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Being involved and informed: Improving appointments about your bone health

Submission date
01/11/2022

Recruitment status
No longer recruiting

Registration date
21/11/2022

Overall study status
Completed

Last Edited
23/05/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
The iFraP study team have developed a web-based visual tool called a 'decision-support tool' to support Fracture Liaison Service (FLS) healthcare professionals to know when to suggest treatments and aid conversations with patients about risk and to make decisions, for instance about starting osteoporosis medicines. The team have also developed training for healthcare professionals to help them use the tool and to ensure that the information they are giving is understandable, that they address patient concerns, and that they give clear, consistent information during the appointment. The decision-support tool and training package together are called the 'iFraP intervention'. The iFraP study will look at whether the iFraP intervention makes decision-making about osteoporosis medicines easier, and whether it is cost-effective, acceptable and practical to deliver.

Who can participate?
Adults aged 50 years old and over who have been referred to an FLS consultation due to experiencing a fragility fracture, and who are able to attend a face-to-face or remote consultation. In addition, FLS clinicians involved in delivering the iFraP intervention and GPs consulting with iFraP intervention participants will be invited to an interview as part of the process evaluation.

What does the study involve?
Participants will be asked to complete 3 questionnaires (one at baseline, one at 2 weeks and one at 3 months after their FLS appointment). They will also have the option to have their appointment recorded as well as a medical record review for information about their prescription initiation and continuation. A selection of participants will be invited to take part in an interview to find out what they thought of their FLS appointment. Participants will be involved in the study for a duration of 3 months follow-up. All participating FLS clinicians will be asked to consent to their consultations being recorded. FLS clinicians delivering the iFraP intervention and GPs consulting with patients after they receive the iFraP intervention will be invited to take part in an interview to discuss their experiences and views of the intervention.

What are the possible benefits and risks of participating?
There are no anticipated direct benefits to the research participants of taking part in this study.

However, the information gained from this study will improve information and advice for future information for FLS patients about their bone health and when considering bone health treatments. The study involves relatively low risks and levels of burden which are considered to be no higher than that of usual medical care.

Where is the study run from?
Keele University (UK)

When is the study starting and how long is it expected to run for?
January 2022 to November 2024

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

Who is the main contact?
Keele Clinical Trials Unit (CTU), ctu.operations@keele.ac.uk

Study website
https://www.ifrap.co.uk

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
315303

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 53843, IRAS 315303

Study information

Scientific Title
A person-centred approach to improving uptake of Fracture Prevention drug Treatments (iFraP): a randomised controlled trial of the iFraP intervention in Fracture Liaison Services

Acronym
iFraP

Study objectives
The iFraP intervention will facilitate shared decision-making, improving patient ease in decision-making about osteoporosis medicines (by increasing the extent that the patient was informed and involved in the consultation), increase informed treatment initiation, and reduce treatment discontinuation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/10/2022, East of Scotland Research Ethics Service REC 1 (Ninewells Hospital & Medical School, Tayside Medical Science Centre (TASC), Residency Block, Level 3, George Pirie Way, Dundee, DD1 9SY, United Kingdom; +44 (0)1382 383848; tay.eosres@nhs.scot), ref: 22/ES/0038

Study design
Randomized interventional parallel-process evaluation qualitative treatment education or self-management study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Injuries and accidents, musculoskeletal

Interventions
This study is an individual randomised controlled trial with parallel process evaluation and health economic evaluation. An individual patient-level randomised controlled trial was chosen to (a) minimise disruption of clinician turn over (b) minimise the complexity of using multiple sites in a cluster design (c) minimise the risk of unbalanced recruitment. Participation in this trial involves the patient attending their appointment (as they would as part of usual care), during which we will seek their consent to record and possibly invite them to an interview. This is described in more detail below.

Participant identification
Potential participants will be identified by sites as part of normal NHS care. NHS site staff will mail potential participants a flyer explaining what Fracture Liaison Services are, in normal NHS practice, and a letter introducing the trial. The letter asks the patient to let Keele know whether they want to receive more information about the study (which will include a Participant Information Sheet, consent and baseline questionnaire), either by telephone, online or by mail. Non-responders will be telephoned by the site after 2 weeks to further explain both the research and normal NHS Fracture Liaison Services and determine their preferences. Additional sites will be enrolled if needed.

Consent
Sites will send Keele CTU an import with pseudonymous data of those that have been invited to take part in the iFraP study. This data will be used to ensure an individual is correctly identified when they return their reply slips and that the member of NHS site staff can call those who have not responded within the specified time frame. Consent for this study is self-directed. In both online and pen & paper study packs, informed consent from willing patients will be required as part of the baseline survey. If it is in paper format, patients will sign it with a wet signature and return it by post to Keele CTU. Each consent form that is returned by post will be checked to ensure that it is complete. Any discrepancies in the completion of the consent form will be followed up with a letter (or telephone call from Keele CTU if appropriate) and the original form /questionnaire will be returned to the patient for completion. The online survey will be through e-consent. Participants will be required to enter their names and indicate their choice for each consent form statement. All potential participants must confirm that they agree to all mandatory questions before they can participate in the study. If the required boxes are not ticked, then the participant cannot continue to provide data on the rest of the survey. The consent form also includes optional statements, as described below, related to the process evaluation data collection. A minimal set of participant-identifiable data will be collected in order to ensure an individual is correctly identified and that the right participant is identifiable for follow-up questionnaire completion.

Questionnaires
All Participants will be asked to complete a baseline questionnaire and follow-up questionnaires, at 2 weeks and 3 months (following the FLS consultation date). Participants will be able to complete all questionnaires on paper or online depending on their preference. Participants who do not respond to their 2-week follow-up questionnaire will receive a reminder postcard (via post or email) after approx. 10 days from the initial follow-up questionnaire being sent. If there is no response after a further ~10 days later (approx. 20 days from the initial 2-week follow-up questionnaire being sent) the Keele admin team will make a telephone call to the participant to request completion of a short (Minimum Data Collection (MDC)) questionnaire by telephone. If no telephone contact can be made, after 3 attempts, a brief 2-week questionnaire will be sent to the participant (via their preferred method of contact). Non-responders to the 3-month follow-up questionnaire will follow the same methods as the 2-week follow-up, outlined above.

Process evaluation
The process evaluation is made up of two components: i) Audio/ video recording of consultations - a sample of iFraP and FLS usual care consultations will be recorded, if both the patient and clinician consent, to assess fidelity of intervention delivery. ii) Semi-structured interviews - conducted with all FLS clinicians delivering the iFraP intervention; a sample of patient participants in the iFraP intervention arm; and GPs who consult with a patient following an iFraP intervention consultation.

Audio/ Video recording of consultations
Patients: A patient consenting to the study will be asked to provide (optional) consent to the audio/video recording of their consultation. FLS clinicians will affirm consent prior to the start of the consultation. For remote consultations, the speaker phone function will be used and the recorder will be placed close by. Following the consultation, the FLS clinician will securely upload the recording to Keele CTU for analysis.

FLS clinicians: FLS clinicians will be asked for their consent to audio/ video record their consultations, with participants who also consent.

Semi-Structured interviews
All participants will be given the opportunity to read the PIS and provide informed consent prior to participating in an interview. Informed consent can be acquired in three ways: face-to-face, online, or by post.

For remote consent, participants will receive the study pack, including PIS, and be asked to complete and return an online or postal consent form. When consent is taken. Remotely, the researcher will always affirm consent prior to the start of the interview.

Interviews may be conducted face-to-face, by telephone or by video software. A mutually convenient time for the interview will be arranged by the researcher once a completed when the consent form is received.

Patients:
The trial consent form includes optional consent statements for audio/ video recording of the FLS consultation and consent to be contacted for an interview. Patients receiving the iFraP intervention, who have consented to contact for an interview, will be invited for the interview once their 2-week questionnaires have been completed and returned. These participants will be contacted by email or telephone. Consent procedures for all interview participants are described above. An interview confirmation letter will be sent specifying the date, time, and location (or telephone number). All participating participants who are interviewed will be offered a £20

voucher to thank them for their time. Once the target sample size of 15-20 participants has been reached, all subsequent participants who expressed interest will be sent a letter thanking them for their interest and informing them that we will not be inviting them to take part on this occasion.

FLS clinicians: FLS clinicians delivering the iFraP consultations will be invited to take part in an interview and will read the PIS and provide optional consent before taking part. Consent procedures for all interview participants are described above. An interview confirmation letter will be sent to the clinician specifying the date, time, and location (or telephone number) of the interview.

GPs: GPs will be invited to take part in an interview, identified from patient questionnaires who received the iFraP intervention or from any GPs contacting the study team directly, where patients have indicated they have visited their GP post-consultation. GPs will be aware of the possibility of being contacted for an interview in the letter sent to notify them of their patient participation in the trial. GPs that consult with participating patients about their FLS appointment since attending their iFraP FLS appointment (as identified by patient self-report) will be contacted by post (sent an interview invitation letter, PIS, consent form, and prepaid envelope), email (to read and complete study documents online / by email) or by telephone either directly or via practice managers. If the GP expresses interest by telephone, they will then be sent a study pack online or by post, as above. GPs who return the consent form will be contacted to schedule a mutually convenient appointment. An interview confirmation letter will be sent to the GP specifying the date, time, and location (or telephone number) of the interview. GPs will be offered remuneration for their time.

Intervention Type
Other

Primary outcome measure
Decisional difficulty measured using the Decisional Conflict Scale at 2 weeks

Secondary outcome measures
Patient level and self-reported:
1. Perceptions of fracture risk assessed using a five-point scale at baseline and 2 weeks
2. Satisfaction with the amount of verbal information and experience assessed using an adapted version of the Satisfaction with Cancer Information Profile at 2 weeks
3. Satisfaction with the amount of written information using an adapted version of the Satisfaction with Cancer Information Profile at 3 months
4. Generic health-related quality of life assessed using the EQ-5D-5L, at baseline, 2 weeks, and 3 months
5. Worry about further falls and fractures assessed using an adapted single item measure at 2 weeks
6. Illness perceptions measured with the Modified Brief Illness Perceptions Questionnaire assessed at baseline, 2 weeks, and 3 months
7. Patient's perception of patient-centred care measured with the Patient-Professional Interaction Questionnaire (PPIQ) at 2 weeks
8. Weight, smoking and alcohol assessed at baseline and 3 months and change in physical activity assessed at 3 months
9. Healthcare resource use using the Healthcare Resource Use Questionnaire developed for the study at baseline and 3 months

If osteoporosis drug treatments were discussed in the consultation:
1. Relative perceived importance of osteoporosis drug treatment benefits and possible side effects and adverse events measured using a bespoke questionnaire at 2 weeks
2. Patient satisfaction with medication information provided using the Satisfaction with Information about Medicines Scale at 2 weeks
3. Medicine perceptions using the Beliefs about Medicines Questionnaire at 2 weeks and 3 months
4. Initiation or intention to initiate (self-report) at 2 weeks and adherence, initiation, persistence, discontinuation, and side effects with osteoporosis drug treatments (self-report) at 3 months
5. Medicine initiation (prescription) and discontinuation from hospital electronic prescribing records at 3 months

Process measures:
1. Clinician-reported fidelity of intervention delivery measured using a self-report eCRF at the time of consultation
2. Observed fidelity of intervention delivery measured using a bespoke Observed Fidelity Checklist of consultation recordings made at the time of consultation
3. Consultation length measured using:
3.1. The length of consultation recordings made at the time of consultation
3.2. Clinician self-reported eCRF at the time of consultation
3.3. Aggregate analytics of CDST use in the consultation (for the intervention arm only)
4. Patient recollection of whether specific aspects were covered in the consultation and receipt of written patient information using bespoke items in the 2-week and 3-month questionnaires respectively
5. Aggregate data on the proportion of clinician drug recommendations in line with clinical guidelines captured via CDST analytics at the time of study close

Observed secondary outcome:
1. Engagement in the decision-making process using the observer-measured OPTION 5 scale to analyse consultation recordings made at the time of consultation

Overall study start date
01/01/2022

Completion date
28/11/2024

Eligibility

Key inclusion criteria
1. Adult patients aged > = 50 years old eligible for FLS consultation based on having a previous fragility fracture(s)
2. Adult patients able to participate in an FLS appointment (face-to-face or remote consultation) with a participating NHS hospital or associated FLS

Process evaluation:
3. As above AND clinicians who deliver iFraP interventions and GPs who consult with an iFraP participant

Participant type(s)
Mixed

Age group
Adult

Lower age limit
50 Years

Sex
Both

Target number of participants
Planned Sample Size: 380; UK Sample Size: 380; plus up to 20 FLS clinicians/GPs for process evaluation

Total final enrolment
372

Key exclusion criteria
1. Patients who are unable to give full informed consent or unable to comply with study procedures
2. Patients with a friend or relative in the study (identified through self-report)

Date of first enrolment
31/03/2023

Date of final enrolment
28/11/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Midlands Partnership NHS Foundation Trust
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Study participating centre
Oxford University Hospitals NHS Foundation Trust
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Study participating centre
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Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

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
The main findings from the iFraP study will be shared with the participating NHS sites and participants via the study website www.ifrap.co.uk and Royal Osteoporosis Society website. The results of this study will also be shared at relevant conferences and through publication in academic journals which are read by a large number of health professionals. Participants will not be identified individually in any poster, report or publication.

Intention to publish date
28/11/2025

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available upon request from Keele University after primary study publication for up to 10 years following the End of Study Declaration, according to Keele CTU's standard operation procedures. Researchers can request access to anonymised data (medical data supplied as aggregated data for consenting participants only) and in the first instance should speak with the CI (SPCSC-internal requests) or

email primarycare.datasharing@keele.ac.uk (SPCSC-external requests). Appropriate data request forms should be completed and must outline the type of data to be obtained, the reason for obtaining this data (research question/objective), and the timing for when the data is required to be available (start date/end date). Checks will be performed by a Data Custodian and Academic Proposals (DCAP) committee at Keele to ensure that the data set requested is appropriately suited to answer the research question/objective and that the request fits with the original ethical approval and participant consent and adheres to funder and legal restrictions.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.1	05/10/2022	10/11/2022	No	Yes
Protocol file	version 1.1	05/10/2022	10/11/2022	No	No
Statistical Analysis Plan	version 1.0	05/10/2022	10/11/2022	No	No
Protocol file	version 1.2	13/12/2022	17/01/2023	No	No
HRA research summary			26/07/2023	No	No
Protocol file	version 1.5	18/10/2023	02/02/2024	No	No
Protocol file	version 1.6	13/12/2023	20/02/2024	No	No
Protocol article		02/04/2024	15/08/2024	Yes	No
Statistical Analysis Plan	version 2.0	31/08/2024	04/09/2024	No	No
Participant information sheet	version 1.3	18/10/2023	21/05/2025	No	Yes