  
Heath Park  
Cardiff  
United Kingdom  
CF14 4YS  
+44 (0)2920 687074  
[RandellE@cardiff.ac.uk](mailto:RandellE@cardiff.ac.uk)

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

## **Integrated Research Application System (IRAS)**

324783

### **Protocol serial number**

CPMS 58743, IRAS 324783

## **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

### **Study design**

Interventional randomized controlled trial

### **Primary study design**

Interventional

### **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**

01/08/2026

## 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

### Sex

All

### 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

31/08/2025

# 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

United Kingdom

CF14 4YS

## Study participating centre

### Cardiff & Vale University Lhb

Woodland House

Maes-y-coed Road

Cardiff

United Kingdom

CF14 4HH

## Study participating centre

### University Hospitals Dorset NHS Foundation Trust

Management Offices

Poole Hospital

Longfleet Road

Poole

United Kingdom

BH15 2JB

## Study participating centre

### Homerton Healthcare NHS Foundation Trust

Homerton Row

London

United Kingdom

E9 6SR

**Study participating centre**  
**Llandaff Campus (podiatry)**  
Cardiff Metropolitan University  
200 Western Avenue  
Cardiff  
United Kingdom  
CF5 2YB

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

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

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

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

**Study participating centre**

**Swansea Bay University Local Health Board**

Tonna Hospital  
Tonna Uchaf  
Tonna  
Neath  
United Kingdom  
SA11 3LX

**Study participating centre**

**Wigan and Leigh Health Services NHS Trust**

Royal Albert Edward Infirmary  
Wigan Lane  
Wigan  
United Kingdom  
WN1 2NN

**Study participating centre**

**Newquay Health Centre**

St Thomas Road  
Newquay  
United Kingdom  
TR7 1RJ

**Study participating centre**

**Compass House Medical Centre**

2 Langdon Ln  
Galmpton  
Brixham  
United Kingdom  
Q5 0PG

**Study participating centre**

**East Quay Medical Centre**

East Quay  
Bridgwater  
United Kingdom  
TA6 4GP

**Study participating centre**

**Bovey Tracey & Chudleigh Practice**

Riverside Surgery

Le Molay-littry Way  
Bovey Tracey  
Newton Abbot  
United Kingdom  
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?
<a href="#">Protocol article</a>		23/08/2024	27/08/2024	Yes	No
<a href="#">Participant information sheet</a>			20/08/2025	No	Yes
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>			20/08/2025	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes