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

Submission date 25/07/2022	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 15/09/2022	**Overall study status** Completed	[X] Statistical analysis plan [_] Results
Last Edited 30/06/2025	**Condition category** Other	[_] Individual participant data [X] 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
Ms Nadia Cross

ORCID ID
https://orcid.org/0000-0002-4148-7180

Contact details
Trial Manager
University of Southampton
Primary Care Research Centre
Aldermoor Health Centre
Southampton
United Kingdom
SO16 5ST
+44 (0)2380 591780
tip@soton.ac.uk

Type(s)
Scientific

Contact name
Prof Felicity L Bishop

ORCID ID
https://orcid.org/0000-0002-8737-6662

Contact details
University of Southampton
Southampton
United Kingdom
SO16 5ST
+44 (0)2380 599020
F.L.Bishop@soton.ac.uk

Type(s)
Scientific

Contact name
Prof Hazel A Everitt

ORCID ID
https://orcid.org/0000-0001-7362-8403

Contact details

Primary Care Research Centre
Aldermoor Health Centre
Southampton
United Kingdom
SO16 5ST
+44 (0)23 8059 1788
H.A.Everitt@soton.ac.uk

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 representatives, 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
Newport Road
Albrighton
Wolverhampton
United Kingdom
WV7 3FA

Study participating centre
NIHR CRN: West of England
Whitefriars
Lewins Mead
Bristol
United Kingdom
BS1 2NT

Study participating centre
NIHR CRN Thames Valley and South Midlands
Level 2 West
Garsington Rd
Oxford
United Kingdom
OX4 6PG

Study participating centre
NIHR CRN Kent, Surrey and Sussex
Unit 58
Canterbury Innovation Centre
University Road
Canterbury
United Kingdom
CT2 7FG

Study participating centre
NIHR CRN South West Peninsula
F7, Bowmoor House
Royal Devon University Healthcare NHS Foundation Trust (Wonford)
Exeter
United Kingdom
EX2 5DW

Study participating centre
NIHR CRN North East and North Cumbria
Regent Point
Regent Farm Road
Gosforth
Newcastle Upon Tyne
United Kingdom
NE3 3HD

Sponsor information

Organisation
University of Southampton

Sponsor details
University Road
Southampton
England
United Kingdom
SO17 1BJ
+44 (0)2380598580
rgoinfo@soton.ac.uk

Sponsor type
University/education

Website
http://www.southampton.ac.uk/

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?
Protocol file	version 2	12/01/2023	05/04/2023	No	No
HRA research summary			28/06/2023	No	No
Statistical Analysis Plan	version 2	08/12/2023	20/06/2024	No	No
Protocol article		19/03/2024	30/06/2025	Yes	No