MUSCULOSKELETAL CARE

Title: Reporting of social deprivation in musculoskeletal trials: an analysis of 402 randomised controlled trials

Running Title: Social deprivation reporting MSK trials

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ABSTRACT

The aim of this study was to determine the frequently to which measures of social deprivation are reported in trials recruiting people with musculoskeletal diseases. We conducted a Pubmed search of randomised controlled trials published between 01 January 2019 to 01 June 2020. We included full-text papers of trials recruiting people with musculoskeletal diseases, irrespective of intervention type or origin. We extracted data relating to trial characteristics, setting, trial design, funding source and musculoskeletal disease. We extracted data on any reported social deprivation index or measure of social deprivation based on internationally adopted indicators. We analysed data descriptively to summarise the reporting of each social deprivation index and measure of social deprivation within trials. In total, from 2133 potentially eligible citations, 402 were eligible. Mean age of participants was 51.7 years; 63% were female. Trials most frequently recruited people with spinal pain (24.6%) or osteoarthritis (10.0%). Two trials (0.5%) reported social deprivation indices/scores. When assessed by discrete measures of social deprivation, 164 trials (40.8%) reported one or more social deprivation measures. The most commonly reported measures were morbidity (20.2%), employment status (17.7%) and educational attainment (15.5%). Race (6.7%), ethnicity (6.2%) and annual salary (1.3%) were infrequently reported. One trial (0.3%) presented subgroup results by social deprivation measures. To conclude, social deprivation is inconsistently reported in musculoskeletal trials. Trialists should report baseline measures of social deprivation in trial reports and aid generalisability to target population, and to examine whether social deprivation might modify treatment effects of interventions for musculoskeletal conditions.

Keywords: orthopaedic; rheumatology; economic status; educational attainment; generalisability; effect modifying; RCT

INTRODUCTION

Musculoskeletal conditions are one of the most common and disabling chronic diseases worldwide (Moradi-Lakeh et al, 2017). For individuals who are economically and socially marginalised, musculoskeletal conditions are often poorly managed and access to adequate services can be limited (Craig et al, 2020). This is reflected in studies that report associations between poor musculoskeletal health and social deprivation (Fliesser et al, 2018; Putrik et al, 2018).

Social deprivation has been broadly defined as the restriction of access an individual has to social or cultural interactions due to poverty, discrimination or other disadvantages (Levitas, 2007). Multiple factors such as education, ethnicity and socioeconomic status are known to contribute to social deprivation. Social deprivation is often measured through indices of material and financial resources which contribute to poor social participation (Levitas, 2007). Common indices used to measure social deprivation include: the Index of Multiple Deprivation (ONS, 2015), the USA Social Deprivation Index (Butler et al, 2013), and the New Zealand Index of Deprivation (NZDep2013)(Atkinson et al, 2014). These indices are derived from measures of specific constructs such as: income, employment, socioeconomic status, education, house ownership, salary, race and ethnicity (Butler et al, 2013).

The 2001 update to the Consolidated Standards of Reporting of Trials (CONSORT) statement (Moher et al, 2010) recommended that randomised controlled trials should report baseline demographic characteristics for health inequalities including social deprivation. This is important to enable assessment of generalisability of trial findings, to target populations defined by health inequalities. Collecting these baseline data may also allow the assessment of treatment effect modifiers. This is important to allow evaluation of whether the intervention under investigation has different effects across strata of society.

The reporting of social deprivation in musculoskeletal trials has not been assessed. Callander and McDermott (2017) assessed the reporting of social deprivation constructs in 414 peer-reviewed papers of cardiovascular disease studies. They found eight percent reported one measure of social deprivation (socioeconomic status) and five percent reported stratified or adjusted effects by socioeconomic status. While social deprivation is a widely acknowledged determinant of outcome in musculoskeletal conditions, it remains unclear how this is considered in the conduct and interpretation of musculoskeletal trials. We aimed to answer the question: how frequently are measures of social deprivation reported in trials recruiting people with musculoskeletal diseases?

METHODS

We conducted a Pubmed search of randomised controlled trials published between 01 January 2019 to 01 June 2020. The search strategy is presented in **Supplementary File 1**. We included full-text papers of trials (phase 3 and 4) recruiting people with musculoskeletal diseases (defined as a disorder primarily affecting body movement through diseases of the musculoskeletal system (i.e. bone, muscles, tendons, ligaments, nerves). We included trials irrespective of intervention type or origin. We excluded protocol papers and non-human trials.

We extracted the following data: trial characteristics (number of participants, gender and age, continent participants recruited from, intervention type (surgical/non-surgical), setting (acute/community/mixed), trial design (full/pilot or feasibility), trial phase (3 or 4)(DeMets et al, 2010), funding source (industry/non-industry/none) and musculoskeletal disease. We extracted data on any reported social deprivation index or measure of social deprivation based on internationally adopted indicators (Butler et al, 2013; Blackwood and Currie, 2020). These measures of social deprivation included: housing, employment, socioeconomic status, car ownership, education, number of people living in household, house ownership, annual salary, parental status, race, ethnicity, living in poverty, morbidity, community mortality, crime, local amenities, housing quality, air quality and road traffic accidents (Butler et al, 2013; Blackwood and Currie, 2020).

We presented data as frequencies and percentages for categorical data and mean and standard deviations (SD) for continuous data. We summarised the reporting of each social deprivation index and measure of social deprivation within trials as frequencies and percentages. We used Stata version 16.0 for Windows (STATA Corp LLC, Texas, USA) for analysis.

RESULTS

In total, 2133 potentially eligible citations were identified and screened as full-text papers. From these, 402 were eligible and included (**Figure 1**).

The characteristics of included trials are presented in **Table 1**. Mean age of participants was 51.7 years (SD: 14.6); 63% were female. The mean number of participants per trial was 203 (SD: 24). The majority of trials were conducted in Europe (41.8%) and Asia (30.4%). Trials most frequently recruited people

with spinal pain (24.6%), osteoarthritis (10.0%), fibromyalgia or multisite musculoskeletal pain (8.7%) and rheumatoid arthritis (6.5%). Seventy-six percent of trials were non-surgical and 93% were undertaken in acute hospital settings. Trials were most frequently phase 3 (95.3%), definitive trials (94.3%); 49% did not report the funding source and 37% were funded by non-industry/non-commercial organisations.

The frequency of reporting social deprivation measures is presented in **Table 2**. Two trials (0.5%) reported social deprivation indices/scores (Darlow et al, 2019; Hewlett et al, 2019). When assessed by discrete measures of social deprivation, 164 trials (40.8%) reported one or more social deprivation measures. The most commonly reported measures were morbidity (20.2%), employment status (17.7%) and educational attainment (15.5%). Race (6.7%), ethnicity (6.2%) and annual salary (1.3%) were infrequently reported. Community-based deprivation indicators such as premature death, quality of life, crime, location to amenities, housing quality, air quality and community status on road traffic accident were not reported in any trial. One trial (0.3%)(Singh et al, 2019) presented subgroup results by social deprivation measures.

DISCUSSION

These findings indicate that social deprivation indices and measures of social deprivation are infrequently and inconsistently reported in musculoskeletal trials. Fewer than half of the trials reported an individual measure of social deprivation such as employment status, educational attainment or participant morbidity. The suboptimal standard of reporting practices in musculoskeletal trials does not allow readers to characterise trial samples by social deprivation. This limits the ability to assess the generalisability of trial results and targeted implementation.

This is the first comprehensive assessment of the reporting of social deprivation measures in musculoskeletal trials. Social deprivation indices and measures of social deprivation are also poorly reported in non-musculoskeletal trials (Callander and McDermott, 2017; Malmivaara, 2019; Petkovic et al, 2020). Measures that are most frequently reported in musculoskeletal trials are similar to those reported in non-musculoskeletal trials, namely education level, employment status and salary. Our review shows social deprivation indices are poorly reported across conditions and settings.

Without consensus on how social deprivation should be reported in trials, it is not surprising that the standard of reporting is suboptimal. Social deprivation measures can be broadly divided into cluster

or individual-level measures. For example, summary indices may represent areas demarcated by geographical or political boundaries (Allik et al, 2016) and individual-level measures could represent the educational status or salary earnings of an individual (Smith et al, 2015). As there is no consensus on which measures should be reported, this decision remains with the researchers. Although the population and intervention under-investigation should drive the selection of appropriate social deprivation measures, a common framework could allow systematised comparisons of social deprivation indices across trials and cohorts (Allik et al 2020).

Two key implications and recommendations arise from this study. Firstly, improved reporting of social deprivation measures is necessary to enable healthcare professionals to better assess the generalisability of trial findings. Because social deprivation indices are currently poorly reported in musculoskeletal trials, it is difficult to determine to whom the trial findings apply. This is a problem for assessing implementability (whether the interventions can be effectively delivered in a given setting) and generalisability (whether one can expect similar effect estimates from the trial if the intervention is successfully implemented in a given setting) (Weiss et al, 2008; Kennedy-Martin et al, 2015). Secondly, trialists should consider *a priori* subgroup analyses based on possible differential effects across social deprivation indices. Previous literature has reported the relationship between social deprivation and musculoskeletal symptoms (Jordon et al, 2008; Fliesser et al, 2018; Putrik et al, 2018; Wright et al, 2019; Rijk et al, 2020). It is therefore possible that certain social deprivation measures could modify the effect of treatments.

Specific social deprivation indices (ONS, 2015; Butler et al, 2013; Atkinson et al, 2014) are rarely measured in musculoskeletal trials. The selection of appropriate social deprivation indices could be guided by the theoretical underpinning of the intervention and the target population and setting for implementation. Similar to core outcome sets, there may be merit in considering a 'core' set of social deprivation measures to facilitate better reporting. Further work that explores why trialists do not report social deprivation in musculoskeletal trials would be useful to devise approaches to improve the quality of reporting.

This study presents with strengths and weakneeses which should be acknowledged. Firstly our sensitive search strategy and broad inclusion criteria captured a large number of trials (402) representing a wide range of musculoskeletal diseases across various settings. The principal limitation to this analysis is that these findings are purely descriptive. We did not examine trial characteristics that might be associated with poor reporting of social deprivation indices. It was not the purpose of

this study to undertake such analyses. Nonetheless, designing future studies to make such inferences could help devise strategies that facilitate better reporting of social deprivation indices.

CONCLUSION

Social deprivation indices and measures of social deprivation are inconsistently reported in musculoskeletal trials. This complicates the ability to generalise trial findings to target populations. Trialists should report baseline measures of social deprivation in trial reports and consider examining whether social deprivation might modify the effects of interventions for musculoskeletal conditions.

FIGURE AND TABLE LEGENDS

Table 1: Characteristics of participants, settings, design and context for 402 included musculoskeletal trials.

Table 2: Frequency of reporting social deprivation indices and measures in musculoskeletal trials.

Figure 1: Flow chart of search results and final included trials.

Supplementary File 1: Pubmed search strategy adopted to identify included published trials.

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Figure 1: Flow chart of search results and final included trials.

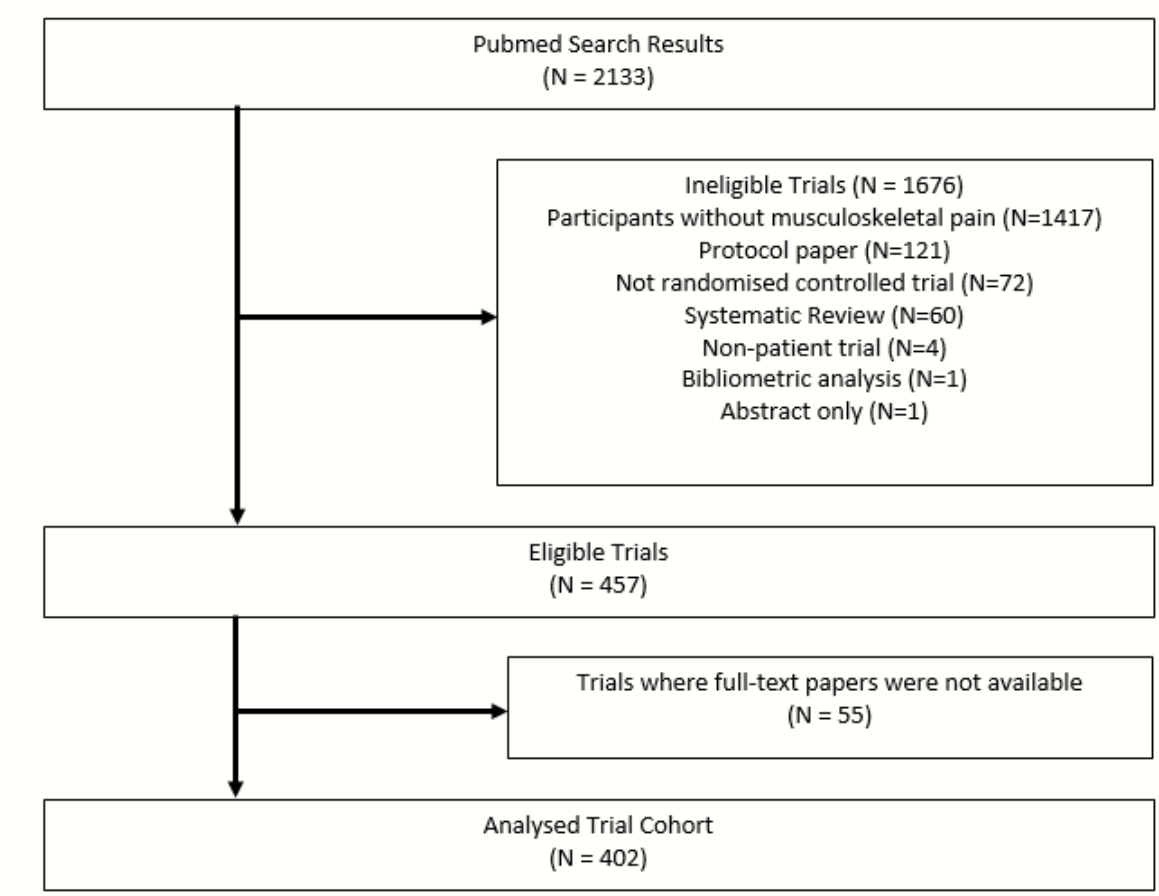

Table 1: Characteristics of participants, settings, design and context for 402 included musculoskeletal trials.

Trial Characteristics		**Frequency (%)**
Study		402
Mean number of participants (SD)		203.1 (1218.8)
Mean percentage female (SD)		62.9 (24.2)
Mean age (years)(SD)		51.7 (14.6)
Origin	Europe	168 (41.8)
	America	81 (20.2)
	Australia/Oceania	22 (5.5)
	Asia	122 (30.4)
	Africa	4 (1.0)
	Cross-continent	5 (1.2)
Musculoskeletal pathology	Spinal pain (cervical/thoracic/lumbar/sacral)	99 (24.6)
	Arthroplasty	62 (15.4)
	Single Lower Limb Joint Pain	56 (13.9)
	Single Upper Limb Joint Pain	40 (10.0)
	Osteoarthritis	40 (10.0)
	Multisite MSK pain or Fibromyalgia	35 (8.7)
	Rheumatoid Arthritis	26 (6.5)
	Fracture	18 (4.5)
	SLE	8 (2.0)
	Axial Spondylitis	4 (1.0)
	Osteoporosis	4 (1.0)
	Psoriatic arthritis	4 (1.0)
	Spinal Cord Injury	3 (0.8)
	Juvenile Idiopathic Arthritis	2 (0.5)
	Giant cell arthritis	1 (0.3)
Intervention	Surgical	95 (23.6)
	Non-surgical	307 (76.4)
Funding	None	195 (48.5)
	Non-industry	150 (37.3)
	Industry	57 (14.2)
Trial Phase	3	383 (95.3)
	4	19 (4.7)
Setting	Acute	375 (93.3)
	Primary/Community	23 (5.7)
	Mixed	4 (1.0)
Design	Definitive/Full Trial	379 (94.3)
	Feasibility/Pilot Trial Design	23 (5.7)

MSK – musculoskeletal; SD – standard deviation; SLE - Systemic lupus erythematosus

Table 2: Frequency of reporting social deprivation indices and measures in musculoskeletal trials.

Measure of Social Deprivation	Frequency (%)
Morbidity	81 (20.2)
Employment	71 (17.7)
Education	62 (15.5)
Race	27 (6.7)
Ethnicity	25 (6.2)
Annual salary	5 (1.3)
Social deprivation score	2 (0.5)
Socioeconomic status	2 (0.5)
Number of people living in household	1 (0.3)
Housing	0 (0.0)
Car ownership	0 (0.0)
House ownership	0 (0.0)
Parental status	0 (0.0)
Living in poverty	0 (0.0)
Community status to premature death	0 (0.0)
Community status to quality of life	0 (0.0)
Crime	0 (0.0)
Location amenities	0 (0.0)
Quality of housing	0 (0.0)
Air quality	0 (0.0)
Community status on road traffic accidents	0 (0.0)

Supplementary File 1: Pubmed search strategy adopted to identify included published trials.

1. randomised controlled trial[Title/Abstract]
2. randomized controlled trial[Title/Abstract]
3. controlled trial[Title/Abstract]
4. RCT[Title/Abstract]
5. OR/1-4
6. bone[Title/Abstract]
7. joint[Title/Abstract]
8. muscle[Title/Abstract]
9. musculoskeletal[Title/Abstract]
10. osteoarthritis[Title/Abstract]
11. rheumatoid arthritis[Title/Abstract]
12. fibromyalgia[Title/Abstract]
13. pain[Title/Abstract]
14. ankylosing spondylitis[Title/Abstract]
15. rheumatic disease[Title/Abstract]
16. psoriatic arthritis[Title/Abstract]
17. lupus[Title/Abstract]
18. connective tissue disorder[Title/Abstract]
19. hypermobility[Title/Abstract]
20. low back pain[Title/Abstract]
21. tendinopathy[Title/Abstract]
22. chronic pain[Title/Abstract]
23. OR/6-22
24. AND/5,23
25. Publication date from 2019/05/01 to 2020/05/01; Humans