

# Talking in Primary Care: communication skills e-learning for practitioners

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<b>Registration date</b> 15/09/2022	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 30/06/2025	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Musculoskeletal pain (pain that relates to muscles, bones and joints) is a common problem for patients and is likely to increase as the population ages. Back, hip, knee and neck pain are common and are often related to conditions such as osteoarthritis. Musculoskeletal pain can be difficult to treat and can affect peoples' social life, wellbeing and employment. Pharmacological treatments often have very small effects and some carry the risk of dependence. Many primary care appointments involve patients who have musculoskeletal pain and it can be tricky for Primary Care Clinicians (GPs, nurses, and primary care physiotherapists) to know how best to help.

Previous research shows that it is possible to improve the way GPs communicate with patients with a brief training package. Changing GP communication can help reduce pain and improve patients' quality of life and satisfaction with their care. Better communication is likely to also increase patients' confidence to self-manage their health conditions and help reduce the impact of their symptoms on their lives. This in turn could reduce the need for further treatments and appointments. Thus, enhancing communication could both improve symptoms and reduce costs for the NHS. This study aims to assess a communication e-learning training package that we developed with patients and clinicians previously. The training package is quick, easy to access, and received good feedback from the GPs, nurses and physiotherapists who tried it. The idea is to help primary care clinicians (GPs, nurses, doctors, physiotherapists) communicate with patients in a way that is positive and empathic within both remote (telephone and video) and in-person primary care consultations. This study will recruit 42 GP surgeries from across England. Half of the GP practices will receive the training, the other half will not. The researchers will compare outcomes in GP practices that have received the communication training with practices ones that have not to see which, if either, improves patients' symptoms, confidence in managing their symptoms, satisfaction with their consultation, and quality of life. The researchers will also see what, if any, impact there is on costs to the NHS. It is hoped that this enhanced communication might benefit all patients, not just those who have musculoskeletal pain, and so the study will also include patients who have appointments for other conditions/symptoms. If shown to be successful, this enhanced communication training could quickly be made available at low cost to primary care practices across the country.

### Who can participate?

1. All general practices serving NHS patients in England are eligible
2. All practitioners working within participating general practices and seeing people with MSK pain are eligible and will be encouraged to undertake the EMPathicO training; this may include GPs, physiotherapists, practice nurses, nurse practitioners, physician's assistants
3. Patients aged over 18 years verbally consulting a participating practitioner about new, recurrent, or ongoing MSK pain (e.g. back, hip, knee, neck pain) face-to-face in surgery, via the telephone, or via videoconference, even if those consultations were initiated via e-consult, email or initial triage call
4. Patients aged over 18 years verbally consulting a participating practitioner about something other than MSK pain

### What does the study involve?

This study involves a communication e-learning training package that was developed and tested in a small feasibility trial. It is accessible and brief. It aims to help increase expressions of empathy and realistic positive communication within remote and in-person primary care consultations. The researchers will compare outcomes in GP practices that have been trained in enhanced communication, with practices that have not had the training. They will measure the effects on patients' pain, confidence in managing their symptoms, other symptoms, and quality of life with online questionnaires and interviews. They will also measure the economic costs of the training compared to any patient benefits. This enhanced communication might benefit all patients (not just those with MSK pain) so the study will also include patients who present with other symptoms.

### What are the possible benefits and risks of participating?

There are no expected risks associated with taking part in this study. The burden would be the time taken to complete questionnaires. The researchers aim to minimise patient burden by making the questionnaires available for completion on a number of online devices (laptops, tablets and phones) and also provide a paper-based version if required. There is a small risk that patients may become uncomfortable or distressed by answering some of the questionnaires (e.g., questions about pain, anxiety, depression) or by talking about their experiences of primary care consultations in a qualitative interview. No patients reported this was an issue in the feasibility study and the PPIE collaborators think it is similarly unlikely to occur in this trial. To address this risk, patients are able to skip questions and at the end of each questionnaire /interview patients are encouraged to contact their GP if questions have raised any health concerns.

### Where is the study run from?

University of Southampton (UK)

### When is the study starting and how long is it expected to run for?

January 2022 to October 2024

### Who is funding the study?

National Institute for Health Research (NIHR) (UK)

### Who is the main contact?

Ms Nadia Cross, TIP@soton.ac.uk

### Study website

<https://www.southampton.ac.uk/research/projects/tip-study-2>

# Contact information

## Type(s)

Scientific

## Contact name

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## **Additional identifiers**

### **EudraCT/CTIS number**

Nil known

### **IRAS number**

312208

### **ClinicalTrials.gov number**

Nil known

### **Secondary identifying numbers**

CPMS 52978, IRAS 312208

## **Study information**

### **Scientific Title**

Talking in Primary Care: a cluster-randomized controlled trial in primary care to test the effectiveness and cost-effectiveness of communication skills e-learning for practitioners on patients' musculoskeletal pain and enablement

### **Acronym**

TIP

### **Study objectives**

This research study aims to assess a communication e-learning training package that we developed with patients and clinicians previously. This study will compare outcomes in GP practices that have received the communication training with outcomes in GP practices that have not received the training. This will permit us to see whether the training improves patients' symptoms, confidence in managing their symptoms, satisfaction with their consultation, and quality of life. This study will also see what, if any, impact there is on costs to the NHS. The primary hypotheses are:

1. Patients consulting clinicians about musculoskeletal symptoms will report reduced pain and improved patient enablement if their clinician has received the training package compared to if their clinician has not received the training package.
2. Patients consulting clinicians about non-musculoskeletal symptoms will report improved patient enablement if their clinician has received the training package compared to if their clinician has not received the training package.

### **Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 01/07/2022, South Central - Hampshire B Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)207 104 8088, +44 (0)20 7104 8289, +44 (0)20 7104 8289; hampshireb.rec@hra.nhs.uk), ref: 22/SC/0145

**Study design**

Randomized; Both; Design type: Treatment, Education or Self-Management, Qualitative

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

GP practice

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

**Health condition(s) or problem(s) studied**

Musculoskeletal pain and other conditions/symptoms

**Interventions**

TIP is a cluster-randomized controlled, two parallel groups superiority trial in primary care. General practices (the clusters) will be randomized 1:1 to EMPathicO training versus usual care. Eligible practitioners within each cluster will be encouraged to undertake EMPathicO training (the intervention) or will consult patients as usual (control).

Practitioners in practices randomized to receive EMPathicO will be given access to the training via the LifeGuide online platform. EMPathicO comprises an evidence-based series of brief interactive e-learning modules focused on communication skills in clinical empathy and realistic optimism. It can be completed in approximately 75 minutes and practitioners can access it at any time or times that suit them.

Practitioners in practices randomized to Usual Care control will not receive training. They will be offered access to the EMPathicO training when they have completed patient recruitment and follow-up.

**Intervention Type**

Other

**Primary outcome measure**

1. Pain intensity measured using the pain intensity subscale from the Brief Pain Inventory at pre-consultation baseline, post-consultation, 1, 3 and 6 months
2. Patient enablement measured using the modified Patient Enablement Index at post-consultation, 1, 3 and 6 months

### **Secondary outcome measures**

1. Patient global impression of symptom severity is measured using the Patient Global Impression of Symptom Severity single item at pre-consultation baseline, post-consultation, 1, 3, and 6 months
2. Patient global impression of symptom change is measured using the Patient Global Impression of Change single item at post-consultation, 1, 3, and 6 months
3. Pain interference is measured using the pain interference subscale from the Brief Pain Inventory at 1 and 6 months
4. Patient satisfaction is measured using the MISS for UK General Practice at post-consultation
5. Patient-reported adverse events are self-reported by patients using standard items at 1, 3, and 6 months

### **Health Economics Outcomes:**

1. Health-related quality of life is measured using the EQ-5D-5L and EQ-VAS at pre-consultation baseline, 1 and 6 months
2. Capability wellbeing is measured using the ICECAP-A at pre-consultation baseline, 1 and 6 months
3. Healthcare utilization is measured using the ModRUM core module at post-consultation, 3 and 6 months
4. Prescribed medication utilization is measured using the ModRUM depth questions at 3 and 6 months
5. Personal expenses are measured using bespoke items at 3 and 6 months
6. Productivity is measured using the Work Productivity and Activity Impairment Questionnaire: General Health (WPAI:GH) at 3 and 6 months

### **Overall study start date**

01/01/2022

### **Completion date**

31/10/2024

## **Eligibility**

### **Key inclusion criteria**

#### **Practices:**

All general practices serving NHS patients in England are eligible. Each hub will work closely with local CRNs to target practices in areas of high deprivation indices and serving patients from diverse ethnic backgrounds. Practices that are part of large multi-practice primary care networks will be eligible but the unit of randomisation will be considered on a case-by-case basis (i.e., randomise as a group or as individual practices). The degree and type of integration and likelihood of contamination between the practices will be considered.

**Practitioners:**

All practitioners working within participating general practices and seeing people with MSK pain are eligible and will be encouraged to undertake the EMPathicO training; this may include GPs, physiotherapists, practice nurses, nurse practitioners, physician's assistants.

**Patients: MSK group:**

1. Adult (aged 18+ years)
2. Verbally consulting a participating practitioner about new, recurrent, or ongoing MSK pain (e.g. back, hip, knee, neck pain - consistent with ICD-11's diseases of the MSK system)
3. Reporting their average pain in the last week as 4 or more on the numerical rating scale from the Brief Pain Inventory at the index consultation (where 0 = no pain; 10 = pain as bad as you can imagine)
4. Consulting face-to-face in surgery, via the telephone, or via videoconference, even if those consultations were initiated via e-consult/email/initial triage call
5. Has capacity to give informed consent

**Patients: non-MSK group:**

1. Adult (aged 18+ years)
2. Verbally consulting a participating practitioner about something other than MSK pain
3. Has capacity to give informed consent
4. Patients who are consulting for MSK pain and reporting their pain in the last week as less than 4 on the numerical rating scale from the Brief Pain Inventory at the index consultation (where 0 = no pain; 10 = pain as bad as you can imagine)

**Participant type(s)**

Mixed

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 1680; UK Sample Size: 1680

**Total final enrolment**

1682

**Key exclusion criteria****Practices:**

The 26 practices (18 from Wessex CRN, 5 from the Keele area) that were involved in the intervention development and feasibility work and have already seen and/or used the intervention

**Practitioners:**

Unwilling to undertake the intervention and the trial procedures

Patients: MSK pain group and non-MSK group:

1. Consulting solely in written forms, e.g., via e-consult/emails (these patients will not be invited into the study)
2. Has pain known to be caused by malignancy
3. Unable to consent
4. Unable to complete questionnaires (for example, because of severe mental illness or distress, terminal illness) (these patients will be screened out pre-invitation by practice staff)
5. Already enrolled in the trial (e.g., if they consulted a participating practitioner twice within the recruitment window)

To support wider access to participation in research and improve sample representativeness, people who do not speak or read/write English will not be excluded; instead, an interpreter will be made available to support non-English speakers. If numbers permit, the researchers plan to test for any differences in intervention effectiveness for patients requiring an interpreter during their consultation.

**Date of first enrolment**

01/09/2022

**Date of final enrolment**

31/12/2023

## **Locations**

**Countries of recruitment**

United Kingdom

**Study participating centre**

**NIHR CRN: Wessex**

Unit 7, Berrywood Business Village  
Tollbar Way  
Hedge End  
Southampton  
United Kingdom  
SO30 2UN

**Study participating centre**

**NIHR CRN: West Midlands**

James House  
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**Study participating centre**  
**NIHR CRN: West of England**  
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**Study participating centre**  
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**Study participating centre**  
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**Study participating centre**  
**NIHR CRN South West Peninsula**  
F7, Bowmoor House  
Royal Devon University Healthcare NHS Foundation Trust (Wonford)  
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**Study participating centre**  
**NIHR CRN North East and North Cumbria**  
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# Sponsor information

## Organisation

University of Southampton

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## Sponsor type

University/education

## Website

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## ROR

<https://ror.org/01ryk1543>

# Funder(s)

## Funder type

Government

## Funder Name

National Institute for Health and Care Research; Grant Codes: 563

## Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal

## Intention to publish date

31/10/2025

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository. The researchers will seek patient and practitioner consent to deposit data in a data archive e.g., for secondary analysis. For participants who consent for their data to be deposited in a data archive, the researchers will take the necessary steps to pseudonymize the data prior to deposit. Data will be deposited in Pure, the University of Southampton’s online data repository, where access will be restricted through gatekeepers (the chief investigators) to suitably qualified individuals with appropriate protocols in place. Statistical code will not be deposited as the pseudonymisation process alters the dataset in a way that impacts the applicability of the statistical code.

## IPD sharing plan summary

Stored in non-publicly available repository

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>	version 2	12/01/2023	05/04/2023	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Statistical Analysis Plan</a>	version 2	08/12/2023	20/06/2024	No	No
<a href="#">Protocol article</a>		19/03/2024	30/06/2025	Yes	No