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Complete List of Authors:	Nomikos, Polykarpos; University of Nottingham, Academic Rheumatology ; University of Nottingham, NIHR Nottingham Biomedical Research Centre Hall, Michelle; University of Nottingham, NIHR Nottingham Biomedical Research Centre ; University of Nottingham, School of Health Sciences Fuller, Amy; University of Nottingham, Academic Rheumatology ; University of Nottingham, NIHR Nottingham Biomedical Research Centre Millar, Bonnie; University of Nottingham, NIHR Nottingham Biomedical Research Centre ; University of Nottingham, Pain Centre Versus Arthritis Ogollah, Reuben; University of Nottingham, Nottingham Clinical Trials Unit Valdes, A; University of Nottingham, NIHR Nottingham Biomedical Research Centre ; University of Nottingham, Pain Centre Versus Arthritis Doherty, Michael ; University of Nottingham, Academic Rheumatology ; University of Nottingham, Pain Centre Versus Arthritis Walsh, David; University of Nottingham, NIHR Nottingham Biomedical Research Centre ; University of Nottingham, Pain Centre Versus Arthritis dasNair, Roshan; University of Nottingham, Institute of Mental Health; University of Nottingham, Division of Psychiatry & Applied Psychology Abhishek, A; University of Nottingham, Academic Rheumatology ; University of Nottingham, NIHR Nottingham Biomedical Research Centre
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Assessing intervention fidelity of a nurse-led non-pharmacological package of care for knee pain

Polykarpos Angelos Nomikos[1,2], Michelle Hall[2,3], Amy Fuller[1,2], Bonnie Millar[2,4], Reuben Ogollah[5], Ana M Valdes[2,4], Michael Doherty[1,4], David Walsh[2,4], Roshan das Nair [6,7], Abhishek Abhishek[1,2]

[1] Academic Rheumatology, University of Nottingham, Nottingham, UK

[2] NIHR Nottingham Biomedical Research Centre, University of Nottingham, Nottingham, UK

[3] School of Health Sciences, University of Nottingham, Nottingham, UK

[4] Pain Centre Versus Arthritis, University of Nottingham, Nottingham, UK

[5] Nottingham Clinical Trials Unit, University of Nottingham, Nottingham, UK

[6] Institute of Mental Health, University of Nottingham, Nottingham, UK

[7] Division of Psychiatry & Applied Psychology, University of Nottingham, Nottingham, UK

Corresponding author:

Polykarpos Angelos Nomikos

A 26 Clinical Sciences Building

Nottingham City Hospital

Hucknall Road

Nottingham

NG5 1PB

UK

E-mail address: Polykarpos.nomikos@nottingham.ac.uk

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ABSTRACT

Objectives: To evaluate the fidelity of delivery of a nurse-led non-pharmacological complex intervention for knee pain.

Setting: Secondary care. Single centre study.

Participants: Eighteen adults (33% women) with chronic knee pain, mean age 68.7 years, and body mass index 31.2 kg/m^2 participated. Fourteen completed all visits.

Inclusion criteria: Age > 40 years, knee pain present for longer than 3 months, knee pain for most days of the previous month, at least moderate pain in two of the five domains of Western Ontario and McMaster Universities Osteoarthritis Index pain scale.

Interventions: Nurse-led non-pharmacological package of care for knee pain comprising holistic assessment, education, exercise, dietary advice, use of hot/cold treatments, footwear modification, walking aids, and weight-loss advice (if required), delivered in 4 sessions over a 5-week period.

Outcome(s): Primary: Fidelity of delivery of intervention, Secondary: nurses' experience of delivering intervention.

Methods: All sessions were video recorded. Fidelity checklists were completed by the research nurse after each session and by an independent blinded researcher after viewing the video-recordings. Fidelity scores (%), percentage agreement and 95% Confidence Intervals (CI) were calculated. Semi-structured interview was conducted with the research nurse to explore the experience of delivering the intervention.

Results: Overall fidelity was higher on nurse self-report (97.7%) than on objective video-rating (84.2%). Percentage agreement between nurse self-report and video-

rating was 73.3% (95% CI: 71.3 - 75.3). Fidelity was lowest for advice on footwear and walking aids. The nurse reported difficulty in advising on thermal treatments, footwear and walking aids, and did not feel confident setting functional goals with participants.

Conclusions: A trained research nurse can deliver most components of an individualised non-pharmacological intervention for knee pain to a high degree of fidelity. Future research should assess fidelity in a clinical setting by nurses, and examine its clinical-effectiveness and cost-effectiveness.

Trial registration number: NCT03670706

KEY WORDS: Knee pain, fidelity, nurse-led intervention, osteoarthritis

STRENGTHS AND LIMITATIONS OF THE STUDY

- This novel mixed methods study used a combination of techniques to assess treatment fidelity.
- We triangulated the fidelity findings with the interview findings and found convergence providing internal validity.
- We identified the specific components of the categories not delivered as intended.
- Only one nurse was involved in delivery of the intervention.
- Lack of formal assessment of nurse knowledge of managing knee OA.

INTRODUCTION

Osteoarthritis (OA) is the commonest form of arthritis and is managed predominantly in primary care. The knee is a commonly affected site, with approximately one third of adults over the age of 50 years in the UK consulting their general practitioner (GP) for knee pain. (1) National Institute for Health and Care Excellence (NICE) guidelines (2) recommend a patient-centred approach with a focus on non-pharmacological interventions including education, strengthening and aerobic exercise, and weight loss if required. However, this can be difficult for general practitioners (GPs) to deliver for several reasons such as time constraint, and, core non-pharmacological treatments are under-utilised. (3, 4) Nurse-led care has been shown to give similar or better outcomes than GP-led care for other chronic diseases. (5-8) However, the efficacy and fidelity of delivery of nurse-led care has not been examined formally for OA.

Fidelity, defined as the degree to which the intervention is delivered as intended, (9) regulates the relationship between interventions and outcomes, and determines the extent to which an intervention affects the outcome. (10) Inferences regarding treatment effect of a complex intervention should therefore not be made without assessing fidelity, because absence of efficacy of an intervention may be due to inadequate implementation of the intervention. (11) Thus, the fidelity of intervention delivery influences the internal and external validity of a study. (12) If fidelity is not assessed, effective interventions may be rejected due to poor delivery. (13, 14)

The present study is part of the East-Midlands Knee Pain Cohort Randomised Controlled Trial (RCT) Study, (15) the overall purpose of which is to evaluate the feasibility of a nurse-led package of care for knee pain. The objective of the present

study was to evaluate the fidelity of delivery of a nurse-led non-pharmacological package of care for knee pain during the package development phase of the RCT.

METHODS

Study Design: A mixed methods study.

Setting: Secondary care.

Participants and Recruitment: The participants were adults with knee pain. Community dwelling adults participating in the Investigating Musculoskeletal Health and Wellbeing (IMHW) cohort study, (16) self-reporting knee pain were sent a postal invitation to participate in this study. People who responded underwent telephone screening to assess eligibility. The inclusion criteria were: age>40 years, ability to read and write in English, knee pain present for longer than three months, pain in or around the knee on most days of the previous month, and at least moderate pain in two of the five domains of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain scale. (17)

Research nurse training: A training programme to enable a nurse to deliver the current NICE guidelines for osteoarthritis management was developed and an educational manual produced. (15) The training included face-to-face learning, case-studies, on-line resources and simulated patients. Practical sessions on delivering and modifying exercise, weight loss advice and use of strategies to encourage adherence were also included.

Patient and Public Involvement: A patient advisory group of three people with hip or knee OA supported the design of this study. All had different experiences in primary and secondary care and provided input into the content of the non-pharmacological package, the training of the nurse, and the use of exercise diaries and educational content.

Intervention: The template for intervention description and replication (TIDieR) checklist (18) was used to describe the intervention and its key features. The items of the non-pharmacological intervention are described in Additional file 1. After the training period, the nurse delivered the intervention in four sessions over a five-week period. The intervention consisted of a holistic assessment of the participant, providing education about the nature of OA and self-management strategies including advice on the role of exercise, maintaining a healthy weight, and use of adjunctive treatments such as the application of heat or cold, foot-wear modification and use of walking aids. The nurse explained aerobic and strengthening exercises and advised each participant on individualised regimens. If required, weight-loss advice was provided. Behaviour change strategies (19) such as goal setting, action planning, assessment of participant confidence to achieve goals, discussion of barriers and facilitators and the use of exercise diaries were used to improve adherence. Functional goals were agreed and were used to facilitate the exercise prescription with goals being Specific, Measurable, Achievable, Relevant, and Timely (SMART). SMART weight loss goals were agreed also with overweight participants.

Consent: All participants including the research nurse gave their written, informed consent prior to treatment delivery, including consent to video record the sessions.

Fidelity assessment: The study followed the National Institutes of Health Behaviour Change Consortium (NIHBCC) guidelines for fidelity assessment. (13) The fidelity checklist was developed a priori (Additional file 2) and comprised eight categories: materials; introduction; assessment; education; exercise; weight loss; advice on adjunctive treatments; and review and planning. However, not all components of the intervention categories were intended to be delivered in each session (Table 1). For

example, advice on the adjunctive treatments, could be provided in any of the four sessions.

The responses of the fidelity checklist were categorical and rated as completed, partially completed, not completed, or not applicable (N/A). All intervention sessions were video-recorded. After each session, the nurse self-rated the fidelity checklist. Blinded to the nurse ratings, the video-recording of each session was independently reviewed and rated by PAN. A second rater (MH) further independently rated 20% of the sessions. Both raters had experience of delivering the intervention and were familiar with the intervention. MH co-designed the nurse training programme and PAN had attended the training. The process for assessment of fidelity followed that of previous studies. (20)

One week after the final session, the nurse took part in a semi-structured interview. The interview guide (Additional file 3) covered the nurse's view on their training, confidence in and experience of delivering the individual components of the non-pharmacological intervention, perceived barriers to delivering it as planned, and opportunities to improve the non-pharmacological package of care. An iterative process was used for data collection, so an additional interview was conducted to capture any salient points raised by the initial quantitative data we collected. The qualitative findings were mapped onto the fidelity checklist categories to assess convergence between the quantitative and qualitative findings. Any areas of uncertainty or gaps were then explored in a second interview with the nurse.

Quantitative data analysis: Mean and standard deviation (SD), median and inter quartile range (IQR) and frequency data (counts and percentages were calculated for descriptive purposes. Fidelity scores were calculated as the percentage of

components that were delivered as intended for overall delivery of the intervention, for each session and for each category.

Components rated as 'completed' were given a score of 2, 'partially completed' a score of 1, and not completed, a score of zero. Partially completed is scored whether the nurse has given the appropriate advice for a particular component but did not followed it up after the participant response. Any components that were rated as not-applicable e.g. weight loss for participants who were not overweight, were excluded from the calculation. Median fidelity scores (%) and inter-quartile range (IQR) were calculated for the entire intervention, per session and per component of the intervention. Fidelity was classified as previously reported: 80-100% 'high', 51-79% 'moderate', and 0-50% 'low' fidelity. (21) Where fidelity was moderate or low in a particular category, we further explored this by examining the fidelity of delivery of their individual components.

Percentage agreement with 95% confidence intervals (CI) was used to estimate the level of agreement between self-report and video-record methods, and for inter-rater agreement.

Qualitative data analysis: The interviews were transcribed verbatim by an external transcription company. The interviewer removed any identifiers and ensured transcripts were accurate. Transcripts were analysed following the principles of the general inductive approach. (22) The first transcript was read several times before data related to the research objectives was identified, labelled and categorised. Categories were discussed between the interviewer and a second researcher (AF). This process identified gaps and led to the second interview and the transcript was analysed in the same way. Following agreement that the categories reflected the

overall account reported by the nurse, extracts were taken from the transcripts to exemplify the findings.

Convergence: A meta-matrix was developed to explore convergence between the findings. This approach enhances study validity by increasing the probability that our findings and interpretations are credible and reliable. (23) Convergence was defined as agreement between both sets of data, and discrepancy as disagreement between them.

Reporting guidelines: The Standards for Quality Improvement Reporting Excellence (SQUIRE) guidelines (24) were used to improve the quality of reporting of this study.

Table 1.The delivery of the intervention components in each session

Content of the non-pharmacological intervention	**Session**			
	1	2	3	4
Materials				
Patient education booklet on OA	✓			
Exercise/activity diary	✓			
Goal setting forms	✓			
Introduction	✓			
Holistic assessment of person with OA	✓	✓	✓	✓
Education	✓	✓	✓	✓
Exercise				
Smart goal setting	✓			
Smart goal reviewed		✓	✓	
Patients level of confidence for the exercise programme determined	✓	✓	✓	✓
Weight loss (if required)	✓	✓	✓	✓
Adjunct treatments				
Use of heat/cold treatments discussed	✓	✓	✓	✓
Walking aids discussed	✓	✓	✓	✓
Footwear discussed	✓	✓	✓	✓
Review and Planning				
Session review: goal setting synopsis and action plan	✓	✓	✓	✓

RESULTS

Quantitative findings:

Eighteen participants (33% women), with a mean age of 68.7 (SD 9.0) years and body mass index of 31.2 (SD 8.4) kg/m^2 respectively took part in the study. Of these, fourteen completed all four visits. The reasons for dropping out were other commitments (n=3), reluctance to lose weight (n=1), and inadequate understanding of the nature of the intervention (n=1).

In total, 62 intervention sessions were delivered. The median (IQR) duration of the first and follow-up sessions was 87 (81–101) minutes, and 46 (37–52) minutes respectively. Overall fidelity was rated high by both nurse self-rated (97.7%) and video-rated scores (84.2%) (Tables 2, 3). Inter-rater agreement for the video-recording checklist was 70.3% (95%CI 64.4, 74.2).

For the nurse self-rated checklist, median fidelity scores for each session ranged from 94.4-100% (Table 2). Individual categories received high ratings except for adjunctive treatments i.e. use of heat/cold therapy and advice on footwear where the fidelity score was moderate in many sessions.

For the video-rated checklists, overall median fidelity scores for each session ranged from 77.7-87.2% (Table 3). Fidelity for education was lower in the first session (78.13%, IQR 74.11, 93.75) but improved in the follow-up session (87.50%, IQR 50,100). Fidelity for review and planning was lower in the first and last sessions. Fidelity scores were low for adjunctive treatments across all sessions, and varied from 0% to 50%. Fidelity of delivery for exercise goal-setting was moderate at 66% and, fidelity for reviewing goals during follow-up sessions was low, ranging between 44-

50%. Additionally, assessment of patients' level of confidence to achieve their exercise goal was low in the follow-up sessions, ranging between 7-40%.

The overall agreement between nurse-rated and video-rated methods was 73.3% (95% CI 71.3 - 75.3). The level of agreement for individual categories is shown in figure 1. Excellent agreement was found for materials, introduction, and assessment. Agreement was below the cut-off point of 80% for education, exercise, weight loss and adjunctive treatment. The level of agreement for review and planning category was 58.1% (95% CI 44.8, 70.5).

Table 2. Nurse-rated fidelity scores for each session

Intervention component	Session 1*	Session 2*	Session 3*	Session 4*
Materials	100 (100, 100)	-	-	-
Introduction	100 (100, 100)	-	-	-
Assessment	100 (98.3, 100)	100 (100, 100)	100 (100, 100)	100 (100, 100)
Education	100 (100, 100)	100 (100, 100)	100 (100, 100)	100 (100, 100)
Exercise	100 (97.5, 100)	100 (100, 100)	100 (97.5, 100)	100 (75, 100)
Weight loss	100 (88.9, 100)	100 (100, 100)	100 (66.7, 100)	100 (79.2, 100)
Adjunct treatments	87.5 (33.3 100)	87.5 (0, 100)	66.7 (45.8, 100)	-
Review and planning	100 (100, 100)	100 (100, 100)	100 (100, 100)	100 (100, 100)

*Values are median% (IQR)

Table 3. Video-rated fidelity scores for each session

Intervention categories	Session 1*	Session 2*	Session 3*	Session 4*
Materials	100 (100, 100)	-	-	-
Introduction	100 (75, 100)	-	-	-
Assessment	91.43 (85, 93.3)	100 (100, 100)	100 (100, 100)	100 (100, 100)
Education	78.13 (74.1, 93.8)	87.5 (50, 100)	87.5 (50, 100)	100 (93.8, 100)
Exercise	94.4 (88.9, 100)	88.9 (75, 94.4)	86.1 (72, 100)	75 (67.6, 82.8)
Weight loss	100 (87.5, 100)	90 (60, 100)	100 (68.9, 100)	80 (49.2, 100)
Adjunct treatments	50 (45.8, 100)	0 (0, 50)	50 (0, 100)	-
Review and planning	75 (75, 100)	100 (100, 100)	100 (100, 100)	75 (37.5, 100)

*Values are median% (IQR)

Qualitative findings:

The duration of the initial and follow-up interview was 94 minutes, and 34 minutes respectively. The nurse reported feeling nervous when she delivered the intervention for the very first time, but felt more comfortable as the sessions progressed.

> *"Very nervous… to start with... I don't think after a few sessions I was uncomfortable, I was probably more comfortable delivering the intervention…after few sessions, got better at getting feedback from patient as well so I think that boosted my confidence".*

The nurse felt that education was not always delivered as well in the first few sessions as in the follow-up sessions.

> *"First few sessions I didn't think of as very good to tell them about the information and then later on, I built that …"*

The nurse felt that patient assessment was easy to deliver considering their previous experience in that particular area.

> *"I would say some of them were easy to find pinpoint the problems…as a nurse we always been asking these questions to patients… in this case but had previous experience in that area"*

However, they initially lacked confidence in prescribing exercise to the patients.

> *"I had to decide after the assessment which exercise I'm going to assign them and I didn't feel comfortable…"I wasn't sure that whatever assessment I have done and the exercise I choose, that's going to make it any better ... I wasn't 100% sure".*

They felt that it was easier to determine and link the exercises for patients who already had obvious abnormalities in their knees such as swelling or when patients were limping.

> *"When there are obviously problems in the knee you can see, you can link what exercise… when you can't see the obvious problems, then it was difficult to determine what exercise you are going to assign"*

The nurse felt more confident and was able to adapt the exercises after delivering several sessions as they became more familiar with the exercises and having received feedback from the patients.

> *"I felt comfortable altering the exercise for them,… knowing that obviously, if it's painful for them then switching to a different exercise."*

However, they felt uncomfortable setting goals and assessing patients' level of confidence for the prescribed exercise.

> *"I couldn't link that, goal setting… I find that part still not comfortable."*

In particular, the nurse found it difficult to motivate and negotiate the goal with each patient further, as they felt that most set high expectations to achieve their goals, whilst patients were scoring their confidence low.

> *"The difficulty is that the goal setting they would expect high but then they when you ask them how likely you are going to achieve this goal their rating will be low… their rating will be like 4 or 5 and how you motivate them to go up to 8 or 7, 8, 9, that one's kind of difficult."*

The nurse delivered the weight loss advice with ease compared with the exercise and managed to explain to every patient why it is good to lose weight where required.

"For the weight loss, you easily do that... I didn't feel too much uncomfortable…so positive from that is that I managed to tell everyone."

The nurse felt it was not difficult to summarise the goal set with every patient at the end of each session.

"Not difficult… we always talked about it, "This is what we discussed today, this is the exercise we have assigned you and if you feel that you can progress further, do so.""

Even though they felt it was not difficult to deliver or incorporate the adjunctive treatments, they occasionally forgot to mention them or felt it was not necessary to repeat this in a subsequent session.

"I do not think it was difficult to ask that or incorporate… it was probably as a human error or that you forgot to mention it…with some patients if you already mentioned once or twice, so with the first session, that if you need to you can use hot and cold therapy, and then they refuse it … then there is no point [mentioning it again]"

The nurse felt that there was a lot of information for the participants to take on board during that first initial assessment session and recommended that the advice could be spread over two or three sessions.

"*I think that session could be divided, erm, the very first one at least in two sessions… so first session, you just get to know the patient and they get their feedback and, don't give them any, too much of a diet and weight loss information"*

Integrating findings: Convergence was found between the fidelity scores and nurse interview (Table 4). The nurse expressed that she did not feel confident in goal setting, which was reflected in the fidelity findings. The nurse felt that education was not always delivered as well in the first session as in the follow-up sessions, which is consistent with the moderate fidelity findings in the first session but with higher fidelity in subsequent sessions. Weight loss advice was delivered with high fidelity and the nurse also felt confident that she was able to deliver weight loss advice fully. A perceived lack of confidence in delivering the exercise component is consistent with fidelity scores for the exercise category that were lower compared with the weight loss category. The adjunctive treatments were not always delivered as intended and that was consistent with the interview findings. Finally, convergence was found for review and planning as the nurse found it easy to summarise patient goals at the end of each session and overall fidelity findings were high. There were no divergent findings.

Table 4. Convergence between observed fidelity and nurse interview findings

Intervention Categories	Overall fidelity (%)*	Qualitative interview findings	Convergence
Overall fidelity score for all categories	*84.2*	*" I find myself that … that I can deliver the care…I was probably more comfortable delivering the intervention…after few sessions"*	Yes
Materials	*100*	*" I had to show them the booklet every patient so I don't think I have forgotten to do that"*	Yes
Introduction	*100*	*"I explain all the study and then explain that whole process again for the purpose of the session"*	Yes
Assessment	*97.8*	*"I would say some of them were easy to find pinpoint the problems…as a nurse we always been asking these questions to patients… in this case but had previous experience in that area"*	Yes
Exercise	86.1	*"We practiced and demonstrated exercises… I felt comfortable altering the exercise for them…I just couldn't think how to link that, erm, goal setting I didn't deliver it good… I don't think I could have delivered it any better than that either… some did actually achieve the goal"*	Yes
Education	*88.3*	*"first few sessions I didn't think of as very good to tell them about the information and then later on, I built that"*	Yes

Weight loss	*92.5*	*"Positive from that is that I managed to tell everyone that, "you need to lose weight", so I think it was kind of structured in a way… I didn't feel too much uncomfortable"*	Yes
Adjunct treatments	*33.3*	*"it was probably as a human error or that you forgot to mention it…with some patients if you already mentioned once or twice so with the first session that you need to you can use hot and cold therapy and then they refuse it and then there is no point"*	Yes
Review and planning	*87.5*	*"Not difficult… we always talked about it this is what we discussed it today this is the exercise we, have assigned you and if you feel that you can progress into further do so"*	Yes

*Overall fidelity scores for the different categories across the four sessions

DISCUSSION

This study evaluated fidelity of delivery of a nurse-led non-pharmacological package of care for knee pain and validated the findings in an interview with the nurse that delivered it. The study was of people with knee pain but none had evidence of inflammatory arthritis and in this age group, OA is the main cause of chronic usage related knee pain. (25) The majority of the non-pharmacological components of the intervention were delivered with good fidelity. Excellent fidelity was found for patient assessment, education, demonstration and advice on exercise and weight loss advice. Components which demonstrated lower fidelity included goal setting and review. These were also perceived as difficult by the nurse. Advice around the use of adjunctive treatments such as the use of hot or cold treatments, walking aids and footwear, were also not delivered as planned. Agreement between the nurse and independent rater was below the cut-off point of 80% for education, exercise, weight loss, adjunctive treatment, and review and planning which is reported as the minimum acceptable agreement between raters in previous research. (26)

Previous studies using mixed methods have found good fidelity of delivery of a physiotherapist-led complex package of care for chronic low-back pain and OA. (20, 27) In our study, the research nurse rated themselves higher than the independent rating using the video recordings. This is consistent with previous studies. (28)

There are several methods to assess treatment fidelity, including direct observation, patient self-report questionnaire, provider self-report checklist and indirect observation using audio or video-recordings. (13) We used a combination of methods as it provides an in-depth fidelity assessment. (27) Direct observation is considered the gold-standard to evaluate fidelity, however it can be intrusive and may affect patient

practitioner interaction, (29, 30) and may not be feasible in large-scale multicentre RCTs. Provider self-report methods are simple and inexpensive but can be inaccurate, (31) and patient report methods are even less reliable. (13) Video-recording the delivery of intervention and independent assessment of fidelity may provide a robust alternative to direct observation. (32) Indeed, (33, 34) it has been shown previously that assessing fidelity using independently rated recordings and provider self-report checklist is feasible and acceptable. (20) We preferred to use video recordings as this is less intrusive than an observer being present, and provides an opportunity to assess reliability, and review the sessions again if needed.

Medical Research Council guidelines for developing and evaluating complex interventions (35) have highlighted the importance of conducting process evaluation. The purpose of this is to assess the quality and quantity of the implementation of intervention, and trials that collect rich qualitative data may identify potential barriers and facilitators to intervention implementation. However, collecting only qualitative or quantitative data to assess treatment delivery would not unearth a comprehensive picture to understand complex constructs within the research outcomes. (23) For this reason, we used a mixed methods approach. (36)

Our study is based on a fidelity checklist that has been previously validated in complex interventions delivered in a research setting. (20) We tailored the checklist according to the intervention and further refined it. Moreover, the reliability of the fidelity checklist was established.

There are a number of limitations to this study. A key caveat is that only one nurse was involved in delivery of the intervention. In a larger trial, there would be more nurses to deliver the intervention across multiple sites, which increases the likelihood of

variation in fidelity between the intervention providers. This study lasted 17 weeks and this is a short period of time over which fidelity would not be expected to fluctuate much. However, this can be an issue with longer studies. (37). A second limitation is a lack of formal assessment of nurse knowledge of managing knee OA. A single research nurse delivered the intervention and was interviewed. In the absence of data from additional participants, categories could not be revised and refined into fully realised themes, however, an inductive approach to analysis was taken to reflect the views of the intervention provider. The intervention was delivered by a research nurse with no background knowledge of musculoskeletal diseases and no previous experience delivering treatment to arthritis patients. This is a particular strength as we were able to assess the effectiveness of our nurse training programme and its shortcomings. Additionally, we video-recorded and evaluated all the consultations that were delivered. One of the key strengths of our study was that we identified the specific components of the categories not delivered as intended. Moreover, we triangulated the findings and found convergence providing internal validity. The nurse was interviewed to address some of the NIHBCC components (study design, provider training) that have not been examined previously. (27)

Complex interventions are often a dynamic interplay between patient and therapist and this is not a package delivered by the nurse and passively received by the patient. Adaptation is a co-creation of the intervention in which therapist behaviour affects patient behaviour and vice versa in order to negotiate goals. (38) Based on the findings, it was challenging to address adaptation and determine the appropriate balance between fidelity and adaptation as the nurse did not feel confident setting goal particularly for exercise. This may be because the weight loss goal was initially set at 5% of body weight, whereas the exercise goal was more flexible and determined with

the participant following the assessment. It appears that confidence, previous knowledge or background, and experience on musculoskeletal diseases delivering the intervention might be associated with intervention adaptation. It would therefore be important for future research to examine whether there is an association between intervention adaptation and nurses' experience or background and confidence. Follow-up training sessions with nurses should also be considered for longer studies to ensure minimal fluctuation of fidelity over time

Our nurse-led delivery of a complex package of care was feasible within a research setting. The research nurse delivered care for patients with knee pain due to OA with high fidelity for most of the components of the intervention except for advice about the use of hot/cold treatments, walking aids, footwear and goal setting. The training package for delivery of the intervention will need to ensure that the nurses are confident in delivering the behavioural change strategies such as goal setting. More training on education, exercise, weight loss, adjunctive treatments, and review and planning should also be undertaken before they score themselves again on the feasibility trial. Future work will need to consider fidelity where there will be more than one nurse delivering the intervention in a clinical setting. Our results, however, show that it is feasible to apply the non-pharmacological package of care in a future feasibility RCT.

LEGENDS

Figure 1. Agreement between nurse-rated and video-rated methods for the individual categories of the intervention

Values shown are % agreement and error bars indicate the 95% CI

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COMPETING INTEREST STATEMENTS

All authors declare no competing interests.

ETHICS APPROVAL

The study received ethical approval by the East Midlands-Derby Research Ethics Committee (REC) (18/EM/0288).

CONTRIBUTORS

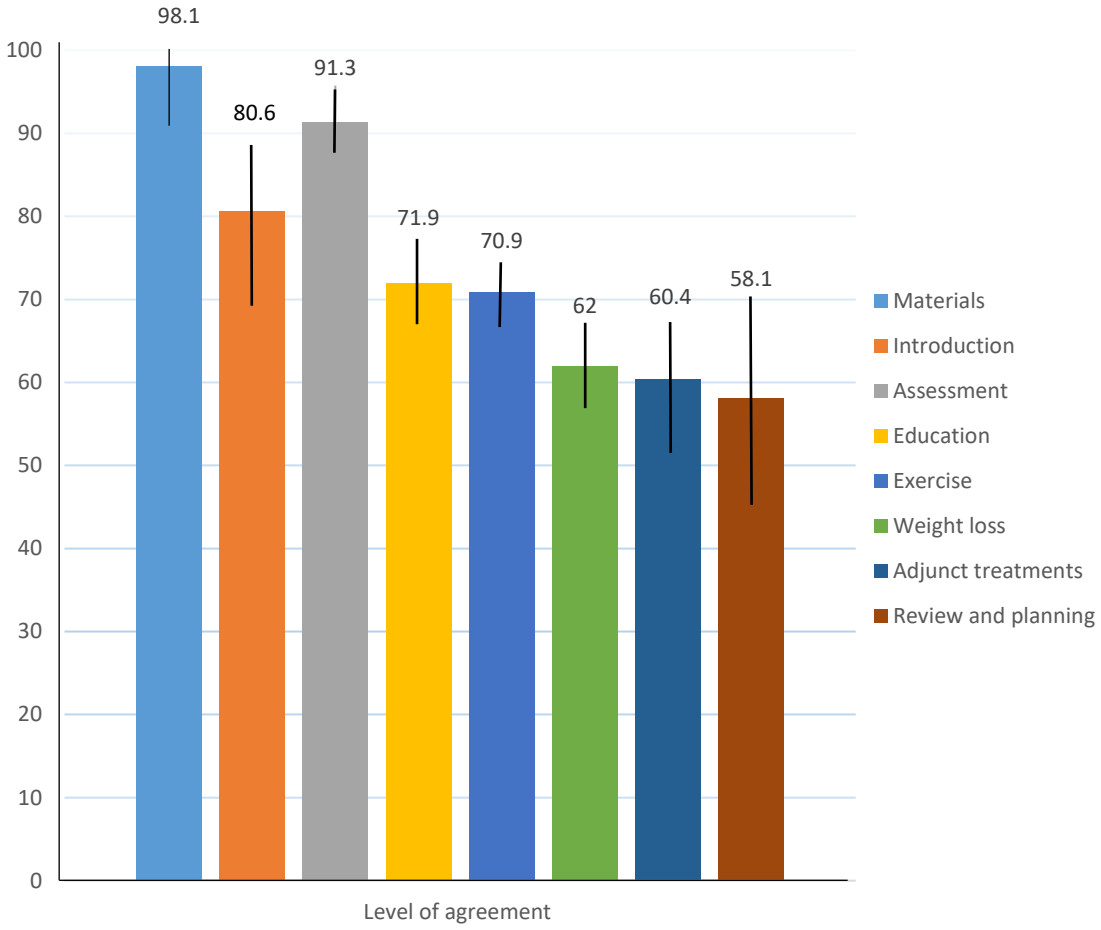
All authors contributed to the design and conception of the study. PAN conducted the quantitative and qualitative data collection and analysis. MH was the independent rater for video assessment of fidelity. AF and RdN provided guidance in the qualitative data collection and analysis. RO, AA and MH provided guidance in the quantitative analysis. BM contributed to the study set up and recruitment. PAN wrote the first draft. All authors have read, provided critical feedback and approved the final manuscript.

PATIENT CONSENT

Obtained

DATA STATEMENT SECTION

TIDieR checklist, quantitative fidelity checklists and interview topic guides have been included as supplementary files. Please email the corresponding author at Polykarpos.nomikos@nottingham.ac.uk whether further information is required.



Additional file 1. Items of the non-pharmacological intervention (TIDieR checklist)

1. Brief name	Non-pharmacological complex intervention comprised of education, exercise, and weight loss advice if required.
2. Aims and Rationale	Development and evaluation of the non-pharmacological treatment component.
3. What was done?	**Training package of the provider**: The content of the package was based on NICE guidelines for the management of OA and a report by Arthritis Research UK on the educational needs of health professionals working with people with OA. The content consisted of a standardised treatment manual. Academic and clinical experts and members of a patient advisory group have provided input into the training package. Their key components were: • The epidemiology and nature of knee pain and knee OA • Assessment of the patient with knee OA • Core NICE guidelines for managing OA • Principles of strengthening and aerobic exercise prescription for knee OA • Information and advice to support weight loss • Strategies to support behaviour change • Pharmacological management of OA and knee pain following a step-wise protocol of optimising analgesia **Mode of delivery:** Four face-to-face individual sessions over a five-week period.

Additional file 1. Items of the non-pharmacological intervention (TIDieR checklist)

4. Who delivered the intervention ?	A trained nurse with no prior knowledge of treating musculoskeletal conditions delivered the non-pharmacological intervention to knee pain people. A rheumatologist and research physiotherapist delivered in total eight sessions of the module over a three-month period.
5. Where was the intervention provided?	Single centre research setting, clinic room, city hospital, Nottingham
6. When and how often or how much of the intervention was provided?	The complex intervention was delivered for up to 1.5 hours in session one and 46 minutes in the follow up sessions. The nurse was endeavoured to provide as much intervention as an individual could tolerate. The amount of the intervention was video recorded.
7. Was the intervention tailored?	Tailoring was built in the intervention. Functional goals were agreed between the nurse and people with knee pain to facilitate exercise prescription. Weight loss goals were agreed with participants who were overweight. The description of the treatment manual highlights procedures for tailoring practice activities. No modifications of the intervention were made during the course of the study.
8. How well was the intervention delivered?	A single research nurse who received training, delivered the intervention and fidelity was assessed by video recording all sessions. After preliminary fidelity analysis, the nurse received additional supervised training to deliver the intervention.

Additional File 2:
Quantitative Fidelity Checklist for non-pharmacological component of intervention

Session 1: **Intervention categories** **individual components**	Completed	Not completed	Partially completed	Not applicable
Materials				
ARUK booklet on OA				
Exercise/activity diary				
Goal Setting forms				
Introduction				
Introductions				
Aim of interventions				
Content				
Structure				
Holistic assessment of person with OA.				
Illness perception of OA explored				
Pain severity explored				
Pain impact on occupation or social activity explored				
Current level of physical activity/ exercise and its intensity explored				
Views and attitudes to weight loss explored (if required)				
Issues with mood explored				
Sleep quality explored				
Support network and caregiver involvement discussed				
Co-morbidities				
Other MSK pain				
Inspection of knee				
Palpation of knee				
Active ROM				
Passive ROM				
Observation of Gait				
Education				
Illness perception of OA addressed				
Nature of OA discussed				
Core treatments for OA addressed				
Rationale for self-management strategies addressed				
Physical Activity /benefits of exercise addressed				
Activity rest cycle/pacing explained				
Reflection on activity/pacing and recommendations discussed				
Participants had the chance to contribute to discussion				
Exercise				
Warm up exercises explained/demonstrated				
Aerobic exercises explained/demonstrated				
Strengthening explained/demonstrated				
Stretching exercises explained/demonstrated				
Participants had the chance to practice prescribed exercises				
Exercise corrected if required				
Smart goals setting				
Action planning to carry out exercise				
Patients' level of confidence for the exercise programme determined				
Barriers and facilitators identified (if confidence low)				
Weight loss (if required)				
Previous efforts to lose weight discussed				

Additional File 2:
Quantitative Fidelity Checklist for non-pharmacological component of intervention

Healthy BMI range and weight loss discussed				
5% weight loss goal calculated with timescale				
Agree weight loss goal				
Action plan for weight loss				
Discuss strategies for weight loss (calorie deficit, portion size, meal planning, tops tips, slimming groups, increasing PA etc)				
Signpost to NHS weight loss plan				
Patients' level of confidence for weight loss goal determined				
Barriers and facilitators identified (if confidence low)				
Adjunct treatments				
Use of heat/cold discussed				
Walking aids discussed				
Footwear discussed				
Review and planning				
Session review: goal setting synopsis and action plan				

Completed = component was fully delivered by the nurse
Not Completed = component was not delivered by the nurse
Partially completed = there was an attempt to deliver this component by the nurse but it was not delivered fully
Not applicable = component was not applicable for example weight loss components if the participant had a body mass index < 25

Additional File 2:
Quantitative Fidelity Checklist for non-pharmacological component of intervention

Follow up session 2, 3: **Intervention categories individual components**	Completed	Not Completed	Partially completed	Not applicable
Assessment				
Pain symptoms since previous visit explored				
Factors influencing pain explored				
Physical activity's levels explored				
Education				
Activity rest cycle/pacing explained				
Individual reflection on activity-rest cycle/pacing facilitated				
Physical activity's levels addressed				
Participants had the chance to contribute to discussion				
Exercise				
Exercise goals and action plan reviewed				
Exercise/activity diary reviewed				
Problem solving of previous weeks action plan				
Previous session exercises reviewed and performed by the participant				
Exercise corrected if required				
Smart goals reviewed				
Strengthening exercises progressed or adapted				
Aerobic exercises progressed or adapted				
Participants had the chance to practice strengthening exercises				
Patients' level of confidence for the exercise programme determined				
Barriers and facilitators carrying out the exercise identified(if confidence low)				
Weight loss (if required)				
Weight loss goal and action plan reviewed				
Weight reviewed				
Action plan updated				
Patients' level of confidence for weight loss goal determined				
Barriers and facilitators identified (if confidence low)				
Adjunct treatments				
Use of heat/cold discussed				
Walking aids discussed				
Footwear discussed				
Review and planning				
Session review: goal setting synopsis and action plan				

Additional File 2:
Quantitative Fidelity Checklist for non-pharmacological component of intervention

Final session: **Intervention categories individual components**	Completed	Not completed	Partially completed	Not applicable
Assessment				
Pain symptoms since previous visit explored				
Factors influencing pain explored				
Physical activity's levels explored				
Education				
Long-term self-management addressed				
Participants had the chance to contribute to discussion				
Exercise				
Exercise goals and action plan reviewed				
Exercise/activity diary reviewed				
Problem solving of previous weeks action plan				
Participants had the chance to attempt and practice previous exercises				
Exercise corrected if required				
Patients' level of confidence for the exercise programme determined				
Barriers and facilitators carrying out the exercise identified (if confidence low)				
Exercises aiming for long term management given				
Weight loss (if required)				
Weight loss goal and action plan reviewed				
Weight reviewed				
Action plan updated				
Patients' level of confidence for weight loss goal determined				
Barriers and facilitators identified (if confidence low)				
Long term action plan for weight loss given				
Review and planning				
Session review – long term goal setting and action planning recap				

Additional file 3. The semi-structured interview guide for the nurse

Nurse's views on experience of delivering the non-pharmacological intervention

We're going to start by discussing your overall views on the knee pain treatment programme, the training you received to deliver it, and then talk about the different components of the intervention separately.

1. Can you tell me what your overall impression of the knee pain treatment programme is, having delivered it for the first time?

Nurse's view of the training received to deliver the non-pharmacological intervention

We are now going to discuss the training you received to deliver this treatment.

2. Can you tell me how you found the training you received
    - Length of training/ number of sessions/ delivery over weeks rather than 2 days condensed
    - Material covered in sessions: too much/too little/about right
    - Opportunities to practice/ feedback
    - Resources/ manual/ electronic material (links to videos)/ links to weight loss resources / exercise sheets/ case-studies

3. How did you find following the manual provided?
    - Probe – reasons for it being easy / difficult to follow.
    - What suggestions do you have to modify the manual to make it easier to use in the future?
    - Any suggestions for improving the training

- How confident did you feel about delivering the treatment once you had completed your training?

Nurse's views on experience of delivering the non-pharmacological intervention

We are now going to discuss how you found delivering the treatment to patients.

4. How did you find delivering this treatment to patients?

- As you know, the treatment package had different components – education on self-managing knee pain, giving the participant exercises, advising them on weight loss, setting individual goals with the participants and assessing patient confidence to achieve goals.
  How did you find delivering these components?

    - [cover ONE at a time]
    - Education
    - Exercise
    - Weight loss
    - Goal setting

Additional file 3. The semi-structured interview guide for the nurse

- Assessing patient confidence to achieve goals
- Using the diaries (exercise and weight loss)

5. How did you find setting goals with patients?
    - Probe - did they actively participate in the discussions?
6. How did you find the follow-up sessions with participants and providing feedback on participants' progress with their exercises and/or weight loss?
    - Prompts - patient receipt of advice / feedback (any challenges with patients accepting advice or adhering to the treatment given)

- Were there any components that you found challenging to implement?
    - What made it challenging to deliver this component? [cover ONE at a time]
    - Were there any other components that you found challenging to implement? Why.
    - What would help support you in delivering this in the future?
- Were any aspects of the intervention not delivered as planned?
    - What were the barriers to delivering [the aspect]? [cover ONE at a time]
    - What would help support you in delivering this in the future?

We are now going to talk about tailoring the treatment to each patient.

7. How did you find the final session with the participants? Did you feel that they would be able to continue with the advice/exercises/weight loss etc independently?

We'd now like to discuss the resources provided to support you delivery the treatment programme.

8. How useful did you find the other resources during the treatment programme?
    - Probe - handouts / training manuals / thera-bands / exercise sheets/ exercise diaries/ NHS weight loss resource (BMI and weigh loss calculator)/ food diaries/ other weight-loss hand outs
    - What suggestions do you have to improve these resources in the future?

Additional file 3. The semi-structured interview guide for the nurse

9. Is there any additional support you need in being able to deliver this treatment?

We have come to the end of the interview. Do you have any further comments about the training and/or treatment package that have not been covered?

Reporting checklist for quality improvement study.

Based on the SQUIRE guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SQUIREreporting guidelines, and cite them as:

Ogrinc G, Davies L, Goodman D, Batalden P, Davidoff F, Stevens D. SQUIRE 2.0 (Standards for QUality Improvement Reporting Excellence): revised publication guidelines from a detailed consensus process

	Reporting Item	Page Number
Title		
#1	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patientcenteredness, timeliness, cost, efficiency, and equity of healthcare)	1

Abstract			
	#02a	Provide adequate information to aid in searching and indexing	3
	#02b	Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions	2,3
Introduction			
Problem description	#3	Nature and significance of the local problem	4
Available knowledge	#4	Summary of what is currently known about the problem, including relevant previous studies	4
Rationale	#5	Informal or formal frameworks, models, concepts, and / or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work	4
Specific aims	#6	Purpose of the project and of this report	4,5
Methods			

Context	#7	Contextual elements considered important at the outset of introducing the intervention(s)	6,7
Intervention(s)	#08a	Description of the intervention(s) in sufficient detail that others could reproduce it	7
Intervention(s)	#08b	Specifics of the team involved in the work	7,8
Study of the Intervention(s)	#09a	Approach chosen for assessing the impact of the intervention(s)	7,8
Study of the Intervention(s)	#09b	Approach used to establish whether the observed outcomes were due to the intervention(s)	7,8
Measures	#10a	Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability	8,9,22,23
Measures	#10b	Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost	9,10
Measures	#10c	Methods employed for assessing completeness and accuracy of data	9
Analysis	#11a	Qualitative and quantitative methods used to draw inferences from the data	8,9,10

Analysis	#11b	Methods for understanding variation within the data, including the effects of time as a variable	8,9
Ethical considerations	#12	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest	28
Results			
	#13a	Initial steps of the intervention(s) and their evolution over time (e.g., time-line diagram, flow chart, or table), including modifications made to the intervention during the project	6,7
	#13b	Details of the process measures and outcome	8,9,10
	#13c	Contextual elements that interacted with the intervention(s)	n/a (the intervention was fully monitored)
	#13d	Observed associations between outcomes, interventions, and relevant contextual elements	12,13
	#13e	Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s).	12,13 16,17,18

	#13f	Details about missing data	n/a (no missing data)
Discussion			
Summary	#14a	Key findings, including relevance to the rationale and specific aims	22
Summary	#14b	Particular strengths of the project	23,24
Interpretation	#15a	Nature of the association between the intervention(s) and the outcomes	22,23
Interpretation	#15b	Comparison of results with findings from other publications	22,23
Interpretation	#15c	Impact of the project on people and systems	n/a (the project determined if it is feasible to apply the non-pharmacological intervention in a feasibility RCT)
Interpretation	#15d	Reasons for any differences between observed and anticipated outcomes, including the influence of context	24
Interpretation	#15e	Costs and strategic trade-offs, including opportunity costs	n/a (The study did not assess cost-effectiveness)
Limitations	#16a	Limits to the generalizability of the work	23

Limitations	#16b	Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis	24
Limitations	#16c	Efforts made to minimize and adjust for limitations	24
Conclusion	#17a	Usefulness of the work	25
Conclusion	#17b	Sustainability	23,24
Conclusion	#17c	Potential for spread to other contexts	23,24
Conclusion	#17d	Implications for practice and for further study in the field	24,25
Conclusion	#17e	Suggested next steps	25
Other information			
Funding	#18	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting	28

Notes:

- 13c: n/a (the intervention was fully monitored)
- 13e: 11,12, 15,16,17

- 13f: n/a (no missing data as all intervention sessions were video recorded)
- 15c: n/a (the project determined if it is feasible to apply the non-pharmacological intervention in a feasibility RCT)
- 15e: n/a (The study did not consider cost-effectiveness) This checklist was completed on 22. September 2020 using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai

BMJ Open

Fidelity assessment of nurse-led non-pharmacological package of care for knee pain in the package development phase of a feasibility randomised controlled trial based in secondary-care: a mixed methods study

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Fidelity assessment of nurse-led non-pharmacological package of care for knee pain in the package development phase of a feasibility randomised controlled trial based in secondary-care: a mixed methods study

Polykarpos Angelos Nomikos[1,2], Michelle Hall[2,3], Amy Fuller[1,2], Bonnie Millar[2,4], Reuben Ogollah[5], Ana M Valdes[2,4], Michael Doherty[1,4], David A Walsh[2,4], Roshan das Nair [6,7], Abhishek Abhishek[1,2]

[1] Academic Rheumatology, University of Nottingham, Nottingham, UK

[2] NIHR Nottingham Biomedical Research Centre, University of Nottingham, Nottingham, UK

[3] School of Health Sciences, University of Nottingham, Nottingham, UK

[4] Pain Centre Versus Arthritis, University of Nottingham, Nottingham, UK

[5] Nottingham Clinical Trials Unit, University of Nottingham, Nottingham, UK

[6] Institute of Mental Health, University of Nottingham, Nottingham, UK

[7] Division of Psychiatry & Applied Psychology, University of Nottingham, Nottingham, UK

Corresponding author:

Polykarpos Angelos Nomikos

A 26 Clinical Sciences Building

Nottingham City Hospital

Hucknall Road

Nottingham

NG5 1PB

UK

E-mail address: Polykarpos.nomikos@nottingham.ac.uk

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ABSTRACT

Objectives: To evaluate fidelity of delivery of a nurse-led non-pharmacological complex intervention for knee pain.

Setting: Secondary care. Single centre study.

Study design: Mixed methods study.

Participants: Eighteen adults with chronic knee pain.

Inclusion criteria: Age > 40 years, knee pain present for longer than 3 months, knee pain for most days of the previous month, at least moderate pain in two of the five domains of Western Ontario and McMaster Universities Osteoarthritis Index pain scale.

Interventions: Nurse-led non-pharmacological intervention comprising assessment, education, exercise, use of hot/cold treatments, footwear modification, walking aids, and weight-loss advice (if required).

Outcome(s): Primary: Fidelity of delivery of intervention, Secondary: nurses' experience of delivering intervention.

Methods: Each intervention session with every participant was video recorded and formed part of fidelity assessment. Fidelity checklists were completed by the research nurse after each session and by an independent researcher, after viewing the video-recordings blinded to nurse ratings. Fidelity scores (%), percentage agreement and 95% Confidence Intervals (CI) were calculated. Two semi-structured interviews were conducted with the research nurse.

Results: Fourteen participants completed all visits. 62 treatment sessions took place. Nurse self-report and assessor video rating scores for all 62 treatment sessions were

included in fidelity assessment. Overall fidelity was higher on nurse self-report (97.7%) than on objective video-rating (84.2%). Percentage agreement between nurse self-report and video-rating was 73.3% (95% CI: 71.3 - 75.3). Fidelity was lowest for advice on footwear and walking aids. The nurse reported difficulty advising on thermal treatments, footwear and walking aids, and did not feel confident negotiating achievable and realistic goals with participants.

Conclusions: A trained research nurse can deliver most components of a non-pharmacological intervention for knee pain to a high degree of fidelity. Future research should assess intervention fidelity in a routine clinical setting, and examine its clinical and cost-effectiveness.

Trial registration number: NCT03670706

KEY WORDS: Knee pain, fidelity, nurse-led intervention, osteoarthritis

STRENGTHS AND LIMITATIONS OF THE STUDY

- This mixed methods study used a combination of techniques to assess treatment fidelity.
- We triangulated the fidelity scores with the findings from interview study and found convergence providing internal validity.
- We identified the components not delivered as intended.
- A single nurse was involved in delivery of the intervention
- Lack of formal assessment of nurse knowledge of managing knee osteoarthritis.

INTRODUCTION

Osteoarthritis (OA) is the commonest form of arthritis and is managed predominantly in primary care in the UK. The knee is commonly affected, with approximately one in four adults over the age of 50 years in the UK self-reporting chronic knee pain, defined as pain for 3-months or longer within the previous 12 months. [1] In the presence of activity related joint pain, no or minimal morning stiffness, and age >= 45 years, a clinical diagnosis of OA may be reached without the need of investigations (e.g. blood tests or radiography) as per the National Institute for Health and Care Excellence (NICE) guidelines. [2] These guidelines [2] also recommend a patient-centred approach when managing OA, with a focus on non-pharmacological interventions including education, strengthening, and aerobic exercise, and weight loss if required. However, this can be difficult for general practitioners (GPs) to deliver for several reasons such as time constraints and, core non-pharmacological treatments are under-utilised. [3 4] Nurse-led care gives similar or better outcomes than GP-led care for other chronic diseases. [5-8] However, the fidelity of delivery of nurse-led care has not been examined for the management of knee OA.

Fidelity, defined as the degree to which an intervention is delivered as intended, [9] regulates the relationship between interventions and outcomes, and determines the extent to which an intervention affects the outcome. [10] Inferences regarding treatment effect of a complex intervention should therefore not be made without assessing fidelity, because lack of efficacy of an intervention may be due to inadequate implementation. [11] Thus, the fidelity of intervention delivery influences the internal and external validity of a study. [12] If fidelity is not assessed, effective interventions may be rejected due to poor delivery. [13 14]

There are several methods to assess treatment fidelity, including direct observation, patient self-report questionnaire, provider self-report checklist, and indirect observation using audio or video-recordings. [13], which may be used singularly or in combination. Direct observation is considered the gold-standard, however, it can be intrusive and may affect patient practitioner interaction, [15 16] and may not be feasible in large randomised controlled trials (RCTs). Provider self-report methods are simple and inexpensive but can be inaccurate, [17] and patient report methods are even less reliable. [13] Video-recording the delivery of intervention and independent assessment of fidelity may provide a robust alternative to direct observation. [18] Indeed, [19 20] it has been shown previously that assessing fidelity using independently rated recordings and provider self-report checklist is feasible and acceptable. [21] A combination of provider self-report and independent assessed video recording was utilised in the current study to provide an in-depth fidelity assessment. [22] Video recordings were chosen as this is less intrusive than direct observation and provide an opportunity to assess reliability.

Medical Research Council guidelines for developing and evaluating complex interventions [23] have highlighted the importance of conducting process evaluation. Its' purpose is to assess the quality and quantity of the implementation of intervention, and trials that collect rich qualitative data may identify potential barriers and facilitators to intervention implementation. However, collecting only qualitative or quantitative data to assess treatment delivery would not unearth a comprehensive picture to understand complex constructs within the intervention. [24] For this reason, a mixed methods approach was utilised. [25]

The present study is part of the East-Midlands Knee Pain Cohort RCT study, [26] the overall purpose of which is to evaluate the feasibility of a nurse-led package of care

for knee pain due to OA. The objective of the present study was to evaluate the fidelity of delivery of a nurse-led non-pharmacological package of care for knee pain during the package development phase of the RCT.

METHODS

Study Design: A mixed methods study with an explanatory sequential and convergent design. This form of mixed methods approach was used to produce additional insights of the issue at hand. In this design, qualitative and quantitative data are collected and complementary results arise from the use of different methods. [27] In the current study, the quantitative data informed the collection of qualitative data and a convergence approach was followed.

Setting: Academic Rheumatology, City Hospital Nottingham.

Participants and Recruitment: The participants were adults self-reporting knee pain. Community dwelling adults participating in the Investigating Musculoskeletal Health and Wellbeing (IMHW) cohort, [28] self-reporting knee pain were sent a postal invitation to participate in this study. People who responded underwent telephone screening to assess eligibility. The inclusion criteria were: age>40 years, ability to read and write in English, knee pain present for longer than three months, pain in or around the knee on most days of the previous month, and at least moderate pain in two of the five domains of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain scale. [29]

Research nurse training: A training programme to enable a nurse to deliver the current NICE guidelines for OA management was developed and an educational manual produced. [26] The training included face-to-face learning, case-studies, on-line resources and simulated patients. Practical sessions on assessing the participant, delivering and modifying exercise, weight loss advice and use of strategies to encourage adherence were also included. The nurse delivering the intervention was working as a research nurse previously and did not have prior knowledge of musculoskeletal diseases, had not worked in rheumatology or allied specialties such

as orthopaedics, rehabilitation or sports medicine, and had never delivered treatments for arthritis.

Patient and Public Involvement: Three PPI members with hip and/or knee OA provided input into the content of the non-pharmacological treatment package, and volunteered for nurse training. They advised that video recording of treatment sessions would be acceptable to participants.

Intervention: The template for intervention description and replication (TIDieR) checklist [30] has been used to describe the intervention and its key features (Additional file 1). In brief, the intervention consisted of a holistic assessment of the participant, providing education about the nature of OA and self-management strategies including advice on the role of exercise, maintaining a healthy weight, and use of adjunctive treatments such as application of heat or cold, foot-wear modification and use of walking aids. At the first visit, the nurse took a medical history, examined the knee joints and explained to the participant that they had knee pain due to OA. Investigations and radiographs were not undertaken as per NICE guidelines. [2] The Chief Investigator (AA) was available for advice if a clinical diagnosis of OA could not be reached. In that case, the participant would be deemed ineligible for the study. All participants were given an Arthritis Research UK leaflet on knee OA. The nurse explained aerobic and strengthening exercises and advised each participant on an individualised regimen that was mutually agreed. If required, weight-loss advice was provided. Behaviour change strategies [31] such as goal setting, action planning, assessment of participant confidence to achieve goals, discussion of barriers and facilitators and the use of exercise diaries were used to improve adherence. Functional goals were agreed and were used to facilitate the exercise prescription with goals being Specific, Measurable, Achievable, Relevant, and Timely (SMART). SMART

weight loss goals were agreed also with overweight participants. The intervention is described in more detail in the protocol. [26] After the training period, the nurse delivered the intervention in four sessions over a five-week period.

Ethical approval: The study received ethical approval by the East Midlands-Derby Research Ethics Committee (REC) (18/EM/0288).

Consent: All study participants including the research nurse gave their written informed consent prior to treatment delivery, including the consent to video record the sessions. Participants had the right to pause or stop the video recording at any point without giving any reasons.

Fidelity assessment: The study followed the National Institutes of Health Behaviour Change Consortium (NIHBCC) guidelines for fidelity assessment. [13] The fidelity checklist was developed a priori [26] and comprised eight components, each with specific tasks: materials; introduction; assessment; education; exercise; weight loss; advice on adjunctive treatments; and review and planning. However, not all components of the intervention were intended to be delivered in each session. [26] For example, advice on the adjunctive treatments could be provided in any of the four sessions. The fidelity checklist was iteratively developed using a five-step methodology. [32] These were: reviewing previous measures, analysing intervention components and developing an intervention framework (intervention manual), developing the fidelity checklist, obtaining feedback about the content and wording of checklist and piloting and refining the checklist to assess and improve reliability. The responses of the fidelity checklist were categorical and rated as completed, partially completed, not completed, or not applicable. Partially completed scores were given for any task that was not delivered to the full extent in the context of that particular

consultation. The scoring criteria of the fidelity checklist followed that of previous published strategies for assessing fidelity in RCTs of complex interventions. [33]

Eighteen participants received the non-pharmacological intervention and all (n=62) sessions were video-recorded. After every session with the participant, the nurse completed the fidelity checklist. Sixty-two checklists, 18 for session 1, 16 for session 2 and 14 each for sessions 3 and 4 were completed. Blinded to the nurse ratings, the video-recording of every session was independently reviewed and rated by PAN. A second-rater (MH) independently rated 20% (n=12) of the sessions. Both raters were familiar with the intervention. The refinement, reliability, and feasibility of the fidelity checklist was established during the initial phases of the data collection process.

Quantitative data analysis: Mean and standard deviation (SD), median and inter quartile range (IQR), and n (%), were calculated for descriptive purposes. Within a component, tasks rated as 'completed' were given a score of 2, 'partially completed' a score of 1, and not completed, a score of zero. To obtain fidelity score for a component of the intervention, individual scores for each task within the component were added and divided by the maximum possible score for that component and converted to a percentage. Any tasks that were rated as not-applicable, were excluded from the calculation.

Median fidelity scores (%) and IQR were calculated for the entire intervention, per participant, per session and per component of the intervention. Fidelity was classified as previously reported: 80-100% 'high', 51-79% 'moderate', and 0-50% 'low' fidelity. [34] Where fidelity was moderate or low in a particular component, we further explored this by examining the fidelity of delivery of the individual tasks.

Percentage agreement with 95% confidence intervals (CI) was used to estimate the level of agreement between self-report and video-record methods, and for inter-rater agreement.

Qualitative phase: One week after the final session, the nurse took part in a semi-structured interview conducted by PAN (PhD student) and AF (trained qualitative researcher). The interview guide (Additional file 2) contained open-ended questions developed by the study team, which included a rheumatologist (AA), physiotherapists (MH, PAN), psychologist (RdN), and qualitative researcher (AF). The guide covered the nurse's view on their training, confidence in and experience of delivering the individual components of the non-pharmacological intervention, perceived barriers to delivering it as planned, and opportunities to improve the non-pharmacological package of care. An iterative process was used for data collection, so an additional interview was conducted 45 weeks later to capture any salient points raised from the initial quantitative and qualitative data collected.

Before starting the interview, it was explained that the nurse's responses would remain confidential and that any quotes included in future publications would not identify them. The nurse was informed of the right to withdraw from the interview at any time. We have not provided demographic details in order to protect the anonymity of the individual nurse. All interviews were conducted in a private room in Academic Rheumatology, City Hospital, Nottingham. The qualitative findings were mapped onto the fidelity checklist to assess convergence between the quantitative and qualitative findings. Any areas of uncertainty or gaps were then explored in the second interview with the nurse.

Qualitative data analysis: The interviews were transcribed verbatim by an external transcription company. The interviewer removed any identifiers and ensured transcripts were accurate. Transcripts were analysed following the principles of the general inductive approach. [35] The latter is a simple straightforward approach, which is used to derive findings from raw qualitative data, condense them into a brief summary format, and link the research objectives with the summary findings.

The first transcript was read several times before data related to the research objectives was identified, labelled and categorised. The categories were discussed between the interviewer and a second researcher (AF). This process identified gaps and led to the second interview and the transcript was analysed in the same way. Following agreement that the categories reflected the overall account reported by the nurse, extracts were taken from the transcripts to exemplify the findings.

Convergence: A meta-matrix was developed to explore convergence between the findings. This approach enhances study validity by increasing the probability that our findings and interpretations are credible and reliable. [24] Convergence was defined as agreement between both sets of data, and discrepancy as disagreement between them.

Reporting guidelines: The Standards for Quality Improvement Reporting Excellence (SQUIRE) guidelines [36] were used to improve the quality of reporting of this study.

RESULTS

Quantitative findings:

Eighteen participants (33% women) with knee pain for longer than 3 months, with a mean age of 68.7 (SD 9.0) years and body mass index of 31.2 (SD 8.4) kg/m^2 respectively took part in the study. Of these, fourteen completed all four visits. The reasons for dropping out were other commitments (n=3), reluctance to lose weight (n=1) and inadequate understanding of the nature of the intervention (n=1).

In total, 62 intervention sessions were delivered. The median (IQR) duration of the initial and follow-up sessions was 87 (81–101) and 46 (37–52) minutes respectively. Overall fidelity was rated high for both nurse self-report (97.7%) and video-rated scores (84.2%) (Tables 1, 2). Inter-rater agreement for the video-recording checklist was 70.3% (95%CI 64.4, 74.2).

For the nurse self-report checklist, median fidelity scores for each session ranged from 94.4-100% (Table 1). Individual components received high ratings except for adjunctive treatments i.e. use of heat/cold therapy and advice on footwear where the fidelity score was moderate in many sessions.

For the video-rated checklists, overall median fidelity scores for each session ranged from 77.7-87.2% (Table 2). Fidelity for education was lower in the first session (78.1%, IQR 74.1, 93.8) but increased in the follow-up session (87.5%, IQR 50,100). Fidelity for review and planning was lower in the first and last sessions. Fidelity scores were low for adjunctive treatments across all sessions, and varied from 0% to 50%. Fidelity of delivery for exercise goal-setting was moderate at 66% and, fidelity for reviewing goals during follow-up sessions was low, ranging between 44-50%. Additionally,

assessment of patients' level of confidence to achieve their exercise goal was low in the follow-up sessions, ranging between 7-40%.

The overall agreement between nurse-rated and video-rated methods was 73.3% (95% CI 71.3 - 75.3). The level of agreement for individual components is shown in Figure 1. Excellent agreement was found for materials, introduction, and assessment. Agreement was below the cut-off point of 80% for education, exercise, weight loss and adjunctive treatment. The level of agreement for review and planning component was 58.1% (95% CI 44.8, 70.5). For individual participants, overall fidelity across the four sessions ranged from 75% to 100% indicating that for most patients the intervention was delivered as intended (Table 3).

Table 1. Nurse self-reported fidelity scores [1]

Intervention component	Session1 (n=18)*	Session 2 (n=16)*	Session 3 (n=14)*	Session 4 (n=14)*
Materials	100 (100, 100)	-	-	-
Introduction	100 (100, 100)	-	-	-
Assessment	100 (98.3, 100)	100 (100, 100)	100 (100, 100)	100 (100, 100)
Education	100 (100, 100)	100 (100, 100)	100 (100, 100)	100 (100, 100)
Exercise	100 (97.5, 100)	100 (100, 100)	100 (97.5, 100)	100 (75, 100)
Weight loss	100 (88.9, 100)	100 (100, 100)	100 (66.7, 100)	100 (79.2, 100)
Adjunct treatments	87.5 (33.3 100)	87.5 (0, 100)	66.7 (45.8, 100)	-
Review and planning	100 (100, 100)	100 (100, 100)	100 (100, 100)	100 (100, 100)

[1]Values are median% (IQR)

*Number of sessions

Table 2. Fidelity scores using video-recordings of the sessions[1]

Intervention Component	Session 1 (n=18)*	Session 2 (n=16)*	Session 3* (n=14)*	Session 4 (n=14)*
Materials	100 (100, 100)	-	-	-
Introduction	100 (75, 100)	-	-	-
Assessment	91.4 (85, 93.3)	100 (100, 100)	100 (100, 100)	100 (100, 100)
Education	78.1 (74.1, 93.8)	87.5 (50, 100)	87.5 (50, 100)	100 (93.8, 100)
Exercise	94.4 (88.9, 100)	88.9 (75, 94.4)	86.1 (72, 100)	75 (67.6, 82.8)
Weight loss	100 (87.5, 100)	90 (60, 100)	100 (68.9, 100)	80 (49.2, 100)
Adjunct treatments	50 (45.8, 100)	0 (0, 50)	50 (0, 100)	-
Review and planning	75 (75, 100)	100 (100, 100)	100 (100, 100)	75 (37.5, 100)

[1]Values are median% (IQR),

*Number of sessions

Table 3. Fidelity scores assessed using video-recordings across participants[1]

Participant number	Overall sessions
Participant 1	88.9 (75, 100)
Participant 2	83.3 (41.7, 100)
Participant 3	100 (67.5, 100)
Participant 4*	96.7 (88.9, 100)
Participant 5	75 (45, 100)
Participant 6	100 (80, 100)
Participant 7	100 (89.9, 100)
Participant 8*	100 (95.8, 100)
Participant 9	92.9 (50, 100)
Participant 10	93.7 (77.5, 100)
Participant 11*	75 (50, 97.2)
Participant 12	73.8 (18.8, 100)
Participant 13	100 (67, 100)
Participant 14	100 (79, 100)
Participant 15	85 (56, 100)
Participant 16	100 (75, 100)
Participant 17	100 (80, 100)
Participant 18*	100 (81, 100)

[1]Values are median% (IQR)

*Participants dropped out. The percentage fidelity score is calculated using scores from the sessions attended.

Qualitative findings:

The duration of the initial and follow-up interview with the nurse was 94 minutes, and 34 minutes respectively. The nurse reported feeling nervous when delivering the intervention for the very first time, but felt more comfortable as the sessions progressed.

> *"Very nervous… to start with... I don't think after a few sessions I was uncomfortable, I was probably more comfortable delivering the intervention…after few sessions, got better at getting feedback from patient as well so I think that boosted my confidence".*

The nurse felt that patient assessment was easy to deliver considering their previous experience of assessing patients for other diseases.

> *"I would say some of them were easy to find pinpoint the problems…as a nurse we always been asking these questions to patients… in this case but had previous experience in that area"*

The nurse felt that education was not always delivered as well in the first few sessions as in the follow-up sessions. They felt that there was a lot of information for the participants to take on board during that first initial assessment session and recommended that the advice could be spread over two or three sessions.

> *"First few sessions I didn't think of as very good to tell them about the information and then later on, I built that …"*

> "*I think that session could be divided, erm, the very first one at least in two sessions… so first session, you just get to know the patient and they get their*

feedback and, don't give them any, too much of a diet and weight loss information"

The nurse described how they initially lacked confidence in prescribing exercise, which was a new skill, to the patients.

"I had to decide after the assessment which exercise I'm going to assign them and I didn't feel comfortable…"I wasn't sure that whatever assessment I have done and the exercise I choose, that's going to make it any better ... I wasn't 100% sure".

On the other hand, it was easier to determine and link the exercises for patients who already had obvious problems in their knees.

"When there are obviously problems in the knee you can see, you can link what exercise… when you can't see the obvious problems, then it was difficult to determine what exercise you are going to assign"

They felt more confident and were able to adapt the exercises as they became more familiar with the exercises and having received feedback from the patients.

"I felt comfortable altering the exercise for them,… knowing that obviously, if it's painful for them then switching to a different exercise."

The nurse delivered the weight loss advice with ease compared with the exercise and was able to explain to patients why it is good to lose weight where required.

"For the weight loss, you easily do that... I didn't feel too much uncomfortable…so positive from that is that I managed to tell everyone."

Even though they felt it was not difficult to deliver or incorporate the adjunctive treatments, they occasionally forgot to mention them or felt it was not necessary to repeat this in a subsequent session.

> *"I do not think it was difficult to ask that or incorporate… it was probably as a human error or that you forgot to mention it…with some patients if you already mentioned once or twice, so with the first session, that if you need to you can use hot and cold therapy, and then they refuse it … then there is no point [mentioning it again]"*

The nurse found it challenging to negotiate realistic goals with some patients, especially those who had high expectations but rated their confidence in achieve their goals as low.

> *"The difficulty is that the goal setting they would expect high but then they when you ask them how likely you are going to achieve this goal their rating will be low… their rating will be like 4 or 5 and how you motivate them to go up to 8 or 7, 8, 9, that one's kind of difficult."*

However, the nurse was able to reduce the expectation that was initially set for that particular goal for those patients.

> *"Obviously there was a previous goal…yes would reduce the expectation when they came back, I would be able to do this, so I am sure you would be able to see through the videotape"*

Integrating findings: Convergence was found between the fidelity scores and nurse interview (Table 4). The excellent fidelity scores for the holistic assessment by the nurse was reflected in their confidence of assessing patients more generally. The moderate fidelity findings for education in the first session that increased in subsequent sessions was confirmed by the nurse and explained in terms of moderating the amount of information that was given to participants in the first session. Weight loss advice was delivered with high fidelity and the nurse also felt confident in being able to deliver weight loss advice fully. A perceived lack of confidence in delivering the exercise component is consistent with lower fidelity scores for the exercise component. The adjunctive treatments were not always delivered as intended and that was consistent with the interview findings. Goal setting was challenging for the nurse which was reflected in the fidelity findings. Finally, convergence was found for review and planning as the nurse found it easy to summarise patient goals at the end of each session. There were no divergent findings.

Table 4. Convergence between fidelity observed using video recordings and the results from the semi-structured nurse interview

Intervention components	Median (%) IQR fidelity *	Qualitative interview findings	Convergence
All components	*84.2*	*" I find myself that … that I can deliver the care…I was probably more comfortable delivering the intervention…after few sessions"*	Yes
Materials	*100 (100, 100)*	*" I had to show them the booklet every patient so I don't think I have forgotten to do that"*	Yes
Introduction	*100 (75, 100)*	*"I explain all the study and then explain that whole process again for the purpose of the session"*	Yes
Assessment	*100 (100, 100)*	*"I would say some of them were easy to find pinpoint the problems…as a nurse we always been asking these questions to patients… in this case but had previous experience in that area"*	Yes
Exercise	*88.9 (72.7, 94.4)*	*"We practiced and demonstrated exercises… I felt comfortable altering the exercise for them…I just couldn't think how to link that, erm, goal setting I didn't deliver it good… I don't think I could have delivered it any better than that either… some did actually achieve the goal"*	Yes
Education	*87.5 (74.1, 100)*	*"first few sessions I didn't think of as very good to tell them about the information and then later on, I built that"*	Yes

Weight loss	*100 (77.8, 100)*	*"Positive from that is that I managed to tell everyone that, "you need to lose weight", so I think it was kind of structured in a way… I didn't feel too much uncomfortable"*	Yes
Adjunct treatments	*50 (0, 50)*	*"it was probably as a human error or that you forgot to mention it…with some patients if you already mentioned once or twice so with the first session that you need to you can use hot and cold therapy and then they refuse it and then there is no point"*	Yes
Review and planning	*100 (25, 100)*	*"Not difficult… we always talked about it this is what we discussed it today this is the exercise we, have assigned you and if you feel that you can progress into further do so"*	Yes

*Median fidelity scores of the individual components across the four sessions

DISCUSSION

This study evaluated fidelity of delivery of a nurse-led non-pharmacological package of care for knee pain due to OA and validated the findings in an interview with the nurse that delivered it. The majority of the non-pharmacological components of the intervention were delivered with good fidelity. Excellent fidelity was found for patient assessment, education, demonstration and advice on exercise and weight loss advice. Tasks that demonstrated lower fidelity within the exercise component included goal setting and review. These were also perceived as difficult by the nurse. Advice around the use of adjunctive treatments such as the use of hot or cold treatments, walking aids and footwear, were also not always delivered as planned. Agreement between the nurse and independent rater was below the cut-off point of 80% for education, exercise, weight loss, adjunctive treatment, and review and planning, which is reported as the minimum acceptable agreement between raters. [37] Fidelity scores across different participants were high overall with the lowest score being 74%.

To the authors' knowledge, this is the first study that has assessed fidelity of a nurse-led non-pharmacological intervention for knee pain due to OA and integrated the findings. Our study is based on a fidelity checklist that has been previously validated in complex interventions delivered in a research setting. [21] We tailored the checklist according to the intervention and further refined it. Moreover, the reliability of the fidelity checklist was established when two independent viewers scored the video recordings of the sessions.

From the interview transcripts, factors that influenced fidelity of delivery are identified. The nurse was less confident to identify appropriate patient goals and prescribe exercise in the first few sessions, but this improved thereafter. This is not a barrier per

se, but suggests that some further training and additional support for nurses in this new role would be needed to ensure fidelity at the start of the study. The nurse was able to draw on her previous experience working with other patient groups to discuss and assess complex issues. Nurse's previous experience assessing patients, therefore, facilitated fidelity of delivery. Although the fidelity for education appeared to be lower in the first session this was because the nurse recognised and responded that participants were being given a lot of information. These findings are not surprising as we aimed to train a nurse with no prior experience of managing musculoskeletal diseases to deliver a complex non-pharmacological package of care for knee pain. Where the nurse identified difficulties in delivering the intervention as intended, she was able to seek additional advice and training from MH. This experience has allowed us to further improve the nurse training programme for use in the feasibility RCT.

Previous studies using mixed methods have explored factors that influenced fidelity and found good fidelity of delivery of a physiotherapist-led complex package of care for chronic low-back pain and OA. [21 22] They report on the factors that influenced fidelity on three levels: provider, participant and programme. Williams *et al* [38] demonstrated good fidelity of delivery of a walking intervention when delivered by nurses and healthcare assistants in primary care. Even though they used a mixed methods approach to assess fidelity, they did not integrate the findings. In our study, the research nurse rated themselves higher than the independent rating using the video recordings consistent with previous studies. [32 39] Similar findings on barriers and facilitators to deliver the intervention have been identified in a complex intervention for people with dementia and chronic low back pain. [22 32] In fact, Walton *et al* [32] extended over the factors that influenced fidelity of delivery reported by Toomey *et al* [22] and recognised that knowledge, providers' attributes, ease of adaptation of the intervention

in relation to participants' needs influenced fidelity. Based on the findings, it was challenging to address adaptation and determine the appropriate balance between fidelity and adaptation in this study. This may indicate some key overlapping themes that may limit fidelity of delivery despite the different types of intervention and conditions.

There are a number of limitations to this study. A key caveat is that only one nurse was involved in delivery of the intervention. In a larger trial, there would be more nurses to deliver the intervention across multiple sites, which increases the likelihood of variation in fidelity. This study lasted 17 weeks and this is a short period of time over which fidelity may not fluctuate much. However, this can be an issue with longer studies. [40]. The nurse who delivered the intervention was interviewed but in the absence of data from additional participants, emerging categories could not be revised and refined into fully realised themes, however, an inductive approach to analysis was taken to reflect the views of the intervention provider. A second interview with the nurse was conducted to capture any salient points not discussed during the first interview. We did not consider to capture engagement of the participants in the study. Complex interventions are often a dynamic interplay between patient and healthcare professionals. Whilst checklists can be helpful in determining whether an intervention has been delivered they do not allow for or capture the flexibility that is required when tailoring an intervention to the individual.

The intervention was delivered by a research nurse with no background knowledge of musculoskeletal diseases and no previous experience delivering treatment for arthritis. This is a particular strength as we were able to assess the effectiveness of our nurse training programme and its shortcomings. Additionally, we video-recorded and evaluated all the consultations that were delivered. One of the key strengths of

our study was that we identified the specific components of the intervention not delivered as intended. Moreover, we triangulated the findings and found convergence providing internal validity. The nurse was interviewed to address some of the NIHBCC components (study design, provider training) that have not been examined previously.[22]

In conclusion, we found that nurse-led delivery of a complex package of care is feasible within a research setting. The research nurse delivered care for patients with knee pain due to OA with high fidelity for most of the components of the intervention except for advice about the use of hot/cold treatments, walking aids, footwear and goal setting. We believe that upskilling nurses to deliver complex non-pharmacological components for the management of knee pain due to OA is feasible. Nurses would have more time to spend with patients and educate them about the condition. The training package for delivery of the intervention will need to ensure that the nurses are confident in delivering the behavioural change strategies such as goal setting. Follow-up training sessions and support during the start of the feasibility when nurses are first delivering the intervention may be helpful in order to improve confidence and delivery. Future work will need to consider fidelity where there will be more than one nurse delivering the intervention in a clinical setting where other factors will also influence fidelity. Our results, nevertheless, show that it is feasible to apply the non-pharmacological package of care in a future feasibility RCT.

LEGENDS

Figure 1. Agreement between nurse-rated and video-rated methods for the components of the intervention Values shown are % agreement and error bars indicate the 95% CI

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COMPETING INTEREST STATEMENTS

All authors declare no competing interests.

ETHICS APPROVAL

The study received ethical approval by the East Midlands-Derby Research Ethics Committee (REC) (18/EM/0288).

CONTRIBUTORS

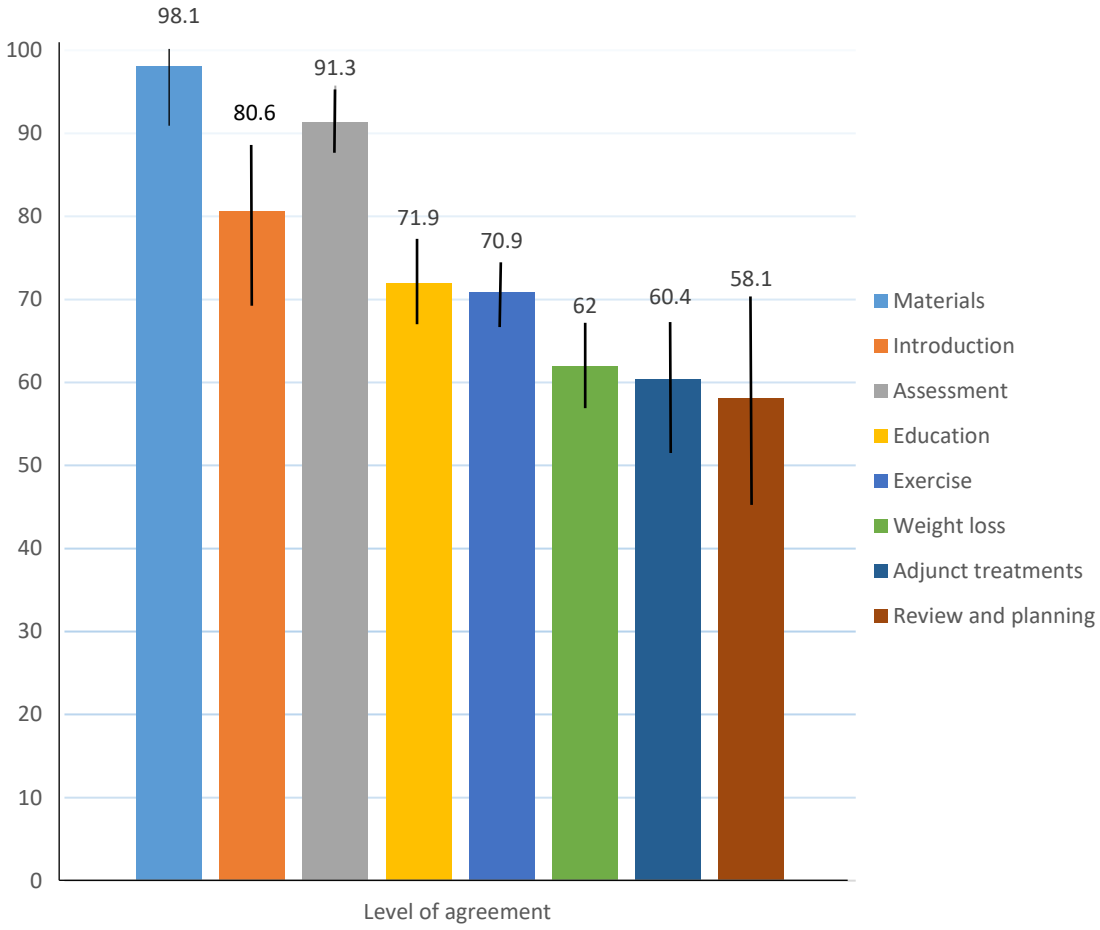
PAN, MH, AF, BM, RO, AMV, RdN, MD, DAW, and AA contributed to the design and conception of the study. PAN conducted the quantitative and qualitative data collection and analysis. MH was the independent rater for video assessment of fidelity. AF and RdN provided guidance in the qualitative data collection and analysis. RO, AA and MH provided guidance in the quantitative analysis. BM contributed to the study set up and recruitment. PAN wrote the first draft. PAN, MH, AF, BM, RO, AMV, RdN, MD, DAW, and AA have read, provided critical feedback and approved the final manuscript. PAN has access to qualitative and quantitative data and vouches to the accuracy of data analysis.

PATIENT CONSENT

Obtained

DATA STATEMENT SECTION

TIDieR checklist, and interview topic guides have been included as supplementary files. Quantitative fidelity checklists are included as supplementary files in the published protocol. Please email the corresponding author at Polykarpos.nomikos@nottingham.ac.uk whether further information is required.



Additional file 1. Items of the non-pharmacological intervention (TIDieR checklist)

1. Brief name	Non-pharmacological complex intervention comprised of education, exercise, and weight loss advice if required.
2. Aims and Rationale	Development and evaluation of the non-pharmacological treatment component.
3. What was done?	**Training package of the provider**: The content of the package was based on NICE guidelines for the management of OA and a report by Arthritis Research UK on the educational needs of health professionals working with people with OA. The content consisted of a standardised treatment manual. Academic and clinical experts and members of a patient advisory group have provided input into the training package. Their key components were: • The epidemiology and nature of knee pain and knee OA • Assessment of the patient with knee OA • Core NICE guidelines for managing OA • Principles of strengthening and aerobic exercise prescription for knee OA • Information and advice to support weight loss • Strategies to support behaviour change • Pharmacological management of OA and knee pain following a step-wise protocol of optimising analgesia **Mode of delivery:** Four face-to-face individual sessions over a five-week period.

Additional file 1. Items of the non-pharmacological intervention (TIDieR checklist)

4. Who delivered the intervention ?	A trained nurse with no prior knowledge of treating musculoskeletal conditions delivered the non-pharmacological intervention to knee pain people. A rheumatologist and research physiotherapist delivered in total eight sessions of the module over a three-month period.
5. Where was the intervention provided?	Single centre research setting, clinic room, city hospital, Nottingham
6. When and how often or how much of the intervention was provided?	The complex intervention was delivered for up to 1.5 hours in session one and 46 minutes in the follow up sessions. The nurse was endeavoured to provide as much intervention as an individual could tolerate. The amount of the intervention was video recorded.
7. Was the intervention tailored?	Tailoring was built in the intervention. Functional goals were agreed between the nurse and people with knee pain to facilitate exercise prescription. Weight loss goals were agreed with participants who were overweight. The description of the treatment manual highlights procedures for tailoring practice activities. No modifications of the intervention were made during the course of the study.
8. How well was the intervention delivered?	A single research nurse who received training, delivered the intervention and fidelity was assessed by video recording all sessions. After preliminary fidelity analysis, the nurse received additional supervised training to deliver the intervention.

Additional file 2. The semi-structured interview guide for the nurse

Nurse's views on experience of delivering the non-pharmacological intervention

We're going to start by discussing your overall views on the knee pain treatment programme, the training you received to deliver it, and then talk about the different components of the intervention separately.

1. Can you tell me what your overall impression of the knee pain treatment programme is, having delivered it for the first time?

Nurse's view of the training received to deliver the non-pharmacological intervention

We are now going to discuss the training you received to deliver this treatment.

2. Can you tell me how you found the training you received
    - Length of training/ number of sessions/ delivery over weeks rather than 2 days condensed
    - Material covered in sessions: too much/too little/about right
    - Opportunities to practice/ feedback
    - Resources/ manual/ electronic material (links to videos)/ links to weight loss resources / exercise sheets/ case-studies

3. How did you find following the manual provided?
    - Probe – reasons for it being easy / difficult to follow.
    - What suggestions do you have to modify the manual to make it easier to use in the future?
    - Any suggestions for improving the training

- How confident did you feel about delivering the treatment once you had completed your training?

Nurse's views on experience of delivering the non-pharmacological intervention

We are now going to discuss how you found delivering the treatment to patients.

4. How did you find delivering this treatment to patients?

- As you know, the treatment package had different components – education on self-managing knee pain, giving the participant exercises, advising them on weight loss, setting individual goals with the participants and assessing patient confidence to achieve goals.
  How did you find delivering these components?

    - [cover ONE at a time]
    - Education
    - Exercise
    - Weight loss
    - Goal setting

Additional file 2. The semi-structured interview guide for the nurse

- Assessing patient confidence to achieve goals
- Using the diaries (exercise and weight loss)

5. How did you find setting goals with patients?
    - Probe - did they actively participate in the discussions?
6. How did you find the follow-up sessions with participants and providing feedback on participants' progress with their exercises and/or weight loss?
    - Prompts - patient receipt of advice / feedback (any challenges with patients accepting advice or adhering to the treatment given)

- Were there any components that you found challenging to implement?
    - What made it challenging to deliver this component? [cover ONE at a time]
    - Were there any other components that you found challenging to implement? Why.
    - What would help support you in delivering this in the future?
- Were any aspects of the intervention not delivered as planned?
    - What were the barriers to delivering [the aspect]? [cover ONE at a time]
    - What would help support you in delivering this in the future?

We are now going to talk about tailoring the treatment to each patient.

7. How did you find the final session with the participants? Did you feel that they would be able to continue with the advice/exercises/weight loss etc independently?

We'd now like to discuss the resources provided to support you delivery the treatment programme.

8. How useful did you find the other resources during the treatment programme?
    - Probe - handouts / training manuals / thera-bands / exercise sheets/ exercise diaries/ NHS weight loss resource (BMI and weigh loss calculator)/ food diaries/ other weight-loss hand outs
    - What suggestions do you have to improve these resources in the future?

Additional file 2. The semi-structured interview guide for the nurse

9. Is there any additional support you need in being able to deliver this treatment?

We have come to the end of the interview. Do you have any further comments about the training and/or treatment package that have not been covered?

Reporting checklist for quality improvement study.

Based on the SQUIRE guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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	Reporting Item	Page Number
Title		
#1	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patientcenteredness, timeliness, cost, efficiency, and equity of healthcare)	1

Abstract			
	#02a	Provide adequate information to aid in searching and indexing	3
	#02b	Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions	2,3
Introduction			
Problem description	#3	Nature and significance of the local problem	4
Available knowledge	#4	Summary of what is currently known about the problem, including relevant previous studies	4,5
Rationale	#5	Informal or formal frameworks, models, concepts, and / or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work	7, 9
Specific aims	#6	Purpose of the project and of this report	6
Methods			

Context	#7	Contextual elements considered important at the outset of introducing the intervention(s)	7
Intervention(s)	#08a	Description of the intervention(s) in sufficient detail that others could reproduce it	8,9
Intervention(s)	#08b	Specifics of the team involved in the work	11
Study of the Intervention(s)	#09a	Approach chosen for assessing the impact of the intervention(s)	9,10,11
Study of the Intervention(s)	#09b	Approach used to establish whether the observed outcomes were due to the intervention(s)	12
Measures	#10a	Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability	4,5,7
Measures	#10b	Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost	11,12
Measures	#10c	Methods employed for assessing completeness and accuracy of data	11,12
Analysis	#11a	Qualitative and quantitative methods used to draw inferences from the data	8,9,10

Analysis	#11b	Methods for understanding variation within the data, including the effects of time as a variable	12, 21-23
Ethical considerations	#12	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest	9, 31
Results			
	#13a	Initial steps of the intervention(s) and their evolution over time (e.g., time-line diagram, flow chart, or table), including modifications made to the intervention during the project	7,8,11
	#13b	Details of the process measures and outcome	9-12
	#13c	Contextual elements that interacted with the intervention(s)	n/a (the intervention was fully monitored)
	#13d	Observed associations between outcomes, interventions, and relevant contextual elements	13,14
	#13e	Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s).	13,14, 18-20

	#13f	Details about missing data	n/a (no missing data)
Discussion			
Summary	#14a	Key findings, including relevance to the rationale and specific aims	24
Summary	#14b	Particular strengths of the project	26,27
Interpretation	#15a	Nature of the association between the intervention(s) and the outcomes	24,25
Interpretation	#15b	Comparison of results with findings from other publications	25,26
Interpretation	#15c	Impact of the project on people and systems	n/a (the project determined if it is feasible to apply the non-pharmacological intervention in a feasibility RCT)
Interpretation	#15d	Reasons for any differences between observed and anticipated outcomes, including the influence of context	26
Interpretation	#15e	Costs and strategic trade-offs, including opportunity costs	n/a (The study did not assess cost-effectiveness)
Limitations	#16a	Limits to the generalizability of the work	26,27

Limitations	#16b	Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis	26
Limitations	#16c	Efforts made to minimize and adjust for limitations	26
Conclusion	#17a	Usefulness of the work	24, 27
Conclusion	#17b	Sustainability	27
Conclusion	#17c	Potential for spread to other contexts	26,27
Conclusion	#17d	Implications for practice and for further study in the field	25,26
Conclusion	#17e	Suggested next steps	27
Other information			
Funding	#18	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting	31

Notes:

- 13c: n/a (the intervention was fully monitored)
- 13f: n/a (no missing data as all intervention sessions were video recorded)

- 15c: n/a (the project determined if it is feasible to apply the non-pharmacological intervention in a feasibility RCT)

- 15e: n/a (The study did not consider cost-effectiveness) The SQUIRE 2.0 checklist is distributed under the terms of the Creative Commons Attribution License CC BY-NC 4.0. This checklist was completed on 22. September 2020 using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai

BMJ Open

Fidelity assessment of nurse-led non-pharmacological package of care for knee pain in the package development phase of a feasibility randomised controlled trial based in secondary-care: a mixed methods study

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Fidelity assessment of nurse-led non-pharmacological package of care for knee pain in the package development phase of a feasibility randomised controlled trial based in secondary-care: a mixed methods study

Polykarpos Angelos Nomikos[1,2], Michelle Hall[2,3], Amy Fuller[1,2], Bonnie Millar[2,4], Reuben Ogollah[5], Ana Valdes[2,4], Michael Doherty[1,4], David A Walsh[2,4], Roshan das Nair [6,7], Abhishek Abhishek[1,2]

[1] Academic Rheumatology, University of Nottingham, Nottingham, UK

[2] NIHR Nottingham Biomedical Research Centre, University of Nottingham, Nottingham, UK

[3] School of Health Sciences, University of Nottingham, Nottingham, UK

[4] Pain Centre Versus Arthritis, University of Nottingham, Nottingham, UK

[5] Nottingham Clinical Trials Unit, University of Nottingham, Nottingham, UK

[6] Institute of Mental Health, University of Nottingham, Nottingham, UK

[7] Division of Psychiatry & Applied Psychology, University of Nottingham, Nottingham, UK

Corresponding author:

Polykarpos Angelos Nomikos

A 26 Clinical Sciences Building

Nottingham City Hospital

Hucknall Road

Nottingham

NG5 1PB

UK

E-mail address: Polykarpos.nomikos@nottingham.ac.uk

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ABSTRACT

Objectives: To evaluate fidelity of delivery of a nurse-led non-pharmacological complex intervention for knee pain.

Setting: Secondary care. Single centre study.

Study design: Mixed methods study.

Participants: Eighteen adults with chronic knee pain.

Inclusion criteria: Age > 40 years, knee pain present for longer than 3 months, knee pain for most days of the previous month, at least moderate pain in two of the five domains of Western Ontario and McMaster Universities Osteoarthritis Index pain scale.

Interventions: Nurse-led non-pharmacological intervention comprising assessment, education, exercise, use of hot/cold treatments, footwear modification, walking aids, and weight-loss advice (if required).

Outcome(s): Primary: Fidelity of delivery of intervention, Secondary: nurses' experience of delivering intervention.

Methods: Each intervention session with every participant was video recorded and formed part of fidelity assessment. Fidelity checklists were completed by the research nurse after each session and by an independent researcher, after viewing the video-recordings blinded to nurse ratings. Fidelity scores (%), percentage agreement and 95% Confidence Intervals (CI) were calculated. Two semi-structured interviews were conducted with the research nurse.

Results: Fourteen participants completed all visits. 62 treatment sessions took place. Nurse self-report and assessor video rating scores for all 62 treatment sessions were

included in fidelity assessment. Overall fidelity was higher on nurse self-report (97.7%) than on objective video-rating (84.2%). Percentage agreement between nurse self-report and video-rating was 73.3% (95% CI: 71.3 - 75.3). Fidelity was lowest for advice on footwear and walking aids. The nurse reported difficulty advising on thermal treatments, footwear and walking aids, and did not feel confident negotiating achievable and realistic goals with participants.

Conclusions: A trained research nurse can deliver most components of a non-pharmacological intervention for knee pain to a high degree of fidelity. Future research should assess intervention fidelity in a routine clinical setting, and examine its clinical and cost-effectiveness.

Trial registration number: NCT03670706

KEY WORDS: Knee pain, fidelity, nurse-led intervention, osteoarthritis

STRENGTHS AND LIMITATIONS OF THE STUDY

- This mixed methods study used a combination of techniques to assess treatment fidelity.
- We triangulated the fidelity scores with the findings from interview study and found convergence providing internal validity.
- We identified the components not delivered as intended.
- A single nurse was involved in delivery of the intervention
- Lack of formal assessment of nurse knowledge of managing knee osteoarthritis.

INTRODUCTION

Osteoarthritis (OA) is the commonest form of arthritis and is managed predominantly in primary care in the UK. The knee is commonly affected, with approximately one in four adults over the age of 50 years in the UK self-reporting chronic knee pain, defined as pain for 3-months or longer within the previous 12 months. [1] In the presence of activity related joint pain, no or minimal morning stiffness, and age >= 45 years, a clinical diagnosis of OA may be reached without the need of investigations (e.g. blood tests or radiography) as per the National Institute for Health and Care Excellence (NICE) guidelines. [2] These guidelines [2] also recommend a patient-centred approach when managing OA, with a focus on non-pharmacological interventions including education, strengthening, and aerobic exercise, and weight loss if required. However, this can be difficult for general practitioners (GPs) to deliver for several reasons such as time constraints and, core non-pharmacological treatments are under-utilised. [3 4] Nurse-led care gives similar or better outcomes than GP-led care for other chronic diseases. [5-8] However, the fidelity of delivery of nurse-led care has not been examined for the management of knee OA.

Fidelity, defined as the degree to which an intervention is delivered as intended, [9] regulates the relationship between interventions and outcomes, and determines the extent to which an intervention affects the outcome. [10] Inferences regarding treatment effect of a complex intervention should therefore not be made without assessing fidelity, because lack of efficacy of an intervention may be due to inadequate implementation. [11] Thus, the fidelity of intervention delivery influences the internal and external validity of a study. [12] If fidelity is not assessed, effective interventions may be rejected due to poor delivery. [13 14]

There are several methods to assess treatment fidelity, including direct observation, patient self-report questionnaires and provider self-report checklists, and indirect observation using audio or video-recordings [13], which may be used singularly or in combination. Direct observation is considered the gold-standard, however, it can be intrusive and may affect patient practitioner interaction, [15 16] and may not be feasible in large randomised controlled trials (RCTs). Provider self-report methods are simple and inexpensive but can be inaccurate, [17] and patient report methods are even less reliable. [13] Video-recording the delivery of intervention and independent assessment of fidelity may provide a robust alternative to direct observation. [18] Indeed, it has been shown previously that assessing fidelity using independently rated recordings and provider self-report checklist is feasible and acceptable. [19 20 21] A combination of provider self-report and independent assessed video recording was utilised in the current study to provide an in-depth fidelity assessment. [22] Video recordings were chosen as this is less intrusive than direct observation and provide an opportunity to assess reliability.

Medical Research Council guidelines for developing and evaluating complex interventions [23] have highlighted the importance of conducting process evaluation. Its' purpose is to assess the quality and quantity of the implementation of intervention, and trials that collect rich qualitative data may identify potential barriers and facilitators to intervention implementation. However, collecting only qualitative or quantitative data to assess treatment delivery would not unearth a comprehensive picture to understand complex constructs within the intervention. [24] For this reason, a mixed methods approach was utilised. [25]

The present study is part of the East-Midlands Knee Pain Cohort RCT study, [26] the overall purpose of which is to evaluate the feasibility of a nurse-led package of care

for knee pain due to OA. The objective of the present study was to evaluate the fidelity of delivery of a nurse-led non-pharmacological package of care for knee pain during the package development phase of the RCT.

METHODS

Study Design: A mixed methods study with an explanatory sequential and convergent design. This form of mixed methods approach was used to produce additional insights of the issue at hand. In this design, qualitative and quantitative data are collected and complementary results arise from the use of different methods. [27] In the current study, the quantitative data informed the collection of qualitative data and a convergence approach was followed.

Setting: Academic Rheumatology, City Hospital Nottingham.

Participants and Recruitment: The participants were adults self-reporting knee pain. Community dwelling adults participating in the Investigating Musculoskeletal Health and Wellbeing (IMHW) cohort, [28] self-reporting knee pain were sent a postal invitation to participate in this study. People who responded underwent telephone screening to assess eligibility. The inclusion criteria were: age>40 years, ability to read and write in English, knee pain present for longer than three months, pain in or around the knee on most days of the previous month, and at least moderate pain in two of the five domains of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain scale. [29]

Research nurse training: A training programme to enable a nurse to deliver the current NICE guidelines for OA management was developed and an educational manual produced. [26] The training included face-to-face learning, case-studies, on-line resources and simulated patients. Practical sessions on assessing the participant, delivering and modifying exercise, weight loss advice and use of strategies to encourage adherence were also included. The nurse delivering the intervention was working as a research nurse previously and did not have prior knowledge of musculoskeletal diseases, had not worked in rheumatology or allied specialties such

as orthopaedics, rehabilitation or sports medicine, and had never delivered treatments for arthritis.

Patient and Public Involvement: Three PPI members with hip and/or knee OA provided input into the content of the non-pharmacological treatment package, and volunteered for nurse training. They advised that video recording of treatment sessions would be acceptable to participants.

Intervention: The template for intervention description and replication (TIDieR) checklist [30] has been used to describe the intervention and its key features (Additional file 1). In brief, the intervention consisted of a holistic assessment of the participant, providing education about the nature of OA and self-management strategies including advice on the role of exercise, maintaining a healthy weight, and use of adjunctive treatments such as application of heat or cold, foot-wear modification and use of walking aids. At the first visit, the nurse took a medical history, examined the knee joints and explained to the participant that they had knee pain due to OA. Investigations and radiographs were not undertaken as per NICE guidelines. [2] The Chief Investigator (AA) was available for advice if a clinical diagnosis of OA could not be reached. In that case, the participant would be deemed ineligible for the study. All participants were given an Arthritis Research UK leaflet on knee OA. The nurse explained aerobic and strengthening exercises and advised each participant on an individualised regimen that was mutually agreed. If required, weight-loss advice was provided. Behaviour change strategies [31] such as goal setting, action planning, assessment of participant confidence to achieve goals, discussion of barriers and facilitators and the use of exercise diaries were used to improve adherence. Functional goals were agreed and were used to facilitate the exercise prescription with goals being Specific, Measurable, Achievable, Relevant, and Timely (SMART). SMART

weight loss goals were agreed also with overweight participants. The intervention is described in more detail in the protocol. [26] After the training period, the nurse delivered the intervention in four sessions over a five-week period.

Ethical approval: The study received ethical approval by the East Midlands-Derby Research Ethics Committee (REC) (18/EM/0288).

Consent: All study participants including the research nurse gave their written informed consent prior to treatment delivery, including the consent to video record the sessions. Participants had the right to pause or stop the video recording at any point without giving any reasons.

Fidelity assessment: The study followed the National Institutes of Health Behaviour Change Consortium (NIHBCC) guidelines for fidelity assessment. [13] The fidelity checklist was developed a priori [26] and comprised eight components, each with specific tasks: materials; introduction; assessment; education; exercise; weight loss; advice on adjunctive treatments; and review and planning. However, not all components of the intervention were intended to be delivered in each session. [26] For example, advice on the adjunctive treatments could be provided in any of the four sessions. The fidelity checklist was iteratively developed using a five-step methodology. [32] These were: reviewing previous measures, analysing intervention components and developing an intervention framework (intervention manual), developing the fidelity checklist, obtaining feedback about the content and wording of checklist and piloting and refining the checklist to assess and improve reliability. The responses of the fidelity checklist were categorical and rated as completed, partially completed, not completed, or not applicable. Partially completed scores were given for any task that was not delivered to the full extent in the context of that particular

consultation. The scoring criteria of the fidelity checklist followed that of previous published strategies for assessing fidelity in RCTs of complex interventions. [33]

Eighteen participants received the non-pharmacological intervention and all (n=62) sessions were video-recorded. After every session with the participant, the nurse completed the fidelity checklist. Sixty-two checklists, 18 for session 1, 16 for session 2 and 14 each for sessions 3 and 4 were completed. Blinded to the nurse ratings, the video-recording of every session was independently reviewed and rated by PAN. A second-rater (MH) independently rated 20% (n=12) of the sessions. Both raters were familiar with the intervention. The refinement, reliability, and feasibility of the fidelity checklist was established during the initial phases of the data collection process.

Quantitative data analysis: Mean and standard deviation (SD), median and inter quartile range (IQR), and n (%), were calculated for descriptive purposes. Within a component, tasks rated as 'completed' were given a score of 2, 'partially completed' a score of 1, and not completed, a score of zero. To obtain fidelity score for a component of the intervention, individual scores for each task within the component were added and divided by the maximum possible score for that component and converted to a percentage. Any tasks that were rated as not-applicable, were excluded from the calculation.

Median fidelity scores (%) and IQR were calculated for the entire intervention, per participant, per session and per component of the intervention. Fidelity was classified as previously reported: 80-100% 'high', 51-79% 'moderate', and 0-50% 'low' fidelity. [34] Where fidelity was moderate or low in a particular component, we further explored this by examining the fidelity of delivery of the individual tasks.

Percentage agreement with 95% confidence intervals (CI) was used to estimate the level of agreement between self-report and video-record methods, and for inter-rater agreement.

Qualitative phase: One week after the final session, the nurse took part in a semi-structured interview conducted by PAN (PhD student) and AF (trained qualitative researcher). The interview guide (Additional file 2) contained open-ended questions developed by the study team, which included a rheumatologist (AA), physiotherapists (MH, PAN), psychologist (RdN), and qualitative researcher (AF). The guide covered the nurse's view on their training, confidence in and experience of delivering the individual components of the non-pharmacological intervention, perceived barriers to delivering it as planned, and opportunities to improve the non-pharmacological package of care. An iterative process was used for data collection, so an additional interview was conducted 45 weeks later to capture any salient points raised from the initial quantitative and qualitative data collected.

Before starting the interview, it was explained that the nurse's responses would remain confidential and that any quotes included in future publications would not identify them. The nurse was informed of the right to withdraw from the interview at any time. We have not provided demographic details in order to protect the anonymity of the individual nurse. All interviews were conducted in a private room in Academic Rheumatology, City Hospital, Nottingham. The qualitative findings were mapped onto the fidelity checklist to assess convergence between the quantitative and qualitative findings. Any areas of uncertainty or gaps were then explored in the second interview with the nurse.

Qualitative data analysis: The interviews were transcribed verbatim by an external transcription company. The interviewer removed any identifiers and ensured transcripts were accurate. Transcripts were analysed following the principles of the general inductive approach. [35] The latter is a simple straightforward approach, which is used to derive findings from raw qualitative data, condense them into a brief summary format, and link the research objectives with the summary findings.

The first transcript was read several times before data related to the research objectives was identified, labelled and categorised. The categories were discussed between the interviewer and a second researcher (AF). This process identified gaps and led to the second interview and the transcript was analysed in the same way. Following agreement that the categories reflected the overall account reported by the nurse, extracts were taken from the transcripts to exemplify the findings.

Convergence: A meta-matrix was developed to explore convergence between the findings. This approach enhances study validity by increasing the probability that our findings and interpretations are credible and reliable. [24] Convergence was defined as agreement between both sets of data, and discrepancy as disagreement between them.

Reporting guidelines: The Standards for Quality Improvement Reporting Excellence (SQUIRE) guidelines [36] were used to improve the quality of reporting of this study.

RESULTS

Quantitative findings:

Eighteen participants (33% women) with knee pain for longer than 3 months, with a mean age of 68.7 (SD 9.0) years and body mass index of 31.2 (SD 8.4) kg/m^2 respectively took part in the study. Of these, fourteen completed all four visits. The reasons for dropping out were other commitments (n=3), reluctance to lose weight (n=1) and inadequate understanding of the nature of the intervention (n=1).

In total, 62 intervention sessions were delivered. The median (IQR) duration of the initial and follow-up sessions was 87 (81–101) and 46 (37–52) minutes respectively. Overall fidelity was rated high for both nurse self-report (97.7%) and video-rated scores (84.2%) (Tables 1, 2). Inter-rater agreement for the video-recording checklist was 70.3% (95%CI 64.4, 74.2).

For the nurse self-report checklist, median fidelity scores for each session ranged from 94.4-100% (Table 1). Individual components received high ratings except for adjunctive treatments i.e. use of heat/cold therapy and advice on footwear where the fidelity score was moderate in many sessions.

For the video-rated checklists, overall median fidelity scores for each session ranged from 77.7-87.2% (Table 2). Fidelity for education was lower in the first session (78.1%, IQR 74.1, 93.8) but increased in the follow-up session (87.5%, IQR 50,100). Fidelity for review and planning was lower in the first and last sessions. Fidelity scores were low for adjunctive treatments across all sessions, and varied from 0% to 50%. Fidelity of delivery for exercise goal-setting was moderate at 66% and, fidelity for reviewing goals during follow-up sessions was low, ranging between 44-50%. Additionally,

assessment of patients' level of confidence to achieve their exercise goal was low in the follow-up sessions, ranging between 7-40%.

The overall agreement between nurse-rated and video-rated methods was 73.3% (95% CI 71.3 - 75.3). The level of agreement for individual components is shown in Figure 1. Excellent agreement was found for materials, introduction, and assessment. Agreement was below the cut-off point of 80% for education, exercise, weight loss and adjunctive treatment. The level of agreement for review and planning component was 58.1% (95% CI 44.8, 70.5). For individual participants, overall fidelity across the four sessions ranged from 75% to 100% indicating that for most patients the intervention was delivered as intended (Table 3).

Table 1. Nurse self-reported fidelity scores [1]

Intervention component	Session1 (n=18)*	Session 2 (n=16)*	Session 3 (n=14)*	Session 4 (n=14)*
Materials	100 (100, 100)	-	-	-
Introduction	100 (100, 100)	-	-	-
Assessment	100 (98.3, 100)	100 (100, 100)	100 (100, 100)	100 (100, 100)
Education	100 (100, 100)	100 (100, 100)	100 (100, 100)	100 (100, 100)
Exercise	100 (97.5, 100)	100 (100, 100)	100 (97.5, 100)	100 (75, 100)
Weight loss	100 (88.9, 100)	100 (100, 100)	100 (66.7, 100)	100 (79.2, 100)
Adjunct treatments	87.5 (33.3 100)	87.5 (0, 100)	66.7 (45.8, 100)	-
Review and planning	100 (100, 100)	100 (100, 100)	100 (100, 100)	100 (100, 100)

[1]Values are median% (IQR)

*Number of sessions

Table 2. Fidelity scores using video-recordings of the sessions[1]

Intervention Component	Session 1 (n=18)*	Session 2 (n=16)*	Session 3* (n=14)*	Session 4 (n=14)*
Materials	100 (100, 100)	-	-	-
Introduction	100 (75, 100)	-	-	-
Assessment	91.4 (85, 93.3)	100 (100, 100)	100 (100, 100)	100 (100, 100)
Education	78.1 (74.1, 93.8)	87.5 (50, 100)	87.5 (50, 100)	100 (93.8, 100)
Exercise	94.4 (88.9, 100)	88.9 (75, 94.4)	86.1 (72, 100)	75 (67.6, 82.8)
Weight loss	100 (87.5, 100)	90 (60, 100)	100 (68.9, 100)	80 (49.2, 100)
Adjunct treatments	50 (45.8, 100)	0 (0, 50)	50 (0, 100)	-
Review and planning	75 (75, 100)	100 (100, 100)	100 (100, 100)	75 (37.5, 100)

[1]Values are median% (IQR),

*Number of sessions

Table 3. Fidelity scores assessed using video-recordings across participants[1]

Participant number	Overall sessions
Participant 1	88.9 (75, 100)
Participant 2	83.3 (41.7, 100)
Participant 3	100 (67.5, 100)
Participant 4*	96.7 (88.9, 100)
Participant 5	75 (45, 100)
Participant 6	100 (80, 100)
Participant 7	100 (89.9, 100)
Participant 8*	100 (95.8, 100)
Participant 9	92.9 (50, 100)
Participant 10	93.7 (77.5, 100)
Participant 11*	75 (50, 97.2)
Participant 12	73.8 (18.8, 100)
Participant 13	100 (67, 100)
Participant 14	100 (79, 100)
Participant 15	85 (56, 100)
Participant 16	100 (75, 100)
Participant 17	100 (80, 100)
Participant 18*	100 (81, 100)

[1]Values are median% (IQR)

*Participants dropped out. The percentage fidelity score is calculated using scores from the sessions attended.

Qualitative findings:

The duration of the initial and follow-up interview with the nurse was 94 minutes, and 34 minutes respectively. The nurse reported feeling nervous when delivering the intervention for the very first time, but felt more comfortable as the sessions progressed.

> *"Very nervous… to start with... I don't think after a few sessions I was uncomfortable, I was probably more comfortable delivering the intervention…after few sessions, got better at getting feedback from patient as well so I think that boosted my confidence".*

The nurse felt that patient assessment was easy to deliver considering their previous experience of assessing patients for other diseases.

> *"I would say some of them were easy to find pinpoint the problems…as a nurse we always been asking these questions to patients… in this case but had previous experience in that area"*

The nurse felt that education was not always delivered as well in the first few sessions as in the follow-up sessions. They felt that there was a lot of information for the participants to take on board during that first initial assessment session and recommended that the advice could be spread over two or three sessions.

> *"First few sessions I didn't think of as very good to tell them about the information and then later on, I built that …"*

> "*I think that session could be divided, erm, the very first one at least in two sessions… so first session, you just get to know the patient and they get their*

feedback and, don't give them any, too much of a diet and weight loss information"

The nurse described how they initially lacked confidence in prescribing exercise, which was a new skill, to the patients.

"I had to decide after the assessment which exercise I'm going to assign them and I didn't feel comfortable…"I wasn't sure that whatever assessment I have done and the exercise I choose, that's going to make it any better ... I wasn't 100% sure".

On the other hand, it was easier to determine and link the exercises for patients who already had obvious problems in their knees.

"When there are obviously problems in the knee you can see, you can link what exercise… when you can't see the obvious problems, then it was difficult to determine what exercise you are going to assign"

They felt more confident and were able to adapt the exercises as they became more familiar with the exercises and having received feedback from the patients.

"I felt comfortable altering the exercise for them,… knowing that obviously, if it's painful for them then switching to a different exercise."

The nurse delivered the weight loss advice with ease compared with the exercise and was able to explain to patients why it is good to lose weight where required.

"For the weight loss, you easily do that... I didn't feel too much uncomfortable…so positive from that is that I managed to tell everyone."

Even though they felt it was not difficult to deliver or incorporate the adjunctive treatments, they occasionally forgot to mention them or felt it was not necessary to repeat this in a subsequent session.

> *"I do not think it was difficult to ask that or incorporate… it was probably as a human error or that you forgot to mention it…with some patients if you already mentioned once or twice, so with the first session, that if you need to you can use hot and cold therapy, and then they refuse it … then there is no point [mentioning it again]"*

The nurse found it challenging to negotiate realistic goals with some patients, especially those who had high expectations but rated their confidence in achieve their goals as low.

> *"The difficulty is that the goal setting they would expect high but then they when you ask them how likely you are going to achieve this goal their rating will be low… their rating will be like 4 or 5 and how you motivate them to go up to 8 or 7, 8, 9, that one's kind of difficult."*

However, the nurse was able to reduce the expectation that was initially set for that particular goal for those patients.

> *"Obviously there was a previous goal…yes would reduce the expectation when they came back, I would be able to do this, so I am sure you would be able to see through the videotape"*

Integrating findings: Convergence was found between the fidelity scores and nurse interview (Table 4). The excellent fidelity scores for the holistic assessment by the nurse was reflected in their confidence of assessing patients more generally. The moderate fidelity findings for education in the first session that increased in subsequent sessions was confirmed by the nurse and explained in terms of moderating the amount of information that was given to participants in the first session. Weight loss advice was delivered with high fidelity and the nurse also felt confident in being able to deliver weight loss advice fully. A perceived lack of confidence in delivering the exercise component is consistent with lower fidelity scores for the exercise component. The adjunctive treatments were not always delivered as intended and that was consistent with the interview findings. Goal setting was challenging for the nurse which was reflected in the fidelity findings. Finally, convergence was found for review and planning as the nurse found it easy to summarise patient goals at the end of each session. There were no divergent findings.

Table 4. Convergence between fidelity observed using video recordings and the results from the semi-structured nurse interview

Intervention components	Median (%) IQR fidelity *	Qualitative interview findings	Convergence
All components	*84.2*	*" I find myself that … that I can deliver the care…I was probably more comfortable delivering the intervention…after few sessions"*	Yes
Materials	*100 (100, 100)*	*" I had to show them the booklet every patient so I don't think I have forgotten to do that"*	Yes
Introduction	*100 (75, 100)*	*"I explain all the study and then explain that whole process again for the purpose of the session"*	Yes
Assessment	*100 (100, 100)*	*"I would say some of them were easy to find pinpoint the problems…as a nurse we always been asking these questions to patients… in this case but had previous experience in that area"*	Yes
Exercise	*88.9 (72.7, 94.4)*	*"We practiced and demonstrated exercises… I felt comfortable altering the exercise for them…I just couldn't think how to link that, erm, goal setting I didn't deliver it good… I don't think I could have delivered it any better than that either… some did actually achieve the goal"*	Yes
Education	*87.5 (74.1, 100)*	*"first few sessions I didn't think of as very good to tell them about the information and then later on, I built that"*	Yes

Weight loss	*100 (77.8, 100)*	*"Positive from that is that I managed to tell everyone that, "you need to lose weight", so I think it was kind of structured in a way… I didn't feel too much uncomfortable"*	Yes
Adjunct treatments	*50 (0, 50)*	*"it was probably as a human error or that you forgot to mention it…with some patients if you already mentioned once or twice so with the first session that you need to you can use hot and cold therapy and then they refuse it and then there is no point"*	Yes
Review and planning	*100 (25, 100)*	*"Not difficult… we always talked about it this is what we discussed it today this is the exercise we, have assigned you and if you feel that you can progress into further do so"*	Yes

*Median fidelity scores of the individual components across the four sessions

DISCUSSION

This study evaluated fidelity of delivery of a nurse-led non-pharmacological package of care for knee pain due to OA and validated the findings in an interview with the nurse that delivered it. The majority of the non-pharmacological components of the intervention were delivered with good fidelity. Excellent fidelity was found for patient assessment, education, demonstration and advice on exercise and weight loss advice. Tasks that demonstrated lower fidelity within the exercise component included goal setting and review. These were also perceived as difficult by the nurse. Advice around the use of adjunctive treatments such as the use of hot or cold treatments, walking aids and footwear, were also not always delivered as planned. Agreement between the nurse and independent rater was below the cut-off point of 80% for education, exercise, weight loss, adjunctive treatment, and review and planning, which is reported as the minimum acceptable agreement between raters. [37] Fidelity scores across different participants were high overall with the lowest score being 74%.

To the authors' knowledge, this is the first study that has assessed fidelity of a nurse-led non-pharmacological intervention for knee pain due to OA and integrated the findings. Our study is based on a fidelity checklist that has been previously validated in complex interventions delivered in a research setting. [21] We tailored the checklist according to the intervention and further refined it. Moreover, the reliability of the fidelity checklist was established when two independent viewers scored the video recordings of the sessions.

From the interview transcripts, factors that influenced fidelity of delivery are identified. The nurse was less confident to identify appropriate patient goals and prescribe exercise in the first few sessions, but this improved thereafter. This is not a barrier per

se, but suggests that some further training and additional support for nurses in this new role would be needed to ensure fidelity at the start of the study. The nurse was able to draw on her previous experience working with other patient groups to discuss and assess complex issues. Nurse's previous experience assessing patients, therefore, facilitated fidelity of delivery. Although the fidelity for education appeared to be lower in the first session this was because the nurse recognised and responded that participants were being given a lot of information. These findings are not surprising as we aimed to train a nurse with no prior experience of managing musculoskeletal diseases to deliver a complex non-pharmacological package of care for knee pain. Where the nurse identified difficulties in delivering the intervention as intended, she was able to seek additional advice and training from MH. This experience has allowed us to further improve the nurse training programme for use in the feasibility RCT.

Previous studies using mixed methods have explored factors that influenced fidelity and found good fidelity of delivery of a physiotherapist-led complex package of care for chronic low-back pain and OA. [21 22] They report on the factors that influenced fidelity on three levels: provider, participant and programme. Williams *et al* [38] demonstrated good fidelity of delivery of a walking intervention when delivered by nurses and healthcare assistants in primary care. Even though they used a mixed methods approach to assess fidelity, they did not integrate the findings. In our study, the research nurse rated themselves higher than the independent rating using the video recordings consistent with previous studies. [32 39] Similar findings on barriers and facilitators have been identified in two complex interventions, one for people with dementia and one for people with chronic low back pain.[22 32] In fact, Walton *et al* [32] extended over the factors that influenced fidelity of delivery reported by Toomey *et al* [22] and recognised that knowledge, providers' attributes, ease of adaptation of the

intervention in relation to participants' needs influenced fidelity. Based on the findings, it was challenging to address adaptation and determine the appropriate balance between fidelity and adaptation in this study. This may indicate some key overlapping themes that may limit fidelity of delivery despite the different types of intervention and conditions.

There are a number of limitations to this study. A key caveat is that only one nurse was involved in delivery of the intervention. In a larger trial, there would be more nurses to deliver the intervention across multiple sites, which increases the likelihood of variation in fidelity. This study lasted 17 weeks and this is a short period of time over which fidelity may not fluctuate much. However, this can be an issue with longer studies. [40]. The nurse who delivered the intervention was interviewed but in the absence of data from additional participants, emerging categories could not be revised and refined into fully realised themes, however, an inductive approach to analysis was taken to reflect the views of the intervention provider. A second interview with the nurse was conducted to capture any salient points not discussed during the first interview. We did not consider to capture engagement of the participants in the study. Complex interventions are often a dynamic interplay between patient and healthcare professionals. Whilst checklists can be helpful in determining whether an intervention has been delivered they do not allow for or capture the flexibility that is required when tailoring an intervention to the individual.

The intervention was delivered by a research nurse with no background knowledge of musculoskeletal diseases and no previous experience delivering treatment for arthritis. This is a particular strength as we were able to assess the effectiveness of our nurse training programme and its shortcomings. Additionally, we video-recorded and evaluated all the consultations that were delivered. One of the key strengths of

our study was that we identified the specific components of the intervention not delivered as intended. Moreover, we triangulated the findings and found convergence providing internal validity. The nurse was interviewed to address some of the NIHBCC components (study design, provider training) that have not been examined previously.[22]

In conclusion, we found that nurse-led delivery of a complex package of care is feasible within a research setting. The research nurse delivered care for patients with knee pain due to OA with high fidelity for most of the components of the intervention except for advice about the use of hot/cold treatments, walking aids, footwear and goal setting. We believe that upskilling nurses to deliver complex non-pharmacological components for the management of knee pain due to OA is feasible. Nurses would have more time to spend with patients and educate them about the condition. The training package for delivery of the intervention will need to ensure that the nurses are confident in delivering the behavioural change strategies such as goal setting. Follow-up training sessions and support during the start of the feasibility when nurses are first delivering the intervention may be helpful in order to improve confidence and delivery. Future work will need to consider fidelity where there will be more than one nurse delivering the intervention in a clinical setting where other factors will also influence fidelity. Our results, nevertheless, show that it is feasible to apply the non-pharmacological package of care in a future feasibility RCT.

LEGENDS

Figure 1. Agreement between nurse-rated and video-rated methods for the components of the intervention. Values shown are % agreement and error bars indicate the 95% CI

CONTRIBUTORS

PAN, MH, AF, BM, RO, AV, RdN, MD, DAW, and AA contributed to the design and conception of the study. PAN conducted the quantitative and qualitative data collection and analysis. MH was the independent rater for video assessment of fidelity. AF and RdN provided guidance in the qualitative data collection and analysis. RO, AA and MH provided guidance in the quantitative analysis. BM contributed to the study set up and recruitment. PAN wrote the first draft. PAN, MH, AF, BM, RO, AV, RdN, MD, DAW, and AA have read, provided critical feedback and approved the final manuscript. PAN has access to qualitative and quantitative data and vouches to the accuracy of data analysis.

COMPETING INTEREST STATEMENTS

All authors declare no competing interests.

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DATA STATEMENT SECTION

TIDieR checklist, and interview topic guides have been included as supplementary files. Quantitative fidelity checklists are included as supplementary files in the published protocol. Please email the corresponding author at Polykarpos.nomikos@nottingham.ac.uk whether further information is required.

ETHICS APPROVAL

The study received ethical approval by the East Midlands-Derby Research Ethics Committee (REC) (18/EM/0288).

PATIENT CONSENT

Obtained

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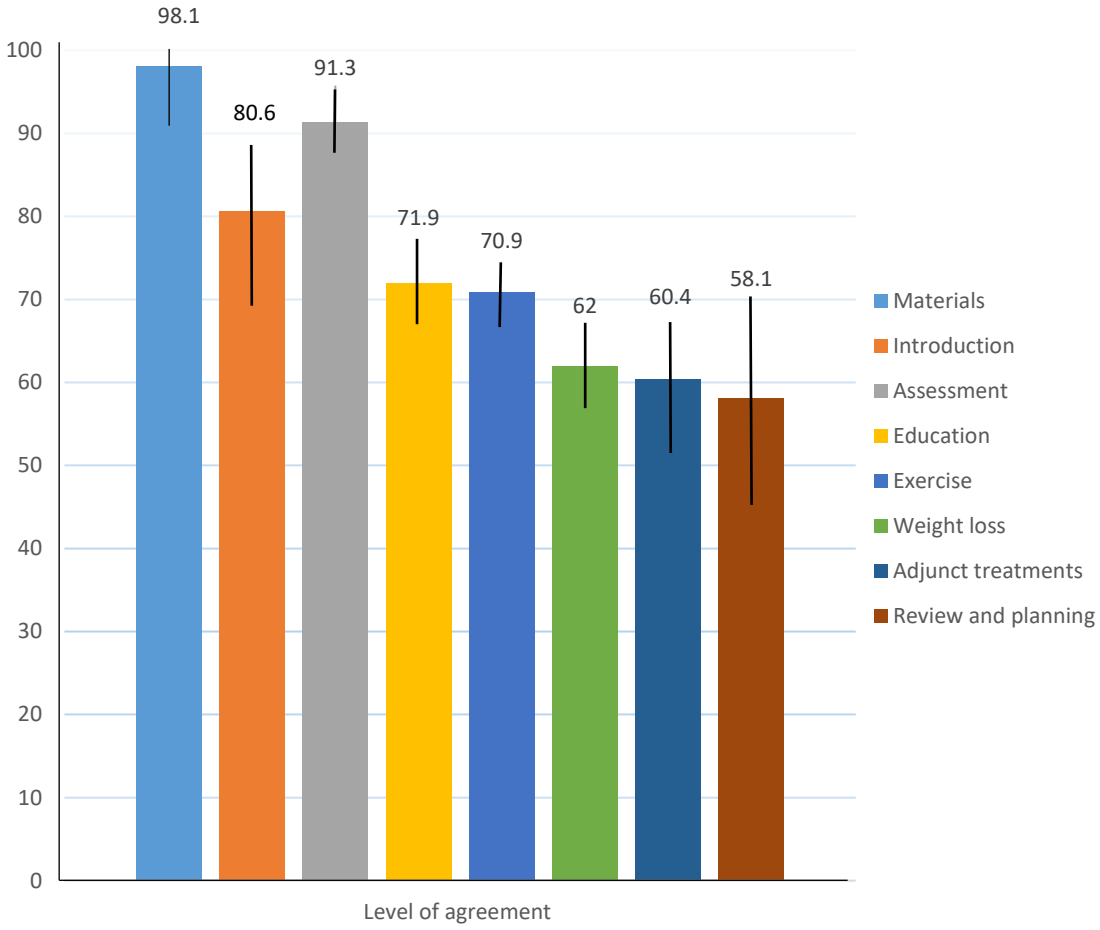

Additional file 1. Items of the non-pharmacological intervention (TIDieR checklist)

1. Brief name	Non-pharmacological complex intervention comprised of education, exercise, and weight loss advice if required.
2. Aims and Rationale	Development and evaluation of the non-pharmacological treatment component.
3. What was done?	**Training package of the provider**: The content of the package was based on NICE guidelines for the management of OA and a report by Arthritis Research UK on the educational needs of health professionals working with people with OA. The content consisted of a standardised treatment manual. Academic and clinical experts and members of a patient advisory group have provided input into the training package. Their key components were: • The epidemiology and nature of knee pain and knee OA • Assessment of the patient with knee OA • Core NICE guidelines for managing OA • Principles of strengthening and aerobic exercise prescription for knee OA • Information and advice to support weight loss • Strategies to support behaviour change • Pharmacological management of OA and knee pain following a step-wise protocol of optimising analgesia **Mode of delivery:** Four face-to-face individual sessions over a five-week period.

Additional file 1. Items of the non-pharmacological intervention (TIDieR checklist)

4. Who delivered the intervention ?	A trained nurse with no prior knowledge of treating musculoskeletal conditions delivered the non-pharmacological intervention to knee pain people. A rheumatologist and research physiotherapist delivered in total eight sessions of the module over a three-month period.
5. Where was the intervention provided?	Single centre research setting, clinic room, city hospital, Nottingham
6. When and how often or how much of the intervention was provided?	The complex intervention was delivered for up to 1.5 hours in session one and 46 minutes in the follow up sessions. The nurse was endeavoured to provide as much intervention as an individual could tolerate. The amount of the intervention was video recorded.
7. Was the intervention tailored?	Tailoring was built in the intervention. Functional goals were agreed between the nurse and people with knee pain to facilitate exercise prescription. Weight loss goals were agreed with participants who were overweight. The description of the treatment manual highlights procedures for tailoring practice activities. No modifications of the intervention were made during the course of the study.
8. How well was the intervention delivered?	A single research nurse who received training, delivered the intervention and fidelity was assessed by video recording all sessions. After preliminary fidelity analysis, the nurse received additional supervised training to deliver the intervention.

Additional file 2. The semi-structured interview guide for the nurse

Nurse's views on experience of delivering the non-pharmacological intervention

We're going to start by discussing your overall views on the knee pain treatment programme, the training you received to deliver it, and then talk about the different components of the intervention separately.

1. Can you tell me what your overall impression of the knee pain treatment programme is, having delivered it for the first time?

Nurse's view of the training received to deliver the non-pharmacological intervention

We are now going to discuss the training you received to deliver this treatment.

2. Can you tell me how you found the training you received
    - Length of training/ number of sessions/ delivery over weeks rather than 2 days condensed
    - Material covered in sessions: too much/too little/about right
    - Opportunities to practice/ feedback
    - Resources/ manual/ electronic material (links to videos)/ links to weight loss resources / exercise sheets/ case-studies

3. How did you find following the manual provided?
    - Probe – reasons for it being easy / difficult to follow.
    - What suggestions do you have to modify the manual to make it easier to use in the future?
    - Any suggestions for improving the training

- How confident did you feel about delivering the treatment once you had completed your training?

Nurse's views on experience of delivering the non-pharmacological intervention

We are now going to discuss how you found delivering the treatment to patients.

4. How did you find delivering this treatment to patients?

- As you know, the treatment package had different components – education on self-managing knee pain, giving the participant exercises, advising them on weight loss, setting individual goals with the participants and assessing patient confidence to achieve goals.
  How did you find delivering these components?

    - [cover ONE at a time]
    - Education
    - Exercise
    - Weight loss
    - Goal setting

Additional file 2. The semi-structured interview guide for the nurse

- Assessing patient confidence to achieve goals
- Using the diaries (exercise and weight loss)

5. How did you find setting goals with patients?
    - Probe - did they actively participate in the discussions?
6. How did you find the follow-up sessions with participants and providing feedback on participants' progress with their exercises and/or weight loss?
    - Prompts - patient receipt of advice / feedback (any challenges with patients accepting advice or adhering to the treatment given)

- Were there any components that you found challenging to implement?
    - What made it challenging to deliver this component? [cover ONE at a time]
    - Were there any other components that you found challenging to implement? Why.
    - What would help support you in delivering this in the future?
- Were any aspects of the intervention not delivered as planned?
    - What were the barriers to delivering [the aspect]? [cover ONE at a time]
    - What would help support you in delivering this in the future?

We are now going to talk about tailoring the treatment to each patient.

7. How did you find the final session with the participants? Did you feel that they would be able to continue with the advice/exercises/weight loss etc independently?

We'd now like to discuss the resources provided to support you delivery the treatment programme.

8. How useful did you find the other resources during the treatment programme?
    - Probe - handouts / training manuals / thera-bands / exercise sheets/ exercise diaries/ NHS weight loss resource (BMI and weigh loss calculator)/ food diaries/ other weight-loss hand outs
    - What suggestions do you have to improve these resources in the future?

Additional file 2. The semi-structured interview guide for the nurse

9. Is there any additional support you need in being able to deliver this treatment?

We have come to the end of the interview. Do you have any further comments about the training and/or treatment package that have not been covered?

Reporting checklist for quality improvement study.

Based on the SQUIRE guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SQUIREreporting guidelines, and cite them as:

Ogrinc G, Davies L, Goodman D, Batalden P, Davidoff F, Stevens D. SQUIRE 2.0 (Standards for QUality Improvement Reporting Excellence): revised publication guidelines from a detailed consensus process

	Reporting Item	Page Number
Title		
#1	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patientcenteredness, timeliness, cost, efficiency, and equity of healthcare)	1

Abstract			
	#02a	Provide adequate information to aid in searching and indexing	3
	#02b	Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions	2,3
Introduction			
Problem description	#3	Nature and significance of the local problem	4
Available knowledge	#4	Summary of what is currently known about the problem, including relevant previous studies	4,5
Rationale	#5	Informal or formal frameworks, models, concepts, and / or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work	7, 9
Specific aims	#6	Purpose of the project and of this report	6
Methods			

Context	#7	Contextual elements considered important at the outset of introducing the intervention(s)	7
Intervention(s)	#08a	Description of the intervention(s) in sufficient detail that others could reproduce it	8,9
Intervention(s)	#08b	Specifics of the team involved in the work	11
Study of the Intervention(s)	#09a	Approach chosen for assessing the impact of the intervention(s)	9,10,11
Study of the Intervention(s)	#09b	Approach used to establish whether the observed outcomes were due to the intervention(s)	12
Measures	#10a	Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability	4,5,7
Measures	#10b	Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost	11,12
Measures	#10c	Methods employed for assessing completeness and accuracy of data	11,12
Analysis	#11a	Qualitative and quantitative methods used to draw inferences from the data	8,9,10

Analysis	#11b	Methods for understanding variation within the data, including the effects of time as a variable	12, 21-23
Ethical considerations	#12	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest	9, 31
Results			
	#13a	Initial steps of the intervention(s) and their evolution over time (e.g., time-line diagram, flow chart, or table), including modifications made to the intervention during the project	7,8,11
	#13b	Details of the process measures and outcome	9-12
	#13c	Contextual elements that interacted with the intervention(s)	n/a (the intervention was fully monitored)
	#13d	Observed associations between outcomes, interventions, and relevant contextual elements	13,14
	#13e	Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s).	13,14, 18-20

	#13f	Details about missing data	n/a (no missing data)
Discussion			
Summary	#14a	Key findings, including relevance to the rationale and specific aims	24
Summary	#14b	Particular strengths of the project	26,27
Interpretation	#15a	Nature of the association between the intervention(s) and the outcomes	24,25
Interpretation	#15b	Comparison of results with findings from other publications	25,26
Interpretation	#15c	Impact of the project on people and systems	n/a (the project determined if it is feasible to apply the non-pharmacological intervention in a feasibility RCT)
Interpretation	#15d	Reasons for any differences between observed and anticipated outcomes, including the influence of context	26
Interpretation	#15e	Costs and strategic trade-offs, including opportunity costs	n/a (The study did not assess cost-effectiveness)
Limitations	#16a	Limits to the generalizability of the work	26,27

Limitations	#16b	Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis	26
Limitations	#16c	Efforts made to minimize and adjust for limitations	26
Conclusion	#17a	Usefulness of the work	24, 27
Conclusion	#17b	Sustainability	27
Conclusion	#17c	Potential for spread to other contexts	26,27
Conclusion	#17d	Implications for practice and for further study in the field	25,26
Conclusion	#17e	Suggested next steps	27
Other information			
Funding	#18	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting	31

Notes:

- 13c: n/a (the intervention was fully monitored)
- 13f: n/a (no missing data as all intervention sessions were video recorded)

- 15c: n/a (the project determined if it is feasible to apply the non-pharmacological intervention in a feasibility RCT)

- 15e: n/a (The study did not consider cost-effectiveness) The SQUIRE 2.0 checklist is distributed under the terms of the Creative Commons Attribution License CC BY-NC 4.0. This checklist was completed on 22. September 2020 using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai