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# Meaningful changes in the Short Form 12 physical and mental summary scores after total knee arthroplasty☆

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ABSTRACT

*Background:* The aim of this study was to identify minimal clinically important difference (MCID), minimal important change (MIC) and minimal detectable change (MDC) for the Short Form (SF-) 12 physical and mental component summary (PCS, MCS) scores after total knee arthroplasty (TKA) using an anchor based methodology.
*Methods:* During a 10-year period, 2589 TKA were performed. SF-12 PCS and MCS scores were recorded preoperatively and at one year postoperatively. At one year, patients were asked "How much did the knee replacement surgery improve the quality of your life?" Their response was recorded as: a great improvement, moderate improvement, little improvement, no improvement at all, or the quality of my life is worse. Patients recording a little ($n = 211$) and no ($n = 115$) were used to calculate the MCID and the MIC. The MDC90 was calculated using distribution based methods for the whole cohort.
*Results:* The MCID was 1.8 ($p = 0.04$) for the PCS and 1.5 ($p = 0.33$) for the MCS score. The MIC was 2.7 ($p = 0.04$) for the PCS and −1.4 ($p = 0.17$) for the MCS score. The MDC90 was 8.9 for the PCS and 13.8 for the MCS score.
*Conclusion:* The MCID for the PCS can be used to compare the outcomes between groups, and the MIC can be used to ensure that a clinical difference has been observed for a cohort of patients. The values for the MDC90 can be used to assess whether or not an individual patient has experienced a change.



## 1. Introduction

Total knee arthroplasty (TKA) is an effective procedure for the treatment of end stage osteoarthritis with relief of pain and improved function [1]. There are numerous validated patient reported outcome measures (PROMs) available to assess the outcome of TKA [2]. There are those that are joint specific such as the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) [3] and the Oxford knee score (OKS) [4], and there are those that assess overall generic health such as the EuroQol and the Short Form (SF-) 12 score [5]. The SF-12 score consists of physical and mental component summary (PCS, MCS) scores that have been consolidated from the longer SF-36 score [6], and is a validated quality of life assessment tool [5]. The advantage of the SF-12 score is that it is less burdensome for the patients to complete, being 24 questions shorter, and has been shown to correlate with the SF-36 after TKA [7].

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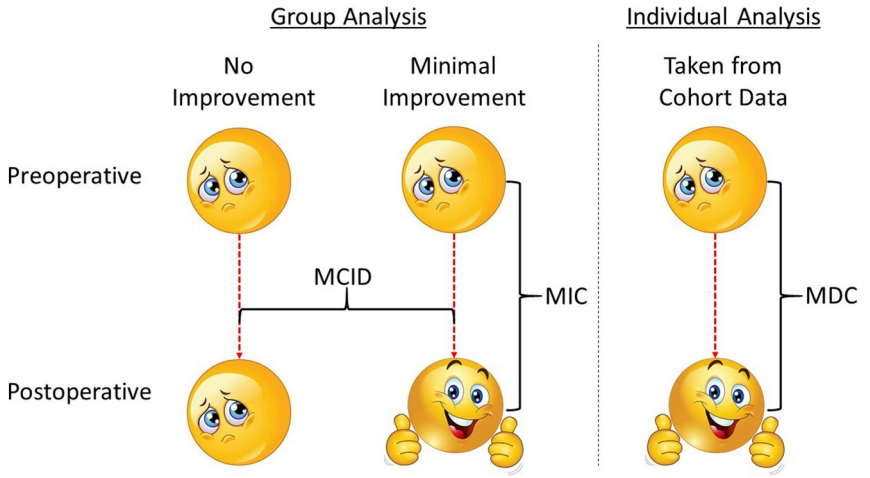


**Figure 1.** Diagrammatic representation of how three meaningful changes are calculated following an operative intervention.

There are three defined statistical terms used to describe meaningful changes in scores: minimally clinically important difference (MCID), minimal important change (MIC), and the minimal detectable change (MDC) (Figure 1). The MCID is the minimal difference in the scoring measure that is perceived by the patient to be beneficial or harmful relative to those that perceive no change [8–10]. The MIC is the change in the scoring measure for a group of patients that perceive their improvement to be minimal (Figure 1) [10]. The MDC is the smallest change for an individual that is likely to be beyond the measurement error of the scoring tool and represent true change (Figure 1) [10]. These definitions are often used interchangeably and can cause confusion in the literature [10–12]. Previous studies have sought to define the MCID in the SF-12 score after knee surgery, however it could be argued that the anchor question may not have represented the minimal difference [13] or have used a simple "rule of thumb" method (half the standard deviation) to calculate the MCID [14–17]. In additional the authors are not aware of any literature defining the MID or the MDC for the SF-12 PCS and MCS score after TKA, or whether the MCID is influenced by preoperative case-mix variables or baseline functional scores.

The aim of this study was to identify the MCID, MIC and MDC for the SF-12 PCS and MCS scores one year after TKA using an anchor based methodology and to assess the effect of preoperative patient case-mix variables and functional status on the MCID.

## 2. Patients and methods

Patients for this study were identified retrospectively from a prospectively compiled arthroplasty database held at the study centre. During a 10-year period (July 2003 to June 2013) 3641 patients undergoing primary TKA at the study centre were asked to complete a pre-operative patient questionnaire. Only patients with primary osteoarthritis were included. Patients who underwent simultaneous bilateral TKA during the study period were excluded, and for those patients that underwent a second TKA, after the index procedure, only the outcome of the first knee was used for analysis. Patients who had a deep infection, did not complete the outcome assessments, or were revised at before one year follow-up were also excluded from analysis. There were 2589 TKA performed during the study period with complete pre and post-operative data that met the inclusion criteria (Figure 2). There were 1187 male patients and 1402 female patients, with a mean age of 68.9 (SD 9.7) years.

### *2.1. Outcomes measured*

The SF-12 is a generic assessment tool to measure a patient's wellbeing, which is assessed using a PCS and a MCS [5]. Both the SF-12 PCS and MCS range from 0% (worst level of functioning) to 100% (best level of functioning).

The WOMAC [3] used in this study was the Likert version 3.1 standardised with English for a British population, consisting of 24 self-administrated questions that were answered for each item on a 5-point Likert scale (none, mild, moderate, severe and extreme). It was reported as a total and as three separate subscales: pain, physical function, and stiffness. The final scores were determined by adding the corresponding items for each dimension, and standardising to a range of values from 0 to 100. According to recent recommendations we have used the reverse option, from 0 (worst) to 100 (best) [18].

Patients were asked one year following their TKA "How much did the knee replacement surgery improve the quality of your life?" This was used as the anchor question. The response was recorded using a five point Likert scale: a great improvement, moderate improvement, little improvement, no improvement at all, or the quality of my life is worse.

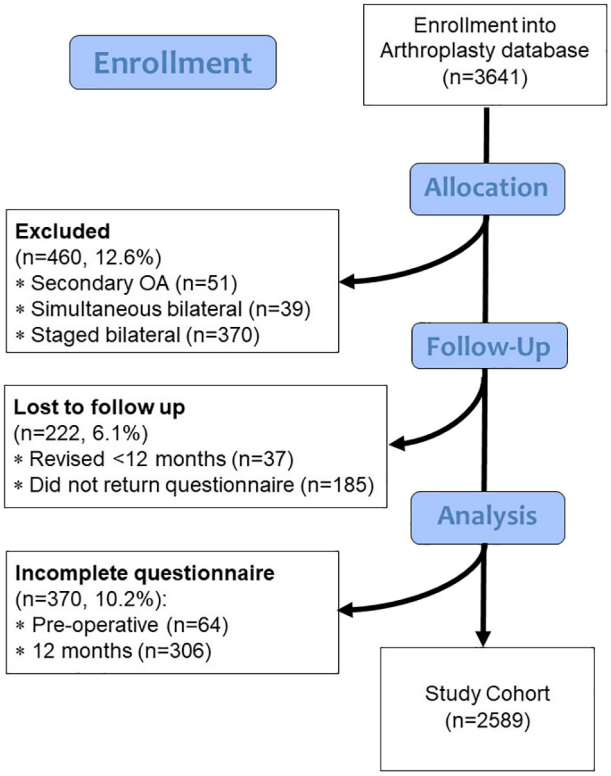


**Figure 2.** Flow diagram demonstrating the enrolment of patients, exclusion and loss to follow-up for the study cohort.

### *2.2. MCID*

The MCID was defined as the clinically relevant difference in health status change between two groups. This value was calculated as the difference in the mean change in the SF-12 PCS and MCS scores for patients who defined their quality of life to have had "no improvement" with those that had a "little improvement" on the patient reported anchor question. Linear regression analysis was used to adjust for pre-operative confounding variables to identify the MCID for the SF-12 PCS and MCS scores [19].

### *2.3. MIC*

The MIC was calculated as the mean change in the SF-12 PCS and MCS scores in patients that defined their quality of life to have "a little improvement" on the patient reported anchor question. Receiver operating characteristic (ROC) curve analysis were used to identify thresholds (cut points) for the change in the SF-12 PCS and MCS scores that predicted patients with "a little improvement" compared to those with "no improvement". The area under the ROC curve (AUC) ranges from 0.5, indicating a test with no accuracy, to 1.0 where the test is perfectly accurate by identifying all satisfied patients. The threshold is equivalent to the point (SF-12 score) at which the sensitivity and specificity are maximal in predicting patient satisfaction [20].

**Table 1**
Change in SF-12 PCS and MCS scores according to perceived level of improvement in quality of life one year after TKA for the study cohort (n = 2589).

| | Improvement in quality of life | | | | | p-Value* |
|---|---|---|---|---|---|---|
| | Great | Moderate | Little | No | Worse | |
| Patients (n, %) | 1583 (61.1) | 613 (23.7) | 211 (8.1) | 115 (4.4) | 67 (2.6) | – |
| SF-12 (mean, SD) | | | | | | |
| PCS | 13.1 (10.2) | 6.5 (8.8) | 4.2 (8.2) | 2.4 (7.1) | −2.1 (8.3) | <0.001 |
| MCS | 3.6 (12.2) | 1.0 (12.4) | −0.5 (12.7) | −2.0 (13.2) | −3.6 (12.5) | <0.001 |

* ANOVA.

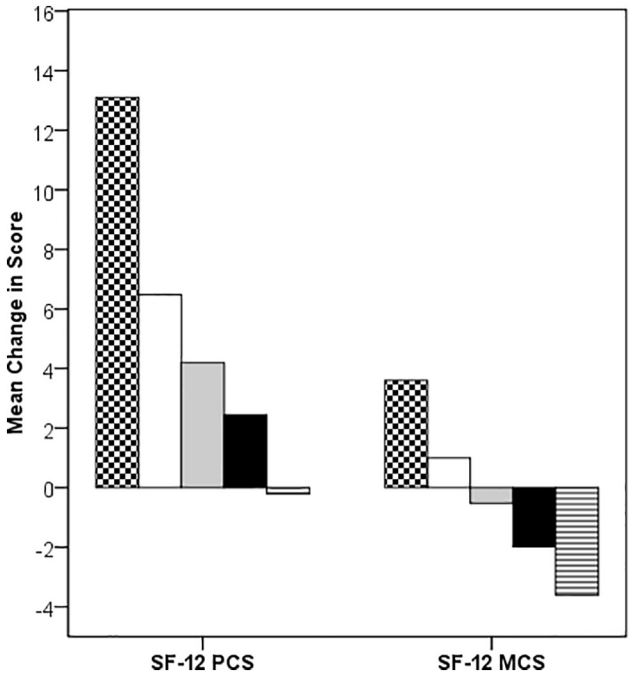


**Figure 3.** Change in the SF-12 PCS and MCS scores at one year for those with great (checker), moderate (white), little improvement (grey), no improvement (black), and worsening (lined) in their quality of life after TKA.

### *2.4. MDC90*

The MDC90 was calculated using a distribution method, which is based on the standard error of the measurement (SEM). The SEM is the range in which a patient's true score lies i.e. the error associated with the measuring tool used. The SEM is calculated using the standard deviation (SD) and the reliability of the measuring tool: SEM = SD × $\sqrt{1}$-reliability. The test–retest reliability values for the PCS and MCS scores were used from the prior validation study of the SF-12 score [5]. The MDC was then calculated by multiplying the SEM by $\sqrt{2}$ (representing two separate occasions in which to measure change). The MDC was then multiplied by a z value representing the chosen confidence intervals (CI), and for a 90% CI this value is 1.65, hence: MDC90 = SEM × $\sqrt{2}$ × 1.65.

**Table 2**
Demographic case-mix variables and pre-operative functional scores according to group.

| Case-mix Variables | | Little (n = 211) | No (n = 115) | Difference/Odds ratio | 95% CI | | p-Value* |
|---|---|---|---|---|---|---|---|
| | | | | | Lower | Upper | |
| Age (years: mean, SD) | | 68.0 (10.9) | 67.9 (10.1) | 0.1 | −2.4 | 2.5 | 0.98 |
| Gender (M/F) (n, % of group) | Male | 90 (42.7) | 71 (61.7) | *0.83* | *0.52* | *1.33* | 0.44** |
| | Female | 121 (57.3) | 44 (38.3) | | | | |
| BMI ($kg/m^2$: mean, SD) | | 30.5 (5.7) | 30.5 (5.8) | 0.2 | −1.3 | 1.4 | 0.97 |
| WOMAC (%; mean, SD) | | | | | | | |
| Pain | | 30.7 (16.4) | 30.8 (18.7) | 0.1 | −3.9 | 4.0 | 0.97 |
| Function | | 31.1 (15.0) | 31.6 (18.3) | 0.4 | −3.1 | 3.9 | 0.81 |
| Stiffness | | 34.5 (19.6) | 33.4 (18.3) | 1.1 | −3.3 | 5.5 | 0.62 |
| Total | | 31.3 (14.6) | 31.6 (15.6) | 2.3 | −3.2 | 3.6 | 0.90 |
| SF-12 (mean, SD) | | | | | | | |
| PCS | | 26.0 (6.8) | 25.8 (7.4) | 0.2 | −1.4 | 1.8 | 0.77 |
| MCS | | 43.3 (13.0) | 41.8 (14.4) | 1.4 | −1.6 | 4.5 | 0.36 |

* t-test unless otherwise stated.
** Chi square test.

**Table 3**
Change in the SF-12 PCS and MCS scores at one year according to group and the differences (MCID) between the groups.

| SF-12 (mean, SD) | Little (n = 211) | No (n = 115) | MCID | 95% CI | | p-Value* |
|---|---|---|---|---|---|---|
| | | | | Lower | Upper | |
| PCS | 4.2 (8.2) | 2.4 (7.1) | 1.8 | 0.1 | 3.5 | 0.044 |
| MCS | −0.5 (12.7) | −2.0 (13.2) | 1.5 | −1.5 | 4.4 | 0.33 |

* t-test.

### 2.5. Statistical analysis

Data analysis were performed using Statistical Package for Social Sciences version 17.0 (SPSS Inc., Chicago, IL, USA). A Student's t-test, paired and unpaired, and one way analysis of variance (ANOVA), with Bonferroni correction for multiple testing, were used to compare linear variables between groups. Dichotomous variables were assessed using a Chi square test. Linear regression analysis was used to identify the MCID when adjusting for confounding variables. A p-value of $<0.05$ was defined as significant.

### 2.6. Ethics

There was no additional patient contact, and as such, this project was performed as a service evaluation without the need for formal ethical approval. The project was registered with the institutions audit department (Newcastle Hospitals NHS Foundation Trust, Project Record Number 3290) and was conducted in accordance with the Declaration of Helsinki and the guidelines for good clinical practice.

## 3. Results

There was a significantly greater improvement in the PCS and MCS score with increasing level of improvement in quality of life gained at one year (Table 1, Figure 3). There were 211 (8.1%) patients that declared they had little improvement and 115 (4.4%) patients that had no improvement in their quality of life. There were no significant differences in the case-mix variables and pre-operative functional scores between patients that had little and no improvement in their quality of life (Table 2).

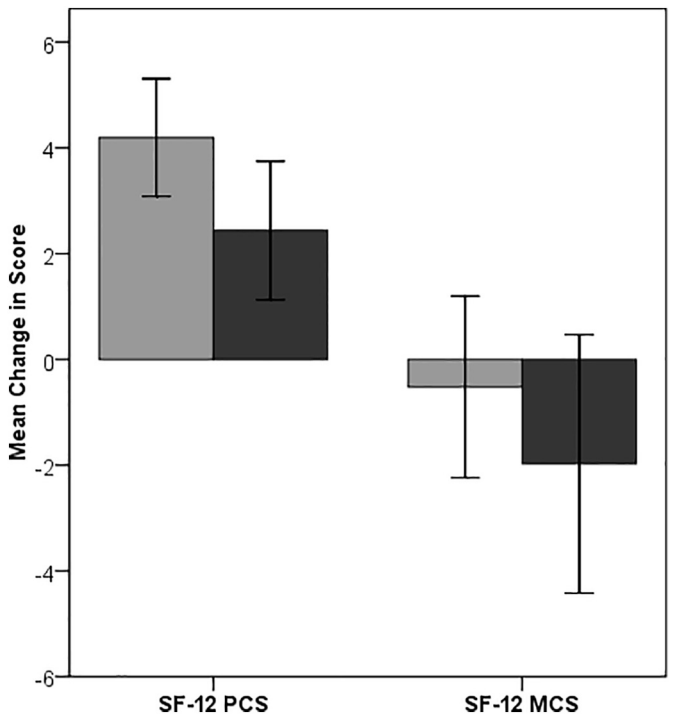


**Figure 4.** Change in the SF-12 PCS and MCS scores at one year for those with little improvement (grey) and no improvement (black) in their quality of life after TKA. Error bars represent the 95% confidence intervals.

**Table 4**
Linear regression analysis for the difference between the groups (MCID) in the SF-12 PCS and MCS scores when adjusting for pre-operative confounding variables. All pre-operative variables from Table 2 were included in each model using "enter" methodology.

| SF-12 | $R^2$ | MCID | 95% CI | | p-Value |
|---|---|---|---|---|---|
| | | | Lower | Upper | |
| PCS | 0.17 | 1.8 | 0.1 | 3.6 | 0.04 |
| MCS | 0.23 | 1.1 | −1.6 | 3.8 | 0.44 |

### 3.1. MCID

The mean difference (MCID) for the change in the PCS and MCS scores between those that had little with those that had no improvement ranged was 1.8 and 1.5, respectively (Table 3, Figure 4). After adjusting for confounding variables (all factors in Table 2) between the groups (little and no improvement) the MCID did not change greatly. The MCID remained 1.8 for the PCS and achieved significance ($p = 0.04$) however the MCID for the MCS fell to 1.1 and was not statistically significant ($p = 0.44$) (Table 4).

### 3.2. MIC

The ROC curve analysis identified patients that had a little improvement from those that had no improvement however the AUC was less than the proposed reliability target of 0.7 (Table 5, Figure 5). The MIC (threshold with maximal specificity and sensitivity) was 2.7 for the PCS which was significant ($p = 0.04$) and −1.4 for the MCS which was not significant ($p = 0.17$) (Table 5).

### 3.3. MDC90

The MDC90 for the PCS was 8.9 and 13.8 for the MCS score (Table 6). The MDC90 value can be interpreted to mean that an individual patient will have experienced a real effect (beyond measurement error) if their score has changed by at least 8.9 points in the PCS or 13.8 points in the MCS score in either direction 90% of the time.

## 4. Discussion

This has defined the MCID for the SF-12 PCS and MCS score using an anchor based method after TKA. The MCID for the PCS score was demonstrated to be 1.8 and was not influenced by pre-operative confounding variables. The MCID in the MCS was 1.5 and fell to 1.1 when adjusting for pre-operative confounding variables however these differences did not achieve significance. The MIC in the PCS was 2.7 and was statistically significant but had low reliability with an AUC of less than 0.7. The MIC in the MCS was 1.4 but again this was not significant and illustrated a low reliability with an AUC of less than 0.7. The MDC90 for the PCS score was 8.9 and 13.8 for the MCS.

A limitation of this study was the relatively early assessment of patient perceived improvement in the quality of their life after TKA one year following surgery. Potentially some patients' perception of pain and or function may continue to improve after this time point and hence their level of satisfaction may change [21]. However, a study of over 27,000 TKA performed in Sweden demonstrated the level of patient satisfaction to be "remarkably constant" one year after surgery for unrevised cases, with no significant change with time [22]. Furthermore, this study did not analyse the effect of factors which have previously been shown to influence patient satisfaction such as back pain [23] and patient expectations [24]. Inclusion of these variables in the analysis may have identified differing MCID however age, gender, body mass index (BMI), preoperative WOMAC scores, mental health, and general physical were accounted for in the regression analysis in the current study.

Keurentjes et al. [25] conducted a systematic review of the literature and reported the MCID for the SF-36 after primary TKA, which was however limited to a single cohort. They demonstrated the MCID to vary according to the dimension assessed with wide 95% confidence intervals. Escobar et al. [25] first described the MCID for the SF-36 score after TKA. However, it could be argued that they defined the MIC as they did not use the difference between the "equal" and "somewhat better" groups but used the absolute improvement in the somewhat group. Interestingly, if the MCID is calculated from the data presented by Escobar et al. [25] there is no difference observed for the mental component which supports the current study. Although the SF36 and

**Table 5**
ROC curve analysis identifying the MIC (threshold) for the SF-12 PCS and MCS scores.

| SF-12 | MIC | AUC | 95% CI | | p-Value |
|---|---|---|---|---|---|
| | | | Lower | Lower | |
| PCS | 2.7 | 0.57 | 0.51 | 0.64 | 0.04 |
| MCS | −1.4 | 0.55 | 0.48 | 0.61 | 0.17 |

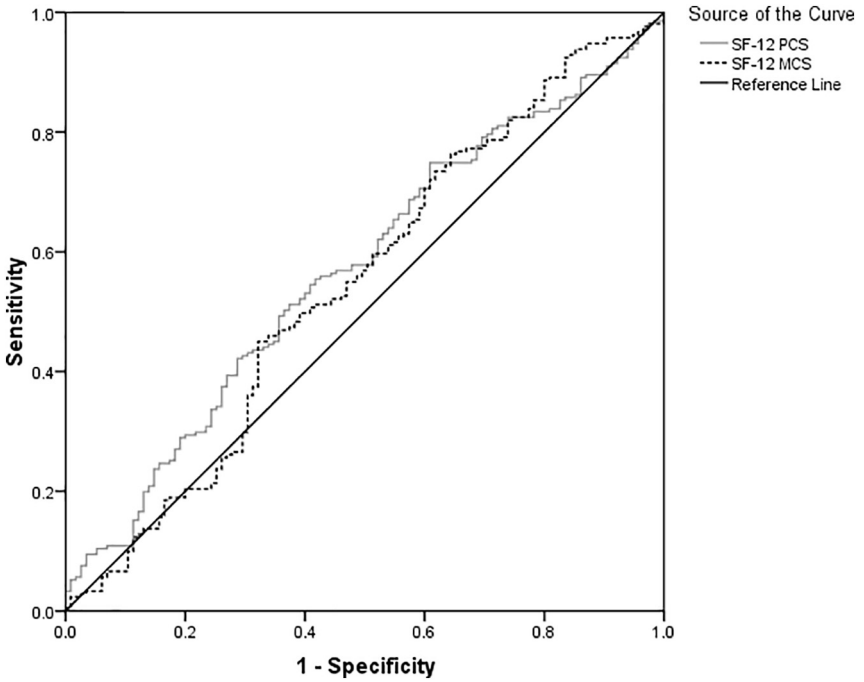


**Figure 5.** ROC curves for the SF-12 scores.

SF-12 use the same questions, the reported scores are not comparable being calculated and weighted differently, and the MCID identified are not applicable to the SF-12 score. Clement et al. [13] is the only published study the authors are aware of that report a MCID after TKA for the PCS score and was thought to be between four and five points. However, they may not have assessed the potential minimal difference and assessed the liner relationship between level of satisfaction with the PCS score. They also raised the point that MCS did not change significantly after TKA, a finding supported in the current study. Parker et al. [26] demonstrated the MCID for the SF-12 PCS to be as small as 2.5 points, which is similar to the current study, and as great as 8.1 points [27] for different spinal procedures. This suggests that the identified MCID varies according the procedure being performed.

The authors believe the MCID identified in the current study, after adjusting for confounding variables represents the most accurate figure for the SF-12 PCS. This could be used to power future randomised controlled trials. Using the MCID of 1.8 and a SD of 9 (effect size of 0.2), to achieve an 80% power and an alpha of 0.05 using a two-tailed calculation would require 394 patients to be randomised to each arm. To power a study to the PCS score would be expensive requiring large number of patients to be randomised due to the low effect size. The OKS in contrast has an effect size of approximately 0.5 [13] and for the same parameters as stated above only 64 patients would need to be randomised to each arm of the study. This probably demonstrates the difference between the generic assessment of the PCS score and the joint specific assessment of the OKS.

The MIC value represents a score beyond which a cohort is considered to have had a “clinically relevant” change. The authors are not aware of literature defining the MIC for the SF-12 PCS or MCS score after TKA other than the current study. The identified MIC allows patient cohorts to be assessed as to whether they have achieved a clinically relevant change in their SF-12 scores. It can be assumed that a cohort undergoing a change in the PCS score of 2.7 points or more have experienced a real change. However, the MIC for the MCS score did not reach statistical significance and therefore may not a good measure of the effect that a TKA has upon a cohort of patients. In contrast, the MDC90 represents the smallest change in an individual patient's score that is beyond the measurement error of the tool used. Using the data from the current study individual patients experiencing a change of 8.9 points in the PCS and 13.9 points in the MCS score have had a real change 90% of the time. The values identified for the MDC90 relate to the scoring measure and not specifically to TKA so are applicable to all interventions being assessed by the SF-12 scores.

**Table 6**
Reliability, standard error of the measure (SEM), and MDC90 for the SF-12 PCS and MCS scores.

| SF-12 | Reliability | SEM | MDC90 |
|---|---|---|---|
| PCS | 0.864 | 3.82 | 8.9 |
| MCS | 0.774 | 5.92 | 13.8 |

## 5. Conclusion

The MCID identified for the PCS score after TKA can be used to compare the outcomes between groups and the MIC can be used to ensure that a clinical difference has been observed for a cohort of patients. The MCS score may not be an appropriate measure to assess the effect of TKA as the MCID and MIC did not reach significance. The values for the MDC90 for both the PCS and MCS can be used to assess whether or not an individual patient has experienced a change.

## Declaration of competing interest

The authors declare no conflict of interest with the content of this study.

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