Introduction

Osteoporosis is a systemic skeletal condition defined by low bone mass and structural decline in bone microarchitecture with an increase in bone fragility and risk of fracture in response to minor stress or trauma. Vertebral fragility fractures (VFF) cause height loss, changes in spinal alignment and body shape, and are associated with back pain, functional disability, low mood, and decreased quality of life [1-3]. Furthermore, VFF elevate the risk of sustaining future fragility fractures and increase the risk of mortality [4]. The incidence and burden of VFF is increasing year over year, and in England alone, an estimated 30,000 patients are admitted to hospitals with VFF each year [5, 6].

Guidelines recommend that people with osteoporosis exercise and keep active to slow the rate of bone loss, to maintain muscle strength, balance, and postural alignment, and to improve physical function and prevent falls [7-9]. Exercise programmes that combine resistance strengthening exercises with posture and balance training and weight-bearing (including low-impact) exercise are recommended for people with VFF [7-9]. Multiple randomised controlled trials (RCTs) have investigated the efficacy of exercise treatments for people with VFFs and report varied benefits to pain, strength, spinal posture, balance, fear of falling, mobility and health related quality of life (HRQoL) [10-12]. A Cochrane systematic review from 2019 concluded there is moderate-quality evidence that exercise improves physical function [13]; however, treatment effects are often small-to-moderate in size and difficult to sustain [10, 11].

Adherence, or the extent to which patients carry out or comply with physiotherapy exercises and self-management advice, has been identified as an issue in many studies [14-

16]. Adherence to clinic-based exercise treatments is estimated to be around 50% and even lower for unsupervised home exercise [14-17]. Partial or non-adherence is associated with worse outcomes, and conversely, higher adherence associated with better outcomes [10, 11, 18]. Adherence is a critical consideration because it affects exercise dose and achieving sufficient exercise is needed to improve bone health and muscle strength. Studies monitoring adherence have shown compliance declines after supervised interventions cease [11, 19]. The trial protocol for the OsteoPorosis Tailored exercise adherence INtervention (OPTIN) trial was published outlining the plan to investigate whether providing integrated support for exercise adherence could increase the efficacy of exercise rehabilitation and improve outcomes for people with VFF, [20]. In this paper we aim to describe the process of developing the OPTIN intervention and to report the intervention in sufficient detail to allow for replication.

Method

OPTIN trial overview

The OPTIN trial is a two-arm, parallel group, RCT with blinded assessments that was set up to test if a package of outpatient physiotherapy exercise rehabilitation with integrated support for exercise adherence had better clinical outcomes for patients compared to physiotherapy exercise rehabilitation alone. Participants were adults aged 55 years or older with at least one VFF and persistent back pain. A full description of the OPTIN trial can be found in the protocol publication [20].

Development of the OPTIN trial intervention

Our paper follows the Medical Research Council guidelines for complex interventions [21], and it is reported in accordance with the Template for Intervention Description and Replication (TIDieR) checklist [22], the Consensus on Exercise Reporting Template (CERT) [23] and Workgroup for Intervention Development and Evaluation Research (WIDER) recommendations for behaviour change interventions [24]. The team developing the intervention included: research physiotherapists with expertise in osteoporosis who had conducted the Physiotherapy Rehabilitation for Osteoporotic VErtebral fracture (PROVE) RCT (n=613), a research physiotherapist with specific interest in physiotherapist-led behaviour change interventions for people with musculoskeletal conditions, clinical experts including physiotherapists, occupational therapists and consultant rheumatologist, an academic health psychologist and NHS physiotherapy service manager, together with people with osteoporosis and other long term musculoskeletal conditions who had received outpatient physiotherapy (Patient and Public Involvement and Engagement: PPIE group) [10, 19].

The development process occurred in broad phases. The early phase included primary research, reference to guidelines and existing evidence, and PPIE, which were focused on three strands: behaviour change, vertebral fragility fracture, and stakeholder views. These three strands led into the intermediate phase containing the initial development of the intervention and a workshop. In the late phase, we refined the intervention with additional PPIE input, re-tested it, and finally, produced our OPTIN adherence intervention. See Figure 1.

Early phase intervention development

In preparation, we conducted a systematic search of the literature regarding evidence about barriers and enablers affecting adherence for older people with osteoporosis and musculoskeletal conditions (such as back pain) and also completed a systematic review of behaviour change interventions used to improve exercise adherence in older people, updating a review previously published [25]. Existing clinical guidelines about the management of vertebral fragility fracture were reviewed, together with those pertaining to exercise adherence [8, 26-28]. Additionally, we searched the evidence, and examined published educational materials and fact sheets for older people related to safe exercise and fall prevention, exercise and bone health [7, 29, 30].

The adherence intervention was developed using the six iterative steps of the Intervention Mapping approach [31], and it is underpinned theoretically by the COM-B behaviour change model, which posits that for any Behaviour (B) to occur the person needs Capability (C), Opportunity (O) and Motivation (M) [32]. Capability may be a person's psychological or physical abilities, opportunity may be physical or social environmental external factors, motivation refers to the internal factors that drive behaviour such as attitudes or values [32].

It built upon a study that investigated the feasibility of using a physiotherapist-led exercise adherence intervention for older patients referred to outpatient physiotherapy for varied musculoskeletal conditions [19]. This feasibility study included a PPIE group that developed and reviewed this intervention [19]. It also drew upon participant views from two qualitative studies, one exploring the views and experiences of participants in the PROVE trial of physiotherapy rehabilitation [33], another of outpatient physiotherapists in the feasibility

97 study of delivering behaviour change interventions to support exercise adherence [34].

98

99 *Intermediate phase intervention development*

100 We mapped numerous factors thought to impact exercise adherence in older people with
101 long term musculoskeletal conditions including; uncertainty about possible benefits, low
102 motivation, depression, insufficient exercise knowledge or skill, physical ability level, co-
103 morbidities, negative views about treatment (such as fear of pain or discomfort), socio-
104 economic status, environmental considerations (time, caring constraints, etc.) and exercise
105 programme design (number of exercises, format etc.) [25, 35, 36]. In addition, for people
106 with osteoporosis we identified the following issues to address fear of falling, fear of further
107 fractures due to exercise, and lack of knowledge and uncertainty about the benefits of
108 exercise for bone health. Considering this complexity, we hypothesized that interventions
109 to support people to follow prescribed exercises must recognise an individual's personal
110 barriers and facilitators (preferences, goals etc.) to exercise [37] and draw from a repertoire
111 of *multiple* adherence approaches to select ones tailored to the individual [38].

112

113 Pulling together the different strands of evidence, an initial version of the OPTIN adherence
114 intervention was drafted. In March 2021, we held an intervention development workshop
115 attended by research staff, service managers, clinical physiotherapists, and occupational
116 therapists with experience of treating people with VFF. Workshop delegates reviewed and
117 discussed the proposed intervention to support exercise adherence, how the adherence
118 intervention was integrated with the exercise programme, and participant materials.
119 Delegates were asked to comment and provide input into the final selection and design of
120 adherence tools, remarking specifically about the practicality of using them within an NHS

setting and with a heterogeneous group of patients with VFF, in terms of age, fragility, and confidence in using technology. They were asked to consider the training needed for physiotherapists to deliver the intervention.

Late phase intervention Development

Feedback from the workshop was used to refine the OPTIN adherence intervention, physiotherapist, and patient materials to produce an initial OPTIN Intervention Toolkit containing patient facing materials, and an accompanying manual and training package for treating physiotherapists. For example, we developed a *Decision Aid* to help physiotherapists in clinic streamline the decision-making process for selecting a behaviour change approach tailored to the patient and included this within the Toolkit (Figure 2). Furthermore, to better reflect clinical practice, the intervention was developed so it could be delivered over 16 weeks and with either the patient attending face-to-face, or remotely over NHS video-call or by telephone. To support this both printed and electronic materials, including short videos were produced.

Separately, we individually consulted people with lived experience of osteoporosis and VFF connected with our hospital PPIE network and/or the Royal Osteoporosis Society patient charity. In response we adjusted the intervention materials such as the wording and format of fact sheets, the design of the templates for facilitating the delivery of behaviour change approaches and included a folder for patients to hold printed materials and exercises in one place. Lastly, the OPTIN Intervention Toolkit and Manual were circulated for any final review and refinement from workshop delegates and tested for delivery in an outpatient physiotherapy clinic with patient and physiotherapist feedback.

OPTIN adherence intervention

The OPTIN adherence invention is designed to be deliverable by registered physiotherapists working with patients with musculoskeletal conditions but without additional post-graduate training in using psychologically informed approaches to patient care. At the start physiotherapists delivering the OPTIN adherence intervention attend a half-day training session, supported by a training manual (digital and printed versions) and access to a study website including training materials and short video recordings demonstrating a physiotherapist using the behaviour change approaches. Training covers the COM-B theoretical framework, and the background to motivational interviewing and how to use motivational interviewing as a communication approach [39]. Training also emphasises the importance of the therapeutic alliance [35]. That is building a positive working relationship between patient and therapist to support behaviour change, encourage collaborative choice of behaviour change techniques, and to plan and review exercise behaviour [40]. Physiotherapists also receive training in the specific behaviour change approaches in the Intervention Toolkit, plus a Toolkit containing printed patient materials to enable the delivery of the intervention and link to patient digital resources.

Participants allocated to the OPTIN intervention arm receive a home exercise programme together with personalised adherence intervention, see Figure 3. Before seeing the physiotherapist (in the waiting room) they are asked to complete the Personalized Exercise Questionnaire (PEQ). The PEQ was developed to support personalised exercise prescription for people with osteoporosis and asks about barriers and facilitators surrounding exercise and goals of treatment [37]. If participants need support to complete the PEQ they can talk

through the same items with the physiotherapist in their assessment. The initial assessment consists of a standard musculoskeletal physiotherapy assessment extended by 30-minutes to facilitate a collaborative discussion between the participant and physiotherapist about their goals, and potential barriers and facilitators surrounding exercise. It uses a motivational interviewing approach and draws on PEQ items as needed to scaffold the discussion and ensure all areas are covered. This initial discussion offers the physiotherapist an in-depth understanding of a patient's circumstances, to strengthen the therapeutic alliance and the participant's own motivations for exercising.

Using their whole assessment findings, the physiotherapist assesses a participant's exercise capability (C), opportunity (O) and motivation (M) to carry out exercise behaviour (B) and selects an approach(s) from the OPTIN Intervention Toolkit. Approaches comprise of the following: (1) Exercise Action Plans, (2) Exercise Coping Plans, (3) Decision Balance Sheets, (4) Implementation Intention Statements, (5) Support Contact (brief telephone call), (6) Self-monitoring and Feedback Strategies, (7) Cues, (8) Falls Advice, and (9) Education. Table 1 outlines each approach in the context of COM-B principles and with the associated individual behaviour change techniques (BCTs) from the Behaviour Change Technique Taxonomy (BCTTv1) [41].

Physiotherapists utilise at least three approaches from the OPTIN Intervention Toolkit over 16 weeks and are given 60 additional clinical minutes to use flexibly across this time to deliver the adherence intervention. In addition to the initial consultation, the Decision aid (Figure 2) is designed to support physiotherapists' selection of the most suitable approaches for the individual. For example, people who identify they find it difficult to establish an

exercise routine or forget to do their exercises might find *Exercise action plans* or *Cues* helpful, those who identify barriers to exercise may use *Implementation Intention Statements*, and others may need help to track progress using *Self-monitoring and Feedback Strategies*. The Decision aid is not an exhaustive resource but serves as a tool with key examples to guide decision-making.

Standard Care

The same, standardised physiotherapy exercise rehabilitation of progressed strength, balance, posture, and functional weight-bearing (including low impact) exercises and related self-management advice is used in both trial arms (see supplementary material). The exercise programme was developed, standardised, and tested in the PROVE trial. Prior to the OPTIN trial it was checked to ensure it was in line with new evidence-based guidelines. Physiotherapists from both OPTIN trial arms have identical materials and training to support safe and effective exercise prescription and exercise progression for people with VFF with access to a *safe exercise at home* checklist, a guide to setting exercise intensity, printed exercises and a link to a digital version of the exercise resources including short exercise videos [26]. To decrease the risk of contamination between arms, physiotherapists delivering the comparator arm were not trained in adherence approaches or given access to toolkits, templates, or related training resources. Treatments and content are summarised according to TIDieR criteria in Table 2.

Measures of Adherence

Adherence to the exercise programme is one of the outcomes of the trial. It is measured by the self-completed Exercise Adherence Rating Scale [42] and by attendance records via the

clinician treatment notes which includes which adherence techniques have been agreed with the patient.

Intervention fidelity, monitoring and safety

Following delivery of training to treating physiotherapists, post-training evaluation forms review training content, structure and duration, and physiotherapists' confidence to deliver the intervention. The fidelity of the intervention is monitored in two ways. Firstly, site monitoring visits occur at least annually to ensure treating physiotherapists adhere to the intervention protocol. Secondly, physiotherapists delivering the OPTIN adherence intervention are asked to complete online treatment logs at the end of each treatment session, consisting of a brief checklist documenting if an adherence technique was delivered and the technique used. The central research team monitors the checklist for deviations and/or discrepancies from protocol. If problems are identified, they are investigated, and supplementary training or other measures taken to address the issue as needed.

In a group of older adults with VFF, many of whom have co-morbid health conditions, falls and other adverse health events are common but adverse events related to the psychological adherence intervention are not expected and our previous PROVE trial demonstrated adverse events associated to physiotherapy exercise are also unlikely [10]. Adverse events are monitored across the study for all participants. Treating physiotherapists and all research staff are trained in the procedure for reporting adverse events, with information also available in study manuals. Falls are tracked specifically across the year in a participant self-report falls diary and trial research clinicians ask about falls and any other adverse events at each follow-up point (4, 8 and 12 months).

Conclusion

We describe the development and details of the OPTIN adherence intervention for improved adherence to an exercise programme for people with VFF and back pain. The clinical effectiveness and cost-analysis of the OPTIN adherence intervention will be reported at the end of the OPTIN trial.

Ethical Approval: The OPTIN trial received ethical approval by West of Scotland Research Ethics Committee [21/WS/0071].

Funding: The work was supported by an independent grant from the Chartered Society of Physiotherapy Charitable Trust [RP/19/01].

Conflict of Interest: Karen Barker is on the Editorial Board of Physiotherapy but has not been involved in the peer review process. The authors declare no conflicts of interest.

References

1. Compston JE, McClung MR, Leslie WD. Osteoporosis. Lancet. 2019;393(10169):364-76. doi:10.1016/S0140-6736(18)32112-3
2. Stanghelle B, Bentzen H, Giangregorio L, et al. Associations between health-related quality of life, physical function and pain in older women with osteoporosis and vertebral fracture. BMC Geriatr. 2019;19(1):298. doi:10.1186/s12877-019-1268-y
3. Chen PE, Chien CW, Tung TH. The Relationship Between Fragility Fractures and Pain Experience: A Systematic Review. Front Med (Lausanne). 2021;8:609318. doi:10.3389/fmed.2021.609318
4. Lee SB, Park Y, Kim DW, et al. Association between mortality risk and the number, location, and sequence of subsequent fractures in the elderly. Osteoporos Int. 2021;32(2):233-41. doi:10.1007/s00198-020-05602-x
5. Tan CW, Sahota O. A 3-year retrospective analysis of patients admitted with clinical vertebral fragility fractures across hospitals in England, UK. Osteoporos Int. 2023;34(3):607-11. doi:10.1007/s00198-022-06647-w
6. Borgstrom F, Karlsson L, Ortsater G, et al. Fragility fractures in Europe: burden, management and opportunities. Arch Osteoporos. 2020;15(1):59. doi:10.1007/s11657-020-0706-y
7. National Osteoporosis Society. Strong, Steady & Straight: NOS Exercise and Osteoporosis Consensus Statement 2019 [Available from: https://www.bgs.org.uk/resources/strong-steady-straight-nos-exercise-and-osteoporosis-consensus-statement].
8. National Osteoporosis Guideline Group. Clinical guideline for the prevention and treatment of osteoporosis 2021 [Available from: https://www.nogg.org.uk/full-guideline/summary-main-recommendations].
9. Gregson CL, Armstrong DJ, Bowden J, et al. UK clinical guideline for the prevention and treatment of osteoporosis. Arch Osteoporos. 2022;17(1):58. doi:10.1007/s11657-022-01061-5
10. Barker KL, Newman M, Stallard N, et al. Physiotherapy rehabilitation for osteoporotic vertebral fracture-a randomised controlled trial and economic evaluation (PROVE trial). Osteoporos Int. 2020;31(2):277-89. doi:10.1007/s00198-019-05133-0
11. Gibbs JC, McArthur C, Wark JD, et al. The Effects of Home Exercise in Older Women With Vertebral Fractures: A Pilot Randomized Controlled Trial. Phys Ther. 2020;100(4):662-76. doi:10.1093/ptj/pzz188
12. Stanghelle B, Bentzen H, Giangregorio L, et al. Effects of a resistance and balance exercise programme on physical fitness, health-related quality of life and fear of falling in older women with osteoporosis and vertebral fracture: a randomized controlled trial. Osteoporos Int. 2020;31(6):1069-78. doi:10.1007/s00198-019-05256-4
13. Gibbs JC, MacIntyre NJ, Ponzano M, et al. Exercise for improving outcomes after osteoporotic vertebral fracture. Cochrane Database Syst Rev. 2019;7(7):CD008618. doi:10.1002/14651858.CD008618.pub3
14. Chester R, Daniell H, Belderson P, et al. Behaviour Change Techniques to promote self-management and home exercise adherence for people attending physiotherapy with musculoskeletal conditions: A scoping review and mapping exercise. Musculoskelet Sci Pract. 2023;66:102776. doi:10.1016/j.msksp.2023.102776
15. Peek K, Sanson-Fisher R, Mackenzie L, et al. Interventions to aid patient adherence to physiotherapist prescribed self-management strategies: a systematic review. Physiotherapy. 2016;102(2):127-35. doi:10.1016/j.physio.2015.10.003
16. Bailey DL, Holden MA, Foster NE, et al. Defining adherence to therapeutic exercise for musculoskeletal pain: a systematic review. Br J Sports Med. 2020;54(6):326-31. doi:10.1136/bjsports-2017-098742
17. Kolt GS, McEvoy JF. Adherence to rehabilitation in patients with low back pain. Man Ther. 2003;8(2):110-6. doi:10.1016/s1356-689x(02)00156-x
18. Falossi F, Azzollini V, Notarstefano C, et al. Adherence to a home physical exercise program in patients with osteoporotic vertebral fractures: A retrospective observational study. J Back Musculoskelet Rehabil. 2022;35(4):777-82. doi:10.3233/BMR-191826
19. Room J, Dawes H, Boulton M, et al. The AERO study: A feasibility randomised controlled trial of individually tailored exercise adherence strategies based on a brief

behavioural assessment for older people with musculoskeletal conditions. Physiotherapy. 2023;118:88-96. doi:10.1016/j.physio.2022.08.006
20. Barker KL, Room J, Knight R, et al. Physiotherapy exercise rehabilitation with tailored exercise adherence support for people with osteoporosis and vertebral fractures: protocol for a randomised controlled trial - the OsteoPorosis Tailored exercise adherence INtervention (OPTIN) study. BMJ Open. 2022;12(9):e064637. doi:10.1136/bmjopen-2022-064637
21. Skivington K, Matthews L, Simpson SA, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. BMJ. 2021;374:n2061. doi:10.1136/bmj.n2061
22. Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ. 2014;348:g1687. doi:10.1136/bmj.g1687
23. Slade SC, Dionne CE, Underwood M, et al. Consensus on Exercise Reporting Template (CERT): Explanation and Elaboration Statement. Br J Sports Med. 2016;50(23):1428-37. doi:10.1136/bjsports-2016-096651
24. Albrecht L, Archibald M, Arseneau D, et al. Development of a checklist to assess the quality of reporting of knowledge translation interventions using the Workgroup for Intervention Development and Evaluation Research (WIDER) recommendations. Implement Sci. 2013;8:52. doi:10.1186/1748-5908-8-52
25. Room J, Hannink E, Dawes H, et al. What interventions are used to improve exercise adherence in older people and what behavioural techniques are they based on? A systematic review. BMJ Open. 2017;7(12):e019221. doi:10.1136/bmjopen-2017-019221
26. Brooke-Wavell K, Skelton DA, Barker KL, et al. Strong, steady and straight: UK consensus statement on physical activity and exercise for osteoporosis. Br J Sports Med. 2022;56(15):837-46. doi:10.1136/bjsports-2021-104634
27. Nuti R, Brandi ML, Checchia G, et al. Guidelines for the management of osteoporosis and fragility fractures. Intern Emerg Med. 2019;14(1):85-102. doi:10.1007/s11739-018-1874-2
28. National Institute for Health and Care Excellence (NICE). Osteoporosis - prevention of fragility fractures 2023 [Available from: https://cks.nice.org.uk/topics/osteoporosis-prevention-of-fragility-fractures/].
29. AGILE. Physiotherapy: a brief guide for organisations and professionals providing care and support for older people 2022 [Available from: https://agile.csp.org.uk/system/files/documents/2022-08/agile_leaflet_organisations_2.pdf].
30. Kunutsor SK, Leyland S, Skelton DA, et al. Adverse events and safety issues associated with physical activity and exercise for adults with osteoporosis and osteopenia: A systematic review of observational studies and an updated review of interventional studies. J Frailty Sarcopenia Falls. 2018;3(4):155-78. doi:10.22540/JFSF-03-155
31. Bartholomew Eldredge LK, Markham CM, Ruiter RAC, et al. Planning Health Promotion Programs: An Intervention Mapping Approach. Fourth ed. San Francisco: John Wiley & Sons; 2016.
32. Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. Implement Sci. 2011;6:42. doi:10.1186/1748-5908-6-42
33. Barker KL, Newman M, Stallard N, et al. Exercise or manual physiotherapy compared with a single session of physiotherapy for osteoporotic vertebral fracture: three-arm PROVE RCT. Health Technol Assess. 2019;23(44):1-318. doi:10.3310/hta23440
34. Room J, Boulton M, Dawes H, et al. Physiotherapists' perceptions of how patient adherence and non-adherence to recommended exercise for musculoskeletal conditions affects their practice: a qualitative study. Physiotherapy. 2021;113:107-15. doi:10.1016/j.physio.2021.06.001
35. Beauvais C. Motivational interviewing to improve treatment adherence. Joint Bone Spine. 2019;86(5):535-7. doi:10.1016/j.jbspin.2019.02.005
36. Rodrigues IB, Adachi JD, Beattie KA, et al. Development and validation of a new tool to measure the facilitators, barriers and preferences to exercise in people with osteoporosis. BMC Musculoskelet Disord. 2017;18(1):540. doi:10.1186/s12891-017-1914-

5
37. Rodrigues IB, Adachi JD, Beattie KA, et al. Determining known-group validity and test-retest reliability in the PEQ (personalized exercise questionnaire). BMC Musculoskelet Disord. 2019;20(1):373. doi:10.1186/s12891-019-2761-3
38. Nicolson PJA, Holden MA. Patient Preferences and Osteoarthritis Care: What Do We Know About What Patients Want from Osteoarthritis Treatment? Current Treatment Options in Rheumatology. 2023;9(3):120-31. doi:10.1007/s40674-023-00208-w
39. Frey AJ, Lee J, Small JW, et al. Mechanisms of Motivational Interviewing: a Conceptual Framework to Guide Practice and Research. Prev Sci. 2021;22(6):689-700. doi:10.1007/s11121-020-01139-x
40. Kinney M, Seider J, Beaty AF, et al. The impact of therapeutic alliance in physical therapy for chronic musculoskeletal pain: A systematic review of the literature. Physiother Theory Pract. 2020;36(8):886-98. doi:10.1080/09593985.2018.1516015
41. Michie S, Richardson M, Johnston M, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. Ann Behav Med. 2013;46(1):81-95. doi:10.1007/s12160-013-9486-6
42. Newman-Beinart NA, Norton S, Dowling D, et al. The development and initial psychometric evaluation of a measure assessing adherence to prescribed exercise: the Exercise Adherence Rating Scale (EARS). Physiotherapy. 2017;103(2):180-5. doi:10.1016/j.physio.2016.11.001

Figure 1. Overview of the intervention development process

Figure 2. Decision aid for physiotherapists delivering the OPTIN adherence intervention

Figure 3. OPTIN adherence intervention components

397 ***Table 1 OPTIN adherence techniques with associated COM-B and Behaviour Change***
398 ***Techniques***

Approach	COM-B domains	BCTs
Exercise Action Plan	Capability & Opportunity	• Problem solving • Action planning • Comparative imagining of future outcomes • Verbal persuasion about capability
Exercise Coping Plan	Opportunity	• Problem solving • Action planning • Commitment
Decision Balance Sheets	Motivation	• Comparative imaging of future outcomes
Implementation Intention Statements	Motivation	• Action planning • Commitment
Support Contact	Opportunity & Motivation	• Problem solving • Feedback on behaviour • Feedback on outcome(s) of behaviour • Verbal persuasion about capability
Self-monitoring and Feedback	Capability & Motivation	• Feedback on behaviour • Self-monitoring of behaviour • Self-monitoring of outcome(s) of behaviour • Monitoring of outcome(s) of behaviour without feedback • Feedback on outcome(s) of behaviour
Falls Advice	Capability	• Instruction on how to perform the behaviour • Information about antecedents • Information about health consequences • Restructuring the physical environment • Mental rehearsal of successful performance
Cues	Opportunity	• Prompts/cues
Education	Capability & Motivation	• Information about health consequences • Information about social and environmental consequences/support • Credible source

399

400 ***Table 2 OPTIN trial interventions based on TIDieR Criteria***

TIDieR Item	**Description**	
BRIEF NAME	OPTIN (Osteoporosis Tailored Exercise Intervention)	
WHY	Physiotherapy exercise rehabilitation for people with vertebral fragility fractures (VFF) has been shown to be effective but effects depend on the adherence to the exercise programme, which can vary and be poor, limiting potential benefits.	
	Standard care (Exercise programme only)	**Exercise programme + adherence intervention**
WHAT	Comparator: Physiotherapy exercise rehabilitation	Intervention: Physiotherapy exercise rehabilitation PLUS integrated, individualised adherence intervention
Materials: Participants	Exercise handouts: • Pictures and descriptions of exercise with repetitions and sets. • Individual exercise videos • Safe exercise at home guide Equipment: • Graded resistance bands • Dumbbell weights • Balance pad	Exercise handouts and equipment as per standard care PLUS: Folder Selected behaviour change approaches and templates, e.g.: (1) Exercise Action Plans, (2) Exercise Coping Plans, (3) Decision Balance Sheets, (4) Implementation Intention Statements, (5) Support Contact, (6) Self-monitoring and Feedback, (7) Cues, (8) Falls Advice, and (9) Education leaflet
Materials: Physiotherapists	Training in osteoporosis, VFF and exercise for bone health. The exercise programme, domains, setting exercise intensity, progression (including handouts and video resource). Therapist Manual A: summarising all aspects of the trial, osteoporosis, VFF and the exercise intervention. Half-day training	Training in osteoporosis, VFF and exercise for bone health. The exercise programme, domains, setting exercise intensity, progression (including handouts and video resource). Therapist Manual A: summarising all aspects of the trial, osteoporosis, VFF and exercise intervention. PLUS Therapist Manual B and training for motivational interview approach, therapeutic alliance, toolkit of 9 exercise behaviour-change approaches, and decision aid. Digital and printed.

		Full day training delivered by OPTIN research team.
Procedures	Initial musculoskeletal physiotherapy assessment followed by prescription of a home exercise programme Evaluated and progressed in follow-up sessions.	PEQ completed before initial appointment. Initial musculoskeletal physiotherapy assessment with extended interview. Followed by prescription of a home exercise programme and integrated with the adherence intervention using at least 3 behaviour change approaches. Evaluated and progressed in follow-up sessions.
WHO PROVIDED	Physiotherapists working in NHS musculoskeletal services	Physiotherapists working in NHS musculoskeletal services
HOW	Musculoskeletal physiotherapy assessment (60-minutes) Individual selection of exercises, intensity, repetitions /load, considering safety and exercise form and progressed in follow up treatments. Domains considered: strength (focus on head/trunk/hip extensors, and functional lower limb strength), balance, posture and weight-bearing exercise. Supporting self-management advice e.g. exercise safety advice	Musculoskeletal physiotherapy assessment (60-minutes) Personalized Exercise Questionnaire (completed prior to appointment) Extended interview using motivational interviewing approach, focus on determining Capability, Opportunity and Motivation surrounding exercise. Individual selection of exercises, intensity, repetitions /load, considering safety and exercise form and progressed in follow up treatments. Domains considered: strength (focus on head/trunk/hip extensors, and functional lower limb strength), balance, posture and weight-bearing exercise. Supporting self-management advice e.g. exercise safety advice At least 3 behaviour change approaches integrated with exercise

		prescription
WHERE	NHS outpatient physiotherapy departments in the UK and in participants homes via video-call.	NHS outpatient physiotherapy departments in the UK and participants homes via video-call.
WHEN and HOW MUCH	Initial appointment within 2 weeks of randomisation. Initial physiotherapy assessment (60 minutes). Six 30-minute follow-up physiotherapy treatments over 16 weeks. Home exercise programme.	Initial appointment within 2 weeks of randomisation. Initial physiotherapy assessment (60 minutes + 30 minutes motivational interview) and six 30-minute follow-up treatments over 16 weeks. Home exercise programme. PLUS additional 60 minutes flexibly allocated to delivering intervention over the 16 weeks.
TAILORING	Education and advice focused on individualised exercise programme based on assessment. Selection of exercises, sets and repetitions / load individualised and progressed. Exercise sets were graded in difficulty, allowing physiotherapists to prescribe a package of exercises at a suitable level for an individual in a standardised way and targeting the same areas. The Rating of Perceived Exertion (RPE) scale used to set initial exercise intensity and guide progression.	Tailoring for exercise programme same as Standard care arm. PLUS utilizing at least 3 approaches, their selection based on determinants of adherence identified through assessment.
MODIFICATIONS	Quick reference guides for modifications of exercises e.g. starting positions, to ensure safe and supported exercise were provided as part of the exercise programme and treatment packages.	
HOW WELL	**Intervention fidelity**	
Training	Training delivery – content, structure, duration and therapists' confidence were evaluated using post-training feedback forms. Treatments were manualised and provided to treating therapists (Therapist Manual A: Trial structure and background to osteoporosis and VFF, Exercise Programme, Therapist Manual B: Adherence Intervention) Therapists were provided with printed manuals and could also access materials digitally, including training videos.	

Physiotherapists	Fidelity was monitored by treatment logs, supplemented by on site monitoring and assurance visits. If any problems were identified supplementary training was provided.	
Participants	Physiotherapist completed session attendance record and log of exercise type provided e.g., strength exercises. Exercise Adherence Rating Scale (EARS) questionnaires to self-report adherence at 4, 8 and 12 months.	Physiotherapist completed session attendance record and log of exercise type provided e.g., strength exercises. Physiotherapist completed session log recoding use of behaviour change approaches
Reporting	Intervention fidelity will be reported with the main trial results.	

401

402