ISRCTN21215037 https://doi.org/10.1186/ISRCTN21215037

Talking in primary care: testing the impact of online training in empathy and optimism for healthcare professionals

Submission date
27/01/2020

Recruitment status
No longer recruiting

Registration date
06/02/2020

Overall study status
Completed

Last Edited
21/07/2025

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Current plain English summary as of 01/06/2020:
Background and study aims
Osteoarthritis (OA) pain is common, costly, and challenging to manage in busy primary care settings. Regardless of which treatment patients receive, excellent practitioner-patient communication can significantly reduce patients' pain while improving quality of life and satisfaction with care. Empathic and optimistic communication is likely to be effective and efficient for patients consulting with OA and will probably also benefit patients consulting with other conditions. Yet primary care practitioners (PCP) vary widely in how much they show empathy, use a positive approach, and/or use key non-verbal skills. A simple intervention concentrating on improving key elements of empathy and non-verbal communication is likely to be effective and efficient. We have developed an online training package for primary care practitioners (including General Practitioners - GPs, physiotherapists, and nurses) to enhance their consultation skills to show more empathy, improve their non-verbal communication skills, and encourage patients with osteoarthritis to have positive yet realistic expectations. We plan to conduct a small 'feasibility' trial to help us design a large, fundable, clinical trial to test the online empathy training package against usual care. Our aims for the feasibility trial are to assess a range of ways to recruit practices and their patients to participate in a trial and what approaches are most effective and acceptable. We will also assess ways to consent patients, the practicalities and acceptability video record consultations, ways to collect our proposed outcome measures and assess PCP use and experience of the online training tool. We will involve patient representatives in the design of the feasibility study to help ensure proposed procedures are relevant and realistic.

Due to COVID-19 we have expanded recruitment via social media to participants who have had a face-to-face, telephone or video consultation with a GP, nurse or physiotherapist in the last two weeks. Data will be collected through two online questionnaires two weeks apart and some participants will be offered a telephone qualitative interview.

Who can participate?
Primary care practitioners and patients at primary care practices within Wessex clinical research network.

Addition to recruitment in view of COVID-19:
The study will collect data via social media from participants living in England who have had a face-to-face, telephone or video consultation with a GP or Nurse in the last two weeks. Data about their symptoms, quality of life, satisfaction and ability of life to cope with their illness, along with a some questions about how COVID-19 may have changed how they feel, will be collected through two questionnaires two weeks apart and participants will be given the opportunity to provide a telephone qualitative interview.

What does the study involve?
Practices will be randomised, and practitioners in 5 of the GP practices will undertake the online training and those in the other 5 GP practices will continue normal practice. Those who continue normal practice will have access to the training after the feasibility study is completed. Two groups of patients will take part - one group who are consulting their practitioner for OA, and one group consulting their practitioner for any other condition. Data collected for the feasibility study will include: video recordings of consultations with patients, patient-reported questionnaires, and practitioner-completed questionnaires.

What are the possible benefits and risks of participating?
For PCPs: Taking part will give PCPs the opportunity of learning new and evidence-based tools that are easy to implement in standard consultations, with the potential to improve patient satisfaction and outcomes. There are no expected risks or disadvantages.
For patients: The opportunity of taking part to help understand more about how clinicians communicate with patients during consultations. There are no expected risks or disadvantages, however some patients might find it embarrassing or intrusive to be video-recorded.

Where is the study run from?
Solent NHS Trust (UK)

When is the study starting and how long is it expected to run for?
February 2020 to March 2021 (updated 05/08/2020, previously: September 2020)

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

Who is the main contact?
Susan Broomfield, tipstudy@soton.ac.uk

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Previous plain English summary:
Background and study aims
Osteoarthritis (OA) pain is common, costly, and challenging to manage in busy primary care settings. Regardless of which treatment patients receive, excellent practitioner-patient communication can significantly reduce patients' pain while improving quality of life and satisfaction with care. Empathic and optimistic communication is likely to be effective and efficient for patients consulting with OA and will probably also benefit patients consulting with other conditions. Yet primary care practitioners (PCP) vary widely in how much they show empathy, use a positive approach, and/or use key non-verbal skills. A simple intervention

concentrating on improving key elements of empathy and non-verbal communication is likely to be effective and efficient. We have developed an online training package for primary care practitioners (including General Practitioners - GPs, physiotherapists, and nurses) to enhance their consultation skills to show more empathy, improve their non-verbal communication skills, and encourage patients with osteoarthritis to have positive yet realistic expectations. We plan to conduct a small 'feasibility' trial to help us design a large, fundable, clinical trial to test the online empathy training package against usual care. Our aims for the feasibility trial are to assess a range of ways to recruit practices and their patients to participate in a trial and what approaches are most effective and acceptable. We will also assess ways to consent patients, the practicalities and acceptability video record consultations, ways to collect our proposed outcome measures and assess PCP use and experience of the online training tool. We will involve patient representatives in the design of the feasibility study to help ensure proposed procedures are relevant and realistic.

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Who is the main contact?
Susan Broomfield (public)
tipstudy@soton.ac.uk
Dr Felicity Bishop (scientific)
f.l.bishop@soton.ac.uk

Study website
https://www.southampton.ac.uk/medicine/academic_units/projects/empathica

Contact information

Type(s)
Public

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 43793

Study information

Scientific Title
Expectation management for patients in primary care: a feasibility trial of a new digital intervention for practitioners

Acronym
TIP

Study objectives
The aims of this feasibility study is to inform the design of a large, fundable, clinical trial to evaluate our online training package in empathy and optimism against usual primary care practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/12/2019, (Health Research Authority, Level 3 Block B, Whitefriars, Bristol REC Centre, BS1 2NT; +44 (0)207 1048 045; nrescommittee.southcentral-hampshireb@nhs.net), ref: 19/SC/0553

Study design
Interventional randomized controlled trial

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
Osteoarthritis

Interventions
Current intervention as of 01/06/2020:
This feasibility trial will be undertaken in a diverse range of general practices in the South of

England and will involve approximately 10 GP practices, 20 primary care practitioners, and up to 180 patients.

Practices will be randomised, and practitioners in 5 of the GP practices will undertake the online training and those in the other 5 GP practices will continue normal practice. Those who continue normal practice will have access to the training after the feasibility study is completed. Two groups of patients will take part - one group who are consulting their practitioner for OA, and one group consulting their practitioner for any other condition.

Data collected for the feasibility study will include: video recordings of consultations with patients, patient-reported questionnaires, and practitioner-completed questionnaires. Video-recorded consultations before practitioners engage in training will form a baseline and a resource to use during the training. Video-recorded consultation after practitioners engage in training will form an outcome measure. Patients will be asked to complete questionnaires at three time points: before they consult with their practitioner, immediately after they consult with their practitioner, and again 2 weeks later. Patient-reported questionnaires ask them about their symptoms, quality of life, satisfaction and ability to cope with their illness. Practitioners and practice staff will be asked to participate in focus groups and/or telephone interviews. Patients will be asked to participate in telephone interviews. The focus groups and interviews will explore how participants found the feasibility study procedures (patients and practitioners) and the online training (practitioners only).

Due to COVID-19, the rtesearchers have introduced recruitment, via social media, of adults who have had a recent consultation with a primary care practitioner face-to-face, by telephone, or video link. They are asked to complete a questionnaire on recruitment and a second one 2 weeks later. These ask about their symptoms, quality of life, satisfaction and ability to cope with their illness. Some patients will also be asked to participate in telephone interviews.

The researchers will collect information on all the feasibility trial procedures to inform the design of a large trial to test the clinical and cost effectiveness of the online training.

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Intervention Type
Other

Primary outcome measure
1. Practice and Primary Care Practitioners (PCPs) recruitment will be recorded as number recruited as a function of number invited
2. PCP attrition rates will be recorded as number and reason for withdrawing from the study
3. Patient recruitment will be recorded as number approached and recruited per recruitment session.
4. Patient attrition rates will be recorded as number, proportion and reason for withdrawal (where possible) of consented patients.
5. Cluster randomisation and consent procedures will be assessed for feasibility
6. Practical and ethical procedures of video-recording consultations will be assessed for feasibility

Secondary outcome measures
Patient-reported clinical outcome measures:
1. Pain symptoms will be assessed though pain intensity, symptom change and symptom bothersomeness pre-consultation and after 2 weeks.
2. OA symptoms will be assessed using the short form of the Hip and Disability Osteoarthritis Score (HOOS-12) and the Knee Injury and Osteoarthritis Score (KOOS-12) pre-consultation and after 2 weeks.
3. Satisfaction with the consultation will be assessed using the Medical Interview Satisfaction Scale (MISS) for UK General practice immediately post consultation
4. Enablement will be measured using the Modified Patient Enablement Instrument (PEI) immediately post consultation and after 2 weeks.
5. Health-related quality of life will be assessed using the SF-12 immediately post consultation and after 2 weeks.
6. Well-being will be measured using the Short Warwick Edinburgh Wellbeing Scale immediately post consultation and after 2 weeks.
7. Pain medication will be assessed using the Bespoke Osteoarthritis Pain Medication Questionnaire after 2 weeks
8. Adverse events will be recorded using a bespoke adverse event form after 2 weeks.

Patient-reported process measures:
1. Perceptions of PCP empathy will be measured using the Consultation and Relational Empathy (CARE) questionnaire immediately post-consultation
2. Anxiety will be measured using the Hospital Anxiety and Depression Scale (HADS) immediately post-consultation
3. Perceptions of PCP response expectancies will be measured using a bespoke measure immediately post-consultation
4. Response expectancies will be measured using the Expectancy subscale of the CEQ and the Treatment Expectation Questionnaire (TEX-Q) immediately post-consultation

5. Treatment credibility will be assessed using the Credibility subscale of the CEQ immediately post-consultation

PCP reported process measures:
1. Self-efficacy for conveying empathy & optimism will be assessed using bespoke self-efficacy scales after completing the intervention.
2. Outcome expectancy for conveying empathy & optimism will be assessed using bespoke outcome expectancy scales
3. Intentions to convey empathy & optimism will be assessed using bespoke intentions scales

Directly assess process measures:
1. PCP empathy behaviours will be assessed by the researchers using the filmed consultations
2. PCP positive response expectancy statements will be assessed by the researchers using the filmed consultations
3. PCP intervention usage will be assessed by the researchers using intervention usage data from Lifeguide platform

Overall study start date
02/12/2019

Completion date
31/03/2021

Eligibility

Key inclusion criteria
Current inclusion criteria as of 01/06/2020:
PRACTICES:
Primary care practices within Wessex CRN.

PRACTITIONERS
Primary care practitioners (e.g. GP, physiotherapist, or practice nurse) seeing people with OA on a regular basis. While we expect most if not all practitioner participants to be GPs, we want to try to recruit first-contact primary care physiotherapists and practice nurses too because these practitioners (particularly physiotherapists) will be increasingly involved in managing patients with OA in primary care in the future.

PATIENTS:
All-consulters: Adults.
OA sub-sample: Consulting a participating PCP in relation to clinically diagnosed hip and/or knee OA, where OA is the only reason for consulting or one of two main reasons for consulting; minimum 45 years old (as per NICE guidance for OA).

Social media recruitment (COVID-19 adaptation)
Adults recruited through social media who have had a face-to-face, telephone or video consultation with a GP, Nurse, or Physio based in primary care.

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Previous inclusion criteria:
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Primary care practices within Wessex CRN.

PRACTITIONERS
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Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 280; UK Sample Size: 280

Key exclusion criteria
PRACTICES
Practices who participated in Empathica Development studies 2 or 4 (think aloud studies), as these involve looking at prototypes of the intervention. If they were to be included in this feasibility trial they could contaminate the control arm.

PRACTITIONERS:
None.

PATIENTS
Patients who are unable to speak English, unable to consent or complete questionnaires (for example, because of severe mental illness, severe distress, very unwell generally, and difficulty reading or writing. While we would like to include patients who are unable to speak English, the involvement of an interpreter would jeopardize a robust test of our intervention because of empathico’s emphasis on verbal as well as non-verbal communication

Date of first enrolment
20/01/2020

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Solent NHS Trust
Highpoint Venue
Bursledon Road
Southampton
United Kingdom
SO19 8BR

Sponsor information

Organisation
University of Southampton

Sponsor details
Research Integrity and Governance Team
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United Kingdom
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+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 Research (NIHR); Grant Codes: 389

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
31/03/2022

Individual participant data (IPD) sharing plan
The quantitative data set generated and analysed during the current study may be available upon request from Dr Felicity Bishop (F.L.Bishop@southampton.ac.uk). Datasets will be shared against pre-specified criteria agreed by the research team and the sponsor. Access to the data will be via an agreed secure method of transfer. The qualitative dataset will not be made available due to ethical concerns.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version V2.0	08/11/2019	06/02/2020	No	No
HRA research summary			28/06/2023	No	No
Results article		18/07/2025	21/07/2025	Yes	No