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Clinical science

The Michael Mason prize: development and feasibility testing of a complex intervention to improve adherence to fracture prevention medicine

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Abstract

Objectives: Only 12% of people recommended fracture prevention medicines remain on treatment 1 year post fracture. The 'improving uptake of Fracture Prevention treatments' (iFraP) intervention aims to improve shared decision-making (SDM) about, and uptake of, osteoporosis medicines in Fracture Liaison Services (FLS). This paper details development and feasibility.

Methods: Intervention development was underpinned by (i) theories of SDM, medicines adherence and behaviour change; (ii) integrated findings from seven development studies; and (iii) extensive patient and clinician contribution, identifying key 'needs' to address and the intervention's content, functionality and scope. Feasibility testing was conducted at one English FLS. Intervention consultations were observed and audio recorded. Interviews completed with FLS clinicians and patients explored perceived acceptability and feasibility.

Results: Intervention development identified patient and clinician unmet needs for personalized and evidence-based information about osteoporosis, its consequences, and its treatment within and after FLS consultations, to facilitate clinical and SDM about medicines. The prototype intervention (osteoporosis decision support tool, clinician skills training and information resources) was designed to meet identified needs and overcome barriers to use. Clinicians delivered the prototype iFraP intervention in 10 consultations with consenting patients. Findings demonstrated that the intervention was acceptable and feasible to deliver, with potential to improve patient outcomes. The intervention was refined to support implementation.

Conclusion: The multi-facilitated approach to intervention development and testing ensured that the iFraP intervention appears acceptable and feasible for use in UK FLS to support SDM about osteoporosis medicines. The iFraP trial will evaluate implementation, and cost and clinical effectiveness.

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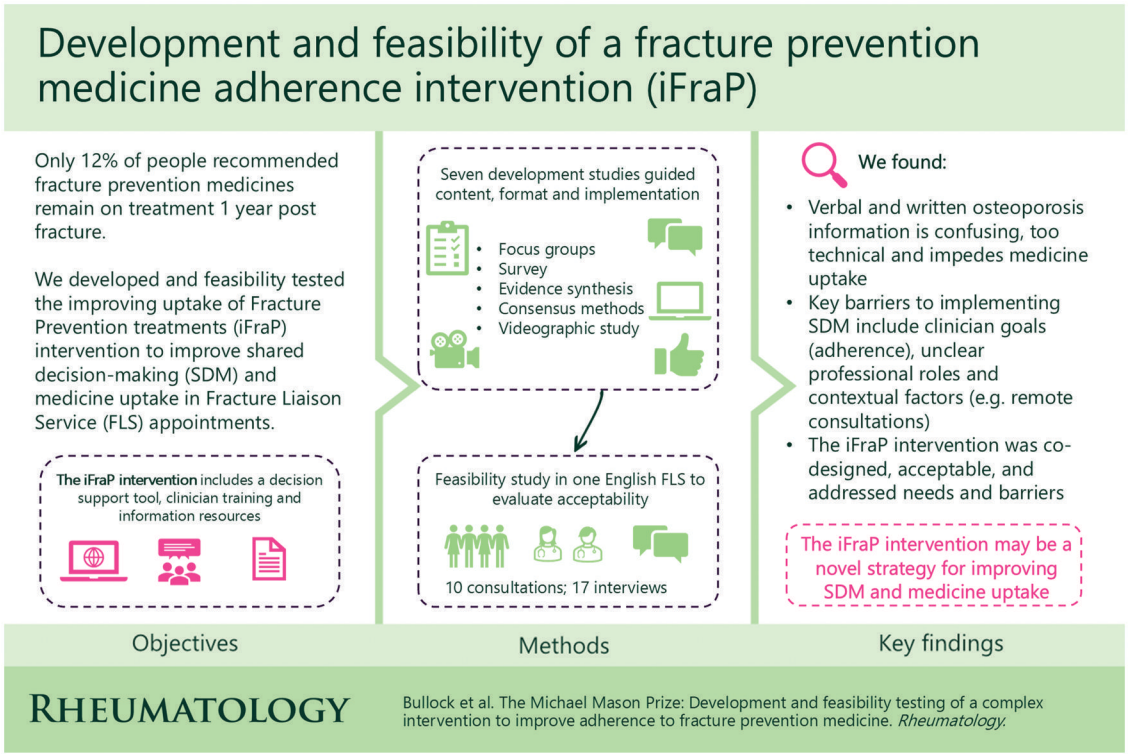
Graphical abstract



Keywords: osteoporosis, shared decision-making, intervention development, fracture liaison service, person-centred care, adherence, behaviour change.

Rheumatology key messages

- Verbal and written communications concerning osteoporosis are currently confusing and technical, and impede decision-making and medicine uptake.
- Key barriers to implementing shared decision-making and decision aids include clinician goals, professional roles and contextual factors.
- A decision tool with clinician training and information resources was co-designed, acceptable, and addressed identified needs and barriers.

Introduction

Osteoporosis is a common condition characterized by a reduction in bone strength which increases propensity to fragility fracture. There are over 500 000 fragility fractures each year in the UK, costing the National Health Service (NHS) £4.7 billion annually [1] and fragility fractures are the fourth leading cause of disability among non-communicable diseases in Europe [1]. Spinal fractures, the most common osteoporotic fracture, lead to long-term pain, mental health impacts, reduced quality of life and an 8-fold increase in mortality [2, 3].

For people with increased fracture risk, evidence-based osteoporosis medicines (anti-resorptive and anabolic treatments) are recommended by clinical guidelines [4–6]. Fracture Liaison Services (FLS) enact secondary fracture prevention by systematically identifying adults aged ≥50 years with fragility fractures, conducting bone health assessments and providing treatment recommendations [7]. However, among those who are recommended osteoporosis medicines by FLS, only 12% of people are reported as taking them 1-year post-fracture [8]. Adherence with osteoporosis medication is reported as worse than in other long-term conditions [9].

Shared decision-making (SDM) has the potential to support osteoporosis medicine adherence [10, 11], by ensuring the treatment is a good 'fit' for the patient [12]. NICE recommend all clinicians support SDM, as a key component of person-centred, personalized care, and use good quality decision support tools (DSTs) where available [13]. Across a range of conditions, DSTs have been shown to increase patient knowledge and participation in decision-making, reduce decisional conflict, and improve the accuracy of risk perception [10].

Following a priority-setting exercise that identified unmet needs in supporting informed decision-making [14], we conducted a programme of work to develop a prototype intervention to improve SDM. The 'improving uptake of Fracture Prevention treatments' (iFraP) intervention consists of a DST and enhanced clinical skills training, aiming to improve SDM about, and uptake of, osteoporosis medicines. This paper

describes the development and feasibility of this prototype intervention.

Methods

Overview and intervention development approach

The Medical Research Council's guidance for developing and evaluating complex interventions was used as an overarching framework [15]. We drew on the three-step implementation of change model [16], which asks three pragmatic questions about the intervention and how it interacts with contextual factors (defined as: 'any feature of the circumstances in which an intervention is conceived, developed, implemented and evaluated' [15]) and future implementation: (i) where do we want to be, (ii) where are we now and (iii) how do we get there? To answer these questions, we used an evidence and theory-based intervention development approach, working in partnership with public contributors and stakeholders [17]. An overview of the dynamic, flexible and iterative development process is shown in Fig. 1. All participants gave written consent. The protocol for the iFraP development work and the findings of each development study are described in detail elsewhere [18–23]. This paper highlights how each study influenced intervention development [reported in accordance with 'Guidance for reporting intervention development studies in health research' (GUIDED) [24]], and the feasibility findings.

Target population and intervention context

The iFraP intervention was developed to be used by UK FLS clinicians and patients. In this research, FLS 'clinicians' include nurses and allied health professionals, allied to rheumatology; the osteoporosis medicines discussed within consultations are usually oral bisphosphonates, but injectable medicines may also be offered.

The iFraP team and co-design approach

The research team included expertise from clinical practice, applied health research, and the third sector with experience in developing and testing complex interventions, software development, behaviour change, health literacy, medicines adherence and communication skills.

A Community of Practice (CoP) brought together stakeholders from across England with a common concern or interest with the aim of improving and learning to do better through regular group interaction [25]. CoP members included FLS clinicians, general practitioners (GPs), osteoporosis specialists, commissioning representatives, public contributors (with lived experience of osteoporosis and/or family members), representatives from the Royal Osteoporosis Society (ROS) and Health Literacy UK. Six CoP meetings supported decision-making and codesign of intervention content and structure.

Public contributors also attended regular Patient and Public Involvement (PPI) meetings as well as study team meetings, steering group meetings and analysis discussions. A public contribution 'impact log' details activities, outcomes and demonstrates enhanced accessibility and inclusivity of the intervention and the research design (see Supplementary Tables S1 and S2).

Step 1: 'where do we want to be?'—make a concrete proposal for change, and develop the content and format of the consultation intervention

Programme theory and underpinning theoretical framework

The intervention programme theory ('logic model') details the iFraP intervention resources, hypothesized mechanisms

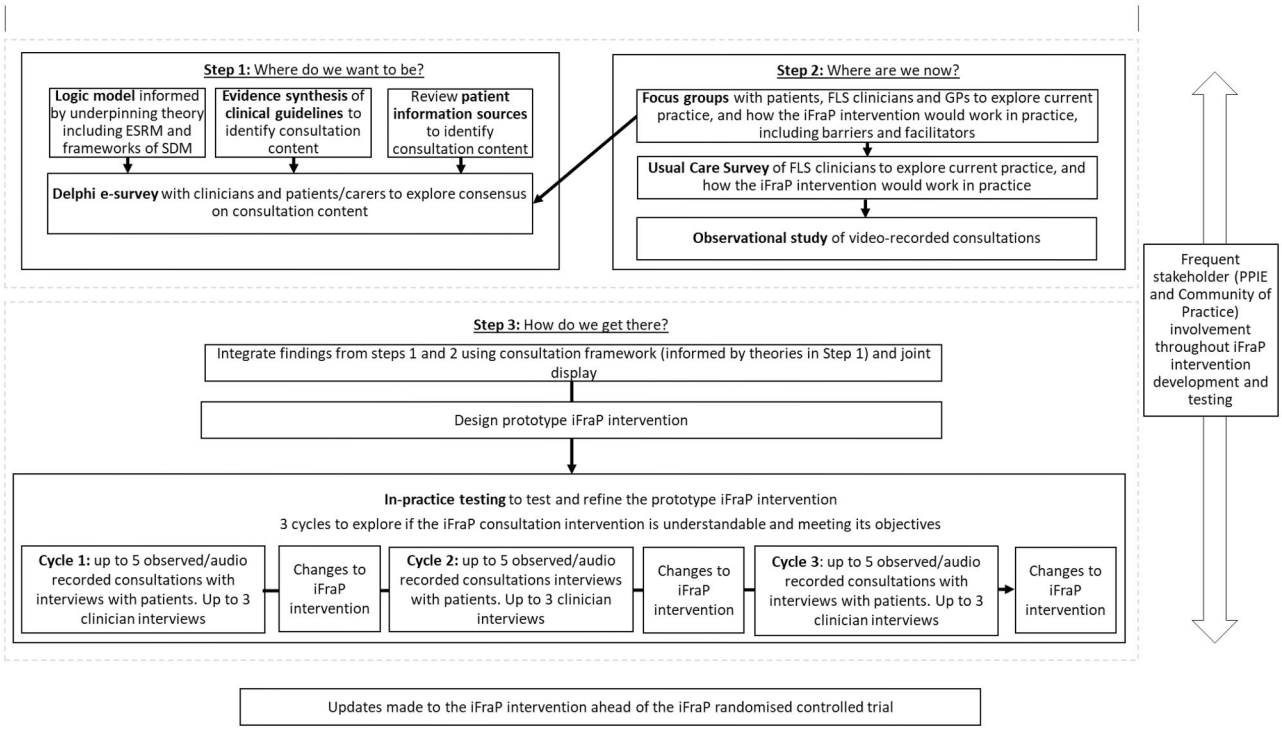


Figure 1. Overview of iFraP development process and methods. ESRM: extended self-regulatory model; SDM: shared decision-making; FLS: Fracture Liaison Service; PPIE: patient and public involvement and engagement; GP: general practitioner

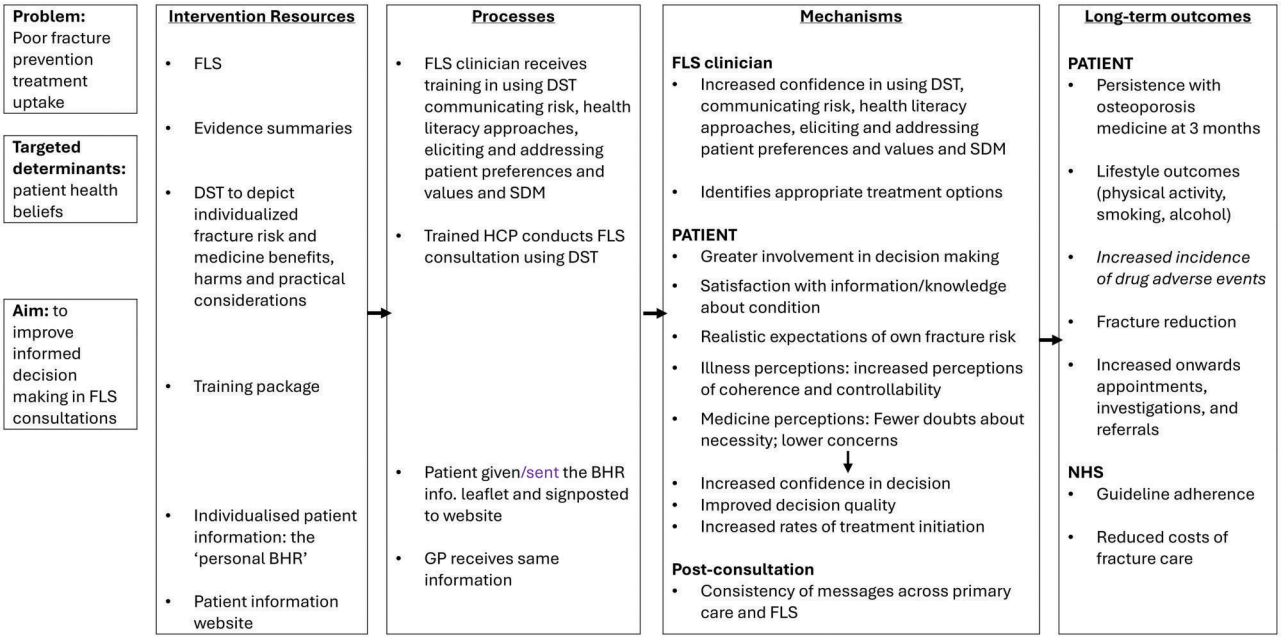


Figure 2. iFraP programme theory. *BHR: bone health record; DST: decision support tool; FLS: Fracture Liaison Service; GP: general practitioner; SDM: shared decision-making. Italics denote 'dark logic' intervention mechanisms/outcomes that may have negative consequences. Purple = key contextual factors identified during intervention development and feasibility testing leading to programme theory updates

and outcomes, and contextual factors, and was refined iteratively throughout development (Fig. 2). The Extended Self-Regulatory Model and the Perceptions and Practicalities Approach (PaPA) [26], explain how a person's beliefs about osteoporosis and treatments are linked to their decision and behaviour to adhere to medicine. For example, it is common for people to not understand their bone health (illness coherence) and have low perceptions about how controllable osteoporosis is (illness controllability) [27]. When patients make decisions about taking medicine, they weigh up their perceived need for the medicine (necessity beliefs) against concerns about (concern beliefs), and practicalities of taking, the medicine [26, 28, 29].

To inform our SDM approach, we used the Ottawa Decision Support Framework [30], a model for designing decision aids, and the SPIKES protocol [31], commonly used to teach person-centred communication skills. These models include the need to elicit and address the patient's illness and medicine beliefs, build on existing knowledge and establish SDM preferences.

Our approach incorporated evidence-based health literacy techniques to: ensure that information shared was understandable (e.g. chunk and check [32]; improve risk communication, including the use of simple frequencies, absolute risks, and positive and negative framing [33]; and check patient understanding using TeachBack [34]).

iFraP intervention development studies

Three intervention development studies guided the content and format of the iFraP consultation intervention. Each study's methods are briefly described below, with further detail reported in their respective publications.

Evidence synthesis of existing osteoporosis decision aids

A core element of complex intervention research is identifying existing interventions [15]. We conducted a systematic review and environmental scan to identify existing osteoporosis decision aids and assess their quality and efficacy and discussed results with public contributors [20].

Evaluating existing patient information about osteoporosis

We purposively sampled online UK patient information resources about osteoporosis. We examined their quality, including readability. We extracted frequently used phrases and descriptors about osteoporosis and osteoporosis medicines and worked with the CoP to review this terminology and identify optimum understandable and accurate language to use in the intervention [18].

Delphi e-survey gaining consensus on intervention content

A modified Delphi survey provided structure and content for the iFraP intervention by determining consensus on tasks for UK practicing clinicians in a model FLS consultation. Statements were generated from: UK clinical guidelines (of assessment and management of osteoporosis/fragility fractures; the conduct of the consultation to enhance patient experience; and medicine adherence); theories and frameworks of SDM; iFraP development studies; and CoP and public contributor discussions [22].

Step 2: 'where are we now?'—understand the current clinical context including barriers and enablers to behaviour change

Four intervention development studies were conducted to understand UK FLS and barriers and enablers to using a DST and implementing SDM in osteoporosis consultations.

Qualitative study with patients and clinicians

To understand current practice and barriers and enablers to facilitating SDM in FLS consultations, we conducted focus groups and semi-structured interviews with patients who had consulted in FLS, FLS clinicians and GPs. We used images of

existing osteoporosis DSTs and Cates plots (presenting absolute fracture risk in simple frequencies) as stimulus material during data collection [21].

Inductive framework analysis [35] was mapped onto the Theoretical Domains Framework (TDF) domains [36] to help understand barriers and enablers to using a DST and improving SDM. We also used the Theoretical Framework of Acceptability (TFA) as an overarching framework [37].

We conducted three additional studies not described in the development protocol:

Video-recorded osteoporosis consultations

In this observational study (secondary analysis) of video-recorded consultations, we explored how beliefs about osteoporosis and osteoporosis medicines are currently elicited and addressed by GPs, using a bespoke coding tool [38].

Exploring how COVID-19 impacted the clinical context: e-survey of FLS usual care and secondary analysis of qualitative data

The iFraP DST was originally conceptualized for use in face-to-face appointments. The COVID-19 pandemic accelerated widespread adoption of remote consultations. We conducted a:

i) usual care e-survey of UK FLS practice to quantify the extent of remote consulting and reassess how the iFraP intervention would function and interact with the changing FLS context [19];
ii) secondary analysis of focus group and interview data to explore the acceptability of, and preferences for, remote consulting [39], using the TFA as a deductive framework [37].

Step 3: 'how do we get there'—develop a strategy to change behaviours, by designing and refining the prototype into a draft intervention and feasibility testing

Integration of findings

Findings of the development studies were summarized using joint displays which were interrogated to identify meta-inferences (see Table 1).

The qualitative findings [21] were used to identify a series of intervention design implication statements and questions, which were discussed within the team and the CoP.

An integration framework was developed, which brought together the underpinning theories and frameworks, the evidence gathered, universal precautions for health literacy, and public contributor and CoP discussions. This outlined the stages of the consultation and how either the DST or training would meet the needs identified.

Intervention design—DST

We employed an 'informed' design mode to make decisions about the prototype iFraP intervention design [40]. This means that we used CoP and public contributor input, alongside theory and evidence, as a conceptual framework to draft a storyboard outlining the DST's key functions, structure, content, visuals and navigation (see Supplementary Fig. S1).

Clinical drug recommendations and the benefits and risks of each osteoporosis medicine were underpinned by the best available scientific evidence and national clinical guidelines [5, 6].

Before formal feasibility testing, the prototype DST underwent iterative internal testing cycles to identify bugs and review written and visual tool content. Clinicians 'tested' the tool's algorithm using simulated patients. Clinicians and public contributors reviewed and provided feedback on usability, written and visual content.

Intervention design—clinician skills training

The iFraP Enhanced Consultation Skills Training (e-learning and facilitated practice) was developed, integrating SDM theory and evidence alongside evidence-based behaviour change techniques (BCTs) to increase use of SDM consultation skills and the DST.

The barriers and enablers to clinician behaviour change were identified using the TDF, in the qualitative intervention development study [21]. The TDF domains map to the Behaviour Change Wheel. This includes the COM-B model of behaviour change which proposes three components for a given behaviour ('B') to occur: capacity (C), opportunity (O) and motivation (M) [41]. Understanding whether the barriers to behaviour change are underpinned by 'capacity', 'opportunity' or 'motivation' guides the selection and incorporation of evidence-based strategies to facilitate behaviour change (known as 'intervention functions'), specific BCTs and the mode of delivery [41].

The APEASE (Acceptability, Practicality, Effectiveness, Affordability, Side-effects/safety, and Equity) criteria [41] helped the training development team (Z.P., L.B., J.F., S.H. R., J.P.) decide which of the appropriate BCTs should be integrated into the enhanced Consultation Skills Training Course, considering the affordability, practicability, (cost-)effectiveness, acceptability, safety and equity of the technique, in collaboration with the wider study team.

Intervention feasibility testing and refinement

Real-world testing of the prototype intervention was completed at one FLS site in England (UK), covering a population of 500 000, selected for convenience as closest to the research institution. Consenting FLS clinicians completed the Consultation Skills Training Course and completed three cycles of prototype testing with consenting FLS patients, with a recent fragility fracture. Consultations were observed by a researcher and audio-recorded to explore intervention fidelity, using a pre-defined fidelity checklist.

Interviews were completed with each patient immediately after their consultation ($n = 10$, median duration 22 min). After each cycle of testing, the FLS clinician(s) delivering the consultation was interviewed (four clinicians participated in seven interviews). Interviews were informed by topic guides, consultation observations and fidelity checklist findings. Interviews were transcribed, and data were inductively coded, using a framework approach [35] by three qualitative researchers (L.B., N.T., Maddy Thompson), and then mapped to the TFA domains. Findings were discussed with the CoP to identify any required intervention refinements. More details of the feasibility testing procedures and methods are detailed in Supplementary Data S1.

Documenting the intervention

The intervention manual is integrated, in an interactive format, as part of the enhanced Consultation Skills Training Course with content detailing:

Table 1. Joint display of key findings from iFraP development studies

Meta-inferences: key needs to address in the iFraP intervention	Development study (Steps 1 and 2) key findings					
	Evidence synthesis of existing osteoporosis DSTs [20]	**Evaluating existing patient information [18]**	**Delphi e-survey gaining consensus on intervention content [22]**	**Qualitative study with patients and clinicians [21] (including secondary analysis to explore remote consultation use in COVID-19 [39])**	**Survey of FLS usual care [19]**	**Video recorded osteoporosis consultations [38]**
Patients need an understanding of osteoporosis and/or its consequences, as important perceptual facilitators of adherence	The consequences of fracture are infrequently discussed in DSTs, but DST use can increase accuracy of patient's perceived fracture risk	Existing written information contains inaccuracies, ambiguities and contradictions The consequences of fracture are infrequently discussed	Eliciting patient perceptions before giving information, explaining osteoporosis using the CSM including consequences, and being positive about treatability were rated as essential for consultation content	Patients reported not taking recommended medicines because of lack of understanding of why osteoporosis medicine was needed or what the benefits were, after a FLS appointment		The consequences of fracture are infrequently discussed in consultations. Clinicians infrequently asked patients what they thought about osteoporosis but frequently used persuasion techniques
Patients need information about osteoporosis and its treatment that is easily understandable	Existing DSTs are too complex to understand	Existing written information is too complex to understand and contains predominance of technical language	Health literacy behaviours were rated as essential for consultation content	Existing verbal explanations are perceived as too complex to understand		Osteoporosis is verbally explained in abstract terms including fracture risk and T scores. Clinicians rarely checked patient understanding
Discussions about osteoporosis need to be personalized and person-centred	DSTs are perceived as more useful when contain personalized risk explanations		Emphasized importance of finding what matters to patients and how treatment benefits are relevant to their goals	FLS clinicians are focused on the goal of adherence and reported not considering patient values or expectations		Clinicians rarely personalized explanations
Patients need to have shared and informed decision-making conversations about osteoporosis medicines within consultations	Public contributors preferred that DSTs could be used within consultations		SDM behaviours were rated as essential for consultation content	Patients did not feel prepared for decision-making and reported decisional uncertainty following FLS appointments	Patients may not have opportunities to have SDM conversations with FLS—30% recommend treatment by letter only	Clinicians infrequently ask questions about existing beliefs to support patient participation in consultations
	Use of DSTs has potential to reduce decisional conflict, but DSTs did not meet basic standards and 3/11 did not discuss benefits and risks in equal detail		The need to discuss drug treatment, in face-to-face consultation if possible, rated as essential	Some patients preferred face to face consultations for decision-making Some FLS clinicians did not feel supporting SDM about medicines was part of their role	Consultations are not usually face to face	

(continued)

Table 1. (continued)

Meta-inferences: key needs to address in the iFraP intervention	Development study (Steps 1 and 2) key findings					
	Evidence synthesis of existing osteoporosis DSTs [20]	**Evaluating existing patient information [18]**	**Delphi e-survey gaining consensus on intervention content [22]**	**Qualitative study with patients and clinicians [21] (including secondary analysis to explore remote consultation use in COVID-19 [39])**	**Survey of FLS usual care [19]**	**Video recorded osteoporosis consultations [38]**
Patients need support with decision-making after the (remote) consultation, with consistent information across healthcare and other settings	Public contributors wanted to refer to DSTs both within and after consultations. Use of DSTs has potential to reduce decisional conflict, but DSTs did not meet basic standards and 3/11 did not discuss benefits and risks in equal detail	Existing patient information often does not contain balanced information about risk and benefits	Sending GP a written copy of individualized fracture risk and risks/benefits of treatment rated as essential task	GPs report lack of confidence in talking about osteoporosis medicine and are keen to know exactly what has been discussed in FLS. Patients and clinicians talked about importance of family friends and other health professionals (including dentists) in decision-making process	FLS clinicians may devolve clinical decision-making to GP or make recommendation after the consultation, meaning patient decision-making takes place after the FLS consultation	–
FLS clinicians need support overcoming barriers to implementing shared decision-making and use of DSTs				Clinicians perceive SDM as not appropriate due to lack of choice, and some reported not part of their role Clinicians perceive DSTs will interfere with goals to promote adherence Clinicians perceive DSTs will adversely affect patient relationship or increase time	Most FLS consultations are conducted remotely	Clinicians used persuasive techniques to encourage adherence
FLS clinicians need support with clinical decision-making				FLS clinicians reported clinical decision-making as challenging in some circumstances	FLS clinicians may devolve clinical decision-making to GP or make recommendation after the consultation	

CSM: Common sense model; iFraP: improving uptake of Fracture Prevention treatments; DST: decision support tool; FLS: Fracture Liaison Service; SDM: shared decision-making; GP: general practitioner.

- intervention components and underpinning concepts
- what the intervention is hoping to achieve and why
- how the intervention was developed
- how to use the DST and integrate its use to suit patient needs and various clinical scenarios

Results

Integration of key findings and intervention design

A summary of the meta-inferences or key findings from the development studies are shown in the joint display (Table 1). In brief, these meta-inferences demonstrate key 'needs' for the intervention to address, for patients:

i) understanding of osteoporosis and/or its consequences, as an important perceptual facilitator of adherence
ii) information about osteoporosis and its treatment that is easily understandable
iii) shared and informed decision-making conversations about osteoporosis medicines within consultations
iv) personalized and person-centred consultations
v) support with decision-making after the (remote) consultation, with consistent information across healthcare and other settings

For FLS clinicians, support is needed:

vi) to overcome barriers to implementing SDM and use of DSTs
vii) with clinical decision-making

From the findings, key decisions were made relating to the scope and functionality of the intervention.

- A series of possible options for how the web-based DST could be used flexibly in telephone consults was considered by CoP and public contributors. Public contributors rejected the option to simultaneously view the DST with the clinician whist on the telephone, due to perceived cognitive burden. Instead, they agreed that the DST should be used by the clinician to guide the consultation with the patient receiving a printout (personal 'Bone Health Record') after the consultation.
- Supporting information resources were important to address information needs after the consultation and consistency of messaging across healthcare providers and in other settings. Information resources include the DST printout (personal 'Bone Health Record') and a card to explain osteoporosis medicines to dental care providers.
- Training modules were identified as needed for SDM, health literacy and risk communication skills, but also a module outlining clear unambiguous language to talk about osteoporosis.

Components of the prototype intervention are described in Table 2. Supplementary Table S3 details the relative roles of the DST and the training at different stages of the consultation, mapped to the underpinning theories and frameworks. Table 3 outlines the process of mapping the qualitative findings to the COM-B framework to identify suitable BCTs to include in the iFraP training course, addressing the identified barriers.

Intervention feasibility testing and refinement

Four clinicians working at Midlands Partnership University NHS Foundation Trust completed the Enhanced Consultation Skills Training and delivered iFraP consultations (eight face-to-face, two remote) with 10 consenting FLS patients. Further details about participants are provided in Supplementary Data S1.

Overall, patients and FLS clinicians found the prototype iFraP intervention to be acceptable and feasible. This was particularly evident through FLS clinicians' and patients' expressed wishes for iFraP to be used in future FLS appointments. Quotes, mapped to each TFA domain, as well as example updates made to the iFraP intervention, are presented in Table 4, with brief descriptions below.

Affective attitudes

Patients and FLS clinicians liked the prototype iFraP DST, suggesting that the DST improved the quality of the consultation.

Intervention coherence

Patients had a clear understanding of the purpose of the iFraP DST, reflecting that similar tools should be used in other clinical scenarios to facilitate shared discussions. The iFraP training helped clinicians make sense of how the DST could facilitate their goals, although one instance where the clinical recommendation did not align with local protocols was described.

Perceived effectiveness

iFraP was perceived as effective in achieving SDM by eliciting and addressing patient beliefs about osteoporosis and medicines, increasing patient involvement, and providing patients with sufficient and accessible information. However, FLS clinicians perceived that relaying information about the effectiveness of medicines and chance of side effects included in the DST may be a threat to adherence.

Burden and opportunity costs

FLS clinicians identified work (burden) required to implement iFraP, suggesting implementation could extend the consultation length. Varying perspectives were expressed as to whether the DST eased or caused additional cognitive burden for patients.

Ethicality

Some FLS clinicians considered how some patient groups may have difficulty engaging with the DST, including those with sensory impairments.

Self-efficacy

Patients and FLS clinicians agreed that the DST increased confidence in the FLS's recommendations. The training, including opportunities to observe, and time to practice using the DST was valued as increasing confidence and meaning the clinicians could use the DST in more flexible ways.

Discussion

The iFraP intervention was developed through a rigorous, iterative and systematic approach, integrating existing evidence, frameworks and theories with primary data collection. Regular collaboration with stakeholders, expert advisors and

Table 2. Final prototype iFraP intervention described using the TIDieR guidance

Intervention components	Description
The iFraP DST	The iFraP DST, developed to be used on the computer during UK FLS consultations, includes two distinct but connected components: 1. Clinical decision-making support: the FLS clinician enters key patient characteristics into the first part of the DST to receive evidence-based treatment recommendations in line with clinical guidelines (NOGG or SIGN, as selected by the clinician). The FLS clinician then selects which treatment(s) they wish to discuss with the patient, including: 'oral bisphosphonates', 'zoledronate', 'romosozumab', 'teriparatide', 'denosumab' or 'no treatment', as appropriate 2. Patient-facing decision aid: used by the patient and clinician together to navigate discussion about: why bone health is important; the patient's bone health (including their t-score, fracture risk score, as appropriate/available); and ways to improve bone health, including lifestyle and drug treatment recommendations. At the end of the DST, the patient and clinician complete a series of questions (to elicit patient perceptions and input personalized information about the medicine recommended, supplements, and follow-up, where appropriate). Responses to the questions populate the PDF 'personalized Bone Health Record', described below in 'information resources'
Enhanced Consultation Skills Training Course	The training course is designed to be completed by FLS clinicians, incorporating evidence and theory on SDM and behaviour change techniques. The training includes two complementary components: 1. A 4-h interactive eLearning package including expert video presentations and example videos of 'model' consultations, with modules introducing and guiding implementation of the iFraP DST in-practice, risk communication techniques, SDM skills, universal precautions for health literacy and talking about osteoporosis. At the end of the eLearning course, FLS clinicians are advised to practice using the iFraP DST in-preparation for their role play session (see below) 2. One 3-h role play session, attended by a group of FLS colleagues. The session is facilitated by experts in osteoporosis, SDM and consultation communication skills. Each FLS clinician role plays with their paired colleague as the (a) clinician using the iFraP DST and implementing eLearning SDM skills (b) and patient engaging with the iFraP DST. Facilitators provided individualized feedback, informed by SDM theory and evidence (e.g. the SPIKES model and universal precautions for health literacy)
Information resources	Information resources (paper and online) for the patient and GP to refer to after the FLS consultation, to facilitate ongoing conversations. This includes: 1. 'Personal Bone Health Record': an individualized A4 PDF output from the iFraP DST. The Bone Health Record includes answers to questions the patient and clinician complete together. A copy of the personal Bone Health Record is given to the patient (if consulting in-person) or sent by post/e-mail (if consulting remotely). The personalized Bone Health Record can also be added to the patient's medical record and sent to their GP alongside, or instead of, usual communications. The personal Bone Health Record includes a URL/QR code directing the patient to more information online, including a video of the iFraP DST being demonstrated and explained 2. Dentist card: the patient can show to their dentist to support conversations about osteoporosis medicine

CSM: Common sense model; iFraP: improving uptake of Fracture Prevention treatments; DST: decision support tool; GP: general practitioner; FLS: Fracture Liaison Service; NOGG: National Osteoporosis Guideline Group; TIDieR: Template for Intervention Description and Replication; SDM: shared decision-making; SIGN: Scottish Intercollegiate Guidelines Network.

public contributors ensured that intervention development centred on those who will deliver, use and benefit from it. Overall, the prototype iFraP intervention was perceived as acceptable and feasible to deliver in FLS, with potential to support SDM conversations about osteoporosis and medicines.

A range of interventions have been investigated to improve adherence in osteoporosis, including pharmacist-led counselling, reminder devices and educational materials; however, those which include strategies to enhance patient-provider communication and elicit and address patient perceptions appear to be most effective [42, 43]. Medicine adherence is optimized if a person believes it is necessary, relevant, safe and practicable [44]. Concerns about side effects have been blamed for poor uptake of osteoporosis medicines, but together these iFraP studies show that patients are often unclear about the 'need' for osteoporosis medicines, particularly because osteoporosis itself is asymptomatic and misunderstood [27], contributing to difficulties making decisions about medicines [21].

Decision aids and DSTs have often been described as 'requiring minimal training for use'. Consequently, few evaluations of DSTs have provided users with training to support implementation. In this development work, we identified the importance of complementary clinical and SDM training to overcome evidenced barriers to DST use [45]. At present, evidence demonstrating the potential for DSTs to improve medicine adherence outcomes is limited [10]. The feasibility study showed promise that the DST could support patient decision-making and uptake of medicines, underpinned by well-evidenced theories of medicine adherence [28, 44]. Finally, our evidence synthesis of existing osteoporosis DSTs indicated that they were not 'fit for purpose' and rarely involved public contributors in their development [20]. The iFraP study integrated extensive public contribution throughout all aspects of development and testing, ensuring that it was understandable and relevant, and addressed their needs. Challenges included providing sufficient, accessible communications to PPI members, maintaining engagement through COVID-19, and collecting and acting on feedback about PPI activities.

A key principle of intervention development is adapting to changing contextual factors to maximize intervention implementation in the real-world [17]. Intervention development required a flexible approach to continually evaluate uncertainties arising from the pandemic and other contextual changes, e.g. the move to remote consulting and introduction of new osteoporosis medicines into UK clinical practice [46]. In line with intervention development guidance [15], we

Table 3. Use of the COM-B model to identify behaviour change techniques, mapped to the TDF domain

Example finding mapped to TDF domain	Action statement: what do we need to do to address this?	Appropriate intervention function: what behaviour change techniques (BCT v1) could be incorporated?	Example of incorporation of BCT in iFraP: how was each BCT incorporated into the iFraP Enhanced Consultation Skills Training Course?
Knowledge and interpersonal and cognitive skills			
FLS clinicians voiced challenges when trying to explain the risks and benefits of osteoporosis medicines, with knowledge gaps between relative and absolute risks	Support FLS clinicians to communicate accurate risks in a way that's understandable for patients	Psychological capability: training	A 'risk communication' eLearning module detailing the difference between 'absolute' and 'relative' risks, simple frequencies, positive and negative framing
Physical skills			
FLS clinicians wished for guidance on how to implement a DST in the FLS consultation to facilitate SDM	Demonstrate flexible use of the DST based consultation type (face to face, telephone, video)	Physical capability: demonstration of the behaviour	Video incorporated into the eLearning package to show the prototype DST being used in an FLS consultation
Memory, attention and decisional processes			
FLS clinicians described uncertainty when deciding if some patients should be recommended osteoporosis medicines	Allow DST to be flexible in function to adapt to decisional uncertainties and local protocols. Ensure that clinicians are aware of the clinical guideline treatment algorithms used for DST logic	Psychological capability: education	A summary of the algorithms used for DST (to provide a treatment recommendation based on NOGG/SIGN) provided in the eLearning to increase confidence and credibility
Environmental context and resources			
FLS clinicians were concerned that use of the DST would extend the length of the FLS consultation	Support use of the DST, to be used in a flexible way, to fit a variety of FLS models of care (including length of appointments)	Physical capability: behavioural practice and feedback	Role play exercises for the FLS clinician to practice using the DST in different scenarios, with opportunities to receive feedback from expert trainers
Social/professional role and identity			
FLS clinicians did not consider the patient to have a 'choice' in the recommended medicine	Support FLS clinicians to see the value in discussing 'choice' with patients—including the choice to accept or not accept the recommended medicine	Reflective motivation: credible source	Provide clinicians with credible evidence (e.g. patient quotes, experts in adherence) in the eLearning to highlight the importance of SDM
Beliefs about consequences			
FLS clinicians thought that use of a DST might mean that important information about the patient to form a management plan would not be obtained	Highlight that use of a DST need not impede effective information gathering and may enhance (rather than impede) patient involvement in the consultation	Reflective motivation: credible source	Provide clinicians with credible evidence (e.g. patient quotes, relevant research) to show that computerized DSTs can increase patient involvement
Beliefs about capabilities			
FLS clinicians questioned their capability to implement a DST into their way of collecting and delivering information in consultations	Support clinicians to feel capable to implement the DST into their workflow	Education: feedback on behaviour	Opportunity to receive feedback from clinical colleagues when practising using the DST in the training role play session
Intentions			
Some FLS clinicians considered the DST to add limited value to their existing high-quality service	Increase FLS intentions to use DST by challenging the perception that 'this is something that they already do'	Reflective motivation: education	Provide education about SDM, health literacy techniques (e.g. TeachBack, chunk and check), and risk communication and how they can be implemented, as part of an FLS consultation to challenge assumptions that SDM 'is being done'

(continued)

Table 3. (continued)

Example finding mapped to TDF domain	Action statement: what do we need to do to address this?	Appropriate intervention function: what behaviour change techniques (BCT v1) could be incorporated?	Example of incorporation of BCT in iFraP: how was each BCT incorporated into the iFraP Enhanced Consultation Skills Training Course?
Goals			
FLS goal was to increase medicine adherence. Some considered SDM (increasing patient autonomy to refuse medicines) to be a threat to their goal	Highlight how SDM and adherence align. Working together with the patient to ensure that the osteoporosis medicine is a right 'fit', based on their values, beliefs and preferences, has potential to increase patient medicine commitment	Reflective motivation: information on health consequences and credible sources	eLearning to align FLS and iFraP goals by providing FLS clinicians with credible evidence that shows the benefits of SDM to increase patient commitment to osteoporosis medicines
Emotion			
FLS clinicians thought that the DST's presentation of osteoporosis consequences (e.g. vertebral fracture) may cause patients to be fearful, shocked or upset	Support FLS clinicians to discuss potential consequences of osteoporosis, with positive messaging around prevention	Automatic motivation: credible source	Provide credible evidence in the eLearning to highlight the importance of addressing patient necessity beliefs (beliefs about the 'need' for treatment) using personalized and positive messaging (e.g. expert testimonial from Professor of Behavioural Medicine and patient experiences)

The TDF domain 'reinforcement' did not reveal any barriers to delivering SDM. TDF: Theoretical Domains Framework; DST: decision support tool; BCT: behaviour change techniques; iFraP, improving uptake of Fracture Prevention treatments; FLS: Fracture Liaison Service; NOGG: National Osteoporosis Guideline Group; SDM: shared decision-making; SIGN: Scottish Intercollegiate Guidelines Network.

Table 4. Intervention feasibility testing findings, mapped the TFA domains

TFA domain	Example quotes	Narrative interpretation	Example updates to the prototype iFraP intervention
Opportunity costs: the extent to which benefits, profits, or values must be given up to engage with, or deliver, the iFraP intervention	Alignment of SDM and adherence goals	Alignment of SDM and adherence goals	
	'I find it awkward when I read side effects. You've sort of sold this idea of having this treatment because you want to prevent it and then you sort of say, 'Now I'll tell you about the side effects' and kind of like putting them off it aren't you?' FLS02	Medicine initiation and persistence are a Key Performance Indicators of FLS. Some FLS clinicians were concerned that elements of the iFraP DST would lead to a patient deciding not to start or continue taking an osteoporosis medicine. Engaging with the DST (and increasing patient autonomy to refuse medicines) may not align with the FLS's goal	
	'We did the online training that research has shown that it's quite important to find out what's important to the patient and why it's important to the patient to give help with them accepting the drug and staying on it. (…) the training did teach me it's a shared agreement and if they don't want treatment then, for me as a health professional, as long as I've provided them with a balanced view, it's up to them what their decision is' FLS01	In contrast, one clinician reflected on the iFraP training, describing how shared decision-making and medicine adherence can be bedfellows	
Affective attitude: how patients and FLS clinicians feel about the iFraP intervention	'I thought it was fantastic (…) as well as looking at the screen she was explaining everything to you' (P07)	Overall, patients and FLS clinicians liked the prototype iFraP DST, suggesting that the DST improved the quality of the consultation	
	'You can actually see the diagrams, and like it's on the screen, somebody's like selecting it (…) it's an opportunity [to say] 'oh, can you just show me what this can cause if I did do this'. And as I say, that is just a brilliant idea being able to see it there' P09		
	'I think it's all useful and relevant, I think it's something I really will use time and time again. Definitely' FLS04		
	'I don't think for one second it isn't a really valid good consultation and an improvement on probably what's happening in fracture liaison services at the moment' FLS01		
	'I feel like my consultations are better with it than they were without it and I do use it all the time (…) the bone health record I'm a massive fan of' FLS02		
Burden: the perceived and experienced effort required to engage with, and deliver, the iFraP intervention	**Cognitive burden**	Most patients described the content and structure of the iFraP DST as reducing cognitive burden	FLS clinicians recommended altering the order of two components of the DST, allowing them to explain osteoporosis, before jumping into the patient's

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Table 4. (continued)

TFA domain	Example quotes	Narrative interpretation	Example updates to the prototype iFraP intervention
			results. This change was implemented to better align with the existing FLS workflow
	'It's information overload isn't it? You might be telling them why it's important, but they haven't had time to digest have they or think about why they're taking it and stuff. So it's just a bit soon to ask them' FLS02	On the other hand, some patients and FLS clinicians thought that using the DST might cause cognitive burden for patients by providing too much information that they require more time to digest before making a decision about medicines	
	'I'm more thinking, "I'll probably do it but I couldn't 100% say because I need to go away and inwardly digest it." Everything tells me that I should be taking it. I think when you reflect back to the very first slide with the T-score, I could see that I was the lower end and that made it more sensible to take the medication' P04	FLS clinicians also considered the burden of implementing the iFraP DST in clinical practice. Many reflected on the practise required to integrate iFraP into their existing workflow and time limited FLS appointment. Some did consider how using the iFraP DST did not add pressures, and, in fact, the Bone Health Record posed opportunities to reduce work, by addressing current gaps in service provision	
	'It's simple. You're not bombarding somebody with something that they won't understand. Very easy to understand' P09		
	Work required to deliver iFraP in-clinic		
	'I think it was a little bit tricky to start with because its, you know, different to what we are used to. But again, I think it's something you just get used to. It did work, it worked for that patient, and she was, you know quite a challenging patient, it worked quite nicely, I thought, you know. So, it's just getting used to it' FLS04		
	'There was nobody more skeptical about it at the beginning than me, I was thinking oh God here we go, another just extra work (…) I was really surprised at the timescale, I really thought that it would really add on to the clinic and put pressure on me. When I found out the timescale, it wasn't really that much more and then in fact I think maybe it could really help a clinic run faster and more smoothly' FLS03		
	Opportunity for iFraP to address service needs		
	'There was some talk about us doing a report for the GPs and a report for the patient, so it's two reports. We haven't got time for that. So without too much work it addresses that. (…) I think the bone health assessment addresses the fact that we are sending the patient a		

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Table 4. (continued)

TFA domain	Example quotes	Narrative interpretation	Example updates to the prototype iFraP intervention
	report on what their bone density results are. To me it's perfect in a very patient-friendly way (…) I just feel it addresses that gap that for our service we've been looking for and we haven't been able to decide or to think what we could do and I feel that addresses it' FLS02		
Ethicality: the extent to which the iFraP intervention has a good fit with the individual's value system	**Opportunity to be used with all patients**	Patients and FLS clinicians reflected that all patients should be given the opportunity to engage with the iFraP DST. One FLS clinician recommended that even patients who don't receive a drug recommendation should be given the opportunity to receive a personalized Bone Health Record (produced by the DST)	DST updated to include the option of 'no treatment', allowing the clinician to override the clinical recommendation produced by the DST algorithm. This allowed the Bone Health Record to be produced for people recommended 'no treatment' including scan results, lifestyle recommendations, and signposting
	'Ideally, everyone should get it, shouldn't they? I think it's a better practice. I'm not putting anybody else down but it's showing better care to people' P04	Some FLS clinicians considered how some patient groups may have difficulty engaging with the DST, including those with sensory impairments	Made DST text more visible, including increasing font size and changing font colours, where possible
	'Yes, I do think it's pretty fair and I do think that it should be made widely available' P01		
	'I think they are very fortunate aren't they to get it? You know it'd be great if all patients did get it and obviously that's the aim. It is unfair isn't it, in a way that some patients don't get it and others do' FLS04		
	'I think there should be an option that they should still have that, even if they don't have drug treatments, because you're still recommending things even though you're not recommending a treatment, you could be recommending lifestyle modifications, or you could be recommending that they up the calcium or … ' FLS02		
	Not appropriate for some groups		
	'It depends how old your patient is as well. My patients can be elderly, so they're not really bothered about their bone health. All they want to do is give them a tablet and they'll quite happily go off and take it. Some people aren't. Some people are very engaged' FLS02		
Intervention coherence: the extent to which the patient and FLS clinician understands the iFraP intervention and how it works	**Making sense of iFraP in FLS**	**Making sense of iFraP in FLS**	Guidance to DST users that clinical judgement should prevail and it's possible to override recommendations produced by the DST to abide to local protocols
	'He asked me questions and then supported it with things on the computer. It just felt more balanced and also there were no issues with answering questions	Patients had a clear understanding of the purpose of the iFraP DST, reflecting that similar tools should be used in other	

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Table 4. (continued)

TFA domain	Example quotes	Narrative interpretation	Example updates to the prototype iFraP intervention
	because he answered the questions that I had. It just felt more of a conversation consultation rather than giving information which was quite nice' P02	clinical scenarios to facilitate shared discussions	
	'I think it's good and they should be doing this for quite a few things when you go and see a doctor or something. I think they should be speaking to you and showing you these things and explaining' P01	The iFraP training demonstrated to FLS clinicians the role of shared decision-making in medicine discussions, helping the intervention to make sense. After using the DST in practice, FLS clinicians could see how it aligned with the goals of their service and FLS more broadly	
	'For FLS services it's probably going to be invaluable (…), they're probably going to be very engaged in using it and wanting it' FLS02	**Alignment of iFraP to local protocols**	
	'At first I was a bit skeptical and I thought well there's paper copies we do is pretty perfect and we've been doing that for years and I'm used to it, what's the point if it ain't broken, don't fix it. But I think after all this I think it's really good and I have enjoyed using it and I think it went really well' FLS03	One clinician reflected that the clinical recommendation produced by the iFraP DST did not align with their local protocols	
	Alignment of iFraP to local protocols		
	'Because [the patient was] over 70 and it's based on the new NOGG [National Osteoporosis Guideline Group] it's like she could be treated because she'd had a fracture, but in actual fact we don't do that, it's over 75 (…) I don't agree with the over 70 either, I think that will cause a lot of controversy really' FLS02		
	Use of DST can feel procedural	**DST can feel procedural**	The iFraP eLearning was updated to include more guidance on practising using the DST with patients and observing the DST being used by other clinicians
	'I think it helps to see things visually, doesn't it? Perhaps it might feel a little bit—no, impersonal is the wrong word but they might feel it's a little bit impersonal' P05	The structure provided by the DST was praised by patients and FLS clinicians to reduce patient's cognitive burden (see 'burden') and guide FLS clinician information giving. However, some patients also reflected that the structured nature of the DST could lead to the consult feeling procedural, particularly when the DST was new or unfamiliar to the FLS clinician. FLS clinicians agreed, wanting more opportunities for greater familiarization with the DST	Increasing FLS clinician exposure to the DST was hoped to increase familiarization with the tool's content and function
	'She was focused on, I need to go through this tool and remember how it works. And which bits do I press here and whatever.		

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Table 4. (continued)

TFA domain	Example quotes	Narrative interpretation	Example updates to the prototype iFraP intervention
	(…) for me, it's not that I didn't find it personal, but it was very go through the motions of it' P08		
	'So when I first started using the tool I was a little bit robotic with it' IPT02		
Perceived (and experienced) effectiveness: the extent to which the iFraP intervention was perceived, or experienced to be, likely to achieve its purpose	**Illness beliefs**	Patients and FLS clinicians described how the iFraP DST helped give understandable explanations of bone health and osteoporosis, the consequences of fracture, and the necessity and side effects of medicines, in a way that was personalized to the individual	
	'It's something I'd never even considered; that that's what a bone looked like and that's what happened. You just think it's just something sort of white [laughter] and snaps like that, don't you? You don't think of the structure of a bone and the fact when it becomes osteopenic or osteoporotic, it's actually thinner and then more likely to break. Again, it just makes it more understandable' P04	Most patients and FLS clinicians considered the DST to be effective at increasing patient involvement in the consultation. The structured DST and Personalised Bone Health Record were viewed as having potential to increase consistency of information and support ongoing conversations	
	'It's like seeing the spines there and being able to visualize what your problem is. I think a visualization always helps and it sinks in with what is going on with yourself' P02	Patients and FLS clinicians considered how the iFraP intervention had potential to support patients to make decisions about medicines	
	'when you see pictures like that with people bent over, I think it brings it home to you that you've got a health problem. You've just got to do the best you can for yourself haven't you and live your life as you can like sort of thing' P07		
	Addressing necessity and concerns about medicines		
	'The benefits, I think it again reconnects with the patient and why it's important (…) that's important to them and just finding out any issues that they may have and just hopefully so that they … so that it helps them to stay on the medication and if they've got any problems with it, you know, maybe that they can have alternative treatments so they just don't stop taking it' FLS01		
	'She was worried about osteonecrosis of the jaw and I couldn't remember the exact figures for it off the top of my head. I didn't want to give her any false information so I quickly went through the tool (…) I do feel I'd addressed her concerns and		

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Table 4. (continued)

TFA domain	Example quotes	Narrative interpretation	Example updates to the prototype iFraP intervention
	she was still willing to go ahead' FLS02 'Obviously, there are side effects and I'd heard there was a lot of side effects on these Facebook pages that are supposed to be friendly and supportive. However, when she went through the numbers of how many people did get this and that, I found that was more beneficial and it kind of shot those people on Facebook out of the water that were saying not to take the tablets because of them' P02 'He [FLS clinician] was going through it and being able to select the things that were important to me' P09 **Patient involvement** 'He spoke to me as if like, I was a person. And not just a patient' P09 'It felt more personal, more prompt, more, shall we say, modern and sophisticated' P08 'It involves them, it breaks the ice, you're not going straight into, 'oh you've got osteoporosis, you need this'. It kind of breaks the ice, gets them involved and gives you an idea of how the patient feels' FLS03 'It is more interactive with the patient, they do seem to get more involved with it' FLS01 **Providing understandable and consistent information** 'I think, you know it's quite straight forward and easy for patients to understand' FLS04 'It's all easy to understand. As far as I'm concerned, it's all easy to understand' P04 'The information was consistent. I said to [the patient], 'It's a new thing we're doing' and she said, 'Oh yes, it was really good.' She just emphasized she was really happy with the information and she was happy that the GP had got the same information' FLS02 'Everything went through in stages on it. It wasn't just rushed, it was all the way through, different parts of it. And it kept you interested in what was going on' P07 'Going back to work, for instance (…) my boss was very concerned, so I think this will alleviate her concerns as well because I'll share [the Bone Health Record] with her' P02		

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Table 4. (continued)

TFA domain	Example quotes	Narrative interpretation	Example updates to the prototype iFraP intervention
	'I think it engages the patient to start with, when you say to them, you know 'what do you understand?' (…) I think is really useful because you know quite often they won't be able to recall what you've said and then it just gives you that chance just to go over it again. so, I think that has worked well actually' FLS04		
	Decision-making about medicines		
	'To see those three percentage points which is actually, you can improve by virtually a third, it puts it into perspective to say, yes, it is worth looking at here' P08		
	'Everything tells me that I should be taking it. I think when you reflect back to the very first slide with the T-score, I could see that I was the lower end and that made it more sensible to take the medication. You go from the first slide to the last slide and it does make it a little bit more understandable as to why you should take it because you're that low in the score' P04		
	'By showing [the patient] the [iFraP DST] pictures and asking them extra questions, "how do you feel … " and involving her, I think that in my opinion swayed the patient to go on treatment. I think if it had just been a paper copy I think I'd have been struggling' FLS03		
	Use of iFraP in telephone consults		
	'It's a visual aid for your patients and that isn't going to be the case with the telephone consultation. So I was apprehensive about using it, very skeptical that it would work. But I was very pleasantly surprised actually. It was very helpful as more of probably a prompt to direct your consultation probably better than it would've been before' FLS02		
	'It depends how well she explains it because I can't see it, and she can't point 'it's this' or 'it's that'. If she says a particular type of part of the body or the actual bone density or anything, without seeing that picture how would I know?' P02		
	'Personally, no, because I'm not particularly computer literate [laughter]. I'm sure there are a lot of people who would find it difficult during a telephone consultation' P05		

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Table 4. (continued)

TFA domain	Example quotes	Narrative interpretation	Example updates to the prototype iFraP intervention
Self-efficacy: the patient's and FLS clinician's confidence that they can engage with, and deliver, the iFraP intervention	**Confidence delivering iFraP**	FLS clinicians overall reported feeling confident delivering the iFraP DST after completing the training skills course	Additional videos were integrated into the eLearning. These videos demonstrated use of the DST and training skills in patient-clinician consultation scenarios, including:
	'I would be comfortable doing it as our standard way of doing our assessments' FLS01	Some clinicians reflected that additional training would be valued to increase confidence delivering the DST in different scenarios (e.g. patients who do not want to take the medicine, telephone consultations)	(i) Patients not recommended medicine
	'I felt confident because I'm experienced, I've been doing it 20 years. If you're going to catch me out on a question you know good luck to you. I felt confident using [the DST], everything on there I knew and I could use it and I could flirt around the screen' FLS03	Patients and FLS clinicians agreed that the DST increased confidence in the FLS's recommendations	(ii) Telephone appointments
	'Quite confident really, it is quite straight forward. The little tabs on the side are nice and easy to navigate. I had a little practise beforehand' FLS04		(iii) Comparing two medicine options
	'But saying that I don't know I'd react to a patient that said, oh no I don't want to take it and had a really low score where you go from there (…) the clinician needs maybe, I would like a little bit of training on what to do if the patient's if'ing and ah'ing or definitely doesn't want to take it and who does need it' FLS03		(iv) Patient not keen on taking a medicine
	'Maybe just the more you do it the less awkward you feel. As you settle into it you'll probably find your own little way of explaining it don't you, like anything, when anything's new' FLS02		(v) Referral to discuss intravenous medicines
	'I recall having a lady last week who I was trying to use this format of the consultation and she started talking about how her fractures come from physical abuse from her husband and it's difficult because (…) I'm not trained really in and things that they may bring up around worry' FLS01		(vi) Patient is already taking an osteoporosis medicine
	'More videos of different scenarios, that would have been useful. That's it really, I think it was good' FLS04		The structure of the role play session was revised to allow clinicians increased allotted time to practise using the DST and communication skills with their colleagues and receiving feedback
	iFraP increased confidence in FLS messaging		Additional signposting added to the 'getting support' component of the DST, including a national domestic abuse helpline. These additions were also incorporated into the Bone Health Record

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Table 4. (continued)

TFA domain	Example quotes	Narrative interpretation	Example updates to the prototype iFraP intervention
	'I think it's a good idea because they can see the information you're using and how they reach the points about yourself and your scores (…) I think seeing it for itself, people might just think, "Yeah, maybe they are useful. Maybe they do know what they're talking about"' P02 'He asked me questions and then supported it with things on the computer' P04 'It wasn't just me talking it's there on the screen and it's like there's two of you here, if you don't believe me the computer doesn't lie kind of thing yeah, it's there in black and white on the computer. It isn't me just making it up' FLS03 'I think it probably helps just to reinforce that you know the treatment is necessary and that we've got the research and the tools behind that to back that up' FLS01		

TFA: Theoretical Framework of Acceptability; iFraP, improving uptake of Fracture Prevention treatments; DST: decision support tool; FLS: Fracture Liaison Service.

sequentially separated 'development' and 'feasibility testing' in two distinct stages. However, these stages were iterative and cyclical, allowing for continued refinement of the intervention to optimize relevance, acceptability and implementation.

Limitations

The iFraP intervention was designed for use in UK FLS. Feasibility testing however was only conducted at one secondary care FLS site in England. Involvement of expert clinical advisors meant the intervention is also designed for use in Scotland where different clinical guidelines are used. However, we cannot assume transferability of the feasibility findings beyond England or of the DST to FLS operating outside of the UK (where treatment guidelines may differ) or different practice settings (such as primary care). Further consideration would be required to determine how the intervention requires adaptation for use in non-FLS and non-UK contexts; we have begun this process to adapt the resources for UK primary care use.

The FLS clinicians who participated in the feasibility study also participated in the focus groups [21]. This approach may have limited our understanding of varied FLS models of care and how the intervention might require adaptation to be implemented.

Impact and future research

The iFraP development studies have already achieved impact. Our recommendations to improve the readability and quality of patient information about osteoporosis [18] led to national providers updating their information. Additionally, iFraP outputs are being incorporated into the ROS FLS implementation toolkit and findings have influenced updates to ROS Clinical Standards for FLS.

Our development work demonstrated while bone density scans are an essential component of FLS, where appropriate [22], information about bone density scans is often confusing [18]. These findings led to further research funding to explore how to optimize patient and clinician understanding of bone density scan results [47].

The iFraP intervention is being tested in a pragmatic, parallel-group, individual RCT in four FLS sites in England (trial registration, ISRCTN55504164) [48], with nested mixed-methods process [49] and economic evaluations [50] to further test effectiveness, cost-effectiveness, acceptability and implementation.

Conclusion

We developed the iFraP intervention underpinned by evidence, theory and extensive contribution from clinicians and public members. Feasibility testing demonstrated that the intervention appears to be acceptable and feasible to use in UK FLS, with potential to improve patient outcomes. The iFraP RCT and nested economic and process evaluations will further evaluate implementation and effectiveness.

Supplementary material

Supplementary material is available at *Rheumatology* online.

Data availability

No new data were created or analysed for this manuscript. Data sharing is not applicable to this article. Data sharing statements for contributory studies cited, are available on request from corresponding author.

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