BMJ Open

The Collaborative Care Model versus usual care for the management of musculoskeletal and co-existing mental health conditions: a randomised feasibility mixed method study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2023-079707
Article Type:	Original research
Date Submitted by the Author:	09-Sep-2023
Complete List of Authors:	Teixeira, Maria; Royal National Orthopaedic Hospital NHS Trust; London South Bank University, Ahmed, Refah; East London NHS Foundation Trust Tehrany, Rokhsaneh; Royal National Orthopaedic Hospital; University College London Jaggi, Anju; Royal National Orthopaedic Hospital Stanmore, Therapies Department Ramanuj, Parashar; Royal National Orthopaedic Hospital NHS Trust
Keywords:	Anxiety disorders < PSYCHIATRY, Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA SURGERY, Depression & mood disorders < PSYCHIATRY, MENTAL HEALTH, Physical Therapy Modalities, Randomized Controlled Trial

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Strengths and limitations of this study

- Pioneering approach: The first to incorporate a collaborative care model for supporting musculoskeletal patients with co-existing anxiety and depression at a tertiary hospital.
- Valuable insights: Evaluating perspectives from both patients and staff allowed the identification of barriers to trial implementation, informing modifications for a future trial.
- Retention strategy: Enhancing communication with participants is necessary for future multicentre studies.
- Generalisability: Due to the tertiary healthcare setting, the results may not be applicable to other healthcare settings and triangulation of patients' experiences based on adherence levels was limited

INTRODUCTION

Musculoskeletal conditions (MSK) are the leading cause of disability worldwide, affecting approximately 1.71 billion people. [1] In the United Kingdom (UK), 17.8 million people are currently affected by MSK chronic conditions, [2] where one in five adults consult their General Practitioner (GP) regarding MSK symptoms each year. [3] Chronic MSK conditions have been associated with approximately 30.8 million working days lost to absence, and a reduced ability to engage in social roles. [2] On an individual level, these conditions can substantially affect aspects of quality of life, such as self-care, functioning and mental health. [1, 2, 4].

Interplay between physical and mental health has become increasingly acknowledged in recent years, as epidemiological evidence suggests that mental health conditions increase the chances of developing physical conditions. [5] In the UK, one in six adults currently has a mental health condition such as anxiety and depression. [6] where the prevalence of self-reported mental health conditions is higher amongst people with MSK conditions, compared to those without (odds ratio 1.4). [7] For patients with both physical and mental health conditions in the orthopaedic setting, there is a greater risk of poor clinical outcomes, reduced patient satisfaction [4,8] and increased needs for both patients and healthcare services. [4]

Mounting evidence supports the biopsychosocial approach to enhance clinical outcomes and quality of life, [4, 8, 9] where integrated healthcare models which facilitate effective management of both physical and mental health conditions have gained widespread acceptance. [9, 10, 11] Previous systematic reviews have focused on psychological interventions such as cognitive behaviour therapy in the management of MSK conditions such as back pain[10, 11] However, there is wide evidence surrounding the management of people living with long-term MSK and mental health conditions.

Liaison Psychiatry already plays an important role in hospital settings to assess and manage co-occurring mental health disorders. [12] However, this approach traditionally operates on referral-and-triage, i.e. a reactive approach. [12] A potential proactive approach to facilitate the integration of physical and mental health care is through the implementation of the 'Collaborative Care Model' (CCM). Collaborative Care was initially developed in the 1990s in the USA to facilitate multidisciplinary working between physicians, psychiatrists, and clinical care coordinators (Case Managers) [13] and has since generated worldwide interest for its clinical and cost effectiveness. [13] The Case Manager is central to facilitating

the integration of care provided by psychological and physical healthcare professionals through screening, systematic follow-ups, and timely provision of care. Findings from RCTs and a systematic review have shown that the implementation of a CCM enhances liaison psychiatry provision with a positive impact on clinical outcomes in specialist physical settings, such as renal care, [12], diabetes [14] and oncology and chronic pain. [15]

Although the CCM has not yet found its place in clinical practice in the UK. [13], the National Institute for Health and Care Excellence (NICE) [16] recommends CCM implementation for people with moderate-severe depression and co-existing cancer and diabetes. [14,15] To our knowledge, only one cluster RCT has investigated the effectiveness of Collaborative Care intervention for managing depression and chronic MSK pain in primary care. [17] This study revealed significant improvements in depression severity after 12 months for patients under the Collaborative Care arm. However, pain levels remained unchanged due to a 'low intensity' intervention design and inadequate adherence by both patients and physicians. Furthermore, no qualitative evaluation explored the potential reasons contributing to low adherence.

Before a multi-centre RCT can test CCM's clinical and cost-effectiveness, feasibility and acceptability must be explored in accordance with the MRC guidelines for developing and evaluating complex interventions. [18] The primary aim of this study was to determine the feasibility and acceptability of conducting a future RCT evaluating the clinical and cost-effectiveness of the CCM for people with MSK and co-existing mental health conditions.

METHODS

Study design

This study followed a pre-registered protocol [19] (Supplementary file 1), where a single centre, parallel arm, non-blinded RCT design using a mixed method approach was implemented between February 2022 to October 2022. Participants were required to remain in the trial for a total of six months. Qualitative data were collected between October 2022 to December 2022. Ethical approval was obtained on January 2022 (**INSERT WHICH COMMITTEE AND REC NUMBER)**. The Consolidated Standards of Reporting Trials (CONSORT) checklist was used.

Setting and Participants

The trial was conducted in a tertiary NHS hospital specialising in orthopaedic conditions, United Kingdom. Healthcare professionals were briefed on the eligibility criteria (Table 1) and introduced the study during initial appointments. Interested participants could meet a research team member post-appointment for further details about the study.

Table 1. Inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
Age ≥18 years old, diagnosed with musculoskeletal conditions and opting for outpatient therapy appointments.	Patients with a diagnosed mental health condition already receiving psychological treatment or are under the care of a specialist mental health service.
A score of ≥ 20 on the Patient Health Questionnaire Anxiety Depression Scale (PHQ-ADS).	A score of <20 on the PHQ-ADS.
Able to provide written informed consent and willing to participate.	Lacking the capacity to consent.
Able and willing to complete study questionnaires and assessments.	Unable or unwilling to complete study questionnaires and assessments.

Screening and Enrolment

Patients gave written consent within 3 weeks of initial contact during MSK appointments. The Principal Investigator screened them with the PHQ-ADS questionnaire, communicating reasons for exclusion (Supplementary file 2).

Randomisation and Blinding

Of the 89 patients who provided consent to take part, 40 participants who matched the eligibility criteria were randomised according to a 1:1 ratio usual care (n=20), CCM (n=20). Allocations were concealed and undertaken via online randomisation software (https://www.sealedenvelope.com/) [21] by the Principal Investigator. Given the focus on evaluating the feasibility of providing Case Manager support (the CCM), blinding healthcare professionals or participants was not possible.

Intervention – Collaborative Care Model (CCM)

The CCM intervention involved a tailored program to facilitate integration of physical and mental healthcare. A Case Manager signpost mental health support for patients under the CCM arm, alongside routine physiotherapy or occupational therapy. The intervention was managed by a dedicated Case Manager through in-person, phone, or video consultations on a monthly basis, but weekly contacts were needed at times. This involved co-ordinating care among physiotherapists, occupational therapists, psychologists, and psychiatrists.

Usual care

Physiotherapists or occupational therapists assessed participants' needs, creating personalised rehabilitation plans. Therapy included 1:1 sessions and potential group classes. Physiotherapy featured exercises and education, while occupational therapy addressed activities of daily living. Additional mental health support was sought through GP referrals or internal Trust mental health services, if required, following standard care procedures.

Data collection

All participants from both arms of the trial were asked to complete four baseline questionnaires after randomisation, PHQ-ADS, [20] EQ-5D-3L, [22] Musculoskeletal Health Questionnaire (MSK-HQ), [23] Numerical Pain Rating Scale (NPRS), [24] and the Pain Disability Index (PDI), [25] which took up to 25 minutes to complete. These included tailored questionnaires on demographic data (age, ethnicity, marital status, highest qualification level, and employment status), medical history, current medication usage and self-reported measures.

Participants repeated baseline self-reported outcome measures at the 6-month follow-up, reported medication changes, and indicated their progress through the Global Rating of Change (GROC). [26] Usage of healthcare resources was documented, collected through face-to-face, phone, or video appointments based on participant choice and availability.

Primary Outcomes

The feasibility outcomes were participation, randomisation, retention, and adherence to the intervention at month 6. Some criteria for progression were established: minimum consent rate of 20%; minimum recruitment rate of 10%; maximum withdrawal rate 25%; minimum adherence rate of 75%.

Participation and Randomisation

This feasibility trial used descriptive analyses without hypothesis testing, hence no formal sample size calculation was performed. The goal was to recruit 40 patients in three months, estimating a recruitment rate within +/- 6% at a 95% confidence level.

Retention and Adherence

Retention was calculated as participants who remained in the study at month 6, while adherence was the percentage of attended appointments out of the total number of booked appointments.

Secondary Outcomes

Secondary outcomes aligned with testing the intervention and its real-world implementation. [27] These outcomes included acceptability of self-reported measures, trial acceptability for patients and professionals (including barriers and facilitators), additional healthcare resource usage, and staff costs estimation for intervention arm.

Acceptability of self-reported measures

Various Patient Reported Outcome Measures (PROMs) were collected, with necessary copyrights obtained. These focused on anxiety, depression, quality of life, physical health, pain, and global change.

Anxiety and depression

The 16-item Patient Health Questionnaire Anxiety and Depression Scale [20] (PHQ-ADS) to measure the severity of anxiety and depressive levels.

Quality of life

The five-item EuroQol-5 Dimension (EQ-5D-3L) [22] is a standardised measure for health-related quality of life (HRQOL), recommended by NICE [16] for clinical trial economic evaluations.

Quality of physical health

The 14-item Musculoskeletal Health Questionnaire (MSK-HQ) [23] assesses several domains: pain severity, physical function, work interference, social interference, sleep, fatigue, emotional health, physical activity, independence, understanding, confidence to self-manage and overall impact.

Level of pain

Two measures were used to assess overall pain levels, namely the 11-point Numerical Pain Rating Scale (NPRS) [24] and the Pain Disability Index (PDI). [25] PDI assesses the impact of chronic pain on patients' daily lives and measures seven life activity categories. NPRS scoring from 0 (no pain) to 10 (worse).

Global change

The 15-item Global Rating of Change (GROC) [26] scale can indicate whether an overall condition is improving or worsening, as well as indicate the extent of this change.

Acceptability of the trial by patients and healthcare professionals

Participant feedback was evaluated through a patient-centric approach. [26] This involved interviews with patients and focus groups with healthcare professionals that were facilitated by the Principal Investigator who is an expert qualitative methodologist and did not have

prior participant contact. Interview and focus group guides were prepared by the research team (Supplementary files 3 and 4). All participants from both arms were invited to participate in interviews within a month of completing the 6-month follow-up either face-to-face, via telephone, or through video-call. Furthermore, 20 healthcare professionals involved in participant care were invited to join two virtual focus groups via Teams, within four weeks after the trial completion.

Additional healthcare resources

Establishing whether additional healthcare resources could be estimated by participant self-report form.

Staff costs and main resources to implement the CCM

Staff costs and resources for the intervention arm were estimated based on the number, type, and duration of appointments conducted by the Case Manager, therapists, and mental health specialist. Data were collected from the hospital therapies appointment booking system and the Case Manager's diary.

Data analysis

Data collected during this study will be made available on request from the corresponding author, if appropriate. The data will not be made publicly available in accordance with General Data Protection Regulation (GDPR).

Quantitative data analysis

This trial primarily focused on assessing the feasibility of a future RCT , involving a descriptive analysis of key process-related outcomes. Quantitative data were analysed using SPSS, [38] with recruitment and retention measured by absolute and relative frequencies. Healthcare resource utilisation was described by type and frequency. Clinical outcomes' acceptability was stated as completion percentages. The statistical analysis plan was planned by the study statistician. Staff costs for CCM participants' care were calculated using the National Cost Index (NCI), [29] except for the Case Manager's hourly cost, as their role was outside the NCI scope.

Qualitative data analysis

Interviews and focus groups were transcribed by an external company, then checked by the Principal Investigator and imported into NVIVO version 12. [30] Two research team members independently analysed participant and healthcare professional transcripts, resolving discrepancies with a third member to establish coding consensus. Analysis, using the 'Normalization Process Theory' (NPT), [31] began soon after data collection began.

SUICIDAL IDEATION AND RISK OF SELF-HARM PROTOCOL

For suicide risk, we implemented the Columbia-Suicide Severity Rating Scale (C-SSRS) protocol with a created flowchart for follow-up actions (Supplementary file 5). A steering committee supervised the trial.

PATIENT AND PUBLIC INVOLVEMENT

Patient stakeholders played a vital role in shaping the study's design, impacting its duration and reducing patient burden. Self-assessment measures were thoughtfully chosen to characterise this specific population. Three patients significantly contributed to creating patient materials and consent forms. Another three patients actively participated in the

steering committee, attending meetings to address emerging issues and ensure the study's smooth operation.

RESULTS

Baseline characteristics

Participant characteristics were mostly well balanced between the two groups at baseline. The average age of participants in the intervention and usual care arm was 48.5 (±15.85) and 47.25 (±18.18) years respectively, where there were more females than males in both groups. The ethnicity of participants under both arms was mostly English, while more participants under the intervention arm has a spouse/partner (n=12 versus n=7). Demographics are presented in Table 2.

Table 2. Patient demographic

Variables		Intervention arm	Control arm
Age mean, ± SD	----------	48.45 (± 15.85)	47.25 (± 18.18)
Gender n (%)	female	16 (40%)	15 (37.5%)
	male	4 (10%)	5 (12.5%)
Ethnicity n (%)	English /Welsh / Scottish / Northern Irish / British	13 (32.5%)	15 (37.5%)
	Indian	1 (2.5%)	1 (2.5%)
	Any other White background	3 (7.5%)	1 (2.5%)
	Black – Caribbean	-	1 (2.5%)
	Pakistani	-	1 (2.5%)
	Any other Mixed/ multiple ethnic background	1 (2.5%)	1 (2.5%)
	Any other Black/ African/ Caribbean background	1 (2.5%)	-
	Bangladeshi	1 (2.5%)	-
Marital status n (%)	Spouse/ partner	12 (30%)	7 (17.5%)
	No spouse/ partner	6 (15%)	5 (12.5%)
	Separated or divorced	2 (5%)	3 (7.5%)
	Widowed	-	2 (5%)
	Prefer not to say	-	3 (7.5%)
Highest qualification level n (%)	Higher (Degree or equivalent)	8 (20%)	8 (20%)
	Further (A level or equivalent)	8 (20%)	5 (12.5%)
	Secondary (GCSE or equivalent)	4 (10%)	3 (7.5%)
	Vocational	-	1 (2.5%)
	None	-	2 (5%)
	Prefer not to say	-	1 (2.5%)
Employment status n (%)	Employed	6 (15%)	6 (15%)
	Retired	2 (5%)	3 (7.5%)
	Unable to work	5 (12.5%)	4 (10%)
	Self-employed	3 (7.5%)	3 (7.5%)
	Out of work but not currently looking for work	3 (7.5%)	3 (7.5%)
	Out of work and looking for work	-	1 (2.5%)
	Informal carer paid full time	1 (2.5%)	-
	Prefer not to say		
Second Employment Status, n (%)	Informal carer paid full time	-	2 (5%)
	Retired	1 (2.5%)	-
	Student	1 (2.5%)	-

Feasibility

Participation and Randomisation

A total of 250 patients were approached and invited to participate during the study recruitment period between January 2022 to May 2022. Eighty-nine (35.6%) of the 250 patients provided consent between February 2022 to May 2022, where 40 of whom were deemed eligible for the trial following the screening process. These 40 participants were subsequently randomised to either the usual care arm (n=20) or the intervention arm (n=20). See CONSORT Flow (figure 1).

INSERT CONSORT FLOW CHART

At baseline, 20 participants (50%) presented with moderate levels of anxiety and depression, while the other 50% reported severe levels. Regarding the risk of suicide, 19 (47.5%) of the 40 participants randomised had risk of suicide: 13 (68.4%) had low risk, 4 (21.1%) had moderate risk and 2 (10.5%) high risk according to CSSR-S. On month 6, of the 25 participants retained, 8 (24%) presented mild levels of anxiety and depression; 10 (40%) moderate levels; and 9 (36%) with severe levels. Only 1 participant presented a low risk of suicide.

Retention and adherence

Twenty-five participants from the intervention and usual care arm were retained until the final follow-up at six months. The overall withdrawal rate was 37.5%, which was higher than the 25% threshold specified within success criteria (Table 3). Nevertheless, retention was similar amongst both groups, i.e., usual care n=8, intervention n=7. Reasons for non-attendance can be found in the CONSORT Flow diagram (Figure 1). A total of 102 appointments were booked for participants under the intervention arm by the Case Manager. Sixty out of the 102 appointments were attended by 17 participants. The average adherence rate for participants under the intervention arm was 58.82%. Monthly variations in adherence rates were observed. Month 4 had the lowest adherence rate (35.29%), while month 6 had the highest (76.4%). All self-reported measures (100%) were completed at baseline and 6-month follow-ups for the 25 retained participants, with only 3 missing data points.

Table 3. Feasibility outcomes summary

Primary Outcomes	Feasibility Outcomes	Expected outcome	Outcomes
Participation	Number of participants consented as a proportion of the number of eligible and invited patients.	Having at least 4,000 new patients per year, assuming 20% are eligible, we intend to consent 20% of the invited patients.	250 participants approached & 89 recruited Participation 35.6 %
Randomised	Uptake/time to recruit 40 patients from mental health categories of interest	Assuming a recruitment rate of 20% eligible and invited patients, this will give an estimate of the recruitment rate with a 95% confidence interval width of ± 6%	Randomised = 94%
Retention	Retention of 36 participants from mental health categories of interest	Assuming an overall withdrawal rate of 10% (4/40), this will give an estimate of the retention rate with a 95% confidence interval width of ± 9%	Retention = 25 participants Withdraw (15/40) = 37.5% Usual care (8/20) = 40% Intervention arm (7/20) = 35%
Patient adherence	Percentage of appointments attended as a proportion of booked appointments	An estimated adherence rate of approximately 90% (32/36 retained patients), will give a 95% confidence interval width of ± 10%	Intervention arm (n=13) 60/ 102 appointments booked Adherence rate = 58.82%

Secondary outcomes

All intervention and usual care participants were interviewed. A total of 25 participants participated in interviews, and 8 of the 20 healthcare professionals joined a focus group.

Acceptability of the trial by patients

Twenty-five participants (intervention arm: n=13, usual care arm: n=12) consented to interviews. Both groups acknowledged the trial's importance in their care, valuing the inclusion of mental health alongside physical health. The Case Manager was a central figure, appreciated by most in the intervention arm, although one participant had higher expectations for their involvement. One participant expected the Case Manager to track investigations and appointments closely. Patients highlighted that this type of intervention should happen earlier in their care Additional information can be found in Supplementary file 6.

> *I think it was really positive. I think you've got the right people. I think the message is very clear. That there is a link between your physical illness and your mental illness. To be able to link the two and understand has been very positive.* **Participant 66, Collaborative Care**

One participant reinforced that the trial changed her life.

> *I think it's made …. life changing for me, really, because as I say, it was - it's gone from me and you having a chat to being able to sit down with [case manager] and get my problems out in the open and talk about them. Then I'm getting a psychiatrist who's helping me with my pain and dealing with that, so that's a massive benefit for me. Then dealing with my psychological problems as well, I've spoken about them, about what my issues are been given some tools to maybe help, to start me off with, before I get a proper appointment.* **Participant 31, Collaborative Care**

Facilitators and Barriers

All 25 participants valued the trial, citing benefits like being heard, access to psychiatric support, and reduced risk of suicide for two participants (one from usual care arm), emphasising trial significance.

> *I think it's important. It's imperative, but it doesn't happen. Mental health is so important but it's so - the service is so overrun at the moment that it's impossible to access anything.* **Participant 82, Usual Care**

Participants reported challenges, such as having to allocate personal time for Case Manager appointments and experiencing emotional discomfort during the trial.

Acceptability of self-reported measures

In interviews, 20 patient participants (intervention=11, usual care=9) provided feedback on questionnaires, highlighting areas for improvement such as clarity, simpler language, and shorter formats. Some found certain questionnaires overly generic and potentially dehumanising. Concerns arose about sensitive topics like suicide, pain, and depression. The summary of PROMs acceptance is in Supplementary file 7. Two participants suggested including open-ended questions in future questionnaires to allow patients to express their opinions and feelings during clinical care.

So, I don't know, maybe if they were changed, perhaps there should be a section where you can actually have a comment perhaps so that it isn't as cut and dried. **Participant 75, Collaborative Care**

Acceptability of the trial by clinicians – focus group

Eight (40%) out of 20 potential healthcare professionals under the intervention and usual care arm participated in the focus groups who had patients allocated to both arms. Baseline characteristics are presented in Table 4. Some quotations from focus groups' findings are presented in Supplementary file 8.

Table 4. Clinicians' demographic

	Gender	Profession	Years of experience in their profession	Clinic	Years of experience	Formal training in mental health
Participant 1	Male	Physiotherapist	8.5 years	Rehabilitation and pain	7 years	No
Participant 2	Female	Physiotherapist	9.5 years	Musculoskeletal	6 years	No
Participant 3	Male	Physiotherapist	6 years	Musculoskeletal	1 year	No
Participant 4	Female	Physiotherapist	4 years	Musculoskeletal	1 year	No
Participant 5	Female	Occupational Therapist	7 years	Shoulder	3 years	Yes
Participant 6	Female	Physiotherapist	38 years	Musculoskeletal	36 years	No
Participant 7	Female	Physiotherapist	8 years	Musculoskeletal	3 years	No
Participant 8	Female	Physiotherapist	12 years	Rehabilitation and pain	6 years	Yes

Overall, healthcare professionals largely viewed the trial as positive. They cited the significance for integrating physical and mental healthcare in an MSK context, addressing holistic patient needs and the importance of anxiety and depression risk scores in their practice. The suicide flowchart was praised for guiding referral pathways and formal mental health training was welcomed. Professionals noted limited mental health resources, highlighting the trial's potential for improving communication among all involved in patient care.

I think it felt really good that it was being recognised that it's not just a physical presentation of a condition that we're able to look at the whole person. **Participant 5**

Clinicians expressed a preference for the Case Manager to offer more comprehensive patient information and engage in formal meetings. They were aware of patients at suicide risk but lacked updates on their care progress or referrals to mental health services.

Probably, similarly. I mean, I just had contact with her [case manager] kind of discussing patients and saying, yes, this patient is happy to chat to you, and all of those interactions were quite positive. But that was probably the extent of it for me. **Participant 8**

Additional healthcare resources

Participants in both the intervention and usual care arms accessed a similar number of additional healthcare resources beyond their regular appointments. Specifically, in the intervention arm, 13 participants accessed a total of 51 appointments (29 with their GP, 15 with a private physiotherapist, 5 A&E visits, 1 with an osteopath, and 1 with a private psychologist). In comparison, the 12 participants in the usual care arm accessed 50 appointments (21 with their GP, 10 with a private physiotherapist, 7 with a chiropractor, 6

gym sessions, 4 A&E visits, 1 obstetric appointment during the trial, 1 with an NHS psychologist outside of the Trust, and 1 with a private psychiatrist)

Staff costs required to deliver the intervention

Thirteen participants in the intervention arm contributed to cost calculations. Case Manager appointments included 62 sessions (30 face-to-face, 19 via Teams, 13 by phone) totalling 65 hours and £1120.6. Booking/rescheduling time was not included. Physiotherapist appointments comprised 34 sessions (13 first, 21 follow-ups), totalling 23.5 hours and £427.46, however Occupational Therapy wasn't accessed. Psychiatrist appointments (5, 1 hour each) cost £1856.5. Seven participants had clinical psychologist triage at £53.22. Initial psychology sessions were post-trial. Overall, delivering the collaborative care model, including all staff and specialities, cost £3457.78 in 6 months, averaging £44.33 per participant per month.

DISCUSSION

The aim of this study was to assess the feasibility and acceptability of conducting a future definitive RCT to evaluate the clinical and cost effectiveness of implementing a CCM for integrating physical and mental healthcare in an MSK setting. The trial met the minimum criteria for consent and recruitment rates, as per pre-defined progression criteria. However, it did not meet the minimum requirements for adherence (58.82% vs. target of 75%) or retention, with 37.5% of participants withdrawing by the final six-month follow-up. Withdrawal rates were slightly higher in the usual care arm (40%) compared to the intervention arm (35%).

A future RCT will first require a pilot study to explore a more robust retention strategy. Maintaining participant retention and adherence to Case Manager appointments is a commonly cited challenge associated with implementing an RCT design and can be costly. [33] These challenges were evident in the current feasibility trial as potential features impacting retention and adherence were multifactorial, although principally attributed to the limited infrastructure and resources available to maintain adherence. [33, 34] Although the research team employed reminders via phone messages and calls, additional strategies are needed for future trials. Options include non-financial incentives, improved tracking methods, such as clinic and home outreach for challenging-to-locate participants, and covering travel and parking costs. [35]

Additionally, improving communication with participants between appointments by using a text message service or trial newsletters, [36] and considering participant communication preferences from the start will be beneficial. Recruitment occurred in a tertiary NHS hospital, where patients with complex physical needs are referred, which could, potentially lead to higher rates of mental health conditions compared to primary or secondary care settings. [37, 38]. It is possible that recruitment rates would be higher in a tertiary care setting due to their greater healthcare needs, hence caution is needed when generalising the findings to other healthcare settings. A future trial should consider employing two full-time research professionals with flexible hours for equitable recruitment and follow-up, accommodating patients in full-time employment.

Despite challenges with maintaining retention and adherence, healthcare professionals and patients largely embraced the trial. Facilitators included feeling heard by the Case Manager and the research team, as well as having access to appropriate psychiatric care (intervention participants). However, barriers involved waiting times for psychological

appointments and limited formal communication between the Case Manager and other healthcare professionals, which must be taken in consideration in a future trial.

Proposed changes to intervention

The qualitative findings offer valuable insights to enhance a future trial. Defining the Case Manager's role comprehensively, [38] specifying communication frequency, and establishing formal agreements with protected time are vital to manage expectations and ensure timely intervention. Establishing a formal agreement with protected time is crucial for timely assessment and intervention for Psychology department referrals. Funding allocation for a part-time Psychologist could improve patient support within the intervention arm, enhancing implementation and communication. Nevertheless, inadequate funding resulted in some participants missing therapy, diluting the intervention's impact. Due to growing evidence to support the effectiveness of psychological interventions delivered by Allied Health Professionals (AHPs), [40] consideration could be made to train AHPs, such as physiotherapists and occupational therapists, to take on the Case Manager's role.

Proposed changes to methodology

Several modifications are proposed. To emphasise physical improvement through mental health optimisation, consider MSK-HQ as the primary outcome in future research. Incorporate the Client Service Receipt Inventory (CSRI) [41] to calculate service use costs. Include open-ended questions at the final follow-up in patient interviews to boost retention and assess the study's social value [42] by providing person-centred care and ensuring participants feel heard. [43] To prevent contamination, explore a cluster randomised design between the intervention and usual care arms.

Conclusions

This feasibility trial offers valuable evidence that clinicians and participants in both arms valued the trial for facilitating integration of physical and psychological care. This trial demonstrates the feasibility of of recruiting to the CCM within a tertiary care centre setting. While retention and adherence rates fell short of expectations, robust retention strategies can mitigate this in a future trial. Qualitative data informed modifications to enhance the intervention, delivery model, and study design for a future multicentre trial.

References

1. WHO. Musculoskeletal conditions [Internet]. 2022. Available from: https://www.who.int/news-room/fact-sheets/detail/musculoskeletal-conditions [accessed Feb 2023].
2. James SL, Abate D, Abate KH, *et al. Global, regional, and national incidence, prevalence, and years lived with disability for 354 Diseases and Injuries for 195 countries and territories* 1990-2017: A systematic analysis for the Global Burden of Disease Study 2017. Lancet. 2018;392(10159):1789–858.
3. Reed M, Brittain R, Dawson-bowling S*, et al.* 18th Annual Report 2021. Njr UK. 2021.
4. ARUK. *Osteoarthritis in general practice: Data and perspectives*. Vol. 222, The Medical Press. 2018.
5. Doherty AM, Gaughran F. *The interface of physical and mental health* Soc Psychiatry Psychiatr Epidemiol. 2014;49(5):673–82.

6. McManus, S, Bebbington, PE, Jenkins, R, & Brugha T. *Mental health and wellbeing in England: the adult psychiatric morbidity survey* 2014. London: NHS digital; 2016.

7. HM Government. *Musculoskeletal conditions profile: short commentary*, May 2022. Available from: https://www.gov.uk/government/publications/musculoskeletal-health-5-year-prevention-strategic-framework (accessed December 2022)

8. Jørgensen R, Zoffmann V, Munk-Jørgensen P, *et al. Relationships over time of subjective and objective elements of recovery in persons with schizophrenia* Psychiatry Res. 2015;228(1):14–9. doi.org/10.1016/j.psychres.2015.03.013

9. NHS England. *The NHS long term plan*. London, NHS Engl. 2019;

10. Saragiotto BT, de Almeida MO, Yamato TP, Maher CG. *Multidisciplinary biopsychosocial rehabilitation for nonspecific chronic low back pain* Phys Ther. 2016;96(6):759–63.

11. Firth J *et al*. *The Lancet Psychiatry Commission: a blueprint for protecting physical health in people with mental illness* The Lancet Psychiatry. 2019;6(8):675–712.

12. Howarth BS, Bourgeois JA, Kates N. *Consultation-Liaison Psychiatry and Collaborative Care Models of the Patient with Renal Disease* Psychonephrology. 2022;147–59.

13. Ramanuj PP, Pincus HA. *Collaborative care: Enough of the why; What about the how?* Br J Psychiatry. 2019;215(4):573–6.

14. Atlantis E, Fahey P, Foster J. *Collaborative care for comorbid depression and diabetes: A systematic review and meta-analysis* BMJ Open. 2014;4(4).

15. Sharpe M, Walker J, Hansen CH, *et al*. *Integrated collaborative care for comorbid major depression in patients with cancer (SMaRT Oncology-2): A multicentre randomised controlled effectiveness trial* Lancet. 2014;384(9948):1099–108. doi.org/10.1016/S0140-6736(14)61231-9

16. NICE. *Depression in adults: recognition and management*. 2009. Available from: https://www.nice.org.uk/guidance/cg90 (accessed December 2022).

17. Skivington K, Matthews L, Simpson SA, *et al.* A new framework for developing and evaluating complex interventions: Update of Medical Research Council guidance. BMJ. 2021;374(2018):1–11.

18. Teixeira MJC, Tehrany R, Jaggi A, Ahmed RZ, Dove L, Ramanuj, P *Collaborative care model versus usual care for people with musculoskeletal conditions and co-existing anxiety and depression: Protocol for a feasibility mixed-methods randomised controlled trial* BJPsych Open. 2023; 9(4), E109. doi:10.1192/bjo.2023.80

19. Kroenke K, Wu J, Yu Z, Bair MJ, Kean J, Stump T, Monahan PO. *Patient Health Questionnaire Anxiety and Depression Scale: Initial Validation in Three Clinical Trials* Am Psychosom Soc. 2016;

20. Sealed Envelope. Simple randomisation service. 2021. Available from: https://www.sealedenvelope.com/ (accessed in February 2022)

21. EuroQol. EQ-5D. 2021 Available from: https://euroqol.org/eq-5d-instruments/ (accessed in July 2021)

22. Hill JC, Kang S, Benedetto E, *et al. Development and initial cohort validation of the Arthritis Research UK Musculoskeletal Health Questionnaire (MSK-HQ) for use across musculoskeletal care pathways* BMJ Open. 2016;6(8):1–10.

23. Cristiana K, Joshua AC. *Visual analogue scale, numeric pain rating scale and the McGill pain Questionnaire: an overview of psychometric properties* Phys Ther Rev.

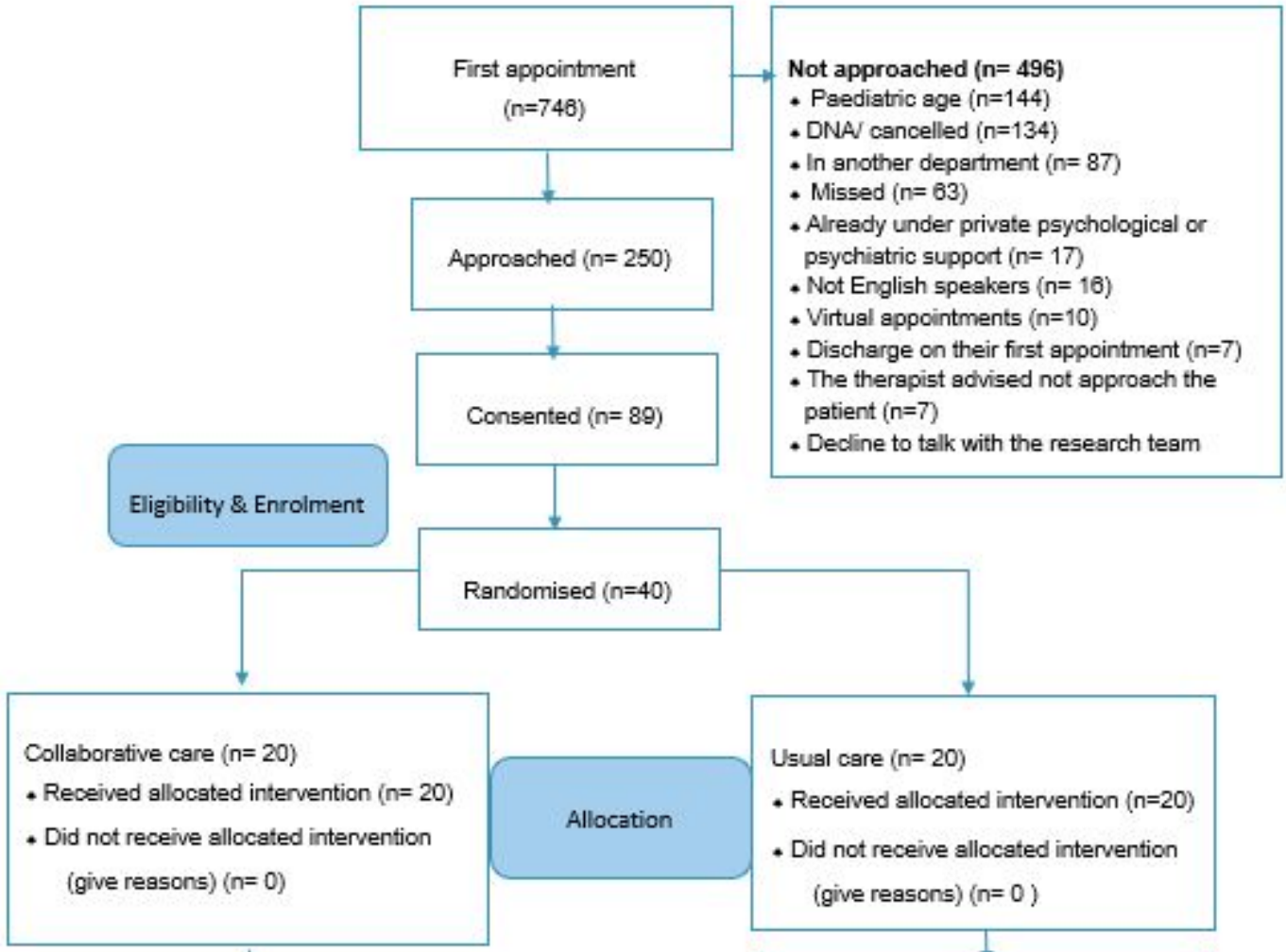
2005;10(2):123–8.

24. Chibnall JT, Tait RC. *The Pain Disability Index: factor structure and normative data* Arch Phys Med Rehabil. 1994;75(10):1082–6.
25. Sharma S, Palanchoke J, Reed D, Haxby Abbott J. *Translation, cross-cultural adaptation and psychometric properties of the Nepali versions of numerical pain rating scale and global rating of change* Health Qual Life Outcomes. 2017;15(1):1–11.
26. Bombard Y, Baker GR, Orlando E, *et al*. *Engaging patients to improve quality of care: A systematic review* Implement Sci. 2018;13(1).
27. Verma JP. Data analysis in management with SPSS software. Springer S. London; 2012.
28. NHS. National Cost Collection for the NHS. Available from: https://www.england.nhs.uk/costing-in-the-nhs/national-cost-collection/ (accessed Dec 2022)
29. Maher C, Hadfield M, Hutchings M, de Eyto A. *Ensuring rigor in qualitative data analysis: A design research approach to coding combining NVivo with traditional material methods* Int J Qual Methods. 2018;17(1):1609406918786362.
30. May CR, Cummings A, Girling M, *et al. Using Normalization Process Theory in feasibility studies and process evaluations of complex healthcare interventions: a systematic review* Implementation Science, 2018;13:1–42.
31. Bjureberg J, Dahlin M, Carlborg A, Edberg H, Haglund A, Runeson B. *Columbia-Suicide Severity Rating Scale Screen Version: Initial screening for suicide risk in a psychiatric emergency department* Psychol Med. 2021;52(16):1-9. 10.1017/S0033291721000751
32. Murphy E, Shiely F, Treweek S. *How much is the lack of retention evidence costing trial teams in Ireland and the UK?* Trials. 2022;23(1):1–13.
33. Kearney A, Daykin A, Shaw ARG, *et al. Identifying research priorities for effective retention strategies in clinical trials* Trials. 2017;18(1):1–12.
34. Robinson KA, Dinglas VD, Sukrithan V, Yalamanchilli R, Mendez-Tellez PA, Dennison-Himmelfarb C, et al. *Updated systematic review identifies substantial number of retention strategies: Using more strategies retains more study participants*. J Clin Epidemiol. 2015;68(12):1481–7.
35. Nelson EA, Maruish ME, Axler JL. Effects of discharge planning and compliance with outpatient appointments on readmission rates. Psychiatr Serv. 2000;51(7):885–9.
36. Rayner L, Matcham F, Hutton J, *et al*. *Embedding integrated mental health assessment and management in general hospital settings: feasibility, acceptability and the prevalence of common mental disorder* Gen Hosp Psychiatry. 2014;36(3):318–24.
37. Bialosky JE, Bishop MD CJ. *Individual expectation: an overlooked, but pertinent, factor in the treatment of individuals experiencing musculoskeletal pain* Phys Ther. 2010;90(9):1345–55.
38. Gunn J, Diggens J, Hegarty K, Blashki G. *A systematic review of complex system interventions designed to increase recovery from depression in primary care* BMC Health Serv Res. 2006;6:1–11.
39. Guerrero AVS, Maujean A, Campbell L, Sterling M. *A Systematic Review and Meta-Analysis of the Effectiveness of Psychological Interventions Delivered by Physiotherapists on Pain, Disability and Psychological Outcomes in Musculoskeletal Pain Conditions* Clin J Pain. 2018;34(9):838–57.

40. Beecham J, Knapp M. Costing *Psychiatric interventions. In: Thornicroft, Graham (ed.), editor. Measuring Mental Health Needs* London; 2001. 200–24.

41. Rid A, Wendler D. *Risk-benefit assessment in medical research--critical review and open questions* Law, Probab Risk. 2010;9(3–4):151–77.

42. Archer J, Bower P, Gilbody S, *et al. Collaborative care for depression and anxiety problems (Review)* Cochrane Database Syst Rev. 2012;(2).



1. **Reasons for not consenting**

Of the 250 patients approached, 162 (64.8%) did not consent:

- 48 (29.6%) were not interested in taking part in the study.
- 33 (20.4%) too much going on.
- 26 (16.0%) never answered the calls done after being approached.
- 21 (13%) were willing to consent. However, they never had their next appointment at outpatient therapies booked.
- 19 (11.7%) were approached. The research team would call them in 1 week's time. Meanwhile, the randomisation numbers were achieved.
- 12 (7.4%) declined to participate, but no reason was given.
- 3 (1.9%) other reasons: 1 patient was a therapist in the team; one patient would like to be consented to outside of the Trust, and 1 patient was willing to consent but disclosed she was under psychiatric support before consent.

2. **Reason to not randomise**

38 (98%) participants (34 – 68.4% females and 14 – 28.6% males) score less than 20 on the PHQ-ADS, and 1 (2%) participant (female) was under private psychiatric.

I. What factors influenced your decision to take part in the trial?

II. Tell me about your experience during the trial?

III. Tell me about your experience with the support you received from the case manager. (Only for participants under the intervention arm)

IV. How was your experience in navigating through the support of the collaborative care model/ support from different professionals at the same time? (Only for participants under the intervention arm). Do you think that this type of support was helpful to you? What could be improved? (Only for participants under the intervention arm)

V. What aspects of the trial went well?

VI. What aspects of the trial could be better or should be changed?

VII. What do you think about the number of follow-ups provided by the case manager? (Only for participants under the intervention arm)

VIII. Did you have any referral to have psychological or psychiatric support during the trial?

IX. (if applicable) Was the psychological/ psychiatric support sufficient? Did it meet your needs and expectations? Would you have preferred some other form of support? (Rephrase this question according to the type of support that participants get through the trial)

X. (if applicable) What helped you to attend appointments booked for you? What prevented you from attending appointments booked for you? (Rephrase in case the levels of adherence of the participant were low during the trial e.g. What prevented you from carrying out these appointments?)

XI. Do you think this type of intervention was useful? Why? (Only for participants under the intervention arm)

XII. What are your feelings about being randomised for the usual care?

XIII. What were the advantages of taking part in the trial?

XIV. What were the disadvantages of taking part in the trial?

XV. Other thoughts about the trial?

XVI. Any other comments?

I. Tell me about your experience of working with patients recruited for the trial.

II. Tell me about your experience of working with patients under the case manager's support.

III. How did you find yourself working with the case manager?

IV. What aspects of this collaborative work went well? What could be improved upon?

V. What aspects of the data collection could be better or should be changed?

VI. What do you think about the psychological/ psychiatric support provided to the participants? (Was there enough provision? Was the provision appropriate to the participant's needs?)

VII. Would you like to see any other or additional support being offered? Why? (Reasons)

VIII. Do you think that this type of intervention was useful to your patients and your own workload? Why?

IX. What do you think about the Suicidal ideation and risk of self-harm flow chart?

X. Other thoughts about the trial?

XI. Any other comments or suggestions?

Suicidal ideation may be identified using the PHQ-ADS for all participants, which asks specifically about thoughts of self-harm. Participants may also disclose this ideation at any point during the study from recruitment to discharge.

For any participant scoring 1 or higher on question 9 of the PHQ-ADS - '*Thoughts that you would be better off dead or of hurting yourself in some way'*, the research team discussed these thoughts with the patient and ask them to answer the Columbia-Suicide Severity Rated Scale Screen (C-SSRS) (1). The C-SSRS Screen is a validated 6-item assessment scale for people with suicidal ideation. It categorises patients into low, medium, and high risk. For example:

- Passive thoughts such as wishing to be dead with no further risk indicators are considered low risk.
- Methods and plans, or active thoughts such as wishing to cause self-harm are considered a moderate risk.
- Suicidal intent and any suicidal behaviour in the past 3 months indicate a high risk.

All triggers of the suicidal ideation and risk of self-harm protocol and the actions that are taken in response were recorded in the Research Risk of Self-Harm form and clinical notes.

Suicidal thoughts before randomisation, during usual care or at the end of study interviews

The research team informed the named clinician responsible for the participant's care of their level of risk via email. It is standard practice at the Trust that all thoughts of self-harm should be discussed with the RNOH Psychiatry Service. The RNOH Psychiatry Service either provided advice or review the participant depending on the level of risk and inform their GP. Participants were also be signposted to the 'Rethink Mental Illness' online resource website which provides information on coping with suicidal thoughts.

For participants who reveal suicidal thoughts for the first time during the end-of-study interview and are no longer under the care of the RNOH outpatient services, or for participants who refused to be referred to the RNOH Psychiatry Service, the research member discussed the participant's presentation with the Chief Investigator, who is a Consultant Psychiatrist, within 24 hours.

Suicidal thoughts reported by participants in the intervention group

If suicidal thoughts emerged in participants allocated to the intervention group, the Case Manager assessed the risk clinically, supported further using the C-SSRS Screening tool. The research team then asked for the participants' consent to make a referral according to the risk level:

1. Participants deemed to be at low risk were flagged up to their GP.
2. Participants at moderate risk were offered to be triaged and risk assessed by the hospital psychiatrist within one week of referral.
3. Participants at high risk were assessed immediately by the hospital psychiatrist.

If the participant refused to be referred due to their risk of self-harm, the Case Manager discussed the participant's presentation with the Chief Investigator. This was immediately for high-risk participants, within 24 hours for moderate-risk participants, and within 48 hours for low-risk participants.

References

1. Blades CA, Stritzke WG, Page AC, Brown JD. The benefits and risks of asking research participants about suicide: A meta-analysis of the impact of exposure to suicide-related content. Clin Psychol Rev [Internet]. 2018;64(July):1–12. doi.org/10.1016/j.cpr.2018.07.001

2. Bjureberg J, Dahlin M, Carlborg A, Edberg H, Haglund A, Runeson B. Columbia-Suicide Severity Rating Scale Screen Version: Initial screening for suicide risk in a psychiatric emergency department. Psychol Med. 2021;52(16):1-9. doi.org/10.1017/S0033291721000751

Dimension	Feedback	Theme	Qualitative feedback	Illustration
Reason for participating	24 participants shared their reason for participating in the trial.	Get additional support for their mental health and pain	20 participants were aiming to get additional support for their mental health (14) and for their pain (6).	*I was dealing a lot mentally and I felt that the support I didn't receive once I had my surgery at Stanmore wasn't good enough, and if I can do anything to help or improve a service that they could potentially offer, I would like to do so, just so someone doesn't have to go through with I had to deal with.* **Participant 20, Usual Care**
		Help others in the future	10 of the participants were also aiming that the results of the trial may help other people in the future.	*So, I think any study to help people with joint issues, whether that's simple back pain to more serious, I'm very happy to participate and share my views, really.* **Participant 66, Collaborative care**
				I think it's important. It's imperative, but it doesn't happen. Mental health is so important but it's so the service is so overrun at the moment that it's impossible to access anything. **Participant 82, Usual Care**
		Previous experiences with services	4 participants shared that their previous experience helped them to decide to participate in the study. 3 had previous negative experiences with their physical and mental support helped them to participate in this study. They want an improvement in the services provided to patients with chronic musculoskeletal diseases.	*Yes, I do. I mean, my first experience with the NHS when my knee first went bad, about 25 years ago, was absolutely appalling. It was rude, obnoxious, and all of the staff in that hospital were really horrible, yelling, saying horrible things to me, and that was the start of it. That was the start of being on the slippery slope because you think, 'Oh, what's going to happen next? It's been a bit of a rollercoaster of just people that work in the NHS.* **Participant 21, Usual Care**
Advantages of participating	18 participants disclosed the benefit of participating in the trial, even though under usual care.	Be heard	12 participants described the importance of being heard.	*Yeah, I think the experience was it was nice to be a part of and I suppose if I didn't get chosen there was someone that needed it more than me, but it was nice to be part of it and to have, to see you now to let you know how I've been and our conversations that we've had. It's been really helpful to me.* **Participant 46, Usual care**
		Managing difficult emotions	2 participants explained that they avoided committing suicide by participating in the study.	*No, related with me. Because six months ago I did feel like killing myself, because I didn't understand my condition. I had suicidal thoughts, and now, sitting here six months on, I don't have them thoughts anymore. I haven't had them thoughts from when I've got therapy, and the occupational therapy and the techniques takes that thought because you kind of have a little bit of hope of what – you can get through that bit. Instead of just giving up, I feel like giving up.* **Participant 62, Usual Care**
		Psychiatric support	2 participants added psychiatric support due to their risk of suicide; 1 participant was under usual care.	*Seeing [psychiatric name] has been a huge milestone and a huge benefit. I hope it will direct me on the right path now.* **Participant 26, Usual Care**

Dimension	Feedback	Theme	Qualitative feedback	Illustration
Disadvantages of participating	3 participants expressed disadvantages in participating in the trial.	Emotional support can have a negative effect	2 participants were sceptic regarding mental health support and the trial made her think about personal anger.	*But you never know what you're going to get and it could be 50-50, whether that actually makes you any better or make you any worse. That's just my view. It might not be that, but because I'm sceptical because of my experiences of the NHS, I'm very wary of them delving into my mind.* **Participant 21, Usual Care**
		Use of personal time	1 participant referred to the use of his own time in the study as a problem.	*Just that I use my time up.* **Participant 10, Collaborative Care**
	8 participants shared their feelings when they were allocated to usual care.	Being randomised to usual care	7 expressed their disappointment about not getting the case manager's support.	*I was disappointed because I think I desperately needed support and I always have, but I've struggled to get it.* **Participant 82, Usual Care**
Opinion about their case manager (intervention arm)	15 participant shared their opinion	Experience of Case Manager	10 participants expressed their experience with the case manager as a very positive experience, with an impact on their emotional and mental health.	*I thought she was wonderful. She was really kind. Really understanding. Really lovely person. I think as we were talking, it transpired that I possibly didn't need the emotional support as much anymore. Because I, over the years, have just managed to cope with things. I am in a better place. But I see her value. I think more of her would be great.* **Participant 66, Collaborative Care**
		More reassurance and review of patient progress on their care plan	5 participants would like to have someone to reassure them on their progress and their treatment plans.	*Maybe a bit more interaction with some people. With me, I didn't mind, because I don't need a lot of interaction. I have a lot going on anyway. But some people might benefit maybe checking in once a month, maybe just to have a conversation. Sometimes it's as easy as that, because if they're a bit lonely or a bit stressed, that [unclear] so they have someone to talk to, and understand their condition and stuff like that.* **Participant 86, Collaborative Care**
Opinion on their physical support	26 participants expressed their opinion about their physical support.	Personalised care	20 participants shared the importance of being listened to by their therapist. Moreover, the fact of personalised plan care makes all difference for them.	*I think my physiotherapist was great, and she was very helpful. She showed me obviously a lot of the exercises. I wasn't exactly great in keeping up with the exercises every single day, but I think - I have noticed a change in the pain in my hip, so the physio must have worked and so yeah, I think the whole overall experience with physio has been a lot better than my physio before when I had surgery when I was 16. It's a lot better this time around.* **Participant 24, Collaborative Care**
		Negative experience	6 participants also expressed negative feelings as the therapists talk too much instead of more concentrated in exercises, the presence of students without requesting permission, and different therapists at each appointment.	*If I'm honest, I feel like it could be a bit more hands on. It took quite a while for me to be like, can you just like examine my shoulders? Or can you do this, can you do that? I felt like it was more just they were talking at me. I didn't really like that. For me, physio is more of a – it's quite a physical thing. It's not just talking.* **Participant 10, Collaborative Car**
Significance of the trial	All participants expressed the importance of the trial.	Integrating mental and physical healthcare	All participants expressed the importance of the trial	*I think it was really positive. I think you've got the right people. I think the message is very clear. That there is a link between your physical illness and your mental illness. To be able to link the two and understand has been very positive.* **Participant 66, Collaborative Care**

Theme	Qualitative feedback	Illustration
Indecision about the option	7 participants found it difficult to select either numeric scales or qualitative options.	*The only thing is that sometimes it's really quite tricky. You really hesitate and you think well, because the whole business I think of assessing pain, you know, what's painful to me and what's painful to somebody else obviously is not the same really. So then I think well, perhaps I'm exaggerating here or perhaps I'm the opposite, you know. Perhaps actually it's a bit worse than that really.* **Participant 73, Usual Care**
A better explanation of some terms	3 participants found it difficult to understand some of the language used in the forms.	*I think I did ask [case manager] to explain a couple of the questions. I can't remember what they were. Again, I'm sure it was only a couple.* **Participant 33, Collaborative Care**
Not customised	4 participants expressed that some forms are generic which can create a feeling of dehumanisation.	*The generic mental health one, obviously I've had it a million times. My frustration sometimes would be like, oh. Just feeling like another person. I'm another person with mental health issues, like it is a bit dehumanising.* **Participant 32, Usual Care**
Sensitive topics	3 participants highlighted sensitive topics e.g. suicide, pain, and depression that can trigger negative emotions in patients.	*Talking about things that affect you. Talking about the lack of sleep you may get. It might bring someone to tears just because this is overwhelming. This is something that I go through. […] I think some of the questions can be a bit triggering.* **Participant 20, Usual Care**
Missing open questions	2 participants suggested that future forms should have opened questions to allow patients to express their opinions and feelings.	*So, I don't know, maybe if they were changed, perhaps there should be a section where you can actually have a comment perhaps so that it isn't as cut and dried.* **Participant 75, Collaborative Care**
Some questionnaires are too long	1 participant found the forms too long.	*I found the questionnaires very long. Sometimes I didn't know why certain questions were being asked, but don't ask me - I just found some of them quite hard to put a number on, to put a feeling on.* **Participant 60, Usual Care**

Dimension	Feedback	Theme	Qualitative feedback	Illustration
Importance of the trial	All participants agreed that the trial was indispensable	Understanding the importance of mental health in patient cohort	All participants expressed the importance of the study in highlighting mental health in patients with chronic musculoskeletal conditions.	*No other way to put that really. I think as we've seen the baseline data from CCOPER, haven't we, and we knew that anecdotally as well about the amount of mental health issues our patients have, whether that be low level or more moderate to severe and we know the impact that that has on their rehab and ability to manage their conditions. So, as we know many people at […] have long-term pain, long-term problems, and the association between mental health and long-term pain is huge we need to be able to target both of those aspects if we are supporting people properly to manage those long-term conditions. So, I think it's a really good thing that we're looking into that.* **Participant 1**
		Highlighted limited local mental health services	6 participants disclosed that the trial highlighted limited local mental health services.	*[…] the mental health of our patients is not the best, and actually they don't really have as much support as they should have, or that they need, and I guess, this is just hopefully helping us move forward and think about how we can better support them in that way, isn't it?* **Participant 7**
		Relief that someone took the time to investigate patients' mental health problems	4 participants shared their sense of relief when patients were recruited because they feel their patients will receive the right support for mental health issues.	*I agree there in terms of, you know, to be honest, it feels like a weight off your own shoulders if I'm totally honest with you. Because it kind of feels like that patient's being looked after by the people who should be looking after them because for me, you need to look after someone's mental health really before you come to treat them in an MSK environment unless it's some kind of acute problem that you're going to rehab quickly.* **Participant 4**
		Brought more evidence about the complexity of the Trust's patients	3 participants reinforced that the trial is essential to bring more evidence to something that everyone knows to be a problem: patients with musculoskeletal problems need more mental health support.	*Well, I think the study is helped us begin to shed some light on the complexity of the pathway. Which has been really, really useful. […] Multiple, multiple layers of it, and managing long term conditions has been a big political agenda for ages, and there's just not the money behind it yet, and we're just struggling at Stanmore trying to help. So, I think it's probably just given us a little bit more evidence about the layers and to maybe just label it better.* **Participant 6**
		Holist care	2 professionals highlighted the importance of the trial by providing a service that permits seeing the person as a whole.	*I think it felt really good that it was being recognised that it's not just a physical presentation of a condition that we're able to look at the whole person.* **Participant 5**

Dimension	Feedback	Theme	Qualitative feedback	Illustration
Experience in being involved in the trial	All participants shared their opinion.	Positive experience	All participants stated that the trial was a very positive experience for them.	*For me, it was just really positive to be honest, the whole experience. I found it like a real change after, you know, after being in MSK for the last four and a bit years, I thought it's about time this has come about, to be honest. Patients being looked after how they should be looked after from day dot. They've got the physio, they've got the mental health support. It was just, it really was compatible with our caseload as well. It worked well, engaging patients, helping them from a mental health point of view, turn their life around some of them.* **Participant 3**
		Confidence in managing difficult emotions	6 participants highlighted the usefulness of the suicide flowchart to understand the different referral paths.	*I think what I remember about it. I think it's useful in those moments – you panic a little bit, don't you because you are like, I don't know what I'm – so sometimes it is useful to go, okay, well, I have something concrete to go back to and refer back to, and I know what questions to ask, and I know what to do next. So, I think if you can't remember it off by heart, it's just knowing that there is something concrete that you can refer back to, I think is quite useful.* **Participant 7**
		Need for more effective communication channels	3 participants expressed that the trial made them think about better communication between all professionals involved in patient care.	*[…] the better outcomes I see happening are the ones where you have those communication pathways so everyone's on the same plan: the psychology team involved, the therapist and the patient. […] I know that's hard with external services, but I think it would be so valuable if we could work out a way to enhance the communication between the two teams.* **Participant 5**
		Understanding the importance of mental health of their patients	2 participants revealed the importance of the anxiety and depression risk scores to their practice.	*I personally haven't got a huge caseload, but I did have a couple of patients that you'd approached, and you needed to speak to me because they'd actually been identified as very high risk with mental health, which I hadn't been – the patient hadn't fully shared their journey with me, with that. So, that was an interesting learning point for me, and you'd escalated it, because he – one of them, particularly, had quite a high level of depression and anxiety.* **Participant 6**
		Awareness of a need for formal mental health training	2 participants shared that the trial made them think they need to have formal mental health training.	*I just hope that it just highlights that all the physios should have some extra training, some in-service or some formal training about it, so we can help our patients more.* **Participant 4**
Experience working with case manager in the trial	All participants shared their opinion.	They do not know who the participants were	All professionals do not have an idea what patients were randomised for the trial. They know who the patients at risk of suicide were.	*Probably, similarly. I mean, I just had contact with her kind of discussing patients and saying, yes, this patient is happy to chat to you and all of those interactions were quite positive. But that was probably the extent of it for me.* **Participant 1**

Dimension	Feedback	Theme	Qualitative feedback	Illustration
Suggestions to improve patient support in a future trial	All participants shared their opinion.	Access to outpatient psychological support	5 participants would like to have outpatient psychologists for their patients.	*I'm really aware that our psychology services are really stretched short staffed, I think because I work so closely with the psychologist.* **Participant 7**
		Community or social prescriber	5 participants suggested that a community or social prescriber should be part of the team to facilitate the discharge process to the community for patients who do not need psychological care/support inputs.	*Yeah, social prescribers, yes. I think that's a big – I know that's difficult because our patients come from all of the place, but I think somebody to link with local community services. I think that's another string to their bow that would be really helpful. Helping people to get involved in what's around them locally, groups or whatever it is, social stuff, and exercise, physical activity stuff.* **Participant 8**
		Duration of case manager support should be personalised	3 participants defended that the duration of the case manager support should be personalised.	*So, actually, for there to actually be change and momentum, and for them to be on the journey, I think you would probably need maybe a year, or a little bit longer to see a thorough change in terms of pathway, and making that more efficient, or helping them better navigate it, I think.* **Participant 7**
		Clear referral pathways for mental health support	3 participants also highlighted the importance of having a clear referral path for patients who need mental health support.	*I think, also my referrals to the psychologists aren't necessarily based on the risk of a patient. I think, if a patient is high risk, like suicide or something, I'm not going to refer them necessarily to our psychologist. I'm going to either call the liaison psychiatrist or call the GP. So, my referrals to psychology are more just if a patient feels stuck from a psychological perspective, or I'm stuck, and they need help with acceptance. [...] I don't know if that's right, or not? That's just kind of what I do.* **Participant 7**
		Better communication channels	2 participants defended better channels to professionals communicate with the case manager and other professionals	*Yeah. I think communication, but like the systems to support communication. Because our workload – we've got so many different systems. Every hospital trust does. But I don't think that helps, particularly.* **Participant 8**
		Formal debriefing for professionals	1 participant highlighted the importance to take of the professionals who should have a formal debriefing.	*You have to have formal debriefing, and we have none of that, and we take a lot of it on board, and we do our best, and we try and let outpatients de-escalate with us, and offload, and have aggression, a challenging group, and you see them in 30 minutes, and in and out and in, and out and there's – that's not right, either, to train us up, but give us none of the support.* **Participant 6**

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1 - abstract
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1 - abstrct
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	1
	2b	Specific objectives or hypotheses	2,3,4,5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	2,3,4,5
Participants	4a	Eligibility criteria for participants	2
	4b	Settings and locations where the data were collected	2,3
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	3 and article protocol
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	2,3,4
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Not applicable
Sample size	7a	How sample size was determined	4
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Not applicable
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	3
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	4
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	3
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	3
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	3

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	Not applicable
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	5
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	N/A feasibility
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	7 – Flow-chart
	13b	For each group, losses and exclusions after randomisation, together with reasons	7- Flow-chart
Recruitment	14a	Dates defining the periods of recruitment and follow-up	7 and 8
	14b	Why the trial ended or was stopped	Not applicable
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	6
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	6,8
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	7,8
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	8
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Not applicable
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	1
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	1, 11, 12
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	7, 8, 9, 10
Other information			
Registration	23	Registration number and name of trial registry	Title page
Protocol	24	Where the full trial protocol can be accessed, if available	Title page
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

Citation: Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMC Medicine. 2010;8:18.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up-to-date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

The Collaborative Care Model versus usual care for the management of musculoskeletal and co-existing mental health conditions: a randomised feasibility mixed method study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2023-079707.R1
Article Type:	Original research
Date Submitted by the Author:	14-Dec-2023
Complete List of Authors:	Teixeira, Maria; Royal National Orthopaedic Hospital NHS Trust; London South Bank University, Ahmed, Refah; East London NHS Foundation Trust Tehrany, Rokhsaneh; Royal National Orthopaedic Hospital; University College London Jaggi, Anju; Royal National Orthopaedic Hospital Stanmore, Therapies Department Ramanuj, Parashar; Royal National Orthopaedic Hospital NHS Trust
Primary Subject Heading:	Mental health
Secondary Subject Heading:	Surgery
Keywords:	Anxiety disorders < PSYCHIATRY, Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA SURGERY, Depression & mood disorders < PSYCHIATRY, MENTAL HEALTH, Physical Therapy Modalities, Randomized Controlled Trial

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

The Collaborative Care Model versus usual care for the management of musculoskeletal and co-existing mental health conditions: a randomised feasibility mixed method study

Short Title: CCOPER trial

Abstract

Objective: To assess the feasibility of a future trial comparing the Collaborative Care Model with usual care for patients with musculoskeletal conditions and co-existing symptoms of anxiety and depression.

Design: A single centre parallel arm, one-to-one, randomised Controlled Trial design using a mixed method approach was utilised. Semi-structured interviews and focus groups were conducted post-intervention with all participants and staff respectively to explore acceptability towards the model and identify recommendations for improvements.

Setting: An orthopaedic rehabilitation outpatient tertiary hospital.

Participants: Adult patients with musculoskeletal conditions and co-existing moderate or severe symptoms of anxiety and depression attending outpatient therapy appointments.

Intervention: The collaborative care model consisted of a tailored management programme to facilitate the integration of care provided by physical and mental healthcare professionals. A Case Manager screened and co-ordinated targeted mental health support for participants. Participants allocated to usual care had no support from the Case Manager.

Main outcomes measure: Feasibility indicators (rates of recruitment, randomisation, and retention), acceptability of clinical outcome measures, usage of additional resources and cost of intervention implementation.

Results: Of the 89 patients who provided consent to take part, 40 participants who matched the eligibility criteria who were randomised to either the intervention (n=20) or usual care arm (n=20). Overall adherence to the intervention was 58.82%, while the withdrawal rate was 37.5% at six months. All of 27 participants who were retained completed self-reported outcomes. Qualitative data highlighted that integrated mental health support was favourably perceived. Besides pre-negotiating protected psychology time, the need for operationalised communication between the Case Manager and clinicians was identified as a recommendation for a future trial.

Conclusions: The trial and intervention were acceptable to patients and healthcare professionals. While the findings demonstrate the feasibility of trial recruitment, a future trial will require optimised retention strategies to improve adherence and withdrawal rates.

Trial Registration: ClinicalTrials.Gov NCT05018039

Keywords Case manager, Chronic Musculoskeletal conditions, Collaborative Care Model, Mental health, Tertiary healthcare

Strengths and limitations of this study

- The study followed a pre-registered protocol to ensure transparency and minimise bias in the research process.
- A mixed method approach provided a holistic view of trial barriers and facilitators from varied perspectives.
- Interviews and focus groups facilitated comprehensive insights from patients and healthcare professionals, complementing objective data
- The study was conducted at a single centre, limiting the generalisability of the results to broader healthcare settings.
- Due to the nature of the intervention, blinding of healthcare professionals and participants was not possible, potentially introducing an element of bias into the study results.

Title Page

Authors
Maria Joao Cardoso Teixeira, [1,2,3,4]
Refah Z Ahmed [5]
Rokhsaneh Tehrany [6, 7]
Anju Jaggi[8]
Parashar Ramanuj[9]

Institutional Addresses
[1] Nursing Research Department, Royal National Orthopaedic Hospital NHS Trust, London, UK
[2] NIHR Nursing and Midwifery, UK
[3] London South Bank University, London, UK
[4] Nuffield Health Oxford, The Manor Hospital, Oxford, UK
[5] Assistant Psychologist, East London NHS Foundation Trust, UK
[6] Therapies Department, Royal National Orthopaedic Hospital NHS Trust, London, UK
[7] Department of Ortho and MSK Science, University College of London, UK
[8] Consultant Physiotherapist/Clinical Director of Therapies department, Royal National Orthopaedic Hospital NHS Trust, UK
[9] Consultant Psychiatrist and Chief Medical Information Officer, Royal National Orthopaedic Hospital NHS Trust, UK

Corresponding author:
Maria Joao Cardoso Teixeira
Email: jo.teixeira1@nhs.net
Telephone number: +44(0)20 3947 0294

Words count: 4357

INTRODUCTION

Musculoskeletal conditions (MSK) are the leading cause of disability worldwide, affecting approximately 1.71 billion people. [1] In the United Kingdom (UK), 17.8 million people are currently affected by MSK chronic conditions, [2] where one in five adults consult their General Practitioner (GP) regarding MSK symptoms each year. [3] Chronic MSK conditions have been associated with approximately 30.8 million working days lost to absence, and a reduced ability to engage in social roles. [2] On an individual level, these conditions can substantially affect aspects of quality of life, such as self-care, functioning and mental health. [1, 2, 4].

Interplay between physical and mental health has become increasingly acknowledged in recent years, as epidemiological evidence suggests that mental health conditions increase the chances of developing physical conditions. [5] In the UK, one in six adults currently has a mental health condition such as anxiety and depression. [6] where the prevalence of self-reported mental health conditions is higher amongst people with MSK conditions, compared to those without (odds ratio 1.4). [7] For patients with both physical and mental health conditions in the orthopaedic setting, there is a greater risk of poor clinical outcomes, reduced patient satisfaction [4,8] and increased needs for both patients and healthcare services. [4]

Mounting evidence supports the biopsychosocial approach to enhance clinical outcomes and quality of life, [4, 8, 9] where integrated healthcare models, which facilitate effective management of both physical and mental health conditions have gained widespread acceptance. [9, 10, 11] Previous systematic reviews have focused on psychological interventions such as cognitive behaviour therapy in the management of MSK conditions such as back pain. [10, 11] However, there is wide evidence surrounding the management of people living with long-term MSK and mental health conditions.

Liaison Psychiatry already plays an important role in hospital settings to assess and manage co-occurring mental health disorders. [12] However, this approach traditionally operates on referral-and-triage, i.e. a reactive approach. [12] A potential proactive approach to facilitate the integration of physical and mental health care is through the implementation of the 'Collaborative Care Model' (CCM). Collaborative Care was initially developed in the 1990s in the USA to facilitate multidisciplinary working between physicians, psychiatrists, and clinical care coordinators (Case Managers) [13] and has since generated worldwide interest for its clinical and cost effectiveness. [13] The Case Manager is central to facilitating the integration of care provided by psychological and physical healthcare professionals through screening, systematic follow-ups, and timely provision of care. Findings from RCTs and a systematic review have shown that the implementation of a CCM enhances liaison psychiatry provision with a positive impact on clinical outcomes in specialist physical settings, such as renal care, [12] diabetes, [14] and oncology and chronic pain. [15]

Although the CCM has not yet found its place in clinical practice in the UK, [13] the National Institute for Health and Care Excellence (NICE) [16] recommends CCM implementation for people with moderate-severe depression and co-existing cancer and diabetes. [14,15] To our knowledge, only one cluster RCT has investigated the effectiveness of Collaborative Care intervention for managing depression and chronic MSK pain in primary care. [17] This study revealed significant improvements in depression severity after 12 months for patients under the Collaborative Care arm. However, pain levels remained

unchanged due to a 'low intensity' intervention design and inadequate adherence by both patients and physicians. Furthermore, no qualitative evaluation explored the potential reasons contributing to low adherence.

Before a multi-centre RCT can test CCM's clinical and cost-effectiveness, feasibility and acceptability must be explored in accordance with the MRC guidelines for developing and evaluating complex interventions. [18] The primary aim of this study was to determine the feasibility and acceptability of conducting a future RCT evaluating the clinical and cost-effectiveness of the CCM for people with MSK and co-existing mental health conditions.

METHODS

Study design

This study followed a pre-registered protocol, [19] where a single centre, parallel arm, non-blinded RCT design using a mixed method approach was implemented between February 2022 to October 2022. Participants were required to remain in the trial for a total of six months. Qualitative data were collected between October 2022 to December 2022. Ethical approval was obtained on January 2022 by Cambs and Herts Research Ethics Committee 21/EE/0257. The Consolidated Standards of Reporting Trials (CONSORT) checklist for pilot or feasibility trial [20] was used.

Setting and Participants

The trial was conducted in a tertiary NHS hospital specialising in orthopaedic conditions, United Kingdom. Healthcare professionals were briefed on the eligibility criteria (Table 1) and introduced the study during initial appointments. Interested participants could meet a research team member post-appointment for further details about the study.

Table 1. Inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
Age ≥18 years old, diagnosed with musculoskeletal conditions and opting for outpatient therapy appointments.	Patients with a diagnosed mental health condition already receiving psychological treatment or are under the care of a specialist mental health service.
A score of ≥ 20 on the Patient Health Questionnaire Anxiety Depression Scale (PHQ-ADS). [21]	A score of <20 on the PHQ-ADS.
Able to provide written informed consent and willing to participate.	Lacking the capacity to consent.
Able and willing to complete study questionnaires and assessments.	Unable or unwilling to complete study questionnaires and assessments.

Screening and Enrolment

Patients gave written consent within 3 weeks of initial contact during MSK appointments. The Principal Investigator screened them with the PHQ-ADS questionnaire, communicating reasons for exclusion (Supplementary file 1).

Randomisation and Blinding

Of the 89 patients who provided consent to take part, 40 participants who matched the eligibility criteria were randomised according to a 1:1 ratio usual care (n=20), CCM (n=20). Allocations were concealed and undertaken via online randomisation software (https://www.sealedenvelope.com/) [22] by the Principal Investigator. Given the focus on

evaluating the feasibility of providing Case Manager support (the CCM), blinding healthcare professionals or participants was not possible.

Intervention – Collaborative Care Model (CCM)

The CCM intervention involved the provision of tailored mental and physical healthcare (delivered by physiotherapists, occupational therapists, psychiatrists and psychologists), which was co-ordinated through the support of a designated Case Manager. The Case Manager (who was an assistant psychologist) organised necessary mental health support according to individual needs that were identified through initial screening procedures. Following screening, the remit of the Case Manager was to:

- Develop personalised care plans
- Co-ordinate psychological and MSK outpatient appointments
- Monitor progress (through validated clinical questionnaires) and adjust support/appointments as necessary
- Streamline communication between physical and mental healthcare providers, as well and maintaining contact with the participant.

The provision of the Case Manger support was delivered in additional to the routine physiotherapy/occupational therapy outpatients' appointments (usual care) through in-person, phone, or video consultations on a monthly basis, but weekly contacts were needed at times.

Usual care

Physiotherapists or occupational therapists assessed participants' needs, creating personalised rehabilitation plans. Therapy included 1:1 sessions and potential group classes. Physiotherapy featured exercises and education, while occupational therapy addressed activities of daily living. Additional mental health support was sought through GP referrals or internal Trust mental health services, if required, following standard care procedures.

Data collection

All participants from both arms of the trial were asked to complete four baseline questionnaires after randomisation, PHQ-ADS, [21] EQ-5D-3L, [23] Musculoskeletal Health Questionnaire (MSK-HQ), [24] Numerical Pain Rating Scale (NPRS), [25] and the Pain Disability Index (PDI), [26] which took up to 25 minutes to complete. These included tailored questionnaires on demographic data (age, ethnicity, marital status, highest qualification level, and employment status), medical history, current medication usage and self-reported measures.

Participants repeated baseline self-reported outcome measures at the 6-month follow-up, reported medication changes, and indicated their progress through the Global Rating of Change (GROC). [27] Usage of healthcare resources was documented, collected through face-to-face, phone, or video appointments based on participant choice and availability.

Primary Outcomes

The feasibility outcomes were participation, randomisation, retention, and adherence to the intervention at month 6. Some criteria for progression were established: minimum consent rate of 20%; minimum recruitment rate of 10%; maximum withdrawal rate 25%; minimum adherence rate of 75%.

Participation and Randomisation
This feasibility trial used descriptive analyses without hypothesis testing, hence no formal sample size calculation was performed. The goal was to recruit 40 patients in three months, estimating a recruitment rate within +/- 6% at a 95% confidence level.

Retention and Adherence
Retention was calculated as participants who remained in the study at month 6, while adherence was the percentage of attended appointments out of the total number of booked appointments.

Secondary Outcomes

Secondary outcomes aligned with testing the intervention and its real-world implementation. [27] These outcomes included acceptability of self-reported measures, trial acceptability for patients and professionals (including barriers and facilitators), additional healthcare resource usage, and staff costs estimation for intervention arm.

Acceptability of self-reported measures
Various Patient Reported Outcome Measures (PROMs) were collected, with necessary copyrights obtained. These focused on anxiety, depression, quality of life, physical health, pain, and global change.

Anxiety and depression
The 16-item Patient Health Questionnaire Anxiety and Depression Scale [21] (PHQ-ADS) to measure the severity of anxiety and depressive levels.
Quality of life
The five-item EuroQol-5 Dimension (EQ-5D-3L) [23] is a standardised measure for health-related quality of life (HRQOL), recommended by NICE [16] for clinical trial economic evaluations.
Quality of physical health
The 14-item Musculoskeletal Health Questionnaire (MSK-HQ) [24] assesses several domains: pain severity, physical function, work interference, social interference, sleep, fatigue, emotional health, physical activity, independence, understanding, confidence to self-manage and overall impact.
Level of pain
Two measures were used to assess overall pain levels, namely the 11-point Numerical Pain Rating Scale (NPRS) [25] and the Pain Disability Index (PDI). [26] PDI assesses the impact of chronic pain on patients' daily lives and measures seven life activity categories. NPRS scoring from 0 (no pain) to 10 (worse).
Global change
The 15-item Global Rating of Change (GROC) [27] scale can indicate whether an overall condition is improving or worsening, as well as indicate the extent of this change.

Acceptability of the trial by patients and healthcare professionals
Participant feedback was evaluated through a patient-centric approach. [28] This involved interviews with patients and focus groups with healthcare professionals that were facilitated by the Principal Investigator who is an expert qualitative methodologist and did not have prior participant contact. Interview and focus group guides were prepared by the research

team (Supplementary files 2 and 3). All participants from both arms were invited to participate in interviews within a month of completing the 6-month follow-up either face-to-face, via telephone, or through video-call. Furthermore, 20 healthcare professionals involved in participant care were invited to join two virtual focus groups via Teams, within four weeks after the trial completion.

Additional healthcare resources

Establishing whether additional healthcare resources could be estimated by participant self-report form.

Staff costs and main resources to implement the CCM

Staff costs and resources for the intervention arm were estimated based on the number, type, and duration of appointments conducted by the Case Manager, therapists, and mental health specialist. Data were collected from the hospital therapies appointment booking system and the Case Manager's diary.

Data analysis

Data collected during this study will be made available on request from the corresponding author, if appropriate. The data will not be made publicly available in accordance with General Data Protection Regulation (GDPR).

Quantitative data analysis

This trial primarily focused on assessing the feasibility of a future RCT, involving a descriptive analysis of key process-related outcomes. Quantitative data were analysed using SPSS, [29] with recruitment and retention measured by absolute and relative frequencies. Healthcare resource utilisation was described by type and frequency. Clinical outcomes' acceptability was stated as completion percentages. The statistical analysis plan was planned by the study statistician. Staff costs for CCM participants' care were calculated using the National Cost Index (NCI), [30] except for the Case Manager's hourly cost, as their role was outside the NCI scope.

Qualitative data analysis

Interviews and focus groups were transcribed by an external company, then checked by the Principal Investigator and imported into NVIVO version 12. [31] Two research team members independently analysed participant and healthcare professional transcripts, resolving discrepancies with a third member to establish coding consensus. Analysis, using the 'Normalization Process Theory' (NPT), [32] began soon after data collection began.

SUICIDAL IDEATION AND RISK OF SELF-HARM PROTOCOL

For suicide risk, we implemented the Columbia-Suicide Severity Rating Scale (C-SSRS) [33] protocol with a created flowchart for follow-up actions (Supplementary file 4). A steering committee supervised the trial.

PATIENT AND PUBLIC INVOLVEMENT

Patient stakeholders played a vital role in shaping the study's design, impacting its duration and reducing patient burden. Self-assessment measures were thoughtfully chosen to characterise this specific population. Three patients significantly contributed to creating patient materials and consent forms. Another three patients actively participated in the

steering committee, attending meetings to address emerging issues and ensure the study's smooth operation.

RESULTS

Baseline characteristics

Participant characteristics were mostly well balanced between the two groups at baseline. The average age of participants in the intervention and usual care arm was 48.5 (±15.9) and 473 (±181) years respectively, where there were more women than men in both groups. The ethnicity of participants under both arms was mostly English, while more participants under the intervention arm has a spouse/partner (n=12 versus n=7). Demographics are presented in Table 2.

Table 2. Patient demographic

Variables		Intervention arm	Control arm
Age mean, ± SD	----------	48.5 (± 19)	47.3 (± 182)
Gender n (%)	Women	16 (40%)	15 (37.5%)
	Men	4 (10%)	5 (12.5%)
Ethnicity n (%)	English /Welsh / Scottish / Northern Irish / British	13 (32.5%)	15 (37.5%)
	Indian	1 (2.5%)	1 (2.5%)
	Any other White background	3 (7.5%)	1 (2.5%)
	Black – Caribbean	-	1 (2.5%)
	Pakistani	-	1 (2.5%)
	Any other Mixed/ multiple ethnic background	1 (2.5%)	1 (2.5%)
	Any other Black/ African/ Caribbean background	1 (2.5%)	-
	Bangladeshi	1 (2.5%)	-
Marital status n (%)	Spouse/ partner	12 (30%)	7 (17.5%)
	No spouse/ partner	6 (15%)	5 (12.5%)
	Separated or divorced	2 (5%)	3 (7.5%)
	Widowed	-	2 (5%)
	Prefer not to say	-	3 (7.5%)
Highest qualification level n (%)	Higher (Degree or equivalent)	8 (20%)	8 (20%)
	Further (A level or equivalent)	8 (20%)	5 (12.5%)
	Secondary (GCSE or equivalent)	4 (10%)	3 (7.5%)
	Vocational	-	1 (2.5%)
	None	-	2 (5%)
	Prefer not to say	-	1 (2.5%)
Employment status n (%)	Employed	6 (15%)	6 (15%)
	Retired	2 (5%)	3 (7.5%)
	Unable to work	5 (12.5%)	4 (10%)
	Self-employed	3 (7.5%)	3 (7.5%)
	Out of work but not currently looking for work	3 (7.5%)	3 (7.5%)
	Out of work and looking for work	-	1 (2.5%)
	Informal carer paid full time	1 (2.5%)	-
	Prefer not to say		
Second Employment Status, n (%)	Informal carer paid full time	-	2 (5%)
	Retired	1 (2.5%)	-
	Student	1 (2.5%)	-

Feasibility

Participation and Randomisation

A total of 250 patients were approached and invited to participate during the study recruitment period between January 2022 to May 2022. Eighty-nine (35.6%) of the 250 patients provided consent between February 2022 to May 2022, where 40 of whom were deemed eligible for the trial following the screening process. These 40 participants were subsequently randomised to either the usual care arm (n=20) or the intervention arm (n=20). See CONSORT Flow (figure 1).

INSERT CONSORT FLOW CHART

At baseline, 20 participants (50%) presented with moderate levels of anxiety and depression, while the other 50% reported severe levels. Regarding the risk of suicide, 19 (47.5%) of the 40 participants randomised had risk of suicide: 13 (68.4%) had low risk, 4 (21.1%) had moderate risk and 2 (10.5%) high risk according to CSSR-S. On month 6, of the 25 participants retained, 8 (24%) presented mild levels of anxiety and depression; 10 (40%) moderate levels; and 9 (36%) with severe levels. Only 1 participant presented a low risk of suicide.

Retention and adherence

Twenty-five participants from the intervention and usual care arm were retained until the final follow-up at six months. The overall withdrawal rate was 37.5%, which was higher than the 25% threshold specified within success criteria (Table 3). Nevertheless, retention was similar amongst both groups, i.e., usual care n=8, intervention n=7. Reasons for non-attendance can be found in the CONSORT Flow diagram (Figure 1). A total of 102 appointments were booked for participants under the intervention arm by the Case Manager. Sixty out of the 102 appointments were attended by 17 participants. The average adherence rate for participants under the intervention arm was 58.8%. Monthly variations in adherence rates were observed. Month 4 had the lowest adherence rate (35.3%), while month 6 had the highest (76.4%). All self-reported measures (100%) were completed at baseline and 6-month follow-ups for the 25 retained participants, with only 3 missing data points.

Table 3. Feasibility outcomes summary

Primary Outcomes	Feasibility Outcomes	Expected outcome	Outcomes
Participation	Number of participants consented as a proportion of the number of eligible and invited patients.	Having at least 4,000 new patients per year, assuming 20% are eligible, we intend to consent 20% of the invited patients.	250 participants approached & 89 recruited Participation 35.6 %
Randomised	Uptake/time to recruit 40 patients from mental health categories of interest	Assuming a recruitment rate of 20% eligible and invited patients, this will give an estimate of the recruitment rate with a 95% confidence interval width of ± 6%	Randomised = 40 = 9%
Retention	Retention of 36 participants from mental health categories of interest	Assuming an overall withdrawal rate of 10% (4/40), this will give an estimate of the retention rate with a 95% confidence interval width of ± 9%	Retention = 25 participants Withdraw (15/40) = 37.5% Usual care (8/20) = 40% Intervention arm (7/20) = 35%
Patient adherence	Percentage of appointments attended as a proportion of booked appointments	An estimated adherence rate of approximately 90% (32/36 retained patients), will give a 95% confidence interval width of ± 10%	Intervention arm (n=13) 60/ 102 appointments booked Adherence rate = 58.8%

Secondary outcomes

All intervention and usual care participants were interviewed. A total of 25 participants participated in interviews, and 8 of the 20 healthcare professionals joined a focus group.

Acceptability of the trial by patients

Twenty-five participants (intervention arm: n=13, usual care arm: n=12) consented to interviews. Both groups acknowledged the trial's importance in their care, valuing the inclusion of mental health alongside physical health. The Case Manager was a central figure, appreciated by most in the intervention arm, although one participant had higher expectations for their involvement. One participant expected the Case Manager to track investigations and appointments closely. Patients highlighted that this type of intervention should happen earlier in their care Additional information can be found in Supplementary file 5.

> *I think it was really positive. I think you've got the right people. I think the message is very clear. That there is a link between your physical illness and your mental illness. To be able to link the two and understand has been very positive.* **Participant 66, Collaborative Care**

One participant reinforced that the trial changed her life.

> *I think it's made …. life changing for me, really, because as I say, it was - it's gone from me and you having a chat to being able to sit down with [case manager] and get my problems out in the open and talk about them. Then I'm getting a psychiatrist who's helping me with my pain and dealing with that, so that's a massive benefit for me. Then dealing with my psychological problems as well, I've spoken about them, about what my issues are been given some tools to maybe help, to start me off with, before I get a proper appointment.* **Participant 31, Collaborative Care**

Facilitators and Barriers

All 25 participants valued the trial, citing benefits like being heard, access to psychiatric support, and reduced risk of suicide for two participants (one from usual care arm), emphasising trial significance.

> *I think it's important. It's imperative, but it doesn't happen. Mental health is so important but it's so - the service is so overrun at the moment that it's impossible to access anything.* **Participant 82, Usual Care**

Participants reported challenges, such as having to allocate personal time for Case Manager appointments and experiencing emotional discomfort during the trial.

Acceptability of self-reported measures

In interviews, 20 patient participants (intervention=11, usual care=9) provided feedback on questionnaires, highlighting areas for improvement such as clarity, simpler language, and shorter formats. Some found certain questionnaires overly generic and potentially dehumanising. Concerns arose about sensitive topics like suicide, pain, and depression. The summary of PROMs acceptance is in Supplementary file 6. Two participants suggested including open-ended questions in future questionnaires to allow patients to express their opinions and feelings during clinical care.

> *So, I don't know, maybe if they were changed, perhaps there should be a section where you can actually have a comment perhaps so that it isn't as cut and dried.* **Participant 75, Collaborative Care**

Acceptability of the trial by clinicians – focus group

Eight (40%) out of 20 potential healthcare professionals under the intervention and usual care arm participated in the focus groups who had patients allocated to both arms. Baseline characteristics are presented in Table 4. Some quotations from focus groups' findings are presented in Supplementary file 7.

Table 4. Clinicians' demographic

	Gender	Profession	Years of experience in their profession	Clinic	Years of experience	Formal training in mental health
Participant 1	Male	Physiotherapist	8.5 years	Rehabilitation and pain	7 years	No
Participant 2	Female	Physiotherapist	9.5 years	Musculoskeletal	6 years	No
Participant 3	Male	Physiotherapist	6 years	Musculoskeletal	1 year	No
Participant 4	Female	Physiotherapist	4 years	Musculoskeletal	1 year	No
Participant 5	Female	Occupational Therapist	7 years	Shoulder	3 years	Yes
Participant 6	Female	Physiotherapist	38 years	Musculoskeletal	36 years	No
Participant 7	Female	Physiotherapist	8 years	Musculoskeletal	3 years	No
Participant 8	Female	Physiotherapist	12 years	Rehabilitation and pain	6 years	Yes

Overall, healthcare professionals largely viewed the trial as positive. They cited the significance for integrating physical and mental healthcare in an MSK context, addressing holistic patient needs and the importance of anxiety and depression risk scores in their practice. The suicide flowchart was praised for guiding referral pathways and formal mental health training was welcomed. Professionals noted limited mental health resources, highlighting the trial's potential for improving communication among all involved in patient care.

> *I think it felt really good that it was being recognised that it's not just a physical presentation of a condition that we're able to look at the whole person.* **Participant 5**

Clinicians expressed a preference for the Case Manager to offer more comprehensive patient information and engage in formal meetings. They were aware of patients at suicide risk but lacked updates on their care progress or referrals to mental health services.

> *Probably, similarly. I mean, I just had contact with her [case manager] kind of discussing patients and saying, yes, this patient is happy to chat to you, and all of those interactions were quite positive. But that was probably the extent of it for me.* **Participant 8**

Additional healthcare resources

Participants in both the intervention and usual care arms accessed a similar number of additional healthcare resources beyond their regular appointments. Specifically, in the intervention arm, 13 participants accessed a total of 51 appointments (29 with their GP, 15 with a private physiotherapist, 5 A&E visits, 1 with an osteopath, and 1 with a private psychologist). In comparison, the 12 participants in the usual care arm accessed 50 appointments (21 with their GP, 10 with a private physiotherapist, 7 with a chiropractor, 6

gym sessions, 4 A&E visits, 1 obstetric appointment during the trial, 1 with an NHS psychologist outside of the Trust, and 1 with a private psychiatrist)

Staff costs required to deliver the intervention

Thirteen participants in the intervention arm contributed to cost calculations. Case Manager appointments included 62 sessions (30 face-to-face, 19 via Teams, 13 by phone) totalling 65 hours and £1120.6. Booking/rescheduling time was not included. Physiotherapist appointments comprised 34 sessions (13 first, 21 follow-ups), totalling 23.5 hours and £427.46, however Occupational Therapy wasn't accessed. Psychiatrist appointments (5, 1 hour each) cost £1856.5. Seven participants had clinical psychologist triage at £53.22. Initial psychology sessions were post-trial. Overall, delivering the collaborative care model, including all staff and specialities, cost £3457.78 in 6 months, averaging £44.33 per participant per month.

DISCUSSION

The aim of this study was to assess the feasibility and acceptability of conducting a future definitive RCT to evaluate the clinical and cost effectiveness of implementing a CCM for integrating physical and mental healthcare in an MSK setting. The trial met the minimum criteria for consent and recruitment rates, as per pre-defined progression criteria. However, it did not meet the minimum requirements for adherence (58.8% vs. target of 75%) or retention, with 37.5% of participants withdrawing by the final six-month follow-up. Withdrawal rates were slightly higher in the usual care arm (40%) compared to the intervention arm (35%).

A future RCT will first require a pilot study to explore a more robust retention strategy. Maintaining participant retention and adherence to Case Manager appointments is a commonly cited challenge associated with implementing an RCT design and can be costly. [34] These challenges were evident in the current feasibility trial as potential features impacting retention and adherence were multifactorial, although principally attributed to the limited infrastructure and resources available to maintain adherence. [34, 35] Although the research team employed reminders via phone messages and calls, additional strategies are needed for future trials. Options include non-financial incentives, improved tracking methods, such as clinic and home outreach for challenging-to-locate participants, and covering travel and parking costs. [36]

Additionally, improving communication with participants between appointments by using a text message service or trial newsletters, [37] and considering participant communication preferences from the start will be beneficial. Recruitment occurred in a tertiary NHS hospital, where patients with complex physical needs are referred, which could, potentially lead to higher rates of mental health conditions compared to primary or secondary care settings. [38, 39] It is possible that recruitment rates would be higher in a tertiary care setting due to their greater healthcare needs, hence caution is needed when generalising the findings to other healthcare settings. A future trial should consider employing two full-time research professionals with flexible hours for equitable recruitment and follow-up, accommodating patients in full-time employment.

Despite challenges with maintaining retention and adherence, healthcare professionals and patients largely embraced the trial. Facilitators included feeling heard by the Case Manager and the research team, as well as having access to appropriate psychiatric care (intervention participants). However, barriers involved waiting times for psychological

appointments and limited formal communication between the Case Manager and other healthcare professionals, which must be taken in consideration in a future trial. These observations reflect findings from existing systematic reviews that have explored perspectives of physiotherapists towards the integration of physical and mental health care [40, 41] evaluated the knowledge, behaviours, attitudes and beliefs of physiotherapists towards their use of psychological interventions. While physiotherapists hold positive views towards the integration of psychological interventions amongst their standard practice, barriers to implementation exist, including time constraints and clarity of role. The impact of these barriers might also vary depending on the specific interventions/healthcare models used to facilitate integration.

As the agenda to improve the care of patients with MSK and co-existing mental health conditions continues to grow, [42] a wide range of integrative healthcare interventions have been developed and evaluated. These interventions can be broadly categorised according to; in-person multi-disciplinary, self-management, digital, education-based and telephone based interventions. However, there is no clear overall consensus regarding their superiority or evidence of routine implementation. [42] The CCM has evolved as a standard component of multiple other physical healthcare settings and populations, with robust evidence to demonstrate its effectiveness for achieving clinically meaningful improvements in mental health symptoms that co-exist alongside diabetes, cancer, cardiac disease and stroke. [43, 44] The basis of the model, which includes proactive screening, co-ordination of care and timely follow-up might all contribute towards the overall effectiveness of the intervention. While it is not possible to quantify the efficacy of individual components, the health related benefits seen in many other conditions/settings, along with the largely positive experiences observed within the current feasibility trial, warrants further investigation of the CCM within the context of chronic MSK pain.

Proposed changes to intervention

The qualitative findings offer valuable insights to enhance a future trial. Defining the Case Manager's role comprehensively, [45] specifying communication frequency, and establishing formal agreements with protected time are vital to manage expectations and ensure timely intervention. Establishing a formal agreement with protected time is crucial for timely assessment and intervention for Psychology department referrals. Funding allocation for a part-time Psychologist could improve patient support within the intervention arm, enhancing implementation and communication. Nevertheless, inadequate funding resulted in some participants missing therapy, diluting the intervention's impact. Due to growing evidence to support the effectiveness of psychological interventions delivered by Allied Health Professionals (AHPs), [46] consideration could be made to train AHPs, such as physiotherapists and occupational therapists, to take on the Case Manager's role.

Proposed changes to methodology

Several modifications are proposed. To emphasise physical improvement through mental health optimisation, consider MSK-HQ as the primary outcome in future research. It may also be beneficial to add quantitative secondary outcomes of changes in physical health such as grip strength as a global measure of physical strength as well as opioid use pre and post intervention. [47] Incorporate the Client Service Receipt Inventory (CSRI) [48] to calculate service use costs. Include open-ended questions at the final follow-up in patient interviews to boost retention and assess the study's social value [49] by providing person-centred care and ensuring participants feel heard. [50] To prevent contamination, explore a cluster randomised design between the intervention and usual care arms.

Conclusions

This feasibility trial offers valuable evidence that clinicians and participants in both arms valued the trial for facilitating integration of physical and psychological care. This trial demonstrates the feasibility of recruiting to the CCM within a tertiary care centre setting. While retention and adherence rates fell short of expectations, robust retention strategies can mitigate this in a future trial. Qualitative data informed modifications to enhance the intervention, delivery model, and study design for a future multicentre trial.

Acknowledgements The authors would like to express their sincere gratitude to the participants, patients and professionals, who gave their time to participate in this study. Thanks to Lucy Dove who contributed to the original idea, shaped the protocol and supported the funding application and Dr Catherine Minns Lowe for her valuable feedback on the protocol and support/considerations for a future multicentre RCT.

Contributors statement A.J. and P.R. initiated and conceptualised the study. A.J., M.T., P.R. and R.T. designed and constructed the study protocol and made substantial contributions to the conception or design of the work, acquisition, analysis, and interpretation of data. M.T. and R.A. wrote the main manuscript text. M.T. created tables, images, and supplementary material. All authors reviewed the manuscript, tables, images and supplementary materials. R.A. and R.T. proofread all documents. All authors (A.J., M.T., P.R., R.A. and R.T.) were involved on the final approval of the version to be published and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved among all authors.

Funding

This work was supported by Royal National Orthopaedic Hospital Charity (1166129).

Data sharing statement For access to the data set, a formal request should be sent to the corresponding author. The request will only be considered when the primary results of the study have been published. The data are not publicly available due to them containing information that could compromise research participant privacy/consent.

Competing interests

Non-financial associations that may be relevant to the submitted manuscript.

Patient consent obtained.

Ethics approval statement Ethical approval was granted by Cambs and Herts Research Ethics Committee 21/EE/0257.

References

1. WHO. Musculoskeletal conditions [Internet]. 2022. Available from: https://www.who.int/news-room/fact-sheets/detail/musculoskeletal-conditions [accessed Feb 2023].
2. James SL, Abate D, Abate KH, *et al. Global, regional, and national incidence, prevalence, and years lived with disability for 354 Diseases and Injuries for 195 countries and territories* 1990-2017: A systematic analysis for the Global Burden of Disease Study 2017. Lancet. 2018;392(10159):1789–858.
3. Reed M, Brittain R, Dawson-bowling S*, et al.* 18th Annual Report 2021. Njr UK. 2021.
4. ARUK. *Osteoarthritis in general practice: Data and perspectives*. Vol. 222, The Medical Press. 2018.
5. Doherty AM, Gaughran F. *The interface of physical and mental health* Soc Psychiatry Psychiatr Epidemiol. 2014;49(5):673–82.
6. McManus, S, Bebbington, PE, Jenkins, R, & Brugha T. *Mental health and wellbeing in England: the adult psychiatric morbidity survey* 2014. London: NHS digital; 2016.
7. HM Government. *Musculoskeletal conditions profile: short commentary*, May 2022. Available from: https://www.gov.uk/government/publications/musculoskeletal-health-5-year-prevention-strategic-framework (accessed December 2022)
8. Jørgensen R, Zoffmann V, Munk-Jørgensen P, *et al. Relationships over time of subjective and objective elements of recovery in persons with schizophrenia* Psychiatry Res. 2015;228(1):14–9. doi.org/10.1016/j.psychres.2015.03.013
9. NHS England. *The NHS long term plan*. London, NHS Engl. 2019;
10. Saragiotto BT, de Almeida MO, Yamato TP, Maher CG. *Multidisciplinary biopsychosocial rehabilitation for nonspecific chronic low back pain* Phys Ther. 2016;96(6):759–63.
11. Firth J *et al*. *The Lancet Psychiatry Commission: a blueprint for protecting physical health in people with mental illness* The Lancet Psychiatry. 2019;6(8):675–712.
12. Howarth BS, Bourgeois JA, Kates N. *Consultation-Liaison Psychiatry and Collaborative Care Models of the Patient with Renal Disease* Psychonephrology. 2022;147–59.
13. Ramanuj PP, Pincus HA. *Collaborative care: Enough of the why; What about the how?* Br J Psychiatry. 2019;215(4):573–6.
14. Atlantis E, Fahey P, Foster J. *Collaborative care for comorbid depression and diabetes: A systematic review and meta-analysis* BMJ Open. 2014;4(4).
15. Sharpe M, Walker J, Hansen CH, *et al*. *Integrated collaborative care for comorbid major depression in patients with cancer (SMaRT Oncology-2): A multicentre randomised controlled effectiveness trial* Lancet. 2014;384(9948):1099–108. doi.org/10.1016/S0140-6736(14)61231-9
16. NICE. *Depression in adults: recognition and management*. 2009. Available from: https://www.nice.org.uk/guidance/cg90 (accessed December 2022).
17. Skivington K, Matthews L, Simpson SA, *et al.* A new framework for developing and evaluating complex interventions: Update of Medical Research Council guidance. BMJ.

2021;374(2018):1–11.

18. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. (2011). *Developing and evaluating complex interventions.* Medical Research Council, UK.
19. Teixeira MJC, Tehrany R, Jaggi A, Ahmed RZ, Dove L, Ramanuj, P *Collaborative care model versus usual care for people with musculoskeletal conditions and co-existing anxiety and depression: Protocol for a feasibility mixed-methods randomised controlled trial* BJPsych Open. 2023; 9(4), E109.
20. Kroenke K, Wu J, Yu Z, Bair MJ, Kean J, Stump T, Monahan PO. *Patient Health Questionnaire Anxiety and Depression Scale: Initial Validation in Three Clinical Trials* Am Psychosom Soc. 2016;
21. Equator Network. (2023). *CONSORT 2010 Statement Extension to Randomised Pilot and Feasibility Trials.* Retrieved from https://www.equator-network.org/reporting-guidelines/consort-2010-statement-extension-to-randomised-pilot-and-feasibility-trials/ (accessed Dec 2023)
22. Sealed Envelope. Simple randomisation service. 2021. Available from: https://www.sealedenvelope.com/ (accessed in February 2022)
23. EuroQol. EQ-5D. 2021 Available from: https://euroqol.org/eq-5d-instruments/ (accessed in July 2021)
24. Hill JC, Kang S, Benedetto E, *et al. Development and initial cohort validation of the Arthritis Research UK Musculoskeletal Health Questionnaire (MSK-HQ) for use across musculoskeletal care pathways* BMJ Open. 2016;6(8):1–10.
25. Cristiana K, Joshua AC. *Visual analogue scale, numeric pain rating scale and the McGill pain Questionnaire: an overview of psychometric properties* Phys Ther Rev. 2005;10(2):123–8.
26. Chibnall JT, Tait RC. *The Pain Disability Index: factor structure and normative data* Arch Phys Med Rehabil. 1994;75(10):1082–6.
27. Sharma S, Palanchoke J, Reed D, Haxby Abbott J. *Translation, cross-cultural adaptation and psychometric properties of the Nepali versions of numerical pain rating scale and global rating of change* Health Qual Life Outcomes. 2017;15(1):1–11.
28. Bombard Y, Baker GR, Orlando E, *et al*. *Engaging patients to improve quality of care: A systematic review* Implement Sci. 2018;13(1).
29. Verma JP. Data analysis in management with SPSS software. Springer S. London; 2012.
30. NHS. National Cost Collection for the NHS. Available from: https://www.england.nhs.uk/costing-in-the-nhs/national-cost-collection/ (accessed Dec 2022)
31. Maher C, Hadfield M, Hutchings M, de Eyto A. *Ensuring rigor in qualitative data analysis: A design research approach to coding combining NVivo with traditional material methods* Int J Qual Methods. 2018;17(1):1609406918786362.
32. May CR, Cummings A, Girling M, *et al. Using Normalization Process Theory in feasibility studies and process evaluations of complex healthcare interventions: a systematic review* Implementation Science, 2018;13:1–42.
33. Bjureberg J, Dahlin M, Carlborg A, Edberg H, Haglund A, Runeson B. *Columbia-Suicide Severity Rating Scale Screen Version: Initial screening for suicide risk in a psychiatric emergency department* Psychol Med. 2021;52(16):1-9. 10.1017/S0033291721000751

34. Murphy E, Shiely F, Treweek S. *How much is the lack of retention evidence costing trial teams in Ireland and the UK?* Trials. 2022;23(1):1–13.

35. Kearney A, Daykin A, Shaw ARG, *et al. Identifying research priorities for effective retention strategies in clinical trials* Trials. 2017;18(1):1–12.

36. Robinson KA, Dinglas VD, Sukrithan V, Yalamanchilli R, Mendez-Tellez PA, Dennison-Himmelfarb C, et al. *Updated systematic review identifies substantial number of retention strategies: Using more strategies retains more study participants*. J Clin Epidemiol. 2015;68(12):1481–7.

37. Nelson EA, Maruish ME, Axler JL. Effects of discharge planning and compliance with outpatient appointments on readmission rates. Psychiatr Serv. 2000;51(7):885–9.

38. Rayner L, Matcham F, Hutton J, *et al*. *Embedding integrated mental health assessment and management in general hospital settings: feasibility, acceptability and the prevalence of common mental disorder* Gen Hosp Psychiatry. 2014;36(3):318–24.

39. Bialosky JE, Bishop MD CJ. *Individual expectation: an overlooked, but pertinent, factor in the treatment of individuals experiencing musculoskeletal pain* Phys Ther. 2010;90(9):1345–55.

40. Driver C, Kean B, Oprescu F, Lovell GP. *Knowledge, behaviors, attitudes and beliefs of physiotherapists towards the use of psychological interventions in physiotherapy practice: a systematic review.* Disabil Rehabil. 2017;39(22):2237-2249.

41. Ribeiro C, Tsang L, Lin B, Kemp-Smith K, Phillips J, Furness J. *Physiotherapists' perceptions of their role in treating and managing people with depression and anxiety disorders: A systematic review.* Physiother Theory Pract. 2022; 29:1-25.

42. Firth J, Siddiqi N, Koyanagi A, Siskind D, Rosenbaum S, Galletly C, at al. *The Lancet Psychiatry Commission: a blueprint for protecting physical health in people with mental illness.* Lancet Psychiatry. 2019;6(8):675-712.

43. Thota AB, Sipe TA, Byard GJ, Zometa CS, Hahn RA, McKnight-Eily LR, et al. *Community Preventive Services Task Force. Collaborative care to improve the management of depressive disorders: a community guide systematic review and meta-analysis.* Am J Prev Med. 2012;42(5):525-38.

44. Bower P, Gilbody S, Richards D, Fletcher J, Sutton *A. Collaborative care for depression in primary care. Making sense of a complex intervention: systematic review and meta-regression.* Br J Psychiatry. 2006;189:484-93.

45. Gunn J, Diggens J, Hegarty K, Blashki G. *A systematic review of complex system interventions designed to increase recovery from depression in primary care* BMC Health Serv Res. 2006;6:1–11.

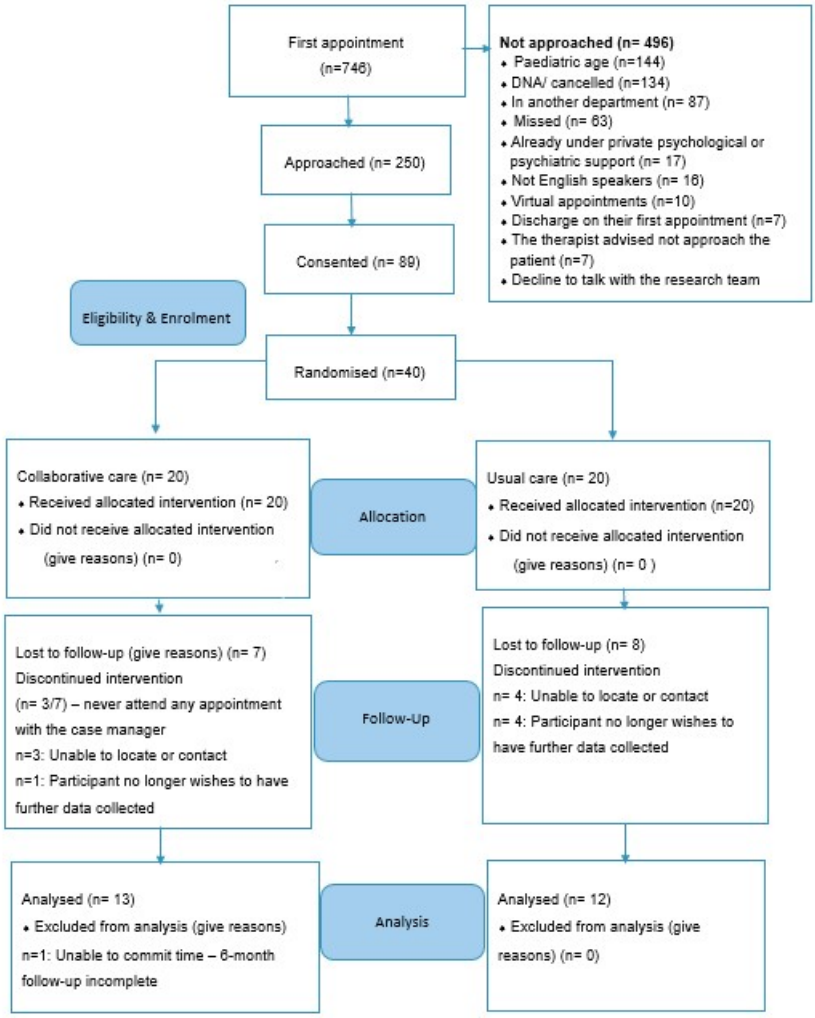
46. Guerrero A, Maujean A, Campbell L, Sterling M. *A Systematic Review and Meta-Analysis of the Effectiveness of Psychological Interventions Delivered by Physiotherapists on Pain, Disability and Psychological Outcomes in Musculoskeletal Pain Conditions* Clin J Pain. 2018;34(9):838–57.

47. Porto J, Nakaishi A, Cangussu-Oliveira L, Freire R, Spilla S, Abreu D. *Relationship between grip strength and global muscle strength in community-dwelling older people*. Arch Gerontol Geriatr. 2019;82:273-278

48. Beecham J, Knapp M. Costing *Psychiatric interventions. In: Thornicroft, Graham (ed.), editor. Measuring Mental Health Needs* London; 2001. 200–24.

49. Rid A, Wendler D. *Risk-benefit assessment in medical research--critical review and open questions* Law, Probab Risk. 2010;9(3–4):151–77.

50. Archer J, Bower P, Gilbody S, *et al. Collaborative care for depression and anxiety problems (Review)* Cochrane Database Syst Rev. 2012;(2).



1. **Reasons for not consenting**

Of the 250 patients approached, 162 (64.8%) did not consent:

- 48 (29.6%) were not interested in taking part in the study.
- 33 (20.4%) too much going on.
- 26 (16.0%) never answered the calls done after being approached.
- 21 (13%) were willing to consent. However, they never had their next appointment at outpatient therapies booked.
- 19 (11.7%) were approached. The research team would call them in 1 week's time. Meanwhile, the randomisation numbers were achieved.
- 12 (7.4%) declined to participate, but no reason was given.
- 3 (1.9%) other reasons: 1 patient was a therapist in the team; one patient would like to be consented to outside of the Trust, and 1 patient was willing to consent but disclosed she was under psychiatric support before consent.

2. **Reason to not randomise**

38 (98%) participants (34 – 68.4% females and 14 – 28.6% males) score less than 20 on the PHQ-ADS, and 1 (2%) participant (female) was under private psychiatric.

I. What factors influenced your decision to take part in the trial?

II. Tell me about your experience during the trial?

III. Tell me about your experience with the support you received from the case manager. (Only for participants under the intervention arm)

IV. How was your experience in navigating through the support of the collaborative care model/ support from different professionals at the same time? (Only for participants under the intervention arm). Do you think that this type of support was helpful to you? What could be improved? (Only for participants under the intervention arm)

V. What aspects of the trial went well?

VI. What aspects of the trial could be better or should be changed?

VII. What do you think about the number of follow-ups provided by the case manager? (Only for participants under the intervention arm)

VIII. Did you have any referral to have psychological or psychiatric support during the trial?

IX. (if applicable) Was the psychological/ psychiatric support sufficient? Did it meet your needs and expectations? Would you have preferred some other form of support? (Rephrase this question according to the type of support that participants get through the trial)

X. (if applicable) What helped you to attend appointments booked for you? What prevented you from attending appointments booked for you? (Rephrase in case the levels of adherence of the participant were low during the trial e.g. What prevented you from carrying out these appointments?)

XI. Do you think this type of intervention was useful? Why? (Only for participants under the intervention arm)

XII. What are your feelings about being randomised for the usual care?

XIII. What were the advantages of taking part in the trial?

XIV. What were the disadvantages of taking part in the trial?

XV. Other thoughts about the trial?

XVI. Any other comments?

I. Tell me about your experience of working with patients recruited for the trial.
II. Tell me about your experience of working with patients under the case manager's support.
III. How did you find yourself working with the case manager?
IV. What aspects of this collaborative work went well? What could be improved upon?
V. What aspects of the data collection could be better or should be changed?
VI. What do you think about the psychological/ psychiatric support provided to the participants? (Was there enough provision? Was the provision appropriate to the participant's needs?)
VII. Would you like to see any other or additional support being offered? Why? (Reasons)
VIII. Do you think that this type of intervention was useful to your patients and your own workload? Why?
IX. What do you think about the Suicidal ideation and risk of self-harm flow chart?
X. Other thoughts about the trial?
XI. Any other comments or suggestions?

Suicidal ideation may be identified using the PHQ-ADS for all participants, which asks specifically about thoughts of self-harm. Participants may also disclose this ideation at any point during the study from recruitment to discharge.

For any participant scoring 1 or higher on question 9 of the PHQ-ADS - '*Thoughts that you would be better off dead or of hurting yourself in some way*', the research team discussed these thoughts with the patient and ask them to answer the Columbia-Suicide Severity Rated Scale Screen (C-SSRS) (1). The C-SSRS Screen is a validated 6-item assessment scale for people with suicidal ideation. It categorises patients into low, medium, and high risk. For example:

- Passive thoughts such as wishing to be dead with no further risk indicators are considered low risk.
- Methods and plans, or active thoughts such as wishing to cause self-harm are considered a moderate risk.
- Suicidal intent and any suicidal behaviour in the past 3 months indicate a high risk.

All triggers of the suicidal ideation and risk of self-harm protocol and the actions that are taken in response were recorded in the Research Risk of Self-Harm form and clinical notes.

Suicidal thoughts before randomisation, during usual care or at the end of study interviews

The research team informed the named clinician responsible for the participant's care of their level of risk via email. It is standard practice at the Trust that all thoughts of self-harm should be discussed with the RNOH Psychiatry Service. The RNOH Psychiatry Service either provided advice or review the participant depending on the level of risk and inform their GP. Participants were also be signposted to the 'Rethink Mental Illness' online resource website which provides information on coping with suicidal thoughts.

For participants who reveal suicidal thoughts for the first time during the end-of-study interview and are no longer under the care of the RNOH outpatient services, or for participants who refused to be referred to the RNOH Psychiatry Service, the research member discussed the participant's presentation with the Chief Investigator, who is a Consultant Psychiatrist, within 24 hours.

Suicidal thoughts reported by participants in the intervention group

If suicidal thoughts emerged in participants allocated to the intervention group, the Case Manager assessed the risk clinically, supported further using the C-SSRS Screening tool. The research team then asked for the participants' consent to make a referral according to the risk level:

1. Participants deemed to be at low risk were flagged up to their GP.
2. Participants at moderate risk were offered to be triaged and risk assessed by the hospital psychiatrist within one week of referral.
3. Participants at high risk were assessed immediately by the hospital psychiatrist.

If the participant refused to be referred due to their risk of self-harm, the Case Manager discussed the participant's presentation with the Chief Investigator. This was immediately for high-risk participants, within 24 hours for moderate-risk participants, and within 48 hours for low-risk participants.

References

1. Blades CA, Stritzke WG, Page AC, Brown JD. The benefits and risks of asking research participants about suicide: A meta-analysis of the impact of exposure to suicide-related content. Clin Psychol Rev [Internet]. 2018;64(July):1–12. doi.org/10.1016/j.cpr.2018.07.001

2. Bjureberg J, Dahlin M, Carlborg A, Edberg H, Haglund A, Runeson B. Columbia-Suicide Severity Rating Scale Screen Version: Initial screening for suicide risk in a psychiatric emergency department. Psychol Med. 2021;52(16):1-9. doi.org/10.1017/S0033291721000751

Dimension	Feedback	Theme	Qualitative feedback	Illustration
Reason for participating	24 participants shared their reason for participating in the trial.	Get additional support for their mental health and pain	20 participants were aiming to get additional support for their mental health (14) and for their pain (6).	*I was dealing a lot mentally and I felt that the support I didn't receive once I had my surgery at Stanmore wasn't good enough, and if I can do anything to help or improve a service that they could potentially offer, I would like to do so, just so someone doesn't have to go through with I had to deal with.* **Participant 20, Usual Care**
		Help others in the future	10 of the participants were also aiming that the results of the trial may help other people in the future.	*So, I think any study to help people with joint issues, whether that's simple back pain to more serious, I'm very happy to participate and share my views, really*. **Participant 66, Collaborative care**
				I think it's important. It's imperative, but it doesn't happen. Mental health is so important but it's so, the service is so overrun at the moment that it's impossible to access anything. **Participant 82, Usual Care**
		Previous experiences with services	4 participants shared that their previous experience helped them to decide to participate in the study. 3 had previous negative experiences with their physical and mental support helped them to participate in this study. They want an improvement in the services provided to patients with chronic musculoskeletal diseases.	*Yes, I do. I mean, my first experience with the NHS when my knee first went bad, about 25 years ago, was absolutely appalling. It was rude, obnoxious, and all of the staff in that hospital were really horrible, yelling, saying horrible things to me, and that was the start of it. That was the start of being on the slippery slope because you think, 'Well, what's going to happen next? It's been a bit of a rollercoaster of just people that work in the NHS*. **Participant 21, Usual Care**
Advantages of participating	18 participants disclosed the benefit of participating in the trial, even though under usual care.	Be heard	12 participants described the importance of being heard.	*Yeah, I think the experience was it was nice to be a part of and I suppose if I didn't get chosen there was someone that needed it more than me, but it was nice to be part of it and to have, to see you now to let you know how I've been and our conversations that we've had. It's been really helpful to me.* **Participant 46, Usual care**
		Managing difficult emotions	2 participants explained that they avoided committing suicide by participating in the study.	*No, related with me. Because six months ago I did feel like killing myself, because I didn't understand my condition. I had suicidal thoughts, and now, sitting here six months on, I don't have them thoughts anymore. I haven't had them thoughts from when I've got therapy, and the occupational therapy and the techniques takes that thought because you kind of have a little bit of hope of what – you can get through that bit. Instead of just giving up, I feel like giving up.* **Participant 62, Usual Care**
		Psychiatric support	2 participants added psychiatric support due to their risk of suicide; 1 participant was under usual care.	*Seeing [psychiatric name] has been a huge milestone and a huge benefit. I hope it will direct me on the right path now*. **Participant 26, Usual Care**

Dimension	Feedback	Theme	Qualitative feedback	Illustration
Disadvantages of participating	3 participants expressed disadvantages in participating in the trial.	Emotional support can have a negative effect	2 participants were sceptic regarding mental health support and the trial made her think about personal anger.	*But you never know what you're going to get and it could be 50-50, whether that actually makes you any better or make you any worse. That's just my view. It might not be that, but because I'm sceptical because of my experiences of the NHS, I'm very wary of them delving into my mind.* **Participant 21, Usual Care**
		Use of personal time	1 participant referred to the use of his own time in the study as a problem.	*Just that I use my time up.* **Participant 10, Collaborative Care**
	8 participants shared their feelings when they were allocated to usual care.	Being randomised to usual care	7 expressed their disappointment about not getting the case manager's support.	*I was disappointed because I think I desperately needed support and I always have, but I've struggled to get it.* **Participant 82, Usual Care**
Opinion about their case manager (intervention arm)	15 participant shared their opinion	Experience of Case Manager	10 participants expressed their experience with the case manager as a very positive experience, with an impact on their emotional and mental health.	*I thought she was wonderful. She was really kind. Really understanding. Really lovely person. I think as we were talking, it transpired that I possibly didn't need the emotional support as much anymore. Because I, over the years, have just managed to cope with things. I am in a better place. But I see her value. I think more of her would be great.* **Participant 66, Collaborative Care**
		More reassurance and review of patient progress on their care plan	5 participants would like to have someone to reassure them on their progress and their treatment plans.	*Maybe a bit more interaction with some people. With me, I didn't mind, because I don't need a lot of interaction. I have a lot going on anyway. But some people might benefit maybe checking in once a month, maybe just to have a conversation. Sometimes it's as easy as that, because if they're a bit lonely or a bit stressed, that [unclear] so they have someone to talk to, and understand their condition and stuff like that.* **Participant 86, Collaborative Care**
Opinion on their physical support	26 participants expressed their opinion about their physical support.	Personalised care	20 participants shared the importance of being listened to by their therapist. Moreover, the fact of personalised plan care makes all difference for them.	*I think my physiotherapist was great, and she was very helpful. She showed me obviously a lot of the exercises. I wasn't exactly great in keeping up with the exercises every single day, but I think - I have noticed a change in the pain in my hip, so the physio must have worked and so yeah, I think the whole overall experience with physio has been a lot better than my physio before when I had surgery when I was 16. It's a lot better this time around.* **Participant 24, Collaborative Care**
		Negative experience	6 participants also expressed negative feelings as the therapists talk too much instead of more concentrated in exercises, the presence of students without requesting permission, and different therapists at each appointment.	*If I'm honest, I feel like it could be a bit more hands on. It took quite a while for me to be like, can you just like examine my shoulders? Or can you do this, can you do that? I felt like it was more just they were talking at me. I didn't really like that. For me, physio is more of a – it's quite a physical thing. It's not just talking.* **Participant 10, Collaborative Car**
Significance of the trial	All participants expressed the importance of the trial.	Integrating mental and physical healthcare	All participants expressed the importance of the trial	*I think it was really positive. I think you've got the right people. I think the message is very clear. That there is a link between your physical illness and your mental illness. To be able to link the two and understand has been very positive.* **Participant 66, Collaborative Care**

Theme	Qualitative feedback	Illustration
Indecision about the option	7 participants found it difficult to select either numeric scales or qualitative options.	*The only thing is that sometimes it's really quite tricky. You really hesitate and you think well, because the whole business I think of assessing pain, you know, what's painful to me and what's painful to somebody else obviously is not the same really. So then I think well, perhaps I'm exaggerating here or perhaps I'm the opposite, you know. Perhaps actually it's a bit worse than that really.* **Participant 73, Usual Care**
A better explanation of some terms	3 participants found it difficult to understand some of the language used in the forms.	*I think I did ask [case manager] to explain a couple of the questions. I can't remember what they were. Again, I'm sure it was only a couple.* **Participant 33, Collaborative Care**
Not customised	4 participants expressed that some forms are generic which can create a feeling of dehumanisation.	*The generic mental health one, obviously I've had it a million times. My frustration sometimes would be like, oh. Just feeling like another person. I'm another person with mental health issues, like it is a bit dehumanising.* **Participant 32, Usual Care**
Sensitive topics	3 participants highlighted sensitive topics e.g. suicide, pain, and depression that can trigger negative emotions in patients.	*Talking about things that affect you. Talking about the lack of sleep you may get. It might bring someone to tears just because this is overwhelming. This is something that I go through. […] I think some of the questions can be a bit triggering.* **Participant 20, Usual Care**
Missing open questions	2 participants suggested that future forms should have opened questions to allow patients to express their opinions and feelings.	*So, I don't know, maybe if they were changed, perhaps there should be a section where you can actually have a comment perhaps so that it isn't as cut and dried.* **Participant 75, Collaborative Care**
Some questionnaires are too long	1 participant found the forms too long.	*I found the questionnaires very long. Sometimes I didn't know why certain questions were being asked, but don't ask me - I just found some of them quite hard to put a number on, to put a feeling on.* **Participant 60, Usual Care**

Dimension	Feedback	Theme	Qualitative feedback	Illustration
Importance of the trial	All participants agreed that the trial was indispensable	Understanding the importance of mental health in patient cohort	All participants expressed the importance of the study in highlighting mental health in patients with chronic musculoskeletal conditions.	*No other way to put that really. I think as we've seen the baseline data from CCOPER, haven't we, and we knew that anecdotally as well about the amount of mental health issues our patients have, whether that be low level or more moderate to severe and we know the impact that that has on their rehab and ability to manage their conditions. So, as we know many people at […] have long-term pain, long-term problems, and the association between mental health and long-term pain is huge we need to be able to target both of those aspects if we are supporting people properly to manage those long-term conditions. So, I think it's a really good thing that we're looking into that.* **Participant 1**
		Highlighted limited local mental health services	6 participants disclosed that the trial highlighted limited local mental health services.	*[…] the mental health of our patients is not the best, and actually they don't really have as much support as they should have, or that they need, and I guess, this is just hopefully helping us move forward and think about how we can better support them in that way, isn't it?* **Participant 7**
		Relief that someone took the time to investigate patients' mental health problems	4 participants shared their sense of relief when patients were recruited because they feel their patients will receive the right support for mental health issues.	*I agree there in terms of, you know, to be honest, it feels like a weight off your own shoulders if I'm totally honest with you. Because it kind of feels like that patient's being looked after by the people who should be looking after them because for me, you need to look after someone's mental health really before you come to treat them in an MSK environment unless it's some kind of acute problem that you're going to rehab quickly.* **Participant 4**
		Brought more evidence about the complexity of the Trust's patients	3 participants reinforced that the trial is essential to bring more evidence to something that everyone knows to be a problem: patients with musculoskeletal problems need more mental health support.	*Well, I think the study is helped us begin to shed some light on the complexity of the pathway. Which has been really, really useful. […] Multiple, multiple layers of it, and managing long term conditions has been a big political agenda for ages, and there's just not the money behind it yet, and we're just struggling at Stanmore trying to help. So, I think it's probably just given us a little bit more evidence about the layers and to maybe just label it better.* **Participant 6**
		Holist care	2 professionals highlighted the importance of the trial by providing a service that permits seeing the person as a whole.	*I think it felt really good that it was being recognised that it's not just a physical presentation of a condition that we're able to look at the whole person.* **Participant 5**

Dimension	Feedback	Theme	Qualitative feedback	Illustration
Experience in being involved in the trial	All participants shared their opinion.	Positive experience	All participants stated that the trial was a very positive experience for them.	*For me, it was just really positive to be honest, the whole experience. I found it like a real change after, you know, after being in MSK for the last four and a bit years, I thought it's about time this has come about, to be honest. Patients being looked after how they should be looked after from day dot. They've got the physio, they've got the mental health support. It was just, it really was compatible with our caseload as well. It worked well, engaging patients, helping them from a mental health point of view, turn their life around some of them.* **Participant 3**
		Confidence in managing difficult emotions	6 participants highlighted the usefulness of the suicide flowchart to understand the different referral paths.	*I think what I remember about it. I think it's useful in those moments – you panic a little bit, don't you because you are like, I don't know what I'm – so sometimes it is useful to go, okay, well, I have something concrete to go back to and refer back to, and I know what questions to ask, and I know what to do next. So, I think, if you can't remember it off by heart, it's just knowing that there is something concrete that you can refer back to, I think is quite useful.* **Participant 7**
		Need for more effective communication channels	3 participants expressed that the trial made them think about better communication between all professionals involved in patient care.	*[…] the better outcomes I see happening are the ones where you have those communication pathways so everyone's on the same plan: the psychology team involved, the therapist and the patient. […] I know that's hard with external services, but I think it would be so valuable if we could work out a way to enhance the communication between the two teams.* **Participant 5**
		Understanding the importance of mental health of their patients	2 participants revealed the importance of the anxiety and depression risk scores to their practice.	*I personally haven't got a huge caseload, but I did have a couple of patients that you'd approached, and you needed to speak to me because they'd actually been identified as very high risk with mental health, which I hadn't been – the patient hadn't fully shared their journey with me, with that. So, that was an interesting learning point for me, and you'd escalated it, because he – one of them, particularly, had quite a high level of depression and anxiety.* **Participant 6**
		Awareness of a need for formal mental health training	2 participants shared that the trial made them think they need to have formal mental health training.	*I just hope that it just highlights that all the physios should have some extra training, some in-service or some formal training about it, so we can help our patients more.* **Participant 4**
Experience working with case manager in the trial	All participants shared their opinion.	They do not know who the participants were	All professionals do not have an idea what patients were randomised for the trial. They know who the patients at risk of suicide were.	*Probably, similarly. I mean, I just had contact with her kind of discussing patients and saying, yes, this patient is happy to chat to you and all of those interactions were quite positive. But that was probably the extent of it for me.* **Participant 1**

Dimension	Feedback	Theme	Qualitative feedback	Illustration
Suggestions to improve patient support in a future trial	All participants shared their opinion.	Access to outpatient psychological support	5 participants would like to have outpatient psychologists for their patients.	*I'm really aware that our psychology services are really stretched short staffed, I think because I work so closely with the psychologist.* **Participant 7**
		Community or social prescriber	5 participants suggested that a community or social prescriber should be part of the team to facilitate the discharge process to the community for patients who do not need psychological care/support inputs.	*Yeah, social prescribers, yes. I think that's a big – I know that's difficult because our patients come from all of the place, but I think somebody to link with local community services. I think that's another string to their bow that would be really helpful. Helping people to get involved in what's around them locally, groups or whatever it is, social stuff, and exercise, physical activity stuff.* **Participant 8**
		Duration of case manager support should be personalised	3 participants defended that the duration of the case manager support should be personalised.	*So, actually, for there to actually be change and momentum, and for them to be on the journey, I think you would probably need maybe a year, or a little bit longer to see a thorough change in terms of pathway, and making that more efficient, or helping them better navigate it, I think.* **Participant 7**
		Clear referral pathways for mental health support	3 participants also highlighted the importance of having a clear referral path for patients who need mental health support.	*I think, also my referrals to the psychologists aren't necessarily based on the risk of a patient. I think, if a patient is high risk, like suicide or something, I'm not going to refer them necessarily to our psychologist. I'm going to either call the liaison psychiatrist or call the GP. So, my referrals to psychology are more just if a patient feels stuck from a psychological perspective, or I'm stuck, and they need help with acceptance. [...] I don't know if that's right, or not? That's just kind of what I do.* **Participant 7**
		Better communication channels	2 participants defended better channels to professionals communicate with the case manager and other professionals	*Yeah. I think communication, but like the systems to support communication. Because our workload – we've got so many different systems. Every hospital trust does. But I don't think that helps, particularly.* **Participant 8**
		Formal debriefing for professionals	1 participant highlighted the importance to take of the professionals who should have a formal debriefing.	*You have to have formal debriefing, and we have none of that, and we take a lot of it on board, and we do our best, and we try and let outpatients de-escalate with us, and offload, and have aggression, a challenging group, and you see them in 30 minutes, and in and out and in, and out and there's – that's not right, either, to train us up, but give us none of the support.* **Participant 6**

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	Yes
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	1 - Abstract
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	3
	2b	Specific objectives or research questions for pilot trial	3,4,5
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	3,4
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	3
	4b	Settings and locations where the data were collected	3
	4c	How participants were identified and consented	3,5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	4
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	4,5,6
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	N/A
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	N/A
Sample size	7a	Rationale for numbers in the pilot trial	4
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	4
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	4
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	4

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	4
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	4
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	6
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	5,6,7
	13b	For each group, losses and exclusions after randomisation, together with reasons	7,8
Recruitment	14a	Dates defining the periods of recruitment and follow-up	8
	14b	Why the pilot trial ended or was stopped	8
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	7
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	7,8
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	9
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	8-12
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	8-9
	19a	If relevant, other important unintended consequences	12-13
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	12-13
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	13
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	12-13
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	12-13
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	1
Protocol	24	Where the pilot trial protocol can be accessed, if available	3
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Yes
	26	Ethical approval or approval by research review committee, confirmed with reference number	3

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up-to-date references relevant to this checklist, see www.consort-statement.org.